CDISC Analysis Data Model (ADaM) Team
Team Charter

Leadership Team

Nate Freimark -Lead
Deborah Bauer
Chris Holland
Susan Kenny
Jack Shostak
John Troxell

ADaM Subteam Leads

Education	Jack Shostak
Metadata	Monika Kawohl
Compliance	Shelley Dunn
Occurrences	Sandra Minjoe
Multiple Endpoints	TBD
Integration	Deborah Bauer

Team Mission

To provide metadata models and examples of analysis datasets used to generate the statistical results for a regulatory submission as well as metadata models and examples covering the statistical results.

Scope

The ADaM Team develops standards for the submission of analysis datasets that support the creation of statistical summaries for clinical trials. The Analysis Data Model (ADaM) assumes that analysis datasets are created primarily from source data compliant with the Study Data Tabulation Model (SDTM). The ADaM is described by two primary documents: the Analysis Data Model (***Model Document***) and its Implementation Guide (***ADaMIG***), as well as supportive appendix documents ADAE, ADTTE, and ODS. ADaM metadata are modeled the same way as SDTM metadata, except that there is increased emphasis on value-level metadata, and there is a unique kind of metadata known as Analysis Results Metadata. Throughout the ADaM, it is acknowledged that clinical trials are unique, and that the design of analysis datasets is driven by the scientific and medical objectives of the study. Clear communication regarding the analyses which support these objectives is a foundational principle.

The ADaM team intends to continue to support and enhance the ***Model Document*** and ***ADaM-IG*** and to support the data standardization needs from the FDA and the Therapeutic-area focused initiatives (e.g., C-PATH, NIH, DCRI).

2014 Goals

The ADaM team will focus full-team and sub-team attention on the following:

- Document on the introduction of ADaM methodologies to support ISS/ISE and an integrated ADSL structure
- Explore integrating ADaM in SHARE
- Development of CFAST/Therapeutic Area ADaM standards
- Development of ADaM examples and best practices for questionnaire data which can be applied across TA standards
- Update Compliance rules for consistency with the current version of ADaM-IG
- Harmonize ADaM model document with Define 2.0 and better address representation of results-level metadata
- Continued work on ADaM-IG updates
- Publication of final versions of ODS v1 and ADaMIG v1.1

Stakeholders/Constituency

- Regulatory Authorities
- Standards Development Organizations
- Pharmaceutical Sponsors
- Medical Devices, Diagnostics
- Contract Research Organizations & Consultants

Collaborations

The ADaM Team works closely with CDISC Teams, who utilize or leverage the ADaM standard to develop their own IG:

- SDTM, Devices, Define
- The ADaM Team also has ties to BRIDG, SHARE, and TA Project Teams
- The ADaM team also participates in PhUSE initiatives

Operating Model & Meetings

- Full team meets every other week on Thursday 12:30-2:00 East Coast time
- Sub-teams set own meeting schedule, and progress on full team calls
- ALT (ADaM leadership team) meets weekly as needed