Expert Answers to Community Questions – July 2021

On 30th July 2021 a team of experts from Industry, CDISC and FDA came together to discuss the topic of 'Technical Conformance Guide & Test Data Submission to the eData FDA Team'. You can watch the recording here.

The panel actively sourced questions prior to the event from the Optimizing the Use of Data Standards Working Group, as well as a 'call out' to our community members who were given the opportunity to submit questions ahead of the event. In addition, on the day questions came in via the Q&A chat from the audience. Many questions were answered 'live' so we encourage you to listen back to the recording on the PHUSE Archive, but those that the panel didn't have time to address have been curated and captured below.

Questions	Team Response
For ADaM, can external data (not SDTM) be used – like an Excel file? How do you submit the external data to the FDA – in the original Excel file, or an SAS file?	We would suggest two potential strategies: (1) if it is a small table, you could include it as an appendix to your ADRG; (2) convert the spreadsheet into an SAS dataset (transport file) and place it in the MISC folder. In both cases you should include text in your ADRG explaining this data and how it was consumed to support your analysis.
If CBER does not accept a test submission, what should unexperienced sponsors do instead if they plan a BLA at CBER?	This was covered during the live session. Please listen back to the recording.
Thanks to the FDA for setting up this process in place. Does the FDA review the data submitted in sample submissions? In some cases of ongoing Phase studies, there will be less data in test submissions and new scenarios may come in the final submission, which should not be of concern to the FDA.	This was covered during the live session. Please listen back to the recording.

Should big companies also follow the sample submission process if that's helpful for the FDA? Does the FDA support/recommend it, to avoid any last-minute surprises?	This was covered during the live session. Please listen back to the recording.
Can the FDA share a platform where sponsors can just upload and test their package as it is technical and not a composite review?	The FDA (CDER) uses Pinnacle 21 Community version to test study data. This was covered during the live session. Please listen back to the recording.
Having submitted many filings to the FDA (without having an RTF), we often wonder to what level of quality the FDA found our eSub Dataset packages. Is there a way that we can obtain feedback from the FDA on the quality of the data packages submitted?	This was covered during the live session. Please listen back to the recording.
Is Technical Rejection Criteria validation applicable to Emergency Use Authorization submission?	This was covered during the live session. Please listen back to the recording.
For the Phase I eSUB with a PK-oriented submission, we do not provide an aCRF. We plan to explain this in the cSDRG. What would be your recommendation for submitting Define-XML without an aCRF?	This was covered during the live session. Please listen back to the recording.
Could this test data be dummy data? Should it be the live study data since they are only interested in seeing the structure of the data?	This was covered during the live session. Please listen back to the recording.
Did the panellist say that Technical Rejection Criteria cannot be checked during the test submission process?	This was covered during the live session. Please listen back to the recording.
Do you have any suggestions for submitting macro programs and any about their programming standards? Are there any to define that don't currently exist?	This was covered during the live session. Please listen back to the recording.
Is a TS file required for new clinical/nonclinical studies under 4.2 and 5.3 and what should it include?	Please refer to the Technical Rejection Criteria and the Technical Conformance Guide.
At the beginning, there was an announcement about the Working Groups' needs. Could you show the names of these groups again or provide a link about this? Thanks.	Details on the Working Groups can be found on the Advance Hub.
I have a few more questions regarding the TCG. If the unique ATC code is not assigned in SDTM/ADaM, what will happen in the gateway or the FDA database? Will the data package be rejected? Or will it be requested to be modified?	The format and content of your CM domain/ADCM analysis dataset is not subject to FDA Technical Rejection Criteria, so it should pass through the gateway successfully. You will likely get feedback from your review division if they expect ATC codes as part of your analysis. This would be a good topic for a Type C meeting or your PreNDA/PreBLA meeting.
Should the sponsor explicitly indicate the version of TCG in any documentation? For example, in the cSDRG or ADRG of each individual study or in the SDSP?	This was covered during the live session. Please listen back to the recording.
Do we need to submit the metadata datasets (intermediate datasets) as part of the submission package used to create the ADaM/TFLs?	It is not required to submit intermediate datasets. If these datasets are necessary to re-create key safety and efficacy analysis endpoints, it is recommended to include them in your submission. We encourage you to ask the FDA review division and discuss the approach prior to the submission.