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FOOD AND DRUG ADMINISTRATION  
Center for Drug Evaluation and Research  
  
Electronic Submission of Adverse Event Reports to FDA  
Adverse Event Reporting System (FAERS) using  
International Council for Harmonisation (ICH) E2B(R3)  
Standards

Silver Spring Civic Building at Veterans Plaza  
The Buffalo Soldiers Great Hall  
One Veterans Place  
Silver Spring, MD, 20993

Monday, March 25, 2019

9:02 a.m.

Job No. 3225484

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A P P E A R A N C E S

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A G E N D A

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Adjourn

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

2 MR. DE: All right. Good morning, everybody.  
3 We will start. I think it's 9:02 -- Monday morning,  
4 March 25, 2019.

5 So before we start, we -- oh, this meeting  
6 today is about Electronic Submission of Adverse Event  
7 Report to FDA FAERS System, which is FDA Adverse Event  
8 Reporting System, using the ICH E2B(R3) Standards. So  
9 we'll go over about three-half or four -- about four  
10 sessions to go over all the regional needs and regional  
11 requirements.

12 So before we start, just a few housekeeping  
13 items. One is a request to silence your cell phone  
14 during the meeting. As you see, the restroom is  
15 located on the far end on the right here. The Wi-Fi  
16 network is MC Guest. Of course we have lunch as your  
17 own and it's an hour long. But I have the fifth  
18 session. I have not got any request for presentation.  
19 So we may -- depending on the first part, we may make  
20 lunch hour to probably add 15-20 more minutes.

21 So this meeting is being webcast for outside  
22 participants, who are on the WebEx. And any questions

1 for them, they should send their comments to our  
2 dockets by April 25th. And then we have -- the  
3 information about submitting the docket are on the  
4 Federal Register notice and also instructions are  
5 available on the registration table on how to submit  
6 your comments to the docket for folks who are here.

7 Parking. You may have seen, I parked on the  
8 right side of the parking lot here. And that's about  
9 it. We're going to have two breaks: one in the  
10 morning, one in the afternoon. Of course there's some  
11 coffee and bagels kept here.

12 So E2B(R3). So this is a topic which FDA is  
13 now ready to start implementing. Today we'll go over  
14 some of the plans of what we're going to do with  
15 E2B(R3). It's a very important topic for us. FDA is  
16 one of the founding members of ICH, so it's mandated  
17 for us as part of -- as a member country to be  
18 implementing this.

19 And we are going to go over some of our plans  
20 of how -- what we are planning to do, some timelines.  
21 And then we will have Meredith, who's going to join us  
22 soon, to talk about electronic submission of IND safety

1 reporting. She's going to talk a little bit about the  
2 pilot which we are doing and which is in the R2  
3 standard and then what is the transition path for  
4 getting into R3. She's going to talk a little more  
5 about the implementation plan, some use case examples.

6 And then we will have Ta-Jen Chen, who's going  
7 to talk more about the ICH R3 regional requirements for  
8 IND safety reporting and then some -- a little more  
9 about the plans on IDMP. And then he's going to go  
10 over a little bit on the model of the regional  
11 requirement with the HL7 RIM model.

12 And then, after lunch, we will actually then  
13 go over the electronic submission on R3 with post-  
14 market safety reporting, where I'll come back and talk  
15 about the regional requirements. We'll talk a little  
16 bit more about some of the forward compatibility. And  
17 then we get into talking about different electronic  
18 submission mechanism and you will hear about two  
19 submission paths: one for post-market and one for pre-  
20 market. And then the plans for what FDA has for you to  
21 validate your E2Bs before you do your submissions, the  
22 method of your validations. And then we'll get into

1 some summary and closing remarks and some of the next  
2 steps.

3 So ICH E2B(R3). I believe we are probably the  
4 third organization here after Japan and Europe to be  
5 implementing ICH E2B(R3).

6 So again, I am Suranjan De. I'm the deputy  
7 director with Regulatory Science Staff in Office of  
8 Surveillance and Epidemiology with CDER.

9 So going on into Session Number 1, I'm going  
10 to talk a little bit about FAERS II, because ICH  
11 E2B(R3) up versioning is part of FAERS II. FAERS II is  
12 a contract which is -- or is a project, is a program  
13 which is upgrading our existing FAER system, which  
14 includes all our case processing, data analytics, and  
15 up versioning of our standards.

16 So the objective of our FAERS II. FAERS, as  
17 we all -- FDA is a very mission-critical system for  
18 CDER and CBER and the idea of FAERS II is to provide a  
19 modernized system for surveillance of now pre-market,  
20 post-market and product quality reports.

21 So current FAERS today just does post-market  
22 safety reporting. New FAERS II will do pre-market,



1 post-market and product quality report, will be a  
2 database for that. This will be a one-stop shop for  
3 intake triage and case processing for all those three  
4 types of reports, and then it will allow for some  
5 enhanced and unified data analytics and signal  
6 management lifecycle.

7 One of the key important objective is to  
8 achieve compliance with data standards, which is ICH  
9 E2B(R3). And of course it helps us in decommissioning  
10 some old tools which are vulnerable to security risk.  
11 And as probably not everybody knows, but actually  
12 Health and Human Services have designated FAERS II as a  
13 modernization priority, and so we have to get this  
14 done.

15 A scope of FAERS II is implementing and  
16 maintenance of pharmacovigilance software for the  
17 submission of case processing for pre, post-market and  
18 product quality and then data analytics. And then of  
19 course the maintenance of that, which end of the day  
20 would decommission some of our legacy systems which are  
21 used in those three types of reports.

22 So the tools which we will be using in FAERS

1 II, our upgrade, for analytics and signal management,  
2 we have picked a tool from a company called RxLogix  
3 called PV Signal and PV Reports. And then for case  
4 processing, we have from ArisGlobal a tool called  
5 LifeSphere, and that's to do just case processing.

6 So this is I think the most important slides  
7 for everybody, okay, and I'll go over it very slow so  
8 that we all can understand where we are, what we are  
9 doing.

10 So if you look at -- our contract for FAERS II  
11 was awarded October -- sorry, September 30, 2018.  
12 Since then, we have installed our tool into our  
13 environment and installing tool into different  
14 environments is going on. Our tools has been in the  
15 GovCloud. So that's where our -- both our tools will  
16 be deployed on.

17 Now, a few important things. Now, if you look  
18 down, is update of FDA E2B(R3) core and regional data  
19 elements. This is -- what we have done is: in ICH if  
20 you have seen the implementation guide, you have seen  
21 all the data elements which are in that PDF document.  
22 We have extracted out and put it into more as Excel

1 spreadsheet. This spreadsheet is also available on the  
2 ICH website today.

3           So we have taken that -- because first thing  
4 at ICH we realized that anybody who is implementing  
5 this -- first thing probably a contractor would come  
6 and then extract all that and put it in a spreadsheet  
7 to manage that, right? So we took all that, took that  
8 from ICH, and then we added our regional elements to  
9 that. So now you will have one spreadsheet of all U.S.  
10 regional requirements.

11           A similar method has been done by PMDA, a  
12 similar has been done by EMA. So the idea would be  
13 that all the data points which are in that spreadsheet  
14 will look the same, okay? And so when an organization  
15 is implementing this, it should be very easy to merge  
16 all of them together. Because end of the day, for an  
17 organization who is submitting, would submit to  
18 different regions, so they would need to have one big  
19 data set of all the data elements, which includes the  
20 ICH core elements and the regional elements from  
21 different regions.

22           So this is one element -- one document which

1 is a spreadsheet. We are adding new data elements to  
2 that and we have started updating that data elements to  
3 that spreadsheet. And as we move through, we will next  
4 start updating like combo data points in R3 -- R2 has  
5 been already published -- but in R3. And then  
6 eventually whatever comments we hear from you all, we  
7 will then go ahead and incorporate that into that  
8 spreadsheet.

9 Now, when FDA publishes this, FDA is going to  
10 publish probably three documents: one will be what we  
11 call as the ICH E2B(R3) technical specification, which  
12 will have some details, some more words in there; the  
13 spreadsheet, which I'm going to show some sample of  
14 that how it's going to look like; and then some sample  
15 E2B(R3) files, data files with some use cases. So  
16 we'll have some use cases and we'll generate some  
17 sample data files for you to consume and test in your  
18 organization.

19 So as we move through adding data points as  
20 our regional requirements, we are also trying to  
21 harmonize that with already implemented VAERS data  
22 elements, which is the electronic vaccine reporting

1 system, because they were already implemented. So as  
2 we're going through some of the data elements which we  
3 need on the drugs and therapeutic biologic side, we're  
4 also looking at harmonizing that with eVAERS. So if  
5 VAERS has a particular data element which is to be used  
6 from the drug side, then we sit down and we are  
7 harmonizing that.

8 So this spreadsheet you will see that many of  
9 the data points will now have saying -- currently, the  
10 way we are doing this is we have the FAERS data  
11 elements, we have the eVAERS data elements, if we  
12 harmonize, that ends up in saying FDA data element. So  
13 there is just one data element which has been  
14 harmonized.

15 Another items which we have is we're going to  
16 have three public meetings. So today is the first  
17 public meeting. We were planned to -- it was initially  
18 scheduled on January 25. But because of the shutdown,  
19 that had to be changed. So we are here today. The  
20 second public meeting will be sometime in July. It's  
21 on the meeting page. And the third public meeting will  
22 be in February.

1           As we go through this public meeting, as we  
2           hear comments, as we get comments on the docket, we  
3           will start updating the technical specification for R3.  
4           Technical specification has details; it has a lot more  
5           words in there. And as we go through, there are some  
6           milestone points where we will be updating the  
7           document. And our plan is to have the document ready  
8           for clearance sometime in October.

9           As I just -- I think last week I understand  
10          that because this is a technical document, it has to go  
11          through a more abbreviated clearance process rather  
12          than a whole guidance, the way it goes through. Our  
13          idea was to -- I gave some few months just in case, as  
14          we know with the clearance process. We were planning  
15          to -- we plan to publish that in March, but if it is  
16          cleared earlier, we will publish that earlier.

17          During this next period, from May through  
18          December, we will be testing in our environment the R3  
19          mechanism and the R3 standards as we create some sample  
20          files for different use case scenarios. And then our  
21          plan is, is March 2020 is when FDA will be ready with  
22          R3 standard. And as we are ready with the R3 standard,

1 FDA also will provide a public URL for ICSR validations  
2 for R3.

3 So I'll go over -- at the end of the day, I'll  
4 go over some methods we plan to incorporate for  
5 somebody from outside could come and test their  
6 submissions first before doing production submission.

7 Right after March is when sponsored testing  
8 could start. You will have the spreadsheet of all the  
9 core and regional data elements, you will have the  
10 updated technical specification, and you'll have the  
11 sample files. Based on which, if you started setting  
12 this up in your organization, after March 2020 you  
13 could start testing your files.

14 And finally, this is a little different than  
15 what we have in the top six, seven lines. As you all  
16 know that we're also doing a pilot of IND safety  
17 reporting. So FDA -- currently, as per regulations,  
18 sponsors have to submit IND safety report as MedWatch  
19 through the eCTD route. We're currently doing a pilot  
20 with a few companies so that they voluntary also are  
21 submitting the E2Bs in R2 format to our gateway, along  
22 with of course the regulation, where they submit their

1 PDFs.

2           So we had gone through a few phases. So phase  
3 -- and Meredith will talk more about -- when she's  
4 here, she will talk more about what were the phases and  
5 how did it go through. The idea would be to FDA be  
6 ready by first of October where companies voluntary  
7 could start submitting E2B -- sorry, IND safety  
8 reporting in E2B(R2) format to the FDA.

9           Of course this is voluntary in nature. We  
10 will have both the safety reporting portal and the E2B  
11 standard available both in R2 to be submitted to FDA.

12           They will -- the draft -- probably we'll be  
13 putting the -- publishing the draft specifications some  
14 time end of May for the R2. And then typically the  
15 idea is -- I mean, we understand that many of the  
16 organizations are already submitting to other agencies  
17 in R2 format for pre-market safety reports, so  
18 hopefully this implementation would be not as complex.  
19 And the best part about that is it basically eliminates  
20 the cover letter, it just eliminates all the 1572s, and  
21 companies can directly submit through their safety  
22 system to FAERS.



1           So with that, I'll go into some of the testing  
2 plan and methods. So before I go into testing plan and  
3 methods, with respect to time -- I'm just looking at  
4 it. I'm waiting for Meredith to come. I can take some  
5 questions if somebody -- if you all in the room have  
6 any questions on the roadmap. By the way, this --  
7 sorry, go ahead. If you can come to the microphone,  
8 that will be -- yeah, so that everybody can hear.

9           UNIDENTIFIED SPEAKER: Just a couple of  
10 questions. Kathy (ph) from Oracle. You indicated that  
11 in terms of reporting, the plan should be ready by  
12 March 2020 for R3 reporting, that you'll publish a URL  
13 and that sponsors can commence testing. What are the  
14 plans for vendors?

15           MR. DE: What are the plans for vendors?

16           UNIDENTIFIED SPEAKER: Yes, for being able to  
17 test. Is it within the same timeframe or --

18           MR. DE: The same timeframe.

19           UNIDENTIFIED SPEAKER: -- it could be before  
20 that? The same timeframe?

21           MR. DE: Yes, it's the same timeframe. After  
22 March 2020, anybody can come and test --

1 UNIDENTIFIED SPEAKER: Okay.

2 MR. DE: -- you know, the sponsor and the --  
3 because we do understand that all sponsors are  
4 dependent on the vendors. And so, yes, they could come  
5 after March 2020 and start testing.

6 UNIDENTIFIED SPEAKER: Okay. And then in  
7 terms of R2 reporting for IND safety reporting, at what  
8 point would the MedWatch actually no longer be required  
9 for sponsors to use? Because IND safety reporting is  
10 the last --

11 MR. DE: Correct.

12 UNIDENTIFIED SPEAKER: -- leg in terms of --

13 MR. DE: So I will just hold that question.  
14 Meredith is here. She's our next presenter, the next -  
15 - after me, she is going to be speaking all about the  
16 IND safety reporting.

17 UNIDENTIFIED SPEAKER: Okay.

18 MR. DE: And she will go over some of the  
19 plans they have for the IND safety reporting.

20 UNIDENTIFIED SPEAKER: Right. Thank you.

21 MR. DE: Okay.

22 UNIDENTIFIED SPEAKER: Hi. Francois Audibert

1 (ph), Vitrana (ph). Do you expect the harmonization  
2 with eVAERS to have an impact on the eVAERS side?

3 MR. DE: Yeah. Look -- sorry, can you repeat  
4 that question again? I'm --

5 UNIDENTIFIED SPEAKER: Do you expect the  
6 harmonization with eVAERS of the data element to have  
7 an impact on the eVAERS side, meaning that the eVAERS  
8 will change and go through a new standard?

9 MR. DE: I don't think we will have any impact  
10 on the eVAERS side, because what we are trying to do is  
11 we're basically trying to harmonize in such a way that  
12 many of the things which eVAERS has done -- for  
13 example, I'll give you -- the race and ethnicity  
14 question which they're asking, we're just taking as is  
15 what they have. The conformance rule which they have,  
16 we're just going with the same conformance rule. All  
17 right?

18 So most of the data element -- so far where we  
19 have reached -- because as we are -- because since we  
20 have three meetings -- today when we talk about --  
21 we're not going to talk about every data element today.  
22 I've kept some for the next sessions too. But so far

1 most of the data elements we have gone through, we are  
2 -- the elements which eVAERS already has, okay, if we  
3 are -- for drugs, we're not using every data element.

4 One example, reporter's address, there are  
5 four lines. It's important for VAERS. But for drug  
6 reporting, maybe two. But ICH only has one. So we may  
7 use one of that and use the same exact specification  
8 and exact conformance rule. So that's how we are  
9 approaching this. So that we have taken into account  
10 that should have the least impact on the sponsors who  
11 are submitting the reports. Yeah.

12 UNIDENTIFIED SPEAKER: One last question in  
13 terms of eSubmitter and the timelines within which  
14 you'll update that system as well to accommodate all  
15 the changes.

16 MR. DE: So eSubmitter currently is only used  
17 in the vaccine reporting. It's not used in the drug  
18 reporting. So for drug reporting, we'll still continue  
19 using -- if anybody has to use that, they will start  
20 using the safety reporting portal which we have. For  
21 post-market it will be used -- for both post-market and  
22 pre-market and that will continue as is. So --

1 UNIDENTIFIED SPEAKER: And that will be  
2 updated in line with the requirement --

3 MR. DE: Right, in line with -- yeah, all the  
4 additional R3 elements. Because if you note, the  
5 safety reporting portal is based on MedWatch form,  
6 right? So that -- we will be updating that based on  
7 some of the data elements in R3. Because you know that  
8 every 3 years the MedWatch is reauthorized.

9 UNIDENTIFIED SPEAKER: Yeah.

10 MR. DE: So based on that --

11 UNIDENTIFIED SPEAKER: I have a question about  
12 that too.

13 MR. DE: -- that's going to happen --

14 UNIDENTIFIED SPEAKER: Yes.

15 MR. DE: --- that's going to happen. So when  
16 we are in March 2020, you'll expect that the safety  
17 reporting portal, which is used by organizations who  
18 don't submit through E2B, will be updated with those  
19 data elements which needs to be there based on the  
20 MedWatch reauthorization.

21 UNIDENTIFIED SPEAKER: And so by then do you  
22 expect the proposed rules for the MedWatch to have been

1 incorporated into --

2 MR. DE: Yes.

3 UNIDENTIFIED SPEAKER: -- the safety reporting  
4 portal?

5 MR. DE: Right. I think the reauthorization  
6 has gone for the clearance now. So some more -- you'll  
7 find some of the new data elements. Or the way the  
8 data elements are captured, you'll find in the MedWatch  
9 there are certain changes in the 3500A Form.

10 UNIDENTIFIED SPEAKER: Yes.

11 MR. DE: Because the B and the 3500 are used  
12 for consumers and healthcare professionals. So yeah.

13 UNIDENTIFIED SPEAKER: Thank you.

14 MR. DE: All right. Some of the testing plans  
15 and methods. So there is no compliance date that has  
16 been set for R3 submission, right? So there's no  
17 compliance date that has been set as of today.

18 As we said, sponsors can start testing any  
19 time after March 2020, which also includes vendors who  
20 can start testing after March 2020.

21 As I said, FDA will provide a validator to  
22 pretest senders' ICSR and these validators can be

1 accessed via the public URL. Once validated, sponsors  
2 then can submit in a pre-production environment and  
3 receive Ack.

4 Now, this is something which I've put here.  
5 The reason being that, yes, you go to the validator,  
6 you test it, right? And you have some errors. You fix  
7 it. You test, re-test it. Done. But now you have an  
8 Ack which is in R3. So you would want to test the  
9 entire cycle.

10 So the idea here is that once you have tested  
11 through the validator, you have a valid URL -- sorry, a  
12 valid XML. You can then submit that through the  
13 gateway in a pre-production environment, get the  
14 submission, get your acknowledgement, and then maybe  
15 able to update your system so that you have gone  
16 through the entire cycle.

17 So that's we thought was important and could  
18 be done. But the prerequisite for that would be that  
19 you have first gone through the validator and tested  
20 your actual XML.

21 Now, the validator will be in the regional  
22 requirement -- with the regional requirement. So it

1 has the core data elements, but will also have the  
2 regional data elements. It will test the regional data  
3 elements too.

4 Sponsors continue to submit ICSRs in R2 format  
5 until they're ready for R3. And so as I said, there  
6 has been no compliance date that has been set, so you  
7 continue to submit in R2. And then of course when  
8 you're ready with R3, you could start submitting in R3.  
9 We will be both backward and forward compatible as we  
10 have not decided on any compliance date yet.

11 Now, these are some of the things which you  
12 may want to -- as a sponsor may want to take into  
13 account. Testing both pre and post-market, which  
14 includes combo products, because that combo products  
15 has certain data elements which are more regional  
16 elements. And combo products will be talked about in  
17 the next meeting. We don't -- we are not talking about  
18 that in today's meeting. And in R3 format. So you  
19 need to -- we want to test both pre and post-market,  
20 including combo products.

21 And then during that time using both routing  
22 mechanisms. We'll explain that in later slides what



1 are the two routing mechanisms. Today we just have one  
2 mechanism of submitting post-market report. And you  
3 will see in the later slides what we have explained  
4 about having two separate paths for submitting pre-  
5 market and post-market.

6           When you do your production submission, when  
7 you're ready for R3, we are just requesting as to  
8 notify just that this is your first submission with R3  
9 in the production environment. So that just we can  
10 keep a track on who is submitting in R3, and if we have  
11 any hiccups, we will be able to immediately contact the  
12 sponsor on their submission.

13           One thing which we want to -- we plan to do in  
14 the future -- we have not -- we don't have it in our  
15 plan yet -- is we plan to conduct a cross regional  
16 testing, just to make sure that if our FDA -- the XML  
17 file which is submitted to the FDA, if the same file  
18 was to be sent to Europe and Japan, what would happen  
19 then. Or if -- now that we will have our parcel and  
20 everything ready, if we got a file from Europe or  
21 Japan, how will it react with our parcel here.

22           We did a small testing, we did at part of our

1 ICH Committee, and most of the results were promising  
2 that it just ignores the regional element of another  
3 country. But that testing is something we want to do  
4 to make sure the sponsors who are submitting have --  
5 don't have all those hiccups of the different elements  
6 they need to include. Hopefully, one day they're able  
7 to generate this one ICSR and be able to submit to all  
8 the regions.

9           And then if you have any questions during the  
10 testing, you want to send it to this e-mail address  
11 which we have called [eprompt@fda.hhs.gov](mailto:eprompt@fda.hhs.gov). And people  
12 are monitoring this mailbox. And as we go through the  
13 meetings today, you can -- first, we want you to submit  
14 all our comments into the docket, and maybe after 30  
15 days if you still have any questions which you have,  
16 you can send it to this e-mail address.

17           So here is the spreadsheet. It's just a long,  
18 long spreadsheet. I've broken down into different  
19 fields. So if you look at the spreadsheet here, this  
20 source will tell you it's an ICH source or an FDA  
21 source, okay? So if it's an ICH source, it is a core  
22 data element of ICH. If the source is FDA, then it is

1 a harmonized data element of FDA. It gives you the  
2 header element. It's gives you the data element  
3 number, data element name, length, data type and  
4 allowed field.

5 Now, this part is the ICH business rule. So  
6 if you see a ICH core element, you will see all it's  
7 rules and conformance and so on. After this, this part  
8 comes, which is for post-market, which talks about the  
9 same data element, what is its conformance and the  
10 business rule behind that.

11 If the same data element is used for IND, then  
12 it will tell you the conformance and the IND business  
13 rule. And if it is used for combo products, it will  
14 tell you the conformance and the combo business rule.

15 We have not put VAERS today, but eventually we  
16 will have the VAERS columns added to that, because  
17 there are still elements we have not harmonized. And  
18 we will -- once we come through the harmonization,  
19 we'll do that.

20 Also future, future plan is eventually have  
21 all safety database as one database in FDA, which we  
22 don't have today. VAERS has its own database; FAERS

1 has its own database. The plan is eventually have all  
2 into one. And we are slowly getting into from post-  
3 market to pre-market to product quality, so eventually  
4 we will get to vaccine.

5 And then it talks about the null flavor, any  
6 field (ph) OIDs. And then this one is basically giving  
7 you the XPath's for the regional elements which we are  
8 defining.

9 So this is a spreadsheet which you will get  
10 and hopefully will be able to see everything in here,  
11 which is like a combination of the ICH IG and the  
12 regional technical spec. Everything taken together and  
13 put into this one spreadsheet for implementation.

14 So with that, I will request Meredith to come  
15 and talk about IND safety reporting. But prior to  
16 that, if anybody has any questions which I can answer  
17 before Meredith comes and speaks on IND safety  
18 reporting? All right, Meredith, the podium is all  
19 yours.

20 MS. CHUK: Good morning, everyone. I'm  
21 pleased to talk to you about and introduce the new  
22 edition -- newest edition to FAERS, which will be IND

1 safety reporting.

2 I think we have plenty of time and the group  
3 is small enough that if you have questions throughout,  
4 please feel free and I'm happy to address them.

5 Because again, since this is a new concept, there maybe  
6 quite a few questions.

7 So what I want to do is just briefly outline a  
8 little bit of the background of the program, where  
9 we've been, where we're going, and then obviously  
10 describe the implementation plans. This is a new  
11 process both for industry and for FDA, so we'll talk a  
12 little bit about the changes on both sides.

13 We'll talk about a pilot and several phases of  
14 the pilot that we have been undergoing for the last  
15 several years. Most importantly, talk about some of  
16 the requirements and the timeline for implementation,  
17 which I'm sure everyone is very interested in. Give a  
18 little bit of information about the data flow, how data  
19 comes into FDA, how it gets to our reviewers, what kind  
20 of acknowledgements the sponsors will receive back.

21 And then discuss in a little bit of detail  
22 about the types of IND safety reports that we will have

1 sponsors submit to FAERS. And then talk about  
2 specifically some of data elements that are ICH data  
3 elements, but used a little bit differently in the pre-  
4 market space as there are different concepts such as  
5 IND that don't exist in the pre-market space and some  
6 of the other regulatory requirements for events that  
7 need criteria for submission are different in pre and  
8 post-market.

9           And then we'll go over a couple of case  
10 examples that we came up with through the course of our  
11 pilot and working with sponsors about particular  
12 questions that may come up in terms of preparing these  
13 IND safety reports in the E2B data standard.

14           So just to remind everybody. So IND safety  
15 reports. Any sponsor who conducts clinical trial under  
16 IND is required to submit certain events -- and we'll  
17 talk about them exactly what they are in a couple of  
18 slides -- in an expedited fashion. And again, when we  
19 talk about IND safety reports, we're talking about the  
20 expedited reports. These are the 7-day reports, the  
21 15-day reports and all associated follow-ups that are  
22 required under 312.32. And it's really important.

1           So nothing about 312.32 is changing. This is  
2 simply a logistic change. It's a change in electronic  
3 format requirement. So the types of events -- serious,  
4 unexpected, suspected to be related to the drug -- are  
5 exactly the same. Again, this is just a change in  
6 format requirement.

7           How we get those data elements and put them  
8 into an E2B data standard, we'll talk about. But what  
9 you need to put in your report, what you are currently  
10 putting in MedWatch or a narrative report or something  
11 like that stays the same. Again, this is just a change  
12 in format requirements. So instead of these reports  
13 going into eCTD format, they'll then be going into  
14 FAERS.

15           So again, just to kind of review the current  
16 process, these are generally submitted at least for  
17 commercial INDs in eCTD format as a PDF. And for the  
18 tens of thousands of these that FDA receives every  
19 year, it's an extremely inefficient and labor-intensive  
20 process for our reviewers to review and there's no  
21 standard tracking mechanism. So this is really a big  
22 leap forward for us in terms of being able to view the

1 safety information as structured data elements.

2           So the new process again, as I mentioned, it  
3 is just a change in format. So instead of MedWatch  
4 forms as PDFs through eCTD, these will be sent as XML  
5 files to FAERS in the ICH E2B data format. And we are  
6 starting in R2. So these will be E2B(R2) data  
7 standards. And that will allow for more consistent  
8 data tracking of the safety signals, data  
9 visualization, and certainly just a more streamline  
10 process for submission and review.

11           Other good things about this process. Again,  
12 as we've heard about before, this obviously is  
13 consistent with what sponsors are doing in the post-  
14 market. Although the regulations for what types of  
15 events are different, the mechanism for submission is  
16 the same. And then it also complies with our existing  
17 Federal Regulations under 312.32, which allows us to  
18 specify electronic format for submission of these IND  
19 safety reports. But again, just format, not content.

20           Any questions about that? Again, please stop  
21 me if you have any questions. I'm happy to address. A  
22 little bit of background about the pilots. So a couple



1 of years ago, we started with these and this really  
2 rose out of a concern about the volume of reports that  
3 we were receiving and the ability to consistently track  
4 these and review them in an efficient manner.

5 So we worked with our colleagues in FAERS to  
6 essentially take a couple of MedWatch forms, see if we  
7 were able to take the information in the MedWatch form  
8 turn it into an XML file that needed to be format and  
9 submitted in a pre-production environment in FAERS.  
10 And as you would imagine, since MedWatch is sort of a  
11 subset of E2B, that worked out fairly well.

12 We worked with several commercial sponsors so  
13 that they were able to submit some legacy files that  
14 they had to FAERS in this pre-production environment so  
15 we are able to view that data recurrently. And then we  
16 moved on to a technical pilot, which is actually still  
17 ongoing.

18 We're working with several commercial sponsors  
19 who are doing a parallel submission. So they submit  
20 their MedWatch forms as PDFs in eCTD format for  
21 regulatory purposes, but then in parallel, they submit  
22 the same IND safety reports formatted in E2B to FAERS.

1 And then we're able to sort of look at the data  
2 elements to ensure that we're getting the same  
3 information in the same way that we want for the IND  
4 safety reports for our review divisions to review this  
5 data. And it also helped us to configure FAERS for  
6 some additional data values that were needed for some  
7 concepts that were not particular -- that were specific  
8 to the pre-market environment that were not used in  
9 post-market. So this helped us to revise and to  
10 finalize our technical specifications document to be  
11 able to do that.

12 And it was actually very helpful for us to do  
13 this because we are able to get a bunch of use cases --  
14 which I'll talk to you about a little bit later -- in  
15 terms of I have a -- you know, some clinical trial  
16 information can be a little bit more complicated than  
17 some of the post-market reporting, the number of drugs,  
18 some of them are approved, some of them non-approved,  
19 and how do we fit that information into the E2B data  
20 standard. So that has been very helpful to us.

21 And we are also looking forward to an end-to-  
22 end pilot before implementation. So this is in the

1 August to September timeframe. And this is really, as  
2 the title implies, is an end-to-end testing of our  
3 systems. Once all of our regulatory systems and all of  
4 our systems that are needed for coding investigational  
5 drugs appropriately, all of the systems that we have in  
6 order for our reviewers to be able to review and  
7 document on these reports are connected, then we'll  
8 work with several commercial sponsors to, over a short  
9 period of time, ensure that we have and that we are  
10 ready for production and to have these reports to be  
11 submitted for regulatory purposes.

12 So here are the requirements and timelines.  
13 So this will be required change in format under 745A of  
14 the FD&C Act. So as you I'm sure know, so the FD&C --  
15 or the 745A are electronic submission requirements.  
16 And currently INDs under 745A are required to be  
17 submitted to an eCTD format. So that's initial INDs  
18 and every subsequent submission.

19 Essentially, what this program will do is just  
20 carve out IND safety reports as a change in format. So  
21 instead of going in eCTD format, IND safety reports  
22 will now be submitted to FAERS.

1           And I'll say we have up here specified IND  
2 safety reports and I'll go into that in a little bit  
3 more detail it in a slide or two. But essentially,  
4 these are IND safety reports that contain individual  
5 patient data. So there are -- 312.32 has a number of  
6 different reports that are required for submission.  
7 But again, the ICH E2B data standard is really for  
8 ICSRs. So these are IND safety reports that fit that  
9 ICSR individual patient level data. And we'll talk  
10 about which of those and what goes where shortly. But  
11 just to let you know.

12           So sponsors will have two options. And again,  
13 because this is 745A, these will be for commercial  
14 INDs, although we encourage sponsors of non-commercial  
15 INDs to use one of these two methods if they are able  
16 as well because we would like to get all of the safety  
17 data into FAERS into the same format.

18           But sponsors will have two options. So either  
19 through the gateway. So if they have the database-to-  
20 database capabilities, they are able to submit directly  
21 their files formatted, it needs to be to FAERS. Or for  
22 sponsors who don't have that capability, the safety

1 reporting portal, which I believe was mentioned and is  
2 currently in use for the post-market, is being  
3 configured to accept IND safety reports. So sponsors  
4 will have the option of a web-based interface that will  
5 then generate an E2B file and be submitted to FAERS.  
6 So those are two options that sponsors will have.

7 The requirement -- because it's considered a  
8 major change in format for 745A, it will be 24 months  
9 after the final guidance is published. So it just  
10 gives you sort of a sense of where we are.

11 However, the goal at this point is to accept  
12 voluntary submissions and encourage voluntary  
13 submissions starting in October. So the guidance will  
14 be out prior to that. And I'll talk about the  
15 communication plan in a bit. And then we'll post on  
16 the FAERS' website 30 days prior when we'll be  
17 beginning to accept voluntary submissions for IND  
18 safety reports.

19 So this timing is a bit different than the R3  
20 implementation. And again, remember we're starting in  
21 R2. And the reason for that is there's no compliance  
22 date set for R3 and we wanted to get going on this

1 program so sponsors can submit an R2 and continue to  
2 submit an R2 for pre and post-market. But again, the  
3 October timeframe is an R2 to for IND safety reports.  
4 Any questions about any of that?

5 UNIDENTIFIED SPEAKER: (Off mic)

6 MS. CHUK: No. So the goal is that regulatory  
7 set forth -- the purposes of regulatory submission in  
8 October, that's a good point, yes. So just one report.  
9 The goal is that that -- you know, the systems will be  
10 up and ready in time to get those reports from FAERS to  
11 our pre-market reviewers and the review divisions will  
12 be using the FAERS' reports for regulatory review.  
13 Yes.

14 So no -- the duplicate submission was really  
15 just part of the technical pilot to ensure that what  
16 we're used to seeing in a MedWatch form and that we're  
17 able to get all of the pre-market elements in the E2B  
18 format. So, yes, that's a great point.

19 So no parallel submission once we go live for  
20 regulatory submission -- for regulatory purposes.

21 Okay. So the -- go ahead.

22 UNIDENTIFIED SPEAKER: (Off mic)

1 MS. CHUK: Yes, yes. So the same process for  
2 -- if you're just starting out submitting to FAERS in  
3 any way, to e-mail -- and I think it's -- it was  
4 certainly on Suranjan's slides and maybe on mine later  
5 on to -- to email the FAERS coordinator to make sure  
6 that you have all of the system requirements to begin  
7 submitting. And then to submit a number of test files  
8 just to make sure that you're receiving -- you know,  
9 that the test file is accepted.

10 And then there's a -- there will be an  
11 opportunity for submission in a pre-production  
12 environment as well too. And I believe Acks will be  
13 given in that pre-production environment. So you can  
14 also see and make sure that you receive the appropriate  
15 acknowledgments when you submit those forms.

16 And we actually strongly encourage sponsors to  
17 do that if you're submitting for the first time either  
18 pre or post-market, but certainly for IND safety  
19 reports given that there will be some data elements  
20 that will be required. And we want to make sure the  
21 sponsors are putting those in the appropriate places.

22 Okay. So in terms of communication plan,

1 obviously we have meetings such as this. We'll have  
2 draft guidance and technical specification document  
3 that is both -- so two of those that are both new for  
4 this program that will be published along with the  
5 updated existing technical specifications document  
6 that's in use for post-market and combination products,  
7 will be updated with data elements for IND safety  
8 reports.

9           There will also be an updated link on the  
10 FAERS' webpage, which has information and a link to a  
11 separate page, which has also -- it has all of those  
12 documents and also has frequently asked questions and  
13 some case examples and things like that that we'll keep  
14 current for IND safety reporting.

15           We're planning on a webinar that will address  
16 some of the comments to the docket on the draft  
17 guidance as well. And then there will be various other  
18 FDA communications so that nobody is caught by surprise  
19 that this is coming.

20           All right. So this is the data flow, just to  
21 give you a sense. And do I have a pointer here  
22 somewhere? Okay, that was not working. Anyway, so



1 we'll start here. And get me a pointer here. So the  
2 sponsor from their PV system will generate an IND  
3 safety report, an XML file in E2B(R2) standards. And  
4 again, 312.32 doesn't change. This is just a change in  
5 format. So our requirements in the pre-market for  
6 events that are serious, unexpected and suspected to be  
7 related to the investigational agent as per the  
8 sponsor's assessment still holds. So it's the same  
9 events that we want; it's just a different format.

10 They will be submitted to the FDA gateway.  
11 The sponsor will receive the appropriate  
12 acknowledgments once it's received in the gateway and  
13 then once it's successfully processed in FAERS. And  
14 then FAERS will have pre-market IND safety reports and  
15 also post-market reports. And then those reports will  
16 be available for reviewers for data analytics and  
17 tracking.

18 And again, the goal to begin accepting IND  
19 safety reports and E2B(R2) on a voluntary basis is  
20 October. And certainly, we'll post that on the FAERS'  
21 website 30 days ahead.

22 So we alluded to before and Suranjan mentioned

1 that there are two separate paths for the pre-market  
2 and the post-market, and this is important. So -- and  
3 FDA has defined new header attributes and routing IDs  
4 for sponsors who are using database-to-database  
5 transmission. And this allows separation. So there  
6 will essentially be two separate submission paths: one  
7 for IND safety reports and one for post-market reports.

8 And as you can see in the schematic down here,  
9 this is the sponsor and here's the ESG. So whether --  
10 if the sponsor either is using AS2 headers or AS2  
11 routing IDs, it's the AERS for the AS2 headers or the  
12 AERS\_Attachments if there is an attachment. And again,  
13 this is post-market. And then if the sponsor is using  
14 routing IDs, it's the FDA\_Errors or  
15 FDA\_Errors\_Attachments if there's an attachment.

16 For the pre-market, essentially all we did was  
17 add IND into that. So for a pre-market, if the sponsor  
18 is using AS2 headers, it will be AERS\_IND and  
19 AERS\_Attachments\_IND if that is an attachment. And if  
20 the sponsor is using routing IDs, it will be  
21 FDA\_AERS\_IND and the same thing for attachments as  
22 well.

1           And this is really critical, because we've had  
2 a lot of questions about this. Obviously, the post-  
3 market data is posted on a quarterly basis and is  
4 available via the public dashboard. IND safety reports  
5 will not be made and will not be posted publicly. And  
6 sponsors have a lot of questions about that. And this  
7 is the main mechanism by which we are assuring that  
8 these are not public -- hosted publicly as well. So it  
9 really is incumbent upon the sponsor to send these to  
10 the appropriate location. Does anybody have any  
11 questions about that?

12           UNIDENTIFIED SPEAKER: (Off mic)

13           MS. CHUK: Great idea. Two reports.

14           UNIDENTIFIED SPEAKER: There will two?

15           MS. CHUK: Yes. So --

16           UNIDENTIFIED SPEAKER: Okay.

17           MS. CHUK: Right.

18           UNIDENTIFIED SPEAKER: Because we know that  
19 (Off mic).

20           MS. CHUK: Right. However, there's IND  
21 information on the IND report. And they're not -- it's  
22 not a -- just because you're submitting an IND safety

1 report doesn't necessarily mean you're submitting a  
2 post-market report and vice versa, because the  
3 reporting requirements are different. So it shouldn't  
4 be a default "if I have one, I'm submitting the other."  
5 But you're right.

6 I mean, if you have an approved drug being  
7 studied under IND, you may meet both reporting  
8 requirements. But there will be two reports. And  
9 primarily for this reason: so that they are truly  
10 separated in the two systems.

11 UNIDENTIFIED SPEAKER: How about death (Off  
12 mic).

13 MS. CHUK: Death reports for pre or post for  
14 IND? I mean, that would be considered a 7-day report.  
15 So same -- you know, the -- again, what's under 312.32,  
16 so the content of the report and the timing for  
17 submission.

18 So a death report that is serious, unexpected  
19 and suspected would have a 7-day timeframe for  
20 submission from when the sponsor receives notice. So  
21 that timeframe remains the same. They're not going to  
22 be treated any differently.

1           And I have a slide coming up about the types  
2 of reports that are required under 312.32. It doesn't  
3 address timing per se. But again, this doesn't change  
4 timing. So something that would be a 15-day report is  
5 still going to be required within 15 days and follow-  
6 ups to those again. Any -- nothing, none of the -- you  
7 know, none of the mandates in 312.32 is going to  
8 change.

9           All right. Oh, and here it is. Okay, so this  
10 is the slide that talks about the different types of  
11 IND safety reports that are required under 312.32.  
12 These are a little bit of an arbitrary bucket. I mean,  
13 obviously the requirements are serious, unexpected --  
14 so not listed in the IB -- suspected to be related, at  
15 least there's a reasonable possibility that the event  
16 was caused by the drug according to the sponsor  
17 assessment.

18           However, 312.32 does provide sort of these  
19 buckets in terms of what types of evidence you might  
20 use to assess whether or not an event would be required  
21 in an IND safety report.

22           So there are six buckets there. And then the

1 two columns are whether or not these submit to FAERS  
2 and whether or not they're continuing to be submitted  
3 in eCTD format.

4 And really the distinction is: is there  
5 individual patient data that would fulfill and would  
6 fit into that E2B data standard, or are these more  
7 narrative summaries that would not fit very well at all  
8 into that data standard? Those continue to be  
9 submitted to eCTD -- in the eCTD format as narrative  
10 summaries.

11 We would appreciate them not being on MedWatch  
12 forms. And that will be listed as well, because they  
13 are narrative summaries that they are something that  
14 can fit in MedWatch form. You should be submitting it  
15 to FAERS.

16 But just to talk a little bit about these  
17 events. So a single occurrence of -- oops. A single  
18 occurrence of an event that's uncommon and known to be  
19 strongly associated with drug and not much else -- so  
20 these are your Steven-Johnsons, your agranulocytosis,  
21 generally one event, one patient information from a  
22 clinical trial -- submit that FAERS.

1           One or more occurrences of events that are not  
2 real common in your population and maybe not so common  
3 with drugs, but there's a reasonable possibility your  
4 drug could have done that with one or more events,  
5 those go to FAERS.

6           The third bucket is an aggregate analysis or a  
7 report that's a result of an aggregate analysis. So  
8 these are events that are common in your population.  
9 Say, pancreatitis is common in your population, but you  
10 get a higher number of reports in the clinical trial  
11 than you would expect baseline, enough to be able to  
12 say, "You know what? My drug may actually cause  
13 pancreatitis."

14           So -- and we'll show you in a couple of slides  
15 how to do this. So you submit the pancreatitis as the  
16 index report and then you submit the X number of ICSRs  
17 that contribute to that assessment. So you'll have  
18 your summary of what that event is. And then all of  
19 your reports linked.

20           And this really is consistent with what we ask  
21 for in the 2012 IND safety reporting guidance that  
22 talks about "if you have a report that's a result of an

1 aggregate analysis, we also want you to submit all of  
2 the MedWatch forms that make up that analysis." So  
3 this is really just doing that within the context of  
4 FAERS.

5           So there will be a particular -- and I'll talk  
6 about this in a couple slides. Those reports will be  
7 designated as an aggregate. So they're only counted as  
8 each of those individual reports, but then they will  
9 all be able to link together for reviewers to see and  
10 people interrogating for the system to know that that  
11 was an index report with all of those cases that are  
12 linked. So it will give us a more appropriate account  
13 of all of those individual cases and keep all of that  
14 safety data together.

15           Now, if you have some change to your clinical  
16 development program, if there's a change in the IB or  
17 informed consent or something like that, that needs to  
18 have some separate action done on several INDs, that  
19 information is separate from the report. That still  
20 goes to eCTD format.

21           Any question about those individual -- so  
22 really these are cases that have individual patient



1 level data that you could very easily fill out a  
2 MedWatch form for any of these. They would go to  
3 FAERS.

4 The other ones are essentially narrative  
5 summaries of events, and this is described in 312.32 as  
6 well. So findings from other studies, whether it's a  
7 literature report or some other where you don't have  
8 patient level data on those trials or not other studies  
9 that were perhaps conducted, SUS (ph), where you don't  
10 have that patient level data. Findings from animal in  
11 vitro studies, the pharm-tox IND safety reports will  
12 still be continued to submit in eCTD format. And  
13 there's an eCTD section where those should  
14 appropriately continue to be submitted.

15 And then an increased rate over a known over  
16 expected event. So, you know, I thought pancreatitis  
17 occurred in X percent. Now, I see it in X plus Y  
18 percent. I think that's a clinically meaningful  
19 increase to pose an additional safety risk. So now I  
20 submit that as an IND safety report. But again, you're  
21 not likely going to have individual patient data on  
22 that increase in incidents. So that's an error of

1 summary; that continues to go to eCTD.

2 Questions about that? All right. So I'm  
3 going to talk -- I'll switch -- talk a little bit about  
4 some of the data elements that are specific and very  
5 important for IND safety reports that are not  
6 necessarily used in the post-market setting.

7 So again, as I mentioned, the tech -- the in  
8 use technical specifications document that's already  
9 published and in use for post-market and for  
10 combination products will be updated with these data  
11 elements for IND safety reporting.

12 And if you remember nothing else from this  
13 session, there are two things I want you to remember,  
14 is this: where to put the ID number and then also the  
15 separate routing. But the ID number is critical. So  
16 this will be a required data element. Essentially, we  
17 cannot process these reports if we don't know which IND  
18 -- under which IND the event occurred.

19 So just like in the same way we wouldn't be  
20 able to process them if they were submitted in eCTD  
21 format, if they're submitted to FAERS with an ID number  
22 that is not in the correct location or that it's not a

1 valid number, these will not be able to be processed.

2           So this is -- so A232 or the sponsor study  
3 number tag is where the IND -- where the clinical event  
4 happened, where that clinical trial is being conducted.  
5 So A232 and then A233, which is essentially going to  
6 talk about the type of report. And these will  
7 generally be report from study. I have it on the next  
8 slide.

9           So that's for the primary IND. Our 2012 IND  
10 safety reporting guidance also states that sponsors  
11 should send these reports to all other INDs under which  
12 they're evaluating that suspect product. We do not  
13 want more than one ICSR in FAERS, but we do need  
14 sponsors to list all of those other INDs.

15           So the way that we're doing that is that the  
16 first block will have the IND safety report -- and  
17 maybe this is a little bit easier to sort of see. So  
18 the first block, the sponsor study number tag, will  
19 have the IND safety report, under which the clinical  
20 trial or the event occurred. And your observed study  
21 type is likely going to be a clinical trial.

22           A2 is a repeatable block. So in that -- for

1 every -- if there are five other INDs where that  
2 suspect product is being investigated, repeat just A232  
3 and A233 for those five INDs, that will have all of  
4 those other IND numbers in each of those separately in  
5 those blocks. And then data element, which is a new  
6 data element number five, which is cross -- oops --  
7 which is cross-referenced INDs.

8 And so does that make sense? Any questions  
9 about that? So only one report, because we don't want  
10 these events to be counted more than once. But it is  
11 still critical for the review divisions who don't have  
12 that IND but are also evaluating that drug to get  
13 notification.

14 So it's A232 with a clinical trial, is the IND  
15 under which the event occurred. And then you repeat  
16 A232, A233 for every other IND under which that drug is  
17 being evaluated with the new data element of the cross-  
18 referenced safety -- cross-referenced IND. There's  
19 also a note here that -- so -- go ahead.

20 UNIDENTIFIED SPEAKER: (Off mic)

21 MS. CHUK: So great question. And that's  
22 where I'm leading up to. So, right. No, that's a

1 great leading -- so if it is a result of an aggregate  
2 analysis. So again, pancreatitis I thought was X  
3 percent. It's X plus Y. I think this is a new signal.  
4 But my analysis expand five INDs. You submit it to  
5 what we call the parent IND. So that is the IND under  
6 which clinical trials were initiated in the U.S. It's  
7 generally the one with the lowest number. This would  
8 be the same concept.

9 So if you don't have -- I'm trying to think  
10 about this. So if it's an ex-U.S. trial and you don't  
11 have an IND, why would you be submitting us a report?

12 UNIDENTIFIED SPEAKER: (Off mic)

13 MS. CHUK: So you do have an open IND for that  
14 product. You're just not conducting the trial. Got  
15 you, got you, got you. Okay. Yes. So if it meets our  
16 reporting requirements, it would be submitted to the  
17 parent IND again. So that's -- sort of the default is:  
18 if you have something that meets 312.32 reporting  
19 requirements and either it -- but you have individual  
20 patient data that -- yes, so send it to the parent IND.

21 A lot of times those things will also have  
22 implications for clinical trial conduction. So you may

1 be also submitting things through eCTD to say "I  
2 changed this. I'm, you know, changing my eligibility  
3 criteria. I'm changing my monitoring," something like  
4 that. So that information about -- or, you know,  
5 here's a protocol amendment to talk about this or an  
6 updated informed consent document, that also goes in  
7 eCTD format. But the IND safety report itself will go  
8 to FAERS under the parent IND.

9           And this just tells you a little bit about how  
10 to put the numbers in the field. And again -- so these  
11 -- so the 8 -- so if -- so if you have an A232, you  
12 need an A233s. So those will be sort of conditionally  
13 required. We at least need to have one. And then if  
14 you have other INDs where you're evaluating that drug,  
15 those two tags will be repeated then in that block.

16           You don't need to repeat everything in the  
17 block. A2 is a big block. But we just need those  
18 repeated. You can. But we just need what's repeated  
19 for A232 and A233.

20           Let's see. So the clinical trial. Generally  
21 -- again, generally speaking, these will be clinical  
22 trials or a report from aggregate analysis as well.

1 Some of these other things were -- you can submit for  
2 individual patient, but they wouldn't be required. And  
3 then these are basically, if you have a report from an  
4 aggregate analysis, those are generally considered 15-  
5 day reports. So that's where this A19, that is --  
6 that's where it's that fulfill expedited criteria, so  
7 that would be a 1 or a yes. And we'll get to that. I  
8 think that's the next one.

9 Right. Okay. So here are some other data  
10 elements that are specific and not necessarily unique  
11 to IND safety reporting, but perhaps more emphasize the  
12 type of report. Again, the default is going to be  
13 report from study, unless there's a good reason not to  
14 have that.

15 The expedited criteria. There is a new data  
16 element here. So that 7-day report is obviously not a  
17 post-market concept. That's unique to the pre-market.  
18 And this gets back to the timing requirements. So the  
19 timing requirements will not change. So if something  
20 is to be submitted in 7 days, you'll just use this --  
21 the data element value of 7 -- or number 6, which is a  
22 7 day. And then number 1 is -- 1 for 15-day expedited.

1 So for IND safety reporting, you'll either be using a 1  
2 or a 6 to denote either a 15-day or a 7-day report.

3 And then obviously your follow-ups to that will be  
4 either a follow up to whichever the initial report was.

5 The clinical trial identification. So for R2  
6 we will be using in this field the eCTD study tag  
7 identification that allows us -- so basically, whatever  
8 that study identifier that you're using in the rest of  
9 the IND submission, when you're submitting an eCTD  
10 format, we're going to use -- we'll have you put that  
11 same study ID in there. And it just allows us to be  
12 able to identify the clinical trial as is being used  
13 and as is being identified for every other FDA  
14 submission.

15 And there's also a recommendation to  
16 concatenate that with the abbreviated trial name,  
17 similar to what's done for EMA, essentially the EudraCT  
18 number concatenating with the abbreviated trial name.  
19 So that's similar.

20 UNIDENTIFIED SPEAKER: (Off mic)

21 MS. CHUK: For -- no. So these are all of the  
22 data elements for anything in FAERS. So I think 5 is a



1 quality product --

2 MR. DE: So when you have a -- when you have  
3 combination products, combination products actually has  
4 a 5-day, which is -- I don't remember the full -- but  
5 there's a 5-day and a 30-day for combination products.  
6 So that's why those values.

7 UNIDENTIFIED SPEAKER: (Off mic)

8 MR. DE: Yes.

9 UNIDENTIFIED SPEAKER: Remedial action?

10 MR. DE: Remedial action, correct.

11 MS. CHUK: Yes. So all of the element values  
12 are listed here. We just highlighted the ones that  
13 will be used for IND safety reporting. Would it -- do  
14 you think it would be clearer in that section -- we can  
15 think about sort of not having that in there. But we  
16 essentially were calling out what you would be using in  
17 the note section if there's something particular and  
18 specific about IND safety reporting and we've tried to  
19 put that in the note section.

20 UNIDENTIFIED SPEAKER: (Off mic) a 7-day  
21 report is fatal or life-threatening?

22 MS. CHUK: I'm sorry, can you come a little

1 closer?

2 UNIDENTIFIED SPEAKER: If it's a fatal report  
3 -- if it's a 7-day report, it's fatal or life-  
4 threatening.

5 MS. CHUK: Uh-huh.

6 UNIDENTIFIED SPEAKER: So then you would mark  
7 off 7-day as your expedited criteria?

8 MS. CHUK: Yes, yes.

9 UNIDENTIFIED SPEAKER: And then normally if  
10 you have additional information, you have another 8  
11 days within which to submit the rest of the  
12 information.

13 MS. CHUK: And that would be a follow up --

14 UNIDENTIFIED SPEAKER: In that case, just go  
15 as one 7-day report to the FDA?

16 MS. CHUK: I mean, if you can meet this -- you  
17 know, if you have that additional information within  
18 that 7 days -- you know, say, you --

19 UNIDENTIFIED SPEAKER: It would all go --

20 MS. CHUK: -- find out about the event and  
21 find out follow-up sort of at the same time and you're  
22 generating an E2B report that meets that 7-day follow

1 up, that's fine -- you know, if that meets that 7-day  
2 requirement, that's fine. Generally, what happens is  
3 that we get sort of the initial 7-day, something  
4 happened, and then there's a follow up later that says  
5 "okay, these are the details." But if you happen to  
6 get all that information at the same time -- but  
7 remember your time clock starts from the sponsor's  
8 receipt of information --

9 UNIDENTIFIED SPEAKER: Yes.

10 MS. CHUK: -- of an event that would qualify  
11 for that 7-day reporting.

12 UNIDENTIFIED SPEAKER: Okay, great. Thank  
13 you.

14 MS. CHUK: So again, this is only format.  
15 This doesn't have any -- and follow-ups are similar to  
16 post-market. So anything that you would submit in an  
17 initial report, you should resubmit in the follow up  
18 and then just add, you know, new things. So it should  
19 be sort of an add-on to that report.

20 So those will be different case version  
21 numbers essentially. So you'll be assigned a case when  
22 you submit the initial report and then every follow up

1 will be a different case version in FAERS.

2 UNIDENTIFIED SPEAKER: (Off mic)

3 MS. CHUK: It's in the notes section. And I  
4 think that it's currently what in use for post-market  
5 for the 15-day expedited. So, you know, do not create  
6 more confusion by creating some things totally separate  
7 for IND safety reports. We're just using the same --  
8 yes, meaning that it's a 15-day expedited. I  
9 completely agree with you that what meets criteria is  
10 different, but the timing is the same. So --

11 MR. DE: So one point that -- actually, the  
12 technical specification for R2 which we have today, the  
13 regional, has explanation in the note section, which  
14 says 1 --

15 MS. CHUK: Yeah.

16 MR. DE: -- means this and 2 means that and 3  
17 means this, just for the slide sake. And then when we  
18 go to R3, you will find this whole concept will be a  
19 little more different than the way -- here we were  
20 trying to fit in existing data elements so that it  
21 doesn't have impact, where just adding a codeless value  
22 helps to resolve this. Because everybody's trying to

1 eventually move to R3, so.

2 MS. CHUK: And in R3 we'll have a field that's  
3 IND number and that's cross-referenced IND number. So,  
4 you know, it will be a little bit clearer. Again,  
5 until we sort of get there, it's a little bit of  
6 repurposing what already exists just to -- as Suranjan  
7 said, to ease the impact.

8 But, yes, once R3 -- and TJ will talk a little  
9 bit more about the sort of -- what kind of maps from R2  
10 to R3 for both pre and post-market as well. But you'll  
11 see those more dedicated data elements that are  
12 specific for U.S. reporting.

13 So the other kind of buckets of data elements  
14 are causality assessment. So again, critical in the  
15 pre-market to be able to -- so that at least one of  
16 these products should be a suspect product for each of  
17 those. There may be several products, but at least one  
18 of them should have a suspected causality as determined  
19 by the sponsor.

20 And again, for the drug assessment source,  
21 given our 312.32 regulations, that it is the  
22 responsibility of the sponsor to determine the criteria

1 that meets reporting. This should always be defaulted  
2 -- this drug assessment source tag field should always  
3 be defaulted to the sponsor.

4 There is a place for investigator assessment  
5 in the narrative and that can be done as well. But in  
6 this field there should be sponsor assessment and at  
7 least one of them should be suspected.

8 And again, down here. So this is actually an  
9 open -- open for whatever sponsors want to put in  
10 there. We have created -- so there are two new element  
11 values: 1 or 2, suspected or not suspected. We  
12 recommend that you pick one of those just for  
13 consistency of how the data is presented. So any  
14 questions about the -- uh-huh.

15 UNIDENTIFIED SPEAKER: (Off mic)

16 MS. CHUK: So that is -- it's the element  
17 value underneath that particular field. So either a 1  
18 or a -- it should be a 1 or a 2. I think it's still an  
19 alphanumeric field. I don't -- Suranjan, we haven't --  
20 that hasn't been changed, right? So, I mean, it's not  
21 mandated to be that, but the recommendation is that  
22 it's 1 or 2. And that will then be coded within the

1 system to be suspected or not suspected.

2           You'll still be able to use that as an  
3 alphanumeric field, but the recommendation is that --  
4 just because that can be dealer's choice for whatever  
5 people want to put in there. It's not a consistent  
6 response in there. We're just encouraging sponsors to  
7 be consistent with either suspected or not suspected.

8           UNIDENTIFIED SPEAKER: (Off mic)

9           MS. CHUK: Right, right. Okay. The narrative  
10 field. So again, critical obviously in pre and post-  
11 market. But there is likely to be more information in  
12 the pre-market setting. And given our 2 (sic)  
13 character limitations, you know, we anticipate that  
14 there may be some challenges. Although -- you know, I  
15 think the encouragement is that sponsors should  
16 construct an informative narrative that should be able  
17 to fit within that 20,000 character limitations,  
18 especially given the ability to structure some of the  
19 other data elements such as laboratory values and tests  
20 and things like that.

21           So, you know, our strong recommendation is  
22 that sponsors be able to use and put that narrative

1 within that field. Because again, for ease of  
2 reviewing for our reviewers, if that information comes  
3 within that field, it's certainly much easier to do so.

4           However, there is always the option to use  
5 attachments for things -- we're encouraging more for  
6 things like autopsy reports or biopsies or something  
7 that truly would not necessarily be within that  
8 narrative field.

9           However, you know, if there is a lengthy  
10 narrative that sponsors would like to convey to the  
11 review division, they can always put what doesn't fit  
12 within that narrative field into an attachment.

13           What we don't want, though, is for sponsors to  
14 not put anything in the field and just to attach a PDF  
15 with a narrative. So again, that's just something to  
16 keep in mind about -- once we get to R3, those  
17 limitations will be less of an issue with 100,000  
18 characters. But in R2, you know, we'll just have to  
19 see how much of an issue it is.

20           But we really are encouraging people to think  
21 about their narratives and be thoughtful about how they  
22 construct them so that they do fit within the fields.



1 And they tend to be a little bit more informative when  
2 they're -- not data dumps as well too.

3 And so the other thing is to be able to  
4 separate some things out. Sponsors can use B52 or the  
5 sender comment to talk a little bit about their  
6 causality assessment and the reason for assessment as  
7 well too. So we encourage them to sort of use the  
8 appropriate narrative -- or fields to convey that  
9 information to not have to use attachments. But the  
10 option is there. Questions about that at all? No?  
11 Okay.

12 For the investigational product -- or any  
13 product identification becomes a little bit more  
14 challenging when they're investigational products.  
15 We're not looking at SPL. So, you know, the two fields  
16 that we'll be looking at are the medicinal product  
17 field and the active substance.

18 Obviously, drugs in the investigational stage  
19 are not necessarily going to have a proprietary  
20 medicinal name. But if there is an INN or a USAN name,  
21 we encourage that information in there. And then to  
22 use a company code if that information is not

1 available.

2 Or for particularly the biologic products, if  
3 the character length is exceeded by the full name of  
4 the product or, you know, the components of the  
5 product, just to use the company code as well. And  
6 then to put the active substance in the other field, as  
7 would normally be done. Questions? Okay.

8 And this is going back to the reports from the  
9 aggregate analysis that I talked about before. So this  
10 is a -- you know, here's an event that is now I think a  
11 signal based upon these X number of individual reports.  
12 So the A112 data element or the linked report number  
13 tag is where all of those individual cases should be  
14 listed in that sort of index report.

15 You don't need to resubmit something that's  
16 already been submitted in the system. If there are new  
17 reports you want to add to that index case, you can do  
18 that, but you don't need to resubmit. As long as all  
19 of those safety report ID numbers, MCN numbers that you  
20 used in those previous cases are within this field, the  
21 system can then link those in there.

22 This is this -- the A232 should be -- we

1 talked about before the parent IND, so again that's --  
2 if this came from a number of INDs, that should be the  
3 IND generally with the lowest number, the one that  
4 investigations in the U.S. were begun.

5 One thing I didn't mention before is that  
6 because -- let me just go back here for a second. For  
7 investigational product information the -- there is the  
8 -- there is another B.4 field that talks about drug  
9 authorization number tag. I don't have it up here, but  
10 I think that's the tag.

11 No need to fill that in for IND because  
12 obviously you're not going to have -- there's not going  
13 be an NDA or a BLA number for an investigational  
14 substance. So we don't want the IND number there.

15 So really for B4 drug authorization number  
16 tag, we don't need any information at all for INDs,  
17 because again there isn't an NDA or a BLA number. And  
18 that's just basically what that means here, is this  
19 B.4.k drug authorization tag. Yeah?

20 UNIDENTIFIED SPEAKER: Is FDA using the self  
21 registration (Off mic)

22 MS. CHUK: Yes.

1 UNIDENTIFIED SPEAKER: -- (Off mic) --

2 MS. CHUK: Not the number, but the --

3 UNIDENTIFIED SPEAKER: (cross talk)

4 MS. CHUK: -- the preferred name.

5 UNIDENTIFIED SPEAKER: Okay.

6 MS. CHUK: Yes, absolutely. If you know what  
7 that is for the SRS, absolutely. And that's basically  
8 what we're using internally.

9 UNIDENTIFIED SPEAKER: Okay. But for the (Off  
10 mic) active ingredient name --

11 MS. CHUK: The active ingredient name, right.

12 UNIDENTIFIED SPEAKER: -- (Off mic).

13 MS. CHUK: Correct, correct, correct. Yes,  
14 yes. Let's see. And then observed study type. This  
15 is for the reports from aggregate analysis. That would  
16 be a data element value of number 4, report from  
17 aggregate analysis for that index case. And then,  
18 again, since there is no patient identifier specific  
19 for that one report that's your index case, the element  
20 value should just be aggregate. So that lets our  
21 system know that it's an aggregate report and it also  
22 doesn't count that as one of the individual numbers

1 when calculating number of reports or reports of a  
2 particular event.

3 MR. DE: Meredith, I want to add something.  
4 So -- because we have those four elements that make a  
5 case, which is -- and one of them is patient, so in the  
6 aggregate -- the only way for us to get this -- patient  
7 being mandatory is to put in the patient identifier the  
8 word aggregate. So that when the system checks, yeah,  
9 there is a patient, but even though it's an aggregate,  
10 it's accepted.

11 MS. CHUK: Questions about those reports?  
12 Okay. So based upon -- so clearly we've talked about  
13 the benefits to FDA. We also think that there are  
14 benefits for industry. And talking with our industry  
15 partners in the context of our pilot, they really  
16 focused on the efficiency gains that are likely to  
17 happen from these reports being sent from their PV  
18 database and not necessarily having to go through  
19 regulatory affairs, because there's no 1571, there's no  
20 cover letter with these reports, so that you have the  
21 ability to automate within the system itself.

22 And we've actually heard that some sponsors

1 say it could save them up to 24 to 48 hours, and on a 7  
2 day report, that's a lot of time. So certainly we  
3 think from a -- it requires a change in process, but  
4 from what we've heard, that change in process really  
5 can be time saving from an efficiency standpoint as  
6 well.

7           And then it also eliminates the need for  
8 duplicate reports for -- if you have 15 INDs evaluating  
9 that product, you only have to send 1 report. We still  
10 need the other 14 INDs listed in that report, but you  
11 only have to send 1 report.

12           It's more comprehensive and more structured,  
13 more data elements, more opportunity for some more  
14 granular unstructured data than the MedWatch form. And  
15 then also it's consistent with ex-U.S. reporting as  
16 well. So hopefully -- again, although not -- we're not  
17 harmonizing the requirements for what criteria or what  
18 events meet submission, but we're trying -- we're  
19 harmonizing the technical solution for how to submit  
20 the reports.

21           I'm going to pause there. Are there any  
22 questions before I'll talk a little bit on the case

1 scenarios? Okay. Uh-huh.

2 UNIDENTIFIED SPEAKER: I just have one  
3 question about (Off mic)

4 MS. CHUK: So for commercial sponsors, the  
5 reporting to FAERS is 24 months after the final  
6 guidance. So whenever -- so draft guidance in the next  
7 couple of months before the -- before voluntary  
8 submission. So whenever the final guidance is  
9 published, it will be -- now the MedWatch form isn't  
10 going to go away. Obviously, it will still be  
11 available. Noncommercial -- sponsors of noncommercial  
12 INDs will be able to use them. But for commercial  
13 sponsors, IND safety reports should not be submitted on  
14 a MedWatch form once the 745A change in format  
15 requirement is in effect, and again, 24 months after  
16 the final guidance.

17 UNIDENTIFIED SPEAKER: Okay.

18 MS. CHUK: Sure. All right. So this is -- in  
19 case you haven't heard this enough, this is just a  
20 demonstration on where to put the IND numbers, how to  
21 put them, and exactly, you know, in which fields they  
22 are to be used.

1           So again, A232, that's the IND for the  
2           clinical event, where the clinical event occurred is  
3           the primary. And then that will likely be in A233 for  
4           a clinical trial. And then you repeat block A232 and  
5           A233 with any subsequent sort of cross referenced IND.

6           So that's for any IND safety report where the  
7           suspect product is being evaluated in more than one  
8           IND. So the onus is still on the sponsor to identify  
9           those particular INDs, but we only want one report  
10          submitted.

11          Case scenario two. So if you have an  
12          investigational drug A compared to approved drugs B and  
13          C, what do you do? So if your suspect drug is drug A  
14          only, in your medicinal product field you would use the  
15          company code. If there's not an established name or if  
16          there is either a proprietary, another established  
17          name, you can put that in that one. And then medicinal  
18          product field and any active substance will be there.

19          If it's -- B or C is your suspect product and  
20          it meets IND safety reporting requirements -- again,  
21          not a default, but if it meets requirements for 312.32,  
22          that product field should have B or C in there with



1 active substance as well.

2 And then if it's B and C, you would just  
3 repeat the medicinal product and the active substance  
4 field twice with all of these A232 being the IND where  
5 the clinical event occurred.

6 So, you know, A232 is higher up at the case  
7 level and that's really what's going to drive the  
8 routing for reporting to the appropriate review  
9 division.

10 And this is just talking a little bit -- so  
11 you have an investigational drug A plus B and C which  
12 are approved compared to B and C -- those are really  
13 all just sort of variations on the same theme, meaning  
14 that you need -- for each product that's a suspect  
15 product it needs -- it needs a separate identification  
16 and a separate field. And you can repeat it twice if  
17 needed. And then just the reminder that these are not  
18 always default IND safety reports if they meet post  
19 market requirements. And we do need two reports, one  
20 with the IND number and one with the NDA, BLA number.

21 So that is really the only time where you  
22 would still need to put in (ph) reports. Although we

1 would argue that they're not necessarily a duplicate  
2 report. It's just to meet -- it is one event that  
3 meets both pre and post-market reporting requirements.  
4 And again, for any of these, it would be the IND number  
5 where the clinical trial is conducted.

6 And similarly, if you have an approved product  
7 that's being studied under an IND, say, for a new  
8 indication and your suspect product is drug A, then  
9 that drug even though it's an approved product,  
10 reporting requirements strictly meet 312.32 versus the  
11 other ones that you would have to meet post-market plus  
12 -- at least for IND reporting you would have to do both  
13 then as well. And again, the same thing IND where the  
14 clinical trial was conducted. Questions?

15 UNIDENTIFIED SPEAKER: (Off mic)

16 MS. CHUK: Uh-huh.

17 UNIDENTIFIED SPEAKER: (Off mic)

18 MS. CHUK: Yeah, the attachment has to be sent  
19 after an R2, yes. So you have to --

20 UNIDENTIFIED SPEAKER: (Off mic)

21 MS. CHUK: Right. Approximately, yes. But  
22 it's the -- it will be considered the same case,

1 essentially that -- and then when you -- and it's a  
2 good point to bring up. So when you have a follow-up  
3 report although we say we want everything from the  
4 initial sort of with everything else added, if it's a  
5 literature case or autopsy report, you don't need to  
6 resubmit those attachments with every version with  
7 every follow-up that you have. So if it's an  
8 attachment that specific to the whole case, that will  
9 stay with the case.

10 UNIDENTIFIED SPEAKER: (Off mic)

11 MS. CHUK: Okay. Uh-huh.

12 UNIDENTIFIED SPEAKER: Any special  
13 considerations for (Off mic)

14 MS. CHUK: I'm sorry. Would you mind coming  
15 to the -- I'm having trouble hearing you -- to the mic  
16 please.

17 UNIDENTIFIED SPEAKER: Any special  
18 considerations for cases that were previously submitted  
19 on paper and are now on R2?

20 MS. CHUK: Right. So, no, we're not  
21 retroactively putting any cases into FAERS. It's  
22 essentially whenever you start. So if you start

1 submitting in eCTD and you're ready to go and are --  
2 you know, any follow up, presumably that would then be  
3 into FAERS. So we're not asking you to resubmit things  
4 that were in PDF.

5 So there's going to be a transition period.  
6 Presumably that follow up should have all of the  
7 information that you had from the initial case. So  
8 someone looking at this in FAERS will be able to know  
9 that that's a follow up and should be able to  
10 reconstruct sort of what that case is. But that  
11 initial report, if that's submitted in PDF and eCTD,  
12 we're not asking you to resubmit those. It all stays.

13 So, you know, we just -- that's the -- it's  
14 what's going to happen when you have a transition, so.  
15 And then, again, sort of overall we're not acting --  
16 we're not asking for any retrospective submission into  
17 FAERS for things that have already been submitted.

18 So whatever you've submitted previously for  
19 regulatory purposes, whenever that line is, then you  
20 can -- what we don't want you to do is go back and  
21 forth, okay? So once you sort of start submitting to  
22 FAERS, we don't want you to go back then to eCTD.

1           And there will be a -- you know, for -- any --  
2   barring any technical complications or things like  
3   that, there will be waiver process that is similar to  
4   eCTD as well too for this process. But again, we  
5   expect that to be temporary and sort of under the same  
6   criteria for that as well too.

7           And it's also a good point because that's the  
8   same thing about the submitting through the gateway and  
9   through SRP. We don't want people to go back and  
10  forth, because there are different case numbers that  
11  are assigned once you submit to FAERS versus submitting  
12  through SRP. So don't start SRP, then go to the  
13  gateway versus the other way -- you know, how those --  
14  although that way is probably okay. But we don't --  
15  ideally, we just don't want people to go back and  
16  forth, because SRP creates a separate case ID than the  
17  gateway does.

18           MR. DE: One most important thing is that the  
19  MCN number at the top right corner (Off mic)

20           MS. CHUK: Right.

21           MR. DE: (Off mic)

22           MS. CHUK: Right. And that's our internal

1 tracking as well. So the same -- you know, even if you  
2 submit it in PDF on a MedWatch form, your MCN number,  
3 yes. So make sure that's the same. And that will  
4 allow reviewers to -- if they need to go back and find  
5 that report in the eCTD format, they're able to do that  
6 and search it by the MCN number. Okay. All right.  
7 Thank you very much. I think -- do we want to go for a  
8 break?

9 MR. DE: Yes. So we'll -- excuse me --  
10 introduce Ta-Jen and go for a break.

11 MS. CHUK: Okay.

12 MR. DE: So the next will be Mr. TJ Chen.  
13 He's going to be talking more about the technicalities  
14 and -- of the data elements, going into the RIM model  
15 and so on. So before we -- he starts, we will take a  
16 15 minute break. But just because we have some time,  
17 we can extend that to about 20 minutes. Thank you.

18 (Break)

19 MR. DE: All right. So we're back. So we  
20 have session number two now, where we will -- where TJ  
21 Chen is going to talk about up versioning to ICH E2B R3  
22 and the regional requirements. So he'll go over some

1 of the data elements, which -- and some of the R3 -- or  
2 regional data elements for R3, and then go over the  
3 model to show you where that comes from and what  
4 typically would be the XPaths for those data elements.  
5 So, TJ, all yours.

6 UP VERSIONING TO ICH E2B R3 - REGIONAL REQUIREMENTS

7 MR. CHEN: All right. Thank you. So as  
8 Suranjan mentioned, for this section I'm going to talk  
9 about the FDA regional data elements. Because we're  
10 using HL7 V3 message, so I would briefly touch some of  
11 the object data type. And also because V3 use OID,  
12 object ID, a lot, so I would also mention a little bit  
13 about OID. And also because ICSR Release 3 also  
14 support the IDMP, which is an important concept, so I  
15 would go through that also.

16 So -- now, first thing first, right? When you  
17 come to up version, the first thing you want to do is  
18 go the ICH website to download this IP (ph) package.  
19 Within the package, once you unzip it, Appendix 1.B is  
20 a folder that includes a spreadsheet that has the  
21 mapping of all of the data elements between R2 and R3.  
22 And then there's also a specification or a

1 recommendation on how do you migrate from R2 to R3.

2 Appendix I.H has schema files. Those are  
3 created by EMA mainly for converting between E2B(R2)  
4 and (R3) the message. That is not a version maintained  
5 by ICH. That is not a version that we use in FDA. But  
6 it's a good tool if you want to use it, all right.

7 So, first, the regional data element. As  
8 Meredith mentioned earlier this morning -- actually,  
9 I'm not going to go through the element as what you  
10 need to support, how you support it. I'll just go  
11 through how you populate into the R3. Okay.

12 So the A19, those -- we're mixing the concept  
13 here, right, because we repurpose this data element, we  
14 try to minimize the impact. I know people are moving  
15 from -- moving away from R2, so we don't want to  
16 introduce new data element in R2. So we repurpose the  
17 data element, adding number 4 for 5 days; number 5, 30  
18 days; and of course number 6 for the 7 days.

19 In R3, this actually split. The C17 is a  
20 Boolean data type, so you can only say yes/no to it.  
21 And we're adding C171 for FDA report type. And here  
22 you have the 15 days periodic report, 5 days, 30 days



1 and 7 days. So that's a new data element.

2 And then the others -- oh, the CU -- the  
3 A110.2, actually that one is interesting. We are  
4 mapping that one to -- the A110.1 and A110.2 are now  
5 combined into C181, OI (ph) unique number. And then  
6 1.8.2 determine whether that initial report is sent by  
7 a regulator or others. So if the company is a first  
8 one to send the report, then you're C11 (ph) or you go  
9 to C181. And only different when you forward report  
10 from other, say, partner or from the regulators. Okay?

11 So this is the HL7 V3 message or what I call  
12 the refined message information model. We're going to  
13 reuse this section. It's called -- can't see -- oh,  
14 investigation characteristic. We're going to use this  
15 class to document C171. This is how it looks. Okay.

16 This investigation characteristic is HL7  
17 observation class. In the observation class, you have  
18 certain attributes. Actually, there are more  
19 attributes than this. This was added out during the  
20 modeling, but here we use the code and the value. The  
21 code determines what the observation is and the value  
22 has a data type called NE, okay. So it depends on what

1 kind of observation you can use different kind of  
2 value.

3 In this case, we're going to use CE coded with  
4 equivalent, okay. Coded with equivalent is HL7 data  
5 type, is a complex data type. You have attributes or  
6 components of the data type. The one that I  
7 highlighted are the one that we will use. Those gray  
8 out are not used in this particular instance, okay.  
9 And the most important are those two used: one is a  
10 code, one is a code system.

11 So how does it work? If you give me a number,  
12 78 -- I think it's 784.0. If you give me this, what it  
13 is I don't know, right? It's a code. But then you  
14 tell me this is ICD9, the code system. Once you give  
15 me the code system, then I know, oh, this is headache,  
16 okay. So the code and code system always go as a pair,  
17 okay. And the code system is a UID. You can use  
18 object ID for that. So I'm going to talk about ID  
19 later, okay. So I hope that we get clear as we go  
20 further down.

21 So in this case, the C171, we reuse this  
22 investigation now -- investigation characteristic. We

1 use the code system. And this is the OID that we get  
2 from ICH. This will be the root of FDA OID. And if  
3 you think about OID, it's like a tree, okay. You come  
4 from a root, you come from a trunk, and then you branch  
5 out, okay. So FDA now get a major trunk or a major  
6 branch, and from that branch, we're going to start  
7 creating more object, more branch to it, okay. And I  
8 will touch upon that later, okay.

9           So for this one, we're going to create --  
10 we're going use a FDA OID with a code for the  
11 observation. So this code will say this is a FDA  
12 report type. So now this observation -- what kind of  
13 an observation is this? This is a FDA report type.  
14 And the value will be a coded equivalent, so you need  
15 to use another code, okay, 1, 2, 4, 5, 6.

16           Now, what is 1 and what is 4? Well, you need  
17 to tell me the code system. Okay, this code system  
18 will be a branch under FDA OID. Okay? Does that make  
19 sense to you? So this is how the XPath is going to  
20 look like. Don't worry about it, because we have not  
21 set on how we're going to structure FDA branch yet, so  
22 this number is still not set in stone yet.

1           Now, the next one is a combination product FAQ  
2 (ph). We're not talking about combination product here  
3 today, but I kind of want to touch this because, again,  
4 this is how we use this investigation characteristic,  
5 okay. We -- the code system here for the code now has  
6 a different number. By looking at this number, now you  
7 know this observation is for combination product, okay.  
8 And the value -- because value can be any data type.  
9 Now, this time we're not using coded equivalent. This  
10 time we use Boolean. So as true or false.

11           So this is the way that HL7 object -- you can  
12 instantiate the object more than once. And every time  
13 when you instantiate the object, you want to tell  
14 people what it is. Observation is a tricky object  
15 because it's almost like catch all, okay. We use  
16 observation for patient's body weight, we use  
17 observation for patient's height, and we use  
18 observation for the cases seriousness. Okay. So I'm  
19 going to touch a little bit on the body weight and  
20 height because we also will use that for other purpose.  
21 Okay.

22           Now, the next one. I'm not going to go

1 through the A14, but for the A233. Again, this morning  
2 Meredith mentioned about how you reuse the A232 and  
3 A233 to record the primary IND where the AE (ph)  
4 happened and the cross reference. In R3, we have the  
5 luxury to create two more data elements and to make it  
6 more clear. So we're going to create this C1 -- C55  
7 and the C5R6. It's R because it's repeatable. This is  
8 a cross reference, okay.

9           So you can -- I mean, like if you have 15  
10 INDs, you have one being the primary, the other 14  
11 would be repeat in C5R6. And C5R6 is going to be  
12 mandatory, okay. And we did it on purpose. If you  
13 don't have a cross reference IND, then you use HL7 null  
14 flavor, put NI, no information. So we want to make you  
15 conscious on what you're sending. If you don't have a  
16 cross reference, just put NI, okay?

17           And this is where we're going to populate this  
18 data element. This is the same object class that you  
19 use for the starting number. And since they fall into  
20 the same concept area, we're going to use this for the  
21 IND number.

22           This is the HL7-8 class. It has data. It has

1 attributes. And again, it -- there are other  
2 attributes that are added out. We're going to use this  
3 ID. The ID is a instant identifier, is a II data type.  
4 Okay. II data type has fours attributes. Again, we  
5 only use these two: the extension -- sorry, I need --  
6 we only use extension and the root. And extension is a  
7 string and the root is again a UID, so it's OID. So  
8 the OID will point to -- the OID will point to the FDA  
9 site and then extension will be the IND. And the M1 --  
10 the branch of M1 would indicate this is a primary IND  
11 and the M2 would indicate this is a cross reference  
12 IND.

13 So this is how the reports are going to come  
14 in. With this XPath, if we see this as M2, then we  
15 know this one is a cross reference. And this extension  
16 is the IND that you put in, okay?

17 And another thing we mentioned this morning is  
18 about street number. In the VAERS, you can have up to  
19 four street lines. In FAERS, we think two might be  
20 enough. And since this is the HL7 postal address data  
21 type AD, this is easy to do. AD is a list of address  
22 part. And the address part, ADXP is address part. So

1 in a part, you have street number, you have CT, you  
2 have state, you have even country, postal code,  
3 anything. So we just repeat the street number twice,  
4 and that's it. So this is easy.

5 FDA also requires reporter e-mail. That is  
6 not a ICH data element. But you -- because this is a  
7 HL7 data type telecom, you can use the same construct  
8 as a C348 sender's e-mail address. It's the same  
9 construct, the XPath will be a little different, but  
10 same construct.

11 And the next one is patient race. Now, here  
12 is the person class, this is HL7 class. We're going to  
13 use this one to capture the race information. And  
14 luckily, the race is a attribute of this class. So all  
15 we need to do is point -- and again, this is CE coded  
16 with equivalence and is a set. That means it's  
17 repeatable. Okay, within this data element, you can  
18 have more than one race. And it's coded with  
19 equivalence. So all we need to do is OID and then  
20 code.

21 We've taken this from eVAERS, okay, and we're  
22 using the NCI Thesaurus as the code, because eVAERS

1 already registered this with NCI. And these are the  
2 code that are maintained by the Census Bureau. So  
3 since this is external, we are thinking not to create  
4 the FDA branch to maintain the code. We may change our  
5 mind. But, I mean, for now we're thinking it makes  
6 sense to point to NCI.

7           And ethnicity. Now, this one unfortunately it  
8 was -- well, it is a attribute in HL7 person class.  
9 However, during the ISO ballot for this human  
10 pharmaceutical model, the attribute was added out. So  
11 it's not in the person anymore. We can add it back.  
12 Because if we put it back to this person class, then it  
13 will fail schema validation, because in the ISO schema  
14 it will not have that attribute. And it would also  
15 cause cross region conflict because -- I mean, of  
16 course you don't send that to Japan or EMEA. But in  
17 case if you do that, it will fail the validation.

18           So to do the workaround is, from a patient  
19 play -- I mean, the person play a role as a patient and  
20 it has some observation here, okay. So we again use  
21 the observation. Now, this observation class has more  
22 attribute than the other one, okay. And this is where



1 actually your patient body weight and the patient  
2 height come. So this is going to be the same XPath,  
3 but with different observation code.

4 Now, you know this type -- so we're going to  
5 step into this observation at least three times, right?  
6 The first time it comes in is the body weight. The  
7 second time is the height. And the third time would be  
8 the ethnicity. How do you tell the difference? The  
9 code, right? I mean, like we mentioned earlier. So to  
10 do that, we need to give it a code system, a code  
11 value. Again, this is going to be for now for  
12 ethnicity same as race. We may use the NCI code, which  
13 is the Census Bureau code, okay. So the OID point to  
14 NCI Thesaurus and then the value is a C value. Okay?  
15 That makes sense?

16 The receiver information. In R3 -- you know,  
17 the HL7 has a patch wrapper, and then within the patch  
18 wrapper, you have individual message wrapper. And then  
19 in that wrapper, then you have the message. So there  
20 is a good mapping between -- at patch level and for the  
21 individual message level. All of the A32 element now  
22 reduced to 1. It's M2R3.

1           We may do -- I mean, earlier Suranjan and  
2 Meredith mentioned about the FDA -- the head session  
3 you have the IND and non-IND thing. We are thinking to  
4 use that in this area and we can even separate CDER or  
5 CBER report. Now, I'm just tossing that out because we  
6 have not, you know, set that yet. But if you have any,  
7 you know, thinking, you can always share with us,  
8 right?

9           So object ID. Object ID is a sequence of  
10 numbers that separate with that. Like I mentioned  
11 earlier, it's like a tree, right? It starts with  
12 trunk. So what is a trunk? The trunk has -- you can  
13 only start with one of the three numbers: 0, 1 or 2. 0  
14 means you initiate this -- everything started from the  
15 International Telecommunication Union. If you start  
16 with 1, then you know that everything -- the whole --  
17 so you have three trees basically, okay. You have  
18 either the ITU tree or the ISO tree or the joint tree.  
19 And then from the tree, you start to develop branch.  
20 So -- and it's hierarchical.

21           So I'm -- so here's the example, okay.  
22 2.16.840.1.113883.3.989.5.1.2, what does that mean?

1 Well, it means, again, start with this trunk, okay.  
2 This is a joint-iso-itu tree. It has a country. Okay,  
3 16 means country. 840 means U.S. And then 1 is  
4 organization. 113883 is HL7. So what is this up to  
5 here? It says HL7 is a organization in U.S. under that  
6 joint tree, okay.

7 And HL7 branch then give -- further branch  
8 out. So it go to this external -- okay, it go to  
9 external use root number 3 and assign 989 to ICH.  
10 Okay. And the ICH also then maintain that -- number 5  
11 would the regional specialized branch. And in that  
12 branch, you have number 1 as a sub region. And dot 2  
13 will be FDA. Dot 1 actually is EMEA and dot 5 is  
14 Swissmedic.

15 So all the ICH member country can -- or  
16 organization can always come into ICH under 989 to get  
17 OID assigned, okay. So we are now appending this OID,  
18 that will be our root almost, right? And we need to  
19 figure out the structure how we branch out.

20 So I just put simply dot N1 earlier for the  
21 type of report. It's not as simple. I mean, we're  
22 going to have to figure it out whether we want to do a

1 dot 1 for CBER, dot 2 for CDER. And then under dot 1,  
2 we have whatever -- I don't know -- I mean, we need to  
3 have an internal discussion because this has a long  
4 term impact to that, okay. But this is how OID work.  
5 Any question before I go to IDMP? Okay.

6 IDMP. Oh, I have more than half an hour.  
7 Okay, let's do IDMP a little longer. Okay. Now, what  
8 is IDMP? IDMP stands for identification for medicinal  
9 product. So this is a suite of five ISO standards,  
10 okay. Within this five standards -- well, maybe let's  
11 go through what it does, right? It defines the data  
12 element and structure to uniquely and unambiguously  
13 identify medicinal product, pharmaceutical product and  
14 substance.

15 So within the standard -- within this IDMP  
16 project, there are five standards. ISO 11615 defines  
17 those element and structure for the medicinal product.  
18 616 for pharmaceutical product and then 11238 for  
19 substance. And the standard also create common  
20 vocabulary for improved people communication and also  
21 machine communication. Because if you have a list of  
22 value -- I think the question Jim (ph) had this morning

1 about that whether we use 1 or 2 for the IND data type.  
2 Code is easier for computing because it's unambiguous.  
3 If you type the character string upper case and lower  
4 case, you know, it sometime gets more difficult for a  
5 query. If you send a code, it's always easier, right?

6           So the common vocabulary is not just for  
7 human, it's also for machine. 11240 -- actually,  
8 11239, pharmaceutical dosage form, unit of presentation  
9 and route of administration try to achieve that. We  
10 try to have a common definition on tablet, a common  
11 definition on injection, right?

12           And then also the ISO standard not -- not  
13 based on -- well, based on this five standards, there  
14 are techno specification on how do you create message  
15 to exchange. So you create this common messaging  
16 standard to provide IT system communication.

17           So we -- I just touched upon those five  
18 standards, expect this 11240. 11240, units of  
19 measurement. It's -- well, when we refer to strengths,  
20 we all want to use the same unit of measurement. U.S.  
21 is the only country -- well, not the only. I mean,  
22 there are two other countries that don't use the

1 international standard. You all know that. I mean, we  
2 use the U.S. convention. And it's always trouble for  
3 you to convert back and forth, right? So a  
4 standardized unit of measurement is kind of important  
5 in many aspects, right? Okay.

6 Medicinal product, maybe I don't need to go  
7 through that. Okay. Medicinal product 11615, okay.  
8 It establishes the definition and concept and also the  
9 detailed description on how do you uniquely identify  
10 medicinal product. Within that, there are like four  
11 types of ID. The first one is medicinal product ID.  
12 The ISO standard says you want to precede with a  
13 country code, followed by the marketing authorization  
14 holder information, and then followed by the country  
15 code.

16 And beneath the medicinal product ID, you can  
17 even go down to the package level, okay? It's called  
18 PCID. And all you need to do is under the MPID you  
19 just get the package description code. And then you  
20 can also go down to the batch level for each of the  
21 product.

22 Now, BAID 1 is for the outer package and BAID

1 2 is for the inner package. In most case it would be  
2 the same, okay. If you have a Tylenol 50 milligram --  
3 I mean, 500 milligram 50 tablets in a bottle put in a  
4 box, most likely BAID 1 equal to BAID 2. But when you  
5 come to the kids' product, okay, if you have multiple  
6 components in this product, each component would have  
7 its own BAID 2. And the outer box would have BAID 1,  
8 likely would be the first one to expire -- likely,  
9 right? Okay.

10 Now, when you look at this MPID, if you kind  
11 of take away the country code -- and for most people  
12 that have been -- deal with FDA, you know, this is very  
13 similar to NDC code, right? So NDC code has the, you  
14 know, marketing authorization holder number, product  
15 code and then package code.

16 So since MPID at ISO description is going to  
17 be implemented regionally due to, you know, the  
18 regulations and all that, it's difficult to get a  
19 international MPID. But because you prefix with  
20 country code, it will be unique, right? So in U.S.,  
21 we're going to use NDC code. The first two segment of  
22 -- the first two segment would be the MPID level. And

1 if you give the whole NDC code, then that would be the  
2 PCID.

3 And the next one is pharmaceutical product ID.  
4 And this is -- this one is very important to link  
5 product together, because earlier I mentioned that MPID  
6 is going to be implemented regionally. So how do you  
7 know that one product in EU equal to a product in FDA?  
8 Well, it all depends on this PHPID.

9 PHPID is a derived ID based on three  
10 components: the substance, strengths and the dosage  
11 form. So it depends on the availability of those three  
12 elements. It defines four levels. Okay, level 1 is  
13 just substance. Level 2 substance and strengths.  
14 Level 3 substance and dosage form. And level 4 will be  
15 everything.

16 So each level gives you a different precision  
17 to map product. So how does it work? Well, you got a  
18 Tylenol Extra Strength tablet. This is a medicinal  
19 product, right? It's marketed in U.S. It has -- as a  
20 pharmaceutical product it has acetaminophen, 500  
21 milligram dosage form tablet. It generates a PHPID,  
22 and with the same PHPID, you can link to the generic



1 version of Tylenol in U.S., right?

2           Now, if internationally or at least cross  
3 region we agree to adopt the same dosage form and we  
4 use the same substance ID, and again, we'll use the  
5 same dosage strength, unit, then we can identify  
6 product cross region, right? So with 11238, we know  
7 that acetaminophen actually equal to Paracetamol. And  
8 the tablet equal to -- all that, well, it's not very  
9 clear but its foreign language, okay? So with that we  
10 know that we can map to, yeah, Panadol. I don't even  
11 know what it is but now I know, okay. So if Panadol is  
12 causing a problem itself, I think this is kind of Asian  
13 product I believe in Vietnam (ph) or somewhere, I don't  
14 know. I mean if there's any pharmacist here who would  
15 know.

16           But anyway, so if Panadol is causing any  
17 severe adverse event in some way, we know that Tylenol  
18 would do the same. We know this Japanese version  
19 Tylenol will do the same, right? And so this is very  
20 useful for pharmacovigilance. It also is useful to  
21 address products shortage, right? If you travel to,  
22 again to Japan, well Japan is Tylenol, it is easy. If

1 you go to China or Taiwan, in Iran also Tylenol, what  
2 do you do? Well, you know you can do this, right. And  
3 again, we also mentioned that PhPID has more than --  
4 has three level or four levels, right? So some time in  
5 the pharmacovigilance the dosage form may not be very,  
6 very -- well it is important, I'm in the release  
7 character is important. But sometimes it's not the  
8 first thing you look at. If a tablet kill -- capsule  
9 will kill, unless you choke on a tablet -- not choke on  
10 the capsule, right? But anyway, so the dosage form may  
11 not be that critical. Also when you run out of -- when  
12 you have product shortage you may not really care about  
13 that dosage form. Again, take out the release  
14 characteristics because that one is different, right?

15 So if you don't do that, you revert to PhPID  
16 Level Two what it's going to be look like. Well, you  
17 can now map to product, Tylenol to all other form of  
18 similar product. And I use similar because instead of  
19 saying pharmaceutical equivalent we might be able to  
20 say that for chemical. But for biological product you  
21 would have some substance based on the ISO standard,  
22 the substance, from different manufacturer that I not

1 consider equivalent, they are biosimilar. So I don't  
2 want to say you link in bioequivalent or pharmaceutical  
3 equivalent. But I say linking like product, okay. So  
4 this is how PhPID can do. Now before I go to next  
5 session because I have a lot of time to kill, I can  
6 share with you the status, okay? Now the -- you will  
7 see this benefit, if we can all agreed to the same  
8 substance ID, use the same unit for restraints and use  
9 the same dosage form, then we will be living in this  
10 happy where everybody will be happy, right. But this  
11 take a lot of agreement, cross region. FDA had been  
12 working -- and also to start with this whole MPID or  
13 IDMP concept started as a ICH project to support E2B,  
14 okay? And because the scope get expanded it went to  
15 ISO. Now under ISO you don't have to send binding like  
16 in ICH, and you don't have the opportunity for the  
17 regulators and the industry to sit down to agree the  
18 term to use, right.

19 So with that understanding we kind of agree to  
20 use EDQM to sustain the provider for dosage from route  
21 administration, and E2B actually is using EDQM for  
22 administration. E2B(R3) is using EDQM term for dosage

1 form and route administration. When we try to  
2 implement that within FDA and we're doing this mapping  
3 we found out this is not that easy, okay. You have  
4 same definition, different term, easy, that's synonym,  
5 okay. We all use extended release in U.S. I think  
6 it's called modified release in EDQM.

7 Now if the concept is the same, easy synonym,  
8 we map that. Now we have definition data not exactly  
9 same, like chewable tablet. In the EDQM definition it  
10 says, whatever, whatever and called it whatever,  
11 whatever, right? When we look at that in U.S., we  
12 don't have uncoated. A chewable can be sugar coated,  
13 can have flavor. So what do we do? I mean are they  
14 the same?

15 At one point we think they are not the same.  
16 And when we take a step back and we say, well,  
17 pharmaceutically it would not affect anything, right?  
18 I mean -- and if you look at the product shortage and  
19 the pharmacovigilance, sugar coated, flavor coated  
20 versus not sugar coated, not favor coated might be  
21 okay. So we might be able to map that, okay. But then  
22 also in EDQM, well, the way EDQM define terms, they

1 have certain characteristic. They have statometer  
2 (ph), they have release calculator, they have site,  
3 they have intended site, they have route. So the  
4 dosage form can be very detailed like, powder for  
5 injection, for whatever. Always a site and route.

6 We may not have the same thing in FDA site.  
7 And the most interesting one is capsule. We have a lot  
8 of the products that are in the capsule dosage form.  
9 EDQM only use hard capsule or soft capsule, and we  
10 cannot map. I mean this is fairly simple one but we  
11 cannot map.

12 They do have capsule at so-called patient-  
13 friendly term. So in EDQM they have different domains,  
14 okay. That one is not in the pharmaceutical dosage  
15 form, sub-area. So what do we do? We still struggle.  
16 We still work -- and we still try to figure out how do  
17 we move forward but we spend a lot of time with help  
18 from NCI, try to map our term. And in the end we were  
19 like, we're not going anywhere, we need to go back EDQM  
20 and discuss further. So that's -- I don't know, 11239.

21 Now because we cannot agree to the same dosage  
22 form then that put the PhPID in jeopardy. And without

1     PhPID you cannot link product together, right? So we  
2     also talked with WHO. WHO want to be the standard  
3     provider for PhPID. Again, PhPID is algorithm  
4     generated. Not every region or every regulators or  
5     even the sponsors has a capacity to generate PhPID on  
6     the fly. So we are thinking that if someone generate  
7     that PhPID and then other can download. That might be  
8     easiest way to do. And also when you have product with  
9     multiple active ingredient, that will make that  
10    generate PhPID become kind of interesting, because  
11    which one go first, okay. I think ISL kind of  
12    addressed that. Hopefully the algorithm is mine after  
13    it would generate same result.

14           And also do you normalize the strengths. So  
15    you have 5 milligram per 10 milliliter. And you have  
16    25 milligram per 50 milliliter. Do you normalize that,  
17    right? So those are -- well, the tech spec tell you  
18    how to do it, but to generate that it take another  
19    step. So we were thinking that if that WHO can  
20    generate that and share with everybody else, that will  
21    be a good idea.

22           So WHO agree to that. Actually it was last

1 year they kick-off -- they invited EMA, FDA, Health  
2 Canada to a meeting to see if we together can work with  
3 WHO to do a pilot to generate PhPID. So that is still,  
4 you know, in progress, okay. So once WHO generate  
5 PhPID, and at that time we need to resolve the problem  
6 with dosage form, because capsule is not just in U.S.  
7 Capsule is also used in Health Canada and I believe  
8 even in EMA, Europe, they got to be capsule. I don't  
9 know -- I mean I don't think everything can be hard or  
10 soft yet, okay. So WHO may need to figure out how to  
11 do it. Maybe they take a step back, right, they do  
12 level two map and put a product together. And then  
13 with human intervention to determine whether they can  
14 do a more precise, maybe no, not. So that's next step.

15 So that's international side. On FDA side,  
16 well, as we say the PhPID -- MPID, we're going to use  
17 NDC code. We look at the reg, I don't remember the  
18 number, I think it's 270, that's 35? Anybody? I don't  
19 know if anybody know that. So if you don't then don't  
20 worry about the number. But basically the FDA, NDC,  
21 there's -- regulatory requirement says when the active  
22 ingredient name change, when manufacture name change,

1 when the package size change, the scoping (ph) change,  
2 when you switch between prescription and LTC or when  
3 you switch between human drug and animal drug, then new  
4 NDC need to assigned. Okay, so those are the data  
5 element that are required to uniquely identify a  
6 medicinal product.

7 The ISO 11615 also has certain data element,  
8 also says the same thing when the name change, when  
9 strands change, when the active ingredient change, also  
10 when the indication change, then you need to assign a  
11 new MPID.

12 Now compare this to -- pretty much they are  
13 the same. The only thing different is on the FDA side  
14 its switching between human and animal. The MPID, the  
15 ISO standard concern only in human pharmaceutical, so  
16 they don't have that language there, that's fine,  
17 right. The 615 also say when an indication challenge,  
18 you can -- not you must, you can assign a new MPID.  
19 FDA does not have that language. And as you now that  
20 aspirin was a pain killer and got a new indication as  
21 blood thinner, they never changed the NDC, right?

22 So in general, we look at that, we know, okay,



1 MPID align with FDA requirements for NDC, we're going  
2 to use NDC code for FDA regional use. Most of you are  
3 familiar with SPL, we already use an SPL to exchange  
4 medicinal product information. SPL actually is a  
5 technical spec at ISO to specify how you exchange  
6 medicinal product information, so we can do that  
7 already, so we're in compliance. PhPID, we're not  
8 doing that. Substance, we have a system called  
9 substance registration system that had been in place  
10 for a long time. It did not go to the same granularity  
11 as ISO 11238. So we have since then upgraded our  
12 system to go again -- to go along with the ISO 11238.

13           And there was a question, actually it was  
14 released this morning about IND. For the safety report  
15 do you send UNI which is a unique ID for the substance  
16 or to using the company code? We have the system in  
17 place. And but the process there's no regulation at  
18 this moment to require pre-registration. So there  
19 would be no UNI assigned in IND. We assign the UNI  
20 only on the when the PQCMC (ph) information sent in.  
21 And that's a time we can identify the substance and we  
22 would assign a UNI.

1           So the timing is not relevant. We're thinking  
2           about pre-registration, and also we need to think about  
3           how do we then send the unit back to sponsor so that  
4           you can use. But because most of you use that company  
5           code, and it does not change throughout the study  
6           phase, so we think that's okay, we think that's okay to  
7           use that. But anyway back to the substance. So as I  
8           mentioned earlier, FDA have been working with EMA  
9           closely. So EMA is taking the same -- so -- well, let  
10          me take another step back, I'm all over the place, FDA  
11          upgraded that SRS into GSRS, Global System Registration  
12          System. This is the system that we co-developed with  
13          NCI or NIH and KET. They use the open source code to  
14          create a system so anybody can take a version of that  
15          and stand up in your organization, okay. That will be  
16          the same system. That EMA is going to take.

17                 And actually, its -- I'm -- it's going to be  
18                 installed in Germany, where I think the project  
19                 management will be under Dutch for EMA. We have  
20                 already stand up the same version in FDA and customize  
21                 to integrate with our internal systems. So we're going  
22                 to figure out how can we exchange information without -

1 - or at least we need to protect our, you know, trade  
2 secret and all that.

3           And even though ISO at one point tried to use  
4 SPL or more precisely the common product model to  
5 exchange that information, but because HL7 is moving  
6 away from V3, now getting to FHIR, EMA is more interest  
7 to create a FHIR resource for the substance  
8 information. And even for the medicinal product  
9 information, so FDA is working closely with EMA, and  
10 HL7 FHIR resource to exchange substance information and  
11 medicinal product information. That does not mean  
12 we're going to change SPL. You're going to continue to  
13 use SPL. Once the FHIR resource mature, it could be a  
14 alternative. if you don't want to do SPL you can do  
15 FHIR. Okay, but that's long way -- that's not in the  
16 next 3 years, that's way down the road. But that's  
17 what we're thinking.

18           So did I -- do I need to keep going? I think  
19 that's about it. I mean unless you have any other  
20 questions. All right. So if there's no questions,  
21 Suranjan?

22           MR. DE: All right. Thank you, TJ. That was

1 a lot of technical sides on how we are planning to  
2 setup these regional elements, where we are picking it  
3 up from in R3. And so eventually when you see the  
4 expats (ph), you will know where it's all coming from,  
5 okay? So with that if anybody has any questions which  
6 they did not ask in the morning from the presentations  
7 which I gave or the presentation that Meredith gave, we  
8 have some time to -- in the room to -- for folks to ask  
9 questions. So if not then it's 11:45, so I guess we  
10 can stop here for lunch. And we can come back around -  
11 - only we can do about 1.00, 1:15, because after that  
12 the next few presentations -- we can actually afford to  
13 start at 1:15. So we'll have little time to peacefully  
14 have lunch. All right. Thank you so much and I'll see  
15 you at 1:15. Thank you.

16 (Lunch)

17 MR. DE: Again, I'm Suranjan De with CDER.  
18 And our Session 3, we'll talk now about electronic  
19 submission post market safety reporting. And we'll go  
20 over all the regional requirements for R-3. Now as I  
21 said, we are not going to talk about combination  
22 product which will be the next session in July. So you

1 will not see any data elements related to combination  
2 products.

3           So our FDA regional requirement, so the FDA's  
4 technical approach, this is the FDA's technical  
5 approach for submitting ICSRs and incorporating  
6 regionally controlled terminology, regional data  
7 elements which are not addressed in the R3  
8 implementation guide. And it's for post-market,  
9 premarket, prescription products, nonprescription  
10 biologic products.

11           Okay, so this region requirement as you all  
12 know that in June 2016 a regional technical  
13 specification was published. So the idea here is to  
14 take that and update the regional technical  
15 specification. Of course eventually when we harmonize  
16 fully with vaccines we would be able to remove this.  
17 But currently it is what it is. So -- and this is a  
18 document which will get updated based on the timeline  
19 what you saw.

20           We followed the core ICH E2B(R3) and we have a  
21 few regional requirements. So we start with a few  
22 regional requirements and, and as I said we'll go over

1 the carbonation product next -- the next session. So  
2 the first regional requirement is batch sender  
3 identifier N.1.3. So in here the sender should use the  
4 DUNS number for N.1.3 using the D&B and the object  
5 identifier which is listed here. The DUNS number for  
6 business entity identifier is used to validate the  
7 business entities in various FDA information system, so  
8 pretty much most of the places we use the DUNS number.  
9 All right.

10 So next is message receiver identifier which  
11 is N.2.r.3. TJ talked about a little bit on this  
12 before the lunch session. And so FDA used two  
13 different message identifiers for test and production  
14 submissions. And these identifiers today are this.  
15 For post-market in the test -- currently this is what  
16 we use today, which is ZZFDATST, is used for post-  
17 market, and for production we use ZZFDA.

18 Now when we go into pre-market, we're talking  
19 about using ZZFDATST\_IND and ZZFDA\_IND. So that  
20 differentiates between post-market and pre-market. Now  
21 there is some considerations here, is this is what we  
22 want to ask you all here as audience that for pre-

1 market, now you have pre-market trial for CBER products  
2 and CDER.

3           So our -- one of our considerations here is  
4 for the pre-market instead of using ZZFDA\_IND what if  
5 you use ZZFDA CDER IND and CBER IND. So that way it  
6 differentiates which are CBER premarket safety reports  
7 and which are CDER pre-market safety reports. So that  
8 especially when it comes to FDA, there is some routing  
9 which needs to be done to retake the report and send it  
10 to the appropriate reviewer. Because you have just one  
11 system, FAERS, to be used by both CDER and CBER, this  
12 will very clearly identify which one goes to which  
13 center.

14           Now this is for consideration. This is  
15 something we would like you all to provide your  
16 comments when you provide your -- when you put the  
17 docket. So something to consider this. I don't know  
18 if I said this, but all these slides will be posted on  
19 the FDA meeting page, by -- within -- the slide and the  
20 video which is being taken will be posted on the  
21 meeting page. So you will have access to that -- it'll  
22 be available for a year.

1           So this is something for consideration. So  
2 please, you know, provide your comments and then we --  
3 we'll accordingly look into and update this. So with  
4 regional requirement there are some conformance which  
5 we -- which FDA supports, so FDA supports the ICH R3  
6 data element conformance categories. We -- FDA data  
7 elements conformance may vary due to regional  
8 regulatory specification which is not addressed in the  
9 ICH E2B(R3) so which will be addressed in that  
10 spreadsheet which I was talking about in the morning  
11 and the technical specification for R3. And now some  
12 exceptions which we -- which are -- which FDA has which  
13 now becomes regional requirements, in the next few  
14 slides you're going to see.

15           Some of the terminologies that FDA uses, so  
16 FDA supports MedDRA for coding. And FDA recommends  
17 that when possible use the LLT term to record. I mean,  
18 in fact if we use the numeric code then it's very  
19 specific, so we can code that too, and you can submit  
20 that too. And basically a sponsor should refer to all  
21 the data elements that specify using MedDRA. So the  
22 data points that R3 core elements uses MedDR are the



1 elements which FDA supports fully.

2           Some other terminology. We use/support UCUM  
3 code for coding unit of measures. And this is one  
4 exception -- regional requirement which we have, is it  
5 uses some of the NCI codes which is the C-code (ph).  
6 And you saw with race and ethnicity we had the C-codes  
7 which we used. And this morning we also talked about  
8 the global substance registration system, the GSRS  
9 where the substance name is used from there.

10           Finally, FDA supports the use of EDQM dosage  
11 form and route of administration for post-market  
12 reporting. All right, before I go to the specific data  
13 elements, any questions?

14           UNIDENTIFIED SPEAKER: Well, you mentioned  
15 sender ID should use (off mic) or is --

16           MR. DE: This one?

17           UNIDENTIFIED SPEAKER: Both. Yeah, it's this,  
18 yeah, this one. If we are already submitting (off mic)  
19 already.

20           MR. DE: So the question here is that the  
21 batch sender identifier, is it mandatory to use the  
22 DUNS number. This is recommended to use the DUNS

1 number because in exactly -- because many other systems  
2 in FDA use DUNS number, for example, when product  
3 quality report comes in the DUNS number is provided.  
4 So it just makes it easier to then connect all of them  
5 together.

6 UNIDENTIFIED SPEAKER: But if you already (off  
7 mic).

8 MR. DE: Yeah, exactly. If you're using that  
9 you can continue to use that.

10 All right. So we'll go into some of the  
11 regional requirements. And the first regional  
12 requirement is Section C, identification of case safety  
13 report. So this is where there is a little difference  
14 between the ICH conformance ruled and the FDA's  
15 conformance rule.

16 ICH's conformance rule -- FDA's conformance  
17 rule does not support nullFlavor, okay? So if case  
18 says fulfill expected criteria, yes or no, true or  
19 false. There is a rule conformance in the Core E2B  
20 which also supports nullFlavor. And FDA says that we  
21 will not -- we will reject any nullFlavor. So this  
22 C.1.7 needs to be true or false. So that's the first

1 exception which we have, regional requirement which we  
2 have.

3 The second regional requirement is  
4 linking initial and follow-up reports. I talked about  
5 it a little bit in the morning. It's very, very, very  
6 important that the safety report unique identifier for  
7 the initial and follow-up needs to be the same, all  
8 right.

9 And the reason why I say this, I pretty much  
10 say this in most of my presentation, the check which we  
11 do FAERS is all based on that number to identify  
12 initial and follow-up. If there's slight difference in  
13 that number it creates initial report again. So it  
14 matches against that number to make sure that we  
15 understand it's initial or follow-up, right? Every  
16 report which comes in with that same number, we just  
17 make them as follow-ups.

18 So we just increment our versions, okay. Like  
19 some organizations have a concept of, you know, a minor  
20 -- follow a minor change versus a major change and then  
21 so whatever you change send us even if you had the age  
22 change from 45 to 46 and you submit that, it just

1 creates another follow-up. And the reviewers pretty  
2 much are looking at the latest and greatest  
3 information. So it's very important that that number  
4 stays the same so that the initials and follow-ups are  
5 appropriately created in our system.

6 UNIDENTIFIED SPEAKER: I have a question. For  
7 c1811 (off mic) what happened if the (off mic) holder  
8 (off mic) for example (off mic) name the change  
9 according to (off mic) so then --

10 MR. DE: So what we have done traditionally is  
11 we have asked to keep the safety report number the same  
12 for the life of the case.

13 UNIDENTIFIED SPEAKER: But you transferred  
14 (off mic).

15 MR. DE: Yeah.

16 UNIDENTIFIED SPEAKER: (off mic) member ID?

17 MR. DE: There is a company ID, I think.

18 UNIDENTIFIED SPEAKER: Company number always  
19 the same.

20 MR. DE: Same.

21 UNIDENTIFIED SPEAKER: Yes, IC (ph).

22 UNIDENTIFIED SPEAKER: Yes.

1 UNIDENTIFIED SPEAKER: But normally according  
2 to IC (ph) guideline when you issue the company name  
3 then the CPI (ph) I think will reflect a new company.

4 MR. DE: Right. Yeah. At least today we  
5 actually -- we keep the same safety report ID --  
6 suggest to keep the same safety report ID through the  
7 life of the case. If the situation happens like that  
8 where what we have recommended if you look at the  
9 technical specification, you will probably find that --  
10 it would probably say that you need to connect with FDA  
11 if this truly need to be a change in the safety report  
12 ID where the number needs to be updated from our end so  
13 that when you submit the next report. But we -- what  
14 we do is we always recommend to -- try to keep the same  
15 number through the life of the case.

16 UNIDENTIFIED SPEAKER: So Suranjan, do you  
17 expect the DUNS number be in there? So what you're  
18 getting at is USA company name which you're now saying  
19 you want the DUNS number.

20 MR. DE: No that's --

21 UNIDENTIFIED SPEAKER: You want that in t he  
22 header?

1 MR. DE: That's in the header.

2 UNIDENTIFIED SPEAKER: Okay, so --

3 MR. DE: So the DUNS -- so yeah.

4 UNIDENTIFIED SPEAKER: You're happy with the  
5 company's name right now?

6 MR. DE: So the question here was that do we  
7 expect DUNS number in the safety report unique  
8 identifier because it's got three sections. So the  
9 answer is the DUNS number is only required -- is in the  
10 header which is a batch sender identifier and not in  
11 the case safety report unique identifier. I mean our  
12 key is that as long as you have the number and you  
13 continue with that number because end of the day inside  
14 FDA we create our own case ID. All our reviewers point  
15 to that review to that case ID.

16 UNIDENTIFIED SPEAKER: So the DUNS number you  
17 have to translate it. So within that you have to  
18 translate (off mic) number.

19 MR. DE: Right. So I think for the safety  
20 report ID, the unique identifier you don't have to have  
21 the DUNS number. I mean we really don't -- are not  
22 going to translate this. We're going to take it as is

1 and that's going to be our manufacturer control number,  
2 right? So when the reviewers look at this report, they  
3 will look at FAERS case ID and the manufacturer control  
4 number so and so. So that's what it's going to be.

5 And if you submit the same manufacturer  
6 control number again, it creates a follow-up in the  
7 system.

8 UNIDENTIFIED SPEAKER: Also I think the DUNS  
9 number is really just primarily for the gateway.

10 MR. DE: Yeah, it's for the gateway.

11 UNIDENTIFIED SPEAKER: Yeah.

12 UNIDENTIFIED SPEAKER: Yeah, for the gateway,  
13 but for the program it's stripped down.

14 MR. DE: Yeah, DUNS number typically we are  
15 looking at the gateway and --

16 UNIDENTIFIED SPEAKER: (Off mic) because I've  
17 seen people use the DUNS number within the company  
18 name. And we don't want that.

19 MR. DE: Yeah. All right. So here it is the  
20 question which you had. Correcting an incorrect safety  
21 report identifier. So if you have a situation like  
22 that in the event that an incorrect safety ID has been

1 used in a follow-up report, you need to contact them so  
2 that, you know, mutually we can work it out to get that  
3 fixed.

4           Okay. Safety report type. TJ talked little  
5 bit about safety report type but this is how that Excel  
6 spreadsheet is going to look like. So in there the  
7 column will talk about the FDA report type. And if you  
8 noticed that anything which is regional has been  
9 prefixed the number -- element ID has been prefixed by  
10 FDA. So that very clearly identifies which are ICH  
11 elements and which are regional FDA elements.

12           Now this element as we said is the FDA report  
13 type, is one numeric, conformance is mandatory and  
14 allowed values are here. So if you look at this for  
15 post-market you typically use 1 and 2, for IND you  
16 would use 1 and 6, and then for combo product -- no,  
17 combo product, I don't think you have periodic, that's  
18 1, 4, and 5.

19           UNIDENTIFIED SPEAKER: Say that again, please.

20           MR. DE: What's that?

21           UNIDENTIFIED SPEAKER: Could you say that  
22 again, please?



1           MR. DE: So for post-market you have 1 and 2,  
2 for IND you have 1 and 6, which is 15-day, 7-day and  
3 for combo product you have 1, 4, and 5. I don't we'll  
4 have a periodic consult (ph), it's a typo here. So  
5 they have 1, 4, and 5. So for this we have to have a  
6 new ID which will make sure those values 1, 2, 4, 5 and  
7 6 are there.

8           Now you may have a question what happened to  
9 3. So the way we use 3 is we use it internally because  
10 we have a concept of direct reports which are voluntary  
11 reports coming to FDA, that comes to our triage system  
12 where we triage those reports because when voluntary  
13 reports are sent to FDA it's just not for drugs or  
14 biologics, it could be tobacco, it could device, it  
15 could be food, so the triage -- when it comes to FDA  
16 the triager is triaging that and sending it to the  
17 appropriate center. Anything which is supposed to be -  
18 - supposed to reside in FAERS comes from the Triage  
19 system as 3.

20           So where they call it as 3 is we call it as  
21 direct reports. So we know these are -- because direct  
22 reports are very important for our reviewers because

1 it's the first time information our reviewers are  
2 getting. For these all other type of reports at least  
3 the sponsor has looked at it. But direct reports are  
4 very important because it's the first time somebody is  
5 looking at it, so.

6 All right. Next regional requirement is  
7 reporter e-mail. So we talked about -- TJ little --  
8 talked little bit, went over the where it comes from.  
9 But again this field is something which ICH does not  
10 have and we are introducing this.

11 Now this has -- actually this field, and I  
12 think the previous one, this one has been harmonized  
13 with the eVAERS vaccine, okay? And they have -- same  
14 numbers have been taken from vaccine and it's C2R28,  
15 reporters' e-mail, and this has 100 alphanumeric, free  
16 text and conformance is optional. So this field was  
17 originated when VAERS was being done. So it did not  
18 come from FAERS. So we just took the same properties  
19 of that data field.

20 Patient characteristics. We have race code  
21 and ethnicity. TJ did talk about this field, where it  
22 comes from. But as far as implementation is concerned,

1 this has a length and type of 10 alphanumeric. We just  
2 took exactly how we have in VAERS and eVAERS, the same  
3 allowed values. The conformance is the same and the  
4 business rule also is the same. There's no change in  
5 that.

6 If you look at ethnicity, again the data type,  
7 data length is the same with 10 alphanumeric, the same  
8 allowed values, conformance is mandatory and uses the  
9 same nullFlavor. And this is where the (inaudible) when  
10 we first started with in drug in CDER, these were  
11 optional fields. Then we looked at VAERS. We found  
12 that these fields are mandatory but uses a nullFlavor.  
13 So we said, okay. We just use it as it because  
14 sponsors may have already done their work in that way  
15 so we will just continue to do it in the same way.

16 Another one is patient information. So this  
17 is Section D. In here the one which I highlighted and  
18 that's the only difference we have between E2B(R3) core  
19 elements and FDA's regional requirement. So basically  
20 it's no information. Because eventually sometimes you  
21 may have like medication errors, you may not have any  
22 patient because the -- because there's no information.

1 There may not be a patient involved in a medication  
2 error or you were unable to get any of these data  
3 fields like age, date of birth, sex, they're all  
4 unknown. So you could use asked but unknown but then  
5 you have -- you may not have -- also have and ever have  
6 any information so you could use the NI.

7 Also another thing is you can use MSK because  
8 there are some foreign reports where you may have  
9 regional privacy restrictions, so that's when you use  
10 the MSK identifiers for -- identifies the race of the  
11 patient and the patient can have more -- of course the  
12 patient can have more than one race but you could use  
13 MSK in that case.

14 All right. So seriousness criteria. So  
15 seriousness criteria, we have 5 seriousness criteria  
16 but there's another one which we actually have called  
17 required intervention which is -- if you look at the  
18 Medwatch form you will see that. It's not there in R3.  
19 So the properties of this still is like the other  
20 seriousness criteria and the properties are it's a  
21 Boolean, allowed nullFlavor which is NI, no information  
22 if it's true. And then you have -- it's mandatory for

1 post-market only, it's not used anywhere else. So this  
2 is a new -- it's not a new but it's a regional  
3 requirement.

4 All right. Next. Before I go there, anybody  
5 -- any questions on any elements which we just went  
6 through? Yeah, just ask me as we go through. Yeah, I  
7 think we have enough time.

8 G.k. drug information. So this is another  
9 section where we're talking about medicinal product  
10 name as reported by the primary source. So we validate  
11 that name against the SPL for post-market. And so when  
12 the product has an SPL file using the naming convention  
13 in ICSRS the name appears in the SPL file, so because  
14 we check against that. And then for the substance,  
15 again we check against the global substance  
16 registration system so which you can submit the name in  
17 G.k.2.3.r.1 for substance name because we get more than  
18 one substance.

19 And if the name is on a foreign product trade  
20 name and need to provide the -- you should provide the  
21 active substance name as it appears in the FDA's, you  
22 know, GSRS as G.k.2.3.r.1 because that will help us to

1 then match up to know the exact product. Of course if  
2 we had IDMP at that time -- I mean IDMP then of course  
3 you should be -- we should be able to do that. But as  
4 we know that we're not already with IDMP so this is how  
5 we will try to match up.

6           Okay. Drug authorization application number.  
7 So we have to have a prefix. And because in R2 as well  
8 as in R3 there is no concept of a type, right? So I  
9 mean ideal would have been a type and a number. But  
10 since we don't have a type so the only way to identify  
11 if the number is an ANDA number or a NDA number or a  
12 BLA number is to provide the prefix. So the prefix  
13 would say ANDA and the number or NDA and a number. If  
14 you're a BLA then biologic application you have BLA and  
15 a number. For prescription product drugs marketed  
16 without an approved application, Rx with no application  
17 say 000000 which we also do today in R2. For non-Rx no  
18 application then we put as 999999, which we do today.  
19 And then compounding product we say COMP99. If we had  
20 a compounding product then it would submit that way.  
21 So this basically is what we do today and we continue  
22 to stay.

1 UNIDENTIFIED SPEAKER: Suranjan, do you see a  
2 problem with INDs, if you can have a space in a number?

3 MR. DE: In INDs, IND because you have the  
4 field at the case level we talked about, yeah, so that  
5 -- yeah, the space has to go away.

6 UNIDENTIFIED SPEAKER: We want the space.

7 MR. DE: No, no, we're going to move the space  
8 away.

9 UNIDENTIFIED SPEAKER: She mentioned the  
10 space.

11 MR. DE: She mentioned the space, yeah, we  
12 have to --

13 UNIDENTIFIED SPEAKER: -- space numbers.

14 MR. DE: No, we'll have to talk about it to  
15 clarify that and when we publish it we'll -- so I think  
16 the idea would be to remove the space because that  
17 creates a problem. But then again, remember for IND  
18 reports it's at the case level. This is at the drug  
19 level.

20 Okay. Now there is another field which we  
21 have regional requirements which is G.k. and drug  
22 information which is G.k.10.r, additional information

1 on the drug. So FDA regionally control -- here is the  
2 -- FDA's regionally controlled terminology for FDA  
3 specialized product category, it's used to provide  
4 characteristics associated with the product  
5 information. So if you had combination product then  
6 you could see it's a Type 1, Type 2 to up to Type 7,  
7 Type 9. And so these are the different types which we  
8 mentioned in the additional information on the drug.  
9 And if you have compounding products then those are the  
10 C codes which you would use in the drug G.k.10.r. So  
11 this course comprised of both combination product and  
12 compounding product.

13 Okay. All right. Now let's go to the  
14 acknowledgment message. We're going to go back because  
15 we talked about this when we -- when we were submitting  
16 the report. Now you get an acknowledgment back. So in  
17 the acknowledgment back we're talking about this  
18 because when Meredith mentioned about the pilot which  
19 we are doing, we had request from some sponsors saying  
20 that, you know, acknowledgment, can you send this back  
21 to us so that we exactly know that this was going  
22 through the IND route or the -- the pre-market route or



1 the post-market route.

2 So then accordingly then we can update our  
3 database to know where it is -- what we send and what  
4 is coming back. Now you also have the routing IDs,  
5 right? But this message is what we -- to this again  
6 the consideration is if we had under IND saying  
7 ZZFDA\_CDOR\_IND and ZZFDA\_CBER\_IND, if we get comment  
8 and we all decide to go with that then this will also  
9 come back, the acknowledgment will come back with the  
10 same thing.

11 UNIDENTIFIED SPEAKER: You're still going to  
12 have to develop those (off mic).

13 MR. DE: Yeah, so we're going to still have  
14 two acknowledgments. We're not going to have three.  
15 The first one will be the gateway, the MDN (ph) coming  
16 up. And next one FAERS accepts it, it's going to send  
17 an acknowledgment out.

18 Thanks for this. So the question was will we  
19 have two acknowledgments and the answer is yes. We'll  
20 continue with two acknowledgments.

21 Okay. All right. So any questions on the  
22 regional requirements on the data elements?

1 UNIDENTIFIED SPEAKER: I just have one  
2 questions. With your outcomes, are you expecting a  
3 null value for everything that's not populated?

4 MR. DE: No, no information, NI.

5 UNIDENTIFIED SPEAKER: NI, so you want  
6 something populated for everyone (off mic) intervention  
7 is also device.

8 MR. DE: Yeah, but sometimes they use in the  
9 medication error side also.

10 UNIDENTIFIED SPEAKER: We just need to change  
11 that (off mic) it definitely says (off mic).

12 MR. DE: Yeah, but again we have no  
13 combination products.

14 UNIDENTIFIED SPEAKER: That's true.

15 MR. DE: So --

16 UNIDENTIFIED SPEAKER: When can we expect the  
17 time to be published so that we can --

18 MR. DE: What's --

19 UNIDENTIFIED SPEAKER: When can we expect all  
20 those times --

21 MR. DE: To be published? So I will just go  
22 back and -- so we will have all that published sometime

1 between this timeframe.

2 UNIDENTIFIED SPEAKER: (Off mic) federal  
3 register (off mic).

4 MR. DE: It'll have to go through federal  
5 registrar. So but between this -- this is the  
6 timeframe when you will -- we will have this published.  
7 Now our publish date is this. But as I said in the  
8 morning that -- because this is a technical document  
9 the clearance process is more like an ANDA process.  
10 I'll give an example, like abbreviated clearance.

11 So this could happen earlier. Could happen  
12 earlier. And if it happens earlier we'll publish it.  
13 As I said, two documents gets -- three things get  
14 published. One is the spreadsheet, okay? Which is  
15 something like this. One is a technical specification  
16 which is published today, that will be updated with all  
17 these new elements. And the third item will be, there  
18 will be sample examples of using some case scenarios  
19 saying that if you have this type of report and that,  
20 this is how your XML is going to look like.

21 If you have this scenario and that, okay, in  
22 this scenario these are the elements, so your XML is

1 going to look like that. So that's what we're going to  
2 put down for -- some of the examples which Meredith  
3 gave in the morning, the case scenarios, we can --  
4 we'll include them also in that example. So those will  
5 be 3 documents which will be published during this  
6 timeframe.

7 UNIDENTIFIED SPEAKER: So if you (off mic)  
8 specification (off mic) details about (off mic)  
9 proposed rule (off mic).

10 MR. DE: Right. So yes, so the Medwatch data  
11 elements which will be there they will be included in  
12 there. And the Medwatch rules data points which are  
13 there, I have not included all of -- not all of them,  
14 not included them at this time because it's still not  
15 published, so probably by July when we have the next  
16 meeting you will probably see a few more data elements  
17 in addition to combination products because hopefully  
18 by then they all will be available and then we will  
19 discuss them there.

20 And they all will be included in the  
21 spreadsheet with its conformance and number and IDs and  
22 everything. They will also be provided in the

1 technical specification. And then of course in the  
2 sample examples which we produced, those will be  
3 included in there.

4 All right. Okay. It's almost 2:00. So I  
5 think based on the number of slides I have now left  
6 probably we'll be done by 2:30. We won't -- probably  
7 won't go to 4:00. But after that I have a suggestion,  
8 if any questions come up we can answer those questions.  
9 But if anybody has any experiences with implementing R3  
10 with other agencies, I would like somebody to speak  
11 about some considerations that FDA could take or the  
12 challenges they may have faced and how they resolved  
13 it. I think it will be a good learning for us to know  
14 that so that we don't go that path and able to  
15 eliminate those kind of challenges.

16 All right. So yeah, so the last section was  
17 all the data elements. So we go into now the routing  
18 mechanisms. Because of IND safety reporting we now  
19 have a new routing mechanism which we have introduced.  
20 This is what happens today. So we have the trading  
21 partners, we have the safety reporting portal, we have  
22 the web trader. They all go through the electronic

1 gateway and then goes into a model -- currently we have  
2 the FAERS system which we have the electronic  
3 submission module which looks up the data, parses and  
4 all, puts it into our system which currently we have  
5 Oracle AERS which -- and then eventually we have FLARe  
6 which we called it first look at report which are those  
7 the triaging which I was talking about. And they goes  
8 as XML R2+ and goes into triage system, CTU and which  
9 is eventually going into our safety database. So this  
10 is the current flow our routing mechanism. So  
11 everything comes through this one path and gets into  
12 our electronic submission module.

13 In this the problem which we see is if we  
14 submit both IND and NDA products pre and post-market,  
15 we wanted to remove the confusion of -- maybe in other  
16 words to make it foolproof and safe that these pre-  
17 market safety reports are not published publicly.  
18 That's the key here. That's the objective here. So in  
19 order to do that whatever methods we could take so that  
20 they are kind of identified separately in the FAERS  
21 database.

22 So Meredith talked about these 2 methods

1 today, the trading partner changes, right? I won't go  
2 over this but then let me go over the two methods which  
3 we have today at FDA. So the two separate routes for  
4 submission for safety reports, so Method 1 is AS2  
5 header attributes or the AS2 routing IDs. And so we  
6 submit pre-market and post-market safety report using  
7 the appropriate attributes and E2B data element IND  
8 were event occurred now will be designated specifically  
9 for pre-market to route reports.

10 So this field is required to route reports, so  
11 that's why this becomes now a mandatory data field.

12 And when it goes into R3, the data field which TJ  
13 talked about, that will become a mandatory data field.  
14 Okay.

15 So in AS2 headers, so the current state is we  
16 had CDER, CBER, the destination. We'll have CDER in  
17 this case. We have post-market, so CDER, we have  
18 attribute values AERS and -- for XMLs and AERS  
19 attachment for PDF. When we move to IND it will become  
20 A\_IND (sic) and AERSATTACHMENT\_IND (sic). Now, this is  
21 R2 and these attribute values are only applicable to R2  
22 and R3. They are all embedded. So this whole

1 attachment concept will go away when we move to R3.

2 But this will still continue to be there.

3 AS2 routing IDs. In AS2 routing IDs we have

4 FDA AERS and FDA AERS attachment. For IND it will

5 become FDA AERS IND and FDA AERS IND attachment IND.

6 And of course it again applies for R2. In R3 the

7 attachments are going to go away. Now this system is

8 right now ready in our preproduction environment, okay?

9 Some of this pilot which Meredith had displayed on the

10 screen actually are submitting in that route and

11 appropriately we are seeing how these reports are

12 getting separated out in our FAERS database.

13 Okay. Now how do we truly segregate in our database?

14 So what we do is our safety reports are submitted by

15 different routes and are stored in different folders.

16 When we pick from that folder if it's picked from the

17 folder where all the pre-market reports are kept, we

18 actually append a -IND to the safety report ID and

19 store it.

20 But when the acknowledgment goes out, it goes

21 out with the original number. Whatever you sent in the

22 safety report unique identifier. So that also is a



1 second method of basically making sure that we have  
2 very clearly identified which ones are pre-market  
3 reports which ones are post-market reports, okay? So  
4 this check safeguards the pre-market reports. And all  
5 reports as IND postfix will be treated different from  
6 the post-market which is without the dash IND. So  
7 that's -- now, this we are doing now, we may also --  
8 there was some talk about maybe introducing a internal  
9 field where we can mark them as pre-market versus post-  
10 market.

11 So here it is, which we have here. You have  
12 the sponsor submission. So the top is pre-market. So  
13 the data comes in. It gets into the database and then  
14 goes in here, appends the -IND and that's how it is  
15 stored. And if you look at the AS2 header and AS2  
16 routing, the underscore IND has been appended.

17 If you look at the bottom part which is the  
18 post-market submission, you have the header as AERS and  
19 routing ID as FDA AERS. I think they should be FDA  
20 AERS IND, no. Oh, this is a post-market so it stays as  
21 the same whatever we had here without the IND.

22 And then you have the safety report ID which

1 goes as the same safety report ID. Now the reason why  
2 we are doing this because we just don't know what the  
3 sponsor is going to submit because remember we had a  
4 question of a post-market -- a marketed product being  
5 studied, okay, under the IND. So in that case we said  
6 to submit two reports.

7 We don't know how the sponsor stores and  
8 report our number, right? So if we had the same number  
9 follow-up. You don't want that to happen. So if you  
10 keep it separately then that's how -- that's the reason  
11 why this is being -- this is being done, to append the  
12 -IND so that we can very clearly separate them out.  
13 But I think also it will probably future help us to  
14 kind of know which report is related to each other. So  
15 you have whatever the report number is without the IND  
16 if I take this part out and try to match with this I  
17 will be able to probably say that.

18 So this is how we envision the future approach  
19 of the triaging of ICSRs electronically would happen.  
20 You will have two routing places to be sent to, one for  
21 pre-market, one for post-market. So it will be very  
22 important where what report goes. Of course since we

1 are checking for this particular field here, so if  
2 accidentally if you try to send this here it will try  
3 to check for this field and probably send you a  
4 rejection, right? And if you try to send this here, in  
5 this case -- in this case we still have to figure out  
6 what will happen. I have not even thought -- I've not  
7 thought about it.

8 But I guess when you -- if you send -- try to  
9 send this here, this will probably still process and  
10 that might -- that might end up in the post-market  
11 side. So that needs to be very -- I mean the sponsor  
12 needs to be aware of where they are sending the pre-  
13 market versus post-market using the appropriate AS2  
14 headers and the routing IDs. Okay.

15 The setup of IND route AS2 headers and routing  
16 IDs are available and here at the two links which you  
17 have where you can see very clearly every information  
18 about that. And that site has still not been updated  
19 with the new IDs because we're still in preproduction.  
20 As we go into production you will find the sites when  
21 you go to click on this, you will go -- you will  
22 eventually see they have been updated with pre-market

1 and post-market. They have still not been updated.  
2 But when you get the slides you will be able to click  
3 on this and I think it opens up. Yeah, that's where it  
4 goes and it shows you where what is. Okay.

5 So we talked about the two routing mechanism,  
6 how the routing should happen and what would be the  
7 setup and how they need to be submitted. So what will  
8 be the changes which the trading partners have to do  
9 because of this? So basically you have to take into  
10 account the attribute values for post-market and the  
11 attribute values for pre-market when you're doing R2  
12 because morning you heard about the IND safety reports.  
13 Of course when you go into R3 you don't have to worry  
14 about this part. You just have to take care of this  
15 part. And same thing with the routing IDs for trading  
16 partners where you have again for XML and the PDFs. Go  
17 to R3, we don't have to worry about this part and we  
18 just have to worry about these two.

19 So with that any questions on the whole  
20 routing mechanism for submitting pre-market and post-  
21 market safety reports?

22 Okay. All right. So with that I'll go into

1 now -- this morning when I was talking about the  
2 validator, what does this validator kind of look like.  
3 We don't have it ready yet but just to give you some  
4 glimpse on how this validator will look like and what  
5 all things you can do about this -- through this  
6 validator. So I am going to the mechanisms to validate  
7 the E2B.

8           So as you know today, if a company has to come  
9 in, a sponsor has to come in and submit E2Bs, still  
10 have to go to the -- first you have to go to the  
11 gateway, okay? Typically the companies first submit 10  
12 files to the FAERS e-sub (ph) e-mail address, okay?  
13 And you get acknowledgment back through the e-mail  
14 saying that okay, here's your acknowledgment files.  
15 Then you start setting up your gateway ESG in a  
16 preproduction site. And once that is done then you  
17 would submit and make sure that the whole cycle is  
18 going right, right? You got submit the file, you got  
19 the acknowledgment, you get both acknowledgments.

20           And then eventually once you have proven that  
21 you have tested that in a preproduction side then ESG  
22 will give you a production account. Of course you have

1 to exchange your certificate and so on and then finally  
2 you start your submission. Okay.

3 So the later two part, probably most of the  
4 companies already have that. You have a preproduction  
5 environment and a production environment, so you don't  
6 have to go through that again, okay? It's the part  
7 where you submit those 10 files, so we want to  
8 eliminate that process because then you're dependant on  
9 FDA to process them and submit them. And what will  
10 happen in R3 implementation. So everybody's trying to  
11 go to R3. So there will be a whole rush of files which  
12 will be coming to us and we have to process them, get  
13 the acknowledgment and e-mail it back to you. So  
14 rather than doing all that the thought process was why  
15 don't we have a public URL where you can either copy or  
16 XML and paste it there or you can browse your XML and  
17 pick the file and say, "Hey, can I validate this?"

18 So that's the whole concept of how do we want  
19 to do it. So the idea is to provide a mechanism to  
20 validate the regional R2 and R3 data element files and  
21 of course to convert an R2 to an R3. So if you upload  
22 an R2 how will it show up in an R3, right? And then a

1 mechanism used before production submission. This  
2 mechanism case is available through a public URL. One  
3 important thing, the uploaded files are never stored,  
4 okay? And this whole information will be also  
5 available on the FAERS electronic submission webpage.

6 Now, the documents which we said, the three  
7 documents which will be publish all will be all  
8 mentioned about in the FAERS electronic submission  
9 webpage. That's a webpage where eventually everybody  
10 will go to. And that page will be updated information  
11 about whatever we have for R2 and plus now with R3. So  
12 this mechanism will run something like this where you  
13 have the source XML -- oh god, it doesn't show up  
14 right. So -- I have to explain this. So this area,  
15 there are basically two windows here, this is one  
16 window and this is the second window. And what this  
17 window is doing is this window says source XML and this  
18 window says converted XML.

19 So you can actually copy and paste your entire  
20 XML here or this is -- this is upload button so you can  
21 click on this and pick a file which will automatically  
22 then show up, the XML will show up here. Once it shows

1 up here this is the window button called validate.  
2 Unfortunately it's showing up here, it doesn't show up  
3 very clearly there.

4           It's a button called validate and a button  
5 called convert and a button called download. So if you  
6 click on validate, then it's going to then validate  
7 against the regional specification. And so this will  
8 be validated and -- this part will validated. And down  
9 below here it will show you all the messages of what  
10 the issues are.

11           If everything is good then it will say, you  
12 know, the validation is -- it's all validated and  
13 everything is good. After uploading, this kind of  
14 shows you the list of all the error messages so  
15 validation messages are displayed after validating  
16 against R2 or R3 regional specification. And the list  
17 of elements whatever there are issues will list down  
18 here.

19           Then you have something as XML viewer there  
20 where now you can see there are certain areas here  
21 which are in different colors. This red in color  
22 actually is the error within that XML file. And then



1 you will -- you can actually go and fix those errors  
2 here. And if you try -- if you fix those errors here  
3 you can actually revalidate again. And once you have  
4 revalidated you can actually then download with a  
5 download button, you can download that same file and  
6 say let me import that into my local database and see  
7 how that works out.

8           So some of these back and forth things which  
9 we have to do can be all done by the sponsor before  
10 doing the next step of getting the submission done  
11 through preproduction to get the acknowledgment back  
12 and then eventually to production.

13           An E2B conversion. So this is where you can  
14 take -- convert taking a regional R2 element on this  
15 side, clicking on this convert here button, it converts  
16 to an R3 based on the forward compatibility where some  
17 of the elements that TJ was showing from R2 how it is  
18 move to R3, okay? Which you can do yourself and vice  
19 versa.

20           So this is the converter which we kind of --  
21 it's some mock up design now. But the idea is to have  
22 something like this available to the sponsors to be

1 able to test their XML files. So any specific  
2 questions, any thoughts about validation and maybe some  
3 feature which you may be interested in to just make  
4 your life easy. Yes?

5 UNIDENTIFIED SPEAKER: Suranjan, one of these  
6 (off mic) you talked (off mic). So when we are using  
7 this validation tool (off mic)?

8 MR. DE: No. So it's -- basically what it is  
9 doing is whatever the schema dictates. So the question  
10 is if we place the file here things like product name  
11 will it go into SPL and check and validate the name of  
12 the product or will it go into the product dictionary?  
13 No, it's not going to go into those dictionaries to  
14 check. It validates the schema to make sure that the  
15 rules that are dictated by the schema is correct or  
16 not.

17 UNIDENTIFIED SPEAKER: So it's not verifying  
18 the (off mic) verifying the structure --

19 MR. DE: Yes, and I'm sure we all know that.  
20 Currently today you hardly get rejections from FDA  
21 because we just check for data elements to make sure  
22 it's a case, most of them. I mean FDA's rules are not

1 as strict as other regulators. So -- and it'll  
2 probably continue for some time -- probably continue, I  
3 mean. But, you know, the hope is that one day, you  
4 know, as companies are submitting to other regulators,  
5 you know, they already have done their checks and data  
6 checks and all that on their end. So hopefully the  
7 files which are coming to FDA are also in that, you  
8 know, post-checked fashion.

9           So this is actually not checking the data  
10 element but yes, I would -- I could say that if you're  
11 looking under the FDA type of report which is an OID,  
12 which is an FDA-defined OID of 1, 2, 4, 5, 6. Now if  
13 you didn't have that right, of course it will get --  
14 because the Schema will dictate that, so it will get,  
15 you know, it will give you the error here. It will  
16 show the error here.

17           But yeah, if you -- if you have a product name  
18 which you have put in there, that data probably you  
19 would want to check to tell you that this product does  
20 not -- because again you're testing here, right? You  
21 can just put some fictitious product name and try to  
22 test this out to make sure that structurally you're

1 correct. And that structurally you have taken care of  
2 all your regional data element, right? So that's the  
3 idea here. So with that I think -- yeah?

4 UNIDENTIFIED SPEAKER: Okay. I just want to  
5 make sure I'm following correctly. So your validator  
6 is checking all the E2B required, right? And then if  
7 there is anything that FDA has now or will in the  
8 future as far as a mandatory data element, they will  
9 also check for the presence of that but not necessarily  
10 the OID and code from -- I'm thinking like patient race  
11 categories as an example. So you're just going to say  
12 are the elements there that (off mic) are you going to  
13 require they have to use that same vocabulary.

14 MR. DE: Right. I think some of them are  
15 dictated by the schema, the way it is defined where you  
16 have the --

17 UNIDENTIFIED SPEAKER: I was thinking like  
18 nullFlavors are things that you can select, right, so  
19 just a presence of a nullFlavor (off mic).

20 MR. DE: No, not for a specific one. I mean  
21 when you say nullFlavor --

22 UNIDENTIFIED SPEAKER: -- I'm thinking like,

1     okay, I'm thinking like (off mic) assessment, right, so  
2     you're saying (off mic) earlier part you want each --  
3     you want an assessment for each (off mic), you can't  
4     just leave it blank. So there is no assessment, but  
5     you have to include NI, right, as the nullFlavor. So  
6     would the validator be checking for that at this stage  
7     or this is --

8             MR. DE: No, the validator would check for  
9     that, yeah.

10            UNIDENTIFIED SPEAKER: Okay.

11            MR. DE: But if you have a data field where  
12     you have a name of a medicinal product name.

13            UNIDENTIFIED SPEAKER: Yeah, but free text --  
14     yeah, yeah --

15            MR. DE: Yeah, yeah, free text, yeah, that  
16     part one.

17            UNIDENTIFIED SPEAKER: -- free text. But I  
18     was just thinking about like in the things that are  
19     hard (off mic) but then you also have to use it,  
20     correct?

21            MR. DE: Correct. So if you have --

22            UNIDENTIFIED SPEAKER: What value or (off mic)

1 or OID, whatever, well, the scheme of that will be  
2 embedded already in the value.

3 MR. DE: So the conformance rules which you  
4 have, right.

5 UNIDENTIFIED SPEAKER: Yeah, that  
6 (off mic) the conformance rules.

7 MR. DE: Right -- exactly.

8 UNIDENTIFIED SPEAKER: Okay, so you're going  
9 to have those embedded.

10 MR. DE: Exactly. Because again then you  
11 don't -- if I can't do that here then there is no point  
12 because once I submit the file there will be a  
13 rejection and you don't want that happen, right? So if  
14 you can get all of that caught here and they can fix it  
15 here then there is -- then when you submit into  
16 production then, you know, it's going to move through.

17 UNIDENTIFIED SPEAKER: Okay. All right.  
18 That's (off mic). Thank you.

19 UNIDENTIFIED SPEAKER: So will the same thing  
20 be true (off mic) choices, they're going to actually  
21 check the choices.

22 MR. DE: Right.

1 UNIDENTIFIED SPEAKER: So your (off mic) to  
2 check the (off mic).

3 MR. DE: And any free text, right, because  
4 sometimes, you know, some free text are such that it  
5 goes and checks against some dictionary in the back  
6 end. That probably -- that won't happen. But anything  
7 which is defined in that schema with the conform is  
8 what we just talked about. Those conformance will be  
9 there.

10 So if you looked at like race, ethnicity,  
11 right, it has a conformance that you have to use these  
12 values. That's the conformance, right? So it will  
13 check that.

14 UNIDENTIFIED SPEAKER: Of course. Just as a  
15 clarification, so basically it's validation of rules  
16 that will eventually accept parsing of the data (off  
17 mic) down the road before data is stolen (off mic)  
18 underlying database. So you can make all these changes  
19 (off mic) so after filing due process it will be  
20 accepted by the FDA (off mic).

21 MR. DE: Correct. So yes, you're right. So  
22 what -- the idea is that if I didn't -- we didn't have

1 that and sponsor submitted that then every time we have  
2 to go back and forth, I mean we'll probably find, okay,  
3 these are list of all the issues and now you fix it.  
4 You fixed it but then you miss something. Then again  
5 you go back and forth. Before that you do this back  
6 and forth, you would have checked all these and then  
7 submitted against that, right?

8 Now yes, if you had submitted a product name  
9 and the product name was not in our dictionary, right?  
10 Yes, what we will do, that report will typically stop  
11 for someone to take some manual intervention. And we  
12 have a whole dictionary team who works on that to make  
13 sure that is taken care of because as you know that for  
14 post-marketing all suspect products are coded to some  
15 name in our dictionary. So that part will probably  
16 still go and continue the same way. But we want to  
17 make sure that ones which are very well-defined data  
18 which has very well-defined conformance rules, they're  
19 all pre-checked before the actual submission is done.

20 UNIDENTIFIED SPEAKER: I have a question. I  
21 would integrate for the nation for the same province as  
22 well because right now (off mic) system in place isn't



1 going to be one-stop-shop for the nation for all the  
2 products we just submitted to FDA including --

3 MR. DE: So right now we have -- since we have  
4 not harmonized all the data element with vaccine. So  
5 this probably is not going to have -- the schema itself  
6 may not have the vaccine elements available now. As we  
7 are moving through data elements which is required by  
8 FAERS, okay, and these regional elements, we're trying  
9 to find out does vaccine already have that. If it has,  
10 let's take that element. But we will probably reach a  
11 point where we'll say, you know, FAERS doesn't need any  
12 more data elements. Okay, FAERS is ready.

13 Next is let's work on the vaccine element as  
14 to what is that delta we need to get in. Now when this  
15 goes to production we may not have the vaccine in  
16 there. It will at least have regional elements which  
17 probably is just required by FAERS -- required by both  
18 FAERS and vaccines and the core data elements. That  
19 it'll have.

20 And as we decide -- because just getting  
21 vaccine is not straightforward because vaccine has a  
22 whole database in CBER. The whole database has to

1 gotten -- has to be gotten, then you have the whole e-  
2 submitter process. They all have to be looked at how  
3 it's going to flow. And you have reports coming  
4 directly to be -- you have e-submitter and then you  
5 have CDC where you have the voluntary direct reports  
6 which are coming in.

7           So they all have to be looked at before we can  
8 say we can transfer that all over into FAERS. So --  
9 but the path to move forward is as we look at new  
10 regional elements make sure that it is there in AERS  
11 (ph) or not. And if it is there, can we get that?  
12 Exactly. Yeah?

13           UNIDENTIFIED SPEAKER: (off mic).

14           MR. DE: So as I said -- so the question is,  
15 are we going to check validations like, you know, one  
16 date is greater than the other date or one date is less  
17 than the other date, so on? So currently as I said  
18 that our rules which we have does not have these kind  
19 of rules which we don't do it in R2 today, so it will  
20 probably not happen in R3.

21           The only rules we will comply -- not comply --  
22 only rules we will check moving to R3 are the rules

1 which are based on the conformance rule which will be  
2 in their spreadsheet, okay?

3           It's -- I mean, and for -- I don't know if you  
4 have looked at the regulation, it's -- regulation very  
5 clearly says the four data elements makes a case, those  
6 four data elements needs to be there, right? And  
7 that's what we do in R2 today, okay?

8           I think another field which we do check is the  
9 narrative. The narrative, it is empty, I think today  
10 we give rejections for that. But otherwise valid  
11 patient, reporter, product and event is the four  
12 elements we check and we'll continue to do that. And  
13 anything which the schema now dictates is going to be  
14 available. Any other -- yes?

15           UNIDENTIFIED SPEAKER: Yeah, the previous  
16 process was formal in the sense that it was (off mic)  
17 this is kind of more informal. But I guess (off mic).

18           MR. DE: So -- but you have to realize, when I  
19 talked about the testing plan you have seen there is  
20 one bullet point which I said that in pre-production  
21 environment you will do a submission to submit file and  
22 get the acknowledgement back. So that will give you

1 the entire path. This is just before you're doing the  
2 submission. Rather than going back and forth, back and  
3 forth -- because I'll tell you what will happen during  
4 that time. Every company is trying to test. Every  
5 company will be submitting saying that, "Hey, can you  
6 test my files? Okay, I'll give you my files." And it  
7 will become a backlog for FDA for testing all of them.  
8 So the idea would be if you could go here, check it  
9 out, test it out, everything is fine, then do the pre-  
10 production, that keeps a record that you have done your  
11 testing through a process where you have submitted a  
12 file, FDA has processed it and you have got an  
13 acknowledgement back.

14 UNIDENTIFIED SPEAKER: This is like file till  
15 the program (off mic). So let me ask you this then, if  
16 I were to (off mic) and then I do (off mic) R3, it's  
17 going to create a file (off mic) where is that? That's  
18 when (off mic) environment then?

19 MR. DE: Yeah, I think it drops it and then  
20 you can -- if it converts it then you have a concept of  
21 downloading it. So once you have downloaded it then --  
22 once you download it then the file is removed.

1 UNIDENTIFIED SPEAKER: Okay. This is test  
2 data only?

3 MR. DE: This is test data only.

4 UNIDENTIFIED SPEAKER: And you can put banners  
5 all over that --

6 MR. DE: Yeah. I mean as I just said, this  
7 whole thing is more like a mock-up which we have kind  
8 of done and then once it becomes real of course it will  
9 all have the disclaimers and all that.

10 UNIDENTIFIED SPEAKER: And will this work for  
11 both the IND products and --

12 MR. DE: Because the scheme is one, DTD is  
13 one, right? So one schema, you have one DTD, so it  
14 will -- has to work on that, you cannot have separate.  
15 So I mean that's the whole idea, is to try to harmonize  
16 all of them together. And believe it or not, every  
17 Friday we have a meeting with CBER where we are  
18 actually harmonizing -- trying to harmonize all that  
19 elements as much as possible so that we can get into  
20 that one -- end of the day the goal is to have just  
21 that one big spreadsheet where it will only have items  
22 saying ICH or FDA, that's it. So that's the goal.

1 Yeah?

2 UNIDENTIFIED SPEAKER: So Suranjan, (off mic)  
3 earlier that you will publish (off mic) test (off mic).

4 MR. DE: Yes, yes. Yeah, so the question is  
5 that are we -- FDA is going to post some sample XML  
6 files? And the answer is yes.

7 UNIDENTIFIED SPEAKER: I think one of the  
8 things that we found that was helpful (off mic) is that  
9 they make (off mic) uses cases that (off mic) specific  
10 to your company that might not (off mic).

11 MR. DE: We would really appreciate that. And  
12 believe it or not, those use cases which you saw that  
13 Meredith had put, they all came from sponsors actually.  
14 There were one or two which we thought about, but then  
15 the sponsors said, oh, you know we have a situation  
16 like this or we have a situation like that. And I e  
17 said, OH, yeah, makes sense. Okay, we will test that  
18 situation, let's test that situation or let's test that  
19 use case.

20 And we would -- we would definitely --  
21 definitely would want sponsors to provide us with some  
22 of those use cases because they know better those use

1 cases and they have exceptions. And so we would  
2 really, truly appreciate if they can provide us with  
3 those use cases.

4 UNIDENTIFIED SPEAKER: And so then my question  
5 is how could other companies or software then become  
6 aware of the feedback that might come --

7 MR. DE: So in addition to these three  
8 documents which will be posted we will add in a Q&A  
9 link. As we are going through this whole process we're  
10 getting -- we're going to get new questions. And just  
11 to add that when combination product came out, with  
12 combination product we had so many questions which had  
13 come out.

14 Many organizations gave lots of questions. We  
15 were just responding back to that organization.  
16 And recently -- right now I'm actually working on  
17 updating that Q&A to make it little more generic so  
18 that this could be now shared with everybody and they  
19 can see this typical questions which are asked.  
20 So same concept will work for that because what will  
21 happen is you will typically start working as we --  
22 when it comes to the March 2020.

1           Or if the specifications are published prior  
2 to that, you may start asking questions to us. But  
3 typical testing as you saw on the timeline that when we  
4 are ready with this available and we are ready to  
5 accept you will probably start testing.

6           And as you go through questionnaires, as you  
7 go through questions, we will document that and start  
8 posting that on to the FAERS electronic submission  
9 fda.gov webpage where you can then look at these  
10 questions and answers.

11           UNIDENTIFIED SPEAKER: So right now this is  
12 more (off mic).

13           MR. DE: This is -- we want to get this ready  
14 by December. So if you look at this timeline -- let me  
15 go back to the timeline, I think it's -- so this work  
16 will probably -- we'll finish it by, normally by this  
17 time, right, because we have to --

18           UNIDENTIFIED SPEAKER: (Off mic).

19           MR. DE: Right, because you're testing -- by  
20 the time we put it into production we will be here. So  
21 when I say production means -- production means we are  
22 ready to accept today R3, okay? And that this public



1 URL is available.

2 Now, the idea of having these three meetings  
3 here is to hear from you so that when we put something  
4 here, okay, hopefully we really don't have to do a 180  
5 degree turn. So that's the idea here.

6 So with these three public meetings we are at  
7 a state where we can say, hey, we have heard from  
8 sponsors, we have heard from vendors and now we are at  
9 a point I think we are probably quite steady with the  
10 specifications. So should not be too much of an  
11 exception when we reach March 2020. That's the idea.

12 UNIDENTIFIED SPEAKER: I just have a comment.  
13 ICH did that spreadsheet, right, all those (off mic)  
14 cases, right (off mic) go ahead and use now, is that  
15 (off mic). And then for FDA on e-ver (ph) site you  
16 have some test files (off mic) still available, like  
17 for example (off mic) elements for example. That's  
18 already out there where you see where it shows that for  
19 the XML file. And then obviously you have (off mic)  
20 any XML editor they can (off mic) for example where you  
21 can take your own XML file blow (ph) it against the  
22 schema file that are also available.

1 MR. DE: Available.

2 UNIDENTIFIED SPEAKER: And you can kind of do  
3 some sort of framework now. And then when this  
4 validator is ready --

5 MR. DE: Yes.

6 UNIDENTIFIED SPEAKER: -- have a file that you  
7 can kind of look around (off mic) 3 or 4 months but  
8 then can kind of log in and then just plug in the rest  
9 of the stuff that's missing (off mic) by that time in  
10 terms of the additional data elements because lot of  
11 the stuff that you already, you know, like the batch  
12 ID, DUNS --

13 MR. DE: Right.

14 UNIDENTIFIED SPEAKER: -- things like that,  
15 that's already published, correct.

16 MR. DE: Yeah, that's already published, yeah.

17 UNIDENTIFIED SPEAKER: -- try to do to help  
18 yourself along.

19 MR. DE: True, true, true. I mean, some of  
20 the data points which I explained there, they're  
21 already there. It's like the type -- FDA report type,  
22 that is something which is new. But when I talked

1 about the DUNS number, and then I talked about, you  
2 know, race, ethnicity, they're all currently published  
3 and they're already there.

4 UNIDENTIFIED SPEAKER: All that stuff is  
5 already out there (off mic).

6 MR. DE: Yeah. Exactly, exactly. So again,  
7 as I said, this timeline is available. The slides will  
8 be posted so you can always share this timeline with  
9 your organization and your colleagues. So finally  
10 going back into this. All right. Any questions on the  
11 area of the validation? Any suggestions you have on  
12 validation, if we can do it, anything better, please do  
13 comment through the docket. I will really appreciate  
14 that. Maybe something we may not have thought about  
15 that right now or you are -- you have not thought about  
16 it right now. Now you can go back and talk to your  
17 colleagues and think about it, so please do comment on  
18 that in the docket, I'll really appreciate that.

19 So with that I'm just doing some summary and  
20 some closing comments. We basically planned -- have  
21 wanted planned for a fifth session which was somebody  
22 to come and basically present to us from the sponsor's

1 side as their experience with R3 implementation.

2 Unfortunately because of this whole meeting which got  
3 cancelled in January and got -- we did in March, things  
4 got messed up there.

5 But for July if anybody is interested to come  
6 and present, we can give them 60 minutes. Come and  
7 present about their experience in implementing R3 with  
8 other regulators. We would really appreciate that.  
9 And you could send an e-mail to [eprompt@fda.hss.gov](mailto:eprompt@fda.hss.gov) to  
10 let us know. And then we can definitely accommodate  
11 that on the next meeting.

12 So today with Session 1 we went into talking  
13 about some of the plans. You saw the timelines. And  
14 then we -- our production date will be March 2020.  
15 Currently very -- we want to be very clear, currently  
16 no compliance timelines have been set for it to be R3  
17 by FDA.

18 And we talked little bit about -- discussed  
19 about the testing plan and the methods. And one of  
20 them is all this validation we are talking about.

21 Session 2 today we talked about the electronic  
22 submission of IND safety reports. We did the

1 introduction of IND safety reports to FAERS and then to  
2 the FDA. We also provided information on the  
3 implementation plan which Meredith. Regional  
4 requirements in R2. And then TJ talked about R3.  
5 Meredith did talk about some use case examples. And  
6 then we talked about the R2 to R3 transformation and  
7 then IDMP, okay?

8           So we talked a lot about IDMP. And hopefully  
9 the talk which TJ gave, the idea was kind of give a  
10 general understanding of where this data elements from  
11 the model we're picking up. And so how the expats will  
12 eventually look like. So that was the idea behind that  
13 presentation.

14           Session 3 I talked about on the post-marketing  
15 side all the regional data elements for R3 and what are  
16 their properties, what are the conformance rules which  
17 we have. As you saw that not too many data elements  
18 which we're adding here. I mean most of them are  
19 already -- have been published.

20           And then finally the Session 4 we talked about  
21 the routing mechanism for pre-market and post-market.  
22 And then we got into the mechanism for industry to or

1 sponsors to validate the E2B R3 regional files based on  
2 this regional schema which we will publish soon.

3 Now, what do we do next? So what do we do next is  
4 today's presentation we'll post it on the FDA meeting  
5 page and the recording which is happening here will be  
6 posted on the FDA meeting page. We invite comments on  
7 today's meeting to the docket and by April 25th, okay.

8           So it's 30 days from the meeting date.  
9 We will start updating the schema with the regional  
10 elements if we -- when we hear things -- when we see  
11 things on the docket we will -- we want -- we will go  
12 ahead and update that. Along with that we start  
13 updating the FDA regional implementation specification,  
14 incorporate the comments we receive via the docket.  
15 Our next meeting is the 17th where we discuss  
16 combination product plus any new elements that got  
17 added to the Medwatch as part of the reauthorization.

18           We start preparing some regional sample E2B R3  
19 file, the schema file and so on based on whatever use  
20 cases we have now. And then after the docket timeframe  
21 if you have any questions please again submit to  
22 eprompt@fda.hss.gov. And so there are folks who are

1 monitoring this mailbox, and so we will respond back as  
2 we get these questions.

3           And so -- and any suggestions if you have for  
4 today's meeting, anything you want us to do  
5 differently, anything where, you know, you want to  
6 present, please shoot an e-mail to the eprompt and we  
7 will make sure we look at those suggestions and then  
8 work on, improve on in the next meeting.

9           After July, the last -- after July, the last  
10 meeting will be in February of 2020 before we go  
11 production because at that time we want to just make  
12 sure that we will summarize all these what we have  
13 talked about in the two meeting and go over in that  
14 third meeting and just make sure we are all on the same  
15 path, we all are thinking the same way. And the idea  
16 is that we have -- we are not turning 180 degrees after  
17 the third meeting.

18           So it's very important that we are all on the  
19 same page, and that's the whole purpose of having these  
20 e-prompt meetings. As we go through these meetings we  
21 will -- next meeting we will also update the timeline  
22 as to where we are, how far have we reached, so we'll

1 get an idea of where FDA is.

2 And so with that, if anybody has any questions  
3 we have -- I've tried to pull it by 2:45 p.m. Not bad.  
4 Any questions, please? And if not then we can adjourn  
5 the meeting for today.

6 UNIDENTIFIED SPEAKER: Suranjan, thank you so  
7 much for the discussion (off mic). Thank you.

8 MR. DE: No, welcome. Everybody welcome. And  
9 -- all right, thank you so much for attending. Really  
10 appreciate everybody's time to come here. And we will  
11 continue the dialog and successfully implement R3 at  
12 the FDA. Thank you so much.

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