Optimizing the Use of Data Standards

Working Group Scope
The development and adoption of data standards over the last decade has shown significant promise in improving efficient delivery of data to support drug product and device submissions as well as the review process. However, there have also been gaps, issues and challenges in the interpretation and use of data standards. This Working Group will identify specific gaps that prevent FDA and industry from Optimizing the Use of Data Standards. This Working Group will collaborate to close those gaps.

Current Projects
Best Practices in Data Standards Implementation Governance
Bioresearch Monitoring (BIMO) Frequently Asked Questions Forum
Clinical Integrated Study Data & Analysis Data Reviewer's Guide
Dataset-JSON as Alternative Transport Format for Regulatory Submissions
Implementation of Estimands (ICH E9 (R1)) using Data Standards
Management of ODS Regulatory Referenced Deliverables
SDTM ADaM Implementation FAQ

PHUSE Collaborative Projects
Electronic Data Submission in Japan

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Janet Low is a Statistical Programmer at Merck where she is focused on study data standards and ensuring that electronic submission deliverables are high-quality and aligned with regulatory submission requirements. Nearly 20 years at Merck, Janet has worked in data management and statistical programming, but she is most passionate about leveraging her M.S. in Quality Assurance and Regulatory Affairs from Temple University to guide teams to submission and audit readiness.

She has provided operational excellence with training, consultation and mentorship to teams in a broad array of therapeutic areas covering drugs and vaccines; early to late stage clinical development; and partnership and collaborations.

In 2019, Janet joined as a co-lead to PHUSE Optimizing the Use of Data Standards Working Group. Prior to her role, she was an active volunteer in PHUSE projects and publications since 2015, including Standardising Data within the Inspection Site Selection Process, SDSP, Industry Experiences Submitting Standardised Study Data to Regulatory Authorities and Clinical Integrated Study Data and Analysis Data Reviewers Guides.

When Janet is not behind a computer, you'll find her volunteering in her community and cooking international dishes.

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Jane has been a part of the Pharmaceutical industry for over twenty-five years. She has been employed at Lilly since 1994 and is currently a Data Strategist supporting Phase II-IV trials in Ulcerative Colitis and Crohn's Disease. She has worked on early phase (first human dose), and last late phase trials for multiple therapeutic areas from a data perspective. She has an in-depth understanding of end-to-end global clinical data sciences and clinical data management, including database structures, data collection methods, data flow management, data analytics and automation, data quality and integrity, data technology, data archiving, data standards, data integration, data mapping and data submission.

In 2017 Jane stepped up to take on the role of Working Group Lead and provides valuable input into the PHUSE Steering Committee. She is a Subject Matter Expert on the Study Data Standardisation Plan and led the Project team to create the template, example documents, and completion guidelines. She also led a Project team incorporating the Legacy Data Conversion Plan and Report into the Clinical Study Data Reviewer's Guide and Analysis Data Reviewer's Guide.

When Jane is not concentrating on data she can be found in a ballroom, dancing to her heart's content. She is also a huge IndyCar fan and during the month of May is at the Indianapolis Motor Speedway whenever her schedule permits.