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 report 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 in Rave.

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 definitions and associated Rave 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, DMASC expects accruing LAOs and AOs to 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	Definition (adapted from MDS Guidelines)	Rave eCRF(s)
Protocol Number	• The unique alphanumeric identifier assigned to a protocol by DCP.	• N/A, populated internally.
Participant ID	• The Participant Identifier (ID) is a unique numeric or alphanumeric identification assigned to a participant in a clinical trial or research study.	• N/A, populated internally.
Participant ZIP Code	• The string of characters used to identify the five-digit zone improvement plan (ZIP) code and the four-digit extension code (if available) that represents the geographic segment that is a subunit of the ZIP code, assigned by the United States (US) Postal Service to a geographic location to facilitate mail delivery; or the postal zone specific to the country, other than the US, where the mail is delivered.	• All studies except UAZ20-01-01 and UAZ20-01-02: *Demography*. • UAZ20-01-01 and UAZ20-01-02: *Registration*.
Participant Country	• The code that represents the country where the addressee is located.	• All studies except UAZ20-01-01 and UAZ20-01-02: *Demography*. • UAZ20-01-01 and UAZ20-01-02: *Registration*.
Participant Birth Date	• The month and year on which the person was born.	• All studies except UAZ20-01-01 and UAZ20-01-02: *CP-CTNet Pre-Screening Form* or *Demography*. • UAZ20-01-01: *CP-CTNet Pre-Screening Form* or *Registration*.

Data Element	Definition (adapted from MDS Guidelines)	Rave eCRF(s)
		• UAZ20-01-02: *Registration*.
Participant Sex	• Text designations that identify gender. Gender is described as the assemblage of properties that distinguish people on the basis of their societal roles. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.	• All studies except UAZ20-01-01 and UAZ20-01-02: *CP-CTNet Pre-Screening Form* or *Demography*. • UAZ20-01-01: *CP-CTNet Pre-Screening Form* or *Registration*. • UAZ20-01-02: *Registration*.
Participant Ethnicity	• The text for reporting information about ethnicity based on the Office of Management and Budget (OMB) categories.	• All studies except UAZ20-01-01 and UAZ20-01-02: *CP-CTNet Pre-Screening Form* or *Demography*. • UAZ20-01-01: *CP-CTNet Pre-Screening Form* or *Registration*. • UAZ20-01-02: *Registration*.
Participant Race	• The text for reporting information about race based on the OMB categories.	• All studies except UAZ20-01-01 and UAZ20-01-02: *CP-CTNet Pre-Screening Form* or *Demography*. • UAZ20-01-01: *CP-CTNet Pre-Screening Form* or *Registration*. • UAZ20-01-02: *Registration*.
Informed Consent Date	• The date on which the patient/participant/legal representative agrees OR disagrees to participation in a protocol, treatment, or other activity by signing an informed consent document.	• All studies except UAZ20-01-01 and UAZ20-01-02: *CP-CTNet Pre-Screening Form*. • UAZ20-01-01: *CP-CTNet Pre-Screening Form* or *Registration*. • UAZ20-01-02: *Registration*.
Screen 1 Date	• Date participant completes Screen 1.	• All studies except UAZ20-01-01 and UAZ20-01-02: *CP-CTNet Screening Form*. • UAZ20-01-01: *CP-CTNet Screening Form* or *Registration*. • UAZ20-01-02: *Registration*.
Screen 2 Date	• Date participant completes Screen 2.	• All studies except UAZ20-01-01 and UAZ20-01-02: *CP-CTNet Screening Form*. • UAZ20-01-01: *CP-CTNet Screening Form* or *Registration*. • UAZ20-01-02: *Registration*.
Registration Date	• The date the participant was enrolled on the protocol.	• All studies: *Registration* or *Registration/Randomization*.
Randomization Date	• Date of a process used in therapeutic trials or other research endeavors for allocating experimental subjects, human or animal, between treatment and control groups, or among treatment groups.	• All randomized studies: *Registration* or *Registration/Randomization*. • All non-randomized studies: N/A, not included on any Rave eCRFs.
Eligibility Status	• The yes/no indicator that asks the investigator to stipulate whether the participant is eligible for inclusion on this protocol.	• All studies: *Registration* or *Registration/Randomization*.

Data Element	Definition (adapted from MDS Guidelines)	Rave eCRF(s)
Participant Enrollment Date	• The date the participant is accepted into the study. The study site may also be notified to the treatment arm and Study Participant Identifier on this date.	• All studies: *Registration* or *Registration/Randomization*.
Registering Consortium	• The designation of a consortium that will be officially recorded as the registering consortium for the study.	• All studies except UAZ20-01-01 and UAZ20-01-02: *Demography*. • UAZ20-01-01: *Registration*. • UAZ20-01-02: *Pre-Registration*.
Registering Institution	• Code that uniquely identifies the institution where the research participant was registered in a clinical trial.	• N/A, populated internally.
Participant Method of Payment	• Text term for an entity, organization, government, corporation, health plan sponsor, or any other financial agent who pays a healthcare provider for the healthcare service rendered to a person or reimburses the cost of the healthcare service.	• All studies except UAZ20-01-01 and UAZ20-01-02: *Demography*. • UAZ20-01-01 and UAZ20-01-02: *Registration*.
TAC	• *Treatment Assignment Code (TAC)* is a coded value representing a treatment assigned to be uniformly administered to a group of study subjects for separate statistical analysis.	• All studies except NWU20-01-03 and UAZ20-01-02: *Intervention Administration*. • NWU20-01-03 and UAZ20-01-02: *Registration*.
TAD	• *Treatment Assignment Description (TAD)* is the free-text field to capture the assignment to a specific treatment.	• N/A, populates automatically on the MDS report based on the *TAC*. **Note:** The *TAD* does not come from Rave.
Intervention Start Date	• The start date for the administration of the intervention.	• All studies except NWU20-01-03 and UAZ20-01-02: *Intervention Administration*. • NWU20-01-03: *Registration*. • UAZ20-01-02: N/A, extended follow-up study.
Intervention End Date	• The end date for the administration of the intervention.	• All studies except NWU20-01-03 and UAZ20-01-02: *Intervention Administration*. • NWU20-01-03: *Registration*. • UAZ20-01-02: N/A, extended follow-up study.
Off Study Date	• The date when the participant is removed from the protocol (i.e., is not being followed and will not be retreated).	• All studies: *Off Study*.
Off Study Reason	• Choice of reasons for removing a participant from a clinical trial.	• All studies: *Off Study*.
Off Study Reason Details	• The text that describes the reason the participant went off study.	• All studies: *Off Study*.

MDS AE Data in Rave

The AE data included in the MDS reports come from the *Adverse Events* eCRF in Rave. **Note:** The *AE Grade Meaning* populates automatically on the MDS report based on the *AE Grade*. The *AE Grade Meaning* does not come from Rave. The table below includes the AE MDS data elements alongside their definitions.

Data Element	Definition (adapted from MDS Guidelines)
Participant ID	• The unique numeric or alphanumeric identification assigned to a participant in a clinical trial or research study.
TAC	• *Treatment Assignment Code (TAC)* is a coded value representing a treatment assigned to be uniformly administered to a group of study subjects for separate statistical analysis.
Adverse Event Verbatim Term	• The text that describes the AE word for word as described by the participant.
CTCAE Category	• The *Common Terminology Criteria for Adverse Events (CTCAE) Category* is based on the Medical Dictionary for Regulatory Activities (MedDRA) System Organ Class (SOC) text term. This text term represents the highest level of a terminology distinguished by anatomical or physiological system, etiology, or purpose, and referencing an international medical terminology (MedDRA, version 12.0), designed to support the classification, retrieval, presentation, and communication of medical information throughout the medical product regulatory cycle.
CTCAE Term	• Text that represents the CTCAE lowest level term name for an AE.
AE Grade	• Numeric representation of the intensity/severity of an unfavorable and unintended sign (including an abnormal laboratory finding), symptom, syndrome, or disease, temporally associated with the use of a medical product or procedure, regardless of whether or not it is considered related to the product or procedure (attribution of unrelated, unlikely, possible, probable, or definite).
AE Grade Meaning	• Definition of the assigned *AE Grade*.
AE Attribution	• Relation of the causality between the treatment modality and the specific AE.
Reported as SAE	• The code representing whether the event was reported as a serious adverse event (SAE).
Event Onset Date	• The date on which the AE was first evident.
Event End Date	• The last or final date of an AE, described using a date or a text response such as Ongoing or Unknown.
Dropped Due to AE?	• Did the participant stop participation due to the AE?
Outcome	• The final status of the participant related to the AE.

Who to Contact with MDS Questions and Comments

MDS Questions and Comments

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

MDS Queries

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

References

Resource	ID	Location
MDS Guidelines	Reference	prevention.cancer.gov