

## PMI CDISC MSRP Re-Screening Eligibility Checklist Template Fact Sheet v2.0

The **PMI CDISC MSRP Re-Screening Eligibility Checklist (EC) Template (Cancer Data Standards Registry and Repository (caDSR) II Form PID 14096450 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 MSRP Re-Screening protocol-specific Eligibility Checklist forms/worksheets.**

**DO NOT edit or change** the existing PMI CDISC MSRP Re-Screening 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 MSRP Re-Screening 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](mailto:caDSR.RA@mail.nih.gov).

For assistance with the OPEN/Rave integration, contact **the CTSU OPEN Team:**  
[CTSUOPENFORMS@westat.com](mailto:CTSUOPENFORMS@westat.com).

III. CDE Requirements for PMI MSRP Re-Screening EC Forms/Worksheets (caDSR II Form PID 14096450 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>					
14148234	Treatment tier for patient re-screening	Optional	Mandatory	Radio Group Vertical	Assists in determining potential treatment assignment for patient re-screening.
7063912	ECOG performance status	Mandatory	Mandatory	Radio Group Vertical	Assists in determining potential treatment assignment for a patient.
<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. This set of questions is repeated two times within the DLAP Module.
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	
8177553	Collection date	Mandatory	Optional	Date Field 3 Part	
<i>Drug Service Module: this field supports the PMI Drug Service integration.</i>					
10984702	<p>Prior therapy name</p> <p>MyeloMATCH Field Help/Instructional Text</p> <p>"Please report if the patient has received All Trans Retinoic Acid (ATRA), Hydroxyurea, Leukapheresis, low-dose cytarabine, lenalidomide, any BCR-ABL tyrosine kinase inhibitor, erythropoiesis-stimulating agent, or thrombopoietin receptor agonist."</p>	Optional	Mandatory	Type Ahead List	<p>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.</p> <p>The Field Help/Instructional Text is for the OPEN Screen and specific to MyeloMATCH; the Westat/CTSU OPEN Team will add this text to the OPEN Screen. This text must be used as-is and should not be updated/modified.</p>