Ahead of the Curve: Leading with Industry Data Requirements

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Pharmaceutical Industry Data Requirements

- Review of the current landscape of data requirements for the pharmaceutical industry, with a focus on clinical data
  - Do not provide in-depth training on CDISC or any other data standard or requirement
  - List resources for obtaining more information

Organizations Driving Data Requirements for Pharma Industry

- **International Council for Harmonisation (ICH)**
- **Regulatory Agencies**
  - Data Standards
  - Disclosure of Clinical Trial Results and Sharing of Patient Data
  - Dictionary Requirements

Organizations Driving Data Requirements for Pharma Industry

- **International Council for Harmonisation (ICH)**
  - Launched in 1990 by representatives from EU, US, and Japan regulatory agencies and industry associations
  - **Goal:** Harmonize regulatory requirements across different countries.
  - Created key foundational guidelines and standards
    - **ICH Guidelines** – a set of key guidelines for the design, conduct, and reporting of clinical trials. Guidelines for GCP updated Nov. 2016.
    - **MedDRA** (Medical Dictionary for Regulatory Activities) – a free standardized dictionary for medical terminology (e.g. Adverse Events).
    - **Common Technical Document** (CTD) – a common format for electronic submissions.

Organizations Driving Data Requirements for Pharma Industry

- **Regulatory Agencies**
  - Currently only US and Japan require data packages but more countries likely to require these in future
  - Requirements from Regulatory Agencies
    - **Data Standards**
    - Disclosure of Clinical Trial Results and Sharing of Patient Data
    - Dictionary Requirements

Organizations Driving Data Requirements for Pharma Industry

- **Regulatory Agencies – Data Standards**
  - Data Standards Catalogs
    - FDA and PMDA both have Data Standards Catalogs, where they specify which data standards and versions should be used in data packages submitted to them
    - Link to FDA Data Standards Catalog
    - Link to PMDA Data Standards Catalog

Organizations Driving Data Requirements for Pharma Industry

- **Study Data Technical Conformance Guides**
  - Technical Specifications for Submissions of Electronic Study Data, e.g.
    - Dataset/File sizes
    - eCTD directory structure
    - Use of Controlled Terminology
    - Reviewers Guides
    - Validation of CDISC data
    - Submission of analysis programs
    - Legacy Data Conversion Plan and Report (FDA)
    - Data Standards for Integrated Analyses
    - Link to FDA Study Data Technical Conformance Guide V3.3
    - Link to PMDA Study Data Technical Conformance Guide

Organizations Driving Data Requirements for Pharma Industry

- **Study Data Standardisation Plans**
  - Requested by FDA in *FDA Guidance on Providing Regulatory Submissions in Electronic Format - Standardized Study Data* (Final FDA Guidance December 2014).
  - Describes the data standardization approach for studies within a development program
  - PhUSE Template and Completion Guidelines available at http://www.phusewiki.org/wiki/index.php?title=Study_Data_Standardization_Plan_(SDSP)
  - PMDA has the Form 8 Document

Organizations Driving Data Requirements for Pharma Industry

- **Regulatory Requirements for CDISC**
  - FDA Technical Rejection Process effective Dec. 2016
  - Requires submission of a Trial Summary (TS) dataset containing Study Start date for every study in a submission, even for non-CDISC studies.

From FDA*Study Data Standards in eCTD:What You Need to Know About the New Technical Rejection Criteria* Webinar on 12-Oct-2016

Organizations Driving Data Requirements for Pharma Industry

- **Differences between FDA and PMDA CDISC Requirements**
  - Different deadlines and rules for requiring CDISC
    - FDA requirement for CDISC is based on study start
    - PMDA requirement for CDISC is based on date of submission
  - Different criteria for rejecting a CDISC data package
    - Link to Pinnacle 21 Webinar on differences
  - PMDA requires specific data & documents for Clinical Pharmacology studies (described in Technical Conformance Guide)
  - PMDA stricter about System International (SI) units and WHO-DRUG
  - PMDA prefers Analysis Results Metadata

Organizations Driving Data Requirements for Pharma Industry

- **Differences between CDISC Model and Regulatory Requirements / Preferences**
  - Examples:
    - FDA Technical Conformance Guide states that FDA wants all applicable SDTM domains to include EPOCH.
    - FDA lists LOINC under terminology standards in Data Standards Catalog and expects to receive it in SDTM LB.LBLOINC – but this variable is permissable in CDISC model

Organizations Driving Data Requirements for Pharma Industry

- **Requirements from Regulatory Agencies**
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Organizations Driving Data Requirements for Pharma Industry

- **Disclosure of Clinical Trial Results and Sharing of Patient Data**
  - Requirements to register trials, publish results, prepare for public sharing of anonymised patient data

1997
FDAMA requires registration of clinical trials

2005
ICMJE requires registration of clinical trials for publication

2007
FDAAA requires submission of summary results in registries

2014
EU requires results be publically available

EU Policy 70: Publication of anonymised info from CSRs and public sharing of patient data

2016
Final Rule of FDAAA requires registration of additional types of trials

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- **Requirements from Regulatory Agencies**
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Organizations Driving Data Requirements for Pharma Industry

- **Dictionary Requirements**
  - PMDA and EMA mandate MedDRA
  - MedDRA is defacto standard in US
  - FDA and PMDA have communicated that they will require WHO-DRUG in future
  - FDA and PMDA expect dictionary versions to be harmonized for integrated analyses

Many Organizations Driving Standards

CDISC/ SHARE

International Organization For Standardization(ISO)

Health Level Seven(HL7)

SNOMED International

UNII,NDF-RT

LOINC

Biomedical Research Integrated Domain Group(BRIDG)

C-PATH/ CFAST/ TransCelerate

CDISC

Areas of Standards Developed:

- Foundational Standards
  - Focus on core principles for defining data standards and include models, domains and specifications for data representations.
- Data Standards for Therapeutic Area
  - Include disease specific metadata
- Healthcare Link
  - Leveraging standards and electronic source data
- SHARE
  - Metadata repository in electronic and machine readable format