Investigating Endpoint Modeling - Biomarkers



Project Scope

While there are many additional endpoints, such as pharmacodynamics, T-Dar, etc., we begin our investigation and exploration in Biomarkers, ADA (Anti-Drug Antibodies), and Immunophenotyping. The group will also research what the clinical side has done with regard to these endpoints to ensure alignment where possible.

Identified Need/Challenge

The question of, "Where does X type of data belong in a SEND dataset?" has been asked frequently. Some believe that there should be a "biomarker" domain or that immunophenotyping data should be separate from other lab data; the initial premise of our group is that most of these endpoints can be modeled within an existing domain. This group will attack the question, "What is the process for identifying whether a data endpoint is part of an existing domain or needs a separate domain?"

Vision

To provide the community with methods to facilitate endpoint modeling using existing domains as opposed creating new or custom domains.

Milestones

March 2015 - May 2015

- Determine a refined scope

June 2015 - Dec 2015

- TBD

Jan 2016 - March 2016

- Publish

Tasks

- Determine endpoints
- Call for Participants
- Maintain Advance Hub (ongoing)
- Research CDISC ADA

Deliverables

Investigating Endpoint Modeling: Nonclinical Biomarker Modeling

Investigating Endpoint Modeling for SEND Datasets Poster – CSS 2016