The Challenges of Standards Governance within a major pharmaceutical company

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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

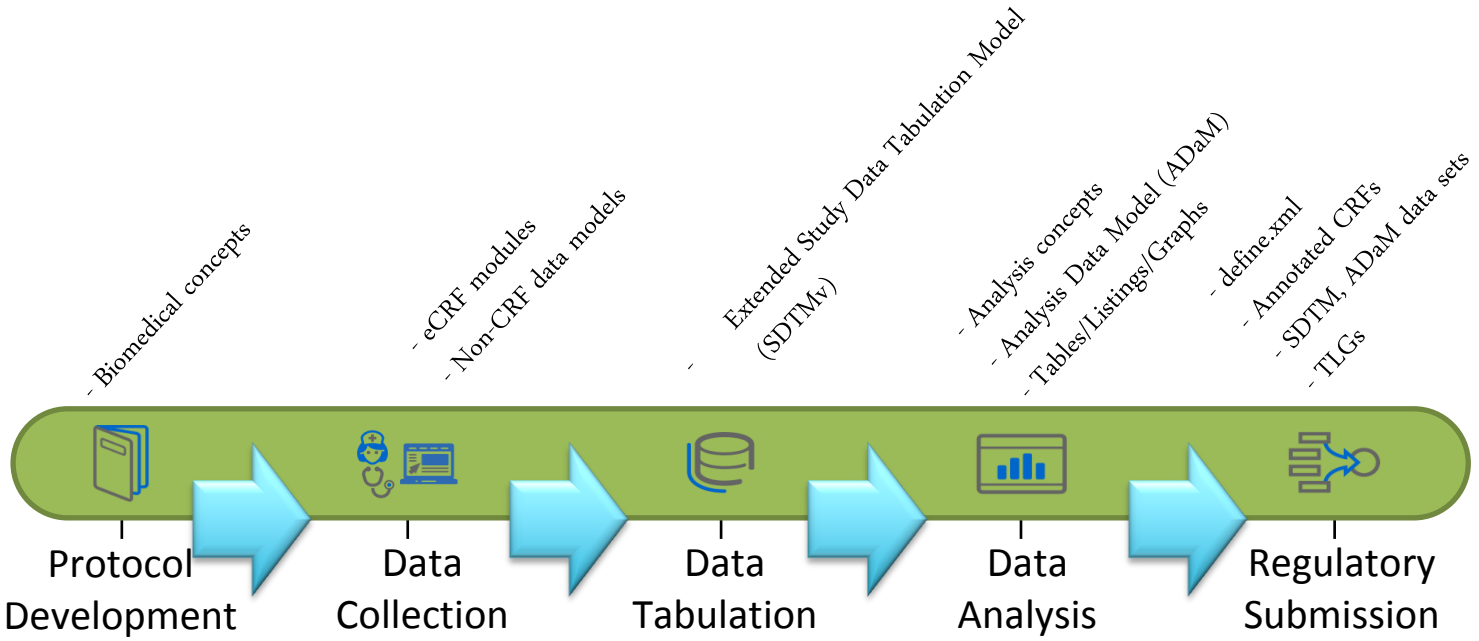
- Main Issues
  - CDISC standards will continue to evolve rapidly across multiple disease areas over the next 5 years
  - In line with the FDA binding guidance, clinical trial sponsors must submit trial data that conforms to these standards
  - Controlled terminology is released every quarter
  - Studies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

Key Challenges

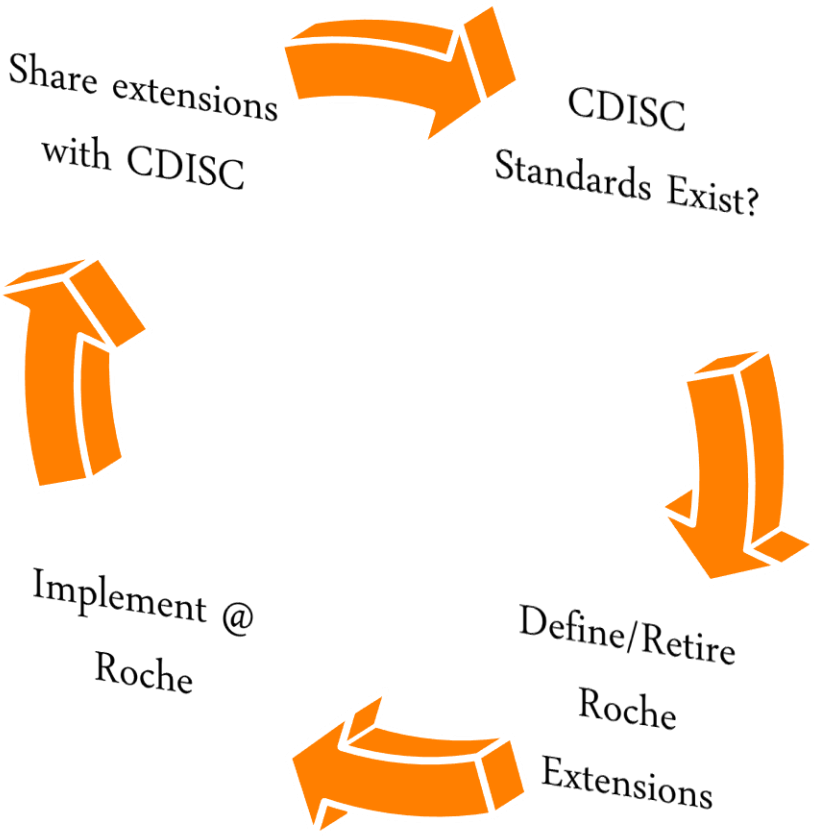
- External
  - Process is still evolving to develop full 'end-to-end' protocol to submission CDISC standards
  - Authoritative, reliable, source of CDISC standards still evolving (SHARE)
- Internal
  - Wait for full set of CDISC standards or fill gaps with sponsor extensions?
  - Industry standards evolving i.e. CDISC TAUGs resulting in internal standards being out of date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.

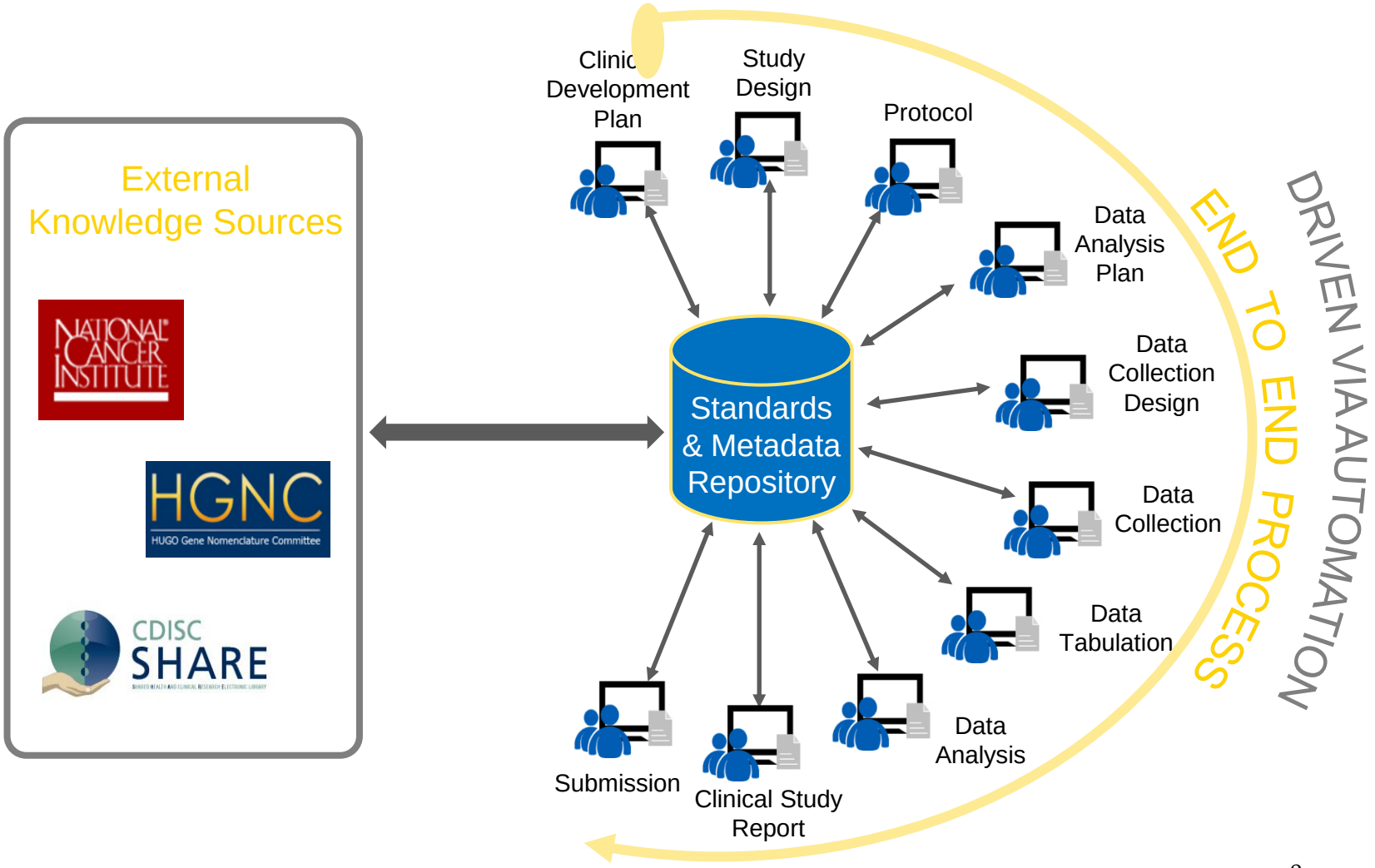


Evolution of Global Data Standards

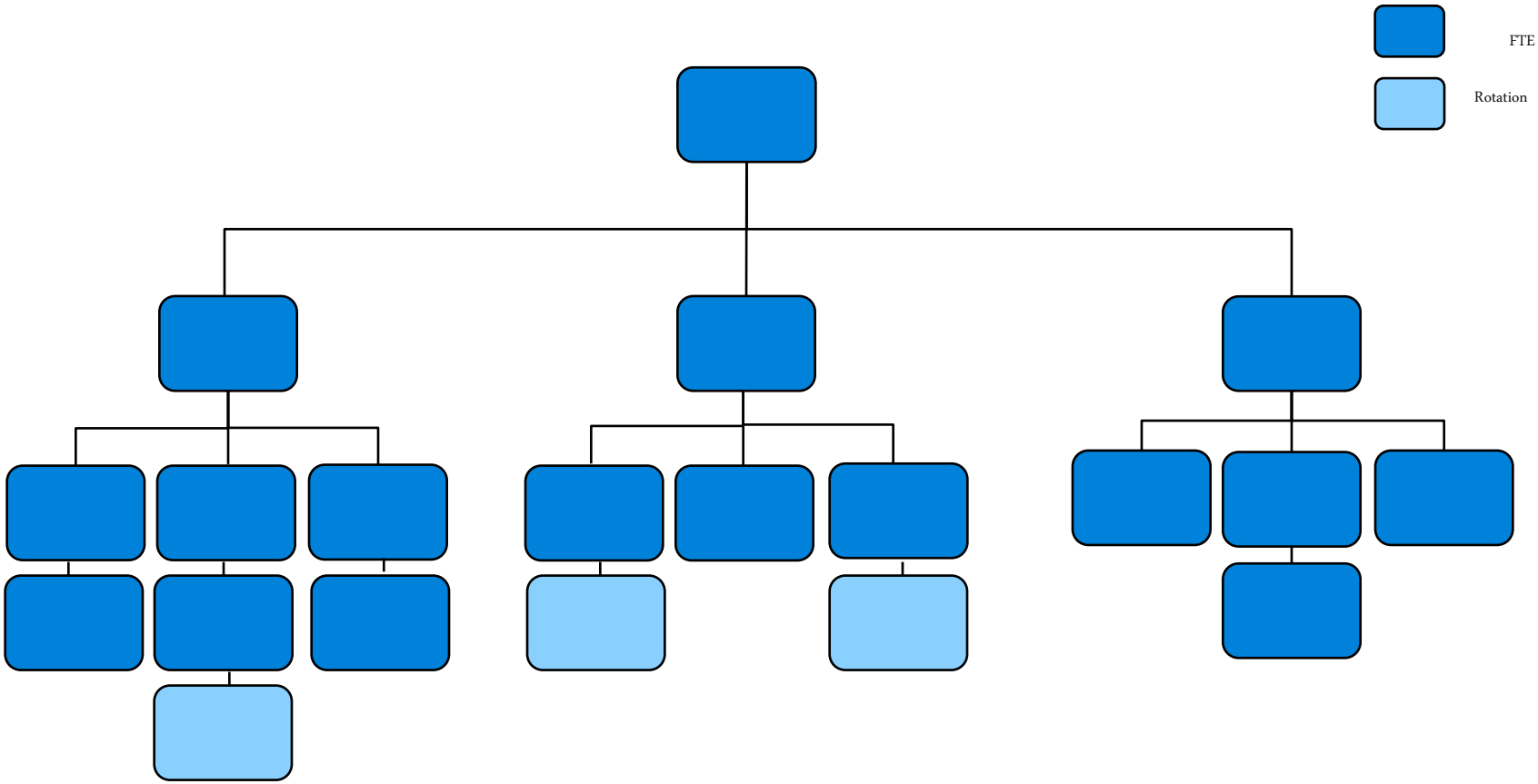


Roche Global Standards - Future State

Standards & Metadata Repository: Integrated Workflow



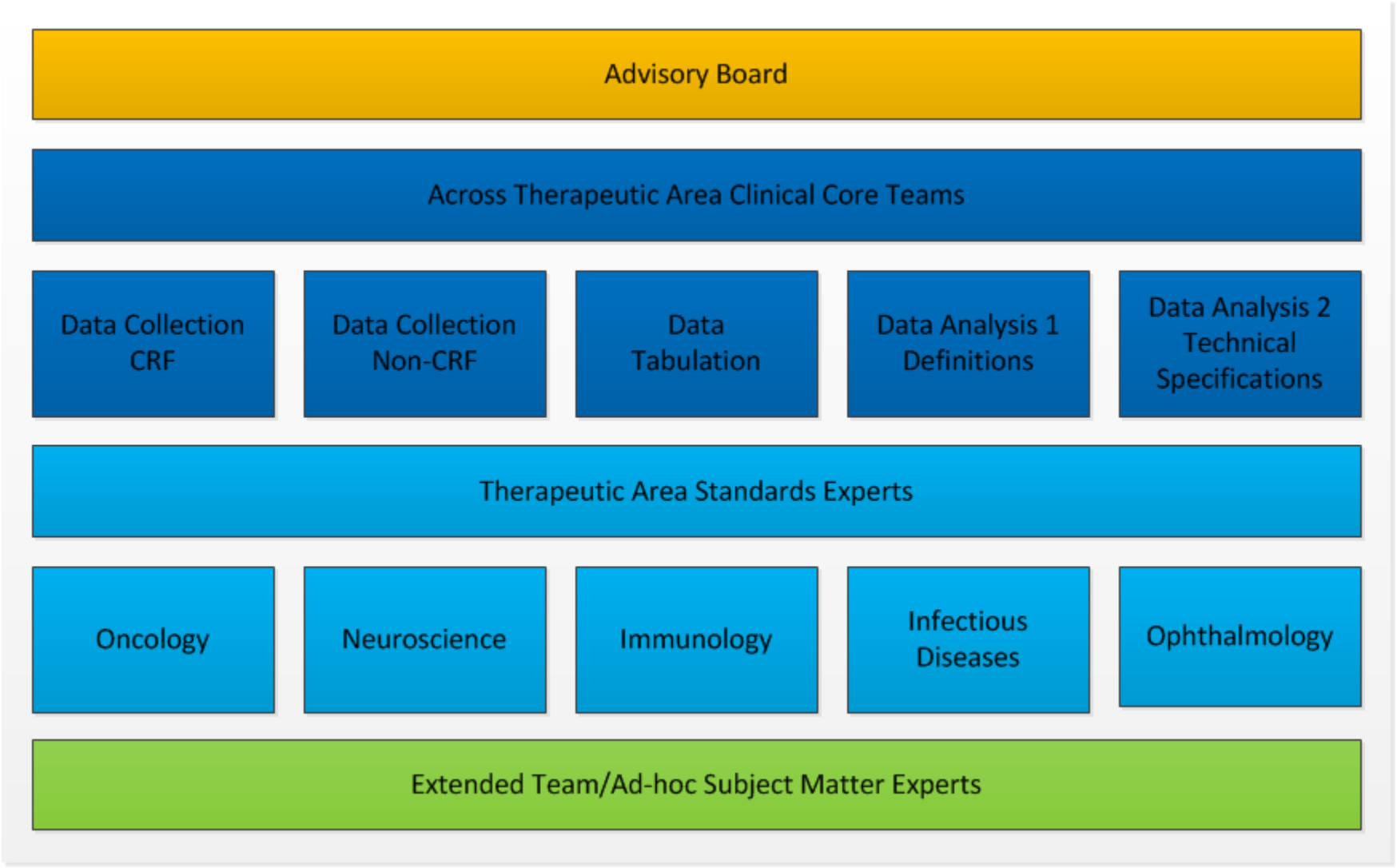
Roche Data Standards Office



GDS Managers

Information Architects

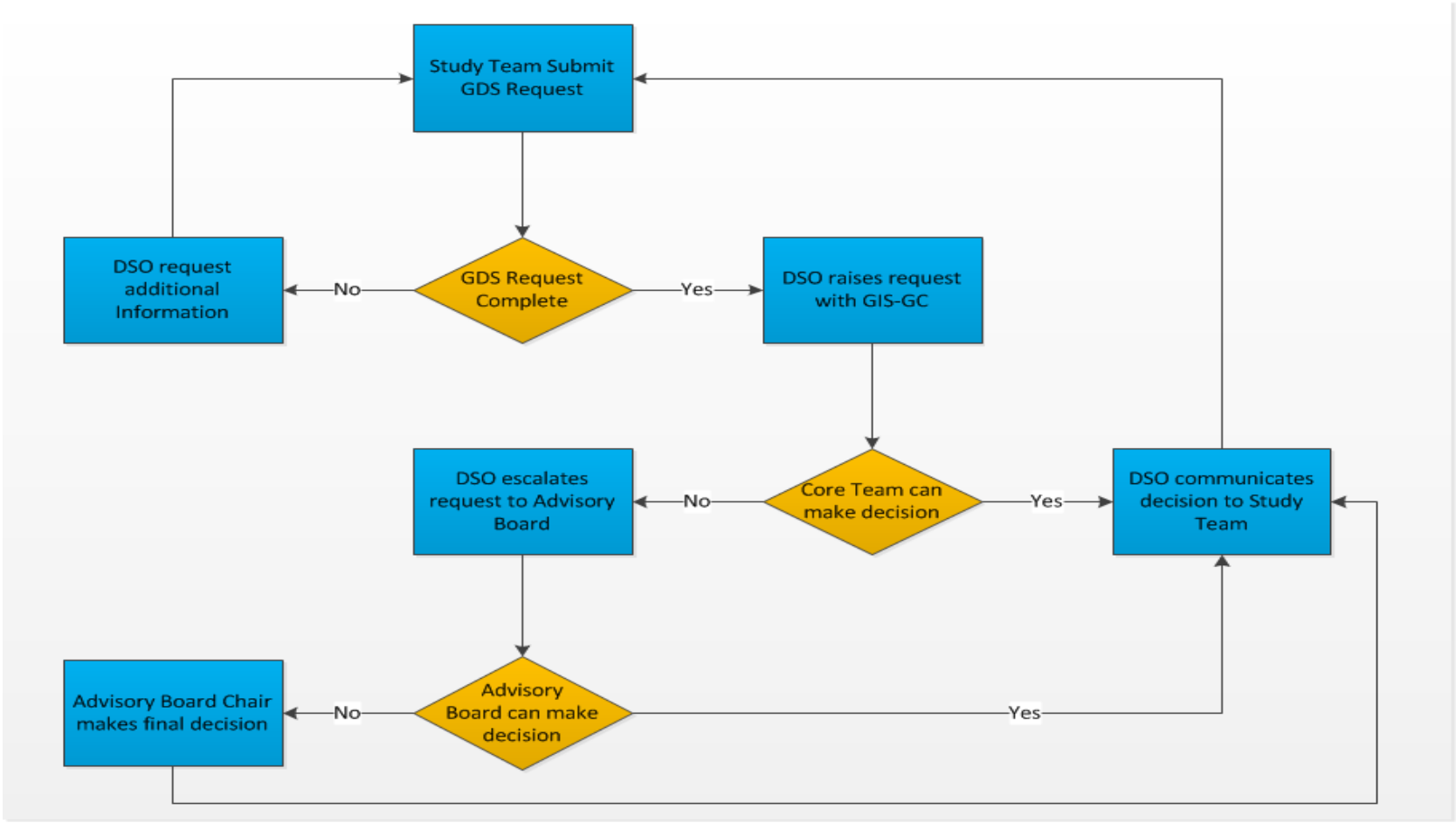
Standards Governance @ Roche



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



Summary

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

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