**An Efficient, Cost Effective Approach to Development of a CDISC Package**

- Takeda’s past CDISC-compliant submissions using mapping of legacy data have proven:
  - Costly
  - Labor intensive
  - Time consuming
- CDISC compliance is difficult to achieve at the end of the data management and analysis process
- Creating an interim Takeda SDTM (T-SDTM) database
  - Maximizes operational efficiencies
  - Minimizes submission creation resources and costs

**Three Past Strategies for Submissions in CDISC Format**

- Remap to CDISC standards before submission
- Two parallel databases during study
- CDISC Standards (almost) from CRFs to submission

**CDISC-Based Standards System**

- CDISC compliant FDA submissions will become an official requirement
- CDISC-related standards are already the industry practice
- This CDISC-Based standards system includes:
  - All core CDISC requirements
  - The operational efficiencies of the legacy system
  - With the final transformation to “pure” CDISC standards handled at submission
- The CDISC-Based system begins at study start:
  - Changes to protocols facilitate CDISC compliance
  - CDASH/SDTM and SDTM compliance
  - Takeda SDTM (T-SDTM) database is a bridge between EDC and SDTM data

**Global Operational Master Specification (GOMS)**

- Single Excel spreadsheet to facilitate management of all data from collection to submission
- Includes specifications for:
  - EDC
  - T-SDTM
  - SDTM
- Includes mapping logic for each transformation step

**Managing Controlled Terminology**

- Multiple T-SDTM datasets contribute to one SDTM domain
  - EDC data before final SDTM creation
  - Retains operational EDC variables to facilitate data cleaning and review
  - Preserves SAS formats for ease of programming
  - Maintains dates and times in programmable and analyzable formats
  - Transposes horizontal EDC structures to vertical SDTM model
  - Retains data organization of CRF to facilitate data review by non-technical team members

**Transforming EDC to T-SDTM**

- Allows integration of non-EDC data before final SDTM creation
- Retains operational EDC variables to facilitate data cleaning and review
- Preserves SAS formats for ease of programming
- Maintains dates and times in programmable and analyzable formats
- Transposes horizontal EDC structures to vertical SDTM model
- Retains data organization of CRF to facilitate data review by non-technical team members

**The Benefits of T-SDTM**

- Minimizes submission creation resources and costs