1 - Summary
The FDA Jumpstart program prepares submitted standardized data for nonclinical and clinical trials into a form that serves the needs of reviewers significantly improving the review process. Jumpstart has been focused on manual preparation of CDISC STDM clinical data for review purposes. SEND standardized nonclinical data will soon need to be submitted in compliance with the recent FDA guidance. In preparation, the FDA has standardized nonclinical study data extracted from sponsor study reports for use by reviewers.

At the FDA, SEND datasets are subjected to automated data fitness checks and creation of analysis views for reviewers. These include histopathology data visualization, clinical pathology trends and controls to combine treatment groups and exclude subjects without manual intervention. Jumpstart clinics that include data consistency and fitness assessments, and walkthroughs of analytic views and visualizations are provided to reviewers. Valuable feedback to improve review tools and the Jumpstart program have been gathered from reviewers.

3 – Data Analysis and Visualization
The typical study data review clinic consists of:
• Data consistency and standardization assessments
• Trial design overview and export of trial summary data for use in reports
• Graphical timeline views of planned protocol events and measurements
• Views of Demographics and Exposure domains
• Tabular and Graphical views of quantitative and qualitative findings data
• Trend comparison across time, dosing groups and measurements
• Consolidated views of Histopathology findings

Reviews of sponsor submitted data may include:
• Clipping of trial sets to reflect sponsor defined dosing groups – this allows reviewers to re-create group summaries in the PDF reports and compare their analyses to the sponsor reported summaries. It also allows reviewers to combine groups as they see fit to perform independent data reviews.
• Use of subject-level exclusion flags to re-analyze study data
• Detailed review of all findings for a single subject
• Assessment of any signals in other studies included in the sponsor submission

4 – What Sponsors can do to get Ready for SEND Submissions and Assure Data Consistency and Quality
Sponsors can initiate SEND Readiness programs focusing on the following areas:
• Prepare to support the new SEND submission process by preparing for the new file structure and data delivery requirements
• Ensure that their data is prepared in a consistent and complete manner to meet the requirements for submission
• Make sure that their data is ready for submission by performing data checks and ensuring that the data meets the standards required for submission
• Provide feedback to the FDA on the new submission process

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Disclaimer
The views and opinions expressed in this poster presentation are those of the authors.