COLOR KEY:

Highlighted in ORANGE – Standards that we dispute its place, and believe should be removed

Highlighted in YELLOW – CDISC controlled terminology items added by CDISC, with which we agree

Highlighted in GREEN – Standards we added that CDISC agrees with

Highlighted in ~~Red and Strikeout~~ – Standards we took out that CDISC agrees should not remain

Highlighted in Pink – Standards in dispute, which we believe should be added

**I-Q: Research**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Interoperability Need: Interoperability Need: Terminology Standards for Use with Submissions to FDA** | | | | | | | |
| **Type** | **Standard/Implementation Specification** | **Standards Process Maturity** | **Implementation Maturity** | **Adoption level** | **Federally Required** | **Cost** | **Test Tool Availability** |
| **~~Standard~~** | [~~CDISC Controlled Terminology for Regulatory Standards Hosted by NCI-EVS~~](https://www.cancer.gov/research/resources/terminology/cdisc) | ~~Final~~ | ~~Production~~ |  | ~~Yes~~ | ~~Free~~ | ~~N/A~~ |
| **~~Standard~~** | ~~[CDISC Controlled Terminology for CDISC](https://www.cancer.gov/research/resources/terminology/cdisc)~~  ~~[Therapeutic Area Standards Hosted by NCIEVS](https://www.cancer.gov/research/resources/terminology/cdisc)~~ | ~~Final~~ | ~~Production~~ |  | ~~No~~ | ~~Free~~ | ~~N/A~~ |
| **~~Standard~~** | ~~[CDISC Controlled Terminology for Medical Devices Hosted by NCIEVS](https://www.cancer.gov/research/resources/terminology/cdisc)~~ | ~~Final~~ | ~~Production~~ |  | ~~No~~ | ~~Free~~ | ~~N/A~~ |
| **Standard** | [CDISC Controlled Terminology for clinical trial tabulation datasets (SDTM)](http://evs.nci.nih.gov/ftp1/CDISC/SDTM/) | Final | Production |  | Yes | Free | N/A |
| **Standard** | [CDISC Controlled Terminology for Clinical Trial Data Acquisition (CDASH)](http://evs.nci.nih.gov/ftp1/CDISC/SDTM/) | Final | Production |  | No | Free | N/A |
| **Standard** | [CDISC Controlled Terminology for Clinical Trial Analysis Data (ADaM)](http://evs.nci.nih.gov/ftp1/CDISC/ADaM/) | Final | Production |  | No | Free | N/A |
| **Standard** | [CDISC Controlled Terminology for Nonclinical Data Exchange (SEND)](http://evs.nci.nih.gov/ftp1/CDISC/SEND/) | Final | Production |  | Yes | Free | N/A |
| **Standard** | [ICH Medical Dictionary for Regulatory Activities (MedDRA)](http://www.meddra.org/) | Final | Production |  | Yes | Free (see note) |  |
| **Standard** | WHO Drug Dictionary | Final | Production |  |  |  |  |
| **Standard** | [LOINC](http://loinc.org/)® | Final | Production |  | Yes | Free | N/A |
| **Standard** | [The Unified Code for Units of Measure (UCUM)](http://unitsofmeasure.org/) | Final | Production |  | Yes | Free | N/A |
| **Limitations, Dependencies, and Preconditions for Consideration:** | | | **Applicable Security Patterns for Consideration:** | | | | |
| * CDISC controlled terminology for SDTM supports routine clinical trial terminology, Therapeutic Area standard terminology and medical device terminology. Refer to the individual standard specifications for details on the appropriate controlled terminology lists for each standard. * The Study Data Tabulation Model (SDTM) provides organization, structure, and format of standard clinical trial tabulation datasets submitted to a regulatory authority such as the US Food and Drug Administration (FDA). * The Clinical Data Acquisition Standards Harmonization (CDASH) defines basic standards for the collection of clinical trial data. * The Analysis Data Model (ADaM) supports efficient generation, replication, and review of analysis results from clinical trials. * The cost of MedDRA is free for non-profit companies, but has a sliding scale charge based on company income and a fixed charge of $2641 for system developers. * The CDISC SDTM has a field in the laboratory submissions file for representing LOINC. Current usage is likely low, but there is a requirement to use it from 03/15/2018 * UCUM is supported by ICH and ISO 11240. | | |  | | | | |

CDISC suggests that the title be renamed the interoperability need to “Representing Data for Protocol Driven Research” to avoid differentiating between regulated and non-regulated research which is important if the words of healthcare and research are to come closer together. They renamed the interoperability need to “Representing Data for Protocol Driven Research” to be consistent with the table in I-Q above. This section lists out the CDISC standards that support protocol driven research and brings in the three highlighted standards that were in other sections of the original draft document. We suggest the title be “Terminology Standards for Use with Submissions to FDA.

CDISC has left the original three rows as they were in the original table but added the first bullet in the “limitations, dependencies…” box below the table to provide an explanation on these. However, we would like for first 3 standards be updated to be replaced by the 4 new standards you added (CDISC Controlled Terminology for SDTM, CDASH, ADaM, and SEND) (in yellow).

SL: We have also added a table of general terminologies, which have been added below:

Interoperability Need: Observational Research and Product Labeling (SNOMED CT and RxNorm)

| Type | Standard/Implementation Specification | Standards Process  Maturity | Implementation Maturity | Adoption Level | Federally Required | Cost | Test Tool Availability |
| --- | --- | --- | --- | --- | --- | --- | --- |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Standard** | AMA Current Procedural Terminology (CPT) Codes | Final | Production |  |  | Yes |  |
| **Standard** | LOINC | Final | Production |  |  | Free |  |
| **Standard** | ICD | Final | Production |  |  | Free |  |
| **Standard** | SNOMED CT | Final | Production |  |  | Free |  |
| **Standard** | RxNorm | Final | Production |  |  | Free |  |

|  |  |
| --- | --- |
| **Limitations, Dependencies, and Preconditions for Consideration:** | **Applicable Value Set(s) and Starter Set(s):** |
| * None of these have federal requirements for *research use*, but most *are* required for either meaningful use or payment - Usage and federal requirements.   They are all used variously in the standards for large data base research such as OHDSI , MiniSentinal   * This list is not comprehensive. It highlights many of the most prominent coding systems available in EMRs and payment systems for various kinds of clinically relevant research. | * Feedback requested |

**II-S: Research**

*MG: Alternative proposal: In going through the exercise of updating the table above it occurred to me that the implementation specifications for each of the standards were not included and should be considered. I realize these were not previously included in the tables in the 2016 ISA and we did not discuss this with Clem during the call on Thursday 12/29. I have mocked up a table that includes those for consideration.*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Interoperability Need: Regulated Protocol Driven Research** | | | | | | | |
| **Type** | **Standard/Implementation Specification** | **Standards Process Maturity** | **Implementation Maturity** | **Adoption level** | **Federally Required** | **Cost** | **Test Tool Availability** |
| **Standard** | [CDISC Study Data Tabulation Model (SDTM)](https://www.cdisc.org/standards/foundational/sdtm) | Final | Production |  | Yes | Free | N/A |
| **Standard** | [CDISC Analysis Dataset Model (ADaM)](https://www.cdisc.org/standards/foundational/adam) | Final | Production |  | No | Free | N/A |
| **Standard** | [CDISC Clinical Data Acquisition Standards](https://www.cdisc.org/standards/foundational/cdash)  [Harmonization (CDASH)](https://www.cdisc.org/standards/foundational/cdash) | Final | Production |  | No | Free | N/A |
| **Standard** | [CDISC Operational Data Model (ODM)](https://www.cdisc.org/standards/foundational/odm) | Final | Production |  | No | Free | N/A |
| **~~Standard~~** | ~~[CDISC Dataset-XML](https://www.cdisc.org/standards/foundational/dataset-xml)~~ | ~~Final~~ | ~~Production~~ |  | ~~Yes~~ | ~~Free~~ | ~~N/A~~ |
| **Standard** | [CDISC Define-XML](https://www.cdisc.org/standards/foundational/define-xml) | Final | Production |  | No | Free | N/A |
| **Standard** | ~~[CDISC Standard for the Exchange of Nonclinical Data (SEND)](https://www.cdisc.org/standards/foundational/send)~~ | Final | Production |  | No | Free | N/A |
| **Standard** | [Study Data Tabulation Model Implementation](https://www.cdisc.org/system/files/members/standard/foundational/sdtmig/stdmig_md_v_1_0.pdf)  [Guide for Medical Devices (SDTMIG-MD)](https://www.cdisc.org/system/files/members/standard/foundational/sdtmig/stdmig_md_v_1_0.pdf) | Final | Production |  | Yes | Free | N/A |
| **Standard** | [CDISC Protocol Representation Model (PRM)](https://www.cdisc.org/standards/foundational/protocol) | Final | Production |  | Yes | Free | N/A |
| **Standard** | [CDISC Study/Trial Design Model (SDM)](https://www.cdisc.org/standards/foundational/sdm-xml) | Final | Production |  | Yes | Free | N/A |
| **~~Standard~~** | ~~[Therapeutic Area Standards (to complement](https://www.cdisc.org/standards/therapeutic-areas)~~  ~~[the aforementioned CDISC foundational](https://www.cdisc.org/standards/therapeutic-areas)~~  ~~[standards that apply across all therapeutic](https://www.cdisc.org/standards/therapeutic-areas)~~  ~~[areas)](https://www.cdisc.org/standards/therapeutic-areas)~~ | ~~Final~~ | ~~Production~~ |  | ~~Yes~~ | ~~Free (see note)~~ |  |
| **Implementation Specification** | [CDISC Study Data Tabulation Model Implementation Guide (SDTMIG)](https://www.cdisc.org/standards/foundational/sdtmig) | Final | Production |  | Yes | Free | N/A |
| **Implementation Specification** | [CDISC Analysis Data Model Implementation Guide (ADaMIG)](https://www.cdisc.org/standards/foundational/adam) | Final | Production |  | No | Free | N/A |
| **Implementation Specification** | ~~[CDISC Clinical Data Acquisition Standards Harmonization User Guide (CDASH-UG)](https://www.cdisc.org/standards/foundational/cdash)~~ | Final | Production |  | No | Free | N/A |
| **Implementation Specification** | [CDISC Standard for Exchange of Nonclinical Data Implementation Guide (SENDIG)](https://www.cdisc.org/standards/foundational/send) | Final | Production |  | No | Free | N/A |
| **Limitations, Dependencies, and Preconditions for Consideration:** | | | **Applicable Security Patterns for Consideration:** | | | | |
|  | | |  | | | | |

MG : I removed SHARE from the list below as it’s not a standard.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Interoperability Need: Pre-population of Research Forms from Electronic Health Records** | | | | | | | |
| **Type** | **Standard/Implementation Specification** | **Standards Process Maturity** | **Implementation Maturity** | **Adoption level** | **Federally Required** | **Cost** | **Test Tool Availability** |
| **Standard** | [CDISC Clinical Data Acquisition Standards](https://www.cdisc.org/standards/foundational/cdash)  [Harmonization (CDASH)](https://www.cdisc.org/standards/foundational/cdash) | Final | Production |  | No | Free | N/A |
| **~~­Standard~~** | [~~CDISC Shared Health And Research Electronic Library (SHARE)~~](http://cdisc.org/cdisc-share) | ~~Final~~ | ~~Production~~ | ~~Adoption level - score of 3 out of 5.~~ | ~~No~~ | ~~Free~~ | ~~N/A~~ |
| **Implementation Specification** | IHE-RFD (Retrieve Form for Data Capture) |  |  |  |  |  |  |
| **Implementation Specification** | IHE Quality, Research, and Public Health  Technical Framework Supplement, Structured  Data Capture, Trial Implementation |  |  |  |  |  |  |
| **Implementation Specification** | ~~IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation~~ |  |  |  |  |  |  |
| **Implementation Specification** | IHE-CRD (Clinical Research Document) |  |  |  |  |  |  |
| **Implementation Specification** | IHE-XUA (Cross-Enterprise User Assertion) |  |  |  |  |  |  |
| **Implementation Specification** | IHE-ATNA (Audit Trail and Node Authentication) |  |  |  |  |  |  |
| **Implementation Specification** | IHE-DEX (Data Element Exchange) |  |  |  |  |  |  |
| **Implementation Specification** | HL7 FHIR DSTU 2, Structured Data Capture (SDC) Implementation Guide |  |  |  |  |  |  |
| **Emerging Implementation Specification** | FHIR Data Access Framework (DAF) Implementation Guide | Balloted Draft | Pilot | Adoption level - score of 1 out of 5 | No |  |  |
| **Emerging Implementation Specification** | HL7 FHIR Resources Study Registry – ResearchStudy  HL7 FHIR Resources Study Registry – ResearchSubject | Balloted Draft | Pilot | Adoption level - score of 1 out of 5 | No |  |  |
| **Standard** | [CDISC Operational Data Model (ODM)](http://www.cdisc.org/odm) | Final | Production | Score of 5 out of 5. | No | Free | N/A |
| **Limitations, Dependencies, and Preconditions for Consideration:** | | | **Applicable Security Patterns for Consideration:** | | | | |
|  | | |  | | | | |

MG: As discussed on the call on Thursday, this section should be removed. ODM, PRM and SDM have been moved up to the “Protocol Driven Research” table.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **~~Interoperability Need: Integrate Healthcare and Clinical Research by Leveraging EHRs and other Health IT Systems while Preserving~~**  **~~FDA’s Requirements~~** | | | | | | | |
| **~~Type~~** | **~~Standard/Implementation Specification~~** | **~~Standards Process Maturity~~** | **~~Implementation Maturity~~** | **~~Adoption level~~** | **~~Federally Required~~** | **~~Cost~~** | **~~Test Tool Availability~~** |
| **~~Implementation Specification~~** | ~~IHE-RFD (Retrieve Form for Data Capture)~~ |  |  |  |  |  |  |
| **~~Standard~~** | ~~HL7 FHIR DSTU 2, Structured Data Capture (SDC) Implementation Guide~~ |  |  |  |  |  |  |
| **~~Standard~~** | ~~[CDISC Clinical Data Acquisition Standards](https://www.cdisc.org/standards/foundational/cdash)~~  ~~[Harmonization (CDASH)](https://www.cdisc.org/standards/foundational/cdash)~~ | ~~Final~~ | ~~Production~~ |  | ~~No~~ | ~~Free~~ | ~~N/A~~ |
| **~~Standard~~** | [~~CDISC Operational Data Model (ODM)~~](https://www.cdisc.org/standards/foundational/odm) | ~~Final~~ | ~~Production~~ |  | ~~No~~ | ~~Free~~ | ~~N/A~~ |
| **~~Standard~~** | [~~CDISC Protocol Representation Model (PRM)~~](https://www.cdisc.org/standards/foundational/protocol) | ~~Final~~ | ~~Production~~ |  | ~~Yes~~ | ~~Free~~ | ~~N/A~~ |
| **~~Standard~~** | [~~CDISC Study/Trial Design Model (SDM)~~](https://www.cdisc.org/standards/foundational/sdm-xml) | ~~Final~~ | ~~Production~~ |  | ~~Yes~~ | ~~Free~~ | ~~N/A~~ |
| **~~Implementation Specification~~** | ~~IHE-RPE (Retrieve Protocol for Execution)~~ |  |  |  |  |  |  |
| **~~Implementation Specification~~** | ~~IHE-CPRC (Clinical Research Process~~  ~~Content)~~ |  |  |  |  |  |  |
| **~~Limitations, Dependencies, and Preconditions for Consideration:~~** | | | **~~Applicable Security Patterns for Consideration:~~** | | | | |
|  | | |  | | | | |

MG: As discussed on the call on Thursday. PRM has been removed from this section.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Interoperability Need:** **Submit Adverse Event Report from an Electronic Health Record to Drug Safety Regulators** | | | | | | | |
| **Type** | **Standard/Implementation Specification** | **Standards Process Maturity** | **Implementation Maturity** | **Adoption level** | **Federally Required** | **Cost** | **Test Tool Availability** |
| **~~Implementation Specification~~** | ~~IHE-RFD (Retrieve Form for Data Capture)~~ |  |  |  |  |  |  |
| **Implementation Specification** | IHE-DSC (Drug Safety Content) |  |  |  |  |  |  |
| **Implementation Specification** | IHE- CPRC (Clinical Research Process Content) |  |  |  |  |  |  |
| **~~Standard~~** | [~~CDISC Protocol Representation Model (PRM)~~](https://www.cdisc.org/standards/foundational/protocol) | ~~Final~~ | ~~Production~~ |  | ~~Yes~~ | ~~Free~~ | ~~N/A~~ |
| **Implementation Specification** | ICH E2B r2 XML standard | Final |  | Score of 5 out of 5. | No | Free |  |
| **Implementation Specification** | ICH E2B r3 XML standard | Final |  |  | No | Free |  |
| **Standard** | HL7 V3 Individual Case Safety Report (ICSR) | Final | Production |  | Yes | Free |  |
| **Standard** | Individual Case Safety Report (ICSR) R1 submissions to CDRH for devices | Final |  |  | No | Free |  |
| **Standard** | Individual Case Safety Report (ICSR) R1 Drugs, Biologics; Required for vaccines | Final |  | Adoption level - score of 2 out of 5. | No | Free |  |
| **Limitations, Dependencies, and Preconditions for Consideration:** | | | **Applicable Security Patterns for Consideration:** | | | | |
|  | | |  | | | | |

MG: SDTM added to this section as we are aware of a number of disease registries developed by C-PATH that use SDTM as the standards for the structure of the registry. Additionally, Sam Volchenboum, at the University of Chicago, is creating a data commons for pediatric oncology with a group of cooperatives that is utilizing SDTM, and CDISC terminology.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Interoperability Need:** **Complete Disease Registry Forms and Submit to Reporting Authority (ACC)** | | | | | | | |
| **Type** | **Standard/Implementation Specification** | **Standards Process Maturity** | **Implementation Maturity** | **Adoption level** | **Federally Required** | **Cost** | **Test Tool Availability** |
| **~~Standard~~** | ~~[CDISC Clinical Data Acquisition Standards](https://www.cdisc.org/standards/foundational/cdash)~~  ~~[Harmonization (CDASH)](https://www.cdisc.org/standards/foundational/cdash)~~ | ~~Final~~ | ~~Production~~ |  | ~~No~~ | ~~Free~~ | ~~N/A~~ |
| **Standard** | [CDISC Study Data Tabulation Model (SDTM)](https://www.cdisc.org/standards/foundational/sdtm) | Final | Production |  | Yes | Free | N/A |
| **~~Implementation Specification~~** | ~~IHE-RFD (Retrieve Form for Data Capture)~~ |  |  |  |  |  |  |
| **~~Implementation Specification~~** | ~~HL7 Clinical Document Architecture (CDA) Release 2.0 Final Edition~~ |  |  |  |  |  |  |
| **Implementation Specification** | HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 - US Realm | Final | Production |  |  | Free |  |
| **Standard** | American College of Cardiology National Cardiovascular Data Registry (ACC NCDR) Implantable Cardioverter Defibrillators ICD Registry | Final | Production |  | Yes |  |  |
| **Standard** | NIH NCATS Global Rare Diseases Patient Registry Data Repository (GRDR) Registry Model Common Data Elements (CDEs) | Final | Production |  |  | Free |  |
| **Standard** | Myasthenia Gravis Patient Registry | Final | Production |  | No | Free | N/A |
| **Limitations, Dependencies, and Preconditions for Consideration:** | | | **Applicable Security Patterns for Consideration:** | | | | |
| * There are hundreds of registries, and we just listed a few of them above as examples. | | |  | | | | |

MG: In this final table, I don’t know whether specifications for the registries should be included as well. I added a limitations note to explain what CTR-XML is for which should address the confusion of it being a registry in competition with the federal registry. ODM is listed here but could be put into a “Base Standards” section if that were added to the document.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Interoperability Need:** **Registering a Clinical Trial** | | | | | | | |
| **Type** | **Standard/Implementation Specification** | **Standards Process Maturity** | **Implementation Maturity** | **Adoption level** | **Federally Required** | **Cost** | **Test Tool Availability** |
| **Standard** | [CDISC Clinical Trial Registry (CTR-XML)](https://www.cdisc.org/standards/foundational/ctr-xml) | Final | Production |  | No | Free | N/A |
| **Standard** | [CDISC Operational Data Model (ODM)](https://www.cdisc.org/standards/foundational/odm) | Final | Production |  | No | Free | N/A |
| **Standard** | ClinicalTrials,Gov specification? |  |  |  |  |  |  |
|  | ~~EudraCT specification~~ |  |  |  |  |  |  |
| **Limitations, Dependencies, and Preconditions for Consideration:** | | | **Applicable Security Patterns for Consideration:** | | | | |
| * Note: CTR-XML provides is a mechanism to populate the three main clinical trial registries ([Clinicaltrials.gov](http://clinicaltrials.gov/), WHO International Clinical Trial Registry Platform, EMA’s EudraCT) from a single XML message * Clinicaltrials.gov has an XML submission specification and is the only submission specification used in the US at present. | | |  | | | | |

Information Models for Observational and Clinical Research

| Type | Standard/Implementation Specification | Standards Process  Maturity | Implementation Maturity | Adoption Level | Federally Required | Cost | Test Tool Availability |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Standard** | FDA Sentinel Common Data Model (SCDM) v6.0 – XML | Final | Production |  |  | Free |  |
| **Standard** | OHDSI Common Data Model | Final | Production |  | No | Free | Yes |
| **Standard** | Biomedical Research Integrated Domain Group (BRIDG) Model | Final | Production |  | No | Free |  |
| **Standard** | Informatics for Integrating Biology and the Bedside (i2b2) |  |  |  |  |  |  |

|  |  |
| --- | --- |
| **Limitations, Dependencies, and Preconditions for Consideration:** | **Applicable Security Patterns for Consideration:** |
| * FDA Sentinel is a national electronic system for medical product safety surveillance. * OHDSI Common Data Model is also known as the OMOP Common Data Model | * Feedback requested |