The Challenges of Standards Governance within a major pharmaceutical company

Presented by Jenny Griffiths

Data Standards Office, PD Biometrics,
F.Hoffmann-La Roche

June, 2015
Disclaimer:

This presentation reflects the views of the author and should not be construed to represent the Roche’s views or policies.
Agenda

• Problem Statement

• Key Challenges

• Standards Adoption @ Roche
  – Roche Global Data Standards
  – Leadership & Governance

• Summary
Problem Statement

• Main Issues

  – CDISC standards will continue to evolve rapidly across multiple disease areas over the next 5 years
  – In line with the FDA binding guidance, clinical trial sponsors must submit trial data that conforms to these standards
  – Controlled terminology is released every quarter
  – Studies continue to evolve with greater complexity
Key Challenges

• External
  – Process is still evolving to develop full ‘end-to-end’ protocol to submission CDISC standards
  – Authoritative, reliable, source of CDISC standards still evolving (SHARE)

• Internal
  – Wait for full set of CDISC standards or fill gaps with sponsor extensions?
  – Industry standards evolving i.e. CDISC TAUGs resulting in internal standards being out of date
  – Close gap between standards approval and implementation
  – Manage organizational complexity
Roche Global Data Standards

- Description of how Roche clinical trial data should be collected, ‘tabulated’, analyzed, and submitted to regulatory authorities aligned with CDISC.
Evolution of Global Data Standards

- CDISC Standards Exist?
- Define/Retire Roche Extensions
- Implement @ Roche
- Share extensions with CDISC
Roche Global Standards - Future State

Standards & Metadata Repository: Integrated Workflow

END TO END PROCESS

DRIVEN VIA AUTOMATION
Roche Data Standards Office

GDS Managers

Information Architects
Standards Governance @ Roche

• The Global Data Standards are developed, governed and maintained, consistent with industry standards, by the Global Information Standards Governance Committee (GIS-GC).

• Key objectives of the GIS-GC are to:
  – Ensure the Roche Group is engaged with, and influencing external data and information standardization efforts across the Industry (CDISC standards and Therapeutic standards - CFAST / Transcelerate projects)
  – Provide strategic direction and prioritization of activities
  – Decision-making body for Roche’s data and information standards

• DSO team manage the Global Data Standard Requests from study teams and will then triage to the Core teams as applicable

• TA teams enable the company to develop standards in specific indications

• TA Standards Experts teams are made up of: Clinical Science, Biostatisticians, Data Management
Standards Governance @ Roche – Request Process

1. Study Team Submit GDS Request
2. GDS Request Complete
   - Yes: DSO raises request with GIS-GC
   - No: DSO request additional Information
3. DSO request additional Information
   - Yes: GDS Request Complete
   - No: DSO escalates request to Advisory Board
4. DSO escalates request to Advisory Board
   - Yes: Core Team can make decision
   - No: Advisory Board Chair makes final decision
5. Core Team can make decision
   - Yes: DSO communicates decision to Study Team
   - No: Advisory Board can make decision
6. Advisory Board Chair makes final decision
   - Yes: DSO communicates decision to Study Team
   - No: Study Team Submit GDS Request
Seamless adoption requires:

- An ‘end-to-end’ approach
- Strong cross-functional support and governance
- A dedicated, empowered internal team to drive it
- Technology to manage the evolution of standards and drive their implementation is key
- Active participation in the development of new CDISC foundational and TA standards, will help to ensure they will meet study requirements
Questions? Contact Jenny.griffiths@roche.com
Doing now what patients need next