

Standards Governance and Implementation in a Time of Rapid Change

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Outline

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Standards Governance

Diane Piper



What is Standards Governance?

“A decision making framework that is logical, robust and repeatable to govern an organization’s development and use of standards” Chris Decker



Standards Governance E2E implementation key points:

- Governance organization spans the clinical development lifecycle
- It consists of multiple cross-functional teams with core and extended members
- Create articles of organization which defines purpose, roles, responsibilities, decision rights and process
- Map out the touch points of the different teams
- Develop operational policies
- Utilize technology/systems to maintain standards metadata and support governance workflow

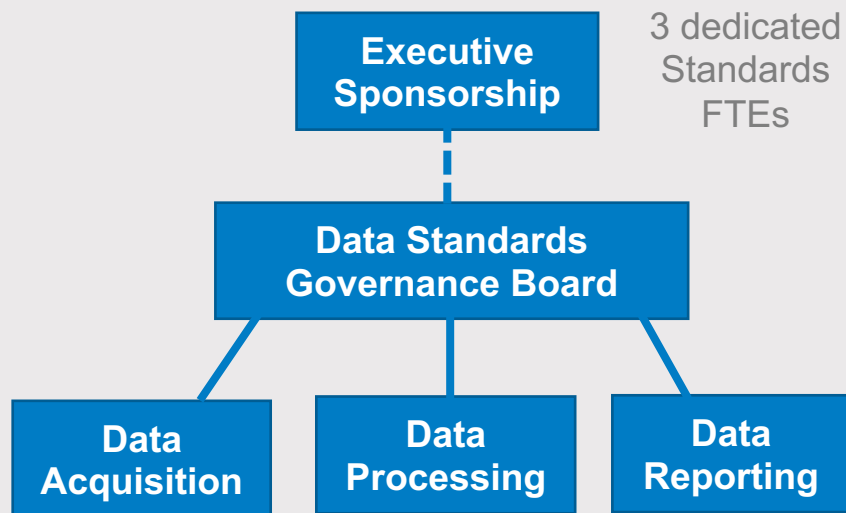


Evolution of Standards Governance

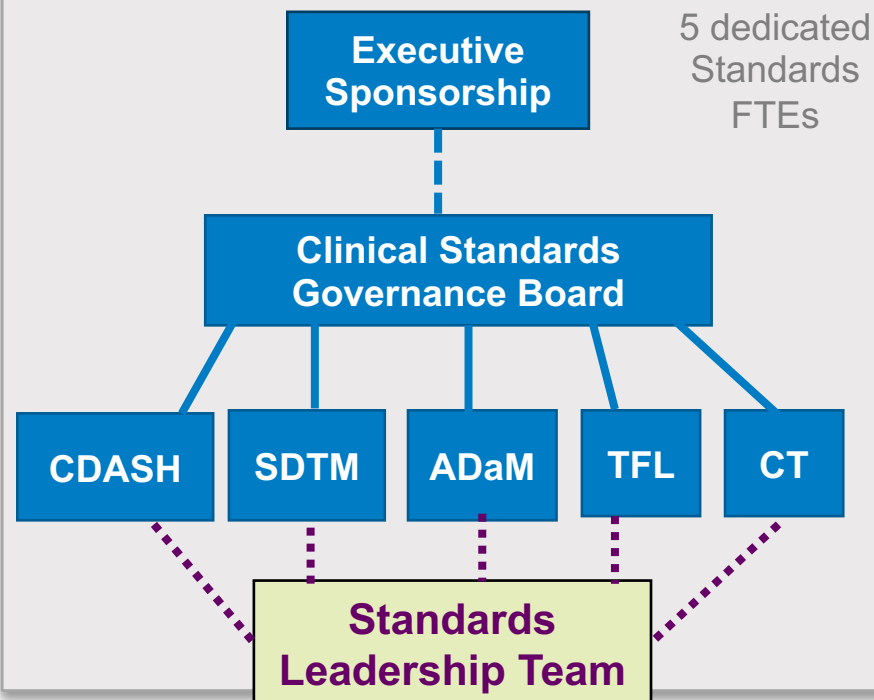
Standards Governance evolves over time to meet the changing organizational and business needs



2012 Rare Disease Division launched a formal Standards Governance framework

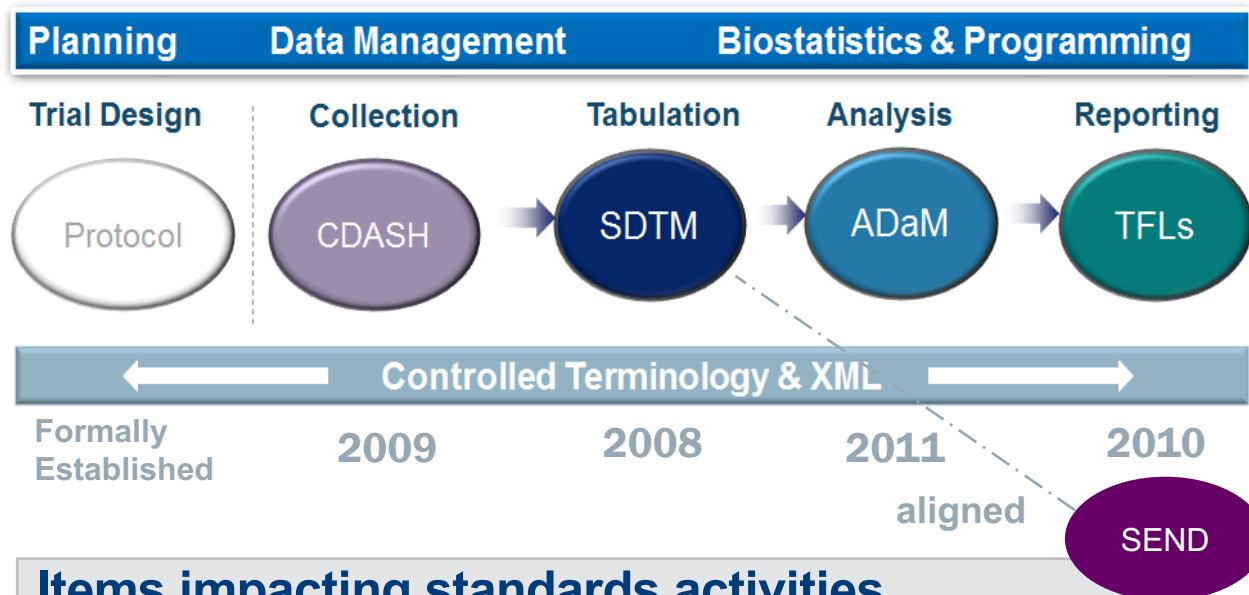


2014 Two Divisions merged leading to a new unified Governance framework



Overview of Shire's Clinical Data Standards

- E2E suite of standards
- Based on CDISC Foundational Standards and CT
- Standards models are underpinned by common terminology
- Annual E2E release yearly in Q4, minor releases as needed
- Release implemented within CRO partners' environments



Items impacting standards activities

- Organizational transformations
- Functional area process or system initiatives
- Program/study/TA standards development needs
- CRO partner organizational, process or system changes
- CDISC new releases & updates
- Regulatory agency/authority requirements and guidances (FDA, PMDA)

Current State: Significant Organizational Transformations

Events

- Between 2014-2016 multiple company and drug compound acquisitions were made
- In 2016, due to a merger the company doubled in size



*"Change is the only **constant** in life."*

Heraclitus



Led to

- Inheritance of legacy data standards and conventions which then needed to be assessed for conformance and compliance
- Supporting the inherited standards plus any partnership standards implementations
- Harmonizing the different standard governance organizations and frameworks
- Change in standards stakeholders due to organizational restructuring
- Company integration activities which affect the pace/content of standard activities
- Optimization and harmonisation of legacy data standards to create a new unified set of company-specific data standards.
- Implementation of the unified set of E2E data standards

Governance Challenges

- Managing change effectively – adjusting standards strategy, activities, priorities and even the governance organization as needed
- Larger the standards governance organization the greater the co-ordination effort
 - Strong and constant communication is needed between the standards governance teams and awareness of the ‘touch points’
- Increasing number of maintained versions of company-specific standards and acquired legacy standards adds complexity from a support perspective
- ‘Remembering’ past decisions - ensuring consistency in governance rulings



Governance Challenges (continued)

- Significant increase in standards consumers leads to
 - Creation of more supportive documentation
 - More educational and training offerings due to increased variation of standards experience and knowledge



Standards Implementation Challenges

Karin LaPann



Operational Challenges

- Interacting with multiple CRO partners with legacy standards implementations of differing maturity
- Having multiple CRO partners led to revamping of the On Demand Trainings to make them more agnostic. New CRO specific guidance documents were created to contain the details
- Updating the standards and implementing at CRO partners has a 6-7 months life-cycle. Implementing E2E standards updates at a CRO partner can cause a revision to the intended updates. This revision could impact multiple standards i.e. have a chain effect.



Operational Challenges (continued)

- Inherited standards are based on older versions of CDISC standards plus do not reflect more recent Technical Conformance Guide concepts e.g. Epoch. Study Teams needed to be made aware of the nuances/issues
- Shire Standards Team members are actively encouraged to share study implementation issues and to relay to Study Teams that they should proactively consult with the Clinical Standards Group
- Keeping track of the difference requirements of the FDA and PMDA and making sure Study Teams are aware



Operational - Standards Challenges

CDASH

- Implementation of CDASH is specific to EDC application
- New CDASH domains require cross-functional review and approval by the board and other teams
- Compliance; ensuring standards are followed and the metadata is followed correctly
- Some standards can be interpreted differently, leading to questions to the CDASH team



SDTM

- Changes in EDC systems or CDASH affect downstream SDTM mappings
- Multiple SDTM versions used across clinical programs
- Different interpretations across multiple TA's requires harmonizing standards & processes

Operational - Standards Challenges (contd.)

ADaM

- Ongoing studies use previous versions, more custom variable names which have now been defined
- Need additional datasets for TA's, Rare Diseases
- Support of non-standard TFLs
- Changing SAPs affect analysis datasets

TFLs

- Identifying waivers from Standard
- Teams want cosmetic changes
- Creating vendor-neutral standards
- Mergers and acquisitions provide alternate templates
- Efficacy Tables often Unique



Updates to Standards by Sponsor

In ever-changing standards world, how do you develop a plan or schedule of standards updates?



Decision: to do once-a-year an end to end standards release with internal guidances and standards templates

- Work internally and with preferred CRO partners to roll out updates in a methodical manner starting with
CDASH → SDTM → ADaM → TFLs
- Allow CRO partners to absorb standards updates
 - CROs review and approve updates
 - CROs conduct UAT to ensure that their tools can handle changes
- Provide updates to training and documentation
- Share in a collaborative environment (SharePoint, other online collaboration forums)

Making Standards Use Palatable

- Provide business use cases to convince that its essential
- Make Standards process dynamic and interactive for end user
 - Questions Trackers
 - Governance Waiver Process
- Provide Value-Added to use of standards
 - Toolkits that simplify specifications-writing tasks
 - Validation process that confirms correct use of standards
 - Metadata and data checking tools
- Ensure standards are supported by external sources (CDISC etc.)
- Enable end-user to go to published documentation to extend standards as needed (TAUG's, CDISC examples)

Spreading the Word on Standards Updates

- Communication from cross-functional team members
- Email blasts on major items
- Standards Newsletter
- Collaboration websites (for actual working documents)
- Internal presentations (Lunch & Learns)
- External presentations (Conferences, Vendor webinars)
- Formal Trainings
- Consultations/open clinics



Questions and Contact info



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