

1 FOOD AND DRUG ADMINISTRATION (FDA)

2 Center for Drug Evaluation and Research (CDER)

3 -----
4 Electronic Submission of Adverse Event Reports
5 to FDA Adverse Event Reporting System (FAERS)
6 using International Council for Harmonisation
7 (ICH) E2B(R3) Standards
8 -----

9 MEETING

10 DATE: Wednesday, February 19, 2020

11 TIME: 9:17 a.m.

12 LOCATION: FDA White Oak Campus

13 10903 New Hampshire Avenue

14 Bldg. 31 Conference Center

15 the Great Room (Rm. 1503, Section A)

16 Silver Spring, MD, 20993

17 REPORTED BY: Eliza Spikes, Notary Public

18 JOB No.: 3662002

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A P P E A R A N C E S

Suranjan De

Ta-Jen Chen

Rick Hester

Una Casey

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

2 SURGANJAN DE: All right. Good
3 morning, everyone. My name is Suranjan De. I am the
4 Deputy Director with Regulatory Science in the Office
5 of Surveillance & Epidemiology in the Center for Drugs
6 at the FDA.

7 So today we have the third meeting.
8 We're going to be going through all that we have
9 discussed at the first two meetings, plus we had a
10 webinar. And we will be going over all the data
11 elements that we have discussed earlier, and here we
12 are talking about all the regional elements that we're
13 talking about.

14 So we're going to have first morning
15 session will be talking about all the different kind
16 of regional data elements with pre-market combination
17 products any other regional elements. Then we'll take
18 a break. We will then have TJ, who's going to talk
19 about some FDA specific OIDS because of these regional
20 data elements. We also have the regional FDA specific
21 OIDS.

22 We're go into lunch. We talked about -

1 - we'll talk about some regional forward compatibility
2 from E2B R3. We'll talk about the submission
3 mechanisms because now we're going to have pre-
4 market/post-market, so the helping mechanism splits.

5 Then we're going to go into the
6 afternoon into the demonstration of the E2B validator.
7 So this is a validator with any sponsor can validate
8 the regional R2 and convert that to a regional R3 or
9 upload a regional R3 and validate that to see if the
10 data is -- the valid -- the data is correct and they
11 could submit -- before they could submit, they could
12 do that check.

13 And then finally, I will have it as an
14 open discussion and not make it too formal for any
15 kind of questions we want to discuss, only specific
16 things that we came across during the day. And we can
17 sit together to come up with a solution, if you have
18 questions or any suggestions that, you know, you all
19 want to provide.

20 So with that, there's some housekeeping
21 items I want to get aside: is one being, you know,
22 please silence your cellphones; the restrooms are

1 located at the far end of the main hallway, the right
2 of the room; wi-fi is available here, the wi-fi
3 network is FDA public and the passcode is public
4 access, all small letters.

5 So we'll save the questions for the end
6 of each session. Lunch is 11:45 to 1:00, and you have
7 seen the kiosks here where you could go and order your
8 food.

9 As you will recall, this meeting has
10 been requested, so there will be a link available on
11 the FDA site once we have the recording, which will
12 also have the transcripts, these slides that we
13 present today, and eventually we will also post the
14 regional data elements that I'm going to go over.

15 When we go over the regional data
16 elements, you will also see that these elements are
17 placed in a huge big Excel spreadsheet that
18 constitutes off all the ICH elements and the regional
19 elements with the variations being highlighted. And
20 you will have 20 to 30 days from this meeting to post
21 your comments in the docket. And how to do that is
22 available at the registration table and our Docket No.

1 is FDA-2018-N-4002.

2 So with that, I will start with my
3 updates on FAERS II. So we'll go over a little bit on
4 the plans and the timelines, and then go swiftly or
5 into the data elements.

6 So we have discussed -- we had talked
7 about this at my first meeting last year, March. Just
8 to revise what was our objectives for FAERS II as
9 FAERS II is very mission critical system for CDER and
10 CBER. And this is to provide a modernized system for
11 pre-market, post-market, and product quality defect
12 reports.

13 And we plan to enhance and unified data
14 analytics and signal management. We have to achieve
15 the data stanDA-rds for ICH E2B R3 and decommission
16 our old tools, and this has been designated by HHS as
17 a modernization priority.

18 So going into the scope. So scope was
19 very straightforward: it's to implement the system,
20 which has a case processing platform and data
21 analytics by including the stanDA-rds of ICH. And
22 then we go into the operation mode and maintain the

1 software tools that we have -- we are implementing,
2 and the decommission of old tools.

3 The tools that we use are implementing
4 is for the analytics, we have the Rx tool, and for
5 case processing, we have the Aris Global LifeSphere
6 tool.

7 So going into some of the timelines.
8 So we had our first ePrompt meeting March 25th; our
9 second one we had on March -- July 17th. Then we
10 drafted our regional elements for public review, so
11 that is what we're going to be presenting today. From
12 March to now, we have been communicating the data
13 elements through these ePrompt meetings. But today
14 we're going to go over, like, a final draft, which
15 then we will provide for your comments.

16 So today is our ePrompt meeting, and
17 then we will go into -- we'll try to post this draft
18 by end of this month so we can post this, all the data
19 elements. So you will see a huge big basically a
20 spreadsheet, actually two spreadsheets: one will have
21 all the data elements; and the second spreadsheet will
22 have the forward compatibility document, which shows

1 how you for the regional elements from an R2 to R3.

2 And then, hopefully, by end of this
3 fiscal year, we will provide -- make the E2B validator
4 available that we're going to demonstrate today and
5 the technical specification. And then sometime by end
6 of this year, we will have this ready for E2B R3
7 testing. So that's, so far, that's the tentative
8 timelines that we have.

9 There has been some change. Initially,
10 our plan was to have something by March, but there
11 have been circumstances where for which we have to
12 move this, and so here's the next tentative timelines
13 that we have planned for.

14 So just to go over some of the testing
15 plans and the methods that, once we have, you know,
16 ready for it to be R3 testing, how will you do some
17 kind of -- this kind of testing when you are ready
18 with the R3 submission, the regional submissions.

19 So first thing first, we have no
20 compliance date defined for R3 submissions, okay.
21 Sponsors can start testing after September 2020, which
22 means here's the date for September 2020 when we have

1 the validator available and the technical spec
2 available. Since you already would have the regional
3 data elements available to you and sponsors could
4 start developing, there are three submission files
5 using those data elements, and then start testing them
6 through the validator, and then eventually also test
7 them by submitting that to FDA in a non-production
8 environment.

9 So as I said, FDA will to provide the
10 validator to pretest sender's ICSR. This validator
11 actually will be available publicly through a URL. We
12 plan to put this validator actually on the electronic
13 submission webpage that we have for FAERS, so you will
14 have a link there and you could go there and use a
15 validator to test your ICSRs.

16 One thing to you know, this validator
17 does not give you an acknowledgement; it gives you the
18 error message right on the screen. But when we got to
19 the process where you actually submit the file to a
20 non-production environment to test through the
21 gateway, we would send acknowledgments back, so you
22 could see those acknowledgements and test it out.

1 So you continue to submit in R2 format
2 until you are ready for R3. And as I said in the
3 first bullet point, there's no compliance date for R3
4 that has been defined.

5 So the idea would be to also test both
6 pre-market or post-market, including combo products if
7 you have in the R3 format with the regional data
8 elements and developing mechanism. This is where I'm
9 going to talk to you around 1:30 of the different
10 routing mechanisms that you need to submit these when
11 you are submitting to a non-production environment for
12 the pre-market and the post-market. There's going to
13 be two different routes and we just can send ours in
14 the afternoon.

15 When you're doing your first production
16 submission, it will be nice if you can just notify
17 that to us when you're ready, and so that we are also
18 prepared from our side to make sure that it's going
19 through, it's passing through. And if you face any
20 issues, then we are able to notify that immediately.

21 And then any questions during your
22 testing, you can send it to this email address.

1 Anything even after the docket, you know, time period
2 is over, you can also shoot an email to this email
3 address with any questions you would have.

4 So as we go through the -- as you go
5 through the data elements, as we go through the list
6 of all the different data elements, the spreadsheet
7 that we're going to post has the headers in this
8 format. So what we have is the first column in this
9 spreadsheet has something called the source. The
10 source will define, there's two values; either the
11 source of this data element is originally from ICH, or
12 the source is FDA. If it says FDA, that means that
13 it's a regional element. Okay?

14 Then you have the element header and
15 the element -- data element number. Any data element
16 number that has been prefixed by an FDA.c.1.1,
17 anything that is prefixed by FDA, that's a regional
18 data element, okay, that has been defined by FDA.

19 Then you have the data element name,
20 you know, you have the max length, data type, and
21 field values allowed. Now, let's say we had data
22 element which was defined by ICH, so the source will

1 say ICH. You have the data element number; there'll
2 be no prefix to those element number. You have the
3 data element name, the max length that was defined by
4 ICH, the data type defined by them. You have the
5 allowed value, and then you have the ICH conformance
6 and the ICH business rule.

7 Now, if you had a data element that was
8 defined by FDA, then you will see -- you'll see the
9 source saying FDA, the data element number will have a
10 prefix of FDA, you will have a data element name, the
11 data max length that was defined by FDA, the data
12 type, the data values, but you won't have any
13 information under ICH conformance and business rules.
14 You will see something like this where you will have
15 the post-market, the conformance, and its business
16 rule; you have pre-market, the conformance and
17 business rule.

18 If a specific data element was truly
19 only used by pre-market, you will find that it will
20 say under the conformance the pre-market business
21 rule; in such case, the post-market conformance and
22 the business rule for post-market will probably be

1 blank or just a hyphen listed there, so printed there.

2 And then for the ICH element or non- --
3 or regional element, it'll say the type of change, and
4 the type of change will say, hey, this is FDA element
5 -- FDA-defined element, or it'll say that this is --
6 it conforms to ICH rules. Any notes, and then you
7 have the non-flavor applicable, the field OIDS, and
8 the HL7 data types.

9 The same spreadsheet also has a second
10 tab which lists all these data elements with the
11 expanse, anything which is the non-expanse or anything
12 which is the values that it has in expanse.

13 So as we go through the data elements
14 after this, you will find that anywhere we have a
15 change that only has been listed in the slides. It
16 also lists down, you know -- basically, they give you
17 the data element name and then lists down the specific
18 sections where we have a change. And once you see the
19 spreadsheet, they are also color-coded, and it
20 highlights in the spreadsheet, you know, which ones
21 are FDA with what other change.

22 Also, we will also find in the

1 spreadsheet that -- and also in the slides, there are
2 some data elements where, you know, we had to make it,
3 let's say, conditional-maNDA-tory based on a
4 particular rule even though the ICH rule have may have
5 said optional. But as far as FDA is concerned, it's
6 conditional-maNDA-tory and it is very clearly
7 highlighted in those, in the spreadsheet and the
8 slides will also say that.

9 So with that, I will go on the second
10 topic. But before I go on the second topic, any
11 questions I can entertain? Yes, sir. Yeah, if you're
12 going to use that, then others could. You can pull it
13 up.

14 RICK HESTER: Hi, Rick Hester,
15 GlaxoSmithKline. Suranjan, a couple of questions
16 related to sort of testing and transition. So will
17 there be a required set of test cases or test reports
18 that will be required by industry to certify in
19 advance with the FDA before transitioning?

20 SURGANJAN DE: So we didn't plan for
21 any specific test cases. I mean, the idea here was
22 since now we have a validator, the expectation would

1 be that sponsors could go to the validator, you know,
2 test maybe different scenarios that they have as part
3 of their submission. And once it's validated, then
4 you would submit that through the gateway, through a
5 non-production environment because we want to test two
6 things here: once is the validity of the data that you
7 have and the structure, and then passing it through
8 the gateway to make sure that you get the
9 acknowledgement.

10 So we're not going to have to typically
11 not do what we done, which was say, hey, send us those
12 10 files in of this type. Here, we would request, if
13 you're looking for a specific type of data files you
14 want to submit, pre-market reports, post-market
15 report, and combination product; that will basically
16 cover all the different types of three general data
17 elements.

18 RICK HESTER: Second question along the
19 same lines. Do you know when you'll be ready to
20 publish a date by which you'll be ready to accept
21 submissions in E2B R3 format?

22 SURGANJAN DE: We, according to the

1 timeline, we would like to start our testing by
2 November. So I think from FDA's perspective, we are
3 targeting to be ready by November, but not enforcing
4 that all sponsors have to be ready to November because
5 we are accepting the data so we need to be ready in
6 some way or form so that if somebody wants to test,
7 they can test, or if somebody's ready, they can
8 submit. So our target date is sometime end of this
9 year to be ready.

10 RICK HESTER: And my last question is
11 to do with your core and regional data element
12 spreadsheet, and you mentioned how there will be
13 clearly identified whether it's a source from ICH or
14 FDA. And I was curious for ICH source data elements,
15 will the FDA change the conformance of the business
16 rules for any of the ICH elements?

17 SURGANJAN DE: So I think there are
18 very few elements where typically what has changed is
19 I think the conformance of the data elements, and the
20 structure, data type, data length has the -- we'd
21 never try, we don't want to even touch them. But
22 there are some rules where if he said that this was,

1 you know, a pre-market data element used for, let's
2 see, I don't know -- I'm just thinking of an example.

3 But if there was an element where FDA
4 is in the post-market side, there's a rule that if
5 this is this, then that should be that, but that data
6 element was an optional data element. But just
7 because, you know, FDA requires a data element, we
8 have made it in such a way that if you don't have it,
9 then you will have to use a non-flavor to kind of
10 compensate with that data element. All right?

11 UNA CASEY: Good morning, Suranjan.
12 Una Casey from Oracle. We just have a couple of
13 questions, one of them being for software vendors.
14 Will there be the opportunity to start testing before
15 the November 2020 timeline?

16 SURGANJAN DE: I think we will be ready
17 -- I mean, you can start once you have the validator
18 available. This afternoon when you see the validator,
19 you will see. I mean, it's as simple as somebody
20 uploading an XML file, which you have, and you have to
21 just click on a button called validate and it'll start
22 showing you if the XML is validated or -- it's a valid

1 XML or what errors it has. It gives you a list of
2 errors.

3 I think your first step probably would
4 be to start using that to test that file is good. And
5 then once you are done with that, the second stage
6 would be to sending it to the gateway so that you want
7 to also test the acknowledgement that will come along
8 with. But, yeah, so based on this timeline, we are
9 targeting that by September, we make this URL
10 available for everyone to use it.

11 UNA CASEY: Okay. Then request as well
12 for the software vendors, we can make our own cases,
13 but it would be helpful to have some sample files of
14 expectations to meet the minimum requirements that you
15 have for the system as well.

16 SURGANJAN DE: Good. So, yeah, even if
17 you look at most of our -- when you look at all the
18 data elements that we -- I mean, this when it comes to
19 a spreadsheet, you will find many of our data
20 elements, especially with FDA. It's very lenient and
21 many of them are optional; very few you will find that
22 there is some conditional-maNDA-tory put in. But most

1 of them, especially all the ICH elements has been to
2 skip as is. And when we added some regional data
3 elements, many of the regional data elements are also
4 kept very optional, you know.

5 So I think the concept here, the way
6 they look at it at -- and I don't want to reject a
7 report because our administration was wrong and it was
8 a fatal report, all right, so you don't want a
9 rejected a report because of that. So that's the
10 reason why many of the data elements are all just
11 skipped, very optional.

12 In pre-market site, there are a few
13 rules, I would say. And also the reason being, we do
14 also understand when you have pre-market report, you
15 know, the data is much better than what you get in a
16 spontaneous report; it is much more controlled. So,
17 yeah, you will see all the different rules as we go
18 through the different data elements.

19 UNA CASEY: Okay. And then as you are
20 talking about E2B R3 data elements, there was a
21 question about when will the SBL routes of
22 administration and dose formulation code must be

1 harmonized for mapping with EDQM and then the ICH code
2 lists. Is there any work in that area, and when will
3 you publish your details?

4 SURGANJAN DE: So that will -- TJ will
5 help me answer that question. TJ, you want to go to
6 the microphone, please?

7 UNA CASEY: I asked that question
8 simply because the EMA have now published their date
9 for MoNDA-y, June 14 of R3, and they also speak about
10 the use of some of the ISO referentials, so it's just
11 having the harmonization in that area.

12 TAN-JEN CHEN: So the EDQM is a
13 complicated case. At ICH, it could be we committed to
14 use EDQM as a dosage form for submission. However,
15 when we tried to map our regional dosage from to EDQM,
16 we found that there's no one-to-one mapping. I mean,
17 try to achieve one-to-one mapping is almost
18 impossible.

19 I can give you a very quick example.
20 For example, we got at vail liquid filled gel that is
21 approved in U.S. as a capsule. Now, EDQM does not
22 have capsule; they have capsule soft or capsule hard,

1 so there's no one-to-one mapping in that case.

2 However, in E2B, we also said you can
3 use the basic dosage from use of rendering term, so
4 that a capsule is available for that, so we need to do
5 some transformation on our end. For U.S. domestic
6 product, you can continue to use EDQM. You would
7 select the one that is most resemble or most close to
8 your product, and we need to do some transformation on
9 our end. At ISO, we are trying to find out a solution
10 so that we can generate this global PHP ID, but that's
11 a separate topic.

12 TAN-JEN CHEN: Yes, it is.

13 UNA CASEY: Okay. So I just want to
14 just have a follow-up question on that. So if a
15 company is following the EMA spec, right, and they
16 just happen to pick an EDQM term to then send the file
17 to FDA, as an example, would you guys reject that file
18 because that's not the code that you are looking for?
19 Okay. Now, the company chooses a current SPL code,
20 would you accept that and not reject the file?

21 TAN-JEN CHEN: I mean, I think from my
22 -- and our last sentence was, I don't think we will

1 reject data element because the dosage form used EDQM
2 value on an SPL value.

3 UNA CASEY: Okay.

4 TAN-JEN CHEN: You know, if I have a
5 fatal report and I just reject a submission with
6 dosage form being incorrect, I don't think -- I mean,
7 I don't think you're going to hear I compliance folks
8 also agree to that. But I think we will still accept
9 it and we will figure out internally how to make and
10 do the appropriate conversion.

11 UNA CASEY: Okay. So that's like an
12 example of what you were trying to describe as that's
13 an optional field, meaning -- well, actually, let me
14 ask the question actually. Is it considered a maNDA-
15 tory field; meaning, you're just going to check to see
16 if anything's populated there, but you wouldn't
17 necessarily again reject the file if the term or the
18 code was not correct. So that's -- you understand
19 what I'm saying? It's like different levels of
20 conformance, right, or validation.

21 TAN-JEN CHEN: Exactly.

22 UNA CASEY: So that's what I was asking

1 about.

2 SURGANJAN DE: All right. Any other
3 questions before I move to the next topic?

4 TAN-JEN CHEN: Actually, let me also
5 jump in here. The dosage form in the E2B actually has
6 three data elements. So you can pick a term, then you
7 provide a version, or you can do free text. So we're
8 not going to reject because one of the element is not
9 mapping to what we need.

10 SURGANJAN DE: All right. So here,
11 we're going to -- so the next session, we're going to
12 go over the R3 regional requirements. I have, even
13 though I said in the sublet pre-market, combination,
14 and other regional elements, I just went over -- I
15 didn't divide that into pre-market and post-market. I
16 just went over the data elements sequentially by the
17 numbers.

18 So as you go through that, I will just
19 say which ones are specifically for pre-market and
20 which ones are for post-market. But within post-
21 market, you know, combination products are also
22 considered within post-market. So when I go over the

1 data elements which is specific to combination
2 products, just assume that they are post-market,
3 they're used for post-market.

4 Okay. So you have these, do have the
5 technical specification that was posted, of course, in
6 2016. We are working on updating the technical spec.
7 So the idea would be something like this: that end of
8 the day, there will be a package, like, how I see it
9 has an implementation type package.

10 So we'll have the FDA regional
11 requirements package, which will have a Word doc, a
12 pdf document which will be the technical specification
13 document, which will -- that will, you know, define
14 some of the data elements of the regional data
15 elements, which will then point to the spreadsheet,
16 which is basically listing of all the data elements in
17 the spreadsheet, and then also it'll point to the
18 hardware compatibility document, right.

19 And then the last thing which we're
20 going to have that I think we're going to put it into
21 the technical specification, the pdf document, are
22 snippets of the regional element as to how will that

1 look with an example XML, right. So if we had a field
2 called, you know, local criteria for reporting, which
3 is, you know, 15-day, 30-day, 5-day, 7-day which FDA
4 has, then how will that look in that snippet of the
5 XML, so that we'll put in the technical spec.

6 So to it could be a package of four or
7 five -- for three or four documents packaged together,
8 and they will be posted on the FDA's FAERS website.
9 But, again, prior to that posting of all the package,
10 we will definitely be sending out by, hopefully, by
11 end of this month the spreadsheet which I've been
12 talking about, so that will come to you by end of this
13 month. We will post that on the meeting page where we
14 post all of today's meeting where you will have those
15 documents available.

16 So going to into the regional
17 requirements, we have, you know, the regional
18 controlled terminology; especially we encourage
19 companies to submit the product names which -- that
20 they have been submitted as part of the SPL. Because
21 just to let you know that when the product gets
22 approved, you know, the final step, you're submitting

1 the as-structured product label wherever that goes to.

2 That, we get the data on a daily basis
3 and update our FAERS product dictionary, and that is
4 then -- those names are used to code the product name
5 that is in the ICS site. Of course, if it's a foreign
6 product, then we'll go through the older dictionary
7 and so forth and we'll do our research. But for all
8 the domestic products, we look at SPL.

9 So these are the different types of
10 reporting that you would probably do as part of your
11 submission where of course, also includes pre-market
12 reports.

13 So as I said, we had posted this on
14 June 23rd. Now, this technical regional
15 implementation specification does not include vaccine
16 reporting. They are a separate deck spec. But when
17 you see this Excel spreadsheet, there's one thing you
18 will notice: there will be many data elements.

19 Now, I need to also tell you this: the
20 way you see here post-market, pre-market, which has
21 its own conformance and business rule, there is a
22 column called FAERS and it has its own conformance and

1 business rule, and the reason being that, you know,
2 they implemented first. We have tried to harmonize
3 many, many data elements so that we use the same
4 observation code, we use the same data point, data
5 element name, data type, data length, and so on and so
6 forth.

7 But there are still some data elements
8 in FAERS where we are working with them to harmonize,
9 especially -- I think the key thing that is left to
10 harmonize is the code list values. Just because --
11 because FAERS implemented first the E2B R3, many of
12 the code list values were values that points to the
13 EVS enterprise -- NCI EVS values, which are the
14 sequels.

15 But now that we have come with the
16 concept of FDA OIDS, and in the beginning, he talks
17 about all the OIDS and dots and dots and dots and dots
18 and where it point to, I think now there is an
19 opportunity that we can manage our own OIDS and be
20 able to migrate all those code list into these OIDS so
21 that it can be totally harmonized.

22 But pretty much, most of the things

1 that are left overs are these code list values. And
2 as a result, what is happening is -- and you will see
3 in the spreadsheet -- is if there was a specific data
4 element, the unfortunate part is some places we have
5 FAERS needs this data element and we had tried to make
6 it as a one numeric because we have one for so-and-so,
7 two for so-and-so, three for so-and-so. But when you
8 start using sequels, you have to have that whole field
9 as an alphanumeric of probably six or eight.

10 I think that's the difference, and we
11 are still trying to harmonize that to get all into
12 making -- using FDA, all right, so we have control
13 over to add new values. All right?

14 So we do support all the ICH E2B R3
15 FAERS. We support all the R3 element, their
16 conformances. There may be very few variances, but
17 these variances we will see and they will be all
18 documented in the technical specification and the
19 spreadsheet of data elements, and then we will go over
20 some of the exceptions that we have in the next few
21 slides.

22 So first let's start with terminology.

1 So when we talk about terminology, we support MedDRA,
2 right. So you can submit -- we encourage to submit
3 the code because then it's easy; we exactly know what
4 the code list operating than the term. So we use the
5 lowest level term, so that's what we use, so MedDRA
6 numeric code rather than the LLT term, so that's one
7 suggestion. And we basically follow what ICH IG is
8 saying all about MedDRA, so there's not -- don't have
9 any variation in that.

10 So we support the UCUM codes, and for
11 terminology for the NCI EVS, we just talked about. So
12 if you send it, it's not going to be rejected. We're
13 just saying that we support this. We're not saying
14 that if you don't send it, we're going to rejected.
15 No, we don't say that. And for substance names, it's
16 just easier for us to call them if the name is used
17 which is registered in the global substance
18 registration system.

19 And, again, as we say, EDQM dosage form
20 and route of administration. We support that from a
21 perspective that, you know, if you send it and we're
22 not going to do any kind of rejection because you

1 didn't send me EVS, but you send me EDQM. No, we're
2 not going to do any kind of rejection.

3 All right. I need my glasses here.

4 All right. So the way, as I said, it does not really
5 -- when you see all the data elements as we go
6 through, they follow a pattern of the way the
7 numbering is, and that's how it follows a pattern.

8 And then I have defined that in such a
9 way that -- so here, it would say that you have a --
10 if this applicable to both pre- and post-market or if
11 you have something like this, then it is applicable to
12 pre-market or post-market. And then when you say only
13 business rule, that means the only change was a
14 business rule. But you may see some places where it
15 may say -- it may say something to do with data type
16 and business rules. So what your region has, areas
17 that has been updated, you will see that on the slide.

18 So for the first one, batch sender
19 identification, you know, sender should use the DUNS
20 number; that just makes it easier. We know exactly
21 what it is for the object identified, you know, the
22 right number it is. Yeah, so that's basically for

1 pre-market and post-market, the batch and the
2 identifier.

3 The batch receiver identified, that's
4 where we're looking for, you know, we use ZZFDA for
5 production, ZZFDATST will come to me with that. And
6 for pre-market, we will have ZZFD_PREMKT and
7 ZZFDATST_PREMKT. Then we send the same thing as part
8 of the acknowledgement, so we exactly know where it
9 comes from and what ICSR in your system you need to
10 update, the close the loop.

11 All right, message sender identifier.
12 Again, here, we're talking about the DUNS number for
13 both post-market and pre-market.

14 Then you have the message receiver
15 identifier. So here, we are talking about the message
16 receiver identifier to use for post-market CDER and
17 for pre-market, you have CDER pre-market and CBER pre-
18 market. I think what will happen is this actually
19 helps us. This is something we can, you know, debate
20 on if it's really required.

21 But the idea here is that when these
22 reports come in to FDA, especially from the pre-market

1 site, you may have a CBER IND and a CDER IND. So this
2 information can help us route the report to the
3 appropriate centers literally submission systems. So
4 today, as you are submitting this IND safety reports
5 in a pdf format through ECTD, for CDER, when you
6 submit that, that goes into a system in FDA called
7 dots, and the same system in CBER is called
8 (inaudible). That's where regulatory submissions are
9 stored.

10 Since these are -- these will come into
11 FAERS first. But to keep a record, to close the loop
12 for the entire IND, which will have so many other
13 documentations of which one is the ICSR. This helps
14 us to actually close the loop where we can send this
15 information of this submission record to those
16 regulatory systems and show them that, hey, we
17 received it and FAERS has it. So that was the purpose
18 of having this particular message identifier to be
19 used.

20 So safety report unique identifier, try
21 to use the same MCN number of the previously submitted
22 paper reports, and this is required for our processing

1 of cases. There is one part which we came out with
2 and I think I want to discuss that with you all, is
3 you have the very unique number now, right? So there
4 are only two numbers. Initially, in R3 -- R2 there
5 were a company, I think a worldwide and a safety
6 report ID, there were three numbers there. Now, there
7 are two in R3.

8 And the idea here is that as we are
9 implementing our core tool, the more and more what we
10 are seeing is I think we have to probably move towards
11 a norm. And the norm that we are looking at is the
12 worldwide unique number, that number does not change.
13 The safety report ID could change because, you know,
14 one company buys another company and there is a
15 marketing partnership between two companies and so on
16 and so forth.

17 So how do we make sure that the
18 initials and follow-ups are appropriately done. And
19 if we know that the worldwide unique number is not
20 going to change, then in that case, how about using
21 the worldwide unique number to do that check. But
22 currently in FAERS with R2, we are doing the check

1 with the manufacturer control number, which is the
2 safety report ID. All right?

3 And so, the thought process is that how
4 do we move. So the way to move is we will continue
5 doing that check, but as we see that the worldwide
6 unique number gets filled up in our database and as we
7 start the worldwide unique number, then we start
8 checking the worldwide unique number where worldwide
9 unique number is available because, yeah, we want to
10 be on the same page with everybody else and just not
11 be different or unique. So something to think about
12 if you -- you know, when you have your comment period,
13 just think about and see if this idea, you know,
14 works.

15 For the type of report we are seeing
16 for pre-market report and are used to report from
17 study. And then documents included both CDER and CBER
18 have harmonized on that, the data type is to be B64.
19 So we don't use compression for U.S. reporting and
20 encoding is limited to B64.

21 So then we have the C.1.7: Does this
22 case fulfill local criteria for an expedited report.

1 For both pre- and post-market, we're not supporting
2 the use of NullFlavor here, so which means if you said
3 true, that means it's expedited; if you say false,
4 it's not expedited because this has now become Boolean
5 field.

6 Now here is a new data element. So if
7 you see a prefix saying FDA, so we have FDA C.1.7.1,
8 we call it local criteria report type for use for both
9 post-market and pre-market. Max length is 1. Data
10 type is numeric. Values allowed: 1 is 15 day, 2 is
11 periodic, 4-5 day, 30 day, and 7 day.

12 This is the same values as we have in
13 R2 with the same fulfill expedited criteria because in
14 R2 that was a numeric field and not Boolean, so we
15 were able to use that field in R2 for these additional
16 values. So in R3, it's a Boolean field, so we have
17 added a new data element. And this conformance is
18 maNDA-tory, and the business rules for post-market is
19 you use day for 15 day -- 1 for 15 day, 2 for periodic
20 or non-expedited. The value 4 for remedial action, 5
21 for malfunctions; and for pre-market, you would use 1
22 for 15-day expedited and 6 for 7-day expedited.

1 And that has a code system, which is
2 this OID, and TJ will talk to you about all the
3 different OIDS after the break.

4 Next element, so case identified is
5 it's more warning than a rejection and acknowledgement
6 to say that if C.1.9.1 is true, then C.1.9.1 -- sorry.
7 If C.1.9.1 is true and C.1.9.1.r.1 is not provided, so
8 that's the source of the case identifier.

9 And then C.1.9.1.r.2., the case
10 identifiers is the rule there is again similar to the
11 previous rule; and for pre-market -- yeah, this needs
12 to go off. I think this was a typo or a copy/paste.
13 Yeah, when you do a -- you should not create slides at
14 midnight, then it doesn't work. So just ignore the
15 pre-market part.

16 FDA C.2.r.2.8, this is reporter's
17 email, which is pre- or post-market, max length 10,
18 alphanumeric, and optional.

19 Okay. When it comes to a study name in
20 pre-market, we're requesting for concatenate study ID
21 with the abbreviated trial name, so that the study ID
22 should be the same value used in the study tagging

1 file format in the eCTD submission.

2 All right. Next data element is a
3 regional element. If you have a study where reaction
4 events were absurd. Now, the reason why this was done
5 is that there's a concept called aggregate report.
6 And, you know, we have heard many times from FDA,
7 especially from merit that what the aggregate
8 reporting is, it's one kind of reporting. And initial
9 thought was, hey, if this value can it be not added to
10 this other study type. The other study type I think
11 today has three or four values. And if we try to add
12 this there and then the OID doesn't match because that
13 has its own OID, right, and that OID has been defined
14 and is part of ICH and it has got four values in
15 there, right. Which would probably say clinical trial
16 and, I forgot, the four values there, I know.

17 So if you're trying to add aggregate,
18 then we are violating the ICH rule. So in that case,
19 the only option that was discussed was to have a
20 specific data type, dictate a field which will have
21 aggregated in the future that it has its own OID, so
22 if you have any other allowed values, FDA has any type

1 of allowed values for other study type. I know we
2 will utilize this data element and not use the study
3 type where reaction event were observed; that is an
4 ICH data element.

5 So many of the data, some places you
6 would find these data elements. We had initially
7 thought of using the ICH data element just because
8 that ICH data elements has the code list values and it
9 is own OID and the OID goes with the data element, it
10 resulted in having FDA specific element in order to
11 accommodate these type of situations.

12 Now these two are very important data
13 fields. These are -- okay, the previous one is to be
14 used in the pre-market side. These two are also in
15 the pre-market side.

16 IND number where the adverse event
17 occurred. So basically, this is like the primary idea
18 where the adverse event occurred and not the cross-
19 reported INDs, all right, so you would have a separate
20 data element for the cross-reported INDs.

21 So this is a data element with max
22 length of 10. It's numeric, so you'll input in the

1 IND number only, the number part; it's conditional-
2 maNDA-tory. And it's based on I think C.1.3.e --
3 yeah, C.1.3 is going to report from study; the format
4 must be just a number. And this field is very
5 important because this actually routes the report to
6 the approved FDA medical officer and who is the
7 primary reviewer of the IND.

8 So the next field is we call it a pre-
9 ender where adverse event occurred, so now we have a
10 BA/BE trial. I think in the first or the second
11 session, we had talked about -- I think Karen had
12 comments. She had talked about the BA/BE trial on the
13 -- you know, try to end the application.

14 In this situation, we have a separate
15 field where you will submit only the number part, and
16 this will then route the report to the appropriate
17 reviewer in our Office of Generic Drug.

18 So the next field is IND number for the
19 cross-report IND, so this is repeatable, so now I
20 don't have to submit my (inaudible) reports on cross-
21 reporting. You have just one report. You just
22 mention the IND numbers of the cross-reported INDs.

1 So in this case, it's -- we have made
2 this -- yeah, in this, the last bullet would say is
3 Null Flavor applicable, NA; that is incorrect. I
4 mean, that has to be and the slash would not be there.
5 But the rule is that if you don't have any cross-
6 reporting, they just use a NullFlavor not applicable.

7 So this will be maNDA-tory if you have
8 filled in especially the pre-market side. If not,
9 then you could have pre- and there will not be a
10 cross-reporting IND, so that will be sent in as NA,
11 non-applicable.

12 All right, so next one is patient
13 initial name are initials D.1. So in this case, what
14 we are looking for is especially on the pre-market
15 side for aggregate reports, if you would enter the
16 patient identifier as aggregate. Now, of course, to
17 have an identifiable patient, you know, either age or
18 date or birth or sex or any of those data elements
19 must be available to have an identifiable patient.

20 But it just helps us to also segregate
21 this report where we see that the foreign aggregate
22 report on the pre-market side, if you have the --

1 because there is no patient, in this case, it was an
2 aggregate of a case series, maybe all related events.
3 So when you send ICSR for an aggregate, then here the
4 decision is to make the B1 use the word aggregate
5 there.

6 For post-market, we have combination
7 products. And with combination products, we could
8 have where just a malfunction occurred and that
9 malfunction occurred prior to reaching the patient, so
10 in that case there's no patient. But if you have to
11 do a check that, you know, you need to have at least
12 identifiable patient, the best way is to put the value
13 of none in the patient name or the patient name or
14 initial, so that will pass through.

15 And then there's a concept of summary
16 report in combination product. So in that case,
17 somebody is a -- somebody of, let's say there were 50
18 malfunction occurred on a particular batch of device,
19 then in that case, there's no patient involved, so in
20 that case you would submit that. You don't submit 50
21 reports. You submit one report mentioning about the
22 50 malfunctions that had not reached the patient; and

1 in that case, the patient initial becomes somebody.

2 Date of birth. If outcome attributed
3 to adverse event is death, then date is required for
4 pre-market only.

5 Next we have a regional element called
6 the patient race code. In this, we are basically
7 harmonized with the way CBER has done it, and that's
8 where they have used the C-codes and we have said
9 that's what we're going to go with. It's max line 10,
10 alphanumeric, and then you have those C-codes.

11 Okay. So in this one, the business
12 rule is incorrect, so just ignore that part. And the
13 next one also business rule is incorrect; please
14 ignore that part and cut it off, check it off.

15 We have the next data element, which is
16 the patient ethnicity code. It has two values. This
17 has been harmonized with the VAER system they used; we
18 use the same C-codes. And it's maNDA-tory, and
19 because they made it maNDA-tory, we also kept it
20 maNDA-tory, and you can use a NullFlavor. Please
21 ignore the business rule on this.

22 This is another field for required

1 intervention. In this case, this was a data element
2 which we have an element watch form also, and it is
3 maNDA-tory. And it acts same way as we have that
4 hospitalization, you know, those fields, life
5 threatening and the allowed flavors, NullFlavor. If
6 you don't have any information, then NA. And
7 typically used in device reporting on medication and
8 are reporting.

9 All right. Next one is
10 characterization of drug role, which is an existing R2
11 -- sorry, existing ICH data element. And in the pre-
12 market side, we're just saying that you would use 1 is
13 suspect, 2 concomitant, and 3 interacting. There is
14 one 4, drug not administered. So in the pre-market
15 side, only these three values are applicable.

16 All right. Now, in same situation
17 where we had the characterization of drug role where
18 if you have read the combination product, there's a
19 concept called similar device. And in there, the
20 concept is that you have an ingredient which was used
21 -- which was in a combination with, let's say, a
22 syringe. Now you could have another ingredient using

1 the similar syringe, so in this case, they're
2 considered a similar device.

3 So if you had an adverse event on the
4 first group, the first product, then you have to also
5 report about the similar product. Now how do you
6 identify that it's a similar product, right? It's not
7 suspect because the adverse event or malfunction did
8 not occur on that, right -- yeah, sorry -- did not
9 occur on that. But then how do you identify that?
10 Now if we had used a concept like the drug rule and
11 used it here, okay, the problem is this has its own
12 OID, right. Now, if I try to add it in this, then I
13 violate, I see its rule, right? So I have -- the only
14 way to do it is have something like this so that I can
15 have my own OID and the rules.

16 And in the future, if we have any other
17 kind, like similar device or something, which came up
18 very recently with the combination product rule. If
19 tomorrow there is something else that FDA comes up
20 with, then this data element gets used and then we
21 don't have to create any new elements or worry about
22 being non-compliant with a specific ICH element.

1 So with this, we call this data element
2 as every other characterization of drug rule, which
3 has, again, right now it has similar device, has only
4 one value. And then use 5, similar, when reporting
5 for similar combination product. It says each ICH
6 must contain at least one suspect interacting or drug
7 not administered. For a similar device, you could
8 G.k.1, drug not administered, and then if 5 is
9 reported, the malfunction must be true.

10 So here's the problem: that if you
11 submit an ICSR, you have to submit this with at least
12 one suspect or interacting or drug not administered,
13 right. So you cannot have just this tag and not have
14 this tag, so you have to have both of the tags.

15 So in order to have both the tags, what
16 do you do with the first tag, right? You're talking
17 about a similar product, right. But the similar
18 products are the only way we thought about it, that
19 similar product was not truly administered. So in
20 such case, if you look at that tag, then you will have
21 the drug characterization of the drug rule as drug not
22 administered, but the FDA regional characterization of

1 the drug rule is 1, which is similar device. So that
2 was the way -- that is what this is depicting and
3 saying that you use drug not administered for that
4 similar renewed reporting for that similar; that's the
5 only way this could be.

6 Now, again, when I'm mentioning all
7 this, in all the slides a little bit later, you guys
8 have time to think about it and send your comments to
9 us. And at the end, you know, I'm also open to having
10 maybe a WebEx even after we have finished the third
11 ePrompt meeting, so you guys can think about, you
12 know...

13 So in this, we have the medicinal
14 product I just talked about that I said this to use,
15 we're committed to use the SPL name, so the name which
16 is in the SPL file. And when you have the merits of
17 the products not provided, but active substance is
18 known, then provide active substance as it appears in
19 the global substance registration system. And if it's
20 a foreign product, then provide a foreign product
21 trade name used free text element, and then here we
22 will figure how to code that to -- we typically use an

1 old drug to look into that foreign product and code
2 that product. And then we have, you know, upload the
3 substance name. If it is registered NDA-, we're going
4 to use that substance name.

5 All right, authorization and
6 application number, especially in the post-market
7 side, you will have, you know, an NDA- or an ANDA-.
8 And how do you report that? This is how you would
9 report that because ICH doesn't have an application
10 type, so it has an authorization application number.
11 So the only way the FDA can identify is to prefix that
12 with an NDA-/ANDA-, and this is all on the post-market
13 side, all with the BLA. If it is no Rx, no
14 application, that six zeros; no Rx, no application,
15 six 9s, and for compounding, we use the comp99. This
16 still stays the same as we have in R2 today.

17 All right. Next is these are specific
18 elements for pre-market. So you have the source of
19 assessment, method of assessment, and result of
20 assessment.

21 In the source of assessment, you have,
22 you know, it's conditional-maNDA-tory if you have

1 report from study. And the recommenda-tion here is
2 defer to sponsor and include investigative assessment
3 in H1, and in R2, it's B.5.1. There is no rules set
4 here where there's a code list value, because this is
5 a free X field. I think it's 60 alphanumeric, I
6 think, or 30 alphanumeric, so are distinct to
7 recommending to put sponsors for sponsors this maNDA-
8 te.

9 And then for method of assessment, what
10 we noticed with our pilot program that we did was
11 there were various method of assessment. European has
12 their own, French has their own and all that. So
13 here, the method of assessment, we're saying FDA
14 because we are most interested in that. This helps us
15 to only pull information, even though the ICS could
16 have this as when (inaudible) has been sent to
17 different other agencies, but we will just, for review
18 purposes, we are most interested in the ones which are
19 -- whose method of assessment would be FDA, so we're
20 asking to default that one FDA.

21 And then finally, you have the result
22 of assessment. This, we are saying to use the value

1 suspected or not suspected, because you have so many
2 different variations that's related possible probable.
3 So our rule is CDS unexpected and suspected, right,
4 for the (inaudible). So is it suspected or not
5 suspected?

6 Okay. So now this is another field,
7 it's an optional field, called FDA specialized product
8 category. We just harmonized this with our VAERS
9 system. So in VAERS, we have this data point and
10 allowed values if you see it mostly with combination
11 products. Again, this conformance is optional. If
12 you have this information, then you could use it; if
13 not, these are optional, so there's no rejections
14 here.

15 And this is a new data element, which
16 will be either be (inaudible) or for pre-ANDA-. Now
17 this is the pre-ANDA- drug rule. This was something
18 that our Office of Generic Drug wants to know about
19 the product, and this is a 1 numeric value, so
20 identified as a test drug instead of reference or
21 placebo or a vehicle. And this is conformance is
22 optional, and that's the OID that you have here.

1 Next is malfunction flag, so here is
2 where we are going into combination products now.
3 From here onwards, I think most of the fields you'll
4 see to the end are combination product. So in this,
5 the combination product data field is malfunction. We
6 have harmonized this with VAERS. And it's an
7 observation code you see here, true or false,
8 conditional-maNDA-tory, and this field must be set to
9 true for at least one suspect product per ICSR if the
10 FDA C.1.7.1, it goes to 5. So C.1.7.1 would probably
11 3 data point I think, which is a malfunction.

12 This reminds me there is one data field
13 I think I missed, and the Excel spreadsheet will
14 probably tell you that. There's a combination product
15 flag. So I don't know the exact field number; it'll
16 still start with an FDA. But maybe during the break I
17 can find that out. It's called a combination product
18 flag, which says that it's a combination product
19 report.

20 All right. So next data element is a
21 follow-up, what type of follow-up. This was an
22 element which we have been using in R2. This is

1 repeatable. So now within the device block, now you
2 have this, so you have the entire product; within the
3 product, you could have multiple devices. And then
4 this is -- you could have one or more values where it
5 was a collection and additional information provided
6 of any -- one or more values could be used in the
7 allowed values.

8 Then you have the device problem code,
9 same C-codes. This is what has been harmonized with
10 CBER on vaccine combination products, so we're using
11 the FDA device problem code list. Yeah, many
12 questions have come, have we harmonized it with MedDRA
13 because MedDRA also does have the whole list of
14 problem codes. And, I mean, there are activities
15 which are going on and eventually making this
16 harmonized, but as of today, we are using the FDA
17 device problem codes.

18 Then we have the device brand name,
19 common device name and the device product code. So
20 these are three elements which identifies the device.
21 So you have a device brand name, which is the free
22 text field. And what we are seeing here is, I mean,

1 if you give us a brand name, then great. But then you
2 have the common device name and then you have the
3 device product code; at least one of them should be
4 there when asked to identify what the constituent part
5 of the device part is furthering that product.

6 So in such case, we have the device
7 brand name, which is at ATL for numeric, free text,
8 conditional-maNDA-tory, and conditional-maNDA-tory
9 just because it's a combination product, flag is
10 checked, then you have to mention about the
11 constituent part. Then you have the device, common
12 device name, which is again a free text, again
13 conditional-maNDA-tory. For the first and the second
14 rule, please ignore that. I don't know it's getting
15 messed up, but please ignore the business rule. The
16 business rule in the first and the second is if it's a
17 combination product.

18 Then the third one is device product
19 code. Device product code is a device product code,
20 it's allowed when using FDA device component codes,
21 which is available on FDA.gov so that they have a code
22 there. Alphanumeric 10 and conditional-maNDA-tory,

1 and the business rule in this case is that it should
2 be a combination product report.

3 And the next is the device is the
4 device manufacturer name; it's an optional field.
5 It's a free text alphanumeric. And device
6 manufacturer also will have address, city, that should
7 be state and this is country. So they are all
8 optional and free text fields. Of course, this is not
9 free text, but they're all optional.

10 Device usage.

11 One thing to remind before I post this,
12 I will have corrected the slides and posted.

13 The device usage. This is another
14 combination product datapoint. Data type, numeric 1,
15 and the values are initial use, device reuse, and
16 unknown. So, again, conformance is optional.

17 Next is device lot number, again,
18 conformance is optional. Operator of the device,
19 again, conformance is optional. All right.

20 Remedial action initiated. In this,
21 the conformance is conditional-maNDA-tory. And if
22 malfunction is true, you see C.1.7 is yes, local for

1 report criteria is 5. This is where the remedial
2 action type of report, which is to be submitted in
3 five days. Then these are the values that needs to be
4 -- these are allowed values for remedial action, and
5 you could have one or more values.

6 All right. So before we take a break,
7 this is the last slide here, and we are probably
8 early; we can have questions.

9 Linking initial and follow-up. This is
10 where I was talking about using the worldwide unique
11 identifier. So if the initial was submitted on paper,
12 but it's follow-up will be submitted electronically
13 include the safety report unique identifier from the
14 initial report in this and worldwide unique identifier
15 in a follow-up electronic submissions.

16 Always use the same identifier for
17 C.1.8 that was assigned to the initial ICSR when
18 submitting the follow-up report. So the second word
19 is very important because that will be used to
20 designate the follow-up reports because we're
21 expecting that that will stay the same and will not
22 change.

1 Now in the first case, the way we are
2 planning to set this up is we have many cases where we
3 just have the safety report ID, we don't have to worry
4 about any kind of device in our database because we
5 have been checking always with the safety report ID
6 for the initial and follow-up. We'll continue to do
7 that until we find that this worldwide unique
8 identifier now has got populated from your
9 submissions.

10 So let's say you had a follow-up
11 report. When you submit the follow-up report, the
12 report comes in. It has got safety report unique
13 identifier and it has got the worldwide. Now, our
14 database, let's say, doesn't have the worldwide; we
15 will still check it with the safety report unique
16 identifier. We'll say, yeah, it's a follow-up. When
17 we update our database, we'll update the database with
18 now the worldwide unique identifier. Now the
19 worldwide unique identifier is available.

20 Next follow-up that you have, then the
21 check will happen saying that, yes, worldwide unique
22 identifier is available, let me check with that, find

1 out if it's a follow-up, yes, it's a follow-up, and
2 set it up as a follow-up report. So that way, you
3 know, probably in a few years, all of our reports will
4 have the worldwide unique identifier and we are
5 checking everything with the worldwide unique
6 identifier.

7 So with that, these were/are basically
8 the data elements, regional elements that we propose
9 for FDA. And with that, you know, if you have any
10 questions now you want to ask, just go ahead. If you
11 have anything you will think about later, then you
12 have the docket or send it to the ePrompt email
13 address.

14 MAN 1: Hi, Suranjan. I just have a
15 couple of questions. Go back to your --

16 SURGANJAN DE: You can't have
17 questions.

18 MAN 1: I have questions. Go back to
19 your last slide. I just want to make sure that the
20 vendors know that their names should not be in there;
21 it should be the sponsors.

22 SURGANJAN DE: Yes, yes.

1 MAN 1: Because we're getting some
2 questions about resubmissions, resubmitting and things
3 like that, so it should all be the sponsor.

4 SURGANJAN DE: It's always the sponsor.
5 And especially what we have also seen is the sender
6 organization names, especially when you have a Seattle
7 working, okay; the name in the sender comes with
8 Seattle's name. Now when we go into compliance,
9 you'll say, hey, how many reports submitted in 15
10 days, how many reports were late, how many reports
11 were this.

12 They all run based on their sender
13 organization. And when we look at that, we said, hey,
14 it's Seattle's name; we can't go behind the Seattle,
15 we have to go to the sponsor, right. So it's very
16 important that, especially when any Seattle is setting
17 up their systems to make sure that the sender
18 organization information is about their client or
19 their sponsor and not theirs.

20 MAN 1: The other question, can you go
21 back to the slides on drug roll. I was confused with
22 this. For the initial drug roll, you have three

1 things: you have suspect, concomitant, and drug
2 interaction. Go to the next slide.

3 SURGANJAN DE: This?

4 MAN 1: That one right there.

5 Shouldn't no. 4 be not administered?

6 SURGANJAN DE: This is only for --

7 MAN 1: Is this R3 or R2?

8 SURGANJAN DE: This is R3, it's only
9 for pre-market.

10 MAN 1: This is only pre-market, okay.
11 Maybe that's where I was confused.

12 SURGANJAN DE: When you have pre-
13 market, then this. So when you have post-market, then
14 you have this for -- I mean, in this case, there is no
15 --

16 MAN 1: There is no 5, right?

17 SURGANJAN DE: No.

18 MAN 1: There should be a 1, right?

19 SURGANJAN DE: So 1 is suspect, I
20 think.

21 MAN 1: No, 1 in this slide should be
22 just similar device.

1 SURGANJAN DE: Because this is a new
2 field.

3 MAN 1: It is a new field.

4 SURGANJAN DE: Right? So when this is
5 a new field, when you set up your tags, your first tag
6 in the drug will be this tag. The second tag will be
7 this tag.

8 MAN 1: Exactly.

9 SURGANJAN DE: 1.

10 MAN 1: Yeah. So the first one, even
11 though it's pre-marketing, post-marketing would use it
12 too.

13 SURGANJAN DE: Yeah, yeah, yeah.

14 MAN 1: And then you'd come or you need
15 to report similar device. This is where you'd only
16 use this field.

17 SURGANJAN DE: Correct. So what I'm
18 saying here is that if when you use this tag to say
19 similar device, you need to make sure that this tag
20 should have one of these, at least this.

21 MAN 1: Exactly, and I would think the
22 first tag would have to have drug not administered,

1 which would be no. 4.

2 SURGANJAN DE: Which is no. 4.

3 MAN 1: Which is back in the old field.

4 SURGANJAN DE: Exactly, okay. In this
5 old field, if I would have given another bullet saying
6 post-market and would have said a business rule that
7 only use this for, which is stanDA-rd, which is an ICH
8 stanDA-rd.

9 MAN 1: Right.

10 SURGANJAN DE: So that's why this is,
11 there was no variation, in this slide, I did not put
12 another bullet to mention about post-market.

13 MAN 1: And there is no 5.

14 SURGANJAN DE: And there's 5. And
15 initially, when we had planned -- remember that we had
16 --

17 MAN 1: That should be a 1, so use a 1
18 in there.

19 SURGANJAN DE: Oh, yeah, yeah, yeah.
20 Yeah, it is 1, sorry.

21 MAN 1: There is no 5, okay, it's a 1.
22 And go back to the other one, it should have 4.

1 SURGANJAN DE: Now, yes. And so, in
2 this case, yeah, you will use 1 as similar device.
3 It's a 1, sorry. Yeah, it's a 1.

4 MAN 1: When you go over the slides, it
5 would be helpful to clarify the business rule.

6 SURGANJAN DE: Oh, yeah. No, I think I
7 need to explain this a little more, maybe with an
8 example, I'd probably make it clearer.

9 MAN 1: So Suranjan, for pre-market for
10 G.k.1, there's no expectation of used drug not
11 administration because the FDA doesn't want screening
12 cases like the ICH requires. That's the key.

13 SURGANJAN DE: That's the key, yeah.

14 MAN 1: That's the message you get
15 across, even though it's the same field.

16 WOMAN 1: I have a follow-up question
17 for the aggregate reports. Are those aggregate
18 reports from a compliance perspective should have a
19 relationship with, like, the summarized data sets that
20 will come in in SDTM, because they have, like, an AE
21 domain and they summarize all of that.

22 SURGANJAN DE: Right.

1 WOMAN 1: So I was just curious about
2 that in terms of the relationship.

3 SURGANJAN DE: I think the way I
4 understood from Office of New Drug. So they have this
5 concept where you have, you know, like similar events
6 and you have -- you may have submitted individual
7 ICSRs.

8 WOMAN 1: Right.

9 SURGANJAN DE: Right?

10 WOMAN 1: So if it's an IND safety
11 report, you'd follow the ICSR rules for that.

12 SURGANJAN DE: Right. I'll make the
13 connection.

14 WOMAN 1: Right. And then, and I was
15 just trying to make the association between the
16 individual reports, the aggregate reports, and then
17 how that maps ultimately to the summarized data sets
18 that come in SDTM. And, again, it may not necessarily
19 be for this group, but that's what I was thinking
20 about and trying to make notes about.

21 SURGANJAN DE: Yeah. Let's put this as
22 a question.

1 TAN-JEN CHEN: Why it mapped, yeah.

2 WOMAN 1: Okay.

3 TAN-JEN CHEN: Come back to the safety
4 SDTM AE domain, yes.

5 WOMAN 1: Okay. Because I was thinking
6 more for a compliance when you're kind of explaining
7 that to a client that uses a CRO. So like Roger was
8 saying, when they're submitting those reports, again,
9 for ICSR, you can't use the CROs sender ID.

10 SURGANJAN DE: Yeah, exactly.

11 WOMAN 1: You have to map it back to
12 the sponsor.

13 SURGANJAN DE: To the sponsor, yeah.
14 And also with the aggregated report, another thing is
15 you may have something unusual ICSRs. But now when
16 you do the aggregate, you look for, you know, some
17 similar events which you have identified and have
18 written a summary, an aggregate summary about that
19 case series that you have. That aggregate results to
20 a single ICSR, but then under the link reports --

21 WOMAN 1: Oh, yeah, that's where you
22 put those.

1 SURGANJAN DE: -- you use those
2 individual reports that you have already sent.

3 WOMAN 1: Yes, got it, okay.

4 SURGANJAN DE: And so that way, we can
5 make the relationship saying that, hey, this was
6 aggregated based on these five reports that you
7 already submitted, right?

8 WOMAN 1: Yeah, got it, okay.

9 SURGANJAN DE: And then you can still
10 have a follow-up, right, for the aggregate where you
11 say, hey, I had filed three more reports. Now, those
12 three reports, also you have sent individually. And
13 now when you send the follow-up on the aggregate, it
14 will be easier to manage to say, hey, yup, the
15 worldwide unique number is the same, it's a follow-up.
16 And under the link report now, you don't have these
17 five, but you have this eight now, and that makes the
18 relationship and the connections. And it also makes
19 the relationship and the connections such a way that
20 when I go and click on that link report, it now opens
21 me.

22 WOMAN 1: Right.

1 SURGANJAN DE: It's the individual ICS
2 up on that link, of course.

3 WOMAN 1: Okay. And then the other
4 question I had was related to the device data
5 elements. Assuming that is harmonized with EMDR or is
6 it the MedWatch form? I mean, I know they have the
7 same elements.

8 SURGANJAN DE: MedWatch, but I think
9 EMDR, their version is based on MedWatch because when
10 they started. But all of the elements that we had
11 have here are basically the elements which come from
12 MedWatch.

13 WOMAN 1: Oh, okay.

14 SURGANJAN DE: So these same elements
15 are in R2 and these are the elements we just
16 (crosstalk).

17 WOMAN 1: Okay. And the reason I was
18 asking was, again, because just trying to pay
19 attention to, like, any field length differences
20 between, you know, again, a company who is doing EMDR
21 reporting, which is separate from ICSR. But if they
22 want to try to again harmonize to --

1 SURGANJAN DE: If you find any fee
2 length differences, please let us know.

3 WOMAN 1: Okay.

4 SURGANJAN DE: Because we still have
5 the opportunity now here to, you know, update the
6 length.

7 WOMAN 2: I have a few more questions.
8 So the first one was about the business rule sheet
9 that you spoke about, and you said the second tab will
10 have the ex-path details listed there. And it was
11 really to find out where they also include the ex-
12 paths for eVAERS as well?

13 SURGANJAN DE: Yes, everything into
14 one. I think what will happen is afternoon, I'm going
15 to have my laptop set up to show the E2B validator.
16 At that point, I can open up the spreadsheet and show
17 that to you. I'll do that because, unfortunately,
18 this is connected to the rooms computer. But
19 afternoon when I do that, you know, please remind me,
20 I can show -- open up this whole spreadsheet for you.

21 WOMAN 2: Okay, and then another
22 question to find out if the validator. Will it also

1 work for vaccine reports, eVAERS, especially for the
2 combination products?

3 SURGANJAN DE: Currently not.

4 Combination products, it will work for the combination
5 products. But if it's vaccine specific, no, but that
6 is not included in that validator. Now, of course,
7 there are future plans to put vaccine into here, but
8 no, not presently.

9 WOMAN 2: Then for the aggregate
10 analysis reports. Is it possible to have a sample
11 file snippet in Excel or something for the aggregate
12 analysis reports?

13 SURGANJAN DE: So for the aggregate
14 report that we're talking about here.

15 WOMAN 2: Yes.

16 SURGANJAN DE: This is an ICSR.

17 WOMAN 2: Yes.

18 SURGANJAN DE: It is considered at an
19 ICSR, right?

20 WOMAN 2: Exactly.

21 SURGANJAN DE: So it will be in ICSR
22 where the type is aggregate; basically, that's where

1 we have an FDA other study type that we have
2 introduced where it would -- your type of report is to
3 a report from study, and then every other report type
4 would say one, which is aggregate, and then your
5 narratives will define -- I'm sorry, will explain the
6 aggregation and some of the similar events and all
7 that kind of explanation. And your linked reports
8 will then point the ICSR numbers, the manufacturer
9 control number and the safety report ID of all those
10 individual ICSRs.

11 So this will be considered as its own
12 entity as an ICSR, and then that's what you would be
13 submitting to.

14 WOMAN 2: Yes.

15 SURGANJAN DE: And that would also be
16 checked.

17 WOMAN 2: We understand that and we can
18 put one together based on the business rules sheet,
19 but it would be helpful to have a sample file.

20 SURGANJAN DE: Oh, sample file, okay.

21 WOMAN 2: Customers, some of our
22 customers don't have a lot of experience with the

1 aggregate in these reports either. So just having a
2 sample to see what it looks like.

3 SURGANJAN DE: Sample file, okay.
4 Yeah, let's document this so we can have -- I mean, I
5 think based on Ray's question, I think what is
6 expected, I think that is something which we can
7 provide as a sample and then during testing, test the
8 aggregate report.

9 WOMAN 2: So I have got quite a few
10 questions, so I'm only trying to pick the ones that
11 link to something that you mentioned during the
12 session that's just taken place. So you did touch on
13 the BA/BE studies. Again, can you provide sample
14 files for those types?

15 SURGANJAN DE: A sample file for those.
16 Yes, we can do that. Yes, we can do that.

17 WOMAN 2: And can you remind us of the
18 timelines for the BA/BE studies; where do they fall in
19 terms of when customers will need to start using that
20 format for reporting.

21 SURGANJAN DE: So for BA/BE studies, I
22 think -- yeah, when the guidance. I think we

1 currently still have a draft guidance, right? So when
2 the draft guidance finally becomes final, then from
3 that point, we are --

4 WOMAN 2: (Off mic).

5 SURGANJAN DE: Yes. Because now
6 there's a conformance document and then there is the
7 technical spec documents and then the 745 is the
8 binding thing. So they are all in the draft stage,
9 which has been published. So once they are made
10 final, then from that point, two years.

11 WOMAN 2: Okay. Then for the data
12 element, C.1.7 for expedited reporting, you talked
13 about the 7-day option. And it's really just to find
14 out if the MedWatch form will be harmonized as the
15 MedWatch describes the use of 7-day for blood ICSRs
16 involving blood supply products. The instructions
17 don't list it as being specifically for fatal and
18 life-threatening ICSRs, and it's just to find out if
19 there'll be harmonization between those two.

20 SURGANJAN DE: Okay, yeah. Let's
21 produced down question because that needs to go to a
22 whole different group to check and see if that...

1 WOMAN 2: Okay. So you talked about
2 the business rule sheet being published at the end of
3 this month. Currently, it's draft, then you're going
4 to receive our comments. Do you have a timeline for
5 when that business rule sheet will become final?

6 SURGANJAN DE: So my target is to get
7 that business rule pretty much final by end of summer.
8 If we're going to get it final by end of summer, then
9 after your comments, because if some comments come
10 that has a change to our system, then, you know, we'll
11 have to accommodate that. But, hopefully, by end of
12 summer, we plan to have that, the business rule
13 document finalized, so that we have received all your
14 comments.

15 WOMAN 2: (Off mic).

16 SURGANJAN DE: End of August, yeah.
17 Towards September, if you want, if you want to give
18 this, the validator out, I would probably see that
19 getting it final by August.

20 MAN 1: Suranjan, can we go back to the
21 causality block. You have some default values that
22 you're expecting in the source method and result tags.

1 So here in the first one, the source you mention
2 include the investigator assessment in H1, the
3 narrative block. Is that telling me that you don't
4 want the investigator assessment in the structured
5 causality block or you'll accept it if it's in this
6 metric block?

7 SURGANJAN DE: We'll accept it, yeah.
8 If it's submitted, we'll accept it. In this, we are
9 not rejecting anything here; we'll accept it. If you
10 say investigator and FDA and suspected, yeah, we will
11 still accept it.

12 MAN 1: And are you also conditionally
13 maNDA-ting that at least one of the drug event
14 assessment is what the value sponsor it's suspected?

15 SURGANJAN DE: Yes, that's the -- yeah,
16 that rule, which is -- which we are expecting that you
17 at least have one suspected sponsors' assessment.

18 MAN 1: Okay, thank you.

19 MAN 3: Hi. Real quick question about
20 the NullFlavors and the approach that FDA is taking to
21 those because those can be kind of tricky. At
22 Astellas, we implemented both the PMDA and the EMA R3,

1 and we found that during those implementations, their
2 use of NullFlavors differed in terms of some things
3 that they would accept and not accept. So those
4 differences made for some tricky mapping and
5 conventions, if you will, about how we're going to use
6 that.

7 So I'm just curious if the FDA has put
8 some thought on which values are going to be accepted,
9 if they're just going to use stanDA-rd ICH across the
10 values?

11 SURGANJAN DE: Yeah. We have -- I
12 don't think we have any value we have used, which is
13 not in ICH, it's NullFlavor values. Right, TJ?

14 TAN-JEN CHEN: We may have different
15 rules. We need to go back and check.

16 MAN 3: My question is more than that,
17 not focused on if you're going to be introduced non-
18 ICH values, but rather if you're going to just simply
19 exclude or not accept certain ICH values as PMDA did
20 because there are certain ones that they just don't
21 accept, even though they're ICH values. And so -- and
22 EMA does, so we found that we had kind of a conflict

1 in the way we had to enter those and map those.

2 SURGANJAN DE: Yeah. I think from our
3 side, I do not see we will be rejecting anything where
4 you have, like, different -- six steps of let's say
5 NullFlavors. And I don't think we have any rules
6 which says, yeah, don't use this and don't use that.
7 There may be some data fields where we may -- I think
8 one or two data fields where we may have said that the
9 NullFlavor wasn't -- I think there's one or two data
10 points where I do remember that the NullFlavor only
11 could do this, this and that, all right, because it
12 just made sense for that particular data point.

13 I don't know where one of the fields I
14 remember we have said that, to use unknown or not
15 applicable or no information. Like, for example,
16 required intervention. So that was one field where we
17 said to use only NI, no information. And that's how I
18 think if you take this field acts very similar to the
19 data field like that life-threatening, hospitalization
20 whose values allowed a true all the NullFlavor NI, so
21 it just stays the same. So we didn't want to make any
22 exceptions there and keep it the same way.

1 If you find something once you see this
2 slide, you find something, please let us know because
3 as much as possible we want to make this as stanDA-rd
4 as possible and not get into too many exceptions.

5 All right, any other questions? If
6 not, I think we are right on the time for break, so we
7 come back at 11:20.

8 (Off the Record.)

9 SURGANJAN DE: All right, so let's
10 start with the next item on the agENDA-. So until
11 now, we heard about the FAERS 2 updates and we went
12 over the E2B(R3) regional data elements. And thank
13 you for all your question that you've had for the
14 first two sessions.

15 So the third session now after the
16 break is the review of FDA-specific object identifiers
17 and you did see that some of the FDA regional data
18 elements have these OIDs mentioned and T.J. will talk
19 about -- to we have T.J. Chen who is a project manager
20 from Office of Strategic Program in CDER and he's
21 going to be talking about these FDA-specific OIDs,
22 what was the concept behind it, how these OIDs were

1 instituted, and then assigned to the appropriate data
2 elements. So with that, T.J., all yours for...

3 TAN-JEN CHEN: And the controller is...
4 All right, thank you, Suranjan, and thank you
5 everyone. I think I have spoke about object ID
6 before, but anyway, we're going to do it again. So
7 I'm going the wrong direction. Right. Very good.
8 It's before lunch, you know. Okay. So object ID or
9 object identifier, OID is a sequence -- normally is a
10 sequence of number and separated by dot. Okay, and
11 it's used in the computer world to uniquely identify
12 an object.

13 It's a tree structure, okay, so you can
14 -- you have a trunk and then you have branch. The
15 branch can have more branch, just keep going on, and
16 in the end it reach to the end point will be the leaf.
17 And at any point of the branch, there will be a ID
18 that is corresponding to that particular object. The
19 OID started by the ITU, the International
20 Telecommunications Union, as the standa-rd for the
21 telecommunication use.

22 And then ISO get involved and so it

1 created this three -- you can call it three trees,
2 okay. It start -- it always start with either zero --
3 it means this is all assigned by ITU -- or start from
4 one. That is ISO. I think we mentioned about ISO
5 country called the (inaudible). I know that if you
6 look at their OID, it will be, like, 1.0.3166. Okay,
7 so by looking at the number 1, you know it's coming
8 from ISO.

9 Zero means it's a stanDA-rd and then
10 the 3166 is a country code. If you see anything start
11 from 2, those are the trunk or the branch starting
12 from the joint ISO-ITU and you're going to see most of
13 those coming from 2 nowadays. So then the object can
14 be represented as a sequence of number, like -- okay,
15 like here you see the 2.16.840.1.113883.6.163. Every
16 number along that sequence represents something.
17 Again, we start with number 2 is a joint ISO-ITU tree
18 and then the first branch out of that tree is number
19 16, which is country.

20 And then the 840 is U.S. And then
21 within U.S., you have .1 is a organization and then
22 113883 is HL7. And then after the HL7, they assign

1 external system number 6 and that system is 163,
2 that's major. So any organization along the tree can
3 register themselves as a registrar, okay. HL7 decided
4 to become a registrar, so if we need a OID, we can go
5 to HL7 and get a OID assigned from that particular
6 branch. Once you get it, you can register yourself as
7 a registrar if you like and then you can start to
8 assign OID to other organization.

9 And if you register as a registrar, you
10 can search the OID and that, I think it's called OID
11 repository. If you go there, enter the sequence, you
12 will find out who -- you can find out a whole branch
13 until the point that the recipient not register. So
14 next one I can -- well, okay. Before that, okay. So
15 why we talk about OID. OID is particularly important
16 with HL7 model V3.

17 In the V3, as you can see, there's a
18 diagram there. There are two classes that I'm -- kind
19 of highlighted. I'm going to kind of blow it out in
20 the next slide. In the HL7, there are data type like
21 CE, CD, those data are even II. Those data type --
22 again, HL7 data type is complex data type. A lot of

1 data types are complex data type. There are
2 attributes within the date type. So give you one that
3 we use a lot, address. HL7 has a data type called
4 address, okay, that is for you to do modeling.

5 But when you go to address, it break
6 down into street, city, state, even have -- I mean,
7 you can repeat street many times. Okay, so HL7 data
8 type is complete -- complex. And this CE data type
9 allow you to transmit a code. But in order for you to
10 understand what a code means, you to provide a code
11 system. And the code system is an object that you
12 need to be able to identify in a computer world.

13 So the code system normally is -- we
14 use OID for the code system. So this -- and also,
15 besides the data type, the HL7 class itself can also
16 use code. This one, we are looking at is observation
17 class, okay. Observation class has certain attribute,
18 as you see here. One of the attribute is called code.
19 So you assign a code to the observation class to let
20 people know what kind of observation that you are
21 performing, okay.

22 So if you make a code as a body weight,

1 then you're observing a person's body weight. If you
2 make a code as height, then you observe -- you are
3 observing a person's height. And in the -- in certain
4 event, for example, if you make a code of seriousness,
5 then you are observing how serious is the event. So
6 the observation class code will keep changing and in
7 order for you to know what code it is, you need to
8 refer to a object ID. Here, we have this HO& -- well,
9 ICHC13 type of report. As you can see, the code could
10 be 1, 2, or 3.

11 Actually -- yeah. And you need to
12 provide a code system so that you know this is a ICH
13 report type. Okay. Like, Suranjan mentioned earlier,
14 we also created FDA regional data element and to do
15 that, we reused the -- we need to fit into HL7 model.
16 So we reused this object class and then use a
17 different OID to show that if you pick that OID and
18 provide a code, then we noticed this will fit FDA
19 regional or local criteria report type.

20 Same thing here. This is about II.
21 Again, II, an instant identifier, has a root and then
22 the extension. The root can be a OID also, so you

1 know what ID you are assigning to. So again, let me
2 go back to that OID tree. At ICH, we went to HL7 and
3 acquired an ID so HL7, if you see that 113AA3, that is
4 HL7. So HL7 assigned that 3 which is a external root
5 and 989 to ICH. And ICH received that note or the
6 branch, then we start to assign further branch out, so
7 we assign number 5 for regional regulator.

8 And then that one for subregion, that 2
9 then is FDA. I think that 1 is -- I think it's EMA or
10 PMDA. So every regulator gets a branch out of this
11 ICH. And once we received that it's like you have --
12 like, when you go to a company and company give you a
13 shared drive on the network. So what do you do first?
14 You create subfolders, right? You're not going to put
15 everything in the same folder.

16 So this is what we do, okay. we create
17 a subfolder, .1, after the FDA branch for FAERS and
18 then dot -- as you can read this, I mean, this again,
19 started from the joint ITU number 2, country, and all
20 the way down and then you see FAERS highlighted and
21 that 2 is for eCTD. So in the future, when eCTD start
22 to assign regional information, they will start with

1 .2, okay, and when FAERS receive .2 from FDA, again,
2 FAERS is going to create subfolders, right.

3 So we use .1 -- well, we have this .1
4 then we'll create .1.1 for the co-list and .2 for the
5 name space and .3 is the HL7 observation class with a
6 class code that are not provided by HL7. Okay, so if
7 you see the number 2 and number 3, any number assigned
8 to that is the end point, is a leaf. Okay, they
9 cannot further branch out. So in a .1, then we create
10 certain co-list.

11 Okay, you may already see that in
12 Suranjan's regional data element. The .1.1.1, the
13 green one, is a local criteria or a local -- local
14 criteria reporting type, okay, and you should see the
15 value. I'm sorry, I kind of mess up -- mixed up with
16 the animations. You should see the green ones with one
17 for 15, two for (inaudible) periodic, right. And then
18 the .6 would be the operator for the device. Okay.
19 And one step up for the 2.

20 Again, we -- it's a name space. So
21 there will be no list of value. So if you see the --
22 well, I'm going to read it. If you see

1 2.16.840.1.113883.3.989.5.1.2.1.2.1, then it's a
2 primary IND. So when you give us a report with a
3 number, we need to know what number it is and whether
4 it is a primary IND or is a primary pre-ender. So by
5 giving us the code, we know what it is. And again,
6 observation code, same here. Suranjan mentioned about
7 a combination (inaudible).

8 It's again, it's observation of the
9 report type and when the observation equal to
10 combination product (inaudible), the value tell you
11 yes or no. Okay. Same thing a single-use device. So
12 that's pretty much about OID and during the break,
13 Lee's going to ask me about why we use some of the
14 NCIC code and why we use some of the FDA regional
15 code.

16 The thought behind that is when --
17 well, first, to begin with, EVAERS implemented before
18 FAERS and at that time, a lot of code system like IDMP
19 for the dosage from the medicinal product ID, those
20 are not available. So EVAERS use SPL dosage
21 (inaudible). And those point to NCI EVS. And so when
22 we try to harmonize with EVAERS, we take that into

1 consideration, race code being 1. Okay race code
2 point to NCI EVS, so we were like, okay, do we create
3 our own OID and a list of value? Then we think about
4 it first.

5 That is not something controlled by
6 FDA. It's actually a OMB controlled list. So we're
7 not in the business of taking a copy of that and
8 create our own regional copy, right, and also EVAERS
9 01:49:27 share data with CDC. So by using a NCI code,
10 that will make sense. So the thought behind it,
11 behind the whole creation of regional code is if the
12 code is available internationally and used by multiple
13 partners, like ISO country code, we're not going to
14 mess with it. Okay.

15 If that's a code used regionally by
16 multiple agencies or even within FDA by multiple
17 centers, we are not going to mess with it. Okay.
18 then if those code really pertaining to FAERS
19 reporting like FDA local report criteria, I mean, who
20 else care? I mean, that's not even provide to CDC.
21 This does not apply to Japan, right, so that is
22 something we truly own.

1 And if for some reason that is a new
2 report that coming up in the future, we don't want to
3 go to NCI and plead them to add a code for us that
4 nobody else would use, only us, right. So when we
5 create regional code list based on the thought.
6 During the implementation, we have discussion with
7 some of the vendor and we heard that some people
8 implemented in a different way. I don't know it's
9 true or not, but I was told that some regulator took
10 ICH OID and make a extension to it as a subversion and
11 create that list behind it.

12 I need to verify that, but this is not
13 a good approach, okay. You only manage the branch you
14 own. You don't manage the branch that you don't own.
15 Okay. Other than that, I don't think there's not much
16 to go on with OIDs. I mean, this is a technical
17 thing, but welcome any question if you have.

18 SURANJAN DE: Yeah, I think this
19 session I asked you to do this to get in just for you
20 all to see a view of, you know, when these elements
21 that I described in the previous sessions and you saw
22 OID number, where did this OID number come from? I

1 think that's what's important for you all to know,
2 that this came from here, because when you go into the
3 ICH IG document, you will not see that OID anywhere.

4 So that's -- was the whole intention of
5 this presentation for T.J. to show where these OIDs
6 are coming from, how we are using it, where did we
7 think to use OID, where did we decide to not use OID,
8 and what was the best method of using OIDs, as you
9 heard from T.J. that, you know, some regions just made
10 a subversion of this, added their criteria, added
11 their code list value into it, and said, hey, this is
12 what we're going to be using.

13 But then you're not managing your own
14 OID, but you're managing somebody else's OID. Also
15 sometimes, we've also heard that, you know, you take
16 that OID which ends up in ICH and then to that OID --
17 of course, to that OID you have created a subversion
18 and added your additional new code list value to it,
19 so tomorrow, what happens to the main OID where let's
20 say, ICH decides in the future, hey, that new code
21 list value, new value next to come in, that doesn't
22 match with this and if you had values of 1 through 4

1 and now you have already added five with some value,
2 but now I see it says five means this, what happens to
3 those things.

4 So I don't -- those kind of
5 discrepancies come into picture so, yeah. Thanks,
6 T.J., for explaining this whole OID thing because it's
7 important that our audience and our sponsors
8 understand what are -- what is going in our thought
9 process of introducing OIDs for some of the regional
10 data elements.

11 TAN-JEN CHEN: Yeah, actually talking
12 about regional data element, I also like to share some
13 of the thought that we had. A good example is a
14 similar device the similar device. So for the --
15 since we're using the same HL7 model, right, we are
16 using the same -- I don't know if that's this guy.
17 Let me take a look. No, not. Okay, anyway. So if
18 you're familiar with HL7 model, you are taking from
19 the investigation or event and go traverse the classes
20 and go to the node, right.

21 So the drug role for the similar
22 product would actually use the same data element of

1 the drug role. So if you look at that as the same X
2 path, okay, on the model, you go to the same location.
3 So at one point, we were thinking, okay, let's just
4 reuse this data element and instead of code it out as
5 a separated item, you use the same data element and
6 then use a different OID and different value. And
7 that's why you see number 5.

8 Okay, so we try to maintain the same
9 data element in HL7 and then you will see as -- you go
10 to the same place but when you want to report similar
11 product, all you need to do is swap out a OID and then
12 pluck in value 5. Okay, so in that case, you will
13 still be able to report similar product. And then we
14 discover, well, after discuss with, you know, some
15 technical people, and they feel like it make the
16 validation a little difficult because X path now need
17 to swap back and forth with the OID.

18 So the recommeNDA-tion is to yank it
19 out. Code it out as a separated item. But because we
20 code it out as a separated item and the original data
21 element is maNDA-tory, so now you have two data
22 element. If you don't code it out as a same data

1 element, it's maNDA-tory, you just say number 5,
2 similar device, you're done. But since you code it
3 out, now you have two data element and the first one's
4 still maNDA-tory.

5 So what do you do when you report
6 similar? And that's why, you know, the suggestion is,
7 then you use -- do not administer. So that -- those
8 are some of the thought process we had when we created
9 the regional data element and how we assign regional
10 OID. Hope that helped.

11 SURANJAN DE: Also with some vendors,
12 we were talking to some of the technical folks, they
13 said hey, now you're saying one field but two OIDs.
14 So you're telling that during submission, you have to
15 swap that and figure out how to swap that, at what
16 instance you will swap, and what instance you will
17 not.

18 So that was something else, yeah, that
19 is not going to be an easy thing to and also storing
20 that, where typically most of the tools you would kind
21 of store in a way, saying that this is a field, this
22 is the X path for that, right. And now, you have to

1 go into the X path and remove that OID and put this
2 other OID in there because the condition is this. I
3 said, no, that is not going to be a easy method, so
4 that got to us, saying that hey, I think we need to
5 split it now and have its own OID.

6 TANJIEN CHEN: And also, the
7 recommenda-tion is cleaner because if, when you report
8 to other region, you know this is FDA regional data
9 item and you just totally ignore this one. You don't
10 worry about X paths. You don't worry about a OID.
11 Nothing. I mean, this is only for FDA.

12 SURANJAN DE: Any question? Anyone?
13 Maybe everybody's hungry. It is -- because we're
14 almost at lunchtime, so. All right. If no questions,
15 we can go for lunch. We'll start at 1 again and T.J.
16 and me, we are here, so any questions you want, we can
17 discuss. No problem. So, all right. So we'll
18 adjourn for lunch and then come back here at 1 where
19 we start with the forward compatibility. We'll talk
20 about, based on regional elements.

21 (Off the Record.)

22 SURANJAN DE: Welcome back. So, after

1 lunch now we have three more topics that we need to go
2 over. And the first topic, which we'll start right
3 now, is that you saw all the data elements for R3 --
4 now, the question is how do we do a forward
5 comparability between the R2 regional elements to the
6 R3 regional elements?

7 We all know what the forward
8 comparability with the ICH elements -- they have the
9 forward and backward comparability. And here the --
10 here, we did not do a backward comparability, and the
11 reason being that, you know, at the end of the day we
12 need to move forward, we need to move from R2 to R3
13 and, of course, there are certain data elements.
14 Sorry.

15 So, we need to move -- from R2 to R3
16 and then again, there are certain data elements which
17 are new in R3 which you will have a data loss when you
18 move from R3 too back to R2. So, with that, we will
19 go over the different data elements. There is one
20 element we identified where we need to...okay.

21 So, let's go over each and every data
22 element. So, if you look at this here, at the first

1 data element, the first data element you have the
2 element called A.1.9, which in R2 used to be called
3 does this case fulfill the local criteria for an
4 expert report? As we said, this data has now become
5 ebullient in R3, so we have the regional data element
6 called Local Criteria Report Type, which has the same
7 values. Now, under the comment, we realized -- which
8 we very recently -- we actually -- I uploaded on
9 Tuesday, this was the values will just go straight.
10 There is no null flavor in there. That was a mistake.
11 And when we move from R2 to R3, A.1.9 moves to FDAC171
12 with the same values. Okay?

13 Then we have the combination product
14 flag. So, in R2 it was called A1.FDA.15; in R3 it is
15 -- sorry -- so, in R2 it's called A1.FDA.15; in R3
16 it's FDA.C.1.12. This was a combination product flag
17 which I was talking about, which I think I missed in
18 the previous slides. And the mapping -- yes, true and
19 no, false. If not set in R2, use is null in R3.

20 Then we have A233, which is a study
21 type where the reaction event observed. So, in this
22 case, in R3 we have this field C54 where, if you look

1 at R2 you have some additional values, which is 4 and
2 5. And when you go R3, C54 will just have those three
3 values, clinical trial, individual patient and 3 as
4 other studies.

5 For 4, if the value of 4 occurs, then
6 you would move that to set your patient identified
7 aggregate and then you will have the new data element
8 which is other FDA study type where adverse reaction
9 occurred. That's where this needs to be moved.

10 And then for 5, which is clause
11 supported IND, if the value is 5, then you would take
12 the numbers, the IND numbers from the sponsor study
13 numbers, which is where the IND numbers are, and
14 populate those -- that regional data element called
15 cross-reported IND. So, which is FDAC.5.R.6.

16 So, again, going back to A2.3.2, for 1,
17 2, 3 it's a straightforward mapping. If you have a 4,
18 then you would have the new field called Other FDA
19 Study -- FDA Other Study Type Where Reaction Event was
20 Observed, which is nothing but this field here. I
21 think I need to go to the field. This is field where
22 you put aggregate.

1 And then if you had 5, then you would
2 use the FDAC5R6 where you would put the cross-reported
3 IND numbers in that field. And if you have more than
4 one cross-reported IND number, you know, if you have
5 seen a technical specification that was posted last
6 year, in there for the IND section, this particular
7 Section A.2.3.2 -- 3.3 repeats for each cross-reported
8 IND, and you would take -- where there's a value of 5,
9 you would take the cross-supported IND number which
10 will be stored in this field, and place it in FDAC5R6.

11 Now, going to A.2.3.2, the sponsor
12 study number, if you have the value of a 1, 2 and 3...
13 Yeah, if all you have is the value of 1, 2, 3, 4 and
14 not 5, then for that IND number which is stored in
15 sponsor study number, is moved to FDAC55A, which is
16 the IND number where the A occurred. And you would
17 only store the number part because FDAC55A is a
18 numeric ten. And for cross-reporting IND I just
19 talked about, if the value of A233 is 5, then you
20 would take the IND number and put it into FDAC5R6.

21 Then there are some other fields where
22 we have that malfunction. If it is yes -- a

1 malfunction as in R2, we have a regional data element
2 called Malfunction. And when we go to R3, there's a
3 regional data element malfunction, if R2 is the value
4 of yes/no, and if it is not set in R3 we're making it
5 true and false as ebullient. So mapping, yes is true,
6 no is false. If not set to R3, then set the values to
7 false in R3.

8 Same with -- oh, so now then you have
9 these fields which are correction additional
10 information response to FDA request. Now, these
11 fields are -- and devise evaluation -- these were four
12 separate data elements in R2. And in R3, that has
13 been combined into one data element -- the element
14 name is a follow-up of what type. So, what type of
15 follow-up has a value 1, 2, 3, 4, and the logic there
16 is if the correction was yes, then the value is set to
17 1. If it is additional information, the value is set
18 to 2, and so on.

19 Since this is a repeating entity, there
20 could be multiple values, so there could be correction
21 and additionally information. So, you need to set
22 that to 1 and 2. The R2 tag value is set up as a

1 repeatable -- yes, that's a repeatable value in R3.
2 And then we're saying if the value of R2 field is no
3 or not set, then don't include them. So, if this
4 value is no, then -- or not set, then you don't need
5 to include them because you're just mapping it to one
6 data element, and we need to know what those values
7 are.

8 So, similarly, we have a data field
9 Remedial Action Initiated. Each codeless value of
10 remedial action in R2 are separate data elements.
11 They all merge into now one data element in R3, just
12 the remedial action. And the same pretty much rule
13 applies as we talked about in this follow-up type.
14 So, anything which is yes is a 1, and that 1 is -- and
15 that is set up when you do a follow-up compatibility.

16 All right, so the next one is -- if you
17 had -- there was a value called Other. And then in
18 that case, if the value is present in R2, then include
19 9 as Other. So, the way in R2 we had it set up, you
20 had all this and then you had a data field called
21 Other, which was a free text. And since in R3 there
22 is a special field called Other, then if there is any

1 value in that field, then -- if there is any value in
2 this field, then you migrate it to this and set it to
3 9 as Other.

4 Then you have the evaluation value,
5 which is a devise problem code, so that goes where --
6 you copy the evaluation value to the devise problem
7 code where the R2 tag evaluation type is equal to
8 devise problem. So, there is a tag in R2 called
9 BK420FDA191A, which is the type of evaluation. I
10 think it could have two or three types of values --
11 devise problem, patient problem and something else.

12 Plan name, common device name and
13 product code, you just copy from the R2 value to the
14 R3 value. Manufacturer name, manufacturer address,
15 city -- this, you copy the value from R2 to R3 as is.
16 Then we have the devise usage. This could be set at
17 1, 2, 3. So, you will basically copy the value as is.

18 Then we have the device lot number.
19 It's a free text and so you copy the value from R2 to
20 R3 as is. Operator of the device. So, the operator
21 of the device is currently a free text and an operator
22 of the device we have health professional, lay user,

1 patient and other. Now, even though we say a free
2 text, there is some suggestions in the technical
3 specification to use health professional or lay user,
4 patient. And what we're saying here is map the R2
5 value of health professional if you have health
6 professional to 1 in R3. Lay user to 2 in R3. If R2
7 value is not health professional or lay user, then set
8 that to other, which is the value of 3.

9 Patient race code. Actually, we don't
10 have any patient race code in R2, and we don't have
11 patient ethnicity or required intervention in R2. So,
12 it's a whole new data element in R3. So, in such
13 case, ethnicity and race are manually treated
14 elements, so you would use a non-flavor of unknown.
15 And requiring an intervention will be NA.

16 Next is characterization of drug role.
17 So, here there is a fix in the -- yeah, R2 is 1, 2, 3
18 and 4. These are the four values. When it comes to
19 R3, we have the FDA other characterization of drug
20 role, which is one similar device. So, we discussed
21 that new regional element.

22 But when you move that, what will you

1 set for the characterization of drug role? Because
2 you have to have that value also. So, in that case,
3 we set the value to Drug Not Administered because
4 we're talking about a similar device and not the
5 suspect.

6 All right, so those are some of the
7 rules that we have documented based on some of the
8 regional elements that we have where some rules apply.
9 Not every element we have a rule that applies because
10 many places they are optional. So, before I get into
11 the routing mechanisms, you know, any questions? Any
12 thoughts? Any ideas?

13 PUBLIC COMMENT: (inaudible) ...to FDA
14 IND are 2 reporting in that the technical
15 specification is specifically for R2 and in this
16 graph. At what point in time would that technical
17 specification be republished and also include the R3
18 data elements? It feels like there's a bit of catch-
19 up between the documentation.

20 So, you've got the forward
21 compatibility document that speaks about IND R2 data
22 elements and it gives the R3 equivalent. And I think

1 the same possibly with the Business Rules spreadsheet,
2 that there'll be IND data elements which also display
3 the R3 details. But the actual FDA IND technical
4 specification only speaks about R2 currently.

5 SURANJAN DE: Correct. So, the R2
6 specification that was published that had -- I think
7 it has combination products and IND -- that
8 specification, there's a change, a minor change that
9 we had to do to include the similar device concept.
10 So, that has gone into revision. I understand that
11 last week we just got a clearance on that document.
12 So, the R2 document. So, that document will have --
13 the document will specify two changes: One is how to
14 use this in R2, which is a similar device. And then
15 the second thing is that when we talked about the
16 causality assessment, it just mentions that you
17 suspected or not suspected or you investigated our
18 sponsor. That's only to use... So, that will get
19 posted now.

20 Now, if you fast-forward now, you will
21 have the spreadsheet which has all the R3 data
22 elements with the forward comparability, with the

1 expats. That we will post it by end of this month.
2 So, my hope is that since the R2 document's already
3 cleared, that should hopefully get posted this week.
4 Because I know it got cleared through our office.
5 Because the technical document doesn't have to go
6 through Regulatory Affairs clearance or Regulatory
7 Policy clearance.

8 So, that, hopefully, we are waiting --
9 I think on the web team to post it on the FDA.gov end
10 of this month. Now you have the R3, so you already
11 have the final R2, you have the R3 the spreadsheet.
12 The document -- the technical spec of R3, right? So,
13 that we are working on to get it, hopefully, by
14 September. The reason being that that needs a lot of
15 change based on all the different regional elements.

16 But that document mostly will not go
17 into the detail of what is the data of an element,
18 what does the data lend, and so on, and so forth,
19 because that's already in the Excel Spreadsheet.
20 It'll just point to that spreadsheet, all right? But
21 it will at least give you what this element is about,
22 maybe a snippet of the example as to how it's going to

1 look like. And all the attributes of that element
2 still will be maintained in that spreadsheet. And
3 that technical specification will come in September.

4 So, if you look at the timeline, we
5 hopefully get our R2 specification out this week. We
6 have by the end of this month, we have the business
7 rule document that has all the elements with the
8 rules, and the expats, and the forward comparability
9 posted by the end of this month. And then the big PDF
10 document of other technical spec come out in
11 September.

12 PUBLIC COMMENT: So, then my second
13 question is are there any -- or is there any
14 information in terms of the date when voluntary IND R2
15 reporting starts? And is there any likelihood that
16 marketing authorization holders or applicants could
17 just go straight to R3 reporting for IND safety
18 records?

19 SURANJAN DE: Right. So, right now,
20 the guidance is still in draft. So, once you have the
21 guidance which is final, after which you have two
22 years to submit. Now, it so happened by that time you

1 have -- you're ready with probably R3. Right? So,
2 you must really jump into R3 at that time because you
3 still have two years from the time the guidance and
4 the rule becomes final for submitting IND
5 electronically. Right?

6 So, you may decide that, hey, I have
7 two years, I can get R3 -- R3 specifications out, and
8 I may just straight go into submitting R3. Of course,
9 until that time, you still have to involve your
10 regulatory affairs to submit those reports through
11 them, through ECTD, right? But if you decide that,
12 hey, you know what? I think I can do R2, R2 -- I'm
13 ready with R2, it's not too much of a hassle to do R2,
14 then you may start doing R2. That means you don't
15 have to now submit anymore the cover letters and all
16 that -- all that administrative, you know,
17 documentation that you have to submit with an ICSR.
18 And while you are working on R3, and then when you're
19 ready with R3, then you move over to R3. Does it make
20 sense?

21 PUBLIC COMMENT: I'm trying to get at
22 whether or not there are applicants that

1 (inaudible)...to stick with what they're doing right
2 now (inaudible)...

3 SURANJAN DE: Right.

4 PUBLIC COMMENT: (inaudible)

5 SURANJAN DE: Right. And that's true.
6 Some companies -- some sponsor that we understand -- I
7 mean, who have been also talking to us and asking us
8 questions on the IND safety reporting. They have been
9 saying, you know, when can FDA ask us to even start
10 voluntarily for us to submit? Because if we can start
11 voluntarily, then we don't have to submit to ECTD.
12 That means it saves all the time where you have to
13 stake that report to the Regulatory Affairs, create
14 the cover letter, and all that -- generating those
15 PDFs, and then submitting it to ECTD.

16 It goes actually through -- probably
17 sponsors have their safety system. That takes care of
18 all the electronic submissions automatically. And
19 then they don't have to worry about the next few steps
20 that they have to do. So, that's why they are very
21 eager to start this process.

22 So, as I said, we are still working on

1 getting our data analytics up and running for post-
2 premarket. And the reason being is, as you can
3 understand, that all this time, the reviewers at the
4 medical offices have been looking at PDF documents in
5 ECTD. Now you give them this whole app system where
6 alerts are coming, they go in the alerts, they see the
7 line listing of INDs, 15-day, 7-day report that has
8 come. They click on that and right there, they take
9 their assessment and do things. Which is very
10 different than going through and printing a PDF and
11 reading through it.

12 So, there's a change management process
13 which we are working through and that's not very easy
14 when you have a medical officer who is looking at --
15 probably got one report in three months, and now you
16 have to train him to feel -- have a feel of the new
17 tool.

18 So, as far as -- we have that setup. I
19 think the website and the FAERS website will say that
20 -- right now it says we don't -- we are not accepting
21 voluntarily. That would then change to say, yes, we
22 have started accepting voluntarily. And if you're

1 ready, yes, you can submit. But, again, as I said,
2 it's voluntary -- on a voluntary basis. Only when the
3 rule is finalized, then from that -- two years from
4 that point, then it becomes maNDA-tory. But many
5 companies want to do it voluntarily because to get rid
6 of that next set of process they have to follow. It's
7 actually -- their Regulatory Affairs are saying, hey,
8 can you just -- when can you start? So...

9 So, it all depends on how the sponsor
10 wants to, you know, work through this process and
11 when.

12 PUBLIC COMMENT: (inaudible)

13 SURANJAN DE: Sure, I mean -- so, there
14 will be a period of time where you can do R2 and R3,
15 right? So, there's no stopping that. And for R3, we
16 don't have a set date that by this date you have to be
17 compliant with R3. So, that's what I talked during
18 the slides in the morning on testing. There's no
19 compliance date for when you have to be R3. So...

20 But definitely -- let's say we don't
21 have a compliance date and let's say middle of this
22 year we have the IND premarket, the final guidance

1 comes out -- becomes final, right? So, now you have
2 two years, right? So, you have 2021, '22. By that
3 time, you have to be compliant with submitting
4 electronically the IND Safety Report. Now, at 2022,
5 do you want us to use still R2 or do you want to jump
6 over to R3 because FDA is ready in 2020 -- ready to
7 accept R3? All right.

8 SHAWN GREEN: Hi. Shawn Green with
9 AVI. I want to revisit the -- or clarify something
10 related to the FDA characterization of drug role. If
11 I understand it correctly, the whole purpose of GK1A
12 is when you have NICSR with two devices that are
13 similar but only one of them is suspect or
14 concomitant. I understand the second one --

15 SURANJAN DE: No.

16 SHAWN GREEN: No.

17 SURANJAN DE: So, in the concept of a
18 similar device, is -- you have a -- so, you have --
19 let's say, let's take it by application number. So,
20 NDA-1, NDA-2. Right? So, NDA-1 has an Active
21 Ingredient 1, which has a Device A. NDA-2 has Active
22 Ingredient 2, but Device A. That's a similar device.

1 SHAWN GREEN: Okay.

2 SURANJAN DE: So, in that -- in this
3 situation, what we're talking about is if you had a
4 malfunction that happened on NDA-1, you have to also
5 report NDA-2 as a similar device.

6 SHAWN GREEN: Okay.

7 SHAWN GREEN: Okay. So that being
8 said, NDA-2, which doesn't have the malfunction, you
9 list G.k.1a as similar device and that field is taken
10 care of. That field is still available for Device 1
11 though, correct? But there's only one value there.
12 What's the guidance for that data point for the first
13 device?

14 SURANJAN DE: So in that case -- so
15 your -- you would repeat the drug block, right? The--

16 SHAWN GREEN: Right.

17 SURANJAN DE: -- product block. So the
18 first product block you would probably NDA -- you
19 would say NDA-1, that drug characterization is
20 suspect.

21 SHAWN GREEN: Right.

22 SURANJAN DE: And then other drug

1 characterization row will be empty.

2 SHAWN GREEN: It's empty, so it's null.

3 SURANJAN DE: Yeah. Because that's not
4 a similar --

5 SHAWN GREEN: There's no (inaudible).

6 SURANJAN DE: Right.

7 SHAWN GREEN: Okay. (inaudible)

8 SURANJAN DE: And then you have the
9 second block --

10 SHAWN GREEN: Right.

11 SURANJAN DE: -- which gets repeated in
12 which your drug characterization would say, Drug Not
13 Administered because that's the value we can use. But
14 this FDA.G.k.1a would then say 1, which is similar.

15 SHAWN GREEN: Right.

16 SURANJAN DE: So that way we would know
17 that that was a suspect, there was a -- and now
18 another thing which I think I understand from the
19 similar concept is if this has to be reported to
20 Europe, they don't care about the similar part.

21 And the question which I think came to
22 us saying that, what if you have to report this whole

1 similar -- we'd report to you but we don't have to
2 report to other agencies. But in that case, if it was
3 similar, you probably will exclude that repeat, next
4 repeated block and say you don't want to repeat that -
5 - you want to report that.

6 Another instance which happens is --
7 the question came to us is, let's say you have a
8 product which was outside U.S., right? Now, the
9 device component is still the same because there is a
10 similar NDA in the U.S. which uses the same device,
11 right? So maybe the company had -- the same company,
12 their one application was outside U.S., and there's an
13 application within U.S., but the ingredients are
14 different, right? But using the same device
15 component.

16 So in that case, how would you report?
17 Now, some of our reviewers are saying -- says -- they
18 say, I don't care about the foreign product. I'm most
19 interested in the U.S. similar product, right? So in
20 that case, you know, what would be the matter of
21 reporting? Currently in R2, the way it is, you have
22 to report that foreign product as well as the similar

1 product, right?

2 But when it comes to R3, because the
3 way this is set up, you could only have one block
4 where characterization is Drug Not Administered, and
5 then the other characterization of drug is similar.
6 And then only one can be submitted.

7 I don't think we -- we're not going to
8 reject the report because if you have reported the
9 foreign product and the U.S. similar product, I mean,
10 maximum what our (inaudible) team is going to do is
11 try to code that foreign product to maybe the
12 (inaudible). Because we code all suspect and -- yeah,
13 all suspect product we code, so we'll probably code it
14 and not reject it. So that's the concept behind the
15 similar...

16 SHAWN GREEN: Okay. And just one more
17 note. I think in the R2 column there, 4 should be
18 Drug Not Administered, right?

19 SURANJAN DE: So in the R2 -- no,
20 (inaudible) R2 doesn't have a value called Drug Not
21 Administered. (inaudible) R2 only has in the
22 (inaudible), only these three are there today. In --

1 SHAWN GREEN: Right, but I'm assuming
2 you listed in there for the R3 (inaudible).

3 SURANJAN DE: No, no. So this column
4 is R2, right? So there is a field in R2 called
5 B.k.4.1 -- B.4.k.1, which is Characterization of drug
6 role, which only has these three values. We are
7 introducing a fourth one as a regional need for R2,
8 which when you migrate to R3 you will be migrating to
9 FDA.G.k.1a, right? And in this case, 1, 2, 3 is
10 straightforward, right?

11 So that's nothing. But when you have
12 this 4, this 4 now moves to a whole different field in
13 R3, okay? And that becomes 1=Equal to Similar Device,
14 but when you make this to Similar Device, there is
15 already a field called FDA.G.k.1, which is called
16 Characterization of the drug role, that needs to have
17 some value, and that value will be set to 4=Drug not
18 administered.

19 SHAWN GREEN: Right. Okay. Thank you.
20 Yeah.

21 WOMAN 1: Is there any possibility that
22 you could -- yeah. Is there any possibility that you

1 could revise that row just to make it clearer and
2 still just include more details about G.k.1? To split
3 it?

4 SURANJAN DE: Yeah.

5 WOMAN 1: To make it make more sense?
6 So that G.k.1 would map to points one to three.

7 SURANJAN DE: Yeah, we can do that.
8 I'll just put another row where we say one, two, three
9 just goes to one, two, three, and the remaining four
10 goes this way. Okay. Yeah. All right. One, 13.
11 All right. So if no other questions, we can start
12 with the next topic.

13 This is a topic where the whole idea is
14 to make sure that the pre-market and the post-market
15 reports are set and put in two different locations,
16 and they are managed appropriately, because we all
17 know that post-market -- redacted post-market reports
18 gets posted publicly, and this is very, very, very
19 important. More so that many of the data elements,
20 especially the current data elements, we don't have
21 too many checks, we do, because we don't want to
22 reject reports.

1 That makes things challenging
2 especially we had had incidents where even though we
3 have not started electronic submission of pre-market
4 safety reports electronically, we have had situations
5 where IND safety report was submitted to our post-
6 market gateway, and that showed up on the (inaudible)
7 public dashboard. Okay?

8 Of course, we found out that as for the
9 checks we can put, we have put those checks, but in
10 this case it just went through and this was something
11 that was -- the company had not directly submitted,
12 but they walked through a (inaudible), and we found
13 out that it came -- (inaudible) had submitted that to
14 us. So yeah.

15 It was a huge big deal, you know. The
16 same company stock price went down like 40 percent in
17 one day. So yeah. So it's very important that we
18 make sure -- and I would also suggest to you all that
19 if you all even can think about some criteria to help
20 us to say hey, after we go through this, what I show
21 here, that hey, you know, maybe you should think about
22 this -- these criteria to clearly identify that this

1 is a pre-market report versus this is a post-market
2 report.

3 Because then there are confusion that
4 comes in, what happens if it's a post-market study
5 report? Right? Then you have two reports to be
6 submitted. One for the IND and one for the NDA,
7 right? So then in that case, how do you basically
8 manage this? Because in these reports, the NDA is
9 redacted and posted publicly.

10 The IND will not get posted. It will
11 be only available here. So -- and the whole two sets
12 of reviewers are there, one from Office of New Drug,
13 who is looking at the IND, and then Office of
14 Surveillance and Epidemiology, who are looking at the
15 post-market.

16 All right. So here's the proposal.
17 And I think some sponsors from here have already
18 probably tried this as part of the pilot program that
19 we had done, last year summer. But two separate
20 routes for submission, right? So we have two methods,
21 first thing. We have the AS2 Header Attributes and
22 the AS2 Routing IDs.

1 And what we are suggesting here is
2 within each of those methods, we split it. So you
3 have AS2 Header Attributes, one for pre-market side,
4 one for post-market. Or if you use AS2 Routing IDs
5 then you have a routing ID for pre-market and one for
6 post-market. So that way, you know...

7 So if we submit the pre-market and
8 post-market safety reports using the appropriate
9 attributes or the routing IDs for R2 and R3... So and
10 then of course we said IND where the adverse event
11 occurred will be -- is a mandatory data element, and
12 will be available -- has to be filled in, so when we
13 see that a pre-market ICSR in R2 or R3 has come
14 through the pre-market route, we'll check for the IND
15 number to make sure the IND number is available. If
16 not -- then without that IND we really can't do
17 anything because the report will go nowhere.

18 So that report will probably get
19 rejected because the IND number is not available. It
20 just will not go anywhere. It will just stay in a
21 black box somewhere because it's all routed based on
22 the IND number and a reviewer. That's how the

1 assignment is set up. So to show how the AS2 Header
2 Attributes could look like -- so what is our current
3 state?

4 So our current state is we have the
5 destination CDER, we have the attribute value AERS,
6 and then we have for the XML and AERS_ATTACHMENT for
7 the PDF, right? Now, if you -- for the proposed
8 future state, this -- the proposed future state, that
9 works very well when you have an R2 submission, but
10 when you go to R3, the whole attachment is embedded,
11 so that basically goes over here, right?

12 So we have the attribute values saying
13 AERS_PREMKT for pre-market. So now the attribute
14 values for the XMLs for post-market stays as AERS, as
15 we do today, and for pre-market it's AERS and just go
16 pre-market, PREMKT. And for attachments, it's
17 appended by _PREMKT. So that way now we know that,
18 okay, this is for post-market and this is for pre-
19 market. Right?

20 So when it comes to E2B R2 of course
21 PDFs are -- is applicable, but when it comes to R3
22 then they're omitted, so there's still no attachment,

1 because attachments are sent later, right? So with
2 that attribute value. If you go to the routing ID
3 mechanism -- I think that's mostly what many of them
4 use -- the current state is the routing ID is FDA_AERS
5 and the attachments is FDAAERS_ATTACHMENT.

6 And the proposed state for IND or pre-
7 market. In this case I would say pre-market because
8 we have also B2B trials. The routing ID stay the
9 FDA_AERS_PREMARKET, and then for the attachment it's
10 FDA_AERS_ATTACHMENTS_PREMARKET. Okay?

11 Okay. So safety reports are submitted
12 to FDA via different routes, are stored in different
13 folders, because they'll eventually automatically go
14 to different folders. The XMLs will go there -- to
15 different folders. Acknowledgement will be sent with
16 the original Safety Report Unique Identification.

17 Now, why do I say this? Number two,
18 the bullet point? I don't know how sponsors will
19 store their ICSR on a post-market study report, okay?
20 If it is stored with the same ICSR number or the
21 safety report or the manufacture control number. If
22 you had a post-market study report, and let's say you

1 had serious and unexpected, not suspected yet, you
2 will probably submit that report to the post-market
3 site because that's the rule, right? For the -- on
4 the NDA.

5 But if you have serious unexpected and
6 suspected, right? So that goes to the post -- pre-
7 market also. So when this data comes into FAERS,
8 right, I will have one safety report ID. But when I
9 start to get the pre-market, I do not want that safety
10 report ID to basically clash with the safety report ID
11 of the post-market safety report ID.

12 So internally what we are doing is when
13 a report comes through the pre-market route, we take
14 the safety report ID and we try to append that with a
15 -IND. That also makes it very clear that these
16 reports do not -- should not be published outside,
17 right?

18 Secondly with that, it's very clear
19 that if just in case, if a post-market safety reviewer
20 looks at the report and say, hey, yeah, this is an IND
21 report. I know that. This is not a post-market site
22 report. Because within FDA, you know, the reviewers

1 can review the entire (inaudible) of these.

2 So when I say that will we send with
3 the original, because we have appended, when the
4 acknowledgement comes out, you will get your original
5 safety report ID, what you had submitted. So that's
6 why the statement -- this is just taking extra
7 precautions of these reports to not get out from where
8 it -- where we store them.

9 FAERS checks the E2B pre-market data
10 elements to safeguard the pre-market reports are
11 identified properly. We also are safeguarding it in
12 such a way that if you had submitted a pre-market
13 report through the pre-market route or the routing ID,
14 okay, or using the appropriate ES2 header, we also
15 mark that report saying that do not publish. All
16 right?

17 So then when it comes for publishing,
18 these reports are never picked up. Basically, there
19 are three levels of checks we try to look into. One
20 is, you know, we appended _IND to the number. We set
21 it up to say, hey, you came through that route, which
22 means these are IND reports and should not be

1 published.

2 And then also look into some of the
3 data elements in those reports to say hey, is it a
4 report from study? Yeah, but report from study could
5 be also report from study for the post-market study
6 report, right? What else can we check, right? Does
7 it have an IND number, that field? Yeah, it has an
8 IND number in the IND where adverse event occurred.

9 And, you know, some of these data
10 elements verify to make sure that these reports are
11 set to a flag saying that do not publish. And they do
12 not get outside the agency. So that's the all pre-
13 market reports will be treated differently from the
14 post-market reports. These are the things why we have
15 to treat it differently.

16 So it is very important, I mean, as
17 much as checks you apply, you know, we try our best to
18 make sure that they do not slip through the crack.
19 But it's very important that also on the sponsor side,
20 it becomes very important that they must submit the
21 pre and post-market ICSRs via the appropriate route so
22 that, you know, they come through that.

1 The biggest challenge which we have is
2 when somebody is submitting a pre-market report and
3 accidentally submits to the post-market route, right?
4 Now, that could be a study report on an NDA, right?
5 We're hoping that the IND on which the adverse event
6 occurred, that also may be filled up, and in that case
7 we might say hey, I see that field filled up, so I am
8 not going to accept this report to the post-market
9 route.

10 But let's say accidentally that field
11 was not filled up. Then I'm not going to check that
12 field to say that if it's empty or not empty, because
13 all of the post-market report, that field could be
14 empty, right? So it becomes very challenging
15 sometimes, and that's where when I said that, you
16 know, I truly encourage you all to think about that,
17 what data elements really can -- I mean, after looking
18 at all the data elements that you have, and once I
19 provide you the list and this business (inaudible)
20 document, if anybody has any suggestions, we are more
21 than happy to, you know, talk about this as to how we
22 can truly segregate this even after it has come

1 through two different routes like this.

2 All right? So then again, here the
3 idea is you see that it's -- you have two different on
4 the pre-market route and the post-market. It comes
5 through and then gets basically routed through two
6 different locations. And even though it's in the same
7 FAERS database, but through appropriate channels and
8 appropriate permissions and data permissions. They
9 are segregated between pre-market and post-market.

10 All right? And also important to see
11 here is, you know, in the pre-market side you have
12 this. Now, this I have only showed for R2 applies to
13 R3 when you have the new field, the G.k field. And
14 for the NDA, you know, this particular will not have
15 that. But if it's a post-market study report, even
16 submitting through this route we'll probably be
17 expected the NDA number on this tag. So...

18 And when I talked about sending the
19 acknowledgement back with the original safety report
20 ID, this is where we were thinking of -- the planning
21 of doing. You will know this have no impact on you,
22 but for us to make sure we have proper checks. Of

1 course, when we do try to, you know, post the data
2 publicly, there's a whole QC check, but we are posting
3 about close to 300,000 reports per quarter, three,
4 400,000 reports.

5 Because our last year report count was
6 2.18 million reports. And so that goes... Luckily,
7 the year before that was 2.15, so the jump has not
8 been that high, but, you know, submitting -- getting
9 all those reports publicly is also a challenge. All
10 right. So routing mechanism. Set up the routing
11 controls. There's two ways to set up the routing
12 controls dictating where the document is sent.

13 So one is add a custom header
14 attribute. So that's attached to the headers. And
15 the second one is the routing IDs. So when you see
16 the slide, these are the locations where, you know, it
17 points out to where on the FDA website the information
18 about those headers are, and the routing IDs are.

19 One of the trading partner changes, you
20 have the AS2 header. You have to make sure that, you
21 know, this change is set when pre-market reports are
22 submitted. And if you're using routing IDs, then

1 these changes are set when you're submitting a pre-
2 market safety report.

3 All right. So with that, if you all
4 have any questions you want to ask, we have like three
5 minutes, four minutes before we take a break and then
6 come with the E2B validator. Okay? Now, this whole
7 routing mechanism is applicable to -- for both R2 and
8 R3, so there's no separation here.

9 MAN 1: Okay, so Suranjan, if they do
10 send it by mistake, do they nullify the report then,
11 quickly? Call the agency, nullify?

12 SURANJAN DE: That's what we have done.
13 As of today, we have -- believe it or not, I think you
14 probably know the number better than I -- we probably
15 have close to four, 5,000 reports in our FAERS
16 database, which are all IND reports. And these
17 reports are all set with -- we basically logically
18 deleted those reports in our database.

19 I mean, even before we ask companies to
20 go and nullify it, which of course the company will
21 take time to set up this and send it. As soon as we
22 are -- we know about it, we make sure we set those up

1 to logically delete those cases, and let the company
2 also know about it, that they have accidentally sent
3 it here.

4 We also let the appropriate sender know
5 that a report has come here so that there may be a IND
6 report with deals with a CBER product that has come to
7 FAERS, okay? And sometimes some sponsors, they think
8 that, you know, if they have submitted the -- at least
9 at the current state, the where we are, where it's not
10 mandated and we have not said that you can submit
11 electronically.

12 And some sponsors will have submitted
13 that electronically to FAERS thinking, hey, we got the
14 acknowledge. Great, we're done. No, you have the --
15 currently the rule is that you submit that eCTD,
16 right? We have still not started getting data
17 voluntarily. We have not said yes. We just recently
18 had one case where a sponsor submitted it and we've
19 said, let's check eCTD to just make sure that this is
20 also there, because then only the reviewer will get
21 the report.

22 And what we find that, yeah, they

1 submitted to FAERS, they got an acknowledgement, we
2 identified that report, we stopped that report, we
3 nullified it, but it is not in eCTD. So that means
4 that report has not gone to any reviewer. So we found
5 out it was a CBER product. We let CBER know, and then
6 from CBER the sponsor was notified and I think later
7 they submitted the eCTD. So...

8 So all right. So with this, if you
9 don't have any other questions, I'll -- I think we'll
10 come back at two because the reason is I have to set
11 up my laptop for showing the E2B validator. Right now
12 I think everything comes from this conference room
13 laptop -- computer. So just give me some time, and
14 then I will also go over the spreadsheet, because on
15 that I should be able to open that through my
16 computer. So...

17 WOMAN 2: (inaudible)

18 MAN 2: So around two o'clock?

19 SURANJAN DE: Two.

20 WOMAN 2: It's two now.

21 MAN 2: It's two now.

22 SURANJAN DE: It's two now? Really?

1 MAN: We're about --

2 WOMAN: (inaudible)

3 SURANJAN DE: Oh. 2:20. My mistake.

4 Sorry.

5 WOMAN 2: It's okay.

6 SURANJAN DE: Two, 2:20. All right.

7 All right.

8 (Off the Record.)

9 SURANJAN DE: So, welcome back after
10 the break. So, with this we're going to start the
11 next topic item, which is to go over the E2 validator.
12 All right, I've thought about this validator the
13 morning, so I think it's time I can show some -- how
14 this validator would function and how you would be
15 able to use this validator. We're still testing
16 through different kinds of files for this, but here to
17 go -- so, the mechanism to validate E2B provides this
18 mechanism to industrious sponsor to validate the E2B
19 R2 and regional E2B R2 data files and you can convert
20 it regionally to be R2 to a regional E2B R3. So,
21 that's what this validator can do. It can validate
22 and also convert. This -- you can use this as a

1 mechanism before your production submission. This
2 validator can very easily access through public URL.
3 The uploaded files are not stored anywhere and once
4 you're done with it, you close it, the files are gone.
5 And then -- and the updated phase of (inaudible) page
6 will have this link some time in September, but you
7 can straight go and click on that to start validating
8 your E2Bs.

9 Just to give you a little bit of view
10 on how it looks like. So, you basically have your
11 source XML file. You can upload this -- you can
12 upload this file here and the XML shows up here. In
13 this case, I think I uploaded an R2. I hit on
14 validate and the message shows up here, the XML is
15 valid. This is where I converted an R2 to an R3, so
16 the same file which I took here, it shows me here and
17 then I click, hit on convert and this converts to an
18 R3 Regional Element. If needed, I can download this
19 file, and which downloads this R3 file.

20 Now once I had downloaded the R3 file,
21 I wanted to check that this will validate, and the
22 conversion has happened correctly. So, it would

1 validate and should validate and say the XML is valid.
2 So, that's what I did. I saved it as a different
3 name, R3 name, and then I browsed, uploaded it and
4 then hit on validate and it gave me this.

5 This is where I had an exception data,
6 so if any kind of errors come up, it will show up here
7 and gives you a message. The element type, so and so.
8 It's (inaudible) and so, if there's no (inaudible).
9 These are some of the data elements where it then
10 tells you when you did this, what kind of E2B tag
11 would this issue come, the original XML value and it
12 gives you a validation detailed message as to what the
13 issue is. And somebody can then go and fix it.

14 So, with that -- so, we will have a
15 link something like this and where this will typically
16 be -- let me see, I think we will be posting this
17 somewhere here. This is my easiest way to get to that
18 page. This is the page, right, that pretty much
19 everybody reviews. And so here we will have a section
20 where you can have a validator or somewhere in the
21 middle here where --

22 MAN: Who built the tool?

1 SURANJAN DE: Huh?

2 MAN: (inaudible)

3 SURANJAN DE: Yeah, it was a late night

4 --

5 (Laughter)

6 SURANJAN DE: No, this was all vendors.

7 MAN: Okay.

8 SURANJAN DE: The vendors. A lot of
9 back and forth with them, mitigate elements. Now that
10 we get (inaudible) go back and make sure that it
11 complies to the entire Excel business tool which I'm
12 going to show next. All right. So, here is a method.
13 I have some folders, some files available in -- so
14 this is basically taking an R2, opening it, validating
15 it, the XML is (inaudible) not valid and if I want to
16 take this R2 and then convert it to a regional --
17 sorry, a regional R2 converted to a general R3 using
18 some of those rules that we went through, it then
19 converts that. So, it uses both the ICH forward
20 compatibility and the regional forward compatibility
21 rule 2 and converts this into an R3. And then from
22 there, I could take this, and I can download this.

1 So, you may want to say, "Hey, let me try in my
2 organization to get an R2, convert to an R3 and take
3 that R3 and try to load it because I have a
4 combination product R2. I may have an IMB R2 and I
5 may want to convert to an R3 and then take that R3 and
6 try to load it into my system to see how my safety
7 database reacts to that same R3. Believe it or not,
8 that's exactly how we are also trying to test this.
9 So, take different kinds of ICSRs, combination product
10 being (inaudible) pre-market, post-market and it's
11 different kinds and then convert this and then take
12 those XMLs and then create some gold-standard files to
13 see every time we can test this if any changes comes
14 in.

15 So, once we have downloaded this, I can
16 take this -- all right and 34B, okay. So, now that
17 same R3 I can clear, browse -- oh, I kept it in
18 documents. Okay. So, this is the R3 file, open and
19 revalidate. Good? So, now the same file I can take
20 it and load it into my safety data base, right?

21 Let's go through a situation where we
22 take a file where we may have an error in the file and

1 if you start to validate, then it kind of gives you
2 the messages at the bottom to say which tag, what
3 value and what the message for that tag value is. Let
4 me also take another file where -- (inaudible) --
5 okay, so, let's take a field syntax error. So, this
6 was again an R2 file. I'm trying to see if I have any
7 R3 -- okay. All right, so most of the files which I
8 have here, they are -- you saw that this is how the
9 check can be done. So, you can use any of these and
10 as soon as you clear, this is all gone, nothing is
11 stored in our data base. So, this E2 validator, as I
12 said, will be available through URL. You can browse,
13 select and it, kind of, recognizes between -- also
14 between the different DTDs that we have today.

15 So, because you could also have an R2,
16 we're still using the DTD2.1 and 2.2. 2.2 is the one
17 where you have combination products. So, if some
18 organization or some sponsor does not have combination
19 products, they can still continue with the DTD2.1, so
20 it knows which one it is and then it does its
21 appropriate conversion to R3. Now, we're not
22 converting DTD2.1 to 2.2, that's not there, but

1 anything from R2 to R3, this conversion would happen.
2 It's a simple web page. I think (inaudible), how
3 you're going to do things and (inaudible) just
4 provides you all the -- so, the intention behind doing
5 this is that as sponsors get to move to R3, there will
6 be a lot of questions which will come, right? But
7 when we did R2, sponsors need to submit a standard to
8 test it out, get acknowledgment and say, "Hey, yeah.
9 Okay. We're ready to submit." So, now there are so
10 many sponsors we're going to be doing this for R3, so
11 this basically, probably helps both the sponsors and
12 us to be able to go there and do the first round of
13 testing before doing the actual -- not actual
14 submission, I won't say -- before doing their, like a
15 pre-submission, pre-production submission to get
16 acknowledgements and be able to view the
17 acknowledgment.

18 There is one more thing which -- it
19 just came to my mind right now -- is, maybe we can
20 also provide that if it is valid, what the
21 acknowledgement is, and they can download
22 acknowledgments from here. Which then could be taken

1 and put into -- and then say, "Hey, yeah. The
2 acknowledgment exactly gives me that because it's
3 valid." Or if there was an error, what will the
4 acknowledgment show, right? So, that way, we
5 basically have the food cycle probably done once and
6 next time you may want to just test it through the
7 gateway. All right?

8 So, let me see if I have another file
9 which has -- I thought there was -- Oh, and also, if
10 you have an XML file, you can actually copy and paste
11 directly here. So, there is no restriction on that.
12 I basically --

13 MAN: (inaudible) libraries, right?

14 SURANJAN DE: What's that?

15 MAN: There's no libraries?

16 SURANJAN DE: No libraries.

17 MAN: Just checking to see if it's the
18 right controlled vocabularies.

19 SURANJAN DE: No. No.

20 MAN: Okay and how about --

21 SURANJAN DE: I mean it all depends on
22 how the (inaudible), right?

1 MAN: And the business rules are there
2 too?

3 SURANJAN DE: Business rules are there
4 too.

5 MAN: Okay, great.

6 SURANJAN DE: Yeah. Yeah because we
7 cannot check through the library because our check
8 through the library is (inaudible) because we consider
9 product name, event, they're all basically -- even
10 though we say it's (inaudible) and all that, we still
11 do our checking to make sure that we -- it matches
12 with our controlled vocabulary and the dictionaries.

13 MAN: So, for combo products, it's the
14 -- for R2, it's the DT2.

15 SURANJAN DE: Yeah.

16 MAN: Does this also accommodate 2.2
17 and 2.1?

18 SURANJAN DE: Yes.

19 MAN: Okay. Thanks.

20 SURANJAN DE: So --

21 MAN2: Does it accommodate all formats?
22 So, EMDR from CDRH (inaudible) or just the FAERS?

1 SURANJAN DE: Just the FAERS.

2 MAN2: Just the FAERS.

3 SURANJAN DE: Yes. Just the FAERS. I
4 mean, this whole purpose of this tool was more to
5 check your R3, but then when we saw this and we said,
6 "Hey, there's a conversion feature also. Yeah, why
7 not just give it" because there may be organizations
8 who are doing R2 today, but if they don't have that
9 experience in R3, this may be a method for the R2 for
10 them to, kind of, convert them just with a click of a
11 button and be able to then play it on with that R3
12 message to see how it got created and how it looked.
13 Right? So -- I mean, initially (inaudible) said,
14 "Okay, you will just upload, and you just have a
15 validate button. That's it." But yeah, now we've got
16 to convert it and download.

17 So -- so, again, this validation takes
18 care of all the rules that we talked about -- sorry,
19 the conversion takes care of all the rules that we
20 talked about in one of the sessions and takes care of
21 all the rules that ICH has defined for transformation
22 from R2 to R3. So, it is a combination, but if you

1 are expecting to just convert pure ICH core data
2 elements from an R2 to an R3, this is not going to
3 work.

4 WOMAN: Can you use the safety
5 reporting for -- to create files? Oh, I'm sorry.
6 Does the safety reporting portal support R3?

7 WOMAN2: No, it's just still R2. Okay.

8 SURANJAN DE: Yeah, R2.

9 WOMAN: I was thinking about a way to
10 cheat and try --

11 SURANJAN DE: I know.

12 WOMAN: And create a file -- okay,
13 well.

14 SURANJAN DE: Yeah, that is still going
15 to be R2. It's basically just the complexity. Right?
16 You know, the safety reporting portal is a front-end
17 tool, so who really cares what happens at the back
18 end, right? So, as far as a sponsor is concerned, go
19 to the safety reporting tool, they submit their
20 information, done. They don't care behind what
21 happens. It's an R2, not R3.

22 WOMAN: Well, I was just thinking so

1 they could at least create a file if they make it --
2 you know, like -- I'm sorry. Like, create a file,
3 then cut and paste here and then do the conversion and
4 then -- that's what my thinking was. Especially for
5 the -- again, the IND. I think you had a question
6 about that. Like, the people, if they start out doing
7 R2, prior to safety reports because the volume's low.
8 That's what I'm thinking.

9 SURANJAN DE: Yeah.

10 WOMAN: You know, so that might be a
11 way to, kind of, start fooling around with some files,
12 but never mind.

13 SURANJAN DE: Yeah, the safety
14 reporting portal and even though we generate
15 (inaudible), our safety reporting portal and then we
16 import that into FAERS, we then don't have any plans
17 to go to R3 yet. And as part of the whole FAERS 2
18 program, there are many organizations within FDA who
19 ask for FAERS data. Okay, within FDA. They would ask
20 for it. Like, recently I got a call from -- for tech
21 products, which is also used in human, right? So,
22 then for certain type of specific events, reporting

1 specific events. Now, how do I share it? So, moving
2 forward in FAERS 2, the idea is to get everyone into
3 the same standard of using probably E2B. That means
4 we all talk the same language. So, if you have a
5 safety system in CVM, if you have a safety system in
6 CTP (Center for Tobacco Products), Center for Food, if
7 we can all talk the same data element with the same
8 definition, with the same language, then it's very
9 easy for me to move -- send you the data.

10 Like, classic example is today, Center
11 for Food actually gets -- so, when we get safety
12 reports voluntarily from consumer healthcare
13 professionals, they get triaged at some point, right?
14 And the triage says, "Okay, because it's a drug and
15 biologic -- teleported biologic, it needs to
16 (inaudible). That (inaudible) needs to go to FAERS.
17 If there is a report which deals with devices, it
18 needs to go to CDRH to their safety system, the
19 (inaudible) system. If it is (inaudible), then it
20 needs to go to their safety system data base called
21 Cares. Now, how do we send it to Cares? Through our
22 triage tool, actually generates an E2B R2 and then

1 they import that into their -- what used to happen
2 before that, we used to send them an attachment or
3 send them that source document just as an attachment
4 to the email to a mailbox and then from there, they
5 would do their data entry and all that. Right now,
6 the report comes in, gets OCRd, whatever gets
7 actionable gets actionable, E2B gets generated and
8 sent to (inaudible).

9 So, the whole idea here is that how
10 much of standard can I get -- we can get into the
11 organization where different Centers are talking to
12 each other through this, basically, one standard.

13 WOMAN3: That's interesting because
14 that's what the whole Med Watch Plus project was about
15 and that's why (inaudible), so you have the Part 1,
16 Part 2 and the Part 2 was just to confirm its profile
17 just for ICH, right? Because they didn't want to
18 carry the extra structure that the other Centers
19 needed like the device class, the animal subject
20 class, things like that. So, that's interesting --

21 SURANJAN DE: And the -- you said it
22 right because there's the Med Watch Plus program,

1 that's when I had -- I was working here and according
2 to the Med Watch Plus and FAERS program, in 2007, '06,
3 yeah, right -- and it was ambitious that to get all
4 five Centers trying to harmonize to get to this. But
5 I guess what now -- the way I see it is, okay, here
6 you have -- let's take CDC first, because they all
7 always work together. They're slowly starting to get
8 into the next Center to show them, "Hey, this is what
9 we have done in CDC. This is the same model you can
10 utilize in your Center." And I think more and more
11 what happens is, now when you have such, kind of, big
12 implementation done once, you have infrastructure, and
13 everything set up already. Okay, for them, now they
14 see it, "Hey, it's just a matter of now just getting
15 the implementation done in the software because all of
16 our infrastructure and everything is ready." So, I
17 think some of those things have played and now,
18 slowly, slowly things are coming to be making it more
19 the whole idea of one safety data base for the agency,
20 right?

21 So, I mean, some good ideas, which, you
22 know, I've not shown this to any other Centers yet.

1 But that may be another thing to show other Centers to
2 show and say, "Hey, we have a validator like this.
3 Maybe you want to use the same validator for your
4 device report and (inaudible) reporting." So, people
5 can then go and do this. Or, working with CBER to
6 say, "Hey, your vaccine reports which are there. You
7 can use (inaudible) validator and we have created this
8 validator to make just one validator for all these
9 different kinds of reports."

10 We have another challenge which, there
11 is no standard today, is reporting of product quality
12 reports (inaudible). Which is currently used in the
13 (inaudible) report (inaudible). We don't have a
14 standard, but the companies still have to submit those
15 reports. So, but I think that's a great idea that --
16 but that's a great idea where something like this
17 validator can be now taken to all other types of
18 reporting to validate. So, as a sponsor, "Hey, I have
19 a (inaudible) file, I want to validate it." It
20 validates. "Hey, I have (inaudible) E2B." It
21 validates, so -- so yeah, so this basically -- I think
22 we're on time. Basically, ends my presentation on the

1 E2B validator. So, any questions, any thoughts, any
2 ideas? Please ask your questions. If not, I would
3 then get into --

4 So, the next thing I have is -- we have
5 -- I mean, I'm going to go over some of the summary
6 and closing comments. But we still have time if
7 anybody wants to put in some thoughts and ideas about
8 all the things I talked about, discussed. I'm going
9 to be here until next -- another hour, so we can talk
10 -- anything specific you want to talk or if you want
11 to discuss this within the group, please feel free to
12 get to the microphone and talk about. Or if you have
13 any -- (inaudible) saying, "Hey, you're thinking this
14 way. Have you thought about this thing and that way?"
15 So, please.

16 So, with that, the summary and the
17 closing comments is -- we looked at -- I did discuss -
18 - I talked about the FAERS updates. We showed some
19 timelines as to when we want to do some -- set up some
20 -- when we want to publish certain things. We did --
21 we went over the E2B R3 regional requirements. We go
22 under the post-market, the pre-market regional

1 requirements. Again, for that, I know there are some
2 slides that I need to fix some things. I'm going to
3 fix that before I post it. TJ talked about all the
4 specific OIDs. Hopefully, I hope that helped
5 everybody to understand the concept of OIDs. How do
6 we use OIDs? Why are we using OIDs and why are we
7 using OIDs in that way? Giving you some use cases as
8 to why these OIDs have to be set up in this way and
9 what are the OIDs. We went over the regional for --
10 and of the forward compatibility. We went over the
11 rules. That document will be posted by end of the
12 month, along with the (inaudible) after this slide.
13 So, summation (inaudible) for pre-market and post-
14 market ICSRs and then finally, demonstration of the
15 E2B validator.

16 So, with that, I think I can -- I don't
17 think I can open it from here -- okay. So, folks who
18 are part of ICH, they are very familiar with this
19 spreadsheet. It looks very colorful and so -- so you
20 will realize that what we had -- and this was
21 something I think we talked about at the ICH where,
22 let's have the spreadsheet with every region put

1 there. So, this spreadsheet actually comes then with
2 all the whole data (inaudible) of ICH and then, as we
3 go through, we start adding the regional elements into
4 this (inaudible). Because as I -- I think one of the
5 ideas was, when you see the IG and the PDF document
6 that tables each element. I mean, the first thing
7 anybody would do is (inaudible) to put into one. So,
8 it's already put into one now, right? And as far as
9 the sponsor is concerned, they would want to see all
10 that into one where if the spreadsheets are very
11 similar, then it's easy to read and understand.

12 So, this is the spreadsheet that we
13 have. To the source where it says, which are the ICH
14 elements and ICH element (inaudible) element
15 (inaudible) for ICH, for post-market, pre-market,
16 FAERS and then it goes into (inaudible).

17 Let's look at an element which is an
18 FDA element. So, this is the element we have been
19 talking about today, right? FDA C1, this local
20 criteria 1 alphanumeric 1, 2, 4, 5, 6. So there is no
21 conformance rule under the ICH because it's not an ICH
22 rule, but under post and pre-market because that's

1 where we'll be using this, right? So, this was a
2 combination indicator. I think I'm going to update
3 the slide with this. I did miss this. So, this is a
4 boolean value and it tells you that it's a combination
5 product or not, right? This includes data elements
6 for FAERS also, right? So, there's many places where,
7 for example, this -- (inaudible) line 2.
8 FAERS is looking for this, but when it comes to post-
9 market and pre-market, we don't care about that. So,
10 many of the data elements in this spreadsheet you will
11 find are all FAERS related. Here is this other one
12 where we talked about FDIC 54A, which is FDA other
13 study report type (inaudible). Initially, this one
14 was a 4 here, so that's where we had to save because
15 of the OID concept, we had to make this and then this
16 is an OID for that, right? And it says that -- where
17 it says, "Conforms with ICH business rules versus FDA
18 regional data element." Because I think, end of the
19 day I will have to remove the colors because
20 (inaudible) compliance and I have to make it such that
21 it's clear that it's FDA. Many of these are FAERS
22 elements.

1 Now, you have a history file. This is
2 the XPATS, so each of those data elements now -- let's
3 take that data element we just looked at, which is the
4 local criteria type report. So, here is the XPAT that
5 has been defined. And please, again, if you find any
6 -- I'm not very expert in this, so I have folks who
7 are expert in finding this XPAT, but if you find any
8 kind of discrepancy in this XPAT, please let us know
9 and we will look into it.

10 WOMAN4: (inaudible)

11 SURANJAN DE: I think -- yeah, I think
12 one is for the (inaudible) and one is the value.
13 Acknowledgment and raw data elements we are not using.
14 Now when you say patient/parent ethnicity, I think the
15 number is different. I believe this field is -- okay,
16 we have to find this -- why this is there. But this
17 is basically the entire ICSR with all the data
18 elements. So, this is what I'm posting by end of this
19 month. This whole spreadsheet. Now, along with this
20 spreadsheet, I would also post this spreadsheet.
21 Okay? It says the R2-R3 data elements and then it
22 goes into each of the domain areas, the ICSR, case

1 safety report, the study, the drug, the patient, the
2 reaction and then each of them has a rule and then
3 there is a rule. Try to make it the same way how ICH
4 has defined it, right? So, and then it goes with each
5 of the rule IDs and then it points out to this to
6 that, this to that. And retired E2B 11s and this is
7 (inaudible).

8 WOMAN5: Full aggregate reports. Do
9 you have any special instructions or additional
10 information in terms of what detail should be included
11 for the event assessment?

12 SURANJAN DE: What information would be
13 included in the event --

14 WOMAN5: -- assessment.

15 SURANJAN DE: Right. So, I think what
16 I understand from our clinical team is that these are
17 the more -- what do you call -- and based on that
18 assessment, the similar events are events with -- I
19 think that is a rule. I think what -- I mean, the
20 cluster or the pattern or the -- or the similar events
21 that you see in the assessments you have done
22 investigation product with all the similar events that

1 you see based on the five ICSRs you have. You will
2 write an aggregate based on that. So, in this case,
3 your events would be the events you are doing an
4 assessment on.

5 WOMAN5: (inaudible) Well, the event
6 assessment, like, for instance, the seriousness, onset
7 date, all of those fields. What's your expectation in
8 terms of what should be populated?

9 SURANJAN DE: Okay. Can we write this
10 down and --

11 WOMAN5: (inaudible)

12 SURANJAN DE: When you come to the
13 aggregate, an aggregate report, I think many of the
14 data points will not be populated just because you're
15 right about the aggregation is in your clinical
16 narrative, right? Because you're taking five ICSRs
17 where you have the details, right? Which now, you're
18 making one aggregate report and you are filling in
19 that report. So, many of the points in that report
20 would -- most (inaudible) part of your clinical
21 narrative. But I think the key information, what, at
22 a minimum, needs to be there, that's something I

1 definitely would want to talk to our pre-market folks
2 to make sure that what I'm saying is correct.

3 MAN3: So, I have one basic question.
4 So, there is (inaudible) R3 to FDA (inaudible) if
5 included any other region so they are (inaudible).
6 For example, in (inaudible). So, is it included any
7 other (inaudible)? Can you accept over FDA?

8 SURANJAN DE: Okay, so basically I
9 think what I'm seeing is going through that thought
10 process where you could want to generate one E2 -- one
11 file so that if that file has got regional elements of
12 other regions and that is submitted to FDA, would you
13 accept that report or not, right? No impact, right?
14 So, that is basically a concept that we had done a
15 little bit in ICH, I think in the cross-regional
16 testing. We have not done that yet. That is
17 something we definitely do plan to work with our
18 vendors to plan that and try that. If it is bad, can
19 it just ignore those data elements? We have not tried
20 that yet, but definitely we would -- we plan to do
21 that as part of our implementation. I have definitely
22 talked to my vendors about this, so hopefully we are

1 able to provide some information after we have done
2 some level of testing.

3 WOMAN5: Just one last question because
4 we have to keep up to date with various other business
5 rule sheets for other health authorities, but also
6 within the FDA. For instance, with EMDR and CDRH
7 implementation packages, do you have any process set
8 up for how applicants and so forth, vendors, will be
9 updated or notified of any changes to the business
10 rule sheets? We find that it can be quite haphazard
11 that you go to the site and see that there's a new
12 sheet uploaded and often, not very well version
13 controlled with very comprehensive changes for your
14 revision history.

15 SURANJAN DE: Okay. Yeah, I think -- I
16 think that is -- I believe that when you register with
17 the FDA's site and become a subscriber, any changes on
18 this gets notified. If not, I think the idea first
19 would be that based on all level electronic submission
20 -- submitters, we actually have a list of, which we
21 maintain to notify sometimes if they don't get
22 notified. The way we have tried to approach everybody

1 on these (inaudible) meetings, I think that would be
2 one mechanism of notifying. The second mechanism of
3 notifying is that whenever we have any kind of
4 changes, we probably set up some webinars to
5 communicate this change. So, say that, "Hey, there is
6 a change, and this is what the change is." This is
7 how we plan to implement it so that we notify well in
8 advance that this is coming, right? They may have a
9 whole different compliance date, but at least if we're
10 ahead, we can tell you because that may have an impact
11 of something else you are already building, right?
12 So, that is another way because now we know that this
13 is a whole new standard that we are implementing and
14 needs more attention than basically the R2, which at
15 stock, needed a lot of attention, but then people
16 became expert and things are pretty much moving in a
17 more (inaudible). We do plan that -- to have a few
18 more webinars to communicate this. Any kind of change
19 that we identify, we would want to communicate that
20 through webinar because as we are implementing, as we
21 are testing, we will find something which may have an
22 impact on this spreadsheet or may have an impact on

1 this spreadsheet. So, we definitely want to
2 communicate this.

3 Another thing which we have done is
4 this (inaudible) meeting actually had over close to
5 591 attendees registered. So, I have the email
6 addresses of all of them that would basically help us
7 in also communicating with, like, a blast email on if
8 any changes are caught or implemented or plan to be
9 implemented. So -- but definitely we have some ideas
10 on how do we want to communicate this because this is
11 something new. So -- and as we also start posting
12 this site also will get updated, so, I believe that
13 there is someplace where you can get feeds when the
14 sites get -- I need to also check with that office of
15 communication because they also have things like if
16 anything gets (inaudible). If you have -- it's posted
17 through (inaudible), Facebook and all that and
18 sometimes updates can go through that FDA has those
19 accounts. So, that is another mechanism that's some
20 thoughts to use those if you always -- you would
21 automatically get updates that happen and the FDA's
22 Facebook page or FDA's (inaudible) can communicate

1 that update.

2 All right. All right, so with that,
3 anything else you guys want to discuss, want to talk?
4 I'm open for that. I'm here and -- but respective of
5 the (inaudible) meeting, I hope I was able to provide
6 some valuable information to you all on how -- what
7 FDA is thinking about, what kind of regional
8 requirements FDA is thinking about, how FDA wants to
9 help in validating your submissions, how FDA wants to
10 help in testing your submissions and some of the
11 thought process that has -- that FDA has had in
12 setting up these requirements for the regional R3.
13 So, if any comments, any thoughts, anything which you
14 would see in the future or you would like to see in
15 the future, please write to us. You have the docket
16 for 30 days and after the docket period, you have the
17 e-prompt email address. We do (inaudible) that. And
18 with that, we will do the following, which is today's
19 presentation, as you see I have a few updates I need
20 to do on this presentation and then post it. Which,
21 again, including the regional requirements spreadsheet
22 and the forward compatibility spreadsheet. I think

1 this is May 20th, May 18th, for the docket. And any
2 update, any comments based on any update any
3 specification based on the comments we receive and
4 then we will start updating the FDA regional
5 implementation specification document, which was last
6 posted in 2016.

7 The second to last, third bullet, sorry
8 -- excuse that. And now we are preparing -- we will
9 prepare some sample regional R3 data files, as
10 requested. So, if it's some of the examples that we
11 have, maybe combination product, maybe pre-market
12 (inaudible) post-standard, post-market product and
13 then you can contact this email address after the
14 docket time frame.

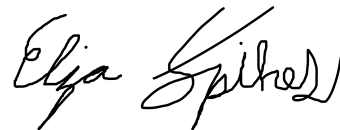
15 So, with that, I thank you all for
16 being here and attending on the (inaudible). Thank
17 you so much. This kind of collaboration really helps
18 us in getting this successful and making sure that
19 (cough) -- excuse me -- just making sure that the
20 sender and the receiver of electronic submissions both
21 are on the same page, are in synch and can end up in
22 being successful. So, thank you again and hope you

1 all enjoyed the session.

2 (Whereupon, at 3:12 p.m., the
3 proceeding was concluded.)
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1 CERTIFICATE OF NOTARY PUBLIC

2 I, ELIZA SPIKES, the officer before whom the
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16 this action.

17 

18 ELIZA SPIKES

19 Notary Public in and for the

20 STATE OF MARYLAND

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I, SONYA LEDANSKI HYDE, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



SONYA LEDANSKI HYDE

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