Project Description/Scope

Pharmacogenomics Subteam
Collaboration with HL7 Clinical Genomics team to develop a coordinated set of standards to support the exchange of “omics” data.

Multiple Dates Subteam
Provide guidance for representing different dates related to a single stated “topic” (Event, Intervention, or Finding) in the SDTM/SDTMIG.

Detailed examples will be developed that will enable us to:
- Communicate information about the nature of the dates
- Provide guidance on appropriate record structure and relationships
- between records
- Describe how to represent associated findings

Oncology Subteam
- Assessment of the change in tumor burden is an important feature of the clinical evaluation of cancer therapeutics: both tumor shrinkage (objective response) and disease progression are useful endpoints in cancer clinical trials.
- RECIST (Response Evaluation Criteria in Solid Tumors) has been widely adopted in solid tumor clinical trials where the primary endpoints are objective response or progression and is accepted by regulatory authorities as an appropriate guideline for these assessments.
- The SDS Oncology Sub Team has developed three SDTM domains, with RECIST Criteria in mind, that are intended to represent data collected in clinical trials where tumors are identified and then repeatedly measured/assessed at subsequent time points and used in an evaluation of response.

Goals

Pharmacogenomics Subteam
- Work with FDA teams to understand and adjust the model to support review team requirements
- Develop standards to support bio-marker research and clinical care observational studies
- Develop information exchange framework that supports all “omics” data and maintains compatibility with HL7 CG models

Multiple Dates Subteam
- Identification of new domains and/or variables, e.g. TESTCDs, QNAMs, and/or controlled terminology as appropriate for inclusion in the SDTM/SDTMIG
- SDTMIG examples (new or revised)
- SDTMIG assumptions, general or domain specific (new or revised)
- SDTMIG CDISC Notes (new or revised)

Oncology Subteam
Development of the following three SDTM domains with controlled terminology:
- TU (Tumor Identification): Represents data that uniquely identifies a tumor for continual tracking purposes.
- TR (Tumor Results): Represents quantitative measurements and/or qualitative assessments of the tumors identified in the TU domain. Measurements are usually taken at baseline, then, at each subsequent visit to support response evaluations.
- RS (Response): Represents the response evaluation determined from data in the TR domain. Data from other sources (i.e. other SDTM domains) might also be used in an assessment of response for example, MacDonald Response Criteria includes a neurological assessment.

Accomplishments

Pharmacogenomics Subteam
- PGX package posted for comments (Gene Expression and Genetic Variation)
- “omics” Domain Analysis model – collaborative effort between HL7 and CDISC (two HL7 informative Ballots)
- Collaboration with NCI to develop a generic layer that will span all “omics” data and help integrate clinical observations

Multiple Dates Subteam
- Agreement seems to have been reached with regard to a working “Multiple Dates” concept, so the team is now moving into evaluating any challenges/adjustments with it.
- Next phase after validating concept will be to review potential ways of implementing that concept using all tools available in the SDTM.
- At present, the following have been evaluated and decided not to implement/pursue as a Multiple Date solution:
  - Add new timing variables
  - Single parent record with dates in SUPP
  - Multiple records in MH (characterize records w/SCAT or SUPP)

Oncology Subteam
- Comments received from an SDS Team review discussed and dispositioned.
- FDA F2F Workshop: A very successful F2F workshop was held with FDA in August to ensure that the domains would meet FDA review requirements. Present were representatives from multiple Review Divisions from both CDER & CBER, NCI, and CDISC.
- Controlled Terminology: Controlled terminology is in the process of being finalized with the CDISC CT team to ensure that terminology requirements are supported once the domains are published.

Next Steps

Pharmacogenomics Subteam
- Add support for Cyogenetics to CDISC PGx package
- DAM extensions include:
  - Add “generic” layer to the model
  - Harmonize with BRIDG – bring in more BRIDG classes as links
  - Apply recommendations from the last ballot
  - Ballot Gene Expression CMET in HL7

Multiple Dates Subteam
- Team kick-off, re-validate Charter
- Agree on [new] working principles
- Propose definitions for concept – review older examples
- Discuss examples/models
- Gather feedback

Oncology Subteam
- Discuss 1st Meeting: Review feedback, select model(s) for SDS Review
- 2nd Meeting: Review package for SDS Team
- Present to SDS Team
- Discuss SDS Team feedback – Adjust proposal plan for implementation

Oncology Subteam
TU, TR & RS domains:
- Finalize and publish the domain packages for public review
- Discuss an disposition all review comments
- Publish the final domain package
- Pathology/Histology domain
- Develop standards for representing pathology/histology domains
- Future work:
  - Prioritize future oncology standards development with FDA

Team Members

Pharmacogenomics Subteam
Joyce Hernandez (team lead), Phil Pochon, Fred Wood

Multiple Dates Subteam
Dan Godoy (team lead), Joyce Hernandez, Janet Reich, Tom Guinter, Gail Stoller, Michael Morozewicz, Madhavi Vemuri, Eric Qi, Scott Bahalvooni, Carlo Radovsky, Fred Wood

Oncology Subteam

As a catalyst for productive collaboration, CDISC brings together individuals spanning the healthcare continuum to develop global, open, consensus-based medical research data standards.