Precision Medicine Initiative (PMI)

Beta PMI Screening Protocols CDISC Standard Forms ALS v1.0 Release Notes
Version 1.0

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Document Information

Revision Information for the Beta PMI Screening Protocols CDISC Standard Forms ALS v1.0 Release Notes

Revision History

#	Date	By	Description
1.0	16-Dec-2022	Anita Kalavar/Suhela Pandit	Initial document.

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1. References

Table 1: References

#	Document	Location	Description
1)	Beta PMI Screening Protocols CDISC Standard Forms ALS v1.0 Release Notes	https://wiki.nci.nih.gov/display/CDISC/PMI+Committee	Specification document for PMI Screening 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, Medidata Rave® was integrated with the Oncology Patient Enrollment Network (OPEN) to allow National Clinical Trials Networks (NCTN) to view and retrieve treatment assignment information for PMI screening protocols in Medidata Rave, and MATCHBox to track Off Study (OS) and Consent Withdrawal (CW) data.

To support this integration, PMI Clinical Data Interchange Standards Consortium (CDISC) Standard Forms have been developed for the NCTNs. These forms are available in the PMI Screening Protocols CDISC Standard Forms Rave Architect Loader Spreadsheet (ALS) file. The PMI Screening Protocols CDISC Standard Forms Rave ALS v1.0 Release Notes provides information about the OPEN-Rave integration of PMI CDISC Step Information (SI) and Treatment Assignment (TA) standard forms, and MATCHBox - Medidata Rave integration for OS and CW Standard Forms and contains configuration details to assist NCTNs in configuring studies to use this integration. The PMI CDISC SI, TA, OS, and CW Standard Forms are CDISC harmonized. Current CDISC versions are used for Common Data Element (CDE) curation.

Instruction: To access the CDISC links in the below table, 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 that have obtained their own account access.

Table 2: CDISC Documents and Links

CDISC Version	Link
Clinical Data Acquisition Standards Harmonization (CDASH) Model	https://www.cdisc.org/standards/foundational/cdash
CDASH Implementation Guide (CDASHIG)	https://www.cdisc.org/standards/foundational/cdash
Both CDASH and Standard Data Tabulation Model (SDTM) Controlled Terminology package *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

CDISC Version	Link
SDTM Model	https://www.cdisc.org/standards/foundational/sdtm
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 (CRF) and Standards-Compliant CDEs across all NCTN instances of Medidata Rave to support MATCHBox-OPEN-Rave integration for treatment assignment information. OPEN provides a standardized web-based environment for the enrollment of all patients in clinical trials across all NCTNs. Integration between MATCHBox-OPEN-Medidata Rave will provide a streamlined method to display treatment assignment information in Rave for PMI screening protocols for NCI, NCTNs and sites to retrieve from Rave, and capture off study information in Rave for PMI screening protocols. The PMI CDISC OS and CW Standard Forms will be used to capture and track off study and consent withdrawal data.

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 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

Acronym	Definition
	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).
CF	Custom Function
CRA	Clinical Research Associate
CRFs	Case Report Forms
CSMS	Clinical Sample Management System
CTEP	Cancer Therapy Evaluation Program
CW	Consent Withdrawal
DD	Data Dictionary
EC	Edit Check
EDC	Rave Electronic Data Capture
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
OID	Object Identifier
OPEN	Oncology Patient Enrollment Network
OS	Off Study
CW	Consent Withdrawal
PMACC	Precision Medicine Analysis and Coordination Center
PMI	Precision Medicine Initiative
SDO	Standards Developing Organization
SDTM	Standard Data Tabulation Model
SDTMIG	Standard Data Tabulation Model Implementation Guide
SI	Step Information
TA	Treatment Assignment

Acronym	Definition
TAC	Treatment Assignment Code
TAD	Treatment Assignment Description
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 for this document.

2.5 Audience

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

3. PMI Screening Protocols CDISC Standard Forms

The following figure depicts the four PMI Screening Protocols CDISC Standard Forms available within the ALS. Groups must not alter the elements defined for these forms as that can break various integrations.

These forms should be used in conjunction with CTSU Standard Forms ALS v7.0 and higher. For PMI Screening Protocols, the CTSU SI and CTSU TA forms, related Custom Functions (CFs) and Edit Checks (ECs) in the CTSU Standard Forms ALS must be replaced with the PMI CDISC SI Standard Form and PMI CDISC TA Standard Form, CFs and ECs from the PMI Screening Protocols CDISC Standard Forms ALS v1.0.

Form OID	DraftFormName
PMI_CDISC_STEP_INFORMATION_STANDARD_FORM	PMI CDISC Step Information Standard Form
PMI_CDISC_TREATMENT_ASSIGNMENT_STANDARD_FORM	PMI CDISC Treatment Assignment Standard Form
PMI_CDISC_OFF_STUDY_STANDARD_FORM	PMI CDISC Off Study Standard Form
PMI_CDISC_CONSENT_WITHDRAWAL_STANDARD_FORM	PMI CDISC Consent Withdrawal Standard Form

Figure 1: PMI Screening Protocols CDISC Standard Forms OID & Name

3.1 Form Level Definition

All forms available in PMI Screening Protocols CDISC Standard Forms ALS v1.0 are not required for every study. These forms are required for PMI screening Protocols only.

Table 4: PMI Screening Protocols CDISC Standard Level Definitions

#	Form Name	Folder	Required for Integration	Description	Entry and View Restrictions
1	PMI CDISC Step Information Standard Form	Enrollment Forms	OPEN-Rave	This form is required for patient initialization in Rave. All the data points in this form are populated programmatically from OPEN to Rave.	No View Restrictions. Entry Restricted for all Rave roles except for Power User and Data Manager.
2	PMI CDISC Treatment Assignment Standard Form	Enrollment Forms	OPEN-Rave	This form is required for patient initialization in Rave. All the data points in this form are populated programmatically from OPEN to Rave.	No View Restrictions. Entry Restricted for all Rave roles except for Power User and Data Manager.
3	PMI CDISC Off Study Standard Form	N/A	Rave-MATCHBox	This form is required to collect off study 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.
4	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

3.2.1 PMI CDISC Step Information and PMI CDISC Treatment Assignment Forms

Figure 22 displays the folder structure for PMI CDISC SI Standard Form and PMI CDISC TA Standard Form used for MATCHBox-OPEN-Rave integration. Groups must follow the folder structure for these forms as displayed in Figure 3 for the integrations to work successfully.

Figure 2: PMI CDISC SI and PMI CDISC TA Standard Forms Folder Setup in Rave

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

Figure 3: PMI CDISC SI and PMI CDISC TA Standard Forms Setup in Rave Matrices

3.2.2 PMI CDISC Off Study Standard Form and PMI CDISC Consent Withdrawal Standard Form

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

The following is the suggested PMI CDISC OS Standard Form and PMI CDISC CW Standard Form matrix setup in Rave.

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

Figure 4: Suggested PMI CDISC OS and PMI CDISC CW Standard Forms Setup in Rave Matrices

3.3   Field Level Definition

3.3.1   PMI CDISC Step Information Standard Form

This form is defined as a log form and form data can change between steps. A new record will be added for each enrolling step. The data on this form is pushed from OPEN.

Table 5: PMI CDISC Step Information Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE1 / NOTE1	This form is automatically populated. Clinical Research Associates (CRAs) should not edit, add log lines or enter data in this form.	This field is used to display form instructions.
DS_DSSPID / Sponsor-Defined Identifier PID6635863_V1_0	Step No	Associated step number.
DS_DSTERM / Disposition Event Reported Term PID6355980_V1_0	Event description	Description for the corresponding step. In case patient transfer occurs without involving a step, a new record needs to be entered with the description *Patient Transfer*.
DS_DSREFID / Reference ID PID6636037_V1_0	Reference ID	Source system's tracking number to identify an enrollment (e.g., This field contains the OPEN tracking #/registration ID, if patient is initialized by OPEN).
SUPPDM_QVAL_TRTINV / Treating Physician Or Participating Investigator Name PID2740424_V1_0	Treating investigator	The physician involved with the patient's treatment for an enrollment. Drugs will be shipped to him or her by default, in case another investigator is not selected for drug shipment.
SUPPDM_QVAL_REGNAM / Protocol Registrar Name PID2172_V3_0	Site registrar	Registrar associated from the enrolling site.
SUPPDM_QVAL_CGRPNAM / Organization Name PID2152_V3_0	Crediting group	Group receiving credit for the enrollment.
DM_INVNAM / Investigator Name PID6355987_V1_0	Investigator name	Physician selected for assigning the cooperative group credit for an enrollment. The Credit Investigator will be accountable for the patient and the site's responsibilities during a cooperative group audit.
PROTASMT / Disposition Supplemental Qualifiers Dataset Qualifier Data Value Clinical Trial Protocol Assignment Name	Protocol assignment name	Protocol assignment name field specifies the name of the subject's protocol assignment.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
PID7765227_V1_0		
DS_DSSTDAT / Disposition Event Start Date PID6384212_V1_0	Event date	Date on which the step enrollment (or patient transfer) was completed. OPEN will transfer the Date when enrollment response was received from RandoNode. Groups can extract this from their own system in case Group system pushes the data.
DS_DSSTTIM / Start Time of Disposition Event PID6341397_V1_0	Event time	Time on which the step enrollment (or patient transfer) was completed. OPEN will transfer the Time when enrollment response was received from RandoNode. Groups can extract this from their own system in case Group system pushes the data.
COHORT / Disposition Supplemental Qualifiers Dataset Qualifier Data Value Cohort Identifier PID7765265_V1_0	Cohort	Cohort classifies a group of individuals, identified by a common characteristic or treatment assignment.
STRATUM / Disposition Supplemental Qualifiers Dataset Qualifier Data Value Stratum Group Category PID7765270_V1_0	Stratum	Stratum categorizes a subset or defined set of attributes of a cohort.
TAC / Treatment Assignment Code PID1967_V4_0	Treatment assignment code (TAC)	TAC is a coded value representing a treatment assigned, to be uniformly administered to a group of study subjects for separate statistical analysis.
TAD / Treatment Assignment Text PID2002699_V5_0	Treatment assignment description (TAD)	TAD is a free-text field to describe the patient's assigned treatment, including dose level and duration. TAD value is populated only when the TAC value is OTHER.
COMMENT_ASMTREAS / Disposition Supplemental Qualifiers Dataset Qualifier Data Value Assignment Reason PID7765280_V1_0	Assignment reason	Assignment reason captures an explanation of the cause of some phenomenon or action for a protocol assignment.

3.3.2   PMI CDISC Treatment Assignment Standard Form

This form is a log form, and the data is derived from the PMI CDISC SI Standard Form and study specific crossover forms. The purpose of this form is to display the treatment arm change history.

Registration systems will not enter data directly on this form but will derive the data from the PMI CDISC SI Standard Form, using a Rave CF that is provided within the Rave ALS file. A new record will be added whenever data is populated in the PMI CDISC SI Standard Form from the registration system. Each log record will display the change history of the arm updates.

Table 6: PMI CDISC Treatment Assignment Standard Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE1 / NOTE1	This form is automatically populated. CRAs should not edit, add log lines, or enter data in this form.	This field is used to display form instructions.
PROTASMT / Disposition Supplemental Qualifiers Dataset Qualifier Data Value Clinical Trial Protocol Assignment Name PID7765227_V1_0	Protocol assignment name	Protocol assignment name field specifies the name of the subject's protocol assignment.
DS_DSSPID / Sponsor-Defined Identifier PID6635863_V1_0	Step No	Step number associated with the arm assignment. Null for crossovers.
DS_DSTERM / Disposition Event Reported Term PID6355980_V1_0	Event description	Event that generated the arm, e.g., Randomization, Crossover, etc.
DS_DSSTDAT / Disposition Event Start Date PID6384212_V1_0	Event date	Date on which arm was assigned by the Group registration system. OPEN will transfer the date when the response was received.
DS_DSSTTIM / Start Time of Disposition Event PID6341397_V1_0	Event time	Time on which arm was assigned by the Group registration system. OPEN will transfer the time when the response was received.
COHORT / Disposition Supplemental Qualifiers Dataset Qualifier Data Value Cohort Identifier PID7765265_V1_0	Cohort	Cohort classifies a group of individuals, identified by a common characteristic or treatment assignment.
STRATUM / Disposition Supplemental Qualifiers Dataset Qualifier Data Value Stratum Group Category PID7765270_V1_0	Stratum	Stratum categorizes a subset or defined set of attributes of a cohort.
TAC / Treatment Assignment Code PID1967_V4_0	Treatment assignment code (TAC)	TAC is a coded value representing a treatment assigned to be uniformly administered to a group of study subjects for separate statistical analysis.
TAD / Treatment Assignment Text PID2002699_V5_0	Treatment assignment description (TAD)	TAD is a free-text field to describe the patient's assigned treatment, including dose level and duration. TAD value is populated only when the TAC value is OTHER.
COMMENT_ASMTREAS / Disposition Supplemental Qualifiers Dataset Qualifier Data Value Assignment Reason PID7765280_V1_0	Assignment reason	Assignment reason captures an explanation of the cause of some phenomenon or action for a protocol assignment.

3.3.3 PMI CDISC Off Study Standard Form

PMI CDISC OS Standard Form is a standard form and will be available for sites to enter off study data for screening Protocols only.

Table 7: PMI CDISC OS 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.
DSNOTE/NOTE_OFF_STUDY	Off Study Details	This is a section header on the form.
DS_DSSTDAT / Disposition Event Start Date PID6384212_V1_0	Off study date	N/A
DS_DSDECOD / Disposition Event Dictionary-Derived/Standardized Term PID6355981_V1_0	Status (when they came off study)	Patient's status when going off study.
DS_DSTERM / Disposition Event Reported Term PID6355980_V1_0	Other, specify	Other, specify value to capture patient's 'Other' off study status.
OSDSFRMDTC / Form Date PID6783869_V1_0	Form date	Current date and time is 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.

3.3.4 PMI CDISC Consent Withdrawal Standard Form

PMI CDISC CW Standard Form is a standard form and will be available for sites to enter consent withdrawal data for screening Protocols only.

Table 8: 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.
DSNOTE/NOTE_CONSENT_WITHDRAWAL	Consent Withdrawal Details	This is a section header.
DS_DSDECOD / Disposition Event Dictionary-Derived/Standardized Term	Status (when they	Status of consent withdrawal.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
PID6355981_V1_0	withdrew consent)	
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 9: PMI CDISC Standard Forms (SI/TA/OS/CW) Data Dictionary Setup

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

3.5 Edit Checks in Group Study ALS

Table 10: PMI CDISC Standard Forms (SI/TA/OS/CW) Edit Checks in Group Study ALS

#	Form Name	Edit Check Name	Comments
1	PMI CDISC Off Study Standard Form	PMI_OFFSTDY_doNotify	This EC executes the CF that routes EC CF action to corresponding CF.
2	PMI CDISC Consent Withdrawal Standard Form	PMI-CONS-WDRAW_doNotify	This EC executes the CF that routes EC CF action to corresponding CF.

3.6 Custom Functions in Group Study ALS

Table 11: PMI CDISC Standard Forms (SI/TA/OS/CW) Custom Functions in Group Study ALS

#	Custom Function Name	Comments
1	PMI_TxAssign_doPopulateDetails	This CF populates data from the PMI CDISC Step Information form to the PMI CDISC Treatment Assignment form.
2	PMI_UTIL_ExceptionHandler	This is a utility CF that handles exceptions.
3	PMIZ_CONFIG_doMapAllOids	This is a customizable CF to implement the logic to plugin static folder OIDs based on the context.
4	PMIZ_CONFIG_getCentralCRFVer	This is a study specific utility CF used to configure the central study CRF version.
5	PMIZ_OS_GRP_ROUTE_doRouteEC	This CF routes PMI CDISC Off Study/Consent Withdrawal Standard Form EC action to corresponding CF.
6	PMIZ-OS_CONFIG_doMapDefaultOids	This is a customizable CF to implement the logic to plugin static Form and Field OIDs.

3.7 Custom Functions in Central Study ALS

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

Table 12: PMI CDISC Standard Forms (SI/TA/OS/CW) Custom Functions 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_doGetActiveRecords	This is a utility CF that returns the active records.
4	PMI_UTIL_ExceptionHandler	This is a utility CF that handles exceptions. This CF should be called from catch block in all the CFs.
5	PMI_UTIL_GetWebserviceConfig	This CF fetches web service URL, username, password from Custom Table.
6	PMI_UTIL_HasAnyQueries	This CF checks if any data points in a record has an open query.
7	PMI_UTIL_InvokeWSViaRaveAPI	This CF routes EC action to appropriate CF.
8	PMI_UTIL_IsDpDataChanged	This CF checks if data point data is changed in this current thread/post.
9	PMI_UTIL_IsSysQueryOnDp	This CF checks if data point has open system query.

#	Custom Function Name	Comments
10	PMI_UTIL_IsSysQueryOnRec	This CF checks if a system query is open on a record.
11	PMI_UTIL_QueryHandler	This CF raises query and attaches the custom query text for a given data point.
12	PMI-CONSENT_doProcessEC	This CF processes the CW form data and executes the call to Matchbox and updates the UUID and message.
13	PMI-CONSENT_MakeRequestJSON	This CF makes input JSON string for the CW form.
14	PMI-OFFSTDY_doProcessEC	This CF processes the OS form data and executes the call to MATCHBox and updates the UUID and message.
15	PMI-OFFSTDY_doQueryOnFields	This CF validates OS form fields and opens queries on fields.
16	PMI-OFFSTDY_MakeRequestJSON	This CF prepares the payload string (JSON format) for the OS form.

3.8 Configuration Requirements

In the PMI Screening 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 MATCHBox-OPEN-Rave integration for PMI Screening Protocols.

1) PMI CDISC Standard forms should be used in conjunction with CTSU Standard Forms ALS v7.0 and above. The CTSU SI and CTSU TA forms, related CFs and ECs must be replaced from the CTSU Standard Forms ALS with the PMI CDISC SI Standard Form and PMI CDISC TA Standard Form, CFs and ECs from the PMI Screening Protocol CDISC Standard Forms ALS v1.0.

2) Ensure the Batch Upload role is enabled for populating the data from OPEN and MATCHBox.

3) The EC to execute CF PMI_TxAssign_doPopulateDetails to derive data from the PMI CDISC SI Standard Form to the PMI CDISC TA Standard Form is not included in the ALS. To derive data from the PMI CDISC SI Standard Form to the PMI CDISC TA Standard Form, the EC in the below screenshot must be added during study build.

If Disposition Event Start Date PID6384212_V1_0 in PMI CDISC Step Information Standard Form in Enrollment Forms IsPresent Or Disposition Event Reported Term PID6355980_V1_0 in PMI CDISC Step Information Standard Form in Enrollment Forms IsPresent Or Disposition Supplemental Qualifiers Dataset Qualifier Data Value Clinical Trial Protocol Assignment Name PID7765227_V1_0 in PMI CDISC Step Information Standard Form in Enrollment Forms IsPresent Or Start Time of Disposition Event PID6341397_V1_0 in PMI CDISC Step Information Standard Form in Enrollment Forms IsPresent Or Treatment Assignment Code PID1967_V4_0 in PMI CDISC Step Information Standard Form in Enrollment Forms IsPresent Or Treatment Assignment Text PID2002699_V5_0 in PMI CDISC Step Information Standard Form in Enrollment Forms IsPresent Or Disposition Supplemental Qualifiers Dataset Qualifier Data Value Cohort Identifier PID7765265_V1_0 in PMI CDISC Step Information Standard Form in Enrollment Forms IsPresent Or Disposition Supplemental Qualifiers Dataset Qualifier Data Value Stratum Group Category PID7765270_V1_0 in PMI CDISC Step Information Standard Form in Enrollment Forms IsPresent Or Disposition Supplemental Qualifiers Dataset Qualifier Data Value Assignment Reason PID7765280_V1_0 in PMI CDISC Step Information Standard Form in Enrollment Forms IsPresent then... execute the "PMI_TxAssign_doPopulateDetails" custom function

Figure 5: EC to execute CF to derive data from PMI CDISC SI Standard Form to PMI CDISC TA Standard Form

4) Update the Central Study CRF version in the CF PMIZ_CONFIG_getCentralCRFVer.

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

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

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. 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)](#).