

PMI CDISC Screening Protocol Eligibility Checklist Template Fact Sheet v2.0

The **PMI CDISC Screening Protocol Eligibility Checklist (EC) Template (Cancer Data Standards Registry and Repository (caDSR) II Form PID 11727676 v2.0)** has been built in the caDSR II for the Precision Medicine Initiative (PMI) ComboMATCH and MyeloMATCH protocols. **This template must be used as the starting point for all PMI Screening protocol-specific Eligibility Checklist forms/worksheets.**

DO NOT edit or change the existing PMI CDISC Screening Protocol 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. Additional CDEs (standard and non-standard) can be added as needed to the existing modules.

Refer to Sections I and III for details regarding use and requirements across PMI Screening 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 Screening Protocol EC Template 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 Screening Protocol Eligibility Checklist Template CDE; **DO NOT** edit or change; these details must be used as-is to support the PMI OPEN-MATCHBox-Rave integrations. Mandatory and Optional CDEs/fields have been denoted for use on protocol-specific EC forms. Remove modules/CDEs that are not mandatory/will not be collected for your study (ComboMATCH vs MyeloMATCH) as per details specified in section III.
- 3) Add **additional standard**/non-standard and/or protocol-specific CDEs as needed to the **protocol-specific EC form**. *Note regarding the modules: any CDEs added to the "Screening 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 v2.0):

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	Mandatory	Mandatory	Radio Group Vertical	Assists in determining potential treatment assignment for a patient.
2178058	Hormone receptor status	Mandatory	Optional	Radio Group Vertical	
2185607	HER2 status	Mandatory	Optional	Radio Group Vertical	
<i>Physician's Choice Module</i>					
10987207	Treatment protocol assignment details	Mandatory	Optional	Group Lookup List	The Physician may recommend a preferred protocol treatment assignment for a patient.
7765280	Clinical justification	Mandatory	Optional	Text Area	
<i>Patient Fitness Module</i>					
12100429	Is the patient fit for intensive chemotherapy?	Optional	Mandatory	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	Mandatory	Optional	Edit Box	Supports the PMI Designated Lab Automation Program (DLAP) integration. The DLAP Scenario ID field is mandatory to be on the EC form but may be left blank by the site user; site entry is based on if the data has/hasn't yet been confirmed in DLAP.
12932659	Processing laboratory name	Mandatory	Optional	Group Lookup List	
8177505	DLAP scenario ID	Mandatory	Optional	Edit Box	
<i>Drug & Disease Service Module 1 (disease): these fields support the PMI Disease Service integration.</i>					
10948385	Topography	Mandatory	Optional	Type Ahead List	Populated by the disease service with an ICD-O-3 topography site/subsite.
10948388	Histology	Mandatory	Optional	Type Ahead List	Populated by the disease service with a histology code.
13345476	Tumor behavior code	Mandatory	Optional	Type Ahead List	Captures the behavior code.
10983888	Grade	Mandatory	Optional	Radio Group Vertical	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	Mandatory	Mandatory	Type Ahead List	Populated with pharmacological substance/drug details per the NCI Thesaurus. Twenty occurrences of this CDE are specified in the PMI CDISC Screening Protocol EC Template.