

Minimum Data Set Overview

The Minimum Data Set (MDS) is a collection of specified administrative, participant demographic, and adverse event (AE) data that serves as a primary source of information about National Cancer Institute (NCI) Division of Cancer Prevention (DCP)-supported clinical trials.

The Data Management, Auditing, and Statistical Center (DMASC) submits the MDS reports for each active study to DCP each month. The DCP Regulatory Contractor and DCP review the MDS reports and inform the LAO and DMASC of any queries that they have based on their review. Depending on the workflow determined between the LAO and DMASC, either the LAO or DMASC sends queries on behalf of the DCP Regulatory Contractor and DCP via email or in Medidata Rave (Rave). Accruing LAOs and AOs are responsible for addressing these queries within 14 calendar days. See [REFGD03 CP-CTNet Master Data Management Plan](#) for more information about addressing queries.

MDS Participant Demographic Data in Rave

The participant demographic data included in the MDS reports come from multiple electronic Case Report Forms (eCRFs) in Rave. The table below includes the participant demographic MDS data elements alongside their associated Rave field(s) and eCRF(s).

Note: If a data element is associated with more than one eCRF for a study, accruing LAOs and AOs need to check both eCRFs in Rave to determine where the data issue is located. DMASC only expects accruing LAOs and AOs to report each data element on one of the available eCRFs. For example, if a data element is associated with both the *CP-CTNet Pre-Screening Form* and *Demography* eCRFs, accruing LAOs and AOs report this data element at pre-screening (if available) on the *CP-CTNet Pre-Screening Form*. If the data element is not available at pre-screening, accruing LAOs and AOs report this data element on the *Demography* eCRF instead.

Data Element	Rave Field(s) and eCRF(s)
<i>Protocol Number</i>	<ul style="list-style-type: none"> N/A, populated by DMASC.
<i>Participant ID</i>	<ul style="list-style-type: none"> N/A, populated by DMASC.
<i>Participant ZIP Code</i>	<ul style="list-style-type: none"> Participant Zip Code field on <i>Demography</i> eCRF.
<i>Participant Country</i>	<ul style="list-style-type: none"> Participant Country Code field on <i>Demography</i> eCRF.
<i>Participant Birth Date</i>	<ul style="list-style-type: none"> Birth Date field on <i>CP-CTNet Pre-Screening Form</i> and <i>Demography</i> eCRFs.
<i>Participant Sex</i>	<ul style="list-style-type: none"> Sex field on <i>CP-CTNet Pre-Screening Form</i> and <i>Demography</i> eCRFs.
<i>Participant Ethnicity</i>	<ul style="list-style-type: none"> Ethnicity field on <i>CP-CTNet Pre-Screening Form</i> and <i>Demography</i> eCRFs.
<i>Participant Race</i>	<ul style="list-style-type: none"> Race fields on <i>CP-CTNet Pre-Screening Form</i> and <i>Demography</i> eCRFs.
<i>Informed Consent Date</i>	<ul style="list-style-type: none"> Consent Date field on <i>CP-CTNet Pre-Screening Form</i> eCRF.
<i>Screen 1 Date</i>	<ul style="list-style-type: none"> Screen 1 Date field on <i>CP-CTNet Screening Form</i> eCRF.
<i>Screen 2 Date</i>	<ul style="list-style-type: none"> Screen 2 Date field on <i>CP-CTNet Screening Form</i> eCRF.
<i>Registration Date</i>	<ul style="list-style-type: none"> Registration Date field on <i>Registration/Randomization</i> eCRF.
<i>Randomization Date</i>	<ul style="list-style-type: none"> Randomized studies: Randomization Date field on <i>Registration/Randomization</i> eCRF. Non-randomized studies: N/A, not included on any Rave eCRFs.
<i>Eligibility Status</i>	<ul style="list-style-type: none"> Is participant eligible for inclusion on this protocol? field on <i>Registration/Randomization</i> eCRF.
<i>Participant Enrollment Date</i>	<ul style="list-style-type: none"> Participant Enrollment Date field on <i>Registration/Randomization</i> eCRF.

Data Element	Rave Field(s) and eCRF(s)
<i>Registering Consortium</i>	<ul style="list-style-type: none"> Registering LAO field on <i>Demography</i> eCRF.
<i>Registering Institution</i>	<ul style="list-style-type: none"> N/A, populated by DMASC.
<i>Participant Method of Payment</i>	<ul style="list-style-type: none"> Participant Method of Payment field on <i>Demography</i> eCRF.
TAC	<ul style="list-style-type: none"> Studies that do not include within-participant dose escalations: Treatment Assignment Code (TAC) field on <i>Intervention Administration</i> eCRF. Studies that include within-participant dose escalations: TAC field on <i>Study Treatment</i> eCRF.
TAD	<ul style="list-style-type: none"> N/A, populates automatically on the MDS report based on the TAC. Note: The TAD does not come from Rave.
<i>Intervention Start Date</i>	<ul style="list-style-type: none"> Agent Start Date field on <i>Intervention Administration</i> eCRF.
<i>Intervention End Date</i>	<ul style="list-style-type: none"> Agent End Date field on <i>Intervention Administration</i> eCRF.
<i>Off Study Date</i>	<ul style="list-style-type: none"> Off Study Date field on <i>Off Study</i> eCRF.
<i>Off Study Reason</i>	<ul style="list-style-type: none"> Off Study Reason field on <i>Off Study</i> eCRF.
<i>Off Study Reason Details</i>	<ul style="list-style-type: none"> Reason Off Study, Specify field on <i>Off Study</i> eCRF.

MDS AE Data in Rave

The AE data included in the MDS reports come from the *Adverse Events* eCRF in Rave. The table below includes the AE MDS data elements alongside their associated Rave field(s).

Data Element	Rave Field(s)
<i>Participant ID</i>	<ul style="list-style-type: none"> N/A, populated by DMASC.
TAC	<ul style="list-style-type: none"> TAC field.
<i>Adverse Event Verbatim Term</i>	<ul style="list-style-type: none"> Adverse Event Verbatim Term field.
<i>CTCAE Category</i>	<ul style="list-style-type: none"> MedDRA System Organ Class field.
<i>CTCAE Term</i>	<ul style="list-style-type: none"> CTCAE Term field.
<i>Other, Specify</i>	<ul style="list-style-type: none"> Studies that involve a vaccine or immunologic agent for which anticipated, acute reactions (local and/or systemic) are similar to those described in protocol section 13.1.3.2 for vaccines and use CTCAE V6.0: Other, Specify field. Studies that do not involve a vaccine or immunologic agent for which anticipated, acute reactions (local and/or systemic) are similar to those described in protocol section 13.1.3.2 for vaccines and use CTCAE V6.0: N/A, not included in the MDS report.
<i>AE Grade</i>	<ul style="list-style-type: none"> AE Grade field.
<i>AE Grade Meaning</i>	<ul style="list-style-type: none"> N/A, populates automatically on the MDS report based on the <i>AE Grade</i>. Note: The <i>AE Grade Meaning</i> does not come from Rave.
<i>AE Attribution</i>	<ul style="list-style-type: none"> AE Attribution field.
<i>Reported as SAE</i>	<ul style="list-style-type: none"> Reported as SAE? field.
<i>Event Onset Date</i>	<ul style="list-style-type: none"> Event Onset Date field.
<i>Event End Date</i>	<ul style="list-style-type: none"> Event End Date field.
<i>Dropped Due to AE?</i>	<ul style="list-style-type: none"> Dropped due to AE? field.
<i>Outcome</i>	<ul style="list-style-type: none"> Outcome field.

Who to Contact

For any questions or comments regarding the MDS, please contact the DCP Protocol Information Office (PIO) by phone at (240) 276-7130 or email at NCI_DCP_PIO@mail.nih.gov.

For any questions or comments regarding the MDS queries sent by DMASC, please contact the DMASC Data Management team by email at DataManagement_CP-CTNet@frontierscience.org.

References

Resource	ID	Location
MDS Guidelines	Reference	prevention.cancer.gov