

PMI CDISC **Treatment Protocol** Eligibility Checklist Template Fact Sheet v1.1***

*** This is an administrative update and versioning to the PMI CDISC Treatment Protocol Eligibility Checklist (EC) Template Fact Sheet only; no changes have been made to Form PID 12130477 v1.0). ***

The PMI CDISC Treatment Protocol Eligibility Checklist (EC) Template (Cancer Data Standards Registry and Repository (caDSR) II Form PID 12130477) 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 Treatment (TX) protocol-specific Eligibility Checklist forms/worksheets.**

DO NOT edit or change the existing PMI CDISC Treatment 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 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 Treatment 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 Treatment 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 Conditional CDEs/fields have been denoted for use on protocol-specific EC forms. Remove modules that are not mandatory 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 "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 Treatment Protocol EC Forms/Worksheets (caDSR II Form PID 12130477 v1.0):

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	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	
<i>Treatment Protocol Module 2</i>					
7765265	Cohort	Conditional	Conditional	Group Lookup List	<p>These fields will specify the Treatment Protocol details for a patient. Inclusion of these fields is dependent upon protocol design:</p> <ul style="list-style-type: none"> – 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 do not need to be specified on the EC if no randomization is required for treatment (i.e., the protocol only has one treatment available for a patient).
7765270	Stratum	Conditional	Conditional		