# Beta 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. Remove modules not required 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 Screening Protocol CDE Requirements

| PMI EC CDE PID | PMI EC Question Text (QT)/Prompt | Combo MATCH | Myelo MATCH | Notes |
|---|---|---|---|---|
| *Miscellaneous Module* | | | | |
| 7063912 | ECOG performance status | Req. | Req. | These fields assist in determining potential treatment assignment for a patient. |
| 2178058 | Hormone Receptor Status | Req. | | |
| 2185607 | HER2 Status | Req. | | |
| *Physician's Choice Module* | | | | |
| 10987207 | Treatment protocol assignment details | Req. | | The Physician may recommend a preferred protocol treatment assignment for a patient. |
| 7765280 | Clinical justification | Req. | | |
| *Patient Fitness Module* | | | | |
| 12100429 | Is the patient fit for intensive chemotherapy? | | Req. | 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 | Req. | | These fields support the PMI Designated Lab Automation Program (DLAP) integration. |
| 12053083 | Processing laboratory name | Req. | | |
| 8177505 | DLAP Scenario ID | Req. | | |
| *Drug & Disease Service Module 1 (disease): these fields support the PMI Disease Service integration.* | | | | |
| 10948385 | Topography | Req. | Req. | This field will be populated by the disease service with an ICD-O-3 topography site/subsite. |
| 10948388 | Morphology | Req. | Req. | This field will be populated by the disease service with a histology + behavior code. |
| 10983888 | Grade | Req. | Req. | This field captures the grade or level of differentiation of malignant neoplasms. |
| *Drug & Disease Service Module 2 (drug): these fields support the PMI Drug Service integration.* | | | | |
| 10984702 | Prior therapy name | Req. | Req. | These fields will be populated with pharmacological substance/drug details per the NCI Thesaurus. Twenty occurrences of each CDE are specified in the PMI CDISC EC Template. |
| 10984716 | Prior therapy code | Req. | Req. | |
| 10987188 | Prior therapy code type | Req. | Req. | |

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

## PMI Treatment Protocol CDE Requirements

| PMI EC CDE PID | PMI EC QT/Prompt | Combo MATCH | Myelo MATCH | Notes |
|---|---|---|---|---|
| *Treatment Protocol Module 1* | | | | |
| 6380045 | Screening protocol ID | Req. | Req. | 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 | Req. | Req. | |
| *Treatment Protocol Module 2* | | | | |
| 7765265 | Cohort | Req. | Req. | These fields will specify the Treatment Protocol details for a patient. |
| 7765270 | Stratum | Req. | Req. | |