

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21

ADEPT-9 Enhancing Diversity and Therapeutics
Development for Pediatric Patients

FDA-University of Maryland CERSI Public
Workshop

Moderated by Lily Mulugeta, Associate Director, Policy
and Research, Division of Pediatrics and Maternal
Health

Friday, September 6, 2024, 8:42 a.m.

Food & Drug Administration
10903 New Hampshire Avenue
Building 31, Great Room 1503 (B+C)
Silver Spring, MD 20903

Reported by: Richard Livengood
JOB NO: 6857379

A P P E A R A N C E S

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21

List of Attendees:

Hilary Marston - Chief Medical Officer, U.S. FDA

Carla Epps - Senior Physician, DPMH, U.S. FDA

Director, Office of Medical Policy

Michelle and Michael Burgess - International

Children's Advisory Network (iCAN) Parent/Patient

Christine Lee - Acting Associate Commissioner and

Director, Office of Minority Health and Health Equity

Pam Simpkins - Managing Partner, Mezzopointe, LLC

Dionna Green - Director, Office of Pediatric

Therapeutics, U.S. FDA

Lois K. Lee - Senior Associate in Pediatrics, Division

of Emergency Medicine, Boston Children's Hospital

Sneha Dave - Executive Director, Generation Patient

Florence Bourgeois - Associate Professor, Pediatrics,

Harvard Medical School

Ann McMahon - Regulatory Scientist, Office of

Pediatric Therapeutics, U.S. FDA

Sue Rahman - Chief Scientific Officer, Health Data

Synthesis Institute

1 A P P E A R A N C E S (Cont'd)

2 List of Attendees (Cont'd):

3 Rachel Randell - Duke University and Duke Clinical
4 Research Institute (DCRI)

5 Ted Love (by videoconference) - Chair of Board of
6 Directors, Biotechnology Innovation Organization

7 Bella Oguno - Vice President, Development Operations,
8 Nuvig Therapeutics

9 Lauren Wood-Heickman - Clinical Reviewer, DDLO, U.S.
10 FDA

11 Martha Donoghue - Acting Associate Director, Pediatric
12 Oncology, Office of Oncologic Diseases, U.S. FDA

13 LaShell Robinson - Head of Diversity, Equity &
14 Inclusion, Clinical Research Department, Takeda

15 Ki Lee Milligan - Executive Director, Pediatric Center
16 for Excellence, Global Drug Development, Novartis

17 Stephen Balevic (by videoconference) - Associate
18 Professor, Medicine and Pediatrics, Duke University
19 and DCRI

20 Billie Jo Kipp - Clinical Psychologist, Indigenous
21 Innovators Collaborative

1 A P P E A R A N C E S (Cont'd)

2 List of Attendees (Cont'd):

3 Lynne Yao - Director, DPMH, U.S. FDA

4 Tamorah Lewis - Division Head for Clinical

5 Pharmacology and Toxicology, SickKids

6 LaToya Williams - Community Clinical Director, Inside
7 Edge Consulting Group8 Anvita Ambardekar - High School Student, Pediatric
9 Perspective iCAN10 Christina Edwards - Director of Clinical Trials,
11 National Minority Quality Forum12 Puja Umaretiya - Assistant Professor, Division of
13 Pediatric Hematology/Oncology, UT Southwestern,
14 Children's Medical Center15 Melissa Penn - Director, Patient Engagement R&D, Bayer
16 Pharmaceuticals

17 Nasrin Sari - Patient/Community Representative

18 Mathilda Fienkeng, Director, Office of Medical Policy

19 Jennifer McKenzie, Pediatric Nephrologist, Boehringer
20 Ingelheim

21

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21

A P P E A R A N C E S (Cont'd)

List of Attendees (Cont'd):

Heidrun Hildebrand, Pediatric Development Alliance
Manager, Bayer

Melva Covington, Abundant Life Bible Church, AGAPE
Strategic Solutions

Michelle McMurray-Heath - BioTechquity Clinical

Meshaun Payne, Support

Iana Zolkowski, Support

Reed Delisle, Support

	C O N T E N T S	
		PAGE
1		
2		
3	Lily Mulugeta	8, 64
4	Lynne Yao	372
5	Hilary Marston	12
6	Mathilda Fienkeng	17
7	Michelle Burgess	31
8	Michael Burgess	31
9	Christine Lee	44, 110, 116
10	Sue Rahman	65
11	Pam Simpkins	79, 112, 120
12	Dionna Green	94
13	Lois K. Lee	95
14	Sneha Dave	95, 226
15	Florence Bourgeois	100
16	Ann McMahon	103
17	Carla Epps	108
18	Billie Jo Kipp	117, 226
19	Rachel Randell	131, 187
20	Ted Love (Virtual)	145, 189, 197, 199
21	Bella Oguno	150

	C O N T E N T S (Cont'd)	
		PAGE
1		
2		
3	Lauren Wood-Heickman	161
4	Anvita Ambardekar	180
5	Martha Donoghue	180
6	LaShell Robinson	180
7	Ki Lee Milligan	181
8	Christina Edwards	181, 282
9	Stephen Balevic (Virtual)	182
10	Tamora Lewis	266
11	Puja Umaretiya	298
12	Nasrin Sari	226
13	LaToya Williams	226
14	Melissa Penn	316
15		
16		
17		
18		
19		
20		
21		

1 P R O C E E D I N G S

2 MS. MULUGETA: Good morning. We're
3 going to go ahead and get started. On behalf of the
4 FDA and the University of Maryland, Center of
5 Excellence and Regulatory Science and Innovation, we
6 welcome you to our ADEPT-9 Workshop on Enhancing
7 Diversity in Therapeutics Development for Pediatric
8 Patients.

9 My name is Lily Mulugeta. I'm the
10 Associate Director for Policy and Research in the
11 Division of Pediatrics and Maternal Health. I will be
12 co-moderating this workshop with my colleague, Dr.
13 Carla Epps, also from the Division of Pediatrics and
14 Maternal Health.

15 Before I introduce the first speaker,
16 I'm going to invite Dr. Lynne Yao, who is the Director
17 for the Division of Pediatrics and Maternal Health, to
18 quickly make a special announcement, and then we can
19 get started with the rest of the agenda.

20 So, Dr. Yao.

21 MS. YAO: Good morning, everybody.

1 Thank you for joining in person. Really appreciate
2 seeing all of you here.

3 So I do have a quick announcement.
4 Actually, it made me think though. I'm sorry. I'm
5 going to take the prerogative of the microphone of the
6 bully pulpit, I guess, and just remind everybody that
7 ADEPT-9 -- you know, does anybody even remember what
8 ADEPT means? ADEPT means Advancing the Development of
9 Pediatric Therapeutics.

10 And I had a conversation with our dear
11 colleague, Diane Murphy, and this was about 11 years
12 ago; okay?

13 And she said, "Well, we want to use
14 these pediatric advisory committees for something that
15 is, you know, more than just reviewing the ten-
16 thousandth safety whatever prescription and review all
17 the safety data at these pediatric advisory
18 committees."

19 And we said, "Well, maybe there's
20 another way to invite the community to come, not
21 necessarily as formal as an advisory committee, and

1 start working on issues that are related to pediatric
2 therapeutics development across academia, industry,
3 and regulatory."

4 And that's how the ADEPT meetings
5 began. And this would have been our 10th year. And
6 the reason it's not is, because during the pandemic we
7 missed one year. So next year, stay tuned, we'll have
8 a grand 10th Anniversary ADEPT.

9 But I did want to give you that
10 perspective. So this year, of course, another topic
11 that I think is obviously important to everybody in
12 the audience. So just wanted to give those brief
13 historical remarks.

14 Now, the important -- and the reason
15 I'm up here is to -- if you wouldn't mind looking at
16 what you have on your table; I'm just going to read
17 this.

18 "Please, be advised that the U.S.
19 General Services Administration is conducting baseline
20 water test at FDA's White Oak Campus and other FDA
21 locations. This is part of a nationwide GSA

1 initiative assessing federal buildings of certain
2 heavy metals and waterborne bacteria.

3 You may see signage posted at
4 designated water fixtures or areas. Please, do not
5 use these fixtures until signage is removed. Out of
6 an abundance of caution, the FDA is recommending
7 occupants refrain from consuming tap water at the
8 White Oak Campus.

9 Where feasible, bottled water and/or
10 water coolers are being made available for use." So
11 there is bottled water for all of the participants
12 today. I can assure you that all the food that's
13 being prepared, the coffee, has been prepared such
14 that it is safe to use and drink.

15 So I just wanted to give you that
16 announcement in case you hadn't heard, and please,
17 feel free to see me if you have any questions. Thank
18 you.

19 MS. MULUGETA: Thank you so much for
20 that, Lynne. So we're going to go ahead and move
21 forward on the agenda. The first speaker is Dr.

1 Hilary Marston. She's the chief medical officer at
2 the FDA, and she's going to walk in momentarily.

3 MS. MARSTON: There we go. Okay.
4 Good. So I want to take a couple of minutes just to
5 recap how we got where we are, where we are right now,
6 et cetera, what the FDA has been doing in this space.

7 So the FDA broadly is committed to
8 making sure that we get safe and effective medical
9 products out to all populations, particularly
10 including children.

11 We know that clinical trials are such
12 an important part of this, and we know that clinical
13 trials historically have inadequately represented
14 diverse populations. We also know that they've
15 inadequately represented children.

16 So when you take those two things
17 together, you obviously have quite a problem that we
18 need to take a concerted effort to address.

19 FDA is committed to doing our part to
20 change this, but we also know that we only play one
21 small part of the ecosystem, but we're doing what we

1 can, and we need the partners in this room to really
2 advance this further.

3 So enrolling diverse populations, just
4 want to take a moment to address what that actually
5 means. So we obviously all think of racial and ethnic
6 diversity, very important aspect of diversity.

7 We also need to think about clinical
8 diversity; right? So what specific comorbidities
9 might people have? What stage of disease might they
10 be in? Also the conditions that they live in; right?
11 So socioeconomic factors.

12 We need to have all of these aspects
13 addressed in our diversity planning for these sorts of
14 trials. So it's definitely not easy.

15 The reasons to do this are a myriad;
16 right? So we want to make sure that the products that
17 we have to treat children, that we understand how
18 they're going to work in all populations. We need to
19 be able to predict that.

20 We also know that it's the moral thing
21 to do; right? So it is the right thing to do to make

1 sure that we are arming clinicians, parents, patients
2 with tools that we truly understand as we're
3 administering them to that. And the only way that we
4 can do that is to make sure that we're actually
5 studying.

6 So importantly, you got to plan for
7 this; right? I mean, I know I'm preaching to the
8 choir, but this is not something that happens on its
9 own. You have to plan and you have to plan in
10 advance.

11 So one of the things that the FDA has
12 been calling for is diversity action plans across all
13 trials. We also call for pediatric study plans.

14 In those diversity action plans -- we
15 actually just put out a guidance on our thinking here,
16 we want to ensure that trial preparers are thinking in
17 advance, delineating the strategies that they're going
18 to use, and thinking first about which aspects of
19 diversity that they want to incorporate into their
20 trials.

21 So you want to think about the patient

1 population that's going to be using the product. That
2 might be different, obviously, from the patient
3 population as a whole; right? So that's the first
4 step.

5 Then thinking about the different
6 challenges that individuals who might be using the
7 products might encounter in their days and how to
8 incorporate that into your trial. So we try to go
9 through in a systematic way, ways that developers can
10 think about it.

11 In addition, we had put out a guidance
12 in 2020 to think about different aspects of
13 development. So there, what we were talking about was
14 really ways to think about the actual individuals that
15 you were going to enroll in the trial and ways to
16 think about eligibility criteria.

17 So moving forward, we have a number of
18 other tools that we're using to look at improving
19 diversity. These are tools, like innovation in
20 clinical trials, for example, decentralized trials.

21 So we like to think about decentralized

1 elements -- the types of things that we can do in
2 order to make sure that trials are more accessible to
3 people.

4 So for example, if you're looking at
5 rural populations, they might not have a clinic near
6 them. These sorts of tools can be helpful.

7 All right. In addition, we want to
8 make sure that we're thinking particularly about
9 community engagement.

10 Community engagement for pediatric
11 trials might well look different. We need to look at
12 ways that we're going to reach not just populations
13 broadly, but how are we going to reach their parents?
14 How are we going to reach their caregivers?

15 The sorts of strategies that you might
16 use in other trials might not be suitable for
17 pediatric.

18 In addition, we want to think about
19 ways that we're going to interact -- not just with the
20 patient population, with their clinicians, with their
21 communities, with their industry, with regulators.

1 So I think in this room we have the
2 right people to take a look at these issues, to really
3 dive into them, to come up with specific strategies,
4 and looking forward to seeing what you guys come up
5 with as we bring these two issues together.

6 So thank you. That's a little bit
7 about where we've been; looking forward to knowing
8 where we're heading. This is the group that will help
9 us find that out. Thank you so much.

10 MS. MULUGETA: Thank you. So thank you
11 so much, Dr. Marston, for that introductory talk.

12 Our next speaker is Mathilda Fienkeng.
13 She's one of the directors in the Office of Medical
14 Policy, and I'm going to invite her to come up to the
15 stage.

16 MS. FIENKENG: Good morning, everyone,
17 and thank you for being here. So as you heard, I am
18 going to give you a brief overview of a workshop that
19 was held in November of last year.

20 So first off, let me go; I have nothing
21 to disclose. And as you heard Dr. Marston say, we

1 talk about clinical trial diversity. Why is it
2 important? Well, clinical trials provide the critical
3 evidence that determines whether a product is safe and
4 effective.

5 And ideally, we want to make sure that
6 the enrolled population, to the extent possible,
7 reflects the diversity of the population that is going
8 to use the product. And FDA is committed to this.
9 And we do this through different means, which I'm not
10 going to reiterate here.

11 In December of 2022, Congress passed
12 the Food/Drug Omnibus Reform Act, FDORA for short.
13 And FDORA had several requirements.

14 One was for FDA to convene a public
15 workshop on diversity in clinical trials, to also
16 publish a report on that; it also requires sponsors to
17 submit diversity action plans, as you heard, and it
18 required FDA to also issue guidance on diversity
19 action plans.

20 So today, I'm going to briefly talk
21 about those things.

1 In November of 2023, we did convene a
2 two-day public workshop to fulfill that requirement.
3 We solicited and received input on increasing
4 diversity in clinical trials specific to
5 underrepresented populations. The workshop attendees
6 were very diverse, as you can see on the screen.

7 We also published a summary report on
8 that, which is available online for you.

9 The topics that we discussed at that
10 workshop were not specific to pediatrics of course,
11 but while the discussions there were general and
12 sometimes specific to other populations, those topics
13 were relevant.

14 They are relevant for pediatric
15 populations as well. And they will be complimentary,
16 as you will see to what we are going to discuss today.
17 But these are the different topics that were
18 discussed, but I'll go in depth to them.

19 We talked about where we are now as it
20 relates to clinical trial diversity. One key takeaway
21 was the fact that despite all the efforts that have

1 been made, a lot of progress have been made. Some
2 population continue to be underrepresented in clinical
3 trials.

4 And also there were common barriers
5 across these different populations. And those common
6 barriers include distrust in research, not being
7 referred to clinical trials -- some people are not
8 even asked to join clinical trials, restrictive
9 eligibility criterias, transportation issues, or
10 providing clinical trial materials in language that is
11 not appropriate for that person or not at their
12 reading level, and finally, lack of community
13 engagement.

14 I know I was sitting today with some
15 advocates, but that community engagement was a key
16 factor that was really talked about. And later on,
17 you'll hear more. Now, efforts to address these
18 barriers can help us to achieve that diversity in
19 clinical trials.

20 During that workshop, the participants
21 and the speakers covered strategies to overcome

1 barriers in clinical trials.

2 And one key takeaway was that sponsors
3 need to diversify the trial investigators, the trial
4 sites, and the trial staff. And this will help with
5 better engagement and also ensure successful
6 recruitment of that diverse population.

7 It was also key to provide language
8 appropriate cultural literacy training for your trial
9 staff, also being mindful of the lack of information,
10 of lack of interest, or lack of trust in the clinical
11 trial enterprise, especially in those populations that
12 historically have been underrepresented.

13 Usually, we talk about building trust
14 and having people trust the clinical trial sponsors,
15 those conducting clinical trials.

16 But it's also key that those who
17 conduct those trials demonstrate trustworthiness that
18 way in turn, those who want to recruit can trust you,
19 and they can enroll in clinical trials.

20 Understanding the population, the
21 target population, understanding what that population

1 looks like, what politically, socially, economically,
2 culturally, and of course engaging a diverse
3 population must begin very early on, when you are
4 still drafting your protocol.

5 You want to get those patient
6 population involved at that stage. That way you are
7 setting yourself up for success. And one thing that
8 was reiterated over and over was to simplify the
9 informed consent forms.

10 We talked about other strategies to
11 overcome barriers, talking about employing targeted
12 patient engagement plans, appropriately using
13 decentralized clinical trial features and digital
14 technologies, diversifying your clinical trial sites,
15 optimizing your protocol, and also using patient
16 concierges, if necessary, to help with scheduling and
17 reimbursement for travel and transportation.

18 Now, when it came to establishing
19 enrollment goals, which we'll hear is part of the
20 requirement for the diversity action plans, the goals
21 should be established based on the stages of your

1 clinical trial participation.

2 So because each stage has its own
3 unique challenges, you want to match your enrollment
4 goals to those. So you're thinking about the initial
5 approach stage, the recruitment stage, and the
6 retention stage.

7 Now, for devices, sponsors are
8 encouraged to really think about the characteristics
9 of various populations with the diseases so that early
10 on in your device design, you can incorporate those
11 characteristics and those factors, so engage with the
12 engineers, the physicians, and the patients early in
13 the planning phase.

14 An example is that historically women
15 were excluded from some medical device trials, because
16 the size of the devices limited enrollment of
17 participants with smaller body sizes.

18 And lastly, appropriately leveraging
19 different data sources. When you think about the
20 prevalence of the disease that you want to use for
21 your enrollment targets, use different sources to come

1 up with those disease prevalence data.

2 Now, many different approaches on
3 including underrepresented populations were also
4 discussed specific to subpopulations and in general.

5 One of the important aspects that was
6 reiterated in that workshop was that we need to
7 collect and track relevant demographic data in real-
8 time. So you want to use a data-driven assessment as
9 your trial goes along to think about that.

10 There are myths; there are
11 misconceptions, and there are fears, and those need to
12 be addressed.

13 One of the examples was the
14 misconception that somebody, for example, with mental
15 illness might not be able to follow or adhere to your
16 study protocol or your study requirements or just
17 excluding, for example, pregnant persons or persons
18 with disabilities or those with complex health
19 conditions.

20 So it's really about a paradigm shift,
21 really shifting from this mindset of "Let's protect

1 this vulnerable population from clinical trials" to a
2 mindset of more "Let's protect this complex
3 populations with clinical trials."

4 So there is that need for that change
5 in the ecosystem, and of course, providing education
6 to those who are part of that ecosystem to take care
7 of stereotypes.

8 Now, we've heard a lot about
9 decentralized studies and digital health tools. When
10 appropriately used, these tools can enhance the
11 inclusion of a representative population in your
12 trials.

13 So if you think about decentralized
14 features, those may be useful when we talk about
15 patients who are in remote areas.

16 You can leverage decentralized trials
17 to maintain trials on certain times, for example,
18 during a pandemic. You can use decentralized trial
19 features during severe weather or during a war.

20 We can also incorporate those
21 decentralized clinical trial elements in trials that

1 are conducted at the point of care. And that can help
2 and enhance getting a diverse patient population.

3 It's important to evaluate the
4 appropriateness of decentralized clinical trials and
5 digital health technologies. For example, is there
6 availability of broadband? What is the digital
7 literacy of the participants you're trying to enroll
8 in your trials?

9 In all of this, building that human
10 connection is critical, regardless of what tools and
11 what methods you use.

12 So after studies are done, it is
13 important to communicate those data. We do not want
14 the drive-by situation, where you come in the
15 community, do the trials, take your results, and move
16 on.

17 But sharing that information with the
18 community, the patients will help highlight the
19 importance and why it is important to have a diverse
20 representation.

21 When you share that information,

1 protecting the privacy of participants is also very
2 important. Transparency is important, using plain
3 language, visual aids, to make that information more
4 accessible and easily understandable, and putting
5 procedures in place to make sure that the information
6 you share is actually accurate information.

7 We have talked a lot about community
8 engagement. It's important to really work
9 collaboratively with the community and face with
10 organizations. That way we are speaking to
11 communities through a voice of trust.

12 Explain to participants why their
13 participation in trials is important, and build that
14 capacity in your overall diversity strategy.

15 And I cannot stress enough -- and in
16 that workshop, bidirectional communication
17 relationship with those communities are key as well.

18 So really to achieve that meaningful
19 representation in clinical trials takes a village. It
20 is important not only for the agencies, but for the
21 sponsors, the clinicians, the patients. It takes a

1 lot of engagement and sharing of ideas, experiences,
2 and best practices.

3 So we're going to shift gear briefly
4 for the remainder of my time and talk a little bit
5 about the diversity action plans.

6 This draft guidance was issued in June
7 of 2024, and it met one of the requirements for FDORA.
8 It actually replaced the April 2022 Diversity Plans
9 guidance that FDA issued.

10 The guidance is actually still out for
11 public comments, so I encourage you to read that
12 guidance and provide any comments you may have. I
13 have the docket number included on this slide.

14 So why? Why do we need diversity
15 action plans? The short answer is to help improve
16 generalizability of the results of clinical trials in
17 an intended population. So the guidance actually
18 assists sponsors in meeting the requirements for
19 submitting the DAP.

20 So it describes the format and the
21 content of the diversity action plan. It describes

1 the criteria and processes for sponsors who might want
2 to request waivers, and also it provides general
3 recommendations for sponsors to publicly post key
4 information regarding the diversity action plans.

5 Now, which studies will require
6 diversity action plans?

7 For drugs, a clinical investigation
8 that is a Phase 3 study or, as appropriate, any other
9 pivotal study of a drug, would require a diversity
10 action plan.

11 For devices, any device, a DAP must be
12 included for any investigational device exemption.
13 And for those that do not require an IDE, the DAP must
14 be included for a pre-market notification, request for
15 classification, and application for pre-market
16 approval.

17 FDA strongly recommended that you think
18 about diversity action planning, the entire clinical
19 development program, not just towards the end, but
20 really we're saying submit them now, but we want you
21 to think about them early on in the process.

1 What should be included in a DAP? Your
2 DAP should include the goals for your enrollment, and
3 those should be desegregated by age, by race, by
4 ethnicity, by sex, so if you think about this for any
5 clinically relevant study population.

6 You should also include a rationale for
7 your goals, and explain how you intend to meet those
8 goals. The guidance also describes the form and the
9 content, as I told you, and it also gives you
10 recommendations to help ensure that the requirements
11 are met.

12 So I have here a list of some selected
13 FDA guidances that speak to diversity in clinical
14 trials, and just for your reference, I need to
15 acknowledge my colleagues in division under different
16 offices.

17 And I am looking forward to a day of
18 learning and sharing with you all. Thank you very
19 much.

20 MS. MULUGETA Thank you so much,
21 Mathilda.

1 We're going to take clarifying
2 questions during the panel discussions. Also of note,
3 we're keeping the introductions very brief.

4 You have QR codes at each table, and
5 you can access the bios, as well as the meeting
6 agenda. For our online participants, the bios are
7 available also on the event website.

8 Something that we've tried to do a bit
9 differently with this workshop is really incorporate
10 the voice of the patients and families throughout the
11 agenda.

12 And we are really happy to have Michael
13 and Michelle Burgess provide the KEYNOTE talk today.
14 They are representatives of the International
15 Children's Advisory Network or iCAN.

16 So Michael and Michelle, please.

17 MS. BURGESS: Good morning.

18 MULTIPLE SPEAKERS: Good morning.

19 MS. BURGESS: My name is Michelle
20 Burgess, and I am here with my son.

21 MR. BURGESS: Michael Burgess.

1 MS. BURGESS: We want to thank you all
2 for having us on today. Like it was currently said,
3 we are representatives of the International Children's
4 Advisory Network, affectionately known as iCAN, and we
5 are so honored and privileged to be with you on today.

6 My iCAN family, I see a couple of you.
7 Can you raise your hands out there? Hi there. I see
8 you. Let's give them applause.

9 So everybody, let me just say this.
10 I'm grateful to be here. I am so thankful for the
11 participants and even the individuals that brought
12 this all together. It takes a lot of work to bring a
13 conference like this together.

14 So I want to thank Dr. Carla Epps.
15 She's been so important in this work and helping to
16 guide us. Thank you to Michelle Pollack, Ms.
17 Jennings. Thank you to Robin Ruger [ph].

18 I haven't even seen your faces yet.
19 I'm from Chicago, so I don't know a lot of people per
20 face, but I want to thank you. Thank you to those who
21 have made this possible for us on today.

1 So now that I have gotten all of the
2 formalities out the way, let me just say this, this is
3 my son's first public speaking engagement. So can you
4 all make him feel right at home?

5 He's not in the hospital today. He is
6 not behind a hospital door in a bed. He's standing
7 with his mom.

8 So thank you, Michael. This is my
9 dream to be with you like this.

10 So we have a presentation for you
11 today. It's called "Enduring Hope." Please, go with
12 us as we take you on a journey of Michael's life and
13 how we have come through some very strong and
14 challenging barriers to clinical trial engagement, but
15 how as a family we have been successful.

16 So I'm going to start us off. It's
17 going to be conversational in tone, and we're just
18 going to go back and forth.

19 So Michael Julian Burgess, my son, was
20 diagnosed with sickle cell SS at the age of 1 week
21 old. Michael had his first pain crisis at age 8

1 months.

2 And I remember the doctors telling us
3 that this is a time bomb; it's ticking, so you won't
4 know exactly how the disease is going to behave until
5 you kind of live it out.

6 So my husband and I were on pins and
7 needles when he was first born, and the first crisis
8 hit at just a tender tiny age of 8 months.

9 During that time -- this is in 2008,
10 the hospitalization frequency was about maybe three
11 times per year. So it was hard, but it was
12 manageable. And Michael started treatments at Lurie's
13 Children's Hospital at the age of 8.

14 MR. BURGESS: So throughout my life
15 I've had multiple surgeries, starting at the age of 3
16 and most recently, about a year and a half ago, I just
17 got my gallbladder taken out.

18 And ever since 2018, the
19 hospitalizations have just been going up just
20 drastically. It was told that it's probably because
21 of me being a teenager and puberty, but we don't know

1 the exact reason yet.

2 And I began this new clinical trial
3 back in April this year, and it's really been helping,
4 and it's really made my life a lot easier.

5 MS. BURGESS: Thank you, Michael.

6 Now, let me just take the formal hat
7 off. This is a picture of my family, you all. So it
8 was a lot to even get us together to take this
9 picture. You know, families are under a lot of stress
10 these days, so just taking a picture is phenomenal;
11 okay?

12 Michael thoroughly enjoys spending time
13 with his loved ones and friends to help ease the
14 stress of constant chronic pain.

15 So Michael has a tribe, and this is his
16 tribe, this is his community. We undergird him when
17 hospitalizations come. Even when clinical trial
18 participation is a factor, we still undergird our son.

19 MR. BURGESS: So back in -- is it 2020?
20 Back in 2020, when I was 12, I was recommended for
21 this clinical trial, which I'm on right now, which is

1 really helping.

2 And I was next in line to get it, and
3 then suddenly the FDA changed the age to 16, and so I
4 was no longer qualified for the clinical trial.

5 And no matter what my parents said, no
6 matter what I said, there was nothing that changed the
7 fact that I had to wait another four years -- enduring
8 pain for another four years, while the
9 hospitalizations kept going up during -- with age.

10 And I started to lose hope that it was
11 never going to get better. And I don't know how I was
12 going to endure these four years, but with my family
13 behind my back supporting me and my friends, I was
14 able to keep going and finally made it.

15 MS. BURGESS: Thank you, Michael.

16 And so Michael has been a participant
17 in several clinical trials during his lifetime. And
18 so these are some of the barriers, the real-time
19 barriers that I've heard some presenters already talk
20 about.

21 Family/community distrust. So we come

1 from a larger tribe of family and community. We are
2 deeply embedded in the heart of our community in one
3 of Chicagoland's most underserved neighborhoods.

4 And so my husband and I are leaders
5 there. And when we would, you know, discuss that
6 we're going to have clinical trials -- we're going to
7 enroll Michael in this trial, his doctor talked to us
8 about it. This could possibly be something that could
9 bring some relief. We don't know.

10 There was a lot of distrust that was
11 already told to us -- that was communicated to us,
12 "Well, why would you let your son do this? Are you
13 sure? Do you remember," or "Do you remember what
14 happened," you know, talking about, you know,
15 historically what has happened in our black and
16 underserved communities to our African Americans.

17 So that was hard to get through. It
18 was hard to go to the hospital, finish that particular
19 treatment for that trial, and to come home and to,
20 "Oh, so you decided to do it; huh? You went against,
21 you know, our better judgment; huh?"

1 And so the distrust, it was hard to
2 overcome that barrier. The validity of suffering is
3 something else that was hard to overcome.

4 Oftentimes, because Michael has what I
5 call an "invisible disability," there are those who
6 would say, "Well, is he really suffering; do you
7 really need to go through this clinical trial," or,
8 "Oh, my God," like, you know -- sometimes even hearing
9 jokes just about the suffering and, "Does it really
10 take all of that," that is a barrier. That's a mental
11 barrier.

12 How many of you all know that comes and
13 attacks your mental health when you hear those things.
14 Distance, underserved communities. We live in Austin,
15 which is a underserved Chicagoland community.

16 It's amazingly the largest community in
17 Chicago with over 475,000 people that live in that
18 particular area. It's well-populated, but it's
19 underserved. That was a barrier to clinical trial --
20 financial constraints, job flexibility.

21 Some of the trials that Michael has

1 been involved in have required so much time off. And
2 I have to pay a mortgage, just like you. So that was
3 really hard, because sometimes our jobs were even
4 threatened.

5 My husband is a high school principal
6 at one of the top high schools in Chicagoland. I am
7 also a district administrator. And our jobs were
8 often threatened with the amount of time that we would
9 have to give towards Michael participating in the
10 clinical trial.

11 Financial participations and
12 stressors -- I'm sorry, family participation and
13 stressors. I have two other children, as you all saw
14 on the previous slides. They have lost their parents.
15 They lost their parents. And oftentimes that's
16 something we talk about as a family.

17 So when my kids hear, "One more thing,
18 ma; one more thing to manage," it's what we have to
19 do. So that's a stressor.

20 So that's a barrier to clinical trial
21 participation and just endurance, mental capacity,

1 just the stress of it all, and disappointment when
2 we're not approved for a clinical trial. So these are
3 all barriers that our family has had to face and had
4 to overcome.

5 MR. BURGESS: So recently when I was
6 talking about in April, I was able to qualify for the
7 trial again, because I was turning 16, and a hope kind
8 of reunited for me, because I was told that this
9 clinical trial, like, really helped for sickle cell
10 patients, and I was very excited to see what life
11 actually feels like to be less in pain.

12 I'm still in pain, but it's a lot less
13 than before, and it's a lot less frequent than before.
14 And it's just been really nice to just have a little
15 bit of stress taken off my life with this clinical
16 trial.

17 And I still wish that this could have
18 happened four years ago, but I know that life happens,
19 and you just got to keep rolling with it, and that's
20 what I'm doing right now.

21 And I was able to be a part of my

1 hospital's advisory board for kids. It's been, I
2 think, three years now, and it's been nice to be able
3 to advocate for other kids and just to be a big help
4 in changing my hospital for the better.

5 And then I was able to go to the
6 international version of that, the iCAN conference,
7 for the past two years.

8 And that has been a really nice journey
9 to be on -- to be able to travel and meet tons of new
10 people that are going through similar challenges that
11 I have and just to know that I'm not alone and that
12 there's other people like me; and it's been very nice.

13 MS. BURGESS: Well, I want to talk
14 about it. Michael just got his driver's permit. So
15 can you all give my son -- that's huge.

16 I mean, it might sound like a little
17 thing, but when you're a kid and you're struggling
18 with a chronic disease that you're told you're going
19 to die with, I mean it's -- the little things really
20 help build that endurance of hope. And clinical
21 trials is another thing that can help build our

1 endurance for hope.

2 So recommendations, everybody. We come
3 to the conclusion of our presentation. So to foster
4 patient and family engagement -- you all have said it
5 already -- so I'll just reiterate it, access to
6 medical resources in their communities.

7 So we live in Austin in Chicago,
8 Illinois. There are very few medical clinics where we
9 are. So Lurie's Children's Hospital is about seven
10 miles from our home. It is a trek.

11 Michael's hospitalizations had spiked
12 up to about three times per month, about four days
13 each time. So the back and forth, it is just hard, so
14 adding a clinical trial participation to that.

15 So that's what we need as real-time
16 community dwellers. We need listening tours to ensure
17 that our needs are met. I know that this particular
18 public workshop is part of a listening tour.

19 Having our voices at the table
20 saying -- you know, equity of voice, "Ms. Burgess,
21 Michael, come to the table; we want to hear from you;

1 we want to hear what you're experiencing and what do
2 you really need," that can help foster, I believe,
3 success in any clinical trial and research.

4 Community town halls to educate
5 communities on the impact and important of disease
6 awareness. See, in our neighborhood the distrust is
7 very high.

8 People would rather stay behind doors
9 and suffer with their disease or illness, self-
10 medicate, self-treat, than actually to go and see a
11 physician until the situation is almost too late.

12 So we would really benefit from
13 community town halls where hospitals and clinicians
14 could send representatives to come out and gather us
15 as a community and say, "Welcome to the table. Your
16 voice and your opinion matters."

17 Finally, political will to eradicate
18 systematic injustices in healthcare. We need you.
19 Like the presenter before me said, this is bringing
20 the human connection.

21 We need you. We need your expertise,

1 coupled with our lived experience, to really bring
2 forth clinical trials that are really going to be
3 impactful and effective.

4 Thank you all so much for this
5 opportunity. I would like to thank Ms. Leanne West
6 from iCAN, who is the president. I would like to
7 thank her team, and I would like to thank all of you.
8 I look forward to meeting you all. You are no longer
9 strangers. You are friends. Thank you.

10 MS. MULUGETA: Thank you so much, Ms.
11 Burgess and Michael.

12 It's really hard to believe this is his
13 first time speaking in public, so maybe if we can give
14 him one more round of applause.

15 Okay. Our next speaker is Christine
16 Lee. She's the acting associate commissioner and
17 director for the Office of Minority Health and Health
18 Equity.

19 MS. C. LEE: Thank you so much.

20 Ms. Burgess, Michael, thank you so much
21 for sharing your story with us. I think it's so

1 important to recognize not only your voices, but your
2 lived experiences, as you mentioned.

3 You said a couple of key words in your
4 talk that I hope that I can also highlight. Equity of
5 voices, town halls, the bidirectional relationship,
6 that connection piece, the humanization element, which
7 I really hope that, you know, in this talk we also
8 amplify.

9 And I also want to point out that I'm
10 going to try to avoid word clouds with this talk and
11 really focus on actions, which I think that everyone
12 is looking more forward into.

13 All right. So I'm going to spend the
14 next 20 minutes or so going over the FDA Office of
15 Minority Health and Health Equity and the work that we
16 have done to really advance pediatric health equity.
17 Here's our standard disclaimer slide.

18 So the FDA Office of Minority Health
19 and Health Equity, also known as OMHHE, our mission is
20 to promote and protect the health of diverse
21 populations through both research and communication

1 that addresses health disparities.

2 We also have a vision. This is, you
3 know, my favorite vision, which is to create a world
4 where health equity is a reality for all.

5 So what do we do in this space? I'm
6 not going to go too much into the operationalization
7 of the office, but we have two programmatic areas. We
8 have the research and collaboration program, and we
9 have an outreach and communication program.

10 The intent for all of our programs is
11 to really connect with the communities that we serve
12 and really advance health equity, including
13 understanding the unmet needs of our diverse
14 communities.

15 So as mentioned, I'm going to avoid
16 word clouds as much as I can here. We all know the
17 right words to use, equity, population health, health
18 disparities. These are words that we all know to use.
19 I want to try to avoid this and show you the actions
20 that we have taken in the last three to four years.

21 In September 2021, we launched our

1 enhanced equity initiative, which really started this
2 action piece when it comes to health equity.

3 In March of 2023, which is about a year
4 and a half ago or so, we launched our Enhanced Equity
5 Research Hub, which I talk about very briefly here.

6 But after talking to some of our
7 audience members, I really think I should have had a
8 couple extra slides here. But please, if I don't have
9 slides here, come up to me afterwards, and I'll walk
10 you through the Enhanced Equity Research Hub.

11 And a year and three months ago, we
12 launched our newest initiative, which one of our PIs
13 is here -- you hear from her in just a little bit --
14 Dr. Billie Jo Kipp, the OMHHE Racial and Ethnic
15 Minority Acceleration Consortium for Health Equity.

16 The key term here is "acceleration,"
17 because many times we tend to talk about this, but
18 where's the action and the acceleration to action?

19 So even though this is only a year and
20 three months old, I think we've done tremendous work,
21 thanks to our wonderful PIs that we have.

1 So going into the first action item
2 here, which is the Enhanced Equity Initiative, the
3 Enhanced Equity Initiative has three equity branches
4 or three equity pillars.

5 The first one is equity in clinical
6 trials, which is the topic of today, and I'll go into
7 some of our projects in this space.

8 The enhanced equity clinical trial area
9 looks at not only understanding barriers and unmet
10 needs, which was shared a little bit earlier today
11 around the clinical trial barriers, but also looking
12 at strategies, especially community-driven strategies
13 on what it means to increase engagement for your
14 community.

15 We also have our equity and data
16 efforts. As we know, there's a lot of missingness
17 when it comes to equity of data. Many times without
18 data, we don't know what direction we're heading in.
19 Are we heading in north, south, west, east; right?

20 So really understanding our
21 comprehensive data when it comes to our diverse

1 populations that we serve.

2 The third element here, which you know,
3 I think it was meant to be, Ms. Burgess talked about
4 equity of voices. This is also one of our equity
5 branches.

6 The equity of voices is a two-part
7 branch. The first part is really understanding the
8 unmet needs. Ms. Burgess talked about town halls
9 going into communities.

10 This is exactly what equity of voices
11 has done through our community leaders, like Dr.
12 Billie Jo Kipp here, for example, in the tribal
13 nations, that she'll talk about in just a couple
14 minutes or so.

15 It's really having the community
16 leaders have these town halls. I always say that many
17 times, if you don't have that trusted connection, why
18 would someone share with you their unmet needs?
19 There's no trust; right?

20 So many times when we do town halls
21 that don't have that trusted element, what ends up

1 happening is that we get another word cloud, because
2 there's the lack of trust.

3 So really having, for example, our
4 tribal colleges, our HBCUs, our fairly qualified
5 healthcare system docs, do the town halls, really
6 connect with the community, what we find is there's a
7 richness of information that comes out. Information
8 that we may not have ever heard of before. The unmet
9 needs really surface to the top.

10 The other thing with equity of voices
11 is after we understand the barriers, the unmet needs,
12 then we can better tailor communication strategies.
13 For example, my sister, she's 10 years younger than
14 me, we communicate very differently.

15 I have no idea of what language she's
16 using half the time. So really understanding, you
17 know, how the communication preferences need to be
18 tailored.

19 Okay. So moving on, we haven't updated
20 this for our FY24, but we will be soon. As you can
21 see, the growth of the OMMHE Enhanced Equity

1 Initiative has grown tremendously from about 10
2 projects in '21 to now we will be topping at more than
3 60 projects, all which can be found on our Enhanced
4 Equity Research Hub.

5 So here, I would really like -- I'm a
6 very visual person, so I'd like to see the growth of
7 our program. So what does it mean? Remember, I
8 promise a lack of word cloud. So here's my stand-in.

9 So our enhanced equity initiative of
10 FY21, our equity of clinical trials, what are the
11 fruits of our labor here?

12 So, of course, I'm a Floridian girl, so
13 I had to use oranges to set the example here. But as
14 you can see here, this is the product -- the fruits of
15 our labor over the last three to four years.

16 We are now at 24, not 22, clinical
17 trial studies that look at the barriers for our
18 populations. Looking at it from an age perspective,
19 from a racial and ethnic minority perspective, from a
20 rural perspective, from a tribal population
21 perspective, it doesn't make any sense to clump

1 diverse populations into one bucket.

2 For example, I talked about my sister a
3 little bit earlier. Although we're both Asian, her
4 communication strategies are very different from mine.
5 Her unmet needs are very different from mine. So it's
6 very important as we're creating these tailored
7 clinical trial strategies that we keep this in mind.

8 The other thing that Ms. Burgess
9 mentioned a little bit earlier was the connection
10 point. So having an ability -- a platform to connect
11 with the FDA.

12 I'll show a couple pictures near the
13 end of platforms -- environments that we have created
14 at the FDA, as well as going into the community.

15 So we're trying to do one here, one
16 within a community; one here again and one within the
17 community, to really get the voices when it comes to
18 meetings, workshops, listening to diverse
19 perspectives.

20 Also, we have our OMHHE guidance
21 document. Mathilda mentioned a little bit earlier the

1 diversity plan guidance. We also have our race and
2 ethnicity standardization guidance document. And we
3 also have our longstanding clinical trial campaign.

4 So here's our longstanding clinical
5 trial campaign. Everything is publicly available. If
6 you want free material shipped to you, we can also do
7 that also.

8 But online, we have about 12 languages
9 available. We have our fact sheets; we have our
10 webpage; we have podcasts; we have webinars, that
11 really highlight the importance and strategies on
12 advancing clinical trial diversity.

13 Here's the guidance that I mentioned in
14 one of the oranges. So this is our guidance on the
15 collection of race and ethnicity data in clinical
16 trials.

17 The purpose of this guidance -- I
18 mentioned it a little bit earlier the importance of
19 data -- the equity of data element. Without
20 standardization of race and ethnicity data reporting,
21 it's very difficult to understand what that data

1 means.

2 So this is our guidance on the
3 collection of race and ethnicity data in clinical
4 trials. The main point here is using standardized
5 terminology for race and ethnicity helps ensure the
6 data is collected consistently and supports
7 demographic data analysis.

8 All right. So this was this past April
9 for our National Minority Health Month. You'll
10 recognize in the middle, in pink, Dr. Billie Jo Kipp,
11 who is here, who will be speaking a little bit later.

12 But this was really a invitation from
13 our communities, from our tribal nations, our racial
14 and ethnic minority populations, our rural
15 populations, to come here and share the strategies
16 that work for their communities.

17 And what was very interesting was that
18 there was very overlapping similarities in what they
19 were saying, but very important, it was important to
20 recognize the nuances too. So that was also
21 highlighted throughout.

1 I mentioned a little bit earlier about
2 the 60 plus projects that we have funded through the
3 Enhanced Equity Initiative. This is just one that was
4 tailored towards our young adults.

5 So here, this was a very interesting
6 process. What we heard through the focus groups with
7 young adults were, yes, we want to participate in
8 clinical trials, but I don't want you to tell me what
9 to do. All right. Second of all, but if you don't
10 tell me, I'm going to be mad at you.

11 All right. So this is where I was
12 like, "Oh, my goodness, I don't know what to do." So
13 they took a bunch of these young adults and threw them
14 in a room, and they're like, "Workshop it"; right?

15 So this was their creation, which I
16 call "a dating app." So this is the clinical trial
17 dating app.

18 So here, what the young adults wanted,
19 they wanted to control over their preferences. So
20 they would put in the app, "I'm looking for this in a
21 clinical trial. I'm looking for this geographic area.

1 I'm looking for -- these are the things that are
2 important to me."

3 And then the app would geolocate those
4 preferences to a clinical trial that matched their
5 preferences. So this is just one of the innovations
6 that come through our Enhanced Equity Innovation
7 Awards.

8 Dr. Ann McMahon will be talking about
9 this in just a couple more minutes. But this is
10 another way for us to really advance research, which
11 is through our intramural grant funding process, which
12 is funding our internal FDA scientists.

13 And here -- I won't talk too much about
14 this, because she'll do a much better job than me, but
15 her study really aims to highlight and test the
16 hypothesis that children of racial and/or ethnic
17 minority populations are underrepresented in pediatric
18 clinical trials.

19 Moving on to the second equity branch
20 are equity of voices. So what have we done in this
21 space? So we have 17 Equity of Voices research

1 projects. Remember it's two parts. One part is
2 really understanding the unmet needs, and the second
3 part is the culturally tailored communication
4 strategies.

5 We also have our Equity of Voices
6 videos that are publicly available online, and anyone
7 can access. We also have our podcasts and webinars.
8 And we also have our language access program that
9 focuses on translation.

10 So here's some of the work that's in
11 this space -- our podcast, which is available online.
12 If you're ever in a long car ride, please tune in.
13 And here's our language access program.

14 Going on to equity of data, we have six
15 projects within this space. And I just wanted to
16 highlight that all of these studies actually
17 contributed to the last orange right there, which is
18 the Enhanced Equity Research Hub, which I mentioned
19 just a little while ago. I'll get to that in just a
20 little bit.

21 So for equity of data, when we talk

1 about equity of data, there's so many challenges in
2 this space from the lack of attention of awareness of
3 the racial and ethnic minority data in real-world data
4 settings, the lack of, you know, understanding of
5 potential covariates and demographic variables that
6 can contribute to confounding outcomes, and a lack of
7 attention to barriers that prevent reporting from
8 racial, ethnic, and other underserved populations.

9 Missingness is a huge problem also.
10 Sometimes the data sets that we look at have
11 missingness from about 60 to 70 percent missing as
12 when it comes to racial and ethnic minority
13 information, which at that point, I'm not really sure
14 what we can do with this data.

15 And then also there's that struggle
16 with understanding prevalence estimates of disease
17 population. Because of all of the challenges listed
18 above, if you have such a high missingness, how can
19 you calculate the prevalence of the disease?

20 Oh, okay. All right. So this is an
21 area that -- you know, one of the studies that we did

1 was we funded a study with Stanford University with
2 Dr. David Rehkopf of Stanford.

3 And he really looked at understanding
4 the American Family Cohort database, which is the
5 largest EHR data set on primary care in the U.S.

6 And this was really our first way of
7 understanding what other types of data are out there
8 that we can look at that doesn't have such a high
9 percentage of missingness.

10 And so this was an area that we have
11 been exploring. I'm running out of time, so I'm going
12 to go through these slides really quickly. But as you
13 can see, you know, here's some of the pediatric data
14 that we have from the study.

15 The Enhanced Equity Research Hub, as
16 mentioned a little bit earlier, and I really wish I
17 had an extra slide or two here to show you the
18 Enhanced Equity Research Hub, but you can search by --
19 this is all publicly available -- just Google Enhanced
20 Equity Research Hub, you can search by race.

21 So for example, if you wanted to look

1 at the work that's been done in the space of the Asian
2 population when it comes to clinical trial strategies,
3 you would pull down here, and you would choose Asian.

4 The Enhanced Equity research aim, let's
5 say you're looking at voices -- you wanted to
6 understand what has been done to elevate and amplify
7 the voices of our diverse communities, you would then
8 scroll down here, and there will be a dropdown, and
9 you would click Equity of Voices or Equity of Clinical
10 Trials.

11 You'll be able to sort by age, so under
12 18, between 18 to 64, and above 64, ethnicity, and
13 then disease/condition of interest.

14 We have not too many in here, but we
15 have sorted it by, like, for example, sickle cell,
16 hepatitis B, et cetera. This is a way for you to also
17 sort by disease state.

18 And as mentioned, our newest
19 initiative, the REACH consortium that was launched one
20 year and three months ago.

21 So as we were growing the orange tree,

1 does anyone want to point out what was missing in the
2 orange tree?

3 Michael, you want to try? No. Okay.
4 All right.

5 So with the orange tree, the problem
6 with the orange tree is that it takes about five years
7 to grow an orange. And that to me is just too long of
8 a time for us to recognize that there's a health
9 equity problem and for us to take action.

10 So the Racial and Ethnic Minority
11 Consortium, REACH -- remember I said, "acceleration,"
12 the A was important here, was a way for us to be
13 responsive to health equity needs.

14 So here -- but we know, and, you know,
15 Ms. Burgess brought this up, you can't be responsive
16 if you don't have trust. If you don't have respect --
17 if you don't have bi-directional relationships, you
18 will not have readiness.

19 That's just not how it works. I cannot
20 ask a population to respond if there is no pre-
21 existing relationship there.

1 So once again, it was developed for it
2 to have a timely and efficient way for the FDA to
3 connect with the diverse communities that we serve.

4 Here's some of the REACH consortium
5 members. So they represent, for example, the
6 federally qualified healthcare systems. In fact, we
7 were just there the last month doing another town hall
8 round table.

9 We have the University of Puerto Rico
10 and the healthcare systems within Puerto Rico. We
11 have the University of Hawaii and the Queens Medical
12 Center within Hawaii. We have the tribal communities
13 that will be presented by Dr. Billie Jo Kipp later on.

14 We have community centers, nonprofits,
15 serving the Asian community, the LGBTQ plus community,
16 rural communities throughout the nation, and we have
17 our HBCU and faith-based organizations.

18 Here's some of our researchers. As you
19 can see, they have a diverse background from
20 physicians to HBCU presidents to tribal college
21 leaders, from pharmacists to researchers, et cetera.

1 Some of the work -- I know I'm totally
2 over time, so I won't go through all of this work, but
3 much of the work that's being done in this space is
4 actually looking at advancing clinical trial
5 enrollment for diverse populations.

6 As mentioned, the next couple slides
7 will just be couple pictures, but here's the FDA REACH
8 panel that happened last April, which brought together
9 our communities. Here's an example of the round
10 tables at the agency. This was focused on rural
11 communities.

12 And we also provide environments for
13 our communities to connect, because as Ms. Burgess
14 says, the humanization is so important.

15 So for the agency to have an ability to
16 connect with the community leaders, with the HBCU
17 presidents, with the tribal leaders, for that
18 connection to happen and to foster and to create an
19 environment for it.

20 And that's it. Any questions, which
21 I'll take later on. Thank you.

1 MS. MULUGETA: Thank you so much,
2 Christine. Our next speaker is Sue Rahman. She's the
3 chief scientific officer at the Health Data Synthesis
4 Institute.

5 Sue.

6 MS. RAHMAN: Thank you.

7 So as a pediatric researcher, I was
8 invited to provide some insights from academia, but as
9 a pediatric clinician, the voice of the patient is
10 incredibly important to me. So the voice of children
11 will feature throughout this presentation.

12 Now, this audience is well aware of the
13 importance of pediatric clinical trials, but you may
14 be less aware of their value outside of medical
15 progress.

16 Years ago we spoke with children
17 engaged in clinical research at our organization and
18 asked them about their experiences, and we learned
19 from them that clinical trials are a way for them to
20 express their altruism; clinical trials allow them to
21 engage with the healthcare system in a manner that may

1 be very different to what they experienced when
2 they're sick, and in their own words, clinical trials
3 offer, "Novel opportunities."

4 And it's my opinion and I'm guessing
5 the opinion of almost everybody here, that those
6 opportunities should be available to all children,
7 irrespective of their circumstances.

8 More recently, we partnered with iCAN
9 to understand children's perspectives on diversity in
10 clinical trials. And the very first question I asked
11 them was, "Is it important that research includes a
12 diverse group of children?" And their affirmation was
13 unanimous.

14 They spoke with us at length about
15 issues related to equity and justice and inclusivity.
16 But it was Ed who brought me to tears when he spoke
17 about their importance to his psychological wellbeing.

18 (Audio plays.)

19 I don't feel alone. Have you heard a
20 more powerful argument for inclusivity efforts in
21 clinical trials?

1 We also asked the kids what they
2 thought of when they heard the term "diversity" in the
3 context of clinical trials. And not surprisingly,
4 they identified age and race and gender and ethnicity
5 at the top of their list.

6 But they also recognized a host of
7 other individual patient factors that in their mind
8 could contribute to the disposition and action of
9 drugs.

10 So back to the topic of my
11 presentation, which is the academic perspective, why
12 is it relevant? This table here offers a snapshot in
13 time at one point last year from clinicaltrials.gov.

14 There were 440 industry-funded studies
15 posted to clinical trials that met the criteria listed
16 there. And those 440 studies were enrolling children
17 from 8,770 trial sites. And when duplicates were
18 removed, 79 percent of those trial sites represented
19 academic organizations.

20 So what this tells me is that the
21 inclusivity behaviors adopted by academic researchers

1 shape the representation patterns we see in nearly all
2 pediatric studies.

3 Apart from an investigator's own
4 personal views on diversity and ensuring
5 representation, can we identify other drivers that
6 influence diversity in academic-led pediatric trials?

7 Well, legislation is one place to look.
8 We have the NIH Revitalization Act of 1993, which
9 assures that race and ethnicity is recorded for every
10 trial that receives federal funding.

11 However, there's no enforcement
12 mechanism in that legislation. Just because an
13 investigator has to record and report racial and
14 ethnic data doesn't mean they're ensuring
15 representation in the trials they oversee.

16 Industry behaviors also influence
17 diversity in academic-led pediatric trials. I've
18 worked with industry sponsors for 25 years on trials
19 and cannot recall a single point in time when I was
20 asked about my experience engaging underserved
21 populations.

1 When information was requested on
2 demographics by way of feasibility questionnaires, it
3 was often for the organization as a whole, rather than
4 for the clinical trials we conduct.

5 So if representation metrics are
6 lacking in industry trials, we may not be asking the
7 right questions of clinical trial sites up front.

8 Industry also influences diversity in
9 academic led pediatric trials through their enrollment
10 strategies.

11 When a sponsor opts to engage a larger
12 number of sites with fewer participants per site, you
13 put investigators in a competitive enrollment
14 situation, and that means they don't have the luxury
15 of time or resources to engage less accessible
16 populations.

17 And fewer resources mean less sustained
18 investment in infrastructure for clinical trial sites,
19 especially those trial sites that serve
20 underrepresented populations.

21 So how are we doing in academia? We

1 chose to look at studies funded under the best
2 Pharmaceuticals for Children's Act as just one
3 indicator of representation in academic studies.

4 Across 34 studies, enrolling at 167
5 study sites, over 11,000 participants, we saw a
6 reasonably strong agreement between observed
7 enrollment and expected enrollment, based on census
8 sampling at the same frequency in the same regions as
9 in the clinical trials.

10 So big picture, it doesn't look bad,
11 but if we restrict our view to this big picture, we
12 are missing a piece of this puzzle.

13 When you start to break it down by
14 geographic region, you can identify clear statistical
15 trends of over and underrepresentation in clinical
16 trials.

17 And when you break it down further by
18 state -- in this example, I'm using an ecological
19 marker of diversity as the metric, you can see a large
20 degree of variability across the country.

21 I suspect that degree of variability

1 would be the same or magnified if we were able to look
2 site by site. But those data aren't yet publicly
3 available and I'm going to argue at the end of this
4 presentation that they very much should be.

5 So let's go back to our kids. Why do
6 they think some studies don't include a diverse group
7 of children? And they had a lot of ideas. And I'm
8 going to give you a second to look at those here, and
9 we are going to dive into some of these in the next
10 few slides.

11 One of the areas where we fall short in
12 academic research is engaging participants with
13 limited English proficiency. These data are from a
14 survey we conducted of major research organizations
15 across the U.S.

16 Now, what we were hoping to identify
17 was the rate of consent form translation in these
18 organizations. What we did identify was that 70
19 percent of the responding organizations were not able
20 to pull this information from their IRB systems --
21 their own institutional IRB systems.

1 And if you can't review the data, you
2 can't track progress or the lack thereof. When
3 consent translation was occurring, it was typically
4 into one other language and that was often Spanish.

5 Now, this issue was so important for us
6 at my former organization that our IRB undertook a
7 five -- a three year -- sorry, pilot study. What the
8 IRB did was offset the cost of all consent translation
9 for any federal or internally funded study.

10 And what we saw was an exponential
11 increase year over year in the number of trials that
12 had translated consent forms.

13 So progress, good, but we also
14 recognize that consent translation is a very small
15 piece of the puzzle of effective engagement strategies
16 for non-native language speaking participants.

17 We also drop the ball when it comes to
18 participants with limited literacy who may not fully
19 understand the implications of participation.

20 And this can affect their interest in
21 enrolling in the study. This can affect their ability

1 to effectively deliver on the requirements of a
2 participant as laid out in the protocol. And this
3 particular challenge requires solutions that are a bit
4 more creative.

5 With funding from the National
6 Endowment for the Arts, we chose to look at
7 illustrated consent forms as one possible solution for
8 this challenge.

9 We partnered with local artists and art
10 students to create illustrations. We partnered with
11 the community to vet those illustrations, and we
12 worked very closely with the IRB to ensure that those
13 illustrated consent forms met the requirements laid
14 out by relevant regulations.

15 By the time I left that organization,
16 we had illustrated consent forms in nine subspecialty
17 programs at the organization.

18 We do a major disservice to our
19 participants and, frankly, ourselves with the
20 misconceptions we have about clinical trial
21 participation.

1 The most misguided and damaging of
2 which is that individuals of the racial and ethnic
3 minorities are not interested in participating in
4 research.

5 These are great data from Wendler, who
6 demonstrate absolutely no evidence of decreased
7 participation in interventional studies, in non-
8 interventional studies, and in surgical studies.

9 But if you look at their data closely,
10 what you will see is the minority populations are
11 offered participation in clinical trials at a much
12 lower rate than the majority.

13 I can corroborate the data from
14 Wendler. I spent 25 years working with
15 underrepresented populations, and whether we were
16 doing cross-sectional studies, longitudinal studies,
17 whole genome studies, our participation rates were
18 exceedingly high. And that comes with effective
19 engagement with the community.

20 We hamstring ourselves by designing
21 clinical trials that are excessively burdensome to

1 participants and their families.

2 And this disproportionately impacts
3 patients and participants of low socioeconomic status
4 who may not have the bandwidth to accommodate
5 disruptions to work or family obligations.

6 We went back and revisited those BPCA
7 studies I mentioned earlier to try to understand how
8 do burdensome elements get introduced into trials.

9 We looked at the elements that were
10 introduced by sponsors. We looked at the elements
11 that were recommended by regulators. And not
12 surprisingly, both parties contribute to adding
13 burdensome elements to protocols.

14 If we want to maintain an abroad
15 population of patients, I recommend we start thinking
16 about burden benefit considerations in the same way
17 we've been taught to think about risk benefit
18 considerations.

19 That means making sure we understand
20 how children perceive burden as well. And we recently
21 undertook a pilot in conjunction with iCAN to get at

1 some of that information.

2 These data from Kite underscore the
3 importance of being thoughtful about what we ask
4 patients and participants to do in clinical trials,
5 especially when we think of the fact that many of the
6 things we may ask them to do never translate into
7 generalizable knowledge.

8 There are systems issues that hamper
9 our ability to ensure representation in clinical
10 trials. Organizational databases may not collect race
11 and ethnicity data adequately, and they may actually
12 collect it incorrectly.

13 This is a striking example of race and
14 ethnicity data as reported by parents on a child's
15 birth certificate versus what winds up in the
16 electronic medical record. And look at the
17 discordance for some of these populations. It really
18 is quite striking.

19 But it's not just a system issue. If
20 patients are reluctant to disclose this information,
21 it may be because we're not asking the question in the

1 right way or we may not be explaining why this
2 information is important to what we're doing.

3 Finally, there has to be an element of
4 accountability, and academia has been doing a better
5 job of making sure that metrics on race and ethnicity
6 participation is made available.

7 This is not the forum to debate the
8 benchmarking metrics that are being used. Needless to
9 say, there are a number of them in that text box.
10 They have their advantages and limitations.

11 But one, these are very big picture
12 metrics, so they don't allow us to drill down. And
13 two, the most striking thing, is that these are all
14 retrospective. So if we want to impact representation
15 in pediatric trials prospectively, we need different
16 types of data.

17 We need to understand who is being
18 provided care in academic organizations and how that
19 compares to who's being offered clinical trial
20 participation in those same organizations.

21 We proposed a metric that takes this

1 into consideration in a 2021 call-to-action paper that
2 I had published.

3 And we encouraged, actually challenged,
4 research organizations to make this data or similar
5 data -- it doesn't have to be this metric, publicly
6 available in the same way that we make outcomes data
7 for interventional procedures like transplant and
8 medical management, like cystic fibrosis, available
9 site by site publicly for everyone to see.

10 A lovely example of where benchmarking
11 can move the needle outside of the healthcare space is
12 in the publishing space.

13 And these are some great data from the
14 Cooperative Children's Book Center at the University
15 of Wisconsin. They look at thousands of children's
16 books every year, and they look at representation in
17 those books and make that information available in
18 creative communications like these.

19 And over the past 40 years, they've
20 been integral in moving the needle on representation
21 in children's books. And there is no reason we can't

1 do the same thing in pediatric clinical trials.

2 I am going to close by sharing what we
3 asked of our children, which is, if you were in charge
4 of research, what would you do to make sure studies
5 were diverse? And they have a lot of ideas. We just
6 have to listen.

7 A lot of the children we spoke to
8 focused on communication and partnering and
9 relationship building. But I will tell you, they
10 astutely recognized that it's going to take an
11 extraordinary effort.

12 These are some fun facts about the kids
13 that I spoke to. And if you want to hear more from
14 them in their own words, we've got excerpts from my
15 interviews with them on the pediatric trials network.

16 But instead of my word, I want to close
17 by giving the final word to one of our kids at iCAN,
18 Rhiannon who when asked, "What would you tell
19 researchers who think that ensuring diversity is too
20 hard," responded with this:

21 (Audio plays.)

1 Thank you.

2 MS. MULUGETA: Thank you so much, Sue,
3 for that great talk and for keeping us on track.

4 We're going to go ahead and take a 10-
5 minute break, so if you can come back to this room at
6 10:30. So a 10-minute break, and come back at 10:30.
7 Thank you.

8 (Off the record.)

9 PAM SIMPKINS: Thank you. Thank you
10 very much, Lily.

11 Good morning, everybody. As Lily said,
12 I'm Pam Simpkins, and I'm a managing partner at
13 Mezzopointe. It's an R&D strategy consulting firm.

14 I've spent about 26 years in the
15 biopharmaceutical industry. I just recently retired,
16 but I have to say that the last 10 years were the most
17 fulfilling, because it was 100 percent dedicated to
18 pediatric product development.

19 So today I'm going to present a
20 landscape overview of pediatric product development
21 from industry's point of view.

1 Okay. So it's skipping some slides.
2 Well, I'll speak to my disclaimer, which should be up
3 there, but I have -- everything that I'm about to
4 discuss today, the data and viewpoints are my own. I
5 also have acknowledgements.

6 First and foremost, I want to thank all
7 of the millions of pediatric patients and their
8 caretakers, who participate in pediatric clinical
9 trials.

10 The other acknowledgement, many things.
11 I'm going to present a lot of data today. I have two
12 data partners.

13 Oh, thank you.

14 My data partners -- as most people know
15 in pediatric product development, a lot of data sets
16 are not structured with pediatrics in mind -- there
17 are many nuances, and so these partners have really
18 helped me with evaluation very appropriately for
19 pediatrics for 6 and 15 years respectively, so I want
20 to give some thanks to both Maria and Sean [ph].

21 Okay. The slides are jumping around.

1 May I have some assistance with the slides? It should
2 be agenda. Okay. Thank you very much.

3 So today, I'm going to cover four
4 important topics, a historical view of industry-
5 sponsored pediatric clinical trials, two short case
6 studies that will bring the data to life, highlights
7 of pediatric specific nuances, and a forward-looking
8 view to set the stage for action planning.

9 Impetus. Okay. Thank you.

10 So why did I do this analysis, and why
11 is it on the agenda? Well, there are many efforts
12 underway to improve pediatric product development.

13 And I think all of those strategies
14 would benefit from contextual information, such as who
15 is conducting pediatric research; what diseases and
16 indications are being studied; where are we going in
17 the world to enroll patients; how long is it taking to
18 bring innovation to children; what are the
19 complexities, and where should we focus our efforts?

20 So I set out to answer those questions,
21 because there are no pediatric-specific comprehensive

1 analyses of historical experience in upcoming trials.

2 I won't have a lot of time today, so
3 I'm just going to focus on information that we can
4 then use with a goal towards setting the context for
5 knowledge expansion and strategy development, setting
6 the stage for later sessions in today's meeting.

7 May I have the historical
8 characterization? Oh, back. No, back from there.
9 All right. Let's see.

10 Okay. Here we are. So let's start
11 with the historical view.

12 So I reviewed 15 years of data, and I
13 was focused only on industry-sponsored pediatric
14 clinical trials. I included all phases, all
15 indications, all countries, modalities, and sponsors.

16 And my resulting data set has 2,500
17 clinical trials all aiming to support the safe and
18 effective use of therapies for children.

19 So what did I find? Who's conducting
20 these studies? Approximately half are conducted by
21 relatively large companies, and the other half by mid-

1 size companies and biotechs.

2 What percentages are required under the
3 law? And some of this was alluded to earlier today.
4 Two-thirds are required by the law, specifically the
5 Pharmaceutical Research Equity Act or PREA, and one-
6 third are voluntary.

7 And the voluntary ones are typically
8 pediatric specific or pediatric-only studies, or they
9 are conducted under the Best Pharmaceuticals for
10 Children Act, or BPCA. And Dr. Heickman, later today,
11 is going to talk more about the laws.

12 In terms of therapeutic area
13 distribution, it wasn't surprising to me revealing
14 dominance by immunology, inflammation, followed by
15 neuroscience, and vaccines.

16 And the size and scope of our trials,
17 excluding vaccines, shows small enrollment, which we
18 expect, and significant dispersion across the world.

19 And I won't have time today, but
20 there's so many other important characterizations to
21 examine, and they will be worthwhile to review

1 certainly in other meetings.

2 Where are we going in the world? Over
3 the 15-year period, the U.S. and the E.U. have been
4 the primary locations for our pediatric trials, and I
5 expect that to be the case going forward.

6 So I was very curious about what has
7 been happening more recently. So in the last five
8 years, I noted some noteworthy changes.

9 The war in Russia and Ukraine has
10 halted research for children in those countries and in
11 neighboring Turkey. China, South Korea, Argentina,
12 and Canada have experienced significant increases in
13 site openings, and South Africa and India have been
14 declining significantly. Further investigation will
15 be needed to understand why.

16 So let's put country enrollment in
17 perspective. And Susan alluded a bit to this in terms
18 of small enrollment per site. So let's dig in a
19 little bit here.

20 So to provide a tangible example of
21 what the last two slides really mean -- so small

1 studies with participants dispersed across the world,
2 I'm going to share oncology.

3 Very low disease prevalence, total
4 enrollment in late phases averages about 70 patients,
5 and as you can see, we would need to go to seven
6 countries to enroll, resulting in approximately ten
7 patients per country. So this is a really good
8 example of high dispersion.

9 In comparison, adult oncology trials
10 are 15 times larger per country. So I highlight this.
11 This is one of only many differences to consider as we
12 craft solutions for children. Our strategies are
13 fundamentally different than those in adult research.

14 So let's talk about time. How do all
15 of these factors and many more that I could not cover
16 today, including study design, contribute to the
17 length of time it takes to complete a pediatric
18 program?

19 An analysis done a few years ago shows
20 that there is a nine-year gap -- nine years, between
21 adult approval and pediatric data in a label. This

1 means that a new drug approved today for psoriasis in
2 adults, as an example, might not have pediatric data
3 until 2033.

4 During eight years of that time,
5 pediatric programs are being conducted, and I think
6 most people will agree this timeline is too long. And
7 over the 15 year period when I looked over all my
8 data, unfortunately, that average has not improved.

9 So as I said, eight years is the
10 average across all indications. But if you drill down
11 to timeline estimates at the indication level, you'll
12 see that each indication varies.

13 So the starting point for ulcerative
14 colitis, as an example, might be nine years, but
15 landscape dynamics will impact this time.

16 What do I mean when I say, "dynamics"?
17 Let's look at UC a little bit more closely. But first
18 some context.

19 UC does occur in children, mostly in
20 adolescents. It's more aggressive in children than in
21 adults. So we do have a sense of urgency. There are

1 approximately 2,000 children in the U.S. with moderate
2 to severe UC.

3 There are no differences in phenotypic
4 presentation that have been noted by race. However,
5 differences in clinical outcomes have been noted by
6 race. Therefore, much more work has to be done. This
7 will require a much better understanding of the
8 science and of social determinants of health.

9 Given this context, let's say a sponsor
10 plans to complete a program in nine years. But that
11 plan must be executed at the same time that several
12 other products are trying to enroll the same
13 participants. In moderate to severe UC, there simply
14 aren't enough children to enroll them in all of these
15 trials.

16 So let's take this example. On the
17 left-hand side you see that there are 16 trials
18 currently enrolling or planning to enroll in moderate
19 to severe UC during the 2024 to 2030 period. These
20 are actual studies.

21 On the right-hand side, some data

1 points. As I mentioned, there are only 2,000 children
2 in the U.S. with moderate to severe UC. 415 of those
3 children, or 20 percent, are currently being
4 prescribed at least one newer drug off-label. So
5 those children will not participate in a trial.

6 Sixteen concurrent trials are active or
7 will be as I mentioned. And so given this situation,
8 it will take 20 years to complete all of these
9 studies, not 9.

10 So I present this example, because in
11 pediatrics, adding in market dynamics and other
12 factors specific to the indication and to the children
13 who suffer from this disease, is absolutely critical.
14 When you do that, the nine-year timeline is clearly
15 unrealistic.

16 Let's switch to an indication with
17 higher prevalence and see how historical data can be
18 used to inform a strategy.

19 So asthma is a good example. We know a
20 lot more about the presentation in children by race
21 and by gender. We also know where the asthma capitals

1 are. These are cities with the highest prevalence,
2 highest ER visits, and highest deaths from asthma.

3 So I mapped those 20 asthma capitals
4 shown here, and I also mapped historical patterns of
5 site activations. In doing so, I identified a sponsor
6 that was very consistent in site activations in those
7 asthma capitals. So I contacted them.

8 I interviewed a leader at that company
9 and received their permission to present this blinded
10 case study.

11 I learned that this sponsor did not
12 face the magnitude of concurrent trials, like my UC
13 example, but they faced other obstacles, and some of
14 those we've covered early this morning.

15 Distrust of research among parents,
16 grandparents, faith-based leaders, and children was a
17 significant issue.

18 In addition, social determinants of
19 health factors like environmental, air quality, living
20 with grandparents, reliance on adults for
21 transportation, use of electronic diaries, all became

1 major considerations in the enrollment and the
2 retention strategy.

3 And so my takeaways from this great
4 interview were these: Go to where the patients are;
5 reduce their burden; know the location, and understand
6 the needs of diverse participants by going into the
7 communities and asking; put a patient-centered
8 strategy to work; community programming around working
9 with school nurses was quite pivotal for this leader;
10 add adolescents to adult trials to drive faster
11 access, and use data science, specifically
12 extrapolation, which is the borrowing of data from
13 other cohorts, either adults or older children
14 whenever that's appropriate.

15 All of these things in this leader's
16 mind were absolutely critical to shortening the
17 timelines.

18 With this in place, the leader's goal
19 was to cut the median timeline almost in half and
20 collect generalizable data, because her participants
21 would reflect the population intended for this

1 therapy.

2 And while she's not quite done with the
3 trial yet, she fully expects that this strategy will
4 help her team collect all the data that they need and
5 exceed their diversity goal. It was a great story,
6 and it was wonderful interviewing her.

7 So at a much higher level, this
8 historical landscape work enables us to narrow our
9 focus on important actions that can have a positive
10 impact on the quality, speed, and efficiency of
11 pediatric product development.

12 It also deepens our understanding of
13 the challenges, all of which I'm confident we can
14 overcome so that we can be proactive and thoughtful in
15 addressing them. And I only list a few here.

16 So let's wrap up the historical view.
17 Pediatric product development continues to be long and
18 complex, and I hope the data and examples I provided
19 gives you perspective on what I really mean when I say
20 that.

21 Given our collective goal to improve

1 the process and outcomes for children, I hope this
2 historical perspective provides good context for
3 forward-looking strategies, including those needed to
4 achieve the appropriate representation in our trials.

5 So with history behind us, let's look
6 forward. How do we know what's coming down the
7 pipeline for pediatrics? Well, what we do, typically,
8 is we look at the adult pipeline.

9 Why? You'll remember earlier I
10 mentioned that 67 percent of pediatric clinical trials
11 are required under PREA, and, therefore, they
12 typically follow the adult approvals.

13 So the adult pipeline is often used to
14 provide directional feel for upcoming industry-
15 sponsored pediatric clinical trial activity.

16 So I looked at the adult pipeline.
17 This slide shows the volume of late stage adult
18 clinical trials currently happening in these six
19 indications.

20 I pulled these six, because they are
21 very relevant for pediatric research. If the products

1 in these indications are approved, it is very likely
2 that a pediatric clinical trial will be required by
3 law.

4 Based on this volume, it's likely that
5 we will have some challenges with multiple concurrent
6 studies in type-2 diabetes, obesity, and atopic dermatitis,
7 very similar to my UC case study, since many companies
8 are pursuing new products in these indications.

9 So my question is, given what we know
10 about these indications and about historical patterns
11 discussed today, what insights can we apply to future
12 pediatric trials? How can we be proactive?

13 Wrapping up, we know what's coming.
14 Significant upcoming pediatric activity will be
15 important in ten plus indications, and we have the
16 opportunity now to plan to do better -- better in
17 trial designs, better in enrollment, better in
18 achieving diversity, better in creating faster access
19 for our children.

20 What I do know is that we can do it
21 together, and I love when Michelle said, "Endurance

1 for hope." I have very strong hope that we can do it
2 together.

3 I'd like us to use this information and
4 our collective knowledge to formulate actionable
5 strategies that benefit all children, so they have
6 speedy access to the therapies they deserve.

7 Thank you so much.

8 MS. MULUGETA: Thank you so much, Pam.

9 We're going to transition to the panel
10 discussion now, and I would like to invite Dr. Dionna
11 Green, who is the director of the Office of Pediatric
12 Therapeutics, as well as Lois Lee, who is a senior
13 associate in Pediatrics in the Division of Emergency
14 Medicine at Boston Children's Hospital, to co-moderate
15 the panel discussion, along with the panelists, if you
16 can go ahead and come up now, please.

17 MS. GREEN: Well, thank you to all the
18 panelists today who have already spoken, and then we
19 have three panelists who are joining, and we have
20 questions from our virtual audience, but also we would
21 love to take questions from all of you.

1 But we are going to start with our
2 three panelists who have not presented yet. And first
3 is Sneha Dave.

4 If you want to, just tell us a little
5 bit about why you're here today.

6 MS. DAVE: Yeah. Hi everyone. My name
7 is Sneha. I am the executive director at Generation
8 Patient, which is an organization I created when I was
9 13 years old.

10 I've been living with severe ulcerative
11 colitis since I was a little under 6 years old. And I
12 had the colectomy surgery, which is the removal of my
13 large intestine, when I was in high school, which
14 prompted me to create one of the only organizations
15 focused on young adults, so thinking about this
16 transition period between pediatric and adulthood.

17 And now, we have four staff members.
18 We're entirely young adult patient led, and we focus
19 on areas of peer support, health policy, which
20 includes clinical trials, and leadership programming.

21 MS. L. LEE: Thank you, Sneha, for

1 joining us today. So we're just going to start with a
2 few questions for you.

3 Given Dr. Abdel-Rahman's presentation
4 included -- I love the videos with the input from our
5 patients regarding their thoughts about clinical trial
6 diversity, what stood out to you about some of the
7 perspectives they shared?

8 MS. DAVE: Yeah, I think the last video
9 with Rhiannon was particularly empowering for me
10 personally, and I think really alludes to the point
11 that there's an urgency that we, as patients, feel
12 that may not always be felt by those who don't have
13 the same lived experience of being a patient.

14 I also think, in general, from the
15 presentation and from the perspectives, it was really
16 fascinating, because I think we think about engagement
17 and about community as part of the trials, and I think
18 maybe 80 percent of the conversations that were being
19 had or problems can be solved by engaging the
20 community members.

21 But I even think it goes beyond

1 engagement and thinking about how can we have patients
2 leading as PIs on some of these projects and some of
3 these clinical trials.

4 I think, you know, we especially as
5 young adult patients, see our role as not only
6 engaging, but also being able to drive some of this
7 research.

8 So for example, on a PCORI award, which
9 is not a clinical trial, we are the youngest PIs on a
10 PCORI award. And so really thinking, you know,
11 differently about how we can be engaging and enabling
12 patients to be driving some of these outcome's
13 endpoint developments from the very beginning I think
14 was really -- yeah, pardon my perspective.

15 I have other things but I'll pause,
16 because I don't want to take up the whole panel.

17 MS. L. LEE: Do we have any questions
18 for the audience? Otherwise, I'll have one more
19 question for Sneha.

20 Okay. One more question for you. As a
21 patient representative, what are some of your key

1 concerns about trial participation that differ across
2 diverse pediatric populations?

3 MS. DAVE: Yeah, I think, for myself --
4 so my parents are both immigrants from India, and so
5 thinking about the different cultural backgrounds of
6 how western medicine has been viewed and really being
7 able to open up conversations about, you know, what
8 are your beliefs as part of this trial, in addition to
9 these standardized therapies that we're thinking
10 about.

11 I also think in terms of being able to
12 communicate things in a plain language, you know,
13 like, "We're testing this for this reason," is the way
14 that you could just make things very clear and simple
15 in terms of communicating what a trial is in the first
16 place, because even the word "clinical trial" feels
17 very scary to a lot of people, especially for kids and
18 younger folks.

19 And then just two other things really
20 quickly on that. I just really feel like there's a
21 huge opportunity with long-term safety data and a lot

1 of questions that we still think about as patients,
2 but also I can only imagine for care partners and
3 parents what that's like.

4 And I think there's a huge opportunity
5 to do a better job with being able to show that this
6 is how we're going to be thinking about long-term
7 safety data after the trial. And, I mean, I know in
8 IVD, there's so much that needs to be done.

9 So anyway, last thing I'll just say is
10 the affordability of the therapeutics, especially as
11 we're aging into adulthood, older adolescents, I mean,
12 we are thinking about the financial repercussions of
13 being able to afford therapeutics after the trial as
14 well.

15 So post-trial access is something that
16 needs to be clarified, because, I mean, personally,
17 I'm on a medication that costs a lot of money, and I
18 have to make decisions about my life based off of
19 that.

20 And so when we're thinking about trust,
21 I think, you know, part of that is are we making sure

1 that these therapeutics are available and accessible
2 and affordable after the trial too.

3 MS. L. LEE: Thank you very much,
4 Sneha.

5 So next I'd like to turn to you, Dr.
6 Bourgeois, to introduce yourself, and then we have a
7 couple of questions for you.

8 MS. BOURGEOIS: Wonderful. Hello,
9 everyone. So nice to be here today. My name is
10 Florence Bourgeois. I'm a clinician scientist at
11 Boston Children's Hospital and Harvard Medical School.

12 My research focus is around building
13 informatics-based tools to support pediatric
14 infrastructures or research infrastructures and
15 clinical trial networks and evaluating methods and new
16 approaches around policies and statistical tools to
17 conduct research towards the development and approval
18 of pediatric therapeutics.

19 MS. L. LEE: Great. Thank you very
20 much. So we just heard from Pam Simpkins, and she
21 really did walk us through a very in-depth pediatric

1 landscape analysis that was rich in data and had quite
2 a few insights that I think will be food for thought
3 for all of us to chew on throughout the rest of the
4 day.

5 But I'd like to start with you to first
6 hear what are some of your thoughts on the information
7 she shared?

8 MS. BOURGEOIS: Yes, thank you for
9 that. So I think Pam's presentation was really
10 terrific and pivoted a little bit from the issue of
11 diversity in clinical trials to the more fundamental
12 question of just equity for kids period compared to
13 adult drug development.

14 So a lot of the data that she showed,
15 again, underscored the need to highlight pediatric
16 research and drug and device development for children,
17 because the focus continues to be for adults.

18 I like to say that most drugs and
19 devices are not developed for children, but they are
20 sometimes eventually studied in children.

21 And so this driver of the adult

1 priorities then being sort of what we end up with for
2 kids is something that we should really think about,
3 and what are some of the approaches to pivot towards a
4 focus that is driven from the pediatric-needs
5 standpoint.

6 MS. L. LEE: And so based on your
7 experience, given your research and looking at
8 participation in diversity, where are some areas that
9 you feel that things are going well in terms of
10 diversity in clinical trials?

11 MS. BOURGEOIS: Yeah, that's a good
12 question. So with drugs and devices in particular,
13 many of these trials are for diseases that are
14 primarily treated in tertiary care organizations --
15 the hospitals, which tend to be in more urban
16 locations.

17 And so for drugs and device trials we
18 tend to see greater diversity, which was actually
19 nicely shown in the study that I think Christine maybe
20 showed where the -- or no, Sue, with the BPCA studies
21 and their representation.

1 So among drug trials there was good
2 representation and diversity for those studies.
3 Again, these are very specialized interventions in
4 patient populations, so we're doing well on that
5 front.

6 But as you pointed out, this may not
7 generalize to all trials across other types of
8 diseases or intervention types.

9 MS. L. LEE: Thank you. And do we have
10 any questions from the audience before we move on to
11 our next panelist?

12 Well, I invite you to think of your
13 questions and please just line up at the mics, and we
14 will call on you once you do. Thank you.

15 MS. GREEN: Next on our panel is Dr.
16 Ann McMahon. So if you could, tell us a little bit
17 about why you're here today and we'll have some
18 questions for you as well.

19 MS. MCMAHON: Thank you. My name is
20 Ann McMahon, and I work at the FDA. I've been here
21 for 22 years. And I think that you heard Dr. Lee talk

1 briefly about the study that they are funding for us
2 to do in the Office of Pediatric Therapeutics that
3 we've been doing over the last year. And so I wanted
4 to just say a few words about that.

5 I just also wanted to give credit to
6 the team, which has been working on this, from the
7 Division of Pediatric and Maternal Health and from the
8 Office of Pediatric Therapeutics and from the Office
9 of Biostatistics.

10 We looked at trials submitted to the
11 FDA under BPCA and PREA and focused on children with
12 diabetes type-1, diabetes type-2, and obesity.

13 We chose those diseases, because there
14 are high proportions of Hispanics and non-whites among
15 children with these diseases in the U.S. Therefore,
16 potential underrepresentation of these groups could
17 have an important effect on the population at large.

18 We used three U.S. databases giving us
19 races and ethnicities in the general population of
20 children with these diseases in the U.S., the Search
21 study for Diabetes in Youth, the National Health and

1 Nutrition Examination Survey, or NHANES that you may
2 have heard of, and the U.S. Census data.

3 We performed chi-squares to compare
4 clinical trial, race, and ethnicity prevalence in the
5 general population with the -- sorry, the clinical
6 trial race and ethnicity prevalence with the
7 background data that is the disease-specific
8 background data and the prevalence of race and ethnic
9 ethnicity in that.

10 So what we found, the preliminary data
11 is that compared to the race ethnicity distribution in
12 the U.S. pediatric population with diabetes type-1,
13 type-2, and obesity, there was strong evidence of
14 underrepresentation at the P less than 0.05 level by
15 race and ethnicity for diabetes type-1, diabetes type-
16 2, and obesity.

17 Yeah. That I can -- I'm not going to
18 go into the specific numbers. We're putting together
19 our data at the moment, but it's definite that there
20 was underrepresentation in a number of the trials
21 submitted to the FDA.

1 MS. GREEN: So it's great to hear about
2 the internal work that's being done at the FDA, as
3 well as we heard about some of the external work being
4 done in academia and industries.

5 So obviously, having everybody's sort
6 of eyes on this, you know, moving forward will help us
7 improve our enrollment and participation.

8 We had sort of talked about some
9 metrics for appropriateness for the prevalence of race
10 and ethnicity in pediatric clinical trials. So are
11 there any existing, you know, metrics that we can kind
12 of look to as we build metrics for the future?

13 MS. MCMAHON: Well, our study gives you
14 an example of a quote metric, which is P less than
15 0.05, comparing to some background group as compared
16 to the clinical trial.

17 But I would not say that that's, by any
18 stretch of the imagination, a metric that has been
19 accepted in the general research community.

20 And I would say that my search of the
21 literature suggests that various statistical methods

1 are generally used to determine underrepresentation,
2 but I didn't find a lot of concurrence about specific
3 statistical methods that should, quote/unquote, be
4 used.

5 MS. GREEN: Thank you. And I think
6 part of the problem has also been pointed out; we
7 don't know the true prevalence of the diseases in some
8 of our population, so it's hard to know what the
9 baseline is, much less where we should be as far as
10 our enrollment. So thank you.

11 MS. MCMAHON: Thank you.

12 MS. L. LEE: So Ann, there was one
13 clarifying question for you online, which was what
14 data sets were used for the pediatric study that
15 you're describing? Can you clarify that those studies
16 were submitted to the agency and maybe just talk a
17 little bit more about that.

18 MS. MCMAHON: Sure. The studies that
19 we used were submitted under BPCA or PREA, and I can't
20 tell you which studies were for which right now, but
21 they were submitted to the agency under BPCA and PREA.

1 Carla, do you want to say more? Okay. Yeah.

2 MS. L. LEE: Okay. Thank you very
3 much. And we have a question from the audience.
4 Please, go ahead, and if you can, say your name,
5 affiliation, and your question.

6 MS. EPPS: Okay. Thank you. Good
7 morning, everybody. My name is Carla Epps. I'm from
8 FDA from the Division of Pediatrics and Maternal
9 Health.

10 My question is about, for me anyways,
11 an elephant in the room that some people don't
12 apparently see, which is the fierce urgency of now --
13 in addressing diversity in the pediatric population.

14 I was actually one of the members of
15 the team that Ann alluded to and for some other of my
16 work.

17 What I wanted to point out is that for
18 the pediatric population in the U.S., it is already a
19 minority majority population, and yet I don't hear how
20 that's being taken into consideration for activities
21 around this issue. So I don't know if people wanted

1 to speak to that.

2 Thank you.

3 MS. L. LEE: Would anyone like to
4 start? Do you need a clarification? I think there
5 needs to be a little clarification on the question.

6 MS. EPPS: I guess one is just, do you
7 hear in activities that you all are involved in about
8 the fact that our children are a very diverse
9 population, more so than the adults, and what does
10 that -- already, and rapidly increasing, and what does
11 that mean in terms of the pace or the focus of
12 activities on increasing diversity in pediatric
13 trials?

14 Thank you.

15 UNIDENTIFIED SPEAKER 1: I don't know
16 if this answers the question exactly, but what I can
17 comment on is the need to capture that diversity more
18 accurately.

19 So right now, when we're making
20 comparisons between diversity in clinical trials and
21 the U.S. population, we're largely using U.S. Census

1 data, which if you look at it, is quite crude and
2 really not reflective of the current demographic
3 diversity in our children.

4 For example, there's an increasing
5 proportion of children who self-identify as multi-race
6 or ethnicity. And that is not accurately captured,
7 neither are many of the other emerging subgroups.

8 So I would say in order to adequately
9 address this moving forward, we also need standardized
10 race and ethnicity classifications that reflect our
11 pediatric population.

12 MS. C. LEE: I just wanted to add to
13 that. That's a great point. So currently right now
14 with our OMB SPD 15, there is an update to our
15 standardization of race and ethnicity capture. So
16 right now, patients can check more than one box.

17 So for example, my son can check Asian
18 and white, as my husband is white. So this will
19 increase our availability of data standards, but
20 going -- sorry, availability of data.

21 But going back to Carla's question, as

1 she's asking the question, I keep thinking back to the
2 last round table that we had, which was in the rural
3 communities.

4 And as we know there is a very high
5 increasing proportion of diverse children in rural
6 communities, and there's, you know, very unique
7 nuances and barriers that we need to increase our
8 awareness to.

9 So thank you so much, Carla, for that
10 question.

11 MS. L. LEE: Thank you. So we're going
12 to take one question from online, and actually it has
13 to do with Michael being willing to share earlier, and
14 again thank you Michael, your struggle with having to
15 wait four years to be in a clinical trial.

16 And so the question is, the individual
17 states that this reminded them about the gap that
18 exists, that Pam pointed out between when a product is
19 approved for use in adults to when there's information
20 for use in children in the labeling.

21 And their question for the full panel

1 is, do you think that diversity action plans will help
2 shorten that gap, or do you think it will become yet
3 another barrier to the prevention of efficient and
4 effective pediatric clinical trials?

5 MS. SIMPKINS: I'd love to start. So
6 as my data showed, we really have to look indication
7 by indication. So I don't want us to make sort of
8 broad sweeping commentary about like all of pediatric
9 product development, because I think that would be a
10 disservice.

11 The last thing I think we want is to
12 add to the number of years. That gap can grow if we
13 make sort of blanket statements or goals about what we
14 ought to achieve.

15 I'll just draw on the example from the
16 ESMA interview. What I found was really striking with
17 this particular leader. The reason she was so
18 confident that she could cut the time was because she
19 was very focused on excellence by design.

20 So at the very beginning of your
21 design, as you're crafting your strategy, you know

1 that diversity has to be very critical to your
2 success.

3 We all want generalizable data. You
4 can't have generalizable data if your data doesn't
5 reflect the population intended for treatment. So
6 that's a tenant that we've always lived by.

7 So start with that as your design at
8 the very beginning, and I'm confident then that
9 actually you will shorten the timeline, because you're
10 looking at the right population that ought to be
11 enrolled.

12 MS. L. LEE: Thank you. That's a great
13 point. Anyone else? I think that summarizes it,
14 because yes, being intentional from the outset, being
15 strategic, and also leveraging best practices, which
16 we hope will come out of a workshop like today, that
17 will help inform other investigators and sponsors
18 about what has worked and what clearly doesn't work,
19 is going to help us move forward.

20 So next we'll go to a question from our
21 audience.

1 MS. MCMURRY-HEATH: Hello, Michelle
2 McMurray-Heath from BioTechquity Clinical. We're a
3 CRO helping companies diversify trials. And I just
4 wanted to expand upon the earlier audience question,
5 which is something I hear a lot from pharmaceutical
6 companies, what does good look like?

7 We know what bad looks like, but what
8 is the goal? Is the goal representation of the
9 general population? Is the goal representation of the
10 diagnosis? Is the goal just enough representation to
11 get statistically significant conclusions?

12 I think we need a conversation about
13 where we're trying to go, so everyone can, you know,
14 adjust accordingly.

15 MS. L. LEE: Very fair points. Thank
16 you very much.

17 Yes, please, Ann.

18 MS. MCMAHON: That's a great question.
19 And you know, we debated it some, but pretty rapidly
20 came to the conclusion that we thought it was fair to
21 compare clinical trial -- the disease or condition

1 that was being studied in the clinical trial, to
2 compare that to that disease or condition in the
3 general population.

4 And in this case it's the general
5 population in the United States, because FDA was the
6 one that was receiving the information.

7 So that's where we came from. I think
8 it's fair, but I know it's not the only possible
9 answer.

10 UNIDENTIFIED SPEAKER 2: One additional
11 thought on that is beyond thinking about sort of the
12 necessity of having generalizable results through good
13 representation, I think another factor to consider is
14 also good needs to mean that we have equity in terms
15 of access to new innovative emerging therapies across
16 diverse populations.

17 So it's not just about
18 generalizability, but it's also about equity to access
19 to these therapeutics.

20 MS. GREEN: One more question from our
21 audience, and then we'll take a question from the

1 virtual audience.

2 MS. KIPP: Thank you for that question,
3 and I wanted to follow up by what is good. And so I
4 think it's -- I am trying to struggle with this,
5 because what is good for one community might not be
6 good for another community, because there are
7 historical difficulties with the medical model with
8 certain communities, and certain communities have
9 struggled and victims been victims of poor research
10 and poor medical research science.

11 So what would good be like in
12 communities? Would that be maybe the community
13 saying -- because I think we're looking for a gold
14 standard of good, and I don't know if that's the
15 answer.

16 I think communities with the researcher
17 with outcomes with clinical trials define what is good
18 for them.

19 MS. C. LEE: Thank you so much, Dr.
20 Kipp. You're always here with so much wisdom. That
21 is entirely correct. In fact, what we have seen is

1 that beyond just the communities themselves, it also
2 depends on the disease state.

3 For example, our work with the
4 Hepatitis B Foundation, what we have found is that
5 religious leaders are a no-go when it comes to
6 clinical trial diversity.

7 So many times with stigmatized
8 conditions, having religious leaders convey the
9 clinical trial message actually prevents the community
10 from engaging in clinical trials.

11 So beyond just race and ethnicity, I
12 think it's very important to look at the disease also.
13 Also, working with the tribal nations, gene therapy
14 has many layers of, you know, I think, nuances before
15 we even get to the conversations when it comes to gene
16 therapy.

17 Another issue that I wanted to
18 highlight from Dr. Kipp's point is that if we are not
19 careful with engagement, many times what we have found
20 is that the community will close its doors to us.

21 So you know, that is something, and it

1 is almost impossible to reengage then, and you might
2 have to wait generations for that next opportunity.

3 So just for something to think about
4 beyond race, ethnicity, age, geographical location,
5 disease states, the nuances are incredibly important
6 to understand.

7 MS. GREEN: Thank you. So we're going
8 to take one question from our virtual audience and
9 then one more question in the audience here.

10 So this is for Dr. Christine Lee. Many
11 clinical trials are global as we've seen today, and in
12 these countries race and ethnicity information is not
13 even disclosed due to privacy concerns -- although,
14 only aggregated data are usually what's reported out,
15 is the FDA collaborating with other health authorities
16 in other countries on this issue?

17 MS. C. LEE: That's a great question.
18 Did this person read my mind? Yes, that is a topic
19 that we are currently exploring in great depths, and
20 we hope to, you know, have something out in the next
21 year or so. So yes. So, you know, I guess they did a

1 spoiler. Oh, yeah.

2 MS. GREEN: Okay. And another question
3 from our in-person audience.

4 MS. HILDEBRAND: Yeah. No. Thank you
5 for allowing me to ask the question. And great
6 discussion so far, and I would, I think, have two
7 points intertwined, which is a little bit started,
8 Pam, by your great presentation on the history of
9 things.

10 I'm not a hundred percent sure that the
11 future will really look the same, and we embark so
12 much on PREA and adult indications. If we look in the
13 upcoming -- what is coming in the science on cell and
14 gene on the high medical need and ultra-rare and rare
15 diseases, which for me pose two questions.

16 I think we may see a much higher need
17 for education for patients and doctors with regard to
18 this, because treatment pathways will even become much
19 more complicated.

20 And on the other hand, studies may
21 become much smaller on the one end, but on the other

1 hand we may really need much more global reach for
2 this.

3 So I think for me it's a question, how
4 can we go in with a diversity paradigm, which focuses
5 and only on the "prevailings" in one country, because
6 I think we -- we really have then to look global
7 and -- if we look in rare diseases, ultra-rare
8 diseases, cell, and gene.

9 So that might be the next iteration,
10 because this is a great start point, but I really
11 wonder what would be the outlook for this.

12 And it's for the whole panel. I don't
13 know who starts.

14 MS. SIMPKINS: Well, I'll start. So as
15 you can fully appreciate in my dataset, there was so
16 much that I could not cover today, but I did see real
17 momentum in cell and gene therapy, and the fact that
18 children -- because many -- you know, these are
19 congenital diseases, you're seeing children enrolled
20 in first-in-human studies; right?

21 So that's going to -- I think that's

1 going to change what we've seen historically with that
2 pattern of children following adults.

3 There's a merge now here between what I
4 think we've been learning in the rare disease
5 community and pediatrics.

6 I mean, you know, you could argue that
7 all pediatric or most pediatric diseases are rare
8 diseases, but I think historically we haven't really
9 talked about them together. But here, we're seeing
10 sort of a natural merge where we can share strategies,
11 learn from each other.

12 But I do think it's going to be a very
13 different paradigm, because we're going to see studies
14 where the first label will include children, at least
15 the cohort of children.

16 MS. L. LEE: Anyone else? Okay. Well,
17 then I would like to turn to youth too, and I want to
18 thank you for your presentation.

19 I think your incorporation of the
20 patient perspective was very powerful, and I had the
21 chance to look at some of the other parts of your

1 interview by going to the link you mentioned, and I
2 hope the rest of the audience will as well, because
3 there's some really important pearls of wisdom that
4 these children are providing to all of us.

5 But my question for you is, based on
6 all you know and all of your experience, where can a
7 investments be made that's going to really help to
8 enhance representation within clinical trials?

9 MS. YAO: I think there are a lot of
10 areas and many of which I touched on in the talk, and
11 I want to kind of leap off from the point you made
12 about these intentional designs when it comes to
13 trials.

14 And we can have the best intention when
15 it comes to intentional trial design, but if your
16 academic partners can't deliver on providing the
17 patients, that's a real problem.

18 And I firmly believe that there should
19 be some benchmarking mechanism that is available. We
20 have to be able to -- if I've got a rare disease and
21 I've got the luxury of resources, I'm going to look

1 for the hospital that's got the best record for
2 outcomes for that disease.

3 And I think industry should be able to
4 look at data preemptively to make intelligent
5 decisions about clinical trial site selection. So I
6 certainly think that's one area.

7 Another area where investments are
8 probably sorely needed, and I think we heard kind of
9 that reinforced through a lot of the presentations
10 today is in educational toolkits, education around
11 communication, and toolkits around communication.

12 We cannot approach partners and their
13 parents, communities, children, for research in the
14 same way we approach them for clinical trials -- I
15 mean, for practice. You know, my communication with a
16 patient is very different when I'm caring for them.

17 It's a lot more paternalistic and
18 informative, as opposed to when I'm trying to engage
19 them in clinical research. Which again, we've heard
20 that term "bi-directional" a lot; it's very bi-
21 directional.

1 It involves a lot more listening than
2 it does communication. And I don't know that we are
3 taught that as we as investigators. I think it's
4 something that we either -- is innately a part of what
5 we do as clinical academics and practitioners or it's
6 not. And I think there needs to be some guidance
7 there.

8 MS. L. LEE: Well, we're very fortunate
9 to have a representative on our panel from Generation
10 Patient, and we would love to hear your thoughts about
11 communication.

12 What are areas where you see that
13 there's maybe training or input that we can all take
14 away to say how best can we communicate to patients
15 and families about the importance of clinical trials,
16 but also ensuring we're listening clearly to their
17 needs?

18 MS. DAVE: Yeah, definitely. I think
19 one thing that's always been really tricky for me to
20 understand is the wide developmental stages of
21 pediatrics. So thinking about the fact that, like, a

1 8-year-old is very different than a 16-year-old, and
2 the materials needed to be delivered to a 16-year-old
3 might not look like cartoons or things that are, like,
4 you know, more for younger children.

5 So I think it's really important to,
6 one, note that, but two, it's really can be confusing
7 sometimes when care partners who have the best
8 intentions are also in the mix.

9 I think sometimes, you know, parents
10 tend to -- with all due respect to my parents, you
11 know, tend to, you know, think that they know what's
12 best for their kids, and they certainly are trying
13 their very best.

14 But at the same time we need to ask
15 kids even if they're 8 years old, 9 years old, we need
16 to give them that agency and that power that they can,
17 you know, make informed decisions or be part of that
18 process.

19 And I think this generation of kids
20 that are coming up are going to have the tools to be
21 able to do that more so than any other generation of

1 kids.

2 And so I think we can utilize social
3 media, graphics, and things like that, and I really do
4 think there's an opportunity for the FDA to even work
5 with more community groups to develop more plain-
6 language materials for their communities.

7 And even education that the FDA is
8 putting out, I think can be designed by community
9 groups for the broader public as well. So yeah.

10 MS. GREEN: Thank you for that
11 perspective.

12 So in our last few minutes, trying to
13 end a little bit on a high note, what is already being
14 done that is successful that we can continue and
15 should build upon? And this is open to all our
16 panelists.

17 MS. SIMPKINS: Okay. I'll jump in. So
18 something I'm really excited about, specifically in
19 pediatrics, is the use of data science. There's so
20 much that we already know and we should be leveraging
21 that data to supplement what we could learn in

1 clinical trials.

2 Almost to the point where in many
3 instances our trials don't have to be as long and as
4 big as they are, because we're borrowing data that
5 already exists that can really inform the safe and
6 effective use of our therapies.

7 I'm thinking specifically of
8 extrapolation -- I'd love to see a stronger uptake
9 there, and really public/private conversations around
10 the use of extrapolation, because I think there's a
11 lot that we can learn from each other, other types of
12 data science techniques, like the use of Bayesian
13 statistics. There are a number of different things
14 that we can do with technology and data to really
15 streamline pediatric product development.

16 If you can't tell already, I continue
17 to be disturbed by the length of time. I do think
18 that we have a lot at our disposal to help bring
19 medicines to children faster.

20 MS. YAO: I would say an area that I'm
21 very excited about is the emergence of remote clinical

1 trial participation. Accessing populations who, you
2 know, Michelle mentioned you're seven miles from
3 Lurie, but seven miles in Chicago takes 40 minutes to
4 get there.

5 So making sure that we are starting to
6 look at trial designs that allow us to go where the
7 patient is instead of having them come to us.

8 UNIDENTIFIED SPEAKER 3: I'll expand
9 just a little bit on the sort of potential of data
10 science that Pam brought up.

11 So in addition to extrapolation, there
12 are vast amounts of digital data now available that
13 can be accessed to augment and complement randomized
14 controlled trials, which as we know are incredibly
15 resource intensive and difficult in small dispersed
16 populations such as many pediatric illnesses.

17 So with all these electronic health
18 record data, for example, insurance claims data, we
19 can conduct observational studies, again to complement
20 our traditional RCTs.

21 The big issue there that remains to be

1 addressed is that beyond just demographic factors,
2 what we really need are many of the variables that get
3 at social determinants of health. And that is
4 currently incredibly challenging.

5 And so thinking of ways that we can
6 better use these observational data sets to capture
7 these relevant variables to get at differential access
8 to healthcare and responses to different types of
9 interventions will be a critical step to make full use
10 of this potential additional resource.

11 MS. MCMAHON: We're providing -- at the
12 moment, working on a article talking about pharmaco
13 epidemiology in pediatrics, and one of the things that
14 we're talking about is putting AI in there, and I
15 would say AI is something that is probably going to
16 make a difference in the coming 10 to 20 years for --
17 exactly as you were saying, for pharmaco epidemiology
18 in pediatrics and in general.

19 And also, I just wanted to say that
20 this kind of a conference that that is being put on
21 today is a great boon for the field. I mean, I think

1 it really gives us a sense of where we need to be
2 going.

3 MS. L. LEE: Excellent. Well, thank
4 you. I think you'll have the last word there, Ann,
5 because we're at time, and I think that's a really
6 nice way to summarize it.

7 This conference is signaling where
8 we're going, but it's also signaling what we're
9 prioritizing.

10 So I want to thank our panelists and
11 speakers for their input this morning and expertise.
12 Please, join me in thanking them.

13 MS. MULUGETA: Thank you so much.
14 Thank you to our moderators and panelists. This marks
15 the end of Session 1, which was Current Status of
16 Pediatric Trial Participation and Lessons Learned.

17 So the rest of the day we'll focus on
18 inclusion strategies. So we're going to go ahead and
19 take a one hour lunch break. So if we can reconvene
20 at 12:30. That's slightly less than an hour, but
21 12:30 if you can please come back so we can get

1 started with the rest of the day.

2 Thanks so much.

3 (Off the record.)

4 MS. MULUGETA: We're going to go ahead
5 and get started.

6 So we're going to go ahead and get
7 started so we can stay on time. So we're going to
8 start Session 2 with some case examples of inclusive
9 trial designs.

10 Our first speaker is Rachel Randell.
11 She's an assistant professor of pediatrics at Duke
12 University and Duke Clinical Research Institute.

13 Rachel.

14 MS. RANDELL: All right. Thank you.
15 And thank you all for being here this afternoon. This
16 morning's content mentioned a couple times,
17 decentralized or remote trials, so I'm very excited to
18 share with you an example of one of these types of
19 trials.

20 At the Duke Clinical Research
21 Institute, we like to call these types of trials --

1 sorry, I'm having some difficulty with the clicker
2 here.

3 Well, I'll just say briefly that at the
4 Duke Clinical Research Institute, we like to call this
5 type of trial "Direct to family" to highlight the
6 critical importance of the family in pediatric trial
7 participation.

8 Thank you.

9 And that includes of course, the
10 primary caregivers, but also the greater family, the
11 community.

12 So these are our funding and
13 disclosures. So I think this group is very well aware
14 that pediatric trials are difficult to conduct for
15 many reasons. However, multicenter research networks
16 have been able to overcome these many challenges to
17 successfully conduct trials in children.

18 One example is the NIH-funded Pediatric
19 Trials Network, or PTN, which has over 200 sites, to
20 date has conducted more than 50 studies, and data from
21 those studies have led to 21 FDA label changes to add

1 pediatric specific information on therapeutic dosing,
2 pharmacokinetics, and safety.

3 Another example that's specific to my
4 field of pediatric rheumatology is the Childhood
5 Arthritis and Rheumatology Research Alliance or CARA
6 Registry.

7 So for those who aren't familiar with
8 the structure of a multicenter research network, I've
9 provided CARA here as an example.

10 So the map on the bottom left-hand
11 corner of the slide, you can see in blue and teal
12 circles, these indicate sites, which are individual
13 children's hospitals or clinics where families and
14 children go to receive their clinical care for their
15 rheumatologic condition and also participate in
16 research.

17 These sites then report to a central
18 site, a coordinating site, which is the Duke Clinical
19 Research Institute actually for both of these
20 examples.

21 And then depending on the structure of

1 the research network, there may also be a separate
2 data coordinating center. So one can imagine that
3 this gets incredibly complicated. It's also expensive
4 and slow.

5 The operational overhead for one of
6 these types of trials is estimated to be about \$10,000
7 and 200 hours per subject enrolled.

8 On this slide, I was planning to
9 discuss some of the potential barriers from the
10 family's perspective. But I think after today's
11 KEYNOTE address and such a wonderful journey that
12 Michael shared and Michelle's talk, there's absolutely
13 nothing more I need to say about that.

14 Instead, I'd like to share with you an
15 approach called "Decentralized trials," also referred
16 to sometimes as "virtual remote" or "direct-to-
17 family," or "direct-to-participant" trials.

18 So instead of asking the family to
19 travel to a research site, which then reports to a
20 central site, we basically flip that on its head, and
21 we, as the central site, work directly with families.

1 There are lots of examples of different
2 types of studies that have been done this way, but
3 really a key underpinning is the use of technology for
4 remote data collection.

5 This occurs through things like video
6 conferencing, devices, wearables, as well as
7 electronic questionnaires that can be completed on a
8 cell phone, tablet, or a computer.

9 It's also possible to obtain biological
10 samples in this type of study. For example, you could
11 have a home health phlebotomist to travel to the
12 family's home to do a blood draw.

13 You could also ask them to travel not
14 to the research site, but to a local commercial
15 laboratory for a lab draw. And it's also possible to
16 self-collect a variety of biospecimens, including
17 blood.

18 So at the DCRI, we were curious to know
19 could a direct-to-family design overcome potential
20 barriers to pediatric trial participation? And we
21 thought, well, maybe.

1 We could schedule these visits flexibly
2 on evenings and weekends outside of typical work and
3 school hours. We could deliver study materials and
4 study personnel directly to the family's home to
5 eliminate transportation barriers.

6 Maybe this could reduce some of the
7 financial burdens. And we also felt that we would be
8 free from the geographical limitations placed by
9 sites.

10 So this inspired the Individual Patient
11 Exposure and Response in Pediatric Lupus or iPERSONAL
12 trial. This was a direct-to-family open label,
13 proposed pilot trial evaluating the preliminary
14 effectiveness of a medication management device on
15 adherence to hydroxychloroquine in pediatric systemic
16 lupus erythema ptosis.

17 Okay. That was a really long
18 statement. I think I had to take four breaths in the
19 middle of it. So let me break this down for
20 everybody.

21 Lupus is a rare chronic autoimmune

1 disease that disproportionately affects women and
2 women from these racial and ethnic groups.

3 It unfortunately is a leading cause of
4 death in young women. Diagnosis during childhood is
5 common and predicts a worse prognosis.

6 Now, the good news is there are safe
7 and effective therapeutics. One of them is
8 hydroxychloroquine, which is a once daily oral anti-
9 malarial medication that's prescribed to almost
10 everyone with lupus, although like with many other
11 chronic conditions, actually taking that medication
12 every day as prescribed is a major challenge.

13 So we saw this as an opportunity to
14 potentially improve lupus health outcomes by promoting
15 adherence to this medication already prescribed as
16 standard of care.

17 And we thought this direct-to-family
18 design would be especially important for lupus, one
19 because of geography. So lupus is rare.
20 Rheumatologists are rare. Pediatric rheumatologists
21 are especially rare.

1 So reducing barriers in terms of
2 transportation we felt was very important. We also
3 know that socioeconomic and other factors that present
4 barriers to research participation also negatively
5 affect lupus health outcomes, and with a lot of other
6 conditions, there is a major issue with racial and
7 ethnic diversity historically in lupus clinical
8 trials.

9 This next slide illustrates basically
10 our study activities. So the intervention was this
11 electronic pill bottle with a sensor in the cap to
12 record bottle openings and closings.

13 It also provided automated reminders,
14 so flashing light, a chime, and automated texts and
15 phone calls around the time that medication was due.

16 All participants received the
17 intervention and were instructed to use it for their
18 hydroxychloroquine that was prescribed and managed by
19 their doctor.

20 After a two week run-in period, we
21 activated reminders, and they remained active for the

1 duration of the six-month study.

2 So throughout this time we had four in-
3 home visits where a home health nurse traveled to the
4 family's home to collect a blood and urine sample,
5 help the family submit data using their devices, and
6 complete questionnaires.

7 At the first visit, we also had the
8 home health nurse connect via videoconference with a
9 remote physician who was licensed in their state to
10 conduct with the nurse a head-to-toe physical
11 examination and disease-activity assessment.

12 In order to identify potentially
13 eligible participants, we partnered with the CARA
14 Registry, which I described to you before.

15 Basically we asked the CARA Registry to
16 provide a list of potentially eligible participants,
17 which they did. We contacted them through emails,
18 physical letters, and then started a phone campaign.

19 The first thing we learned was that in
20 general, people did not answer our phone calls, but of
21 the people who answered our phone calls, more than

1 half were interested in the study and actually
2 scheduled consenting calls.

3 So I mentioned this was a pilot study.
4 Our original goal was to enroll 20 participants. We
5 met that goal in ten days.

6 So because of the overwhelming
7 enthusiasm for this study, we increased our sample
8 size to as many as we could afford, which was 26, and
9 added an additional 18 participants to a backup list.

10 This slide shows some selected
11 demographics of those 26 participants, and the map on
12 the right shows, highlighted in red, the states that
13 were represented in this study.

14 Although our numbers were small, we
15 were pleased to see that self-reported race and
16 ethnicity looked a little bit more like the U.S.
17 population with lupus, as compared to traditional
18 lupus clinical trials.

19 Although, as discussed before, we did
20 have a lot of people who self-selected race as
21 "other."

1 In terms of study operations, we found
2 this was highly feasible. So we conducted the entire
3 study from first patient, first visit to last patient,
4 last visit in under ten months, and that includes the
5 six months of follow-up.

6 We were able to conduct 97 home visits,
7 collect 94 urine and 88 blood samples and nearly 4,000
8 dosing records on hydroxychloroquine. And note this
9 all occurred in the first year and a half of the
10 COVID-19 pandemic.

11 On the right-hand side, you can see
12 responses to our satisfaction survey. Overwhelmingly,
13 our participants said they felt comfortable, that they
14 would take part in a study like this again, and
15 actually that they preferred this over a site.

16 You can also see some of the selected
17 comments, which I think highlight the experience,
18 especially during the COVID pandemic.

19 So we learned a lot from this study. I
20 think overall we found that this direct-to-family
21 design was desirable, feasible, and satisfactory in

1 the pediatric lupus population.

2 And although this was a small pilot
3 study and a niche population, we think this is a
4 potentially promising approach to increased geographic
5 and other types of diversity in pediatric clinical
6 trials. That's not to say there weren't challenges
7 and limitations; of course, there were.

8 First thing to consider, in terms of
9 safety, so by design, we selected a medication with an
10 incredibly safe profile that's already prescribed and
11 managed per standard of care. And our intervention
12 was actually this medication management device that
13 was incredibly low risk.

14 That's not to say other types of
15 invention -- or interventions -- excuse me, can't be
16 studied with this type of design, but will require
17 some additional considerations.

18 We did find that as it turns out,
19 location matters for having study team members that
20 were licensed and able to travel to families' homes.

21 Technology and data integration, this

1 actually ended up being a huge thing; could be a
2 separate talk on its own. From a scientific
3 standpoint, we did have a lot of additional
4 considerations in terms of dealing with data quality,
5 device use or misuse or malfunction, what to do with
6 that.

7 And then we did require a complex data
8 integration flow that we fortunately had the resources
9 to build in-house, but did collect data streams coming
10 from different devices and different platforms.

11 From an equity standpoint, in terms of
12 technology, we wanted to make sure that we weren't
13 simply trading one barrier, like transportation, for
14 another barrier, like having a smartphone.

15 So we did provide a study iPhone for
16 all participants to use for the duration of the study.
17 We also downloaded all of the study apps on the phone
18 before we gave it to the family to help with potential
19 issues with digital literacy.

20 We did, however, require that the
21 families have access to wifi or cellular data. So

1 that's an important limitation and something that
2 definitely needs to be considered from the beginning
3 for these types of studies.

4 We also found that -- I think has
5 already been talked a little bit about today, but I
6 think there will be more to come about the critical
7 importance of partnerships.

8 So we had a wonderful patient and
9 family advisory group that we involved from the very
10 beginning to help design the trial, determine what
11 would be reasonable to ask families to do in their
12 homes.

13 We involved the CARA Registry, as I
14 mentioned. We also had great partnership from the
15 Lupus Foundation of America, just to name some of our
16 partners here.

17 If you're interested in learning more,
18 we have a couple publications and hopefully our
19 primary adherence analysis coming soon.

20 So with that, I would like to
21 acknowledge our fearless leader and principal

1 investigator, Stephen Balevic, who will be on
2 virtually for the upcoming panel presentation.

3 I'd also like to acknowledge and thank
4 everyone else mentioned on this slide. I wish I had
5 more time to thank you all individually.

6 I'm happy to address any questions
7 later or by email, and that's all I've got for you.
8 Thank you.

9 MS. MULUGETA: Thank you so much
10 Rachel. Our next talk is actually a duo. We have Ted
11 Love, who's the chair of Board of Directors at
12 Biotechnology Innovation Organization, or Bio, as well
13 as Bella Oguno, who's vice president of Development
14 Operations at Nuvig Therapeutics. I'll turn it over
15 to Bella.

16 MS. OGUNO: Do we have Ted on the line?

17 MR. LOVE: Yes, can you all hear me?

18 MS. OGUNO: We can, Ted.

19 MR. LOVE: Okay. Great. Well, I'll
20 get us kicked off, and then I'll turn things over to
21 Bella.

1 The first thing I want to do is thank
2 everyone for putting together this conference. I've
3 had the benefit of listening for much of the morning.
4 It's been absolutely excellent.

5 I'd also then like to begin with a few
6 words about sickle cell disease and about Global Blood
7 Therapeutics, because much of what we're going to talk
8 about is very relevant to specific challenges that we
9 face in pediatric drug development.

10 So starting with sickle cell disease,
11 this is a relatively rare disease in the U.S. It
12 affects about a hundred thousand people in the U.S.,
13 so it is a rare disease.

14 It actually results from a single amino
15 acid change on hemoglobin, which unfortunately results
16 in profound anemia in affected individuals starting at
17 about 6 to 9 months of age.

18 Many people classically know these
19 patients suffer from severe pain crises, but what's
20 less appreciated, quite frankly, is that they all
21 suffer from chronic organ hypoxemia.

1 And as a result, they die typically in
2 their 30s and 40s from chronic organ failure. And
3 that's really what GBT was focused on solving.

4 The sickle cell population in the U.S.
5 is more than 90 percent African Americans, and quite
6 frankly, solutions for sickle cell disease have been
7 chronically under-invested in by our government, as
8 well as by industry, and the patient community was
9 very aware of it.

10 The fact that our patients were
11 predominantly black and brown and often poor meant
12 that we were focused on a patient population, which
13 was not only historically poorly represented in
14 clinical trials, but who had often had very poor
15 experience with the medical system, with the
16 significant amount of distrust for the system.

17 So GBT was really focused on solving
18 the disease, but also solving a lot of the social
19 issues around the disease.

20 The first note that GBT worked on is
21 now approved. It's called Oxbryta, and the

1 development program, which you'll hear more about from
2 Bella, focused on helping individuals all the way from
3 6 months old all the way to more than 60; patients
4 occasionally live that long.

5 We started the development plan
6 actually in a patient population that was greater than
7 12, because we wanted to focus on patient report
8 symptoms, which obviously at a certain age you could
9 not collect. And we also initially only had a tablet
10 formulation, which was not suitable for many children,
11 less than 12.

12 This was actually the HOPE study, which
13 was the basis of the approval. This is a fairly large
14 study of 274 patients if you want to read about it.
15 It was published in the New England Journal of
16 Medicine in June of 2019.

17 And just in terms of the pediatric
18 component, 16 to 18 percent of the participants in the
19 study were, in fact, under the age of 18.

20 And the FDA did use extrapolation,
21 which was something mentioned earlier, to support the

1 approval in that less than 18- and greater than 12-
2 year-old population group.

3 We also agreed with the FDA to conduct
4 a confirmatory study to show stroke risk reduction, as
5 measured by TCD, in kids in the age range of 2 to less
6 than 15. This was called the HOPE Kid's Study and
7 again, it was a sizeable study of 224 kids.

8 Our plan was then to lower the
9 indicated age to 4 to 12, and then ultimately to down
10 to 6 months by using extrapolation, again, with the
11 FDA supporting safety, as well as continued efficacy
12 as measured by reduction in the magnitude of the
13 anemia these patients suffer from, and these work for
14 smaller studies.

15 The last thing I want say is that
16 sickle cell disease is rare in the U.S., but it's
17 highly prevalent in a number of countries,
18 particularly in the sub-Saharan African countries.

19 Therefore, GBT actually had the
20 opportunity and, quite frankly, as you'll hear about
21 from Bella, the challenge of not only enrolling our

1 studies in the U.S. and Europe, but also in many
2 countries where clinical trials have rarely been
3 conducted.

4 Another challenge is that the treatment
5 and death rates for sickle cell disease can vary
6 dramatically, particularly in geographies in sub-
7 Sahara Africa. And that's something that we had to,
8 of course, navigate in collaboration with the Food and
9 Drug Administration.

10 So with those high-level -- I'll turn
11 it over to Bella. And I really want to give a huge
12 shout out to Bella. She led the team that really did
13 all the work to do these incredibly difficult, complex
14 studies all around the world.

15 So I'll turn it over to you, Bella.

16 MS. OGUNO: Thank you, Ted.

17 All right. So with that lovely
18 introduction, I'd just like to point out the work that
19 we did at GBT to support the enrollment of our sickle
20 cell studies.

21 So we were really energized around

1 serving a sickle cell community, and this is an
2 understatement.

3 From Ted on down, we partnered from the
4 very beginning with CBOs in the U.S. and the E.U.,
5 tried to understand the landscape by identifying the
6 key opinion leaders and then also the physicians that
7 were treating the patients. Where are they? What can
8 we do to help, and how do we support the
9 implementation of clinical trials?

10 So in the U.S. -- you see in this slide
11 here, we're looking at where are the sites, but
12 sometimes when you're looking at the sites, that does
13 not overlay where the patients are, and there's a
14 disconnect, because those communities or those
15 hospitals might not be conducting the clinical trial,
16 so you don't have access to that patient population.

17 And that was one of the challenges that
18 we had. We know where they are, but do we have
19 clinical trials or clinical research staff to support
20 executing that clinical study?

21 And as Ted mentioned, the prevalence in

1 the U.S. is not as high as it is in the ex-U.S.,
2 specifically sub-Saharan Africa. So we saw this as an
3 opportunity to augment our recruitment and pivoted
4 towards the sub-Saharan Africa.

5 And that came with a lot of questions
6 and some challenges that we really try to address. I
7 call this "Looking at a diversity within the
8 diversity"; right? We know the patient population,
9 but what else can we do?

10 And I also call this the "Era of yes,
11 and." So once we made the commitment to go to sub-
12 Saharan Africa -- and we went to Egypt as well and
13 Middle Eastern countries, the challenges and the
14 considerations came up.

15 So the logistical challenges, well, how
16 are you going to get drug in? How are you going to
17 get lab samples out? Yes, and let's work with vendors
18 that can support that.

19 So collecting samples within Africa and
20 testing them within Africa and having method
21 validation transfer, so that could be done.

1 All right. How do you address the
2 expertise challenges? Yes, and let's train the
3 physicians. Let's have training seminars. Let's go
4 there to understand their perspective.

5 And let's not forget they see a higher
6 number of these patients in the world. They know
7 these patients; they know this disease.

8 All right. What about the resource
9 challenges? Yes, and let's help them build capacity.
10 Let's help them identify the resources, study
11 coordinators, nurses, training, so they can conduct a
12 study.

13 Okay. What about the logistical
14 challenges from conducting the trial perspective?
15 Yes, and let's provide that to them. Let's
16 understand -- for example, someone mentioned wifi and
17 access to the internet, that can be challenging
18 sometime.

19 How do we support that in sub-Saharan
20 Africa where that's a challenge. Or even electricity
21 where you're storing samples, and they need to be

1 refrigerated before you ship them out. Yes, and let's
2 give them that -- right, and have generators and
3 backup generators, so they can conduct the studies.

4 So we were constantly faced with the
5 challenges and the response was, "Yes, and how do we
6 support this community to be able to implement these
7 studies?"

8 And how do we do this? I think one of
9 the aspects that was really important to us -- if I
10 can advance this slide, is the "how." One of the
11 critical aspects is engaging the sub-Saharan African
12 team early on, not just in time.

13 So in 2019 is when I started going to
14 Africa to understand who are the key opinion leaders
15 here, who are the physicians, who are the community
16 based leaders that we need to be aware of, and also
17 the cultural aspect is really important.

18 It's not just understanding who they
19 are, but how do we communicate. And it's not just
20 picking up the phone and saying, "Do you want to do
21 this clinical study?" It's being in person.

1 So I went there several times to
2 understand that hierarchy and how to get them engaged,
3 so other team members can also participate in that
4 clinical study.

5 So it took time to build that trust.
6 It took time to build the trust also of the parents
7 who were conducting -- who would be consenting for
8 their children to participate in the clinical study.

9 And I'll give an example of how that
10 was really important for us to build that trust at
11 that level. There was a listening tour before we
12 started implementing the study.

13 There was still a lot and there still
14 is a lot of stigma around sickle cell. So with that
15 comes the treatment, the medication that they don't
16 even want to access, because it gives away that they
17 have sickle cell; right?

18 Transportation is a big thing in
19 Africa. Some of these patients are coming from two to
20 three hours away. So imagine having a 2- to 3- to 4-
21 year-old taking a bus, not even coming by car, but

1 taking a bus to come to the site, being there all day,
2 and then having to go back.

3 So making sure that we were aware of
4 those challenges and the way we developed the
5 protocol, the way we make sure that they had the
6 transportation was also really important for us as we
7 understood how do we implement this study in sub-
8 Saharan Africa.

9 Equipment as well. And one of the
10 things when we were engaging with the KOLs and the
11 team members -- I will never forget this discussion, I
12 had a doctor in Kenya say, "Well, you want to access
13 our patients and get our data, take it all out, and
14 now, do we have access to that data? And are we even
15 going to have access to that treatment later on?"

16 So these are the difficult discussions
17 that I brought back to Ted -- I brought back to GBT,
18 so we can be intentional around developing a response,
19 not just a knee-jerk reaction to placate those
20 concerns, but to really address how are we really
21 going to collaborate with this patient population --

1 with this region to build trust, so they feel
2 confident in enrolling their children in this clinical
3 trial.

4 So that trust exercise took over a
5 year. We started in 2019 before we implemented the
6 study, and then in 2020 everyone knows what happened.

7 So in 2020 everything came to a
8 standstill, but we still needed to move forward. And
9 I remember specifically in October of 2020, I said,
10 "Ted, I have to go to Africa. No one is traveling.
11 No one is doing anything, but I have to go to Africa.
12 I have to go to Nigeria to do the training for TCD."

13 This is transcranial Doppler training
14 to conduct a study. So we needed to train the
15 sonographers, each of the sites in Africa, and we
16 needed participants to do that, and that's children
17 from 2 to 10 or 12 years old.

18 So imagine having to coordinate that at
19 the height of the pandemic in 2020. Coordinate a
20 hotel that will let you do it. Coordinate informed
21 consent of patients and the children, coordinate COVID

1 tests for all of them, coordinate transportation,
2 coordinate the space, make sure there's enough social
3 distancing, coordinate technology, so we have people
4 from the U.K., from the U.S., all over the world
5 dialing in to ensure that the training is being
6 conducted appropriately.

7 I think this is the level of
8 collaboration and commitment that it took from not
9 just GBT, but our partners, whether it's vendors, the
10 parents, the regulators, the physicians, to ensure
11 that we completed the training on time.

12 And I'm happy to say that no kids were
13 sick; everyone was able to complete the training. You
14 just have to make sure there's a lot of food, a lot of
15 coloring books, cartoons; everyone can run around and
16 get tired and then do the training.

17 But it took a big effort and trust, and
18 that was also an opportunity for the parents and
19 caregivers, for me to share the importance of a
20 clinical trial.

21 Some of these parents had never heard

1 of clinical trials in the first place or much less
2 participated, now have their children participate, or
3 have heard of GBT or even questioning a sickle cell
4 study. Yeah, we have the greatest prevalence but
5 we've never even heard of the actual opportunity to
6 participate in a study.

7 So that was one of the benefits that we
8 garnered from collaborating and collaborating early on
9 and taking some risks, quite frankly. And this just
10 elaborates again, what we implemented and how we were
11 able to be successful in executing this study.

12 It was continuous process improvement,
13 risk mitigation, execution, and revisiting that
14 strategy day in and day out. There were always
15 challenges that crept up. That's just the nature of
16 clinical research 101 and being in the region.

17 But how do we continue to show that
18 collaboration and be determinant in how we execute and
19 recruit in the study?

20 And again, with the support of the FDA,
21 as Ted mentioned, after implementing the study in the

1 sub-Saharan African region, we were able to recruit
2 the study fully and quickly with those countries.

3 And I think the key lesson here is not
4 to be deterred by how difficult it is, because
5 everything that's difficult is not what we're doing.
6 But also having a vision for how you're going to get
7 it done and having that commitment internally and
8 externally dedicating the resources.

9 This took a long time and it was a
10 heavy lift again from our organization from having the
11 right team members and the resources financially to
12 get this done, because we're also helping to build
13 capacity.

14 I mentioned the TCD machines. We
15 developed a process that after we were able to do the
16 training and they use this for the study, they could
17 keep the TCD machines to continue that assessment for
18 their patients long term; right?

19 So how do we continue with capacity
20 building when we're working with these countries, when
21 we know that the resources are lower, but the data is

1 just as valuable, and working with those patients are
2 just as valuable?

3 The last slide is not here, which is
4 why do we do that? And I remember Ted always said,
5 "Because we need to do the right thing for patients
6 and that means all patients, and when you do the right
7 thing for patients, we do the right thing for our
8 organization as a company, but also the development of
9 a molecule or the drug."

10 And that's all I have. Thanks,
11 everyone.

12 MS. MULUGETA: Thank you so much, Bella
13 and Ted. Now, I'm going to ask Lauren Wood-Heickman,
14 who is a clinical reviewer at the FDA, to provide the
15 last talk before we move into the panel discussion.

16 MS. WOOD-HEICKMAN: Just testing it
17 out. Good afternoon.

18 Can I move the presenter view down?
19 Can you move it to the left, please? Thank you.

20 Okay. Great. So my name is Lauren
21 Wood-Heickman. I am a pediatric endocrinologist and

1 medical officer in the Division of Diabetes, Lipid
2 Disorders, and Obesity.

3 And the purpose of my talk today is to
4 discuss diversity in pediatric type-2 diabetes trials,
5 illustrated by an example of an assessment I performed
6 on a sample of trials submitted to the FDA in the
7 support of approved drugs to see how they measure up
8 in terms of representing our diverse population of
9 patients with pediatric type-2 diabetes.

10 Also, I'll be referring to type-2
11 diabetes as "T2D" throughout this presentation.

12 Oh, sorry. There we go.

13 So please, note the views expressed in
14 this presentation are mine and should not necessarily
15 be interpreted as those of the FDA. I have no
16 financial conflicts of interest to report.

17 First, I'm going to provide an
18 introduction to youth onset type-2 diabetes, or T2D.
19 Then I'll discuss FDA's approach to encouraging
20 representative studies through regulations impacting
21 pediatric trials and the new guidance related to

1 diversity action plans and how it applies to
2 pediatrics.

3 Next, I'll highlight some unique
4 challenges in conducting clinical trials in youth-
5 onset T2D. Then I'll discuss an assessment of
6 representativeness for a sample of pediatric trials
7 submitted to my division.

8 Lastly, I'll discuss lessons learned
9 and future directions on how to move forward with this
10 information. Type-2 diabetes, or T2D, in youth is a
11 serious disease with an aggressive clinical course.

12 Complications of diabetes develop
13 rapidly in children resulting at a high risk of
14 debilitating complications like cardiovascular
15 disease, kidney, and eye disease by young adulthood.

16 Mortality in children with T2D is two
17 to three times higher than the general population.
18 Diabetes is common, affecting 1 in 10 Americans, and
19 approximately 90 to 95 percent of cases of diabetes
20 are type-2 diabetes, according to the CDC.

21 However, youth onset T2D is relatively

1 rare, so versus 1 in 10, it's one in 1,500 U.S. youth
2 under 20 who is impacted by type-2 diabetes. And the
3 prevalence of approximately 43 million U.S. youth from
4 ages 10 to 19 in the U.S., approximately 28,800 have
5 T2D.

6 And as for incidents, each year about
7 5,000 youth under 20 are diagnosed with T2D.
8 Although, this is increasing. And in contrast,
9 greater than three times as many youth in the age
10 group are diagnosed with type-1 diabetes.

11 And unlike type-2 diabetes in adults,
12 which tends to be equal among females and males, type-
13 2 diabetes in youth differentially impacts females
14 versus male youth.

15 While youth-onset T2D is still
16 relatively rare, there's a rising number of diagnoses
17 in children every year. The yearly rate or annual
18 incidents of newly-diagnosed youth with T2D almost
19 doubled from the years 2002 to 2018.

20 And in the U.S., racial and ethnic
21 minority youth carries the largest burden of this

1 increase in youth-onset T2D.

2 As shown in the figure below, looking
3 at the annual incidents of newly diagnosed T2D in
4 youth ages 10 to 19 years over time -- so with years
5 2002 on the left and 2016 on the right, along the
6 bottom of the chart, an increasing number of diagnoses
7 can be seen among American Indian youth in red at the
8 top, non-Hispanic black in purple, Hispanic in blue,
9 and Asian and Pacific Islander in gray, compared to
10 their non-Hispanic white peers, the line in green,
11 with the red dotted line showing the average incidents
12 for all youth over time.

13 So as you can see, because there's a
14 differential impact on youth and there's an increasing
15 number of diagnoses, this becomes very crucial in
16 order to understand the benefits of the treatment in
17 all populations.

18 So evaluating the safety and
19 effectiveness in medical care and treatments for a
20 representative and diverse population is critical to
21 advancing health equity.

1 For pediatric T2D, there's a
2 disproportionate impact on ethnic and minority youth,
3 including a higher race rate of diagnoses and moreover
4 differences in both health outcomes and differences in
5 risk factors for health outcomes observed by race and
6 ethnicity.

7 Therefore, representation in youth-
8 onset T2D trials is important in ensuring that
9 positive health outcomes from treatments being
10 investigated apply to all patients.

11 Now that I've gone through a primer on
12 T2D in youth and the importance of representation in
13 clinical trials, I'll provide an overview of FDA's
14 regulations impacting pediatric trial diversity and
15 the mechanisms by which FDA has used to encourage more
16 representative trials in kids.

17 On the left, the Pediatric Research
18 Equity Act or PREA, a law passed in 2003, requires
19 pediatric studies for certain drugs and biological
20 products being developed for adults, if FDA determines
21 that the product is likely to be used in pediatric

1 patients or if it would provide a meaningful benefit
2 over available therapies.

3 The other mechanism, on the right, the
4 Best Pharmaceuticals for Children Act, or BPCA, passed
5 in 2002, is a voluntary mechanism. FDA requests a
6 sponsor conduct pediatric trials by issuing a written
7 request.

8 The emphasis here is that the BPCA on
9 the right is voluntary. In terms of the written
10 requests are fulfilled, sponsors may receive an
11 additional months' of marketing exclusivity.

12 Within the guidance on the right,
13 there's a mechanism for which the FDA has used to
14 encourage diversity, in terms of the BPCA.

15 So they can encourage that they shall
16 take into account adequate representation of children
17 of ethnic and racial minorities.

18 So in summary, on the left, there's two
19 mechanisms in which the FDA requires pediatric
20 studies. If they are going by the required mechanism,
21 the Pediatric Research of Equity Act, on the left,

1 there's less criteria, less requirements.

2 But if you're going on the BPCA, on the
3 right, there are more requirements, including the
4 requirement to take into account adequate
5 representation of children and ethnic racial
6 minorities.

7 So for the diabetes division, a lot or
8 most of our studies are conducted under BPCA and have
9 accounted this.

10 There's also new guidance, the draft
11 guidance for Industry, "Diversity Plans to Improve
12 Enrollment of Participants from Underrepresented
13 Racial and Ethnic Populations in Clinical Trials."

14 Would you mind scrolling down a little
15 bit in the script? I just want to make sure I get my
16 wording right. Thanks, guys.

17 Okay. That's okay. Let me pull it
18 down. Sorry, guys. I think I have it written out
19 too.

20 Sorry, guys. The regulations are
21 really important.

1 So the recent regulatory draft
2 guidance -- let me pull it up here, was published in
3 June 2024, and it's entitled "Diversity Plans to
4 Improve Enrollment of Participants from
5 Underrepresented Racial and Ethnic Populations in
6 Clinical Trials."

7 And this draft guidance, which applies
8 to Phase 3 trials or pivotal clinical trials submitted
9 to the FDA, recommends that sponsors submit a
10 diversity action plan that specifies goals for
11 clinical study enrollment by race, ethnicity, sex, and
12 age group.

13 And so once this guidance is final,
14 regardless of whether sponsors will be conducting
15 pediatric studies under PREA on the left or under BPCA
16 on the right, they will need to come up with a plan
17 for representativeness that takes into account
18 adequate representation of children from racial and
19 ethnic minority backgrounds.

20 Okay. So now I'd like to set the stage
21 to discuss some of the unique challenges associated

1 with drug development, in type-2 diabetes in
2 particular, by showing the history and current
3 landscape of FDA-approved treatments.

4 So in 2000, the FDA approved metformin
5 to be used in youth with T2D. Prior to 2000, insulin
6 was the only FDA-approved medication to be used for
7 this condition until 2019 when Victoza or liraglutide
8 was approved.

9 Therapeutic options other than insulin
10 or metformin were not available to youth, despite many
11 drugs becoming available for adults with type-2
12 diabetes.

13 As shown here, over the last four years
14 there have been a burst of approvals for new drugs for
15 treatment of youth with T2D.

16 It's important to note that the studies
17 leading to these approvals were prompted by the
18 regulations that I discussed earlier and requiring
19 pediatric trials to be conducted for drugs that would
20 benefit populations.

21 So this slide highlights some good news

1 and some bad news. There was a gap in care for youth
2 with T2D prior to PREA or BPCA, which has arguably led
3 to many approvals in this area.

4 But there was a sizable delay between
5 when drugs became available in adults and when they
6 became available in kids, as highlighted by Pam
7 earlier.

8 When looking only at the approved drugs
9 pictured in the red box, the lag time on average was
10 8.6 years between adult approval and pediatric
11 approval with a range from 7 to 10 years, depending on
12 the drug.

13 So PREA/BPCA are arguably leading to
14 increasing approval in kids. But why the delay? Over
15 the next slide I'll discuss the challenges faced by
16 clinical trials in youth with T2D.

17 So there are several challenges faced
18 when conducting trials in youth-onset T2D, and despite
19 pediatric type-2 diabetes trials actually being pretty
20 short -- they're typically only 6 to 12 months
21 duration, the time required to complete these trials

1 have been long due to very slow enrollment.

2 From a recent published analysis of
3 U.S. Phase 3 or 4 pediatric trials conducted from 2000
4 to 2020, only 5 of 17 studies, or 30 percent, of the
5 studies met projected enrollment targets in less than
6 4 years, meaning that the majority of the
7 studies -- so 70 percent, took longer than 4 years to
8 enroll the required number of subjects into the study.

9 Challenges to enrollment are
10 multifactorial, including restrictive eligibility
11 criteria, a small pool of eligible participants, and
12 lack of dedicated pediatric research infrastructure,
13 among other reasons.

14 However, as you could likely see, the
15 longer times to enroll subjects in clinical trials
16 contributes to longer timelines to approval of drugs
17 to pediatric type-2 diabetes.

18 Okay. So now that I've reviewed the
19 unique challenges in clinical studies for youth with
20 T2D, I'm going to present my assessment of how these
21 trials measure up in terms of representativeness.

1 So my goal was to compare the race and
2 ethnicity breakdown of trials submitted to the
3 diabetes division to the known race and ethnicity
4 breakdown of children with type-2 diabetes in the U.S.
5 This would give me a good sense for how representative
6 the trials are of the diverse population of patients
7 with T2D.

8 I limited my investigation to five
9 clinical trials conducted for approved drugs. In
10 order to get a feel for representativeness, I needed a
11 good benchmark study to see how studies were doing,
12 and I determined the best source of representativeness
13 data we have for U.S. youth would be the SEARCH for
14 Diabetes in Youth study mentioned earlier by Ann.

15 So the SEARCH study is the largest
16 surveillance effort of youth-onset type-2 diabetes
17 conducted to date and is CDC-funded, and NIH-
18 supported, and it surveyed physician-diagnosed
19 diabetes in five U.S. states, as well as several
20 American Indian reservations from 2000 to 2020.

21 And the SEARCH study was designed to

1 actually represent or overrepresent certain youth
2 thought to be at highest risk for youth-onset type-2
3 diabetes.

4 And then CDC actually reports the
5 prevalence and incidence data from the search study
6 for youth-onset type-2 diabetes.

7 Now, I'm going to present the results
8 of the representativeness assessment, and on the left,
9 you can see the results of the most recent analysis
10 from 2017 for 1,230 patients with youth-onset T2D in
11 the SEARCH study.

12 As I mentioned before, there's some
13 limitations to this SEARCH study, including
14 overrepresentation of certain groups, and how the
15 SEARCH study grouped the data is a little bit
16 different than how clinical trials report data on race
17 and ethnicity.

18 For example, the non-Hispanic Asian
19 population in light blue also includes Native Hawaiian
20 or other Pacific Islander, a group that's typically
21 reported separately, so this may not be directly

1 comparable to how clinical trials typically report
2 race.

3 So on the right, in an effort to the
4 match the data we get from pediatric clinical trials
5 to what we see in patients with youth-onset T2D, I'm
6 showing the race and ethnicity breakdown for five
7 trials FDA approved for the treatment of pediatric
8 T2D. And it's for 811 subjects.

9 It's important to note that these 5
10 trials are global trials, which, in total, 42 percent
11 of the subjects came from the U.S., so 58 percent from
12 non-U.S.

13 And U.S. subject enrollment in these
14 studies range from making up, at the low, end 15
15 percent of the study population and to 68 percent at
16 the highest end.

17 You can see that non-Hispanic black in
18 red, American Indian and Alaska Native in purple
19 appear to be greatly underrepresented, while non-
20 Hispanic white in green, Hispanic in dark blue, and
21 Asian in light blue are overrepresented in the five

1 global pediatric T2D trials submitted to the agency.

2 Now, I'm going to show you the same
3 analyses for the 5 studies, but limited to the 339
4 subjects enrolled only in the U.S.

5 On the right, I've enlarged the figure
6 a bit to show the race and ethnicity breakdown for the
7 studies a little bit more clearly.

8 So it looks like the trials are doing
9 reasonably well in terms of representing non-Hispanic
10 black youth in red, with overrepresentation of
11 Hispanic youth in dark blue and non-Hispanic white
12 youth in green.

13 In the subjects enrolled in the U.S.,
14 there's also an underrepresentation of non-Hispanic
15 American Indian or Alaska Native in purple, Asian in
16 light blue, and Native Hawaiian or other Pacific
17 Islander in orange.

18 But keeping in mind that the SEARCH
19 study on the left isn't directly comparable, as the
20 light-blue Asian category on the left represents
21 Asian, along with Native Hawaiian or other Pacific

1 Islander youth.

2 So depending on how you look at this,
3 you could determine that pediatric T2D trials are
4 generally doing pretty well in representation for some
5 groups. But there are definitely gaps where
6 representativeness could improve. This type of
7 analysis allows us to understand areas of focus for
8 future studies.

9 So in conclusion, this case study
10 identified several gaps in the representativeness of
11 pediatric T2D trials submitted to my division of the
12 FDA, but was also generally encouraging.

13 So American Indian and Alaska Native,
14 Asian, and Native Hawaiian or other Pacific Islander
15 patients with youth-onset T2D from the U.S. are
16 underrepresented, based on this analysis.

17 In terms of lessons learned, this
18 strategy could be applied to other pediatric trials'
19 programs to evaluate the relative representativeness
20 of the clinical trials being conducted in order to get
21 to those gaps and ensure better representation in

1 clinical trials going forward.

2 There are several opportunities moving
3 forward to continue to address barriers in
4 representativeness, in addition to addressing other
5 challenges in conducting efficient youth-onset T2D
6 trials.

7 Firstly, in conjunction with the
8 Division of Pediatrics and Maternal Health, or DPMH,
9 we're planning to hold a workshop for pediatric type-2
10 diabetes in spring of 2025 to further address
11 challenges faced in the conduct of trials in this
12 disease area.

13 Next, in addition to written requests,
14 our division, and others at the FDA, managing
15 pediatric applications can integrate the 2024 Race and
16 Ethnicity Diversity Plan guidance and to face three
17 pediatric trials designed to address PREA
18 requirements, encouraging sponsors to establish goals
19 early in the pediatric development program for
20 representativeness.

21 And as for further investigations into

1 representativeness, I'm also planning to work with a
2 fellow in FDA's Indigenous Knowledge Fellowship
3 Program to further investigate the notable gap in
4 representation of American Indian, Alaska Native
5 populations observed ,since T2D disproportionately
6 impacts this population in youth.

7 There's more work to be done to further
8 understand what can be done to address gaps in this
9 area.

10 Thank you so much for your attention.
11 I've learned so much from you and this conversation
12 that we've had together. Thank you.

13 MS. MULUGETA: Thank you so much,
14 Lauren.

15 I'm going to ask my co-moderator, Sue
16 Rahman, to join me along with panelists.

17 So we actually have had close to 500
18 online participants, and we have a large number of
19 questions we're triaging.

20 So after the new panelists get a chance
21 to introduce themselves, perhaps we can start with

1 those questions, while you consider whether you have
2 additional questions for our speakers and panelists.

3 MS. RAHMAN: Perhaps we can go ahead
4 and get started with introductions by Anvita.

5 MS. AMBARDEKAR: Hi. My name is
6 Anvita, and I'm a pediatric patient representing iCAN,
7 the International Children's Advisory Network.

8 I personally am a pediatric patient,
9 and I have IBD, and I am very passionate about
10 advocating for patients and hope to continue that
11 here.

12 MS. RAHMAN: Yes, please.

13 MS. DONOGHUE: Hi, everyone. Good
14 afternoon. My name is Martha Donoghue. I'm a
15 pediatric oncologist, and I am the associate director
16 for Pediatric Oncology in Rare Cancers in the Oncology
17 Center of Excellence at the FDA. And I just want to
18 thank everyone for the conversation and for inviting
19 me here today.

20 MS. ROBINSON: Good afternoon. My name
21 is LaShell Robinson, and I'm the senior director and

1 head of DE & I in Clinical Research at Takeda
2 Pharmaceuticals, where I lead the company strategy
3 related to DE&I in Clinical Research to make sure that
4 we have proper representativeness in our clinical
5 research trials.

6 MS. MILLIGAN: Hello, everyone. I'm
7 also with Industry, colleague Lashelle. I'm Ki. I'm
8 a pediatrician. I work at Novartis, and prior to my
9 current role, I've lived and worked in Asia, Europe,
10 and the Middle East in public and private sector jobs.

11 And I only say this because
12 understanding that housing, transportation, insurance,
13 language, visa immigration status, navigating that as
14 a moving target, I can only begin to understand that
15 before attempting to understand clinical trials at the
16 same time.

17 Thank you.

18 MS. EDWARDS: Good afternoon everyone.
19 My name is Christina Edwards. I work at the National
20 Minority Quality Forum in our Center for Clinical and
21 Social Research as the director of Clinical Trials.

1 National Minority Quality Forum, NMQF
2 for short, is a health research equity and educational
3 and advocacy organization.

4 MS. RAHMAN: And we're also joined
5 online by Stephen. Do you want to go ahead and
6 introduce yourself?

7 MR. BALEVIC: Yes, thanks very much.
8 I'm Stephen Balevic. I'm a pediatric and adult
9 rheumatologist at Duke University and a researcher at
10 the Duke Clinical Research Institute.

11 So I'm wearing my academia hat today
12 and happy to talk about the diversity in clinical
13 trials. Thank you for having me.

14 MS. MULUGETA: Wonderful. So the first
15 couple questions are actually directed to Rachel and
16 Stephen. So the first question is, was the direct-to-
17 family global trial, could you also comment on the
18 overall monitoring and GCP compliance for such a
19 trial?

20 MR. BALEVIC: Yes. Thank you very much
21 for that question. Yes, this trial was only conducted

1 in the United States, and largely because we were
2 still working out a lot of the legal and regulatory
3 implications, you know, that I think are hinted at in
4 your question.

5 And what we learned when we were
6 putting this trial together -- just to, you know,
7 ensure that we were, you know, meeting clients and
8 also staying within the state medical legal
9 guidelines, we actually surveyed 15 different states,
10 in terms of what their telemedicine and telehealth
11 laws were, because it wasn't totally clear to us that
12 there's a line drawn in the sand between what we would
13 call tele-research versus telemedicine.

14 And so that gets very complicated very
15 quickly. And so for the sake of time, I won't go into
16 details too much, but you know, it was very important
17 for us to try to navigate a lot of this gray area
18 between what is the practice of medicine versus
19 research across many states and what can be done
20 virtually versus what requires an in person visit.

21 And so I'm happy to answer more

1 specific questions and tell you a little bit of the
2 learning that we've have from a medical legal
3 perspective.

4 But it is a major challenge with
5 virtual trials, and I think one of the things we can
6 do moving forward is try to get some clarity,
7 especially from state medical boards, where there's
8 some uncertainty.

9 Dr. Mulugeta, I don't know if you had
10 any follow up.

11 MS. MULUGETA: Just one additional
12 comment. Who provided the in-home nursing visits?
13 Was it one company, multiple companies? Were
14 experienced pediatric nurses a requirement?

15 MR. BALEVIC: Yes, thank you. That's a
16 great question. So we did partner with a single
17 company that was able -- that they had a network of
18 both in-state physicians and in-state nurses
19 throughout the country.

20 And so we partnered with them, and they
21 were able to provide home-health nurses through all of

1 the states we were recruiting.

2 You know, for a decentralized trial,
3 you don't necessarily need a registered nurse, if all
4 you're doing is, let's say, a blood draw, for example.

5 But in our case, we were not only
6 drawing blood, but we were facilitating a
7 telemedicine -- and so that required somebody with a
8 medical background -- with medical expertise, you
9 know, to be able to, you know, auscultate the lungs,
10 examine the joints, along with the physician. So
11 that's why in our case, we did use registered nurses
12 in those cases.

13 MS. MULUGETA: Thank you so much. Any
14 questions from the in-person audience?

15 MS. COVINGTON: Good afternoon. Thank
16 you very much. I'm enjoying the conference. It's for
17 anyone, but particularly Dr. Heickman.

18 You mentioned showed some, "gray
19 statistics" about what you compared in the clinical
20 trials versus what you compared, I think, in the real
21 world or what you actually -- the comparison from what

1 we had before to the representativeness of child
2 clinical trials.

3 Here's my question. My question is --
4 it seems like you did a very good job. By the way.
5 My name is Melva Covington, I represent Abundant Life
6 Bible Church, as well as AGAPE Strategic Solutions.

7 Here's my question. Is it sufficient
8 for us, especially from an FDA perspective, to be able
9 to just say that we're able to collect data from
10 patients that are at the right proportion?

11 And I say this, because we just
12 conducted a study with PEP!IN, People Empowering
13 People for Inclusion Now, in which we surveyed
14 people -- diverse communities, and 20 percent of them
15 were in clinical trials.

16 When we asked them about the value of
17 the clinical trials that they participated in, it
18 decreased. So everyone a hundred percent said, "I got
19 into trial; I understood what it was about; I got
20 the -- even protocols."

21 But when you ask them about the value

1 that they had once they were through the study, then
2 they were, like -- 55 percent said, "I got no value
3 out of it."

4 So is just representation enough?
5 Should we be looking at what then is the experience
6 and using the experience that people have to not only
7 develop the protocols and study designs, but to create
8 the experience that people can use and understand and
9 value as they go through these processes?

10 What do you think?

11 MS. RANDELL: I think that's an
12 excellent question. I think that you -- so my
13 understanding, I believe that there is inherent value
14 in representation in clinical trials beyond just
15 proportionate representation.

16 And even though it's a goal to meet, in
17 terms of the disease, this is what the disease looks
18 like. These are the people impacted by the disease.

19 We need to make sure that the studies
20 represent the people who are going to be treated so
21 that they feel confident that the drugs are safe and

1 effective in them.

2 I think that there's questions beyond
3 "Can we get achieve that by meeting those
4 proportions." I think one of the earlier questions
5 was, "What is good?" And I think that's really
6 important to continue to communicate through these
7 workshops. And I'd love to hear from the other
8 panelists too.

9 The other thing is, with these
10 diversity action plans, they're in the phase of pre-
11 implementation. So it's at this stage where public
12 commentary and public feedback is crucial.

13 And so there's several guidance
14 documents that tell sponsors what our goals are, but
15 there's also an opportunity here to figure out the
16 best way to implement these strategies and to
17 communicate those things.

18 So really, I think that's a really
19 great question, and I would love to hear the rest of
20 the panelists thoughts on it too.

21 MR. LOVE: I'll get that. I think it

1 was a great question as well, and honestly, it kind of
2 reminds me of the history of colleges in the United
3 States enrolling students of color and sometimes
4 adding women to the student body without making any
5 adaptations.

6 They just expected those individuals to
7 come in and flourish in the environment, just as the
8 prior students had. And I think it's critical.

9 In fact, what we're trying to do in
10 these clinicals from home is get information on this
11 patient population, but as someone said already, we're
12 also trying to bring this population into the world of
13 drug discovery and drug development, as well as into
14 the ecosystem of excellent healthcare and
15 participation in utilization of these discoveries when
16 we develop.

17 So if you're going to do all of that,
18 you really do need to make sure that you're creating
19 an environment where these patients feel just as
20 valued, just as respected, and they benefit just as
21 much as other patients from this setting. So I think

1 it's a great point.

2 MS. MULUGETA: Martha, did you want to
3 add to that?

4 MS. DONOGHUE: Yeah. No. I was
5 pondering the question, because it has so many layers
6 to it, and I would absolutely love to devote a whole
7 workshop to questions like this.

8 Because I think, you know, what you're
9 asking goes beyond -- you know, it is simply are we
10 thinking about just looking at the numbers and really
11 high-level numbers, and can we pat ourselves on the
12 back if we look at the numbers and feel reassured by
13 them?

14 And I think, you know, at a bare
15 minimum, it is helpful to know, you know, as the
16 highest-level target or maybe the lowest bar, whether
17 we're actually enrolling patients, you know, with
18 respect to diversity in a way that's equitable.

19 But just looking at the numbers alone
20 and even those initial numbers is just a start,
21 because I think about our experience in pediatric

1 oncology where our data is relatively reassuring with
2 respect to representativeness when you look at race.

3 We also find that, in terms of
4 reporting over the past 20 years in some of the
5 studies we see, that we have huge holes in our data
6 with respect to ethnicity.

7 We're also not thinking about
8 geographic distribution of patients where, you know,
9 by and large they tend to be, you know, hugging the
10 coast of the U.S., as opposed to more rural areas,
11 thinking about socioeconomic and other factors.

12 So I think the point you're bringing up
13 by this provocative question, which is pretty easy to
14 answer, because I think most of us would say no -- we
15 can't say that's enough, you know, is it really
16 important?

17 And I think it's incumbent upon us not
18 only to, like, finish a trial, get the results, and,
19 you know, kind of say, "Okay; let's move on to the
20 next trial," I think it's also really important to do
21 what you're implying, which is -- and what you have

1 done, is to ask patients and families, "Was this a
2 valuable experience."

3 Going beyond whether the drug works,
4 which of course we all want them to work, thinking
5 about was this a positive experience; do you think it
6 was worth worthwhile, and feeding that knowledge into
7 future trial designs.

8 And, you know, I think it's integral to
9 drug development for now and in the future that we are
10 trying to take advantage of that input and
11 incorporating that in the very early stages of future
12 trials.

13 So thanks for the question.

14 MS. ROBINSON: And I would just add
15 too, did it improve your experience or opinion of the
16 healthcare ecosystem? Because when we look at one of
17 the main challenges when we're talking about
18 underrepresented populations is the lived treatment
19 that we are getting in the interaction with healthcare
20 providers; right? And that mistrust that exists.

21 So I would also move a step forward,

1 did it improve your overall experience and outcome and
2 your opinion of the healthcare system that we're
3 dependent on to improve our health disparities?

4 MS. RAHMAN: Any other comments from
5 the panel?

6 MS. UMARETIYA: I would thank you Melva
7 for the question. I would also like to echo what the
8 panelist said and add another question on top of that
9 is, who defines benefit?

10 So I think now that we have, you know,
11 this beautiful concept of equity of voice, it's
12 actionable through FDA policies.

13 You know, when we talk about risk
14 benefit or burden benefit, maybe the definition also
15 requires broader stakeholders to bring that into
16 definition and perception of benefit.

17 MS. RAHMAN: Our next question was from
18 the center of the room.

19 MS. SARI: Hi. Sorry. I'm Nasrin
20 Sari. I am about to be a panelist in a bit. I'm also
21 a patient and community representative.

1 And my question is mostly directed at
2 Dr. Heickman, and it's sort of based off of -- I just
3 read an article published in 2023, which basically
4 called for the need of inclusion of Middle Eastern and
5 North African peoples in diabetes trials.

6 Basically citing that globally, that
7 region, the Middle Eastern and North African region,
8 has the highest prevalence of diabetes in the world.

9 But with the way that our government, I
10 guess, and our systems characterized and categorize
11 people, it's sort of an invisible group.

12 And even we could see in a lot of the
13 data that you were citing -- I mean it was a great
14 presentation, but it didn't take that into account.

15 So I guess what I would ask is -- I'm
16 wondering what the perspective on this is in the field
17 or if there is even a perspective; are people aware of
18 this issue and of this lack of representation?

19 And I guess anybody who has experience
20 can answer, but it was mostly directed at Dr.
21 Heickman.

1 MS. WOOD-HEICKMAN: Yes. That's an
2 excellent question too. And Dr. Christine Lee cited
3 that there is a new OMB data collection standard.

4 A lot of the limitations to these
5 analyses that you can do have to do with the patient
6 level of reporting -- of their self-reporting, and
7 that may be different culturally. It may change over
8 time. People may identify in a different way.

9 And so it sounds like the OMB
10 standards, they're changing to add North African and
11 also Middle Eastern as a category.

12 And then they're also allowing people
13 to check multiple boxes and enter, within American
14 Indian, the specific, like, region they come from.

15 And so we have more data, and so our
16 ability to interpret it will become better. But you're
17 right; we're working with data that was collected ten
18 years ago or eight years ago, in the case of some of
19 these studies.

20 And we basically -- how they decided to
21 report that data in those trials are how we have to

1 deal with it.

2 But another portion of your question
3 is, that these are actually global studies; right?
4 Like, these diseases, we regulate them at the FDA and
5 the U.S., and we advocate for our population of the
6 U.S. to be represented within these trials.

7 But you have to realize that they're
8 also applying for these drugs to be studied worldwide.
9 And so many of these are global efforts.

10 So that's an excellent question. We
11 advocate for our population, but we also oftentimes
12 have bigger studies, because they're global efforts.
13 And that's a benefit, but you also have to consider,
14 do some of the global populations represent our U.S.
15 patients?

16 And they may in some cases, but in some
17 cases you have to -- you develop more questions, based
18 on more data, which I think is exciting, but it also
19 unwraps another layer of onion.

20 So thank you for that great question.

21 MS. SARI: Thank you.

1 MS. WOOD-HEICKMAN: Anybody else?

2 MS. MULUGETA: Actually, if I can add
3 to the question that Nasrin posed, we had one question
4 specific to Bella and Ted's presentation, which builds
5 on this topic.

6 Will patients enrolled in Africa be
7 considered representative of African American patients
8 in the U.S. to meet the enrollment goals and diversity
9 plans?

10 So maybe, Bella, you can get us
11 started, and then I'm going to ask others to chime in
12 as well.

13 How do we determine whether patients
14 from other countries are representative of U.S.
15 populations?

16 MS. OGUNO: I'm back here, but I'll let
17 Ted start it, and I can add to Ted's thoughts.

18 MR. LOVE: You know, it's an
19 interesting question. I don't think we actually had
20 that particular discussion with the FDA.

21 Sickle cell is somewhat unique. I

1 think the bigger issue with sickle cell actually is
2 the same issue that we encounter in cancer and other
3 diseases, where the standard of care in that geography
4 is very different than the U.S.

5 And unfortunately, in sickle cell
6 disease, unlike many of our cancers, prior to GBT,
7 there weren't many differences, because we were
8 basically just using hydroxyurea and occasionally
9 transfusion.

10 Most patients with sickle cell disease
11 really were not on any kind of treatment for their
12 underlying disease.

13 So the ethnic issue, we didn't discuss.
14 The treatment, kind of, differential, we did discuss
15 with the FDA, and sadly in many ways the difference
16 wasn't as dramatic as you might expect.

17 MS. OGUNO: I just wanted to comment on
18 the previous question, in terms of being inclusive
19 Middle Eastern and North Africa.

20 When we looked at GBT'S study for
21 sickle cell, we went where the patients were. And

1 when we think about sickle cell, we think of the
2 African descent, but we were also knowing that, or saw
3 the data, where Middle Eastern population was also
4 impacted.

5 So we were intentional about going to
6 Egypt, Lebanon, and Oman. So even there were
7 challenges there as well, but we really went where the
8 data told us where the patients are and making an
9 effort to recruit those participants.

10 I wanted just to kind of shout out to
11 the question you had and really being intentional
12 about where you're going and where the patients are
13 recruited.

14 MS. RAHMAN: I think our next
15 question --

16 MR. LOVE: And maybe the other thing to
17 add scientifically is that sickle cell disease is a
18 genetic disorder, and there are different genotypes.
19 So we did look at the data also by genotype, whether
20 you were SC, SS, you know, S rated zero.

21 So we looked at the genotypes, which

1 probably are more important than your geography. But
2 anyway, we looked at everything.

3 MS. RAHMAN: I think our next question
4 was from over here.

5 UNIDENTIFIED SPEAKER 4: Good
6 afternoon. I think my question is for Dr. Randell.
7 Rachel; correct?

8 With your study you ran it, and it was
9 a great benefit to kind of run it during the pandemic,
10 unfortunately.

11 Would you run it again, now that the
12 world is open, in a more hybrid scenarios for a lot of
13 people? I know during the pandemic, I had nothing,
14 but times to be at my house, and I specifically knew
15 what time I would be out of my house.

16 I still had to go on site, but I knew
17 what specific 12 hours a day I would be gone. So I
18 had nothing, but time. I picked up a lot of habits
19 and hobbies.

20 And I have a -- I guess it's like a
21 three-part too. Did you also have scarcity issues

1 with hydrochloroquine [sic] during the pandemic and
2 people's perceptions of that due to news that was out
3 there concerning that drug?

4 And yeah, again, would you run this in
5 a hybrid scenario to see if you would get the same
6 participation and also the same lack of attrition?

7 MS. RANDELL: Thanks for those
8 questions.

9 And just, Stephen, I'll take this one.

10 So first off -- well, it sounds like we
11 had a lot of similar thoughts during 2020 to 2022-ish.
12 In terms of the question of if I would do this outside
13 of the COVID-19 pandemic, absolutely.

14 So actually, this study was planned and
15 designed well before the pandemic hit and while most
16 traditional research at Duke was basically shut down,
17 put on pause March 2020, we were able to launch this
18 study a couple months later and really, like, went
19 without a hitch.

20 There were two participant family
21 members who had COVID during the study, but we found

1 that because of the virtual design, we could offer
2 them an option of just a video-visit-only type of
3 study visit or reschedule with a lot more flexibility
4 than if they were traveling to a site.

5 I thought -- and I hope the data I
6 shared with you today convinces you of this as well,
7 but I thought the direct-to-family design worked
8 really well, and our patients and their families
9 really liked it.

10 So I have actually two other direct-to-
11 family studies that I'm currently working on, another
12 one in lupus and another one in juvenile idiopathic
13 arthritis.

14 So I'm really excited about the
15 opportunities for this design. I think I forgot the
16 third part of that question.

17 UNIDENTIFIED SPEAKER 4: Oh, did you
18 have scarcity issues with --

19 MS. RANDELL: Oh, with the medication?
20 Oh.

21 UNIDENTIFIED SPEAKER 4: -- getting

1 that specific drug?

2 MS. RANDELL: Yeah.

3 UNIDENTIFIED SPEAKER 4: And then what
4 were people's perceptions or did you take any feedback
5 on people's perceptions of that drug per what was
6 being dispersed in the news?

7 MS. RANDELL: Oh yeah, great question.
8 So fortunately, not an issue for this study.
9 Hydroxychloroquine was already being prescribed by the
10 participant's doctor -- their healthcare provider, per
11 standard of care.

12 This is a medication that is generally
13 prescribed for a very long time for lupus. So the
14 families who were in the study did not encounter the
15 difficulties, I think, that you're referring to.

16 And the timing occurred just far enough
17 into the pandemic that the, like, mad rush on the
18 world's hydroxychloroquine supplies had kind of, like,
19 abated a little bit, so it wasn't an issue.

20 But certainly great questions to think
21 about for any type of direct-to-consumer, direct-to-

1 family design. So we're not providing the study drug,
2 which has some benefits, but it also relinquishes our
3 control over being able to control the study drug and
4 the supply and whatever else may happen.

5 So in this sort of decentralized design
6 you do -- that's just one example of different aspects
7 of the trial that you're then decentralizing --
8 putting into other people's hands to manage that are
9 out of your control.

10 Thank you.

11 UNIDENTIFIED SPEAKER 4: Thanks.

12 MS. MULUGETA: So I know we have
13 several questions in the audience, but I want to make
14 sure we give our patient and community representatives
15 a chance to speak as well.

16 So you both have heard throughout the
17 day perspectives on how to make trials more inclusive,
18 but as a patient, what do you think are things that
19 are key to making trials more inclusive?

20 Maybe, Anvita, we can start with you
21 and then, Christina, if you can chime in.

1 MS. AMBARDEKAR: Yeah, definitely.

2 Thank you so much for the question.

3 So I think the main thing is just
4 making it available to people, making them aware that
5 there are trials. I know for me personally, like I
6 knew what clinical trials were and that they were
7 conducted, but I never knew if there was one for me --
8 if there was one that would be the right fit for me.

9 So kind of even just providing a guide
10 on how can you figure out if you know enrolling in a
11 clinical trial is right for you, and then also kind of
12 just making it more aware that there are trials out
13 there that are looking for pediatric patients to
14 enroll.

15 MS. MULUGETA: Thank you.

16 Christina.

17 MS. EDWARDS: I'll talk about this a
18 little bit in my presentation, but I think what I will
19 focus on is engaging with the community and making
20 sure your approach is patient centered.

21 You know, you always want to get their

1 perspective. I think they are the bottom line
2 essentially. So just making sure they are -- from
3 protocol, development, planning, that should be your
4 focus is the patient's perspective, and what do they
5 need -- their wants.

6 MS. MULUGETA: Thank you.

7 MS. MCKENZIE: I have one comment and
8 then a question for the patients. I'm Jennifer
9 McKenzie. I am a pediatric nephrologist that works at
10 Boehringer Ingelheim. It's a pharmaceutical company.

11 My first comment is about the diabetes
12 example that you used for the diversity plan. I think
13 that is an excellent example, and it was very cool to
14 be able to see the overlay of what's happening in the
15 trials versus what's happening in the United States.

16 I work in a space where we do not have
17 that data. I can tell you what's happening in
18 Southern Israel, but I can't necessarily tell you what
19 the prevalence or incidence is in the United States or
20 even globally.

21 So I think that some of those other

1 diseases that don't necessarily have that natural
2 history data are going to struggle with coming up with
3 diversity plans that mimic the population.

4 My second question is for the patients
5 on the panel. Pediatric academic centers are the
6 primary places where we are able to do clinical
7 trials. They're not everywhere; right? This a very
8 finite resource, and that's where most of the clinical
9 trial sites are going to be for investigational drugs
10 or devices.

11 If you found out that you were eligible
12 or might be eligible for a clinical trial that was
13 distant to your site or not associated with your
14 primary hospital, how willing would you be or do you
15 think your peers might be to travel longer distances
16 or see people that you are unfamiliar with in your
17 treatment?

18 MS. WOOD-HEICKMAN: So for your first
19 question, that's something that I have observed as
20 well. I think that diabetes has benefited from the
21 fact that -- has rich data.

1 There's rich data because of the fact
2 that diabetes is so prevalent in adults, pediatric
3 diabetes community has benefited from that.

4 But then also that the type-1 diabetes
5 community and type-2 diabetes communities came
6 together, in terms of research, and did the SEARCH
7 study. So they joined in order to create this data
8 from a partnership with the CDC and the NIH, who
9 recognized that it was it was an issue that was
10 evolving.

11 And so for rarer diseases, that's
12 always a challenge, in terms of getting that data. So
13 I can just acknowledge that challenge, but I can't
14 speak to it too much.

15 And I know the question was for you
16 next.

17 MS. AMBARDEKAR: Yes. To answer your
18 second question, so personally, for me, I think
19 traveling a little bit far for a clinical trial would
20 really depend on two factors. First one is, what time
21 of day is it? You know, is it during classes? Is it

1 during a traffic time?

2 Because a lot of these times these
3 centers are in big cities where traffic is a big
4 factor than just the distance.

5 And then also, how much is the trial
6 going to benefit me? Is it more to, like, make me
7 feel better, or is it maybe, like, testing out some
8 new imaging or something like that?

9 UNIDENTIFIED SPEAKER 5: And just to
10 add to that, I think it depends on the disease state;
11 right? When we're speaking about type-2 diabetes and
12 type-1 diabetes, it's a little more prevalent.

13 But taking that to a rare case, I can
14 speak from experience, where we did have patients that
15 boarded planes, because they were going to the centers
16 where the Centers of Excellence were, knowing that
17 they would actually get better care -- right, because
18 that person was a Center of Excellence or that center
19 was that physician.

20 So I think there is a little bit of
21 nuance with that when there's a higher disease

1 prevalence, maybe not as much willingness, but if it's
2 a rare disease, we have seen patients and families
3 really take leaps and bounds to get to clinical
4 research.

5 And I think we have to create our
6 budgets and our contracts when we're talking about us
7 as pharmaceutical companies to account for those
8 nuances.

9 Thank you.

10 MS. RAHMAN: Take the next question
11 from this side of the room.

12 MS. MCMAHON: Hi. Dr. Ann McMahon from
13 the FDA. This is a question for Doctors Randell and
14 Balevic.

15 My question is -- and maybe I missed
16 this, it's possible that I miss this, but I wondered
17 whether it was possible that this model of providing
18 care is going to be something that is way too
19 expensive for anyone to ever do, or whether it's
20 possible that routinely this type of thing could
21 actually be done?

1 MS. RANDELL That's a great question.

2 Oh, sorry. Go ahead, Stephen.

3 MR. BALEVIC: Okay. Great. Yeah.

4 Thanks very much for that question.

5 So I think you hit on a very important
6 point, which is the decentralized trials really hinge
7 very closely on technology, and, you know, technology
8 is really that key -- you have to be able to reach,
9 you know, families in their homes where they are.

10 That requires, you know, not only
11 telemedicine software, but all these decentralized,
12 you know, protocols and nurses and centralized IRBs.

13 And so that infrastructure can be
14 expensive. But one of the great things about
15 technology is that it can become less expensive over
16 time.

17 And so it really -- this is, I think, a
18 model where, with the right investment and academia
19 and industry and regulatory sort of partnerships, that
20 cost can be driven down, and I think it could become a
21 regular model.

1 I'll pass the mic to Dr. Randell.

2 MS. MCMAHON: Thank you.

3 MS. RANDELL: I was just going to say,
4 I wish I could answer that question in, like, three
5 years from now, because the current project that I'm
6 working on is to try to replicate the things that went
7 well in iPERSONAL on an NIH K23 research budget, which
8 is much smaller.

9 But for example, instead of paying a
10 home-health nurse to travel to family's homes, maybe
11 we can try something like a self-collected blood
12 sample that the participant and their family can do at
13 home and simply ship back to us.

14 Just as an example of some areas where
15 we could take lessons learned from this type of trial
16 and try to replicate them at cheaper or maybe in
17 something that's like a hybrid between a traditional
18 site-based and a fully virtual trial.

19 MS. MCMAHON: Thank you.

20 MS. RAHMAN: How about for center of
21 the room?

1 MS. HILDEBRAND: Yeah. Heidrun
2 Hildebrand from Bayer, again. Also question or maybe
3 comment to the decentralized trials. I think that's a
4 great example, and as I come from Bayer, you know, we
5 also work with you on some of decentralized
6 activities, but mainly in the Phase 4 or in the
7 observational study.

8 And I think also what you showed here
9 is a clinical trial, but more in the Phase 4 setting.
10 And I think the challenges might be a little bit
11 higher when we go to pivotal studies, but I also think
12 that decentralized technology is a great thing, and it
13 is not black and white.

14 Because we, in industry, I think, most
15 of the companies in the room do that in the meanwhile.
16 We use certain elements of decentralization to go
17 specifically into pediatric studies where we do a part
18 of it.

19 But our learning is also that there are
20 high sharing just with investigators, because they
21 don't want to be our technology hub.

1 So instead getting the patients, they
2 do the work. And we also have families who tell us
3 they want to get out of some of these decentralized
4 activities, because for them, the burden is even
5 higher than going into the center and have the doctor
6 managed everything or the study nurse managed
7 everything.

8 So I think it's a fine balance what we
9 have to do. I think it's a great future, but it's a
10 great balance, and especially if I look to the sickle
11 cell example.

12 Going into regions outside of Europe or
13 U.S. or even in some of the European regions, you may
14 not have the data infrastructure to do that. So I
15 think it's a fine line.

16 MS. MULUGETA: Thank you so much.
17 Maybe a question to Martha, and there's a second
18 aspect that's industry specific, so maybe LaShell and
19 Ki, if you can take that.

20 So the question is, does the FDA
21 foresee requiring sponsors to develop formal diversity

1 action plans as an adjunct to pediatric study plans?

2 And the second question is, what is the
3 current experience with industry, including diversity
4 plans or plans to include diverse populations within
5 the pediatric study plans?

6 MS. DONOGHUE: Okay. thank you for the
7 question. So if I'm understanding it correctly,
8 you're asking whether FDA anticipates requiring
9 diversity action plans as part of the pediatric study
10 plans that are part of our requirements under PREA
11 that Dr. Heickman had spoken of earlier?

12 I can't speak for FDA in that sense.
13 And also, I'm coming from oncology; the scope of most
14 of our pediatric study plans are limited to Phase 1
15 and 2 development, whereas the diversity action plan
16 guidance really speaks mostly to phase three
17 development.

18 So would I like to be able to require
19 them? Absolutely, in oncology. But short of having a
20 requirement, I will tell you that when we are
21 reviewing our initial pediatric study plans that are

1 coming into oncology, we are asking those questions.

2 We are saying, "Please, describe and
3 tell us how you are anticipating, you know, enrolling
4 a representative population. Please, speak to the
5 sites that you're going to enroll. Is your trial
6 going to be run through a cooperative group? How are
7 you going to assess whether you're achieving
8 representativeness?"

9 So we are asking those questions and,
10 you know, we're asking for answers and reviewing them
11 as part of, of our review.

12 Having said that, it's -- and I think
13 it goes to some other questions that others have
14 alluded to. These are generally smaller studies -- 60
15 patient studies, rare cancers, rare subsets of rare
16 cancers.

17 And so, you know, I personally don't
18 want to add additional impediment to efficient conduct
19 of those trials, but it's a balance.

20 And I think part of achieving our
21 mutual goals is really to make sure people are

1 thinking about this and doing, you know, what's right
2 to try to, to the best of our ability, ensure
3 representativeness to the population that has access
4 to these trials.

5 Because, you know, parents of pediatric
6 patients and pediatric patients themselves with
7 cancer, you know, they are loud and clear telling us
8 how important it's that they have access.

9 MS. MULUGETA: Thank you.

10 MS. MILLIGAN: Yeah, I'll start, and
11 then open to LaShell.

12 So I think, you know, this kind of --
13 so the question on, you know, sponsors and diversity
14 and pediatric trials, I think it's multifaceted.

15 And it comes back to the principle that
16 we approach pediatrics with is, before we go into a
17 vulnerable population, is there a prospect of direct
18 benefit to that population?

19 And are we doing everything to reduce
20 the investigational risk and investigational burden as
21 much as feasible? I think we heard really good

1 approaches on that earlier today -- data science,
2 real-world evidence.

3 And then the other thing is when we
4 have no other option, but to do a randomized or a
5 prospective study, does that study answer the research
6 question?

7 So are we able to generate the data
8 that conclusively gives us and the regulatory decision
9 makers information on the drug's efficacy, safety; is
10 this the right dose?

11 So there's a lot of uncertainty. And I
12 think one thing that I want to highlight just
13 historically, in terms of the R&D ecosystem, there was
14 a time not too long ago where data for drug
15 development was mostly men.

16 So we changed that. Then there was
17 women. And then it was mostly adults, and then we
18 changed that, and then there was children.

19 So I think my point is we are equipped
20 to do this. I don't think that we have the answers
21 to -- you know, we don't have all the answers, but we

1 are equipped.

2 And then the other part of that is
3 there have been some real-life success stories. So
4 also, LaShell and I were talking. So some of this,
5 you know, you'll hear from her also.

6 During the COVID pandemic, there was a
7 public/private partnership to look at repurposed
8 medicines for COVID. And one of these studies, the
9 ACTIV-6 study, actually met and exceeded its diversity
10 target. This was not in pediatrics, but it did that
11 through real-time monitoring and pivoting for
12 engagement.

13 And on that one for the public/private
14 partnership side, it elevated all stakeholders' voice,
15 including community and patients so that community and
16 patients also had access to review trial metrics and
17 suggest how to pivot and meet diversity targets.

18 So that was a very recent win, and it
19 was something that I just wanted to share. And I'll
20 turn it over to LaShell.

21 MS. ROBINSON: Absolutely. And I think

1 it's important to celebrate the successes, because as
2 you mentioned, progress has come. I mean, obviously,
3 there's more work to do, but I think it's important to
4 highlight that.

5 And also with proactive planning, so
6 there was a question about whether diversity action
7 planning can actually work, and with proactivity and
8 starting from the very beginning, that always sets you
9 up for success when you're thinking with the end in
10 mind, and you have at least something to start with.

11 We had great examples during the COVID-
12 19 pandemic across multiple companies where we
13 actually saw them meet trial metrics, because there
14 was a concerted effort, and there was even real-time
15 pivoting.

16 And going back to one of the calls on
17 the diversity action plan is around trial management.
18 How are you actually going to monitor the metrics?

19 And I can't underscore the importance
20 of looking at those metrics in real-time to make real-
21 time decisions. So for example, really vetting your

1 sites from the very beginning, and not only looking at
2 what they're reporting is their patient population,
3 but does that actually match the ZIP code, and does
4 that match the historic trial data?

5 Because for a lot of these clinical
6 sites, they've participated in our clinical trials
7 before, and that can tell you a lot about cultural
8 competency training that may need to be in place or
9 even helping them with community engagement if there's
10 a lack of representation in the actual practice.

11 And then taking it one step further,
12 when the trial is actually enrolling, and looking at
13 those metrics in real-time to see who is enrolling as
14 you expected, and if not, approaching those sites.

15 A perfect example that we were speaking
16 about was, there was a site that really said that they
17 were doing great with diversity, and that was part of
18 the reason that we actually selected this particular
19 site for participation.

20 But as we were watching during the
21 trial, and I was asked to approach that particular

1 site to get past practices, I noticed that it was like
2 90 percent white participants. Oh, there's a problem.

3 So in reaching out to that
4 investigator, they were not even aware that was their
5 enrollment. And as we had a further discussion, she
6 mentioned, "Oh, you know, I don't think I ever got the
7 Spanish ICF."

8 In addition to that, she also
9 mentioned, "I also don't remember us getting those
10 materials that were translated into multiple languages
11 that you mentioned. We don't have those. This is all
12 word of mouth." And so that real-time engagement and
13 actually having an action, it becomes extremely
14 important.

15 And so, again, proactive planning, but
16 also having a center that's monitoring those metrics
17 in real-time, so you can make those decisions and
18 pivot as needed, can really set you up for success in
19 meeting those metrics and also is the reason why you
20 need a plan.

21 MS. RAHMAN: Thank you. We have

1 reached our time, but please join me in thanking our
2 panel very much for an excellent discussion.

3 MS. MULUGETA: All right. So we're
4 going to take a quick break and reconvene at 2:15, so
5 please come back at 2:15.

6 (Off the record.)

7 MS. MULUGETA: We're going to go ahead
8 and get started, so if you can, please find your
9 seats.

10 We're going to continue with the
11 agenda. The next panel is a community engagement and
12 trust building discussion panel. And I'm going to
13 turn it over to my colleague, Carla Epps, from the
14 Division of Pediatrics and Maternal Health.

15 MS. EPPS: All right. Thank you.
16 While people are coming up, I'll just quickly
17 introduce myself. Yes. I'm Carla Epps. I'm a
18 pediatrician with the Division of Pediatrics and
19 Maternal Health here at FDA.

20 Really thrilled to be part of this
21 meeting. Let's see. Do we have everybody that's

1 going to be in this panel. Come on up, folks. Come
2 on up.

3 -- have everybody up here. I'm going
4 to get started with the questions. What I'm going to
5 ask is everybody to just introduce yourselves when you
6 speak and hopeful we'll start with the folks who
7 hadn't had a chance to speak yet today.

8 Let me just start off before we get
9 into the questions. So this panel discussion is on
10 community engagement and trust.

11 And I was struck by the conversations
12 this morning about things we are doing and that we
13 could do better that included things, like keeping a
14 track of, you know, who is involved in the trials,
15 using things like extrapolation and AI, that speak a
16 lot to headcounts, and that's some really important
17 quantitative information.

18 But then I heard later on, discussions
19 about what was the value and what it felt like to be
20 in a trial. And I guess I'm going to start off by
21 saying, as a member of a couple minority populations,

1 with all the multi-ethnicity we have in our country,
2 being a part of a group or community doesn't mean you
3 feel included.

4 And I'll say that just as a physician.
5 And there's still times when, you know, yes I've got
6 the degrees and everything. That doesn't mean that
7 people make me feel included in that community.

8 And so I think it's important to talk
9 about how we measure people feeling not a part of a
10 trial, but included in a trial. That's a very
11 different thing.

12 So on that note -- and it's a hopeful
13 note, I think, let me get started with the questions
14 with folks.

15 So the first question I want to ask you
16 all around community engagement and trust is, what
17 does the word "community" mean to you?

18 And who has not had a chance to speak
19 yet? Has everybody had a -- no. So let's start
20 first. Go ahead, introduce.

21 UNIDENTIFIED SPEAKER 6: And do you

1 want us to introduce ourselves?

2 MS. EPPS: Yes, please.

3 MS. KIPP: Good afternoon. I'm Dr.
4 Billie Kipp. I'm an enrolled member of the Blackfeet
5 Tribe, and I am an indigenous child psychologist.

6 MS. SARI: Hello. I am Nasrin Sari.
7 I'm here as a patient and community representative.
8 I've had some experience, you know, with various
9 different positions as a patient. Yeah. And I'm here
10 representing various different groups.

11 MS. DAVE: Hi, everyone. I'm Sneha,
12 and I am a patient and also the executive director at
13 Generation Patient.

14 MS. WILLIAMS: Hello, everyone. My
15 name is LaToya Williams. I am the community clinical
16 director at Inside Edge Consulting Group, which is a
17 healthcare consultant firm, and we bridge the
18 community with underserved communities and
19 biopharmaceutical companies.

20 I'm also serving as a pediatric patient
21 from the past with lived experience and how it's

1 translating into my adult experience.

2 MS. AMBARDEKAR: Good afternoon. My
3 name's Anvita, and I'm here as a patient
4 representative and on behalf of iCAN, the
5 International Children's Advisory Network.

6 MS. EPPS: Thank you. So, Dr. Kipp,
7 maybe you could start us off, because I don't think
8 the group has had a chance to hear from you about what
9 the word "community" means to you.

10 MS. KIPP: Well, I think community is
11 defined by where you come from and what group you're
12 with. And so for me community means tribal community.

13 And tribal community is a collection of
14 folks who have same beliefs, practices, and value
15 systems. And oftentimes in tribal communities, and
16 that's where I'm going to speak from, is we're very
17 closed systems. So we're on reservations; we're very
18 isolated, very rural.

19 And just to show you how important a
20 closed system like that is to medical health, when the
21 COVID came and started wiping people out, the tribes

1 across the nation start closing their borders.

2 Because you have a collective people
3 who live there and who have been there generations,
4 you know -- there's generations of people at home on
5 my res, and so they start closing their borders in
6 order to help mitigate COVID coming into the
7 reservation.

8 I also did a study for John Hopkins at
9 that time to see why our folks weren't getting
10 vaccinated, even though it was having horrendous
11 effects in our tribal communities.

12 And it was our younger people in that
13 study that said, "We don't trust the government. We
14 don't trust what they're giving us is what we need.
15 We suspect that we are guinea pigs for the
16 government."

17 So, again, back to that trust, and the
18 effects on closed communities and tribal communities
19 is very prevalent and very systematic, and we have to
20 protect ourselves in ways that are maybe not seen as
21 very healthy, but they're a rudimentary response to an

1 overwhelming pandemic in our tribal people.

2 We've been there and done that. We've
3 had smallpox. We've had, you know, all those things
4 that wiped out three-quarters of our tribe. So it was
5 a very traumatic response that you've seen tribes do.

6 So our tribal communities, almost every
7 tribal community closed their borders. So that is how
8 it can affect health and health outcomes.

9 MS. SARI: Hi. So for me, I think
10 sort of similarly, "community" means, you know, it's
11 any sort of shared value system, belief system or
12 shared experiences that can tie a group of people
13 together.

14 And for me that's a lot of things.
15 That's the Iranian American community. That's the
16 transgender or LGBTQ community.

17 And I think as we communicate and exist
18 within our communities that --sort of, again, building
19 off of what you said, it is this trust, and it is this
20 level of connection that we have with each other that
21 I think is valuable not only in a social and personal

1 sense, but also when we're talking about things, like
2 healthcare. Yeah.

3 MS. AMBARDEKAR: Yeah. Just to build
4 off of that too, I think for our young adult patient
5 community, a big thing about trust is people of the
6 same age and the same sort of generation in a lot of
7 ways.

8 So I think a lot of our community --
9 like, if we have a parent telling us something -- I
10 think someone earlier said, "Don't tell Gen Z what to
11 do." And I think that rings really true. You can
12 tell them, like, how to think, but not, like, create
13 that forced opinion.

14 So for my community, it's very much,
15 like, are we of the same age; do we have the same,
16 like, quote/unquote, "vibe"?

17 And so I think that all plays, like, a
18 huge role in disease management and acceptance and
19 identity formation, particularly when you're young and
20 sick and you don't, you know, see other folks your age
21 having to be part of hospital systems or take lots of

1 medications, that sort of thing. So yeah,

2 MS. WILLIAMS: To continue building off
3 this conversation, the work "community" means to me
4 the body of connection. During a very profound
5 conversation I had recently, this person said to me
6 that outside of your mother's womb, the community
7 becomes your womb.

8 And that resonated with me, because the
9 womb provides a nurturing environment. And if I had
10 to add to that statement, the community should become
11 the body in which we stay connected to be nourished
12 and fed.

13 A healthy, thriving community means
14 that people should feel a sense of belonging and
15 connected to others who make up this body. So whether
16 it be through relationships or shared experience,
17 where we live, work, and play and even congregate
18 virtually, we have to address this issue of isolation
19 in our communities.

20 If we think back hundreds of thousands
21 of years ago, communities, tribes, they relied on one

1 another for survival. And today's America is only
2 widening the gap, and this isolation should definitely
3 be looked at as one of the social determinants of
4 health.

5 MS. DAVE: To me, I think there's kind
6 of two types of communities. There's one that's
7 already established, you know, based on maybe what
8 medical condition you have or race, ethnicity, things
9 like that.

10 And then the other community is the one
11 that you build. It's the support system that you
12 build for yourself and the people that, you know, you
13 can rely on or have been in your shoes, and they're
14 the people that will always be there for you.

15 MS. EPPS: Thank you so much.
16 Actually, then I want to ask a follow-on question
17 about that. LaToya, you mentioned -- I actually had a
18 sidebar earlier with Dr. Kipp talking about
19 isolation -- or a word that Dr. Kipp used was
20 "segregation" of an individual from their community.

21 Did you all have any comments about

1 that?

2 MS. YAO: I think it's really
3 critically important when we look at clinical trials
4 and we're looking at one member of a community that
5 has that disease or that disorder and we remove them -
6 - we extrapolate them from the community to engage in
7 clinical trials, we haven't looked at the collective
8 of that community.

9 So if you come into the reservation,
10 and you take a child, and you say, "They're going to
11 get clinical trials," but you don't explain to auntie
12 and uncle and the tribe, this is what's going to
13 happen, and this is how they got access; then you've
14 eliminated a sustainability community that they're
15 going to return to.

16 And I think of Ms. Burgess, to you and
17 your son, and I heard you say that "We got this, but
18 people weren't happy about it for us."

19 And so, you know, if we're not working
20 with the community around clinical trials, the
21 propensity to sabotage, the propensity to feel like,

1 "Oh, I'm embarrassed, because I got this and some so
2 and so didn't get it," and to be treated differently
3 by your community -- so if we don't do that community
4 education and that community engagement and let the
5 community know, "This is what's happening," "Here's
6 how you -- here's some education around it; here's a
7 town hall; here's whatever," then to create that
8 understanding for communities that haven't had access
9 historically and have never had access, then you
10 create strengths, you create sustainability, and you
11 created a community to hold those people as they get
12 well.

13 MS. WILLIAMS: I'll add to that in my
14 introduction, I alluded that I was a pediatric
15 patient, and I had very complex health issues as a
16 child that has followed me into adulthood.

17 And sadly, the systemic issues that
18 existed for me as a pediatric patient still exists for
19 me as an adult.

20 I think back to the year 1991. I was
21 all of 13 years old and discovered a breast lump the

1 size of an egg. And during that timeframe, I also
2 experienced both of my grandmother's passing away from
3 breast cancer just eight months apart.

4 So that was extremely unusual, and also
5 I look at it as a missed opportunity for my
6 pediatrician and network of providers to discuss the
7 option of considering me for a pediatric trial, as
8 another source of care, and interventions could have
9 happened earlier that may have changed the trajectory
10 of my disease, as I'd later be diagnosed with stage-3
11 breast cancer as a young adult.

12 I was misdiagnosed at 29, accurately
13 diagnosed at 30, because I was not being heard, taken
14 seriously, even with my history of finding that breast
15 lump at the age of 13.

16 And the feeling I remember was how
17 isolated my parents felt -- my family felt. In the
18 early '90s social media didn't exist; the internet did
19 not exist as we know it today, and I wouldn't dare
20 tell my peers at the age of 13 that I just had breast
21 surgery.

1 So this history has led to me and
2 having this lifelong career in research at a community
3 level. And community-based engagement is only now
4 gaining traction, and few drug developers have the
5 vision and support to support this paradigm shift.

6 So the innovative work that I do at
7 Inside Edge Consulting Group, I'm leading a team
8 across the country -- boots on the ground, and we're
9 focused at a community level to enhance participation
10 in clinical trials in an intentional way to educate,
11 demystify, and co-create with these communities health
12 solutions that leads to higher enrollment in clinical
13 trials.

14 MS. DAVE: Yeah, I was just going to
15 add to that and what Dr. Kipp was saying about
16 community engagement and trust building.

17 I think the way that it's done, at
18 least in our community, needs to come from a lens of
19 peer support and really providing that basis of, like,
20 first, this is a place where you come to support each
21 other and to seek support and to understand your

1 condition and the way that your identity has shifted
2 with that condition, and then we can talk about things
3 like clinical trials, which feel like very sterile and
4 often long removed topics from the actual everyday
5 experience of being a patient.

6 So we do six peer support meetings per
7 month at Generation Patient, and we did one, I think,
8 last year focused on clinical trials and just, like, a
9 open discussion about it.

10 And I think the fact that this group
11 has been meeting -- like, some of them have come for
12 over 300 peer support meetings at this point, but
13 they're able to ask questions in a way that are very
14 much centered on their experience.

15 And I think that's how you start to
16 build community and to build that trust is not coming
17 in as a lens of, "Here, let's talk about clinical
18 trials," but, "Let's talk about your experience first
19 and get to know you as a person and then talk about
20 trials." So yeah.

21 MS. WILLIAMS: Just to add on a little

1 bit to what Sneha said, I think in the pediatric
2 population and our generation, there's a little bit of
3 stigma around, like, talking about chronic medical
4 conditions, and that's when you feel that community is
5 not necessarily there for you, or there's not a sense
6 of trust.

7 And that's when you kind of start to
8 find a different group of people that are supportive
9 and where there's a little bit less stigma about
10 talking about healthcare conditions.

11 MS. EPPS: Go ahead, Nasrin.

12 MS. SARI: I just want to, you know,
13 build off of what everyone else has said around the
14 sort of isolation aspect, where I think especially
15 when you are from a diverse perspective, whether that
16 be an ethnic or racial minority or, you know, gender
17 diverse or of a certain sexual orientation or
18 anything, there's already a level of isolation that
19 you're exposed to within your community.

20 And then if you have a chronic illness
21 or if you are undergoing any sort of long-term or

1 short-term treatment that just, it compounds on
2 itself, and it creates really difficult mental health
3 situations for patients who are already having
4 difficulties with their medical health.

5 MS. EPPS: Well, I would love to ask a
6 follow-on question along those lines. And it's maybe
7 not so eloquently worded, but it has to do with
8 cultural values within a particular community.

9 And then what I'm hearing, there's some
10 values that may work to be supportive in one
11 particular community identified with, but there may be
12 some that you feel are not supportive for your
13 particular situation from a particular community.

14 And you belong to not just a single --
15 I don't think anybody belongs to a single community.
16 So my question is, why is it important for researchers
17 to be aware of these values for a particular
18 community?

19 And can you maybe give an example of,
20 you know, why this is so important?

21 MS. KIPP: So I'll start, as you know

1 from numerous shout outs from Christine, we are the
2 recipients of a REACH contract.

3 And what we've looked at and what we
4 found is we've looked across several Indian
5 reservations across the United States and our impetus
6 has been to work with tribal colleges, because tribal
7 colleges are the repository for education and any
8 intellectual property within that tribe.

9 And our early findings -- and actually,
10 we already wrote one article about this, indicate that
11 as native folks, that there are cultural values around
12 blood draws. There's cultural values around taking
13 hair samples and blood samples. There's cultural
14 values around tattoos and different-- this varies
15 among tribe.

16 And so if we, as interventionists, try
17 to engage a community, we have to be aware that there
18 is going to be some historical trauma related to the
19 medical model of systems.

20 And we got to put that in perspective.
21 When we look at Indian Country -- now, that's where

1 I'm going to speak from, is Indian Country is
2 dependent on a socialized medical model called "Indian
3 Health Service."

4 It was seeded to us from the government
5 for our lands. Remember we got education, health and
6 welfare; right? Oh, yeah, that worked really great.

7 So we've got the highest disease,
8 lowest college attainment rates, all those things.
9 But the issue is the system has set us up to distrust
10 it, because IHS is severely underfunded.

11 So it's either life or limb with IHS.
12 There's no intervention. There's no prevention.
13 It's, like, "Are you going to die? Okay. We'll send
14 you out."

15 I'm working with a tribe now on medical
16 device systems for diabetes, and the tribe told me,
17 "We can't afford it." So here's what we do. We have
18 a committee. If the person is on two insulins, then
19 they might get a medical device. If the person has
20 several emergency room, then they might.

21 So that's where we're at. We're at the

1 Hunger Games in Indian Country for good medical care.
2 And we're talking here about intervention for our
3 children for access to clinical trials.

4 We found that we've got to start at the
5 basic with our people around education, around
6 listening to fears, around helping understand those
7 fears, and then moving forward.

8 It's imperative that you can't go into
9 a community that has been traumatized by a medical
10 model and say, "Here's some more medical model that we
11 don't know if it's going to work or not."

12 So that's why we got to develop those
13 paraprofessional pathways. We use a lot of -- we
14 partner with community health workers, promotoras
15 community health -- we call them community health --
16 to deliver the message, because they're the auntie who
17 sits across the table and tells Grandma, you know,
18 "It's time for you to check your device," and tells
19 the grandkids, "Don't let Grandma have these potato
20 chips"; right?

21 And so that community model has not

1 occurred in clinical trials, and that's what we're
2 trying to move forward with our pieces of research is
3 we got to engage the community through community-
4 based, participatory research in an equitable model of
5 service and collaborative care.

6 MS. SARI: First of all, I have to say
7 I absolutely agree with what was just said.

8 I think especially in a pediatric
9 space, you have to engage, you know, parents or
10 caregivers or community in a way that is actually
11 meaningful and then there based off of their values.

12 And values differ across not just
13 different communities, but different sub-sectors
14 within those communities and then different people.

15 And so when you're, you know, modeling
16 these things, when you're designing a clinical trial,
17 or when you're in a research team and you're trying to
18 understand the values of a group of people, you have
19 to actually get in there and listen to their values.

20 You can't just say, "Well, we're going
21 to take into consideration the values of what we think

1 this group believes in," because members of that group
2 are multifaceted. I'm multifaceted.

3 You might take, you know, me as an
4 example and say, "Okay. This person's ethnic
5 background is from a majority Muslim country, and so
6 you know, this person's values are going to be highly
7 religious," and you know, maybe whatever preconceived
8 notions come along with that.

9 But then when you come onto my level,
10 my values could differ from whatever your assumptions
11 are. My values could be more based around my
12 experience as a transgender person and, you know,
13 moving through life with that sort of label,
14 especially when it's a highly politicized sort of
15 thing.

16 And so understanding what that person,
17 on an individual level and then a family level and
18 then a community level -- understanding what the
19 patients have gone through and then understanding
20 where their values come from, I think is really vital,
21 and then using that when you're effectively --

1 hopefully effectively communicating with their
2 families and communities.

3 MS. DAVE: I was just really quickly
4 going to add to that too. I think one of the things
5 that we have heard a lot from our community about is
6 the hesitancy to approach topics that can feel very
7 sensitive, like sexual and reproductive health.

8 And I think even when we're thinking
9 about pediatric patients, these are really important
10 topics to bring up in a way that's sensitive to the
11 individual cultural backgrounds of the person, but
12 also creating room for questions to be asked in a way
13 that doesn't feel, I think, interventional in a bad
14 way -- if that makes sense, anyway, to the family.

15 So I think that is, like, the biggest
16 thing is that we don't sometimes know how to ask about
17 these things. And so being able to create
18 opportunities for those pathways, but also for
19 explicit discussion of that.

20 So just really quickly, for example
21 too, we developed a sexual and reproductive health,

1 like, checklist type of thing for physicians to ask
2 for young adult patients about questions that they
3 might have.

4 So I think these are really great
5 opportunities to really bring people in and get their
6 questions asked that they might otherwise be scared
7 to.

8 MS. WILLIAMS: I got to say that I'm
9 really impressed with these young voices on this
10 panel.

11 The brilliance that they're bringing to
12 this conversation is something that I applaud, because
13 when I think about values and I think about my own
14 family, I had to be that generational curse breaker.

15 I have two grandmothers that passed
16 from breast cancer, one from the deep south, one from
17 the Caribbean that immigrated to the U.S., and they
18 had the same mindset that we don't talk about disease
19 or the big C in the family.

20 So they tried to self-medicate until it
21 got to the point they were already at stage-4. It was

1 too late. And I did not want that for my life,
2 because in my young mind, cancer equaled death.

3 So I became that voice. I became that
4 outspoken component and representative of my family.
5 I check in with my family. You know, we need to know
6 our family history, especially when it comes to
7 genetic testing.

8 When I did genetic testing after my
9 diagnosis, I realized beyond my grandmothers, I don't
10 know my family history. I can't tell you what my
11 grandfather passed of. I can't tell you what type of
12 cancer my uncle passed of.

13 That's not okay, because then that
14 skewed the results of your genetic testing. So we
15 can't be silent about this. Sometimes we have our
16 cultural values, but when it comes to health, we have
17 to be intentional in knowing our family history

18 MS. DAVE: And just adding on to what
19 the other panelists have said, I think that when the,
20 you know, study investigator or whoever is conducting
21 the clinical trial is aware of these cultural values,

1 you're able to facilitate that communication better.

2 And I think it overall improves the
3 experience for everyone, because it's more
4 accommodating, and it makes you feel almost more
5 appreciated for being a part of the trial.

6 MS. EPPS: Yeah. Can I just say, to
7 add on to just how phenomenal you younger folks, which
8 means everybody up here, you know, compared to me, are
9 on this, is that when you're talking about isolation
10 or talking about where there's sort of uncomfortable
11 subjects, you all are here talking about them, which
12 is huge.

13 There is, in other realms that I won't
14 go into, people who won't talk about things that need
15 to be talked about, who are a lot older than you are.

16 So I commend you. I hope you continue.
17 This is not the end of this discussion, but I just
18 want to bring that out, because I think it begs the
19 question, and we were talking about teaching or
20 learning about values, who's going to lead that
21 teaching?

1 And my suggestion would be folks like
2 you all, because you have the nuances about these
3 things. It's not black and white what a chronic
4 disease at a young age means, what you may or may not
5 choose as a gender or sexual identity means for
6 somebody.

7 You know, these are things that we old
8 folks maybe -- we just don't get it. So that's what I
9 wanted to say about that.

10 So moving on along that then, what are
11 steps that institutions -- and I had on my list
12 industry and academic, but I'm going to say a bunch of
13 institutions -- they can be community institutions,
14 such as, you know, churches, synagogues, mosques, you
15 know, institutions, what steps can they take to build
16 and maintain trust between members of a community and
17 researchers, you know, clinical trial folks?

18 So you all have at it.

19 MS. KIPP: I think if we used more the
20 community-based participatory research model that has
21 been developed by Dr. Wallerstein and Dr. Isabelle --

1 and I can't -- her name is failing me, because I've
2 been a practitioner of CBPR ever since going into
3 research, because it's really an equitable model.

4 If you look at CBPR, it's an equitable
5 model of engaging communities in dialogue around what
6 does this mean to you?

7 And sometimes it's a basic question of
8 how does culture play? So we've already done this
9 among several tribes around clinical trials in gene
10 therapy.

11 And what we're finding at this present
12 moment, real-time, is that native folks don't
13 understand clinical trials. They want to know more
14 before they make the decision.

15 And so what a lot of the tribal
16 colleges have said and tribal leaders have said is we
17 want curriculum, we want people to come to our
18 isolated reservation in whatever part of the country
19 and talk with us about that.

20 And we want people who look like you,
21 meaning me, because I did the focus group. So those

1 things are critical, and I'm not trying to be
2 ethnocentric, but our people have to have trust and
3 their levels of trust isn't from the MD and the white
4 coat, because that hasn't worked well for us. Maybe;
5 maybe not.

6 But it's not removing them too; it's
7 the pairing of them in a relationship base; that this
8 is research, and this is -- we're trying to find out
9 what's best for you; how can that work for you; what
10 won't work?

11 And we even asked the question, who
12 will you talk to think if you're going to take a
13 clinicals trial? We had medicine people who were
14 concerned about how do clinical trials mesh with our
15 traditional medicines.

16 These are critical needs that tribal
17 communities ask and need response to, but we need to
18 treat them and be with them. It's not equitable.
19 It's not clinical trials on us. It's clinical trials
20 with us.

21 And that means us; that means the

1 researchers; that means the docs; it means the
2 interventionists; we become the "us."

3 But if you keep saying it's, "Oh, we're
4 bringing this to you as a gift," no, it's about "with
5 us," because we can do that and extrapolate people for
6 a clinical trial, but they have to return to the
7 community.

8 And the community is the community that
9 will heal them. And so we're leaving out the healing
10 part for our people.

11 MS. DAVE: I think as a patient,
12 there's a couple things that I would want to see in
13 these with these institutions.

14 The first one is just transparency,
15 like being transparent about why a test is being done
16 or why a study is being prolonged or shortened and
17 just being kept up to date through, like, standard
18 communication about what's going on, like how's the
19 research data of the study going and maybe, like, an
20 overview of the next steps.

21 And then I think the other thing, like,

1 leading into that is facilitating communication and
2 just being informed that a lot of the times in
3 pediatric studies it feels like the investigators or
4 whoever is facilitating the study is talking directly
5 to the parents. And sometimes, like, bypassing the
6 pediatric patient.

7 So, like, obviously, with taking age
8 group into account for maybe, like, patients above the
9 age of 10 to 12, incorporating them into the
10 conversation with them being the main focus, as
11 opposed to the parents.

12 And since parents are the ones that are
13 consenting, they obviously have a lot of questions and
14 want to know a lot about the study.

15 But I think it's also important that
16 the students questions are addressed first, because
17 from personal experience, a lot of times at a
18 healthcare office or at the doctor's office, you know,
19 parents get through their list of questions with the
20 doctor, and by that time it's either, you know, been a
21 while or you forget what the question is.

1 And so I think it's important to
2 address pediatric questions and concerns, just as much
3 as parents.

4 MS. SARI: I agree. Absolutely. And
5 I'd say it doesn't even necessarily have to be 10 to
6 12. I think that at any age a pediatric patient has
7 to be included in that conversation.

8 And I think beyond that, it has to be
9 an effective language; it has to be communicated in a
10 way that people can understand, whether that pertains
11 to age or preferred language or anything.

12 It has to be in a way that people can
13 latch onto, and they can really understand what's
14 about to happen, because especially with these
15 clinical trials, it's their lives, and it's their
16 quality of life that is in the hands of these doctors.

17 And if they don't fully understand
18 what's going on, then that's not truly informed
19 consent, to be honest.

20 And then beyond that, I think that in
21 terms of building trust, it can't just be about, you

1 know, going and telling a community what the
2 information is.

3 That's an important aspect, but it also
4 has to be -- I think it was called "bidirectional"
5 before.

6 It has to come from both sides, because
7 I think just as important as disseminating accurate
8 information is understanding what that community needs
9 specifically, and then beyond that, taking actual
10 action on it and not just, you know, saying, "Okay;
11 we've heard you," because that's an important first
12 step, but then it's taking action to demonstrate
13 trustworthiness. So yeah.

14 MS. DAVE: Yeah. And one of the things
15 that I think about with this question for institutions
16 in particular is, are you taking steps to deserve that
17 trust and deserve the engagement?

18 One of the just personal frustrations
19 that I've had is I really struggle to get access to
20 data. So, like, when I was looking at a
21 multidisciplinary review, I saw a lot of information

1 redacted.

2 And whether that's academic-in-
3 confidence, commercial-in-confidence data, that is not
4 my problem to solve. But the problem is, is that as a
5 patient, how am I supposed to trust when information
6 that I want to know is redacted?

7 How am I supposed to trust when the
8 medication that I'm being a part of for this trial is
9 not affordable? How am I supposed to trust when long-
10 term safety data is not available as a young person
11 who has decades to go through for life?

12 So I think these are some broader
13 questions that need to be addressed when we're
14 thinking about building diverse populations and
15 clinical trials, especially for the next generation of
16 patients who are going to need this data and need this
17 information.

18 MS. EPPS: Thank you. Let me ask you a
19 follow-on question on that. When you're talking about
20 bidirectionality and -- or that's a word. So who was
21 it, Dr. Lee, this morning that said, "No more word

1 clouds"?

2 But about the patients, you know,
3 taking leads and things, what are areas you consider
4 really important that gives the patients -- well, let
5 me back up for one second.

6 Let me just say, as a now decades-long
7 pediatrician, I agree 200 percent that a child of any
8 age can tell you what they want or how they feel, even
9 including nonverbal kids.

10 If they don't trust you, you know it.
11 If they're not happy with it, you know it, whether
12 they can say a word or not.

13 So, you know, soliciting information
14 from the patient and the parents too. But that's
15 huge. I think people forget that.

16 But what are sort of really important
17 areas of empowering the patients in this process, and
18 even a pre-question is, when is all this supposed to
19 take place?

20 When are these activities taking place?
21 As the protocol is being developed? Is this something

1 to plan for, you know, a couple years from now we'll
2 have stuff in place, so we can have a trial in our
3 area? So those are two questions for you.

4 MS. KIPP: I think that as we look at
5 the development of research, what we've done -- and
6 I'll just use what we've done as an example, is we've
7 included the tribal colleges in the questions of the
8 focus groups. Will this fit here? Does this work?

9 And then we did reiterations; huh? So
10 we went back to FDA, and FDA said, well we need to
11 know this. And so we did that community engagement
12 even around the development of the focus group
13 question.

14 And so those methods of empowerment are
15 really systematic through focus group, but they're
16 relationship based.

17 So we all know all the docs sitting
18 here that people don't get better unless they believe
19 they're going to get better; right? People don't get
20 better unless the doc has a trusting relationship with
21 that person.

1 So why is it then that we look at
2 clinical trials and extrapolate, instead of developing
3 those critical relationships? And we don't have to do
4 it.

5 We have to have people in the community
6 paraprofessionals, community health workers who can
7 also do that and then follow up on assessing did they
8 take their medicine today; did they do this?

9 But we've got to engage the community
10 in a system that's been very keen on eliminating
11 communities and individualized treatment.

12 I, as a clinical psychologist, have
13 recognized the need that even in individual therapy, I
14 still will go into the community and provide community
15 information on mental health around depression and
16 anxiety and historical trauma, because the community
17 has to support the movement of wellness in the
18 community.

19 The World Health Organization defines a
20 healthy community this way. A healthy community is
21 when the health is at the local level. And a local

1 level means cultural and language level that the local
2 folks can understand. None of the jargon.

3 I'm going to finish this by honoring my
4 mother and what not to do. My mother died when she
5 was 96 years old. I lived on the reservation for
6 quite a while with my mother, and then I returned to
7 become the tribal college president.

8 And as she was dying, she had a little
9 file at Indian Health about this thick. And she would
10 get sick, and I would tell her, "Come on, Mom. Let's
11 go to the hospital." And she'd say, "No, Billie, I'm,
12 I'm not going there, because they talk to me like I'm
13 stupid."

14 And she wouldn't go. So we can't
15 jargon people. We have to talk with them in a
16 language that they can understand. We have to talk
17 with their networks and under language that we
18 understand, and we have to engage the community for
19 better health outcomes.

20 MS. WILLIAMS: So when it comes to
21 trust, I no longer have blind trust. Defining

1 conversations is how I seek out trust, accountability,
2 and build connections. And it was a recent visit to
3 my GI doctor, and I realized that I'm still dealing
4 with implicit bias.

5 I've been seeing this doctor for five
6 years now. We've built a rapport, but I just asked
7 him during my recent visit, I said, "Why haven't you
8 recommended me for a clinical trial?"

9 Is it because the visits are always
10 rushed, or you don't think I would agree to it, or
11 maybe you just don't know enough and how to direct me
12 to towards a trial?"

13 So, you know, he's a Caucasian man, and
14 he kind of stopped in his tracks, but then said, "You
15 know what, thank you for asking me that question,
16 because it's all of the above."

17 Then he got excited to tell me about a
18 TED talk that the hospital recently did, and he wanted
19 me to watch the video.

20 So I want to speak to my non-scientific
21 audience. Allow yourselves to ask questions, give

1 yourself that permission, because questions are more
2 transforming than answers, and questions, unlike
3 answers, demand that engagement that we need for that
4 transparency.

5 I don't know if young people say, "I
6 like people to keep it real with me." You know, I
7 want to hear those unpopular answers, because that's
8 how I build trust.

9 MS. AMBARDEKAR: And just going a
10 little bit to that aspect of where pediatric patients
11 can kind of use their voice, I think kind of giving
12 feedback at every stage in the developmental process
13 of the clinical trial.

14 You know, asking a focus group of
15 patients that includes ones who might potentially be
16 in that clinical trial, but also ones who would not,
17 and kind of just getting feedback that, you know,
18 "This is a clinical trial. This is why it's being
19 conducted, and this is what it's planned out. There
20 is these tests and these study visits, and how do you
21 think we could make this more comfortable and more

1 accommodating to the target age group?"

2 And I think that would help build trust
3 also just knowing from a patient standpoint that my
4 peers have provided feedback and kind of reviewed that
5 study and made it more accommodating for this
6 population.

7 MS. EPPS: Go ahead.

8 MS. DAVE: I was just going to say, I
9 said in the previous panel, but I really do think that
10 patients have the ability and capability to be equal
11 contributors to the entire process.

12 And last year we published eight peer
13 reviewed journals -- or publications, all of which had
14 a young adult patient as a first author and majority
15 were drafted by young adult patients.

16 So I think there's a real opportunity
17 to shift the way that we think about including
18 patients to really ensure that they have part of the
19 leadership of the trial design, the protocol, and what
20 comes after.

21 And I think that's a way to get that

1 integrated feedback of lived experience throughout the
2 cycle and really give ownership, like, "We trust you
3 as an equal partner; we want to give you authorship;
4 we want to give you that same opportunity as we would
5 someone with a PhD or MD," whatever that looks like
6 too.

7 MS. SARI: Sure. I think a lot of the
8 ideas that have been discussed have been really good.
9 And I specifically want to talk about what Anvita was
10 saying, where it's, like, it has to be throughout
11 every stage. It has to be a consideration from the
12 beginning and from planning the clinical trial.

13 Because if there's not a space for
14 groups where there typically isn't a space, then how
15 are they supposed to start trusting in these
16 institutions?

17 And then sort of like LaToya was
18 saying, I think that the transparency aspect and also
19 you, Billie Jo -- yes, sorry -- your name is right
20 there, that the transparency aspect is really vital.

21 Because if you're using this jargon or

1 if you're just, you know, throwing around slogans or
2 language that we can't necessarily understand, based
3 off of generational divide or based off of any sort of
4 anything that could cause a difference in language,
5 then trust starts to break down.

6 Because I think that when we start to
7 hear, you know, slogans, it feels like something is
8 being sold, and I think that when something is being
9 sold, then we're less likely to trust it. So yeah.

10 MS. EPPS: Wow. So on that, I hope you
11 all took notes, because I think it's pretty much all
12 there, so I'm just going to thank you, the wonderful
13 panel, and pass it on to the next.

14 My apologies folks. I'm advocating my
15 responsibilities. Let me introduce the next part of
16 the program. And so this is going to be three
17 presenters on best practices that help children and
18 families to stay in clinical trials.

19 So we'll have Tamorah Lewis who is a
20 chair at Pharmacology and Pharmacogenetics in
21 Hospitals for Sick Children. That's in Toronto, I

1 believe. Christina Edwards will follow, and she is
2 director of Clinical Trials at the National Minority
3 Quality Forum, and then Puja Umaretiya -- sorry -- I'm
4 going to slay your name, Umaretiya, who is assistant
5 professor in Pediatric Hematology/Oncology at UT
6 Southwestern. Yay, UT.

7 So I'll let those guys go ahead and --
8 those ladies take over, and thank you.

9 MS. LEWIS: Good afternoon, everyone.

10 So as mentioned, there's three of us
11 who are going to speak in the next 45 minutes and
12 really our goal is to share different perspectives
13 about how to help families start and stay in clinical
14 trials.

15 So as mentioned, my name's Tamorah
16 Lewis. I'm a physician and a scientist from SickKids
17 in Toronto. And my talk is about strategies to combat
18 structural racism, how we can improve diversity in
19 pediatric clinical trials.

20 So today, in 15 minutes, I hope we can
21 discuss how structural racism can impede a family's

1 ability to enroll and to stay in clinical trials and
2 to speak about potential solutions that can help us
3 combat structural racism specifically as a barrier for
4 optimizing clinical trial enrollment and
5 participation.

6 So I think I'm speaking to the choir
7 here, but it's always helpful late in the day to
8 ground ourselves in why we're here and why this is so
9 important.

10 So we know that different demographic
11 groups have variations in health outcomes, disease
12 prevalence, and response to our treatments. And by
13 increasing diversity in our trials, we can better
14 understand these variations and develop healthcare
15 interventions that are more effective and equitable
16 for all patient groups.

17 In addition, when our clinical trials
18 are diverse, we know that our results are more
19 generalizable. The results may not be applicable or
20 safe for all groups if these different groups are not
21 enrolled in the original clinical trials.

1 And lastly, clinical trials can be a
2 mechanism to identify disparities. So if we don't
3 have diversity in our clinical trials, we don't
4 understand differential efficacy or differential
5 safety signals that can be crucial for developing more
6 targeted interventions in the future.

7 We know that drug metabolism, drug side
8 effects, and drug treatment response can vary among
9 different racial and ethnic groups.

10 So if we don't have adequate
11 representation in our trials, we won't know how
12 efficacy and safety differ by specific populations.
13 And a diverse study population can enhance the
14 robustness and reliability of our research findings.

15 And very importantly, based on the
16 panel that we just heard, you know, we have a duty to
17 enhance public trust, so patients are aware of
18 differential ability to enroll in clinical trials and
19 differential ability to stay on clinical trial
20 protocols.

21 And we as a research community really

1 have the burden to repair the mistrust that
2 marginalized communities feel. And building this
3 trust is crucial for recruiting participants and
4 conducting ethical research.

5 So now we're going to talk specifically
6 about structural racism. And when we think about
7 structural racism, really another word for this is
8 structural disadvantage.

9 So we know that certain racial ethnic
10 and other marginalized groups in the United States
11 experience different ways that resources are
12 distributed. There's different ways that people
13 relate to each other, both on an institutional level
14 and an interpersonal level.

15 There's clear variation in who has
16 power, and this plays out in how institutions are
17 organized, which patient populations are prioritized,
18 and the type of medical care that families have access
19 to.

20 And this table from the Kaiser Family
21 Foundation really does a great job outlining all the

1 social and economic factors that drive differential
2 health outcomes. But more importantly, I think can
3 also drive research participation.

4 So we know that families from different
5 backgrounds have different levels of economic
6 stability, neighborhood and physical environments,
7 education and food resources, community and social
8 context, and healthcare systems that can all affect
9 medical outcomes, but really importantly affect a
10 family's ability to participate in research.

11 And I've outlined and read some of the
12 things that I think are most important to consider
13 when scientists partner with communities to design
14 clinical trials.

15 So a research team that is truly
16 invested in diversity in clinical trials will actually
17 take the time upfront at the time of early community
18 engagement and at the time of protocol development to
19 explicitly address each of these different columns and
20 explicitly try to understand how their target clinical
21 trial participants might be affected by these factors

1 and what they can do in their protocol design to
2 actually mitigate some of these barriers.

3 And we know that societal disadvantage
4 affects families in many different ways. And I'm just
5 going to show you three very simple graphics that beg
6 us to ask ourselves the question, do all families have
7 equal opportunity to show up at our clinical trial
8 sites with adequate emotional and cognitive bandwidth
9 ready to engage in complex research related
10 discussions?

11 So we have to take a moment and think
12 about a family's lived experience outside of the walls
13 of the hospital, outside of the walls of the clinic.
14 And then imagine how that lived experience and the
15 differential lived experience affects their ability to
16 come and sit and engage with you to discuss a consent
17 form or to discuss a clinical trial protocol.

18 So this figure on the left shows what
19 many of you might already know, that income and wealth
20 varies significantly among different racial and ethnic
21 backgrounds in the United States.

1 And you can imagine how a family that
2 is growing through chronic financial stress is in a
3 very different situation to consider enrolling their
4 child in a clinical trial than a family with relative
5 wealth.

6 We also know that different racialized
7 groups face social injustices, such as incarceration,
8 at very different rates.

9 So if a community is in chronic crisis,
10 because, let's say, the men and boys from their
11 community are being arrested in incarcerated, that
12 affects a family's ability to show up, ready to
13 discuss clinical trials.

14 And we also know that different
15 racialized groups experience gun violence and death by
16 gun violence at very different rates.

17 And so these are just three very basic
18 examples where we have stark data of differential
19 lived experience by race and ethnicity in the United
20 States and how if we're going to try to,
21 quote/unquote, "Conduct diverse clinical trials"

1 without thinking deeply about these topics and
2 engaging with these topics and understanding where
3 families are coming from when they walk through our
4 clinic doors, we're going to have trouble with
5 success.

6 So now, we'll talk specifically about
7 some solutions for clinical research, diversity, and
8 equity.

9 This is a wonderful paper published in
10 2023. The name of the paper is at the top of the
11 slide. And we're going to tackle two big topics from
12 this paper, which are barriers to clinical trial
13 participation and solutions.

14 The first barrier is limited access to
15 healthcare, and this is a very major barrier that can
16 affect clinical trial recruitment and differential
17 access to basic healthcare, as mentioned in the prior
18 panel, really can disproportionately impact racial and
19 ethnic minority groups.

20 So this figure is from a website called
21 milkeninstitute.gov, and the on this website you can

1 search by different disease status and look at the
2 density of clinical trial sites across the United
3 States. And this is an example where I just typed in
4 sickle cell disease.

5 So we know that limited access to
6 healthcare disproportionately affects racial and
7 ethnic minorities and can be a major hindrance to
8 their enrollment in clinical trials.

9 Research sites are often distant from
10 the most minoritized and marginalized populations,
11 making participation very difficult due to basic
12 things, such as transportation challenges and having
13 to navigate very unfamiliar locations.

14 In addition, we know that people who
15 have limited financial resources can really have
16 insurmountable caregiver burdens. So caregivers from
17 racial and ethnic minority groups may face additional
18 challenges in participating, because they can't get
19 out of elder care or childcare responsibilities.

20 And also, racialized and rural
21 individuals may be in more service-intensive or labor-

1 intensive occupations with limited paid time off.

2 So as opposed to someone like myself
3 who has the luxury of taking a day or two off each
4 month to participate in a clinical trial, another
5 person may miss an entire day of pay and not be able
6 to feed their family if they decide to participate in
7 a clinical trial.

8 So what are some tangible solutions?
9 And these are the things that we have to consider when
10 we actually design our budgets for our clinical
11 trials, because if you haven't budgeted for these
12 solutions, you are not going to be able to enroll
13 participants who face these barriers.

14 And so it really takes intentionality
15 and planning upfront. So how are we going to include
16 incentives and compensation in our budgets at the
17 institutional level?

18 So we know that financial remuneration
19 and reimbursements, just for study-related lost
20 resources, can really help bolster families and their
21 ability to weather the financial stress of clinical

1 trial participation.

2 Transportation support. So you know,
3 actually doing something very tangible, like Lyft
4 vouchers or Uber vouchers or having -- you know, if
5 you're getting multiple patients from a certain rural
6 community, having structured transportation plans to
7 bring them to clinical trial sites can help address
8 transportation-related barriers.

9 Childcare and elder-care support. So
10 you know, I think a lot of times research teams think
11 about these things in theory or in an abstract way,
12 but if you really want to enroll families with
13 increased caregiver burden, you actually have to
14 budget for how you're going to help them provide care
15 for family members when they bring their patient for
16 clinical trial site visits.

17 And also, how can we take clinical
18 trial conduct out into community-based clinics? So if
19 we place our research clinics in community-based
20 ambulatory primary care offices, that can both allow
21 easier geographic access, but also allow patients to

1 engage in clinical research in a site that feels
2 comfortable and less intimidating.

3 And lastly, flexible timing. So we
4 know that our clinical trial visits are really timed
5 around convenience for physicians and researchers.

6 And so if we want to allow families to
7 participate who have the types of jobs where they
8 can't miss work, we really have to get creative about
9 flexible timing, allowing evening and weekend
10 research-related activities or virtual activities that
11 don't force families to miss so much time from work.

12 And this figure is from a company that
13 works to improve research diversity. And you can see
14 on the horizontal axis different ways that research
15 participants learn about different research
16 opportunities.

17 And patients from different racial
18 backgrounds actually report very different ways that
19 they first learn about research. So an important part
20 of diversity is using non-traditional or alternative
21 routes to advertise your clinical trial that might

1 allow different research participants to learn about
2 it.

3 So taking extra caution when we develop
4 eligibility criteria is a key step. Are we
5 functionally excluding certain patient groups because
6 of the way our protocols are designed?

7 And then also we heard today about
8 decentralized trials. What study procedures can we
9 perform remotely? And are there easy to reach
10 community sites where we can conduct certain study
11 procedures?

12 We're next going to talk about racism
13 as a barrier. So complex issues surrounding perceived
14 interpersonal, institutional, and structural racism
15 serve as a major obstacle to recruitment of racialized
16 groups.

17 And we know, based on many
18 conversations today, that lack of trust in the medical
19 and scientific community affects racialized patients.

20 There have been historical abuses and
21 in some situations there are ongoing abuses of

1 racialized communities, both in residential schools
2 and nutritional research, other types of examples that
3 lead to this deep seated mistrust trust.

4 There's explainable and very
5 understandable fear of experimentation, present day
6 discrimination that racialized families experience in
7 their day-to-day encounters with the medical system.

8 And we know that there are worse health
9 outcomes for racialized communities. And importantly,
10 patients from racialized communities also know this
11 critical fact.

12 And so all of these examples of the
13 effect of racism really can affect a family's ability
14 to enroll in clinical trials.

15 This study is in adult transplant
16 patients, and they ask transplant patients their
17 experience of medical racism.

18 And you can see that there are big
19 differences in the way African American patients and
20 white patients respond to these questions like doctors
21 treat African American and white patients the same.

1 And you'd better be cautious when you
2 decide which healthcare organizations to trust your
3 family with. And patients sometimes can be deceived
4 or misled by healthcare organizations.

5 So these are, you know, patient
6 responses and patient experiences of their medical
7 care. So you can imagine if patients are having these
8 worries about their medical care, it can affect their
9 ability to engage with research.

10 So we're getting to my last slides and
11 these are just examples of how to address racism
12 barriers. And I think a very important one that's
13 come up today is this concept of historical trauma and
14 educating research teams about cultural and historical
15 trauma.

16 So if a family comes to you and you can
17 only speak to them in a way that you would speak to
18 the most privileged family -- you know, you cannot
19 engage with them about their cultural history with
20 medicine -- you don't feel comfortable talking about
21 issues of mistrust, you're really going to have a

1 tough time for your research coordinators and your
2 research team to enroll diverse participants.

3 And so I loved how the panel talked
4 about values and how cultural values can be so
5 personal. And so what we don't want to do is go and
6 say, "Talk to all black patients this way. Talk to
7 all LGBTQ patients this way."

8 We want to teach our research teams to
9 actually have deep cultural humility. So when you
10 approach a family, you spend time saying, "What's
11 important? What are values important to your family?
12 In your culture, what are some barriers that might
13 make research scary? What are some values in your
14 culture that might make research exciting?"

15 And spend the time and have that
16 cultural humility, and the research team is not
17 fearful of engaging in those conversations.

18 So to conclude, structural racism and
19 structural disadvantage undoubtedly impede research
20 entry and participation for many racialized families.

21 And a study team that's committed to

1 diversity actually will not talk about these things in
2 a theoretical sense, but actually sit and focus and
3 talk about practical ways that they're going to
4 address these barriers before clinical trial launch.

5 And in the two talks that are going to
6 follow me, we're going to talk about inclusivity best
7 practices from a nonprofit research lens, and also how
8 do we improve diversity in vulnerable pediatric groups
9 such as oncology clinical trials.

10 Thank you.

11 MS. EDWARDS: Okay. Good afternoon,
12 everyone. My name is Christina Edwards. I'll be
13 talking about continuing the conversation from what
14 Tamorah discussed on best practices that help children
15 and families to stay in clinical trials.

16 Again, from the nonprofit perspective,
17 I personally work as a director of Clinical Trials in
18 our Center for Clinical and Social Research with NMQF
19 being a health research, education, and advocacy
20 organization.

21 No conflicts of interest here.

1 So we're going to first take a look at
2 these two diagrams here. So on our left, we have our
3 U.S. demographics from 2020. And on the right, we
4 have a clinical trial participation statistics.

5 So you see here on the left, from the
6 2020 census, the largest blue image here, we have 60
7 percent of the U.S. white population.

8 While you see on the right, they do
9 account for 80 percent of clinical trial participants.
10 Moving clockwise, we see 13 percent of the black
11 population according to the 2020 census. And they
12 only account for 10 percent of clinical trial
13 participants.

14 Moving up that, you see a huge
15 discrepancy again in our 19 percent Hispanic Latinx
16 community, only accounting for 6 percent of the
17 population.

18 So that's just a very quick look at
19 some of the disparities that we see generally in
20 clinical trials.

21 Here we have another diagram taking a

1 look at the multi-level barriers to clinical research.
2 I'll go through this real quickly. You heard a lot of
3 these throughout the day to day, but on the individual
4 level, some of the issues that come up is time,
5 resource constraints, language, interpersonal
6 attitudes and police of patient and provider, bias,
7 mistrust, lack of awareness and engagement.

8 Institutional, again, lack of trust,
9 competing goals, eligibility criteria. On the policy,
10 you see here funding mechanisms, accountability, and
11 support for BIPOC investigators.

12 So I'm going to talk a little bit -- on
13 a high level, three approaches, starting with
14 community engagement and working with some of these
15 best practices on the community engagement level.

16 So how you engage with the community,
17 depending on the population that you are entering, it
18 can have a pretty determinant factor in the success
19 that you will have in that study with respect to that
20 population.

21 So for starters, you want to -- you

1 industry, the sponsor, whoever is bringing their
2 trial, you want to conduct outreach and engage your
3 community-based organizations, advocacy groups,
4 community leaders to gain buy-in, to gain their trust
5 of the community.

6 So for starters, evaluate the needs of
7 community. What may be publicly available, something
8 like a community needs assessment, you can maybe start
9 there, but you more so want to actually speak with the
10 community, conduct educational seminars, host events.

11 What that may look like, there's health
12 fairs; there's drives; there's toy drives; there's
13 clothes drives. It will be centered on the needs of
14 the community.

15 And on the basis of those findings that
16 you have during these town halls against seminars, you
17 gain additional insight into the issues that they're
18 having, into the comorbidities that they're dealing
19 with, into the care options, and, of course, you'll
20 also use these spaces to spread information on
21 clinical trials.

1 Again, you want to liaise with trusted
2 community members. Who are the figureheads? You want
3 to utilize their support, endorsement to help bridge
4 the gap between the sponsor and the community, and,
5 again, partner with organizations already doing the
6 work.

7 You won't be the first trying to get
8 into the community. There's going to be people there
9 who have been on the ground and putting in the work to
10 develop their own mechanism -- their own relationships
11 that they have.

12 So seek those out. Seek those partners
13 out. See what they're doing. It's not always
14 necessary to start from scratch. Amend and tailor,
15 you know, what you need to do, of course, to what has
16 already been done. See how you can build upon that.

17 And lastly, what you see here is have a
18 dedicated team. When you place yourselves in these
19 communities, it is nice to, you know, not have a round
20 robin of people.

21 If you have a team that's going into a

1 community, have a set team. Maybe a team may not be
2 in in the budget. Have a particular contact person.
3 So when you meet with these trusted community members,
4 when you partner with these organizations, you have a
5 point of contact that they have that they can call to,
6 that they can trust when they reach out to you.

7 So essentially, you form a coalition
8 when you go into these communities. You have
9 researchers. You have these various stakeholders.
10 You'll have physicians as well. You'll have the
11 industry perspective, and then, you know, you'll
12 eventually form that type of relationship.

13 And it should be longstanding. It
14 should go beyond your initiative. It should go beyond
15 your program. It should be ongoing. Before a trial,
16 before any of that is started, you want to make your
17 presence known.

18 So at NMQF, we have a few programs, one
19 of them with our Center for Sustainable Health Equity
20 and Engagement.

21 So with promoting health equity through

1 education and clinicians and community leaders, we
2 focus on clinician engagement and community
3 engagement.

4 So clinical teams, pharmacists, partner
5 with SHC to implement QI in community engagement
6 projects in underserved communities.

7 And then we also have community
8 engagement partnerships with churches, barber shops,
9 and hair salons around the community -- around the
10 country -- excuse me, to engage, educate, and connect
11 people of color to health and social services.

12 So these are the names for those that I
13 just mentioned, our Faith Health Alliance, our
14 Wellness Warriors, and our Community Pharmacists.

15 Faith Health Alliance deals with deals
16 with faith health leaders, Hair Wellness Warriors,
17 barbershops, hairdressers.

18 Essentially we train these people. We
19 educate them. We speak with them. We meet with them.
20 We form relationships with them. And then they,
21 essentially, in their line of business, they go out,

1 and they disseminate the information to their patrons.

2 So it may not -- the information
3 doesn't always have to come from you. You know, work
4 with who is already in line and who they would be
5 susceptible to listen to

6 Just a quick image of where we are.

7 So a little more community engagement.
8 Ensure the use of culturally tailored education.
9 Again, something we've heard all throughout the day,
10 communities are incredibly nuanced.

11 You want to be sure to be culturally
12 sensitive. One community is not the same, you know,
13 within one given language, just multiple dialects.
14 Just be cognizant of that and what's going on.

15 Could tailor customized materials in
16 disengagement in your outreach, advertising and
17 recruitment materials, including social media;
18 marketing and outreach should be tailored to your
19 targeted community.

20 And then optimizing study teams. So
21 working with community is not only on the clinical

1 participant side. It also means the research team,
2 the investigator, the physicians that you'll engage,
3 where you'll choose to put your studies, the site
4 you'll choose, who will be the PIs on your study.

5 So you want to ensure -- well, I don't
6 know if you can ensure. You want to do your best to
7 have the principal investigators, the study staff,
8 they should represent the population of people that
9 you want to eventually enroll.

10 If we're going for diverse and
11 inclusivity, it is nice when the people that you seek
12 your care from are reflective of you.

13 Another initiative that we have ongoing
14 at the National Minority Quality Forum in a
15 collaboration with Biogen, so we developed the
16 clinical trial learning community model to identify
17 and mitigate disparities in clinical research.

18 So the model has been working directly
19 with medical professionals to expand their knowledge
20 on cultural competency and the importance of clinical
21 research via virtual training modules and community

1 town halls and educational sessions.

2 I think, again, someone spoke earlier
3 that it shouldn't be assumed that the physician is
4 privy to clinical trials and what that it all entails.

5 Of course, you know, they're a doctor,
6 you know, but they might not participate in research
7 since, like, residency or fellowship. They still need
8 training or understanding on how to present clinical
9 trials to their patients.

10 So next, after community engagement, we
11 have effective communication practices. Again,
12 communication style and preferences will vary by
13 family.

14 We talked about the informed consent
15 process as being such a pivotal time point. And
16 during these times, you want to allocate additional
17 time for participants during visits, especially during
18 enrollment.

19 Many moons ago, as a clinical research
20 coordinator, you often didn't get someone to enroll on
21 the first time you presented the study to them. And

1 so working in pediatrics, they're going to take that
2 consent form home; they're going to show it to their
3 family; they're going to highlight; they're going to
4 have questions, and allow that.

5 You know, you shouldn't put pressure on
6 them. You want to ensure where translation services
7 are needed, utilize interpreters and translated
8 documents. Ideally, all study materials should be in
9 the participant's language.

10 I know if you're able to have study
11 staff that are able to communicate in the language,
12 that's always great. Utilizing interpreters can be,
13 in real-time, a little difficult, you know. It's
14 often over the phone. But where you can, make it
15 work.

16 And then communicating trial details,
17 it should be effectively conveyed for total
18 understanding -- study purpose, requirements,
19 benefits.

20 Benefits are pretty important. You
21 want to -- you know, is there immediate benefit? What

1 do they get out of this in the moment? Is it more
2 long term? Is it more for people who suffer with my
3 disease, but I won't see any many immediate benefit,
4 but people will after me? So you want to make sure
5 you properly convey that to the family.

6 During the trial, be available and
7 accessible. This helps to build trust and
8 relationships. You know, you will have to go the
9 extra mile. You know, it's not an adult trial.
10 You're dealing with family, and family is very
11 complex.

12 So reassure families you are available
13 for questions and concerns. This may include coming
14 earlier, coming later, but keeping an open line of
15 communication.

16 And as one of our patient advocates
17 said earlier today, "Keep them in the know"; share
18 results and achievements with families. Of course,
19 where allowed, inform families of study progress or
20 any stages -- or any changes, excuse me, and keeping
21 continuous communication; conduct outreach during

1 visits.

2 So our next approach here, community
3 engagement, effective communication. We have
4 comprehensive care. So when we say comprehensive
5 care, we're thinking holistic support for the
6 participant -- for the child.

7 Tamorah touched on this a little bit,
8 but there are going to be barriers; there are going to
9 be issues that the family is facing.

10 So you just want to be cognizant of
11 these different challenges that they're facing. And
12 while it's not directly study related, it's going to
13 impact retention; it's going to impact how they're
14 able to navigate the study. So take that all into
15 account.

16 A lot of these -- and with taking this
17 into account, again, as Tamorah mentioned, it's going
18 to require a budget. So when planning, when
19 development on the site side, make sure you negotiate
20 for that.

21 You know your patients, you know what

1 they will need. Take all that into consideration.

2 Incentives, as simple as put, monetary
3 incentives should align with time and effort required
4 of participant and family.

5 But as you heard earlier, while it may
6 just be a one-hour visit in your office, you don't
7 know what that family took to get there. So always
8 keep that in in mind.

9 You know, it should be reflected of
10 time and effort. You have to worry about fair market
11 value. But when putting it in your budget, when
12 negotiating, push it to the limit, and make sure that
13 you know families and the participants, they get what
14 they deserve for participating in your trial.

15 Should be easily redeemable. We used
16 to give cash. Most people don't keep cash in their
17 research sites anymore. It's usually a ClinCard or a
18 gift card of some sort.

19 But even the assumption that, depending
20 on the community, that they know how to use that, you
21 know, or if they go to an ATM, there's an admin. fee,

1 so they don't necessarily get their full compensation,
2 because a part of that was taken out.

3 All that just should be considered when
4 trying to -- when issuing incentives. And consider
5 alternative incentives where applicable, when
6 available, of course.

7 Institution policy may kind of knock
8 that down. But be creative, and see what you can do
9 and make sure it aligns with their needs.

10 I think it's my last slide here. So
11 again, with comprehensive care, patient navigation
12 with respect to budget -- it's a budget question as
13 well.

14 I think many people don't necessarily
15 put patient navigator, social worker, or case worker
16 into their budget. Oftentimes, while it may not be
17 under that label, your clinical research coordinator
18 is going to be doing that.

19 So if you can, get that put in to your
20 study budget; it works. And with comprehensive care,
21 just considering the participant's full health. It's

1 on a spectrum outside of disease indication that they
2 have come in for; you have to consider everything else
3 outside of that, and that is going to impact them.

4 So when they know that, there's a plan
5 for them, they know there's a continuum of care; they
6 know what's going to happen post this study,
7 especially if they have a chronic disease; the trial
8 is working; everything is going great; what's going to
9 happen when this is over.

10 So when they know that, you know,
11 there's a plan for them -- there's a plan for their
12 healthcare, keep them in the know of that, so there's
13 less angst surrounding that.

14 And if you, the research carrier -- if
15 you're just a research side or maybe you are in a
16 larger academic institution, be prepared to refer or
17 coordinate those services. Yeah. Again, just make
18 sure you have some post-trial plans and options
19 available.

20 And that's it. So we covered community
21 engagement, having effective communication, and

1 continuum of care, comprehensive care, just a holistic
2 look at the participants and their families for
3 consideration when working with them and trying to
4 increase your retention rate and get value out of
5 their participation.

6 MS. UMARETIYA: Hi, everyone. I am
7 Puja Umaretiya. I'm a pediatric oncologist at the
8 University of Texas Southwestern Medical Center.

9 And I just want to say how exciting
10 it's been to be a part of this stay and to hear so
11 many perspectives and to be a part of this shared
12 cause to advance clinical trial equity. I'm going to
13 be talking about it from my lens as a pediatric
14 oncologist.

15 I have no disclosures.

16 So we've heard this echoed over and
17 over, over the course of the day, so I won't belabor
18 it, but enhancing and maintaining trial diversity is a
19 priority for all of us.

20 I want to use pediatric oncology in
21 some of my work as a case study really to examine

1 frontline clinical trial enrollment and participation
2 by race, ethnicity, and poverty status to amplify the
3 experiences of black and Hispanic parents regarding
4 research participation in oncology and then really to
5 focus on our group's work targeting social
6 determinants of health in the same manner and with the
7 same rigor that we used to design drug trials and to
8 hopefully inspire all of us to think about how we can
9 begin to do this alongside our therapeutic trials.

10 So we've heard about the multiple
11 places along the clinical trial pipeline where
12 inequities can arise. I want to acknowledge that my
13 work really focuses on the later part of this pathway,
14 and that is because in pediatric oncology that's a
15 rare diagnosis or rare disease.

16 The majority of children with cancer in
17 the United States will receive care at a tertiary
18 center and at one of the 190 COG centers, the
19 Children's Oncology Group, which is a cooperative
20 group that runs our clinical trials, and so most
21 children in the United States with cancer will already

1 have access to a center with clinical trial options.

2 And so one of the first things that I
3 wanted to do is really look at who enrolls on clinical
4 trials in pediatric oncology, and specifically looking
5 at a population of patients with high risk
6 neuroblastoma, the most common extra cranial solid
7 tumor in pediatrics.

8 We looked among a cohort of children
9 who were enrolled in neurobiology study, which
10 captures most, we think, of the children in the United
11 States with neuroblastoma who goes on to enroll on a
12 frontline clinical trial.

13 And we looked by race and ethnicity --
14 of trial collected race and ethnicity, and then we
15 used a series of proxy socioeconomic status measures.

16 We looked at household poverty, which
17 we defined as public insurance only. We looked at
18 area poverty, which we defined as those living in ZIP
19 codes where greater than 20 percent of the population
20 lives below the federal poverty line. And we looked
21 at urban and rural again using ZIP code linked

1 measures.

2 And what we found in what you see here
3 on these graphs is that there was virtually no
4 significant difference in enrollment to frontline
5 therapeutic trials by race, ethnicity, or proxy to SES
6 and that somewhere between 35 to 40 percent of
7 children enroll on frontline therapeutic trials.

8 We then leveraged this data set to look
9 at who discontinues trial participation; getting at
10 this idea of is participation on clinical trials too
11 burdensome for particular populations?

12 And so we looked at specifically trial
13 withdrawal for reasons other than disease progression
14 and, again, looked by race, ethnicity, and our proxy
15 SES measures and found that while nearly 40 percent of
16 children discontinue participation on their frontline
17 clinical trial, that this did not significantly vary
18 by race, ethnicity, or our proxy to SES measures.

19 And as we've heard many times today,
20 you know, while this doesn't suggest that there are
21 significant disparities in who enrolls on clinical

1 trial or continues to participate on clinical trials,
2 this isn't the full story.

3 And so what I really wanted to do was
4 to understand the experiences of parents from those
5 communities who have been historically excluded or
6 marginalized in our academic communities.

7 And so I conducted a single center
8 mixed-method study in Boston at the Dana-Farber to
9 understand black and Hispanic parent perspectives
10 regarding clinical trial and research participation,
11 and specifically focusing on barriers and
12 facilitators.

13 We used some of the recruitment
14 strategies that you've heard already today, really
15 focused on trust, transparency, and minimizing burden
16 to enroll a cohort of 60 parents.

17 We had a 94-percent participation rate,
18 100 percent of parents completed participation, and we
19 had 98 percent complete data, and we enrolled this
20 cohort in 3 months.

21 And I just want to share a few of those

1 perspectives. So when we asked parents about their
2 perceptions of research and clinical trials, we heard
3 that research and clinical trials are experiments,
4 that research and clinical trials are a way to
5 advanced medicine. And for many of these parents,
6 they were both of these things at the same time.

7 And so this mother said to us, "For me,
8 clinical trial, I can't help but think of, like,
9 experiment for some reason, because, I mean, it's
10 something that's new and being done to learn about
11 something.

12 So for me, the word would be
13 experiment. That's what would automatically come to
14 mind, but not, like, in a bad way; in a good way to
15 learn and hopefully advance in the treatment of
16 whatever they're trying to learn about."

17 When we probed on motivations for
18 participating in research and clinical trials, we
19 heard that they were motivated to access novel or the
20 most advanced therapies to have an opportunity for
21 decreased toxicity to improve care for future patients

1 and families. And we've heard these themes over the
2 course of today.

3 But a unique theme that we heard was
4 really to represent the experiences of black and
5 Hispanic patients. And so this mother went on to say,
6 "The majority of research probably involves
7 Caucasians, but I want to provide people with, like,
8 an aspect from an African American family, because
9 it's not -- there aren't as many."

10 And when we probed on hesitations for
11 participating in research and clinical trials, we
12 heard again things that have been echoed today, fear
13 of the unknown, particularly efficacy and side
14 effects, a desire to protect their child from
15 unnecessary treatments and tests, and then we heard a
16 theme that has also come up today, the history of
17 maltreatment of black and Hispanic patients in
18 research.

19 And this father of a child with
20 leukemia said, "As a black culture, we were test
21 dummies. A lot of things were done to us in the

1 hospitals, just to get a better understanding of our
2 race and culture. Some we were aware of, and some
3 that was just -- it was forced upon us. For me, as a
4 black man, having those things done to my ancestors
5 over time, I think when I had first heard about
6 clinical trials, I'm like, no, thank you.

7 But I think with the understanding that
8 it was happening to my child and that we needed to
9 gather and get more information, I agreed more so to
10 advance her treatment and her care." And he went on
11 to enroll his child on our frontline trial for
12 pediatric leukemia.

13 As we were designing this study -- as
14 we were thinking about our a priori hypotheses about
15 barriers to participation, something that has come up
16 a lot today was distrust.

17 We measured this quantitatively and
18 qualitatively in our interviews, quantitatively using
19 the trust in the oncologist scale, a series of
20 questions with a Likert scale, where 1 is no trust and
21 5 is complete trust.

1 And our mean was 4.6 in this
2 population, indicating near complete trust. That's
3 not to say that there aren't real reasons for mistrust
4 and distrust, but I'll talk a little bit about some of
5 the things that engender trust in this population.

6 The second, which we've heard also
7 today, was that information sharing would be a
8 challenge.

9 And this father told us, "As the
10 parent, finding out that your kid has cancer, you're
11 asked to read, even with all of the threats that are
12 going on at that moment, you have basically a 24 hour
13 time limit to read all the paperwork, possibly do your
14 own research, in order to make a decision that affects
15 your child's life, and you've got an hour to do so."

16 And I think that speaks to a lot of the
17 limitations in pediatric oncology where we are sharing
18 with a family that their child has cancer and then
19 expecting them to make these decisions in this
20 pressured time.

21 And I think there have been a lot of

1 great ideas today about how we can improve this
2 informed consent process that we need to think about
3 in pediatric oncology.

4 And then our third hypothesis about
5 barriers was unmet social needs. And as you can see
6 here, 73 percent of this cohort reported an unmet
7 social need in transportation, utilities, housing, or
8 food -- about a quarter in transportation and
9 utilities; about half had housing insecurity, and 40
10 percent had food insecurity.

11 And this causes a lot of stress during
12 the experience of caring for a child with cancer.
13 This mom told us, "Or you can have a family like mine,
14 where it's a struggle for everything.

15 Extra visits for a clinical trial would
16 be a lot more added to my plate. But then at the same
17 time, if I'm thinking about my child, if this is
18 something that is going to help him, I'll find a way.
19 But will it cause more stress?"

20 And I think we've heard a lot today
21 about potentially innovative ways we can decrease the

1 burden of trial participation for our families.

2 And so I want to caveat some of this
3 data, because pediatric cancer is really rare. And I
4 think in the face of something that is life-
5 threatening, like pediatric cancer, families really
6 are willing to do anything and everything for their
7 child. So I'm not saying that all of this can be
8 extrapolated to other contexts.

9 And I think that in pediatric oncology,
10 we have the privilege of being able to build
11 longitudinal relationships with our families that are
12 quite intimate and allow us to engender trust in a way
13 that may not also be able to be extrapolated to other
14 settings.

15 But at the same time, I think that this
16 data suggests that relatively equitable trial
17 participation is achievable and that distress should
18 not be used as an excuse for underrepresentation.

19 I think that we've heard a lot of ideas
20 today about how we can engender trust and how we, as
21 academic institutions, can begin to be more

1 trustworthy so that families are wanting to engage and
2 participate in clinical trials.

3 And I think some of the data that I
4 shared from the parents in our study suggests that
5 parents really want to have these conversations with
6 us and that information sharing and unmet social needs
7 are real barriers that can impact enrollment and
8 retention.

9 So for the last portion of my
10 presentation, I really want to focus on this concept
11 of unmet social needs, which is where my research is.

12 We know that measuring social
13 determinants of health and social needs are feasible
14 across the cancer trajectory. We know that one in
15 three children with cancer at diagnosis has an unmet
16 social need.

17 I presented data that shows that three
18 of four black and Hispanic families have unmet social
19 needs during cancer care, where they have access to
20 resource specialists and social workers at our
21 tertiary care centers.

1 And I think this is, in part, related
2 to some of the structural racism and structural
3 disadvantage that Tamorah brought up, and that at the
4 time of advanced cancer relapse or progression, one in
5 two children with cancer has an unmet social need.
6 And I think this speaks to financial toxicity that
7 accumulates over the course of cancer and care.

8 In our group, we've demonstrated that
9 it's feasible to actually embed these types of
10 questionnaires in our clinical trials. And we've now
11 embedded these in multiple frontline national clinical
12 trials.

13 We've completed thousands of these
14 surveys with a greater than 85 percent consent rate, a
15 greater than 85 percent completion rate, and less than
16 2 percent missing data.

17 And I think when we think about data
18 equity, these data are more specific and potential
19 drivers of inequities in a way that proxy measures of
20 SES or race and ethnicity really are not.

21 And now, in our group, we're working on

1 targeting social determinants of health in the same
2 way that we target molecular operations in pediatric
3 cancer.

4 And so we have designed in work --
5 really primarily led by the woman at the top, Dr. Kira
6 Bona, one of my research mentors, and two of our
7 colleagues, Rahela Aziz-Bose and Colleen Kelly, we've
8 designed a series of interventions targeting unmet
9 social needs and social determinants of health.

10 So I'll just briefly speak to them,
11 just to provide insight into the types of things that
12 I think are feasible in this context.

13 So PD Care is an intervention that
14 centrally delivers groceries and transportations to
15 low-income families at the time of a new child cancer
16 diagnosis for six months.

17 And this is an intervention that has
18 undergone pilot testing, feasibility testing across
19 two centers, and now is embedded in a Phase 3 trial
20 for pediatric leukemia through the Dana-Farber
21 consortia across 8 sites.

1 Pediatric RISE is an unrestricted cash
2 transfer intervention, again, for low-income families
3 with either a new cancer diagnosis or a diagnosis of
4 advanced cancer.

5 This is a six-month intervention that's
6 undergone a single center pilot and is undergoing a
7 two-center randomized feasibility study.

8 CHEF is a intervention that provides
9 meal kits and assisted nutrition benefits enrollment.
10 This is for families with food insecurity in the first
11 year after cancer therapy. And this is something
12 that's undergone a pilot study.

13 And then as Assist is our newest
14 intervention. This is a means tested benefits
15 navigator intervention for low-income families at the
16 time of a cancer diagnosis. The idea is for it to
17 provide support for 12 months. And we are planning a
18 pilot study this fall.

19 At the same time, we heard that
20 information sharing was a challenge. And so I want to
21 amplify the work of Dr. Paula Aristizabal at UCSD, who

1 has designed a cultural and linguistic clinical trial
2 peer navigator to assist with the informed consent
3 process and has demonstrated improved comprehension of
4 trial components for families who are Hispanic or
5 speak a language other than English. And this is
6 undergoing a multicenter RCT across four centers in
7 the country.

8 And what I want to leave us with, I
9 think is the question that we've been wrestling with
10 all day today, which is what is good enough?

11 And in pediatric oncology -- this goes
12 back to our neuroblastoma data, on the left is a graph
13 showing survival curves, where the red is children who
14 don't have household poverty, and blue is children who
15 do have household poverty exposure, meaning that they
16 have public insurance. And you can see that survival
17 curve is not the same.

18 On the right is children with high-risk
19 neuroblastoma with data disaggregated by race and
20 ethnicity. The green line is children who are non-
21 Hispanic white; the red line is children who are

1 Hispanic. The blue line is children who are non-
2 Hispanic black. And you can see that those survival
3 curves are not the same either.

4 And so even when children have access
5 to clinical trials and are receiving the same
6 standardized therapies, our survival is not the same.

7 And so I would argue that we will be
8 good enough when those survival curves are all the
9 same, and we are not there yet.

10 And so, you know, I think equitable
11 trial participation is achievable, but this is just
12 the first step to ensuring equitable outcomes.

13 And I think that things like social
14 determinants of health measurement and interventions
15 targeting social determinants of health are both
16 feasible, may work on improving some of these outcome
17 inequities, and hopefully can be embedded alongside
18 our drug clinical trials.

19 MS. EPPS: Okay, you all. Hopefully
20 we're going to finish strong. If I can have the
21 panelists -- we've got our big panel.

1 At the beginning of our meeting Dr.
2 Fienkeng talked about it takes a village. So we're
3 bringing the whole village up for this last panel
4 discussion. So whoever is still with us and wants to
5 participate on the panel, come on up.

6 In the meantime, I wanted to say thank
7 you so much to Dr. Lewis, to Ms. Edwards and Dr.
8 Umaretiya. Really great presentations.

9 Just so it's not a commentary on our
10 company, but Dr. Kipp is going to have to leave early
11 for her travel. So she is going to participate in
12 part of the panel, but not the whole panel.

13 Do we need more chairs up here, or are
14 we okay?

15 UNIDENTIFIED SPEAKER 7: We're good.

16 MS. EPPS: Okay. So I'm going to let
17 Dr. Kipp lead us off on the questions.

18 MS. KIPP: Okay. So we want to thank
19 our esteemed panelists, which there are many today.

20 And so what we're wanting to discuss
21 is, as you know, best practices that how do we sustain

1 our children in clinical trials? And we've heard a
2 number of things. So this is kind of our "What have
3 you learned today from this"?

4 And so I'll start with the first
5 question. Is there something you've learned from
6 today's gathering that you'll bring back to your
7 family or community as a best practice?

8 And so I'll just -- whoever wants to
9 start, start. You're all very dignified.

10 MS. YAO: Actually, can we have --

11 MS. KIPP: Go ahead.

12 MS. YAO: There is one person I think
13 who hasn't presented or spoken.

14 MS. KIPP: Okay. Go ahead.

15 MS. YAO: So we'll start with it, which
16 is Dr. Melissa Penn, and then anybody else after that.

17 MS. KIPP: Okay. Thank you.

18 MS. PENN: Oh, the "on" button. And
19 now -- okay. Great. Well, thank you. Thank you so
20 much. It's been a really tremendous day. A lot of
21 learnings.

1 So my name is Melissa Penn. I work at
2 Bayer. My role is patient engagement R&D. So I get
3 the privilege of thinking about how do we get early,
4 meaningful, and continuous input from patients along
5 the entire research process. And I believe that
6 patient engagement is inextricable with diversity and
7 representation.

8 My background is as a lawyer and in
9 public health. And for the ten years before I got to
10 Bayer, I founded and ran a nonprofit in rare disease,
11 and I am a rare disease mom.

12 And through that and continuously
13 today, I look at this through the lens of nothing
14 about us without us, but in the takeaways -- so many
15 good takeaways, I love iCAN. I love what you said.

16 And I think about -- I thought it was
17 really interesting, actually, that adolescents were
18 saying that altruism was one important reason to
19 participate. And that was -- I mean, it makes sense,
20 but it was still eye-opening.

21 I loved the comment, "Hey, if you don't

1 think it's important, maybe it's not the right job for
2 you." And then I'm going to take away Bella, the
3 "Yes, and." I just want to work in that model.

4 MS. EPPS: Anyone else want to answer
5 that question? What will you take with you today as a
6 best practice?

7 MS. OGUNO: I can speak from an
8 industry perspective, is looking at the wider
9 opportunity, in terms of the data that we collect.

10 Do we need to collect ten blood samples
11 versus three; right? Do we need to collect all this
12 information? Not just because we can, but what is the
13 impact? What are we testing? What is the answer that
14 we're looking for?

15 And I think one of the patient
16 panelists brought a good point, how do we bring the
17 information back; right?

18 Because as an industry, we're thinking
19 from a competitive perspective. So we black a lot of
20 the things out. We don't want others to know. We
21 just want to have that information until it's ready to

1 be shared publicly.

2 But from a patient perspective, how do
3 we share that data back, so they can take that and
4 that continues to empower their journey as a patient
5 and have that information to take back with them to
6 make more empowered decisions?

7 So how do we bridge that gap, in terms
8 of the data being available?

9 MS. KIPP: Thank you. Please remember
10 to turn your microphone off at the end. Thank you.

11 Anyone else want to mention what
12 they're taking back from here today?

13 MS. WILLIAMS: Sure.

14 MS. KIPP: Thank you, LaToya.

15 So I think the biggest takeaway is that
16 boots on the ground must be a part of the clinical
17 trial process.

18 We need to look at our communities, not
19 as the problems that they have, but more so of the
20 assets and possibilities they can bring to this
21 process.

1 I loved what I witnessed in Christina's
2 presentation, that she's working with the faith-based
3 communities and pharmacists. And, you know, they have
4 communities that are far reaching that, you know, we
5 can't touch from a lab or from behind our desk.

6 So I would say when working with
7 communities, move at the speed of trust, anchor
8 ourselves in outcomes, and definitely remain boots on
9 the ground. That's one takeaway.

10 The other takeaway is around AI. We
11 need to find a way to build that, to make it
12 convenient, not just for researchers, but for
13 providers and community members as well.

14 When I think about providers, they too
15 need the education on how to make an effective
16 recommendation. Let's make it easier for them on how
17 to connect people to a trial that they're eligible
18 for.

19 So when I think of AI, I think of how
20 do we make it convenient? Amazon sells convenience.
21 Nike sells motivation. Disney sells dreams. So I

1 think we really need to look at AI and convenience in
2 that space.

3 MS. EPPS: Thank you. So -- thank you.
4 Please.

5 MS. YAO: Hi, Lynne Yao, FDA. So I
6 think the biggest overall takeaway for me today is,
7 like we've said at different times during our sort of,
8 you know, adventure in developing therapeutics for
9 children that, you know, we used to say, "Oh, just do
10 any research, and that's better than nothing."

11 And then we said, "Well, you know,
12 regulatory-grade research, you know, incorporating
13 standards, like clear endpoints, interpretable data,
14 like, that's all good research."

15 But I think what I'm taking away today
16 overall is that everything that's been discussed today
17 is not an afterthought, is not good to have; that if
18 we really want to do high-quality research, everything
19 that's been discussed today must be incorporated.

20 It's not a "like to" or "wish to." It
21 has to be a "need to." So that's the major thing I'm

1 taking away today.

2 MS. EPPS: Thank you. Thank you for
3 that. So on that -- thank you. Oh, go ahead, please.
4 Thank you. Thank you, Ms. Burgess.

5 MR. BURGESS: So I don't really have,
6 like, a big takeaway from today, but I do want to
7 highlight something about in clinical trials, that the
8 doctors should include the patients in the big
9 discussion about what's going on, and they should
10 include the patient's opinion no matter how they are,
11 because although the parents have a lot more wisdom
12 and they're a lot older, I feel like it's the
13 patient's life that's being affected mostly, so the
14 patient should be having a big say in it.

15 And yeah, that's it.

16 MS. BURGESS: Michael, you didn't have
17 to say, "A lot older," but that's okay.

18 MS. EPPS: Thank you, Michael. We
19 needed to hear that, specifically.

20 So anybody can answer this. How can
21 collaboration between community, industry, and

1 academia, and FDA regulatory agencies improve
2 inclusivity, including people in pediatric drug
3 trials? That's a lot. Sorry.

4 Please.

5 MS. WILLIAMS: I would say through an
6 integrated approach within underrepresented
7 communities, combining medical treatment with
8 comprehensive family and community support to create a
9 robust network that helps families navigate this
10 complex, fragmented system and the challenges.

11 I believe this approach ensures that
12 the emotional, social, and practical needs are met,
13 promoting resilience and better overall outcomes.

14 From a regulatory standpoint, it should
15 be strongly considered incorporating clinical trials
16 into the conversation as a standard with the mandated
17 checkbox that prompt providers during the history and
18 physical to have that conversation with families as
19 another option to care as part of the comprehensive
20 care plan.

21 MS. EPPS: Any academic partners want

1 to talk? Please, Ms. Burgess; go ahead.

2 MS. BURGESS: I think what we're doing
3 now and continuing what we're doing is the most
4 impactful. I think that word of mouth is more
5 powerful than we think.

6 You know, I have a few of you -- I got
7 your numbers; I got your information; I'll be
8 following up with you, but just that few can touch
9 more people, which can grow and expand.

10 This is a grassroot ground movement.
11 And if we all are all on board, once I get home, I'll
12 take it back to my tribe; right? And my tribe will
13 then discover, okay; maybe this isn't as scary.

14 It's really all about word of mouth and
15 being consistent and having all of the elements, the
16 FDA, the researchers; we have the sponsors; everyone
17 is coming together, creating a huge think tank.

18 But if we continue this platform, we
19 can see this groundswell go even further. So I think
20 it's just the consistency with this.

21 MS. EPPS: Thank you Ms. Burgess.

1 MS. LEWIS: Tamorah Lewis, a physician
2 scientist from Toronto. So the question about
3 collaboration is a really important one, and I've been
4 having conversations with the IRBs -- and in Canada,
5 we call them "REBs", about what role the ethics boards
6 can play in diversity and equity.

7 And I think that one very -- what feels
8 like low hanging fruit, is for patients and sponsors
9 and regulators to all get together and talk about, you
10 know, what would maybe a universal budget template
11 look like.

12 If we were to design a trial with the
13 most marginalized and the most disadvantaged families
14 in mind, what would be all the key budget items that a
15 sponsor or a site would need to consider in order to
16 allow for true unburdened participation?

17 Because right now, I feel like every
18 IRB is struggling with this and reinventing the wheel.
19 Each sponsor is kind of probably doing some version of
20 this, but it doesn't have to be that way.

21 We could collaborate together and come

1 up with some template that could be universally used,
2 and with the key input of the patients and parents,
3 not miss any of the important details that even we
4 probably don't understand

5 MS. EPPS: So universally used and user
6 friendly. Thank you. Thank you for that.

7 Anybody else want to tackle that
8 question? Thank you.

9 UNIDENTIFIED SPEAKER 8: Yeah, so one
10 more thought. So as we think about how to our
11 obligation to patients, we want to ensure that the
12 clinical trials that we enroll them to are high
13 quality and likely to generate impactful, meaningful
14 results.

15 And so along those lines, I'd like to
16 go back to some of the data that Pam presented this
17 morning around multiple trials enrolling for specific
18 conditions with small populations.

19 So it's interesting to think about is
20 there an opportunity for academic centers, along with
21 regulators and sponsors, to coordinate efforts around

1 diseases or specific drug types, such that we can
2 prioritize a limited number of high-quality trials
3 that are most likely to generate the results needed
4 for that population around a specific therapeutic, as
5 opposed to maybe the current model, where it largely
6 sponsors who are responding to requirements and are
7 sort of forced to conduct multiple trials in parallel
8 for a given condition, but they're drawing from such a
9 small population.

10 MS. EPPS: Thank you very much. Other
11 thoughts on collaboration? I'm going to put you
12 "youngins" on the spot, because, you know, Michael,
13 you said we are a lot older, and, yes, I am.

14 But what do you all have is wisdom?
15 And I really would like to hear from the patient
16 represents again about collaboration, any thoughts you
17 have.

18 MS. SARI: Sorry. We're sharing, yes.
19 So on collaboration between these institutions, I
20 think that it's really important that from, I guess, a
21 regulatory side that certain standards on diversity

1 are set up, but they're set up in such a way that,
2 because it was said before in a question from virtual
3 attendees -- they were wondering if these diversity
4 requirements might impede the process of a trial or
5 slow it down.

6 And I think that these groups need to
7 collaborate, and they need to find a way where they
8 can have effective and excellent clinical trials that
9 are also diverse.

10 And I think from a regulatory side and
11 from an academia side and from an industry side, that
12 level of collaboration really has to happen on that
13 specific issue.

14 MS. EPPS: Thank you. Let me ask a
15 slightly different angle of the same question on
16 follow-up -- what you said Nasrin about having
17 regulations. That's where people are being told they
18 must do these things, but there's another -- so that's
19 a mandate in regulations. There's also incentives in
20 regulations.

21 Are there areas of incentives that you

1 think that might make people, you know, want to be
2 involved in some of these activities?

3 And I'm not asking just you or that is
4 a question we answer right this second, but if someone
5 has some thoughts on that right now, that would be
6 interesting.

7 MS. SARI: Are you saying incentives
8 for patients or incentives for these organizations to
9 be more diverse?

10 MS. EPPS: For those who are involved
11 in these activities. So yes, definitely
12 organizations.

13 I can tell you right now, there are
14 incentives for, you know, sponsors who are doing drug
15 trials to do them. We have certain incentives. You
16 know, what they say or how they set up, you know,
17 those exist. If there was some idea of an incentive
18 of what you think might have people be more involved,
19 I was just curious.

20 MS. OGUNO: I can try to answer just
21 quickly. I'll be taking a step back to your previous

1 question in speaking about the collaboration between
2 patients, healthcare, academic and industry, and the
3 FDA.

4 I think listening to what really
5 matters; my experience in sickle cell and other
6 aspects is looking at the endpoints; right? One of
7 the critical aspects is that we're looking at, oh, for
8 example, pain.

9 This is what clinical endpoint is
10 that's critical here. This is what we're looking at;
11 this is what we're testing. Where the patients might
12 say, "I don't care about pain; it's the fatigue."

13 That's what we need to solve for. So
14 while everyone's focusing on one area, maybe listening
15 to the participants. So what really matters to them
16 helps us to develop better clinical trials, develop
17 better molecule that addresses that, and then work
18 with the FDA or other organizations to look at
19 endpoints that addresses what the patients are
20 actually looking for versus what historically we had
21 looked at as data, which might not even be meaningful

1 as we develop drugs.

2 So I think that's a way we can
3 triangulate, in terms of what really matters. We know
4 what's historical, but what's critical now, and how do
5 we as an industry, as caregivers, as the patients, and
6 as regulators develop what's critical in how we look
7 at this indication or this treatment or this disease,
8 and move forward.

9 MS. BURGESS: And to add to that, I
10 feel, speaking as a parent and a mom, as an advocate,
11 I'm a professional advocate for a living for my nine
12 to five.

13 I think it's really important to
14 advocate for lifting the barrier, the weight of
15 clinical trials from the families, the financial
16 weight; having an incentive for even something as
17 simple as gas -- you know, just travel; having an
18 incentive, you know, something as simple as a grocery
19 store gift card.

20 And I say that with the fullest of
21 transparency, because having a child with a chronic

1 illness myself, I jokingly call it "hospital living,"
2 where we're, like, living in the hospital sometimes
3 weeks at a time.

4 And then to participate in a clinical
5 trial on top of just getting out of the hospital,
6 sometimes finances -- you are drained. So having an
7 incentive -- I heard someone say, "Lifting that
8 barrier, that" -- excuse me, "that burden from the
9 families would be so helpful from a family/patient
10 perspective."

11 MS. SIMPKINS: Yeah. You know, Tamorah
12 brought this up, about the bioethics and thinking
13 about this from the IRB perspective too.

14 When I think about this from the topic
15 of collaboration, the reasonable reimbursement for
16 time, burden, and effort is something that there seems
17 to be some confusion, even though I don't think there
18 really is that much confusion; right?

19 And maybe some IRBs look at this
20 differently, although there have been a number of
21 webinars saying, "Hey, Industry, you kind of have

1 gotten this wrong; the IRBs are allowing this."

2 I think the bigger conversation and
3 when we talk about this space of collaboration, this
4 is something that should be very clear so that
5 everybody going into it actually knows it's a matter
6 of equity and that they're not doing the wrong thing;
7 they're doing the right thing.

8 And I do believe that message through
9 the collaboration that you were talking about can get
10 out there much more quickly so that -- it's not
11 ambiguous; it's not, but for some reason there's still
12 the perception that it is,

13 MS. EPPS: Let me ask you all a related
14 question along collaboration and lack of ambiguity and
15 so forth, and it's the issue that's been talked about
16 several times, which is transparency.

17 So what do we do in a sort of
18 collaborative space to improve transparency, so we
19 really can assist families in making decisions about
20 being part of this process? What are your all's
21 thoughts on that?

1 Dr. Yao is busting at the seam over
2 here.

3 Please, go ahead.

4 MS. YAO: I don't know if this is too
5 controversial for -- what, 4:15 in the afternoon, but,
6 you know, I've been thinking a lot about this, and one
7 of the things that -- I guess Tamorah sort of brought
8 it up on this panel, but, you know, we don't know how
9 much things cost.

10 And one thing that it would be helpful
11 to know about and be more transparent about is how
12 much does it cost to do this? Because I think it
13 would be really helpful in understanding where that
14 money ought to go if we know where the money is
15 currently going.

16 And that's one place that -- and I'm
17 not sure that it would be appropriate for FDA to be
18 involved in that conversation, but I think it needs to
19 be a part of the conversation, because it all comes
20 down to -- everything I've heard about all comes down
21 to, well, you know, this is going to cost some money.

1 And so how do we create the
2 efficiencies? How do we create the right place for
3 the money to go, you know, for getting these trials to
4 incorporate all the things we've talked about today?

5 How do we know how to do that if we
6 don't know how much things cost? So I'm just going to
7 throw that out there.

8 MS. OGUNO: I think there's also the
9 opportunity, when you're having a discussion with your
10 participants, to understand what are the challenges
11 and take that back to the sponsor.

12 So being me, on the sponsor side, I'm
13 knee deep with my team in developing the ICF,
14 developing the budget for the sites, and I am emphatic
15 about whatever the sites need -- transportation,
16 reimbursement, let's make sure we have it in the
17 budget, and they know that, so they can also pass that
18 on to the participants.

19 So I would, on the other side, raise
20 your hand and say, "Hey, can you approach the sponsor
21 to reimburse for A, B, C?" Because, to your point,

1 sometimes we don't know what we don't know. We don't
2 know what the patient experience really is from one
3 that's in California to one that's in New York -- one
4 that's at Texas. It's very different.

5 So I would encourage you to take that
6 back to the coordinator, to the PI, and say, "Is there
7 an opportunity to have this reimbursed, because this
8 is a burden for us."

9 And maybe you didn't think about that
10 when the study was being designed or the ICF was being
11 developed, but it is, and I -- at least for me, but
12 I'm sure with my colleagues as well, they will
13 absolutely take that back.

14 And whatever is to make it right, we
15 will do; we just need to know about it.

16 MS. RANDELL: When I think about
17 transparency, my mind goes to having really vulnerable
18 conversations with families during clinical trial
19 discussion and recruitment.

20 So, you know, I think helping local
21 research teams get really comfortable feeling

1 uncomfortable and being willing to open space to
2 discuss hard things will allow racialized and
3 marginalized communities to engage with research in a
4 way that they haven't been able to before.

5 So, you know, being able to ask about,
6 "What's your family's experience with your child's
7 medical care, and do you have any concerns that there
8 might be different experiences based on your family's
9 identity?"

10 You know, "Do you have any fears or
11 concerns about participating in research, based on
12 your culture or based on your family's, you know,
13 cultural history?"

14 You know, those are very simple, basic
15 questions that we don't ask that could create a safe
16 space for families to discuss things that could help
17 them overcome their mistrust or, you know, their
18 fears. But we don't create space for families to
19 discuss those things when we talk about clinical
20 trials. And that's not transparent.

21 Like the way that we do it right now,

1 it centers our own comfort. And so, you know, I think
2 that there's so much space for creating curriculum
3 around this, creating education around this so that
4 research teams can become more comfortable having
5 those conversations.

6 MS. EPPS: I'm going to bring up
7 another thing that maybe at 4:15, 4:20 we shouldn't
8 talk about, but money makes people uncomfortable. But
9 it goes along the lines of what you're talking about,
10 difficult conversations.

11 And they certainly run all across
12 healthcare. Like, people -- you know, I have elderly
13 parents talk about things, like advanced directives.
14 Nobody wants to talk about that with, you know,
15 somebody who is 90 something years old, and yet they
16 should.

17 But to get to my point is -- let me
18 first just ask, have any of you all had a bad
19 experience within a healthcare system? So not
20 necessarily a provider, but another part where someone
21 didn't treat you right? I know I have.

1 And for me, it's the accountability
2 when people are -- you know, do you feel comfortable,
3 you know, telling somebody, "Those folks over there
4 just didn't treat me right, and this is why I think
5 so; this is what they did, and this is why think so."
6 And, you know, having systems for accountability for
7 that, because it exists. I know in my experience.

8 I don't know if you all wanted to speak
9 to that -- any of you all.

10 MS. WILLIAMS: I can speak to that.

11 MS. BURGESS: Yes, I --

12 MS. WILLIAMS: Okay. I can speak to
13 that. I get doctors, nurses, they're overworked.
14 They have far too many patients. And there was a time
15 where I was mistreated, and I learned the power of the
16 Department of Patient Relations, and I expressed my
17 grievance to that, and it was addressed quickly. But,
18 you know, just having empathy for the doctors and the
19 nurses is important.

20 But I just wanted to go back to the
21 previous question about transparency. I feel -- I

1 don't know what the right answer is, but I feel like
2 there needs to be some sort of quality improvement
3 built into this in the sense of capacity-building
4 projects.

5 How are these dollars being spent by
6 these systems? Because from what I observed in my
7 previous work, working with federally qualified health
8 centers, I was trained as a quality improvement coach
9 to go in there and find out what their gaps are.

10 And we did things, like process mapping
11 and PDSAs. And a lot of it, when you get to the money
12 part, they were not allocating those resources
13 properly.

14 So when we went through the process and
15 we redesigned their workflow, you know, we were
16 starting to see an improvement with their patient
17 screening rates and vaccination rates with youth.

18 So I don't know if that's the same
19 concept that can be used in a clinical trial process,
20 but maybe it should be considered we, because systems
21 are not going to be forthcoming and say, "Hey, I don't

1 know how to do this."

2 But if we have a team to work with them
3 to improve their process, perhaps that could be how
4 resources and sponsors can spend their money with the
5 capacity building project.

6 MS. BURGESS: Thank you for that
7 comment.

8 As a parent, I have experienced great
9 discomfort on numerous occasions on how I was treated
10 in the ER once I brought Michael to the hospital when
11 the pain crisis had escalated to the point nothing
12 would work at home.

13 So the validity of suffering was
14 something that, unfortunately, was not validated, even
15 by the healthcare professionals. And I remember
16 specifically a nurse letting Michael sit for hours
17 screaming and crying and suffering.

18 And so with that being said, you know,
19 going back to what we originally were talking about, I
20 just think that using the voice is powerful.

21 I spoke to patient relations right

1 away. I let them know what was going on with my son,
2 and it escalated all the way to the top at the
3 hospital. And that nurse actually has never worked
4 with Michael again, and he was 13 at the time.

5 So I think using the voice is powerful,
6 but when it comes to clinical trials and doctors
7 becoming very comfortable in the uncomfortable and
8 engaging and clinicians engaging with families about
9 uncomfortable conversations, you know, families, like
10 myself, we will open up, and we will talk, but we have
11 to feel like the playing ground is level.

12 So patients will open up. We'll say
13 what we need. We'll make sure that the voice is
14 heard, but if -- I think the comment was made earlier,
15 "But if we feel talked at, instead of talked to, then
16 we'll hide."

17 And that's when you won't have the
18 participation. That's when families will, you know,
19 pull back, instead of families being retained to go
20 the long haul in a clinical trial.

21 So, you know, it's all about patient

1 voice. It's all about collaboration. It's all about
2 feeling like we're heard and we're seen and just
3 keeping that accountability going between the
4 relationship, because we're all at the table at this
5 point.

6 MS. EPPS: Thank you very much. Let me
7 ask you then a question. There's a question from
8 online, and it ties somewhat into what we've been
9 talking about, about collaboration and who you trust.

10 And it starts as a comment, that "There
11 seems to be an evolving trend in the pharmaceutical
12 industry to move away from pediatric centers of
13 excellence or pediatric groups within the companies.

14 What actions can be taken to ensure
15 pediatric needs, with kids who are an underserved
16 group, receive appropriate attention and priority
17 within pharmaceutical companies?"

18 So I guess my question is a little bit
19 broader than that, which is just sort of the idea of
20 especially if we're trying to get out into
21 communities, there are not Pediatric Centers of

1 Excellence all over the country; right?

2 So what do we do to get the level of
3 excellence we want, given that may or may not be
4 attached to a so-called "Center of Excellence" in the
5 pediatric are?

6 Or should we just make sure there's
7 some sort of connection at all times that way? Is
8 that feasible?

9 See, I made the harder questions for
10 the end of the day; right?

11 Or let me rephrase this. Have people
12 received care within primarily pediatric-focused
13 centers are your experiences, or do you have
14 experiences where the care is largely outside of a
15 pediatric center?

16 MS. SARI: I mean, in what I've
17 experienced, it's been within pediatric spaces. And,
18 I mean, I can't speak to what other people are
19 experiencing, and I don't know if that is a trend that
20 person was commenting on, but I haven't personally
21 experienced that.

1 MS. EPPS: Anyone else? Okay. thank
2 you. Yeah, I mean, I wish Dr. Kipp were still here,
3 because I know --

4 UNIDENTIFIED SPEAKER 9: Yeah.
5 Maybe -- yeah, I can --

6 MS. EPPS: -- that she works with the
7 communities that don't have large centers of anything
8 near where they live. So she may have had somewhere
9 to say that yes, please,

10 MS. HILDEBRAND: Yeah. Heidrun
11 Hildebrand from Bayer. If I understood that question
12 correctly, I think it was looking more inside of
13 companies.

14 And I think what may confuse patients,
15 clinical site, academic centers at large is that we in
16 industry are used that we somehow get reorganized
17 every month -- no, but every two years at least, and
18 with that reorganization, names of department and
19 groups are changes.

20 So there might be that the word
21 "pediatric" get lost in the new name, but that doesn't

1 mean that the expertise, which is available in the
2 company, has vanished.

3 It may be grouped differently also.
4 And I can very much understand that for people from
5 the outside or for patients and also for sites who
6 used to work with the person with a certain name tag,
7 and now the name tag changed, they think maybe the
8 focus has changed.

9 But I would think that is really due to
10 the mania in industry to reorganize every time and
11 ongoingly.

12 Thank you.

13 MS. EPPS: Thank you so much.

14 You know, we've been talking also about
15 sort of things to do to build that take investments,
16 whether, you know, it's finding funds or finding --
17 putting groups together.

18 Let me ask you something sort of to
19 maybe there's some low-hanging fruit that people could
20 focus on now.

21 So let me just ask you, are there

1 specific activities or features of a clinical trial
2 program that would make you feel the trial is
3 inclusive, that are things that maybe, you know, could
4 happen sooner and later, such as transportation
5 services or offering the materials that are in large
6 print or in a certain language?

7 So is there any specific activities you
8 say, "Well, look, that should be achievable -- doable,
9 you know, sooner, rather than later," that again makes
10 people feel included -- makes them feel inclusive?

11 Go ahead.

12 MS. YAO: I'm not going to speak for
13 the people who are on the front lines designing the
14 trials and the patients who, you know, obviously want
15 to provide.

16 It's critical -- we've already heard,
17 that we get patients to provide their input from the
18 beginning to hear what those barriers are, what the
19 burdens are.

20 But as I'm thinking about it -- and I
21 think Martha Donoghue was asked kind of the question

1 about, you know, is ADEPT going to be required in a
2 pediatric -- you know, a PIP or a PSP? How is ADEPT
3 going to be implemented by regulators?

4 And regardless of the process we do or
5 we use to incorporate the things that we've heard
6 today, whether it's a DAP or in the PSP or in the
7 PIP -- I think what I've heard today and when I think
8 low-hanging fruit, from my perspective at FDA, is when
9 we send comments back to a sponsor about, you know,
10 "How have you considered increasing the diversity of
11 your clinical trial in children," we can give them
12 concrete questions that we can ask.

13 "How are you decreasing burden? How
14 are you allowing for patients to -- how have you
15 incorporated the patient's voice in the design of this
16 trial?" I mean, we can ask those questions directly
17 as we work with companies to help incorporate some of
18 the suggestions we've heard today.

19 So I think that's one way that we can
20 easily -- FDA -- I say, "easily" -- nothing is ever
21 easy at FDA, but easily, I think we could begin to

1 implement even just asking those questions as part of
2 pediatric development plans.

3 MS. EPPS: So I'm just going to quickly
4 say I speak FDAE. So I'm just going to translate a
5 couple of things. We love acronyms. DAP, Diversity
6 Action Plan, it took me a minute to remember that.
7 And PIP is a Paediatric Investigation Plan.

8 So these are things that they're
9 related, but just so people are tracking. So yes,
10 thank you.

11 MS. SIMPKINS: So from the industry
12 perspective, and it builds on what you're saying, it's
13 actually -- it's circular; right? How do we do it?
14 And then you also make sure that we're accountable for
15 it, because if we're not doing it, you're going to ask
16 about it.

17 But some particular sort of low-hanging
18 fruit that I can think of in this space are both about
19 the process and then a couple of examples about
20 specific activities.

21 So obviously everybody talks about

1 trust. You need to have the trust in place, but the
2 co-creation from the beginning, you can co-create an
3 inclusive trial, and who are you bringing in to have
4 these discussions, and how do you have that continual
5 discussion.

6 So we've done this in the adult space
7 in kidney, and having a standing counsel that is
8 actually looking at diversity in a particular trial.

9 And so there's another topic of we can
10 have that council in place to have the trial, like, as
11 early on -- you know, all the aspect of study design
12 and study conduct, informed consent, all of that.

13 But then when you have this group in
14 place, you can go back to them with transparent
15 information and say, "Okay. This is where we're at
16 with recruitment and retention." And actually say,
17 "All right. Percentages here are this."

18 And that's been incredibly useful, and
19 it really builds trust, where you're just very open
20 and saying, "I don't understand," or, "This is what's
21 happening," and, "This site is not really recruiting."

1 So having that ongoing conversation.

2 And then within that group,
3 potentially, we've had a really good experience
4 bringing patients to PI meetings and talking about the
5 topic of diversity.

6 And so we've done it sort of at all
7 stages, and now, one new trial, we're going to do it
8 at the very first meeting.

9 And I think that hearing it from the
10 patient and patient community and from a sponsor
11 bringing that, I just think it sort of helps that
12 whole credibility and transparency.

13 Another step there that has been really
14 useful I think is -- and people have talked about
15 this, who are the credible messengers, and how do you
16 get the information out?

17 So when you're thinking about an
18 inclusive trial and you have co-created materials,
19 well, there are a number of patient groups that have
20 ambassadors that can provide that peer education, and
21 that sort of immediately brings the credible

1 messengers there and raises awareness about the trial,
2 so it's the dissemination piece as well.

3 But then in specific activities and, I
4 would say, low-hanging fruit, it is really important
5 though. So maybe it's not as low-hanging, because we
6 don't always think about this.

7 But specific activities that are
8 related to disability can very quickly help with
9 inclusion. And I feel like this is not something that
10 we call out a lot.

11 And the disability could be specific to
12 the condition, or it just could be because people have
13 disabilities, and how are we making our trials
14 inclusive?

15 And I think that if we think about
16 this, it's going to be -- there's always a tagline in
17 this space, essential for some, helpful for all.

18 When we think about the sites that
19 we're selecting, I think physical accessibility is
20 something that we need to be thinking about.

21 But when we're thinking about the

1 creation of materials, there's very low-hanging fruit
2 that can be done to make materials accessible; right?
3 Do 16-point font. Don't do lower than 16-point font.
4 Have everything closed-captioned and a number of other
5 very tangible examples in this space.

6 And then even when I think about DCT,
7 which could make a huge difference for people with
8 disabilities, if you're not intentional from the
9 beginning and creating your digital accessibility,
10 then you're actually still going to be excluding a
11 large group that doesn't need to be excluded.

12 And so I think it's low-hanging fruit,
13 but I just don't think we talk about it enough.

14 MS. EPPS: Thank you. I have a follow-
15 on question about that -- follow-on, sort of segue
16 question.

17 And if I may, Michael, I wanted to
18 start with you. If I recall, you're on an advisory
19 board; is that correct?

20 So I mean, where are you involved in
21 activities? You know, are they asking about stuff,

1 saying, "Hey, we're planning to do something, like,
2 next year," this and that? Do they ask you thoughts
3 there, or what sort of ways are they asking you to
4 help out?

5 MR. BURGESS: So one way that -- an
6 activity that I have helped with planning is a prom
7 that they have every year for the hospital patients.
8 I think it can be any teenagers.

9 But yeah, I help. Me and the other
10 kids help plan the prom and, like, what floor it's
11 going to be on and what's going to be there, what type
12 of music, and how long it's going to be, stuff like
13 that.

14 MS. EPPS: That's great. And so the
15 prom, was it -- who had the idea of the prom? Why did
16 they want to do it? Did they have kids feel like the
17 hospital was someplace that wasn't just a place where
18 you got stuff done to you; you could also have fun, or
19 what was the theme to do prom?

20 MR. BURGESS: So I don't know who first
21 came up with it, because it's been out for a while.

1 But yeah, the main idea was just to have the kids have
2 fun, even though they're in a hospital; they're
3 missing their own real dances at the school.

4 MS. EPPS: Got you.

5 MR. BURGESS: They can still feel like
6 they're included and still feel like they don't miss
7 out on these important events in their life

8 MS. EPPS: So they can have a little
9 bit of normal life even when they're not in their
10 normal life space, like home?

11 MR. BURGESS: Mm-hmm.

12 MS. EPPS: Yeah, that's really
13 interesting. Thank you.

14 Well, that sounds like important low-
15 hanging fruit. No. I mean, kids want to feel like
16 life is normal -- right, whether they're in a trial or
17 not. And so if you can do activities like that to
18 help a kid, that sounds a worthy to me.

19 So let me ask then, how do we create --
20 again, this is my not elegantly worded, how do we
21 create space for you all, Michael, Nasrin, Anvita, and

1 kids and their families to take an active role in
2 designing and being involved in how these trials are
3 designed and conducted? What are things that you all
4 think needs to happen from anyone?

5 MS. SARI: In terms of creating space,
6 I think it's really important to create channels of
7 communication. I think sort of it's been touched on,
8 the way that we disseminate information to
9 communities, but then also the way that communities
10 can express their needs, and not just communities, but
11 also individuals, can express their needs as patients
12 or as parents, because in the pediatric space, family
13 is also really vital.

14 And so I think just in terms of
15 creating space, you have to start with communication.
16 You have to start with creating channels for
17 communication between, you know, research
18 institutions, between primary care physicians, between
19 patients and their families, and, you know, not just
20 one line of communication, but several -- interlinking
21 these groups to build the most effective solutions to

1 issues presented by patients and their families or to
2 needs or constraints from researchers or
3 organizations.

4 MS. OGUNO: One thing that I can add
5 that I think has been really helpful for us at GBT
6 and, you know, afterwards is implementing patient
7 advisory boards to review your protocol, not after
8 implementation and it's not recruiting, but a year
9 before.

10 We have an idea of when the protocol is
11 being developed -- submitted to the FDA. Bring a
12 patient advisory board together. You don't have to
13 have the full protocol developed. Schedule of
14 assessment, inclusion, exclusion, how does this impact
15 you? Would you enroll in this clinical study?

16 And we also have the opportunity to
17 select where the advisory board is -- where they're
18 coming from, so making sure that it's geographically
19 diverse, racially diverse, all the different diverse
20 aspects that we want to make sure we get feedback on.

21 So I think this is a call to the

1 industry to involve patients in the very beginning,
2 not when things start going south, because we're not
3 recruiting.

4 And it does provide benefit. There's
5 such insight that you're able to glean and take the
6 data back -- right, to say, "Hey, CEO, I know you're
7 not going to like this, but we need to include A, B, C
8 in the protocol, because the response is this is not
9 going to recruit. We need to include A, B, C site or
10 A, B, C country to make sure that it's diverse
11 enough."

12 So it's an opportunity that we can take
13 back as well to get the feedback ahead of time, not
14 just as a reaction.

15 MS. EPPS: So let me throw in real
16 quick a little add on to the same question that's
17 coming from online, because they're saying when you
18 all are doing that, should the focus be on social
19 determinants of health or racial and ethnic diversity?

20 And is it an "either/or" or --

21 MS. SARI: I don't think it is an

1 "either/or."

2 MS. EPPS: Yeah.

3 MS. SARI: I think that racial and
4 ethnic diversity goes right hand in hand with social
5 determinants of health. It's easily observable to see
6 that they interact with one another and affect one
7 another.

8 And so I think what you'll see is if
9 racial and ethnic diversity is considered in the
10 design of a pediatric clinical trial and that space is
11 created, whether it be through, you know, cultural
12 competency or anything like that, then you'll also
13 start to see that correlates with impacts on social
14 determinants of health. So yeah.

15 MS. EPPS: I kind of agree. No. So
16 I'm hearing -- so you're saying get on it early --
17 right, when people get on it early, as far as hearing
18 what the members of the community and families are
19 saying about what the proposal is.

20 And great. Other things to do along
21 that line?

1 MS. WILLIAMS: If I heard this
2 correctly earlier that most trials are not looking at
3 the diversity until the pivotal moment. And if that
4 is the case, then we have a bloated pipeline.

5 So I agree with my fellow panelists
6 that we must involve our community leaders, the
7 stakeholders; they are the gatekeepers. And what I
8 mean by "involving" them is to let them be a part of
9 the design of a clinical trial for adults and
10 pediatric patients, because they have the ability to
11 raise awareness in their communities and mobilize
12 their communities so that way you're kind of tilling
13 the soil.

14 When researchers come in and they need
15 to do this recruitment, you can go to your churches,
16 your community-based organizations and recruit from
17 within these stakeholder networks.

18 So I think it's important to look at it
19 way before you get to that pivotal moment.

20 MS. EPPS: So let me ask you a really
21 loaded question then. It's like in the U.N. where

1 they had the voting members and non-voting members.

2 When we're talking about who's helping
3 to -- I'm going to blow this way up; right? No. But
4 seriously, maybe not a 3-year-old; right? But how
5 much of a boat do kids and/or their families, versus
6 other people putting protocols together, have in
7 what's thumbs up and what's thumbs down?

8 And I don't know it's a one size fits
9 all, but is there a space? Is there a spectrum
10 across, which there may be, in certain cases, a lot a
11 weight given to the non-research part of it --
12 community/family part, on making some decisions versus
13 others.

14 So I just wanted to hear people's
15 thoughts on that.

16 MS. WILLIAMS: We need to continue to
17 keep amplifying these young voices. You hear these
18 young people today.

19 MS. EPPS: I heard them.

20 MS. WILLIAMS: It sounds like they've
21 already got their medical degree. So amplifying their

1 voices to evoke that emotion is so important and
2 critical, and they too can be gatekeepers to the
3 community. They have formed their own groups.

4 So I think they should very well be a
5 part of the conversation when decisions are being made
6 about their care.

7 MS. SIMPKINS: So I actually think they
8 have a tremendous vote. It is almost impossible not
9 to consider when you hear it. So what I found really
10 helpful is, from the industry perspective, to invite
11 the budget holders, the decision makers in on these
12 conversations.

13 And then, like, when I have -- I have
14 several different standing patient councils, and I
15 love to invite our clinical development team, because
16 they're also going to be the ones interacting with the
17 sites.

18 But I think it is -- how much of a
19 vote? I think it's tremendously impactful, should
20 only continue to be impactful. I actually appreciate
21 the FDA guidance calling out sustained community

1 engagement. I think it is -- my perspective is it's a
2 big vote.

3 It's hard to ignore. It doesn't mean
4 that everything gets accepted and it may mean that
5 that's where the transparency comes in of, "Hey, this
6 is why we do it like this."

7 And it's the feedback mechanism of when
8 a group makes a suggestion, and if it's a suggestion
9 that you bring back and it's not taken, why it's not,
10 because I think that builds trust too; right?

11 Just to understand the research process
12 more. But I think it is, I think it's a big vote.

13 MS. YAO: As you were speaking, it made
14 me think of the comment that Dr. Kipp made in an
15 earlier session, that if you are coming in and
16 deciding to agree to enroll in a clinical trial, this
17 is very late; right?

18 And that there may be even members of
19 your own community who question why you're doing it
20 and that may even isolate you from the community,
21 because you decided you wanted to enroll that trial.

1 But it seems to me if you turn it on
2 its head and that you have those patients -- those
3 trusted emissaries that sit at the table as a patient
4 advocacy group at the inception of the development of
5 that trial, that when the trial then -- it's time to
6 enroll, that the person who was sitting at the table
7 can say, "This was something we, our community, had a
8 voice in, and I am there to prove it."

9 So it seems like that could kind of
10 turn it on its head.

11 MS. EPPS: You know, we're coming near
12 the end the time, and so what I'd like to do in
13 closing this session out is to ask each one of you all
14 to share, if you will, what your call to action would
15 be coming out of this meeting. I'll start with my
16 own. Just, like, kids and families speak up.

17 Anybody else who wants to share?

18 UNIDENTIFIED SPEAKER 10: I thought it
19 was really interesting to see data around the
20 willingness to participate. I think that an ongoing
21 sort of misperception is that families from different

1 race ethnicities a less willing to participate.

2 It doesn't look like that bears out.

3 And so really there needs to be more effort around how
4 do we reach all these families. And so that's
5 something that I'd like to think about.

6 MS. EPPS: Mine is on. You can walk up
7 to whoever has got an open mic. That's strange.

8 MS. SARI: I guess the call to action,
9 I would say that -- mentioned earlier about that gap
10 between -- pediatric -- inclusive and diverse and how
11 much wider is that gap for -- sorry, for people with
12 diverse perspectives.

13 And I think looking into that and
14 understanding that whether you are a patient or a
15 community member or love someone who has a chronic
16 illness or, you know, are working in the field, that
17 understanding just how wide that gap is, is really
18 vital in taking the first steps in moving forward to
19 close it. So --

20 MS. EDWARDS: I think my call to action
21 is that I see the onus on the industry and on policy.

1 You know, if it's not mandated, if it's not a
2 requirement, if, you know, it's left up to our own
3 intrinsic motivations, it's not going to happen.

4 So I think there needs to be some
5 order. There needs to meet some requirements put in
6 place, and then move from there. And I think that
7 will have a trickle-down effect, because there is only
8 one; they have no choice.

9 So I think some people are going to
10 have to get in line to make things happen.

11 MS. UMARETIYA: I think for me, what
12 Sue said earlier about thinking about the ratio of
13 burden to benefit, rather than just risk and benefit,
14 is something that I'll take away as a pediatric
15 oncologist and someone that thinks about oncology
16 clinical trials, because I think that there are a lot
17 of things that were shared today that we could likely
18 incorporate in our trial design to decrease the burden
19 of participation.

20 MS. BURGESS: My personal call to
21 action is -- I am on the iCAN volunteer board, as I do

1 the community engagement work of iCAN.

2 So my call to action is to create a
3 community within the community that can really get
4 around and embrace, not only, you know, getting
5 clinical trials disseminated properly, but also coming
6 together to feel that this community feels seen and
7 heard, validated, and supported; that the community
8 within the community feels, like, there's a
9 cohesiveness there.

10 So if it starts there, then we can work
11 our way out. So my call to action is to create this
12 space within iCAN coming up in the '24, '25 year.

13 MS. SIMPKINS: So my call to action is,
14 is at this table. I think involving adolescents and
15 young adults is so essential, but also the
16 innovation -- the different way of looking at it and
17 the passion that you bring, so it's tremendous.

18 So I feel very privileged to have heard
19 this, and this is my call to action, to continue to,
20 and more strongly, involve adolescents and young
21 adults in the co-creation process.

1 MS. OGUNO: Thanks. My call to action
2 are, I think, two things, continue to listen early and
3 listen often and getting feedback where needed and as
4 appropriate with the indication that we're working in
5 and then not being afraid to lean in into those
6 difficult discussions, specifically with our sites and
7 with our partners, in terms of how do you plan to
8 recruit appropriately.

9 It's not something you want to lead it,
10 but it's important now. So I think have some energy
11 around that, and it needs to happen. It's not
12 "should," "could," "would"; it must.

13 So having that intention to have those
14 discussions early with our partners to ensure that
15 when we're thinking, we're thinking with the end in
16 mind, and it's not just, again, a response, but it's
17 really what we intentionally developed.

18 MS. WILLIAMS: My call to action is to
19 continue doing exactly what I'm doing and that's
20 forging these deep human connections between
21 underserved communities and medical innovators and

1 expanding my clinical trial program across the
2 country, building up the stakeholders network so we
3 can reach more people.

4 MS. LEWIS: My call to action is
5 actually directed at the FDA. So I learned such
6 inspiring things today about -- I think it's OMHHE,
7 and this office and all the pilot projects that
8 they're doing and all the things that they're
9 investing in and all the things that they're learning.

10 But I didn't know a lot about that,
11 even though I'm in this space. And so my call to
12 action is for the FDA to really think creatively about
13 how to share all these learnings across all these
14 stakeholder groups so that we can all benefit from the
15 amazing work that's being done in that office.

16 UNIDENTIFIED SPEAKER 11: Yeah, I
17 couldn't agree with you more, Tamorah. I think that
18 my call to action is, number one, to disseminate this
19 information across FDA and to help to disseminate it
20 across industry when we can.

21 I think the other call to action for me

1 is to co-opt Bella's phrase. And so in your sponsors
2 now, when you go back and you see comments on your
3 documents that when you've, you know, provided a
4 rationale for why you can or can't do this, I'm going
5 to start saying, "Yes, and."

6 So if you see that on an FDA response,
7 you know where that came from. That came from this
8 meeting right here.

9 No, seriously, I think that what I have
10 learned today, I am still processing, but I think what
11 we can do at FDA immediately is to put this
12 information together, get it out in the public, and
13 promote some of the programs that we already have at
14 FDA to further the causes here today.

15 MS. EPPS: Thank you so much, you all.
16 So if I heard it right, to sum up, you know, just what
17 we already knew as kids -- what we learn in
18 kindergarten, sharing. So if we share everything, we
19 can really go further.

20 On that note, it's been my pleasure and
21 honor to be moderator and to hear all you all,

1 especially you all young people who just amaze me.

2 And so thank you so much. And on that note, I'll turn
3 it over to Dr. Yao.

4 MS. YAO: So Michael and Nasrin and
5 Anvita don't go too far.

6 Okay. So I have the enviable position
7 of providing some closing remarks.

8 And, you know, one of the things I will
9 say before I give you my key takeaways is that a lot
10 of times at five o'clock, I'm like, "Can we just be
11 over already?" But I have to say that the sessions
12 today and the people that have been involved,
13 particularly the young people, have given me kind of
14 some energy.

15 So I'm kind of disappointed that we
16 have to end now. But we do have to end now. So I'm
17 going to give you just a couple of reflections on what
18 my takeaways are.

19 And please, don't view this as the
20 official FDA takeaways. These are just my takeaways.
21 Some thoughts that I think were triggered in the

1 discussions today.

2 In Session 1, you know, what I heard
3 was that FDA is doing some things, and we've done
4 some -- we had that big meeting for adults.

5 Many of the themes, the challenges, the
6 solutions, they're not that different in terms of what
7 we have heard are the challenges in adults.

8 But there are unique challenges related
9 to diversity in pediatric clinical trials. I think
10 it's more challenging to provide equity in voices when
11 those voices come from children.

12 I think that solutions for diversity in
13 the pediatric space can't necessarily be extrapolated
14 from adults, but probably there are some places where
15 we can extrapolate.

16 I think it's going to -- you know,
17 we've already done quite a bit to improve diversity,
18 but I think what I've heard today is that we're just
19 touching the tip of the iceberg.

20 And this notion of bidirectional
21 communication, meaningful engagement, building trust,

1 and avoiding mistakes that may take a generation to
2 correct were I think some poor key takeaways from the
3 first session.

4 In Session 2, I thought we heard some
5 excellent examples of inclusive trial designs. I was
6 really impressed. It really impressed upon me that
7 proportionate representation is just more than a
8 similar population compared to the proportion with the
9 disease.

10 You know, we need to think about what
11 the real goal is. What is really good? We're not
12 necessarily measuring what we ought to measure if
13 we're just limited to race, ethnicity, age, and sex.

14 And we have to think hard about what
15 the correct metrics are in order to, I guess, get it
16 right or advance the real goal.

17 I heard a lot about being intentional
18 and planning early, about what a representative
19 population really means. And that doesn't necessarily
20 mean it's those four areas.

21 It might mean the disease

1 considerations. It might mean the geographic
2 considerations. It might mean who has the burden?

3 Inclusive trial designs, I heard this a
4 lot, and I think this is a clear takeaway that
5 patient-centric trials don't just mean that we invite
6 someone to come in at an advisory committee and chat
7 about a trial that's already done. I think it means,
8 you know, throughout the lifecycle of drug
9 development.

10 And I heard that decentralized clinical
11 trials aren't cheap, but there may be ways to increase
12 efficiency, and with that increasing efficiency, maybe
13 it will ultimately be cost effective to be inclusive.

14 Panel 3 was just terrific, and I have
15 too much here to really go over, but I really have to
16 give credit to those who were a part of Panel 3,
17 particularly our young panelists.

18 You know, we talked about what is
19 community, how does community affect enrollment,
20 community based engagement, and how do community
21 institutions build and maintain trust. So much there.

1 So rich.

2 And I won't read through this, but
3 hopefully we'll be able to share it with you as slides
4 in follow-up.

5 Oops. Screen sharing has stopped.
6 There you go. Screen sharing has stopped, and the
7 shared window is closed. There we go. I don't know
8 what that zoom thing is. There we go.

9 Session 4, you know, I think -- we
10 heard a lot from Session 3, but so many great talks
11 about recognizing structural racism; that it affects
12 the ability to enroll children in clinical trials;
13 that community engagement, but also clinician
14 engagement is important to promote health equity.

15 Effective communication and
16 comprehensive holistic care is again, an important way
17 to encourage families and children to both enroll and
18 stay in clinical trials.

19 And I think the talk from Puja was
20 great about opportunities to advance clinical trial
21 equity in pediatric oncology.

1 And, you know, one of the things that I
2 heard was that, you know, the enrollment in clinical
3 trials -- we saw this in a lot of data today, that
4 enrollment in clinical trials didn't vary a lot by
5 SES.

6 I think some of the data that Pam
7 presented, it looked pretty good, but it doesn't tell
8 the whole story. And I think that's what impressed
9 upon me; that just looking at kind of the data on the
10 diversity in the clinical trials doesn't tell the
11 whole story.

12 Where are we going? What's going on
13 here? Okay. This thing has a mind of its own;
14 doesn't it? So I can't move it now.

15 Here we go. Session 3, Session 4.
16 There we go. Session 4.

17 Anyway, just some thoughts. So before
18 we end today -- and I did want, if I could, call up
19 Michael, Anvita, and Nasrin to the podium, please.

20 So talk about brave; right? I mean,
21 can you imagine coming up here, like, a, you know,

1 young adult or high school student to a bunch of
2 professionals here?

3 I think if we could just give them
4 really our thanks and appreciation.

5 And I also want to acknowledge -- thank
6 you. Thanks to all three of you. Really terrific.

7 And I want to acknowledge Sneha too.
8 But you know what? You're too old now.

9 Imagine that, Sneha, you're too old
10 now. But thank to Sneha too for your participation.

11 And then finally, can we advance to the
12 last slide? Maybe? Oops. There we go.

13 Before we end today and before I
14 adjourn, I want to really thank all the presenters and
15 panelists. Fabulous job today from all of you. I
16 can't tell you how much I learned. It's been really a
17 wonderful day.

18 Thank you so much to our colleagues
19 from M-CERSI, Dana, James, Heather, Eric, for the
20 support.

21 And I need to have our folks here on

1 the side who ran the session today, Julie, Iana, and
2 Reed, thank you so much for OND meaning support.

3 And finally to the staff that we have
4 in the Division of Pediatrics and Maternal Health,
5 particularly Carrie Ann [ph], Michelle, Meshاون,
6 Carla, and Lily. I mean, you guys did a fantastic job
7 in organizing this meeting today.

8 With that, I'd like to adjourn the
9 meeting. Oh, sorry, one last thing. I meant to say
10 this at one of the breaks, and I forgot.

11 Part of the beauty of being back in
12 person is making these personal connections, so don't
13 be shy. If you see someone wanting to run out, grab
14 them and say, "Can I just get your email, so we can
15 talk later?"

16 If you can, stay for a little bit after
17 we adjourn so that folks can come in and talk to each
18 other about what they can do and how you can help, I
19 would love for that to be another outcome of the
20 meeting.

21 Again, thank you so much for joining,

1 and thanks, again, for everything. Bye.

2 (Whereupon, the meeting concluded at

3 5:07 p.m.)

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21

CERTIFICATE

I, RICHARD LIVENGOOD, the officer before whom the foregoing proceedings were taken, do hereby certify that any witness(es) in the foregoing proceedings, prior to testifying, were duly sworn; that the proceedings were recorded by me and thereafter reduced to typewriting by a qualified transcriptionist; that said digital audio recording of said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

Richard Livengood

RICHARD LIVENGOOD

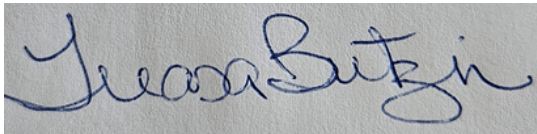
Notary Public in and for the

State of Maryland

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21

CERTIFICATE OF TRANSCRIBER

I, TREASA BUTZIN, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



TREASA BUTZIN

&	112 6:11	187 6:19	2000 170:4,5
& 1:13 3:13 181:1	116 6:9	189 6:20	172:3 173:20
0	117 6:18	19 141:10	2002 164:19
0.05 105:14 106:15	12 6:5 35:20 53:8 148:7,11	164:4 165:4	165:5 167:5
1	149:1,9 157:17	201:13 220:12	2003 166:18
1 33:20 104:12 105:12,15 109:15 130:15 163:18 164:1 164:10 208:4 209:12 215:14 305:20 372:2	171:20 200:17	283:15	2008 34:9
1,230 174:10	253:9 254:6	190 299:18	2016 165:5
1,500 164:1	312:17	197 6:20	2017 174:10
10 50:13 51:1 79:4,6,16 129:16 157:17 163:18 164:1,4 165:4 171:11 253:9 254:5 283:12 364:18	120 6:11	199 6:20	2018 34:18
10,000 134:6	12:30 130:20 130:21	1991 234:20	164:19
100 6:15 79:17 302:18	13 95:9 234:21 235:15,20 283:10 342:4	1993 67:8	2019 148:16
101 159:16	131 6:19	2	154:13 157:5
103 6:16	145 6:20	2 93:6 104:12 105:13,16 115:10 131:8 149:5 155:20 157:17 162:4,9 162:10,18 163:10,20 164:2,11,13 170:1,11 171:19 172:17 173:4,16 174:2 174:6 178:9 208:5 209:11 215:15 310:16 373:4	170:7
108 6:17	15 80:19 82:12 84:3 85:10 86:7 110:14 149:6 175:14 183:9 266:20	2,000 87:1 88:1	2020 15:12 35:19,20 157:6 157:7,9,19 172:4 173:20 201:11,17 283:3,6,11
10903 1:14	150 6:21	2,500 82:16	2021 46:21 77:1
10:30 79:6,6	1503 1:15	20 45:14 88:3,8 89:3 129:16 140:4 164:2,7 186:14 191:4 300:19	2022 18:11 28:8 201:11
10th 10:5,8	16 36:3 40:7 87:17 125:1,2 148:18 353:3,3	200 132:19 134:7 257:7	2023 19:1 47:3 194:3 273:10
11 9:11 369:16	161 7:3		2024 1:11 28:7 87:19 169:3 178:15
11,000 69:5	167 69:4		2025 178:10
110 6:9	17 6:6 56:21 172:4		2030 87:19
	18 60:12,12 140:9 148:18 148:19 149:1		2033 86:3
	180 7:4,5,6		20903 1:16
	181 7:7,8		21 51:2 132:21
	182 7:9		22 51:16 103:21
			224 149:7
			226 6:14,18 7:12,13

<p>24 51:16 306:12 367:12 25 67:18 73:14 367:12 26 79:14 140:8 140:11 266 7:10 274 148:14 28,800 164:4 282 7:8 28435 380:17 29 235:12 29640 381:14 298 7:11 2:15 223:4,5</p>	<p>202:21 203:3 204:11 213:6,9 246:21 375:9 376:15,16 4,000 141:7 4.6 306:1 40 77:19 128:3 301:6,15 307:9 40s 147:2 415 88:2 42 175:10 43 164:3 44 6:9 440 66:14,16 45 266:11 475,000 38:17 4:15 334:5 338:7 4:20 338:7</p>	<p>216:14 283:6 302:16 64 6:3 60:12,12 65 6:10 67 92:10 68 175:15 6857379 1:19</p>	<p>95 6:13,14 163:19 96 260:5 97 141:6 98 302:19</p>
<p>3</p>	<p>40s 147:2 415 88:2 42 175:10 43 164:3 44 6:9 440 66:14,16 45 266:11 475,000 38:17 4:15 334:5 338:7 4:20 338:7</p>	<p>7</p>	<p>a</p>
<p>3 29:8 34:15 128:8 155:20 169:8 172:3 235:10 302:20 311:19 361:4 374:14,16 375:10 376:15 30 172:4 235:13 300 237:12 30s 147:2 31 1:15 6:7,8 316 7:14 339 176:3 34 69:4 35 301:6 372 6:4</p>	<p>5</p>	<p>7 171:11 315:15 70 58:11 70:18 85:4 172:7 73 307:6 79 6:11 66:18</p>	<p>a.m. 1:11 abated 203:19 abdel 96:3 ability 52:10 63:15 71:21 75:9 195:16 217:2 263:10 267:1 268:18 268:19 270:10 271:15 272:12 275:21 279:13 280:9 360:10 375:12 380:10 381:7 able 13:19 24:15 36:14 40:6,21 41:2,5 41:9 60:11 70:1,19 97:6 98:7,11 99:5 99:13 122:20 123:3 125:21 132:16 141:6 142:20 154:6 158:13 159:11 160:1,15 184:17,21 185:9 186:8,9 201:17 204:3 206:14 207:6 211:8 215:18</p>
<p>4</p>	<p>5 172:4 175:9 176:3 209:9 305:21 5,000 164:7 50 132:20 500 179:17 55 187:2 58 175:11 5:07 379:3</p>	<p>8</p>	<p>8 6:3 33:21 34:8,13 125:1 125:15 311:21 326:9 8,770 66:17 8.6 171:10 80 96:18 283:9 811 175:8 85 310:14,15 88 141:7 8:42 1:11</p>
<p>4 149:9 155:20 172:3,6,7 200:5 202:17</p>	<p>6</p>	<p>8</p>	<p>9</p>
<p>4 149:9 155:20 172:3,6,7 200:5 202:17</p>	<p>6 1:11 80:19 95:11 146:17 148:3 149:10 171:20 219:9 225:21 283:16 60 51:3 55:2 58:11 148:3</p>	<p>9 1:1 8:6 9:7 88:9 125:15 146:17 345:4 90 147:5 163:19 222:2 338:15 90s 235:18 94 6:12 141:7 302:17</p>	<p>9</p>

218:7 237:13 245:17 248:1 275:5,12 292:10,11 294:14 308:10 308:13 337:4,5 358:5 375:3 above 58:18 60:12 253:8 261:16 abroad 74:14 absolutely 73:6 88:13 90:16 134:12 146:4 190:6 201:13 215:19 219:21 243:7 254:4 336:13 abstract 276:11 abundance 11:6 abundant 5:5 186:5 abuses 278:20 278:21 academia 10:2 64:8 68:21 76:4 106:4 182:11 211:18 323:1 328:11 academic 66:11,19,21 67:6,17 68:9 69:3 70:12 76:18 122:16 207:5 249:12 256:2 297:16	302:6 308:21 323:21 326:20 330:2 345:15 academics 124:5 acceleration 47:15,16,18 61:11 acceptance 230:18 accepted 106:19 363:4 access 31:5 42:5 57:7,8,13 90:11 93:18 94:6 99:15 115:15,18 129:7 143:21 151:16 153:17 155:16 156:12 156:14,15 217:3,8 219:16 233:13 234:8,9 242:3 255:19 269:18 273:14 273:17 274:5 276:21 277:14 300:1 303:19 309:19 314:4 accessed 128:13 accessibility 352:19 353:9 accessible 16:2 27:4 68:15 100:1 293:7 353:2	accessing 128:1 accommodate 74:4 accommodati... 248:4 263:1,5 account 167:16 168:4 169:17 194:14 210:7 253:8 283:9,12 294:15,17 accountability 76:4 261:1 284:10 339:1,6 343:3 accountable 349:14 accounted 168:9 accounting 283:16 accumulates 310:7 accurate 27:6 255:7 380:9 381:5 accurately 109:18 110:6 235:12 achievable 308:17 314:11 347:8 achieve 20:18 27:18 92:4 112:14 188:3 achievements 293:18 achieving 93:18 216:7,20	acid 146:15 acknowledge 30:15 144:21 145:3 208:13 299:12 377:5,7 acknowledge... 80:10 acknowledge... 80:5 acronyms 349:5 act 18:12 67:8 69:2 83:5,10 166:18 167:4 167:21 acting 2:8 3:11 44:16 action 14:12,14 18:17,19 22:20 28:5,15,21 29:4,6,10,18 47:2,18,18 48:1 61:9 66:8 77:1 81:8 112:1 163:1 169:10 188:10 215:1,9,15 220:6,17 222:13 255:10 255:12 349:6 364:14 365:8 365:20 366:21 367:2,11,13,19 368:1,18 369:4 369:12,18,21 380:12,16 381:8,12
--	---	--	---

<p>actionable 94:4 193:12</p> <p>actions 45:11 46:19 91:9 343:14</p> <p>activ 219:9</p> <p>activated 138:21</p> <p>activations 89:5,6</p> <p>active 88:6 138:21 356:1</p> <p>activities 108:20 109:7 109:12 138:10 213:6 214:4 257:20 277:10 277:10 329:2 329:11 347:1,7 349:20 352:3,7 353:21 355:17</p> <p>activity 92:15 93:14 139:11 354:6</p> <p>actual 15:14 87:20 159:5 221:10 237:4 255:9</p> <p>actually 9:4 13:4 14:4,15 27:6 28:8,10 28:17 40:11 43:10 57:16 63:4 75:11 77:3 102:18 108:14 111:12 113:9 117:9 133:19 137:11</p>	<p>140:1 141:15 142:12 143:1 145:10 146:14 148:6,12 149:19 171:19 174:1,4 179:17 182:15 183:9 185:21 190:17 196:3 197:2,19 198:1 201:14 202:10 209:17 210:21 219:9 220:7,13,18 221:3,12,18 222:13 232:16 232:17 240:9 243:10,19 270:16 271:2 275:10 276:3 276:13 277:18 281:9 282:1,2 285:9 310:9 316:10 317:17 330:20 333:5 342:3 349:13 350:8,16 353:10 362:7 362:20 369:5</p> <p>adaptions 189:5</p> <p>add 90:10 110:12 112:12 132:21 190:3 192:14 193:8 195:10 197:2 197:17 199:17 209:10 216:18 231:10 234:13</p>	<p>236:15 237:21 245:4 248:7 331:9 357:4 358:16</p> <p>added 140:9 307:16</p> <p>adding 42:14 74:12 88:11 189:4 247:18</p> <p>addition 15:11 16:7,18 89:18 98:8 128:11 178:4,13 222:8 267:17 274:14</p> <p>additional 115:10 129:10 140:9 142:17 143:3 167:11 180:2 184:11 216:18 274:17 285:17 291:16</p> <p>address 12:18 13:4 20:17 110:9 134:11 145:6 152:6 153:1 156:20 178:3,10,17 179:8 231:18 254:2 270:19 276:7 280:11 282:4</p> <p>addressed 13:13 24:12 129:1 253:16 256:13 339:17</p> <p>addresses 46:1 330:17,19</p>	<p>addressing 91:15 108:13 178:4</p> <p>adept 1:1 8:6 9:7,8,8 10:4,8 348:1,2</p> <p>adequate 167:16 168:4 169:18 268:10 271:8</p> <p>adequately 75:11 110:8</p> <p>adhere 24:15</p> <p>adherence 136:15 137:15 144:19</p> <p>adjourn 377:14 378:8,17</p> <p>adjunct 215:1</p> <p>adjust 114:14</p> <p>admin 295:21</p> <p>administering 14:3</p> <p>administration 1:13 10:19 150:9</p> <p>administrator 39:7</p> <p>adolescents 86:20 90:10 99:11 317:17 367:14,20</p> <p>adopted 66:21</p> <p>adult 85:9,13 85:21 90:10 92:8,12,13,16 92:17 95:18 97:5 101:13,21</p>
--	---	--	--

119:12 171:10 182:8 227:1 230:4 234:19 235:11 246:2 263:14,15 279:15 293:9 350:6 377:1	advantages 76:10 adventure 321:8 advertise 277:21 advertising 289:16 advised 10:18 advisory 2:7 9:14,17,21 31:15 32:4 41:1 144:9 180:7 227:5 353:18 357:7 357:12,17 374:6 advocacy 182:3 282:19 285:3 364:4 advocate 41:3 196:5,11 331:10,11,14 advocates 20:15 293:16 advocating 180:10 265:14 affect 71:20,21 138:5 229:8 270:8,9 273:16 279:13 280:8 359:6 374:19 affected 146:16 270:21 322:13 affecting 163:18 affectionately 32:4	affects 137:1 146:12 271:4 271:15 272:12 274:6 278:19 306:14 375:11 affiliation 108:5 affirmation 65:12 afford 99:13 140:8 241:17 affordability 99:10 affordable 100:2 256:9 afraid 368:5 africa 84:13 150:7 152:2,4 152:12,19,20 153:20 154:14 155:19 156:8 157:10,11,15 197:6 198:19 african 37:16 147:5 149:18 154:11 160:1 194:5,7 195:10 197:7 199:2 279:19,21 304:8 afternoon 131:15 161:17 180:14,20 181:18 185:15 200:6 226:3 227:2 266:9 282:11 334:5	afterthought 321:17 agape 5:5 186:6 age 30:3 33:20 33:21 34:8,13 34:15 36:3,9 51:18 60:11 66:4 118:4 146:17 148:8 148:19 149:5,9 164:9 169:12 230:6,15,20 235:15,20 249:4 253:7,9 254:6,11 257:8 263:1 373:13 agencies 27:20 323:1 agency 63:10 63:15 107:16 107:21 125:16 176:1 agenda 8:19 11:21 31:6,11 81:2,11 223:11 ages 164:4 165:4 aggregated 118:14 aggressive 86:20 163:11 aging 99:11 ago 9:12 34:16 40:18 47:4,11 57:19 60:20 64:16 85:19 195:18,18
--	--	--	---

218:14 231:21 291:19 agree 86:6 243:7 254:4 257:7 261:10 359:15 360:5 363:16 369:17 agreed 149:3 305:9 agreement 69:6 ahead 8:3 11:20 79:4 94:16 108:4 130:18 131:4,6 180:3 182:5 211:2 223:7 225:20 238:11 263:7 266:7 316:11,14 322:3 324:1 334:3 347:11 358:13 ai 129:14,15 224:15 320:10 320:19 321:1 aids 27:3 aim 60:4 aiming 82:17 aims 56:15 air 89:19 alaska 175:18 176:15 177:13 179:4 align 295:3 aligns 296:9 all's 333:20 alliance 5:3 133:5 288:13	288:15 allocate 291:16 allocating 340:12 allow 64:20 76:12 128:6 261:21 276:20 276:21 277:6 278:1 292:4 308:12 325:16 337:2 allowed 293:19 allowing 119:5 195:12 277:9 333:1 348:14 allows 177:7 alluded 83:3 84:17 108:15 216:14 234:14 alludes 96:10 alongside 299:9 314:17 alternative 277:20 296:5 altruism 64:20 317:18 amaze 371:1 amazing 369:15 amazingly 38:16 amazon 320:20 ambardekar 4:8 7:4 180:5 205:1 208:17 227:2 230:3 262:9	ambassadors 351:20 ambiguity 333:14 ambiguous 333:11 ambulatory 276:20 amend 286:14 america 144:15 232:1 american 59:4 165:7 173:20 175:18 176:15 177:13 179:4 195:13 197:7 229:15 279:19 279:21 304:8 americans 37:16 147:5 163:18 amino 146:14 amount 39:8 147:16 amounts 128:12 amplify 45:8 60:6 299:2 312:21 amplifying 361:17,21 analyses 82:1 176:3 195:5 analysis 54:7 81:10 85:19 101:1 144:19 172:2 174:9 177:7,16	ancestors 305:4 anchor 320:7 anemia 146:16 149:13 angle 328:15 angst 297:13 ann 2:18 6:16 56:8 103:16,20 107:12 108:15 114:17 130:4 173:14 210:12 378:5 anniversary 10:8 announcement 8:18 9:3 11:16 annual 164:17 165:3 answer 28:15 81:20 115:9 116:15 139:20 183:21 191:14 194:20 208:17 212:4 218:5 318:4,13 322:20 329:4 329:20 340:1 answered 139:21 answers 109:16 216:10 218:20 218:21 262:2,3 262:7 anti 137:8 anticipates 215:8
--	---	--	---

<p>anticipating 216:3</p> <p>anvita 4:8 7:4 180:4,6 204:20 227:3 264:9 355:21 371:5 376:19</p> <p>anxiety 259:16</p> <p>anybody 9:7 194:19 197:1 239:15 316:16 322:20 326:7 364:17</p> <p>anymore 295:17</p> <p>anyway 99:9 200:2 245:14 376:17</p> <p>anyways 108:10</p> <p>apart 67:3 235:3</p> <p>apologies 265:14</p> <p>app 55:16,17 55:20 56:3</p> <p>apparently 108:12</p> <p>appear 175:19</p> <p>applaud 246:12</p> <p>applause 32:8 44:14</p> <p>applicable 267:19 296:5</p> <p>application 29:15</p>	<p>applications 178:15</p> <p>applied 177:18</p> <p>applies 163:1 169:7</p> <p>apply 93:11 166:10</p> <p>applying 196:8</p> <p>appreciate 9:1 120:15 362:20</p> <p>appreciated 146:20 248:5</p> <p>appreciation 377:4</p> <p>approach 23:5 123:12,14 134:15 142:4 162:19 205:20 217:16 221:21 245:6 281:10 294:2 323:6,11 335:20</p> <p>approaches 24:2 100:16 102:3 218:1 284:13</p> <p>approaching 221:14</p> <p>appropriate 20:11 21:8 29:8 90:14 92:4 334:17 343:16 368:4</p> <p>appropriately 22:12 23:18 25:10 80:18 158:6 368:8</p>	<p>appropriaten... 26:4 106:9</p> <p>approval 29:16 85:21 100:17 148:13 149:1 171:10,11,14 172:16</p> <p>approvals 92:12 170:14 170:17 171:3</p> <p>approved 40:2 86:1 93:1 111:19 147:21 162:7 170:3,4 170:6,8 171:8 173:9 175:7</p> <p>approximately 82:20 85:6 87:1 163:19 164:3,4</p> <p>apps 143:17</p> <p>april 28:8 35:3 40:6 54:8 63:8</p> <p>area 38:18 48:8 55:21 58:21 59:10 83:12 123:6,7 127:20 171:3 178:12 179:9 183:17 258:3 300:18 330:14</p> <p>areas 11:4 25:15 46:7 70:11 95:19 102:8 122:10 124:12 177:7 191:10 212:14 257:3,17</p>	<p>328:21 373:20</p> <p>argentina 84:11</p> <p>arguably 171:2 171:13</p> <p>argue 70:3 121:6 314:7</p> <p>argument 65:20</p> <p>aristizabal 312:21</p> <p>arming 14:1</p> <p>arrested 272:11</p> <p>art 72:9</p> <p>arthritis 133:5 202:13</p> <p>article 129:12 194:3 240:10</p> <p>artists 72:9</p> <p>arts 72:6</p> <p>asia 181:9</p> <p>asian 52:3 60:1 60:3 62:15 110:17 165:9 174:18 175:21 176:15,20,21 177:14</p> <p>asked 20:8 64:18 65:10 66:1 67:20 78:3,18 139:15 186:16 221:21 245:12 246:6 251:11 261:6 303:1 306:11 347:21</p>
---	---	---	--

<p>asking 68:6 75:21 90:7 111:1 134:18 190:9 215:8 216:1,9,10 261:15 262:14 329:3 349:1 353:21 354:3</p> <p>aspect 13:6 154:17 214:18 238:14 255:3 262:10 264:18 264:20 304:8 350:11</p> <p>aspects 13:12 14:18 15:12 24:5 154:9,11 204:6 330:6,7 357:20</p> <p>assess 216:7</p> <p>assessing 11:1 259:7</p> <p>assessment 24:8 139:11 160:17 162:5 163:5 172:20 174:8 285:8 357:14</p> <p>assets 319:20</p> <p>assist 312:13 313:2 333:19</p> <p>assistance 81:1</p> <p>assistant 4:12 131:11 266:4</p> <p>assisted 312:9</p> <p>assists 28:18</p> <p>associate 1:7 2:8,13,16 3:11</p>	<p>3:17 8:10 44:16 94:13 180:15</p> <p>associated 169:21 207:13</p> <p>assumed 291:3</p> <p>assumption 295:19</p> <p>assumptions 244:10</p> <p>assure 11:12</p> <p>assures 67:9</p> <p>asthma 88:19 88:21 89:2,3,7</p> <p>astutely 78:10</p> <p>atm 295:21</p> <p>atopic 93:6</p> <p>attached 344:4</p> <p>attacks 38:13</p> <p>attainment 241:8</p> <p>attempting 181:15</p> <p>attendees 2:2 3:2 4:2 5:2 19:5 328:3</p> <p>attention 58:2 58:7 179:10 343:16</p> <p>attitudes 284:6</p> <p>attorney 380:14 381:10</p> <p>attrition 201:6</p> <p>audience 10:12 47:7 64:12 94:20 97:18 103:10 108:3 113:21 114:4</p>	<p>115:21 116:1 118:8,9 119:3 122:2 185:14 204:13 261:21</p> <p>audio 65:18 78:21 380:8 381:3</p> <p>augment 128:13 152:3</p> <p>auntie 233:11 242:16</p> <p>auscultate 185:9</p> <p>austin 38:14 42:7</p> <p>author 263:14</p> <p>authorities 118:15</p> <p>authorship 264:3</p> <p>autoimmune 136:21</p> <p>automated 138:13,14</p> <p>automatically 303:13</p> <p>availability 26:6 110:19,20</p> <p>available 11:10 19:8 31:7 53:5 53:9 57:6,11 59:19 65:6 70:3 76:6 77:6 77:8,17 100:1 122:19 128:12 167:2 170:10 170:11 171:5,6 205:4 256:10</p>	<p>285:7 293:6,12 296:6 297:19 319:8 346:1</p> <p>avenue 1:14</p> <p>average 86:8 86:10 165:11 171:9</p> <p>averages 85:4</p> <p>avoid 45:10 46:15,19</p> <p>avoiding 373:1</p> <p>award 97:8,10</p> <p>awards 56:7</p> <p>aware 64:12,14 132:13 147:9 154:16 156:3 194:17 205:4 205:12 222:4 239:17 240:17 247:21 268:17 305:2</p> <p>awareness 43:6 58:2 111:8 284:7 352:1 360:11</p> <p>aziz 311:7</p>
			b
			<p>b 1:15 60:16 117:4 335:21 358:7,9,10</p> <p>back 33:18 35:3,19,20 36:13 42:13 66:10 70:5 74:6 79:5,6 82:8,8 110:21 111:1 130:21</p>

156:2,17,17 190:12 197:16 212:13 217:15 220:16 223:5 228:17 231:20 234:20 257:5 258:10 313:12 316:6 318:17 319:3,5,12 324:12 326:16 329:21 335:11 336:6,13 339:20 341:19 342:19 348:9 350:14 358:6 358:13 363:9 370:2 378:11 background 62:19 105:7,8 106:15 185:8 244:5 317:8 backgrounds 98:5 169:19 245:11 270:5 271:21 277:18 backup 140:9 154:3 bacteria 11:2 bad 69:10 114:7 171:1 245:13 303:14 338:18 balance 214:8 214:10 216:19 balevic 3:17 7:9 145:1 182:7,8,20 184:15 210:14	211:3 ball 71:17 bandwidth 74:4 271:8 bar 190:16 barber 288:8 barbershops 288:17 bare 190:14 barrier 38:2,10 38:11,19 39:20 112:3 143:13 143:14 267:3 273:14,15 278:13 331:14 332:8 barriers 20:4,6 20:18 21:1 22:11 33:14 36:18,19 40:3 48:9,11 50:11 51:17 58:7 111:7 134:9 135:20 136:5 138:1,4 178:3 271:2 273:12 275:13 276:8 280:12 281:12 282:4 284:1 294:8 302:11 305:15 307:5 309:7 347:18 base 251:7 based 22:21 62:17 69:7 89:16 93:4 99:18 100:13 102:6 122:5	154:16 177:16 194:2 196:17 212:18 232:7 236:3 243:4,11 244:11 249:20 258:16 265:2,3 268:15 276:18 276:19 278:17 285:3 320:2 337:8,11,12 360:16 374:20 baseline 10:19 107:9 basic 242:5 250:7 272:17 273:17 274:11 337:14 basically 134:20 138:9 139:15 194:3,6 195:20 198:8 201:16 306:12 basis 148:13 236:19 285:15 bayer 4:15 5:4 213:2,4 317:2 317:10 345:11 bayesian 127:12 bears 365:2 beautiful 193:11 beauty 378:11 becoming 170:11 342:7 bed 33:6 beg 271:5	began 10:5 35:2 beginning 97:13 112:20 113:8 144:2,10 151:4 220:8 221:1 264:12 315:1 347:18 350:2 353:9 358:1 begs 248:18 behalf 8:3 227:4 behave 34:4 behaviors 66:21 67:16 belabor 298:17 belief 229:11 beliefs 98:8 227:14 believe 43:2 44:12 122:18 187:13 258:18 266:1 317:5 323:11 333:8 believes 244:1 bella 3:7 6:21 145:13,15,21 148:2 149:21 150:11,12,15 161:12 197:4 197:10 318:2 bella's 370:1 belong 239:14 belonging 231:14 belongs 239:15
---	--	---	---

benchmark 173:11	56:14 76:4 87:7 93:16,16	363:2,12 372:4	95:5 101:10
benchmarking 76:8 77:10 122:19	93:17,17,18 99:5 129:6 177:21 195:16	bigger 196:12 198:1 333:2	103:16 107:17 119:7 126:13
benefit 43:12 74:16,17 81:14 94:5 146:3 167:1 170:20 189:20 193:9 193:14,14,16 196:13 200:9 209:6 217:18 292:21 293:3 358:4 366:13 366:13 369:14	209:7,17 224:13 248:1 258:18,19,20 260:19 267:13 280:1 305:1 321:10 323:13 330:16,17	biggest 245:15 319:15 321:6	128:9 140:16 144:5 168:15 174:15 176:6,7 184:1 193:20 203:19 205:18 208:19 209:20 213:10 238:1,2 238:9 262:10 284:12 294:7 306:4 343:18 355:9 372:17 378:16
benefited 207:20 208:3	beyond 96:21 115:11 117:1 117:11 118:4 129:1 187:14 188:2 190:9 192:3 247:9	billie 3:20 6:18 47:14 49:12 54:10 62:13 226:4 260:11 264:19	black 37:15 147:11 165:8 175:17 176:10 213:13 249:3 281:6 283:10 299:3 302:9 304:4,17,20 305:4 309:18 314:2 318:19
benefits 159:7 165:16 204:2 292:19,20 312:9,14	254:8,20 255:9 287:14,14	bio 145:12 332:12	blackfeet 226:4
best 28:2 69:1 83:9 113:15 122:14 123:1 124:14 125:7 125:12,13 167:4 173:12 188:16 217:2 251:9 265:17 282:6,14 284:15 290:6 315:21 316:7 318:6 380:10 381:6	bi 61:17 123:20 123:20	biogen 290:15	blanket 112:13
better 21:5 36:11 37:21 41:4 50:12	bias 261:4 284:6	biological 135:9 166:19	blind 260:21
	bible 5:5 186:6	biopharmace... 79:15 226:19	blinded 89:9
	bidirectional 27:16 45:5 255:4 372:20	bios 31:5,6	bloated 360:4
	bidirectionality 256:20	biospecimens 135:16	blood 135:12 135:17 139:4 141:7 146:6 185:4,6 212:11 240:12,13 318:10
	big 41:3 69:10 69:11 76:11 127:4 128:21 155:18 158:17 209:3,3 230:5 246:19 273:11 279:18 314:21 322:6,8,14	biostatistics 104:9	blow 361:3
		biotechnology 3:6 145:12	blue 133:11 165:8 174:19
		biotechquity 5:7 114:2	
		biotechs 83:1	
		bipoc 284:11	
		birth 75:15	
		bit 17:6 28:4 31:8 40:15 47:13 48:10 52:3,9,21 53:18 54:11 55:1 57:20 59:16 72:3 84:17,19 86:17	

175:20,21 176:11,16,20 283:6 313:14 314:1 board 3:5 41:1 145:11 324:11 353:19 357:12 357:17 366:21 boarded 209:15 boards 184:7 325:5 357:7 boat 361:5 body 23:17 189:4 231:4,11 231:15 boehringer 4:19 206:10 bolster 275:20 bomb 34:3 bona 311:6 book 77:14 books 77:16,17 77:21 158:15 boon 129:21 boots 236:8 319:16 320:8 borders 228:1 228:5 229:7 born 34:7 borrowing 90:12 127:4 bose 311:7 boston 2:14 94:14 100:11 302:8 bottle 138:11 138:12	bottled 11:9,11 bottom 133:10 165:6 206:1 bounds 210:3 bourgeois 2:16 6:15 100:6,8 100:10 101:8 102:11 box 76:9 110:16 171:9 boxes 195:13 boys 272:10 bpc 74:6 83:10 102:20 104:11 107:19 107:21 167:4,8 167:14 168:2,8 169:15 171:2 171:13 branch 49:7 56:19 branches 48:3 49:5 brave 376:20 break 69:13,17 79:5,6 130:19 136:19 223:4 265:5 breakdown 173:2,4 175:6 176:6 breaker 246:14 breaks 378:10 breast 234:21 235:3,11,14,20 246:16 breaths 136:18	bridge 226:17 286:3 319:7 brief 10:12 17:18 31:3 briefly 18:20 28:3 47:5 104:1 132:3 311:10 brilliance 246:11 bring 17:5 32:12 37:9 44:1 81:6,18 127:18 189:12 193:15 245:10 246:5 248:18 276:7,15 316:6 318:16 319:20 338:6 357:11 363:9 367:17 bringing 43:19 191:12 246:11 252:4 285:1 315:3 350:3 351:4,11 brings 351:21 broad 112:8 broadband 26:6 broader 126:9 193:15 256:12 343:19 broadly 12:7 16:13 brought 32:11 61:15 63:8 65:16 128:10 156:17,17	310:3 318:16 332:12 334:7 341:10 brown 147:11 bucket 52:1 budget 212:7 276:14 287:2 294:18 295:11 296:12,12,16 296:20 325:10 325:14 335:14 335:17 362:11 budgeted 275:11 budgets 210:6 275:10,16 build 27:13 41:20,21 106:12 126:15 143:9 153:9 155:5,6,10 157:1 160:12 230:3 232:11 232:12 237:16 237:16 238:13 249:15 261:2 262:8 263:2 286:16 293:7 308:10 320:11 346:15 356:21 374:21 building 1:15 21:13 26:9 78:9 100:12 160:20 223:12 229:18 231:2 236:16 254:21 256:14 269:2
--	--	--	--

<p>340:3 341:5 369:2 372:21 buildings 11:1 builds 197:4 349:12 350:19 363:10 built 261:6 340:3 bully 9:6 bunch 55:13 249:12 377:1 burden 74:16 74:20 90:5 164:21 193:14 214:4 217:20 269:1 276:13 302:15 308:1 332:8,16 336:8 348:13 366:13 366:18 374:2 burdens 136:7 274:16 347:19 burdensome 73:21 74:8,13 301:11 burgess 2:6 6:7 6:8 31:13,17 31:19,20,21,21 32:1 33:19 34:14 35:5,19 36:15 40:5 41:13 42:20 44:11,20 49:3 49:8 52:8 61:15 63:13 233:16 322:4,5 322:16 324:1,2 324:21 331:9</p>	<p>339:11 341:6 354:5,20 355:5 355:11 366:20 burst 170:14 bus 155:21 156:1 business 288:21 busting 334:1 button 316:18 butzin 381:2 381:15 buy 285:4 bye 379:1 bypassing 253:5</p>	<p>367:11,13,19 368:1,18 369:4 369:11,18,21 376:18 called 33:11 134:15 147:21 149:6 194:4 241:2 255:4 273:20 344:4 calling 14:12 362:21 calls 138:15 139:20,21 140:2 220:16 campaign 53:3 53:5 139:18 campus 10:20 11:8 canada 84:12 325:4 cancer 198:2 217:7 235:3,11 246:16 247:2 247:12 299:16 299:21 306:10 306:18 307:12 308:3,5 309:14 309:15,19 310:4,5,7 311:3,15 312:3 312:4,11,16 cancers 180:16 198:6 216:15 216:16 cap 138:11 capability 263:10</p>	<p>capacity 27:14 39:21 153:9 160:13,19 340:3 341:5 capitals 88:21 89:3,7 captioned 353:4 capture 109:17 110:15 129:6 captured 110:6 captures 300:10 car 57:12 155:21 cara 133:5,9 139:13,15 144:13 card 295:18 331:19 cardiovascular 163:14 care 25:6 26:1 59:5 76:18 99:2 102:14 125:7 133:14 137:16 142:11 165:19 171:1 198:3 203:11 209:17 210:18 235:8 242:1 243:5 269:18 274:19 276:9 276:14,20 280:7,8 285:19 290:12 294:4,5 296:11,20 297:5 298:1,1</p>
	<p style="text-align: center;">c</p> <p>c 1:15 2:1 3:1 4:1 5:1 6:1 7:1 8:1 44:19 110:12 116:19 118:17 246:19 335:21 358:7,9 358:10 calculate 58:19 california 336:3 call 14:13 38:5 55:16 77:1 103:14 131:21 132:4 152:7,10 183:13 242:15 287:5 325:5 332:1 352:10 357:21 364:14 365:8,20 366:20 367:2</p>		

299:17 303:21 305:10 309:19 309:21 310:7 311:13 323:19 323:20 330:12 337:7 344:12 344:14 356:18 362:6 375:16 career 236:2 careful 117:19 caregiver 274:16 276:13 caregivers 16:14 132:10 158:19 243:10 274:16 331:5 caretakers 80:8 caribbean 246:17 caring 123:16 307:12 carla 2:4 6:17 8:13 32:14 108:1,7 111:9 223:13,17 378:6 carla's 110:21 carrie 378:5 carrier 297:14 carries 164:21 cartoons 125:3 158:15 case 11:16 81:5 84:5 89:10 93:7 115:4 131:8 177:9 185:5,11 195:18 209:13	296:15 298:21 360:4 cases 163:19 185:12 196:16 196:17 361:10 cash 295:16,16 312:1 categorize 194:10 category 176:20 195:11 caucasian 261:13 caucasians 304:7 cause 137:3 265:4 298:12 307:19 causes 307:11 370:14 caution 11:6 278:3 cautious 280:1 caveat 308:2 cbos 151:4 cbpr 250:2,4 cdc 163:20 173:17 174:4 208:8 celebrate 220:1 cell 33:20 40:9 60:15 119:13 120:8,17 135:8 146:6,10 147:4 147:6 149:16 150:5,20 151:1 155:14,17 159:3 197:21	198:1,5,10,21 199:1,17 214:11 274:4 330:5 cellular 143:21 census 69:7 105:2 109:21 283:6,11 center 3:15 4:14 8:4 62:12 77:14 134:2 180:17 181:20 193:18 209:18 209:18 212:20 214:5 222:16 282:18 287:19 298:8 299:18 300:1 302:7 312:6,7 344:4 344:15 centered 90:7 205:20 237:14 285:13 centers 62:14 207:5 209:3,15 209:16 299:18 309:21 311:19 313:6 326:20 338:1 340:8 343:12,21 344:13 345:7 345:15 central 133:17 134:20,21 centralized 211:12 centrally 311:14	centric 374:5 ceo 358:6 cersi 1:4 377:19 certain 11:1 25:17 116:8,8 148:8 166:19 174:1,14 213:16 238:17 269:9 276:5 278:5,10 327:21 329:15 346:6 347:6 361:10 certainly 84:1 123:6 125:12 203:20 338:11 certificate 75:15 380:1 381:1 certify 380:4 381:2 cetera 12:6 60:16 62:21 chair 3:5 145:11 265:20 chairs 315:13 challenge 72:3 72:8 137:12 149:21 150:4 153:20 184:4 208:12,13 306:8 312:20 challenged 77:3 challenges 15:6 23:3 41:10 58:1,17 91:13
---	---	--	--

93:5 132:16 142:6 146:8 151:17 152:6 152:13,15 153:2,9,14 154:5 156:4 159:15 163:4 169:21 171:15 171:17 172:9 172:19 178:5 178:11 192:17 199:7 213:10 274:12,18 294:11 323:10 335:10 372:5,7 372:8 challenging 33:14 129:4 153:17 372:10 chance 121:21 179:20 204:15 224:7 225:18 227:8 change 12:20 25:4 121:1 146:15 195:7 changed 36:3,6 218:16,18 235:9 346:7,8 changes 84:8 132:21 293:20 345:19 changing 41:4 195:10 channels 356:6 356:16 characteristics 23:8,11	characterizati... 82:8 characterizati... 83:20 characterized 194:10 charge 78:3 chart 165:6 chat 374:6 cheap 374:11 cheaper 212:16 check 110:16 110:17 195:13 242:18 247:5 checkbox 323:17 checklist 246:1 chef 312:8 chew 101:3 chi 105:3 chicago 32:19 38:17 42:7 128:3 chicagoland 38:15 39:6 chicagoland's 37:3 chief 2:3,20 12:1 64:3 child 186:1 226:5 233:10 234:16 257:7 272:4 294:6 304:14,19 305:8,11 306:18 307:12 307:17 308:7 311:15 331:21	child's 75:14 306:15 337:6 childcare 274:19 276:9 childhood 133:4 137:4 children 12:10 12:15 13:17 39:13 56:16 64:10,16 65:6 65:12 66:16 70:7 74:20 78:3,7 81:18 82:18 83:10 84:10 85:12 86:19,20 87:1 87:14 88:1,3,5 88:12,20 89:16 90:13 92:1 93:19 94:5 101:16,19,20 104:11,15,20 109:8 110:3,5 111:5,20 120:18,19 121:2,14,15 122:4 123:13 125:4 127:19 132:17 133:14 148:10 155:8 157:2,16,21 159:2 163:13 163:16 164:17 167:4,16 168:5 169:18 173:4 218:18 242:3 265:17,21 282:14 299:16	299:21 300:8 300:10 301:7 301:16 309:15 310:5 313:13 313:14,18,20 313:21 314:1,4 316:1 321:9 348:11 372:11 375:12,17 children's 2:7 2:14 4:14 31:15 32:3 34:13 42:9 65:9 69:2 77:14,15,21 94:14 100:11 133:13 180:7 227:5 299:19 chime 138:14 197:11 204:21 china 84:11 chips 242:20 choice 366:8 choir 14:8 267:6 choose 60:3 249:5 290:3,4 chose 69:1 72:6 104:13 christina 4:10 7:8 181:19 204:21 205:16 266:1 282:12 christina's 320:1 christine 2:8 6:9 44:15 64:2 102:19 118:10
---	--	---	---

195:2 240:1	clear 69:14	55:21 56:4,18	172:15,19
chronic 35:14	98:14 183:11	60:2,9 63:4	173:9 174:16
41:18 136:21	217:7 269:15	64:13,17,19,20	175:1,4 177:20
137:11 146:21	321:13 333:4	65:2,10,21	178:1 181:1,3
147:2 238:3,20	374:4	66:3,15 68:4,7	181:4,15,20,21
249:3 272:2,9	clearly 88:14	68:18 69:9,15	182:10,12
297:7 331:21	113:18 124:16	72:20 73:11,21	185:19 186:2
365:15	176:7	75:4,9 76:19	186:15,17
chronically	click 60:9	78:1 80:8 81:5	187:14 205:6
147:7	clicker 132:1	82:14,17 87:5	205:11 207:6,8
church 5:5	clients 183:7	92:10,15,18	207:12 208:19
186:6	clincard	93:2 95:20	210:3 213:9
churches	295:17	96:5 97:3,9	221:5,6 226:15
249:14 288:8	clinic 16:5	98:16 100:15	233:3,7,11,20
360:15	271:13 273:4	101:11 102:10	236:10,12
circles 133:12	clinical 3:3,9	105:4,5 106:10	237:3,8,17
circular 349:13	3:14,20 4:4,6	106:16 109:20	242:3 243:1,16
circumstances	4:10 5:7 12:11	111:15 112:4	247:21 249:17
65:7	12:12 13:7	114:2,21 115:1	250:9,13
cited 195:2	15:20 18:1,2	116:17 117:6,9	251:14,19,19
cities 89:1	18:15 19:4,20	117:10 118:11	252:6 254:15
209:3	20:2,7,8,10,19	122:8 123:5,14	256:15 259:2
citing 194:6,13	21:1,10,14,15	123:19 124:5	259:12 261:8
claims 128:18	21:19 22:13,14	124:15 127:1	262:13,16,18
clarification	23:1 25:1,3,21	127:21 131:12	264:12 265:18
109:4,5	26:4 27:19	131:20 132:4	266:2,13,19
clarified 99:16	28:16 29:7,18	133:14,18	267:1,4,17,21
clarify 107:15	30:13 33:14	138:7 140:18	268:1,3,18,19
clarifying 31:1	35:2,17,21	142:5 147:14	270:14,16,20
107:13	36:4,17 37:6	150:2 151:9,15	271:7,17 272:4
clarity 184:6	38:7,19 39:10	151:19,19,20	272:13,21
classes 208:21	39:20 40:2,9	154:21 155:4,8	273:7,12,16
classically	40:15 41:20	157:2 158:20	274:2,8 275:4
146:18	42:14 43:3	159:1,16	275:7,10,21
classification	44:2 48:5,8,11	161:14 163:4	276:7,16,17
29:15	51:10,16 52:7	163:11 166:13	277:1,4,21
classifications	53:3,4,12,15	168:13 169:6,8	279:14 282:4,9
110:10	54:3 55:8,16	169:11 171:16	282:15,17,18

283:4,9,12,20 284:1 285:21 288:4 289:21 290:16,17,20 291:4,8,19 296:17 298:12 299:1,11,20 300:1,3,12 301:10,17,21 302:1,10 303:2 303:3,4,8,18 304:11 305:6 307:15 309:2 310:10,11 313:1 314:5,18 316:1 319:16 322:7 323:15 326:12 328:8 330:9,16 331:15 332:4 336:18 337:19 340:19 342:6 342:20 345:15 347:1 348:11 357:15 359:10 360:9 362:15 363:16 366:16 367:5 369:1 372:9 374:10 375:12,18,20 376:2,4,10 clinically 30:5 clinical 189:10 251:13 clinicaltrials.... 66:13 clinician 64:9 100:10 288:2	375:13 clinicians 14:1 16:20 27:21 43:13 288:1 342:8 clinics 42:8 133:13 276:18 276:19 clockwise 283:10 close 78:2,16 117:20 179:17 365:19 closed 227:17 227:20 228:18 229:7 353:4 375:7 closely 72:12 73:9 86:17 211:7 closing 228:1,5 364:13 371:7 closings 138:12 clothes 285:13 cloud 50:1 51:8 clouds 45:10 46:16 257:1 clump 51:21 coach 340:8 coalition 287:7 coast 191:10 coat 251:4 code 221:3 300:21 codes 31:4 300:19 coffee 11:13	cog 299:18 cognitive 271:8 cognizant 289:14 294:10 cohesiveness 367:9 cohort 59:4 121:15 300:8 302:16,20 307:6 cohorts 90:13 colectomy 95:12 colitis 86:14 95:11 collaborate 156:21 325:21 328:7 collaborating 118:15 159:8,8 collaboration 46:8 150:8 158:8 159:18 290:15 322:21 325:3 327:11 327:16,19 328:12 330:1 332:15 333:3,9 333:14 343:1,9 collaborative 3:21 243:5 333:18 collaboratively 27:9 colleague 8:12 9:11 181:7 223:13	colleagues 30:15 311:7 336:12 377:18 collect 24:7 75:10,12 90:20 91:4 135:16 139:4 141:7 143:9 148:9 186:9 318:9,10 318:11 collected 54:6 195:17 212:11 300:14 collecting 152:19 collection 53:15 54:3 135:4 195:3 227:13 collective 91:21 94:4 228:2 233:7 colleen 311:7 college 62:20 241:8 260:7 colleges 50:4 189:2 240:6,7 250:16 258:7 color 189:3 288:11 coloring 158:15 columns 270:19 combat 266:17 267:3 combining 323:7
--	--	---	---

<p>come 9:20 17:3 17:4,14 23:21 26:14 33:13 35:17 36:21 37:19 42:2,21 43:14 47:9 54:15 56:6 79:5,6 94:16 113:16 128:7 130:21 144:6 156:1 169:16 189:7 195:14 213:4 220:2 223:5 224:1,1 227:11 233:9 236:18,20 244:8,9,20 250:17 255:6 260:10 271:16 280:13 284:4 289:3 297:2 303:13 304:16 305:15 315:5 325:21 360:14 372:11 374:6 378:17 comes 38:12 47:2 48:17,21 50:7 52:17 58:12 60:2 71:17 73:18 117:5,15 122:12,15 155:15 217:15 247:6,16 260:20 263:20 280:16 334:19 334:20 342:6</p>	<p>363:5 comfort 338:1 comfortable 141:13 262:21 277:2 280:20 336:21 338:4 339:2 342:7 coming 92:6 93:13 119:13 125:20 129:16 143:9 144:19 155:19,21 207:2 215:13 216:1 223:16 228:6 237:16 273:3 293:13 293:14 324:17 357:18 358:17 363:15 364:11 364:15 367:5 367:12 376:21 commend 248:16 comment 109:17 182:17 184:12 198:17 206:7,11 213:3 317:21 341:7 342:14 343:10 363:14 commentary 112:8 188:12 315:9 commenting 344:20 comments 28:11,12 141:17 193:4</p>	<p>232:21 348:9 370:2 commercial 135:14 256:3 commissioner 2:8 44:16 commitment 152:11 158:8 160:7 committed 12:7,19 18:8 281:21 committee 9:21 241:18 374:6 committees 9:14,18 common 20:4,5 137:5 163:18 300:6 communicate 26:13 50:14 98:12 124:14 154:19 188:6 188:17 229:17 292:11 communicated 37:11 254:9 communicati... 98:15 245:1 292:16 communicati... 27:16 45:21 46:9 50:12,17 52:4 57:3 78:8 123:11,11,15 124:2,11 248:1 252:18 253:1 291:11,12</p>	<p>293:15,21 294:3 297:21 356:7,15,17,20 372:21 375:15 communicati... 77:18 communities 16:21 27:11,17 37:16 38:14 42:6 43:5 46:11,14 49:9 54:13,16 60:7 62:3,12,16 63:9,11,13 90:7 111:3,6 116:8,8,12,16 117:1 123:13 126:6 151:14 186:14 208:5 226:18 227:15 228:11,18,18 229:6,18 231:19,21 232:6 234:8 236:11 243:13 243:14 245:2 250:5 251:17 259:11 269:2 270:13 279:1,9 279:10 286:19 287:8 288:6 289:10 302:5,6 319:18 320:3,4 320:7 323:7 337:3 343:21 345:7 356:9,9 356:10 360:11 360:12 368:21</p>
--	--	--	---

community 4:6 4:17 9:20 16:9 16:10 20:12,15 26:15,18 27:7 27:9 35:16 36:21 37:1,2 38:15,16 42:16 43:4,13,15 48:12,14 49:11 49:15 50:6 52:14,16,17 62:14,15,15 63:16 72:11 73:19 90:8 96:17,20 106:19 116:5,6 116:12 117:9 117:20 121:5 126:5,8 132:11 147:8 151:1 154:6,15 193:21 204:14 205:19 208:3,5 219:15,15 221:9 223:11 224:10 225:2,7 225:16,17 226:7,15,18 227:9,10,12,12 227:13 229:7 229:10,15,16 230:5,8,14 231:3,6,10,13 232:10,20 233:4,6,8,14 233:20 234:3,3 234:4,5,11 236:2,3,9,16	236:18 237:16 238:4,19 239:8 239:11,13,15 239:18 240:17 242:9,14,15,15 242:21 243:3,3 243:10 244:18 245:5 249:13 249:16,20 252:7,8,8 255:1,8 258:11 259:5,6,9,14 259:14,16,18 259:20,20 260:18 268:21 270:7,17 272:9 272:11 276:6 276:18,19 278:10,19 283:16 284:14 284:15,16 285:3,4,5,7,8 285:10,14 286:2,4,8 287:1,3 288:1 288:2,5,7,9,14 289:7,12,19,21 290:16,21 291:10 294:2 295:20 297:20 316:7 320:13 322:21 323:8 351:10 359:18 360:6,16 361:12 362:3 362:21 363:19 363:20 364:7 365:15 367:1,3	367:3,6,7,8 374:19,19,20 374:20 375:13 comorbidities 13:8 285:18 companies 82:21 83:1 93:7 114:3,6 184:13 210:7 213:15 220:12 226:19 343:13 343:17 345:13 348:17 company 89:8 161:8 181:2 184:13,17 206:10 277:12 315:10 346:2 comparable 175:1 176:19 compare 105:3 114:21 115:2 173:1 compared 101:12 105:11 106:15 140:17 165:9 185:19 185:20 248:8 373:8 compares 76:19 comparing 106:15 comparison 85:9 185:21 comparisons 109:20	compensation 275:16 296:1 competency 221:8 290:20 359:12 competing 284:9 competitive 68:13 318:19 complement 128:13,19 complete 85:17 87:10 88:8 139:6 158:13 171:21 302:19 305:21 306:2 completed 135:7 158:11 302:18 310:13 completion 310:15 complex 24:18 25:2 91:18 143:7 150:13 234:15 271:9 278:13 293:11 323:10 complexities 81:19 compliance 182:18 complicated 119:19 134:3 183:14 complications 163:12,14 complimentary 19:15
---	---	--	---

component 148:18 247:4	conclusions 114:11	150:3 158:6	congenital 120:19
components 313:4	conclusively 218:8	168:8 170:19	congregate 231:17
compounds 239:1	concrete 348:12	172:3 173:9,17	congress 18:11
comprehension 313:3	concurrence 107:2	177:20 182:21	conjunction 74:21 178:7
comprehensive 48:21 81:21 294:4,4 296:11 296:20 298:1 323:8,19 375:16	concurrent 88:6 89:12 93:5	186:12 205:7	connect 46:11
computer 135:8	condition 60:13 114:21 115:2 133:15 170:7 232:8 237:1,2 327:8 352:12	262:19 302:7 356:3	50:6 52:10 62:3 63:13,16 139:8 288:10 320:17
concept 193:11 280:13 309:10 340:19	conditions 13:10 24:19 117:8 137:11 138:6 238:4,10 326:18	conducting 10:19 21:15 81:15 82:19 151:15 153:14 155:7 163:4 169:14 171:18 178:5 247:20 269:4	connected 231:11,15
concerned 251:14	conduct 21:17 68:4 100:17 128:19 132:14 132:17 139:10 141:6 149:3 153:11 154:3 157:14 167:6 178:11 216:18 272:21 276:18 278:10 285:2 285:10 293:21 327:7 350:12	conference 32:13 41:6 129:20 130:7 146:2 185:16	connection 26:10 43:20 45:6 49:17 52:9 63:18 229:20 231:4 344:7
concerning 201:3	conducted 26:1 70:14 82:20 83:9 86:5 132:20 141:2	conferencing 135:6	connections 261:2 368:20 378:12
concerns 98:1 118:13 156:20 254:2 293:13 337:7,11		confidence 256:3,3	consent 22:9 70:17 71:3,8 71:12,14 72:7 72:13,16 157:21 254:19 271:16 291:14 292:2 307:2 310:14 313:2 350:12
concerted 12:18 220:14		confident 91:13 112:18 113:8 157:2 187:21	
concierges 22:16		confirmatory 149:4	
conclude 281:18		conflicts 162:16 282:21	
concluded 379:2		confounding 58:6	
conclusion 42:3 114:20 177:9		confuse 345:14	
		confusing 125:6	consenting 140:2 155:7 253:13
		confusion 332:17,18	consider 85:11 115:13 142:8 180:1 196:13

257:3 270:12 272:3 275:9 296:4 297:2 325:15 362:9 consideration 77:1 108:20 243:21 264:11 295:1 298:3 considerations 74:16,18 90:1 142:17 143:4 152:14 374:1,2 considered 144:2 197:7 296:3 323:15 340:20 348:10 359:9 considering 235:7 296:21 consistency 324:20 consistent 89:6 324:15 consistently 54:6 consortia 311:21 consortium 47:15 60:19 61:11 62:4 constant 35:14 constantly 154:4 constraints 38:20 284:5 357:2 consultant 226:17	consulting 4:7 79:13 226:16 236:7 consumer 203:21 consuming 11:7 cont'd 3:1,2 4:1 4:2 5:1,2 7:1 contact 287:2,5 contacted 89:7 139:17 content 28:21 30:9 131:16 context 66:3 82:4 86:18 87:9 92:2 270:8 311:12 contexts 308:8 contextual 81:14 continual 350:4 continue 20:2 126:14 127:16 159:17 160:17 160:19 178:3 180:10 188:6 223:10 231:2 248:16 324:18 361:16 362:20 367:19 368:2 368:19 continued 149:11 continues 91:17 101:17 302:1 319:4	continuing 282:13 324:3 continuous 159:12 293:21 317:4 continuously 317:12 continuum 297:5 298:1 contract 240:2 contracts 210:6 contrast 164:8 contribute 58:6 66:8 74:12 85:16 contributed 57:17 contributes 172:16 contributors 263:11 control 55:19 204:3,3,9 controlled 128:14 controversial 334:5 convene 18:14 19:1 convenience 277:5 320:20 321:1 convenient 320:12,20 conversation 9:10 114:12 179:11 180:18 231:3,5 246:12	253:10 254:7 282:13 323:16 323:18 333:2 334:18,19 351:1 362:5 conversational 33:17 conversations 96:18 98:7 117:15 127:9 224:11 261:1 278:18 281:17 309:5 325:4 336:18 338:5 338:10 342:9 362:12 convey 117:8 293:5 conveyed 292:17 convinces 202:6 cool 206:13 coolers 11:10 cooperative 77:14 216:6 299:19 coordinate 157:18,19,20 157:21 158:1,2 158:3 297:17 326:21 coordinating 133:18 134:2 coordinator 291:20 296:17 336:6
--	--	--	--

coordinators 153:11 281:1	couple 12:4 32:6 45:3 47:8	95:14 187:7 208:7 210:5	criteria 15:16 29:1 66:15
corner 133:11	49:13 52:12	230:12 234:7	168:1 172:11
correct 116:21 200:7 353:19 373:2,15	56:9 63:6,7 100:7 131:16 144:18 182:15	234:10,10 236:11 245:17 323:8 335:1,2	278:4 284:9 criteria s 20:9
correctly 215:7 345:12 360:2	201:18 224:21 252:12 258:1	337:15,18 350:2 355:19 355:21 356:6	critical 18:2 26:10 88:13 90:16 113:1
correlates 359:13	349:5,19 371:17	367:2,11	129:9 132:6 144:6 154:11
corroborate 73:13	coupled 44:1	created 52:13 95:8 234:11 351:18 359:11	165:20 189:8 251:1,16 259:3 279:11 330:7
cost 71:8 211:20 334:9 334:12,21 335:6 374:13	course 10:10 19:10 22:2 25:5 51:12 132:9 142:7 150:8 163:11	creates 239:2 creating 52:6 93:18 189:18 245:12 324:17	330:10 331:4,6 347:16 362:2
costs 99:17	192:4 285:19 286:15 291:5	338:2,3 353:9 356:5,15,16	critically 233:3 cro 114:3
council 350:10	293:18 296:6 298:17 304:2 310:7	creation 55:15 350:2 353:1 367:21	cross 73:16 crucial 165:15 188:12 268:5 269:3
councils 362:14	covariates 58:5	367:21	crude 110:1
counsel 350:7 380:11,14 381:7,10	cover 81:3 85:15 120:16	creative 72:4 77:18 277:8 296:8	crying 341:17 cultural 21:8 98:5 154:17 221:7 239:8 240:11,12,13 245:11 247:16 247:21 260:1 280:14,19 281:4,9,16 290:20 313:1 337:13 359:11
countries 82:15 84:10 85:6 118:12,16 149:17,18 150:2 152:13 160:2,20 197:14	covered 20:21 89:14 297:20	creatively 369:12	
country 69:20 84:16 85:7,10 120:5 184:19 225:1 236:8 240:21 241:1 242:1 244:5 250:18 288:10 313:7 344:1 358:10 369:2	covid 141:10 141:18 157:21 201:13,21 219:6,8 220:11 227:21 228:6	credibility 351:12 credible 351:15 351:21	
	covington 5:5 185:15 186:5	credit 104:5 374:16	
	craft 85:12	crept 159:15	
	crafting 112:21	crises 146:19	
	cranial 300:6	crisis 33:21 34:7 272:9 341:11	
	create 46:3 63:18 72:10		culture 250:8 281:12,14

304:20 305:2 337:12 curious 84:6 135:18 329:19 current 110:2 130:15 170:2 181:9 212:5 215:3 327:5 currently 32:2 87:18 88:3 92:18 110:13 118:19 129:4 202:11 334:15 curriculum 250:17 338:2 curse 246:14 curve 313:17 curves 313:13 314:3,8 customized 289:15 cut 90:19 112:18 cycle 264:2 cystic 77:8	dare 235:19 dark 175:20 176:11 data 2:20 9:17 23:19 24:1,7,8 26:13 48:15,17 48:18,21 53:15 53:19,19,20,21 54:3,6,7 57:14 57:21 58:1,3,3 58:10,14 59:5 59:7,13 64:3 67:14 70:2,13 71:1 73:5,9,13 75:2,11,14 76:16 77:4,5,6 77:13 80:4,11 80:12,14,15 81:6 82:12,16 85:21 86:2,8 87:21 88:17 90:11,12,20 91:4,18 98:21 99:7 101:1,14 105:2,7,8,10 105:19 107:14 110:1,19,20 112:6 113:3,4 113:4 118:14 123:4 126:19 126:21 127:4 127:12,14 128:9,12,18,18 129:6 132:20 134:2 135:4 139:5 142:21 143:4,7,9,21 156:13,14	160:21 173:13 174:5,15,16 175:4 186:9 191:1,5 194:13 195:3,15,17,21 196:18 199:3,8 199:19 202:5 206:17 207:2 207:21 208:1,7 208:12 214:14 218:1,7,14 221:4 252:19 255:20 256:3 256:10,16 272:18 301:8 302:19 308:3 308:16 309:3 309:17 310:16 310:17,18 313:12,19 318:9 319:3,8 321:13 326:16 330:21 358:6 364:19 376:3,6 376:9 database 59:4 databases 75:10 104:18 dataset 120:15 date 132:20 173:17 252:17 dating 55:16 55:17 dave 2:15 6:14 95:3,6 96:8 98:3 124:18 226:11 232:5 236:14 245:3	247:18 252:11 255:14 263:8 david 59:2 day 19:2 30:17 101:4 130:17 131:1 137:12 156:1 159:14 159:14 200:17 204:17 208:21 267:7 275:3,5 279:5,7,7 284:3,3 289:9 298:17 313:10 316:20 344:10 377:17 days 15:7 35:10 42:12 140:5 dcri 3:4,19 135:18 dct 353:6 ddlo 3:9 de 181:1 de&i 181:3 deal 196:1 dealing 143:4 261:3 285:18 293:10 deals 288:15,15 dear 9:10 death 137:4 150:5 247:2 272:15 deaths 89:2 debate 76:7 debated 114:19 debilitating 163:14
d			
d 8:1 daily 137:8 damaging 73:1 dana 302:8 311:20 377:19 dances 355:3 dap 28:19 29:11,13 30:1 30:2 348:6 349:5			

<p>decades 256:11 257:6</p> <p>deceived 280:3</p> <p>december 18:11</p> <p>decentralizati... 213:16</p> <p>decentralized 15:20,21 22:13 25:9,13,16,18 25:21 26:4 131:17 134:15 185:2 204:5 211:6,11 213:3 213:5,12 214:3 278:8 374:10</p> <p>decentralizing 204:7</p> <p>decide 275:6 280:2</p> <p>decided 37:20 195:20 363:21</p> <p>deciding 363:16</p> <p>decision 218:8 250:14 306:14 362:11</p> <p>decisions 99:18 123:5 125:17 220:21 222:17 306:19 319:6 333:19 361:12 362:5</p> <p>declining 84:14</p> <p>decrease 307:21 366:18</p> <p>decreased 73:6 186:18 303:21</p>	<p>decreasing 348:13</p> <p>dedicated 79:17 172:12 286:18</p> <p>dedicating 160:8</p> <p>deep 246:16 279:3 281:9 335:13 368:20</p> <p>deepens 91:12</p> <p>deeply 37:2 273:1</p> <p>define 116:17</p> <p>defined 227:11 300:17,18</p> <p>defines 193:9 259:19</p> <p>defining 260:21</p> <p>definite 105:19</p> <p>definitely 13:14 124:18 144:2 177:5 205:1 232:2 320:8 329:11</p> <p>definition 193:14,16</p> <p>degree 69:20 69:21 361:21</p> <p>degrees 225:6</p> <p>delay 171:4,14</p> <p>delineating 14:17</p> <p>delisle 5:10</p> <p>deliver 72:1 122:16 136:3 242:16</p>	<p>delivered 125:2</p> <p>delivers 311:14</p> <p>demand 262:3</p> <p>demographic 24:7 54:7 58:5 110:2 129:1 267:10</p> <p>demographics 68:2 140:11 283:3</p> <p>demonstrate 21:17 73:6 255:12</p> <p>demonstrated 310:8 313:3</p> <p>demystify 236:11</p> <p>density 274:2</p> <p>department 3:14 339:16 345:18</p> <p>depend 208:20</p> <p>dependent 193:3 241:2</p> <p>depending 133:21 171:11 177:2 284:17 295:19</p> <p>depends 117:2 209:10</p> <p>depression 259:15</p> <p>depth 19:18 100:21</p> <p>depths 118:19</p> <p>derm 93:6</p> <p>descent 199:2</p>	<p>describe 216:2</p> <p>described 139:14</p> <p>describes 28:20 28:21 30:8</p> <p>describing 107:15</p> <p>desegregated 30:3</p> <p>deserve 94:6 255:16,17 295:14</p> <p>design 23:10 85:16 112:19 112:21 113:7 122:15 135:19 137:18 141:21 142:9,16 144:10 202:1,7 202:15 204:1,5 263:19 270:13 271:1 275:10 299:7 325:12 348:15 350:11 359:10 360:9 366:18</p> <p>designated 11:4</p> <p>designed 126:8 173:21 178:17 201:15 278:6 311:4,8 313:1 336:10 356:3</p> <p>designing 73:20 243:16 305:13 347:13 356:2</p>
--	---	---	--

<p>designs 93:17 122:12 128:6 131:9 187:7 192:7 373:5 374:3</p> <p>desirable 141:21</p> <p>desire 304:14</p> <p>desk 320:5</p> <p>despite 19:21 170:10 171:18</p> <p>details 183:16 292:16 326:3</p> <p>determinant 159:18 284:18</p> <p>determinants 87:8 89:18 129:3 232:3 299:6 309:13 311:1,9 314:14 314:15 358:19 359:5,14</p> <p>determine 107:1 144:10 177:3 197:13</p> <p>determined 173:12</p> <p>determines 18:3 166:20</p> <p>deterred 160:4</p> <p>develop 126:5 163:12 187:7 189:16 196:17 214:21 242:12 267:14 278:3 286:10 330:16 330:16 331:1,6</p>	<p>developed 62:1 101:19 156:4 160:15 166:20 245:21 249:21 257:21 290:15 336:11 357:11 357:13 368:17</p> <p>developers 15:9 236:4</p> <p>developing 156:18 259:2 268:5 321:8 335:13,14</p> <p>development 1:2 3:7,16 5:3 8:7 9:8 10:2 15:13 29:19 79:18,20 80:15 81:12 82:5 91:11,17 100:17 101:13 101:16 112:9 127:15 145:13 146:9 148:1,5 161:8 170:1 178:19 189:13 192:9 206:3 215:15,17 218:15 258:5 258:12 270:18 294:19 349:2 362:15 364:4 374:9</p> <p>developmental 124:20 262:12</p> <p>developments 97:13</p>	<p>device 23:10,15 29:11,12 101:16 102:17 136:14 142:12 143:5 241:16 241:19 242:18</p> <p>devices 23:7,16 29:11 101:19 102:12 135:6 139:5 143:10 207:10</p> <p>devote 190:6</p> <p>diabetes 93:6 104:12,12,21 105:12,15,15 162:1,4,9,11 162:18 163:10 163:12,18,19 163:20 164:2 164:10,11,13 168:7 170:1,12 171:19 172:17 173:3,4,14,16 173:19 174:3,6 178:10 194:5,8 206:11 207:20 208:2,3,4,5 209:11,12 241:16</p> <p>diagnosed 33:20 164:7,10 164:18 165:3 173:18 235:10 235:13</p> <p>diagnoses 164:16 165:6 165:15 166:3</p>	<p>diagnosis 114:10 137:4 247:9 299:15 309:15 311:16 312:3,3,16</p> <p>diagram 283:21</p> <p>diagrams 283:2</p> <p>dialects 289:13</p> <p>dialing 158:5</p> <p>dialogue 250:5</p> <p>diane 9:11</p> <p>diaries 89:21</p> <p>die 41:19 147:1 241:13</p> <p>died 260:4</p> <p>differ 98:1 243:12 244:10 268:12</p> <p>difference 129:16 198:15 265:4 301:4 353:7</p> <p>differences 85:11 87:3,5 166:4,4 198:7 279:19</p> <p>different 15:2,5 15:12 16:11 18:9 19:17 20:5 23:19,21 24:2 30:15 52:4,5 65:1 76:15 85:13 98:5 121:13 123:16 125:1 127:13 129:8</p>
--	---	---	---

135:1 143:10	274:11 292:13	348:16	discomfort
143:10 174:16	338:10 368:6	director 1:7 2:5	341:9
183:9 195:7,8	difficulties	2:9,11,15 3:11	disconnect
198:4 199:18	116:7 203:15	3:15 4:3,6,10	151:14
204:6 225:11	239:4	4:15,18 8:10	discontinue
226:9,10 238:8	difficulty 132:1	8:16 44:17	301:16
240:14 243:13	dig 84:18	94:11 95:7	discontinues
243:13,14	digital 22:13	180:15,21	301:9
266:12 267:10	25:9 26:5,6	181:21 226:12	discordance
267:20 268:9	128:12 143:19	226:16 266:2	75:17
269:11,12	353:9 380:8	282:17	discover
270:4,5,19	381:3	directors 3:6	324:13
271:4,20 272:3	dignified 316:9	17:13 145:11	discovered
272:6,8,14,16	dionna 2:11	disabilities	234:21
274:1 277:14	6:12 94:10	24:18 352:13	discoveries
277:15,17,18	direct 132:5	353:8	189:15
278:1 294:11	134:16,17	disability 38:5	discovery
321:7 328:15	135:19 136:12	352:8,11	189:13
336:4 337:8	137:17 141:20	disadvantage	discrepancy
357:19 362:14	182:16 202:7	269:8 271:3	283:15
364:21 367:16	202:10 203:21	281:19 310:3	discrimination
372:6	203:21 217:17	disadvantaged	279:6
differential	261:11	325:13	discuss 19:16
129:7 165:14	directed	disaggregated	37:5 80:4
198:14 268:4,4	182:15 194:1	313:19	134:9 162:4,19
268:18,19	194:20 369:5	disappointed	163:5,8 169:21
270:1 271:15	direction 48:18	371:15	171:15 198:13
272:18 273:16	directional	disappointme...	198:14 235:6
differentially	61:17 92:14	40:1	266:21 271:16
164:13	123:20,21	disclaimer	271:17 272:13
differently	directions	45:17 80:2	315:20 337:2
31:9 50:14	163:9	disclose 17:21	337:16,19
97:11 234:2	directives	75:20	discussed 19:9
332:20 346:3	338:13	disclosed	19:18 24:4
difficult 53:21	directly 134:21	118:13	93:11 140:19
128:15 132:14	136:4 174:21	disclosures	170:18 264:8
150:13 156:16	176:19 253:4	132:13 298:15	282:14 321:16
160:4,5 239:2	290:18 294:12		321:19

discussion 94:10,15 119:6 156:11 161:15 197:20 222:5 223:2,12 224:9 237:9 245:19 248:17 315:4 322:9 335:9 336:19 350:5	267:11 274:1,4 293:3 297:1,7 299:15 301:13 317:10,11 331:7 373:9,21	disruptions 74:5 disseminate 289:1 356:8 369:18,19 disseminated 367:5 disseminating 255:7 dissemination 352:2 disservice 72:18 112:10 distance 38:14 209:4 distances 207:15 distancing 158:3 distant 207:13 274:9 distress 308:17 distributed 269:12 distribution 83:13 105:11 191:8 district 39:7 distrust 20:6 36:21 37:10 38:1 43:6 89:15 147:16 241:9 305:16 306:4 disturbed 127:17 dive 17:3 70:9	diverse 12:14 13:3 19:6 21:6 22:2 26:2,19 45:20 46:13 48:21 52:1,18 60:7 62:3,19 63:5 65:12 70:6 78:5 90:6 98:2 109:8 111:5 115:16 162:8 165:20 173:6 186:14 215:4 238:15 238:17 256:14 267:18 268:13 272:21 281:2 290:10 328:9 329:9 357:19 357:19,19 358:10 365:10 365:12 diversify 21:3 114:3 diversifying 22:14 diversity 1:1 3:13 8:7 13:6,6 13:8,13 14:12 14:14,19 15:19 18:1,7,15,17 18:18 19:4,20 20:18 22:20 27:14 28:5,8 28:14,21 29:4 29:6,9,18 30:13 53:1,12 65:9 66:2 67:4 67:6,17 68:8
discussions 19:11 31:2 156:16 224:18 271:10 350:4 368:6,14 372:1	diseases 3:12 23:9 81:15 102:13 103:8 104:13,15,20 107:7 119:15 120:7,8,19 121:7,8 196:4 198:3 207:1 208:11 327:1		
disease 13:9 23:20 24:1 34:4 41:18 43:5,9 58:16 58:19 60:13,17 85:3 88:13 105:7 114:21 115:2 117:2,12 118:5 121:4 122:20 123:2 137:1 139:11 146:6,10,11,13 147:6,18,19 149:16 150:5 153:7 163:11 163:15,15 178:12 187:17 187:17,18 198:6,10,12 199:17 209:10 209:21 210:2 230:18 233:5 235:10 241:7 246:18 249:4	disengagement 289:16 disney 320:21 disorder 199:18 233:5 disorders 162:2 disparities 46:1 46:18 193:3 268:2 283:19 290:17 301:21 dispersed 85:1 128:15 203:6 dispersion 83:18 85:8 disposal 127:18 disposition 66:8 disproportio... 166:2 disproportio... 74:2 137:1 179:5 273:18 274:6		

69:19 78:19	104:7 108:8	296:18 324:2,3	200:6 210:12
91:5 93:18	162:1 163:7	325:19 329:14	212:1 215:11
96:6 101:11	168:7 173:3	333:6,7 349:15	226:3 227:6
102:8,10,18	177:11 178:8	358:18 363:19	232:18,19
103:2 108:13	178:14 223:14	368:19,19	236:15 249:21
109:12,17,20	223:18 378:4	369:8 372:3	249:21 256:21
110:3 112:1	doable 347:8	dollars 340:5	311:5 312:21
113:1 117:6	doc 258:20	dominance	315:1,7,7,10
120:4 138:7	docket 28:13	83:14	315:17 316:16
142:5 152:7,8	docs 50:5 252:1	donoghue 3:11	334:1 345:2
162:4 163:1	258:17	7:5 180:13,14	363:14 371:3
166:14 167:14	doctor 37:7	190:4 215:6	draft 28:6
168:11 169:3	138:19 156:12	347:21	168:10 169:1,7
169:10 178:16	203:10 214:5	door 33:6	drafted 263:15
182:12 188:10	253:20 261:3,5	doors 43:8	drafting 22:4
190:18 197:8	291:5	117:20 273:4	drained 332:6
206:12 207:3	doctor's 253:18	doppler 157:13	dramatic
214:21 215:3,9	doctors 34:2	dose 218:10	198:16
215:15 217:13	119:17 210:13	dosing 133:1	dramatically
219:9,17 220:6	254:16 279:20	141:8	150:6
220:17 221:17	322:8 339:13	dotted 165:11	drastically
266:18 267:13	339:18 342:6	doubled 164:19	34:20
268:3 270:16	document	downloaded	draw 112:15
273:7 277:13	52:21 53:2	143:17	135:12,15
277:20 282:1,8	documents	dpmh 2:4 4:3	185:4
298:18 317:6	188:14 292:8	178:8	drawing 185:6
325:6 327:21	370:3	dr 8:12,16,20	327:8
328:3 348:10	doing 12:6,19	11:21 17:11,21	drawn 183:12
349:5 350:8	12:21 40:20	32:14 47:14	draws 240:12
351:5 358:19	62:7 68:21	49:11 54:10	dream 33:9
359:4,9 360:3	73:16 76:2,4	56:8 59:2	dreams 320:21
372:9,12,17	89:5 103:4	62:13 83:10	drill 76:12
376:10	104:3 157:11	94:10 96:3	86:10
divide 265:3	160:5 173:11	100:5 103:15	drink 11:14
division 1:8	176:8 177:4	103:21 116:19	drive 26:14
2:13 4:4,12	185:4 217:1,19	117:18 118:10	90:10 97:6
8:11,13,17	221:17 224:12	184:9 185:17	270:1,3
30:15 94:13	276:3 286:5,13	194:2,20 195:2	

<p>driven 24:8 48:12 102:4 211:20</p> <p>driver 101:21</p> <p>driver's 41:14</p> <p>drivers 67:5 310:19</p> <p>drives 285:12 285:12,13</p> <p>driving 97:12</p> <p>drop 71:17</p> <p>dropdown 60:8</p> <p>drug 1:13 3:16 18:12 29:9 86:1 88:4 101:13,16 103:1 146:9 150:9 152:16 161:9 170:1 171:12 189:13 189:13 192:3,9 201:3 203:1,5 204:1,3 218:14 236:4 268:7,7 268:8 299:7 314:18 323:2 327:1 329:14 374:8</p> <p>drug's 218:9</p> <p>drugs 29:7 66:9 101:18 102:12,17 162:7 166:19 170:11,14,19 171:5,8 172:16 173:9 187:21 196:8 207:9 331:1</p>	<p>due 118:13 125:10 138:15 172:1 201:2 274:11 346:9</p> <p>duke 3:3,3,18 131:11,12,20 132:4 133:18 182:9,10 201:16</p> <p>duly 380:5</p> <p>dummies 304:21</p> <p>duo 145:10</p> <p>duplicates 66:17</p> <p>duration 139:1 143:16 171:21</p> <p>duty 268:16</p> <p>dwellers 42:16</p> <p>dying 260:8</p> <p>dynamics 86:15,16 88:11</p> <p style="text-align: center;">e</p> <p>e 2:1,1 3:1,1 4:1,1 5:1,1 6:1 7:1 8:1,1</p> <p>e.u. 84:3 151:4</p> <p>earlier 48:10 52:3,9,21 53:18 55:1 59:16 74:7 83:3 92:9 111:13 114:4 148:21 170:18 171:7 173:14 188:4 215:11 218:1 230:10</p>	<p>232:18 235:9 291:2 293:14 293:17 295:5 342:14 360:2 363:15 365:9 366:12</p> <p>early 22:3 23:9 23:12 29:21 89:14 154:12 159:8 178:19 192:11 235:18 240:9 270:17 315:10 317:3 350:11 359:16 359:17 368:2 368:14 373:18</p> <p>ease 35:13</p> <p>easier 35:4 276:21 320:16</p> <p>easily 27:4 295:15 348:20 348:20,21 359:5</p> <p>east 48:19 181:10</p> <p>eastern 152:13 194:4,7 195:11 198:19 199:3</p> <p>easy 13:14 191:13 278:9 348:21</p> <p>echo 193:7</p> <p>echoed 298:16 304:12</p> <p>ecological 69:18</p> <p>economic 270:1,5</p>	<p>economically 22:1</p> <p>ecosystem 12:21 25:5,6 189:14 192:16 218:13</p> <p>ed 65:16</p> <p>edge 4:7 226:16 236:7</p> <p>educate 43:4 236:10 288:10 288:19</p> <p>educating 280:14</p> <p>education 25:5 119:17 123:10 126:7 234:4,6 240:7 241:5 242:5 270:7 282:19 288:1 289:8 320:15 338:3 351:20</p> <p>educational 123:10 182:2 285:10 291:1</p> <p>edwards 4:10 7:8 181:18,19 205:17 266:1 282:11,12 315:7 365:20</p> <p>effect 104:17 279:13 366:7</p> <p>effective 12:8 18:4 44:3 71:15 73:18 82:18 112:4 127:6 137:7 188:1 254:9</p>
---	---	--	--

267:15 291:11 294:3 297:21 320:15 328:8 356:21 374:13 375:15 effectively 72:1 244:21 245:1 292:17 effectiveness 136:14 165:19 effects 228:11 228:18 268:8 304:14 efficacy 149:11 218:9 268:4,12 304:13 efficiencies 335:2 efficiency 91:10 374:12 374:12 efficient 62:2 112:3 178:5 216:18 effort 12:18 78:11 158:17 173:16 175:3 199:9 220:14 295:3,10 332:16 365:3 efforts 19:21 20:17 48:16 65:20 81:11,19 196:9,12 326:21 egg 235:1 egypt 152:12 199:6	ehr 59:5 eight 86:4,9 195:18 235:3 263:12 either 90:13 124:4 241:11 253:20 312:3 314:3 358:20 359:1 elaborates 159:10 elder 274:19 276:9 elderly 338:12 electricity 153:20 electronic 75:16 89:21 128:17 135:7 138:11 elegantly 355:20 element 45:6 49:2,21 53:19 76:3 elements 16:1 25:21 74:8,9 74:10,13 213:16 324:15 elephant 108:11 elevate 60:6 elevated 219:14 eligibility 15:16 20:9 172:10 278:4 284:9	eligible 139:13 139:16 172:11 207:11,12 320:17 eliminate 136:5 eliminated 233:14 eliminating 259:10 eloquently 239:7 email 145:7 378:14 emails 139:17 embark 119:11 embarrassed 234:1 embed 310:9 embedded 37:2 310:11 311:19 314:17 embrace 367:4 emergence 127:21 emergency 2:14 94:13 241:20 emerging 110:7 115:15 emissaries 364:3 emotion 362:1 emotional 271:8 323:12 empathy 339:18 emphasis 167:8	emphatic 335:14 employed 380:11,14 381:8,11 employee 380:13 381:10 employing 22:11 empower 319:4 empowered 319:6 empowering 96:9 186:12 257:17 empowerment 258:14 enables 91:8 enabling 97:11 encounter 15:7 198:2 203:14 encounters 279:7 encourage 28:11 166:15 167:14,15 336:5 375:17 encouraged 23:8 77:3 encouraging 162:19 177:12 178:18 ended 143:1 endocrinolog... 161:21 endorsement 286:3
--	---	---	---

endowment 72:6	71:15 73:19 96:16 97:1	51:3,9 55:3 56:6 57:18	205:10 216:3 221:12,13
endpoint 97:13 330:9	117:19 219:12 221:9 222:12	59:15,18,19 60:4	272:3 326:17 enrollment
endpoints 321:13 330:6 330:19	223:11 224:10 225:16 234:4 236:3,16	enhancing 1:1 8:6 298:18	22:19 23:3,16 23:21 30:2
ends 49:21	255:17 258:11	enjoying 185:16	63:5 68:9,13 69:7,7 83:17
endurance 39:21 41:20 42:1 93:21	262:3 270:18 284:7,14,15 287:20 288:2,3	enjoys 35:12 enlarged 176:5	84:16,18 85:4 90:1 93:17
endure 36:12	288:5,8 289:7	enroll 15:15 21:19 26:7	106:7 107:10 150:19 168:12
enduring 33:11 36:7	291:10 294:3 297:21 317:2,6	37:7 81:17 85:6 87:12,14	169:4,11 172:1 172:5,9 175:13
energized 150:21	363:1 367:1 372:21 374:20	87:18 140:4 172:8,15	197:8 222:5 236:12 267:4
energy 368:10 371:14	375:13,14	205:14 216:5 267:1 268:18	274:8 291:18 299:1 301:4
enforcement 67:11	engaging 22:2 67:20 70:12	275:12 276:12 279:14 281:2	309:7 312:9 374:19 376:2,4
engage 23:11 64:21 68:11,15 123:18 233:6 240:17 243:3,9 259:9 260:18 271:9,16 277:1 280:9,19 284:16 285:2 288:10 290:2 309:1 337:3	117:10 154:11 156:10 205:19 250:5 273:2 281:17 342:8,8 engender 306:5 308:12,20	290:9 291:20 300:11 301:7 302:16 305:11 326:12 357:15 363:16,21 364:6 375:12 375:17	enrolls 300:3 301:21 ensure 14:16 21:5 30:10 42:16 54:5 72:12 75:9 158:5,10 177:21 183:7 217:2 263:18 289:8 290:5,6 292:6 326:11 343:14 368:14
engaged 64:17 155:2	engineers 23:12	enrolled 18:6 113:11 120:19 134:7 176:4,13 197:6 226:4 267:21 300:9 302:19	ensures 323:11 ensuring 67:4 67:14 78:19 124:16 166:8 314:12
engagement 4:15 16:9,10 20:13,15 21:5 22:12 27:8 28:1 33:3,14 42:4 48:13	england 148:15 english 70:13 313:5 enhance 25:10 26:2 122:8 236:9 268:13 268:17 enhanced 47:1 47:4,10 48:2,3 48:8 50:21	enrolling 13:3 66:16 69:4 71:21 87:18 149:21 157:2 189:3 190:17	

entails 291:4	326:5 327:10	59:20 60:4,9,9	essentially
enter 195:13	328:14 329:10	61:9,13 65:15	206:2 287:7
entering	333:13 338:6	83:5 101:12	288:18,21
284:17	343:6 345:1,6	115:14,18	establish
enterprise	346:13 349:3	143:11 165:21	178:18
21:11	353:14 354:14	166:18 167:21	established
enthusiasm	355:4,8,12	182:2 193:11	22:21 232:7
140:7	358:15 359:2	273:8 287:19	establishing
entire 29:18	359:15 360:20	287:21 298:12	22:18
141:2 263:11	361:19 364:11	310:18 325:6	esteemed
275:5 317:5	365:6 370:15	333:6 372:10	315:19
entirely 95:18	equal 164:12	375:14,21	estimated
116:21	263:10 264:3	er 89:2 341:10	134:6
entitled 169:3	271:7	era 152:10	estimates 58:16
entry 281:20	equaled 247:2	eradicate 43:17	86:11
enviable 371:6	equipment	eric 377:19	et 12:6 60:16
environment	156:9	erythema	62:21
63:19 189:7,19	equipped	136:16	ethical 269:4
231:9	218:19 219:1	es 380:4	ethics 325:5
environmental	equitable	escalated	ethnic 13:5
89:19	190:18 243:4	341:11 342:2	47:14 51:19
environments	250:3,4 251:18	esma 112:16	54:14 56:16
52:13 63:12	267:15 308:16	especially	58:3,8,12
270:6	314:10,12	21:11 48:12	61:10 67:14
epidemiology	equity 2:9 3:13	68:19 75:5	73:2 105:8
129:13,17	42:20 44:18	97:4 98:17	137:2 138:7
epps 2:4 6:17	45:4,15,16,19	99:10 137:18	164:20 166:2
8:13 32:14	46:4,12,17	137:21 141:18	167:17 168:5
108:6,7 109:6	47:1,2,4,10,15	184:7 186:8	168:13 169:5
223:13,15,17	48:2,3,3,4,5,8	214:10 238:14	169:19 198:13
226:2 227:6	48:15,17 49:4	243:8 244:14	238:16 244:4
232:15 238:11	49:4,6,10	247:6 254:14	268:9 269:9
239:5 248:6	50:10,21 51:4	256:15 291:17	271:20 273:19
256:18 263:7	51:9,10 53:19	297:7 343:20	274:7,17
265:10 314:19	55:3 56:6,19	371:1	358:19 359:4,9
315:16 318:4	56:20,21 57:5	essential	ethnicities
321:3 322:2,18	57:14,18,21	352:17 367:15	104:19 365:1
323:21 324:21	58:1 59:15,18		

<p>ethnicity 30:4 53:2,15,20 54:3,5 60:12 66:4 67:9 75:11,14 76:5 105:4,6,9,11 105:15 106:10 110:6,10,15 117:11 118:4 118:12 140:16 166:6 169:11 173:2,3 174:17 175:6 176:6 178:16 191:6 225:1 232:8 272:19 299:2 300:13,14 301:5,14,18 310:20 313:20 373:13</p> <p>ethnocentric 251:2</p> <p>europe 150:1 181:9 214:12</p> <p>european 214:13</p> <p>evaluate 26:3 177:19 285:6</p> <p>evaluating 100:15 136:13 165:18</p> <p>evaluation 80:18</p> <p>evening 277:9</p> <p>evenings 136:2</p> <p>event 31:7</p> <p>events 285:10 355:7</p>	<p>eventually 101:20 287:12 290:9</p> <p>everybody 8:21 9:6 10:11 32:9 42:2 65:5 79:11 108:7 136:20 223:21 224:3,5 225:19 248:8 333:5 349:21</p> <p>everybody's 106:5</p> <p>everyday 237:4</p> <p>everyone's 330:14</p> <p>evidence 18:3 73:6 105:13 218:2</p> <p>evoke 362:1</p> <p>evolving 208:10 343:11</p> <p>ex 152:1</p> <p>exact 35:1</p> <p>exactly 34:4 49:10 109:16 129:17 368:19</p> <p>examination 105:1 139:11</p> <p>examine 83:21 185:10 298:21</p> <p>example 15:20 16:4 23:14 24:14,17 25:17 26:5 49:12 50:3,13 51:13 52:2 59:21 60:15 62:5</p>	<p>63:9 69:18 75:13 77:10 84:20 85:8 86:2,14 87:16 88:10,19 89:13 97:8 106:14 110:4,17 112:15 117:3 128:18 131:18 132:18 133:3,9 135:10 153:16 155:9 162:5 174:18 185:4 204:6 206:12 206:13 212:9 212:14 213:4 214:11 220:21 221:15 239:19 244:4 245:20 258:6 274:3 330:8</p> <p>examples 24:13 91:18 131:8 133:20 135:1 220:11 272:18 279:2,12 280:11 349:19 353:5 373:5</p> <p>exceed 91:5</p> <p>exceeded 219:9</p> <p>exceedingly 73:18</p> <p>excellence 3:16 8:5 112:19 180:17 209:16 209:18 343:13 344:1,3,4</p>	<p>excellent 130:3 146:4 187:12 189:14 195:2 196:10 206:13 223:2 328:8 373:5</p> <p>excerpts 78:14</p> <p>excessively 73:21</p> <p>excited 40:10 126:18 127:21 131:17 202:14 261:17</p> <p>exciting 196:18 281:14 298:9</p> <p>excluded 23:15 302:5 353:11</p> <p>excluding 24:17 83:17 278:5 353:10</p> <p>exclusion 357:14</p> <p>exclusivity 167:11</p> <p>excuse 142:15 288:10 293:20 308:18 332:8</p> <p>execute 159:18</p> <p>executed 87:11</p> <p>executing 151:20 159:11</p> <p>execution 159:13</p> <p>executive 2:15 3:15 95:7 226:12</p> <p>exemption 29:12</p>
--	--	--	---

<p>exercise 157:4</p> <p>exist 229:17 235:18,19 329:17</p> <p>existed 234:18</p> <p>existing 61:21 106:11</p> <p>exists 111:18 127:5 192:20 234:18 339:7</p> <p>expand 114:4 128:8 290:19 324:9</p> <p>expanding 369:1</p> <p>expansion 82:5</p> <p>expect 83:18 84:5 198:16</p> <p>expected 69:7 189:6 221:14</p> <p>expecting 306:19</p> <p>expects 91:3</p> <p>expensive 134:3 210:19 211:14,15</p> <p>experience 44:1 67:20 82:1 96:13 102:7 122:6 141:17 147:15 187:5,6,8 190:21 192:2,5 192:15 193:1 194:19 209:14 215:3 226:8,21 227:1 231:16 237:5,14,18</p>	<p>244:12 248:3 253:17 264:1 269:11 271:12 271:14,15 272:15,19 279:6,17 307:12 330:5 336:2 337:6 338:19 339:7 351:3</p> <p>experienced 65:1 84:12 184:14 235:2 341:8 344:17 344:21</p> <p>experiences 28:1 45:2 64:18 229:12 280:6 299:3 302:4 304:4 337:8 344:13 344:14</p> <p>experiencing 43:1 344:19</p> <p>experiment 303:9,13</p> <p>experimentat... 279:5</p> <p>experiments 303:3</p> <p>expertise 43:21 130:11 153:2 185:8 346:1</p> <p>explain 27:12 30:7 233:11</p> <p>explainable 279:4</p>	<p>explaining 76:1</p> <p>explicit 245:19</p> <p>explicitly 270:19,20</p> <p>exploring 59:11 118:19</p> <p>exponential 71:10</p> <p>exposed 238:19</p> <p>exposure 136:11 313:15</p> <p>express 64:20 356:10,11</p> <p>expressed 162:13 339:16</p> <p>extent 18:6</p> <p>external 106:3</p> <p>externally 160:8</p> <p>extra 47:8 59:17 278:3 293:9 300:6 307:15</p> <p>extraordinary 78:11</p> <p>extrapolate 233:6 252:5 259:2 372:15</p> <p>extrapolated 308:8,13 372:13</p> <p>extrapolation 90:12 127:8,10 128:11 148:20 149:10 224:15</p> <p>extremely 222:13 235:4</p>	<p>eye 163:15 317:20</p> <p>eyes 106:6</p> <p style="text-align: center;">f</p> <p>fabulous 377:15</p> <p>face 27:9 32:20 40:3 89:12 146:9 178:16 272:7 274:17 275:13 308:4</p> <p>faced 89:13 154:4 171:15 171:17 178:11</p> <p>faces 32:18</p> <p>facilitate 248:1</p> <p>facilitating 185:6 253:1,4</p> <p>facilitators 302:12</p> <p>facing 294:9,11</p> <p>fact 19:21 36:7 53:9 62:6 75:5 109:8 116:21 120:17 124:21 147:10 148:19 189:9 207:21 208:1 237:10 279:11</p> <p>factor 20:16 35:18 115:13 209:4 284:18</p> <p>factors 13:11 23:11 66:7 85:15 88:12 89:19 129:1 138:3 166:5</p>
--	--	---	--

191:11 208:20 270:1,21 facts 78:12 failing 250:1 failure 147:2 fair 114:15,20 115:8 295:10 fairly 50:4 148:13 fairs 285:12 faith 62:17 89:16 288:13 288:15,16 320:2 fall 70:11 312:18 familiar 133:7 families 31:10 35:9 74:1 124:15 133:13 134:21 142:20 143:21 144:11 192:1 202:8 203:14 210:2 211:9 214:2 245:2 265:18 266:13 269:18 270:4 271:4,6 273:3 275:20 276:12 277:6 277:11 279:6 281:20 282:15 293:12,18,19 295:13 298:2 304:1 308:1,5 308:11 309:1 309:18 311:15 312:2,10,15	313:4 323:9,18 325:13 331:15 332:9 333:19 336:18 337:16 337:18 342:8,9 342:18,19 356:1,19 357:1 359:18 361:5 364:16,21 365:4 375:17 family 32:6 33:15 35:7 36:12,21 37:1 39:12,16 40:3 42:4 59:4 74:5 132:5,6,10 134:17,18 135:19 136:12 137:17 139:5 141:20 143:18 144:9 182:17 201:20 202:7 202:11 204:1 212:12 235:17 244:17 245:14 246:14,19 247:4,5,6,10 247:17 269:20 272:1,4 275:6 276:15 280:3 280:16,18 281:10,11 291:13 292:3 293:5,10,10 294:9 295:4,7 304:8 306:18 307:13 316:7 323:8 332:9	356:12 361:12 family's 134:10 135:12 136:4 139:4 212:10 266:21 270:10 271:12 272:12 279:13 337:6,8 337:12 fantastic 378:6 far 107:9 119:6 203:16 208:19 320:4 339:14 359:17 371:5 farber 302:8 311:20 fascinating 96:16 faster 90:10 93:18 127:19 father 304:19 306:9 fatigue 330:12 favorite 46:3 fda 1:4 2:3,4,12 2:19 3:10,12 4:3 8:4 10:20 11:6 12:2,6,7 12:19 14:11 18:8,14,18 28:9 29:17 30:13 36:3 45:14,18 52:11 52:14 56:12 62:2 63:7 103:20 104:11 105:21 106:2 108:8 115:5 118:15 126:4,7	132:21 148:20 149:3,11 159:20 161:14 162:6,15 166:15,20 167:5,13,19 169:9 170:3,4 170:6 175:7 177:12 178:14 180:17 186:8 193:12 196:4 197:20 198:15 210:13 214:20 215:8,12 223:19 258:10 258:10 321:5 323:1 324:16 330:3,18 334:17 348:8 348:20,21 357:11 362:21 369:5,12,19 370:6,11,14 371:20 372:3 fda's 10:20 162:19 166:13 179:2 fdae 349:4 fdora 18:12,13 28:7 fear 279:5 304:12 fearful 281:17 fearless 144:21 fears 24:11 242:6,7 337:10 337:18
--	---	---	--

feasibility 68:2 311:18 312:7 feasible 11:9 141:2,21 217:21 309:13 310:9 311:12 314:16 344:8 feature 64:11 features 22:13 25:14,19 347:1 fed 231:12 federal 11:1 67:10 71:9 300:20 federally 62:6 340:7 fee 295:21 feed 275:6 feedback 188:12 203:4 262:12,17 263:4 264:1 357:20 358:13 363:7 368:3 feeding 192:6 feel 11:17 33:4 65:19 92:14 96:11 98:20 102:9 157:1 173:10 187:21 189:19 190:12 209:7 225:3,7 231:14 233:21 237:3 238:4 239:12 245:6 245:13 248:4 257:8 269:2 280:20 322:12	325:17 331:10 339:2,21 340:1 342:11,15 347:2,10,10 352:9 354:16 355:5,6,15 367:6,18 feeling 225:9 235:16 336:21 343:2 feels 40:11 98:16 253:3 265:7 277:1 325:7 367:6,8 fellow 179:2 360:5 fellowship 179:2 291:7 felt 96:12 136:7 138:2 141:13 224:19 235:17 235:17 females 164:12 164:13 fewer 68:12,17 fibrosis 77:8 field 129:21 133:4 194:16 365:16 fiengkeng 4:18 6:6 17:12,16 315:2 fierce 108:12 figure 165:2 176:5 188:15 205:10 271:18 273:20 277:12	figureheads 286:2 file 260:9 final 78:17 169:13 finally 20:12 36:14 43:17 76:3 377:11 378:3 finances 332:6 financial 38:20 39:11 99:12 136:7 162:16 272:2 274:15 275:18,21 310:6 331:15 financially 160:11 380:15 381:11 find 17:9 50:6 82:19 107:2 142:18 191:3 223:8 238:8 251:8 307:18 320:11 328:7 340:9 finding 235:14 250:11 306:10 346:16,16 findings 240:9 268:14 285:15 fine 214:8,15 finish 37:18 191:18 260:3 314:20 finite 207:8 firm 79:13 226:17	firmly 122:18 first 8:15 11:21 14:18 15:3 17:20 33:3,21 34:7,7 44:13 48:1,5 49:7 59:6 65:10 80:6 86:17 95:2 98:15 101:5 120:20 121:14 131:10 139:7,19 141:3 141:3,9 142:8 146:1 147:20 159:1 162:17 182:14,16 201:10 206:11 207:18 208:20 225:15,20 236:20 237:18 243:6 252:14 253:16 255:11 263:14 273:14 277:19 283:1 286:7 291:21 300:2 305:5 312:10 314:12 316:4 338:18 351:8 354:20 365:18 373:3 firstly 178:7 fit 205:8 258:8 fits 361:8 five 61:6 71:7 84:7 173:8,19 175:6,21 261:5 331:12 371:10
--	--	---	--

fixtures 11:4,5	focusing	257:15	30:17 44:8
flashing 138:14	302:11 330:14	forging 368:20	45:12 81:7
flexibility	folks 98:18	forgot 202:15	84:5 92:3,6
38:20 202:3	224:1,6 225:14	378:10	106:6 110:9
flexible 277:3,9	227:14 228:9	form 30:8	113:19 157:8
flexibly 136:1	230:20 240:11	70:17 271:17	163:9 178:1,3
flip 134:20	248:7 249:1,8	287:7,12	184:6 192:21
floor 354:10	249:17 250:12	288:20 292:2	242:7 243:2
florence 2:16	260:2 265:14	formal 9:21	331:8 365:18
6:15 100:10	339:3 377:21	35:6 214:21	foster 42:3
floridian 51:12	378:17	formalities	43:2 63:18
flourish 189:7	follow 24:15	33:2	found 51:3
flow 143:8	92:12 116:3	format 28:20	105:10 112:16
focus 45:11	141:5 184:10	formation	117:4,19 141:1
55:6 81:19	232:16 239:6	230:19	141:20 144:4
82:3 91:9	256:19 259:7	formed 362:3	201:21 207:11
95:18 100:12	266:1 282:6	former 71:6	240:4 242:4
101:17 102:4	328:16 353:14	forms 22:9	301:2,15 362:9
109:11 130:17	353:15 375:4	71:12 72:7,13	foundation
148:7 177:7	followed 83:14	72:16	117:4 144:15
205:19 206:4	234:16	formulate 94:4	269:21
250:21 253:10	following	formulation	founded
258:8,12,15	121:2 324:8	148:10	317:10
262:14 282:2	font 353:3,3	forth 33:18	four 36:7,8,12
288:2 299:5	food 1:13 11:12	42:13 44:2	40:18 42:12
309:10 346:8	18:12 101:2	333:15	46:20 51:15
346:20 358:18	150:8 158:14	forthcoming	81:3 95:17
focused 63:10	270:7 307:8,10	340:21	111:15 136:18
78:8 82:13	312:10	fortunate	139:2 170:13
95:15 104:11	force 277:11	124:8	309:18 313:6
112:19 147:3	forced 230:13	fortunately	373:20
147:12,17	305:3 327:7	143:8 203:8	fragmented
148:2 236:9	foregoing	forum 4:11	323:10
237:8 302:15	380:3,4 381:4	76:7 181:20	frankly 72:19
344:12	foremost 80:6	182:1 266:3	146:20 147:6
focuses 57:9	foresee 214:21	290:14	149:20 159:9
120:4 299:13	forget 153:5	forward 11:21	free 11:17 53:6
	156:11 253:21	15:17 17:4,7	136:8

frequency 34:10 69:8 frequent 40:13 friday 1:11 friendly 326:6 friends 35:13 36:13 44:9 front 68:7 103:5 347:13 frontline 299:1 300:12 301:4,7 301:16 305:11 310:11 fruit 325:8 346:19 348:8 349:18 352:4 353:1,12 355:15 fruits 51:11,14 frustrations 255:18 fulfill 19:2 fulfilled 167:10 fulfilling 79:17 full 111:21 129:9 296:1,21 302:2 357:13 fullest 331:20 fully 71:18 91:3 120:15 160:2 212:18 254:17 fun 78:12 354:18 355:2 functionally 278:5 fundamental 101:11	fundamentally 85:13 funded 55:2 59:1 66:14 69:1 71:9 132:18 173:17 funding 56:11 56:12 67:10 72:5 104:1 132:12 284:10 funds 346:16 further 13:2 69:17 84:14 178:10,21 179:3,7 221:11 222:5 324:19 370:14,19 380:13 381:9 future 93:11 106:12 119:11 163:9 177:8 192:7,9,11 214:9 268:6 303:21 fy21 51:10 fy24 50:20	286:4 319:7 365:9,11,17 gaps 177:5,10 177:21 179:8 340:9 garnered 159:8 gas 331:17 gatekeepers 360:7 362:2 gather 43:14 305:9 gathering 316:6 gbt 147:3,17,20 149:19 150:19 156:17 158:9 159:3 198:6 357:5 gbt's 198:20 gcp 182:18 gear 28:3 gen 230:10 gender 66:4 88:21 238:16 249:5 gene 117:13,15 119:14 120:8 120:17 250:9 general 10:19 19:11 24:4 29:2 96:14 104:19 105:5 106:19 114:9 115:3,4 129:18 139:20 163:17 generalizabil... 28:16 115:18	generalizable 75:7 90:20 113:3,4 115:12 267:19 generalize 103:7 generally 107:1 177:4,12 203:12 216:14 283:19 generate 218:7 326:13 327:3 generation 2:15 95:7 124:9 125:19 125:21 226:13 230:6 237:7 238:2 256:15 373:1 generational 246:14 265:3 generations 118:2 228:3,4 generators 154:2,3 genetic 199:18 247:7,8,14 genome 73:17 genotype 199:19 genotypes 199:18,21 geographic 55:21 69:14 142:4 191:8 276:21 374:1 geographical 118:4 136:8
	g 8:1 gain 285:4,4,17 gaining 236:4 gallbladder 34:17 games 242:1 gap 85:20 111:17 112:2 112:12 171:1 179:3 232:2		

geographically 357:18	344:3 361:11 371:13	213:16 217:16 223:7 225:20	359:4
geographies 150:6	gives 30:9 91:19 106:13	238:11 242:8 248:14 256:11	going 8:3,16 9:5 10:16
geography 137:19 198:3 200:1	130:1 155:16 218:8 257:4	259:14 260:11 260:14 263:7	11:20 12:2 13:18 14:17
geolocate 56:3	giving 78:17 104:18 228:14	266:7 281:5 284:2 287:8,14	15:1,15 16:12 16:13,14,19
getting 26:2 192:19 202:21 208:12 214:1 222:9 228:9 262:17 276:5 280:10 301:9 332:5 335:3 367:4 368:3	262:11 glean 358:5 global 3:16 118:11 120:1,6 146:6 175:10 176:1 182:17 196:3,9,12,14	287:14 288:21 293:8 295:21 316:11,14 322:3 324:1,19 326:16 334:3 334:14 335:3 339:20 340:9 342:19 347:11 350:14 360:15 370:2,19 371:5 374:15 375:6,7 375:8 376:15 376:16 377:12	17:14,18 18:7 18:10,20 19:16 28:3 31:1 33:16,17,18 34:4,19 36:9 36:11,12,14 37:6,6 41:10 41:18 44:2 45:10,13,14 46:6,15 48:1 49:9 52:14 55:10 57:14 59:11 70:3,8,9 78:2,10 79:4 79:19 80:11 81:3,16 82:3 83:11 84:2,5 85:2 90:6 94:9 95:1 96:1 99:6 102:9 105:17 110:20,21 111:11 113:19 118:7 120:21 121:1,12,13 122:1,7,21 125:20 129:15 130:2,8,18 131:4,6,7 146:7 152:16 152:16 154:13 156:15,21
gi 261:3	globally 194:6 206:20	342:19 347:11 350:14 360:15 370:2,19 371:5 374:15 375:6,7 375:8 376:15 376:16 377:12	
gift 252:4 295:18 331:19	go 8:3 11:20 12:3 15:8 17:20 19:18 33:11,18 37:18 38:7 41:5 43:10 46:6 48:6 59:12 63:2 70:5 79:4 85:5 90:4 94:16 105:18 108:4 113:20 114:13 117:5 120:4 128:6 130:18 131:4,6 133:14 152:11 153:3 156:2 157:10,11,12 162:12 180:3 182:5 183:15 187:9 200:16 211:2 213:11	goal 82:4 90:18 91:5,21 114:8 114:8,9,10 140:4,5 173:1 187:16 266:12 373:11,16	
girl 51:12		goals 22:19,20 23:4 30:2,7,8 112:13 169:10 178:18 188:14 197:8 216:21 284:9	
give 10:9,12 11:15 17:18 32:8 39:9 41:15 44:13 70:8 80:20 104:5 125:16 150:11 154:2 155:9 173:5 204:14 239:19 261:21 264:2,3 264:4 295:16 348:11 371:9 371:17 374:16 377:3		god 38:8 goes 24:9 96:21 190:9 216:13 300:11 313:11 336:17 338:9	
given 87:9 88:7 91:21 93:9 96:3 102:7 289:13 327:8			

160:6 161:13	290:10 292:1,2	180:20 181:18	graphics 126:3
162:17 167:20	292:3,3 294:8	185:15 186:4	271:5
168:2 172:20	294:8,12,13,17	188:5 200:5	graphs 301:3
174:7 176:2	296:18 297:3,6	217:21 226:3	grassroot
178:1 179:15	297:8,8 298:12	227:2 242:1	324:10
187:20 189:17	306:12 307:18	264:8 266:9	grateful 32:10
192:3 197:11	314:20 315:10	282:11 303:14	gray 165:9
199:5,12 207:2	315:11,16	313:10 314:8	183:17 185:18
207:9 209:6,15	318:2 322:9	315:15 317:15	great 1:15 73:5
210:18 212:3	327:11 333:5	318:16 321:14	77:13 79:3
214:5,12 216:5	334:15,21	321:17 351:3	90:3 91:5
216:6,7 220:16	335:6 338:6	373:11 376:7	100:19 106:1
220:18 223:4,7	340:21 341:19	goodness 55:12	110:13 113:12
223:10,12	342:1 343:3	google 59:19	114:18 118:17
224:1,3,4,20	347:12 348:1,3	gotten 33:1	118:19 119:5,8
227:16 233:10	349:3,4,15	333:1	120:10 129:21
233:12,15	351:7 352:16	government	144:14 145:19
236:14 240:18	353:10 354:11	147:7 194:9	161:20 184:16
241:1,13	354:11,12	228:13,16	188:19 189:1
242:11 243:20	358:2,7,9	241:4	190:1 194:13
244:6 245:4	361:3 362:16	grab 378:13	196:20 200:9
248:20 249:12	366:3,9 370:4	grade 321:12	203:7,20 211:1
250:2 251:12	371:17 372:16	grand 10:8	211:3,14 213:4
252:18,19	376:12,12	grandfather	213:12 214:9
254:18 255:1	gold 116:13	247:11	214:10 220:11
256:16 258:19	good 8:2,21	grandkids	221:17 241:6
260:3,12 262:9	12:4 17:16	242:19	246:4 269:21
263:8 265:12	31:17,18 71:13	grandma	292:12 297:8
265:16 266:4	79:11 85:7	242:17,19	307:1 315:8
266:11 269:5	88:19 92:2	grandmother's	316:19 341:8
271:5 272:20	102:11 103:1	235:2	354:14 359:20
273:4,11	108:6 114:6	grandmothers	375:10,20
275:12,15	115:12,14	246:15 247:9	greater 102:18
276:14 278:12	116:3,5,6,11	grandparents	132:10 148:6
280:21 282:3,5	116:14,17	89:16,20	149:1 164:9
282:6 283:1	137:6 161:17	grant 56:11	300:19 310:14
284:12 286:8	170:21 173:5	graph 313:12	310:15
286:21 289:14	173:11 180:13		

<p>greatest 159:4 greatly 175:19 green 2:11 6:12 94:11,17 103:15 106:1 107:5 115:20 118:7 119:2 126:10 165:10 175:20 176:12 313:20 grievance 339:17 groceries 311:14 grocery 331:18 ground 236:8 267:8 286:9 319:16 320:9 324:10 342:11 groundswell 324:19 group 4:7 17:8 65:12 70:6 106:15 132:13 144:9 149:2 164:10 169:12 174:20 194:11 216:6 225:2 226:16 227:8 227:11 229:12 236:7 237:10 238:8 243:18 244:1,1 250:21 253:8 258:12 258:15 262:14 263:1 299:19 299:20 310:8 310:21 343:16</p>	<p>350:13 351:2 353:11 363:8 364:4 group's 299:5 grouped 174:15 346:3 groups 55:6 104:16 126:5,9 137:2 174:14 177:5 226:10 258:8 264:14 267:11,16,20 267:20 268:9 269:10 272:7 272:15 273:19 274:17 278:5 278:16 282:8 285:3 328:6 343:13 345:19 346:17 351:19 356:21 362:3 369:14 grow 61:7 112:12 324:9 growing 60:21 272:2 grown 51:1 growth 50:21 51:6 gsa 10:21 guess 9:6 109:6 118:21 194:10 194:15,19 200:20 224:20 327:20 334:7 343:18 365:8 373:15</p>	<p>guessing 65:4 guidance 14:15 15:11 18:18 28:6,9,10,12 28:17 30:8 52:20 53:1,2 53:13,14,17 54:2 124:6 162:21 167:12 168:10,11 169:2,7,13 178:16 188:13 215:16 362:21 guidances 30:13 guide 32:16 205:9 guidelines 183:9 guinea 228:15 gun 272:15,16 guys 17:4 168:16,18,20 266:7 378:6</p>	<p>49:20 50:5 285:16 291:1 halted 84:10 hamper 75:8 hampshire 1:14 hamstring 73:20 hand 87:17,21 119:20 120:1 133:10 141:11 335:20 359:4,4 hands 32:7 204:8 254:16 hanging 325:8 346:19 348:8 349:17 352:4,5 353:1,12 355:15 happen 63:18 204:4 233:13 254:14 297:6,9 328:12 347:4 356:4 366:3,10 368:11 happened 37:14,15 40:18 63:8 157:6 235:9 happening 50:1 84:7 92:18 206:14 206:15,17 234:5 305:8 350:21 happens 14:8 40:18</p>
		h	
		<p>habits 200:18 hair 240:13 288:9,16 hairdressers 288:17 half 34:16 47:4 50:16 82:20,21 90:19 140:1 141:9 307:9 hall 62:7 234:7 halls 43:4,13 45:5 49:8,16</p>	

happy 31:12 145:6 158:12 182:12 183:21 233:18 257:11	45:15,15,16,18 45:19,20 46:1 46:4,12,17,17 47:2,15 54:9 61:8,13 64:3 87:8 89:19 95:19 104:7,21 108:9 118:15 128:17 129:3 135:11 137:14 138:5 139:3,8 165:21 166:4,5 166:9 178:8 182:2 184:21 193:3 212:10 223:14,19 227:20 229:8,8 232:4 234:15 236:11 239:2,4 241:3,5 242:14 242:15,15 245:7,21 247:16 259:6 259:15,19,21 260:9,19 267:11 270:2 279:8 282:19 285:11 287:19 287:21 288:11 288:13,15,16 296:21 299:6 309:13 311:1,9 314:14,15 317:9 340:7 358:19 359:5 359:14 375:14 378:4	healthcare 43:18 50:5 62:6,10 64:21 77:11 129:8 189:14 192:16 192:19 193:2 203:10 226:17 230:2 238:10 253:18 267:14 270:8 273:15 273:17 274:6 280:2,4 297:12 330:2 338:12 338:19 341:15 healthy 228:21 231:13 259:20 259:20 hear 20:17 22:19 38:13 39:17 42:21 43:1 47:13 78:13 101:6 106:1 108:19 109:7 114:5 124:10 145:17 148:1 149:20 188:7,19 219:5 227:8 262:7 265:7 298:10 322:19 327:15 347:18 361:14 361:17 362:9 370:21 heard 11:16 17:17,21 18:17 25:8 36:19 50:8 55:6 65:19 66:2	100:20 103:21 105:2 106:3 123:8,19 158:21 159:3,5 204:16 217:21 224:18 233:17 235:13 245:5 255:11 268:16 278:7 284:2 289:9 295:5 298:16 299:10 301:19 302:14 303:2,19 304:1 304:3,12,15 305:5 306:6 307:20 308:19 312:19 316:1 332:7 334:20 342:14 343:2 347:16 348:5,7 348:18 360:1 361:19 367:7 367:18 370:16 372:2,7,18 373:4,17 374:3 374:10 375:10 376:2 hearing 38:8 239:9 351:9 359:16,17 heart 37:2 heath 5:7 114:1 114:2 heather 377:19 heavy 11:2 160:10 heickman 3:9 7:3 83:10
--	---	---	--

161:13,16,21 185:17 194:2 194:21 195:1 197:1 207:18 215:11 heidrun 5:3 213:1 345:10 height 157:19 held 17:19 hello 100:8 114:1 181:6 226:6,14 help 17:8 20:18 21:4 22:16 26:1,18 28:15 30:10 35:13 41:3,20,21 43:2 91:4 106:6 112:1 113:17,19 122:7 127:18 139:5 143:18 144:10 151:8 153:9,10 228:6 263:2 265:17 266:13 267:2 275:20 276:7 276:14 282:14 286:3 303:8 307:18 337:16 348:17 352:8 354:4,9,10 355:18 369:19 378:18 helped 40:9 80:18 354:6 helpful 16:6 190:15 267:7	332:9 334:10 334:13 352:17 357:5 362:10 helping 32:15 35:3 36:1 114:3 148:2 160:12 221:9 242:6 336:20 361:2 helps 54:5 293:7 323:9 330:16 351:11 hematology 4:13 266:5 hemoglobin 146:15 hepatitis 60:16 117:4 hereto 380:15 381:11 hesitancy 245:6 hesitations 304:10 hey 317:21 332:21 335:20 340:21 354:1 358:6 363:5 hi 32:7 95:6 180:5,13 193:19 210:12 226:11 229:9 298:6 321:5 hide 342:16 hierarchy 155:2 high 4:8 39:5,6 43:7 58:18	59:8 73:18 85:8 95:13 104:14 111:4 119:14 126:13 150:10 152:1 163:13 190:11 213:20 284:13 300:5 313:18 321:18 326:12 327:2 377:1 higher 88:17 91:7 119:16 153:5 163:17 166:3 209:21 213:11 214:5 236:12 highest 89:1,2 89:2 174:2 175:16 190:16 194:8 241:7 highlight 26:18 45:4 53:11 56:15 57:16 85:10 101:15 117:18 132:5 141:17 163:3 218:12 220:4 292:3 322:7 highlighted 54:21 140:12 171:6 highlights 81:6 170:21 highly 141:2 149:17 244:6 244:14 hilary 2:3 6:5 12:1	hildebrand 5:3 119:4 213:1,2 345:10,11 hindrance 274:7 hinge 211:6 hinted 183:3 hispanic 165:8 165:8,10 174:18 175:17 175:20,20 176:9,11,11,14 283:15 299:3 302:9 304:5,17 309:18 313:4 313:21 314:1,2 hispanics 104:14 historic 221:4 historical 10:13 81:4 82:1,7,11 88:17 89:4 91:8,16 92:2 93:10 116:7 240:18 259:16 278:20 280:13 280:14 331:4 historically 12:13 21:12 23:14 37:15 121:1,8 138:7 147:13 218:13 234:9 302:5 330:20 history 92:5 119:8 170:2 189:2 207:2
---	--	---	---

235:14 236:1 247:6,10,17 280:19 304:16 323:17 337:13 hit 34:8 201:15 211:5 hitch 201:19 hmm 355:11 hobbies 200:19 hold 178:9 234:11 holders 362:11 holes 191:5 holistic 294:5 298:1 375:16 home 33:4 37:19 42:10 135:11,12 136:4 139:3,3 139:4,8 141:6 184:12,21 189:10 212:10 212:13 228:4 292:2 324:11 341:12 355:10 homes 142:20 144:12 211:9 212:10 honest 254:19 honestly 189:1 honor 370:21 honored 32:5 honoring 260:3 hope 33:11 36:10 40:7 41:20 42:1 45:4,7 91:18 92:1 94:1,1	113:16 118:20 122:2 148:12 149:6 180:10 202:5 248:16 265:10 266:20 hopeful 224:6 225:12 hopefully 144:18 245:1 299:8 303:15 314:17,19 375:3 hoping 70:16 hopkins 228:8 horizontal 277:14 horrendous 228:10 hospital 2:14 33:5,6 34:13 37:18 41:4 42:9 94:14 100:11 123:1 207:14 230:21 260:11 261:18 271:13 332:1,2 332:5 341:10 342:3 354:7,17 355:2 hospital's 41:1 hospitalization 34:10 hospitalizatio... 34:19 35:17 36:9 42:11 hospitals 43:13 102:15 133:13 151:15 265:21	305:1 host 66:6 285:10 hotel 157:20 hour 130:19,20 295:6 306:12 306:15 hours 134:7 136:3 155:20 200:17 341:16 house 143:9 200:14,15 household 300:16 313:14 313:15 housing 181:12 307:7,9 how's 252:18 hub 47:5,10 51:4 57:18 59:15,18,20 213:21 huge 41:15 58:9 98:21 99:4 143:1 150:11 191:5 230:18 248:12 257:15 283:14 324:17 353:7 hugging 191:9 huh 37:20,21 258:9 human 26:9 43:20 120:20 368:20 humanization 45:6 63:14	humility 281:9 281:16 hundred 119:10 146:12 186:18 hundreds 231:20 hunger 242:1 husband 34:6 37:4 39:5 110:18 hybrid 200:12 201:5 212:17 hydrochloroq... 201:1 hydroxychlor... 136:15 137:8 138:18 141:8 203:9,18 hydroxyurea 198:8 hypotheses 305:14 hypothesis 56:16 307:4 hypoxemia 146:21
i			
iana 5:9 378:1 ibd 180:9 ican 2:7 4:9 31:15 32:4,6 41:6 44:6 65:8 74:21 78:17 180:6 227:4 317:15 366:21 367:1,12			

iceberg 372:19	illustrates	impacting	important
icf 222:7	138:9	162:20 166:14	10:11,14 12:12
335:13 336:10	illustrations	impacts 74:2	13:6 18:2 24:5
ide 29:13	72:10,11	164:13 179:6	26:3,13,19
idea 50:15	image 283:6	359:13	27:2,2,8,13,20
301:10 312:16	289:6	impede 266:21	32:15 43:5
329:17 343:19	imagination	281:19 328:4	45:1 52:6
354:15 355:1	106:18	impediment	54:19,19 56:2
357:10	imagine 99:2	216:18	61:12 63:14
ideally 18:5	134:2 155:20	imperative	64:10 65:11
292:8	157:18 271:14	242:8	71:5 76:2 81:4
ideas 28:1 70:7	272:1 280:7	impetus 81:9	83:20 91:9
78:5 264:8	376:21 377:9	240:5	93:15 104:17
307:1 308:19	imaging 209:8	implement	117:12 118:5
identified 66:4	immediate	154:6 156:7	122:3 125:5
89:5 177:10	292:21 293:3	188:16 288:5	137:18 138:2
239:11	immediately	349:1	144:1 154:9,17
identify 67:5	351:21 370:11	implementati...	155:10 156:6
69:14 70:16,18	immigrants	151:9 188:11	166:8 168:21
110:5 139:12	98:4	357:8	170:16 175:9
153:10 195:8	immigrated	implemented	183:16 188:6
268:2 290:16	246:17	157:5 159:10	191:16,20
identifying	immigration	348:3	200:1 211:5
151:5	181:13	implementing	217:8 220:1,3
identity 230:19	immunology	155:12 159:21	222:14 224:16
237:1 249:5	83:14	357:6	225:8 227:19
337:9	impact 43:5	implications	233:3 239:16
idiopathic	76:14 86:15	71:19 183:3	239:20 245:9
202:12	91:10 165:14	implicit 261:4	253:15 254:1
ignore 363:3	166:2 273:18	implying	255:3,7,11
ihc 241:10,11	294:13,13	191:21	257:4,16 267:9
illinois 42:8	297:3 309:7	importance	270:12 277:19
illness 24:15	318:13 357:14	26:19 53:11,18	280:12 281:11
43:9 238:20	impacted 164:2	64:13 65:17	281:11 292:20
332:1 365:16	187:18 199:4	75:3 124:15	317:18 318:1
illnesses 128:16	impactful 44:3	132:6 144:7	325:3 326:3
illustrated 72:7	324:4 326:13	158:19 166:12	327:20 331:13
72:13,16 162:5	362:19,20	220:19 290:20	339:19 352:4

355:7,14 356:6 360:18 362:1 368:10 375:14 375:16 importantly 14:6 268:15 270:2,9 279:9 impossible 118:1 362:8 impressed 246:9 373:6,6 376:8 improve 28:15 81:12 91:21 106:7 137:14 168:11 169:4 177:6 192:15 193:1,3 266:18 277:13 282:8 303:21 307:1 323:1 333:18 341:3 372:17 improved 86:8 313:3 improvement 159:12 340:2,8 340:16 improves 248:2 improving 15:18 314:16 inadequately 12:13,15 incarcerated 272:11 incarceration 272:7 incentive 329:17 331:16	331:18 332:7 incentives 275:16 295:2,3 296:4,5 328:19 328:21 329:7,8 329:14,15 inception 364:4 incidence 174:5 206:19 incidents 164:6 164:18 165:3 165:11 include 20:6 30:2,6 70:6 121:14 215:4 275:15 293:13 322:8,10 358:7 358:9 included 28:13 29:12,14 30:1 82:14 96:4 224:13 225:3,7 225:10 254:7 258:7 347:10 355:6 includes 65:11 95:20 132:9 141:4 174:19 262:15 including 12:10 24:3 46:12 85:16 92:3 135:16 166:3 168:3 172:10 174:13 215:3 219:15 257:9 263:17 289:17 323:2	inclusion 3:14 25:11 130:18 186:13 194:4 352:9 357:14 inclusive 131:8 198:18 204:17 204:19 347:3 347:10 350:3 351:18 352:14 365:10 373:5 374:3,13 inclusivity 65:15,20 66:21 282:6 290:11 323:2 income 271:19 311:15 312:2 312:15 incorporate 14:19 15:8 23:10 25:20 31:9 335:4 348:5,17 366:18 incorporated 321:19 348:15 incorporating 192:11 253:9 321:12 323:15 incorporation 121:19 incorrectly 75:12 increase 48:13 71:11 110:19 111:7 165:1 298:4 374:11	increased 140:7 142:4 276:13 increases 84:12 increasing 19:3 109:10,12 110:4 111:5 164:8 165:6,14 171:14 267:13 348:10 374:12 incredibly 64:10 118:5 128:14 129:4 134:3 142:10 142:13 150:13 289:10 350:18 incumbent 191:17 india 84:13 98:4 indian 165:7 173:20 175:18 176:15 177:13 179:4 195:14 240:4,21 241:1 241:2 242:1 260:9 indicate 133:12 240:10 indicated 149:9 indicating 306:2 indication 86:11,12 88:12 88:16 112:6,7 297:1 331:7 368:4
--	---	---	--

indications 81:16 82:15 86:10 92:19 93:1,8,10,15 119:12	330:2 331:5 332:21 343:12 345:16 346:10 349:11 358:1 362:10 365:21 369:20	259:15 285:20 289:1,2 305:9 306:7 309:6 312:20 318:12 318:17,21 319:5 324:7 350:15 351:16 356:8 369:19 370:12	81:18 145:12 367:16 innovations 56:5 innovative 115:15 236:6 307:21 innovators 3:21 368:21 input 19:3 96:4 124:13 130:11 192:10 317:4 326:2 347:17 insecurity 307:9,10 312:10 inside 4:6 226:16 236:7 345:12 insight 285:17 311:11 358:5 insights 64:8 93:11 101:2 inspire 299:8 inspired 136:10 inspiring 369:6 instances 127:3 institute 2:21 3:4 64:4 131:12,21 132:4 133:19 182:10 institution 269:16 296:7 297:16 institutional 70:21 269:13
indicator 69:3 indigenous 3:20 179:2 226:5 individual 66:7 111:16 133:12 136:10 232:20 244:17 245:11 259:13 284:3 individualized 259:11 individually 145:5 individuals 15:6,14 32:11 73:2 146:16 148:2 189:6 274:21 356:11 industries 106:4 industry 10:2 16:21 66:14 67:16,18 68:6 68:8 79:15 81:4 82:13 92:14 123:3 147:8 168:11 181:7 211:19 213:14 214:18 215:3 249:12 285:1 287:11 318:8,18 322:21 328:11	industry's 79:21 inequities 299:12 310:19 314:17 inextricable 317:6 inflammation 83:14 influence 67:6 67:16 influences 68:8 inform 88:18 113:17 127:5 293:19 informatics 100:13 information 21:9 26:17,21 27:3,5,6 29:4 50:7,7 58:13 68:1 70:20 75:1,20 76:2 77:17 81:14 82:3 94:3 101:6 111:19 115:6 118:12 133:1 163:10 189:10 218:9 224:17 255:2,8 255:21 256:5 256:17 257:13	informative 123:18 informed 22:9 125:17 157:20 253:2 254:18 291:14 307:2 313:2 350:12 infrastructure 68:18 172:12 211:13 214:14 infrastructures 100:14,14 ingelheim 4:20 206:10 inherent 187:13 initial 23:4 190:20 215:21 initially 148:9 initiative 11:1 47:1,12 48:2,3 51:1,9 55:3 60:19 287:14 290:13 injustices 43:18 272:7 innately 124:4 innovation 3:6 8:5 15:19 56:6	

275:17 278:14 284:8 institutions 249:11,13,13 249:15 252:13 255:15 264:16 308:21 327:19 356:18 374:21 instructed 138:17 insulin 170:5,9 insulins 241:18 insurance 128:18 181:12 300:17 313:16 insurmounta... 274:16 integral 77:20 192:8 integrate 178:15 integrated 264:1 323:6 integration 142:21 143:8 intellectual 240:8 intelligent 123:4 intend 30:7 intended 28:17 90:21 113:5 intensive 128:15 274:21 275:1 intent 46:10 intention 122:14 368:13	intentional 113:14 122:12 122:15 156:18 199:5,11 236:10 247:17 353:8 373:17 intentionality 275:14 intentionally 368:17 intentions 125:8 interact 16:19 359:6 interacting 362:16 interaction 192:19 interest 21:10 60:13 71:20 162:16 282:21 interested 73:3 140:1 144:17 380:15 381:12 interesting 54:17 55:5 197:19 317:17 326:19 329:6 355:13 364:19 interlinking 356:20 internal 56:12 106:2 internally 71:9 160:7 international 2:6 31:14 32:3 41:6 180:7	227:5 internet 153:17 235:18 interpersonal 269:14 278:14 284:5 interpret 195:16 interpretable 321:13 interpreted 162:15 interpreters 292:7,12 intertwined 119:7 intervention 103:8 138:10 138:17 142:11 241:12 242:2 311:13,17 312:2,5,8,14 312:15 interventional 73:7,8 77:7 245:13 interventioni... 240:16 252:2 interventions 103:3 129:9 142:15 235:8 267:15 268:6 311:8 314:14 interview 90:4 112:16 122:1 interviewed 89:8	interviewing 91:6 interviews 78:15 305:18 intestine 95:13 intimate 308:12 intimidating 277:2 intramural 56:11 intrinsic 366:3 introduce 8:15 100:6 179:21 182:6 223:17 224:5 225:20 226:1 265:15 introduced 74:8,10 introduction 150:18 162:18 234:14 introductions 31:3 180:4 introductory 17:11 invention 142:15 invested 147:7 270:16 investigate 179:3 investigated 166:10 investigation 29:7 84:14 173:8 349:7
--	--	---	--

investigational 29:12 207:9 217:20,20	329:10,18 334:18 353:20 356:2 371:12	198:1,2,13 203:8,19 208:9 231:18 241:9 328:13 333:15	jobs 39:3,7 181:10 277:7
investigations 178:21	involves 124:1 304:6	issued 28:6,9	john 228:8 join 20:8 130:12 179:16 223:1
investigator 67:13 145:1 222:4 247:20 290:2	involving 360:8 367:14	issues 10:1 17:2,5 20:9 65:15 75:8 143:19 147:19 200:21 202:18 234:15,17 278:13 280:21 284:4 285:17 294:9 357:1	joined 182:4 208:7 joining 9:1 94:19 96:1 378:21
investigator's 67:3	iphone 143:15 iranian 229:15	issuing 167:6 296:4	joints 185:10 jokes 38:9 jokingly 332:1 journal 148:15
investigators 21:3 68:13 113:17 124:3 213:20 253:3 284:11 290:7	irb 70:20,21 71:6,8 72:12 325:18 332:13	item 48:1	journals 263:13
investing 369:9	irbs 211:12 325:4 332:19 333:1	items 325:14	journey 33:12 41:8 134:11 319:4
investment 68:18 211:18	irrespective 65:7	iteration 120:9	judgment 37:21
investments 122:7 123:7 346:15	isabelle 249:21	ivd 99:8	judgment 37:21
invisible 38:5 194:11	ish 201:11	j	judgment 37:21
invitation 54:12	islander 165:9 174:20 176:17 177:1,14	james 377:19	judgment 37:21
invite 8:16 9:20 17:14 94:10 103:12 362:10 362:15 374:5	isolate 363:20 isolated 227:18 235:17 250:18	jargon 260:2 260:15 264:21	judgment 37:21
invited 64:8	isolation 231:18 232:2 232:19 238:14 238:18 248:9	jennifer 4:19 206:8	judgment 37:21
inviting 180:18	israel 206:18	jennings 32:17	judgment 37:21
involve 358:1 360:6 367:20	issue 18:18 71:5 75:19 89:17 101:10 108:21 117:17 118:16 128:21 138:6 194:18	jerk 156:19	judgment 37:21
involved 22:6 39:1 109:7 144:9,13 224:14 329:2		jo 3:20 6:18 47:14 49:12 54:10 62:13 264:19	judgment 37:21
		job 1:19 38:20 56:14 76:5 99:5 186:4 269:21 318:1 377:15 378:6	judgment 37:21
			k
			k 2:13 6:13 k23 212:7 kaiser 269:20 keen 259:10 keep 36:14 40:19 52:7

111:1 160:17 252:3 262:6 293:17 295:8 295:16 297:12 361:17 keeping 31:3 79:3 176:18 224:13 293:14 293:20 343:3 kelly 311:7 kenya 156:12 kept 36:9 252:17 key 19:20 20:15 21:2,7 21:16 27:17 29:3 45:3 47:16 97:21 135:3 151:6 154:14 160:3 204:19 211:8 278:4 325:14 326:2 371:9 373:2 keynote 31:13 134:11 ki 3:15 7:7 181:7 214:19 kicked 145:20 kid 41:17 306:10 355:18 kid's 149:6 kidney 163:15 350:7 kids 39:17 41:1 41:3 66:1 70:5 78:12,17 98:17 101:12 102:2	125:12,15,19 126:1 149:5,7 158:12 166:16 171:6,14 257:9 343:15 354:10 354:16 355:1 355:15 356:1 361:5 364:16 370:17 kind 34:5 40:7 106:11 122:11 123:8 129:20 189:1 191:19 198:11,14 199:10 200:9 203:18 205:9 205:11 217:12 232:5 238:7 261:14 262:11 262:11,17 263:4 296:7 316:2 325:19 332:21 347:21 359:15 360:12 364:9 371:13 371:15 376:9 kindergarten 370:18 kipp 3:20 6:18 47:14 49:12 54:10 62:13 116:2,20 226:3 226:4 227:6,10 232:18,19 236:15 239:21 249:19 258:4 315:10,17,18 316:11,14,17	319:9,14 345:2 363:14 kipp's 117:18 kira 311:5 kite 75:2 kits 312:9 knee 156:19 335:13 knew 200:14 200:16 205:6,7 370:17 knock 296:7 know 9:7,15 12:11,12,14,20 13:20 14:7 20:14 32:19 34:4,21 35:9 36:11 37:5,9 37:14,14,21 38:8,12 40:18 41:11 42:17,20 45:7 46:3,16 46:18 48:16,18 49:2 50:17 55:12 58:4,21 59:13 61:14,14 63:1 80:14 88:19,21 90:5 92:6 93:9,13 93:20 97:4,10 98:7,12 99:7 99:21 106:6,11 107:7,8 108:21 109:15 111:4,6 112:21 114:7 114:13,19 115:8 116:14 117:14,21	118:20,21 120:13,18 121:6 122:6 123:15 124:2 125:4,9,11,11 125:11,17 126:20 128:2 128:14 135:18 138:3 146:18 151:18 152:8 153:6,7 160:21 183:3,6,7,16 184:9 185:2,9 185:9 190:8,9 190:14,15,15 190:17 191:8,9 191:15,19 192:8 193:10 193:13 197:18 199:20 200:13 204:12 205:5 205:10,21 208:15,21 211:7,9,10,12 213:4 216:3,10 216:17 217:1,5 217:7,12,13 218:21 219:5 222:6 224:14 225:5 226:8 228:4 229:3,10 230:20 232:7 232:12 233:19 234:5 235:19 237:19 238:12 238:16 239:20 239:21 242:11 242:17 243:9
--	---	--	--

243:15 244:3,6 244:7,12 245:16 247:5,5 247:10,20 248:8 249:7,14 249:15,17 250:13 253:14 253:18,20 255:1,10 256:6 257:2,10,11,13 258:1,11,17 261:11,13,15 262:5,6,14,17 265:1,7 267:10 267:18 268:7 268:11,16 269:9 270:4 271:3,19 272:6 272:14 274:5 274:14 275:18 276:2,4,10 277:4 278:17 279:8,10 280:5 280:18 286:15 286:19 287:11 289:3,12 290:6 291:5,6 292:5 292:10,13,21 293:8,9,17 294:21,21 295:7,9,13,20 295:21 297:4,5 297:6,10,10,12 301:20 309:12 309:14 314:10 315:21 318:20 320:3,4 321:8 321:9,11,12	324:6 325:10 327:12 329:1 329:14,16,16 331:3,17,18 332:11 334:4,6 334:8,8,11,14 334:21 335:3,5 335:6,17 336:1 336:1,2,15,20 337:5,10,12,14 337:17 338:1 338:12,14,21 339:2,3,6,7,8 339:18 340:1 340:15,18 341:1,18 342:1 342:9,18,21 344:19 345:3 346:14,16 347:3,9,14 348:1,2,9 350:11 353:21 354:20 356:17 356:19 357:6 358:6 359:11 361:8 364:11 365:16 366:1,2 367:4 369:10 370:3,7,16 371:8 372:2,16 373:10 374:8 374:18 375:7,9 376:1,2,21 377:8 knowing 17:7 199:2 209:16 247:17 263:3	knowledge 75:7 82:5 94:4 179:2 192:6 290:19 380:10 381:6 known 32:4 45:19 173:3 287:17 knows 157:6 333:5 kols 156:10 korea 84:11	284:7,8 333:14 lacking 68:6 ladies 266:8 lag 171:9 laid 72:2,13 lands 241:5 landscape 79:20 86:15 91:8 101:1 151:5 170:3 language 20:10 21:7 27:3 50:15 57:8,13 71:4,16 98:12 126:6 181:13 254:9,11 260:1 260:16,17 265:2,4 284:5 289:13 292:9 292:11 313:5 347:6 languages 53:8 222:10 large 69:19 82:21 95:13 104:17 148:13 179:18 191:9 345:7,15 347:5 353:11 largely 109:21 183:1 327:5 344:14 larger 37:1 68:11 85:10 297:16 largest 38:16 59:5 164:21 173:15 283:6
		I	
		I 95:21 97:17 100:3,19 102:6 103:9 107:12 108:2 109:3 111:11 113:12 114:15 121:16 124:8 130:3 lab 135:15 152:17 320:5 label 85:21 88:4 121:14 132:21 136:12 244:13 296:17 labeling 111:20 labor 51:11,15 274:21 laboratory 135:15 lack 20:12 21:9 21:10,10 50:2 51:8 58:2,4,6 71:2 172:12 194:18 201:6 221:10 278:18	

<p>lashell 3:13 7:6 180:21 214:18 217:11 219:4 219:20</p> <p>lashelle 181:7</p> <p>lastly 23:18 163:8 268:1 277:3 286:17</p> <p>latch 254:13</p> <p>late 43:11 85:4 92:17 247:1 267:7 363:17</p> <p>latinx 283:15</p> <p>latoya 4:6 7:13 226:15 232:17 264:17 319:14</p> <p>launch 201:17 282:4</p> <p>launched 46:21 47:4,12 60:19</p> <p>lauren 3:9 7:3 161:13,20 179:14</p> <p>law 83:3,4 93:3 166:18</p> <p>laws 83:11 183:11</p> <p>lawyer 317:8</p> <p>layer 196:19</p> <p>layers 117:14 190:5</p> <p>lead 181:2 248:20 279:3 315:17 368:9</p> <p>leader 89:8 90:9 112:17 144:21</p>	<p>leader's 90:15 90:18</p> <p>leaders 37:4 49:11,16 62:21 63:16,17 89:16 117:5,8 151:6 154:14,16 250:16 285:4 288:1,16 360:6</p> <p>leadership 95:20 263:19</p> <p>leading 97:2 137:3 170:17 171:13 236:7 253:1</p> <p>leads 236:12 257:3</p> <p>lean 368:5</p> <p>leanne 44:5</p> <p>leap 122:11</p> <p>leaps 210:3</p> <p>learn 121:11 126:21 127:11 277:15,19 278:1 303:10 303:15,16 370:17</p> <p>learned 64:18 89:11 130:16 139:19 141:19 163:8 177:17 179:11 183:5 212:15 316:3,5 339:15 369:5 370:10 377:16</p> <p>learning 30:18 121:4 144:17 184:2 213:19</p>	<p>248:20 290:16 369:9</p> <p>learnings 316:21 369:13</p> <p>leave 313:8 315:10</p> <p>leaving 252:9</p> <p>lebanon 199:6</p> <p>led 67:6,17 68:9 95:18 132:21 150:12 171:2 236:1 311:5</p> <p>lee 2:8,13 3:15 6:9,13 7:7 44:16,19 94:12 95:21 97:17 100:3,19 102:6 103:9,21 107:12 108:2 109:3 110:12 111:11 113:12 114:15 116:19 118:10,17 121:16 124:8 130:3 195:2 256:21</p> <p>left 72:15 87:17 133:10 161:19 165:5 166:17 167:18,21 169:15 174:8 176:19,20 271:18 283:2,5 313:12 366:2</p> <p>legal 183:2,8 184:2</p>	<p>legislation 67:7 67:12</p> <p>length 65:14 85:17 127:17</p> <p>lens 236:18 237:17 282:7 298:13 317:13</p> <p>lesson 160:3</p> <p>lessons 130:16 163:8 177:17 212:15</p> <p>letters 139:18</p> <p>letting 341:16</p> <p>leukemia 304:20 305:12 311:20</p> <p>level 20:12 86:11 91:7 105:14 150:10 155:11 158:7 190:11,16 195:6 229:20 236:3,9 238:18 244:9,17,17,18 259:21 260:1,1 269:13,14 275:17 284:1,4 284:13,15 328:12 342:11 344:2</p> <p>levels 251:3 270:5</p> <p>leverage 25:16</p> <p>leveraged 301:8</p> <p>leveraging 23:18 113:15 126:20</p>
---	---	---	---

<p>lewis 4:4 7:10 265:19 266:9 266:16 315:7 325:1,1 369:4</p> <p>lgbtq 62:15 229:16 281:7</p> <p>liaise 286:1</p> <p>licensed 139:9 142:20</p> <p>life 5:5 33:12 34:14 35:4 40:10,15,18 81:6 99:18 186:5 219:3 241:11 244:13 247:1 254:16 256:11 306:15 308:4 322:13 355:7,9,10,16</p> <p>lifecycle 374:8</p> <p>lifelong 236:2</p> <p>lifetime 36:17</p> <p>lift 160:10</p> <p>lifting 331:14 332:7</p> <p>light 138:14 174:19 175:21 176:16,20</p> <p>liked 202:9</p> <p>likely 93:1,4 166:21 172:14 265:9 326:13 327:3 366:17</p> <p>likert 305:20</p> <p>lily 1:7 6:3 8:9 79:10,11 378:6</p> <p>limb 241:11</p>	<p>limit 295:12 306:13</p> <p>limitation 144:1</p> <p>limitations 76:10 136:8 142:7 174:13 195:4 306:17</p> <p>limited 23:16 70:13 71:18 173:8 176:3 215:14 273:14 274:5,15 275:1 327:2 373:13</p> <p>line 36:2 103:13 145:16 165:10,11 183:12 206:1 214:15 288:21 289:4 293:14 300:20 313:20 313:21 314:1 356:20 359:21 366:10</p> <p>lines 239:6 326:15 338:9 347:13</p> <p>linguistic 313:1</p> <p>link 122:1</p> <p>linked 300:21</p> <p>lipid 162:1</p> <p>liraglutide 170:7</p> <p>list 2:2 3:2 4:2 5:2 30:12 66:5 91:15 139:16 140:9 249:11 253:19</p>	<p>listed 58:17 66:15</p> <p>listen 78:6 243:19 289:5 368:2,3</p> <p>listening 42:16 42:18 52:18 124:1,16 146:3 155:11 242:6 330:4,14</p> <p>literacy 21:8 26:7 71:18 143:19</p> <p>literature 106:21</p> <p>little 17:6 28:4 40:14 41:16,19 47:13 48:10 52:3,9,21 53:18 54:11 55:1 57:19,20 59:16 84:19 86:17 95:4,11 101:10 103:16 107:17 109:5 119:7 126:13 128:9 140:16 144:5 168:14 174:15 176:7 184:1 203:19 205:18 208:19 209:12,20 213:10 237:21 238:2,9 260:8 262:10 284:12 289:7 292:13 294:7 306:4 343:18 355:8</p>	<p>358:16 378:16</p> <p>live 13:10 34:5 38:14,17 42:7 148:4 228:3 231:17 345:8</p> <p>lived 44:1 45:2 96:13 113:6 181:9 192:18 226:21 260:5 264:1 271:12 271:14,15 272:19</p> <p>livengood 1:18 380:2,18</p> <p>lives 254:15 300:20</p> <p>living 89:19 95:10 300:18 331:11 332:1,2</p> <p>llc 2:10</p> <p>loaded 360:21</p> <p>local 72:9 135:14 259:21 259:21 260:1 336:20</p> <p>location 90:5 118:4 142:19</p> <p>locations 10:21 84:4 102:16 274:13</p> <p>logistical 152:15 153:13</p> <p>lois 2:13 6:13 94:12</p> <p>long 57:12 61:7 81:17 86:6 91:17 98:21 99:6 127:3</p>
---	---	--	--

136:17 148:4	285:11 298:2	looks 22:1 48:9	306:21 307:11
160:9,18 172:1	300:3 301:8	114:7 176:8	307:16,20
203:13 218:14	317:13 319:18	187:17 264:5	308:19 316:20
237:4 238:21	321:1 325:11	lose 36:10	318:19 322:11
256:9 257:6	330:18 331:6	lost 39:14,15	322:12,17
293:2 342:20	332:19 347:8	275:19 345:21	323:3 327:13
354:12	360:18 365:2	lot 20:1 25:8	334:6 340:11
longer 36:4	looked 59:3	27:7 28:1	352:10 361:10
44:8 172:7,15	74:9,10 86:7	32:12,19 35:4	366:16 369:10
172:16 207:15	92:16 104:10	35:8,9 37:10	371:9 373:17
260:21	140:16 198:20	40:12,13 48:16	374:4 375:10
longitudinal	199:21 200:2	70:7 78:5,7	376:3,4
73:16 308:11	232:3 233:7	80:11,15 82:2	lots 135:1
longstanding	240:3,4 300:8	88:20 98:17,21	230:21
53:3,4 287:13	300:13,16,17	99:17 101:14	loud 217:7
look 15:18	300:20 301:12	107:2 114:5	love 3:5 6:20
16:11,11 17:2	301:14 330:21	122:9 123:9,17	93:21 94:21
44:8 51:17	376:7	123:20 124:1	96:4 112:5
58:10 59:8,21	looking 10:15	127:11,18	124:10 127:8
67:7 69:1,10	16:4 17:4,7	138:5 140:20	145:11,17,19
70:1,8 72:6	30:17 45:12	141:19 143:3	188:7,19,21
73:9 75:16	48:11 51:18	147:18 152:5	190:6 197:18
77:15,16 86:17	55:20,21 56:1	155:13,14	199:16 239:5
92:5,8 106:12	60:5 63:4 81:7	158:14,14	317:15,15
110:1 112:6	92:3 102:7	168:7 183:2,17	349:5 362:15
114:6 117:12	113:10 116:13	194:12 195:4	365:15 378:19
119:11,12	151:11,12	200:12,18	loved 35:13
120:6,7 121:21	152:7 165:2	201:11 202:3	281:3 317:21
122:21 123:4	171:8 187:5	209:2 218:11	320:1
125:3 128:6	190:10,19	221:5,7 224:16	lovely 77:10
177:2 190:12	205:13 220:20	229:14 230:6,8	150:17
191:2 192:16	221:1,12 233:4	242:13 245:5	low 74:3 85:3
199:19 214:10	255:20 300:4	248:15 250:15	142:13 175:14
219:7 233:3	318:8,14 330:6	253:2,13,14,17	311:15 312:2
235:5 240:21	330:7,10,20	255:21 264:7	312:15 325:8
250:4,20 258:4	345:12 350:8	276:10 284:2	346:19 348:8
259:1 274:1	360:2 365:13	294:16 304:21	349:17 352:4,5
283:1,18 284:1	367:16 376:9	305:16 306:16	353:1,12

355:14 lower 73:12 149:8 160:21 353:3 lowest 190:16 241:8 lump 234:21 235:15 lunch 130:19 lungs 185:9 lupus 136:11 136:16,21 137:10,14,18 137:19 138:5,7 140:17,18 142:1 144:15 202:12 203:13 lurie 128:3 lurie's 34:12 42:9 luxury 68:14 122:21 275:3 lyft 276:3 lynne 4:3 6:4 8:16 11:20 321:5	152:11 263:5 342:14 344:9 362:5 363:13 363:14 magnified 70:1 magnitude 89:12 149:12 main 54:4 192:17 205:3 253:10 355:1 maintain 25:17 74:14 249:16 374:21 maintaining 298:18 major 70:14 72:18 90:1 137:12 138:6 184:4 273:15 274:7 278:15 321:21 majority 73:12 108:19 172:6 244:5 263:14 299:16 304:6 make 8:18 13:16,21 14:4 16:2,8 18:5 27:3,5 33:4 51:21 77:4,6 77:17 78:4 98:14 99:18 112:7,13 123:4 125:17 129:9 129:16 143:12 156:5 158:2,14 168:15 181:3 187:19 189:18	204:13,17 209:6 216:21 220:20 222:17 225:7 231:15 250:14 262:21 281:13,14 287:16 292:14 293:4 294:19 295:12 296:9 297:17 306:14 306:19 319:6 320:11,15,16 320:20 329:1 335:16 336:14 342:13 344:6 347:2 349:14 353:2,7 357:20 358:10 366:10 makers 218:9 362:11 makes 245:14 248:4 317:19 338:8 347:9,10 363:8 making 12:8 74:19 76:5 99:21 109:19 128:5 156:3 175:14 189:4 199:8 204:19 205:4,4,12,19 206:2 274:11 333:19 352:13 357:18 361:12 378:12 malarial 137:9 male 164:14	males 164:12 malfunction 143:5 maltreatment 304:17 man 261:13 305:4 manage 39:18 204:8 manageable 34:12 managed 138:18 142:11 214:6,6 management 77:8 136:14 142:12 220:17 230:18 manager 5:4 managing 2:10 79:12 178:14 mandate 328:19 mandated 323:16 366:1 mania 346:10 manner 64:21 299:6 map 133:10 140:11 mapped 89:3,4 mapping 340:10 march 47:3 201:17 marginalized 269:2,10 274:10 302:6
m			
m 377:19 ma 39:18 machines 160:14,17 mad 55:10 203:17 made 9:4 11:10 20:1,1 32:21 35:4 36:14 76:6 122:7,11			

325:13 337:3 maria 80:20 marker 69:19 market 29:14 29:15 88:11 295:10 marketing 167:11 289:18 marks 130:14 marston 2:3 6:5 12:1,3 17:11,21 martha 3:11 7:5 180:14 190:2 214:17 347:21 maryland 1:4 8:4 380:20 match 23:3 175:4 221:3,4 matched 56:4 material 53:6 materials 20:10 125:2 126:6 136:3 222:10 289:15 289:17 292:8 347:5 351:18 353:1,2 maternal 1:8 8:11,14,17 104:7 108:8 178:8 223:14 223:19 378:4 mathilda 4:18 6:6 17:12 30:21 52:21	matter 36:5,6 322:10 333:5 matters 43:16 142:19 330:5 330:15 331:3 mckenzie 4:19 206:7,9 mcmahon 2:18 6:16 56:8 103:16,19,20 106:13 107:11 107:18 114:18 129:11 210:12 210:12 212:2 212:19 mcmurray 5:7 114:2 mcmurry 114:1 md 1:16 251:3 264:5 meal 312:9 mean 14:7 41:16,19 51:7 67:14 68:17 84:21 86:16 91:19 99:7,11 99:16 109:11 115:14 121:6 123:15 129:21 194:13 220:2 225:2,6,17 250:6 303:9 306:1 317:19 344:16,18 345:2 346:1 348:16 353:20 355:15 360:8	363:3,4 373:20 373:21 374:1,2 374:5 376:20 378:6 meaning 172:6 250:21 313:15 378:2 meaningful 27:18 167:1 243:11 317:4 326:13 330:21 372:21 means 9:8,8 13:5 18:9 48:13 54:1 68:14 74:19 86:1 161:6 227:9,12 229:10 231:3 231:13 248:8 249:4,5 251:21 251:21 252:1,1 260:1 290:1 312:14 373:19 374:7 meant 49:3 147:11 378:9 measure 162:7 172:21 225:9 373:12 measured 149:5,12 305:17 measurement 314:14 measures 300:15 301:1 301:15,18	310:19 measuring 309:12 373:12 mechanism 67:12 122:19 167:3,5,13,20 268:2 286:10 363:7 mechanisms 166:15 167:19 284:10 media 126:3 235:18 289:17 median 90:19 medical 2:3,5 2:17 4:14,18 12:1,8 17:13 23:15 42:6,8 62:11 64:14 75:16 77:8 100:11 116:7 116:10 119:14 147:15 162:1 165:19 183:8 184:2,7 185:8 185:8 227:20 232:8 238:3 239:4 240:19 241:2,15,19 242:1,9,10 269:18 270:9 278:18 279:7 279:17 280:6,8 290:19 298:8 323:7 337:7 361:21 368:21 medicate 43:10 246:20
---	--	---	---

medication 99:17 136:14 137:9,11,15 138:15 142:9 142:12 155:15 170:6 202:19 203:12 256:8	melva 5:5 186:5 193:6	232:17 266:10 266:15 273:17 288:13 294:17 365:9	mezzopointe 2:10 79:13
medications 231:1	member 224:21 226:4 233:4 365:15	mentors 311:6	mic 212:1 365:7
medicine 2:14 3:18 94:14 98:6 148:16 183:18 251:13 259:8 280:20 303:5	members 47:7 62:5 95:17 96:20 108:14 142:19 155:3 156:11 160:11 201:21 244:1 249:16 276:15 286:2 287:3 320:13 359:18 361:1,1 363:18	merge 121:3,10 mesh 251:14 meshaun 5:8 378:5	michael 2:6 6:8 31:12,16,21 33:8,19,21 34:12 35:5,12 35:15 36:15,16 37:7 38:4,21 39:9 41:14 42:21 44:11,20 61:3 111:13,14 134:12 322:16 322:18 327:12 341:10,16 342:4 353:17 355:21 371:4 376:19
medicines 127:19 219:8 251:15	men 218:15 272:10	message 117:9 242:16 333:8	michelle's 33:12 42:11
meet 30:7 41:9 187:16 197:8 219:17 220:13 287:3 288:19 366:5	mental 24:14 38:10,13 39:21 239:2 259:15	messengers 351:15 352:1	michelle 2:6 5:7 6:7 31:13 31:16,19 32:16 93:21 114:1 128:2 378:5
meeting 28:18 31:5 44:8 82:6 183:7 188:3 222:19 223:21 237:11 315:1 351:8 364:15 370:8 372:4 378:7,9,20 379:2	mention 319:11	met 28:7 30:11 42:17 66:15 72:13 140:5 172:5 219:9 323:12	microphone 9:5 319:10
meetings 10:4 52:18 84:1 237:6,12 351:4	mentioned 45:2 46:15 52:9,21 53:13 53:18 55:1 57:18 59:16 60:18 63:6 74:7 88:1,7 92:10 122:1 128:2 131:16 140:3 144:14 145:4 148:21 151:21 153:16 159:21 160:14 173:14 174:12 185:18 220:2 222:6,9,11	metabolism 268:7	mics 103:13
melissa 4:15 7:14 316:16 317:1		metals 11:2 metformin 170:4,10 method 152:20 302:8 methods 26:11 100:15 106:21 107:3 258:14 metric 69:19 76:21 77:5 106:14,18 metrics 68:5 76:5,8,12 106:9,11,12 219:16 220:13 220:18,20 221:13 222:16 222:19 373:15	mid 82:21 middle 54:10 136:19 152:13 181:10 194:4,7 195:11 198:19 199:3

mile 293:9	51:19 54:9,14	mistrust	modules
miles 42:10	56:17 58:3,12	192:20 269:1	290:21
128:2,3	61:10 73:10	279:3 280:21	molecular
milkeninstitu...	108:19 164:21	284:7 306:3	311:2
273:21	166:2 169:19	337:17	molecule 161:9
milligan 3:15	181:20 182:1	misuse 143:5	330:17
7:7 181:6	224:21 238:16	mitigate 228:6	mom 33:7
217:10	266:2 273:19	271:2 290:17	260:10 307:13
million 164:3	274:17 290:14	mitigation	317:11 331:10
millions 80:7	minute 79:5,6	159:13	moment 13:4
mimic 207:3	349:6	mix 125:8	105:19 129:12
mind 10:15	minutes 12:4	mixed 302:8	250:12 271:11
52:7 66:7	45:14 49:14	mm 355:11	293:1 306:12
80:16 90:16	56:9 126:12	mobilize	360:3,19
118:18 168:14	128:3 266:11	360:11	momentarily
176:18 220:10	266:20	modalities	12:2
247:2 295:8	misconception	82:15	momentum
303:14 325:14	24:14	model 116:7	120:17
336:17 368:16	misconceptio...	210:17 211:18	monetary
376:13	24:11 72:20	211:21 240:19	295:2
mindful 21:9	misdiagnosed	241:2 242:10	money 99:17
mindset 24:21	235:12	242:10,21	334:14,14,21
25:2 246:18	misguided 73:1	243:4 249:20	335:3 338:8
mine 52:4,5	misled 280:4	250:3,5 290:16	340:11 341:4
162:14 307:13	misperception	290:18 318:3	monitor 220:18
365:6	364:21	327:5	monitoring
minimizing	missed 10:7	modeling	182:18 219:11
302:15	210:15 235:5	243:15	222:16
minimum	missing 58:11	moderate 87:1	month 42:12
190:15	61:1 69:12	87:13,18 88:2	54:9 62:7
minorities 73:3	310:16 355:3	94:14	139:1 237:7
167:17 168:6	missingness	moderated 1:7	275:4 312:5
274:7	48:16 58:9,11	moderating	345:17
minoritized	58:18 59:9	8:12	months 34:1,8
274:10	mission 45:19	moderator	47:11,20 60:20
minority 2:9	mistakes 373:1	179:15 370:21	141:4,5 146:17
4:11 44:17	mistreated	moderators	148:3 149:10
45:15,18 47:15	339:15	130:14	167:11 171:20

<p>201:18 235:3 302:20 311:16 312:17 moons 291:19 moral 13:20 morning 8:2,21 17:16 31:17,18 79:11 89:14 108:7 130:11 146:3 224:12 256:21 326:17 morning's 131:16 mortality 163:16 mortgage 39:2 mosques 249:14 mother 260:4,4 260:6 303:7 304:5 mother's 231:6 motivated 303:19 motivation 320:21 motivations 303:17 366:3 mouth 222:12 324:4,14 move 11:20 26:15 77:11 103:10 113:19 157:8 161:15 161:18,19 163:9 191:19 192:21 243:2 320:7 331:8</p>	<p>343:12 366:6 376:14 movement 259:17 324:10 moving 15:17 50:19 56:19 77:20 106:6 110:9 178:2 181:14 184:6 242:7 244:13 249:10 283:10 283:14 365:18 multi 110:5 225:1 284:1 multicenter 132:15 133:8 313:6 multidiscipli... 255:21 multifaceted 217:14 244:2,2 multifactorial 172:10 multiple 31:18 34:15 93:5 184:13 195:13 220:12 222:10 276:5 289:13 299:10 310:11 326:17 327:7 mulugeta 1:7 6:3 8:2,9 11:19 17:10 30:20 44:10 64:1 79:2 94:8 130:13 131:4 145:9 161:12 179:13 182:14</p>	<p>184:9,11 185:13 190:2 197:2 204:12 205:15 206:6 214:16 217:9 223:3,7 murphy 9:11 music 354:12 muslim 244:5 mutual 216:21 myriad 13:15 myths 24:10</p> <hr/> <p style="text-align: center;">n</p> <hr/> <p>n 2:1 3:1 4:1 5:1 6:1,1 7:1,1 8:1 name 8:9 31:19 95:6 100:9 103:19 108:4,7 144:15 161:20 180:5,14,20 181:19 186:5 226:15 250:1 264:19 266:4 273:10 282:12 317:1 345:21 346:6,7 name's 227:3 266:15 names 288:12 345:18 narrow 91:8 nasrin 4:17 7:12 193:19 197:3 226:6 238:11 328:16 355:21 371:4</p>	<p>376:19 nation 62:16 228:1 national 4:11 54:9 72:5 104:21 181:19 182:1 266:2 290:14 310:11 nations 49:13 54:13 117:13 nationwide 10:21 native 71:16 174:19 175:18 176:15,16,21 177:13,14 179:4 240:11 250:12 natural 121:10 207:1 nature 159:15 navigate 150:8 183:17 274:13 294:14 323:9 navigating 181:13 navigation 296:11 navigator 296:15 312:15 313:2 near 16:5 52:12 306:2 345:8 364:11 nearly 67:1 141:7 301:15 necessarily 9:21 162:14</p>
--	--	---	---

185:3 206:18 207:1 238:5 254:5 265:2 296:1,14 338:20 372:13 373:12,19 necessary 22:16 286:14 necessity 115:12 need 12:18 13:1,7,12,18 16:11 21:3 24:6,11 25:4 28:14 30:14 38:7 42:15,16 43:2,18,21,21 50:17 76:15,17 85:5 91:4 101:15 109:4 109:17 110:9 111:7 114:12 119:14,16 120:1 125:14 125:15 129:2 130:1 134:13 153:21 154:16 161:5 169:16 185:3 187:19 189:18 194:4 206:5 221:8 222:20 228:14 247:5 248:14 251:17,17 256:13,16,16 258:10 259:13 262:3 286:15 291:7 295:1	307:2,7 309:16 310:5 315:13 318:10,11 319:18 320:11 320:15 321:1 321:21 325:15 328:6,7 330:13 335:15 336:15 342:13 350:1 352:20 353:11 358:7,9 360:14 361:16 373:10 377:21 needed 84:15 92:3 123:8 125:2 157:8,14 157:16 173:10 222:18 292:7 305:8 322:19 327:3 368:3 needle 77:11,20 needles 34:7 needless 76:8 needs 42:17 46:13 48:10 49:8,18 50:9 50:11 52:5 57:2 61:13 90:6 99:8,16 102:4 109:5 115:14 124:6 124:17 144:2 236:18 251:16 255:8 285:6,8 285:13 296:9 307:5 309:6,11 309:13,19 311:9 323:12	334:18 340:2 343:15 356:4 356:10,11 357:2 365:3 366:4,5 368:11 negatively 138:4 negotiate 294:19 negotiating 295:12 neighborhood 43:6 270:6 neighborhoods 37:3 neighboring 84:11 neither 110:7 380:11 381:7 nephrologist 4:19 206:9 network 2:7 31:15 32:4 78:15 132:19 133:8 134:1 180:7 184:17 227:5 235:6 323:9 369:2 networks 100:15 132:15 260:17 360:17 neurobiology 300:9 neuroblastoma 300:6,11 313:12,19 neuroscience 83:15	never 36:11 75:6 156:11 158:21 159:5 205:7 234:9 342:3 new 1:14 35:2 41:9 86:1 93:8 100:15 115:15 148:15 162:21 168:10 170:14 179:20 195:3 209:8 303:10 311:15 312:3 336:3 345:21 351:7 newer 88:4 newest 47:12 60:18 312:13 newly 164:18 165:3 news 137:6 170:21 171:1 201:2 203:6 nhanes 105:1 nice 40:14 41:2 41:8,12 100:9 130:6 286:19 290:11 nicely 102:19 niche 142:3 nigeria 157:12 nih 67:8 132:18 173:17 208:8 212:7 nike 320:21 nine 72:16 85:20,20 86:14 87:10 88:14
--	---	--	---

331:11 nmqf 182:1 282:18 287:18 non 71:16 73:7 104:14 165:8 165:10 174:18 175:12,17,19 176:9,11,14 261:20 277:20 313:20 314:1 361:1,11 nonprofit 282:7,16 317:10 nonprofits 62:14 nonverbal 257:9 normal 355:9 355:10,16 north 48:19 194:5,7 195:10 198:19 notable 179:3 notary 380:19 note 31:2 125:6 126:13 141:8 147:20 162:13 170:16 175:9 225:12,13 370:20 371:2 noted 84:8 87:4 87:5 notes 265:11 noteworthy 84:8 noticed 222:1	notification 29:14 notion 372:20 notions 244:8 nourished 231:11 novartis 3:16 181:8 novel 65:3 303:19 november 17:19 19:1 nuance 209:21 nuanced 289:10 nuances 54:20 80:17 81:7 111:7 117:14 118:5 210:8 249:2 number 15:17 28:13 68:12 71:11 76:9 105:20 112:12 127:13 149:17 153:6 164:16 165:6,15 172:8 179:18 316:2 327:2 332:20 351:19 353:4 369:18 numbers 105:18 140:14 190:10,11,12 190:19,20 324:7 numerous 240:1 341:9	nurse 139:3,8 139:10 185:3 212:10 214:6 341:16 342:3 nurses 90:9 153:11 184:14 184:18,21 185:11 211:12 339:13,19 nursing 184:12 nurturing 231:9 nutrition 105:1 312:9 nutritional 279:2 nuvig 3:8 145:14	obstacle 278:15 obstacles 89:13 obtain 135:9 obviously 10:11 12:17 13:5 15:2 106:5 148:8 220:2 253:7,13 347:14 349:21 occasionally 148:4 198:8 occasions 341:9 occupants 11:7 occupations 275:1 occur 86:19 occurred 141:9 203:16 243:1 occurring 71:3 occurs 135:5 october 157:9 offer 65:3 202:1 offered 73:11 76:19 offering 347:5 offers 66:12 office 2:5,9,11 2:18 3:12 4:18 17:13 44:17 45:14,18 46:7 94:11 104:2,8 104:8 253:18 253:18 295:6 369:7,15 officer 2:3,20 12:1 64:3
		o	
		o 6:1 7:1 8:1 o'clock 371:10 oak 10:20 11:8 obesity 93:6 104:12 105:13 105:16 162:2 obligation 326:11 obligations 74:5 observable 359:5 observational 128:19 129:6 213:7 observed 69:6 166:5 179:5 207:19 340:6	

162:1 380:2 offices 30:16 276:20 official 371:20 offset 71:8 oftentimes 38:4 39:15 196:11 227:15 296:16 oguno 3:7 6:21 145:13,16,18 150:16 197:16 198:17 318:7 329:20 335:8 357:4 368:1 oh 37:20 38:8 55:12 58:20 80:13 82:8 119:1 162:12 202:17,19,20 203:7 211:2 222:2,6 234:1 241:6 252:3 316:18 321:9 322:3 330:7 378:9 okay 9:12 12:3 35:11 44:15 50:19 58:20 61:3 80:1,21 81:2,9 82:10 97:20 108:1,2 108:6 119:2 121:16 126:17 136:17 145:19 153:13 161:20 168:17,17 169:20 172:18 191:19 211:3	215:6 241:13 244:4 247:13 255:10 282:11 314:19 315:14 315:16,18 316:14,17,19 322:17 324:13 339:12 345:1 350:15 371:6 376:13 old 33:21 47:20 95:9,11 125:1 125:1,2,15,15 148:3 149:2 155:21 157:17 234:21 249:7 260:5 338:15 361:4 377:8,9 older 90:13 99:11 248:15 322:12,17 327:13 oman 199:6 omb 110:14 195:3,9 ombhe 45:19 47:14 50:21 52:20 369:6 omnibus 18:12 once 62:1 103:14 137:8 152:11 169:13 187:1 324:11 341:10 oncologic 3:12 oncologist 180:15 298:7 298:14 305:19	366:15 oncology 3:12 4:13 85:2,9 180:16,16 191:1 215:13 215:19 216:1 266:5 282:9 298:20 299:4 299:14,19 300:4 306:17 307:3 308:9 313:11 366:15 375:21 ond 378:2 ones 35:13 83:7 253:12 262:15 262:16 362:16 ongoing 278:21 287:15 290:13 351:1 364:20 ongoingly 346:11 onion 196:19 online 19:8 31:6 53:8 57:6 57:11 107:13 111:12 179:18 182:5 343:8 358:17 onset 162:18 163:5,21 164:15 165:1 166:8 171:18 173:16 174:2,6 174:10 175:5 177:15 178:5 onus 365:21	oops 375:5 377:12 open 98:7 126:15 136:12 200:12 217:11 237:9 293:14 337:1 342:10 342:12 350:19 365:7 opening 317:20 openings 84:13 138:12 operational 134:5 operationaliz... 46:6 operations 3:7 141:1 145:14 311:2 opinion 43:16 65:4,5 151:6 154:14 192:15 193:2 230:13 322:10 opportunities 65:3,6 178:2 202:15 245:18 246:5 277:16 375:20 opportunity 44:5 93:16 98:21 99:4 118:2 126:4 137:13 149:20 152:3 158:18 159:5 188:15 235:5 263:16 264:4 271:7
---	---	--	--

303:20 318:9 326:20 335:9 336:7 357:16 358:12 opposed 123:18 191:10 253:11 275:2 327:5 opt 370:1 optimizing 22:15 267:4 289:20 option 202:2 218:4 235:7 323:19 options 170:9 285:19 297:18 300:1 opts 68:11 oral 137:8 orange 57:17 60:21 61:2,5,6 61:7 176:17 oranges 51:13 53:14 order 16:2 110:8 139:12 165:16 173:10 177:20 208:7 228:6 306:14 325:15 366:5 373:15 organ 146:21 147:2 organization 3:6 64:17 68:3 71:6 72:15,17 95:8 145:12	160:10 161:8 182:3 259:19 282:20 organizational 75:10 organizations 27:10 62:17 66:19 70:14,18 70:19 76:18,20 77:4 95:14 102:14 280:2,4 285:3 286:5 287:4 329:8,12 330:18 357:3 360:16 organized 269:17 organizing 378:7 orientation 238:17 original 140:4 267:21 originally 341:19 ought 112:14 113:10 334:14 373:12 outcome 193:1 314:16 378:19 380:16 381:12 outcome's 97:12 outcomes 58:6 77:6 87:5 92:1 116:17 123:2 137:14 138:5 166:4,5,9	229:8 260:19 267:11 270:2,9 279:9 314:12 320:8 323:13 outlined 270:11 outlining 269:21 outlook 120:11 outreach 46:9 285:2 289:16 289:18 293:21 outs 240:1 outset 113:14 outside 64:14 77:11 136:2 201:12 214:12 231:6 271:12 271:13 297:1,3 344:14 346:5 outspoken 247:4 overall 27:14 141:20 182:18 193:1 248:2 321:6,16 323:13 overcome 20:21 22:11 38:2,3 40:4 91:14 132:16 135:19 337:17 overhead 134:5 overlapping 54:18 overlay 151:13 206:14	overrepresent 174:1 overrepresen... 174:14 176:10 overrepresen... 175:21 oversee 67:15 overview 17:18 79:20 166:13 252:20 overwhelming 140:6 229:1 overwhelmin... 141:12 overworked 339:13 own 14:9 23:2 65:2 67:3 70:21 78:14 80:4 143:2 246:13 286:10 286:10 306:14 338:1 355:3 362:3 363:19 364:16 366:2 376:13 ownership 264:2 oxbryta 147:21
p			
<p>p 2:1,1 3:1,1 4:1,1 5:1,1 8:1 105:14 106:14 p.m. 379:3 pace 109:11 pacific 165:9 174:20 176:16</p>			

176:21 177:14 paediatric 349:7 page 6:2 7:2 paid 275:1 pain 33:21 35:14 36:8 40:11,12 146:19 330:8 330:12 341:11 pairing 251:7 pam 2:10 6:11 79:9,12 94:8 100:20 111:18 119:8 128:10 171:6 326:16 376:6 pam's 101:9 pandemic 10:6 25:18 141:10 141:18 157:19 200:9,13 201:1 201:13,15 203:17 219:6 220:12 229:1 panel 31:2 63:8 94:9,15 97:16 103:15 111:21 120:12 124:9 145:2 161:15 193:5 207:5 223:2,11,12 224:1,9 246:10 263:9 265:13 268:16 273:18 281:3 314:21 315:3,5,12,12 334:8 374:14	374:16 panelist 103:11 193:8,20 panelists 94:15 94:18,19 95:2 126:16 130:10 130:14 179:16 179:20 180:2 188:8,20 247:19 314:21 315:19 318:16 360:5 374:17 377:15 paper 77:1 273:9,10,12 paperwork 306:13 paradigm 24:20 120:4 121:13 236:5 parallel 327:7 paraprofessio... 242:13 paraprofessio... 259:6 pardon 97:14 parent 2:7 230:9 302:9 306:10 331:10 341:8 parents 14:1 16:13 36:5 39:14,15 75:14 89:15 98:4 99:3 123:13 125:9,10 155:6 158:10,18,21 217:5 235:17	243:9 253:5,11 253:12,19 254:3 257:14 299:3 302:4,16 302:18 303:1,5 309:4,5 322:11 326:2 338:13 356:12 part 10:21 12:12,19,21 22:19 25:6 40:21 42:18 49:6,7 57:1,3 96:17 98:8 99:21 107:6 124:4 125:17 141:14 200:21 202:16 213:17 215:9,10 216:11,20 219:2 221:17 223:20 225:2,9 230:21 248:5 250:18 252:10 256:8 263:18 265:15 277:19 296:2 298:10 298:11 299:13 310:1 315:12 319:16 323:19 333:20 334:19 338:20 340:12 349:1 360:8 361:11,12 362:5 374:16 378:11 participant 36:16 72:2	134:17 201:20 212:12 290:1 294:6 295:4 participant's 203:10 292:9 296:21 participants 11:11 20:20 23:17 26:7 27:1,12 31:6 32:11 68:12 69:5 70:12 71:16,18 72:19 74:1,3 75:4 85:1 87:13 90:6,20 138:16 139:13,16 140:4,9,11 141:13 143:16 148:18 157:16 168:12 169:4 172:11 179:18 199:9 222:2 269:3 270:21 275:13 277:15 278:1 281:2 283:9,13 291:17 295:13 298:2 330:15 335:10,18 participate 55:7 80:8 88:5 133:15 155:3,8 159:2,6 270:10 275:4,6 277:7 291:6 302:1 309:2 315:5,11 317:19 332:4
---	--	---	---

364:20 365:1 participated 159:2 186:17 221:6 participating 39:9 73:3 274:18 295:14 303:18 304:11 337:11 participation 23:1 27:13 35:18 39:12,21 42:14 71:19 72:21 73:7,11 73:17 76:6,20 98:1 102:8 106:7 128:1 130:16 132:7 135:20 138:4 189:15 201:6 221:19 236:9 267:5 270:3 273:13 274:11 276:1 281:20 283:4 298:5 299:1,4 301:9 301:10,16 302:10,17,18 305:15 308:1 308:17 314:11 325:16 342:18 366:19 377:10 participations 39:11 participatory 243:4 249:20 particular 37:18 38:18	42:17 72:3 102:12 112:17 170:2 197:20 221:18,21 239:8,11,13,13 239:17 255:16 287:2 301:11 349:17 350:8 particularly 12:9 16:8 96:9 149:18 150:6 185:17 230:19 304:13 371:13 374:17 378:5 parties 74:12 380:12,14 381:8,11 partner 2:10 79:12 184:16 242:14 264:3 270:13 286:5 287:4 288:4 partnered 65:8 72:9,10 139:13 151:3 184:20 partnering 78:8 partners 13:1 80:12,14,17 99:2 122:16 123:12 125:7 144:16 158:9 286:12 323:21 368:7,14 partnership 144:14 208:8 219:7,14	partnerships 144:7 211:19 288:8 parts 57:1 121:21 pass 212:1 265:13 335:17 passed 18:11 166:18 167:4 246:15 247:11 247:12 passing 235:2 passion 367:17 passionate 180:9 past 41:7 54:8 77:19 191:4 222:1 226:21 pat 190:11 paternalistic 123:17 pathway 299:13 pathways 119:18 242:13 245:18 patient 2:7,15 4:15,17 14:21 15:2 16:20 22:5,12,15 26:2 42:4 64:9 66:7 90:7 95:8 95:18 96:13 97:21 103:4 121:20 123:16 124:10 128:7 136:10 141:3,3 144:8 147:8,12	148:6,7 151:16 152:8 156:21 180:6,8 189:11 193:21 195:5 204:14,18 205:20 216:15 221:2 226:7,9 226:12,13,20 227:3 230:4 234:15,18 237:5,7 252:11 253:6 254:6 256:5 257:14 263:3,14 267:16 269:17 276:15 278:5 280:5,6 284:6 293:16 296:11 296:15 317:2,6 318:15 319:2,4 322:14 327:15 332:9 336:2 339:16 340:16 341:21 342:21 351:10,10,19 357:6,12 362:14 364:3 365:14 374:5 patient's 206:4 322:10,13 348:15 patients 1:2 8:8 14:1 23:12 25:15 26:18 27:21 31:10 40:10 74:3,15 75:4,20 80:7 81:17 85:4,7
---	--	--	--

90:4 96:5,11	280:3,7 281:6	64:7,9,13 67:2	180:6,8,15,16
97:1,5,12 99:1	281:7 291:9	67:6,17 68:9	182:8 184:14
110:16 119:17	294:21 300:5	76:15 78:1,15	190:21 205:13
122:17 124:14	303:21 304:5	79:18,20 80:7	206:9 207:5
146:19 147:10	304:17 317:4	80:8,15 81:5,7	208:2 213:17
148:3,14	322:8 325:8	81:12,15,21	215:1,5,9,14
149:13 151:7	326:2,11 329:8	82:13 83:8,8	215:21 217:5,6
151:13 153:6,7	330:2,11,19	84:4 85:17,21	217:14 226:20
155:19 156:13	331:5 339:14	86:2,5 91:11	234:14,18
157:21 160:18	342:12 345:14	91:17 92:10,15	235:7 238:1
161:1,5,6,7	346:5 347:14	92:21 93:2,12	243:8 245:9
162:9 166:10	347:17 348:14	93:14 94:11	253:3,6 254:2
167:1 173:6	351:4 354:7	95:16 98:2	254:6 262:10
174:10 175:5	356:11,19	100:13,18,21	266:5,19 282:8
177:15 180:10	357:1 358:1	101:15 102:4	298:7,13,20
186:10 189:19	360:10 364:2	104:2,7,8	299:14 300:4
189:21 190:17	patrons 289:1	105:12 106:10	305:12 306:17
191:8 192:1	pattern 121:2	107:14 108:13	307:3 308:3,5
196:15 197:6,7	patterns 67:1	108:18 109:12	308:9 311:2,20
197:13 198:10	89:4 93:10	110:11 112:4,8	312:1 313:11
198:21 199:8	paula 312:21	121:7,7 127:15	323:2 343:12
199:12 202:8	pause 97:15	128:16 130:16	343:13,15,21
205:13 206:8	201:17	132:6,14,18	344:5,12,15,17
207:4 209:14	pay 39:2 275:5	133:1,4 135:20	345:21 348:2
210:2 214:1	paying 212:9	136:11,15	349:2 356:12
217:6,6 219:15	payne 5:8	137:20 142:1,5	359:10 360:10
219:16 239:3	pcori 97:8,10	146:9 148:17	365:10 366:14
244:19 245:9	pd 311:13	161:21 162:4,9	372:9,13
246:2 253:8	pdsas 340:11	162:21 163:6	375:21
256:16 257:2,4	pearls 122:3	166:1,14,17,19	pediatrician
257:17 262:10	pediatric 1:2	166:21 167:6	181:8 223:18
262:15 263:10	2:11,19 3:11	167:19,21	235:6 257:7
263:15,18	3:15 4:8,13,19	169:15 170:19	pediatrics 1:8
268:17 276:5	5:3 8:7 9:9,14	171:10,19	2:13,16 3:18
276:21 277:17	9:17 10:1	172:3,12,17	8:11,13,17
278:19 279:10	14:13 16:10,17	175:4,7 176:1	19:10 80:16,19
279:16,16,19	19:14 45:16	177:3,11,18	88:11 92:7
279:20,21	56:17 59:13	178:9,15,17,19	94:13 108:8

121:5 124:21 126:19 129:13 129:18 131:11 163:2 178:8 217:16 219:10 223:14,18 292:1 300:7 378:4 peer 95:19 236:19 237:6 237:12 263:12 313:2 351:20 peers 165:10 207:15 235:20 263:4 penn 4:15 7:14 316:16,18 317:1 people 13:9 16:3 17:2 20:7 21:14 32:19 38:17 41:10,12 43:8 80:14 86:6 98:17 108:11,21 139:20,21 140:20 146:12 146:18 158:3 186:12,13,14 187:6,8,18,20 194:11,17 195:8,12 200:13 205:4 207:16 216:21 223:16 225:7,9 227:21 228:2,4 228:12 229:1 229:12 230:5	231:14 232:12 232:14 233:18 234:11 238:8 242:5 243:14 243:18 246:5 248:14 250:17 250:20 251:2 251:13 252:5 252:10 254:10 254:12 257:15 258:18,19 259:5 260:15 262:5,6 269:12 274:14 286:8 286:20 288:11 288:18 290:8 290:11 293:2,4 295:16 296:14 304:7 320:17 323:2 324:9 328:17 329:1 329:18 338:8 338:12 339:2 344:11,18 346:4,19 347:10,13 349:9 351:14 352:12 353:7 359:17 361:6 361:18 365:11 366:9 369:3 371:1,12,13 people's 201:2 203:4,5 204:8 361:14 peoples 194:5 pep 186:12	perceive 74:20 perceived 278:13 percent 58:11 66:18 70:19 79:17 88:3 92:10 96:18 119:10 147:5 148:18 163:19 172:4,7 175:10 175:11,15,15 186:14,18 187:2 222:2 257:7 283:7,9 283:10,12,15 283:16 300:19 301:6,15 302:17,18,19 307:6,10 310:14,15,16 percentage 59:9 percentages 83:2 350:17 perception 193:16 333:12 perceptions 201:2 203:4,5 303:2 perfect 221:15 perform 278:9 performed 105:3 162:5 period 84:3 86:7 87:19 95:16 101:12 138:20	permission 89:9 262:1 permit 41:14 person 9:1 20:11 51:6 118:18 119:3 154:21 183:20 185:14 209:18 231:5 237:19 241:18,19 244:12,16 245:11 256:10 258:21 275:5 287:2 316:12 344:20 346:6 364:6 378:12 person's 244:4 244:6 personal 67:4 229:21 253:17 255:18 281:5 366:20 378:12 personally 96:10 99:16 180:8 205:5 208:18 216:17 282:17 344:20 personnel 136:4 persons 24:17 24:17 perspective 4:9 10:10 51:18,19 51:20,21 66:11 84:17 91:19 92:2 97:14 121:20 126:11 134:10 153:4
--	---	--	---

153:14 184:3 186:8 194:16 194:17 206:1,4 238:15 240:20 282:16 287:11 318:8,19 319:2 332:10,13 348:8 349:12 362:10 363:1 perspectives 52:19 65:9 96:7,15 204:17 266:12 298:11 302:9 303:1 365:12 pertains 254:10 ph 32:17 80:20 378:5 pharmaceutical 83:5 114:5 206:10 210:7 343:11,17 pharmaceutic... 4:16 69:2 83:9 167:4 181:2 pharmacists 62:21 288:4,14 320:3 pharmaco 129:12,17 pharmacogen... 265:20 pharmacokin... 133:2 pharmacology 4:5 265:20	phase 23:13 29:8 169:8 172:3 188:10 213:6,9 215:14 215:16 311:19 phases 82:14 85:4 phd 264:5 phenomenal 35:10 248:7 phenotypic 87:3 phlebotomist 135:11 phone 135:8 138:15 139:18 139:20,21 143:17 154:20 292:14 phrase 370:1 physical 139:10,18 270:6 323:18 352:19 physician 2:4 43:11 139:9 173:18 185:10 209:19 225:4 266:16 291:3 325:1 physicians 23:12 62:20 151:6 153:3 154:15 158:10 184:18 246:1 277:5 287:10 290:2 356:18	pi 336:6 351:4 picked 200:18 picking 154:20 picture 35:7,9 35:10 69:10,11 76:11 pictured 171:9 pictures 52:12 63:7 piece 45:6 47:2 69:12 71:15 352:2 pieces 243:2 pigs 228:15 pill 138:11 pillars 48:4 pilot 71:7 74:21 136:13 140:3 142:2 311:18 312:6 312:12,18 369:7 pink 54:10 pins 34:6 pip 348:2,7 349:7 pipeline 92:7,8 92:13,16 299:11 360:4 pis 47:12,21 97:2,9 290:4 pivot 102:3 219:17 222:18 pivotal 29:9 90:9 169:8 213:11 291:15 360:3,19	pivoted 101:10 152:3 pivoting 219:11 220:15 placate 156:19 place 27:5 67:7 90:18 98:16 159:1 221:8 236:20 257:19 257:20 258:2 276:19 286:18 334:16 335:2 350:1,10,14 354:17 366:6 placed 136:8 places 207:6 299:11 372:14 plain 27:2 98:12 126:5 plan 14:6,9,9 28:21 29:10 53:1 87:11 93:16 148:5 149:8 169:10 169:16 178:16 206:12 215:15 220:17 222:20 258:1 297:4,11 297:11 323:20 349:6,7 354:10 368:7 planes 209:15 planned 201:14 262:19 planning 13:13 23:13 29:18 81:8 87:18 134:8 178:9
---	---	--	--

179:1 206:3	223:5,8 226:2	policies 100:16	142:1,3 147:4
220:5,7 222:15	319:9 321:4	193:12	147:12 148:6
264:12 275:15	322:3 323:4	policy 1:7 2:5	149:2 151:16
294:18 312:17	324:1 334:3	4:18 8:10	152:8 156:21
354:1,6 373:18	345:9 371:19	17:14 95:19	162:8 163:17
plans 14:12,13	376:19	284:9 296:7	165:20 173:6
14:14 18:17,19	pleased 140:15	365:21	174:19 175:15
22:12,20 28:5	pleasure	political 43:17	179:6 189:11
28:8,15 29:4,6	370:20	politically 22:1	189:12 196:5
87:10 112:1	plus 55:2 62:15	politicized	196:11 199:3
163:1 168:11	93:15	244:14	207:3 216:4
169:3 188:10	podcast 57:11	pollack 32:16	217:3,17,18
197:9 207:3	podcasts 53:10	pondering	221:2 238:2
215:1,1,4,4,5,9	57:7	190:5	263:6 268:13
215:10,14,21	podium 376:19	pool 172:11	283:7,11,17
276:6 297:18	point 26:1 45:9	poor 116:9,10	284:17,20
349:2	52:10 54:4	147:11,14	290:8 300:5,19
plate 307:16	58:13 61:1	373:2	306:2,5 327:4
platform 52:10	66:13 67:19	poorly 147:13	327:9 373:8,19
324:18	79:21 86:13	populated	populations
platforms	96:10 108:17	38:18	12:9,14 13:3
52:13 143:10	110:13 113:13	population	13:18 16:5,12
play 12:20	117:18 120:10	15:1,3 16:20	19:5,12,15
231:17 250:8	122:11 127:2	18:6,7 20:2	20:5 21:11
325:6	150:18 190:1	21:6,20,21,21	23:9 24:3 25:3
playing 342:11	191:12 211:6	22:3,6 25:1,11	45:21 49:1
plays 65:18	218:19 237:12	26:2 28:17	51:18 52:1
78:21 230:17	246:21 287:5	30:5 46:17	54:14,15 56:17
269:16	291:15 318:16	51:20 58:17	58:8 63:5
please 10:18	335:21 338:17	60:2 61:20	67:21 68:16,20
11:4,16 31:16	341:11 343:5	74:15 90:21	73:10,15 75:17
33:11 47:8	353:3,3	104:17,19	98:2 103:4
57:12 94:16	pointed 103:6	105:5,12 107:8	115:16 128:1
103:13 108:4	107:6 111:18	108:13,18,19	128:16 165:17
114:17 130:12	points 88:1	109:9,21	168:13 169:5
130:21 161:19	114:15 119:7	110:11 113:5	170:20 179:5
162:13 180:12	police 284:6	113:10 114:9	192:18 196:14
216:2,4 223:1		115:3,5 140:17	197:15 215:4

224:21 256:14 268:12 269:17 274:10 301:11 326:18 portion 196:2 309:9 pose 119:15 posed 197:3 position 371:6 positions 226:9 positive 91:9 166:9 192:5 possibilities 319:20 possible 18:6 32:21 72:7 115:8 135:9,15 210:16,17,20 possibly 37:8 306:13 post 29:3 99:15 297:6,18 posted 11:3 66:15 potato 242:19 potential 58:5 104:16 128:9 129:10 134:9 135:19 143:18 267:2 310:18 potentially 137:14 139:12 139:16 142:4 262:15 307:21 351:3 poverty 299:2 300:16,18,20 313:14,15	power 125:16 269:16 339:15 powerful 65:20 121:20 324:5 341:20 342:5 practical 282:3 323:12 practice 123:15 183:18 221:10 316:7 318:6 practices 28:2 113:15 222:1 227:14 265:17 282:7,14 284:15 291:11 315:21 practitioner 250:2 practitioners 124:5 pre 29:14,15 61:20 188:10 257:18 prea 83:5 92:11 104:11 107:19,21 119:12 166:18 169:15 171:2 171:13 178:17 215:10 preaching 14:7 preconceived 244:7 predict 13:19 predicts 137:5 predominantly 147:11	preemptively 123:4 preferences 50:17 55:19 56:4,5 291:12 preferred 141:15 254:11 pregnant 24:17 preliminary 105:10 136:13 prepared 11:13 11:13 297:16 381:3 preparers 14:16 prerogative 9:5 prescribed 88:4 137:9,12 137:15 138:18 142:10 203:9 203:13 prescription 9:16 presence 287:17 present 79:19 80:11 88:10 89:9 138:3 172:20 174:7 250:11 279:5 291:8 presentation 33:10 42:3 64:11 66:11 70:4 87:4 88:20 96:3,15 101:9 119:8 121:18 145:2	162:11,14 194:14 197:4 205:18 309:10 320:2 presentations 123:9 315:8 presented 62:13 95:2 291:21 309:17 316:13 326:16 357:1 376:7 presenter 43:19 161:18 presenters 36:19 265:17 377:14 president 3:7 44:6 145:13 260:7 presidents 62:20 63:17 pressure 292:5 pressured 306:20 pretty 114:19 171:19 177:4 191:13 265:11 284:18 292:20 376:7 prevailings 120:5 prevalence 23:20 24:1 58:16,19 85:3 88:17 89:1 105:4,6,8 106:9 107:7 151:21 159:4
---	---	--	---

164:3 174:5 194:8 206:19 210:1 267:12 prevalent 149:17 208:2 209:12 228:19 prevent 58:7 prevention 112:3 241:12 prevents 117:9 previous 39:14 198:18 263:9 329:21 339:21 340:7 primarily 102:14 311:5 344:12 primary 59:5 84:4 132:10 144:19 207:6 207:14 276:20 356:18 primer 166:11 principal 39:5 144:21 290:7 principle 217:15 print 347:6 prior 170:5 171:2 181:8 189:8 198:6 273:17 380:5 priori 305:14 priorities 102:1 prioritize 327:2 prioritized 269:17	prioritizing 130:9 priority 298:19 343:16 privacy 27:1 118:13 private 127:9 181:10 219:7 219:13 privilege 308:10 317:3 privileged 32:5 280:18 367:18 privy 291:4 proactive 91:14 93:12 220:5 222:15 proactivity 220:7 probably 34:20 123:8 129:15 200:1 304:6 325:19 326:4 372:14 probed 303:17 304:10 problem 12:17 58:9 61:5,9 107:6 122:17 222:2 256:4,4 problems 96:19 319:19 procedures 27:5 77:7 278:8,11 proceeding 381:4	proceedings 380:3,5,6,9 381:6 process 29:21 55:6 56:11 92:1 125:18 159:12 160:15 257:17 262:12 263:11 291:15 307:2 313:3 317:5 319:17 319:21 328:4 333:20 340:10 340:14,19 341:3 348:4 349:19 363:11 367:21 processes 29:1 187:9 processing 370:10 product 15:1 18:3,8 51:14 79:18,20 80:15 81:12 91:11,17 111:18 112:9 127:15 166:21 products 12:9 13:16 15:7 87:12 92:21 93:8 166:20 professional 331:11 professionals 290:19 341:15 377:2 professor 2:16 3:18 4:12	131:11 266:5 proficiency 70:13 profile 142:10 profound 146:16 231:4 prognosis 137:5 program 29:19 46:8,9 51:7 57:8,13 85:18 87:10 148:1 178:19 179:3 265:16 287:15 347:2 369:1 programmatic 46:7 programming 90:8 95:20 programs 46:10 72:17 86:5 177:19 287:18 370:13 progress 20:1 64:15 71:2,13 220:2 293:19 progression 301:13 310:4 project 212:5 341:5 projected 172:5 projects 48:7 51:2,3 55:2 57:1,15 97:2 288:6 340:4 369:7
---	---	---	--

prolonged 252:16	prospectively 76:15	provider 203:10 284:6 338:20	219:13 268:17 300:17 313:16 317:9 370:12 380:19
prom 354:6,10 354:15,15,19	protect 24:21 25:2 45:20 228:20 304:14	providers 192:20 235:6 320:13,14 323:17	publications 144:18 263:13
promise 51:8	protecting 27:1	provides 29:2 92:2 231:9 312:8	publicly 29:3 53:5 57:6 59:19 70:2 77:5,9 285:7 319:1
promising 142:4	protocol 22:4 22:15 24:16 72:2 156:5 206:3 257:21 263:19 270:18 271:1,17 357:7 357:10,13 358:8	providing 20:10 25:5 122:4,16 129:11 204:1 205:9 210:17 236:19 371:7	publish 18:16 published 19:7 77:2 148:15 169:2 172:2 194:3 263:12 273:9
promote 45:20 370:13 375:14	protocols 74:13 186:20 187:7 211:12 268:20 278:6 361:6	provocative 191:13	publishing 77:12
promoting 137:14 287:21 323:13	prove 364:8	proxy 300:15 301:5,14,18 310:19	puerto 62:9,10 puja 4:12 7:11 266:3 298:7 375:19
promotoras 242:14	provide 18:2 21:7 28:12 31:13 63:12 64:8 84:20 92:14 139:16 143:15 153:15 161:14 162:17 166:13 167:1 184:21 259:14 276:14 304:7 311:11 312:17 347:15,17 351:20 358:4 372:10	psoriasis 86:1 psp 348:2,6 psychological 65:17	pull 60:3 70:20 168:17 169:2 342:19
prompt 323:17	provided 76:18 91:18 133:9 138:13 184:12 263:4 370:3	psychologist 3:20 226:5 259:12	pulled 92:20 pulpit 9:6 purple 165:8 175:18 176:15
prompted 95:14 170:17		ptn 132:19 ptosis 136:16 puberty 34:21	purpose 53:17 162:3 292:18
propensity 233:21,21		public 1:4 18:14 19:2 28:11 33:3 42:18 44:13 126:9 127:9 181:10 188:11 188:12 219:7	pursuing 93:8 push 295:12
proper 181:4			put 14:15 15:11 55:20 68:13 84:16 90:7 129:20
properly 293:5 340:13 367:5			
property 240:8			
proportion 110:5 111:5 186:10 373:8			
proportionate 187:15 373:7			
proportions 104:14 188:4			
proposal 359:19			
proposed 76:21 136:13			
prospect 217:17			
prospective 218:5			

201:17 240:20 290:3 292:5 295:2 296:15 296:19 327:11 366:5 370:11 putting 27:4 105:18 126:8 129:14 146:2 183:6 204:8 286:9 295:11 346:17 361:6 puzzle 69:12 71:15	question 65:10 75:21 93:9 97:19,20 101:12 102:12 107:13 108:3,5 108:10 109:5 109:16 110:21 111:1,10,12,16 111:21 113:20 114:4,18 115:20,21 116:2 118:8,9 118:17 119:2,5 120:3 122:5 182:16,21 183:4 184:16 186:3,3,7 187:12 188:19 189:1 190:5 191:13 192:13 193:7,8,17 194:1 195:2 196:2,10,20 197:3,3,19 198:18 199:11 199:15 200:3,6 201:12 202:16 203:7 205:2 206:8 207:4,19 208:15,18 210:10,13,15 211:1,4 212:4 213:2 214:17 214:20 215:2,7 217:13 218:6 220:6 225:15 232:16 239:6 239:16 248:19	250:7 251:11 253:21 255:15 256:19 257:18 258:13 261:15 271:6 296:12 313:9 316:5 318:5 325:2 326:8 328:2,15 329:4 330:1 333:14 339:21 343:7,7,18 345:11 347:21 353:15,16 358:16 360:21 363:19 questioning 159:3 questionnaires 68:2 135:7 139:6 310:10 questions 11:17 31:2 63:20 68:7 81:20 94:20,21 96:2 97:17 99:1 100:7 103:10,13,18 119:15 145:6 152:5 179:19 180:1,2 182:15 184:1 185:14 188:2,4 190:7 196:17 201:8 203:20 204:13 216:1,9,13 224:4,9 225:13 237:13 245:12 246:2,6 253:13	253:16,19 254:2 256:13 258:3,7 261:21 262:1,2 279:20 292:4 293:13 305:20 315:17 337:15 344:9 348:12,16 349:1 quick 9:3 223:4 283:18 289:6 358:16 quickly 8:18 59:12 98:20 160:2 183:15 223:16 245:3 245:20 284:2 329:21 333:10 339:17 349:3 352:8 quite 12:17 75:18 90:9 91:2 101:1 110:1 146:20 147:5 149:20 159:9 260:6 308:12 372:17 quote 106:14 107:3 230:16 272:21
q			r
qi 288:5 qr 31:4 qualified 36:4 50:4 62:6 340:7 380:7 qualify 40:6 qualitatively 305:18 quality 4:11 89:19 91:10 143:4 181:20 182:1 254:16 266:3 290:14 321:18 326:13 327:2 340:2,8 quantitative 224:17 quantitatively 305:17,18 quarter 307:8 quarters 229:4 queens 62:11			2:1 3:1 4:1 5:1 8:1 r&d 4:15 79:13 218:13 317:2 race 30:3 53:1 53:15,20 54:3

54:5 59:20 66:4 67:9 75:10,13 76:5 87:4,6 88:20 105:4,6,8,11 105:15 106:9 110:5,10,15 117:11 118:4 118:12 140:15 140:20 166:3,5 169:11 173:1,3 174:16 175:2,6 176:6 178:15 191:2 232:8 272:19 299:2 300:13,14 301:5,14,18 305:2 310:20 313:19 365:1 373:13 races 104:19 rachel 3:3 6:19 131:10,13 145:10 182:15 200:7 racial 13:5 47:14 51:19 54:13 56:16 58:3,8,12 61:10 67:13 73:2 137:2 138:6 164:20 167:17 168:5 168:13 169:5 169:18 238:16 268:9 269:9 271:20 273:18 274:6,17	277:17 358:19 359:3,9 racialized 272:6,15 274:20 278:15 278:19 279:1,6 279:9,10 281:20 337:2 racially 357:19 racism 266:18 266:21 267:3 269:6,7 278:12 278:14 279:13 279:17 280:11 281:18 310:2 375:11 rahela 311:7 rahman 2:20 6:10 64:2,6 179:16 180:3 180:12 182:4 193:4,17 199:14 200:3 210:10 212:20 222:21 rahman's 96:3 raise 32:7 335:19 360:11 raises 352:1 ran 200:8 317:10 378:1 randell 3:3 6:19 131:10,14 187:11 200:6 201:7 202:19 203:2,7 210:13 211:1 212:1,3 336:16	randomized 128:13 218:4 312:7 range 149:5 171:11 175:14 rapidly 109:10 114:19 163:13 rapport 261:6 rare 119:14,14 120:7,7 121:4 121:7 122:20 136:21 137:19 137:20,21 146:11,13 149:16 164:1 164:16 180:16 209:13 210:2 216:15,15,15 299:15,15 308:3 317:10 317:11 rarely 150:2 rarer 208:11 rate 70:17 73:12 164:17 166:3 298:4 302:17 310:14 310:15 rated 199:20 rates 73:17 150:5 241:8 272:8,16 340:17,17 rather 43:8 68:3 347:9 366:13 ratio 366:12	rationale 30:6 370:4 rct 313:6 rcts 128:20 reach 16:12,13 16:14 60:19 61:11 62:4 63:7 120:1 211:8 240:2 278:9 287:6 365:4 369:3 reached 223:1 reaching 222:3 320:4 reaction 156:19 358:14 read 10:16 28:11 118:18 148:14 194:3 270:11 306:11 306:13 375:2 readiness 61:18 reading 20:12 ready 271:9 272:12 318:21 real 24:7 36:18 42:15 58:3 120:16 122:17 185:20 218:2 219:3,11 220:14,20,20 221:13 222:12 222:17 250:12 262:6 263:16 284:2 292:13 306:3 309:7 355:3 358:15
--	---	---	---

373:11,16 reality 46:4 realize 196:7 realized 247:9 261:3 really 9:1 13:1 15:14 17:2 20:16 23:8 24:20,21 27:8 27:18 29:20 31:9,12 35:3,4 36:1 38:6,7,9 39:3 40:9,14 41:8,19 43:2 43:12 44:1,2 44:12 45:7,11 45:16 46:11,12 47:1,7 48:20 49:7,15 50:3,5 50:9,16 51:5 52:17 53:11 54:12 56:10,15 57:2 58:13 59:3,6,12,16 75:17 80:17 84:21 85:7 91:19 96:10,15 97:10,14 98:6 98:19,20 100:21 101:9 102:2 110:2 112:6,16 119:11 120:1,6 120:10 121:8 122:3,7 124:19 125:5,6 126:3 126:18 127:5,9 127:14 129:2	130:1,5 135:3 136:17 147:3 147:17 150:11 150:12,21 152:6 154:9,17 155:10 156:6 156:20,20 168:21 188:5 188:18,18 189:18 190:10 191:15,20 198:11 199:7 199:11 201:18 202:8,9,14 208:20 210:3 211:6,8,17 215:16 216:21 217:21 220:21 221:16 222:18 223:20 224:16 230:11 233:2 236:19 239:2 241:6 244:20 245:3,9,20 246:4,5,9 250:3 254:13 255:19 257:4 257:16 258:15 263:9,18 264:2 264:8,20 266:12 268:21 269:7,21 270:9 273:18 274:15 275:14,20 276:12 277:4,8 279:13 280:21 298:21 299:4 299:13 300:3	302:3,14 304:4 308:3,5 309:5 309:10 310:20 311:5 315:8 316:20 317:17 321:1,18 322:5 324:14 325:3 327:15,20 328:12 330:4 330:15 331:3 331:13 332:18 333:19 334:13 336:2,17,21 346:9 350:19 350:21 351:3 351:13 352:4 355:12 356:6 356:13 357:5 360:20 362:9 364:19 365:3 365:17 367:3 368:17 369:12 370:19 373:6,6 373:11,19 374:15,15 377:4,6,14,16 realms 248:13 reason 10:6,14 35:1 77:21 98:13 112:17 221:18 222:19 303:9 317:18 333:11 reasonable 144:11 332:15 reasonably 69:6 176:9	reasons 13:15 132:15 172:13 301:13 306:3 reassure 293:12 reassured 190:12 reassuring 191:1 rebs 325:5 recall 67:19 353:18 recap 12:5 receive 133:14 167:10 299:17 343:16 received 19:3 89:9 138:16 344:12 receives 67:10 receiving 115:6 314:5 recent 169:1 172:2 174:9 219:18 261:2,7 recently 34:16 40:5 65:8 74:20 79:15 84:7 231:5 261:18 recipients 240:2 recognize 45:1 54:10,20 61:8 71:14 recognized 66:6 78:10 208:9 259:13
---	--	---	---

recognizing 375:11	358:3	reflects 18:7	211:19 218:8
recommend 74:15	recruitment 21:6 23:5	reform 18:12	321:12 323:1
recommenda... 320:16	152:3 273:16	refrain 11:7	323:14 327:21
recommenda... 29:3 30:10	278:15 289:17	refrigerated 154:1	328:10
42:2	302:13 336:19	regard 119:17	rehkopf 59:2
recommended 74:11 261:8	350:16 360:15	regarding 29:4	reimburse 335:21
recommending 11:6	red 140:12	96:5 299:3	reimbursed 336:7
recommends 169:9	165:7,11 171:9	302:10	reimbursement 22:17 332:15
reconvene 130:19 223:4	175:18 176:10	regardless 26:10 169:14	335:16
record 67:13	313:13,21	348:4	reimburseme... 275:19
75:16 79:8	redacted 256:1	region 69:14	reinforced 123:9
123:1 128:18	256:6	157:1 159:16	reinventing 325:18
131:3 138:12	redeemable 295:15	160:1 194:7,7	reiterate 18:10
223:6 380:9	redesigned 340:15	195:14	42:5
381:5	reduce 90:5	regions 69:8	reiterated 22:8
recorded 67:9	136:6 217:19	214:12,13	24:6
380:6	reduced 380:7	registered 185:3,11	reiterations 258:9
recording 380:8 381:4	reducing 138:1	registry 133:6	relapse 310:4
records 141:8	reduction 149:4,12	139:14,15	relate 269:13
recruit 21:18	reed 5:10 378:2	144:13	related 10:1
159:19 160:1	reengage 118:1	regular 211:21	65:15 162:21
199:9 358:9	refer 297:16	regulate 196:4	181:3 240:18
360:16 368:8	reference 30:14	regulations 72:14 162:20	271:9 275:19
recruited 199:13	referred 20:7	166:14 168:20	276:8 277:10
recruiting 185:1 269:3	134:15	170:18 328:17	294:12 310:1
350:21 357:8	referring 162:10 203:15	328:19,20	333:13 349:9
	reflect 90:21	regulators 16:21 74:11	352:8 372:8
	110:10 113:5	158:10 325:9	380:11 381:7
	reflected 295:9	326:21 331:6	relates 19:20
	reflections 371:17	348:3	relations 339:16 341:21
	reflective 110:2	regulatory 2:18 8:5 10:3	
	290:12	169:1 183:2	

relationship 27:17 45:5 61:21 78:9 251:7 258:16 258:20 287:12 343:4	remains 128:21 remarks 10:13 371:7 remember 9:7 34:2 37:13,13 51:7 57:1 61:11 92:9 157:9 161:4 222:9 235:16 241:5 319:9 341:15 349:6	repercussions 99:12 rephrase 344:11 replaced 28:8 replicate 212:6 212:16 report 18:16 19:7 67:13 133:17 148:7 162:16 174:16 175:1 195:21 277:18 reported 1:18 75:14 118:14 140:15 174:21 307:6 reporting 53:20 58:7 191:4 195:6,6 221:2 reports 134:19 174:4 repository 240:7 represent 62:5 174:1 186:5 187:20 196:14 290:8 304:4 representation 26:20 27:19 67:1,5,15 68:5 69:3 75:9 76:14 77:16,20 92:4 102:21 103:2 114:8,9 114:10 115:13 122:8 166:7,12	167:16 168:5 169:18 177:4 177:21 179:4 187:4,14,15 194:18 221:10 268:11 317:7 373:7 representative 4:17 25:11 97:21 124:9 162:20 165:20 166:16 173:5 193:21 197:7 197:14 216:4 226:7 227:4 247:4 373:18 representativ... 163:6 169:17 172:21 173:10 173:12 174:8 177:6,10,19 178:4,20 179:1 181:4 186:1 191:2 216:8 217:3 representatives 31:14 32:3 43:14 204:14 represented 12:13,15 66:18 140:13 147:13 196:6 representing 162:8 176:9 180:6 226:10 represents 176:20 327:16
relationships 61:17 231:16 259:3 286:10 288:20 293:8 308:11	remind 9:6 reminded 111:17 reminders 138:13,21 reminds 189:2 remote 25:15 127:21 131:17 134:16 135:4 139:9 remotely 278:9 removal 95:12 remove 233:5 removed 11:5 66:18 237:4 removing 251:6 remuneration 275:18 reorganization 345:18 reorganize 346:10 reorganized 345:16 repair 269:1		
relative 177:19 272:4 380:13 381:10			
relatively 82:21 146:11 163:21 164:16 191:1 308:16			
relevant 19:13 19:14 24:7 30:5 66:12 72:14 92:21 129:7 146:8			
reliability 268:14			
reliance 89:20			
relied 231:21			
relief 37:9			
religious 117:5 117:8 244:7			
relinquishes 204:2			
reluctant 75:20			
rely 232:13			
remain 320:8			
remainder 28:4			
remained 138:21			

reproductive 245:7,21	215:8	252:19 258:5	reservation 228:7 233:9
repurposed 219:7	res 228:5	268:14,21	250:18 260:5
request 29:2,14 167:7	reschedule 202:3	269:4 270:3,10 270:15 271:9	reservations 173:20 227:17 240:5
requested 68:1	research 1:8 3:4,14 8:10	273:7 274:9 276:10,19	residency 291:7
requests 167:5 167:10 178:13	20:6 43:3 45:21 46:8	277:1,10,13,14 277:15,19	residential 279:1
require 29:5,9 29:13 87:7 142:16 143:7 143:20 215:18 294:18	47:5,10 51:4 56:10,21 57:18 59:15,18,20 60:4 64:17 65:11 70:12,14 73:4 77:4 78:4	278:1 279:2 280:9,14 281:1 281:2,8,13,14 281:16,19 282:7,18,19 284:1 290:1,17 290:21 291:6	resilience 323:13
required 18:18 39:1 83:2,4 92:11 93:2 167:20 171:21 172:8 185:7 295:3 348:1	81:15 83:5 84:10 85:13 89:15 92:21 97:7 100:12,14 100:17 101:16 102:7 106:19 116:9,10 123:13,19 131:12,20 132:4,15 133:5 133:8,16,19 134:1,19 135:14 138:4 151:19 159:16 166:17 167:21 172:12 181:1,3 181:5,21 182:2 182:10 183:13 183:19 201:16 208:6 210:4 212:7 218:5 236:2 243:2,4 243:17 249:20 250:3 251:8	284:1 290:1,17 290:21 291:6 291:19 295:17 296:17 297:14 297:15 299:4 302:10 303:2,3 303:4,18 304:6 304:11,18 306:14 309:11 311:6 317:5 321:10,12,14 321:18 336:21 337:3,11 338:4 356:17 361:11 363:11	resonated 231:8
requirement 19:2 22:20 168:4 184:14 215:20 366:2		290:21 291:6 291:19 295:17 296:17 297:14 297:15 299:4 302:10 303:2,3 303:4,18 304:6 304:11,18 306:14 309:11 311:6 317:5 321:10,12,14 321:18 336:21 337:3,11 338:4 356:17 361:11 363:11	resource 128:15 129:10 153:8 207:8 284:5 309:20
requirements 18:13 24:16 28:7,18 30:10 72:1,13 168:1 168:3 178:18 215:10 292:18 327:6 328:4 366:5		302:10 303:2,3 303:4,18 304:6 304:11,18 306:14 309:11 311:6 317:5 321:10,12,14 321:18 336:21 337:3,11 338:4 356:17 361:11 363:11	resources 42:6 68:15,17 122:21 143:8 153:10 160:8 160:11,21 269:11 270:7 274:15 275:20 340:12 341:4
requires 18:16 72:3 166:18 167:19 183:20 193:15 211:10		304:11,18 306:14 309:11 311:6 317:5 321:10,12,14 321:18 336:21 337:3,11 338:4 356:17 361:11 363:11	respect 61:16 125:10 190:18 191:2,6 284:19 296:12
requiring 170:18 214:21		researcher 64:7 116:16 182:9	respected 189:20
		researchers 62:18,21 66:21 78:19 239:16 249:17 252:1 277:5 287:9 320:12 324:16 357:2 360:14	respectively 80:19
			respond 61:20 279:20
			responded 78:20

<p>responding 70:19 327:6</p> <p>response 136:11 154:5 156:18 228:21 229:5 251:17 267:12 268:8 358:8 368:16 370:6</p> <p>responses 129:8 141:12 280:6</p> <p>responsibilities 265:15 274:19</p> <p>responsive 61:13,15</p> <p>rest 8:19 101:3 122:2 130:17 131:1 188:19</p> <p>restrict 69:11</p> <p>restrictive 20:8 172:10</p> <p>result 147:1</p> <p>resulting 82:16 85:6 163:13</p> <p>results 26:15 28:16 115:12 146:14,15 174:7,9 191:18 247:14 267:18 267:19 293:18 326:14 327:3</p> <p>retained 342:19</p> <p>retention 23:6 90:2 294:13 298:4 309:8 350:16</p>	<p>retired 79:15</p> <p>retrospective 76:14</p> <p>return 233:15 252:6</p> <p>returned 260:6</p> <p>reunited 40:8</p> <p>revealing 83:13</p> <p>review 9:16 71:1 83:21 216:11 219:16 255:21 357:7</p> <p>reviewed 82:12 172:18 263:4 263:13</p> <p>reviewer 3:9 161:14</p> <p>reviewing 9:15 215:21 216:10</p> <p>revisited 74:6</p> <p>revisiting 159:13</p> <p>revitalization 67:8</p> <p>rheumatologic 133:15</p> <p>rheumatologist 182:9</p> <p>rheumatologi... 137:20,20</p> <p>rheumatology 133:4,5</p> <p>rhiannon 78:18 96:9</p> <p>rich 101:1 207:21 208:1 375:1</p>	<p>richard 1:18 380:2,18</p> <p>richness 50:7</p> <p>rico 62:9,10</p> <p>ride 57:12</p> <p>right 12:5 13:8 13:10,16,21,21 14:7 15:3 16:7 17:2 33:4 35:21 40:20 45:13 46:17 48:19 49:19 54:8 55:9,11 55:14 57:17 58:20 61:4 68:7 76:1 82:9 87:21 107:20 109:19 110:13 110:16 113:10 120:20 131:14 140:12 141:11 150:17 152:8 153:1,8 154:2 155:17 160:11 160:18 161:5,6 161:7 165:5 167:3,9,12 168:3,16 169:16 175:3 176:5 186:10 192:20 195:17 196:3 205:8,11 207:7 209:11 209:17 211:18 217:1 218:10 223:3,15 241:6 242:20 258:19 264:19 283:3,8</p>	<p>313:18 318:1 318:11,17 324:12 325:17 329:4,5,13 330:6 332:18 333:7 335:2 336:14 337:21 338:21 339:4 340:1 341:21 344:1,10 349:13 350:17 353:2 355:16 358:6 359:4,17 361:3,4 363:10 363:17 370:8 370:16 373:16 376:20</p> <p>rigor 299:7</p> <p>rings 230:11</p> <p>rise 312:1</p> <p>rising 164:16</p> <p>risk 74:17 142:13 149:4 159:13 163:13 166:5 174:2 193:13 217:20 300:5 313:18 366:13</p> <p>risks 159:9</p> <p>robin 32:17 286:20</p> <p>robinson 3:13 7:6 180:20,21 192:14 219:21</p> <p>robust 323:9</p> <p>robustness 268:14</p>
--	--	--	---

<p>role 97:5 181:9 230:18 317:2 325:5 356:1 rolling 40:19 room 1:15 13:1 17:1 55:14 79:5 108:11 193:18 210:11 212:21 213:15 241:20 245:12 round 44:14 62:8 63:9 111:2 286:19 routes 277:21 routinely 210:20 rudimentary 228:21 ruger 32:17 run 138:20 158:15 200:9 200:11 201:4 216:6 338:11 378:13 running 59:11 runs 299:20 rural 16:5 51:20 54:14 62:16 63:10 111:2,5 191:10 227:18 274:20 276:5 300:21 rush 203:17 rushed 261:10 russia 84:9</p>	<p>s s 2:1 3:1 4:1 5:1 6:1 7:1 8:1 199:20 sabotage 233:21 sadly 198:15 234:17 safe 11:14 12:8 18:3 82:17 127:5 137:6 142:10 187:21 267:20 337:15 safety 9:16,17 98:21 99:7 133:2 142:9 149:11 165:18 218:9 256:10 268:5,12 sahara 150:7 saharan 149:18 152:2,4,12 153:19 154:11 156:8 160:1 sake 183:15 salons 288:9 sample 139:4 140:7 162:6 163:6 212:12 samples 135:10 141:7 152:17 152:19 153:21 240:13,13 318:10 sampling 69:8 sand 183:12</p>	<p>sari 4:17 7:12 193:19,20 196:21 226:6,6 229:9 238:12 243:6 254:4 264:7 327:18 329:7 344:16 356:5 358:21 359:3 365:8 satisfaction 141:12 satisfactory 141:21 saw 39:13 69:5 71:10 137:13 152:2 199:2 220:13 255:21 376:3 saying 29:20 42:20 54:19 116:13 129:17 154:20 216:2 224:21 236:15 252:3 255:10 264:10,18 281:10 308:7 317:18 329:7 332:21 349:12 350:20 354:1 358:17 359:16 359:19 370:5 says 63:14 sc 199:20 scale 305:19,20 scarcity 200:21 202:18 scared 246:6</p>	<p>scary 98:17 281:13 324:13 scenario 201:5 scenarios 200:12 schedule 136:1 357:13 scheduled 140:2 scheduling 22:16 school 2:17 4:8 39:5 90:9 95:13 100:11 136:3 355:3 377:1 schools 39:6 279:1 science 8:5 87:8 90:11 116:10 119:13 126:19 127:12 128:10 218:1 scientific 2:20 64:3 143:2 261:20 278:19 scientifically 199:17 scientist 2:18 100:10 266:16 325:2 scientists 56:12 270:13 scope 83:16 215:13 scratch 286:14 screaming 341:17</p>
---	---	--	--

<p>screen 19:6 375:5,6</p> <p>screening 340:17</p> <p>script 168:15</p> <p>scroll 60:8</p> <p>scrolling 168:14</p> <p>seam 334:1</p> <p>sean 80:20</p> <p>search 59:18 59:20 104:20 106:20 173:13 173:15,21 174:5,11,13,15 176:18 208:6 274:1</p> <p>seated 279:3</p> <p>seats 223:9</p> <p>second 55:9 56:19 57:2 70:8 207:4 208:18 214:17 215:2 257:5 306:6 329:4</p> <p>sectional 73:16</p> <p>sector 181:10</p> <p>sectors 243:13</p> <p>see 11:3,17 19:6,16 32:6,7 40:10 43:6,10 50:21 51:6,14 59:13 62:19 67:1 69:19 73:10 77:9 82:9 85:5 86:12 87:17 88:17 97:5</p>	<p>102:18 108:12 119:16 120:16 121:13 124:12 127:8 133:11 140:15 141:11 141:16 151:10 153:5 162:7 165:13 172:14 173:11 174:9 175:5,17 191:5 194:12 201:5 206:14 207:16 221:13 223:21 228:9 230:20 252:12 277:13 279:18 283:5,8 283:10,14,19 284:10 286:13 286:16,17 293:3 296:8 301:2 307:5 313:16 314:2 324:19 340:16 344:9 359:5,8 359:13 364:19 365:21 370:2,6 378:13</p> <p>seeded 241:4</p> <p>seeing 9:2 17:4 120:19 121:9 261:5</p> <p>seek 236:21 261:1 286:12 286:12 290:11</p> <p>seems 186:4 332:16 343:11 364:1,9</p>	<p>seen 32:18 116:21 118:11 121:1 165:7 210:2 228:20 229:5 343:2 367:6</p> <p>segregation 232:20</p> <p>segue 353:15</p> <p>select 357:17</p> <p>selected 30:12 140:10,20 141:16 142:9 221:18</p> <p>selecting 352:19</p> <p>selection 123:5</p> <p>self 43:9,10 110:5 135:16 140:15,20 195:6 212:11 246:20</p> <p>sells 320:20,21 320:21</p> <p>seminars 153:3 285:10,16</p> <p>send 43:14 241:13 348:9</p> <p>senior 2:4,13 94:12 180:21</p> <p>sense 51:21 86:21 130:1 173:5 215:12 230:1 231:14 238:5 245:14 282:2 317:19 340:3</p>	<p>sensitive 245:7 245:10 289:12</p> <p>sensor 138:11</p> <p>separate 134:1 143:2</p> <p>separately 174:21</p> <p>september 1:11 46:21</p> <p>series 300:15 305:19 311:8</p> <p>serious 163:11</p> <p>seriously 235:14 361:4 370:9</p> <p>serve 46:11 49:1 62:3 68:19 278:15</p> <p>service 241:3 243:5 274:21</p> <p>services 10:19 288:11 292:6 297:17 347:5</p> <p>serving 62:15 151:1 226:20</p> <p>ses 301:5,15,18 310:20 376:5</p> <p>session 130:15 131:8 363:15 364:13 372:2 373:3,4 375:9 375:10 376:15 376:15,16 378:1</p> <p>sessions 82:6 291:1 371:11</p> <p>set 51:13 59:5 81:8,20 82:16</p>
---	---	--	--

169:20 222:18 241:9 287:1 301:8 328:1,1 329:16 sets 58:10 80:15 107:14 129:6 220:8 setting 22:7 82:4,5 189:21 213:9 settings 58:4 308:14 seven 42:9 85:5 128:2,3 several 18:13 36:17 87:11 155:1 171:17 173:19 177:10 178:2 188:13 204:13 240:4 241:20 250:9 333:16 356:20 362:14 severe 25:19 87:2,13,19 88:2 95:10 146:19 severely 241:10 sex 30:4 169:11 373:13 sexual 238:17 245:7,21 249:5 shape 67:1 share 26:21 27:6 49:18 54:15 85:2 111:13 121:10 131:18 134:14	158:19 219:19 266:12 293:17 302:21 319:3 364:14,17 369:13 370:18 375:3 shared 48:10 96:7 101:7 134:12 202:6 229:11,12 231:16 298:11 309:4 319:1 366:17 375:7 sharing 26:17 28:1 30:18 44:21 78:2 213:20 306:7 306:17 309:6 312:20 327:18 370:18 375:5,6 shc 288:5 she'd 260:11 she'll 49:13 56:14 sheets 53:9 shift 24:20 28:3 236:5 263:17 shifted 237:1 shifting 24:21 ship 154:1 212:13 shipped 53:6 shoes 232:13 shops 288:8 short 18:12 28:15 70:11 81:5 171:20 182:2 215:19	239:1 shorten 112:2 113:9 shortened 252:16 shortening 90:16 shout 150:12 199:10 240:1 show 46:19 52:12 59:17 99:5 149:4 159:17 176:2,6 227:19 271:5,7 272:12 292:2 showed 101:14 102:20 112:6 185:18 213:8 showing 165:11 170:2 175:6 313:13 shown 89:4 102:19 165:2 170:13 shows 83:17 85:19 92:17 140:10,12 271:18 309:17 shut 201:16 shy 378:13 sic 201:1 sick 65:2 158:13 230:20 260:10 265:21 sickkids 4:5 266:16 sickle 33:20 40:9 60:15	146:6,10 147:4 147:6 149:16 150:5,19 151:1 155:14,17 159:3 197:21 198:1,5,10,21 199:1,17 214:10 274:4 330:5 side 87:17,21 141:11 210:11 219:14 268:7 290:1 294:19 297:15 304:13 327:21 328:10 328:11,11 335:12,19 378:1 sidebar 232:18 sides 255:6 signage 11:3,5 signaling 130:7 130:8 signals 268:5 signature 380:17 381:14 significant 83:18 84:12 89:17 93:14 114:11 147:16 301:4,21 significantly 84:14 271:20 301:17 silent 247:15 silver 1:16 similar 41:10 77:4 93:7
--	--	--	---

<p>201:11 373:8 similarities 54:18 similarly 229:10 simpkins 2:10 6:11 79:9,12 100:20 112:5 120:14 126:17 332:11 349:11 362:7 367:13 simple 98:14 271:5 295:2 331:17,18 337:14 simplify 22:8 simply 87:13 143:13 190:9 212:13 single 67:19 146:14 184:16 239:14,15 302:7 312:6 sister 50:13 52:2 sit 271:16 282:2 341:16 364:3 site 68:12 70:2 70:2 77:9,9 84:13,18 89:5 89:6 123:5 133:18,18 134:19,20,21 135:14 141:15 156:1 200:16 202:4 207:13 212:18 221:16</p>	<p>221:19 222:1 276:16 277:1 290:3 294:19 325:15 345:15 350:21 358:9 sites 21:4 22:14 66:17,18 68:7 68:12,18,19 69:5 132:19 133:12,17 136:9 151:11 151:12 157:15 207:9 216:5 221:1,6,14 271:8 274:2,9 276:7 278:10 295:17 311:21 335:14,15 346:5 352:18 362:17 368:6 sits 242:17 sitting 20:14 258:17 364:6 situation 26:14 43:11 68:14 88:7 239:13 272:3 situations 239:3 278:21 six 57:14 92:18 92:20 139:1 141:5 237:6 311:16 312:5 sixteen 88:6 sizable 171:4 size 23:16 83:1 83:16 140:8 235:1 361:8</p>	<p>sizeable 149:7 sizes 23:17 skewed 247:14 skills 380:10 381:6 skipping 80:1 slay 266:4 slide 28:13 45:17 59:17 92:17 133:11 134:8 138:9 140:10 145:4 151:10 154:10 161:3 170:21 171:15 273:11 296:10 377:12 slides 39:14 47:8,9 59:12 63:6 70:10 80:1,21 81:1 84:21 280:10 375:3 slightly 130:20 328:15 slogans 265:1,7 slow 134:4 172:1 328:5 small 12:21 71:14 83:17 84:18,21 128:15 140:14 142:2 172:11 326:18 327:9 smaller 23:17 119:21 149:14 212:8 216:14 smallpox 229:3</p>	<p>smartphone 143:14 snapshot 66:12 sneha 2:15 6:14 95:3,7,21 97:19 100:4 226:11 238:1 377:7,9,10 social 87:8 89:18 126:2 129:3 147:18 158:2 181:21 229:21 232:3 235:18 270:1,7 272:7 282:18 288:11 289:17 296:15 299:5 307:5,7 309:6 309:11,12,13 309:16,18,20 310:5 311:1,9 311:9 314:13 314:15 323:12 358:18 359:4 359:13 socialized 241:2 socially 22:1 societal 271:3 socioeconomic 13:11 74:3 138:3 300:15 socioeconom... 191:11 software 211:11 soil 360:13</p>
---	---	---	---

sold 265:8,9	sorely 123:8	source 173:12	216:4 224:6,7
solicited 19:3	sorry 9:4 39:12	235:8	224:15 225:18
soliciting	71:7 105:5	sources 23:19	227:16 241:1
257:13	110:20 132:1	23:21	261:20 266:11
solid 300:6	162:12 168:18	south 48:19	267:2 280:17
solution 72:7	168:20 193:19	84:11,13	280:17 285:9
solutions 5:6	211:2 264:19	246:16 358:2	288:19 311:10
72:3 85:12	266:3 323:3	southern	313:5 318:7
147:6 186:6	327:18 365:11	206:18	339:8,10,12
236:12 267:2	378:9	southwestern	344:18 347:12
273:7,13 275:8	sort 60:11,17	4:13 266:6	349:4 364:16
275:12 356:21	102:1 106:5,8	298:8	speaker 8:15
372:6,12	112:7,13	space 12:6 46:5	11:21 17:12
solve 256:4	115:11 121:10	48:7 56:21	44:15 64:2
330:13	128:9 194:2,11	57:11,15 58:2	109:15 115:10
solved 96:19	204:5 211:19	60:1 63:3	128:8 131:10
solving 147:3	229:10,11,18	77:11,12 158:2	200:5 202:17
147:17,18	230:6 231:1	206:16 243:9	202:21 203:3
somebody	238:14,21	264:13,14	204:11 209:9
24:14 185:7	244:13,14	321:2 333:3,18	225:21 315:15
249:6 338:15	248:10 257:16	337:1,16,18	326:9 345:4
339:3	264:17 265:3	338:2 349:18	364:18 369:16
someplace	295:18 321:7	350:6 352:17	speakers 20:21
354:17	327:7 333:17	353:5 355:10	31:18 130:11
somewhat	334:7 340:2	355:21 356:5	180:2
197:21 343:8	343:19 344:7	356:12,15	speaking 27:10
son 31:20	346:15,18	359:10 361:9	33:3 44:13
33:19 35:18	349:17 351:6	367:12 369:11	54:11 71:16
37:12 41:15	351:11,21	372:13	209:11 221:15
110:17 233:17	353:15 354:3	spaces 285:20	267:6 330:1
342:1	356:7 364:21	344:17	331:10 363:13
son's 33:3	sorted 60:15	spanish 71:4	speaks 215:16
sonographers	sorts 13:13	222:7	306:16 310:6
157:15	16:6,15	spd 110:14	special 8:18
soon 50:20	sound 41:16	speak 30:13	specialists
144:19	sounds 195:9	80:2 109:1	309:20
sooner 347:4,9	201:10 355:14	204:15 208:14	specialized
	355:18 361:20	209:14 215:12	103:3

<p>specific 13:8 17:3 19:4,10 19:12 24:4 81:7,21 83:8 88:12 105:7,18 107:2 133:1,3 146:8 184:1 195:14 197:4 200:17 203:1 214:18 268:12 310:18 326:17 327:1,4 328:13 347:1,7 349:20 352:3,7,11</p> <p>specifically 83:4 90:11 126:18 127:7 152:2 157:9 200:14 213:17 255:9 264:9 267:3 269:5 273:6 300:4 301:12 302:11 322:19 341:16 368:6</p> <p>specifies 169:10</p> <p>spectrum 297:1 361:9</p> <p>speed 91:10 320:7</p> <p>speedy 94:6</p> <p>spend 45:13 281:10,15 341:4</p> <p>spending 35:12</p> <p>spent 73:14 79:14 340:5</p>	<p>spiked 42:11</p> <p>spoiler 119:1</p> <p>spoke 64:16 65:14,16 78:7 78:13 291:2 341:21</p> <p>spoken 94:18 215:11 316:13</p> <p>sponsor 68:11 87:9 89:5,11 167:6 285:1 286:4 325:15 325:19 335:11 335:12,20 348:9 351:10</p> <p>sponsored 81:5 82:13 92:15</p> <p>sponsors 18:16 21:2,14 23:7 27:21 28:18 29:1,3 67:18 74:10 82:15 113:17 167:10 169:9,14 178:18 188:14 214:21 217:13 324:16 325:8 326:21 327:6 329:14 341:4 370:1</p> <p>spot 327:12</p> <p>spread 285:20</p> <p>spring 1:16 178:10</p> <p>squares 105:3</p> <p>ss 33:20 199:20</p> <p>stability 270:6</p>	<p>staff 21:4,9 95:17 151:19 290:7 292:11 378:3</p> <p>stage 13:9 17:15 22:6 23:2,5,5,6 81:8 82:6 92:17 169:20 188:11 235:10 246:21 262:12 264:11</p> <p>stages 22:21 124:20 192:11 293:20 351:7</p> <p>stakeholder 360:17 369:14</p> <p>stakeholders 193:15 219:14 287:9 360:7 369:2</p> <p>stand 51:8</p> <p>standard 45:17 116:14 137:16 142:11 195:3 198:3 203:11 252:17 323:16</p> <p>standardization 53:2,20 110:15</p> <p>standardized 54:4 98:9 110:9 314:6</p> <p>standards 110:19 195:10 321:13 327:21</p> <p>standing 33:6 350:7 362:14</p> <p>standpoint 102:5 143:3,11</p>	<p>263:3 323:14</p> <p>standstill 157:8</p> <p>stanford 59:1,2</p> <p>stark 272:18</p> <p>start 10:1 33:16 69:13 74:15 82:10 95:1 96:1 101:5 109:4 112:5 113:7 120:10,14 131:8 179:21 190:20 197:17 204:20 217:10 220:10 224:6,8 224:20 225:19 227:7 228:1,5 237:15 238:7 239:21 242:4 264:15 265:6 266:13 285:8 286:14 316:4,9 316:9,15 353:18 356:15 356:16 358:2 359:13 364:15 370:5</p> <p>started 8:3,19 34:12 36:10 47:1 119:7 131:1,5,7 139:18 148:5 154:13 155:12 157:5 180:4 197:11 223:8 224:4 225:13 227:21 287:16</p>
--	--	---	--

<p>starters 284:21 285:6</p> <p>starting 34:15 86:13 128:5 146:10,16 220:8 284:13 340:16</p> <p>starts 120:13 265:5 343:10 367:10</p> <p>state 60:17 69:18 117:2 139:9 183:8 184:7,18,18 209:10 380:20</p> <p>statement 136:18 231:10</p> <p>statements 112:13</p> <p>states 111:17 115:5 118:5 140:12 173:19 183:1,9,19 185:1 189:3 206:15,19 240:5 269:10 271:21 272:20 274:3 299:17 299:21 300:11</p> <p>statistical 69:14 100:16 106:21 107:3</p> <p>statistically 114:11</p> <p>statistics 127:13 185:19 283:4</p>	<p>status 74:3 130:15 181:13 274:1 299:2 300:15</p> <p>stay 10:7 43:8 131:7 231:11 265:18 266:13 267:1 268:19 282:15 298:10 375:18 378:16</p> <p>staying 183:8</p> <p>step 15:4 129:9 192:21 221:11 255:12 278:4 314:12 329:21 351:13</p> <p>stephen 3:17 7:9 145:1 182:5,8,16 201:9 211:2</p> <p>steps 249:11,15 252:20 255:16 365:18</p> <p>stereotypes 25:7</p> <p>sterile 237:3</p> <p>stigma 155:14 238:3,9</p> <p>stigmatized 117:7</p> <p>stood 96:6</p> <p>stopped 261:14 375:5,6</p> <p>store 331:19</p> <p>stories 219:3</p> <p>storing 153:21</p> <p>story 44:21 91:5 302:2</p>	<p>376:8,11</p> <p>strange 365:7</p> <p>strangers 44:9</p> <p>strategic 5:6 113:15 186:6</p> <p>strategies 14:17 16:15 17:3 20:21 22:10 48:12,12 50:12 52:4,7 53:11 54:15 57:4 60:2 68:10 71:15 81:13 85:12 92:3 94:5 121:10 130:18 188:16 266:17 302:14</p> <p>strategy 27:14 79:13 82:5 88:18 90:2,8 91:3 112:21 159:14 177:18 181:2</p> <p>streamline 127:15</p> <p>streams 143:9</p> <p>strengths 234:10</p> <p>stress 27:15 35:9,14 40:1 40:15 272:2 275:21 307:11 307:19</p> <p>stressor 39:19</p> <p>stressors 39:12 39:13</p>	<p>stretch 106:18</p> <p>striking 75:13 75:18 76:13 112:16</p> <p>stroke 149:4</p> <p>strong 33:13 69:6 94:1 105:13 314:20</p> <p>stronger 127:8</p> <p>strongly 29:17 323:15 367:20</p> <p>struck 224:11</p> <p>structural 266:18,21 267:3 269:6,7 269:8 278:14 281:18,19 310:2,2 375:11</p> <p>structure 133:8 133:21</p> <p>structured 80:16 276:6</p> <p>struggle 58:15 111:14 116:4 207:2 255:19 307:14</p> <p>struggled 116:9</p> <p>struggling 41:17 325:18</p> <p>student 4:8 189:4 377:1</p> <p>students 72:10 189:3,8 253:16</p> <p>studied 81:16 101:20 115:1 142:16 196:8</p>
---	--	--	---

studies 25:9 26:12 29:5 51:17 57:16 58:21 66:14,16 67:2 69:1,3,4 70:6 73:7,8,8 73:16,16,17 74:7 78:4 81:6 82:20 83:8 85:1 87:20 88:9 93:6 102:20 103:2 107:15,18,20 119:20 120:20 121:13 128:19 132:20,21 135:2 144:3 149:14 150:1 150:14,20 154:3,7 162:20 166:19 167:20 168:8 169:15 170:16 172:4,5 172:7,19 173:11 175:14 176:3,7 177:8 187:19 191:5 195:19 196:3 196:12 202:11 213:11,17 216:14,15 219:8 253:3 290:3 study 14:13 24:16,16 29:8 29:9 30:5 56:15 59:1,14 69:5 71:7,9,21	85:16 89:10 93:7 102:19 104:1,21 106:13 107:14 135:10 136:3,4 138:10 139:1 140:1,3,7,13 141:1,3,14,19 142:3,19 143:15,16,17 148:12,14,19 149:4,6,7 151:20 153:10 153:12 154:21 155:4,8,12 156:7 157:6,14 159:4,6,11,19 159:21 160:2 160:16 169:11 172:8 173:11 173:14,15,21 174:5,11,13,15 175:15 176:19 177:9 186:12 187:1,7 198:20 200:8 201:14 201:18,21 202:3 203:8,14 204:1,3 208:7 213:7 214:6 215:1,5,9,14 215:21 218:5,5 219:9 228:8,13 247:20 252:16 252:19 253:4 253:14 262:20 263:5 268:13 275:19 278:8	278:10 279:15 281:21 284:19 289:20 290:4,7 291:21 292:8 292:10,18 293:19 294:12 294:14 296:20 297:6 298:21 300:9 302:8 305:13 309:4 312:7,12,18 336:10 350:11 350:12 357:15 studying 14:5 stuff 258:2 353:21 354:12 354:18 stupid 260:13 style 291:12 sub 149:18 150:6 152:2,4 152:11 153:19 154:11 156:7 160:1 243:13 subgroups 110:7 subject 134:7 175:13 subjects 172:8 172:15 175:8 175:11 176:4 176:13 248:11 submit 18:17 29:20 139:5 169:9 submitted 104:10 105:21 107:16,19,21	162:6 163:7 169:8 173:2 176:1 177:11 357:11 submitting 28:19 subpopulations 24:4 subsets 216:15 subspecialty 72:16 success 22:7 43:3 113:2 219:3 220:9 222:18 273:5 284:18 successes 220:1 successful 21:5 33:15 126:14 159:11 successfully 132:17 suddenly 36:3 sue 2:20 6:10 64:2,5 79:2 102:20 179:15 366:12 suffer 43:9 88:13 146:19 146:21 149:13 293:2 suffering 38:2 38:6,9 341:13 341:17 sufficient 186:7 suggest 219:17 301:20
--	---	---	---

<p>suggestion 249:1 363:8,8</p> <p>suggestions 348:18</p> <p>suggests 106:21 308:16 309:4</p> <p>suitable 16:16 148:10</p> <p>sum 370:16</p> <p>summarize 130:6</p> <p>summarizes 113:13</p> <p>summary 19:7 167:18</p> <p>supplement 126:21</p> <p>supplies 203:18</p> <p>supply 204:4</p> <p>support 5:8,9 5:10 82:17 95:19 100:13 148:21 150:19 151:8,19 152:18 153:19 154:6 159:20 162:7 232:11 236:5,5,19,20 236:21 237:6 237:12 259:17 276:2,9 284:11 286:3 294:5 312:17 323:8 377:20 378:2</p> <p>supported 173:18 367:7</p>	<p>supporting 36:13 149:11</p> <p>supportive 238:8 239:10 239:12</p> <p>supports 54:6</p> <p>supposed 256:5 256:7,9 257:18 264:15</p> <p>sure 12:8 13:16 14:1,4 16:2,8 18:5 27:5 37:13 58:13 74:19 76:5 78:4 99:21 107:18 119:10 128:5 143:12 156:3,5 158:2 158:14 168:15 181:3 187:19 189:18 204:14 205:20 206:2 216:21 264:7 289:11 293:4 294:19 295:12 296:9 297:18 319:13 334:17 335:16 336:12 342:13 344:6 349:14 357:18 357:20 358:10</p> <p>surface 50:9</p> <p>surgeries 34:15</p> <p>surgery 95:12 235:21</p> <p>surgical 73:8</p> <p>surprising 83:13</p>	<p>surprisingly 66:3 74:12</p> <p>surrounding 278:13 297:13</p> <p>surveillance 173:16</p> <p>survey 70:14 105:1 141:12</p> <p>surveyed 173:18 183:9 186:13</p> <p>surveys 310:14</p> <p>survival 232:1 313:13,16 314:2,6,8</p> <p>susan 84:17</p> <p>susceptible 289:5</p> <p>suspect 69:21 228:15</p> <p>sustain 315:21</p> <p>sustainability 233:14 234:10</p> <p>sustainable 287:19</p> <p>sustained 68:17 362:21</p> <p>sweeping 112:8</p> <p>switch 88:16</p> <p>sworn 380:5</p> <p>symptoms 148:8</p> <p>synagogues 249:14</p> <p>synthesis 2:21 64:3</p> <p>system 50:5 64:21 75:19</p>	<p>147:15,16 193:2 227:20 229:11,11 232:11 241:9 259:10 279:7 323:10 338:19</p> <p>systematic 15:9 43:18 228:19 258:15</p> <p>systemic 136:15 234:17</p> <p>systems 62:6 62:10 70:20,21 75:8 194:10 227:15,17 230:21 240:19 241:16 270:8 339:6 340:6,20</p>
			t
			<p>t 6:1,1 7:1,1</p> <p>t2d 162:11,18 163:5,10,16,21 164:5,7,15,18 165:1,3 166:1 166:8,12 170:5 170:15 171:2 171:16,18 172:20 173:7 174:10 175:5,8 176:1 177:3,11 177:15 178:5 179:5</p> <p>table 10:16 31:4 42:19,21 43:15 62:8 66:12 111:2 242:17 269:20</p>

343:4 364:3,6 367:14 tables 63:10 tablet 135:8 148:9 tackle 273:11 326:7 tag 346:6,7 tagline 352:16 tailor 50:12 286:14 289:15 tailored 50:18 52:6 55:4 57:3 289:8,18 take 9:5 12:4 12:16,18 13:4 17:2 25:6 26:15 31:1 33:12 35:6,8 38:10 61:9 63:21 78:10 79:4 87:16 88:8 94:21 97:16 111:12 115:21 118:8 124:13 130:19 136:18 141:14 156:13 167:16 168:4 192:10 194:14 201:9 203:4 210:3,10 212:15 214:19 223:4 230:21 233:10 243:21 244:3 249:15 251:12 257:19 259:8 266:8 270:17 271:11	276:17 283:1 292:1 294:14 295:1 318:2,5 319:3,5 324:12 335:11 336:5 336:13 346:15 356:1 358:5,12 366:14 373:1 takeaway 19:20 21:2 319:15 320:9 320:10 321:6 322:6 374:4 takeaways 90:3 317:14,15 371:9,18,20,20 373:2 takeda 3:14 181:1 taken 34:17 40:15 46:20 108:20 235:13 296:2 343:14 363:9 380:3,12 381:9 takes 27:19,21 32:12 61:6 76:21 85:17 128:3 169:17 275:14 315:2 talk 17:11 18:1 18:20 21:13 25:14 28:4 31:13 36:19 39:16 41:13 45:4,7,10 47:5 47:17 49:13 56:13 57:21	79:3 83:11 85:14 103:21 107:16 122:10 134:12 143:2 145:10 146:7 161:15 162:3 182:12 193:13 205:17 225:8 237:2,17,18,19 246:18 248:14 250:19 251:12 260:12,15,16 261:18 264:9 266:17 269:5 273:6 278:12 281:6,6 282:1 282:3,6 284:12 306:4 324:1 325:9 333:3 337:19 338:8 338:13,14 342:10 353:13 375:19 376:20 378:15,17 talked 19:19 20:16 22:10 27:7 37:7 49:3 49:8 52:2 106:8 121:9 144:5 248:15 281:3 291:14 315:2 333:15 335:4 342:15 342:15 351:14 374:18 talking 15:13 22:11 37:14 40:6 47:6 56:8	129:12,14 192:17 210:6 219:4 230:1 232:18 238:3 238:10 242:2 248:9,10,11,19 253:4 256:19 280:20 282:13 298:13 333:9 338:9 341:19 343:9 346:14 351:4 361:2 talks 282:5 349:21 375:10 tamorah 4:4 7:10 265:19 266:15 282:14 294:7,17 310:3 325:1 332:11 334:7 369:17 tangible 84:20 275:8 276:3 353:5 tank 324:17 tap 11:7 target 21:21 181:14 190:16 219:10 263:1 270:20 311:2 targeted 22:11 268:6 289:19 targeting 299:5 311:1,8 314:15 targets 23:21 172:5 219:17 tattoos 240:14 taught 74:17 124:3
--	--	---	---

tcd 149:5 157:12 160:14 160:17	157:10 159:21 161:4,13 197:17 261:18	tenant 113:6	304:20
teach 281:8	ted's 197:4,17	tend 47:17 102:15,18 125:10,11 191:9	tested 312:14
teaching 248:19,21	teenager 34:21	tender 34:8	testifying 380:5
teal 133:11	teenagers 354:8	tends 164:12	testing 98:13 152:20 161:16 209:7 247:7,8 247:14 311:18 311:18 318:13 330:11
team 44:7 91:4 104:6 108:15 142:19 150:12 154:12 155:3 156:11 160:11 236:7 243:17 270:15 281:2 281:16,21 286:18,21 287:1,1 290:1 335:13 341:2 362:15	tele 183:13	term 47:16 66:2 98:21 99:6 123:20 160:18 238:21 239:1 256:10 293:2	tests 158:1 262:20 304:15
teams 276:10 280:14 281:8 288:4 289:20 336:21 338:4	telehealth 183:10	terminology 54:5	texas 298:8 336:4
tears 65:16	telemedicine 183:10,13 185:7 211:11	terms 83:12 84:17 98:11,15 102:9 109:11 115:14 138:1 141:1 142:8 143:4,11 148:17 162:8 167:9,14 172:21 176:9 177:17 183:10 187:17 191:3 198:18 201:12 208:6,12 218:13 254:21 318:9 319:7 331:3 356:5,14 368:7 372:6	text 76:9
techniques 127:12	tell 55:8,10 78:9,18 95:4 103:16 107:20 127:16 184:1 188:14 206:17 206:18 214:2 215:20 216:3 221:7 230:10 230:12 235:20 247:10,11 257:8 260:10 261:17 329:13 376:7,10 377:16	terrific 101:10 374:14 377:6	texts 138:14
technologies 22:14 26:5	telling 34:2 217:7 230:9 255:1 339:3	tertiary 102:14 299:17 309:21	thank 9:1 11:17,19 17:6 17:9,10,10,17 30:18,20 32:1 32:14,16,17,20 32:20 33:8 35:5 36:15 44:4,5,7,7,9,10 44:19,20 63:21 64:1,6 79:1,2,7 79:9,9 80:6,13 81:2,9 94:7,8 94:17 95:21 100:3,19 101:8 103:9,14,19 107:5,10,11 108:2,6 109:2 109:14 111:9 111:11,14 113:12 114:15 116:2,19 118:7 119:4 121:18 126:10 130:3
technology 127:14 135:3 142:21 143:12 158:3 211:7,7 211:15 213:12 213:21	tells 66:20 242:17,18	test 10:20 56:15 252:15	
ted 3:5 6:20 145:10,16,18 150:16 151:3 151:21 156:17	template 325:10 326:1		
	ten 9:15 85:6 93:15 140:5 141:4 195:17 317:9 318:10		

130:10,13,14 131:14,15 132:8 145:3,5 145:8,9 146:1 150:16 161:12 161:19 179:10 179:12,13 180:18 181:17 182:13,20 184:15 185:13 185:15 193:6 196:20,21 204:10 205:2 205:15 206:6 210:9 212:2,19 214:16 215:6 217:9 222:21 223:15 227:6 232:15 256:18 261:15 265:12 266:8 282:10 305:6 315:6,18 316:17,19,19 319:9,10,14 321:3,3 322:2 322:2,3,4,4,18 324:21 326:6,6 326:8 327:10 328:14 341:6 343:6 345:1 346:12,13 349:10 353:14 355:13 370:15 371:2 377:5,10 377:14,18 378:2,21 thankful 32:10	thanking 130:12 223:1 thanks 47:21 80:20 131:2 161:10 168:16 182:7 192:13 201:7 204:11 211:4 368:1 377:4,6 379:1 theme 304:3,16 354:19 themes 304:1 372:5 theoretical 282:2 theory 276:11 therapeutic 83:12 133:1 170:9 299:9 301:5,7 327:4 therapeutics 1:1 2:12,19 3:8 8:7 9:9 10:2 94:12 99:10,13 100:1,18 104:2 104:8 115:19 137:7 145:14 146:7 321:8 therapies 82:18 94:6 98:9 115:15 127:6 167:2 303:20 314:6 therapy 91:1 117:13,16 120:17 250:10 259:13 312:11	thereof 71:2 thick 260:9 thing 13:20,21 22:7 39:17,18 41:17,21 50:10 52:8 76:13 78:1 99:9 112:11 124:19 139:19 142:8 143:1 146:1 149:15 155:18 161:5,7,7 188:9 199:16 205:3 210:20 213:12 218:3 218:12 225:11 230:5 231:1 244:15 245:16 246:1 252:21 321:21 333:6,7 334:10 338:7 357:4 375:8 376:13 378:9 things 12:16 14:11 16:1 18:21 38:13 41:19 56:1 75:6 80:10 90:15 97:15 98:12,14,19 102:9 119:9 125:3 126:3 127:13 129:13 135:5 145:20 156:10 184:5 188:17 204:18 211:14 212:6 224:12,13,15	229:3,14 230:1 232:8 237:2 241:8 243:16 245:4,17 248:14 249:3,7 251:1 252:12 255:14 257:3 270:12 274:12 275:9 276:11 282:1 300:2 303:6 304:12 304:21 305:4 306:5 311:11 314:13 316:2 318:20 328:18 334:7,9 335:4 335:6 337:2,16 337:19 338:13 340:10 346:15 347:3 348:5 349:5,8 356:3 358:2 359:20 366:10,17 368:2 369:6,8 369:9 371:8 372:3 376:1 think 9:4 10:11 13:5,7 14:21 15:10,12,14,16 15:21 16:18 17:1 23:8,19 24:9 25:13 29:17,21 30:4 41:2 44:21 45:11 47:7,20 49:3 70:6 74:17 75:5 78:19 81:13
--	--	--	--

[think - thinking]

Page 91

86:5 96:8,10	197:19 198:1	256:12 257:15	341:20 342:5
96:14,16,16,17	199:1,1,14	258:4 261:10	342:14 345:12
96:21 97:4,13	200:3,6 202:15	262:11,21	345:14 346:7,9
98:3,11 99:1,4	203:15,20	263:2,9,16,17	347:21 348:7,7
99:21 101:2,9	204:18 205:3	263:21 264:7	348:19,21
102:2,19	205:18 206:1	264:18 265:6,8	349:18 351:9
103:12,21	206:12,21	265:11 267:6	351:11,14
107:5 109:4	207:15,20	269:6 270:2,12	352:6,15,15,18
112:1,2,9,11	208:18 209:10	271:11 276:10	352:19 353:6
113:13 114:12	209:20 210:5	276:10 280:12	353:12,13
115:7,13 116:4	211:5,17,20	291:2 296:10	354:8 356:4,6
116:13,16	213:3,8,10,11	296:14 299:8	356:7,14 357:5
117:12,14	213:14 214:8,9	300:10 303:8	357:21 358:21
118:3 119:6,16	214:15 216:12	305:5,7 306:16	359:3,8 360:18
120:3,6,21	216:20 217:12	306:21 307:2	362:4,7,18,19
121:4,8,12,19	217:14,21	307:20 308:4,9	363:1,10,12,12
122:9 123:3,6	218:12,19,20	308:15,19	363:14 364:20
123:8 124:3,6	219:21 220:3	309:3 310:1,6	365:5,13,20
124:18 125:5,9	222:6 225:8,13	310:17,17	366:4,6,9,11
125:11,19	227:7,10 229:9	311:12 313:9	366:16 367:14
126:2,4,8	229:17,21	314:10,13	368:2,10 369:6
127:10,17	230:4,8,10,11	316:12 317:16	369:12,17,21
129:21 130:4,5	230:12,17	318:1,15	370:9,10
132:13 134:10	231:20 232:5	319:15 320:14	371:21 372:9
136:18 141:17	233:2,16	320:19,19	372:12,16,18
141:20 142:3	234:20 236:17	321:1,6,15	373:2,10,14
144:4,6 154:8	237:7,10,15	324:2,4,5,17	374:4,7 375:9
158:7 160:3	238:1,14	324:19 325:7	375:19 376:6,8
168:18 183:3	239:15 243:8	326:10,19	377:3
184:5 185:20	243:21 244:20	327:20 328:6	thinking 14:15
187:10,11,12	245:4,8,13,15	328:10 329:1	14:16,18 15:5
188:2,4,5,18	246:4,13,13	329:18 330:4	16:8 23:4
188:21 189:8	247:19 248:2	331:2,13	74:15 95:15
189:21 190:8	248:18 249:19	332:14,17	97:1,10 98:5,9
190:14,21	251:12 252:11	333:2 334:12	99:6,12,20
191:12,14,17	252:21 253:15	334:18 335:8	111:1 115:11
191:20 192:5,8	254:1,6,8,20	336:9,16,20	124:21 127:7
193:10 196:18	255:4,7,15	338:1 339:4,5	129:5 190:10

191:7,11 192:4 217:1 220:9 245:8 256:14 273:1 294:5 305:14 307:17 317:3 318:18 332:12 334:6 347:20 351:17 352:20,21 366:12 368:15 368:15 thinks 366:15 third 49:2 83:6 202:16 307:4 thirds 83:4 thoroughly 35:12 thought 66:2 101:2 114:20 115:11 135:21 137:17 174:2 202:5,7 317:16 326:10 364:18 373:4 thoughtful 75:3 91:14 thoughts 96:5 101:6 124:10 188:20 197:17 201:11 327:11 327:16 329:5 333:21 354:2 361:15 371:21 376:17 thousand 146:12 thousands 77:15 231:20	310:13 thousandth 9:16 threatened 39:4,8 threatening 308:5 threats 306:11 three 34:10 41:2 42:12 46:20 47:11,20 48:3,4 51:15 60:20 71:7 94:19 95:2 104:18 155:20 163:17 164:9 178:16 200:21 212:4 215:16 229:4 265:16 266:10 271:5 272:17 284:13 309:15,17 318:11 377:6 threw 55:13 thrilled 223:20 thriving 231:13 throw 335:7 358:15 throwing 265:1 thumbs 361:7,7 ticking 34:3 tie 229:12 ties 343:8 tilling 360:12 time 24:8 28:4 34:3,9 35:12 36:18 39:1,8 42:13,15 44:13	50:16 59:11 61:8 63:2 66:13 67:19 68:15 72:15 82:2 83:19 85:14,17 86:4 86:15 87:11 112:18 125:14 127:17 130:5 131:7 138:15 139:2 145:5 154:12 155:5,6 158:11 160:9 165:4,12 171:9 171:21 181:16 183:15 195:8 200:15,18 203:13 208:20 209:1 211:16 218:14 219:11 220:14,20,21 221:13 222:12 222:17 223:1 228:9 242:18 250:12 253:20 270:17,17,18 275:1 277:11 281:1,10,15 284:4 291:15 291:17,21 292:13 295:3 295:10 303:6 305:5 306:13 306:20 307:17 308:15 310:4 311:15 312:16 312:19 332:3 332:16 339:14	342:4 346:10 358:13 364:5 364:12 timed 277:4 timeframe 235:1 timeline 86:6 86:11 88:14 90:19 113:9 timelines 90:17 172:16 timely 62:2 times 25:17 34:11 42:12 47:17 48:17 49:17,20 85:10 117:7,19 131:16 155:1 163:17 164:9 172:15 200:14 209:2 225:5 253:2,17 276:10 291:16 301:19 321:7 333:16 344:7 371:10 timing 203:16 277:3,9 tiny 34:8 tip 372:19 tired 158:16 today 11:12 18:20 19:16 20:14 31:13 32:2,5,21 33:5 33:11 48:6,10 79:19 80:4,11 81:3 82:2 83:3
---	---	---	---

83:10,19 85:16	93:21 94:2	topics 19:9,12	tracks 261:14
86:1 93:11	105:18 121:9	19:17 81:4	traction 236:4
94:18 95:5	146:2 179:12	237:4 245:6,10	trading 143:13
96:1 100:9	183:6 208:6	273:1,2,11	traditional
103:17 113:16	229:13 324:17	topping 51:2	128:20 140:17
118:11 120:16	325:9,21	toronto 265:21	201:16 212:17
123:10 129:21	346:17 357:12	266:17 325:2	251:15 277:20
144:5 162:3	361:6 367:6	total 85:3	traffic 209:1,3
180:19 182:11	370:12	175:10 292:17	train 153:2
202:6 218:1	told 30:9 34:20	totally 63:1	157:14 288:18
224:7 235:19	37:11 40:8	183:11	trained 340:8
259:8 266:20	41:18 199:8	touch 320:5	training 21:8
278:7,18	241:16 306:9	324:8	124:13 153:3
280:13 293:17	307:13 328:17	touched 122:10	153:11 157:12
301:19 302:14	tone 33:17	294:7 356:7	157:13 158:5
304:2,12,16	tons 41:9	touching	158:11,13,16
305:16 306:7	took 55:13	372:19	160:16 221:8
307:1,20	155:5,6 157:4	tough 281:1	290:21 291:8
308:20 313:10	158:8,17 160:9	tour 42:18	trajectory
315:19 316:3	172:7 265:11	155:11	235:9 309:14
317:13 318:5	295:7 349:6	tours 42:16	transcranial
319:12 321:6	toolkits 123:10	towards 29:19	157:13
321:15,16,19	123:11	39:9 55:4 82:4	transcriber
322:1,6 335:4	tools 14:2	100:17 102:3	381:1
348:6,7,18	15:18,19 16:6	152:4 261:12	transcript
361:18 366:17	25:9,10 26:10	town 43:4,13	381:3,5
369:6 370:10	100:13,16	45:5 49:8,16	transcriptionist
370:14 371:12	125:20	49:20 50:5	380:8
372:1,18 376:3	top 39:6 50:9	62:7 234:7	transfer 152:21
376:18 377:13	66:5 165:8	285:16 291:1	312:2
377:15 378:1,7	193:8 273:10	toxicity 303:21	transforming
today's 82:6	311:5 332:5	310:6	262:2
134:10 232:1	342:2	toxicology 4:5	transfusion
316:6	topic 10:10	toy 285:12	198:9
toe 139:10	48:6 66:10	track 24:7 71:2	transgender
together 12:17	118:18 197:5	79:3 224:14	229:16 244:12
17:5 32:12,13	332:14 350:9	tracking 349:9	transition 94:9
35:8 63:8	351:5		95:16

translate 75:6 349:4	traumatic 229:5	tree 60:21 61:2 61:5,6	105:6 106:16 111:15 114:21
translated 71:12 222:10 292:7	traumatized 242:9	trek 42:10	115:1 117:6,9 122:15 123:5
translating 227:1	travel 22:17 41:9 134:19 135:11,13	tremendous 47:20 316:20 362:8 367:17	128:1,6 130:16 131:9 132:5,6 135:20 136:12
translation 57:9 70:17 71:3,8,14 292:6	142:20 207:15 212:10 315:11 331:17	tremendously 51:1 362:19	136:13 144:10 151:15 153:14 157:3 158:20
transparency 27:2 252:14 262:4 264:18 264:20 302:15 331:21 333:16 333:18 336:17 339:21 351:12 363:5	traveled 139:3	trends 69:15	166:14 182:17 182:19,21 183:6 185:2 186:19 191:18 191:20 192:7 204:7 205:11 207:9,12 208:19 209:5 212:15,18 213:9 216:5 219:16 220:13 220:17 221:4 221:12,21 224:20 225:10 225:10 235:7 243:16 247:21 248:5 249:17 251:13 252:6 256:8 258:2 261:8,12 262:13,16,18 263:19 264:12 267:4 268:19 270:21 271:7 271:17 272:4 273:12,16 274:2 275:4,7 276:1,7,16,18
transparent 252:15 334:11 337:20 350:14	traveling 157:10 202:4 208:19	triaging 179:19	
transplant 77:7 279:15,16	treasa 381:2,15	trial 14:16 15:8 15:15 18:1 19:20 20:10 21:3,3,4,8,11 21:14 22:13,14 23:1 24:9 25:18,21 33:14 35:2,17,21 36:4 37:7,19 38:7,19 39:10 39:20 40:2,7,9 40:16 42:14 43:3 48:8,11 51:17 52:7 53:3,5,12 55:16,21 56:4 60:2 63:4 66:17,18 67:10 68:7,18,19 72:20 76:19 88:5 91:3 92:15 93:2,17 96:5 97:9 98:1 98:8,15,16 99:7,13,15 100:2,15 105:4	
transportation 20:9 22:17 89:21 136:5 138:2 143:13 155:18 156:6 158:1 181:12 274:12 276:2,6 276:8 307:7,8 335:15 347:4	treat 13:17 43:10 251:18 279:21 338:21 339:4		
transportations 311:14	treated 102:14 187:20 234:2 341:9		
trauma 240:18 259:16 280:13 280:15	treating 151:7		
	treatment 37:19 113:5 119:18 150:4 155:15 156:15 165:16 170:15 175:7 192:18 198:11,14 207:17 239:1 259:11 268:8 303:15 305:10 323:7 331:7		
	treatments 34:12 165:19 166:9 170:3 267:12 304:15		

277:4,21 282:4	26:8,15 27:13	134:6,15,17	259:2 265:18
283:4,9,12	27:19 28:16	138:8 140:18	266:2,14,19
285:2 287:15	30:14 36:17	142:6 147:14	267:1,13,17,21
290:16 292:16	37:6 38:21	150:2 151:9,19	268:1,3,11,18
293:6,9 295:14	41:21 44:2	159:1 162:4,6	270:14,16
297:7,18	48:6 51:10	162:21 163:4,6	272:13,21
298:12,18	53:16 54:4	166:8,13,16	274:8 275:11
299:1,11 300:1	55:8 56:18	167:6 168:13	278:8 279:14
300:12,14	60:10 64:13,19	169:6,8,8	282:9,15,17
301:9,12,17	64:20 65:2,10	170:19 171:16	283:20 285:21
302:1,10 303:8	65:21 66:3,15	171:18,19,21	291:4,9 299:7
305:11 307:15	67:6,15,17,18	172:3,15,21	299:9,20 300:4
308:1,16	68:4,6,9 69:9	173:2,6,9	301:5,7,10
311:19 313:1,4	69:16 71:11	174:16 175:1,4	302:1 303:2,3
314:11 319:17	73:11,21 74:8	175:7,10,10	303:4,18
320:17 325:12	75:4,10 76:15	176:1,8 177:3	304:11 305:6
328:4 332:5	78:1,15 80:9	177:11,18,20	309:2 310:10
336:18 340:19	81:5 82:1,14	178:1,6,11,17	310:12 314:5
342:20 347:1,2	82:17 83:16	181:5,15,21	314:18 316:1
348:11,16	84:4 85:9	182:13 184:5	322:7 323:3,15
350:3,8,10	87:15,17 88:6	185:20 186:2	326:12,17
351:7,18 352:1	89:12 90:10	186:15,17	327:2,7 328:8
355:16 359:10	92:4,10,18	187:14 192:12	329:15 330:16
360:9 363:16	93:12 95:20	194:5 195:21	331:15 335:3
363:21 364:5,5	96:17 97:3	196:6 204:17	337:20 342:6
366:18 369:1	101:11 102:10	204:19 205:5,6	347:14 352:13
373:5 374:3,7	102:13,17	205:12 206:15	356:2 360:2
375:20	103:1,7 104:10	207:7 211:6	366:16 367:5
trials 4:10	105:20 106:10	213:3 216:19	372:9 374:5,11
12:11,13 13:14	109:13,20	217:4,14 221:6	375:12,18
14:13,20 15:20	112:4 114:3	224:14 233:3,7	376:3,4,10
15:20 16:2,11	116:17 117:10	233:11,20	triangulate
16:16 18:2,15	118:11 122:8	236:10,13	331:3
19:4 20:3,7,8	122:13 123:14	237:3,8,18,20	tribal 49:12
20:19 21:1,15	124:15 127:1,3	242:3 243:1	50:4 51:20
21:17,19 23:15	128:14 131:17	250:9,13	54:13 62:12,20
25:1,3,12,16	131:19,21	251:14,19,19	63:17 117:13
25:17,21 26:4	132:14,17,19	254:15 256:15	227:12,13,15

228:11,18	251:2,3 254:21	123:18 125:12	type 93:6
229:1,6,7	255:17 256:5,7	126:12 189:9	104:12,12
240:6,6 250:15	256:9 257:10	189:12 192:10	105:12,13,15
250:16 251:16	260:21,21	243:2,17 251:1	105:15 132:5
258:7 260:7	261:1 262:8	251:8 286:7	135:10 142:16
tribe 35:15,16	263:2 264:2	296:4 298:3	162:4,9,10,18
37:1 226:5	265:5,9 268:17	303:16 343:20	163:10,20
229:4 233:12	269:3 278:18	tumor 300:7	164:2,10,11,12
240:8,15	279:3 280:2	tune 57:12	170:1,11
241:15,16	284:8 285:4	tuned 10:7	171:19 172:17
324:12,12	287:6 293:7	turkey 84:11	173:4,16 174:2
tribes 227:21	302:15 305:19	turn 21:18	174:6 177:6
229:5 231:21	305:20,21	100:5 121:17	178:9 202:2
250:9	306:2,5 308:12	145:14,20	203:21 208:4,5
trickle 366:7	308:20 320:7	150:10,15	209:11,12
tricky 124:19	343:9 350:1,1	219:20 223:13	210:20 212:15
tried 31:8	350:19 363:10	319:10 364:1	246:1 247:11
151:5 246:20	372:21 374:21	364:10 371:2	269:18 287:12
triggered	trusted 49:17	turning 40:7	354:11
371:21	49:21 286:1	turns 142:18	typed 274:3
trouble 273:4	287:3 364:3	two 12:16 17:5	types 16:1 59:7
true 107:7	trusting 258:20	19:2 39:13	76:16 103:7,8
230:11 325:16	264:15	41:7 46:7 49:6	127:11 129:8
380:9 381:5	trustworthiness	57:1 59:17	131:18,21
truly 14:2	21:17 255:13	76:13 80:11	134:6 135:2
254:18 270:15	trustworthy	81:5 83:4	142:5,14 144:3
trust 21:10,13	309:1	84:21 98:19	232:6 277:7
21:14,18 27:11	try 15:8 45:10	119:6,15 125:6	279:2 310:9
49:19 50:2	46:19 61:3	138:20 155:19	311:11 327:1
61:16 99:20	74:7 152:6	163:16 167:18	typewriting
155:5,6,10	183:17 184:6	201:20 202:10	380:7
157:1,4 158:17	212:6,11,16	208:20 232:6	typical 136:2
223:12 224:10	217:2 240:16	241:18 246:15	typically 71:3
225:16 228:13	270:20 272:20	258:3 273:11	83:7 92:7,12
228:14,17	329:20	275:3 282:5	147:1 171:20
229:19 230:5	trying 26:7	283:2 310:5	174:20 175:1
236:16 237:16	52:15 87:12	311:6,19 312:7	264:14
238:6 249:16	114:13 116:4	345:17 368:2	

u	ultra 119:14 120:7	312:12	165:16 177:7
u.k. 158:4	umaretiya 4:12	underlying 198:12	179:8 181:14
u.n. 360:21	7:11 193:6	underpinning 135:3	181:15 187:8
u.s. 2:3,4,12,19 3:9,12 4:3 10:18 59:5 70:15 84:3 87:1 88:2 104:15,18,20 105:2,12 108:18 109:21 109:21 140:16 146:11,12 147:4 149:16 150:1 151:4,10 152:1,1 158:4 164:1,3,4,20 172:3 173:4,13 173:19 175:11 175:12,13 176:4,13 177:15 191:10 196:5,6,14 197:8,14 198:4 214:13 246:17 283:3,7	266:3,4 298:6 298:7 315:8 366:11	underreprese... 69:15 104:16 105:14,20 107:1 176:14 308:18	236:21 242:6 243:18 250:13 254:10,13,17 260:2,16,18 265:2 267:14 268:4 270:20 302:4,9 326:4 335:10 346:4 350:20 363:11
uber 276:4	unanimous 65:13	underreprese... 19:5 20:2 21:12 24:3 56:17 68:20 73:15 168:12 169:5 175:19 177:16 192:18 323:6	understandable 27:4 279:5
uc 86:17,19 87:2,13,19 88:2 89:12 93:7	unburdened 325:16	underscore 75:2 220:19	understanding 21:20,21 46:13 48:9,20 49:7 50:16 57:2 58:4,16 59:3,7 87:7 91:12
ucsd 312:21	uncertainty 184:8 218:11	underscored 101:15	154:18 181:12 187:13 215:7 234:8 244:16 244:18,19 255:8 273:2 291:8 292:18 305:1,7 334:13 365:14,17
ukraine 84:9	uncle 233:12 247:12	underserved 37:3,16 38:14 38:15,19 58:8 67:20 226:18 288:6 343:15 368:21	understatement 151:2
ulcerative 86:13 95:10	under 30:15 35:9 60:11 69:1 83:2,9 92:11 95:11 104:11 107:19 107:21 141:4 147:7 148:19 164:2,7 168:8 169:15,15 215:10 260:17 296:17	understand 13:17 14:2 50:11 53:21 60:6 65:9 71:19 74:7,19 76:17 84:15 90:5 118:6 124:20 151:5 153:4,16 154:14 155:2	understood 156:7 186:19 345:11
ultimately 149:9 374:13	underfunded 241:10		undertook 71:6 74:21
	undergird 35:16,18		underway 81:12
	undergoing 238:21 312:6 313:6		
	undergone 311:18 312:6		

undoubtedly 281:19	unknown 304:13	23:20,21 24:8 25:18 26:11	187:6 198:8 224:15 244:21
unfamiliar 207:16 274:13	unmet 46:13 48:9 49:8,18	46:17,18 51:13 82:4,18 89:21	264:21 277:20 300:21 305:18
unfortunately 86:8 137:3 146:15 198:5 200:10 341:14	50:8,11 52:5 57:2 307:5,6 309:6,11,15,18 310:5 311:8	90:11 94:3 111:19,20 126:19 127:6 127:10,12	341:20 342:5 usually 21:13 118:14 295:17
unidentified 109:15 115:10 128:8 200:5 202:17,21 203:3 204:11 209:9 225:21 315:15 326:9 345:4 364:18 369:16	unnecessary 304:15	129:6,9 135:3 138:17 143:5 143:16 148:20 160:16 185:11 187:8 213:16 242:13 258:6 262:11 285:20 289:8 295:20 298:20 348:5	ut 4:13 266:5,6 utilities 307:7,9 utilization 189:15 utilize 126:2 286:3 292:7 utilizing 292:12
unique 23:3 111:6 163:3 169:21 172:19 197:21 304:3 372:8	unpopular 262:7	used 25:10 76:8 88:18 92:13 104:18 107:1,4,14,19 166:15,21 167:13 170:5,6 206:12 232:19 249:19 295:15 299:7 300:15 302:13 308:18 321:9 326:1,5 340:19 345:16 346:6	v
united 115:5 183:1 189:2 206:15,19 240:5 269:10 271:21 272:19 274:2 299:17 299:21 300:10	unquote 107:3 230:16 272:21	unrestricted 312:1	vaccinated 228:10 vaccination 340:17 vaccines 83:15 83:17 validated 341:14 367:7 validation 152:21 validity 38:2 341:13 valuable 161:1 161:2 192:2 229:21 value 64:14 186:16,21 187:2,9,13 224:19 227:14 229:11 295:11 298:4
universal 325:10	unrealistic 88:15	unusual 235:4	
universally 326:1,5	unrestricted 312:1	unwraps 196:19	
university 1:4 3:3,18 8:4 59:1 62:9,11 77:14 131:12 182:9 298:8	unquote 107:3 230:16 272:21	upcoming 82:1 92:14 93:14 119:13 145:2	
	unrealistic 88:15	update 110:14 updated 50:19 upfront 270:17 275:15	
	unrestricted 312:1	uptake 127:8	
	unusual 235:4	urban 102:15 300:21	
	unwraps 196:19	urgency 86:21 96:11 108:12	
	upcoming 82:1 92:14 93:14 119:13 145:2	urine 139:4 141:7	
	update 110:14 updated 50:19 upfront 270:17 275:15	use 9:13 11:5 11:10,14 14:18 16:16 18:8	
	uptake 127:8		
	urban 102:15 300:21		
	urgency 86:21 96:11 108:12		
	urine 139:4 141:7		
	use 9:13 11:5 11:10,14 14:18 16:16 18:8		

valued 189:20	361:5,12	vision 46:2,3	volunteer
values 239:8,10	vet 72:11	160:6 236:5	366:21
239:17 240:11	vetting 220:21	visit 139:7	vote 362:8,19
240:12,14	vibe 230:16	141:3,4 183:20	363:2,12
243:11,12,18	vice 3:7 145:13	202:2,3 261:2	voting 361:1,1
243:19,21	victims 116:9,9	261:7 295:6	vouchers 276:4
244:6,10,11,20	victoza 170:7	visits 89:2	276:4
246:13 247:16	video 96:8	136:1 139:3	vulnerable
247:21 248:20	135:5 202:2	141:6 184:12	25:1 217:17
281:4,4,11,13	261:19	261:9 262:20	282:8 336:17
vanished 346:2	videoconfere...	276:16 277:4	w
variability	3:5,17 139:8	291:17 294:1	wait 36:7
69:20,21	videos 57:6	307:15	111:15 118:2
variables 58:5	96:4	visual 27:3	waivers 29:2
129:2,7	view 69:11	51:6	walk 12:2 47:9
variation	79:21 81:4,8	vital 244:20	100:21 273:3
269:15	82:11 91:16	264:20 356:13	365:6
variations	161:18 371:19	365:18	wallerstein
267:11,14	viewed 98:6	voice 27:11	249:21
varies 86:12	viewpoints	31:10 42:20	walls 271:12,13
240:14 271:20	80:4	43:16 64:9,10	want 9:13 10:9
variety 135:16	views 67:4	193:11 219:14	12:4 13:4,16
various 23:9	162:13	247:3 262:11	14:16,19,21
106:21 226:8	village 27:19	341:20 342:5	16:7,18 18:5
226:10 287:9	315:2,3	342:13 343:1	21:18 22:5
vary 150:5	violence 272:15	348:15 364:8	23:3,20 24:8
268:8 291:12	272:16	voices 42:19	26:13 29:1,20
301:17 376:4	virtual 6:20 7:9	45:1,5 49:4,6	32:1,14,20
vast 128:12	94:20 116:1	49:10 50:10	41:13 42:21
vendors 152:17	118:8 134:16	52:17 56:20,21	43:1 45:9
158:9	184:5 202:1	57:5 60:5,7,9	46:19 53:6
version 41:6	212:18 277:10	246:9 361:17	55:7,8 61:1,3
325:19	290:21 328:2	362:1 372:10	74:14 76:14
versus 75:15	virtually 145:2	372:11	78:13,16 80:6
164:1,14	183:20 231:18	volume 92:17	80:19 95:4
183:13,18,20	301:3	93:4	97:16 108:1
185:20 206:15	visa 181:13	voluntary 83:6	112:7,11 113:3
318:11 330:20		83:7 167:5,9	

121:17 122:11	357:20 368:9	61:12 62:2	we've 17:7 25:8
130:10 146:1	376:18 377:5,7	64:19 68:2	31:8 47:20
148:14 149:15	377:14	74:16 76:1	74:17 78:14
150:11 154:20	wanted 10:12	77:6 98:13	89:14 104:3
155:16 156:12	11:15 55:18,19	123:14 130:6	113:6 118:11
168:15 180:17	57:15 59:21	135:2 148:2,3	121:1,4 123:19
182:5 190:2	60:5 104:3,5	156:4,5 186:4	159:5 179:12
192:4 204:13	108:17,21	188:16 190:18	184:2 229:2,2
205:21 213:21	110:12 114:4	194:9 195:8	229:3 240:3,4
214:3 216:18	116:3 117:17	210:18 236:10	241:7 242:4
218:12 225:15	129:19 143:12	236:17 237:1	250:8 255:11
226:1 232:16	148:7 198:17	237:13 243:10	258:5,6,6
238:12 247:1	199:10 219:19	245:10,12,14	259:9 261:6
248:18 250:13	249:9 261:18	254:10,12	289:9 298:16
250:17,17,20	300:3 302:3	259:20 263:17	299:10 301:19
252:12 253:14	315:6 339:8,20	263:21 276:11	304:1 306:6
256:6 257:8	353:17 361:14	278:6 279:19	307:20 308:19
261:20 262:7	363:21	280:17 281:6,7	310:8,10,13
264:3,4,9	wanting 309:1	303:4,14,14	311:7 313:9
276:12 277:6	315:20 378:13	307:18 308:12	314:21 316:1
281:5,8 284:21	wants 206:5	310:19 311:2	321:7 335:4
285:2,9 286:1	315:4 316:8	320:11 325:20	343:8 346:14
286:2 287:16	338:14 364:17	328:1,7 331:2	347:16 348:5
289:11 290:5,6	war 25:19 84:9	337:4,21 342:2	348:18 350:6
290:9 291:16	warriors	344:7 348:19	351:3,6 372:3
292:6,21 293:4	288:14,16	354:5 356:8,9	372:17
294:10 298:9	watch 261:19	360:12,19	wealth 271:19
298:20 299:12	watching	361:3 367:11	272:5
302:21 304:7	221:20	367:16 375:16	wearables
308:2 309:5,10	water 10:20	ways 15:9,14	135:6
312:20 313:8	11:4,7,9,10,11	15:15 16:12,19	wearing 182:11
315:18 318:3,4	waterborne	129:5 198:15	weather 25:19
318:20,21	11:2	228:20 230:7	275:21
319:11 321:18	way 9:20 14:3	269:11,12	webinars 53:10
322:6 323:21	15:9 21:18	271:4 277:14	57:7 332:21
326:7,11 329:1	22:6 27:10	277:18 282:3	webpage 53:10
344:3 347:14	33:2 56:10	307:21 354:3	website 31:7
354:16 355:15	59:6 60:16	374:11	273:20,21

<p>week 33:20 138:20 weekend 277:9 weekends 136:2 weeks 332:3 weight 331:14 331:16 361:11 welcome 8:6 43:15 welfare 241:6 wellbeing 65:17 wellness 259:17 288:14 288:16 wendler 73:5 73:14 went 37:20 74:6 152:12 155:1 198:21 199:7 201:18 212:6 258:10 304:5 305:10 340:14 west 44:5 48:19 western 98:6 wheel 325:18 white 10:20 11:8 110:18,18 165:10 175:20 176:11 213:13 222:2 249:3 251:3 279:20 279:21 283:7 313:21 whites 104:14</p>	<p>wide 124:20 365:17 widening 232:2 wider 318:8 365:11 wifi 143:21 153:16 williams 4:6 7:13 226:14,15 231:2 234:13 237:21 246:8 260:20 319:13 323:5 339:10 339:12 360:1 361:16,20 368:18 willing 111:13 207:14 308:6 337:1 365:1 willingness 210:1 364:20 win 219:18 window 375:7 winds 75:15 wiped 229:4 wiping 227:21 wisconsin 77:15 wisdom 116:20 122:3 322:11 327:14 wish 40:17 59:16 145:4 212:4 321:20 345:2 withdrawal 301:13</p>	<p>witness 380:4 witnessed 320:1 woman 311:5 womb 231:6,7 231:9 women 23:14 137:1,2,4 189:4 218:17 wonder 120:11 wondered 210:16 wonderful 47:21 91:6 100:8 134:11 144:8 182:14 265:12 273:9 377:17 wondering 194:16 328:3 wood 3:9 7:3 161:13,16,21 195:1 197:1 207:18 word 45:10 46:16 50:1 51:8 78:16,17 98:16 130:4 222:12 225:17 227:9 232:19 256:20,21 257:12 269:7 303:12 324:4 324:14 345:20 worded 239:7 355:20 wording 168:16</p>	<p>words 45:3 46:17,18 65:2 78:14 104:4 146:6 work 13:18 27:8 32:12,15 45:15 47:20 54:16 57:10 60:1 63:1,2,3 74:5 87:6 90:8 91:8 103:20 106:2,3 108:16 113:18 117:3 126:4 134:21 136:2 149:13 150:13,18 152:17 179:1,7 181:8,19 192:4 206:16 213:5 214:2 220:3,7 231:3,17 236:6 239:10 240:6 242:11 251:9 251:10 258:8 277:8,11 282:17 286:6,9 289:3 292:15 298:21 299:5 299:13 311:4 312:21 314:16 317:1 318:3 330:17 340:7 341:2,12 346:6 348:17 367:1 367:10 369:15 worked 67:18 72:12 113:18 147:20 181:9</p>
--	--	--	--

<p>202:7 241:6 251:4 342:3 worker 296:15 296:15 workers 242:14 259:6 309:20 workflow 340:15 working 10:1 73:14 90:8 104:6 117:13 129:12 160:20 161:1 183:2 195:17 202:11 212:6 233:19 241:15 284:14 289:21 290:18 292:1 297:8 298:3 310:21 320:2,6 340:7 365:16 368:4 works 61:19 192:3 206:9 277:13 296:20 345:6 workshop 1:5 8:6,12 17:18 18:15 19:2,5 19:10 20:20 24:6 27:16 31:9 42:18 55:14 113:16 178:9 190:7 workshops 52:18 188:7 world 46:3 58:3 81:17</p>	<p>83:18 84:2 85:1 150:14 153:6 158:4 185:21 189:12 194:8 200:12 218:2 259:19 world's 203:18 worldwide 196:8 worries 280:8 worry 295:10 worse 137:5 279:8 worth 192:6 worthwhile 83:21 192:6 worthy 355:18 wow 265:10 wrap 91:16 wrapping 93:13 wrestling 313:9 written 167:6,9 168:18 178:13 wrong 333:1,6 wrote 240:10</p>	<p>yeah 95:6 96:8 97:14 98:3 102:11 105:17 108:1 119:1,4 124:18 126:9 159:4 190:4 201:4 203:2,7 205:1 211:3 213:1 217:10 226:9 230:2,3 231:1 236:14 237:20 241:6 248:6 255:13 255:14 265:9 297:17 322:15 326:9 332:11 345:2,4,5,10 354:9 355:1,12 359:2,14 369:16 year 10:5,7,7 10:10 17:19 34:11,16 35:3 47:3,11,19 60:20 66:13 71:7,11,11 77:16 84:3 85:20 86:7 88:14 104:3 118:21 125:1,1 125:2 141:9 149:2 155:21 157:5 164:6,17 234:20 237:8 263:12 312:11 354:2,7 357:8 361:4 367:12</p>	<p>yearly 164:17 years 9:11 36:7 36:8,12 40:18 41:2,7 46:20 50:13 51:15 61:6 64:16 67:18 73:14 77:19 79:14,16 80:19 82:12 84:8 85:19,20 86:4,9,14 87:10 88:8 95:9,11 103:21 111:15 112:12 125:15,15 129:16 157:17 164:19 165:4,4 170:13 171:10 171:11 172:6,7 191:4 195:18 195:18 212:5 231:21 234:21 258:1 260:5 261:6 317:9 338:15 345:17 york 336:3 young 55:4,7 55:13,18 95:15 95:18 97:5 137:4 163:15 230:4,19 235:11 246:2,9 247:2 249:4 256:10 262:5 263:14,15 361:17,18 367:15,20 371:1,13</p>
	<p>y</p>		
	<p>yao 4:3 6:4 8:16,20,21 122:9 127:20 233:2 316:10 316:12,15 321:5,5 334:1 334:4 347:12 363:13 371:3,4 yay 266:6</p>		

[young - zoom]

Page 103

374:17 377:1
younger 50:13
 98:18 125:4
 228:12 248:7
youngest 97:9
youngins
 327:12
youth 104:21
 121:17 162:18
 163:4,10,21
 164:1,3,7,9,13
 164:14,15,18
 164:21 165:1,4
 165:7,12,14
 166:2,7,12
 170:5,10,15
 171:1,16,18
 172:19 173:13
 173:14,16
 174:1,2,6,10
 175:5 176:10
 176:11,12
 177:1,15 178:5
 179:6 340:17

z

z 230:10
zero 199:20
zip 221:3
 300:18,21
zolkowski 5:9
zoom 375:8