
Every Study is Special! Governing Data Standards

Elizabeth Nicol & Chris Price



Data Standards Office

Global Data Standards

Global Information Standards Governance Committee

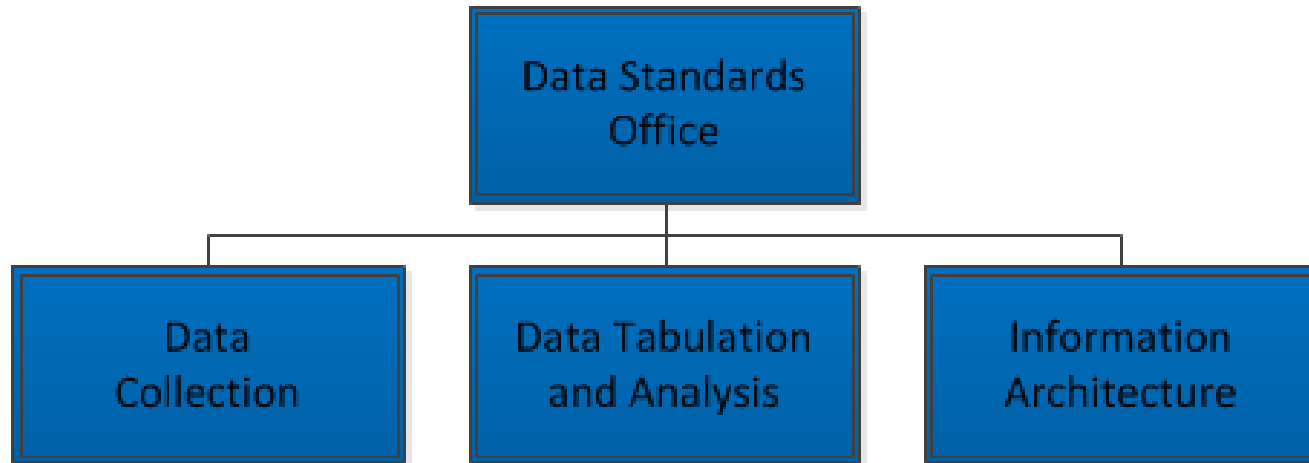
New Global Data Standards Development

Study Level Implementation

Summary

Data Standards Office

Organizational Structure



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Information Layer vs. Implementation Layer

Biomedical Concepts

e.g. Definition and properties of an Adverse Event (AE)

Logical Data Model

e.g. AE, AE intensity, AE onset date, relationship between an AE and treatments for that AE

Information Layer
Tool independent

Data Models for each System

e.g. Data model to capture AE data, AE domain in SDTM, ADAE analysis data set

Implementation Layer
Tool dependent

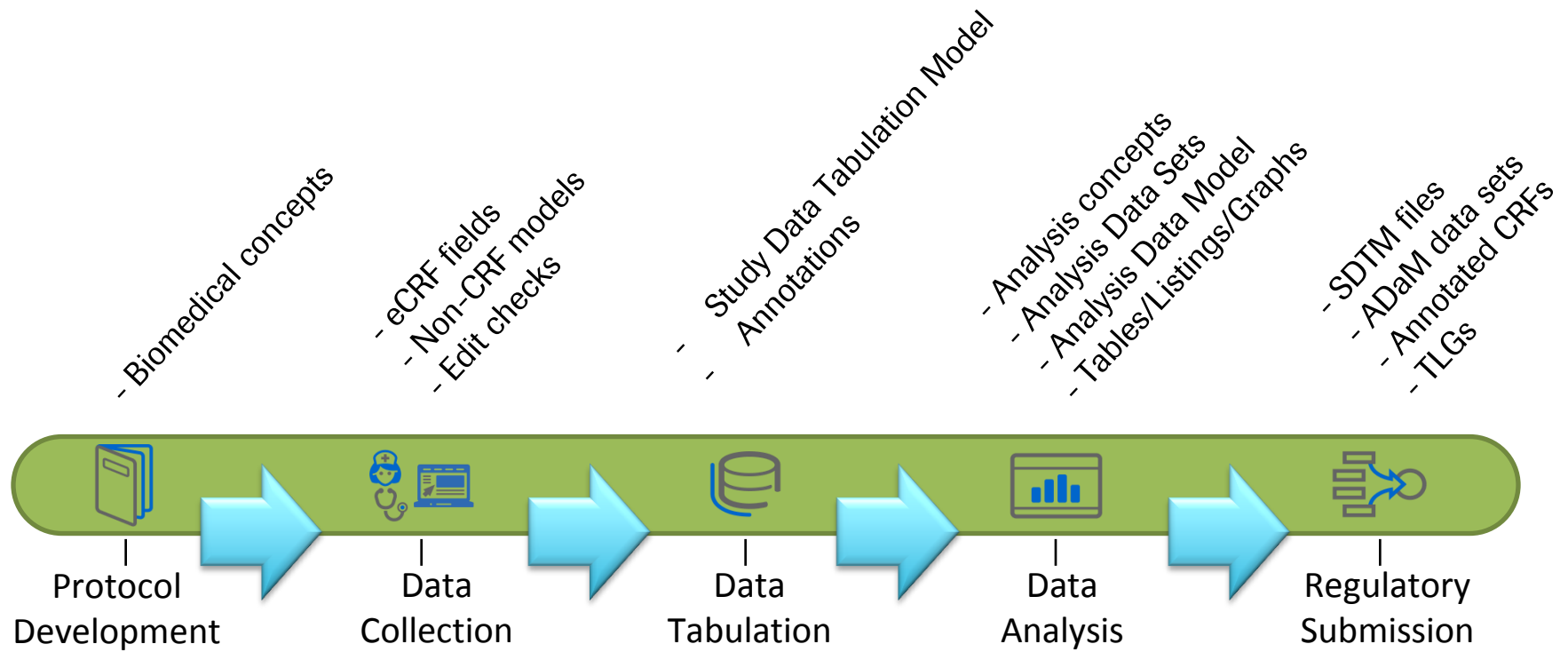
Systems

e.g. EDC, Programming Environment

Global Data Standards

What are Global Data Standards

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



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Global Information Standards Governance Committee

Structure

Advisory Board

Across Therapeutic Area Clinical Core Teams

Data Collection
CRF

Data Collection
Non-CRF

Data
Tabulation

Data Analysis 1
Definitions

Data Analysis 2
Technical
Specifications

Therapeutic Area Standards Experts

Oncology

Neuroscience

Immunology

Infectious
Diseases

Ophthalmology

Extended Team/Ad-hoc Subject Matter Experts

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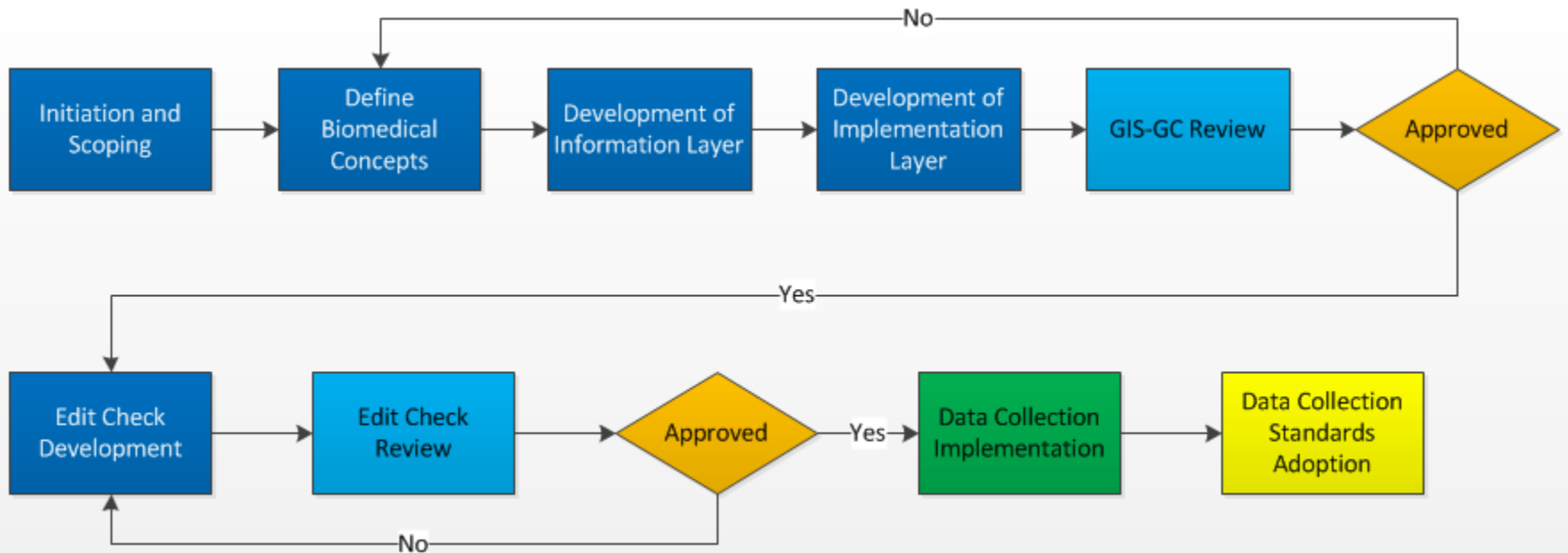
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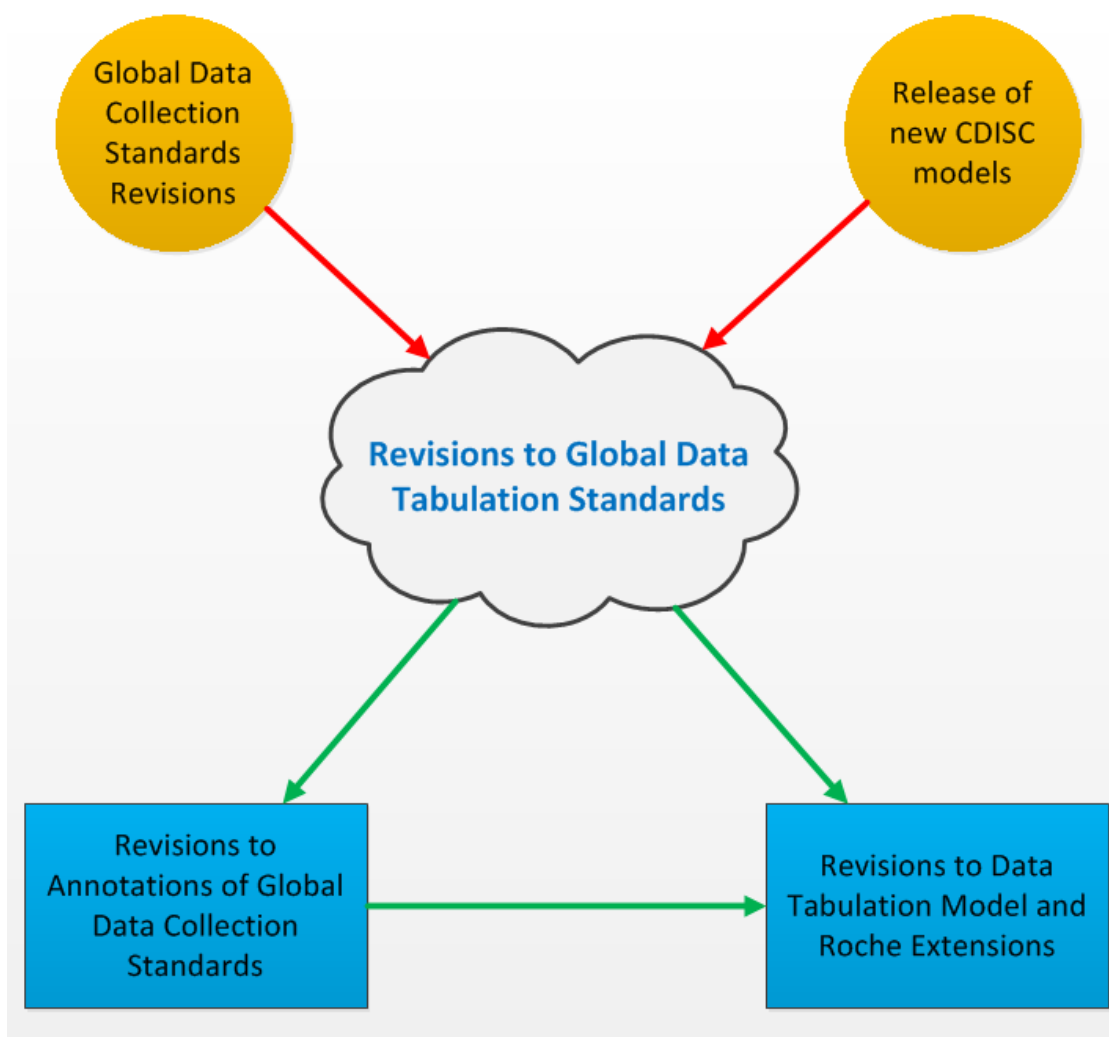
New Global Data Standards Development

Data Collection Standards



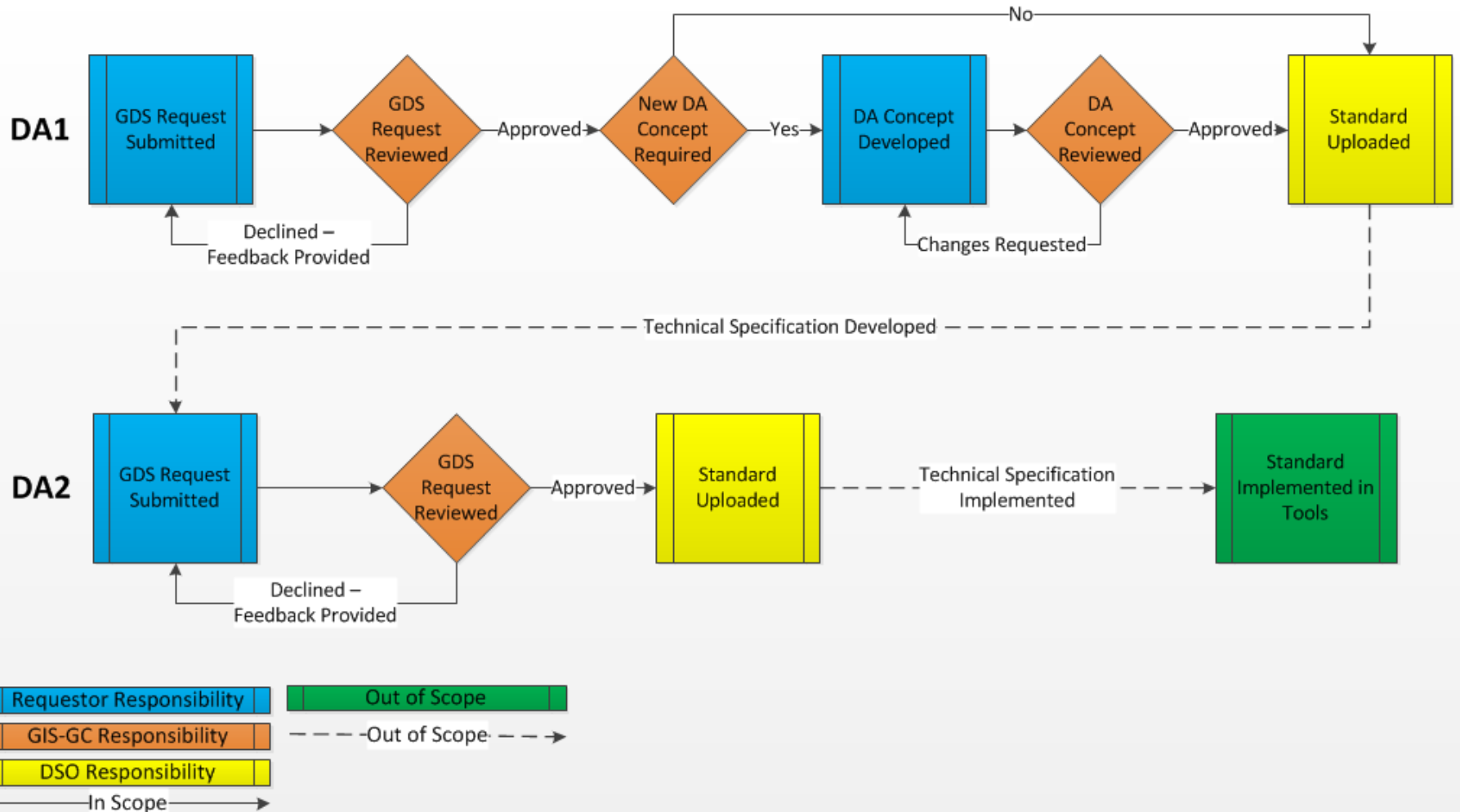
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Data Tabulation Standards



New Global Data Standards Development

Data Analysis Standards



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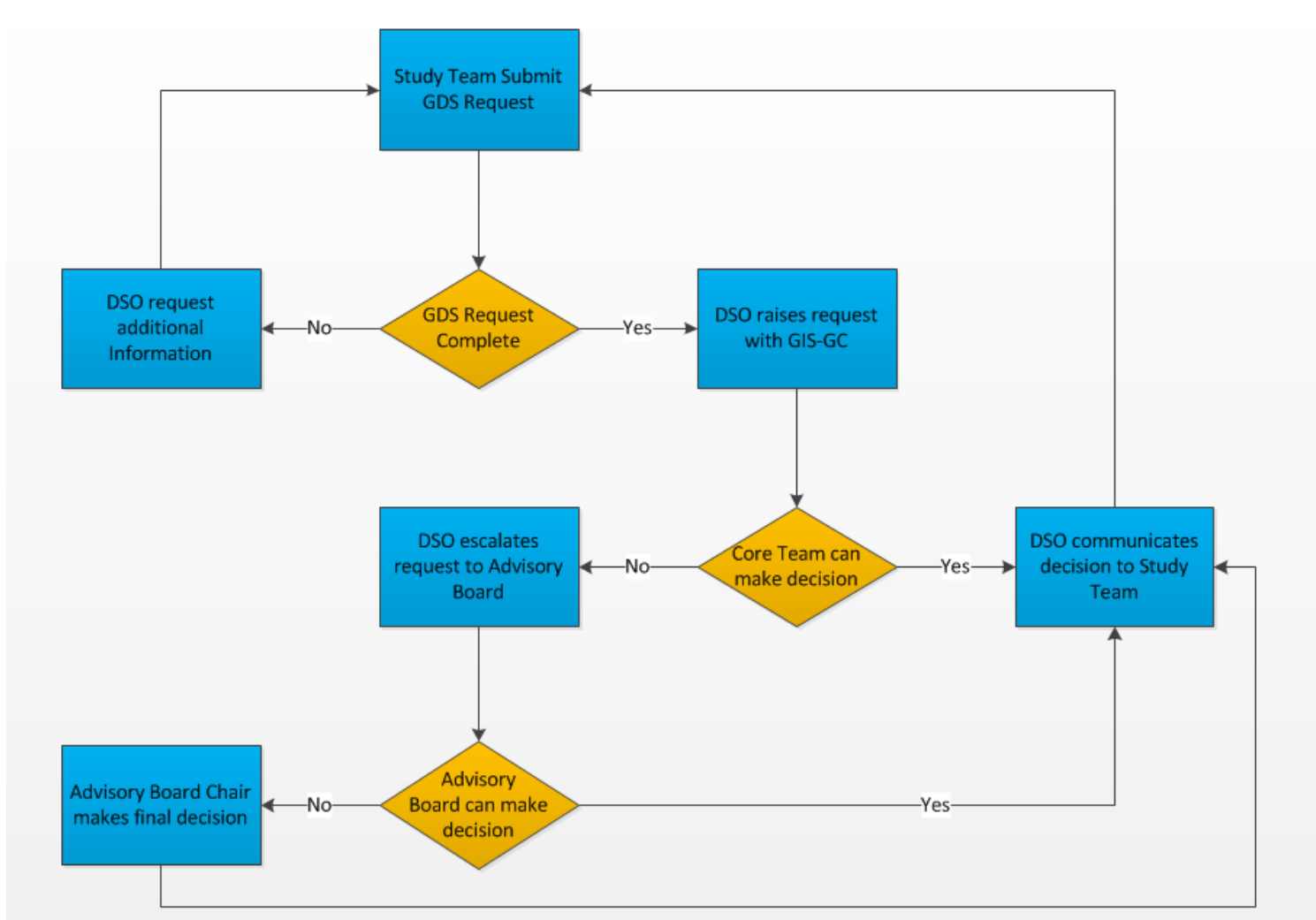
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Study Level Implementation

Global Data Standards Request Process



Study Level Implementation

Global Data Standards Request Forms

eCRF GDS Request Form

Please complete this form to submit a request for Global Data Standards

Data load - if you saved data from your previous sessions you can upload it here

Load file:

Section A - Requestor and Study Information

Date of request:

Requestor Name:

Site:

PDL Name (if applicable):

Program/Molecule Name:

Study# (if applicable):

Check if study is: PD study gRED study

Is this study: new study start up EDC amendment

Section B - GDS Request Information

Select the standard for this request:

Select type of request: Add new form Modify/Add field to existing standard form

standard field or form Other

Is there a precedent to this request? Yes No

If Yes, copy jIRA precedent number in this field (e.g. GLDATST-2994):

Describe the specific change you want to make:

Note that the maximum length of this field is 2000 characters.

2000 characters remaining on your input limit

Describe the scientific, business and/or data integrity rationale for this request and the problem this intends to resolve. IMPORTANT: We highly recommend that you work with your team to provide a strong rationale to support this request. A well written and complete rationale will speed up the processing of your request.

Note that the maximum length of this field is 2000 characters.

2000 characters remaining on your input limit

Please make sure to attach a copy of your protocol, Architect Loader file and any additional file to your request. The Architect Loader file must include the proposed change to the standards or the new proposed form and/or field. This information is required to process your request. If multiple requests are submitted at the same time, you may only attach this information to your first request.

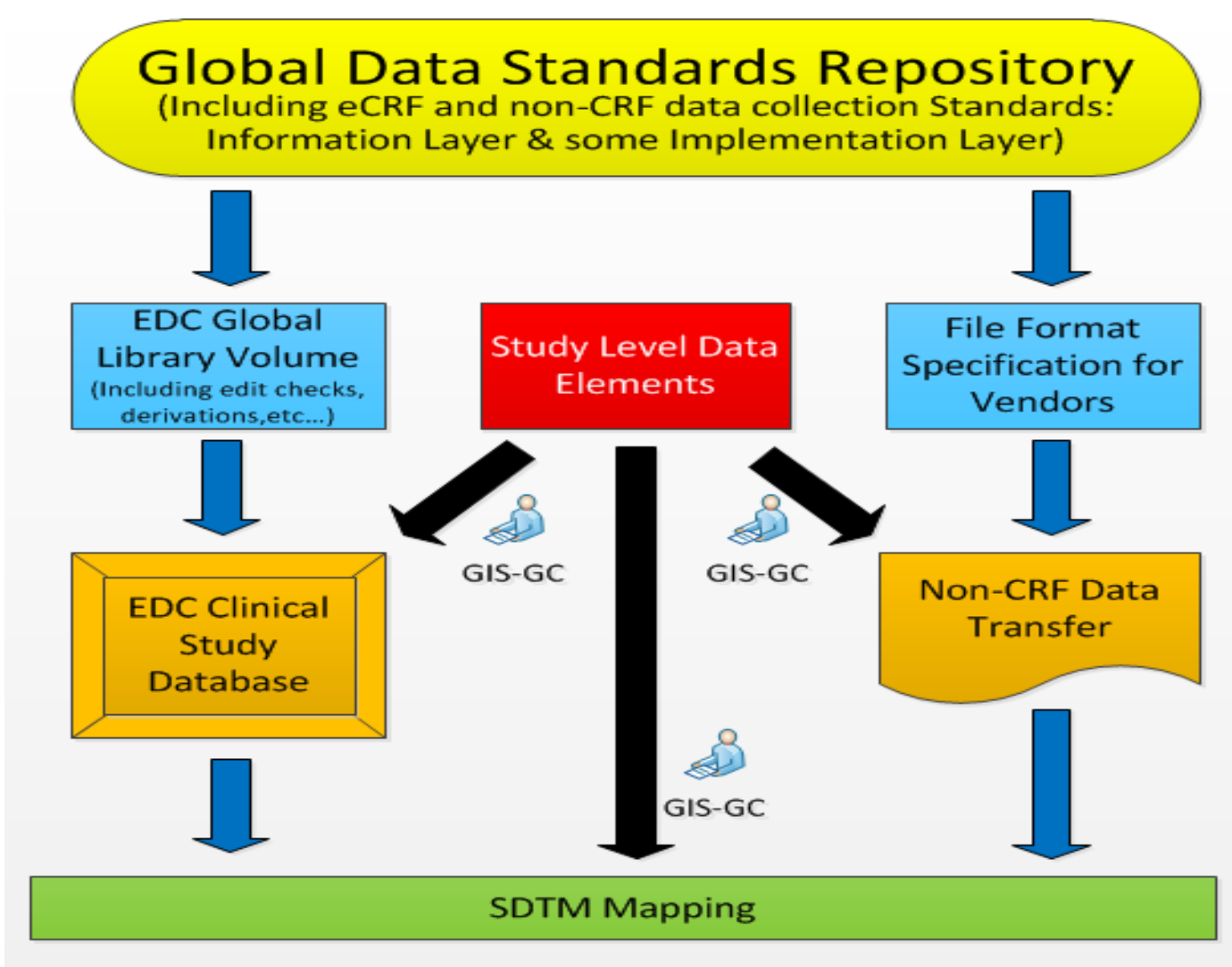
Attach Files (up to 5 files): [add more files](#)

Study Level Implementation Challenges



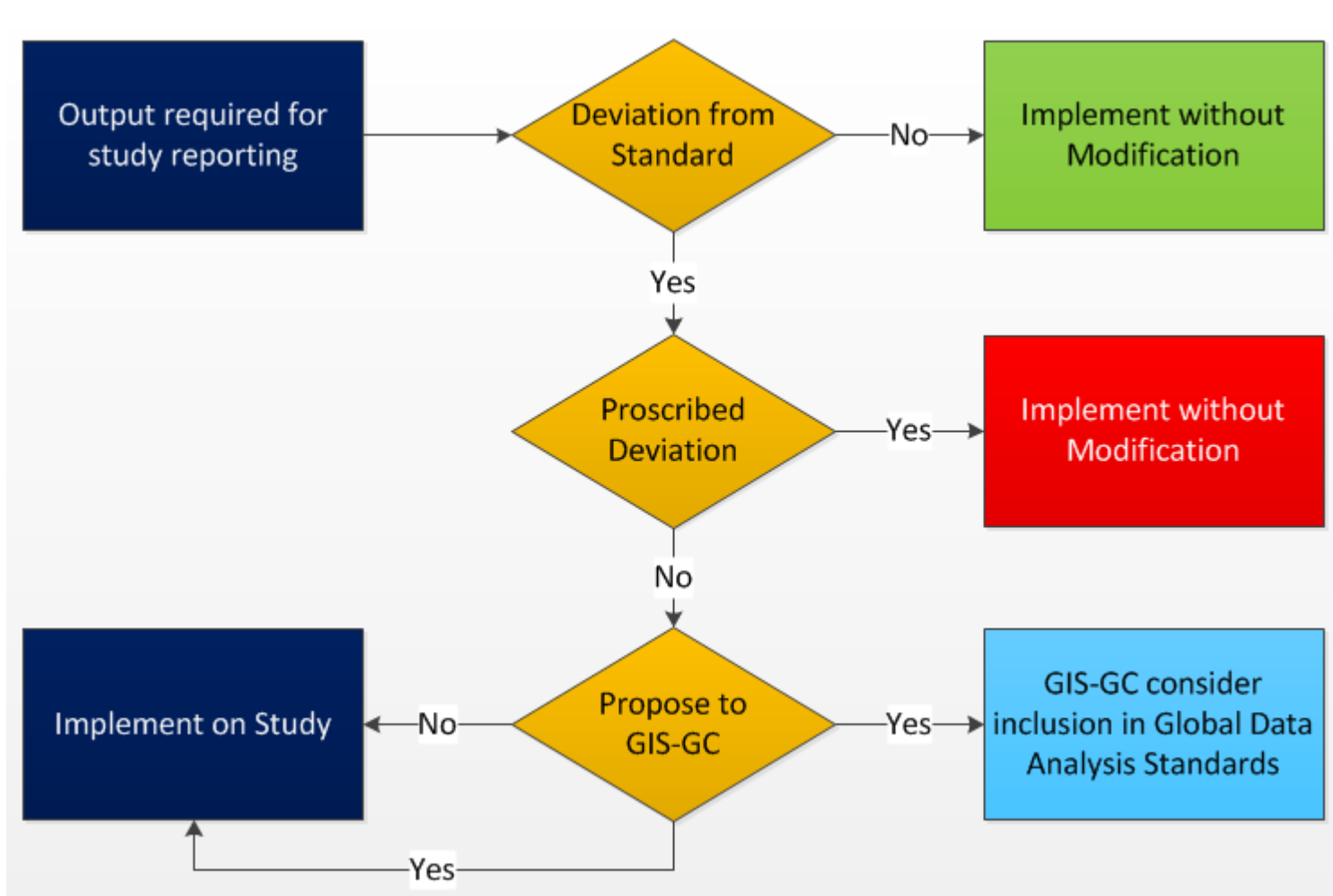
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Data Collection and Data Tabulation



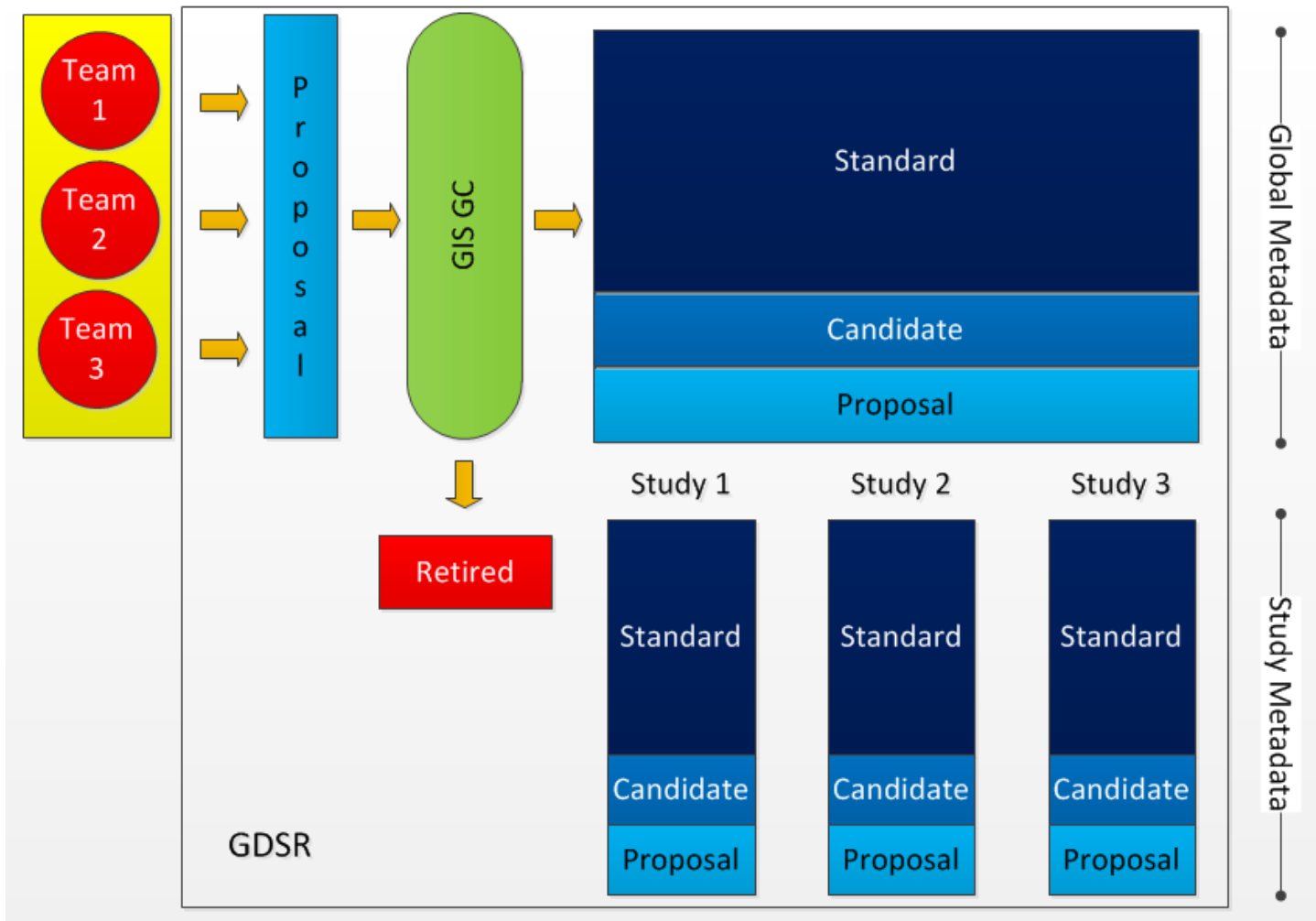
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Data Analysis



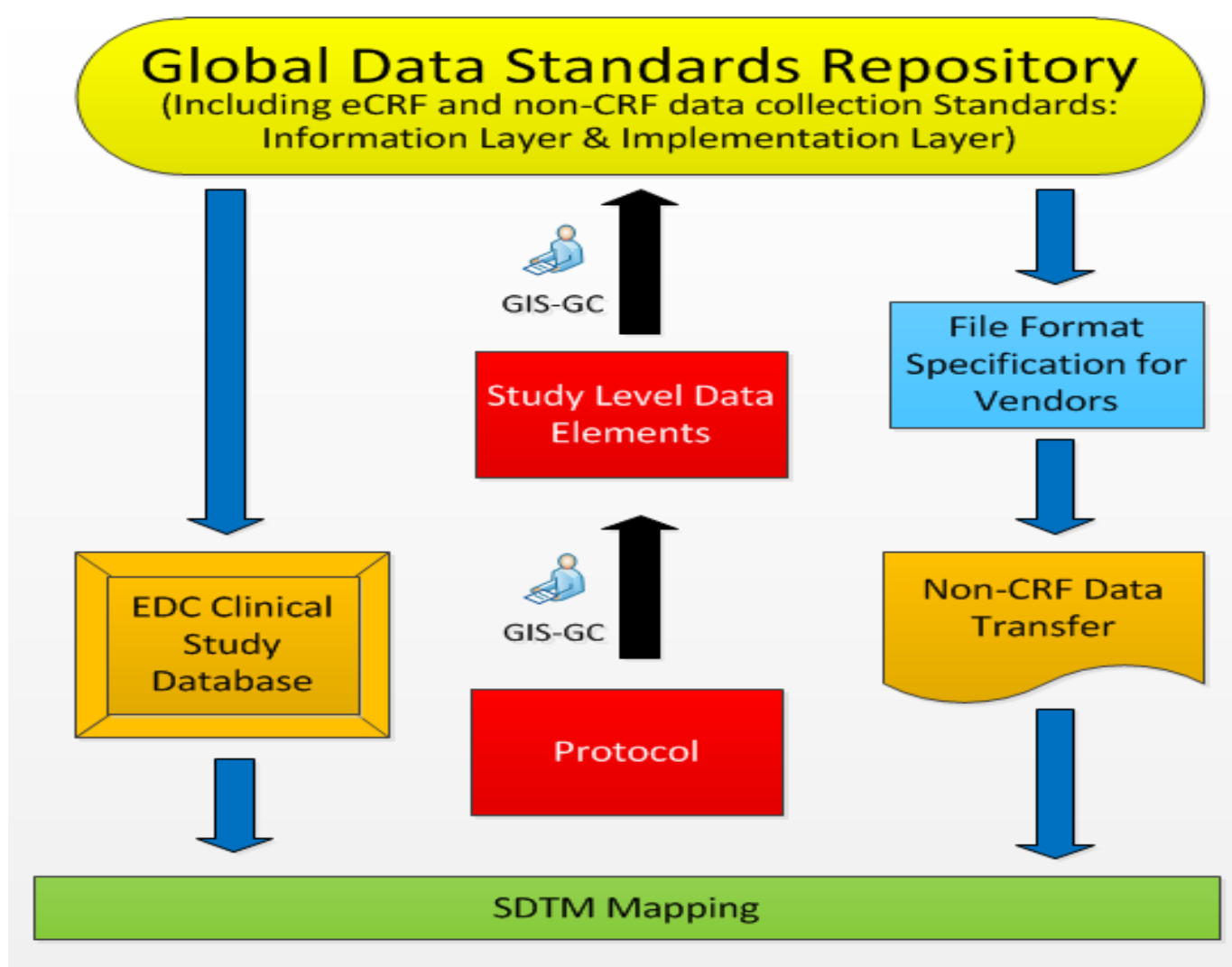
Study Level Implementation

Future Plans



Study Level Implementation

Future State



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- Initial development of the Global Data Standards was just the beginning
- The Global Data Standards need to be continually developed and maintained
- Effective Governance is key to a successful implementation across all studies
- A cross-functional governance model helps support effective decision-making
- Challenges in the implementation of Global Data Standards can be addressed using both technology and process



Doing now what patients need next