
JIRA work flow used for Standards Governance within a major pharmaceutical company

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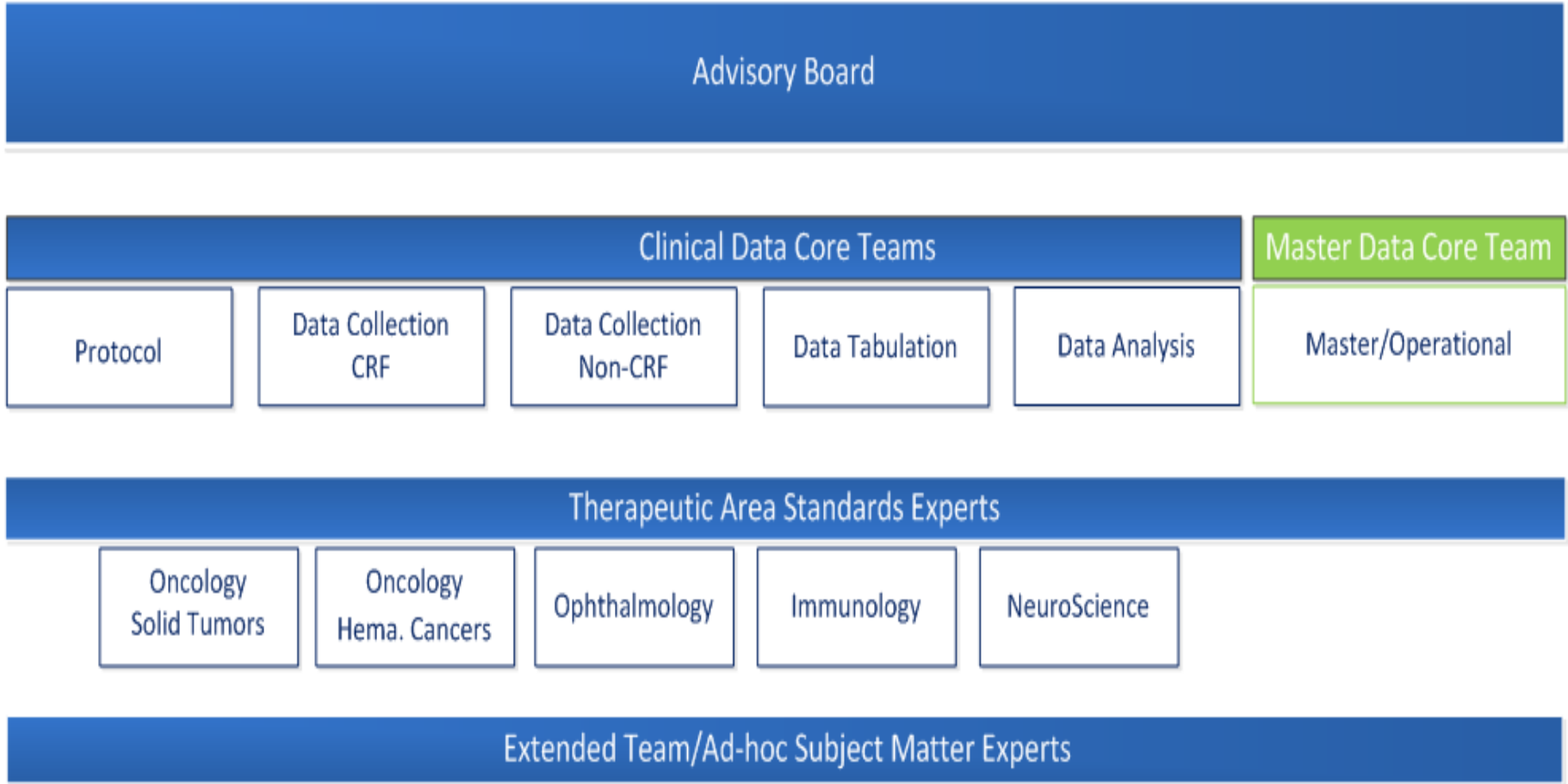
Points to cover

- Standards Governance at Roche
- Standards requests
- JIRA workflows
- Questions

Introduction

- At Roche, a centralized data standards group (Data Standards Office (DSO)), is responsible for leading the development, maintenance, implementation and governance of end to end standards working closely with a cross-functional Global Information Standards Governance Committee (GIS-GC).
- Key objectives of the DSO and GIS-GC are to:
 - Develop and maintain information standards for both clinical and master data
 - 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 standards activities
 - Serve as a decision-making body for Roche's data and information standards

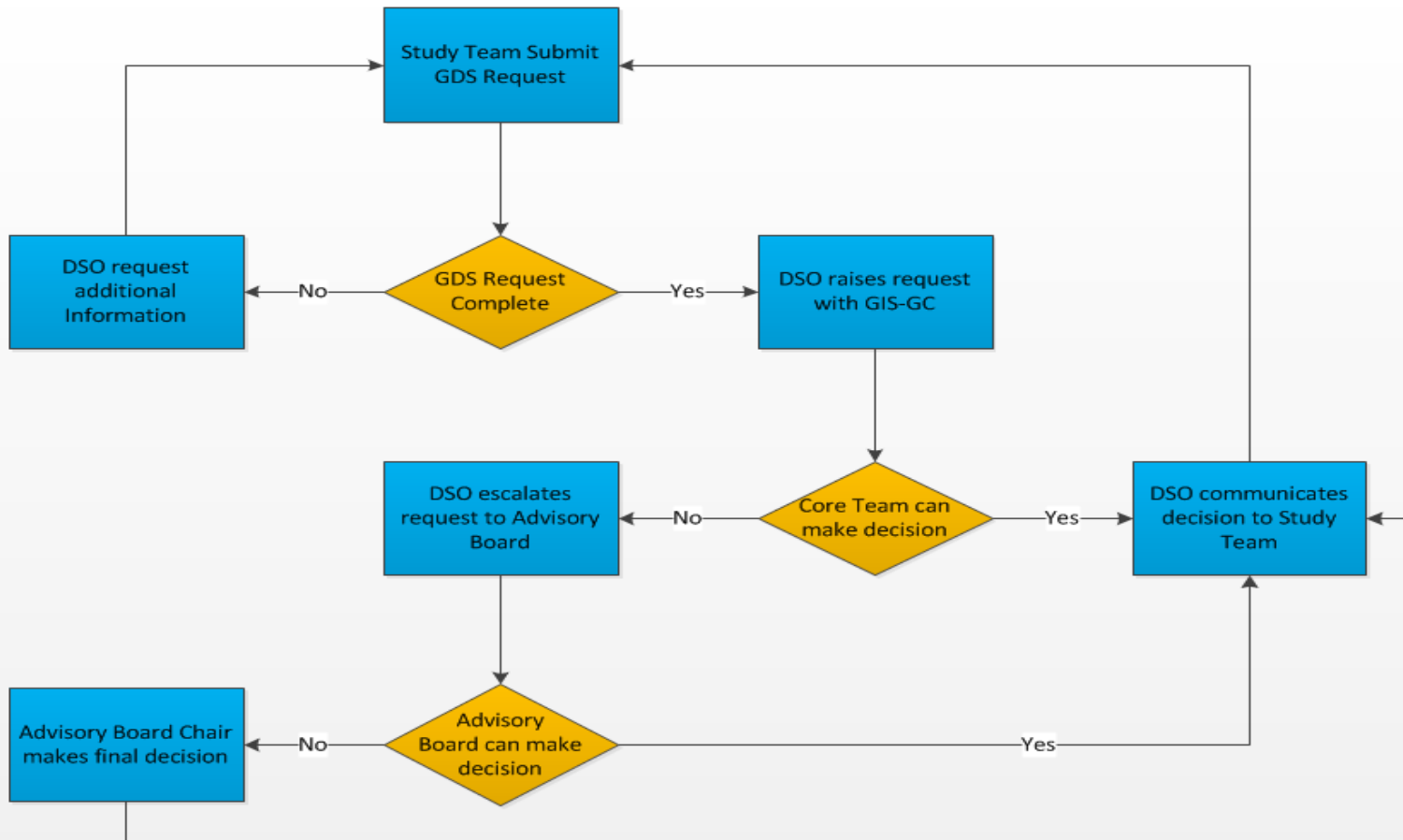
Standards Governance @ Roche



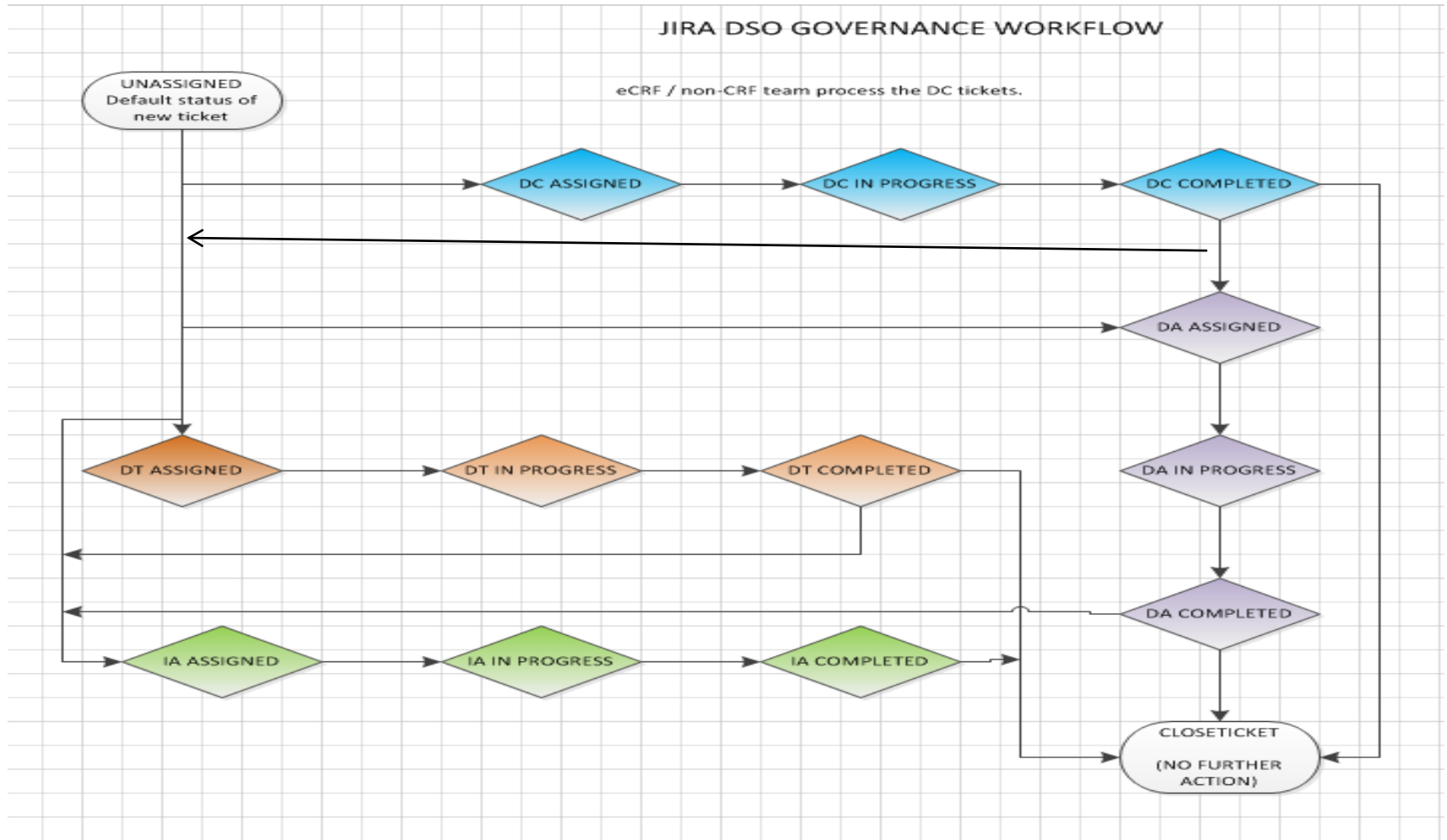
Standards Request Process @ Roche

- Study teams submit standard requests in JIRA
- There are different types of request, for example:
 - New eCRF fields and / or e-forms – Data Collection (DC) request
 - New metadata e.g. lab analytes – Data Collection (DC) request
 - SDTMv mapping issues / questions – Data Tabulation (DT) request
 - New analysis concepts – Data Analysis (DA) request
- Data Standards Office (DSO) team are split into the 3 teams above, to manage these different types of requests appropriately
- DSO team members manage the standard requests from study teams
- If applicable will triage them to the Core teams or TA teams

Standards Request Process Workflow



JIRA DSO STANDARDS GOVERNANCE WORKFLOW



Summary

Establishing a good JIRA workflow results in:

- GDS requests are processed by the correct people / teams
- An 'end-to-end' approach to each request from Data Collection to Data Analysis, and input into the Global Data Standards Repository (GDSR)
- Able to make good decisions and identify 'data elements' missing from current standards
- Forms the basis of the development of new company standards

Questions? Contact Jenny.griffiths@roche.com



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