

Beta PMI CDISC Eligibility Checklist Template Fact Sheet **v1.1**

The *PMI CDISC Screening Protocol Eligibility Checklist (EC) Template (Cancer Data Standards Registry and Repository (caDSR) II Form PID 11727676)* and the *PMI CDISC Treatment Protocol Eligibility Checklist (EC) Template (caDSR II Form PID 12130477)* have been built in the caDSR II for the Precision Medicine Initiative (PMI) ComboMATCH and MyeloMATCH protocols. **These templates must be used as the starting point for all PMI protocol-specific Eligibility Checklist forms/worksheets.**

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, III, and IV for details regarding use and requirements across PMI Screening and 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. Remove modules not required for your study (ComboMATCH vs MyeloMATCH) as per details specified in sections III and IV.
- 3) Add non-standard and/or protocol-specific CDEs as needed to the **protocol-specific EC form**. *Note regarding the PMI CDISC Treatment Protocol Eligibility Checklist 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 Screening Protocol EC Forms/Worksheets (caDSR II Form PID 11727676):

PMI Screening Protocol CDE Requirements					
PMI EC CDE PID	PMI EC Question Text (QT)/Prompt	Combo MATCH	Myelo MATCH	OPEN Widget Type	Notes
<i>Miscellaneous Module</i>					
7063912	ECOG performance status	Req.	Req.	Radio Group Vertical	These fields assist in determining potential treatment assignment for a patient.
2178058	Hormone Receptor Status	Req.		Radio Group Vertical	
2185607	HER2 Status	Req.		Radio Group Vertical	
<i>Physician's Choice Module</i>					
10987207	Treatment protocol assignment details	Req.		Group Lookup List	The Physician may recommend a preferred protocol treatment assignment for a patient.
7765280	Clinical justification	Req.		Text Area	
<i>Patient Fitness Module</i>					
12100429	Is the patient fit for intensive chemotherapy?		Req.	Radio Group Vertical	The Physician's determination of a patient's fitness for potential intensive or non-intensive chemotherapy treatment assignment.
<i>DLAP Module</i>					
12053081	LAB internal tracking ID	Req.		Edit Box	These fields support the PMI Designated Lab Automation Program (DLAP) integration.
12053083	Processing laboratory name	Req.		Dropdown Box	
8177505	DLAP Scenario ID	Req.		Edit Box	
<i>Drug & Disease Service Module 1 (disease): these fields support the PMI Disease Service integration.</i>					
10948385	Topography	Req.	Req.	Type Ahead List	This field will be populated by the disease service with an ICD-O-3 topography site/subsite.
10948388	Morphology	Req.	Req.	Type Ahead List	This field will be populated by the disease service with a histology + behavior code.
10983888	Grade	Req.	Req.	Radio Group Vertical	This field captures the grade or level of differentiation of malignant neoplasms.
<i>Drug & Disease Service Module 2 (drug): this field supports the PMI Drug Service integration.</i>					
10984702	Prior therapy name	Req.	Req.	Type Ahead List	This field will be populated with pharmacological substance/drug details per the NCI Thesaurus. Twenty occurrences of this CDE are specified in the PMI CDISC EC Template.

IV. CDE Requirements for PMI Treatment Protocol EC Forms/Worksheets (caDSR II Form PID 12130477):

PMI Treatment Protocol 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	Req.	Req.	Edit Box	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	Req.	Req.	Edit Box	
<i>Treatment Protocol Module 2</i>					
7765265	Cohort	Req.	Req.	Group Lookup List	These fields will specify the Treatment Protocol details for a patient.
7765270	Stratum	Req.	Req.		