

PhUSE WG Activity Introduction – Clinical Legacy Data Conversion Plan & Report

WG: Optimizing the Use of Data Standards

SDE in Tokyo, Japan

11th May, 2018

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Clinical Legacy Data Conversion Plan & Report

- In the Study Data Technical Conformance Guide that accompanies the guidance the identification of a Legacy Data Conversion Plan was highlighted for clinical studies. ([Technical Conformance Guide v3.3 March 2017](#)).
- This team will update the cSDRG to include a Clinical Legacy Data Conversion Plan & Report section. There are 3 scenarios in which the Example Documents will be updated: 1) Conversion of clinical legacy tabulation data to SDTM after legacy analysis has been created, 2) Conversion of SDTM IG 3.1.1 clinical data to a version of SDTM that is supported in the Data Standards Catalog, 3) No conversion was done. The ADRG will also be updated for the scenarios in which converted clinical SDTM data is the source used to create ADaM and clinical legacy analysis is the source used to create ADaM.
- The goal of the team is to provide an updated templates, completion guidelines, and example documents within the cSDRG and ADRG.



**Computational Science
Working Groups**



Clinical Legacy Data Conversion Plan & Report

- Started in 2014
- More than 60 members on the list across industry (Regulatory authority, CDISC, Sponsor companies and vendors)
- Led by Jane Lozano from Eli Lilly
- Project team meeting every 2-3 weeks
 - Discussion on suggested changes/updates
 - Sub-groups
 - Completion Guideline
 - Example document – SDRG, ADRG



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Clinical Legacy Data Conversion Plan & Report

Collaboration Tools

- Working with PhUSE Wiki (public)
 - [http://www.phusewiki.org/wiki/index.php?title=Clinical Legacy Data Conversion Plan %26 Report](http://www.phusewiki.org/wiki/index.php?title=Clinical_Legacy_Data_Conversion_Plan_%26_Report)
- That's all – (Most of) discussion and deliverables are public!



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Clinical Legacy Data Conversion Plan & Report

Walkthrough of Wiki and deliverables on the website



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ご静聴ありがとうございました。

&

みなさんのWorking Groupへのご参加をお待ちしております！



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