Implementing Clinical Trial Data Standards – Virtually Almost There…

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Implementing Clinical Trial Data Standards

- Clinical Development Business Trends
- Resistance to Adopting CDSIC Standards
- Business Impacts
- Phased CDISC Implementation & Business Benefits
- Summary

Clinical Development Business Trends

- Outsourced Business Model
- Co-development Business Partnerships
- In-licensing Opportunities
- Mergers & Acquisitions
- Academic Collaborations

- Increased need for expedited data exchange to support collaboration – Data on Demand

Clinical Development Business Trends

- Regulatory Requirement for Meta-analysis
- Meta-analysis post-approvals
- Data Mining post-approval (Marketing / HEOR)
- Increased emphasis on Modeling & Simulation
  - FDA Critical Path Initiative

- Need to be able to quickly pool data across studies and compounds for analysis

Resistance to Adopting CDSIC Standards

- Standards? Yes, we use data standards…
  - Too costly and time consuming to transition from internally developed standards…
  - We need to get the Trials started now, can't wait for enterprise-wide data standard initiatives to catch up
  - We'll convert the data to CDISC STDM as part of the submission process…
- Need flexibility to go where the science leads us…
- Is CDISC the best standard? What about HL7?
- But CDISC keeps changing…

Resistance to Adopting CDSIC Standards

- Which CDISC standard should we use?
- But CDISC doesn't cover the data we need to collect
- CROs we work with do not have any expertise with CDISC (particularly true with CROs outside US/EU)
- Even if the FDA endorses STDM, where is the Janus project going? It's still a pilot…

Business Impacts

- Convert company standards to STDM at submission
  - Significantly increase the cost and time required for the submissions
  - May discover that data collection plan and internal representation prevents adequate/accurate conversion
- Company standards evolving over time and across regions without reconciliation
  - Substantial costs to convert data for regulatory requested meta-analysis projects
  - Request to extend meta-analysis project to support post-approval data mining project jeopardized by prohibitive costs

Business Impacts

- Co-development partnership with different standards
  - Company specific standards and CDISC standards
  - 7 figure cost estimate to be able to pool data if needed
  - Risk increase regulatory scrutiny if time required to address questions seems excessive
- In-licensing project with company specific standards
  - Increased costs to convert data from completed and ongoing studies
- Company acquisition – company specific standards
  - Increased costs to convert data from completed and ongoing studies

Phased CDISC Implementation & Benefits

2006 2007

- Post-merger decision to transition to CDISC SDTM
- SDTM is a framework that is flexible for storing data
- Studies starting up to use CDISC STDM
- Ongoing studies already using STDM will continue as is

Phased CDISC Implementation & Benefits

2006 2007 2008

- Education – external & internal training on STDM
- Criteria for CRO selection
- Convert ongoing & completed studies to STDM
- Develop additional SDTM domains as needed using guidelines – promote within CDISC

Phased CDISC Implementation & Benefits

2006 2007 2008 2009

- Increased focus on CDISC compliance checking
- > 85% of studies structurally conform to STDM standard*
- Ability to browse data across studies – no programming
- Start to develop a Modeling & Simulation Platform (M&SP) with cross study / compound data pooling capabilities

* Data from In-Licensing & Acquisitions pending conversion

Phased CDISC Implementation & Benefits

- M&SP with cross study / compound data pooling capabilities released into production
- Development of Biomarker Data Repository initiated
- Data from CRO Phase I EDC System loaded directly into Clinical Data Repository (CDR) in STDM structure

Phased CDISC Implementation & Benefits

- SDTM is sub-optimal for “user friendly” data processing (SUBQUAL data and vertical data structures)
- Need to manage content – CDISC Controlled Terminology / Company Controlled Terminology
  - Proof of concept pilot to use dictionary management and medical encoding system to manage / map controlled terminology
- Need to reduce the time lag in transferring data from EDC to CDR for Phase II-III studies

Phased CDISC Implementation & Benefits

- Standard eCRF & ODM libraries developed in parallel
- Project initiated to extract EDC data via ODM and load CDASH (or as-collected data) and STDM format into CDR
  - Increased timeliness and ease of use for ongoing data review
  - Increase consistency and quality of STDM datasets
- Education – external & internal training on ADaM

Phased CDISC Implementation & Benefits

- Extend use of ETL process to create ADaM datasets
  - Extend usability of data “as stored” to “as analyzed”
- Initiate project to generate standard TFLs
- Significantly reduce CRO outsourcing costs
- Significantly reduce the effort and cost required to support regulatory submissions

Benefits

- Data on Demand - Expedited data exchange to support collaboration
- Reduce costs of Outsourced Business Model, Co-development Partnerships, In-licensing, and Mergers & Acquisitions
- Support Modeling & Simulation and Biomarker Data Repositories which reduces Clinical Development costs

Benefits

- Reduce the time and costs to pool data for meta-analyses and data mining
- Reduce the costs to support regulatory submissions
- Increase responsiveness to regulatory queries

Benefits

- Lower cost of virtual R&D
- Data-on-Demand
- Effective collaboration
- Lower regulatory risk
- Lower barrier for in-licensing & acquisitions
- Support Translational Medicine
- M&S and Data Mining
- Support post-hoc analyses
- Effectively communicate with discovery

Barriers

- Press of business – the trials must go on…
- Executive management support and commitment
- Global adoption of CDISC
- Lack of awareness (sponsor & CROs)
- Transition Costs
- Time and resources required
- Uncertainty about exact standard

Standards are your friends

Where else would we get?

RADs, AMPs, ERGs, OHMs…

Zip codes…

Area codes…

Betamax…