Area Purpose and Scope

The Interventions, Events & Findings About Area oversees maintenance and development of

- Domains within SDTMIG Sections 6.1, 6.2, 6.4
- Variables within SDTM Sections 2.2.1, 2.2.2, 2.2.3.1
- Conventions and examples within and across the Sections

New, updated or clarified concepts are coordinated with relevant Teams (e.g., CDASH, ADaM, Controlled Terminology) to support end-to-end data standards development.

Accomplishments

Supplements Released for Public Comment

- Exposure Supplement
  Clarifications: 1) the EX domain is recognized as a derived dataset reflecting subject exposure(s) to protocol-specified study treatment(s) in protocol-specified unit(s); 2) EXDOSU should reflect protocol-specified unit(s) and EXVAMT reflects the total amount of the prepared product (treatment + vehicle)
  Standard Representations: 1) Collected doses not taken, not given, or missed; 2) Collected reason why a dose was not taken, not given, or missed; 3) Collected intended dose details; 4) Concentration / dosage strength; 5) Masked records
  Exposure as Collected (EC) domain was developed

- Prior/Concomitant Medications (CM)
  Leads: Ola Strandberg, Shannon Labout, Fred Wood
  Supplement drafted to 1) Enhance standardization of dictionary-encoded values; 2) Reserve QNAMs for ATC values and codes; 3) Include additional examples
  Draft Supplement presented at multiple WHO Drug Dictionary User Groups between 2012-09/2012-10
  Feedback to be reviewed, updates incorporated and Supplement prepared for post-SDTM v1.4 / SDTMIG v3.1.4

- Procedures (PR)
  Draft domain model to be released in next batch of SDTM documents for public comment with production release targeted for SDTMIG v3.1.4

Events

- HealthCare Encounters (HO)
  Draft development slated for post-SDTM v1.4 / SDTMIG v3.1.4

Findings About

- Multiple Dates Represented as Findings About
  Leads: Dan Godoy, Gail Stoner
  Draft supplement slated for release in next batch of SDTM documents for public comment with production release targeted for SDTMIG v3.1.4

- Skin Response (SR)
  Lead: Madhavi Vemuri
  Supplement received ~100 public comments; incorporating updates and dispositioning comments between 2012-09/2012-10
  Target production release for SDTMIG v3.1.4

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