

D2Refine Usability Study – User Analysis Questionnaire

Introduction

Hello, my name is Deepak Sharma, software professional at Clinical Semantic Services at Division of Information Management & Analytic Systems, Mayo Clinic. I am conducting a usability study on behalf of the CACDE-QA project team (PI: Dr. Guoqian Jiang). We are seeking Clinical Modeler, Vocabulary Engineers, Study Developers and Users with similar knowledge and domain exposure to provide their feedback for a metadata standardization & harmonization platform called D2Refine.

The D2Refine platform is being designed and developed to help create, standardize and serialize metadata in clinical study data dictionaries. This platform is still under development and we will be using its initial release for this usability study. We will try to assess how useful, usable and satisfying this platform is, as compare to a couple of other similar platforms. Your participation will definitely help us gauge the usability of D2Refine and help guide current and future development efforts.

1. General Questions

- a. **Date:**
- b. **Name:**
- c. **Contact** (Email, Phone):
- d. **Location:**
 - ☐ On site (in-person)
 - ☐ Remote
- e. **What is your current role?**
 - ☐ Study Developer
 - ☐ Metadata/Vocabulary Engineer
 - ☐ Clinical Model Developer
 - ☐ Information Technology Professional
 - ☐ Other: _____

2. User Environment

- a. Metadata - ‘Metadata’ means – ‘dataset definition’, ‘data dictionary’, ‘clinical model’, ‘clinical archetype’, or ‘study case report forms’ - for a given dataset.
 - i. **How do you currently create metadata? What tools you use?**
 - ☐ MS Office (Excel, Word...), Text Files
 - ☐ Proprietary Solution: _____
 - ☐ Open-Source Solution: _____
 - ☐ Other: _____

ii. How do you store metadata? Are you aware of the format the metadata is persisted in? If yes then please describe.

- ☐ Microsoft Excel or Comma Separated Values (CSV) files
- ☐ Not sure
- ☐ Standard format
 - ☐ OpenEHR Archetype Definition Language (ADL)
 - ☐ Archetype Modeling Language (AML)
 - ☐ HL7 FHIR
 - ☐ Other: _____
- ☐ Other: _____

iii. How do you search (existing) metadata for possible re-use?

- ☐ Existing solution provides integrated search function
- ☐ I don't search existing metadata; create new each time
- ☐ Other: _____

iv. How do you share metadata with outside world?

- ☐ I don't share the metadata with outside world
- ☐ Sharing requires with additional documentation or custom tools
- ☐ Existing tool does not provide a way a share metadata
- ☐ Existing tool provides additional tooling/format to share metadata
- ☐ Other: _____

b. Controlled Vocabularies

i. What all controlled vocabularies, value-sets, code-lists, ref-sets or clinical models you use? (Please suffix any specific version that you use, if known)

- ☐ SNOMED
- ☐ ICD
- ☐ MedDRA
- ☐ RxNORM
- ☐ LOINC
- ☐ NCI Thesaurus
- ☐ NLM ValueSet Authority Center (VSAC)
- ☐ Homegrown or Locally defined
- ☐ Others (Please list) _____

ii. How do you use controlled terminology?

- ☐ To bind/associate a code-system term for study variable definition
- ☐ For lookup or reference

- ☐ To bind/associate a value-set/code-list for valid values
- ☐ Other: _____

iii. How do you search for an item in controlled terminology provided?

- ☐ Existing user tool provides an integrated search function
- ☐ Manual lookup
- ☐ I do not use search
- ☐ Other: _____

c. Metadata Usage & Processing

i. How do you use the metadata once created?

- ☐ To collect and validate instance data
- ☐ Use in local and collaborating studies
- ☐ Not sure
- ☐ Other: _____

ii. Do you use a Reference Information Model?

- ☐ Yes - _____
- ☐ Do not use a reference information model
- ☐ Not sure about a reference information model.

iii. How do you manage changes to the metadata?

- ☐ Manual _____
- ☐ Tool managed
- ☐ No multiple versions are kept
- ☐ Other: _____

iv. How do you check and validate metadata with requirements?

- ☐ Manual _____
- ☐ Tool managed
- ☐ No validation is performed
- ☐ Other: _____

3. Problems & Expectations

- a. What problems you are having with metadata creation, versioning, serializing, sharing and instance data processing?
- b. What are your expectations? What you would like to see in a tool, that manages the metadata for given workflow or study?