Precision Medicine Initiative (PMI)

Beta PMI Treatment Protocols CDISC Standard Forms ALS v1.0 Release Notes

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1. References

Table 1: References

#	Document	Location	Description
1)	Beta Precision Medicine Initiative (PMI) Treatment Protocols CDISC Standard Forms ALS v1.0 Release Notes	https://wiki.nci.nih.gov/display/CDISC/Precision+Medicine+Initiative	Specification document for PMI Treatment Protocols CDISC Standard Forms ALS v1.0 release.

2. Introduction

2.1 Overview

National Cancer Institute's (NCI) MATCHBox is part of the Precision Medicine Initiative (PMI) which focuses on expanding precision medicine clinical protocols, overcoming drug resistance, developing new laboratory models for research, and developing a national cancer knowledge system. To support this initiative, the Medidata Rave® and MATCHBox were integrated with the Oncology Patient Enrollment Network (OPEN) for PMI treatment protocols to capture off treatment and consent withdrawal information for treatment re-assignment.

The PMI Cancer Therapy Evaluation Program (CTEP) Clinical Data Interchange Standards Consortium (CDISC) Off Treatment (OT) and Consent Withdrawal (CW) Standard Forms have been developed for the National Clinical Trials Networks (NCTNs). These standard forms are available in the PMI Treatment Protocols CDISC Standard Forms Rave Architect Loader Spreadsheet (ALS) v1.0 file. The PMI Treatment Protocols CDISC Standard Forms ALS v1.0 Release Notes provides information about the MATCHBox - Medidata Rave integration of the PMI CDISC OT and CW Standard Forms, and contains configuration details to assist NCTNs in configuring their studies to use this integration. The PMI CDISC OT and CW Standard Forms are CDISC harmonized. Current CDISC versions are used for the Common Data Elements (CDE) curation.

Instructions: 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 Group staff members that have obtained their own account access.

Table 2: CDISC Documents and Links

CDISC Version	Link
Clinical Data Acquisition Standard Harmonization (CDASH) Model	https://www.cdisc.org/standards/foundational/cdash
CDASH Implementation Guide (CDASHIG)	https://www.cdisc.org/standards/foundational/cdash
CDASH and Standard Data Tabulation Model (SDTM) Controlled Terminology *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 Metadata Table	https://www.cdisc.org/cdisc-library https://www.cdisc.org/members-only/cdisc-library-archives
SDTM Model	https://www.cdisc.org/standards/foundational/sdtm

CDISC Version	Link
SDTM Implementation Guide (SDTMIG)	https://www.cdisc.org/standards/foundational/sdtmig
SDTMIG Metadata Table	https://www.cdisc.org/cdisc-library https://www.cdisc.org/members-only/cdisc-library-archives

2.2 Background

PMI/Precision Medicine Analysis and Coordination Center (PMACC) requires standardized Case Report Forms (CRFs) and Standards-Compliant CDEs across all NCTN instances of Medidata Rave to support the MATCHBox-OPEN-Rave integration for treatment protocols to capture off treatment and consent withdrawal information for treatment re-assignment. OPEN provides a standardized web-based environment for the enrollment and treatment assignment and re-assignment of all patients in clinical trials across all NCTNs. Integration between MATCHBox-OPEN-Medidata Rave will provide a streamlined method to capture off treatment information in Rave for PMI treatment protocols.

2.3 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
ALS	Architect Loader Spreadsheet
ANDAs	Abbreviated New Drug Applications
API	Application Programming Interface
BLAs	Biologics License Applications
CDASH	Clinical Data Acquisition Standards Harmonization. Basic standards for the collection of clinical trial data and how to implement the standard for specific 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).

Acronym	Definition
CDE	Common Data Element
CDISC	Clinical Data Interchange Standards Consortium, a standards developing organization (SDO).
CF	Custom Function
CRA	Clinical Research Associate
CRFs	Case Report Forms
CRRI	Clinical Reporting and Research Informatics
CTEP	Cancer Therapy Evaluation Program
CW	Consent Withdrawal
DD	Data Dictionary
EC	Edit Check
FDA	Food and Drug Administration
IND	Investigational New Drug
NCI	National Cancer Institute
NCTN	National Clinical Trials Network
NDA	New Drug Application
NIH	National Institutes of Health
OT	Off Treatment
OID	Object Identifier
OPEN	Oncology Patient Enrollment Network
PMACC	Precision Medicine Analysis and Coordination Center
PMI	Precision Medicine Initiative
SAE	Serious Adverse Event
SDO	Standards Developing Organization
SDTM	Standard Data Tabulation Model
SDTMIG	Standard Data Tabulation Model Implementation Guide
TCG	Technical Conformance Guide
UUID	Universally Unique Identifier

2.4 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 SDTM compliant datasets but does not mandate the use of CDISC compliant variables for data collection.

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

2.5 Audience

This document is intended for use by NCTNs operational staff members, managers, and Rave Study Builders.

3. PMI Treatment Protocols CDISC Standard Forms

The following figure depicts the PMI CDISC OT and CW Standard Forms available within the ALS. These forms must be used for PMI treatment protocols only. These forms should be used in conjunction with CTSU Standard Forms ALS v7.0 and higher.

Form OID	DraftFormName
PMI_CDISC_OFF_TREATMENT_STANDARD_FORM	PMI CDISC Off Treatment Standard Form
PMI_CIDISC_CONSENT_WITHDRAWAL_STANDARD_FORM	PMI CDISC Consent Withdrawal Standard Form

Figure 1: PMI CDISC OT & CW Standard Form Names and OIDs

3.1 Form Level Definition

Table 4: PMI CDISC OT & CW Standard Form Level Definitions

#	Form Name	Folder	Required for Integration	Description	Entry and View Restrictions
1	PMI CDISC Off Treatment Standard Form	N/A	Rave-MATCHBox	This form is required to collect off treatment data in Rave. Data on this form will be entered by site user.	No Entry or View Restrictions. View and/or Entry Restrictions for fields used for integration purposes only.
2	PMI CDISC Consent Withdrawal Standard Form	N/A	Rave-MATCHBox	This form is required to collect consent withdrawal data in Rave. Data on this form will be entered by site user.	No Entry or View Restrictions. View and/or Entry Restrictions for fields used for integration purposes only.

3.2 Folder Setup in Rave

The folder setup for the PMI CDISC OT and CW Standard Forms is configurable and will be determined by the NCTNs based on protocol requirements.

The following is the suggested PMI CDISC OT Standard Form and PMI CDISC CW Standard Form folder setup in Rave.

Figure 2: Suggested PMI CDISC OT & PMI CDISC CW Standard Forms Folder Setup in Rave

	Subject	Enrollment Forms	NCI Reporting	Off Treatment
Subject Enrollment				
Demography		✓		
Step Information		✓		
Treatment Assignment		✓		
Patient Information for NCI Reporting			✓	
PMI CDISC Off Treatment Standard Form				✓
PMI CDISC Consent Withdrawal Standard Form				✓

Figure 3: Suggested PMI CDISC OT & PMI CDISC CW Standard Forms Setup in Rave Matrices

3.3 Field Level Definition

3.3.1 PMI CDISC Off Treatment Standard Form

The PMI CDISC OT Standard Form will be available for sites to enter off treatment data for treatment Protocols only.

Table 5: PMI CDISC OT Standard Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
DSNTERR / Note/Error	Note/Error	Note/Error is a field used to display any note or error caused while processing the Application Programming Interface (API) call.
DSNOTE1 / NOTE_OFF_TREATMENT	Off Treatment Details	This is a section header on the form.
DS_DSSTDAT / Disposition Event Start Date PID6384212_V1_0	Off treatment date	N/A
DS_DSDECOD/ Disposition Event Dictionary-Derived/Standardized Term PID6355981_V1_0	Status (when they came off treatment)	Patient's status when going off treatment.
DS_DSTERM/ Disposition Event Reported Term PID6355980_V1_0	Other, specify	Other, specify value to capture patient's 'Other' off treatment status.
OTFRMDTC/ Form Date PID6783869_V1_0	Form date	Current date and time are added to this field when the form is saved. This is used for internal purposes. This field is view restricted to all but the Power User.
MATCHUUID / MATCHUUID	MATCHBox Service UUID (derived)	This field is used to populate the MATCHBox Service ID and is used for internal purposes. This field is view restricted to all but the Power User.

3.3.2 PMI CDISC Consent Withdrawal Standard Form

The PMI CDISC CW Standard Form will be available for sites to enter consent withdrawal data for treatment Protocols only.

Table 6: PMI CDISC CW Standard Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
DSNTERR / Note/Error	Note/Error	Note/Error is a field used to display any note or error caused while processing the API call.
DSNOTE1 / NOTE_CONSENT_WITHDRAWAL	Consent Withdrawal Details	This is a section header on the form.
DS_DSDECOD/ Disposition Event Dictionary-Derived/Standardized Term PID6355981_V1_0	Status (when they withdrew consent)	Status of consent withdrawal.
DS_DSSTDAT/ Disposition Event Start Date PID6384212_V1_0	Consent withdrawn date	N/A
DS_DSTERM/ Disposition Event Reported Term PID6355980_V1_0	Specify reason	Enter additional details regarding why consent was withdrawn for the subject.
CWFRMDTC/ Form Date PID6783869_V1_0	Form date	Current date and time are added to this field when the form is saved. This is used for internal purposes. This field is view restricted to all but the Power User.
MATCHUUID / MATCHUUID	MATCHBox Service UUID (derived)	This field is used to populate the MATCHBox Service ID and is used for internal purposes. This field is view restricted to all but the Power User.

3.4 Data Dictionary Setup

Table 7: PMI CDISC OT & CW Standard Forms: Data Dictionaries

#	DD Name	Comments
1	CDISC_SDTM_RE_PID6352263_V1_0_1F	Data Dictionary (DD) added for field DS_DSDECOD for FormOID PMI_CDISC_OFF_TREATMENT_STANDARD_FORM
2	CDISC_SDTM_RE_PID6352263_V1_0_2F	DD added for field DS_DSDECODfor FormOID PMI_CDISC_CONSENT_WITHDRAWAL_STANDARD_FORM

3.5 Edit Checks in Group Study ALS

Table 8: PMI CDISC OT and CW Standard Forms: Edit Checks in Group Study ALS

#	Form Name	Edit Check Name	Comments
1	PMI CDISC Off Treatment Standard Form	PMI-OFFTX_doNotify	This Edit Check (EC) executes the Custom Function (CF) that routes EC CF action to the corresponding CF.
2	PMI CDISC Consent Withdrawal Standard Form	PMI—CONS-WDRAW_doNotify	This EC executes the CF that routes EC CF action to the corresponding CF.

3.6 Custom Functions in Group Study ALS

Table 9: PMI CDISC OT and CW Standard Forms: CFs in Group Study ALS

#	Custom Function Name	Comments
1	PMI_UTIL_ExceptionHandler	This is a utility CF that handles exception.
2	PMIZ_CONFIG_doMapAllOids	This is a customizable CF to implement the logic to plugin static folder Object Identifiers (OIDs) based on the context.
3	PMIZ_CONFIG_doMapDefaultOids	This is a customizable CF to implement the logic to plugin static Form and Field OIDs.
4	PMIZ_CONFIG_getCentralCRFVer	This is a study specific utility CF used to configure the central study CRF version.
5	PMIZ_GRP_ROUTE_doRouteEC	This CF routes EC action to corresponding CF.

3.7 Custom Functions in Central Study ALS

The Central Study contains CFs to validate and open queries on the OT form, create and send payload for the OT and CW forms to MATCHBox, populate messages returned from MATCHBox to the OT and CW forms, and generic utility CFs.

Table 10: PMI CDISC OT and CW Standard Forms: CFs in Central Study ALS

#	Custom Function Name	Comments
1	PMI_CONFIG_doSetMessages	This is the CF used to set customized validation messages for OS and OT forms.
2	PMI_UTIL_doEnterData	This is a utility CF to enter data to a data point.
3	PMI_UTIL_ExceptionHandler	This is a utility CF that handles exceptions. This CF should be called from catch block in all the CFs.
4	PMI_UTIL_GetWebserviceConfig	This CF fetches web service URL, username, password from Custom Table.
5	PMI_UTIL_HasAnyQueries	This CF checks if any data points in a record has an open

#	Custom Function Name	Comments
		query.
6	PMI_UTIL_InvokeWSViaRaveAPI	This CF Routes EC Action to appropriate CF.
7	PMI_UTIL_IsDpDataChanged	This CF checks if data point data is changed in this current thread/post.
8	PMI_UTIL_IsSysQueryOnDp	This CF checks if data point has open system query.
9	PMI_UTIL_QueryHandler	This CF raises query and attaches the custom query text for a given data point.
10	PMI-CONSENT_doProcessEC	This CF processes the CW form data, facilitates the call to MATCHBox, and updates the UUID and message.
11	PMI-CONSENT_MakeRequestJSON	This CF makes input JSON string for the CW form.
12	PMI-OFFTX_doProcessEC	This CF processes the OT form data and executes the call to MATCHBox and updates the UUID and message.
13	PMI-OFFTX_doQueryOnFields	This CF validates OT form fields and opens queries on fields.
14	PMI-OFFTX_MakeRequestJSON	This CF prepares the payload string (JSON format) for the OT form.

3.8 Configuration Requirements

In the PMI Treatment Protocols CDISC Standard Forms ALS v1.0, there are some configuration changes required for new study setup. The configurations mentioned below must be completed for studies using the PMI CDISC OT and CW Standard Forms for PMI treatment protocols.

1) Make sure the Batch Upload role is enabled for populating data from MATCHBox.
2) Update the Central Study CRF version in CF PMIZ_CONFIG_getCentralCRFVer.
3) Configure CF PMIZ_CONFIG_doMapDefaultOIDs to map the treatment protocol-specific Eligibility Checklist form/worksheet OIDs.

   NOTE: A PMI CDISC Eligibility Checklist Template has been built in the caDSR II per PMI requirements and integration needs. This template must be utilized as the starting point for PMI protocol-specific Eligibility Checklist forms. The CDEs on the template must be used as-is, to support the PMI OPEN-MATCHBox-Rave integrations.

   PMI CDISC Eligibility Checklist Template CDEs with Field OIDs are required for successful OT and CW integration transactions. Refer to the **PMI CDISC Eligibility Checklist Template Fact Sheet** for use requirement details; this document is available via the Precision Medicine Initiative - NCI CDISC Implementation - NCI Wiki (nih.gov).

4) The fields provided in the PMI Treatment Protocols CDISC Standard Forms ALS v1.0 must be used as-is; Groups can add non-standard/protocol-specific questions to the PMI CDISC OT and CW Standard Form as needed.

There is no restriction on the order of completion of OT and CW standard forms. Cross-form validations between OT and CW standard forms can be added as needed.

3.9 CTSU Standard Forms ALS Use Requirements

The steps detailed below must be completed to use the PMI Treatment Protocols CDISC Standard Forms ALS with the CTSU Standard Forms ALS for building PMI treatment studies in Rave.

1) Copy the following from the CTSU Standard Forms ALS v7.0 and above to setup the PMI treatment protocol.
    a. OPEN-Rave Integration and Patient Information for NCI Reporting forms along with the related DDs (**required**):
        i. Subject Enrollment
        ii. Step Information
        iii. Treatment Assignment
        iv. Demography
        v. Patient Information for NCI Reporting
    b. The following ECs and CFs related to the CTSU Standard Forms/integrations (**required**):
        i. Edit Checks:
            1. CTSUX_Set_SubjectName
            2. CTSU_TREATMENT_ASSIGNMENT_PopulateData_FromStepInfo
        ii. Custom Functions:
            1. CTSU_TxAssign_doPopulateDetails
            2. CTSU_UTIL_doEnterData
            3. CTSU_UTIL_ExceptionHandler
    c. Folders ‘Enrollment Forms’ and ‘NCI Reporting’ (**required**)
    d. Other CTSU Standard Forms (integration-related) as needed (e.g., Central Monitoring Alert form, Serious Adverse Event (SAE) reporting integration, etc.) (**as needed**)
    e. If other CTSU Standard Forms (integration-related) are copied from the CTSU Standard Forms ALS, then all related DDs, ECs, CFs, derivations, and Folders must be copied (**as needed**)
2) Copy the PMI CDISC OT and CW Standard Forms and all related items from the PMI Treatment Protocols CDISC Standard Forms ALS v1.0 (**required**).