

ECSEL JU – IMI CDISC Data Standard Partner

ECSEL-2020-3-RIA-IMI-ECSEL-joint-activity Call

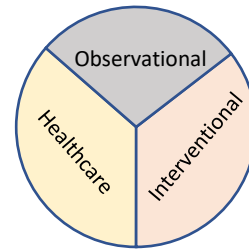
ClinBuild

Éanna Kiely

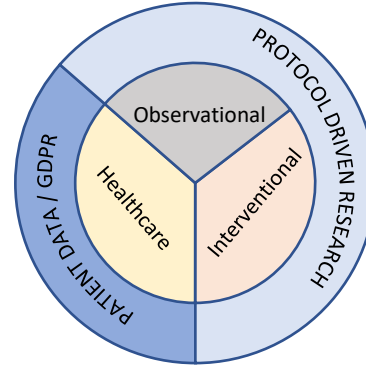
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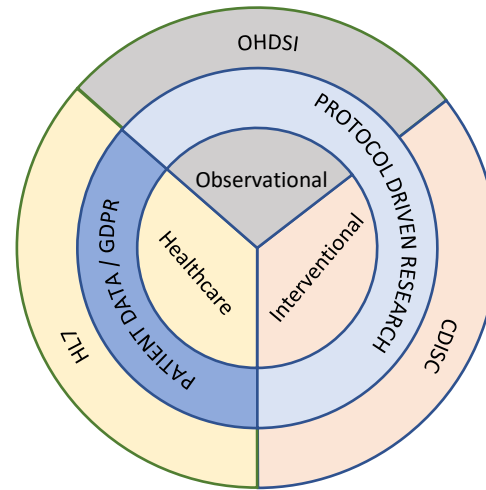
Different Types of Patient Data



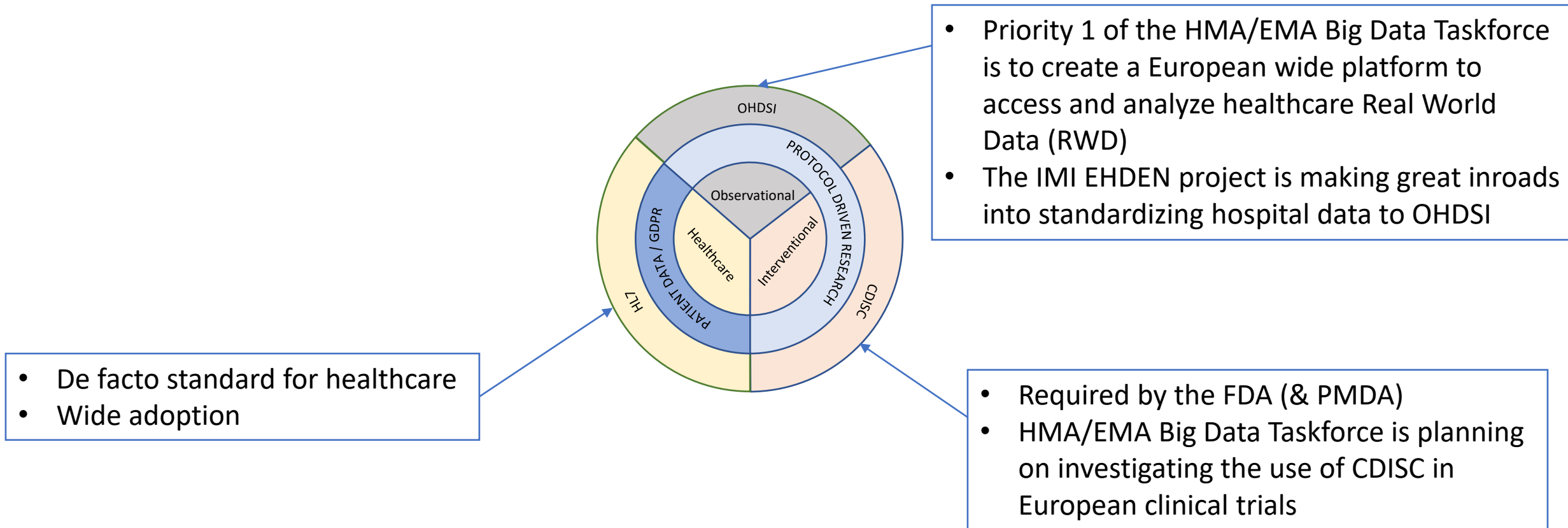
Patient Data Considerations



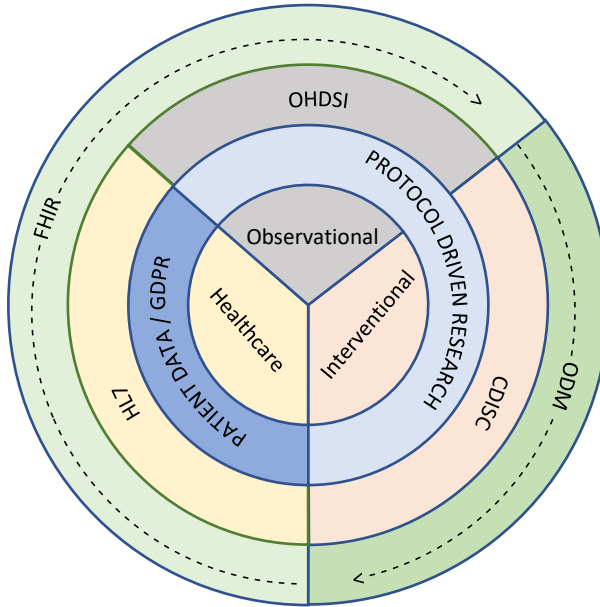
Standards Development Organizations (SDOs)



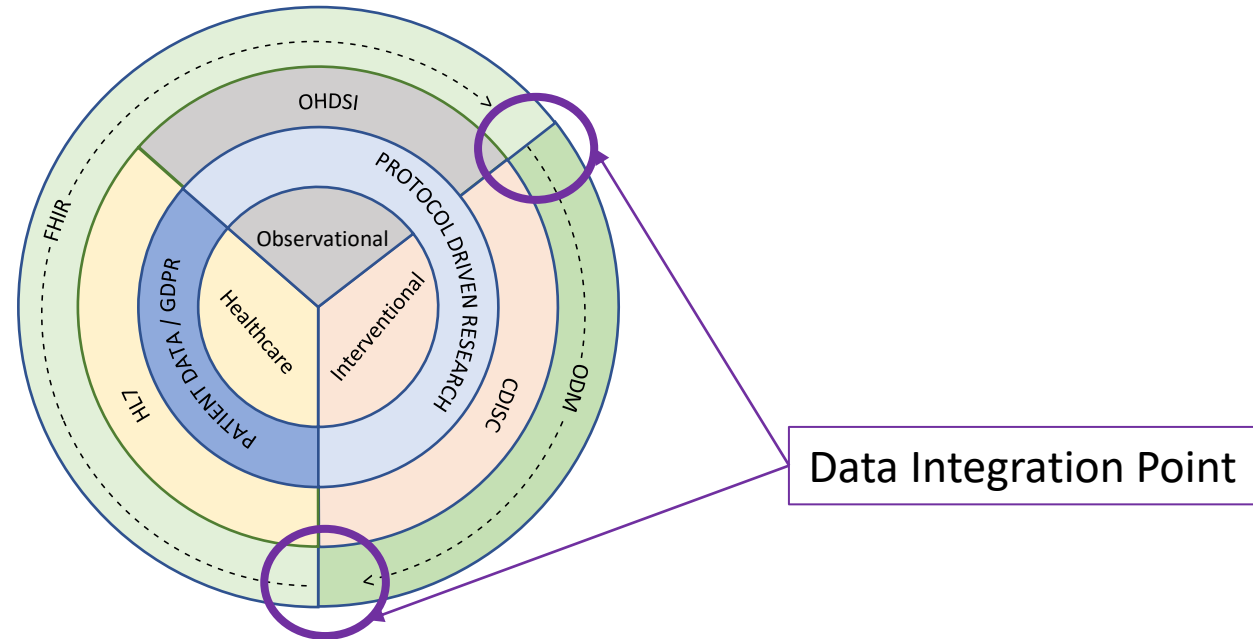
Standards Development Organizations (SDOs)



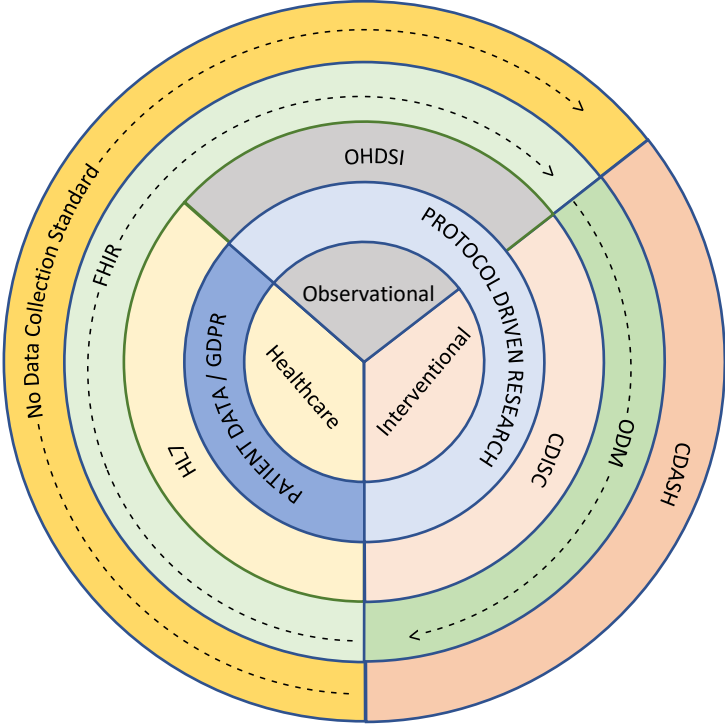
Data Exchange Standards



Data Exchange Standards



Data Collection Standards



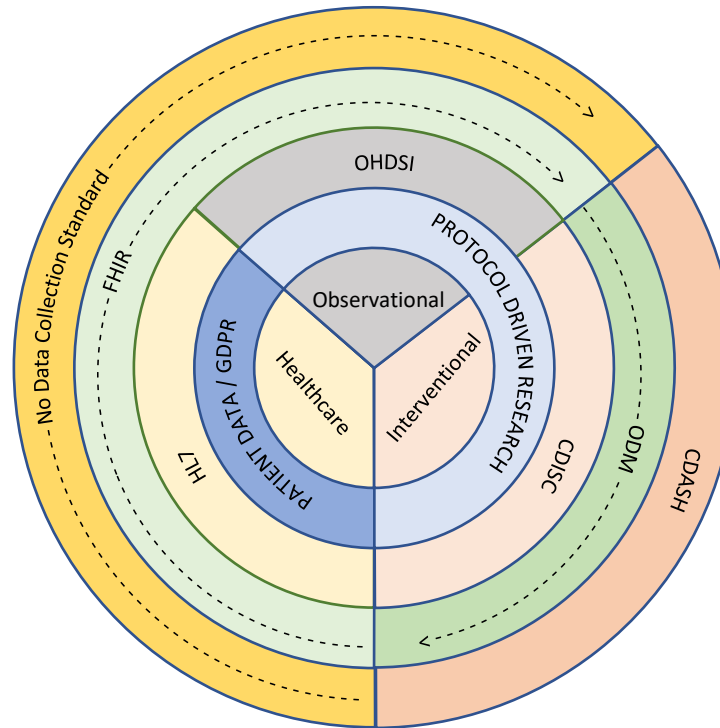
Data Collection Standards

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.



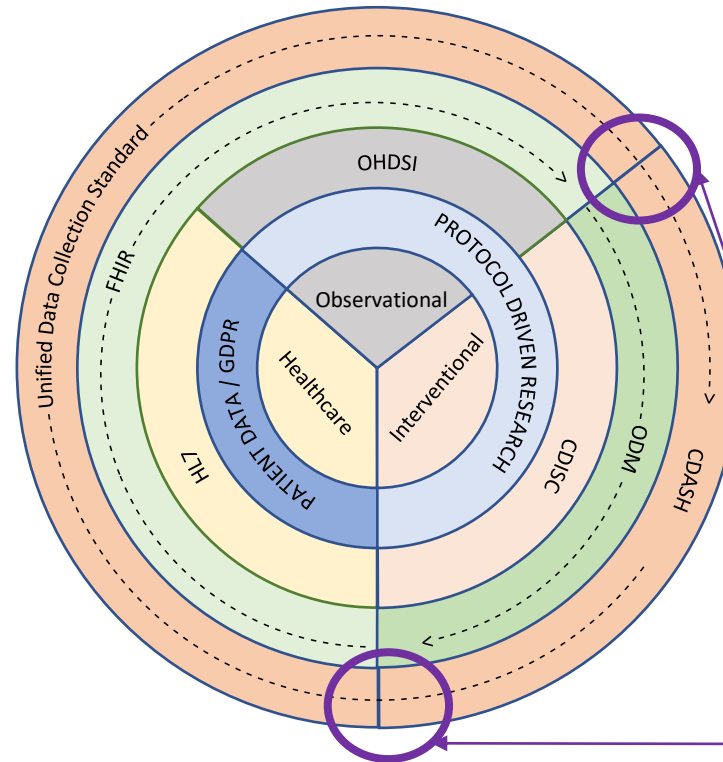
Unified Data Collection Standards

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.

Data Integration Point

Collecting Vital Signs Height and Weight

Height HEIGHT_VSORRES	VSORRES where VSTESTCD = "WEIGHT"	<input type="text"/> <input type="text"/> cm	<input type="checkbox"/> Not Done HEIGHT_VSSTAT
Weight WEIGHT_VSORRES	VSORRES where VSTESTCD = "WEIGHT"	<input type="text"/> <input type="text"/> kg	<input type="checkbox"/> Not Done WEIGHT_VSSTAT

CDASH CRF with CDASHIG 2.0 section 5.1.5: Variable Naming Conventions

CDASH Variable	Question Text	Prompt	Type	SDTMIG	CT	Permissible Values	Pre-Populated Value	Query Display
HEIGHT_VSORRES	What was the result of the height measurement?	Height	Float	VSORRES; VSTEST; VSTESTCD				Prompt
HEIGHT_VSORRESU	What was the unit of the height measurement?	Height Unit	Text	VSORRESU	(VSRESU)		cm	Prompt

CDASH metadata

Study Identifier	Domain Abbreviation	Unique Subject Identifier	Sequence Number	Vital Signs Test Short Name	Vital Signs Test Name	Result or Finding in Original Units	Original Units
Req	Req	Req	Req	Req	Req	Exp	Exp
STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSORRES	VSORRESU
T@H	VS	T@H-01001	1	HEIGHT	Height	175	cm
T@H	VS	T@H-01001	2	WEIGHT	Weight	78	kg
T@H	VS	T@H-01002	1	HEIGHT	Height	155	cm
T@H	VS	T@H-01002	2	WEIGHT	Weight	62	kg

SDTM data

<https://www.hl7.org/fhir/bodyweight.html>

<https://loinc.org/29463-7/>

Common Data Element



Available as a Partner

- Éanna Kiely
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- Author:
 - CDASH IG 2.0
 - SDTM IG 3.3
- CDASH and SDTM Team Member
 - SDTM Laboratory Representative
- Authorized CDASH Instructor
 - SDTM and Controlled Terminology instructor in training

