Data Transparency

CSS 2018 Webinar

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PhUSE Data Transparency WG 2018 Projects

Data De-Identification standard

PhUSE Standard for SDTM

PhUSE Standard for ADaM

Date Offset Methodology

Risk Framework

Policy 0070 Interpretations

Policy 0070 Submissions Review

Narratives

Data Utility

Risk CSR

Data Transparency Roadmap

DT Roadmap Visual

DT Roadmap White Paper

Policy, Guidance and Material Reviews

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Health Canada

FDA

TransCelerate BIOPHARMA INC.

Cochrane

NEW

GDPR

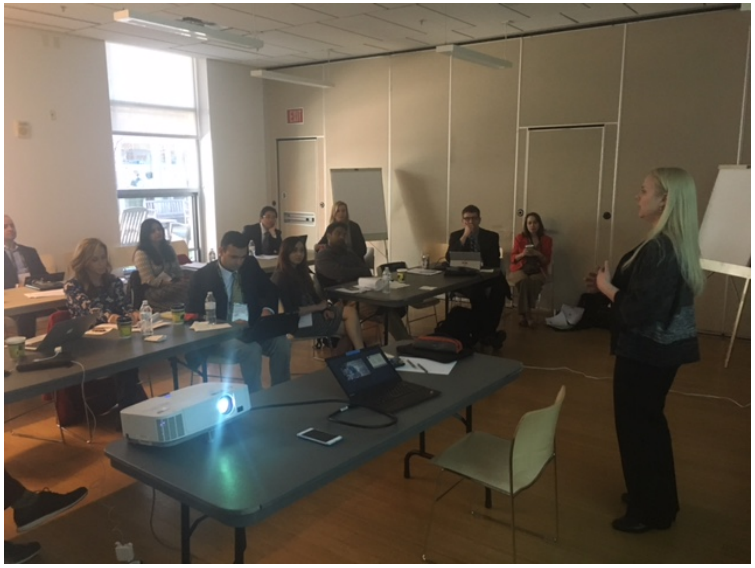
Data Sharing Processes

De-Identification Automation & Risk Analysis

Anonymization of Imaging Data

Handling of "Highly" Re-identifying Data

Computational Science Working Groups



Computational Science Working Groups

FDA's CSR Disclosure Pilot

Presentation by Ann Witt (FDA)

- Presentation and Q&A with Ann Witt (FDA)
- Discuss differences with EMA and Health Canada Data Sharing Initiatives

FDA Statement

FDA Commissioner Scott Gottlieb, M.D., on new steps FDA is taking to enhance transparency of clinical trial information to support innovation and scientific inquiry related to new drugs

For Immediate Release

January 16, 2018

Statement

Scientific progress and new drug innovation don't take place in a vacuum. The exchange of information that informs decisions to undertake research, invest in new scientific endeavors, and prescribe and use certain treatments effectively are a critical part of enabling the development and dissemination of new medical technology. Transparency related to this information can play a critical role in maximizing the public health value of the resulting innovations.

As part of our efforts to enhance transparency around our drug approval decisions, we're exploring new ways the U.S. Food and Drug Administration can continue to build on its obligation to share information about product approvals. We're especially focused on information that can improve patient care and better inform providers about the products they prescribe. One place where we are evaluating how we can release information that may better inform scientists, providers, and patients is clinical study reports (CSRs).

Right now, when a drug is approved, the FDA releases certain information that the agency used when reviewing the new drug application (NDA). This includes summaries written by our medical reviewers that capture their assessment of the data, the proposed labeling or other requirements, and other important, relevant data supporting safe and effective use. This information is included in our **drug approvals database (https://www.accessdata.fda.gov/scripts/cder/daf/)**, Drugs@FDA.

These summaries provide important context on the basis for our approval decisions. But they are packaged in a format that can sometimes make it difficult for external audiences to extract all of the detailed clinical evidence that supported the FDA's approval decisions.

Today we're launching a new pilot program to evaluate whether disclosing certain information included within CSRs following approval of a NDA improves public access to drug approval information. In this pilot, we will select up to nine recently-approved NDA whose sponsors volunteer to participate and post portions of clinical trial-related summaries from the pivotal trials that were submitted to the FDA by the drug's sponsor on Drugs@FDA.

Data Transparency Roadmap

- Review of Visual
- Feedback on White Paper Structure

Computational Science Working Groups

GLOBAL VIEW OF CLINICAL TRIAL TRANSPARENCY AND DISCLOSURE EVENTS FOR A SINGLE STUDY AND PRODUCT SUBMISSIONS

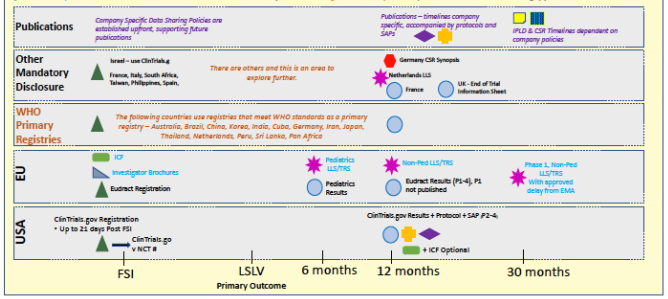
Authors: Julie Holtzople and the CTT PhUSE Workstream

What is the purpose of these pictures?

Global requirements for Clinical Trial Transparency and Disclosure are growing rapidly across the world. This poster is designed to show the numerous Clinical Trial Transparency and Disclosure events over the life of a single study, and over the course of a product submission. We have included the global view for a single study and a full submission. The current scope of this poster is **Phase 1-4 interventional studies** with a single end point and no arms.
The poster demonstrates how the various clinical documents are re-used over time for different publishing and disclosure events over the documents lifecycle. For example, the protocol is used to support registration, will be published with results on the FDA ClinicalTrials.Gov site, and is one of the required documents to be publicly shared according to EMA Policy 0070 and potentially additional future global requirements.

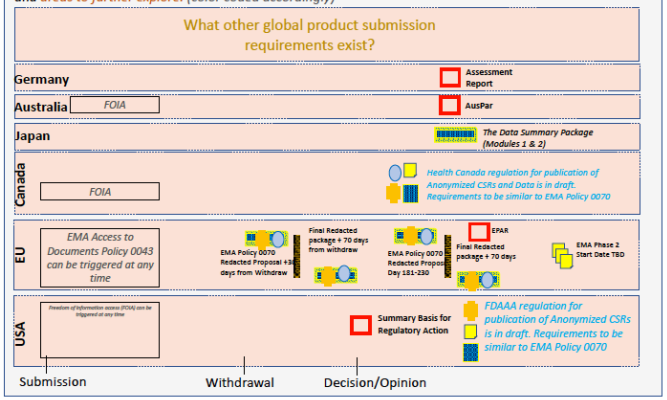
STUDY/TRIAL LEVEL CLINICAL TRIAL TRANSPARENCY AND DISCLOSURE EVENTS MET BY INDUSTRY SPONSORS

*SCOPE: This picture depicts study specific disclosure requirements for Phase 1-4 interventional studies, driven by Regulations and Legal Policies for current regulations as of Jan 2018. We have also included **current requirements**, future requirements, Best Practices not mandatory, areas to further explore. (color coded accordingly)*



PRODUCT SUBMISSION CLINICAL TRIAL TRANSPARENCY AND DISCLOSURE EVENTS MET BY INDUSTRY SPONSORS

*SCOPE: This picture depicts submission based disclosures driven by global regulators for New Medicines and Line Extensions. We have also included **current requirements**, future requirements, Best Practices, **and** areas to further explore. (color coded accordingly)*



Key

SAPs · Protocol · LLS/TRS · CSR · Registrations · Results · Redacted Package · Regulatory Summaries · CSR Synopsis · Investigator Brochure · ICF · IPLD

Definition of Key Terms

- **ClinTrials.gov** - ClinicalTrials.gov
- **FSI** – First Subject In
- **ICF** – Informed Consent Form
- **LSLV** – Last Subject Last Visit
- **LLS/TRS** – EMA Lay Language Summary aka Trial Results Summary aka Plain Language Summary
- **IPLD** – Individual Patient Level Data
- **SAP** – Statistical Analysis Plan
- **FOIA** – Freedom of Information Act
- **Publications** – Manuscripts published in journals outside country requirements i.e. ICMJE but are increasingly playing a key role in the way clinical research information is disclosure to the public
- **CSR** – Clinical Study Report
- **Redacted Package** – This is the term for a package of redacted documents and potentially data delivered to an agency, such as Japan and the EMA. Note, EMA requires Modules 2 and 5, where as Japan requires Modules 1 and 2
- **WHO Primary Network Registries** – The World Health Organization has established standards for clinical trial registries. This poster includes those categorized as Primary Registries. These WHO Registry Networks meet specific criteria for content, quality and validity, accessibility, unique identification, technical capacity and administration. Primary Registries also meet the requirements of the ICMJE.

Narratives and Data Utility

- **Narratives**
  - Discuss White paper on Reactive Approach
  - Discuss Pro-active Approach and Process/Organizational Impact and Changes
  - Define Business Requirements of an Industry Solution to tackle Reactive Anonymization of CSR that is Policy 0070 Compliant
- **Data Utility**
  - Define Qualitative and Quantitative Scale to measure Data Utility in Anonymized CSRs

Next Steps

- <u>Finalize and Publish:</u>
  - Data Transparency Roadmap Visual
  - Data Transparency Roadmap White Paper
  - Narratives White Paper
  - Data Utility Scales
  - Overview and Comparison of EMA, Health Canada and FDA Data Sharing initiatives

Thanks

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