Missing clinical research elements in United States Core Data for Interoperability (USCDI)

This report is one of the FDA deliverables for Objective 3. Extend the functionality of CDMs to allow submissions of Clinical Trials data to FDA. Focusing on a short 508-compliant and agency-cleared report on missing clinical research elements in USCDI.

Table 1 captures a list of data classes and data elements that need to be modified based on the missing clinical research data elements required to conduct clinical trials.

Data Class	Data Element	Suggestion Type (Change, Add, Remove)	Comment	Existing Text	Proposed Text
Clinical Note	Operative Note	Clarify the difference between a "Operative Note" and "Procedure Note".	In hospitals, there are "Operative Notes" that occur in the "Operating Room" or "Surgery" and there are "Procedures that occur in "Interventional Radiology" and the "Cardiac Catheterization Laboratory" or the "Electrophysiology Lab". There are cases where procedures done in the operating room resemble those done in a procedure room. The notes are similar to the area. Standardly speaking, should an "Operative Note" mean there was an "incision" or "opening of a body cavity" and the "Procedure Note mean" these were done in a "non-invasive fashion"? Does the fact that "Anesthesia" was there make a difference? In most surgery cases, "Anesthesia" is involved while in the other cases the nurses administer the sedation unless there is high risk with the sedation or the procedure and airway concerns. There are cases in the intensive care unit (ICU) where invasive surgeries and procedures occur at the bedside. They are often "free text" in the progress notes. The may have "Operative Note" as a header OR "Procedure Note" as a header. Examples, "Tracheotomy", "Insertion of Triple Lumen Catheter", "Insertion of Invasive Heart Pressure Monitoring (Swan-Ganz) Cathether", "Endotracheal intubation". How would these be categorized? Loinc code - https://loinc.org/11504-8 These components are found in op notes. The term "surgery" is defined as "the setting". However, as noted above there is overlap dependent on healthcare organization and hospital which may vary depending on location and both national and international definitions of these terms	Defined as: "Summary of surgical procedure." "Usage note: May include procedures performed, operative and anesthesia times, findings observed, fluids administered, specimens obtained, and complications identified."	Defined as: "Summary of surgical procedure defined as involving an incision and the removal or replacement of a diseased organ or tissue" Consider, "requiring anesthesia"? (no change recommended to "Usage note")

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Clinical Notes	Procedure Note	Clarify the difference between a "Operative Note" and "Procedure Note".	See above note. Loinc code - https://loinc.org/28570-0 Loinc key point - " do not involve incision or excision as the primary act."	Defined as: "Summary of non-operative procedure." "Examples include but are not limited to interventional cardiology, gastrointestinal endoscopy, and osteopathic manipulation."	Defined as: "Summary of non-invasive procedure where the diagnostic or therapeutic procedure is done using tubes and catheters without incision to remove, repair or examine diseased organ or tissue." (no change recommended to "example sentence".
Immunization	Lot Number	Clarify the description. https://loinc.org/74714-7	For "Immunization Lot Number" it seems like this would be the same for a "Medication Lot Number", should there be a differentation in the definition specific to the type? If keeping generic, consider adding to "Medications", and "Medical Devices" Data Classes as well because there are use cases there. It would not be necessary for medications to be mandatory (just in instances where research necessitates it). This will enable lot #s for study drugs, study devices, pacemakers, pacemaker wires, and post market devices currently being tracked for safety. It seems better to keep this generic. Loinc is generic too. The definition here is better than the LOINC one.	Defined as: "Sequence of characters representing a specific quantity of manufactured material within a batch."	Lot Number (Code C70848) NCIt- A distinctive alpha-numeric identification code assigned by the manufacturer or distributor to a specific quantity of manufactured material or product within a batch.

Data Class	Data Element	Suggestion Type (Change, Add, Remove)	Comment	Existing Text	Proposed Text
Medications	Route	Consider "Route of Administration"	This clarifies that the term is administered or given.	Defined as: "Physiological administration path of a therapeutic agent into or onto a patient." "Examples include but are not limited to oral, topical, and intravenous."	Define as: "Part of the body the substance/pharmaceutical product is administered or taken into the body." (Examples are okay)
Medications	Route	Please rename data element to "Route of Administration"	This adds clarity.	Route	Route of Administration
Outcomes	Serious Adverse Event	Consider for promotion	Will aid in drug safety, patient safety and clinical research. HL7 Vulcan Adverse Event working group is close to publishing two implementation guides to clarify this: http://hl7.org/fhir/uv/ae-research-ig/2023Sep/StructureDefinition-AdverseEvent-clinical-research.html https://build.fhir.org/ig/HL7/fhir-ae-research-backport-ig/index.html The FHIR AdverseEvent Resource is Maturity Level 2 http://build.fhir.org/adverseevent.html		

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Biologically Derived Product	Product Code; Unique Identifier	Promote these for patient safety reasons. Priority elements are Product Code, Unique Identifier.	Product Code and Unique Identifier data elements are recorded in the documentation, having descrete elements will help with tracking reactions and improve patient safety. Adding these data elements will inform clinical research and serious adverse event evaluations during clinical trials. The serious adverse event adjudication committee will have more information to understand the factors surrounding biological products which may provide insight into study drug adverse events and the relationship to a study drug.		
Genomics	Gene Studied; Varient Data; Variant Interpretation; Variant Type	Promote these because genomics data inform relationships between conditions, medications, and study drugs.	Having genomics data exchanged in real world data will inform observational research and perhaps lead to randomized control trials to further enlighten the science.		
Medications	Medication	Would like the ONC and USCDI to promote the use of FHIR MedicationAdministration Resource elements to support the HL7 US Core to use case.	This will help researchers be able have all aspects of the medication, the request (order), the dispense (pharmacy filling), the statement (patient/participant stating meds taken) and finally, the most important in healthcare - the medication administration (the health providers giving the drugs to the patients).	Current US Core which is informed by USCDI does not include the MedicationAdministration Resource.	