

LPO OPEN ALS 7.0 Quick Start Guide for UAT

This document provides an overview of the tasks that the Lead Protocol Organizations (LPOs) should follow to configure protocols in the UAT environment of the Oncology Patient Enrollment Network (OPEN), for using Architect Loader Spec (ALS) version 7.0.

1. Background

NCI requested that OPEN (and its integrated systems) support Clinical Data Interchange Standards Consortium (CDISC) Common Data Elements (CDEs). OPEN forms that use ALS 7.0 are CDISC compliant.

With the release of OPEN version 9.0, CTSU (in collaboration with the LPOs and other organizations) created a new OPEN Standard Demography form that uses CDISC-compliant CDEs.

2. Instructions

Table 1 lists the steps for configuring an OPEN protocol for ALS 7.0 and the organization (LPO or CTSU) that should perform each step. Click any of the tasks to jump to the appropriate section.

Table 1: Overview of steps for configuring an OPEN protocol for ALS 7.0

Step #	Task:	Performed By:
1)	Complete the CTSU OPEN Rave Request Form	LPO
2)	Download the Form(s) into OPEN UAT	CTSU
3)	Configure ALS 7.0 Protocol Settings in OPEN, CENTER, and RSS	CTSU
4)	Configure CTEP-AERS Settings (If Applicable)	CTSU
5)	Configure the LPO RandoNode	LPO
6)	Configure the Protocol in Rave	LPO
7)	Configure Protocol Layout and Edit Checks in OPEN UAT	LPO
8)	Testing Protocol Forms in OPEN UAT	LPO and CTSU
9)	Release the Protocol in OPEN Production	CTSU

Table 2 provides a list of reference links for the LPO tasks described in this document.

Table 2: List of references for LPO tasks

Reference	Address
CTSUSU OPEN Rave Request Form	https://www.ctsu.org/open/Group_Resources/Forms/CTSUSU_OPEN_RaveReqForm_OMB.pdf
CTSUSU OPEN Registrar team	CTSUSUOPENFORMS@westat.com
CTSUSU-CDISC-CCDR RandoNode Setup	https://www.ctsu.org/open/Group_Resources/Randonode/Documents/CTSUSU-CDISC-CCDR-RandoNode-Setup.pdf
Demography Mapping File	https://www.ctsu.org/open/Group_Resources/Randonode/RandoNode_Starter_Kit/DemographicsPublicIdMapping.xml
OPEN Portal Group User Guide	https://www.ctsu.org/open/Group_Resources/Training/Users_Manual/CTSUSU-OPEN-GroupUserGuide.pdf

2.1 Step 1: Complete the CTSUSU OPEN Rave Request Form

- The LPOs will complete the CTSUSU OPEN Rave Request form and submit it to CTSUSU.
- The LPOs should follow their existing internal work instructions to configure the protocol form(s) in the Cancer Data Standards Repository (caDSR).

Instructions:

- 1) Download the [CTSUSU OPEN Rave Request Form](#).
- 2) For question 3.4 (*OPEN-Rave ALS Version Used for the Protocol?*) select 7.0.

3.4*	OPEN-Rave ALS Version Used for the Protocol?	<input type="checkbox"/> 4.0 <input checked="" type="checkbox"/> 7.0* <small>*RN should be upgraded to support ALS 7.0</small>
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Table 3: Select 7.0 for the ALS version question on the CTSUSU OPEN Rave Request Form

- 3) Submit the completed form to the [CTSUSU OPEN Registrar team](#).

2.2 Step 2: Download the Form(s) into OPEN UAT

- The CTSUSU will download the protocol’s form(s) into OPEN UAT.

2.3 Step 3: Configure ALS 7.0 Protocol Settings in OPEN, CENTER, and RSS

- The CTSU will configure the protocol settings in the OPEN, the CTSU Enterprise Network Transaction Engine for RAVE (CENTER), and the Regulatory Support System (RSS) applications.

2.4 Step 4: Configure CTEP-AERS Settings (If Applicable)

The CTSU will configure the Cancer Therapy Evaluation Program Adverse Event Reporting System (CTEP-AERS) settings (for studies that will use CTEP-AERS).

2.5 Step 5: Configure the LPO RandoNode

- **The LPO** will configure their RandoNode for using ALS 7.0.

This section will provide background information on the changes made to the OPEN Standard Demography form and instructions for configuring the LPO RandoNode to use ALS 7.0.

Background:

The most notable differences between the CDISC and non-CDISC versions of the OPEN Standard Demography forms include:

- 1) For the Sex question (previously Gender), a new value (Intersex) was added.
- 2) For the Country question (previously Country of residence), the country code format changed from two-characters (e.g. US) to three-characters (e.g. USA). In addition, added new countries to the list of values.
- 3) Updated the VALIDATE_POSTAL_CODE edit check to take into account the three-character country code.

Refer to Figure 1 and Figure 2 to compare the differences between the CDISC and non-CDISC versions of the OPEN Standard Demography forms.

Patient Demography	
<input type="checkbox"/> Standard_Patient_Identifier	
Last <input type="text"/>	First <input type="text"/> Middle <input type="text"/>
Social Security Number (USA Only) <input type="text"/>	Hospital No. <input type="text"/>
<input type="checkbox"/> Standard_Demographics	
* Date of Birth <input type="text"/> / <input type="text"/> <input type="text"/> <input type="button" value="Clear"/>	
* Ethnicity <input type="radio"/> Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown	* Sex <input type="radio"/> Female <input type="radio"/> Male <input type="radio"/> Unknown <input type="radio"/> Intersex
* Country <input type="text"/>	Zip Code (USA Only) <input type="text"/>
<input type="checkbox"/> Standard_Race	
* Race <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Not Reported <input type="checkbox"/> Unknown <input type="checkbox"/> White	
<input type="checkbox"/> Standard_Method_of_Payment	
* Method of Payment <input type="radio"/> PRIVATE INSURANCE <input type="radio"/> MEDICARE <input type="radio"/> MEDICARE AND PRIVATE INSURANCE <input type="radio"/> MEDICAID <input type="radio"/> MEDICAID AND MEDICARE <input type="radio"/> MILITARY OR VETERANS SPONSORED NOS <input type="radio"/> MILITARY SPONSORED (INCLUDING CHAMPUS & TRICARE) <input type="radio"/> VETERANS SPONSORED <input type="radio"/> SELF PAY (NO INSURANCE) <input type="radio"/> NO MEANS OF PAYMENT (NO INSURANCE) <input type="radio"/> OTHER <input type="radio"/> Unknown	
<input type="checkbox"/> Standard_NCI_Reporting	
* Disease Code <input type="text"/> Select Clear	

Figure 1: The new CDISC-compliant OPEN Standard Demography form

Non-CDISC Question Text (CDE Public ID)		CDISC Question Text (CDE Public ID)	
Non-CDISC Short Name	Non-CDISC Values	CDISC Short Name	CDISC Values
First (2658182) PT_F_INIT_NM	1 letter	First (2658182) PT_F_INIT_NM	1 letter
Middle (2658163) PT_F_INIT_NM	1 letter	Middle (2658163) PT_MID_INIT_NM	1 letter
Patient SSN (780) PT_SSN_NUM	9 numbers	Patient SSN (780) PT_SSN_NUM	9 numbers
Patient hospital number (905) PT_MED_REC_NUM	Patient's hospital number	Patient hospital number (905) PT_MED_REC_NUM	Patient's hospital number
Ethnicity (2192217) ETHN_GRP_CAT_TXT	Hispanic or Latino Not Hispanic or Latino Not Reported Unknown	Ethnicity (6338619) DM_ETHNIC	HISPANIC OR LATINO NOT HISPANIC OR LATINO NOT REPORTED UNKNOWN
Gender (2200604) PRSN_GENDER_TXT_TP	Female Male Unknown	Sex (6343385) DM_SEX	F M U UNDIFFERENTIATED
Patient's date of birth (793) PER_BIR_DT	DATE	Date of Birth (6341138) DM_BRTHDAT	DATE
Country of residence (315) PT_ADDR_CTRY_NAME	The two character country ISO codes. There are 247 country codes as per the CDE permissible values.	Country (2006183) SC_SCORRES_CNTRYRES	The three character country ISO-alpha3 codes
Zip code (2179606) ADDR_POSTAL_CD	Patient's Zip Code	Zip Code (2179606) SC_SCORRES_ZIPCD	Patient's Zip Code
Race (2192199)	American Indian or Alaska Native	Race (6412503)	AMERICAN INDIAN OR ALASKA NATIVE

Non-CDISC Question Text (CDE Public ID)		CDISC Question Text (CDE Public ID)	
Non-CDISC Short Name	Non-CDISC Values	CDISC Short Name	CDISC Values
RACE_CAT_TXT	Asian Black or African American Native Hawaiian or other Pacific Islander White Not Reported Unknown	DM_CRACE	ASIAN BLACK OR AFRICAN AMERICAN NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER WHITE NOT REPORTED UNKNOWN
Method of payment (2003309) PYMT_METH	PRIVATE INSURANCE MEDICARE MEDICARE AND PRIVATE INSURANCE MEDICAID MEDICAID AND MEDICARE MILITARY OR VETERANS SPONSORED NOS MILITARY SPONSORED (INCLUDING CHAMPUS & TRICARE) VETERANS SPONSORED SELF PAY (NO INSURANCE) NO MEANS OF PAYMENT (NO INSURANCE) OTHER Unknown	Method of Payment (58384) SC_SCORRES_PAYMETH	PRIVATE INSURANCE MEDICARE MEDICARE AND PRIVATE INSURANCE MEDICAID MEDICAID AND MEDICARE MILITARY OR VETERANS SPONSORED NOS MILITARY SPONSORED (INCLUDING CHAMPUS & TRICARE) VETERANS SPONSORED SELF PAY (NO INSURANCE) NO MEANS OF PAYMENT (NO INSURANCE) OTHER Unknown
Disease code (2004425) MedDRA_CODE	CTEP simplified disease code	Disease Code (2004425) SUPPMH_QVAL_MHDSXCD	CTEP simplified disease code

Instructions:

- 1) The LPO will use the [CTSUSU-CDISC-CCDR RandoNode Setup](#) instructions document to update their RandoNode to support ALS 7.0.
- 2) In addition, the LPO will need to upload the [Demography Mapping File](#) to their RandoNode.

2.6 Step 6: Configure the Protocol in Rave

- The LPO will configure their instance of Rave for the protocol.

Instructions:

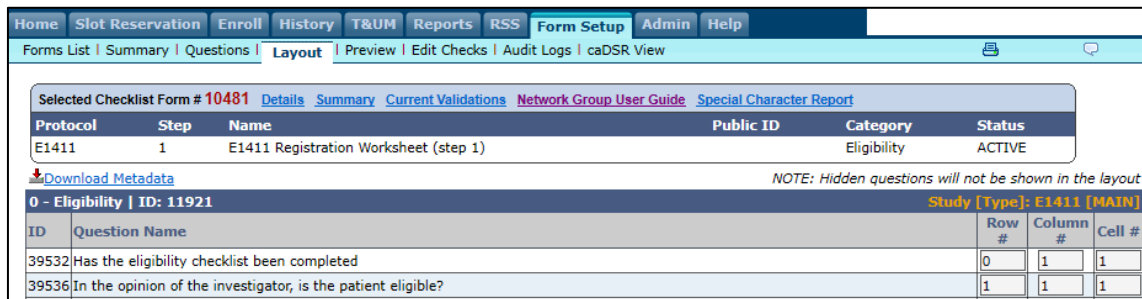
- 1) Configure the LPO instance of Rave, as per the CTSU OPEN Rave Activation Checklist.
- 2) Use the ALS 7.0 for study building in Rave.

2.7 Step 7: Configure Protocol Layout and Edit Checks in OPEN UAT

- The LPO will configure the protocol form(s) layout and edit checks in OPEN UAT.

Instructions:

- 1) Follow the instructions in the [OPEN Portal Group User Guide](#) for configuring the form layout and edit checks for a protocol’s form(s) (see Figure 3 and Figure 4).



Protocol	Step	Name	Public ID	Category	Status
E1411	1	E1411 Registration Worksheet (step 1)		Eligibility	ACTIVE

[Download Metadata](#) NOTE: Hidden questions will not be shown in the layout

0 - Eligibility ID: 11921		Study [Type]: E1411 [MAIN]		
ID	Question Name	Row #	Column #	Cell #
39532	Has the eligibility checklist been completed	0	1	1
39536	In the opinion of the investigator, is the patient eligible?	1	1	1

Figure 3: Configure the Layout subtab for a protocol form

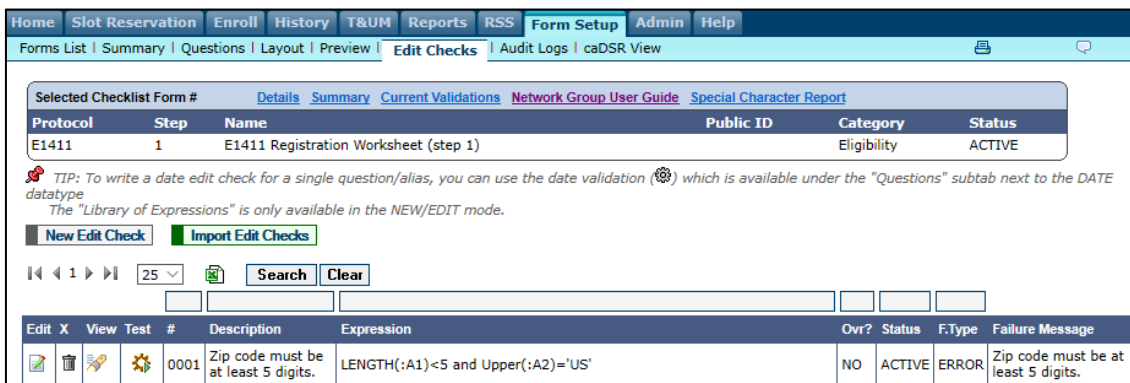


Figure 4: Configure the Edit Checks subtab for a protocol form

- 2) For edit checks relating to updated Demography questions (Gender, Country of residence), if they are being imported into a CDISC form from a non-CDISC form, make sure to update the edit checks so they will operate with the updated questions and permissible values.
- 3) Notify CTSU once form testing in OPEN UAT can begin.

2.8 Step 8: Testing Protocol Forms in OPEN UAT

- The LPO and CTSU will test the protocol forms in OPEN UAT.

Instructions:

- 1) Form testing for the protocol will be performed in OPEN UAT:
 - a) The LPO will perform their form testing in OPEN UAT per their internal work instructions.
 - b) The CTSU Registrars will perform their internal testing procedures.

2.9 Step 9: Release the Protocol in OPEN Production

The CTSU will release the protocol to OPEN production.

Revision History

#	Date	By	Description
1	25-Oct-2019	Thomas Healand, Mark Stauffer	<p>07-Oct-2019 TH: Created document based on the original quick start guide. Removed CTSU specific content.</p> <p>07-Oct-2019 MS: Reviewed content, removed CTSU SOP references.</p> <p>08-Oct-2019 MS: Added hyperlink to the three-digit ISO country codes.</p> <p>18-Oct-2019 MS: Updated the URLs in table 2 to hyperlinks. Added bold formatting to highlight LPO sections. Added CDISC variable name, per Mangayarkarasi Thiyagarajan.</p> <p>25-Oct-2019 MS: Addressed suggestions from the AET team.</p>