PMI CDISC Screening Protocol Eligibility Checklist Template Fact Sheet v3.0

The *PMI CDISC Screening Protocol Eligibility Checklist (EC) Template* **(Cancer Data Standards Registry and Repository (caDSR) II Form PID 11727676 v3.0)** 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.

PMI Screening Protocol CDE Requirements					
PMI EC CDE PID	**PMI EC Question Text (QT)/Prompt**	**Combo MATCH**	**Myelo MATCH**	**OPEN Widget Type**	**Notes**
Miscellaneous Module					
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	
Physician's Choice Module					
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	
Patient Fitness Module					
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.
DLAP Module					
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	
13567050	**Genetic sample type**	Mandatory	*Optional*	Radio Group Vertical	This set of questions is repeated two times within the DLAP Module.
8177553	**Collection date**	Mandatory	*Optional*	Date Field 3 Part	
Drug & Disease Service Module 1 (disease): these fields support the PMI Disease Service integration.					
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.
Drug & Disease Service Module 2 (drug): this field supports the PMI Drug Service integration.					
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.