# 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 postapproval 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





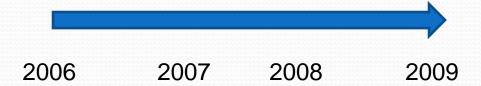
- Post-merger decision to transition to CDISC SDTM
- SDTM is a framework that is flexible for storing data
- Studies starting up to use CDISC STDM
- Ongoing studies already using STDM will continue as is





- 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





- 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



<sup>\*</sup> Data from In-Licensing & Acquisitions pending conversion



- 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





- 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





- 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



2006 2007 2008 2009 2010 2011 2012+

- 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, Codevelopment 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 metaanalyses 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...