THE NATIONAL CANCER INSTITUTE

NCI CDMS Usage Guidelines, v. 1.0

The following guidelines are intended to facilitate consistent practices in electronic data capture by users of the Clinical Data Management Systems (CDMS) made available by the National Cancer Institute (NCI).

1. Case Report Forms

a. When developing case report forms (CRFs) within the CDMS, CDMS user organizations should utilize "RELEASED" forms in the Cancer Data Standards Registry and Repository (caDSR) (https://cabig.nci.nih.gov/concepts/caDSR/) as follows:

1. CRFs in the NCI Standard Template Forms classification are the highest level of "RELEASED" forms in the caDSR and therefore should be used before lower levels of "RELEASED" forms.

2. When new forms are added to the NCI Standard Template Forms collection, they should be used in place of lower level "RELEASED" forms that will have been harmonized into the NCI Standard Template Forms collection.

3. If additional data elements are needed for an approved CRF template, such changes shall be curated in caDSR and designated as "RELEASED" before use in individual instances of the CDMS. A CDMS user organization must create a request to add the data element to the existing template; once the request is approved, the data element can be added to the existing CRF template and imported into the CDMS.

4. If new CRFs are required, they must be developed and designated as RELEASED through caDSR before use.

5. CRFs in any of the "RELEASED" workflow statuses in caDSR should be used "as-is," i.e., without modification though existing forms may be combined.

6. CDMS user organizations that require additional data elements for CRFs may utilize CDE curation support provided by NCI CBIIT. However, organizations that require dedicated curation support are free to obtain their own CDE curators and/or Form Builder(s), provided that such CDE curators and/or Form Builder(s) are appropriately trained and certified by NCI CBIIT as proficient in the creation and maintenance of content in the caDSR.

b. In order to use the preconfigured extraction process for Theradex submission, CDMS user organizations should use a file format for monitoring or a file format for CDUS reporting. The specific set of caDSR forms should be used without modification. If CDMS users wish to use a new or changed form, the extraction process will not work without modification.

2. Operating Procedures

Organizations that install their own instances of a CDMS available from the NCI are responsible for establishing and complying with any procedures needed to operate their individual instances.

3. Revisions to CDMS Usage Guidelines

These guidelines may be revised from time to time by NCI in order to facilitate consistent practices in electronic data capture by CDMS users. Users will be informed and provided with at least 30 days' notice prior to the effective date of updated versions of these guidelines.