

PMI CDISC Treatment Protocol Cohort Migration EC Template Fact Sheet v1.0

The *PMI CDISC Treatment Protocol Cohort Migration Eligibility Checklist (EC) Template (Cancer Data Standards Registry and Repository (caDSR) II Form PID 14019856)* has been built in the caDSR II for the Precision Medicine Initiative (PMI) ComboMATCH and MyeloMATCH protocols. **Use of this form will be protocol-specific; if said protocol includes cohort migration, then this template is required. Accordingly, this template must be used as the starting point for all PMI protocol-specific Eligibility Checklist forms/worksheets related to cohort migration.**

DO NOT edit or change the existing PMI CDISC Eligibility Checklist Template Module/Common Data Element (CDE) details, including the specified Module Names, Short Names/Alternate Names, Permissible Values (PVs)/Permissible Value Meanings (PVMs), and CDE order. These details must be used as-is to support the PMI OPEN-MATCHBox-Rave integrations. Non-standard CDEs can be added as needed to the existing modules.

Refer to Sections I and III for details regarding use and requirements across PMI Treatment protocols for ComboMATCH and MyeloMATCH.

I. Using the PMI CDISC EC Templates to Build a Protocol-specific EC Form/Worksheet:

- 1) Make a copy of the applicable PMI CDISC EC Template (Screening or Treatment) in the caDSR II to begin protocol-specific EC form/worksheet form building activities.
- 2) Use Modules, Short Names/Alternate Names, Question Text, PVs/PVMs/Alt Meanings as specified for each protocol-specific PMI CDISC Eligibility Checklist Template CDE; **DO NOT** edit or change; these details must be used as-is to support the PMI OPEN-MATCHBox-Rave integrations. Conditional and Optional CDEs/fields have been denoted for use on protocol-specific EC forms. Utilize the CDEs/fields/modules for your study (ComboMATCH vs MyeloMATCH) as per details specified in section III.
- 3) Add non-standard and/or protocol-specific CDEs as needed to the **protocol-specific EC form**. *Note regarding the PMI CDISC Treatment Protocol Cohort Migration EC Template modules: any CDEs added to the "Treatment Protocol Module 1" will be displayed in OPEN in the Prerequisite Screen.*
- 4) Create a caDSR Architect Loader Specification (ALS) Download Collection file for the **protocol-specific EC form** via the caDSR II Download Collection module.
- 5) **DO NOT ALTER** any existing details in the caDSR ALS Download Collection file for the **protocol-specific EC form**, including the items specified below; these details must be used as-is to support the PMI OPEN-MATCHBox-Rave integrations.
 - a. *DraftFieldNames + appended integers*
 - b. *FieldOIDs & VariableOIDs*
 - c. *DataDictionaryNames*
 - d. *DataDictionary CodedData & UserDataStrings*

II. Whom to Contact for Assistance:

For assistance with caDSR II technical issues, contact **NCI caDSR Helpdesk Support:**

caDSR.RA@mail.nih.gov.

For assistance with the OPEN/Rave integration, contact the **CTSU OPEN Team:**

CTSUOPENFORMS@westat.com.

III. CDE Requirements for **PMI Treatment Protocol Cohort Migration EC Forms/Worksheets (caDSR II Form PID 14019856)**:

PMI Treatment Protocol Cohort Migration CDE Requirements					
PMI EC CDE PID	PMI EC QT/Prompt	Combo MATCH	Myelo MATCH	OPEN Widget Type	Notes
<i>Treatment Protocol Module 1</i>					
6380045	Screening protocol ID	Conditional*	Optional	Edit Box	Groups should designate this module to the "Pre-Requisite" screen under the OPEN Questions screen. These fields will be (1) validated against the data on the CTSU Demography Standard Form, (2) are required for successful transactions for the PMI CDISC Off Treatment (OT) and PMI CDISC Consent Withdrawal (CW) Forms, and (3) used to validate patient enrollment in OPEN to the correct treatment protocol per treatment assignment from MATCHBox.
6380049	Screening participant ID	Conditional*	Optional	Edit Box	
<i>Treatment Protocol Module 2</i>					
10987207	<p>Cohort migration assignment</p> <p><UPDATED FOR PMI COMMITTEE REVIEW></p> <p>Field Help/Instructional Text</p> <p>"Patients receiving the assigned control treatment who experience disease progression may be eligible to migrate to another cohort and receive combination treatment, provided a slot is available for enrollment into the new cohort. Eligibility criteria should be verified by site staff prior to submitting a request for a cohort migration.</p> <p>**Click on 'Request' to ask for a cohort migration slot (for a patient verified by site staff as eligible per protocol requirements); subsequent review will be initiated to determine a potential cohort migration assignment for the patient.</p> <p>**Click on 'Cancel' to cancel and withdraw an approved request.</p> <p>If a cohort migration assignment is not assigned, an appeal request may be submitted to the PMI ComboMATCH Help Desk for review."</p>	Conditional*	Optional	Data Request	<p>This field will specify the Cohort Migration details for a patient.</p> <p>The Field Help/Instructional Text is for the OPEN Screen; this text will be added to the OPEN Screen by the Westat/CTSU OPEN Team.</p>

*Use of this form is conditional/protocol specific for ComboMATCH; if said ComboMATCH protocol includes cohort migration, then this form and the corresponding fields are required.