Informatics : Data Element Use Cases

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(Page Editor: Meredith Nahm) This page shows the current snap shot of the use cases for a CTSA Human Studies Database. Both **high level** and detailed (numbered) use cases are provided. The use cases are categorized into three areas, 1.) Research characterization, 2.) Research Operations, and 3.) Cross Institutional. After discussion and edits from the Human Studies Database project team, these use cases will be shared with the larger CTSA Informatics group and the CTSA PIs for prioritization. Following use case prioritization, data elements will be defined. Potential Use Cases for the first implementation of the CTSA Metadata Repository include:

(Priority 1) Research Characterization - Report research purpose and clinical aims (Columbia Univ.) (UC Davis) (UT Southwestern X 2)(Mayo x2)(UCSF x 2)(Duke x 2) Total 10

1. Identify primary purpose* of study (Tx, prevention, diagnostic, supportive care, screening, health services research, basic science, other)
2. Document primary outcome measure*^ and secondary outcome measure*^ of studies, Identify different ways that the same outcome (e.g., mortality, BP) has been measured/modeled/analyzed across studies at an institution.
3. Identify condition^ or focus of study*
4. Identify intervention type* (drug, device, biological/vaccine, procedure/surgery, radiation, behavioral, genetic, dietary supplement, other) and intervention name*^
5. Characterize projects at an institution that involve biospecimen retention* and biospecimen description* need structured information about the bio-sample collection (type of sample collected, min. clinical annotation set) rather than text description as in clinicaltrials.gov

(Priority 4) Research Characterization - Report research population and demographics(Columbia Univ.) (UC Davis) (UT Southwestern) (UCSF X 2) (Duke) Total 6

1. Identify study population description* (population from which individuals will be selected)
2. Identify eligibility criteria*^ (best to use standard for describing each?, Arden, OCL if possible at this level of abstraction?)
3. Identify gender* of study participants (both, male, female)
4. Identify age range of study participants (min age*, max age*)
5. Identify whether or not the study accepts healthy volunteers* (yes, no)

(Priority 6) Research Characterization - Report research design (Columbia Univ.)(UC Davis) (UCSF) (Duke) Total 4

1. Identify study type* (Interventional, Observational, Expanded access)
2. Identify kind of studies (registry, clinical trial, ...)
3. Identify studies by Phase* (Phase I, II, II, IV)
4. Identify studies by intervention model* (design) (single group, parallel, cross-over, factorial), Masking*, allocation*, study classification*
5. Document arms*, arm type*, group*, group description*
6. Identify studies by target enrollment*^ and Actual enrollment
7. Identify observational studies by observational study model* (cohort, case control, case only, case-crossover, ecologic or community studies, family-based, other)
8. Identify studies by time perspective* (prospective, retrospective, cross-sectional, other)

(Priority 6) Research Characterization - Report research leadership, sponsorship, and regulatory authority (Columbia Univ.)(UC Davis) (UCSF) (Duke) Total 4

1. Document the official title* Brief Title* (for lay people), and Acronym* of a project
2. Identify ClinicalTrials.gov registration number (NCT)^
3. Identify funding source(s)^ for projects (NIH institute and other funding sources)
4. Identify sources of non-monetary support^
5. Identify FDA regulated interventions* (projects containing FDA regulated interventions)
6. Identify Primary Sponsor^ (IND/IDE holder) and IND/IDE Number* for projects
7. Identify any secondary Sponsors^
8. Identify Primary contact for public questions about the research^
9. Identify Primary contact for scientific questions about the research^
10. Identify IND/IDE grantor*

(Priority 7) Research Characterization - Report research status and disposition (Columbia Univ.) (UCSF) (Duke) Total 3

1. Identify studies by status (planning, enrolling, follow-up, completed, hold)
2. List overall recruitment status*^ (not yet recruiting, recruiting, enrolling by invitation, active not recruiting, completed, suspended, terminated, withdrawn)
3. List study start date*(enrollment date^), planned completion date*, and actual completion date*
4. List reason a study was stopped*

Research Characterization - Report entities participating in research¿

1. Identify the study PI (will have to figure out how best to represent PI of entire trial, site PI, versus Sponsor/investigator)
2. Identify clinical investigational sites for multicenter studies where the institution is the coordinating center (will have to figure out a way to represent an admin, clinical, data, statistical center for trials, and combinations, they all do this differently)
3. Identify facility* (clinical investigational sites)
4. Identify core facilities (core labs, central labs, etc)
5. Identify approving IRB (s)
6. Identify countries of recruitment^

(Priority 6) Research Products - Report research data and results(Columbia Univ.)(UT Southwestern X 2) Total 3

1. Provide tables or figures showing study primary and secondary endpoints (is this duplicative with the link to primary manuscript in Medline?)
2. Document MEDLINE Identifier* (PMID) for primary manuscript (results reference from clinicaltrials.gov?), and other manuscripts generated from a trial. Facilitate an institution in making sure that a¿results manuscript has been published for each trial.
3. Document link to study web site
4. Document link to study datashare

Research Characterization - Report non-result research artifacts(Mayo x2) Total 2

1. Provide structured research protocol (protocol representation project within HL7 / BRIDG)
2. Provide data elements (ISO11179 metadata) used in the protocol
3. Provide rendering of study data collection forms
4. Provide Investigator Brochure
5. Provide Manual of Operations or similar procedure documentation
6. Provide data quality assessment (quantitative results i.e. database error rate measured source to database or CRF to database of data auditing during study or at database lock)

(Priority 2) Research Operations - Facilitate reporting to standard clinical trial registries (ClinicalTrials.gov)(Columbia Univ.)(UC Davis)(UT Southwestern X 2)(Mayo x2) (UCSF X 2) (Duke) Total 9

1. Facilitating official institution automated trial registration into ClinicalTrials.gov

(Priority 5) Research Operations - Facilitate research inventory and portfolio management within institutions (Interested: Harold Lehmann)***(Columbia Univ.)(UC Davis)(Mayo x2) (Duke) Total 5***

1. Differentiate studies where the institution is a site, versus core lab, versus coordinating center.
2. Differentiate studies by study characterization characteristics listed in the study characterization section
3. Maintain a unique study identifier^
4. Maintain date of registration in trial registry^
5. Document the institutional project unique ID*^, i.e. secondary IDs*^ (e.g. Sponsor's project number, grant or contract number)

Research Operations- Facilitate study operations and management within institutions(UC Davis) (Duke) Total 2

1. Facilitate comparison of study designs across sets of related studies (e.g., see CTeXplorerfrom The Trial Bank Project and CHISEL Lab)
2. Facilitate identification of common design choices in a clinical domain (e.g, eligibility criteria, intervention regimens, outcome definitions)
3. Facilitating identification of potential collaborators

4. Facilitate tracking of IND/IDEs (submission dates, report due dates)
5. Facilitate tracking of IRB approval status* (not yet submitted, pending, approved, submitted and exempt, submitted and denied, submission not required)
6. List IRB number* for projects
7. List current (IRB approved) Informed Consent Form (ICF) and Protocol version date
8. Facilitate recruitment of participants
9. Track enrollment to studies
10. Track patient care costs to assigned payer (e.g. Patient, third party, study)
11. Report study budgets/actuals (patient care, labor, other) by institutional division/dept
12. Facilitate accurate billing

Cross institutional - ***Facilitate research inventory and study level portfolio management across CTSA institutions(Columbia Univ.)(UC Davis)(Mayo) Total 3***

1. Report counts and percentages of items listed in Study Characterization) e.g. type of studies in each institution, and across all CTSA institutions, studies conducted at each Phase (Phase I, II, II, IV), studies by intervention type, studies by funding source, INDs/IDEs by institution

Cross institutional - ***Facilitate common metrics and benchmarking across CTSA institutions(UC Davis) (Duke) Total 2***

1. Time to IRB approval, percent approved on first submission
2. Time to executed site contract
3. Time from IRB approval to first patient enrolled
4. Time from last patient last visit to database lock
5. Time from database lock to manuscript publication
6. Screened to enrolled ratio by therapeutic area
7. Percent attrition of enrolled patients by therapeutic area

(Priority 3) Cross institutional - ***Catalog current research activities at institutions to facilitate collaborations (who's working on what)(Columbia Univ.)(UC Davis)(UT Southwestern X 3)(Mayo) (UCSF) Total 7***

1. Facilitate identification of potential collaborators through visibility of current work and interests

¿ *Clinicaltrials.gov data element, ^WHO data element

Please add your ideas!