



CTSUS

Cancer Trials Support Unit

CTSUS-CDISC-CCDR RandoNode Setup

Version 1.1

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1. Acronyms

This section describes acronyms that are used within this document.

Table 1: Acronyms

| Acronym | Description |
|-----------|--|
| caDSR | Cancer Data Standards Registry and Repository |
| CCDR | Cancer Care Delivery Research |
| CDASH | Clinical Data Acquisition Standards Harmonization |
| CDE | Common Data Element |
| CDISC | Clinical Data Interchange Standards Consortium |
| CDUS | Clinical Data Update System |
| CTEP | Cancer Therapy Evaluation Program |
| CTEP-AERS | Clinical Therapy Evaluation Program Adverse Event Reporting System |
| CTSUS | The Cancer Trials Support Unit |
| DCP | Division of Cancer Prevention |
| EC | Eligibility Checklist |
| FDA | Food and Drug Administration |
| IND | Investigational New Drugs |
| LPO | Lead Protocol Organization |
| NCI | National Cancer Institute |
| NRDS | Network Rave Data Standards |
| OPEN | Oncology Patient Enrollment Network System |
| SDTM | Study Data Tabulation Model |

2. Introduction

The use of Clinical Data Interchange Standards Consortium (CDISC) standards is required for data submissions to the US Food and Drug Administration (FDA). CDISC submissions to the FDA require the use of controlled terminology and datasets formatted according to Study Data Tabulation Model (SDTM). Collecting clinical data using Clinical Data Acquisition Standards Harmonization (CDASH) facilitates this submission process.

The Division of Cancer Prevention (DCP) developed Cancer Care Delivery Research (CCDR) trials to collect questionnaire information from non-patients (i.e., patient caregivers, clinicians, and other clinical site staff). The National Cancer Institute (NCI) requested that OPEN support non-patient enrollments for the CCDR trials.

2.1 Overview

The following provides an overview of the NCI's CDISC implementation, as per the NCI CDISC Implementation Wiki:

"The FDA has mandated sponsors whose studies start after Dec 17, 2016, must submit their clinical study data sets in the SDTM standard format. For Investigational New Drugs (INDs), the requirement applies for studies that start after Dec. 17, 2017. SDTM provides a standard for organizing and formatting data to streamline the process in collection, management, analysis and reporting. The CDISC is a global nonprofit standards development organization with a worldwide team of staff and volunteer experts across the medical community. CDISC provides data standards to streamline clinical research, one of which being SDTM. CDISC is also developing CDASH which establishes a standard way to collect data in a similar way across studies and sponsors so that data formats and structures provide clear traceability of submission into the SDTM. To support the FDA mandate of submitting clinical study data sets to the FDA in the SDTM format, the NCI is transitioning their current Network Rave Data Standards (NRDS) Initiative, led by the Cancer Therapy Evaluation Program (CTEP) into the CDISC implementation."

"The NCI/CTEP is transitioning the existing NRDS initiative to the CDISC Implementation initiative to meet the FDA mandate of submitting clinical study data sets in the SDTM format. The NCI is working in collaboration with CDISC to collect data in the CDASH format for the Oncology Patient Enrollment Network System (OPEN), Clinical Therapy Evaluation Program Adverse Event Reporting System (CTEP-AERS) and the Clinical Data Update System (CDUS). According to the FDA Study Data Technical Conformance Guide, section 4.1.2 (SDTM General Considerations), it is recommended that sponsors implement the collection of data in a format that is harmonized with SDTM such as CDASH."

Per the NCI, all IND studies activated on or after 01/01/2020 must be CDISC-compliant.

OPEN has also been enhanced to allow non-patient enrollments for CCDR trials, so that the DCP can collect and expand its patient-care data, which will enable NCI to further improve cancer clinical trials.

2.2 Scope

The Cancer Trials Support Unit (CTSUS) is supporting the NCI's CDISC implementation by developing a CDISC-Compliant OPEN Demography form and transferring data to the RandoNode, Rave, and CTEP-AERS. In order for RandoNode to process CDISC-compliant demography data, an XML mapping file must be upgraded in the RandoNode. The Lead Protocol Organizations (LPOs) will use this mapping file to process CDISC-compliant demography forms in the RandoNode.

The Cancer Trials Support Unit (CTSUS) is also supporting the DCP's CCDR implementation by developing CCDR-Compliant OPEN Prerequisite forms for Providers and Other Professional Disciplines. In order for RandoNode to process CCDR data, an XML mapping file must be upgraded in the RandoNode. LPOs will use this mapping file to process CCDR forms in the RandoNode.

2.3 Organization of this Document

- Section 3 provides the changes made to accommodate CDISC-compliance.
- Section 4 provides the changes made to accommodate CCDR.
- Section 5 provides the RandoNode upgrade process.
- Section 6 provides References.

3. Changes to Accommodate CDISC-compliance

3.1 OPEN Demography Form Changes

When an Eligibility Checklist (EC) form is downloaded in OPEN from the Cancer Data Standards Registry and Repository (caDSR) form builder, a standard demography form is attached with the downloaded EC form. Legacy studies (those activated prior January 1, 2020) will continue to use the existing standard demography form, whereas the CDISC-compliant Demography form will be attached to new studies. Each LPO RandoNode needs to have the ability to process both demography forms.

To comply with the CDISC standards, the OPEN Demography form will go through the changes described in Table 2.

Table 2: OPEN Demography Form Updates

| Question | Current CDE Public ID | Change Description |
|-------------------------|---|--|
| Patient's date of birth | 6341138 | A new Common Data Element (CDE) will be used. The CDE Public ID will be changed from 793 to 6341138 |
| Ethnicity | 6338619 | A new CDE will be used. The CDE Public ID will be changed from 2192217 to 6338619 |
| Gender | 6343385 | A new CDE will be used. The CDE Public ID will be changed from 2200604 to 6343385 |
| Country | 2006183 | A new CDE will be used. The CDE Public ID will be changed from 315 to 2006183. Note: The three letter country code (e.g. USA) will replace two letter country code (US) |
| ZIP | 2179606 | A new short name to be used for the same CDE |
| Method of Payment | 58384 | A new CDE will be used. The CDE Public ID will be changed from 2003309 to 58384 |
| Race | 6412503 | A new CDE will be used. The CDE Public ID will be changed from 2192199 to 6412503 |
| MedDRA Code | 2004425 | A new short name to be used for the same CDE |
| Patient Initials | 2658183 (L), 2658182 (F), 2658163 (M) | The CDEs used in OPEN did not change. However, Rave uses a CDE for combined initials. |

3.2 RandoNode Starter Kit Changes

A new release of RandoNode starter kits version 3.0.0.1 will be provided to handle CDISC and Non CDISC standard demography form. The RandoNode starter kits can be downloaded from https://www.ctsu.org/open/Group_Resources/Randonode/RandoNode_Starter_Kit/java/Version_3.0.0.1

The RandoNode code refers to a mapping file, DemographicsPublicIdMapping.xml, which is used to map demographic elements. This XML mapping file lists the CDE public IDs of demography elements which

need to be supported across studies. Previously, there was a single version of the Demography form, in which each of these elements had a single public ID listed. With the introduction of CDISC-compliant CDEs, some of these CDEs will have multiple public IDs listed. See Figure 1 for an example of the updated demography mapping file.

```
<?xml version="1.0" encoding="UTF-8" ?>
<odmToDemographics>
  <attribute name="lastInitial">
    <publicId>2658183</publicId>
  </attribute>
  <attribute name="firstInitial">
    <publicId>2658182</publicId>
  </attribute>
  <attribute name="middleInitial">
    <publicId>2658163</publicId>
  </attribute>
  <attribute name="patientSsn">
    <publicId>780</publicId>
  </attribute>
  <attribute name="patientHospitalNbr">
    <publicId>905</publicId>
  </attribute>
  <attribute name="ethnicity">
    <publicId>2192217</publicId>
    <publicId>6338619</publicId>
  </attribute>
  <attribute name="gender">
    <publicId>2200604</publicId>
    <publicId>6343385</publicId>
  </attribute>
  <attribute name="patientDateOfBirth">
    <publicId>793</publicId>
    <publicId>6341138</publicId>
  </attribute>
  <attribute name="countryOfResidence">
    <publicId>315</publicId>
    <publicId>2006183</publicId>
  </attribute>
</odmToDemographics>
```

Figure 1: Snapshot Example of Updated Demography Mapping

For the complete file of demography updates, access the [Demographics PublicID Mapping.xml](#).

4. Changes Made to Accommodate CCCR

In order for OPEN to support CCCR enrollments, the OpenRegistration.otherValues attribute has been appended with an XML section to indicate the enrollment type and the provider type for non-patient enrollments. The provider type is only added for non-patient enrollments.

4.1 Patient Type Enrollments

A new xml attribute is required for the otheValue node tag. This new attribute value identifies the enrollment type. The attribute name is IS_PATIENT_YN". The attribute values is either "YES" for patient enrollment or "NO" for non-patient enrollment.

4.1.1 Patient Type Enrollment XML Example

4.1.1.1 Patient Enrollment XML

```
<otherValues>  
  <otherValue name="IS_PATIENT_YN" value="YES"/>  
</otherValues>
```

4.1.1.2 Non-Patient Enrollment XML

```
<otherValues>  
  <otherValue name="IS_PATIENT_YN" value="NO"/>  
</otherValues>
```

4.1.2 Non-Patient Type Enrollment XML Example

4.1.2.1 Non-Patient Enrollment PROVIDER XML

```
<otherValues>  
  <otherValue name="IS_PATIENT_YN" value="NO"/>  
  <otherValue name="NON_PATIENT_TYPE" value="PROVIDER"/>  
</otherValues>
```

4.1.2.2 Non-Patient Enrollment CARE_GIVER XML

```
<otherValues>  
  <otherValue name="IS_PATIENT_YN" value="NO"/>  
  <otherValue name="NON_PATIENT_TYPE" value="CARE_GIVER"/>  
</otherValues>
```

4.1.2.3 Non-Patient Enrollment OTHER_PROF_DISCIPLINE XML

```
<otherValues>  
  <otherValue name="IS_PATIENT_YN" value="NO"/>  
  <otherValue name="NON_PATIENT_TYPE" value="OTHER_PROF_DISCIPLINE"/>  
</otherValues>
```

5. RandoNode Upgrade Process

The updated RandoNode starter kits and the updated demography mapping file, DemographicsPublicIdMapping.xml, will be distributed to LPOs to support CDISC-compliant studies.

The following steps need to be performed by LPOs to upgrade the RandoNode:

- 1) Replace the RandoNode.jar version 3.0.0.0 with the latest from the CTSU web site. The new RandoNode.jar is versioned with 3.0.0.1.
- 2) Replace the existing DemographicsPublicIdMapping.xml file with the new version. The mapping file is located under {CTSUS_HOME} \RandoNode\config folder ({CTSUS_HOME} may indicate C:\CTSUS\Applications or D:\CTSUS\Applications folder).
- 3) Download the study-specific Metadata file for CDISC-compliant studies and place under {CTSUS_HOME} \RandoNode\meta folder.
- 4) Restart the RandoNode application server.
- 5) Test CDISC-compliant and legacy studies using the OPEN practice enrollment feature

Contact the CTSU OPEN Team at CTSUSOPENFORMS@westat.com for any further assistance.

6. References

Table 3: References

| # | Name | Location (Intranet) | Location (Internet) |
|----|------------------------|---------------------|---|
| 1. | CDISC Implementation | | https://wiki.nci.nih.gov/display/CDISC/NCI+CDISC+Implementation+Home |
| 2. | CDISC Project Overview | | https://wiki.nci.nih.gov/display/CDISC/CDISC+Implementation+Project+Overview |