Every Study is Special!
Governing Data Standards

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Data Standards Office

Organizational Structure

- Data Standards Office
- Data Collection
- Data Tabulation and Analysis
- Information Architecture
Data Standards Office

Global Data Standards

Global Information Standards Governance Committee

New Global Data Standards Development

Study Level Implementation

Summary
Global Data Standards

**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

- **Data Models for each System**
  - e.g. Data model to capture AE data, AE domain in SDTM, ADAE analysis data set

- **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
Data Standards Office

Global Data Standards

Global Information Standards Governance Committee

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Summary
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
New Global Data Standards Development

Data Collection Standards

- Initiation and Scoping
- Define Biomedical Concepts
- Development of Information Layer
- Development of Implementation Layer
- GIS-GC Review
- Approved

- Edit Check Development
- Edit Check Review
- Approved
- Yes: Data Collection Implementation
- No: Data Collection Standards Adoption
New Global Data Standards Development

Data Tabulation Standards
New Global Data Standards Development

Data Analysis Standards

DA1
- GDS Request Submitted
- GDS Request Reviewed
- Approved
- New DA Concept Required
- Yes → DA Concept Developed
- DA Concept Reviewed
- Approved → Standard Uploaded
  - No → Changes Requested
  - Technical Specification Developed

DA2
- GDS Request Submitted
- GDS Request Reviewed
- Approved
- Standard Uploaded
  - Technical Specification Implemented
  - Standard Implemented in Tools
  - Requestor Responsibility
  - GIS-GC Responsibility
  - DSO Responsibility
  - Out of Scope
  - In Scope
Study Level Implementation

**Global Data Standards Request Process**

1. **Study Team Submit GDS Request**
   - **DSO request additional information**
     - No:
       - **GDS Request Complete**
     - Yes:
       - **DSO raises request with GIS-GC**
2. **DSO raises request with GIS-GC**
   - **Core Team can make decision**
     - No:
       - **DSO escalates request to Advisory Board**
     - Yes:
       - **DSO communicates decision to Study Team**
3. **DSO communicates decision to Study Team**
   - **Advisory Board can make decision**
     - No:
       - **Advisory Board Chair makes final decision**
     - Yes:
       - **No further action required**
Study Level Implementation

Global Data Standards Request Forms

Section A - Requestor and Study Information
- Date of request
- Requestor Name
- Site
- PDL Name (if applicable)
- Program/Molecular Name
- Study# (if applicable)
- Check if study is:
  - FD study
  - gRED study
  - new study start up
  - EDC amendment
- Is this study:
  - Yes
  - No

Section B - GDS Request Information
- Select the standard for this request: Please Choose
- Select type of request:
  - Add new form
  - Modify/ Add field to existing standard form
  - Add field to existing standard form
  - Other
- Is there a precedent to this request?
  - Yes
  - No
- If Yes, copy jIRA precedent number in this field (e.g. GLDATST-2984):

Describe the specific changes 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): Choose File | No file chosen

Save For | Submit | Clear
Study Level Implementation

Challenges

- Completeness of Requests
- Protocol Governance
- Study Build Timelines
- Quality of Requests
- Awareness & Understanding
- Vendors
Study Level Implementation

**Data Collection and Data Tabulation**

- **Global Data Standards Repository**
  - Including eCRF and non-CRF data collection Standards: Information Layer & some Implementation Layer

- **EDC Global Library Volume**
  - Including edit checks, derivations, etc...

- **Study Level Data Elements**

- **EDC Clinical Study Database**

- **File Format Specification for Vendors**

- **Non-CRF Data Transfer**

- **SDTM Mapping**
Study Level Implementation

Data Analysis

- Output required for study reporting
- Deviation from Standard
  - No: Implement without Modification
  - Yes: Proscribed Deviation
    - Yes: Implement without Modification
    - No: Propose to GIS-GC
      - No: Implement on Study
      - Yes: GIS-GC consider inclusion in Global Data Analysis Standards
Study Level Implementation

Future Plans

- Team 1
- Team 2
- Team 3

Global Metadata

GDSR

Study 1: Standard, Candidate, Proposal
Study 2: Standard, Candidate, Proposal
Study 3: Standard, Candidate, Proposal

Retired
Study Level Implementation

Future State

Global Data Standards Repository
(Including eCRF and non-CRF data collection Standards: Information Layer & Implementation Layer)

- GIS-GC
  - Study Level Data Elements
    - EDC Clinical Study Database
    - Protocol
    - Non-CRQ Data Transfer
    - File Format Specification for Vendors

SDTM Mapping
Summary
Summary

• 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