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A P P E A R A N C E S

List of Attendees:

Suranjan De, MS, MBA, Deputy Director Regulatory
Science Staff (RSS), Office of Surveillance &
Epidemiology (OSE), CDER, U.S. FDA

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

2 THE REPORTER: Good morning. Today is
3 Tuesday, November 7th, 2023.

4 MR. DE: All right. So good morning,
5 everyone. My name is Suranjan De. I am the Deputy
6 Director of Regulatory of Science in the Office of
7 Surveillance & Epidemiology in CEDR FDA.

8 So, good morning. And today's topic is
9 a topic -- is a topic on reporting premarket and
10 postmarket safety reports to FDA using ICH E2B(R3)
11 Standard.

12 So this is a follow-up of the
13 presentation that I had in April of this year. And so
14 this is the second one and one of the last ones before
15 FDA -- and it goes into making this a live interaction
16 system.

17 All right. So this is my standard
18 disclosure. So, next slide, please.

19 All right. So what is the FAERS
20 session overview? So this session will review updates
21 to requirements for submitting safety reports for,

1 INDs, IND_Exempt BA/BE studies, and approve drugs and
2 therapeutic biologic products, but excluding vaccine,
3 using the ICH E2B(R3) format.

4 Also, we will discuss about
5 implementation plan and progress and that's the most
6 exciting thing probably everybody is looking forward
7 for as to where we are with it and when will FDA be
8 ready with this.

9 We'll give you something on testing
10 updates. So we know that we -- you know, as sponsors,
11 you would want to invest with us to make sure that,
12 you know, your submissions are good.

13 And of course, we will also talk about
14 FDA's readiness and submitter preparedness. So FDA
15 readiness would be more of our FDA's, some timelines
16 that we will share with you. And of course, with
17 submitter preparedness, we want to give you some tips
18 on more things that a submitter will do from their end
19 to be prepared for submission ICSR using the E2B(R3)
20 format.

21 So as for the objectives, so we will

1 have basically three objectives. And this is
2 something that many in our organization would like to
3 understand and know what the objective is of this
4 presentation since they are attending this. Is we
5 recognize that FDA will require reporting of IND and
6 postmarket safety reports to be submitted in the R3
7 format to FAERS to the Gateway or Safety Reporting
8 Portal.

9 And then also, understand updated
10 regional extensions that are key for postmarket, IND,
11 and IND_Exempt. And of course, we communicate our
12 implementation status and readiness.

13 As for the second, regional extension,
14 I won't go into too much detail of the regional
15 extension because I did that in the April
16 meeting. Today, I will just talk about a few updates
17 that we had with regional extension based on the
18 testing that we did on some of our industry models.

19 All right. So today's agenda -- so
20 today's agenda, we're going to recap from the previous
21 public meeting. We will talk about the implementation

1 plan and progress, external and internal testing
2 updates. We'll take a break for 15 minutes. We'll
3 talk about the regional extension updates, FDA
4 readiness, submitter preparedness, and we'll go into a
5 summary.

6 Now, to recap from the previous public
7 meeting. In the recap, we'll also go over some of the
8 questions that were asked at the previous meeting
9 which we were unable to provide an answer during that
10 meeting. So many of these kind of slides, which will
11 talk about some of the questions that you had asked,
12 and we have prepared some answers and responses for
13 these questions.

14 All right. So the recap from the
15 previous public meeting. We had that meeting on April
16 4th. It was a six-hour meeting. All right. And six
17 hours of my talking. And the meeting agenda,
18 presentation, and slides, and recordings are available
19 at this link. So you can always go back and look at
20 the recordings of the previous meeting.

21 Before I get into the next slide, I

1 just wanted to let you know, I actually have a little
2 record. My voice may sound that I have a cold. So
3 I'm trying to stay away from everyone. So just excuse
4 me if my voice cracks. All right. Let's go to the
5 next slide.

6 So some recap from previous public
7 meeting. So what did we talk about last time? So we
8 talked about the implementation of R3 submissions of
9 both premarket and postmarket at the same time. We
10 still have the same plan. We will have a new date for
11 voluntary reporting and we will communicate that in
12 the future slides that you will see.

13 And we will also communicate all of
14 that in the FAERS Electronic Submission web page. We
15 have not done that yet. I know our plan was as we go
16 through the final implementation date. We know the
17 month, just final date in that month, and then we will
18 update the FAERS Electronic Submission web page.

19 I'll also be referring to the -- one of
20 the important documents, which is a Core and Regional
21 Data Elements document and everybody needs to be using

1 that to understand all the core and regional
2 elements. We talked about Controlled Terminology, the
3 Separate Submission -- Separate Submission Path, and
4 the rules.

5 So one of the paths for IND vs.
6 IND_Exempt vs. postmarket. It's very important
7 because that helps us in different shading in the
8 reports such that premarket reports to market
9 published publicly versus postmarket published
10 publicly. The submission methods and mechanisms are
11 based on the AS2 header and Routing ID. Also, we had
12 talked about Safety Reporting Portal, that is also
13 another option that companies have. All right. Next
14 slide.

15 So as for the rules of triaging of
16 ICSRs via ESG, so we had talked about how the reports
17 would come. So we have the premarket ICSRs submission
18 and the postmarket. In the premarket side, now you
19 have the AS2 Header. And for the premarket, CBER. So
20 those XML files will come and it appears in the
21 reporting system, so this -- the left-hand side, all

1 you will see is basically the submission that you will
2 do and then how will it show up in our FAERS System,
3 so we know that that's a premarket report.

4 Same thing for CDER INDs. And the
5 reason why we have these two separately because there
6 are some IND numbers which coincide, we can see that
7 in CBER, so to differentiate whose report is for
8 who. And then to send it to the right reviewer. We
9 have that routing and the XML file and the destination
10 already set.

11 Then we go into the
12 postmarket. Postmarket, we have kept it as the same
13 as we have today as we do with R2. So none of those
14 headers and the IDs have changed. And that report
15 gets sent there and now we are able to differentiate
16 between premarket and postmarket reports.

17 And within the premarket reports, we
18 are also able to differentiate who the safety reviewer
19 is and see they are in CBER. And this reports that
20 accordingly. Published or not published and
21 accordingly sent to the right reviewer. Okay. Next

1 slide, please.

2 So the Submission Path Business
3 Rules. This is, again, very important while we were
4 doing system testing and while we were doing investor
5 testing. We had to review this and make sure that
6 everybody understands. So that's why I have to point
7 us back again.

8 If you look at this table here, we have
9 the premarket ICSR, if it is 4CDER_IND or CBER_IND, or
10 IND_Exempt_BA/BE, viability -- ICSRs, then in that
11 case, the values are provided. For AS2 header, for
12 routing IDs, and N.1.4 should be inside the XML file,
13 which means the values of N.1.4, and within a batch,
14 you will have messages which is N.2.R.3 and what
15 should be the values for that.

16 So it's important that is followed
17 because this actually -- N.1 extend makes it all
18 foolproof that these reports will stay and not get
19 exposed publicly. And the report needs to be
20 published, also it makes sure that it goes to the
21 right reviewer for review, so it's very important that

1 these values are maintained and set in your systems so
2 that when you send these XMLs, and send it to the
3 right headers.

4 We also have rules where it says that
5 if you send something with an AS2 header or a routing
6 ID but does not have an N.1.4 or N.2.R.3 values, then
7 there will be a rejection. So -- and -- so for all
8 messages -- for all messages received that are in the
9 file, which is CDER and on the batch receiver and
10 different ZZFDA. So if you had that as CDER or your
11 N.1.4 was ZZFDA_PREMKT, then you're going to get a
12 rejection.

13 And similarly, that if you had N.2.R.3
14 as CDER_IND, or CBER_IND, or IND_Exempt_BA/BE, then
15 N.1.4 must be ZZFDA_PREMKT. If it was only ZZFDA, you
16 will get a rejection.

17 So -- so, yes. So these rules are very
18 important and you follow them so that we can
19 appropriately have these, you know, set in our
20 database, in our FAERS system, and that these reports
21 are secure and not -- and also, remember, just to

1 note, that based on this setup, we have in our FAERS
2 system, a concept of a published flag, which gets set
3 based on this. So it probably sets it up to not
4 publish.

5 So we are very -- because now that
6 FAERS is going to start getting premarket safety
7 reports, which it used to not before because
8 everything was in CTD, so more and more -- it becomes
9 more and more important that we take the right
10 precautions and right controls in order to safeguard
11 these ICSRs. Okay. Next slide, please.

12 Okay. Some other things that we had
13 discussed was the regional extensions for IND,
14 IND_Exempt_BA/BE, and postmarket safety reporting. We
15 have plans for validation and implementation. We have
16 the E2B validated. We will be posting that on the
17 Electronic Submission web page as a link. And I'll
18 let you know what the date is, it's on one of the
19 slides. This validator will actually help you in
20 testing your excimals [ph] before your submission.

21 We also last time talked about

1 regional-specific rejection and warning rules that we
2 have. There has been some updates to those rules
3 based on our industry testing, which I'll go over. We
4 also talked about FDA OIDs in our regional
5 extensions.

6 And also, the R2 to R3 forward
7 compatibility. It's mostly applicable for postmarket
8 safety reports, because premarket, we never had R2
9 standard. So this has not changed, still the same.

10 So -- so for forward compatibility --
11 and that is very -- also very important that we have
12 also noticed, especially in our organization, when we
13 are talking about R2 and R3, everybody is looking only
14 at the ICHS BFC document, which is the backup forward
15 compatibility. But BFC document will not talk
16 anything about the regional data elements.

17 So it is all -- it is important that
18 you also look at the regional data elements for that,
19 look at the FDA's forward compatibility document which
20 is also posted on the FAERS Electronic Submission
21 page. So both documents are important to see. Next

1 slide, please.

2 All right. So just -- and I'm changing
3 gears a little bit. I have got some questions I have
4 received recently on ESG NextGen. And I know this is
5 not part of -- this is not E2B, this is not E2B R.3
6 standard, but I just wanted to give a little
7 information on where we are and -- and you know, what
8 the status is.

9 So the ESG NextGen offers an
10 application like an API assistance with tasks
11 including initial and subsequent submissions. All of
12 the ESGs NextGen are built using RESTful Standards for
13 ease of integration. And the API standards for
14 security enforcement to ensure data exchange is
15 secure, data is secure.

16 So with ESG NextGen, the industry can
17 use API to generate the API submission ID, create
18 submission payload, and submit the payload to the FDA
19 to process. The combination client ID and the secret
20 key is a unique identifier that each industry partner
21 will use to submit data to the FDA. The FDA will

1 publish more details in the future, but the draft
2 specifications is here.

3 How this is going to have an impact on
4 what you have today will also be communicated, which
5 currently it's not, but we will definitely communicate
6 that to you all as to what in fact -- will it have an
7 impact on the way it's working today with our
8 industry. Next.

9 And FDA will also disseminate this
10 testing information in advance so industry partners
11 can update their respective process to be prepared for
12 the testing. So there will be a good amount of time
13 that will be provided to do that testing. But as of
14 now, this is what the status is, nothing has advanced
15 much.

16 So as of now, you know, the status quo
17 is whatever you were doing, continue with it. And
18 when new updates come, you know, you definitely will
19 get notified of those. All right.

20 All right. So next then we will talk
21 about some of the comments and questions that were

1 asked in the previous meeting that we had on this
2 April meeting in April. And I'll go over a few
3 questions I think that will be important for you to
4 understand. And we made these questions more an FAQ
5 and posted up on our FAERS Electronic Submission
6 page.

7 So going into some of the questions, so
8 one question was that, yes, there has been change to
9 the latest MedWatch. This is dealing with certain
10 data elements that the MedWatch had. Like, for
11 example, gender was a new data element, and there was
12 one more data element that was added to the MedWatch
13 form.

14 And the question was does R3 technical
15 specification -- consider these new gender data
16 elements. When we had published this R3 the first
17 time, these data elements weren't there. But once the
18 authorization happened, these data elements came
19 in. And so let's go into the answer.

20 So FDA is considering updating the R3
21 to include the gender data. We still have to -- just

1 to add a new data element is just -- R3 is flexible,
2 but it's not that easy. We have to work through
3 the -- through the -- you know, the H07 [ph], B3
4 model, so -- so right now, yes, we are looking into
5 it, but currently, we are not going to be updating our
6 technical spec to include this data element right
7 away. But at some point, we will incorporate this, so
8 we are considering updating for the future of the
9 specification, but not right now.

10 All right. Another question, once 7-
11 day or 15-day IND safety reports are submitted via
12 either submission method, the ESG or the SRP, does the
13 sponsor still need to submit in eCTD format or notify
14 the FDA project manager? So once the IND safety
15 reports are submitted electronically via the -- via
16 SRP or the Gateway, submitters do not need to submit
17 them in the eCTD format or notify FDA project
18 manager.

19 Because once it has come, it comes into
20 FAERS, the project managers -- the FDA project
21 managers and the clinical reviewers will automatically

1 get notified based on that submission that has come
2 into FAERS for those IND safety reports.

3 All right. For a small business
4 sponsor that has an ESG account but does not have in-
5 house XML capability, are they able to submit ICSRs
6 through SRP? And the answer is, yes, they can submit
7 using the Safety Reporting Portal. That's the whole
8 reason why we have the Safety Reporting Portal. We
9 have registered the Safety Reporting Portal. And once
10 you are registered, you have an account, then you
11 should be able to log in and submit safety reports
12 through the Safety Reporting Portal.

13 All right. Next. So if we -- so if we
14 are cross-reporting ICSRs, which IND number should be
15 in the header? The IND for the study in which the
16 event occurred or the IND for which we are submitting
17 to? And the answer to that is sponsors should use the
18 IND number under which the clinical trial where the
19 event occurs is conducted as the primary IND number in
20 the indicated E2B data field.

21 So when you have a cross-reporter,

1 that's what -- the primary IND number will be in the
2 primary IND number field and the cross-referenced INDs
3 will be the in cross-referenced IND fields. Given
4 that these two fields are regional elements that the
5 FDA has defined.

6 Can we upload an XML file in SRP
7 instead of entering data manually? And the response
8 is, no. Because if you have XML, then might as well
9 use the Webtrader and submit the XML. Right? Because
10 Webtrader is something which doesn't cost, and you can
11 have an account, and you should be able to submit. In
12 Webtrader, of course, you can only submit one file at
13 a time. But with SRP, the whole purpose of SRP was
14 that the data is to be entered in, which becomes
15 structured, and then -- and then we get that data and
16 put it into our FAERS system. So -- so no, SRP, you
17 have to manually enter all the data. If you already
18 an XML, then you can use the Webtrader to submit.

19 All right. So is there any work being
20 done to sync the required fields between FAERS, VAERS,
21 and MedWatch? And the answer is, yes. FAERS has

1 harmonized the data elements between these to the
2 extent possible. We have tried as much as possible to
3 -- to make sure that the required fields are in sync.

4 But with the VAERS data elements, there
5 are some additional VAERS elements that we don't
6 have. We will -- we do have plans to work on making
7 sure that the FAERS and the VAERS structure or the
8 technical specification is combined into one
9 harmonized specification. We have not done that
10 yet. We want to get our affairs started. When we
11 work with VAERS, we will work that through.

12 But to an extent, we have tried to make
13 sure that core values, the data element properties
14 that is being used between FAERS and VAERS are the
15 same.

16 All right. Please confirm if
17 FDA.C.1.7.1 must be set to a value of six, which is 7-
18 day when submitting follow-up information to an
19 unexpected fatal or life-threatening adverse event
20 study for a clinical trial. And the answer is, yes,
21 that is correct. This is a very straightforward

1 answer. Okay. Next question.

2 Okay. Regarding the Medicinal Product
3 Name as Reported, presumably, it would be preferred to
4 use the coded product description and local tradename
5 from the company's product library rather than the
6 verbatim medicinal product name as reported; is that
7 correct? And the answer is, please refer to the FDA
8 Regional Implementation Guide that we have talked
9 about in the Section 4.2.5.3, Data Element G.k.2.2, it
10 stands for medicinal product name as reported by the
11 primary source.

12 So what would FDA prefer? FDA would
13 prefer to receive the United States Local Medicinal
14 Product Name, which would be the same name submitted
15 in the structured product labeling format as a
16 standard format for the exchange of drug listing.

17 So this also supports auto-coding of
18 the submitted safety reports. This is something we
19 really encourage all the companies, that when you are
20 submitting the -- the suspect product name, especially
21 with a primary suspect product that you have, please,

1 please, please use the name that you're registered
2 with through SPL. Because that's the name that is --
3 in also in our product dictionary. So when a report
4 comes in, it auto auto codes and we don't have to stop
5 to report for manual intervention. So it's very
6 important that those names are the same.

7 All right. Next -- another question is
8 regarding the data element FDA.G.k.13.r. That is FDA
9 Specialized Product Category, for combination
10 products, would this be entered for any combination
11 product ICSR or just malfunction or 5-day? Also,
12 would this be provided as -- provided in addition to
13 FDA Procode? The response is, yes. I missed the why,
14 sorry. Yes. The FDA Specialized Product Category for
15 combination product is applicable for all ICSRs for
16 combination products.

17 So if you have a product report, yes,
18 that special category is useful. And just not only
19 for malfunctions, but -- but any combination
20 product. It just gives us additional information
21 about that combination product. So it has different

1 categories, and depending upon the category, you can
2 provide that information in the FDA.G.k.13.r.

3 All right. Could you please confirm that when cross-
4 reporting IND -- okay.

5 Cross-reporting IND Safety Reports to
6 FAERs, sponsor needs to only submit one report to the
7 primary IND and provide a list of all of the affected
8 INDs? All right. And the answer is, yes, that is
9 correct. Sponsors should use the Data Element FDA
10 C.5.5a. It stands for IND number where AE occurred,
11 to report the IND number under which the clinical
12 trial where the event occurred. And sponsors should
13 also use the indicated repeatable Data Element, which
14 is FDA.C.5.r6, IND number for cross-reported IND to
15 submit individually other relevant INDs.

16 So if you also have -- you can report
17 all the cross-reported INDs, you don't have any kind
18 of -- any kind of criteria to say only reporting these
19 ones and not that one. So if you had cross-reported
20 INDs for that primary IND, then just put all the
21 cross-reported INDs in that Data Element

1 FDA.C.5.r6. Okay. Next.

2 Okay. Is the mechanism to validate
3 E2B(R3) available only to the WebTrader account? Will
4 anyone with a Gateway-to-Gateway connection be able to
5 access the validator tool? And the response is, the
6 E2B(R3) validator tool is independent of the
7 submission mechanism. Okay. Submitters may validate
8 XML files prior to submitting ICSRs to the agency. If
9 rejected, submitters may adjust their XML generator
10 and then submit the ICSR via WebTrader or the
11 Gateway.

12 So WebTrader or Gateway is basically
13 the -- basically, I consider them as more like the --
14 the postman who says the XML is the letter and the
15 letter has been validated through the validator. So
16 the validator is independent of that. And that will
17 be available on FAERS Electronic Submission page. I
18 think this month, we are planning to put that
19 validator so that you can start accessing it.

20 All right. Next question. All
21 right. Does the E2B validator show both soft

1 validation and hard validation? Suppose if we receive
2 validation errors, does it mean it will fail the
3 transmission of the case? All right. So the ETB
4 validator shows both rejection and warning. Any
5 rejection will send a negative acknowledgment to the
6 submitter and the ICSR will not transmit to the
7 FDA. I mean, not transmit. It's not the right
8 language. I think the ICSRs will not be committed by
9 FAERS, basically. I would say that. Because
10 transmission, you have already transmitted, but now
11 the transmission has a negative acknowledgment.

12 So I will change the answer to say it
13 will not be committed by the FAERS database so you get
14 a negative acknowledgment if there was a rejection.

15 Warnings? Yes, we will accept it. But
16 again, the warnings are given just for that. And
17 follow -- then you get a follow-up -- when you submit
18 a follow-up, the idea would be to correct that warning
19 and submit that to us. The warning is not going to --
20 not going to reject that submission.

21 All right. Next question. Can

1 premarket ICSRs be submitted via ESG database to
2 database during the voluntary submission period? The
3 answer is, yes. During the voluntary submission
4 period, premarket ICSRs can be submitted via ESG in
5 E2B(R3) format only. There is no R2 format for
6 premarket ICSRs; okay? So just remember that
7 premarket ICSRs, we don't accept any R2, it only has
8 to be R3.

9 For postmarket, during the voluntary
10 period, you can submit through R2. And as you're
11 moving through R3, you transition over to R3. So keep
12 in mind about the transition period that for your
13 information you may want to have.

14 All right. Okay. A few more
15 questions. What do you mean when saying a single
16 batch must have the same sender? This is an
17 interesting one. Can you please provide an
18 example? Okay. So the response to that is, this
19 applies to a Contract Research Organization, CRO, who
20 are submitting reports for multiple sponsors or
21 application holders. So when more than one ICSR is

1 sent in one batch, then all ICSRs must have the same
2 Message Sender Identifier Information.

3 So which means that if you have company
4 A and company B, two different companies, so in one
5 batch when you are sending an ICSR, do not send ICSR
6 where ICSR 1 is company A and ICSR 2 in the same batch
7 is for company B.

8 So if you're sending, please send that
9 all in one batch. So if you had ICSR 1, 5, 6, and 7
10 for company A, then put it in that one batch. And if
11 ICSR 2, 8, 10, and 12 are for company B, then put it
12 in a separate batch. Don't mix them up. So that's
13 what this particular question -- this particular
14 response behind saying the single batch must have the
15 same sender is talking about.

16 Then regarding sending literature
17 attachments, many times we do not have the final
18 literature document ready for -- ready at the time of
19 submission due to various reasons, maybe translation
20 is required. When we would send the final literature
21 attachment, would this be sent as an amendment? The

1 answer is, please send the final literature attachment
2 as a follow-up ICSR.

3 For more information about reporting
4 follow-up, we all know where to look for. But it can
5 be submitted later. Once you have, you can submit
6 that, and then it can be sent as an amendment or it
7 can be sent as a follow-up with an attachment.

8 Can we still submit FDA codes for
9 devices or IMDRF codes only? The answer is that you
10 can submit either the FDA codes or the IMDRF codes for
11 the device, problem codes. So I believe that's about
12 in FAERS. When it comes to the postmarket combination
13 reports.

14 Okay. All right. So with that, there
15 weren't too many questions, but I wanted to address
16 these questions because we didn't have time the last
17 time and we wanted to make sure that what would be a
18 good answer we have for you to answer.

19 So with that, we will go into the next
20 topic, which is implementation plan and
21 progress. Where is FDA with the implementation of

1 E2B(R3)? Okay. All right. So this is just one
2 slide, there are a lot of things here. I had
3 presented this slide the last time also. There were a
4 lot of things that had not started. Right now, we are
5 at a state where a lot of things are completed or in
6 progress.

7 So we published the Regional
8 Specifications. So this is the Regional Spec, which
9 is all the documentation, so we produced them as a
10 package because it has got, I think, three or four
11 documents. And this was published initially in April
12 2022. And then we had it published updated in August
13 and September. I think I missed one. There was one
14 also updated in October of 2023.

15 So if you go to the FAERS Electronic
16 Submission web page, the document which was last
17 published in October of 2023 was the Code and the
18 Regional Elements and the Excel Spreadsheet of all the
19 data elements. There was some updates that were
20 done. All updates are documented in the -- the change
21 history. So you will see what has been updated.

1 So this has to do with all the
2 Published Regional Specs. Again, as I said, I will
3 repeat, please also look into the follow-up
4 compatibility. If you miss that, you may face an
5 issue because in the follow-up compatibility, there
6 are some data points that in R2, FDA would consider
7 them as -- as numeric values. But when it came to R3,
8 that same data field has become -- and so that is
9 FDA's rule for follow-up compatibility and is
10 documented in that. Okay.

11 There are some data elements in the
12 follow-up compatibility which has original data
13 points. When it was an R2, each had its own tag, but
14 now it has become repeatable. So -- in R3. So please
15 keep an eye on the follow-up compatibility of the
16 Regional Elements.

17 Then we come into tool
18 enhancements. So enhancing both our intake and
19 analytic tool to include regional extensions. This
20 work has already been done. The main theme here is
21 why this is in progress because -- because of this R3

1 implementation.

2 We also have to make sure that some of
3 our downstream systems are able to accommodate the R3
4 model. Because the downstream systems we have in our
5 data mining tools, and so on and so forth, and that
6 they are able to accommodate this. So that's where we
7 have -- that's why we have in progress. But the first
8 bullet is completed. Because the first bullet is
9 completed, we were able to complete all other areas
10 that we have.

11 So we have the ESG setup. That is
12 completed in preproduction environment. That's the
13 reason we were able to do industry testing. And --
14 and the setup completed for inbound and outbound
15 folders. And of course, we have also completed our
16 production environment setup for the routing IDs. We
17 have not notified, but internally, we have completed
18 that and we are ready.

19 So once we publish on our Electronic
20 Submission web page about that we are ready, you know,
21 whatever is in the technical specification for the

1 routing IDs and production, it becomes applicable.

2 If you were to test with FDA, and when
3 you are ready, we are open to test. With FDA, our
4 preproduction environment will be open. Only that we
5 have to use the preproduction routing ID. With the
6 routing ID, we have to use the word TST as a prefix, I
7 believe. No, post-fix. I think post-fix. We use the
8 word TST. So everything stays the same, but you have
9 a post-fix of TST. So you can test with us, you
10 can -- my recommendation would be to try with the E2B
11 validator first, making sure that XML file is good,
12 and then you can submit that.

13 Testing through the Gateway will
14 actually tell you your acknowledgment files. That's
15 what you may want to -- you would like to test.

16 From the FDA's perspective, system
17 testing is completed, all issues have been identified
18 and fixed. And for industry -- we did some industry
19 testing with eight companies, tested both premarket
20 and postmarket ICSRs through the Gateway. Two-phase
21 testing was completed. Tested E2B validator. And

1 testing completed with a few issues that were
2 identified, and of course, corrected.

3 We also tried to test large files,
4 small files, and so on and so forth. And that is
5 something that I would recommend also for you all to
6 do. Have a big batch, have a -- you know, what do you
7 say? A file with a large attachment. And those are
8 some of the tips we will talk about in the future
9 slides that I have.

10 And then finally, public communication,
11 that is also in progress and it's ongoing. We have
12 done some public communication. For example, today, I
13 am presenting to you on what we have done so far, our
14 readiness, and so forth. We are preparing, as I said,
15 an FAQ for the technical specification, onboarding,
16 and any inquiries.

17 So all these questions that we answered
18 today, some of these will be put onto the FAQ. And as
19 we are getting questions from companies, we have been
20 getting individual questions from sponsors, so we are
21 documenting them. They will come into an FAQ. And we

1 will, of course, communicate the go-live date and
2 we'll tell you in the future slides. I have a slide
3 on the FDA's readiness, which will tell you the go-
4 live date of things.

5 So with this implementation plan and
6 progress, this is where we are. Most likely, all this
7 will be complete by the end of this year. And most
8 likely, we will be done with all these activities by
9 the end of this year. So -- but these are some of the
10 steps that we have followed. And -- yeah. And I
11 really appreciate all of the companies who actually
12 tested with us. And I think we had a good
13 testing. Because these companies were ready with the
14 Regional Elements, also. Which was most important
15 because everybody is probably ready with the Core
16 Regional Elements, but we had to get it with the code,
17 as well as the FDA's Regional Elements.

18 So yeah -- so I think we are in a good
19 state here with the implementation plan and
20 progress.

21 All right. Now, on to -- now, that we

1 had this presentation today until we give you a date
2 and we force that on the Electronic Submission -- our
3 FAERS Electronic Submission web page, please continue
4 to submit ICSRs in eCTD format and postmarket ICSRs
5 need to be in E2B(R2) format until we notify that
6 date.

7 So just don't start submitting the
8 premarket -- premarket ICSRs -- I have a typo
9 there. Okay. It should be premarket. Premarket
10 ICSRs need to be R3 format right away. But just let
11 us give you the date, and then after that.

12 Now, again, as I said, when we give the
13 date, from that point, you have two years of one and
14 two repeated before you become already -- and the
15 compliance date is put for submission of the ICSRs in
16 R3 format.

17 All right. Okay. Based on my
18 presentation, we might have the -- I may continue with
19 the next topic because based on the presentation and
20 the timing, we are running fast.

21 All right. External and internal

1 testing update. So how did we do? This might help
2 you also in testing with the FDA, as to what we did
3 with our industry partners when we did our
4 testing. So it might help you when you're doing
5 testing with us.

6 So let's go over -- so first thing,
7 this was some of the internal testing that we did
8 that, again, might help you in doing your internal
9 testing. So multiple scenario testing was
10 conducted. We had a whole bunch of different types of
11 scenarios. We took premarket. We said, okay, let's
12 do premarket safety reports. Okay. IND safety
13 reports.

14 Also, have a separate testing for
15 aggregate safety reports. And also have a testing for
16 safety reports with cross-referenced INDs. So let's
17 do all this in the premarket safety reports. We also
18 have the IND_Exempt BA/BE safety reports.

19 We also have done it like if it was the
20 same IND number but for different CDER and and CBER,
21 making sure that N.1.4 and N.2.R.3 are appropriately

1 set. So we did that testing also.

2 And then we also -- then going into
3 postmarket, making sure that we have, you know, the
4 safety reports including combination products,
5 attachments, postmarket study reports. And then there
6 will be two reports that will be submitted. Looking
7 at all the different rules that has been defined, the
8 Business Rules of Data Checks. They have been testing
9 all of those where -- as part of our list.

10 Then we wanted to -- we also tested for
11 both positive and negative acknowledgments. So we are
12 expecting that this file will give me a negative
13 acknowledgment, and did I get it? Or this file is
14 going to give me a positive acknowledgment and did I
15 get it?

16 So all this type of testing was done
17 internally. Yes, it did take us some time preparing
18 our test files and so on and so forth. You could
19 actually some of our XML files that we have posted,
20 and that could be a baseline, and then you can
21 manipulate those files to do your testing. You know,

1 and all -- of course, you'll have to do your testing
2 once you generate XML from that file -- those external
3 instances may not be useful, but useful to compare.

4 But you'll have to generate from your
5 system, get to the validator, see what failed, go back
6 to your system, do that fix, generate again, back to
7 the validator. If everything is good. then you know
8 that you have worked it out. All right. Next slide.

9 So the external testing we conducted in
10 two phases. So phase 1 testing was that you submit
11 those ICRs along with the regional extension. Of
12 course, to start with those testing, companies first
13 went to the validator. We gave them access to this
14 validator. They went and walked back through. All
15 those seven-eight companies that worked with us, they
16 really liked the validators. It actually gave them --
17 because they were able to prepare a lot of things
18 ahead of time before the submission and getting the
19 acknowledgment. So the validator was really useful.

20 And in that validator -- once they did
21 their submissions, they also used the different types

1 of criteria's that we had done during our internal
2 testing. Submitting premarket and postmarket. We did
3 that sometime in July with 7 companies as
4 participants. We received over 169 XMLs from 4
5 companies, 3 in postmarket, which was a good number to
6 start with. And with that, we then identified
7 issues.

8 And our finding during our phase 1
9 testing was external connection URLUs need to be
10 validated. We had some issues with the URL, I think
11 we got it fixed. And now, when we publish it, I think
12 it should be all okay.

13 Then we also have the ESG Routing ID
14 and AS2 Header changed to receive industry file, use
15 the TST prefix. I think we used just the prefix
16 TST. I think that was the one that for testing, we
17 had to do that. And that's what you're going to do
18 when you test with us.

19 Our dosage unit not accepting UCUM
20 codes, so that was something we had identified to get
21 fixed in phase 1 testing. Updating the rejection and

1 warning tag for non-aggregate reports. So there was
2 some XML tags related to that that had to be
3 fixed. Country code EU was not getting accepted,
4 which was fixed. The IND numbers were aversive in
5 that code. Currently, only six IND numbers were
6 getting accepted, that was fixed after phase 1. They
7 basically accept -- that field is, I think, ten
8 characters -- ten numbers long. So as long as you
9 have the right number, we will accept it.

10 Then the ability to download the list
11 of warnings and rejections shown in E2B validator tool
12 to Excel. That was something that was a change
13 request for the validator. We were unable to finish
14 through that. We have kept it now backlogged. At
15 some point, we will work through it. But it shows you
16 the list of all the warnings and rejections. This was
17 some additional request to download that list. So
18 that was kind of a few things that we found in phase 1
19 testing. Next slide.

20 Some recommendations we got from phase
21 1 testing was in a FAERS test environment

1 availability. The FDA's ESG Gateway and FAERS testing
2 environment will remain open for use. You can
3 continue to submit (R3) files for internal testing and
4 development efforts.

5 Data setup in FAERS. Now, this is
6 something that you will have to work with us,
7 especially for IND safety reports. You will have to
8 let us know on -- which INDs or cross-reported INDs
9 you are reporting on. We do have our FAERS dictionary
10 where we have got all our INDs.

11 But if you -- before you start testing,
12 if you notice this to us, then what happens is you
13 will not get a rejection. Because if the IND numbers
14 don't match, then you will get a rejection. So it'll
15 be good to notify us or the organization which IND
16 numbers you are going to be reporting on and the
17 cross-referenced IND numbers too.

18 Communication. If you have any
19 questions or need further clarification, please do not
20 hesitate to reach us out for our test. And for this -
21 - when you reach out for E2B(R3) testing, please put

1 in the subject line E2B(R3) Testing that helps us to
2 triage which question or which inquiry is for
3 what. Because we also have so many other types of
4 inquiries through the FAERSESUB. So that will help
5 us.

6 If you need -- if needed, we are
7 available to set up a one-on-one for any further
8 discussion and clarification.

9 And then, of course, after the phase 1
10 testing, we finally addressed our retesting in phase
11 2. We did that. But the first four bullets are
12 something that is applicable to all of you. We're not
13 part of investor testing, but when you start your
14 testing, the first four bullets are applicable to you
15 all, and you can really -- we can collaborate to make
16 sure that you are fully set and ready for submitting,
17 you know, ICSRs in R3 format. Next slide.

18 All right. In phase 2 testing, so we
19 retest the issues reported and we did some performance
20 testing. So use the same -- you know, we use the same
21 Routing IDs and AS2 Headers, but we did some rigorous

1 testing to submit files -- batch files with multiple
2 ICSRs, attachments, and all R3 supported format, you
3 know, large size files. And there was one also
4 recommendation for the E2B Validator. We also
5 incorporated that and went in to test that
6 too. Okay.

7 So this is also important that you may
8 want to do some rigorous testing of large files. I
9 think our technical-specific problem will tell what is
10 a max size that we can take, but -- but I would
11 recommend that you also -- that you do that. There
12 are situations that happen where some company may
13 later realize that there was a whole bunch of ICSRs
14 which are nonexpedited, but they were identified late,
15 and they weren't all submitted in a big batch. Yes,
16 you can submit, but we need to make sure that these
17 batches are not so large.

18 And also, we know that R3 XML files of
19 large size is really -- makes it really bigger than
20 R2. So we want to make sure that you're getting your
21 acknowledgements on time. I think we have a 24-

1 hour -- I believe 24 to 48-hour turnaround to get your
2 acknowledgments. Small size files, I think you will
3 probably get it in two hours, within two hours. But
4 large size files, it may be more. So please do test
5 that. All right. Next slide.

6 Okay. So all the issues we resolved
7 from phase 1 testing, and the reason I am telling you
8 this is because this has got updated in the
9 implementation -- FDA's regional implementation
10 package. So the big spreadsheet actually has these
11 changes.

12 So updated rejection R2 and D.2
13 warnings. So this one became from a rejection to a
14 warning. Changed the existing rejection to a
15 warning. And the condition was if the type of report
16 is a report from study, and the IND number where AE
17 occurred is provided, and the identification number of
18 the report linked to this is populated. That means
19 you're talking about an aggregate report. And your
20 patient identified must have the value of aggregate.

21 So this is what used to be a rejection,

1 we made it into a warning, so the file won't get
2 rejected, we'll just give you a warning.

3 Another one is system must allow
4 submission of IND numbers with less than six
5 digits. So we had a situation where the IND number
6 was ten digits, so now we just said, let's go to six
7 digit and five digit. We have the IND number as ten
8 numeric. As long as the IND number is a valid IND
9 number. Okay. It could be a five-digit, it could be
10 a six-digit, it could be more, it could be a seven-
11 digit, but it has to have a valid IND number. So that
12 is when you will get a rejection. So that's the rule
13 that was put in for this.

14 Looking at the length, that was -- of
15 course, if you give me an 11 numeric data value, yes,
16 it's going to get rejected. But anything 10 and
17 below, but it has to be a valid number, and we will
18 accept it. Next slide.

19 Okay. So postmarket study report
20 logic. So that I want to mention it because it's very
21 important. We submit two reports. So when it comes

1 to the premarket, so you will have to have your Batch
2 Receiver Identifier, that's ZZFDA_PREMKT, which I
3 mentioned earlier. The N.2.r.3, that should be
4 CDER_IND or CBER_IND. And then type of report is 2
5 report from study type where the reaction was observed
6 is 1, which is clinical trials.

7 This is for the postmarket
8 report. Now, with these values, this report will not
9 get posted publicly. Because the public -- the
10 published flag will be automatically set to know.

11 Now, for the postmarket side, you will
12 say the Batch Receiver Identifier is ZZFDA, so I know
13 this is coming from the postmarket route, but on a
14 postmarket study. And how do I know? Because the
15 type of report is 2, which is report from study;
16 okay? And observe type is 1. And the good advantage
17 of this, setting them up this way, this report also
18 won't get published publicly.

19 So all postmarket study reports will
20 not get published publicly. But it will go to the
21 right reviewer, who is supposed to review this

1 report.

2 We have not talked about yet should we
3 make it into one report or not as most of the -- all
4 of the regulators are getting us two reports, so we
5 have also -- we are doing it in these two
6 reports. But they probably, at some point, we may all
7 discuss together to see if this could be just one
8 report submitted to FDA.

9 But as of now, it's two reports. And
10 these are the values that need to be used to define
11 those two reports for the postmarket
12 study. Okay. Next slide.

13 Okay. Remedial Action Initiated tag
14 value. So the earlier system was providing warning
15 for Remedial Action when a malfunction is true and
16 local criteria is 4, which is 5-day. System will now
17 generate a warning if Remedial Action is not provided;
18 right? And malfunction is true and local report is 5,
19 which is 30-day. So this one, I think, should be
20 probably 4 -- 4-5 day report. Because then you are
21 saying there's a Remedial Action because it was

1 immediately taken. So 5-day -- no. 5-day, 30-day is
2 fine, because that's a malfunction report.

3 So in this case, the -- it will just
4 provide a warning and there's no rejection in
5 this. Next -- next. Okay.

6 There were some defects and issues. I
7 talked about UCUM codes not accepted, this is now
8 going to be accepted. Date of death, null flavor not
9 accepted. This will get accepted, especially when the
10 report is a premarket report. And when I say
11 premarket report, one thing that I keep in mind is I
12 translate that into N.1.4 equal to ZZFDA_PREMKT and
13 N.2.R.3 is CDER_IND or CBER_IND. And you know, if
14 it's an IND, then IND with adverse code is -- so
15 that's kind of things I keep in mind when I talk about
16 the premarket report.

17 So in this case, if it is a premarket
18 report and there was -- if result in death is true,
19 then the death date is required. But if you don't
20 have the death date, you can submit a null
21 flavor. But this will only happen with the premarket

1 report.

2 EU country code not accepted. This
3 will now start accepting, so not a problem, we have
4 fixed it. And the system will start accepting it.

5 Okay. E2B Validator UI changes. So
6 the validator only had one change. We added an
7 indicator called severity to indicate if the XML file
8 has any warning or rejection. So this was something
9 that was not there. Because it will tell you what the
10 error is, but it will tell you it was a warning error
11 or a rejection error. So we now are displaying that
12 on the validator. So those are changes with the
13 validator. Next slide, please.

14 Okay. During the testing, we had some
15 frequently asked questions. When will FDA start
16 accepting ICSRs in ETB(R3) format? So from this slide
17 onwards, you will start getting the hints of when FDA
18 is starting to accept in E2B(R3) format. As we go
19 through this presentation to the end, you'll probably
20 get some hints and all of that.

21 So during the voluntary period, you may

1 begin -- begin submitting both pre and postmarket in
2 R3 format. So we anticipate that companies may begin
3 to accept postmarket format in January 2024. And we
4 hope to have the final Guidance for Industry in March
5 of 2024 for the IND safety reports. And will begin
6 accepting ICSRs at that time.

7 You may ask, hey, I thought you said
8 the pre and post are going at the same time, but here,
9 they say January and March. And the reason is that
10 you also have to understand that for the premarket or
11 the IND safety reports, we have been getting PDFs of
12 MedWatch.

13 So we have a big change management that
14 we have to do within our organization to move our
15 clinical reviewer from looking at a MedWatch to
16 looking at this digitized ICSR. So that's why we need
17 some more time for the -- for the premarket
18 one. Post-market one, I would review. It's already
19 getting R3, so they already are used to and accustomed
20 to looking at the ICSR in a particular format. So
21 that's -- that makes it more easier.

1 Will I be able to submit R3 files for
2 both pre and post-prior to the mandatory reporting
3 start date? Yes. During the two-year voluntary
4 period, you will be able to submit both pre and
5 postmarket reports.

6 Can a company choose to submit
7 postmarket reports in R3 format and paper for
8 premarket prior to the compliance date? Yes. The
9 company can choose to submit postmarket safety reports
10 in R3 format and premarket safety reports using the
11 eCTD format. Okay.

12 So it's very important in eCTD format,
13 not paper, prior to the compliance date. All
14 right. And as I said, that is a two-year voluntary
15 period. So if the -- yeah. I'll go into the slide
16 and that'll show you what the voluntary period is
17 going to be and when the compliance date is going to
18 be.

19 When will the E2B(R3) Validator tool be
20 available? So here is a date. So I'm trying to make
21 it available by -- starting November 20th. I believe

1 that's a Monday. And I just got the okay from our
2 security team that URL can be posted publicly.

3 So we will post that on the Electronic
4 Submission web page and I will have my office -- our
5 communication team will get that for us and they will
6 make sure. And as soon as they are -- I think people
7 who are subscribed to the page will automatically get
8 a notification. But starting November 20th, we will
9 have that E2B Validator available.

10 And then, of course, we'll an FAQ which
11 we will post on the same FAERS Electronic Submission
12 page. Okay. All right. Next slide. All right.

13 So today, I wanted to also discuss with
14 you about the E2B Validator, what it is, and how you
15 can use it.

16 So FDA will provide this E2B Validator,
17 as I said, November 20th, you'll have it, to
18 facilitate the validation of E2B(R3) XML files from
19 your safety database during your pilot testing
20 phase. So once you generate from your safety
21 database, the XML file, you can come here, browse, and

1 test it.

2 And so this validator will provide a
3 web-based interface and it will enable to select the
4 E2B XML file and validate. And it also provides you a
5 status of the results that are displayed to the
6 user.

7 So I'm going to give you a live demo of
8 the validator. And in doing that, we will first click
9 on that link here, which then opens up the
10 validator. All right. So I hope everybody can see
11 the validator. And in this validator, as you see at
12 the top, it says what it is. It validates, just not
13 the code. ICHS Elements, it validates also against
14 the Regional Technical Specification. FDA's Regional
15 Technical. So it has all of that.

16 And then -- so you can either paste --
17 copy and paste a file or you can browse. The one
18 important thing about this here is that when you
19 browse an XML file or you paste an XML file and that
20 shows up in the big box at the bottom under XML
21 source, we don't store this anywhere in our database

1 or in our location. It's just in that session. You
2 want to close that, it's gone; okay? So just to let
3 you know that when you're testing.

4 Now, what you could do is if you copy,
5 you can copy and paste. Or if you have an XML file,
6 we'll click on browse. When you click on browse, you
7 can pick one file, open and it's going to give us a
8 positive acknowledgment. We open that. And then you
9 see here the XML shows up here; right? And that XML
10 file can show up here. So if you scroll down in the
11 small scroll bar, and you see that XML, and that XML
12 file is here; okay?

13 Now, what we will do is you can do --
14 next, is to click on the validate button. And -- and
15 you see that validation status that shows up at the
16 bottom, it says validate XML file, that means your
17 file is a valid file; right? Now, you know
18 what? Let's say in this particular file, can we
19 scroll up in the file? Yes. Scroll up all the way
20 up. Let's see. So in this file, let's say we go and
21 change a value in this file itself. If you scroll

1 slightly down a little bit. Okay. Hold there. And
2 let's say in this we update -- we just changed some
3 value. Let's say extension is CDER. So --
4 no. Scroll a little more down. A little more. Some
5 more. A little more down. Okay. Availability time
6 value.

7 All right. So let's go to the row that
8 says availability time value code 2.22 and add a zero
9 after the number four. Okay. Now, hit
10 unvalidate. Now, you see there is a problem with the
11 latest receive date.

12 So from -- from an industry
13 perspective, you can also manipulate this file to see
14 what you can do; okay? This is something which also
15 helped us that, okay, we fixed this, I saw what the
16 issue is, I fixed it right in this file, and then take
17 a copy of this file, and then I know what things have
18 to be fixed. So if you go back and remove the zero
19 again, that will be that zero. Yes. And hit
20 unvalidate. You will see that it will say it's a
21 valid file.

1 All right. So now, let's clear this,
2 and let's find a file which has got some issues and
3 click on that. It will give you a negative
4 acknowledgment. All right. And here is the XML file
5 that we have. Same thing. And we will click on
6 validate now. So if you click on validate, it says
7 it's an invalid XML. And it tells you the issue.

8 Now, here is where the severity is. It
9 tells you -- it says rejection auto warning. So --
10 and it gives you the validation detail message, so you
11 know what the issue is, and you can accordingly go and
12 fix the data there, and fix the issue there. And then
13 begin validate, and if everything is good, that means
14 you're ready to submit that to the FDA.

15 So this validator, at least for all the
16 companies that we tested with, our partners, they --
17 they really liked it. They said, you know, it really
18 helps us in prechecking things before things are
19 submitted. This also helps the FDA, because then
20 everybody who wants to test, test, test, you know, you
21 would like to -- we would want them to test here first

1 before they do. Because our hope is that if
2 everything is good here, then when you submit the XML
3 through the Gateway, you should get your appropriate
4 acknowledgments.

5 And in that case, the hope is that you
6 will get a positive acknowledgment. So it is
7 important that you perform all your testing here and
8 then get into submitting to the Gateway.

9 So with that, this is the
10 validator. We go back into our slides. All
11 right. So we talked about the validator, what it
12 does, how it checks, the interface, and it displays
13 you the results right there. All right. Next
14 slide. Okay.

15 So I think I'm almost there on
16 time. It's what? 10:15. 14. We wanted to take a
17 15-minute break and come back at 10:35. So I guess,
18 we can give a 20-minute break and come back at
19 10:35. So we'll take a break. Yeah. My throat has
20 started hurting now. But we'll take a break and come
21 back at 10:35 and continue with some other updates on

1 FDA's readiness, and preparedness, and go into the
2 Q&A. All right. So, thank you. And we'll see you in
3 about 20 minutes.

4 (Off the record.)

5 MR. DE: Okay. So we are back and we
6 will continue with some other topics that we have
7 planned for today. And the next topic in the agenda
8 is the regional extension updates.

9 So since we had the last meeting, there
10 has been some updates to the regional extensions and
11 we will go over some of those updates. All right.

12 So there was some -- going into this,
13 there are some good number of items here. One is that
14 we corrected the OID value in XPath for data elements
15 listed here. There were some void value which were
16 incorrect, we realized that, we have fixed that. We
17 corrected the XPath for specifically the element FDA
18 because that's a regional element. We identified it
19 was an issue, so we corrected it.

20 Then we also had a date element, which
21 was FDA.G.k.10a.r, we changed that to remove the .r,

1 so that field is not repeatable. We had a few
2 questions on that if it's repeatable or not
3 repeatable. So it's not repeatable. We updated the
4 Rejection and Warning Rules tabs to shorten the error
5 description.

6 The error descriptions that you saw in
7 the validator tool is the same error description that
8 you will see in the acknowledgment file, just an
9 FYI. It is basically the same error description data
10 that is coming from the same place. And our E2B
11 Validator and actual check that happens is actually
12 looking at the same place. So if tomorrow we have an
13 update to a data check, it will automatically be
14 applicable to both the validator and the actual
15 submission. So it is -- it is that -- important that,
16 you know, to know that the error messages will be same
17 as the error message that -- that you saw in the
18 validator. So that XML file -- the acknowledgment
19 file will have the same message.

20 XML file also will have a message which
21 kind of divides that same -- one of the warning

1 messages versus one of the rejections messages. So
2 you will be able to very clearly identify.

3 All right. A few things that we
4 changed. Device problem codes. So as long as we --
5 we added a warning rule with an error ID W0008,
6 provide valid FDA or IMDRF device problem code.

7 So message sender identifier
8 N.2.r.3. N.2.r.3 provided is not the same for all
9 reports and does not match the Batch Sender
10 Identifier. This is a situation where you had --
11 where I explained about in a batch you have senders
12 from different companies. So the same batch should
13 have the same sender.

14 Added rejection rule with error ID,
15 R0101. This is a report nullification or
16 amendment. That this is only -- this is -- you cannot
17 do a nullification or an amendment for an initial
18 report. An amendment or nullification always is
19 for -- for a noninitial report. You had a follow-up,
20 to that follow-up, you had the initial report
21 submitted, and then to that you do an

1 amendment. That's okay. But I need to have that
2 reported into my database to say that that was an
3 amendment or nullification. So that's the rule.

4 IND number of cross-reported IND. IND
5 number for cross-reported IND must be a valid number
6 registered with the FDA. So whatever the numbers that
7 you are providing, they must be valid IND numbers as
8 registered with the FDA, because that will be
9 checked. Just because this is a cross-report IND,
10 we'll give you a warning, but definitely, we will be
11 checking it. Next slide.

12 Okay. Remedial Action
13 Initiated. Remedial Action Initiated is required if
14 malfunction is true and Local Criteria Report Type is
15 4. So I think I had a typo in that previous
16 slide. It should be a 4 5-day report. So warning
17 error said 30-day, it should be a 5-day. So that was
18 a fix that was done. So the actual spreadsheet where
19 the rejection and error rules are, they are
20 corrected.

21 Okay. Business rule generated an error

1 and rejected the ICSR. That was original and updated
2 one was Error ID R0028, that reduced to warning, and
3 added additional criteria for the data element D.1.

4 So this is the one when I was talking
5 on the aggregate report, it says the Identification
6 Number of the report, which is linked to this report,
7 and the IND Number where AE occurred is populated,
8 then the patient name ID must have the value of
9 aggregate. Of course, this is part of IND report and
10 IND aggregate. So this will give you a warning
11 instead of a rejection.

12 Okay. Then we have another one, which
13 is the Medicinal Product Name as reported by the
14 primary source. So this is where we had -- we have a
15 rule where -- that when we try -- if an Medicinal
16 Product Name is matched, it does not match the
17 registered product name for the application number
18 reported. Then it gives you a warning.

19 And what we did was we updated that to
20 say that the error description was updated to now say
21 that G.k.2.2, the product number, does not match the

1 registered product name for the application number
2 reported. So whatever the application number is
3 reporting and the registered product name, they kind
4 of have to match to each other; okay?

5 Now, this was a warning given by --
6 because yes, if it does not match, okay, we will give
7 you a warning. But please ignore this message for
8 comparator study product. Because in that case, you
9 may not have the right combination match. So -- but
10 otherwise, it's a warning that's given, so saying that
11 if your application number is so and so, then it
12 didn't match with the right product name, that gives
13 you a warning so that you can actually correct and fix
14 your product and submit. Okay.

15 So -- but with comparator product --
16 study product, I mean, that was not possible, you may
17 not know, and in such case, so you can ignore this
18 message for comparator study product. Next.

19 All right. For error ID R0065, now,
20 what is this error? This error says that error
21 description, that F.r.3.1 must be provided when

1 F.r.3.2 and F.r.3.4 is -- 3.4 is not provided. So
2 this is for test results. So basically, what we are
3 saying here is we changed the error description to
4 shorten it. Because again, when it comes to the
5 acknowledgment file, we don't want it too big. So --
6 because acknowledgment, the description has specific
7 bend [ph] on what we can put it. I think it's
8 2,000. So trying to fit within that.

9 So we just want to give one simple
10 error message saying that at least one of the test
11 results, F.r.3.2 and 3.4 must contain a value when
12 F.r.2.2b is provided. So basically, that's the
13 message that's going to come for any of those three
14 data points that is listed on the first three rows.

15 The fourth one is error type of the
16 reaction event. So this is where original error ID is
17 R0066, so it's a rejection. Only check for message --
18 only check for N.2.r.3, which is CEDR_IND or CBER_IND,
19 but not CDER_IND_EXEMPT_BA_BE. So also check for that
20 because -- because whenever we see the IND -- IND and
21 BA_BE, it is also premarket report and the value must

1 be 1 clinical trial because that's what the study is.

2 So the value must be 1 when you have
3 the value of -- when you have N.2.r.3 as CEDR_IND, or
4 CBER_IND, or CEDR_IND_EXEMPT_BA_BE, and that type of
5 report is 2. So the -- we are missing the
6 CEDR_IND_EXEMPT_BA_BE, so that was corrected. Next
7 slide.

8 All right. Going into some of the
9 characterization of drug role. So G.k.1 must be
10 provided with Observation Code Value of 1, 3, or 4
11 when N.2.r.3 CDER. That means it's a postmarket study
12 report -- or postmarket report, then you at least must
13 have 1, 3, or 4. So that is -- that is the rule that
14 this one says.

15 The next rule that we corrected/updated
16 was added rejection rule with error ID R0104. So the
17 rejection rule was if type of report is 2, the message
18 receiver is CDER, the batch receiver is ZZFDA, then
19 the observation code value of 1, 2, or 3 for study
20 type where reaction/events were occurred. So this was
21 the rule that we had to add. So because it's CDER and

1 ZZFDA, so it's a postmarket.

2 But when it comes to an ID report, you
3 could have a value of 1, which is clinical trial. Or
4 if you have -- if you have a report which is from a
5 PSP program, this program, then you may have a value
6 of 2 or 3. Okay. So for the -- for C.5.4, so that's
7 why we had to make sure that we allow them.

8 Added rejection rule with error ID
9 R0105. So this is IND number where AE occurred must
10 be valid number registered with the FDA. So this rule
11 wasn't there, so that's a new rule that we added.

12 Next one was the same thing, 106 is for
13 the pre-ANDA number for IND_EXEMPT_BA_BE, it must be
14 registered with the FDA.

15 And then the last one is that there was
16 an update. The original rule said R0103 error ID, if
17 type of report is 1, it's a spontaneous report, and
18 message receiver is CDER, observation code value of 2
19 and 3 for the study type. This was a rule and what we
20 are saying that this cannot happen because 1 is a
21 spontaneous report. So if it is a spontaneous report,

1 then you cannot have a study type where
2 reactions/events were observed because it's a
3 spontaneous report. It was a PSP program, then your
4 type of report would have been become 2, which is
5 report from study, and then -- and then C.5.4 would
6 have been 2 or a 3.

7 So that's what the updated rule is. A
8 spontaneous report cannot have -- must not be provided
9 with a C.5.4. Okay. Next.

10 All right. Now, comes all the exciting
11 slides. Probably everybody is -- excuse me. I'm
12 waiting for it. So as you see, the changes are not
13 too many, there are business rules changes. No new
14 element was added. No new data attributes have
15 changed. Maybe a few expired were fixed, not
16 many. So -- so with all that, we posted in October of
17 2023 all updated business rules and so on with that
18 document, which call is the Report and Regional
19 Element Business Rules. And you will be able to see
20 all of them there.

21 All right. So with that, we have the

1 next topic, which is FDA readiness. All right. So
2 what is our path forward? How are going to go? So
3 our proposed timelines to implementation.

4 All right. First one. All
5 right. January 2024, we communicate -- we will
6 communicate via the FAERS Electronic Submission page
7 notifying the FAERS system is ready to accept
8 postmarket safety reports using E2B(R3) standard. So
9 in January, we'll be ready. And I also explained why
10 we will go in January with postmarket first and then
11 premarket. It's because of the change management
12 process that we have to accommodate.

13 That's where the voluntary period
14 starts. When I say voluntary period starts, the
15 voluntary period for E2B(R3) submission of postmarket
16 safety reports. Okay. If you're not ready with
17 submitting postmarket safety reports in E2B(R3)
18 standard, then you continue to submit that in E2B(R2)
19 standard until you're ready with R3. All right.

20 So that is why that is a voluntary
21 period for the R3 standard. Okay. When it comes to

1 postmarket.

2 So that's -- we're targeting January
3 2024. What's the exact date in January? I don't know
4 that yet. But we will be updating through the FAERS
5 Electronic Submission web page the exact date because
6 it all has to happen at the right time. But
7 definitely happening in January.

8 All right. Next. All right. Comes
9 March 2024. What do we do in March 2024? So we
10 anticipate a publication of the final guidance, along
11 with an FR notice. Okay. Concurrent to the
12 publication of this guidance, FDA will begin to accept
13 premarket ICSRs in E2B(R3) format to FAERS. It will
14 also -- the safety reporting portal also will be ready
15 during that time. Because they all have to go at the
16 same time.

17 So the day the guidance is published
18 with the notice, the same day we have the website,
19 that tells you that you can submit an R3 and at the
20 same time the Safety Reporting Portal is also ready
21 for companies to submit. Companies who want to submit

1 through the Safety Reporting Portal because maybe they
2 are not ready with E2B(R3). Please, right after that,
3 start your registration so that you can get
4 registered. But once you have moved to the Gateway,
5 then we will have the similar account in that -- in
6 Safety Reporting Portal. The Safety Reporting Portal
7 cannot be a backup plan.

8 Because -- because submitting through
9 Safety Reporting Portal and then submitting through
10 the Gateway, it disrupts the -- the reports, the same
11 report coming from two different places. We have seen
12 sometimes it creates two separate cases through the
13 system, and so on. And so we just want one method of
14 reporting and backup reporting. And refer to the
15 FAERS Electronic Submission web page for the updates.

16 So this is when the premarket we
17 anticipate to start. What date in March? Again, we
18 will be posting that. We don't have an exact date, as
19 we are going through our change management
20 process. Okay. Next point.

21 All right. So once we have in March,

1 then from that point in March to February 2026, about
2 two years, will be the voluntary period. So again,
3 when we start in March 2024, that's when the voluntary
4 period starts of submitting ICSRs and E2B -- using
5 ETB(R3) standard.

6 Of course, if you're not ready, you
7 continue to submit in eCTD. But once you are ready
8 and you're moved, during that voluntary period, you do
9 not revert back to the latest methods. So once you've
10 done the ETB(R3), you continue with the ETB(R3). And
11 our hope is that once you have converted everything,
12 you converted both post and premarket ETB(R3), and
13 everything is coming through that.

14 As you know, there is big advantages in
15 moving everything to R3 just because then you don't
16 have to go through regulatory affairs, you don't have
17 to, you know, send 1572 cover letter, and so on and so
18 forth. You don't have to sub with more people. ICSRs
19 or cross-reference INDs. And there's a lot of
20 advantages that you have. So the March to February
21 will be that voluntary period.

1 And then finally, March 2026, companies
2 then must submit premarket and postmarket ICSRs
3 electronically to FAERS in the ETB(R3) format or SRP,
4 whichever they have chosen.

5 So this is the proposed timeline to
6 implementation. We are targeting these
7 timelines. And as the time comes, we will start
8 seeing updates happening on the FAERS and Electronic
9 Submission web page, which then also will trigger all
10 other notifications that need to happen. So keep an
11 eye on that. And I have been getting a lot of
12 questions about when we believe it will be ready.

13 Please make sure that just being ready
14 for FDA includes taking into account all the FDA's
15 regional extensions; okay?

16 So this also kind of is something that
17 you may have to work with your vendors of your safety
18 databases, because any safety database that you use
19 may probably today do the regional requirements for
20 other regulators who have already mandated. It will
21 do the code ICH elements, but may not do that in FDA's

1 regional elements. And we need to make sure that they
2 also do the FDA's regional elements. So -- and they
3 are tested, and so on, and so forth.

4 So you can start working on
5 this. These are timelines so we're telling you when
6 FDA will be able -- you know, when FDA says it's ready
7 in January and March, does not mean you have to submit
8 in January and March. You know, you have two -- two
9 years of voluntary period to prepare yourself,
10 develop, test -- get ready, test with us, so on and so
11 forth, and then have the process to move through.

12 So, yeah. So that is very
13 important. Because also, remember, I think -- we
14 don't have this problem, but from an industry
15 perspective, you have one global database. You submit
16 to different agencies around the world. They have
17 different rules; right? And now, you are introducing
18 FDA with its own -- with its own rule.

19 So, yeah. You have more effort to
20 report because of the -- of the regional extensions
21 that different regions have. So again, be cautious,

1 but -- but these are the dates that we are
2 anticipating that we will go live with FAERS. All
3 right. Next slide.

4 Okay. Submitter preparedness. So with
5 submitter preparedness, there are a few things that as
6 a submitter you can start. And these are, again,
7 suggestions that we are providing, nothing is
8 mandatory here. But let's go into the slides on some
9 of the preparedness items that you can have.

10 So first and foremost, make sure you
11 have downloaded the guidance and the technical
12 specification documents posted on the FAERS Electronic
13 Submission web page. All right. So you have to make
14 sure that -- all the documents that you have, you have
15 downloaded all of the documents. Just downloading the
16 ICH documents won't work, you have to download the
17 regional ones also. Okay.

18 All right. Review the regional
19 extensions very carefully. So it's very important
20 that you review the regional extensions. What it
21 says, what it is, you know, there's a whole section

1 for combination products, there's a section for IND
2 safety reports, and so on and so forth.

3 Then prepare your safety database
4 accounting for the regional extensions. So this is
5 also very important, that your safety database should
6 account for the regional extensions that we
7 have. This is where you probably will work with your
8 vendors. If you have a vendor -- if you have in-house
9 and you like to work with your in-house, you know,
10 intergrader or contractor to -- to get these regional
11 elements in there.

12 Account for regional forward
13 compatibility. And I specifically say that again and
14 again because I just have seen very recently that,
15 yeah, we are R3 ready, we have translated from R2 to
16 R3, they did that, forgot the regional elements to
17 translate and do a forward compatibility of the
18 regional elements. So please keep in mind on the
19 regional elements. Ask us questions if you have any
20 doubts.

21 Generate the XML files and test them

1 using the E2B Validator. So once your XML comes out
2 of this database, then send to be validated. We
3 provided the link. The link will be provided on the
4 FAERS Electronic Submission page. And as I said, by
5 development, you will have -- you will see on the
6 FAERS Electronic Submission page, a link which you can
7 click which can open up E2B and FDA to be validated.

8 Okay. Correct any issues identified by
9 the validator. That means you've corrected that, gone
10 back to your database, you fixed them, and so on. And
11 again, some of these things here you are to work
12 probably with your vendor or your in-house
13 contractors.

14 Then perform the Gateway setup. Now,
15 for postmarket, you already have a setup. But for the
16 premarket ones, you only have to do a setup of your
17 Gateway so that you're in the right parameters. The
18 routing ID or AS2 Header is set. In a preproduction
19 environment, by the way.

20 Then you test your XML files. Sample
21 XML files that has cleared the FDA E2B Validator via

1 the preproduction Gateway. So now you've tested the
2 XML files, you've fixed everything, begin your tester,
3 everything looks good, your Gateway is set up. Now,
4 you submit the files, and you should be getting the
5 acknowledgements back. Okay. And most likely, you
6 should get a positive acknowledgment.

7 Now, there may be instances where you
8 may get a negative acknowledgment, especially if your
9 routing ID is not equal -- not in line with the batch,
10 the receiver, or message receiver, then you may get a
11 negative acknowledgment. That test, we cannot do
12 through the E2B Validator, because as you know, the
13 Gateway IDs are not available for the E2B
14 Validator. So we will not be doing test on that. But
15 that is a rule when you actually submit through the
16 Gateway.

17 Then you are -- next is once everything
18 looks good in the preproduction environment, then you
19 go into your production environment to set up things,
20 and you set up based on the technical
21 specification. And you have set up your Gateway setup

1 for in the production environment.

2 All right. So these are some of the
3 tips that we could think of to give you. I'm sure you
4 will have exhaustive validation plans, and so on, and
5 so forth. But some of the things that we could help
6 you, we just list it down here. Next slide.

7 Okay. When you send files to the
8 preproduction environment or preproduction Gateway,
9 you can test the following. You could test the
10 premarket safety report.

11 Now, when you test a premarket safety
12 report, making sure that the IND number has to be the
13 right IND number. So if you can let us know that this
14 is the IND number, then we can say, this is in our
15 dictionary, it's all good.

16 During the industry testing, we just
17 created some dummy ID numbers so that they can be
18 tested. But in the preproduction, we can test with
19 the appropriate IND numbers. You can test it and it
20 will begin -- we created dummy INDs. But if you feel
21 that, you know, you want to get some dummy ID numbers,

1 we can always do that.

2 Also, including IND aggregate safety
3 reports and cross-referenced IDs. The postmarket
4 side, test the postmarket report. But one thing I
5 will also suggest, create a mega file that has got all
6 the data elements in there. Lots of help. And
7 including combination production and safety
8 reports. Combination productions are also
9 tested. And safety reports with attachments. Large-
10 size safety reports. Batch submissions of safety
11 reports.

12 And please make sure you test for both
13 positive and negative acknowledgments. So you send a
14 bad file and you are -- what are you expecting that
15 the header should be when getting that in the
16 acknowledgment? And same with the positive
17 acknowledgement. So these are some of the things that
18 are tips, and tricks, and suggestions that we reviewed
19 in testing the -- in doing your testing with the
20 agency.

21 So with that, I think I'm going to be

1 early. So there are a few case scenarios that I kind
2 of presented here so that it gives you some ideas of -
3 - on how you could prepare your XML.

4 So the first one is premarket report on
5 an IND or IND_EXEMPT_BA_BE. So if you had that, then
6 your batch sender identifier must be the
7 ZZFDA_PREMKT. So the batch is of the premarket
8 batch. The message within that batch, you're saying
9 it's a CDER_IND or a CBER_IND or
10 IND_EXEMPT. Okay. It can't be all, it has to be
11 either one.

12 All right. Then the report type is 2
13 because it's a premarket report from study. Study
14 type where adverse event is observed is 1, which is
15 clinical trial for premarket. And then if it was an
16 IND, then the IND number where adverse event
17 occurred. You put the IND number, which will become
18 mandatory now because it's a premarket, on the Pre-
19 ANDA number where the adverse event occurred.

20 So the Pre-ANDA number has become
21 mandatory, depending on what your reporting in the

1 message receiver identifier is. Okay. So that is the
2 first scenario on premarket report on IND and
3 IND_EXEMPT.

4 Now, if you have a solicited report or
5 reports from Organized Data Collection Systems. So in
6 such case, we ask to consider them like a study report
7 but they are like on the postmarket product.

8 So in such case, you will be sending
9 that report to the postmarket site. Based on the
10 routing ID and the -- the routing ID, you would send
11 it to the postmarket site. But within the XML, your
12 batch sender has to be ZZFDA. The message receiver is
13 CDER. The report type is 2 report from study. And
14 the study type where the reaction event was observed
15 is 2 individual patient use or 3 other type of
16 studies.

17 All right. So that is what --
18 currently what we have, these values. And that is
19 what you will use. So this will tell us that these
20 are not fully for clinical trials, but they are for
21 other type of studies that we have. Next slide, next

1 scenario.

2 Number three. So this is premarket
3 aggregate report. So this is where you're aggregating
4 all the -- all the ICSRs and submitting on. So this
5 will have the batch. You will submit it to the
6 premarket site, the routing ID. The batch sender
7 identifier within the XML should say
8 ZZFDA_PREMKT. Message receiver identifier would be
9 CDER_IND or CBER_IND.

10 Aggregate reports, I think do not apply
11 for IND_EXEMPT_BA_BE. Then the type of report is 2
12 report from study. Study type is 1 clinical trial IND
13 number. The IND number on which where AE
14 occurred. You have the patient name, you put it as
15 the aggregate because it's multiple patients or --
16 since this is an individual report but an aggregate,
17 so we can put the patient in front of the aggregate,
18 and then the list of all the sender case report ID on
19 which you're doing the allegation.

20 And that -- those cases should be
21 reported under the data field C.1.10.r. Okay. So

1 this would be for the premarket aggregate reports.

2 Let's see. Scenario number

3 four. Premarket report with cross-referenced IDs. So
4 in such case, you have ZZFDA, again, you're submitting
5 through the routing ID of premarket. You will have
6 ZZFDA_PREMKT. Message receiver identifier is CDER or
7 CBER_IND. Type of report from study, it's a clinical
8 trial. The IND number where AE occurred and all the
9 other cross-reported INDs in our regional data element
10 are IND number of cross-reported INDs. So that's --
11 .r, that means a repeatable. So on the cross-report,
12 INDs can be reported there. Okay.

13 The next scenario is postmarket study
14 reports. You submit two reports, one on the IND. And
15 two, on the NDA or BLA. In this case, I just gave the
16 NDA or BLA just as an example. So show what report
17 number one and report number two look like.

18 So if you look at report number one,
19 you have -- it is on the IND. So in such case, of
20 course, you will be sending the report through the
21 routing ID for routing -- routing ID on the premarket

1 side. Batch sender identifier, again,
2 ZZFDA_PREMKT. CDER or CBER_IND for message receiver
3 identifier. Type of report, 2 report from study. The
4 observed, clinical trial, study type where the
5 reaction was observed is 1, clinical trial. And then
6 IND number where the AE occurred is the IND number.

7 When it comes to the postmarket side,
8 the report number two that you submit, so that's
9 ZZFDA, CDER, 2 report from study, 1 clinical
10 trial. And then on that report, the two other fields
11 we recommend that -- two or three. One of the fields
12 we recommend that when you put the Medicinal Product
13 Name, along with that, put the job authorization
14 number of the NDA number. Don't put the IND number
15 there. Because IND number, you have already put in
16 the previous report. So put the drug authorization
17 number, so we know that it's a study report, but it's
18 against that -- that marketed product with that IND
19 number.

20 And every time -- another suggestion
21 that we would like to give you is, every time you have

1 a product, and if it is your product and you know that
2 is your product, which of course, always doesn't
3 happen, please supply the submitter application number
4 also along with it -- along with the product
5 number. If it has an NDA, BLA, or an ANDA, if you
6 know it is yours, then please do submit that.

7 Many times, we don't get that. Of
8 course, we understand, many times you will not know
9 that it is truly your product or not because you just
10 know the active ingredient. You may not know it, but
11 if you know it is yours, then please do submit that
12 identification number in the postmarket report.

13 Okay. All right. So with all the
14 scenarios, we come to basically the last slide that we
15 have. Now, before I go to the last slide, please note
16 that this entire session that I'm doing today is being
17 recorded, and the recording will be available on that
18 meeting page of FDA in about two weeks. So you will
19 have the entire video recording with the slides and
20 the agenda, everything available publicly in about two
21 weeks.

1 So right now, on that meeting page, you
2 have the previous sessions I have had before, all the
3 recordings. Today's recording, it takes us about two
4 weeks after we have gone through it, reviewed it, and
5 then publish it. Okay. So just letting you all
6 know.

7 So as a summary, we will recap our
8 previous public meeting. So you saw all these
9 questions. And as I said, the slides, the questions,
10 the answers, this recording today, all will be
11 published, so you will have all the questions and
12 answers. Many of those questions and answers will go
13 get into an FAQ. So my team will be working on an
14 FAQ, which will be published by the -- January when we
15 publish -- when we say that FDA is ready for
16 postmarket in R3.

17 We will also -- of course, as I said,
18 everything will be there. And the validator also will
19 be made available by November 20th. So a lot of
20 things will be published in about two
21 weeks. Okay. So we had the recap.

1 Next, we discussed the implementation
2 plan and progress showing the activities completed and
3 ones that are in progress. You saw that. A lot of
4 things have been completed.

5 Next, we talked about conducting
6 external and internal testing that we did. And as the
7 reason, as I said, I mentioned about all this because
8 maybe some tips and bullet points may interest you to
9 say, hey, okay, we need to do this kind of testing
10 with FDA to be very sure with our testing. So that
11 was the reason we -- I mentioned all about our
12 internal and external testing.

13 Okay. Next, issues that were
14 identified were fixed, implemented, and retested. I
15 told you, they all have been updated in the technical
16 specification. Not the PDF document, but the big
17 Excel spreadsheet. Many of the updates, as you see,
18 will go into that big spreadsheet of the code and
19 regional elements, just because that is a document I
20 can update and don't have to go through an elaborate
21 clearance.

1 If I go and update the PDF document
2 that was posted, that -- every time I go through an
3 elaborate clearance, so we just wanted to make sure
4 that the spreadsheet is the one that we get updated
5 most often. And PDF, actually, I think it has got a
6 lot of words and a lot of paragraphs of explanation,
7 but they all point eventually to that spreadsheet of
8 all the data evidence. All right.

9 Next slide -- or I'm sorry, next
10 bullet. Update to regional extensions are posted in
11 (v 1.5). So this was posted on October 2023. So you
12 will have a version 1.5.

13 Okay. Next, we discussed the FDA
14 readiness with some plan dates. So I hope all this
15 anxiety that you all have of when, when, when, when is
16 FDA going to go live, we now have some tentative
17 dates. And we believe that these dates will be
18 attained, and we will be able to complete this. So --
19 so, yes, those are the dates that we have.

20 Hopefully, then you can work around
21 with your vendors, work around with your releasors,

1 work around with your testing, and all of
2 that. Because as we all know, that we also have to
3 work around with our vendors, with different
4 releasors, with their releasors, with our releasors,
5 and so on and so forth. So everything had to be
6 worked around to make sure that it was successfully
7 done.

8 Next bullet point. So update on FDA
9 Electronic Submission web page, as I said, a lot of
10 this information that we have all talked about will go
11 into the FAERS Electronic Submission web page. We
12 will be updating with the E2B Validator. You know,
13 the FAERS Electronic Submission web page will also
14 point to the meeting page where you will have all of
15 this information available. And finally, the FAERS
16 Electronic Submission web page.

17 At some point, we'll get
18 revamped. Because we're going to make one page a main
19 page, and from there, there will be two links. One
20 going to E2B(R2) and (R3). So that once the time
21 comes that we are reconditioning R2, the link to the

1 R2 page will be gone, and it will be only
2 R3. Okay. So you will probably see a revamp page in
3 January of the FAERS Electronic Submission page.

4 Okay. Next, we communicated what
5 submitters can do to prepare themselves. So these are
6 all some, you know, suggestions. And hopefully, that
7 will help you in testing with us.

8 And next bullet point. And we
9 recommend some scenarios to test. We gave you some
10 scenarios, we listed some scenarios. You know, please
11 do test them, that will be great. We will want you to
12 all have positive acknowledgments and files getting
13 into FAERS.

14 If a file does not get into FAERS, that
15 means you have a negative acknowledgment. And please
16 do make sure that you've got the
17 acknowledgment. Sometimes the acknowledgement is a
18 little delayed, but should come. If the
19 acknowledgment does not come, then you will contact
20 us. But you should get an acknowledgment.

21 So that kind of keeps the loop closed,

1 to say that you submitted something and you got an
2 acknowledgment. So that loop is closed. And make
3 sure that you have -- because a negative, of course,
4 you have to resubmit correct -- with the corrections
5 and all of that.

6 All right. Next bullet
7 point. Okay. So this is basically my last
8 slide. And this slide is basically talking about all
9 the differences that we have, where what is. All the
10 links to everything.

11 Of course, the dates may change when we
12 publish something, but the links will still be the
13 same because it will have the latest and the greatest
14 document of the information there.

15 Once we publish things like the rough
16 guidance becomes a final guidance, and that will
17 become a final guidance, anything that is to do
18 with -- with the -- with any kind of binding items and
19 all of that, so they will all be published. And so --
20 so, yeah. So this page -- this link. Keep a bookmark
21 on this. If you just put a bookmark on the first link

1 that you have, all of these are under that. So you
2 will be able to go find all the documents under the
3 main web page.

4 So with that, today, I know I finished
5 early. But my throat has started hurting. But we
6 will take a -- probably a ten-minute break and then
7 start with some questions and answers that we can
8 answer. We will probably -- instead of noon, we'll
9 probably end this by around 11:45. 15 minutes
10 earlier.

11 But basically, a ten-minute break so
12 that I can go over some of the questions and answers,
13 and then come back at 11:30 to answer some of the
14 questions that we have got through the question-and-
15 answer window on Zoom.

16 All right. So with that, thank
17 you. And I will see you at 11:30. Thank you.

18 (Off the record.)

19 MR. DE: So welcome back again. We're
20 going to have a 15-minute session for answering the
21 questions. And I will be answering whatever I can

1 answer in the 15 minutes and then the meeting will be
2 definitely posted. Because some of the questions and
3 answers, we have to go back and walk through
4 that. Some dealing with compliance things, we have to
5 work through some clearances. And we will definitely
6 then post those questions for you.

7 Okay. So there is a question about if
8 you're a small academic entity and if you need to
9 submit a premarket ICSR via SRP, then you all have all
10 other documents. Yes, the other documents are to be
11 submitted. The ICSRs are only to be submitted by SRP
12 if you're a small entity. If you don't use a Gateway
13 process, or a Gateway system, or a Gateway setup, then
14 just submit -- you will use the SRP to submit those
15 ICSRs.

16 So there could be other documents, and
17 you know, risk management plan, change with the
18 protocol and all of that, so those still need to be
19 submitted through the ACTD. And same also applies for
20 other sponsors that those type of documents you will
21 submit to ACTD. If it's ICSRs, you can use the

1 Gateway to submit to FAERS.

2 Okay. All right. Next question. So
3 if you have something -- if something, you know, was
4 sent as expedited incorrectly, but it was non-
5 expedited, do we need to collect it immediately or
6 wait for the next significant follow-up and send a
7 downgrade then?

8 So I mean, if you have identified that
9 it is an issue, then you should immediately notify
10 that to us by submitting it so we can follow up to say
11 that this was a nonexpedited report, we can correctly
12 submit it as an expedited report.

13 But we will also recommend that you put
14 down a sentence in the narrative stating that this was
15 incorrectly submitted, and so we have corrected
16 it. Because just changing an expedited to a non-
17 expedited, you know, sometimes we may be wondering
18 what happened here. Why did an expedite suddenly
19 become a nonexpedited; right? So giving a little bit
20 of a line or so in the narrative will really help us
21 to know that.

1 Then we have another question that --
2 so if you only have an AS2 account, where and how can
3 I find and use E2B Validator? As I said, that it is
4 to account for an E2B Validator there with each
5 other. The E2B Validator is as simple as you have a
6 bookmark on your browser. You just go to your
7 browser, click on the bookmark, the screen that you
8 saw will come up. You test everything. It has
9 nothing to do with the Gateway; okay? It's totally
10 independent.

11 So -- all right. Let's see. So when
12 does FDA finally begin accepting adverse event under
13 the new regulation? I wouldn't say it's a new
14 regulation, it's a new standard that is under the
15 Electronic Submission. So I gave you the
16 timelines. So postmarket, we will start in January
17 and premarket will start in March.

18 How long will there be acceptance on
19 R2? As I said, it will be two years of voluntary
20 period.

21 And let me see. Any other

1 questions? Okay. How do attachments work? Yes,
2 attachment is part of the XML. It's not separate, so
3 it's part of the XML.

4 So the ICH needs to be -- the
5 implementation guide will tell you how attachments are
6 to be embedded with that XML and sub. And
7 specifically, our technical team should be also able
8 to set that up for you. But yes, it is part of the
9 XML. And like R2, they are supposed to be
10 separate. R3, it's all embedded.

11 Okay. So E2B(R3) Gateway will be
12 launched or initially testing and productive use by
13 end of this year 2023. So we said that if by the end
14 of this year 2023, we will have our system all set up
15 ready and everything to be done.

16 So we -- our actual launch -- so when
17 we said it's the end of this year, that's our double
18 end up work, our testing, everything so we can say we
19 are ready to launch. And we will give it a few days
20 and then our launch date, as I said, will be
21 January.

1 And how do you know about the launch
2 date? The FAERS Electronic Submission web page will
3 notify you that and say, hey, FDA -- it will probably
4 say something like, FDA is now ready to submit R3 to
5 accept postmarket safety reports in ICH E2B(R3)
6 format, along with the regional data elements, and so
7 on, and so forth. So that is what those dates will
8 say.

9 How would solicited ICSRs be
10 sent? ZZFDA_PREMKT or -- as I said, it will all be
11 ZZFDA. And I gave some examples, some scenarios in
12 some of the slides. So when you go back and look at
13 the slides, you will be able to see those scenarios.

14 What are the size limitations of the
15 batch? The batch, I think, is 100 GB. And each ICSR,
16 I think what we are saying is -- wherever there is a -
17 - the ICSR submission size is less than 100
18 megabytes. So -- so the entire big size of the entire
19 batch could be up to 100 GB. So that's what FDA can
20 accept through the Gateway.

21 Okay. So there's another question,

1 what would be the impact of having multiple warnings
2 on a -- for ICSRs? Again, warnings are something that
3 we have brought for our sponsors to go back and please
4 look at it and see if they can correct it and send it
5 to us in a future follow-up.

6 I mean, if you don't correct it, of
7 course, nothing is going to get rejected, but I think
8 it's a good idea that -- to have better data quality,
9 both from our side and our side, and so that we can do
10 better review and for better public health assessments
11 that we do. You know, good data is important.

12 And so we will suggest and recommend
13 that you correct the warnings and send it to us, but
14 if you don't send it, you know, it's just going to
15 stay the same, nothing is going to happen. But of
16 course, rejections definitely will be rejection.

17 Okay. Then -- yes. Can you please
18 confirm if the validator will be available post the
19 mandatory data -- validator will be available
20 throughout. I mean, it will be on the Electronic
21 Submission web page. And we are not going to get that

1 down. It's going to be available throughout. Because
2 in future, let's say we find there is some data points
3 that are an issue, and we are constantly seeing that
4 we may have a change in data rules.

5 Of course, we will notify that way
6 ahead of time, but we will update the validator to
7 make sure that that is checked. So the validator is -
8 - will be available and that you can also check that
9 for those changes in the validator.

10 Okay. The messages that shows up in
11 the validator is the same messages that will show up
12 in the acknowledgment. So there is a question that --
13 will the messages be the same? Yes, the messages will
14 be the same in both the validator and the actual
15 acknowledgment.

16 How long will the transition from R2 to
17 R3 be? So again, as we said, it's approximately a
18 two-year transition period. That means that two years
19 is a voluntary period. Which means -- what is the
20 voluntary period? It means that if you have not moved
21 over to R3 during that two-period -- two-year period,

1 fine. But right after the two-period is over, we are
2 expecting an R3. We will not accept any R2
3 submission. So that is the voluntary period.

4 That means, if you're ready, please go
5 ahead and start submitting in R3. That's the two-year
6 one repeated. So it could be -- you can consider
7 yourself as a two-year transition period. The sooner
8 you do, the better it is.

9 So a question is, can you elaborate on
10 the report and case nullification? Are the
11 requirements same for both pre and postmarket? And
12 how about spontaneous report in pre and post --
13 yes. I mean case nullification is case
14 nullification. That's -- that's if the case was --
15 was -- should not be -- probably is not your case,
16 somebody else's case, somebody -- another company case
17 and you wanted to move it from your database and you
18 have submitted it accidentally, then yes, we'll
19 nullify that report and then that nullification will
20 come to us and we will nullify. We'll get it
21 nullified.

1 But if you had a change, saying, I did
2 not want to submit this version of the report, I
3 wanted to -- then in that case, that we cannot nullify
4 because it's always a case nullification, not a report
5 nullification.

6 So you may want to submit just a
7 follow-up to correct any kind of information or an
8 amendment to correct any kind of information. So --
9 so, yes. So it is what a case nullification is, to
10 nullify an entire report.

11 Where is the report? Everything is
12 available at the webinar. So what is available in the
13 webinar is -- so let's click on the first link. It
14 says accessible at. So this is the -- whenever I say
15 FAERS Electronic Submission web page, this is the
16 page. This is the page in which the E2B Validator
17 link also will be available.

18 Okay. Now, on this page, let's go to
19 the bottom of the page. And there are different
20 resources for you. In the resources for you, the
21 third one, which is a public meeting, if you click on

1 that, it takes you to the meeting page. This is where
2 all the previous meetings are put; right? So the last
3 meeting that happened was -- so and so. The last
4 meeting's information is also provided with the
5 recording and everything, the agenda, and
6 everything.

7 So now you see under November 4th --
8 April 4th, you have the agenda, you have the
9 presentation slides, it also has the recording down at
10 the bottom. Same way -- yeah. I think they have the
11 live recording for April 4th. Same way for November
12 7th, today. You only have the agenda. You will have
13 the presentation slides and we'll convert in PDF. And
14 the live recordings will also show up here.

15 So this is where you can see the entire
16 thing. If anyone has missed anything or anyone
17 have -- if colleagues have missed anything, they can
18 all go in here and look at it.

19 Okay. All right. Maybe we can take
20 one more question. Maybe two more
21 questions. Okay. So this is a question about the

1 population of the local criteria report type, which is
2 the 5-day, 7-day, 15-day, all that kind of thing.

3 So the question is, my understanding is
4 the sponsor should report fatal life-threatening ICSR
5 within seven days of initial receipt of the
6 information. This ICSR would reflect the 7-day
7 report, which is 46. Can we as a sponsor continue to
8 send follow-up for this scenario as a 7-day
9 report? And the answer is, yes, you can continue to
10 submit that as a 7-day report. It's basically follow-
11 up information on the 7-day report that should be
12 submitted.

13 Are there communications going on with
14 safety database senders? Yes, there are
15 communications going on. But in my personal view, is
16 I don't know how communication is going -- should be
17 going on to an extent that it's going on right now. I
18 would think that with all our specifications submitted
19 and all that, you know, they will be connecting with
20 us. And what can you ask? Because I do understand
21 that things have changed. It was not those days when

1 we implemented E2B(R2). Now, most of the companies
2 have their own -- they have exports. So they have
3 vendors. So if the vendors have updated their systems
4 and they provide that release to all their customers,
5 then all the customers are now E2B(R3) ready.

6 But -- so I don't know at what -- they
7 do send us questions, we do answer them. But I still
8 feel that it's probably not enough. Or maybe they are
9 -- their exports now, with looking at the
10 specifications, that our specifications are so good
11 and so well-organized that it's very clear to
12 everyone. But yes, we do get some sometimes, we get
13 questions from these vendors.

14 But I would, again, suggest that, you
15 know, work with your vendors, talk to them, and you
16 know, the better connected we are, I think the better
17 smooth implementation will happen. We really do not
18 want any glitch happening. We do not want -- because
19 it's good for both of us. Because you won't be asking
20 us too many questions on this and we are spending too
21 much time on the specifications again. So the sooner

1 we can do this, the better it is. And work with your
2 vendors, talk to your vendors, and -- and they can
3 also talk to us.

4 Another thing that we give the vendors,
5 we told the vendors that they can have actual access
6 to the WebTrader on the preproduction environment,
7 which we used to never give the vendors. We actually
8 gave the vendors this and I only probably know one,
9 maybe two vendors, who have taken an account on the
10 WebTrader, because they all wanted to test
11 this. So -- so encourage your vendors to get access
12 to the WebTrader and preproduction so they can test
13 before the releases come to you.

14 All right. One last question. During
15 the voluntary period, can a particular company submit
16 some reports in E2B(R2) and some E2B(R3) format? It's
17 a very tricky question. It's -- if you're submitting
18 on the same ICSRs and there's a problem, if you have
19 the same safety report ID; right? Because the case
20 has come as an E2B(R2), you submit on that.

21 And now, you're submitting an R3 on

1 that. And if you go back to an R2, then there's a
2 problem. Yes, some can continue to be R2, then you
3 have some continue to R3. But I -- the way I see it
4 is if you move to R3, you probably will have moved to
5 R3 for all the reports.

6 But yes, there is a choice that you can
7 go -- as I said, you can start with postmarket to do
8 R2, and then move to premarket in R3; right? Or you
9 could have postmarket going to R3 first, and then
10 going to premarket in R3; right?

11 So it's up to you. So all the
12 postmarket reports have come in as R2, as you are
13 submitting today, but you are focused on premarket
14 first and then postmarket.

15 So, yes, then that is possible. But
16 it's important that once you submit a report in R3
17 format, you cannot go back to an R2 format for that
18 report; okay?

19 So -- so for all the comments, and
20 questions, slides, they all will be posted. So don't
21 worry, we will post -- we may post even the

1 presentation slides first and then the recording. So
2 we may have -- I think we should be able to post the
3 presentation slides hopefully by this week, you
4 know? So you will have all of that. So don't worry
5 about that, you will get everything.

6 So with that, I end my presentation, I
7 end my talk. Thank you so much for your time and for
8 your effort. We want to be collaborative. We want to
9 work together. Better communication -- you know,
10 communicate better, and so that we make this as a
11 success with E2B(R3) submissions to the FDA.

12 And we really look forward for your
13 cooperation and your help. And -- and to even make
14 this as a success for all of us from your sponsors'
15 perspective, as well as from the agency's
16 perspective.

17 So thank you. If you have any further
18 questions, please do send the questions through the
19 docket. Or you can send the questions to the EPrompt
20 mailbox that we have, Eprompt@fda.hhs.gov. And we
21 will make sure that we will try to answer those

1 questions. And of course, also these questions and
2 answers will get into an FAQ.

3 So, thank you. And have a wonderful
4 day and a wonderful week. Bye-bye.

5 (Whereupon, the meeting concluded at
6 11:51 a.m.)

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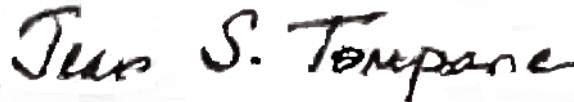
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CERTIFICATE

I, JEAN TOMPANE, the officer before whom the foregoing proceedings were taken, do hereby certify that any witness(es) in the foregoing proceedings, prior to testifying, were duly sworn; that the proceedings were recorded by me and thereafter reduced to typewriting by a qualified transcriptionist; that said digital audio recording of said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



JEAN TOMPANE

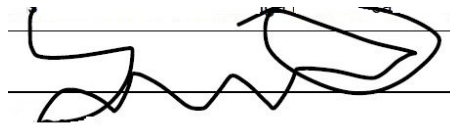
Notary Public in and for the

State of Maryland

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CERTIFICATE OF TRANSCRIBER

I, SAMANTHA TAMBURRINO, 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.

A handwritten signature in black ink, appearing to read 'Samantha Tamburrino', is written over two horizontal lines. The signature is stylized and somewhat cursive.

SAMANTHA TAMBURRINO

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