# CDISC TMF Controlled Terminology, 2024-09-27

Source: NCI EVS Terminology Resources website: http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc

| NCI Code | CDISC Submission Value | Codelist Name | CDISC Definition | Codelist Extensible |
|---|---|---|---|---|
| C208283 | Central and Local Testing Zone | Central and Local Testing Zone | The terminology codelist for the Trial Master File Reference Model that contains the sections and artifacts relevant to the Central and Local Testing Zone. | |
| C208277 | Central Trial Documents Zone | Central Trial Documents Zone | The terminology codelist for the Trial Master File Reference Model that contains the sections and artifacts relevant to the Central Trial Documents Zone. | |
| C208285 | Data Management Zone | Data Management Zone | The terminology codelist for the Trial Master File Reference Model that contains the sections and artifacts relevant to the Data Management Zone. | |
| C208281 | IP and Trial Supplies Zone | IP and Trial Supplies Zone | The terminology codelist for the Trial Master File Reference Model that contains the sections and artifacts relevant to the IP and Trial Supplies Zone. | |
| C208279 | IRB or IEC and Other Approvals Zone | IRB or IEC and Other Approvals Zone | The terminology codelist for the Trial Master File Reference Model that contains the sections and artifacts relevant to the IRB or IEC and Other Approvals Zone. | |
| C208278 | Regulatory Zone | Regulatory Zone | The terminology codelist for the Trial Master File Reference Model that contains the sections and artifacts relevant to the Regulatory Zone. | |
| C208282 | Safety Reporting Zone | Safety Reporting Zone | The terminology codelist for the Trial Master File Reference Model that contains the sections and artifacts relevant to the Safety Reporting Zone. | |
| C208280 | Site Management Zone | Site Management Zone | The terminology codelist for the Trial Master File Reference Model that contains the sections and artifacts relevant to the Site Management Zone. | |
| C208286 | Statistics Zone | Statistics Zone | The terminology codelist for the Trial Master File Reference Model that contains the sections and artifacts relevant to the Statistics Zone. | |
| C208284 | Third Parties Zone | Third Parties Zone | The terminology codelist for the Trial Master File Reference Model that contains the sections and artifacts relevant to the Third Parties Zone. | |
| C208287 | TMF-RM Sections | TMF-RM Sections | The terminology codelist for the Sections associated with the Trial Master File Reference Model. | |
| C208275 | TMF-RM Zones | TMF-RM Zones | The terminology codelist for the Zones associated with the Trial Master File Reference Model. | |
| C208276 | Trial Management Zone | Trial Management Zone | The terminology codelist for the Trial Master File Reference Model that contains the sections and artifacts relevant to the Trial Management Zone. | |

## Central and Local Testing Zone (Central and Local Testing Zone)

NCI Code: C208283, Codelist extensible:

| C208283 | Central and Local Testing Zone | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C207194 | Certification or Accreditation | | Documentation verifying the competence of a testing facility by an accrediting body. | Testing Facility Certification or Accreditation Documentation |
| C207177 | Filenote | | Documentation pertaining to any decision or clarifying any information of the clinical trial, but not specifically listed in this Reference Model. | Clinical Trial Filenote Documentation |
| C207199 | Head of Facility Curriculum Vitae | | Documentation detailing the education, qualification and work experience of the head of the testing facility participating in the clinical trial. | Clinical Trial Head of Facility Curriculum Vitae Documentation |
| C207196 | Laboratory Results Documentation | | Documentation of laboratory results for the clinical trial. | Clinical Trial Laboratory Results Documentation |
| C207195 | Laboratory Validation Documentation | | Documentation verifying the ability of a laboratory to produce consistent and reliable results for the clinical trial. | Clinical Trial Laboratory Validation Documentation |
| C207197 | Manual | | Documentation describing the procedures for collection, handling, and shipping of specimens for the clinical trial. | Clinical Trial Testing Facility Manual Documentation |
| C207176 | Meeting Material | | Documentation pertaining to meetings not otherwise listed in the Reference Model. | Clinical Trial Meeting Material Documentation |
| C71474 | Normal Ranges | | Documentation defining the acceptable limits for a measurement assessed for the clinical trial. | Reference Range |
| C115570 | Record of Retained Samples | | Documentation pertaining to the identification and location of retained specimens for the clinical trial. | Clinical Trial Record of Retained Biological Samples Documentation |
| C207174 | Relevant Communications | | Documentation pertaining to agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. | Clinical Trial Relevant Communications Documentation |
| C115635 | Sample Import or Export Documentation | | Documentation pertaining to the importation or exportation of specimens for the clinical trial. | Clinical Trial Biological Sample Import or Export Documentation |
| C115535 | Sample Storage Condition Log | | Documentation detailing the monitoring and tracking of the specimens storage conditions for the clinical trial. | Clinical Trial Biological Sample Storage Condition Log Documentation |
| C207200 | Shipment Records | | Documentation detailing the shipment of specimens for the clinical trial. | Clinical Trial Specimen Shipment Records Documentation |
| C115528 | Specimen Label | | Documentation detailing the identification and collection of a specimen for the clinical trial. | Clinical Trial Specimen Label Documentation |
| C115653 | Standardization Methods | | Documentation confirming the ability of two or more testing facilities to achieve consistent results when performing the same test or procedure for the clinical trial. | Clinical Trial Interfacility Standardization Methods Documentation |
| C207198 | Supply Import Documentation | | Documentation pertaining to the importation of testing facility supplies for the clinical trial. | Clinical Trial Supply Import Documentation |
| C207175 | Tracking Information | | Documentation pertaining to the tracking of clinical trial activities, but not specifically listed in this Reference Model. | Clinical Trial Tracking Information Documentation |

## Central Trial Documents Zone (Central Trial Documents Zone)

NCI Code: C208277, Codelist extensible:

| C208277 | Central Trial Documents Zone | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C115462 | Advertisements for Subject Recruitment | | Template documentation used in the clinical trial recruitment campaigns. | Clinical Trial Subject Recruitment Advertisement Documentation |
| C115573 | Bioanalytical Report | | Documentation describing final or interim results of the bioanalytical aspects of the clinical trial. | Clinical Trial Bioanalytical Report Documentation |
| C79176 | Clinical Study Report | | Documentation describing final or interim results and interpretation of the clinical trial. | Clinical Trial Reports and Related Information Documentation |
| C207177 | Filenote | | Documentation pertaining to any decision or clarifying any information of the clinical trial, but not specifically listed in this Reference Model. | Clinical Trial Filenote Documentation |
| C207179 | Financial Disclosure Summary | | Documentation summarizing the financial interests and arrangements of the investigator(s) for the clinical trial. | Clinical Trial Investigators Financial Disclosure Form Summary Documentation |
| C208325 | Informed Consent Form | | Template documentation used to explain that the appropriate information has been given to subjects regarding the clinical trial to support their ability to give fully informed consent and to document their consent to trial participation in writing. | Template Informed Consent Form Documentation |
| C115651 | Insurance | | Documentation confirming appropriate insurance coverage is available for the clinical trial. | Clinical Trial Insurance Documentation |
| C115526 | Investigator's Brochure | | Documentation providing relevant and current clinical and non-clinical data on the investigational product(s) that is related to the study of the product(s) in human subjects. | Clinical Trial Investigator Brochure Documentation |
| C207180 | Marketed Product Material | | Documentation of materials found in the legal pharmacologic description of the clinical trial investigational product(s). | Marketed Clinical Trial Investigational Product Material Legal Documentation |
| C207176 | Meeting Material | | Documentation pertaining to meetings not otherwise listed in the Reference Model. | Clinical Trial Meeting Material Documentation |
| C115518 | Other Information Given to Subjects | | Template documentation provided to the subject to further assist with understanding the clinical trial requirements or concepts. | Clinical Trial Subject Miscellaneous Form Documentation |
| C207178 | Protocol Amendment | | Documentation describing the subsequent versions of the original clinical study protocol as well as supporting documents that may include description of change(s) to or formal clarification of the protocol. | Clinical Study Protocol Amendment Documentation |
| C115628 | Protocol Synopsis | | Documentation summarizing the key points of the clinical study protocol. | Clinical Study Protocol Synopsis Documentation |
| C25320 | Protocol | | Documentation describing the objective(s), design, methodology, statistical considerations and organization (and optionally, background and rationale) of the clinical trial. | Clinical Study Protocol |
| C207174 | Relevant Communications | | Documentation pertaining to agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. | Clinical Trial Relevant Communications Documentation |
| C125431 | Report of Prior Investigations | | Documentation reporting all prior clinical, animal, and laboratory testing of a medical device. | Medical Device Report of Prior Investigations Documentation |
| C40988 | Sample Case Report Form | | Template documentation used to capture the data points of the clinical study protocol. | Case Report Form |
| C115589 | Subject Diary | | Template documentation used to capture data recorded by the subject. | Subject Diary Documentation |
| C115517 | Subject Information Sheet | | Template documentation used to provide information to the subjects to support their decision about whether or not to participate in the clinical trial. | Clinical Trial Subject Information Form Documentation |
| C115519 | Subject Participation Card | | Template documentation provided to the subject to carry to document clinical trial participation. | Clinical Trial Subject Participation Form Documentation |
| C115559 | Subject Questionnaire | | Template documentation used to capture specific subject related information through a series of questions. | Clinical Trial Subject Questionnaire Documentation |
| C207175 | Tracking Information | | Documentation pertaining to the tracking of clinical trial activities, but not specifically listed in this Reference Model. | Clinical Trial Tracking Information Documentation |

## Data Management Zone (Data Management Zone)

NCI Code: C208285, Codelist extensible:

| C208285 | Data Management Zone | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C115749 | Annotated CRF | | Documentation describing the process to map and assign subject information collected on the case report form into the proper structure of a dataset for the clinical trial. | Case Report Form Annotation Guideline Documentation |
| C207207 | Approval for Database Activation | | Documentation verifying the completion of all requirements for the clinical trial database activation specification. | Clinical Trial Approval for Database Activation Documentation |
| C115750 | CRF Completion Requirements | | Documentation providing the instruction for completing the case report form for the clinical trial. | Case Report Form Guideline Documentation |
| C207209 | Data Entry Guidelines (Paper) | | Documentation describing the proper entry of data from a paper document to the clinical trial database. | Clinical Trial Data Entry Guidelines From Paper Forms Documentation |
| C115756 | Data Management Plan | | Documentation describing the overall data management process for the clinical trial. | Clinical Trial Data Management Plan Documentation |
| C207210 | Data Review Documentation | | Documentation pertaining to the creation and implementation of, and the output from the Quality Control Plan or Data Review Plan for the clinical trial. | Clinical Trial Data Review Documentation |
| C125438 | Database Change Control | | Documentation detailing the changes made to the clinical trial database. | Clinical Trial Database Change Control Documentation |
| C207211 | Database Lock and Unlock Approval | | Documentation confirming the completion and satisfaction of all the requirements for a database lock and unlock for the clinical trial. | Clinical Trial Database Lock and Unlock Approval Documentation |
| C207203 | Database Requirements | | Documentation describing the framework and process required to build the clinical trial database for paper and electronic data capture. | Clinical Trial Database Requirements Documentation |
| C115714 | Dictionary Coding | | Documentation describing the process and tools used in the medical coding for the clinical trial. | Clinical Trial Medical Dictionary Coding Documentation |
| C115521 | Documentation of Corrections to Entered Data | | Documentation used to query database discrepancies and record approved corrections to the clinical trial database. | Clinical Trial Corrections to Entered Data Documentation |
| C207204 | Edit Check Plan | | Documentation describing the process of edit checks and database validation for the clinical trial. | Clinical Trial Database Validation Plan Documentation |
| C207205 | Edit Check Programming | | Documentation about the programs that satisfy the edit check specification details and rules specified by the Database Validation Plan for the clinical trial. | Clinical Trial Edit Check Programming Documentation |
| C207206 | Edit Check Testing | | Documentation verifying the correct implementation of data edit checks and validation rules for the clinical trial. | Clinical Trial Data Validation Testing Documentation |
| C207208 | External Data Transfer Specifications | | Documentation specifying the import, export and transfer of the external data for the clinical trial. | Clinical Trial External Data Transfer Specification Documentation |
| C207177 | Filenote | | Documentation pertaining to any decision or clarifying any information of the clinical trial, but not specifically listed in this Reference Model. | Clinical Trial Filenote Documentation |
| C207202 | Final Subject Data | | Documentation pertaining to the final subject data for the clinical trial. | Clinical Trial Final Subject Data Documentation |
| C207176 | Meeting Material | | Documentation pertaining to meetings not otherwise listed in the Reference Model. | Clinical Trial Meeting Material Documentation |
| C207174 | Relevant Communications | | Documentation pertaining to agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. | Clinical Trial Relevant Communications Documentation |
| C115725 | SAE Reconciliation | | Documentation verifying that the safety database is consistent with the clinical trial database. | Clinical Trial Safety and Clinical Database Reconciliation Documentation |
| C115687 | System Account Management | | Documentation providing the account management details for users who require access to a system for the clinical trial. | Clinical Trial System Account Management Documentation |
| C207212 | Technical Design Document | | Documentation pertaining to the design elements required to build and test the electronic data capture system used for the clinical trial. | Clinical Trial Electronic Data Capture System Technical Design Documentation |
| C207175 | Tracking Information | | Documentation pertaining to the tracking of clinical trial activities, but not specifically listed in this Reference Model. | Clinical Trial Tracking Information Documentation |
| C207213 | Validation Documentation | | Documentation pertaining to the validation of the electronic data capture system used for the clinical trial. | Clinical Trial Electronic Data Capture System Validation Documentation |

## IP and Trial Supplies Zone (IP and Trial Supplies Zone)

NCI Code: C208281, Codelist extensible:

| C208281 | IP and Trial Supplies Zone | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C115473 | Certificate of Analysis | | Documentation confirming the investigational product(s) are the correct identity, purity and strength for use in the intended clinical trial. | Clinical Trial Investigational Product Certificate of Analysis Documentation |
| C207177 | Filenote | | Documentation pertaining to any decision or clarifying any information of the clinical trial, but not specifically listed in this Reference Model. | Clinical Trial Filenote Documentation |
| C115564 | IP Accountability Documentation | | Documentation detailing the dispensing and return of the investigational product(s) for the clinical trial. | Clinical Trial Investigational Product Accountability Documentation |
| C115472 | IP Certificate of Destruction | | Documentation describing and certifying the destruction of the investigational product(s) for the clinical trial. | Clinical Trial Investigational Product Certificate of Destruction Documentation |
| C115525 | IP Instructions for Handling | | Documentation describing the safe handling, storage, distribution, and return of the investigational product(s) for the clinical trial. | Clinical Trial Investigational Product Handling Instruction Documentation |
| C115522 | IP Quality Complaint Form | | Documentation of the complaint directed against the investigational product(s) for the clinical trial. | Clinical Trial Investigational Product Quality Complaint Documentation |
| C115759 | IP Re-labeling Documentation | | Documentation detailing the re-labeling of the investigational product(s) for the clinical trial. | Clinical Trial Investigational Product Relabeling Documentation |
| C115758 | IP Recall Documentation | | Documentation detailing the recall of the investigational product(s) for the clinical trial. | Clinical Trial Investigational Product Recall Documentation |
| C115708 | IP Regulatory Release Documentation | | Documentation detailing the regulatory release of the investigational product(s) for the clinical trial. | Clinical Trial Investigational Product Regulatory Release Documentation |
| C125435 | IP Retest and Expiry Documentation | | Documentation describing the batch retesting of the investigational product(s) for the clinical trial. | Clinical Trial Investigational Product Retest and Expiry Documentation |
| C115566 | IP Return Documentation | | Documentation providing information regarding the return of the investigational product(s) for the clinical trial. | Clinical Trial Investigational Product Return Documentation |
| C115527 | IP Sample Label | | A sample of each investigational product label used in the clinical trial. | Clinical Trial Investigational Product Sample Label |
| C115567 | IP Shipment Documentation | | Documentation providing information regarding the shipment of the investigational product(s) for the clinical trial. | Clinical Trial Investigational Product Shipment Documentation |
| C207189 | IP Storage Condition Documentation | | Documentation pertaining to the storage conditions of the investigational product(s) for the clinical trial. | Clinical Trial Investigational Product Storage Condition Documentation |
| C207190 | IP Storage Condition Excursion Documentation | | Documentation describing any excursions from a required storage condition for the investigational product(s) of the clinical trial. | Clinical Trial Investigational Product Storage Condition Excursion Documentation |
| C115760 | IP Supply Plan | | Documentation describing the supply management of the investigational product(s) for the clinical trial. | Clinical Trial Investigational Product Supply Plan Documentation |
| C115568 | IP Transfer Documentation | | Documentation detailing the transfer of the investigational product(s) for the clinical trial. | Clinical Trial Investigational Product Transfer Documentation |
| C207188 | IP Treatment Allocation Documentation | | Documentation describing the treatment allocation of the investigational product(s) to subjects in the clinical trial. | Clinical Trial Investigational Product Treatment Allocation Documentation |
| C115572 | IP Treatment Decoding Documentation | | Documentation describing the actions taken after breaking the blind for the clinical trial. | Clinical Trial Investigational Product Treatment Decoding Documentation |
| C116349 | IP Unblinding Plan | | Documentation describing the processes and procedures for breaking the blind for the clinical trial. | Clinical Trial Investigational Product Unblinding Plan Documentation |
| C207187 | IP Verification Statements | | Documentation required to verify the quality, source, manufacture, ingredients or other aspects of the investigational product(s) for the clinical trial. | Clinical Trial Investigational Product Verification Statements Documentation |
| C115470 | IRT User Acceptance Testing (UAT) Certification | | Documentation pertaining to the user acceptance testing performed on the interactive response technology. | Interactive Response Technology User Acceptance Testing Certification Documentation |
| C207193 | IRT User Account Management | | Documentation pertaining to the user account management of the interactive response technology system. | Interactive Response Technology User Account Management Documentation |
| C115540 | IRT User Manual | | Documentation providing operational instructions for the interactive response technology. | Interactive Response Technology User Manual Documentation |
| C115592 | IRT User Requirement Specification | | Documentation describing the end user requirements of the interactive response technology. | Interactive Response Technology User Specification Documentation |
| C115471 | IRT Validation Certification | | Documentation confirming the validation of the interactive response technology. | Interactive Response Technology Validation Certification Documentation |
| C207191 | Maintenance Logs | | Documentation pertaining to the assessment of the quality and condition, and maintenance of the investigational product(s)(IP), non-IP(s) and other supplies used in the clinical trial. | Clinical Trial Maintenance Logs Documentation |
| C207176 | Meeting Material | | Documentation pertaining to meetings not otherwise listed in the Reference Model. | Clinical Trial Meeting Material Documentation |
| C115661 | Non-IP Return Documentation | | Documentation providing information regarding the return of the non-investigational product(s) and supplies for the clinical trial. | Clinical Trial Non-Investigational Product Supplies Documentation of Return |
| C115563 | Non-IP Shipment Documentation | | Documentation providing information regarding the shipment of the non-investigational product(s) and other supplies for the clinical trial. | Clinical Trial Non-Investigational Product Supplies Shipment Documentation |
| C207192 | Non-IP Storage Documentation | | Documentation pertaining to the storage conditions of the non-investigational product(s) and supplies used for the clinical trial. | Clinical Trial Non-Investigational Product Supplies Storage Documentation |
| C115754 | Non-IP Supply Plan | | Documentation describing the supply management of the non-investigational product(s) and other supplies for the clinical trial. | Clinical Trial Non-Investigational Product Supplies Plan Documentation |
| C115720 | QP (Qualified Person) Certification | | Documentation from a Qualified Person confirming that the investigational product(s) for the clinical trial have been manufactured according to Good Manufacturing Processes. | Clinical Trial Qualified Person Investigational Product Certification Documentation |
| C207174 | Relevant Communications | | Documentation pertaining to agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. | Clinical Trial Relevant Communications Documentation |
| C207175 | Tracking Information | | Documentation pertaining to the tracking of clinical trial activities, but not specifically listed in this Reference Model. | Clinical Trial Tracking Information Documentation |

## IRB or IEC and Other Approvals Zone (IRB or IEC and Other Approvals Zone)

NCI Code: C208279, Codelist extensible:

| C208279 | IRB or IEC and Other Approvals Zone | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C207177 | Filenote | | Documentation pertaining to any decision or clarifying any information of the clinical trial, but not specifically listed in this Reference Model. | Clinical Trial Filenote Documentation |
| C115594 | IRB or IEC Compliance Documentation | | Documentation confirming the Institutional Review Board or Independent Ethics Committee is in compliance with written operating procedures, Good Clinical Practices, and applicable regulatory requirements. | Institutional Review Board Independent Ethics Committee Compliance Documentation |
| C115694 | IRB or IEC Composition | | Documentation pertaining to the membership of the Institutional Review Board or Independent Ethics Committee regarding their qualifications and experience to review and evaluate the science, medical aspects, and ethics of the clinical trial. | Institutional Review Board Independent Ethics Committee Composition Documentation |
| C207182 | IRB or IEC Decision | | Documentation detailing the decisions made by the Institutional Review Board or Independent Ethics Committee of the clinical trial. | Institutional Review Board Independent Ethics Committee Decision Documentation |
| C115695 | IRB or IEC Documentation of Non-Voting Status | | Documentation verifying investigator, sub-investigator, or other party of the clinical trial has not voted, if they are members of the Institutional Review Board or Independent Ethics Committee. | Institutional Review Board Independent Ethics Committee Documentation of Non-Voting Status |
| C115699 | IRB or IEC Notification of Trial Termination | | Documentation detailing the communications to the Institutional Review Board or Independent Ethics Committee of the termination or closure of the clinical trial. | Institutional Review Board Independent Ethics Committee Notification of Trial Termination or Closure Documentation |
| C126092 | IRB or IEC Progress Report | | Documentation containing regular reports of the clinical trial conduct, other than safety reports, submitted to the Institutional Review Board or Independent Ethics Committee. | Institutional Review Board Independent Ethics Committee Progress Report Documentation |
| C115616 | IRB or IEC Submission | | Documentation submitted to an Institutional Review Board or Independent Ethics Committee for approval of the clinical trial, and any changes or updates made to that trial. | Institutional Review Board Independent Ethics Committee Submission Documentation |
| C207176 | Meeting Material | | Documentation pertaining to meetings not otherwise listed in the Reference Model. | Clinical Trial Meeting Material Documentation |
| C115698 | Notification to IRB or IEC of Safety Information | | Documentation submitted to the Institutional Review Board or Independent Ethics Committee detailing the safety of subjects in the clinical trial. | Institutional Review Board Independent Ethics Committee Notification of Safety Information Documentation |
| C115736 | Other Approvals | | Documentation detailing the decisions made by other committee(s) of the clinical trial. | Clinical Trial Other Committees Decisions Documentation |
| C126093 | Other Submissions | | Documentation submitted to other committee(s) for approval of the clinical trial, and any changes or updates made to that trial. | Clinical Trial Submission to Other Committees Documentation |
| C207174 | Relevant Communications | | Documentation pertaining to agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. | Clinical Trial Relevant Communications Documentation |
| C207175 | Tracking Information | | Documentation pertaining to the tracking of clinical trial activities, but not specifically listed in this Reference Model. | Clinical Trial Tracking Information Documentation |

## Regulatory Zone (Regulatory Zone)

NCI Code: C208278, Codelist extensible:

| C208278 | Regulatory Zone | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C207177 | Filenote | | Documentation pertaining to any decision or clarifying any information of the clinical trial, but not specifically listed in this Reference Model. | Clinical Trial Filenote Documentation |
| C115530 | Import or Export Documentation | | Documentation authorizing the import or export of an investigational product, and/or clinical supplies into/out of its territory. | Clinical Trial Import or Export Documentation |
| C115466 | Import or Export License Application | | Documentation submitted to regulatory authorities requesting a license to import or export an investigational product, and/or clinical supplies. | Clinical Trial Import-Export License Application Documentation |
| C207176 | Meeting Material | | Documentation pertaining to meetings not otherwise listed in the Reference Model. | Clinical Trial Meeting Material Documentation |
| C115717 | Notification of Regulatory Identification Number | | Documentation of the unique identification number assigned by a regulatory authority used to identify the clinical trial. | Clinical Trial Notification of Regulatory Identification Number Documentation |
| C115551 | Notification of Safety or Trial Information | | Documentation submitted to the regulatory authorities pertaining to any events that may impact the safety of subjects or the conduct of the clinical trial. | Clinical Trial Notification of Safety or Other Trial Information Documentation |
| C115734 | Public Registration | | Documentation pertaining to the registration of the clinical trial in public registries. | Clinical Trial Public Registration Documentation |
| C79189 | Regulatory Authority Decision | | Documentation detailing the decisions made by the regulatory authorities of the clinical trial. | Clinical Trial Regulatory Authority Decision Documentation |
| C115662 | Regulatory Notification of Trial Termination | | Documentation detailing the communications to regulatory authorities of the termination or closure of the clinical trial. | Clinical Trial Regulatory Notification of Termination or Closure Documentation |
| C207181 | Regulatory Progress Report | | Documentation containing regular reports of the clinical trial conduct, other than safety reports, submitted to the regulatory authorities. | Clinical Trial Regulatory Progress Report Documentation |
| C70885 | Regulatory Submission | | An assembly of one or more regulatory submission units supporting a specific regulatory purpose or decision. In most cases, the compilation of the submission units is utilized in the assessment of a regulated medical product quality, safety and/or effectiveness. | Regulatory Submission |
| C207174 | Relevant Communications | | Documentation pertaining to agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. | Clinical Trial Relevant Communications Documentation |
| C207175 | Tracking Information | | Documentation pertaining to the tracking of clinical trial activities, but not specifically listed in this Reference Model. | Clinical Trial Tracking Information Documentation |

## Safety Reporting Zone (Safety Reporting Zone)

NCI Code: C208282, Codelist extensible:

| C208282 | Safety Reporting Zone | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C115574 | Expedited Safety Report | | Documentation describing unexpected serious adverse events experienced by the subject and other safety information in the clinical trial, which are submitted to regulatory authorities and Institutional Review Boards or Independent Ethics Committees. | Clinical Trial Expedited Safety Report Documentation |
| C207177 | Filenote | | Documentation pertaining to any decision or clarifying any information of the clinical trial, but not specifically listed in this Reference Model. | Clinical Trial Filenote Documentation |
| C207176 | Meeting Material | | Documentation pertaining to meetings not otherwise listed in the Reference Model. | Clinical Trial Meeting Material Documentation |
| C115534 | Pharmacovigilance Database Line Listing | | Documentation containing the clinical trial data used for safety evaluations of investigational product(s). | Clinical Trial Pharmacovigilance Data Line List Documentation |
| C115578 | Pregnancy Report | | Documentation pertaining to a pregnancy and its outcome as experienced by the female subject, or by the partner of the male subject during the clinical trial. | Clinical Trial Pregnancy Report Documentation |
| C207174 | Relevant Communications | | Documentation pertaining to agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. | Clinical Trial Relevant Communications Documentation |
| C115587 | SAE Report | | Documentation describing a serious adverse event experienced by the subject in the clinical trial, which is defined by the clinical study protocol. | Clinical Trial Serious Adverse Event Report Documentation |
| C115755 | Safety Management Plan | | Documentation describing the safety evaluation process of investigational product(s) during the clinical trial. | Clinical Trial Safety Management Plan Documentation |
| C115558 | Special Events of Interest | | Documentation describing an event of special interest experienced by the subject in the clinical trial, which is defined by the clinical study protocol. | Clinical Trial Special Events of Interest Documentation |
| C207175 | Tracking Information | | Documentation pertaining to the tracking of clinical trial activities, but not specifically listed in this Reference Model. | Clinical Trial Tracking Information Documentation |

## Site Management Zone (Site Management Zone)

NCI Code: C208280, Codelist extensible:

| C208280 | Site Management Zone | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C115711 | Acceptance of Investigator Brochure | | Documentation confirming the receipt of the investigator brochure at the clinical trial site. | Investigator Brochure Acceptance Documentation |
| C115737 | Additional Monitoring Activity | | Documentation of additional clinical trial site monitoring activities. | Clinical Trial Site Additional Monitoring Activity Documentation |
| C60777 | Clinical Trial Agreement | | Documentation detailing the agreement of the clinical trial requirements between the sponsor or representative of the sponsor and the investigator or institution. | Clinical Trial Agreement Documentation |
| C115476 | Confidentiality Agreement | | Documentation detailing the agreement between the sponsor or representative of the sponsor and the investigator or institution that contains the provisions governing the access and use of confidential information pertaining to the clinical trial. | Clinical Trial Site Investigator Confidentiality Agreement Documentation |
| C125426 | Coordinating Investigator Documentation | | Documentation pertaining to a coordinating investigator in the clinical trial. | Clinical Trial Coordinating Investigator Documentation |
| C115474 | Data Privacy Agreement | | Documentation containing the provisions governing the use of, and access to, any and all data obtained from the clinical trial. | Clinical Trial Data Privacy Agreement Documentation |
| C115668 | Feasibility Documentation | | Documentation describing site feasibility for the clinical study protocol. | Clinical Trial Site Feasibility Documentation |
| C207177 | Filenote | | Documentation pertaining to any decision or clarifying any information of the clinical trial, but not specifically listed in this Reference Model. | Clinical Trial Filenote Documentation |
| C115581 | Final Trial Close Out Monitoring Report | | Documentation of the monitoring activities conducted to ensure that the clinical trial site meets requirements for closure. | Final Clinical Trial Site Close Out Monitoring Report Documentation |
| C207185 | Financial Disclosure Form | | A document pertaining to the financial interests and arrangements of the investigator(s) for the clinical trial. | Clinical Trial Investigators Financial Disclosure Form |
| C115648 | Financial Documentation | | Documentation containing information pertaining to the finances of the clinical trial. | Clinical Trial Financial Documentation |
| C54623 | Form FDA 1572 | | A federal form that is the statement of the investigator that he will abide by the federal guidelines set forth in the Code of Federal Regulations for the use of drugs in an investigational setting. [NCI] | Form FDA 1572 |
| C115649 | Indemnity | | Documentation certifying legal protection in the event of any unforeseen adverse circumstance arising during the course of the clinical trial. | Clinical Trial Indemnity Documentation |
| C115477 | Investigator Regulatory Agreement | | Documentation containing the agreement by any/all investigators of the clinical trial that all trial activities will conform fully to all regulations as set forth by the law, or any other supervisory authority. | Clinical Trial Investigator Regulatory Agreement Documentation |
| C125432 | Investigators Agreement (Device) | | Documentation pertaining to the non-financial agreement for medical devices between the sponsor and the clinical trial investigator(s) documenting various responsibilities. | Clinical Trial Medical Device Investigators Agreement Documentation |
| C115710 | IP Site Release Documentation | | Documentation approving the clinical trial site to receive a supply of investigational product(s). | Investigational Product Clinical Trial Site Release Documentation |
| C207176 | Meeting Material | | Documentation pertaining to meetings not otherwise listed in the Reference Model. | Clinical Trial Meeting Material Documentation |
| C125443 | Monitoring Visit Follow-up Documentation | | Documentation pertaining to the follow-up of a monitoring visit of the clinical trial site. | Clinical Trial Site Monitoring Visit Follow-up Documentation |
| C115577 | Monitoring Visit Report | | Documentation of ongoing monitoring activities conducted for the evaluation of clinical trial conduct, and regulatory compliance of the clinical trial site. | Clinical Trial Site Monitoring Visit Report Documentation |
| C115663 | Notification to Investigators of Safety Information | | Documentation verifying distribution and receipt of the communications related to the safety of the clinical trial to the investigators. | Clinical Trial Notification to Investigators of Safety Information Documentation |
| C207183 | Other Curriculum Vitae | | Documentation detailing the education, qualification and work experience of additional clinical trial site personnel (excluding principal and sub-investigators) involved in the conduct of the clinical trial. | Clinical Trial Site Other Personnel Curriculum Vitae Documentation |
| C115475 | Other Financial Agreement | | Documentation detailing the agreement of the clinical trial requirements between sponsor or representative of the sponsor and other parties (excluding the investigator and institution) involved in the conduct of the clinical trial. | Clinical Trial Financial Agreement Documentation |
| C115586 | Pre Trial Monitoring Report | | Documentation of monitoring activities conducted to evaluate whether a clinical trial site is qualified to participate in the clinical trial. | Pre-Clinical Trial Site Evaluation Report Documentation |
| C115487 | Principal Investigator Curriculum Vitae | | Documentation detailing the education, qualification and work experience of the principal investigator involved in the conduct of the clinical trial. | Clinical Trial Principal Investigator Curriculum Vitae Documentation |
| C115718 | Protocol Amendment Signature Page | | Documentation signed by investigators confirming the agreement of the clinical trial site to follow the amendments to the clinical study protocol. | Clinical Study Protocol Amendment Signature Page Documentation |
| C115664 | Protocol Deviations | | Documentation detailing any non-compliance or deviations from the clinical study protocol. | Clinical Study Protocol Deviation Documentation |
| C115719 | Protocol Signature Page | | Documentation signed by investigators confirming the agreement of the clinical trial site to follow the clinical study protocol. | Clinical Study Protocol Signature Page Documentation |
| C207174 | Relevant Communications | | Documentation pertaining to agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. | Clinical Trial Relevant Communications Documentation |
| C115671 | Site Contact Details | | Documentation detailing the contact information of the clinical trial site personnel. | Clinical Trial Site Personnel Contact Detail Documentation |
| C115674 | Site Evidence of Training | | Documentation verifying the completion of training of the clinical trial site personnel. | Clinical Trial Site Training Completion Documentation |
| C115673 | Site Signature Sheet | | Documentation tracking the task delegation made by the principal investigator to the site personnel conducting the clinical trial. | Clinical Trial Site Task Assignment Documentation |
| C207184 | Site Staff Qualification Supporting Information | | Documentation detailing the additional education, training, qualification and work experience of the clinical trial site personnel (excluding curriculum vitae), involved in the conduct of the clinical trial. | Clinical Trial Site Staff Qualification Supporting Information Documentation |
| C115604 | Site Training Material | | Documentation used to train site personnel involved in the conduct of the clinical trial. | Clinical Trial Site Training Material Documentation |
| C115739 | Sites Evaluated but not Selected | | Documentation pertaining to potential clinical trial sites that were evaluated, but not selected, for the clinical trial. | Unselected Clinical Trial Site Documentation |
| C125433 | Source Data Verification | | Documentation describing source data and associated verification activities for the clinical trial. | Clinical Trial Source Data Verification Documentation |
| C125442 | Source Data | | Documentation pertaining to the source data collected from the clinical trial. | Clinical Trial Source Data Documentation |
| C115488 | Sub-Investigator Curriculum Vitae | | Documentation detailing the education, qualification and work experience of the sub-investigator(s) involved in the conduct of the clinical trial. | Clinical Trial Sub-Investigator Curriculum Vitae Documentation |
| C125427 | Subject Eligibility Verification Forms and Worksheets | | Documentation verifying a subject is an appropriate candidate to participate in the clinical trial, as outlined by the clinical study protocol. | Clinical Trial Subject Eligibility Verification Form and Worksheet Documentation |
| C125434 | Subject Identification Log | | Documentation identifying all the subjects screened, screen failed and enrolled for the clinical trial. | Clinical Trial Subject Identification Log Documentation |
| C207186 | Subject Log | | Documentation anonymously listing all the subjects screened, screen failed and enrolled for the clinical trial. | Clinical Trial Subject Log Documentation |
| C207175 | Tracking Information | | Documentation pertaining to the tracking of clinical trial activities, but not specifically listed in this Reference Model. | Clinical Trial Tracking Information Documentation |
| C115576 | Trial Initiation Monitoring Report | | Documentation of monitoring activities conducted to ensure the clinical trial site meets requirements to begin participation in the clinical trial. | Clinical Trial Site Initiation Monitoring Report Documentation |
| C115536 | Visit Log | | Documentation listing all clinical trial site monitoring visit dates and attendees. | Clinical Trial Site Visit Log Documentation |

## Statistics Zone (Statistics Zone)

NCI Code: C208286, Codelist extensible:

| C208286 | Statistics Zone | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C207217 | Analysis QC Documentation | | Documentation pertaining to the quality control (QC) procedures and programs, which are used to QC the tabulation dataset, analysis dataset and the Tables, Listings, and Figures, for the clinical trial. This also includes documentation of the output files generated from quality control. | Clinical Trial Tabulation and Analysis Quality Control Documentation |
| C207216 | Data Definitions for Analysis Datasets | | Documentation defining and describing the programming logic and derivation required to transform a raw dataset to tabulation and analysis datasets for the clinical trial. | Clinical Trial Data Definitions for Tabulation and Analysis Dataset Documentation |
| C207215 | End of Trial or Interim Unblinding | | Documentation authorizing the release of randomization code to reveal subject(s) clinical trial group allocation data either during or at the end of the trial. | Clinical Trial End of Trial or Interim Unblinding Documentation |
| C207177 | Filenote | | Documentation pertaining to any decision or clarifying any information of the clinical trial, but not specifically listed in this Reference Model. | Clinical Trial Filenote Documentation |
| C115492 | Final Analysis Datasets | | Dataset files generated from a final analysis for the clinical trial. | Clinical Trial Final Analysis Datasets Documentation |
| C115554 | Final Analysis Output | | Tables, listings, and figures output files generated from a final analysis for the clinical trial. | Clinical Trial Final Analysis Output Documentation |
| C115483 | Final Analysis Programs | | Program files used to generate final analysis dataset and output as referenced by the statistical analysis plan of the clinical trial. | Clinical Trial Final Analysis Programs Documentation |
| C207219 | Final Analysis Raw Datasets | | Documentation pertaining to the raw data used for a final tabulation and analysis of results for the clinical trial. | Clinical Trial Raw Dataset for Final Tabulation and Analysis Documentation |
| C115493 | Interim Analysis Datasets | | Dataset files generated from an interim analysis for the clinical trial. | Clinical Trial Interim Analysis Datasets Documentation |
| C115555 | Interim Analysis Output | | Tables, listings, and figures output files generated from an interim analysis for the clinical trial. | Clinical Trial Interim Analysis Output Documentation |
| C115484 | Interim Analysis Programs | | Program files used to generate interim analysis dataset and output as referenced by the statistical analysis plan of the clinical trial. | Clinical Trial Interim Analysis Programs Documentation |
| C207218 | Interim Analysis Raw Datasets | | Documentation pertaining to the raw data used for an interim tabulation and analysis of results for the clinical trial. | Clinical Trial Raw Dataset for Interim Tabulation and Analysis Documentation |
| C115585 | Interim Statistical Report(s) | | Documentation detailing the statistical aspects of an interim analysis for the clinical trial. | Clinical Trial Interim Statistical Report Documentation |
| C115533 | Master Randomization List | | A document describing the assignment of subjects to the clinical study protocol-specified treatment groups in the clinical trial. | Clinical Trial Master Randomization List |
| C207176 | Meeting Material | | Documentation pertaining to meetings not otherwise listed in the Reference Model. | Clinical Trial Meeting Material Documentation |
| C115778 | Randomization Plan | | Documentation describing the details of the randomization scheme for the clinical trial. | Clinical Trial Randomization Plan Documentation |
| C116348 | Randomization Procedure | | Documentation describing how subjects are randomized in the clinical trial. | Clinical Trial Randomization Procedure Documentation |
| C115479 | Randomization Programming | | Documentation about the computer code used to generate randomization numbers for treatment assignment in the clinical trial. | Clinical Trial Randomization Programming Documentation |
| C115621 | Randomization Sign Off | | Documentation verifying the correct randomization number and treatment assignment have been generated by the randomization program being used in the clinical trial. | Clinical Trial Randomization Validation Documentation |
| C207174 | Relevant Communications | | Documentation pertaining to agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. | Clinical Trial Relevant Communications Documentation |
| C207214 | Sample Size Calculation | | Documentation describing the statistical methods used to calculate the sample size for the clinical trial. | Clinical Trial Sample Size Calculation Documentation |
| C115761 | Statistical Analysis Plan | | Documentation describing the statistical aspects of the clinical trial design; the process of data selection for analyses; the detailed analyses of data items; the procedures and methods employed for analyzing the data; the planned presentation of results in formats such as tables, listings, and figures. | Clinical Trial Statistical Analysis Plan Documentation |
| C115582 | Statistical Report | | Documentation detailing the statistical aspects of a final analysis for the clinical trial. | Clinical Trial Final Statistical Report Documentation |
| C115735 | Subject Evaluability Criteria and Subject Classification | | Documentation detailing the decisions that define the criteria used to evaluate and assign subjects to a population group, which are established by the statistical analysis plan of the clinical trial. | Clinical Trial Subject Evaluability Criteria and Subject Classification Documentation |
| C207175 | Tracking Information | | Documentation pertaining to the tracking of clinical trial activities, but not specifically listed in this Reference Model. | Clinical Trial Tracking Information Documentation |

## Third Parties Zone (Third Parties Zone)

NCI Code: C208284, Codelist extensible:

| C208284 | Third Parties Zone | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C115465 | Confidentiality Agreement | | Documentation detailing the agreement between the sponsor or representative of the sponsor and the vendor that contains the provisions governing the access and use of confidential information pertaining to the clinical trial. | Clinical Trial Vendor Confidentiality Agreement Documentation |
| C207201 | Contractual Agreement | | Documentation detailing the agreement between two parties defining the distribution of tasks and obligations for the clinical trial. | Clincial Trial Contractual Agreement Documentation |
| C207177 | Filenote | | Documentation pertaining to any decision or clarifying any information of the clinical trial, but not specifically listed in this Reference Model. | Clinical Trial Filenote Documentation |
| C207176 | Meeting Material | | Documentation pertaining to meetings not otherwise listed in the Reference Model. | Clinical Trial Meeting Material Documentation |
| C125428 | Ongoing Third Party Oversight | | Documentation confirming that a vendor continues to meet all relevant criteria to fulfill a contractual obligation for the clinical trial. | Clinical Trial Ongoing Vendor Oversight Documentation |
| C115690 | Qualification and Compliance | | Documentation confirming that a vendor meets all criteria to fulfill a contractual obligation for the clinical trial. | Clinical Trial Vendor Qualification and Compliance Documentation |
| C207174 | Relevant Communications | | Documentation pertaining to agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. | Clinical Trial Relevant Communications Documentation |
| C125440 | Third Party Curriculum Vitae | | Documentation detailing the education, qualification and work experience of the vendor team members participating in the clinical trial. | Clinical Trials Vendor Curriculum Vitae Documentation |
| C207175 | Tracking Information | | Documentation pertaining to the tracking of clinical trial activities, but not specifically listed in this Reference Model. | Clinical Trial Tracking Information Documentation |
| C115747 | Vendor Selection | | Documentation describing the identification and selection of a vendor for the clinical trial. | Clinical Trial Vendor Selection Documentation |

## TMF-RM Sections (TMF-RM Sections)

NCI Code: C208287, Codelist extensible:

| C208287 | TMF-RM Sections | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C115632 | Analysis | | A collection of documents related to the statistical analysis of the clinical trial. | TMF-RM Statistics Analysis Section |
| C115643 | Data Capture | | A collection of documents related to data capture for the clinical trial. | TMF-RM Data Capture Section |
| C115683 | Data Management Oversight | | A collection of documents related to data management oversight for the clinical trial. | TMF-RM Data Management Oversight Section |
| C115688 | Database | | A collection of documents related to the database used for the Electronic Data Capture system for the clinical trial. | TMF-RM Database Section |
| C115689 | EDC Management | | A collection of documents related to the management of the Electronic Data Capture system for the clinical trial. | TMF-RM EDC Management Section |
| C115645 | Facility Documentation | | A collection of documents related to the testing facilities participating in the clinical trial. | TMF-RM Facility Documentation Section |
| C207156 | General | | A collection of general documents for the clinical trial not elsewhere in the zone. | TMF-RM General Section |
| C115652 | Interactive Response Technology | | A collection of documents related to the interactive response technology used for the clinical trial. | TMF-RM Interactive Response Technology Section |
| C115702 | Investigational Medicinal Product | | A collection of documents related to the regulatory import and/or export of investigational medicinal product(s) for the clinical trial. | TMF-RM Investigational Medicinal Product Section |
| C207222 | IP Allocation Documentation | | A collection of documents related to the allocation of the investigational product(s) and trial supplies for the clinical trial. | TMF-RM IP Allocation Documentation Section |
| C115705 | IP Documentation | | A collection of documents related to the management of investigational product(s) and trial supplies for the clinical trial. | TMF-RM IP Documentation Section |
| C115709 | IP Release Process Documentation | | A collection of documents related to the release process of the investigational product(s) and trial supplies for the clinical trial. | TMF-RM IP Release Process Documentation Section |
| C115696 | IRB or IEC Trial Approval | | A collection of documents related to the Institutional Review Board or Independent Ethics Committee decisions for the clinical trial. | TMF-RM IRB or IEC Trial Approval Section |
| C207155 | Meetings | | A collection of documents related to trial management meetings for the clinical trial. | TMF-RM Trial Management Meetings Section |
| C115660 | Non-IP Documentation | | A collection of documents related to the management of non-investigational product(s) for the clinical trial. | TMF-RM Non-IP Documentation Section |
| C207161 | Other Committees | | A collection of documents related to the other committees established for the clinical trial. | TMF-RM Other Committees Section |
| C207157 | Product and Trial Documentation | | A collection of documents related to the product and trial documentation for the clinical trial. | TMF-RM Product and Trial Documentation Section |
| C115722 | Randomization | | A collection of documents related to the randomization scheme for the clinical trial. | TMF-RM Randomization Section |
| C207224 | Report | | A collection of documents related to the statistical reports for the clinical trial. | TMF-RM Statistics Reports Section |
| C207159 | Reports | | A collection of documents related to results reporting for the clinical trial. | TMF-RM Central Trial Reports Section |
| C115630 | Safety Documentation | | A collection of documents related to the safety management and reporting for the clinical trial. | TMF-RM Safety Documentation Section |
| C115655 | Sample Documentation | | A collection of documents related to the management of the samples collected for the clinical trial. | TMF-RM Sample Documentation Section |
| C115669 | Site Initiation | | A collection of documents related to site initiation for the clinical trial. | TMF-RM Site Initiation Section |
| C207221 | Site Management | | A collection of documents related to site management for the clinical trial. | TMF-RM Site Management Section |
| C115672 | Site Selection | | A collection of documents related to site selection for the clinical trial. | TMF-RM Site Selection Section |
| C207220 | Site Set-up | | A collection of documents related to site set-up for the clinical trial. | TMF-RM Site Set-up Section |
| C115733 | Statistics Oversight | | A collection of documents related to the statistics oversight for the clinical trial. | TMF-RM Statistics Oversight Section |
| C115677 | Storage | | A collection of documents related to the storage of the investigational product(s) and trial supplies for the clinical trial. | TMF-RM IP Storage Section |
| C207158 | Subject Documentation | | A collection of documents related to the subject documentation for the clinical trial. | TMF-RM Subject Documentation Section |
| C115744 | Third Party Oversight | | A collection of documents related to vendor oversight for the clinical trial. | TMF-RM Vendor Oversight Section |
| C207223 | Third Party Set-up | | A collection of documents related to vendor set-up for the clinical trial. | TMF-RM Vendor Set-up Section |
| C115665 | Trial Approval | | A collection of documents related to the regulatory trial approval for the clinical trial. | TMF-RM Trial Regulatory Approval Section |
| C207154 | Trial Committee | | A collection of documents related to the trial committee for the clinical trial. | TMF-RM Trial Committee Section |
| C207153 | Trial Oversight | | A collection of documents related to trial oversight for the clinical trial. | TMF-RM Trial Oversight Section |
| C207160 | Trial Status Reporting | | A collection of documents related to the reporting of trial status for the clinical trial. | TMF-RM Trial Status Reporting Section |
| C115617 | Trial Team | | A collection of documents related to the trial team for the clinical trial. | TMF-RM Trial Team Section |

## TMF-RM Zones (TMF-RM Zones)

NCI Code: C208275, Codelist extensible:

| C208275 | TMF-RM Zones | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C115642 | Central and Local Testing | | The Trial Master File Reference Model zone that contains the collection of documents relating to the testing vendors and sample management, including central and local testing facilities for the clinical trial. | TMF-RM Central and Local Testing Zone |
| C115636 | Central Trial Documents | | The Trial Master File Reference Model zone that contains the collection of documents relating to the clinical study protocol, investigator's brochure, key subject documentation and study reports for the clinical trial. | TMF-RM Central Trial Documents Zone |
| C115682 | Data Management | | The Trial Master File Reference Model zone that contains the collection of documents relating to data management activities for the clinical trial. | TMF-RM Data Management Zone |
| C115703 | IP and Trial Supplies | | The Trial Master File Reference Model zone that contains the collection of documents relating to the management, shipping, storage, dispensing, and destruction of Investigational Product(s) and supplies for the clinical trial. | TMF-RM Investigational Products and Trial Supplies Zone |
| C115691 | IRB or IEC and Other Approvals | | The Trial Master File Reference Model zone that contains the collection of documents relating to the interactions with the Institutional Review Board (IRB)/Independent Ethics Committee (IEC), including submissions, decisions, acknowledgments, and oversight information about the IRB/IEC for the clinical trial. | TMF-RM Institutional Review Board or Independent Ethics Committee and Other Approvals Zone |
| C115723 | Regulatory | | The Trial Master File Reference Model zone that contains the collection of documents relating to the interactions with regulatory authorities, including submissions, decisions, notifications, and registrations for the clinical trial. | TMF-RM Regulatory Zone |
| C115667 | Safety Reporting | | The Trial Master File Reference Model zone that contains the collection of documents relating to the safety and pharmacovigilance management of the clinical trial. | TMF-RM Safety Reporting Zone |
| C115782 | Site Management | | The Trial Master File Reference Model zone that contains the collection of documents relating to the selection, setup, initiation and management of the investigational sites as well as multi-site records and communications for the clinical trial. | TMF-RM Site Management Zone |
| C115732 | Statistics | | The Trial Master File Reference Model zone that contains the collection of documents relating to biostatistics and statistical programming activities for the clinical trial. | TMF-RM Statistics Zone |
| C115743 | Third Parties | | The Trial Master File Reference Model zone that contains the collection of documents relating to the establishment, maintenance and oversight of relationships between sponsors and vendors for the clinical trial. | TMF-RM Vendors Zone |
| C115766 | Trial Management | | The Trial Master File Reference Model zone that contains the collection of documents relating to the general design, management and oversight of the clinical trial. | TMF-RM Trial Management Zone |

## Trial Management Zone (Trial Management Zone)

NCI Code: C208276, Codelist extensible:

| C208276 | Trial Management Zone | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C115469 | Audit Certificate | | Documentation that confirms an audit has been conducted. | Audit Certificate Documentation |
| C125424 | Committee Member Confidentiality Disclosure Agreement | | Documentation describing the provisions governing the nondisclosure requirements between a sponsor or vendor and a member from a committee established for the clinical trial. | Clinical Trial Committee Member Confidentiality Disclosure Agreement Documentation |
| C125423 | Committee Member Contract | | Documentation describing the contractual responsibilities between a sponsor or vendor and a member from a committee established for the clinical trial. | Clinical Trial Committee Member Contract Documentation |
| C207173 | Committee Member Curriculum Vitae | | Documentation detailing the education, qualification and work experience of a member from a committee established for the clinical trial. | Clinical Trial Committee Member Curriculum Vitae Documentation |
| C125422 | Committee Member Financial Disclosure Form | | A document pertaining to the financial interests and arrangements of the committee members for the clinical trial. | Clinical Trial Committee Member Financial Disclosure Form Documentation |
| C207171 | Committee Member List | | Documentation describing the current composition of a committee established for the clinical trial. | Clinical Trial Committee Member List Documentation |
| C207172 | Committee Output | | Documentation describing and supporting any decision regarding the clinical trial conduct from a committee established for the clinical trial. | Clinical Trial Committee Output Documentation |
| C207170 | Committee Process | | Documentation describing the purpose and operational processes of a committee established for the clinical trial. | Clinical Trial Committee Process Documentation |
| C115783 | Communication Plan | | Documentation describing the communication strategy between stakeholders of the clinical trial. | Clinical Trial Stakeholder Communication Plan Documentation |
| C115593 | Debarment Statement | | Documentation verifying that the applicant or any of its principals should be excluded from certain rights, privileges and practices due to debarment or other circumstances. | Debarment Statement Documentation |
| C115531 | Filenote Master List | | Documentation providing a consolidated list or index of file notes generated during the clinical trial. | Clinical Trial Filenotes Master List Documentation |
| C207177 | Filenote | | Documentation pertaining to any decision or clarifying any information of the clinical trial, but not specifically listed in this Reference Model. | Clinical Trial Filenote Documentation |
| C115544 | Investigator Newsletter | | Documentation that informs investigative staff of common implementation issues and the progress of the clinical trial. | Clinical Trial Investigator Newsletter Documentation |
| C115599 | Investigators Meeting Material | | Documentation pertaining to the clinical trial investigator meeting. | Clinical Trial Investigator Meeting Material Documentation |
| C115600 | Kick-off Meeting Material | | Documentation pertaining to the clinical trial kick-off meeting. | Clinical Trial Kick-off Meeting Material Documentation |
| C115779 | List of SOPs Current During Trial | | Documentation describing the standard operating procedures used during the clinical trial. | Clincial Trial Standard Operating Procedure List Documentation |
| C115752 | Medical Monitoring Plan | | Documentation describing the medical surveillance of subjects during the clinical trial. | Clinical Trial Medical Monitoring Plan Documentation |
| C207176 | Meeting Material | | Documentation pertaining to meetings not otherwise listed in the Reference Model. | Clinical Trial Meeting Material Documentation |
| C115753 | Monitoring Plan | | Documentation describing the strategy, methods, responsibilities, and requirements for monitoring the clinical trial. | Clinical Trial Monitoring Plan Documentation |
| C125421 | Operational Oversight | | Documentation describing clinical trial operations oversight by a sponsor. | Clinical Trial Operational Oversight Documentation |
| C115764 | Operational Procedure Manual | | Documentation describing clinical trial-related work processes. | Clinical Trials Operational Procedure Manual Documentation |
| C115557 | Publication Policy | | Documentation describing the publication of clinical trial results. | Clinical Trial Publication Policy Documentation |
| C115777 | Quality Plan | | Documentation describing the operational techniques and activities undertaken within the quality management system to verify that the requirements for quality of the clinical trial-related activities have been fulfilled. | Clinical Trial Quality Assurance Plan Documentation |
| C115769 | Recruitment Plan | | Documentation describing the subject enrollment and recruitment goals during the clinical trial. | Clinical Trial Recruitment Plan Documentation |
| C207174 | Relevant Communications | | Documentation pertaining to agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. | Clinical Trial Relevant Communications Documentation |
| C207167 | Risk Management Plan | | Documentation describing the potential hazards associated with the clinical trial. | Clinical Trial Risk Management Plans Documentation |
| C125429 | Roles and Responsibility Matrix | | Documentation describing the range and distribution of tasks and responsibilities. | Clinical Trial Roles and Responsibilities Matrix Documentation |
| C207175 | Tracking Information | | Documentation pertaining to the tracking of clinical trial activities, but not specifically listed in this Reference Model. | Clinical Trial Tracking Information Documentation |
| C207168 | Transfer of Regulatory Obligations | | Documentation describing the transfer of regulatory obligations of the clinical trial. | Clinical Trial Transfer of Regulatory Obligations Documentation |
| C115780 | Trial Management Plan | | Documentation describing the overall strategy for timelines, management and conduct of the clinical trial. | Clinical Trial Management Plan Documentation |
| C115765 | Trial Master File Plan | | Documentation describing how clinical trial records are managed and stored during and after the clinical trial. | Clincial Trial Master File Plan Documentation |
| C115580 | Trial Status Report | | Documentation that contains routine trial status progress. | Clinical Trial Status Report Documentation |
| C207169 | Trial Team Curriculum Vitae | | Documentation detailing the education, qualification and work experience of a specific sponsor team member participating in the clinical trial. | Clinical Trial Sponsor Team Member Curriculum Vitae Documentation |
| C115659 | Trial Team Details | | Documentation defining the structure, roles and contact details of the clinical trial team (both sponsor and vendors). | Clinical Trial Team Details Documentation |
| C125425 | Trial Team Evidence of Training | | Documentation verifying clinical trial team training completion. | Clinical Trial Team Evidence of Training Documentation |
| C115606 | Trial Team Training Material | | Documentation pertaining to the training materials for the clinical trial team. | Clinical Trial Team Training Material Documentation |
| C126094 | Vendor Management Plan | | Documentation describing the overall management strategy for vendors used to conduct clinical trial-related activities. | Clinical Trial Vendor Management Plan Documentation |