

Test Submission Forum Group



Project Scope

- Industry Survey
- Barrier identification
- Identify incentives for companies to complete test submissions
- What are the benefits to the FDA, companies that participate as well as the industry as a whole to increasing the number of test submissions (Better communication of potential value to all players)
- How can we get the CRO perspective
- Identify what companies/industry want to see in the feedback provided with the test submissions
- Industry Webinar to review entire test submission process (initiated via PHUSE or FDA??)
- Poster at CSS2017
- White Paper
- Test Submission FAQ Advance Hub space

Identified Need/Challenge

Increase the number of test submissions submitted to the FDA and demystify this process. With the issuance of the Federal Register Notice, Providing Regulatory Submissions in Electronic Format-Standardized Study Data, Guidance for Industry, there was the thought that those creating SEND datasets would start to participate in the test submission process implemented by the FDA. The lack of such test submission has lead to the creation of this team to look at ways to help identify the barriers to submitting test submissions and propose ways to overcome these barriers.

Vision

With the requirement effective date to provide regulatory submissions in electronic format for nonclinical data (SEND) fast approaching both the industry and the FDA are looking to ensure that the transition is smooth. To that end, the FDA had indicated that test submissions can be made to not only aid the industry in reviewing their processes but also aid the agency with their processes as well. To date there have not been many test submission made our team will dive into the barriers that there may be associated with completing test submission as well as investigate ways to demystify the process.

To establish the barriers that are associated with this a brief survey will be sent out and from the results of this survey the team will determine what deliverables could developed to increase the number of test submissions, address the barriers and establish a forum where questions associated with the test submission process can be asked, discussed and answered. To do this the team will work with the SEND Implementation team to add space to the Advance Hub already in place.

Additional potential outputs from this team may also include a white paper, a poster at the PHUSE 2017 CSS as well as a webinar hosted by PHUSE or FDA surrounding the test submission process.

Development of a list of questions to submit to the FDA that surrounds the demystification of how they are going to use the data/information provided within these test submissions.

Plans

March 2016 - April 2016

- Poll SEND CDISC audience to determine what the barriers may be to their participation in submitting test submission to the agency

April 2016 - July 2016

- Using the results of the survey determine what deliverables could developed to increase the number of test submissions, address the barriers and establish a forum where questions associated with the test submission process can be asked, discussed and answered.
- Development of Advance Hub Test Submission FAQ section

July 2016 - August 2016

- Depending on barriers may schedule Webinar around Test Submission
- Development/creation of list of questions for the FDA to address regarding transparency around the information they receive within test submissions. "Demystify" what they do with the data received within the test.

August 2016 - March 2016

- Create and publish a White Paper
- Poster for PHUSE CSS 2017

Tasks

- Determine meeting schedule
- Create and circulate Poll to determine barriers
- Review survey results and determine deliverables
- Develop FAQ Advance Hub section for Test Submission Questions
- Develop list of questions for FDA to demystify Test Submissions
- Develop White Paper and Poster

Deliverables

[2016 Poll Results](#)

[Document of test submission questions and wish lists](#)

[eData team questions surrounding test submissions](#)