## **CDISC MRCT Controlled Terminology, 2024-03-29**

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

NCI Code	CDISC Submission Value	Codelist Name	CDISC Definition	Codelist Extensible
C203912	MRCT Center Clinical Research Glossary	MRCT Center Clinical Research Glossary	The terminology relevant to the plain language glossary of the Multi-Regional Clinical Trial (MRCT) Center of Brigham and Women's Hospital and Harvard.	

NCI Code: C203912, Codelist extensible:

	C203912	MRCT Center Clinical Research			
0000011	NCI Code	Glossary CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C203914		additive effect		The combined effect when two or more things are used together. (https://mrctcenter.org/glossaryterm/additive-effect/)	Additive Effect
C25729 C41331		adherence adverse event		Following the study directions and requirements. (https://mrctcenter.org/glossaryterm/adherence/) Any health problem that happens during the study. (https://mrctcenter.org/glossaryterm/adverse-	Adherence Adverse Event
C41332		adverse reaction		event/) A health problem that happens during the study and is reported as possibly caused by the study	Adverse Reaction
C142392		anonymize		treatment. (https://mrctcenter.org/glossaryterm/adverse-reaction/) Remove, change, or hide personal details to protect participant privacy.	Anonymization
C268		antigen		(https://mrctcenter.org/glossaryterm/anonymize/) A substance that causes the body's immune system to react.	Antigen
C15538		arm		(https://mrctcenter.org/glossaryterm/antigen/) A group of participants in a research study who all receive the same study treatment.	Protocol Treatment Arm
C203934		assent form		(https://mrctcenter.org/glossaryterm/arm/)  A document used to explain the details of a research study to children or people who are unable to	Assent Form
				give legal consent. (https://mrctcenter.org/glossaryterm/assent-form/)	
C161418		assent		Willingness to take part in a research study by someone who is not able to give legal consent. (https://mrctcenter.org/glossaryterm/assent/)	Informed Assent
C25217		assessment		Information that is collected and analyzed from a study participant. (https://mrctcenter.org/glossaryterm/assessment/)	Assessment
C142400		baseline assessment		Information that is collected and analyzed from a study participant at the start of a study. (https://mrctcenter.org/glossaryterm/baseline-assessment/)	Baseline Assessment
C165823		basket trial		A research study that tests one study treatment for different diseases and conditions. (https://mrctcenter.org/glossaryterm/basket-trial/)	Basket Protocol
C203915		benefits of a research study		The ways a research study might help the participant and others. (https://mrctcenter.org/glossaryterm/benefits-of-a-research-study/)	Benefits of a Research Study
C28232		bias (research)		Flaws in the way a study is designed, done, or analyzed that lead to one conclusion being favored over another. (https://mrctcenter.org/glossaryterm/research-bias/)	Bias
C16342		biomarker		Something in the body that is measured as an indicator of personal health or disease. (https://mrctcenter.org/glossaryterm/biomarker/)	Biomarker
C37932 C17610		birth control blood draw		A way to prevent pregnancy. (https://mrctcenter.org/glossaryterm/birth-control/) Taking a sample of blood by using a needle. (https://mrctcenter.org/glossaryterm/blood-draw/)	Contraception Blood Sample
C142422		clinical benefit		A health change that researchers measure to show that the study treatment helps the study	Clinical Benefit
C51811		Clinical Research Coordinator		participants. (https://mrctcenter.org/glossaryterm/clinical-benefit/) A research staff member \( \text{N} \) helps manage studies. (https://mrctcenter.org/glossaryterm/clinical-	Clinical Coordinator
C142435		(CRC) clinical research		research-coordinator-crc/) A controlled method of studying health and illness in people.	Clinical Research and Development
C71104		clinical trial		(https://mrctcenter.org/glossaryterm/clinical-research/) A research study that tests drugs, devices and treatments to see if they are safe and work in	Clinical Trial
C85499		clinician		people. (https://mrctcenter.org/glossaryterm/clinical-trial/) A health care provider. (https://mrctcenter.org/glossaryterm/clinician/)	Clinician
C61512		cohort		A group of study participants that are similar in some way.  (https://mrctcenter.org/glossaryterm/cohort/)	Cohort
C203916		Comparative Effectiveness Research (CER)		A study comparing two or more treatments. (https://mrctcenter.org/glossaryterm/comparative-effectiveness-research-cer/)	Comparative Effectiveness Research
C39490		compliance		Following research requirements. (https://mrctcenter.org/glossaryterm/compliance/)	Patient Compliance
C17204		Computerized Tomography (CT) scan		A way to take pictures of the inside of a person's body using a type of radiation and a computer. (https://mrctcenter.org/glossaryterm/computerized-tomography-ct-scan/)	Computed Tomography
C153144 C53324		conduct confidence interval		To do a study or procedure. (https://mrctcenter.org/glossaryterm/conduct/) The defined range of numbers used to describe where the results are expected to fall.	Study Conduct Confidence Interval
C16466		confidentiality		(https://mrctcenter.org/glossaryterm/confidence-interval/) Protecting personal information from people who should not have access.	Confidentiality
C203917		confounding		(https://mrctcenter.org/glossaryterm/confidentiality/) When the study outcome is influenced by outside conditions that were not expected by the study	Confound
C16468		consent form		researchers. (https://mrctcenter.org/glossaryterm/confounding/) A document used to explain the planned research before a person decides whether or not to join a	Consent Form
C54148		Contract Research Organization		study. (https://mrctcenter.org/glossaryterm/consent-form/) A group that is paid by the study sponsor to support research studies.	Contract Research Organization
C28143		(CRO) control group		(https://mrctcenter.org/glossaryterm/contract-research-organization-cro/) The people in a study who do not receive the study treatment or do not have the condition being	Control Group
				studied. (https://mrctcenter.org/glossaryterm/control-group/)	·
C48834 C142489		correlation Data Monitoring Committee/Data		When two or more measures are linked. (https://mrctcenter.org/glossaryterm/correlation/) An independent group of experts that reviews study data to make sure that patient safety is	Correlation Data Monitoring Committee
		and Safety Monitoring Board (DMC/DSMB)		protected. (https://mrctcenter.org/glossaryterm/data-monitoring-committee-data-and-safety-monitoring)	
C25474		data		Information collected from or about people taking part in a research study. (https://mrctcenter.org/glossaryterm/data/)	Data
C142444		discontinue (participant)		To remove a study participant from a study. (https://mrctcenter.org/glossaryterm/discontinue- participant/)	Study Subject Discontinuation
C49502		discontinue (study treatment)		To stop a study treatment in a participant. (https://mrctcenter.org/glossaryterm/discontinue-study-treatment/)	Drug Withdrawn
C17747 C17751		disease progression disease-free survival		An illness getting worse over time. (https://mrctcenter.org/glossaryterm/disease-progression/) The length of time after treatment that a person lives without the illness coming back.	Disease Progression Disease-Free Survival
C90475		dose escalation study		(https://mrctcenter.org/glossaryterm/disease-free-survival/) A kind of study where increasing amounts of a study treatment are given to different groups to find	Titration Study
C15228		double-blind study		the best dose. (https://mrctcenter.org/glossaryterm/dose-escalation-study/)  A study that is set up so that the study treatment that each participant receives is not known by the	Double Blind Study
		·		participants or the researchers. (https://mrctcenter.org/glossaryterm/double-blind-study/)	·
C203920		e-consent (form)		An electronic version of an informed consent form. (https://mrctcenter.org/glossaryterm/e-consent-form/)	Electronic Consent Form
C142522 C88183		effectiveness efficacy		How well a treatment works. (https://mrctcenter.org/glossaryterm/effectiveness/) How well a study treatment works in the study. (https://mrctcenter.org/glossaryterm/efficacy/)	Effectiveness Efficacy
C16112		eligibility criteria		The reasons a person can be included in, or excluded from, a study. (https://mrctcenter.org/glossaryterm/eligibility-criteria/)	Clinical Trial Eligibility Criteria
C96966		Emergency Use Authorization (EUA)		A process to make a treatment or vaccine available during a public health emergency, before all research is complete, and before full approval is granted.	Emergency Use Authorization
C25212		endpoint		(https://mrctcenter.org/glossaryterm/emergency-use-authorization-eua/) A measure of the expected effect of the study treatment.	End Point
C37948		enroll		(https://mrctcenter.org/glossaryterm/endpoint/) The action of a participant joining the study after providing informed consent.	Enrollment
C17843		epidemiologist		(https://mrctcenter.org/glossaryterm/enroll/) A person who studies where, why, how often, and to what populations health concerns and	Epidemiologist
C17043		equivalence		diseases happen. (https://mrctcenter.org/glossaryterm/epidemiologist/) When two or more things in a study are about the same.	Equivalence Trial
C142539		equivalence equivalent (effect)		(https://mrctcenter.org/glossaryterm/equivalence/)	•
C203921 C25370		exclusion criteria		The same or almost the same result. (https://mrctcenter.org/glossaryterm/equivalent-effect/) A list of reasons a person cannot be included in a study.	Equivalent Effect Exclusion Criteria
C98722		expanded access		(https://mrctcenter.org/glossaryterm/exclusion-criteria/) A process for a doctor to request an unapproved treatment for a seriously ill patient.	Expanded Access Study
C147146		exploratory research		(https://mrctcenter.org/glossaryterm/expanded-access/) A process to find facts that can guide the design of future studies.	Exploratory Research
C25515		frequency		(https://mrctcenter.org/glossaryterm/exploratory-research/) How often something happens over a period of time.	Temporal Frequency
C142429		generalizability		(https://mrctcenter.org/glossaryterm/frequency/) How research results can apply to people who were not part of the study.	Clinical Generalizability
C93150		hazard ratio		(https://mrctcenter.org/glossaryterm/generalizability/) A measure of risk that compares two treatments in the same study.	Hazard Ratio
C49651		healthy volunteer		(https://mrctcenter.org/glossaryterm/hazard-ratio/) A study participant who does not have a disease or condition, including the one being studied.	Healthy Subject
C27998		hereditary		(https://mrctcenter.org/glossaryterm/healthy-volunteer/) A parent's features and traits being passed to their biological children before birth.	Hereditary
				(https://mrctcenter.org/glossaryterm/hereditary/)	•
C142668 C16726		hypothesis incidence		An idea that is tested in a research study. (https://mrctcenter.org/glossaryterm/hypothesis/)  Number of new cases or events during a period of time.	Research Hypothesis Incidence
C25532		inclusion criteria		(https://mrctcenter.org/glossaryterm/incidence/) A list of requirements a person must meet to take part in a study.	Inclusion Criteria
C16735		informed consent		(https://mrctcenter.org/glossaryterm/inclusion-criteria/) The process of learning and discussing the details of a research study before deciding whether to	Informed Consent
C15388		infusion		take part. (https://mrctcenter.org/glossaryterm/informed-consent/) A way to give a fluid to the study participant, usually through a vein.	Infusion Procedure
				(https://mrctcenter.org/glossaryterm/infusion/)	

16741 202579 41161 25936 15273 16809 25564 53319 28007 25570 61256	NCI Code	CDISC Submission Value Institutional Review Board (IRB) investigational medicine	CDISC Synonym	CDISC Definition  A team of people who review studies to protect the rights and welfare of study participants.	NCI Preferred Term Institutional Review Board
41161 25936 15273 16809 25564 53319 28007		investigational modicine			
25936 15273 16809 25564 53319 28007		investigational medicine		(https://mrctcenter.org/glossaryterm/institutional-review-board-irb/) A treatment or drug that is not yet approved for the condition being studied.	Investigational Medicinal Produc
15273 16809 25564 53319 28007		investigational product		(https://mrctcenter.org/glossaryterm/investigational-medicine/) A drug, device, vaccine or other treatment being tested in a study.	Protocol Agent
16809 25564 53319 28007		investigator		(https://mrctcenter.org/glossaryterm/investigational-product/) A person who leads a research study. (https://mrctcenter.org/glossaryterm/investigator/)	Investigator
25564 53319 28007 25570		longitudinal study		Research that collects data from the same participants over a long time. (https://mrctcenter.org/glossaryterm/longitudinal-study/)	Longitudinal Study
53319 28007 25570		Magnetic Resonance Imaging (MRI)		A way to take pictures of the inside of a person's body with a machine that uses strong magnets and radio waves. (https://mrctcenter.org/glossaryterm/magnetic-resonance-imaging-mri/)	Magnetic Resonance Imaging
28007 25570		maximum		The most or largest amount. (https://mrctcenter.org/glossaryterm/maximum/)	Maximum Arithmetic Mean
		mean median		The average. (https://mrctcenter.org/glossaryterm/mean/) The middle number in a set of numbers when listed in order from lowest to highest.	Median
31256		minimal	minimum	(https://mrctcenter.org/glossaryterm/median/) Very small. (https://mrctcenter.org/glossaryterm/minimal/)	Minimum
		monitor		To observe, check or evaluate something in a study over time. (https://mrctcenter.org/glossaryterm/monitor/)	Monitoring
184382		morbidity (rate)		The number of people who develop a disease or illness in a group over time. (https://mrctcenter.org/glossaryterm/morbidity-rate/)	Morbidity Rate
16880		mortality (rate)		The number of deaths in a group of people over time. (https://mrctcenter.org/glossaryterm/mortality-rate/)	Mortality Rate
16104		multicenter trial		A study that takes place at more than one research center. (https://mrctcenter.org/glossaryterm/multicenter-trial/)	Multi-Institutional Clinical Trial
35681		negative test result		A test result that shows a person does not have what was tested for. (https://mrctcenter.org/glossaryterm/negative-test-result/)	Negative Test Result
203922		negligible		So small that it has little to no impact. (https://mrctcenter.org/glossaryterm/negligible/)	Negligible
91752 184386		non-compliance non-inferiority trial		Not following research requirements. (https://mrctcenter.org/glossaryterm/non-compliance/) A study to test if a study treatment works about as well as another treatment for the same condition.	Patient Noncompliance Non-Inferiority Study
142450		objective		(https://mrctcenter.org/glossaryterm/non-inferiority-trial/) A purpose or goal of a study. (https://mrctcenter.org/glossaryterm/objective/)	Clinical Trial Objective
16084		observational study		A study that collects health information about study participants without giving a treatment. (https://mrctcenter.org/glossaryterm/observational-study/)	Observational Study
16932		odds ratio		The chance of a health event happening in one group compared with the chance of the same event	Odds Ratio
125600		off-label		happening in another group. (https://mrctcenter.org/glossaryterm/odds-ratio/)  The use of a treatment in a different way or for a condition other than what it is approved for.	Off-Label Treatment
19659		open-label		(https://mrctcenter.org/glossaryterm/off-label/)  A type of study where participants and research staff know which treatment participants are being	Open Label Study
204098		outcome (of study)		given. (https://mrctcenter.org/glossaryterm/open-label/) A description of the overall results of the study. (https://mrctcenter.org/glossaryterm/outcome-of-	Study Outcome
93407		outcome measure		study/) The way that a study endpoint is measured. (https://mrctcenter.org/glossaryterm/outcome-	Study Outcome Measurement
14185		p-value (probability value)		measure/) A number that researchers use to show that a result did not occur by chance.	P-Value
				(https://mrctcenter.org/glossaryterm/p-value-probability-value/)	
95401		Patient Reported Outcomes (PROs)		The information that patients share about their own health or well-being to answer questions in a study. (https://mrctcenter.org/glossaryterm/patient-reported-outcomes-pros/)	Patient Reported Outcome
6963 19662		peer review Pharmacodynamic (PD) study		Evaluation by independent experts. (https://mrctcenter.org/glossaryterm/peer-review/) A study that measures the effects of a drug on the human body.	Peer Review Pharmacodynamic Study
15299		Pharmacokinetic (PK) study		(https://mrctcenter.org/glossaryterm/pharmacodynamic-pd-study/) A study that measures what happens to a drug in a person's body over time.	Pharmacokinetics
42637		pharmacovigilance		(https://mrctcenter.org/glossaryterm/pharmacokinetic-pk-study/) A process to detect, review, and make decisions about drug safety to protect patients.	Pharmacovigilance
8281		phase		(https://mrctcenter.org/glossaryterm/pharmacovigilance/) A step in the overall clinical research process to test a new drug, device, or treatment.	Trial Phase
		•		(https://mrctcenter.org/glossaryterm/phase/) Something that looks like the treatment being studied, but doesn't contain any medicine.	
753		placebo		(https://mrctcenter.org/glossaryterm/placebo/)	Placebo
203925		placebo-controlled study		A study with two or more groups where one group is given a placebo. (https://mrctcenter.org/glossaryterm/placebo-controlled-study/)	Placebo-Controlled Study
165829		platform trial		A research study that tests and compares two or more study treatments for a disease or condition, with study treatment groups being added or removed during the study period.	Platform Protocol
38758		positive test result		(https://mrctcenter.org/glossaryterm/platform-trial/) A test result that shows a person has what was tested for.	Positive Finding
187706		post-trial access		(https://mrctcenter.org/glossaryterm/positive-test-result/) When participants can still receive a study treatment after their participation has ended.	Continued Access Study
142642		preclinical study		(https://mrctcenter.org/glossaryterm/post-trial-access/) A study to test a treatment in the lab or in animals before testing it in people.	Preclinical Study
17010		prevalence		(https://mrctcenter.org/glossaryterm/preclinical-study/) Number of known cases or events in a group. (https://mrctcenter.org/glossaryterm/prevalence/)	Prevalence
94496		primary endpoint		A study measure that is used to answer the main research question.	Primary Endpoint
54154		probability		(https://mrctcenter.org/glossaryterm/primary-endpoint/) The likelihood or chance that something might happen.	Probability
28234		progression-free survival		(https://mrctcenter.org/glossaryterm/probability/) The length of time without a person's illness getting worse.	Progression-free Survival
142646		prospective study		(https://mrctcenter.org/glossaryterm/progression-free-survival/) Research that uses new data collected from participants.	Prospective Study
142451		protocol		(https://mrctcenter.org/glossaryterm/prospective-study/) A complete description of the research plan and procedures.	Clinical Trial Protocol
19264		•		(https://mrctcenter.org/glossaryterm/protocol/)	
		proxy		A person who is legally allowed to make research decisions for someone else. (https://mrctcenter.org/glossaryterm/proxy/)	Proxy
03926		pseudonymize		Replace personal details with a code so that data are protected. (https://mrctcenter.org/glossaryterm/pseudonymized/)	Pseudonymize
7047		Quality of Life (QOL)		How someone feels and functions day to day. (https://mrctcenter.org/glossaryterm/quality-of-life-qol/)	Quality of Life
7048		questionnaire		A list of questions for study participants to answer as part of the study. (https://mrctcenter.org/glossaryterm/questionnaire/)	Questionnaire
5196		randomization		A way to use chance to place study participants into different study treatment groups. (https://mrctcenter.org/glossaryterm/randomization/)	Randomization
16079		randomized controlled trial		Research that uses chance for participants to be assigned to the study treatment group or a comparison group. (https://mrctcenter.org/glossaryterm/randomized-controlled-trial/)	Randomized Controlled Clinical Trial
65830		Real World Data (RWD)		Health-related information collected from many different types of records and used for research purposes. (https://mrctcenter.org/glossaryterm/real-world-data-rwd/)	Real-world Data
65831		Real World Evidence (RWE)		Findings from analyzing real world data. (https://mrctcenter.org/glossaryterm/real-world-evidence-	Real-world Evidence
3453		registry (study)		rwe/) An organized list of research information. (https://mrctcenter.org/glossaryterm/registry-study/)	Study Registry
3152		relative risk		The chance of a harmful event happening in one study group compared to another. (https://mrctcenter.org/glossaryterm/relative-risk/)	Relative Risk
03930 3312		results (study) retrospective study		Findings from the study. (https://mrctcenter.org/glossaryterm/results-study/) Research that uses already existing data. (https://mrctcenter.org/glossaryterm/retrospective-study/)	Study Results Retrospective Study
03928		risk-benefit ratio		A comparison of the possible bad and potential good things that could happen if a participant joins a research study. (https://mrctcenter.org/glossaryterm/risk-benefit-ratio/)	Risk-Benefit Ratio
42718		risks of a research study		The possible harms of being in a research study. (https://mrctcenter.org/glossaryterm/risks-of-a-research-study/)	Subject Risk
3190		sample size		The number of participants in a study or study group. (https://mrctcenter.org/glossaryterm/sample-	Sample Size
42678		schedule of assessments		size/) A chart that lists the study activities and when they will happen during a study.	Schedule Of Assessments
8262		screening		(https://mrctcenter.org/glossaryterm/schedule-of-assessments/) Tests and questions to find out if a person can join a study.	Trial Screening
39173		secondary endpoint		(https://mrctcenter.org/glossaryterm/screening/) A measure used to answer other important questions in the study that are not the main research	Secondary Endpoint
1394		sensitivity (medical test)		question. (https://mrctcenter.org/glossaryterm/secondary-endpoint/) How well a medical test can accurately identify people who have a disease or trait.	Diagnostic Sensitivity
				(https://mrctcenter.org/glossaryterm/sensitivity-medical-test/)	·
2861		side effect		A health change that is not the intended effect of the treatment and usually considered a problem. (https://mrctcenter.org/glossaryterm/side-effect/)	Side Effect
28233		single-blind study		A study that is set up so that the study treatment each participant receives is not known by the participants but is known by the researchers. (https://mrctcenter.org/glossaryterm/single-blind-	Single Blind Study
41395		specificity (medical test)		study/) How well a medical test can accurately identify people who do not have a disease or trait.	Diagnostic Specificity
70793		sponsor		(https://mrctcenter.org/glossaryterm/specificity-medical-test/) The group that is in charge of, or pays for, a research study.	Clinical Study Sponsor

	C203912	MRCT Center Clinical Research Glossary			
	NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C94396		standard of care		The usual treatment given to patients for an illness. (https://mrctcenter.org/glossaryterm/standard-of-care/)	Best Practice
C61040		statistically significant		Results that are very unlikely to have occurred by chance. (https://mrctcenter.org/glossaryterm/statistically-significant/)	Statistical Significance
C15320		study design		The way a study is set up to answer the study question. (https://mrctcenter.org/glossaryterm/study-design/)	Study Design
C25218		study intervention		A treatment given to the participants in a study. (https://mrctcenter.org/glossaryterm/study-intervention/)	Intervention or Procedure
C203929		study life cycle		The steps of a research study from beginning to end. (https://mrctcenter.org/glossaryterm/study-life-cycle/)	Study Life Cycle
C142710		study participant		A person who joins a research study. (https://mrctcenter.org/glossaryterm/study-participant/)	Study Participant
C70833		study population		All the participants in a study. (https://mrctcenter.org/glossaryterm/study-population/)	Study Population
C142737		study statistician		A person who uses math to help design a study and interpret the data. (https://mrctcenter.org/glossaryterm/study-statistician/)	Trial Statistician
C198230		substudy		A study with a smaller group of participants already enrolled in the main study. (https://mrctcenter.org/glossaryterm/substudy/)	Substudy
C142722		superiority trial		A study to test if a study treatment works better than another treatment for the same condition. (https://mrctcenter.org/glossaryterm/superiority-trial/)	Superiority Trial
C203931		synergistic effect		When two or more things used together have a greater effect than each thing alone. (https://mrctcenter.org/glossaryterm/synergistic-effect/)	Synergistic Effect
C38032		treatment effect		How much a study treatment changes a condition, symptom, or function. (https://mrctcenter.org/glossaryterm/treatment-effect/)	Therapeutic Effect
C165842		umbrella trial		A research study that tests and compares two or more study treatments for one disease or condition. (https://mrctcenter.org/glossaryterm/umbrella-trial/)	Umbrella Protocol
C203933		voluntary participation		Choosing to participate in research without feeling pressured. (https://mrctcenter.org/glossaryterm/voluntary-participation/)	Voluntary Participation
C42872		wash-out		A time before starting a study treatment when a person stops taking other medicines. (https://mrctcenter.org/glossaryterm/wash-out/)	Washout Period
C49634		withdraw		To stop being a participant in a study. (https://mrctcenter.org/glossaryterm/withdraw/)	Withdrawal by Subject
C38101		X-ray		A way of taking pictures of the inside of a person's body using X-ray radiation. (https://mrctcenter.org/glossaryterm/x-ray/)	X-Ray Imaging