PMI CDISC Eligibility Checklist Template Fact Sheet v1.0

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. Mandatory and Conditional CDEs/fields have been denoted; the remaining fields are optional for use on protocol-specific EC forms. Remove modules that are not mandatory 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 <u>PMI Screening Protocol</u> EC Forms/Worksheets (caDSR II Form PID 11727676):

PMI EC CDE PID	PMI EC Question Text (QT)/Prompt	Combo MATCH	Myelo MATCH	OPEN Widget Type	Notes
PMI Screening Protocol CDE Requirements					
Miscellaneous Module					
7063912	**ECOG performance status**	Mandatory	Mandatory	Radio Group Vertical	These fields assist in determining potential treatment assignment for a patient.
2178058	**Hormone Receptor Status**	Mandatory		Radio Group Vertical	
2185607	**HER2 Status**	Mandatory		Radio Group Vertical	
Physician's Choice Module					
10987207	**Treatment protocol assignment details**	Mandatory		Group Lookup List	The Physician may recommend a preferred protocol treatment assignment for a patient.
7765280	**Clinical justification**	Mandatory		Text Area	
Patient Fitness Module					
12100429	**Is the patient fit for intensive chemotherapy?**		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		Edit Box	These fields support 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.
12053083	**Processing laboratory name**	Mandatory		Dropdown Box	
8177505	**DLAP Scenario ID**	Mandatory		Edit Box	
Drug & Disease Service Module 1 (disease): these fields support the PMI Disease Service integration.					
10948385	**Topography**	Mandatory		Type Ahead List	This field will be populated by the disease service with an ICD-O-3 topography site/subsite.
10948388	**Morphology**	Mandatory	Mandatory	Type Ahead List	This field will be populated by the disease service with a histology + behavior code.
10983888	**Grade**	Mandatory		Radio Group Vertical	This field 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	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 Screening Protocol EC Template.

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

PMI EC CDE PID	PMI EC QT/Prompt	Combo MATCH	Myelo MATCH	OPEN Widget Type	Notes
PMI Treatment Protocol CDE Requirements					
Treatment Protocol Module 1					
6380045	**Screening protocol ID**	Mandatory	Mandatory	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**	Mandatory	Mandatory	Edit Box	
Treatment Protocol Module 2					
7765265	**Cohort**	Conditional	Conditional	Group Lookup List	These fields will specify the Treatment Protocol details for a patient. Inclusion of these fields is dependent upon protocol design:
7765270	**Stratum**	Conditional	Conditional		— The Cohort and/or Stratum field must be on the EC if randomization is required for treatment (i.e., the protocol has more than one Treatment/Cohort/Arm that a patient may be randomized to). One of these fields or both fields might be included on the project-specific TX EC. — The Cohort and Stratum fields need not be on the EC if no randomization is required for treatment (i.e., the protocol only has one treatment available for a patient.