ECSEL JU – IMI
CDISC Data Standard Partner

ECSEL-2020-3-RIA-IMI-ECSEL-joint-activity Call
ClinBuild
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2020-06-18
Different Types of Patient Data
Patient Data Considerations
Standards Development Organizations (SDOs)
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- Priority 1 of the HMA/EMA Big Data Taskforce is to create a European wide platform to access and analyze healthcare Real World Data (RWD)
- The IMI EHDEN project is making great inroads into standardizing hospital data to OHDSI

- De facto standard for healthcare
- Wide adoption

- Required by the FDA (& PMDA)
- HMA/EMA Big Data Taskforce is planning on investigating the use of CDISC in European clinical trials
Data Exchange Standards
Data Exchange Standards

Data Integration Point
Data Collection Standards
Observational Data Collection Standards

Why do we need a data collection standard?

Using CDASH or any data collection standard reduces **variability**

Clinical sites, investigators and site staff start to see the same fields for the same data between Case Report Forms (CRFs) on different studies and sponsors.

This will be **more important when patients** start to enter their own data since we do not want to subject them to the mental burden of seeing inconsistencies in data collection between sponsors.

**Additional benefits of CDASH**

Organizations that use CDASH are working to internationally agreed data collection standards.

CRFs and collected data can be exchanged or shared with partners and other researchers.

Standard CRFs and tools can be built by organizations and the companies and sold commercially.

The CDASH standard is easy to learn because it is **not necessary to understand the underlying SDTM model** to collect the data.

Data managers, application designers and clinicians can map their CRFs to CDASH format.
Unified Data Collection Standards

Why do we need a unified data collection standard?

Using ~CDASH as the “front-end” data collection standard consistently creates common data element that any of the standards can map to in the backend.

What the investigators or patients see will be the front end.

Creating a FHIR-OHDSI-CDISC (CDASH) Integration Implementation Guide will aid any application developers or researchers in preparing their CRFs for research wide data sharing.

Additional benefits of CDASH

HL7 and OMOP do not have a data collection component
Using the CDASH collection standard address this front-end challenge and creates an integration point for the end users that is not technical in nature.
Collecting Vital Signs Height and Weight

CDASH CRF with CDASHIG 2.0 section 5.1.5: Variable Naming Conventions

CDASH metadata

SDTM data

https://www.hl7.org/fhir/bodyweight.html
https://loinc.org/29463-7/

Common Data Element
Available as a Partner

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