CTSU

Cancer Trials Support Unit

Cancer Care Delivery Research Subject Enrollment Form ALS v1.0 Release Notes

Version 1.0

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Document Information

Revision Information for the Cancer Care Delivery Research Subject Enrollment Form ALS v1.0 Release Notes

Revision History

#	Date	By	Description
1.0	22-Dec-2020	Mangayarkarasi Thiyagarajan	Initial release.
2.0	22-Dec-2020	Lela Makbul	Performed QC review.

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1. References

Table 1: References

#	Document	Location	Description
1)	CCDR Subject Enrollment Form ALS v1.0 Release Notes	Collaboration Portal (CTSU Website) **Path:** CTSU→CDMS Support Center →Integrations→General Documents →CTSU-CCDR-SubjectEnrollment-Form→v1.0	Specification document for standard CCDR Subject Enrollment Form ALS v1.0 release.

2. Introduction

2.1 Overview

The Cancer Trials Support Unit (CTSU) developed a Clinical Data Interchange Standards Consortium (CDISC) compliant Cancer Care Delivery Research (CCDR) Subject Enrollment Form with guidance from National Cancer Institute (NCI). The purpose of this form is to collect enrollment information at the subject level for patients and non-patients in Rave for CCDR studies. The Lead Protocol Organizations (LPOs) are expected to implement this form during study build at the subject level and are required to use with CTSU Standard Forms Architect Loader Specification (ALS) v7.0 and above. This form is available in the CCDR Subject Enrollment Form Rave ALS v1.0 file.

The CCDR Subject Enrollment Form is complaint with the CDISC version mentioned in the *CDISC Version and Links* table (Table 2).

Instruction: To access the links, first log in to the CDISC website using your National Institutes of Health (NIH) email address. These links only work for NIH staff members or LPOs that have obtained their own account access.

Table 2: CDISC Version and Links

CDISC Version	Link
Clinical Data Acquisition Standard Harmonization (CDASH) Model v1.0	https://www.cdisc.org/standards/foundational/cdash/cdash-model-v1-0-0
CDASH Implementation Guide (CDASHIG) v2.0	https://www.cdisc.org/standards/foundational/cdash/cdashig-v2-0-0
CDASH and Standard Data Tabulation Model (SDTM) Controlled Terminology package 38 released on June 28, 2019 *Note: Controlled Terminology are released quarterly. You can access the prior versions via the CDISC Library Archive.*	https://evs.nci.nih.gov/ftp1/CDISC/SDTM
CDASHIG v2.0 Metadata Table	https://www.cdisc.org/cdisc-library https://www.cdisc.org/members-only/cdisc-library-archives
SDTM Model v1.7	https://www.cdisc.org/standards/foundational/sdtm/sdtm-v1-7
SDTM Implementation Guide (SDTMIG) v3.3	https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3
SDTMIG v3.3 Metadata Table	https://www.cdisc.org/cdisc-library https://www.cdisc.org/members-only/cdisc-library-archives

2.1.1 Background of Cancer Care Delivery Research Subject Enrollment Form

CCDR Oncology Patient Enrollment Network (OPEN) protocols capture information about the caregivers, practices (sites), providers (doctors, nurse practitioners), and other professional disciplines (research nurse, nutritionist) for patients that were enrolled in OPEN. Additional updates were made with this release to enable the capability to push non-patient data from OPEN to Rave for CCDR studies.

2.2 Acronyms and Definitions

This section lists acronyms used within the document, as well as common acronyms related to the CTSU program.

Table 3: Acronyms and Definitions

Acronym	Definition
ANDA	Abbreviated New Drug Application
ALS	Architect Loader Specification
BLA	Biologics License Application
caDSR	Cancer Data Standards Registry and Repository
CCDR	Cancer Care Delivery Research
CDASH	Clinical Data Acquisition Standards Harmonization. Basic standards for the collection of clinical trial data and implementation of the standard for specific Case Report Forms (CRFs), optimized for data capture, investigator site activities and data cleaning. The CDASH standard includes the CDASHIG (including the metadata) and the CDASH Model.
CDASHIG	CDASH Implementation Guide provides information on the implementation of CDASH standards for specific topics of data. Each topic is represented by a CDASH domain. CDASH domains, variables and controlled terminology are aligned with SDTM. Each CDASHIG domain contains a description of the data topic, a specification table, including standard metadata for data collection, general assumptions/rules and example forms.
CDASH Model	Provides a general framework and root metadata for creating fields to collect information on forms for which there is not already a domain specified in the CDASHIG. Root metadata includes root variables and root questions. The root CDASH Model variables are intended to facilitate mapping to the SDTMIG variables while addressing specific data collection needs.
CDASH Metadata Table	Includes variables commonly implemented by a significant number of the organizations/companies for a particular topic of data (e.g., Medical History, Adverse Events)
CDE	Common Data Element
CDISC	Clinical Data Interchange Standards Consortium, a standards developing organization (SDO)
CRA	Clinical Research Associate
CRFs	Case Report Forms

Acronym	Definition
CTEP	Cancer Therapy Evaluation Program
CTSU	Cancer Trials Support Unit
DDs	Data Dictionaries
DD	Data Dictionary
EDC	Rave Electronic Data Capture
FDA	Food and Drug Administration
IND	Investigational New Drug
LPO	Lead Protocol Organization
NCI	National Cancer Institute
NIH	National Institutes of Health
NDA	New Drug Application
NRDS	Network Rave Data Standards
OID	Object Identifier
OPEN	Oncology Patient Enrollment Network
SAS	Statistical Analysis System
SDTM	Study Data Tabulation Model
SDTMIG	Study Data Tabulation Model Implementation Guide
TCG	Technical Conformance Guide
UI	User Interface

2.3 Scope

The use of CDISC standards is required for data submissions to the US Food and Drug Administration (FDA). A mandate issued by the FDA in 2016 requires data to be submitted to the FDA in Study Data Tabulation Model (SDTM) compliant datasets but does **not** mandate the use of CDISC compliant variables for data collection. NCI/Cancer Therapy Evaluation Program (CTEP) is transitioning the existing Network Rave Data Standards (NRDS) initiative to the CDISC Implementation initiative to meet the FDA mandate of submitting clinical study data sets in the SDTM format. All CTEP IND studies activated on and after 3/1/2020 shall be CDISC compliant.

The Study Data Technical Conformance Guide (TCG) provides specifications, recommendations, and general considerations on how to submit standardized study data using FDA-supported data standards located in the FDA Data Standards Catalog. The TCG supplements the guidance for industry providing Regulatory Submissions in Electronic Format — Standardized Study Data and provides technical recommendations to sponsors for the submission of animal and human study data and related information in a standardized electronic format in investigational new drug (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs). Refer to Study Data TCG for more information.

Although the FDA does not require data to be collected in a certain format, the NCI is working in collaboration with CDISC to collect data in the CDASH format. The CTSU, in coordination with the NCI, has developed a CDISC compliant CCDR Subject Enrollment Form. This document outlines the details of the CCDR Subject Enrollment Form included in the CCDR Subject Enrollment Form ALS v1.0.

The process of developing other Rave forms (CRFs) is out of the scope of this document.

2.4 Audience

This document is intended for use by LPO operational staff members, managers, and Rave study builders.

3. Cancer Care Delivery Research Subject Enrollment Form

Figure 1 depicts the CCDR Subject Enrollment Form available within the ALS. LPOs must not alter the elements defined for this form.

Form Name	OID
CCDR Subject Enrollment	CTSU_SUBJECT_ENROLLMENT_CCDR

Figure 1: CCDR Subject Enrollment Form Name and OID

3.1 Form Setup in Rave

Figure 2 displays the CCDR Subject Enrollment Form setup in Rave. LPOs are required to set up this form at the subject level in Rave for both the main study and the sub-study for CCDR studies, and follow the setup displayed in Figure 2 for the form to successfully work.

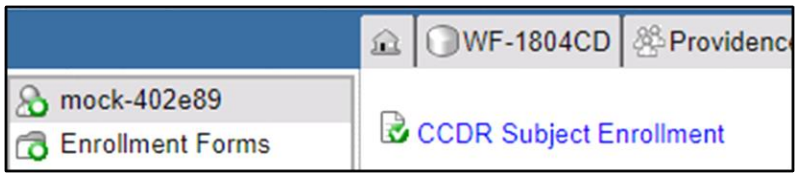
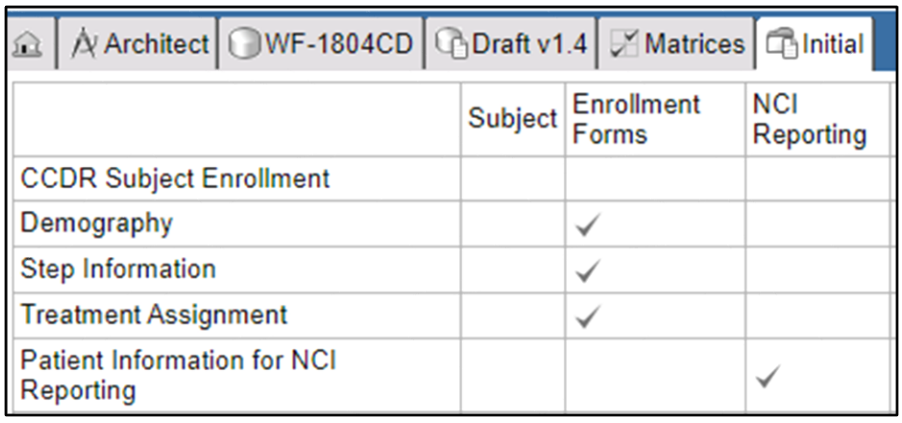


Figure 2: CCDR Subject Enrollment Form Setup in Rave



	Subject	Enrollment Forms	NCI Reporting
CCDR Subject Enrollment			
Demography		✓	
Step Information		✓	
Treatment Assignment		✓	
Patient Information for NCI Reporting			✓

Figure 3: CCDR Subject Enrollment Form Setup in Rave Matrices

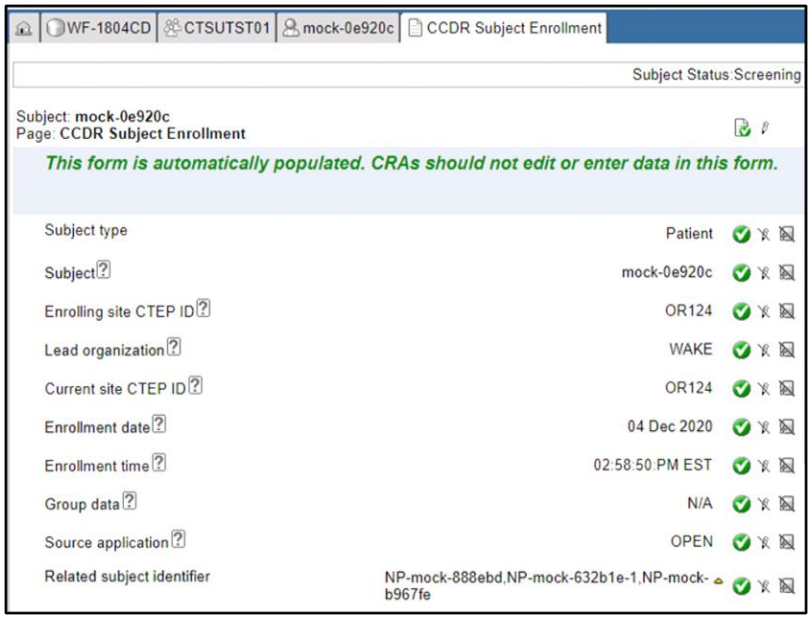


Figure 4: CCDR Subject Enrollment Form Setup in Rave for main study

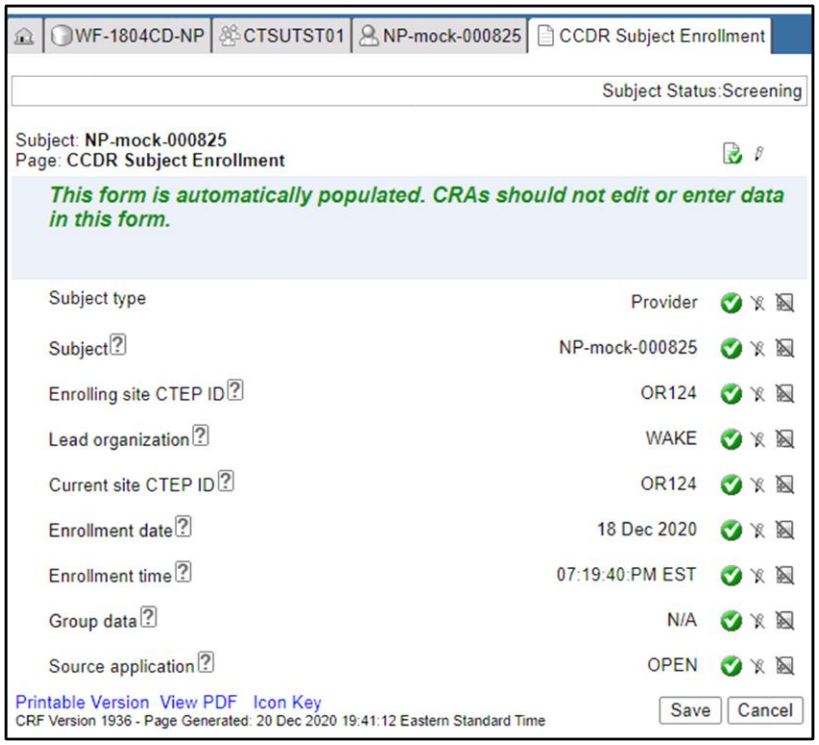


Figure 5: CCDR Subject Enrollment Form in Rave for sub-study (Non-Patients)

3.2 Form & Field Level Definition

The Subject Enrollment Form serves as the Rave Primary Form for all CTEP studies. OPEN transfers the subject enrollment data into the Rave Primary Form at the time of patient initialization. The Subject Enrollment Form contains the primary enrollment information. Two new fields (Subject Type and Related Subject Identifier) are added to the existing Subject Enrollment Form.

Table 4 illustrates the form level definition.

Table 4: CCDR Subject Enrollment Form Level Definition

#	Form Name/ OID	Folder	Required for Integration	Description	Entry and View Restrictions
1	CCDR Subject Enrollment/ CTSU_SUBJECT_ENROLLMENT_CCDR	N/A	Y	Subject Enrollment Form to be used for CCDR studies.	No view restrictions exist in the ALS but LPOs are required to set view restrictions for all roles (except for Batch Upload and Power User roles) for the Related Subject Identifier field in the sub-study for non-patients. Fields are entry restricted for site staff.

Table 5 illustrates the field level definitions.

Table 5: CCDR Subject Enrollment Field Level Definition

#	Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
1	NOTE1 / NOTE1	This form is automatically populated. CRAs should not edit or enter data in this form.	This field is used to display form instructions.
2	SC_SCORRES_SUBJTYP / Subject Type PID7533553_V1_0	Subject type	New field added to collect the subject type. OPEN pushes Patient for the main study and the below values for the sub-study: • Practice • Caregiver • Provider • Other professional discipline

#	Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
3	SUBJID / Subject Identifier for the Study PID6380049_V1_0	Subject	-
4	SITE_CTEPID / Study Site Identifier PID6380048_V1_0	Enrolling site CTEP ID	-
5	SPONSOR / Lead Institution PID2192796_V1_0 Lead Organization	Lead organization	-
6	CSITE_CTEPID / Current Site CTEP ID PID3314243_V1_0 Current Site CTEP ID	Current site CTEP ID	-
7	DS_DSSTDAT / Disposition Event Start Date PID6384212_V1_0	Enrollment date	-
8	DS_DSSTTIM / Start Time of Disposition Event PID6341397_V1_0	Enrollment time	-
9	GRPDATA / Group Type PID3212399_V1_0	Group data	-
10	SRCAPP / Source Application PID3302840_V1_0	Source application	-
11	RSUBJID / Related Subject Identifier PID7533554_V1_0	Related subject identifier	New field to collect the related subject identifiers. This is a free text field and will hold the non-patient IDs separated by commas. View restrictions are to be set by LPOs for all roles except Batch Upload and Power User role for the sub-

#	Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
			study collecting non-patient information.

3.3 Data Dictionary Setup

Table 6: CCDR Subject Enrollment Form Data Dictionaries

#	Data Dictionary (DD) Name	Comments
1	SUBJECT_TYPE_PID7533547_V1_0F	DD contains the list of subject types that can be enrolled for the study

3.4 Configuration Requirements

In the CCDR Subject Enrollment Form ALS v1.0, the configurations mentioned below must be completed when using this form for CCDR studies.

1. The CCDR Subject Enrollment Form is to be used for both the main CCDR study and the sub-study. The sub-study name should be same as the main study followed by a suffix *-NP* (ex: Main Study as WF1804CD and sub-study as WF1804CD-NP). The sub-study should be treated like the main study where it should be given access to the CTSUTST01 sites for UAT testing.
2. The CCDR Subject Enrollment Form should be used in conjunction with CTSU Standard Forms ALS v7.0 and above, replacing the Subject Enrollment Form from the CTSU Standard Forms ALS with the Subject Enrollment Form from the CCDR Subject Enrollment Form ALS. Edit checks referencing Subject Enrollment Form from the CTSU Standard Forms ALS is required to be replaced with the CCDR Subject Enrollment Form.
3. LPOs are required to set the view restrictions for all roles except Batch Upload and Power User roles for the Related Subject Identifier field in the sub-study for non-patients.