

Data Consistency - SEND Datasets and Study Reports: Request for Collaboration in the Dynamic SEND Landscape

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The Data Consistency Journey....

- The “Data Consistency: SEND Datasets and the Study Report” Working Group was formed at PhUSE CSS 2016 to identify inconsistencies that were being discovered between nonclinical datasets and study reports.
- Team members drew from experience, and the Nonclinical FDA Fit-for-Use Pilot for ~ one year to identify data discrepancies.
- We intended to share the discrepancies and recommendations as to how to handle them in a white paper which we worked on for ~ another year.



Proposed Solution – Real Time Crowd Sourcing

- As work progressed, the team realized that identification of new inconsistencies and our evolving understanding of regulatory needs would quickly make the paper obsolete.
- Sharing information in this dynamic space needs an agile solution.
- With this in mind, we propose a live, but monitored, wiki page where the community is invited to contribute new scenarios and possible solutions.
- This approach may be applicable to other nonclinical projects. Our poster provides a look into the process, progress, and future of the team's work.



Co-leads:

Fred Wood, Independent Consultant

Maria Francomacaro, Merck

Current Team Members:

Catherine (Cathy) Roy, Merck

Carol Spicer, Smithers Avanza

Michael Rosentreter, Bayer

Don Fish, Pfizer

Kathy Brown, Sanofi

Lindsay Eickhoff, BASi

Brian Argo, MPI

Christy Kubin, MPI

Debra Oetzman, Instem

Wenxian Wang, Xybion

Past Members:

George Kahlbaugh, Boehringer-Ingelheim

Gerard Randolph, Roche

Keli Arnold, Pfizer

Kristi Johnson, PointCross

Montserrat Cases, Bayer

Tania Strimple, Covance

Anthony Fata

Thomas Gade Bjerregaard, Novo Nordisk

