CISCRP

Center for Information and Study on Clinical Research Participation

Advancing Health Equity in Medical Devices

Patient Engagement Advisory Committee Annual Meeting
Center for Devices and Radiological Health
September 06, 2023

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About CISCRP

- Independent, 501(C)(3) non-profit
- Globally active & Boston-based
- Since 2003, engaging the public and patients as partners in clinical research
- Collaborate with foundations, associations, advocacy groups, industry, academic institutions, and government agencies

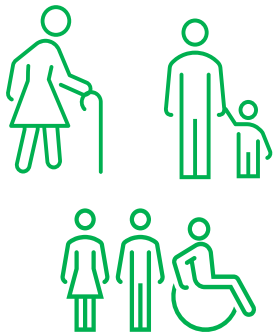
INTERNATIONAL EDUCATION & AWARENESS

RESEARCH SERVICES

COMMUNITY ENGAGEMENT

HEALTH COMMUNICATION SERVICES

The Two Health Literacies



Personal health literacy

The degree to which individuals have the ability to **find, understand, and use information and services** to inform health-related decisions and actions for themselves and others.

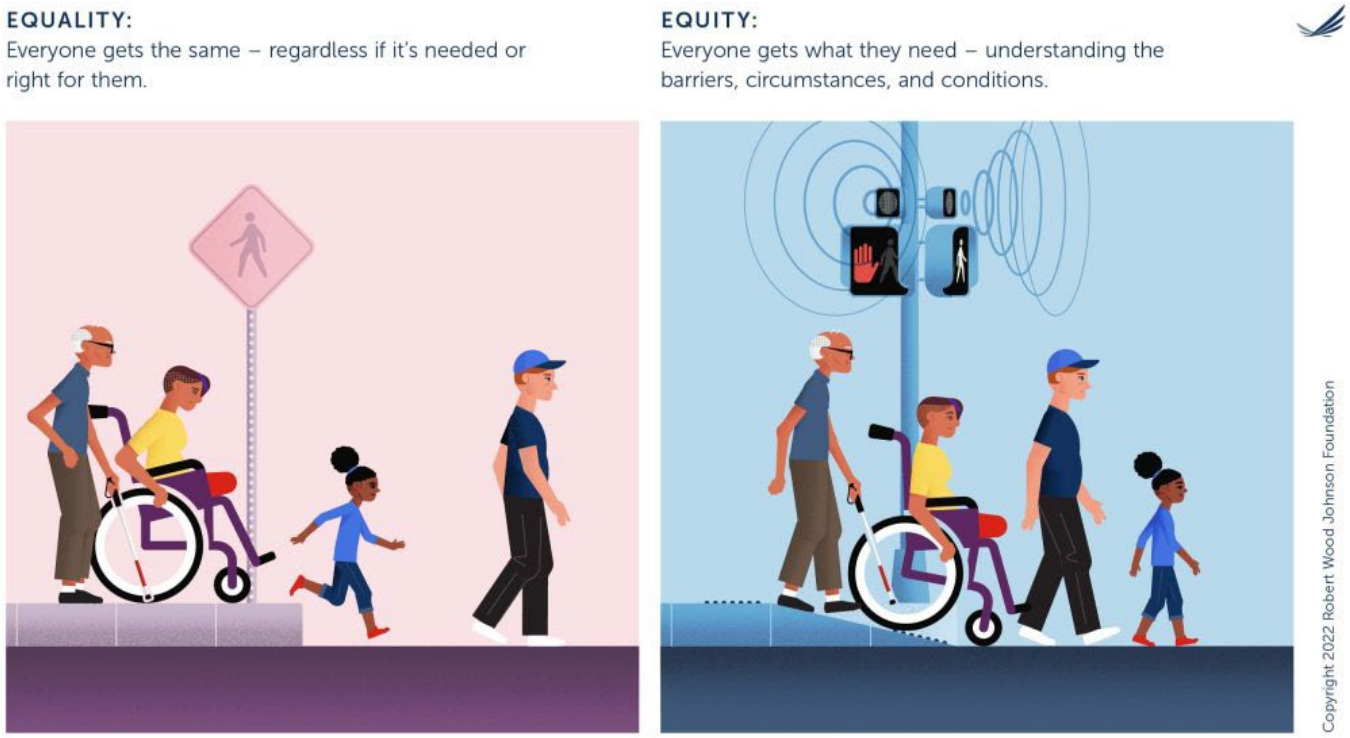
Organizational health literacy

The degree to which organizations **equitably enable individuals** to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

https://www.cdc.gov/healthliteracy/learn/index.html

Equality < Equity

Equality	Equity
Treat everyone as equal	Treat everyone fairly and impartially
Does not consider individual needs or requirements of people	Does consider individual needs and requirements
Everyone gets the same resources and privileges, ***regardless of differences in needs***	Everyone gets the resources and privileges, ***based on their needs and differences***

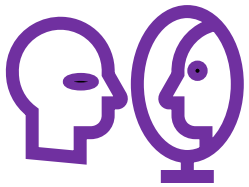


Understanding and Respecting Cultures

Awareness: Learn and understand the audience's attitudes and values

Competency: Match the audience's Logic, Language, & Experience (LLE)

- **Logic**: recognize attitudes and beliefs, address misconceptions with educational messages
- **Language**: phrases and terms familiar to the audience can be used if appropriate and related to technical terms
- **Imagery**: sensitive and relevant to content
- **Experience**: provide examples, model ideal behaviors, and ensure the recommended behaviors are realistic



Humility: Examine the effect of one's own attitudes and values

- Towards the recommended behavior
- Towards the target audience: implicit bias testing

Closing Health Literacy Gaps, Together

- ✓ **Co-development with community members and other subject matter experts** who have experience working with those communities
- ✓ **User-testing via anonymous survey of 500 community members**
  - ✓ Diversity of ethnic and racial, genders and socioeconomic backgrounds
- ✓ **Culturally relevant and competent** topics, language, images, and design
- ✓ **Address key concerns** and barriers to participation, and guide decision-making

Barriers To Diversity

Mistrust

- Misinformation and misconceptions about clinical trials
- Mistrust of pharmaceutical companies
- Past injustices create fear of harm and unethical treatment
- Research community does not acknowledge past injustices
- Data privacy concerns

Accessing Information

- Limited or low-quality internet access
- Lack of awareness on locating clinical trials information
- Lack of research results transparency
- Lack of materials in multiple languages
- Lack of materials that connect with diverse communities
- Lack of access to information from trusted sources

Participating in Trials

- Limited diversity of trial doctors and staff
- Strict health requirements prevent participating in trials
- Lack of compensation for childcare and time off work
- Lack of health insurance coverage
- Use of technology in trials
- Limited transportation assistance and flexible scheduling
- Minimal telemedicine options
- General lack of access to medical care or treatment

Perceptions and Insights Global Surveys

- Measuring Clinical Research Perceptions and Experiences

- 12,400+ respondents globally
  - Past trial participants
  - Members of the public

- Biannual
  - 2021 was 4th iteration
  - **2023 reports expected in Fall 2023**

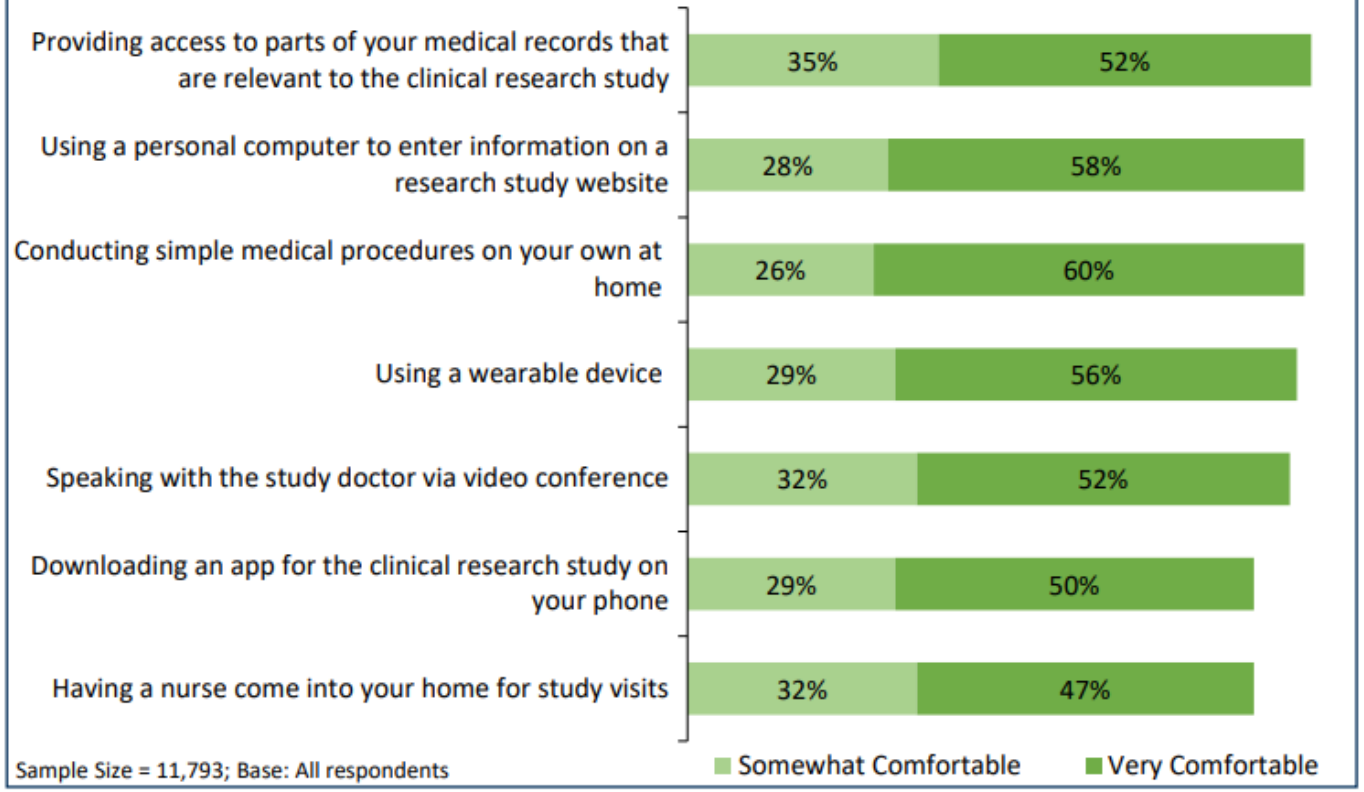
- Publically Available Data
  - Reports (sub-group stratification)
  - Publications (longitudinal analysis)
  - Webinars

https://www.ciscrp.org/services/research-services/perceptions-and-insights-study/

Technology Preferences for Research Participation

The majority of respondents report being comfortable providing access to their medical records and completing elements of the clinical research study at home, such as using a personal computer to enter information and conducting simple medical procedures.

If you were to participate in a clinical research study, how comfortable would you be with each of the following:



Sample Size = 11,793; Base: All respondents

For those not comfortable with using technology, privacy concerns are raised, highlighting the need for additional safety reassurances.

- Black respondents were more likely to be concerned about their privacy and confidentiality (64%) than White (53%) and Asian (49%) respondents.

Reasons not comfortable:
(top mentions)

- ✓ I am concerned my privacy/confidentiality would not be protected (53%)
- ✓ I do not feel comfortable using this/these type(s) of technology (43%)
- ✓ I am concerned the use of technology may cost me money (e.g., data/internet usage) (32%)

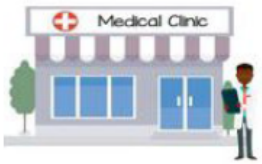
Sample Size = 3,256
Base: Those indicating 'Not very' or 'Not at all' comfortable with video conference, app, or wearable device

Notably, results showed that White and non-Hispanic respondents were more comfortable providing access to parts of their medical records (55%, 55%) than Black (46%) and Asian respondents (39%), as well as Hispanic respondents (44%).

The Immovable Physical Site

CLINICAL RESEARCH STUDY MODELS

How willing would you be to participate in each of the following types of clinical research studies?



Having **all** study visits at the study clinic and seeing the study doctor and staff in-person at the clinic **only**

Having **some** study visits at home and **some** visits at the study clinic, and seeing the study doctor sometimes via video conference from home or in-person at the clinic

Having a nurse come to your home for **all** of your study visits and speaking to the study doctors via video conference from home

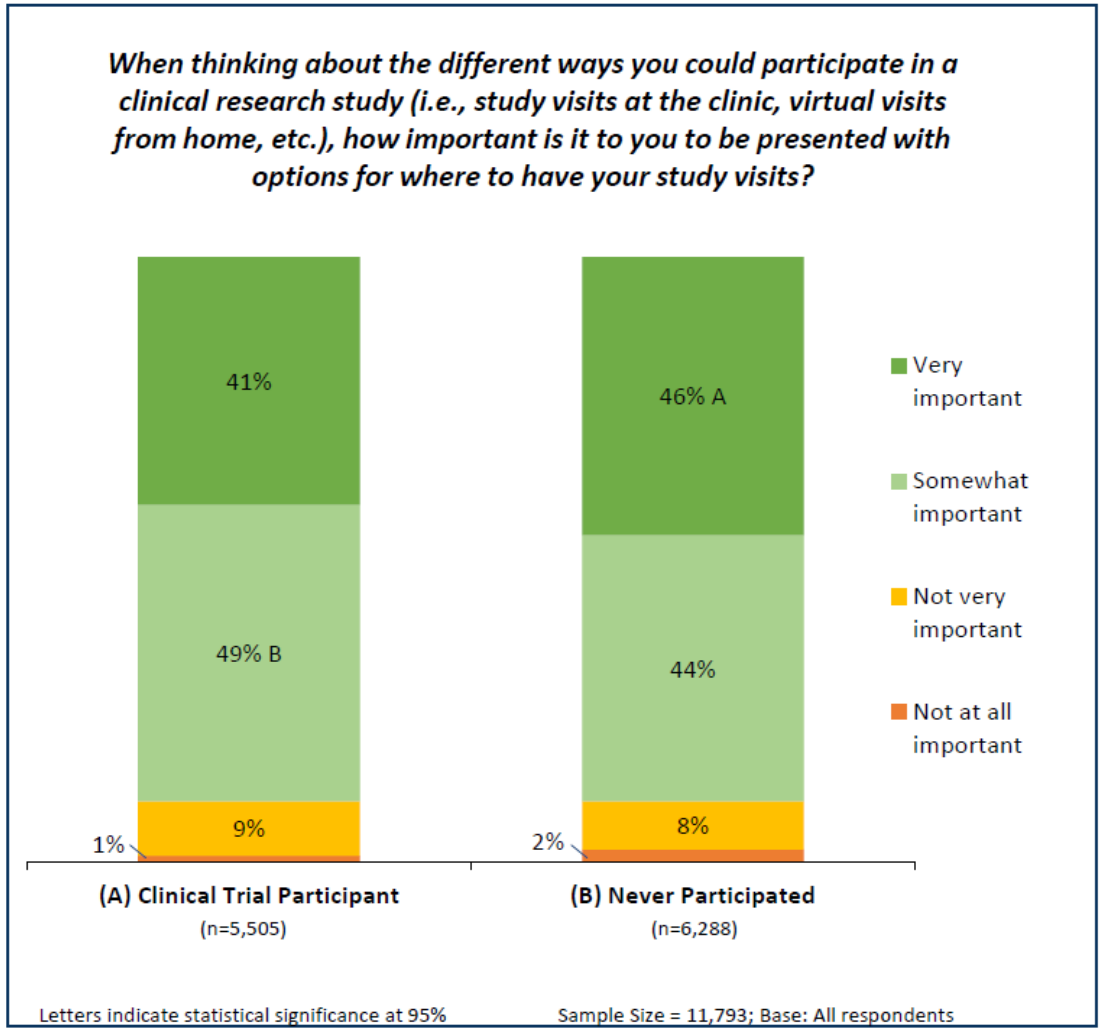
Collecting **all** of your health data on your own at home using technology and only talking to the study team via video conference from home

Sample Size = 11,793; Base: All respondents

CISCRP 2021 Perceptions and Insights Global Study
https://www.ciscrp.org/services/research-services/perceptions-and-insights-study/

Choice: An Indicator Of Equity and Centricity

PROVIDING OPTIONS FOR STUDY VISITS



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How to Increase Trust

Trust in pharmaceutical companies can be improved by sharing information, increasing education, and having inclusive practices.

What, if anything, might increase your trust in pharmaceutical companies? *(top mentions)*

- ✓ By the company sharing more information about health risks/benefits of their medicines (63%)
- ✓ By the company sharing more information about the clinical research that has been done on their medicines (60%)
- ✓ By the company sharing more information about the drug approval process for their medicines (54%)
- ✓ By knowing that the company included a diverse set of participants in their clinical trials (49%)

CISCRP 2021 Perceptions and Insights Global Study
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Clinical Research Literacy

Ability to access, understand, and utilize information to make clinical research-related decisions, across the life-cycle of research

Pre-study

- General Education on Device Development/ Research
- Population Specific Education
- Study Registry Postings
- Protocol Synopsis
- Informed Consent

In-Study

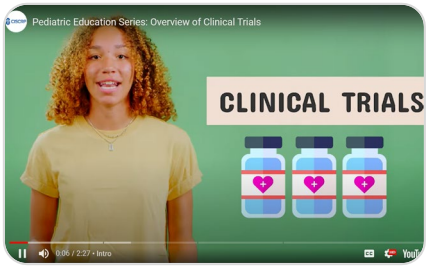
- Engagement Communications
- Research Status Updates
- Continuing Consent
- Incidental Findings

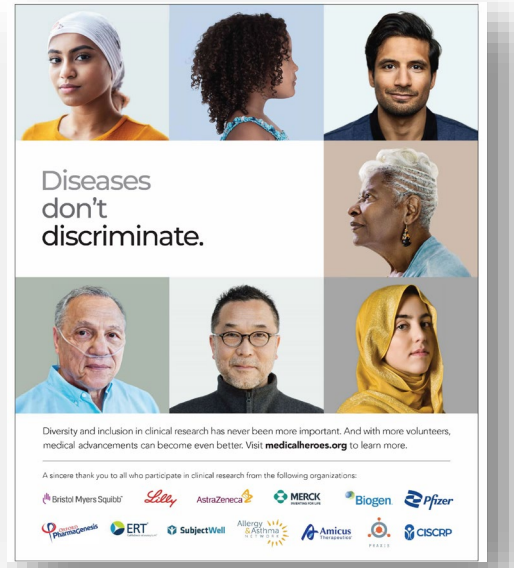
Post Study

- Individual Results
- Aggregates Results
- Coordinated Return to Care
- Post Study Communication

General Education and Awareness

- ✓ Enhance public awareness, literacy and understanding of clinical research with educational content
- ✓ Improve public perception about clinical research study participants
- ✓ Highlight the critical importance of Diversity, Equity and Inclusion





Innovative Engagement

Grass-roots campaigns to engage and educate patients and the public in clinical research

- ✓ Live Education Events
- ✓ MT Pharmacy
- ✓ Journey to Better Health

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Thank you!

Stay Connected

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Involve Patients & Other Stakeholders

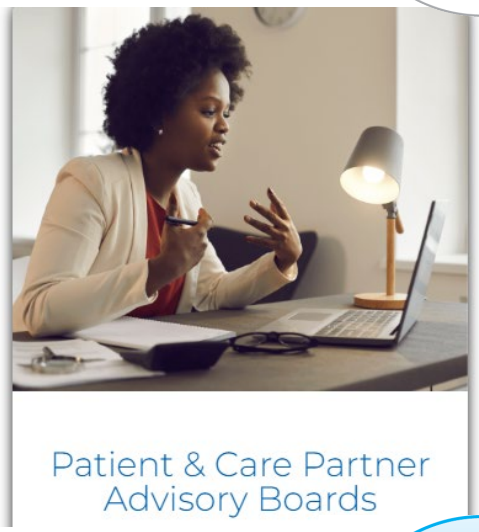
Engaging patients, carers, patient experts and advocates, patient advocacy organizations, health care professionals, and people from communities who have been underrepresented in clinical research

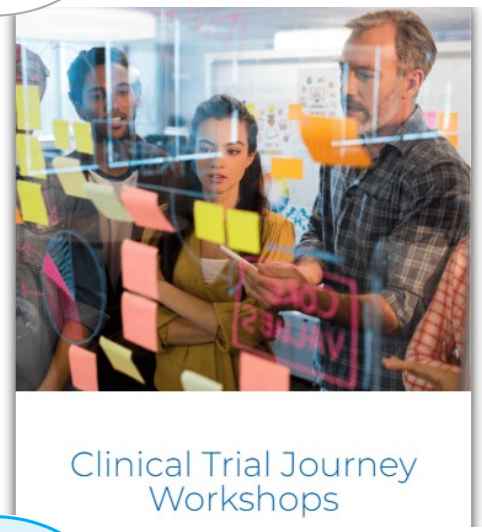
Methods:

- Review Panels
- Co-development projects
- Feedback Forums
- Patient Advisory Board
- Patient Journey Workshops

Ensures materials are:

- Effective and addressing patient/community concerns
- Unbiased and non-promotional
- Culturally appropriate
- Easy to use (understand and navigate)





…at the Right Time

1. Pre-development

Research and define population-specific needs e.g., delivery format and contents

(i.e., endpoints of interest)

2. Development

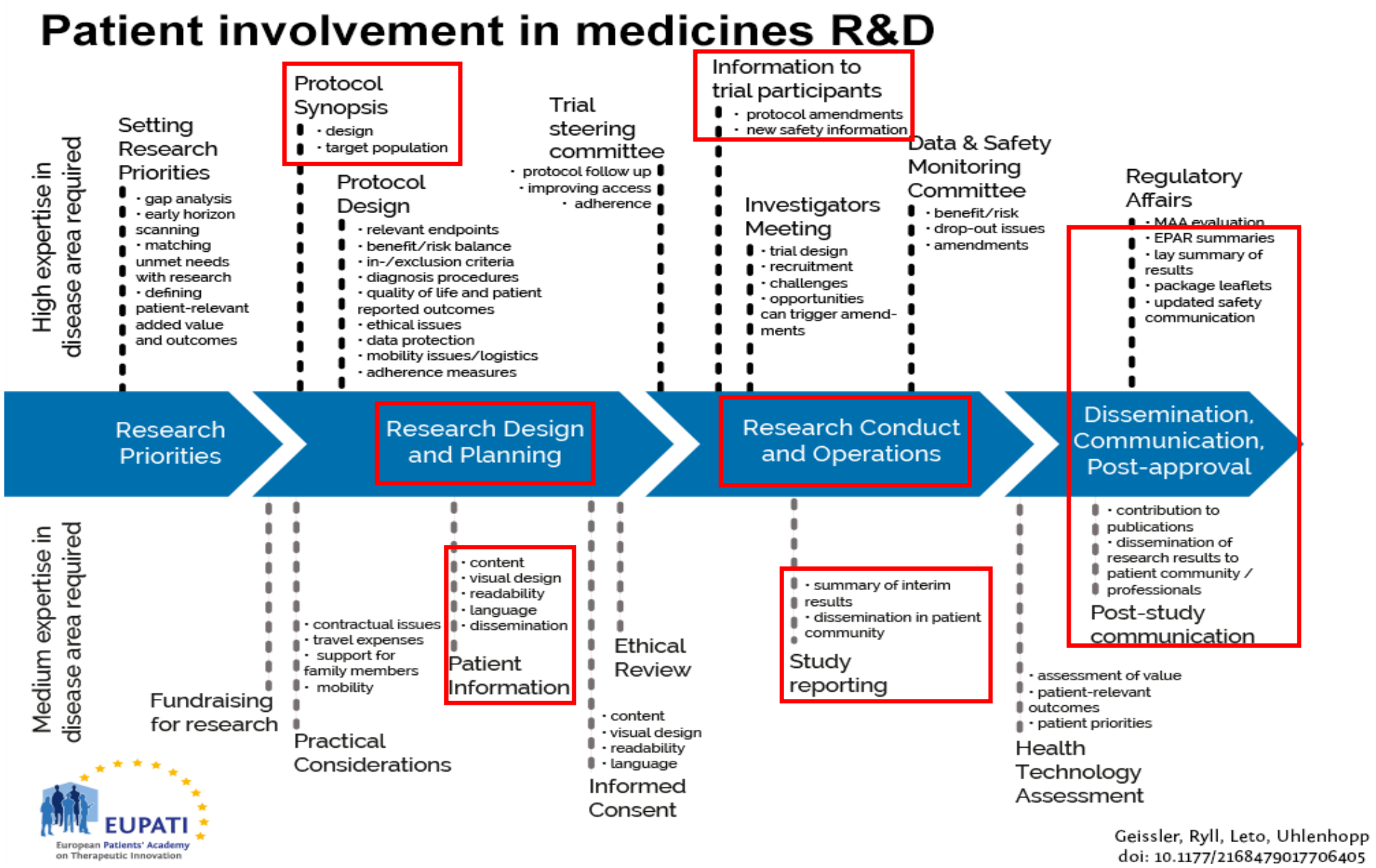
Patient/Advocate Review (at least!)

Consider co-development

3. Evaluation

Assess and improve e.g., access, clarity, perception of bias

Involve Patients Throughout!



Geissler, Ryll, Leto, Uhlenhopp
doi: 10.1177/2168479017706405

Measuring the Value of Patient Centricity

Expansion of Expected Net Present Value Framework for Evaluating Patient Engagement Methods

CLINICAL TRIALS TRANSFORMATION INITIATIVE

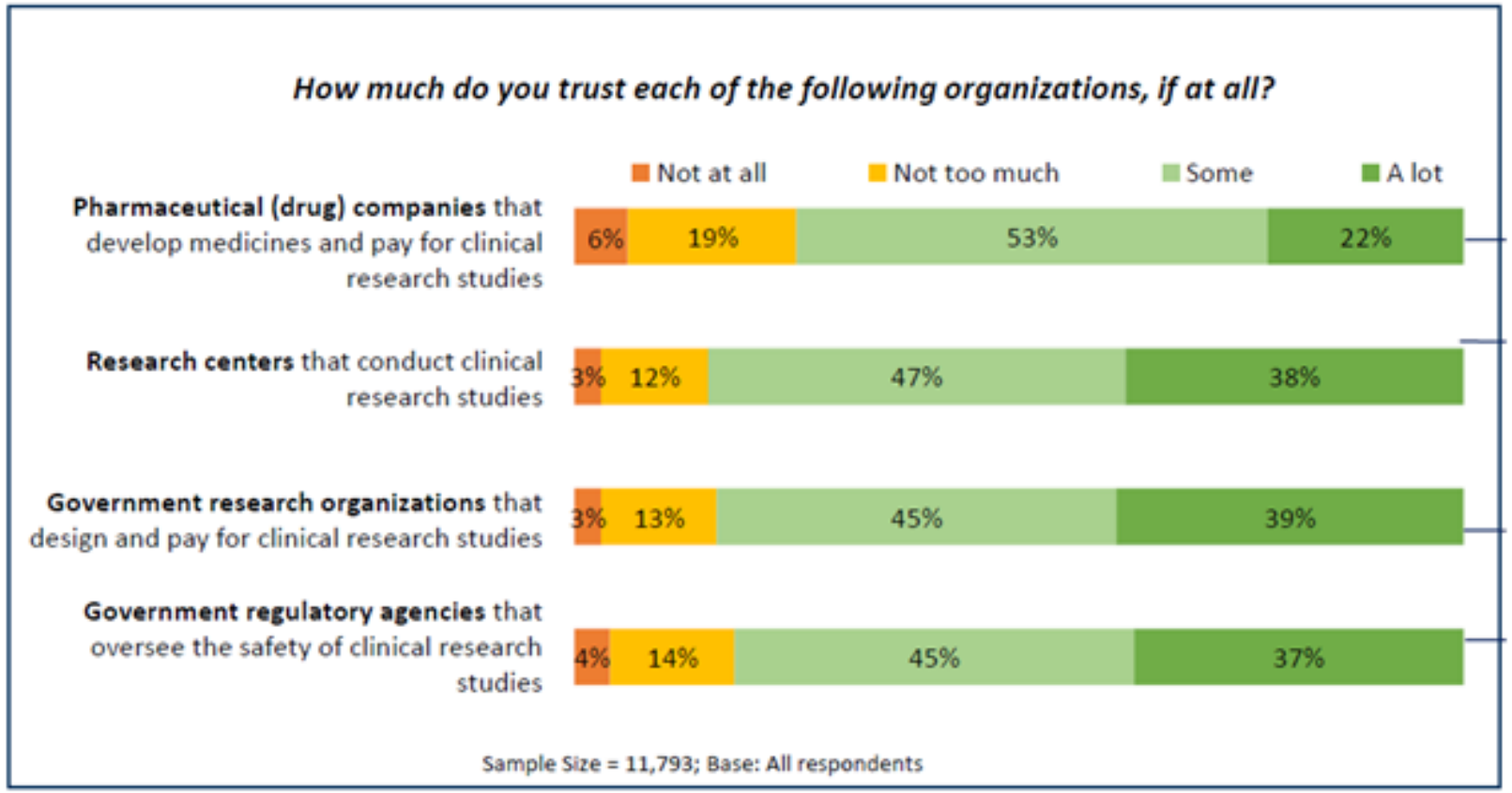
NOTABLE REPORTED IMPACT AREAS

Advocacy Group Collaboration	Advisory Boards/Panels to Inform Protocol Design, Study Feasibility	Solutions Improving Participation Convenience	Plain Language Clinical Trial Results
• IRB review and approval cycle: 1 month • Study planning cycle time: 3 months • Patient enrollment cycle time: 20%–30% reduction in overall cycle time • Increase in patient participation rates: 15%–20%	• On average, 1.3 visits removed from the protocol schedule • On average, 1.5 procedures removed from the protocol • 3.8 changes made to the language in the informed consent form • 7 changes to study positioning and communication material • On average, added 3 months of additional time to the clinical trial planning process	• Increased interest/willingness to participate resulting in higher recruitment rates • Increased patient satisfaction levels resulting in higher retention rates • Improved retention rates by 30%–40% • Reduced study timeline 20%-35% • Telemedicine trials reduced typical clinical trial costs by 30%	• Improved recruitment rates by 15%–20% • Improved retention rates by 40%–50% • Contributed to significantly higher levels of overall participation satisfaction

https://ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI_Patient_Group_eNVP_Report.pdf

Building Trust Remains a Top Objective

PUBLIC TRUST



While the public's trust in research centers/clinics, government research organizations, and regulatory agencies increased since 2019, trust in pharmaceutical companies remains low.

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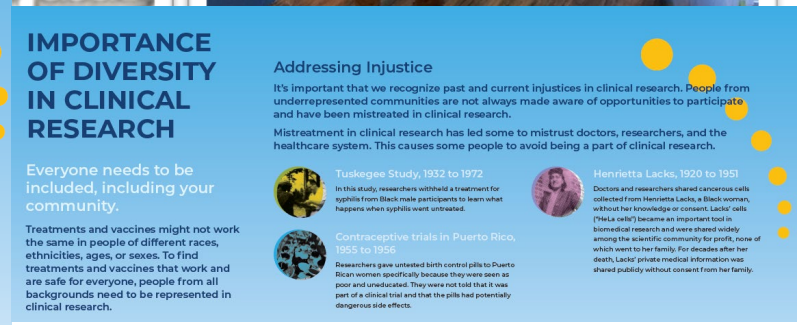
Journey to Lasting Impact

2018

- "Journey to Better Health RV"
- Los Angeles
- Identify and train community educators
- Improve education event registration

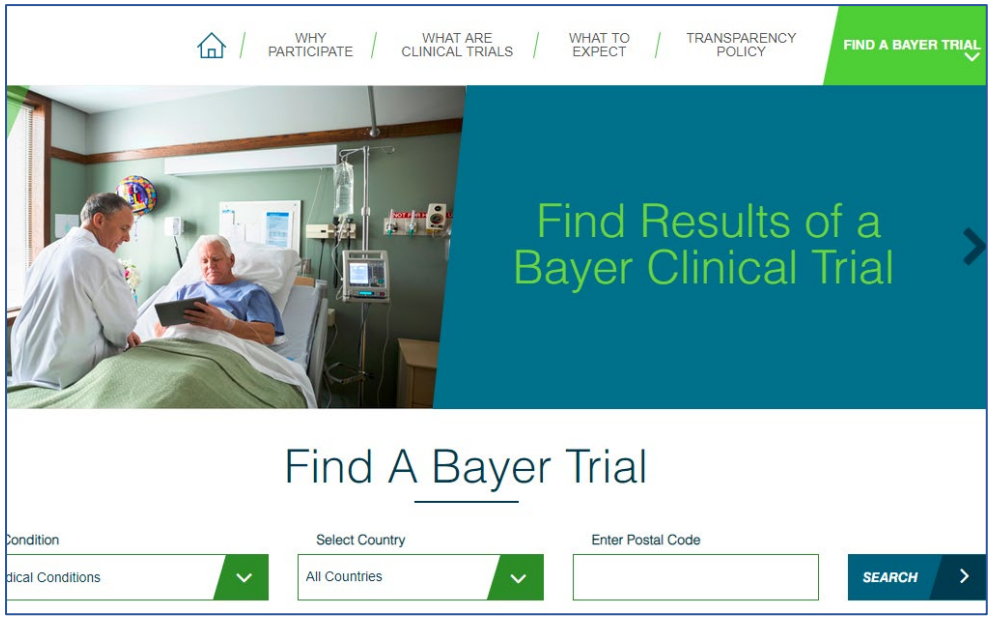
2023+

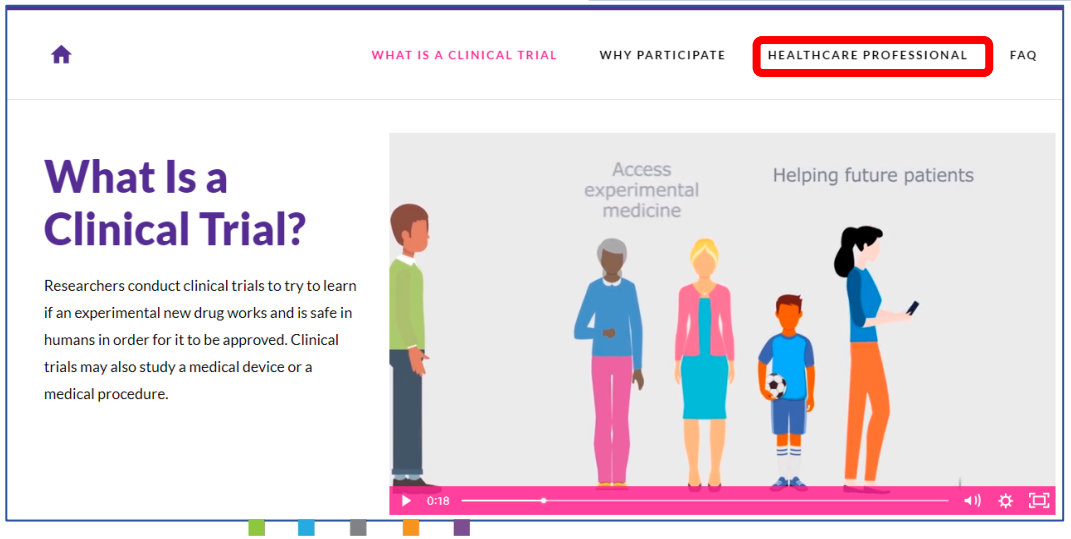
- FDA's Office of Minority Health and Health Equity Innovation AWARD
- "Evaluating Impact of Mobile Community Education Engagement Initiative…"
- Philadelphia & Baltimore – FALL 2023
- Partner with community leaders
- Collaborate with organizers of existing events to enhance receptivity and impact



Registry and Disclosure Websites

- ✓ Improve Clinical Research Literacy with Educational content (videos, infographics, narrative)
- ✓ Make Finding Trials Easier! (Plain Language Registry)
- ✓ Disclosures (ex. Patient-friendly Aggregate Results)
- ✓ Enable HCPs!
- ✓ Separation from corporate sites (i.e. remain non-promotional)





Registry Listings

- Offer simple and engaging study information for posting on registry and trial-finder websites
- Empower patients and study staff by easing the communication burden from the very beginning stages of study conduct
- Establish consistency and improve efficiency by utilizing the plain language study title, purpose, condition, and inclusion/exclusion criteria

Clinical Trial Registry Listing Template

1. Study Title

- No more than 300 characters
- As close as possible with the original protocol official title
- The title should include, where possible, information on the participants, condition being evaluated, and intervention(s) studied
- If abbreviations are used, they should be explained

2. Brief Summary

- No more than 5,000 characters
- A short description of the clinical study, including a brief statement of the clinical study's hypothesis, written in language intended for the lay public
- Include the main objective/purpose of the study;
- Include medical condition
- Include treatment duration, drug administration route/frequency / dosage, frequency of visits / total study duration
- Include age range and gender of the participants
- Include description of the health measurements participants will experience
- If abbreviations are used, it should be explained

3. MEDICAL CONDITION

- No more than 200 characters

Protocol Synopsis

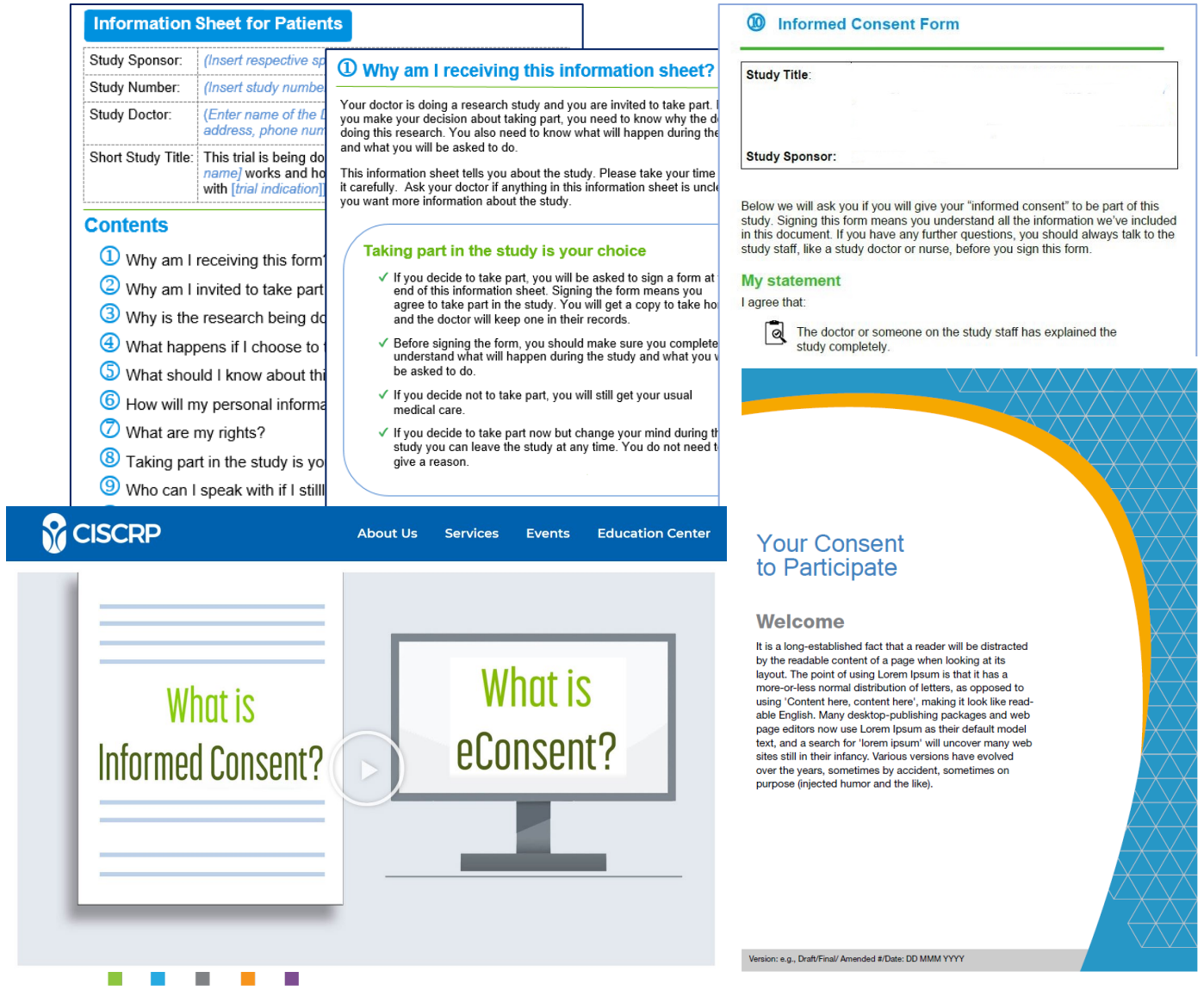
- Meets the EU No 536/2014, Annex I, D24 request to provide protocol synopsis in plain language
- Meets the UK ISRCTN registry requirement
- Utilizes template for efficiency
- Creative solutions to page and word count limits

Required Elements (per EU CTR Q&A v6.1)

1. EU trial number and full trial title
2. Rationale
3. Objective
4. Main trial endpoints
5. Secondary trial endpoints
6. Trial design
7. Trial population
8. Interventions
9. Ethical considerations relating to the clinical trial including the expected benefit to the individual subject or group of patients represented by the trial subjects as well as the nature and extent of burden and risks

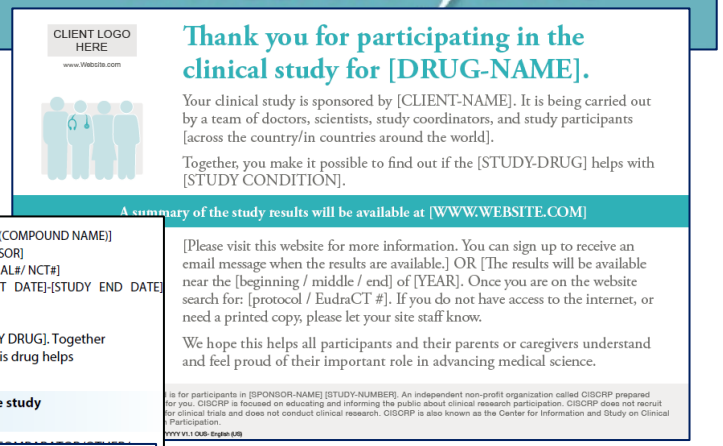
Informed Consent Innovations

- ✓ **Ensure understanding** in Informed Consent Process and improve adherence (plain language > legal language)
- ✓ Create a **navigable and visually engaging** document or eConsent application (TOC, headings, color, icons)
- ✓ **Videos and Infographics** to supplement the ICF
- ✓ **Empowered** in the decision-making process (e.g. take their time, speak with others, ask questions)
- ✓ **Clear and accessible > short!**



Thank, Engage and Unblind Participants

- ✓ Thank and recognize Participants for their role in advancing medical science
- ✓ Set expectations and provide instructions for accessing study results
- ✓ Share treatment assignments (unblinding)
- ✓ Provide educational information
  - Phases
  - Timelines
  - Blinding
  - Placebo
  - Custom topics


CLIENT LOGO HERE

www.Website.com

Thank you for participating in the clinical study for [DRUG-NAME].

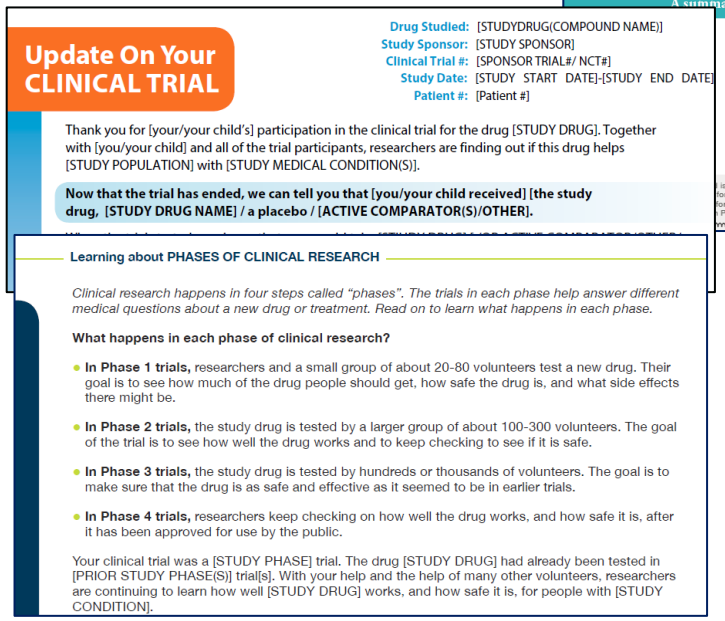
Your clinical study is sponsored by [CLIENT-NAME]. It is being carried out by a team of doctors, scientists, study coordinators, and study participants [across the country/in countries around the world].

Together, you make it possible to find out if the [STUDY-DRUG] helps with [STUDY CONDITION].

A summary of the study results will be available at [WWW.WEBSITE.COM]

[Please visit this website for more information. You can sign up to receive an email message when the results are available.] OR [The results will be available near the [beginning / middle / end] of [YEAR]. Once you are on the website search for: [protocol / EudraCT #]. If you do not have access to the internet, or need a printed copy, please let your site staff know.

We hope this helps all participants and their parents or caregivers understand and feel proud of their important role in advancing medical science.


Update On Your CLINICAL TRIAL

Drug Studied: [STUDYDRUG(COMPOUND NAME)]
Study Sponsor: [STUDY SPONSOR]
Clinical Trial #: [SPONSOR TRIAL#/ NCT#]
Study Date: [STUDY START DATE]-[STUDY END DATE]
Patient #: [Patient #]

Thank you for [your/your child's] participation in the clinical trial for the drug [STUDY DRUG]. Together with [you/your child] and all of the trial participants, researchers are finding out if this drug helps [STUDY POPULATION] with [STUDY MEDICAL CONDITION(S)].

Now that the trial has ended, we can tell you that [you/your child received] [the study drug, [STUDY DRUG NAME] / a placebo / [ACTIVE COMPARATOR(S)/OTHER].

Learning about PHASES OF CLINICAL RESEARCH

Clinical research happens in four steps called "phases". The trials in each phase help answer different medical questions about a new drug or treatment. Read on to learn what happens in each phase.

What happens in each phase of clinical research?

- **In Phase 1 trials,** researchers and a small group of about 20-80 volunteers test a new drug. Their goal is to see how much of the drug people should get, how safe the drug is, and what side effects there might be.
- **In Phase 2 trials,** the study drug is tested by a larger group of about 100-300 volunteers. The goal of the trial is to see how well the drug works and to keep checking to see if it is safe.
- **In Phase 3 trials,** the study drug is tested by hundreds or thousands of volunteers. The goal is to make sure that the drug is as safe and effective as it seemed to be in earlier trials.
- **In Phase 4 trials,** researchers keep checking on how well the drug works, and how safe it is, after it has been approved for use by the public.

Your clinical trial was a [STUDY PHASE] trial. The drug [STUDY DRUG] had already been tested in [PRIOR STUDY PHASE(S)] trial[s]. With your help and the help of many other volunteers, researchers are continuing to learn how well [STUDY DRUG] works, and how safe it is, for people with [STUDY CONDITION].

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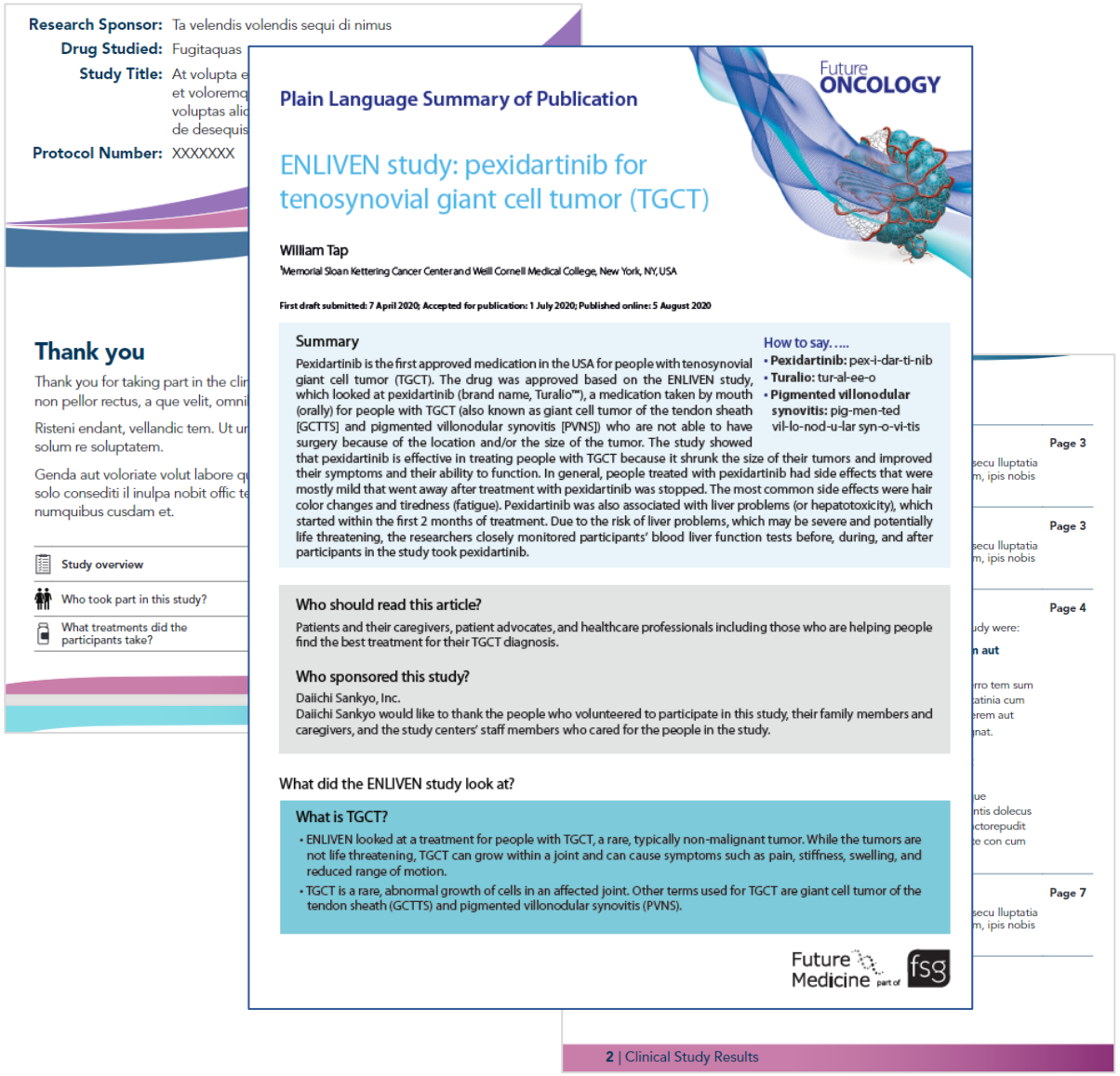
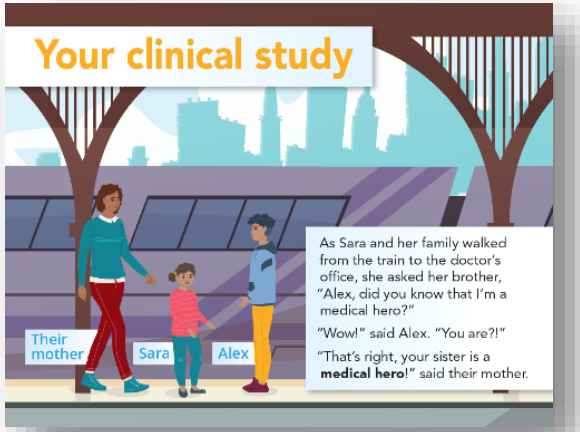
Trial Results Sharing

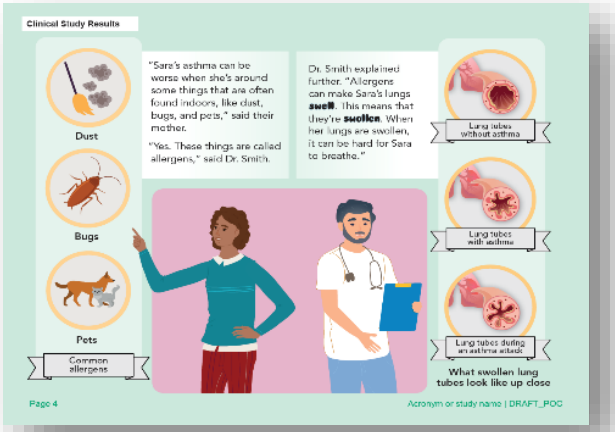


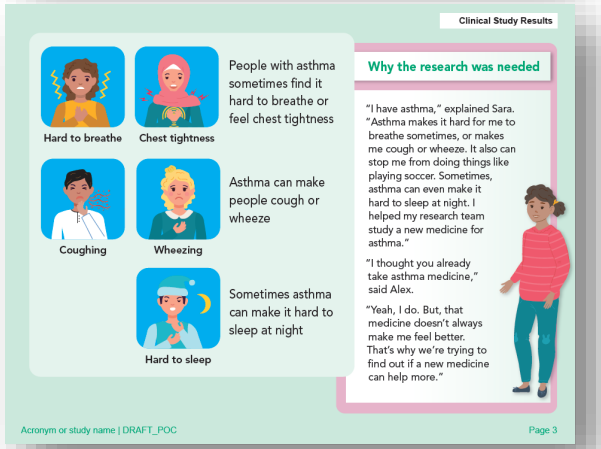
- ✓ Develop and disseminate aggregate study and individual participant results
- ✓ Ensure results are easy-to-understand, unbiased and non-promotional
- ✓ Produce high-quality, professional formats
  - Plain Language Summary
  - Plain Language Summary Publication
  - Webinar
  - Video and animation
- ✓ Align with regulatory requirements and relevant results sharing guidelines
- ✓ Include graphical elements critical for clarity and comprehension

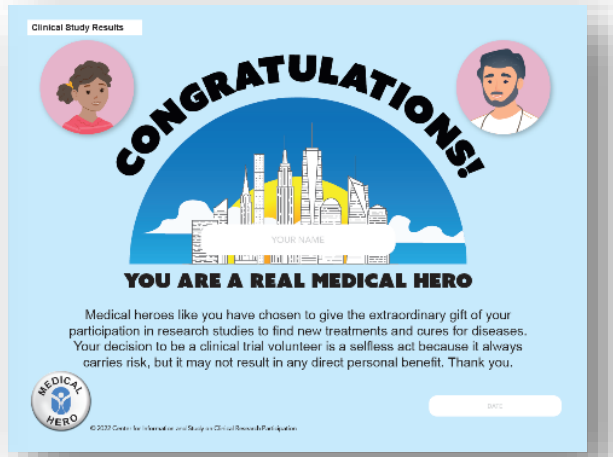
Trial Results Summaries for Pediatric Audiences

- Kid-friendly supplement to a standard plain language Trial Results Summary
- Each pediatric supplement will:
  - Include storytelling, pictures, graphics, and simple text
  - Consider cultural norms and values
  - Use shorter sentences, simpler words, and more white space









Investigator/Site Education & Training

Improve awareness, knowledge and skills with workshops, webinars, videos, infographics

- Diversity, Equity, and Inclusivity (DEI) Awareness
- DEI and Cultural Competency Practices
- Health Literacy Techniques for Informed Consent Process
- Patient Engagement Practices to Improve Recruitment & Retention