Every Study is Special!
Governing Data Standards

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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

- Data Collection
- Data Tabulation and Analysis
- Information Architecture
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
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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
New Global Data Standards Development
Data Tabulation Standards

Global Data Collection Standards Revisions

Release of new CDISC models

Revisions to Global Data Tabulation Standards

Revisions to Annotations of Global Data Collection Standards

Revisions to Data Tabulation Model and Roche Extensions
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
- Declined - Feedback Provided

DA2
GDS Request Submitted → GDS Request Reviewed → Approved
- Standard Uploaded → Technical Specification Implemented → Standard Implemented in Tools
- Declined - Feedback Provided

Requestor Responsibility
GIS-GC Responsibility
DSO Responsibility

Out of Scope
In Scope
Data Standards Office

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Summary
Study Level Implementation

Global Data Standards 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 raises request with GIS-GC
4. DSO escalates request to Advisory Board
   - No: Advisory Board Chair makes final decision
   - Yes: Core Team can make decision
5. Core Team can make decision
   - Yes: DSO communicates decision to Study Team
   - No: Advisory Board can make decision
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...)

EDC Clinical Study Database

Study Level Data Elements

File Format Specification for Vendors

Non-CRF Data Transfer

SDTM Mapping
Study Level Implementation

Data Analysis

Output required for study reporting

Deviation from Standard

Yes

Proscribed Deviation

Yes

Implement without Modification

No

Implement without Modification

Yes

Propose to GIS-GC

Yes

GIS-GC consider inclusion in Global Data Analysis Standards

No

Implement on Study

Yes

No
Study Level Implementation

Future Plans

- Team 1
- Team 2
- Team 3

GDSR

Proposal

Standard

Candidate

Proposal

Study 1

Study 2

Study 3

Standard

Candidate

Proposal
Study Level Implementation

Future State

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

EDC Clinical Study Database

Study Level Data Elements

Protocol

File Format Specification for Vendors

Non-CRFT Data Transfer

SDTM Mapping
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