ICH M11 Controlled Terminology, 2025-12-19

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

NCI Code	ICH Preferred Term	Codelist Name	ICH Definition	Codelist Extensible
C217274	Amendment Details Statement Response Terminology	Amendment Details Statement Response Terminology	A valid value set relevant to the amendment details statement responses within the ICH M11 protocol template.	No
C217275	Amendment Scope Enrollment Description Response Terminology	Amendment Scope Enrollment Description Response Terminology	A valid value set relevant to the amendment scope enrollment description responses within the ICH M11 protocol template.	No
C217047	Amendment Scope Response Terminology	Amendment Scope Response Terminology	Terminology associated with the amendment scope value set codelist of the ICH M11 protocol template.	No
C217279	Control Type Response Terminology	Control Type Response Terminology	A valid value set relevant to the control type responses within the ICH M11 protocol template.	No
C217351	ICH M11 Section 10 Terminology	ICH M11 Section 10 Terminology	Terminology relevant to the data elements in section 10 of the ICH M11 protocol template.	No
C217352	ICH M11 Section 11 Terminology	ICH M11 Section 11 Terminology	Terminology relevant to the data elements in section 11 of the ICH M11 protocol template.	No
C217353	ICH M11 Section 12 Terminology	ICH M11 Section 12 Terminology	Terminology relevant to the data elements in section 12 of the ICH M11 protocol template.	No
C217354	ICH M11 Section 13 Terminology	ICH M11 Section 13 Terminology	Terminology relevant to the data elements in section 13 of the ICH M11 protocol template.	No
C217355	ICH M11 Section 14 Terminology	ICH M11 Section 14 Terminology	Terminology relevant to the data elements in section 14 of the ICH M11 protocol template.	No
C217342	ICH M11 Section 1 Terminology	ICH M11 Section 1 Terminology	Terminology relevant to the data elements in section 1 of the ICH M11 protocol template.	No
C217343	ICH M11 Section 2 Terminology	ICH M11 Section 2 Terminology	Terminology relevant to the data elements in section 2 of the ICH M11 protocol template.	No
C217344	ICH M11 Section 3 Terminology	ICH M11 Section 3 Terminology	Terminology relevant to the data elements in section 3 of the ICH M11 protocol template.	No
C217345	ICH M11 Section 4 Terminology	ICH M11 Section 4 Terminology	Terminology relevant to the data elements in section 4 of the ICH M11 protocol template.	No
C217346	ICH M11 Section 5 Terminology	ICH M11 Section 5 Terminology	Terminology relevant to the data elements in section 5 of the ICH M11 protocol template.	No
C217347	ICH M11 Section 6 Terminology	ICH M11 Section 6 Terminology	Terminology relevant to the data elements in section 6 of the ICH M11 protocol template.	No
C217348	ICH M11 Section 7 Terminology	ICH M11 Section 7 Terminology	Terminology relevant to the data elements in section 7 of the ICH M11 protocol template.	No
C217349	ICH M11 Section 8 Terminology	ICH M11 Section 8 Terminology	Terminology relevant to the data elements in section 8 of the ICH M11 protocol template.	No
C217350	ICH M11 Section 9 Terminology	ICH M11 Section 9 Terminology	Terminology relevant to the data elements in section 9 of the ICH M11 protocol template.	No
C217357	ICH M11 Section Amendment Details Terminology	ICH M11 Section Amendment Details Terminology	Terminology relevant to the data elements in the amendment details section of the ICH M11 protocol template.	No
C217356	ICH M11 Section Title Page Terminology	ICH M11 Section Title Page Terminology	Terminology relevant to the data elements in the title page of the ICH M11 protocol template.	No
C217282	Independent Committee Name Response Terminology	Independent Committee Name Response Terminology	A valid value set relevant to the independent committee name responses within the ICH M11 protocol template.	No
C217277	Intervention Model Response Terminology	Intervention Model Response Terminology	A valid value set relevant to the intervention model responses within the ICH M11 protocol template.	No
C217284	Intervention Type Response Terminology	Intervention Type Response Terminology	A valid value set relevant to the intervention type responses within the ICH M11 protocol template.	No
C217285	Intervention Use Response Terminology	Intervention Use Response Terminology	A valid value set relevant to the intervention use responses within the ICH M11 protocol template.	No
C217052	Investigational Intervention Sourcing Response Terminology	Investigational Intervention Sourcing Response Terminology	Terminology associated with the sourcing value set codelist of the ICH M11 protocol template.	No
C217286	Investigational Medicinal Product Indicator Response Terminology	Investigational Medicinal Product Indicator Response Terminology	A valid value set relevant to the investigational medicinal product indicator responses within the ICH M11 protocol template.	No
C217046	No Yes Response Terminology	No Yes Response Terminology	Terminology associated with the no yes value set codelist of the ICH M11 protocol template.	No
C217278	Population Type Response Terminology	Population Type Response Terminology	A valid value set relevant to the population type responses within the ICH M11 protocol template.	No
C217272	Protocol Section Name and Number Response Terminology	Protocol Section Name and Number Response Terminology	A valid value set relevant to the protocol section name and number responses within the ICH M11 protocol template.	No
C217276	Reason for Amendment Response Terminology	Reason for Amendment Response Terminology	A valid value set relevant to the reason for amendment responses within the ICH M11 protocol template.	No
C217283	Trial Arm Type Response Terminology	Trial Arm Type Response Terminology	A valid value set relevant to the trial arm type responses within the ICH M11 protocol template.	No
C217281	Trial Blinding Role Response Terminology	Trial Blinding Role Response Terminology	A valid value set relevant to the trial blinding role responses within the ICH M11 protocol template.	No
C217051	Trial Blinding Schema Response Terminology	Trial Blinding Schema Response Terminology	Terminology associated with the trial blind schema value set codelist of the ICH M11 protocol template.	No
C217280	Trial Intervention Assignment Method Response Terminology	Trial Intervention Assignment Method Response Terminology	A valid value set relevant to the trial intervention assignment method responses within the ICH M11 protocol template.	No
C217045	Trial Phase Response Terminology	Trial Phase Response Terminology	Terminology associated with the trial phase value set codelist of the ICH M11 protocol template.	No
C217287	Trial-Related Safety Event Type Response Terminology	Trial-Related Safety Event Type Response Terminology	A valid value set relevant to the trial-related safety event type responses within the ICH M11 protocol template.	No
C217049	Trial Site Distribution Response Terminology	Trial Site Distribution Response Terminology	Terminology associated with the site distribution value set codelist of the ICH M11 protocol template.	No
C217050	Trial Site Geographic Scope Response Terminology	Trial Site Geographic Scope Response Terminology	Terminology associated with the site geographic scope value set codelist of the ICH M11 protocol template.	No
C217048	Unit of Measure Terminology	Unit of Measure Terminology	Terminology associated with the units of measure value set codelist of the ICH M11 protocol template.	No

Amendment Details Statement Response Terminology (Amendment Details Statement Response Terminology)

NCI Code: C217274, Codelist extensible: No

C217274	Amendment Details Statement Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218486	This is the first protocol amendment.		This is the first protocol amendment.	First Protocol Amendment
C218487	This protocol has been amended previously. Details of prior amendments are presented in Section 12.3 Prior Protocol Amendment(s).		This protocol has been amended previously. Details of prior amendments are presented in Section 12.3 Prior Protocol Amendment(s).	Protocol Previously Amended, Details Presented
C218488	This protocol has been amended previously. The Protocol Amendment Summary of Changes for the current amendment is located directly before the Table of Contents. Prior amendment(s) to this protocol are listed in the table below, beginning with the most recent.		This protocol has been amended previously. The Protocol Amendment Summary of Changes for the current amendment is located directly before the Table of Contents. Prior amendment(s) to this protocol are listed in the table below, beginning with the most recent.	Protocol Previously Amended See Summary of Changes Before the Table of Contents
C218485	This protocol has not been amended.		This protocol has not been amended.	Protocol Not Amended

Amendment Scope Enrollment Description Response Terminology (Amendment Scope Enrollment Description Response Terminology)

NCI Code: C217275, Codelist extensible: No

C217275	Amendment Scope Enrollment Description Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218489	By Cohort		Covering or affecting a cohort of individuals.	By Cohort
C68846	Globally		Covering or affecting the whole of a system.	Global
C41065	Locally		Covering or affecting a portion of the system.	Locally

Amendment Scope Response Terminology (Amendment Scope Response Terminology)

NCI Code: C217047, Codelist extensible: No

C217047	Amendment Scope Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C68846	Global		Covering or affecting the whole of a system.	Global
C217026	Not Global		Covering or affecting a portion of the system.	Not Global

Control Type Response Terminology (Control Type Response Terminology)

NCI Code: C217279, Codelist extensible: No

C217279	Control Type Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C49649	Active Comparator		A type of control, which has a demonstrated effect, administered as a comparator to participants in a clinical trial.	Active Control
C218505	Different Dose or Regimen		A type of control that comprises a different dose or dosage regimen in comparison to the investigational intervention dose or dosage regimen.	Different Dose or Regimen Control
C120841	Dose Response		A type of control using different doses or regimens of the same treatment across the treatment arms.	Dose Response Control
C218506	External		The use of external control data as a control arm for those studies where ethical concerns and/or underserved disease indications may make it difficult to enroll participants.	External Control
C28280	No Control		A clinical study that lacks a comparison (i.e., a control) group.	Uncontrolled Study
C49648	Placebo		An inactive, identical-appearing drug or treatment that does not contain the test product.	Placebo Control
C184727	Sham Procedure		A type of negative control in which a procedure is performed that mimics the procedure under study but does not include investigational processes or components.	Sham Control

ICH M11 Section 10 Terminology (ICH M11 Section 10 Terminology)

NCI Code: C217351, Codelist extensible: No

C217351	ICH M11 Section 10 Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218807	Analyses Associated with the Exploratory Objective(s)		A description of the statistical model, hypothesis, and methods of analyses for each exploratory objective within the trial.	Exploratory Objective Statistical Analysis Method
C218802	Analyses of Demographics and Other Baseline Variables		A description of analyses relevant to variables at baseline, for example demographics, related to the trial.	Description of Trial Baseline Variable Analysis
C218801	Analysis Sets		A description of the set of participants whose data are to be included in the analyses.	Description of the Participants Included in Data Analysis
C164387	General Considerations		Careful thought or deliberation related to the planned conduct of statistical analyses within the context of the trial.	General Statistical Consideration
C218803	Handling of Data in Relation to Primary Estimand(s)		A description of how data will be handled for the statistical analysis in line with the primary estimand.	Handling of Data in Relation to Primary Estimand(s)
C218805	Handling of Data in Relation to Secondary Estimand(s)		A description of how data will be handled for the statistical analysis in line with the secondary estimand.	Handling of Data in Relation to Secondary Estimand(s)
C218804	Handling of Missing Data in Relation to Primary Estimand(s)		A description of how missing data associated with the primary estimand will be handled, including the rationale for the approach.	Handling of Missing Data in Relation to Primary Estimand(s)
C218806	Handling of Missing Data in Relation to Secondary Estimand(s)		A description of how missing data associated with the secondary estimand will be handled, including the rationale for the approach.	Handling of Missing Data in Relation to Secondary Estimand(s)
C142582	Interim Analyses		A description of any analysis intended to compare treatment arms with respect to efficacy or safety at any time prior to the formal completion of a trial.	Interim Analysis
C218810	Multiplicity Adjustments		A description of the statistical adjustments needed to limit the probability of false positive findings in trials where there are multiple simultaneous hypotheses.	Multiplicity Adjustments
C218809	Other Analyses		A description of the analyses that are different than the one(s) previously specified or mentioned.	Other Analysis
C218808	Safety Analyses		A description of the analyses of relevant safety variables, including adverse events of special interest.	Safety Analysis
C115467	Sample Size Determination		A statistical calculation to determine the number of participants required for the primary analysis, which should be large enough to provide a reliable answer to the questions addressed and should be determined by the primary objective of the trial. If the sample size is determined on some other basis, then this should be made clear and justified.	Sample Size Calculation
C218480	Sensitivity Analysis		A description of the series of analyses conducted to explore the robustness of inferences from the main estimator to deviations from its underlying modeling assumptions and limitations in the data.	Treatment Effect Sensitivity Analysis
C218482	Statistical Analysis Method		A description of the statistical model, hypothesis, and methods of analyses for each objective within the trial.	Trial-Related Statistical Analysis Method
C218481	Supplementary Analysis		A description of the analyses that are conducted in addition to the main and sensitivity analysis with the intent to provide additional insights into the understanding of the treatment effect.	Treatment Effect Supplementary Analysis

ICH M11 Section 11 Terminology (ICH M11 Section 11 Terminology)

NCI Code: C217352, Codelist extensible: No

C217352	ICH M11 Section 11 Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218819	Committees		A description of the type and administrative structure of any committee associated with the trial.	Committee Description
C218829	Criteria for Early Closure		The requirements that must be met in order to close a trial site prematurely.	Criteria for Early Trial Site Closure
C218831	Data Dissemination		A description of whether and which public databases the clinical trial, and results if applicable, will be registered.	Study Data Dissemination
C218822	Data Governance		A description of the key processes to ensure data integrity, traceability and security, in order to enable accurate collection, reporting, monitoring, transfer, retention, access and publication.	Data Governance
C218823	Data Protection		A description of the measures taken to protect the privacy and confidentiality of person information of trial participants in accordance with applicable regulatory requirements on personal data protection and any measures that should be taken in case of a data security breach.	Data Protection
C218828	Decision Rights for Site Closure		A description of the legal principles of entitlement for the sponsor to close a trial site, or for the investigator to initiate the closure of a trial site.	Decision Rights for Trial Site Closure
C218815	Description of Assent Process		A description of the assent process for those individuals unable to give informed consent on their own behalf, to participate in the trial.	Description of Assent Process
C218816	Description of Emergency Consent Process		A type of informed consent process that may occur during an emergency situation in which the participant or their legally authorised representative is not available to give consent.	Description of Emergency Consent Process
C184390	Description of Informed Consent Process		The procedure by which informed consent is obtained and documented by means of a written, signed, and dated informed consent form. This process may include obtaining assent from participants with legally authorised representatives.	Informed Consent Process
C222675	Identification of Source Records		A description of how trial-related source records will be identified.	Identification of Source Records Description
C218817	Informed Consent for Rescreening		A description of the consent requirements for participants in the event of screen failure and rescreening.	Informed Consent Requirements for Rescreening
C218818	Informed Consent for Use of Remaining Samples in Exploratory Research		A description of the consent requirements for exploratory research using the remainder of mandatory samples. If applicable, this may include text in the original consent that address the use of remaining samples or additional text.	Informed Consent Requirements for Use of Remaining Samples in Exploratory Research
C218820	Insurance and Indemnity		A concise summary of the arrangements for participants insurance and indemnity as required by the applicable regulatory body.	Insurance and Indemnity Summary
C218825	Investigator Expectations for Source Records		A description of the obligations of the investigator with respect to maintaining and ensuring availability of the source records.	Investigator Expectations for Source Records
C218813	Investigator Responsibilities		A description of the obligations of the investigator with respect to the trial.	Investigator Responsibilities
C218827	Protocol Deviations		A description of plans for detecting, reviewing, and reporting any deviations from the protocol.	Protocol Deviation Management
C218811	Regulatory and Ethical Considerations		Careful thought or deliberation related to the regulatory and ethical aspects of the trial.	Trial Regulatory and Ethical Consideration
C218830	Responsibilities Following Early Site Closure		The responsibilities of the sponsor and/or investigator following an unplanned early termination or suspension of the trial at an individual site.	Responsibilities Following Early Trial Site Closure
C218821	Risk-Based Quality Management		A description of how potential risks and critical to quality factors associated with the trial will be identified and handled.	Risk-Based Quality Management
C218824	Source Records Introduction		A description of trial-related source records including the importance of source record maintenance and expectations for data traceability.	Trial-Related Source Records Description
C218814	Sponsor Responsibilities		A description of the obligations of the sponsor with respect to the trial.	Sponsor Responsibilities
C218826	Trial Monitor Expectations for Source Records		A description of the obligations of the trial monitor with respect to maintaining and ensuring availability of the source records.	Trial Monitor Expectations for Source Records
C218812	Trial Oversight		A description of the planned processes and procedures to govern and conduct a clinical trial in order to protect the rights, safety and welfare of the trial participants.	Trial Oversight Procedure Description

ICH M11 Section 12 Terminology (ICH M11 Section 12 Terminology)

NCI Code: C217353, Codelist extensible: No

C217353	ICH M11 Section 12 Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C220640	Additional Appendices		Extra or supplementary appendices added to the end of a document.	Additional Document Appendices
C218477	Amendment Identifier		A sequence of characters used to uniquely identify a protocol amendment.	Amendment Identifier
C218695	Amendment Scope Enrollment Description		The enrollment description as to whether the amendment scope applies globally, locally, or per cohort across the trial.	Amendment Scope Enrollment Description
C218478	Approximately <#/%> enrolled		The value (expressed either numerically or as a percentage) for the estimated number of participants enrolled at the time of the protocol amendment.	Approximate Participant Enrollment At Time of Sponsor Approval
C181233	Brief Rationale for Change		The brief reason for the change introduced in the current or prior version of the protocol.	Brief Rationale for Protocol Change
C25294	Clinical Laboratory Tests		Any procedure that involves testing or manipulating a sample of blood, urine, or other body substance in a laboratory setting.	Laboratory Procedure
C218832	Country/Region Identifier		A sequence of characters used to identify and/or name a country or region.	Country and/or Region Identifier
C218834	Country/Region Specific Protocol Clarifications		A description of any country or region-specific clarifications related to a protocol item.	Country and/or Region-Specific Protocol Clarifications Description
C218833	Country/Region-Specific Requirements		A description of any country or region-specific requirements related to the trial but not related to individual items in the protocol.	Country and/or Region-Specific Trial Requirements
C218483	Description of Change		A description of the change introduced in the current or prior version of the protocol.	Description of Protocol Change
C218835	Prior Protocol Amendment(s)		An indication as to whether the protocol has not been amended, is the first protocol amendment, or a statement that the protocol has been amended previously.	Prior Protocol Amendment Indicator
C218479	Section # and Name		The protocol section number and name containing the change introduced in the current or prior version of the protocol.	Protocol Change Section Number and Name
C218836	specify alternative location		The physical or virtual location of the overview of changes from each prior amendment.	Alternative Location of Protocol Changes
C132352	Sponsor Approval Date		The date that the sponsor approved a version of the protocol.	Protocol Approval by Sponsor Date

ICH M11 Section 13 Terminology (ICH M11 Section 13 Terminology)

NCI Code: C217354, Codelist extensible: No

C217354	ICH M11 Section 13 Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218837	Glossary of Terms and Abbreviations		A list of terms with their abbreviations and/or definitions.	Glossary of Terms and Abbreviations

ICH M11 Section 14 Terminology (ICH M11 Section 14 Terminology)

NCI Code: C217355, Codelist extensible: No

C217355	ICH M11 Section 14 Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C184397	References		The curated list of sources that are cited within the reference section of the document.	Reference List

ICH M11 Section 1 Terminology (ICH M11 Section 1 Terminology)

NCI Code: C217342, Codelist extensible: No

C217342	ICH M11 Section 1 Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218706	Adaptive Trial Design Indicator		An indication as to whether the clinical trial uses an adaptive trial design.	Adaptive Trial Design Indicator
C218838	Additional Description of Duration		A narrative providing additional details about the duration of a participant's use of a trial intervention or their planned participation time in the trial.	Additional Description of Duration
C218714	Alternate Description of Planned Duration of Trial Intervention		An alternative textual narrative for the planned duration of trial intervention.	Alternate Description of Planned Duration of Trial Intervention
C218717	Alternate Description of Planned Duration of Trial Participation		An alternative narrative for the planned duration of trial participation.	Alternate Description of Planned Duration of Trial Participation
C218709	Blinded Roles		An identifying designation assigned to a blinded individual within a clinical trial that corresponds with their function.	Blinding Role
C49647	Control Type		A characterisation or classification of the comparator against which the study intervention is evaluated.	Control Type
C218708	Drug/Device Combination Product Indicator		An indication as to whether the clinical trial is testing a drug-device combination product.	Drug/Device Combination Product Indicator
C218718	Independent Committees		An independent group of experts that has oversight over, and conducts periodic review of, specific trial activities.	Independent Oversight Committee
C142585	INN		A unique name that is globally recognised and public property, which identifies pharmaceutical substances or active pharmaceutical ingredients.	International Nonproprietary Name
C218475	Intervention Assignment Method		The technique used to assign trial participants to a trial intervention or trial arm.	Intervention Assignment Method
C98746	Intervention Model		The overall design configuration for assigning intervention to participants.	Intervention Model
C218707	Master Protocol Indicator		An indication as to whether the protocol is a master protocol.	Master Protocol Indicator
C49694	Maximum Age		The anticipated maximum age of the participants to be entered in a clinical trial.	Planned Maximum Age of Subjects
C49693	Minimum Age		The anticipated minimum age of the participants to be entered in a clinical trial.	Planned Minimum Age of Subjects
C97054	Nonproprietary Name(s)		Drug name that is not protected by a trademark, usually descriptive of its chemical structure, and sometimes a public name.	Generic Name
C98771	Number of Arms		The planned number of intervention groups.	Planned Number of Arms
C49692	Number of Participants		The planned number of participants to be entered in a clinical trial.	Planned Subject Number
C218719	Other Committees		A committee that is different than the one(s) previously specified or mentioned.	Other Committee
C223138	Other Intervention Assignment Method		Description of any intervention assignment method that is different than the one(s) previously specified or mentioned.	Other Intervention Assignment Method
C112038	Population Diagnosis or Condition		A description of the condition, disease or disorder that the clinical trial is intended to investigate or address.	Trial Indication
C218703	Population Type		A characterisation or classification of the trial population.	Population Type
C218839	Primary and Secondary Objectives and Estimands		A descriptive summary of the primary and secondary objectives and their associated estimands related to the trial.	Primary and Secondary Objectives and Estimands Summary
C223137	Randomisation Type		A characterisation or classification of the randomisation used to assign trial participants to treatment or control groups.	Randomization Type
C218711	randomly assigned to trial intervention/enrolled		The target or maximum number of participants who have been randomly assigned to the trial intervention or enrolled in the trial.	Number of Participants Randomly Assigned to Trial Intervention or Enrolled
C132349	Schedule of Activities		A standardised representation of planned clinical trial activities including interventions (e.g., administering drug, surgery) and study administrative activities (e.g., obtaining informed consent, distributing clinical trial material and diaries, randomisation) as well as assessments.	Schedule of Activities
C218720	Schema Notes		A brief written record describing the trial schematic.	Trial Schematic Note
C218704	Site Distribution		An indication as to whether the occurrence applies to a single or multiple trial sites.	Site Distribution Indicator
C218705	Site Geographic Scope		An indication as to whether the trial is taking place in one or more countries.	Site Geographic Scope Indicator
C223136	Stratification Indicator		An indication as to whether stratification is used as part of the randomisation process.	Stratification Indicator
C218710	Target/Maximum		A characterisation or classification of the trial participant numbers as to whether the numbers reflect a target or maximum.	Trial Participation Number Target or Maximum Indicator
C218713	total planned duration of trial intervention unit of time		The unit of time associated with the numeric value for the planned duration of trial intervention.	Planned Duration of Trial Intervention Unit of Time
C218712	total planned duration of trial intervention		The numeric value for the planned duration of trial intervention.	Planned Duration of Trial Intervention
C218716	total planned duration of trial participation unit of time		The unit of time associated with the numeric value for the planned duration of trial participation.	Planned Duration of Trial Participation Unit of Time
C218715	total planned duration of trial participation		The numeric value for the planned duration of trial participation.	Planned Duration of Trial Participation
C49658	Trial Blind Schema		The type of experimental design used to describe the level of awareness of the trial participants and/ or personnel as it relates to the respective intervention(s) or assessments being observed, received or administered.	Trial Blinding Schema
C93682	Trial Schema		A diagram that outlines the decision points (e.g. randomisation, response evaluation) that define the different paths a participant could take through the trial.	Study Schematic
C50400	Units of Age		Those units of time that are routinely used to express the age of a person.	Age Unit

ICH M11 Section 2 Terminology (ICH M11 Section 2 Terminology)

NCI Code: C217343, Codelist extensible: No

C217343	ICH M11 Section 2 Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218724	Benefit Summary		A short textual description containing the potential physical, psychological, social, legal, and other benefits to the trial participant.	Trial Participant Benefit Summary
C218725	Overall Risk-Benefit Assessment		A short textual description containing the risks and benefits associated with participation in the trial.	Overall Risk-Benefit Assessment Description
C146997	Purpose of Trial		The overall rationale, reason, or intention of the clinical trial.	Study Purpose
C218721	Trial-specific Intervention Risks and Mitigations		A description of the potential risks associated with the trial interventions and mitigation strategies to be employed within the trial.	Trial-specific Intervention Risks and Mitigation Strategy Description
C218723	Trial-specific Other Risks and Mitigations		A description of the potential risks associated with the trial procedures and mitigation strategies to be employed within the trial that are different than the one(s) previously specified or mentioned.	Trial-specific Other Risks and Mitigation Strategy Description
C218722	Trial-specific Procedure Risks and Mitigations		A description of the potential risks associated with the trial procedures and mitigation strategies to be employed within the trial.	Trial-specific Procedure Risks and Mitigation Strategy Description

ICH M11 Section 3 Terminology (ICH M11 Section 3 Terminology)

NCI Code: C217344, Codelist extensible: No

C217344	ICH M11 Section 3 Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C188856	Description of Intercurrent Event		A description of the intercurrent event.	Intercurrent Event Description
C25212	Endpoint		The variable to be obtained for each patient that is required to address the clinical question. The specification of the variable might include whether the patient experiences an intercurrent event.	End Point
C163559	Exploratory Objective		The exploratory reason for performing a study in terms of the scientific questions to be answered by the analysis of data collected during the study.	Trial Exploratory Objective
C188857	Intercurrent Event Strategy		A description of the planned strategy to address intercurrent events.	Intercurrent Event Strategy
C70833	Population		The population of patients targeted by the clinical question. This will be represented by the entire trial population, a subgroup defined by a particular characteristic measured at baseline, or a principal stratum defined by the occurrence (or non-occurrence, depending on context) of a specific intercurrent event.	Study Population
C188853	Population-level Summary		Population level summary for the clinical endpoint of interest, which provides a basis for comparison between treatment conditions.	Population-Level Summary
C85826	Primary Objective		The principle reason for performing a study in terms of the scientific questions to be answered by the analysis of data collected during the study.	Trial Primary Objective
C85827	Secondary Objective		The secondary reason for performing a study in terms of the scientific questions to be answered by the analysis of data collected during the study.	Trial Secondary Objective
C49236	Treatment		The treatment condition of interest and, as appropriate, the alternative treatment condition to which comparison will be made (referred to as "treatment" through the remainder of this document). These might be individual interventions, combinations of interventions administered concurrently, e.g. as add-on to standard of care, or might consist of an overall regimen involving a complex sequence of interventions.	Therapeutic Procedure

ICH M11 Section 4 Terminology (ICH M11 Section 4 Terminology)

NCI Code: C217345, Codelist extensible: No

C217345	ICH M11 Section 4 Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218738	Access to Trial Intervention After End of Trial		A narrative description containing information about whether and how trial participants have access to the trial interventions after the trial ends.	Access to Trial Intervention after End of Trial
C218728	Additional Description of Trial Design		An extra or further textual description of the trial design.	Additional Description of Trial Design
C218727	Description of Level and Method of Blinding		A description of the level of awareness of the study participants and/or personnel to the respective intervention(s) or assessments being observed, received or administered, and the methodology by which study participants or personnel are blinded.	Description of Level and Method of Blinding
C219658	Description of Method of Assignment to Trial Intervention		A description of the methodology used to assign trial participants to a trial intervention or trial arm.	Description of Method of Assignment to Trial Intervention
C218726	Description of Trial Duration		A description of the trial duration.	Description of Trial Duration
C218737	End of Trial		A description containing a concise explanation, any local regulatory requirements and considerations, extensions, follow-up, and analysis for the trial end.	End of Trial Explanation
C147139	Overall Description of Trial Design and Description of Intervention Model		A description summarizing the overall trial design and intervention model.	Study Design Description
C142705	Overall Rationale for Trial Design		An explanation as to the scientific reasons for the choice of the trial design.	Study Design Rationale
C218733	Rationale for Adaptive or Novel Trial Design		An explanation as to the scientific reasons for why an adaptive or novel trial design was chosen for the trial.	Rationale for Adaptive or Novel Trial Design
C218731	Rationale for Control Type		An explanation as to the scientific reasons for the choice of the control types used in the trial.	Rationale for Trial Control Type
C218730	Rationale for Estimand(s)		An explanation as to the scientific reasons for the choice of the trial estimand(s).	Rationale for Trial Estimand
C218734	Rationale for Interim Analysis		An explanation for the analysis comparing intervention groups at any time before the formal completion of the trial, usually before recruitment is complete.	Rationale for Interim Analysis
C215629	Rationale for Intervention Model		An explanation as to the scientific reasons for why the intervention model was chosen for the trial.	Interventional Study Design Rationale
C218735	Rationale for Other Trial Design Aspects		An explanation as to the scientific reasons for additional trial design considerations that are different than the one(s) previously specified or mentioned.	Rationale for Other Trial Design Aspects
C218732	Rationale for Trial Duration		An explanation as to the scientific reasons for the trial duration.	Rationale for Trial Duration
C218729	Stakeholder Input into Design		A description of the way in which trial stakeholders were consulted when determining the trial design and how that input was applied.	Stakeholder Input into Trial Design
C218736	Start of Trial		A description containing a concise explanation, any local regulatory requirements and considerations, extensions, follow-up, and analysis for the trial start.	Start of Trial Explanation
C142698	Trial Stopping Rules		A criterion that, when met by the accumulating data, indicates that the trial can or should be stopped early to avoid putting participants at risk unnecessarily or because the intervention effect is so great that further data collection is unnecessary.	Stopping Rules

ICH M11 Section 5 Terminology (ICH M11 Section 5 Terminology)

NCI Code: C217346, Codelist extensible: No

C217346	ICH M11 Section 5 Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218744	Caffeine, Alcohol, Tobacco, and Other Restrictions		A description of the restrictions related to participant intake of caffeine, alcohol, tobacco, and other habit-forming substances during the trial.	Trial Participant Caffeine, Alcohol, Tobacco, and Other Substance Restrictions
C218741	Contraception Requirements		A description of the requirements for the prevention of conception or impregnation by the use of devices or drugs or surgery within a context of a trial, or state not applicable.	Trial Participant Contraception Requirements
C218740	Definitions Related to Childbearing Potential		A concise explanation of the meaning of participants of childbearing potential and nonchildbearing potential within the context of a trial, or state not applicable.	Definitions Related to Trial Participant Childbearing Potential
C218739	Description of Trial Population and Rationale		A description of the rationale for selection of trial population describing how the selected population can meet the trial objectives and how the enrollment criteria reflect the targeted populations.	Description of Trial Population and Rationale
C25370	Exclusion Criterion		List of characteristics in a protocol, any one of which excludes a potential participant from participation in a study. (CDISC glossary)	Exclusion Criteria
C25532	Inclusion Criterion		The criteria in a protocol that prospective participants must meet to be eligible for participation in a study. (CDISC glossary)	Inclusion Criteria
C218742	Lifestyle Restrictions		A description of the restrictions related to trial participant lifestyle such as diet, substance intake, and physical or other daily activities.	Trial Participant Lifestyle Restrictions
C218743	Meals and Dietary Restrictions		A description of the restrictions related to participant diet during the trial.	Trial Participant Meals and Dietary Restrictions
C218746	Other Activity Restrictions		An activity restriction that is different than the one(s) previously specified or mentioned.	Other Activity Restrictions
C218745	Physical Activity Restrictions		A description of the restrictions related to participant physical activity during the trial.	Trial Participant Physical Activity Restrictions
C179373	Rescreening		The process of active consideration of participants for enrollment in a trial, for those potential participants who have failed a prior screening attempt.	Rescreening
C49628	Screen Failure		The potential participant who does not meet eligibility (inclusion/exclusion) criteria during the screening period.	Trial Screen Failure

ICH M11 Section 6 Terminology (ICH M11 Section 6 Terminology)

NCI Code: C217347, Codelist extensible: No

C217347	ICH M11 Section 6 Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C176267	Accountability of Investigational Trial Intervention		The act or process for documenting the storage, inventory tracking, and disposition of the investigational trial intervention.	Study Product Accountability
C93729	Arm Name		The literal identifier (i.e. distinctive designation) for the arm.	Arm Name
C172457	Arm Type		A characterisation or classification of the study arm.	Study Arm Type
C222329	Background Trial Intervention		Description of medicinal products that are administered to each clinical trial participant, regardless of randomisation group, a) to treat the indication which is the object of the study, or b) required in the protocol as part of standard care for a condition that is not the indication under investigation, and is relevant for the clinical trial design. (CDISC Glossary)	Description of Background Trial Intervention
C53630	Concomitant Therapy		Description of any pharmaceutical agent, other than the trial interventions, that is administered to or used by the participant prior to or during a specified time period.	Concomitant Therapy
C218751	Description of Investigational Trial Intervention		A description of the investigational trial intervention.	Description of Investigational Trial Intervention
C218759	Description of Noninvestigational Trial Intervention		A description of the noninvestigational trial intervention.	Description of Noninvestigational Trial Intervention
C218747	description of the overview of trial interventions or a heading for the optional table		A free text description of the trial intervention; alternatively can be used as a heading for a table containing information about the trial intervention.	Trial Intervention Overview or Informational Table Header
C94394	Dosage Level(s)		Specified quantity of a medicine, to be taken at one time or at stated intervals.	Cumulative Dose
C142517	Dosage Strength(s)		The strength of a drug product, which indicates the amount of each active ingredient in a given dosage form, measured in units of volume or concentration.	Dose Strength
C218757	Emergency Unblinding at the Site		A description of the methodology used for unblinding of the trial treatment in the case of a sudden unforeseen crisis that requires immediate medical care of the participant.	Emergency Unblinding at the Site
C218749	IMP or NIMP		An indication as to whether the trial intervention is an investigational medicinal product or an auxiliary medicinal product.	IMP or NIMP Indicator
C177930	Intervention Name		The literal identifier (i.e. distinctive designation) for the study intervention.	Intervention Name
C98747	Intervention Type		The kind of product or procedure studied in a trial.	Intervention Type
C218758	Investigational Trial Intervention Adherence		A description of the measures taken to ensure trial intervention adherence, including mandatory documentation to be filled out and the source data that will be used to document investigational trial intervention compliance.	Investigational Trial Intervention Adherence Measures Description
C218753	Investigational Trial Intervention Administration		The way in which the investigational trial intervention is dispensed, applied, or tendered to the trial participant.	Investigational Trial Intervention Administration
C218754	Investigational Trial Intervention Dose Modification		A change, alteration, or adjustment to the dose of an investigational trial intervention.	Investigational Trial Intervention Dose Modification
C218755	Management of Investigational Trial Intervention Overdose		A description of how a potential investigational trial intervention overdose will be handled.	Management of Investigational Trial Intervention Overdose
C189349	Measures to Maintain Blinding		A description of the measures taken to ensure the blinding is maintained.	Study Blinding Procedure
C218761	Other Noninvestigational Trial Intervention		Description of any noninvestigational intervention that is different than the one(s) previously specified or mentioned.	Description of Other Noninvestigational Trial Intervention
C218756	Participant Assignment to Investigational Trial Intervention		The technique used to assign trial participants to a trial arm.	Participant Assignment to Investigational Intervention Method
C218763	Permitted Concomitant Therapy		Concomitant therapy that is approved for use in the trial.	Permitted Concomitant Therapy
C42636	Pharmaceutical Dose Form		Physical characteristics of a drug product, (e.g., tablet, capsule, or solution) that contains a drug substance, generally-but not necessarily-in association with one or more other ingredients. (CDISC Glossary)	Pharmaceutical Dosage Form
C176274	Preparation of Investigational Trial Intervention		The way in which the investigational trial intervention is prepared for use or administration to the trial participant.	Study Product Preparation
C218762	Prohibited Concomitant Therapy		Concomitant therapy that is banned from use in the trial.	Prohibited Concomitant Therapy
C25196	Randomisation		The process of assigning trial participants to treatment or control groups using an element of chance to determine the assignments in order to reduce bias. (CDISC Glossary)	Randomization
C218752	Rationale for Investigational Trial Intervention Dose and Regimen		An explanation as to the scientific reasons for the choice of the trial intervention dose and dose regimen.	Rationale for Investigational Trial Intervention Dose and Regimen
C15697	Regimen/Treatment Period/Vaccination Regimen		A description of the schedule and periodicity of a treatment or vaccination regimen.	Treatment Regimen
C222330	Rescue Therapy		Description of any rescue medications, treatments, and/or procedures identified in the protocol as those that may be administered to participants when the efficacy of the investigational intervention is not satisfactory, its effect is too great and is likely to cause a hazard to the participant, or to manage an emergency situation.	Description of Rescue Therapy
C38114	Route of Administration		Path by which the pharmaceutical product is taken into or makes contact with the body.	Route of Administration
C218750	Sourcing		An indication as to whether the investigational intervention is centrally or locally sourced.	Investigational Intervention Sourcing Indicator
C115525	Storage and Handling of Investigational Trial Intervention		A narrative description containing information about the handling, storage, and distribution of investigational trial intervention.	Clinical Trial Investigational Product Handling Instruction Documentation
C218748	Use		The reason or intention for the use of the trial intervention within the trial arm.	Trial Intervention Intent

ICH M11 Section 7 Terminology (ICH M11 Section 7 Terminology)

NCI Code: C217348, Codelist extensible: No

C217348	ICH M11 Section 7 Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218768	Management of Loss to Follow-Up		The mitigation strategies to be employed for the loss or lack of continuation of a participant to follow-up, including the frequency by which follow-up occurs.	Management of Loss to Follow-Up
C218767	Participant Discontinuation or Withdrawal from Trial		The rationale for why the participant either discontinued or withdrew from the trial.	Study Subject Discontinuation Rationale
C218764	Permanent Discontinuation of Trial Intervention		The requirements that must be met in order to permanently discontinue the administration of trial intervention.	Requirements for Permanent Discontinuation of Trial Intervention
C218766	Rechallenge		The requirements that must be met in order to reintroduce previously withdrawn or temporarily discontinued medical intervention in the same participant.	Rechallenge Requirement
C218765	Temporary Discontinuation of Trial Intervention		The requirements that must be met in order to temporarily discontinue the administration of trial intervention.	Requirements for Temporary Discontinuation of Trial Intervention

ICH M11 Section 8 Terminology (ICH M11 Section 8 Terminology)

NCI Code: C217349, Codelist extensible: No

C217349	ICH M11 Section 8 Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218771	Baseline Assessments and Procedures		Trial assessments and procedures related to the baseline epoch of the trial.	Baseline Assessments and Procedures Description
C218774	Clinical Laboratory Assessments		Trial-related laboratory assessments and procedures.	Clinical Laboratory Assessment
C218772	Efficacy Assessments and Procedures		Trial assessments and procedures related to trial intervention efficacy.	Efficacy Assessments and Procedures Description
C168186	Electrocardiograms		The procedures for the recordings produced by the variations in electrical potential caused by electrical activity of the heart muscle and detected at the body surface, as a method for studying the action of the heart muscle.	Electrocardiogram
C218777	Genetics, Genomics, Pharmacogenetics and Pharmacogenomics		A narrative description containing information about the collection, use, and retention of biospecimens, and their use in genetic, genomic, pharmacogenetic and pharmacogenomic biomarker assessments within the trial.	Genetics, Genomics, Pharmacogenetics and Pharmacogenomics Assessment
C218780	Immunogenicity Assessments		A narrative description containing information about the collection, use, and retention of biospecimens, and their use in immunogenicity assessments within the trial.	Immunogenicity Assessment
C176849	Medical Resource Utilisation and Health Economics		A narrative description containing information about medical resource utilisation and the health outcome measures, collection method and participant burden.	Healthcare Utilization
C218779	Other Biomarkers		A narrative description containing information about the collection, use, and retention of biospecimens, and their use in other biomarker assessments within the trial.	Other Biomarker Assessment
C218778	Pharmacodynamic Biomarkers		A narrative description containing information about the collection, use, and retention of biospecimens, and their use in pharmacodynamic biomarker assessments within the trial.	Pharmacodynamics Assessment
C218776	Pharmacokinetics		A narrative description containing information about the collection, use, and retention of biospecimens, and their use in pharmacokinetic assessments within the trial.	Pharmacokinetic Assessment
C20989	Physical Examination		The procedures for a physical examination of the body and its functions to be conducted for the trial.	Physical Examination
C92949	Pregnancy Testing		Any examination performed to assess if a female is gravid.	Pregnancy Test
C218773	Safety Assessments and Procedures		A description of the assessments and procedures related to participant safety within the trial.	Safety Assessments and Procedures Description
C218770	Screening Assessments and Procedures		Trial assessments and procedures related to the screening epoch of the trial.	Screening Assessments and Procedures Description
C218775	Suicidal Ideation and Behaviour Risk Monitoring		A description of data collection procedures and analysis related to suicidal ideation and behaviour risk monitoring.	Suicidal Ideation and Behaviour Risk Monitoring
C218769	Trial Assessments and Procedures Considerations		A description of general considerations applicable across trial assessments and procedures.	Trial Assessments and Procedures Considerations Description
C154628	Vital Signs		The procedures for measurements of the body's basic functions that provide insight into the health status of the person.	Vital Signs

ICH M11 Section 9 Terminology (ICH M11 Section 9 Terminology)

NCI Code: C217350, Codelist extensible: No

C217350	ICH M11 Section 9 Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C217358	Adverse Events of Special Interest		A description of the processes and procedures used to define, measure, confirm, and report the occurrence of adverse events that are of special interest to the specific trial, or state not applicable.	Adverse Event of Special Interest
C218790	Back-up Method for Reporting		A description of alternative techniques by which trial related events, such as adverse events, serious adverse events, product complaints, medical device product complaints, and pregnancy and postpartum events, are reported to the sponsor and/or regulatory authority.	Trial Event Back-Up Reporting Method
C82552	Causality		The description of the degree of causality (attributability) between a trial intervention and an event.	Causality
C218476	Definitions of Adverse Events		A concise explanation of the meaning of adverse events within the context of the trial.	Definition of Adverse Events
C218783	Definitions of Medical Device Product Complaints		A concise explanation of the meaning of medical device product complaints within the context of the trial.	Definition of Medical Device Product Complaints
C218782	Definitions of Product Complaints		A concise explanation of the meaning of product complaints within the context of the trial.	Definition of Product Complaints
C218781	Definitions of Serious Adverse Events		A concise explanation of the meaning of serious adverse events within the context of the trial.	Definition of Serious Adverse Events
C218797	Disease-related Events or Outcomes Not Qualifying as AEs or SAEs		A description of events or outcomes related to the trial disease indication but not qualifying as adverse events or serious adverse events within the trial, or state not applicable.	Disease-related Events or Outcomes Not Qualifying as Adverse Events or Serious Adverse Events
C218791	Event Collection and Reporting Timing		A description of the timing as it relates to the collection and reporting of trial related events, and the frequency of collection of those events to the sponsor or designee.	Event Collection and Reporting Timing Description
C218784	Event Type		A characterisation or classification of trial-related safety events, such as adverse events, serious adverse events, product complaints, medical device product complaints, and pregnancy and postpartum events.	Trial-Related Safety Event Type
C218794	Follow-up		A description of the procedures for follow-up, including the assessment tools that will be used to monitor an event and the duration of follow-up.	Event Follow-up Procedure Description
C218792	Identification		A description of how trial-related events, such as adverse events, serious adverse events, product complaints, medical device product complaints, and pregnancy and postpartum events, will be identified.	Trial-Related Event Identification
C218789	Method for Reporting		A description of the technique by which trial related events, such as adverse events, serious adverse events, product complaints, medical device product complaints, and pregnancy and postpartum events, are reported to the sponsor and/or regulatory authority.	Trial Event Reporting Method
C222263	Other Event Type		An event type that is different than the one(s) previously specified or mentioned.	Other Trial-Related Safety Event Type
C218798	Participants Who Become Pregnant During the Trial		A description of the processes and procedures used to collect pregnancy data for a trial participant who becomes pregnant while the participant is in the trial, as well as data collection about the foetus, neonate, infant, or child.	Participants Who Become Pregnant During the Trial Data Collection
C218799	Participants Whose Partners Become Pregnant During the Trial		A description of the processes and procedures used to collect pregnancy data for a trial participant's partner, who becomes pregnant while the participant is in the trial.	Participants Whose Partners Become Pregnant During the Trial Data Collection
C218793	Recording		A description for the procedures used to document an event.	Event Recording Procedure Description
C218796	Regulatory Reporting Requirements		A description of the requirements for the sponsor/designee to report adverse events, serious adverse events, pregnancy and postpartum events, and medical device product complaints, including the criteria for reporting, to the relevant regulatory authority.	Regulatory Reporting Requirements for Trial-Related Events
C218787	Reportable Period End		The date on which reporting will cease for trial related events such as adverse events, serious adverse events, product complaints, medical device product complaints, and pregnancy and postpartum events.	Reportable Period End Date
C218786	Reportable Period Start		The date on which reporting will begin for trial related events such as adverse events, serious adverse events, product complaints, medical device product complaints, and pregnancy and postpartum events.	Reportable Period Start Date
C218795	Reporting		A description of the method and timelines for reporting adverse events, serious adverse events, pregnancy and postpartum events, and medical device product complaints to the sponsor.	Event Reporting Procedure Description
C25676	Severity		The description of the intensity (severity) of an event.	Severity
C218785	Situational Scope		A description of the specific circumstances and context in which safety events are collected and monitored.	Safety Event Situational Scope Description
C218800	Special Safety Situations		A characterisation or classification of those trial specific situations that are associated with the trial intervention(s) and require regulatory reporting, but that do not qualify as an adverse event or serious adverse event for the given trial.	Special Safety Situation Type
C218788	Timing for Reporting to Sponsor or Designee		A description of the timing window between trial related events and their reporting to the sponsor or designee.	Timing Description for Reporting to Sponsor or Designee

ICH M11 Section Amendment Details Terminology (ICH M11 Section Amendment Details Terminology)

NCI Code: C217357, Codelist extensible: No

C217357	ICH M11 Section Amendment Details Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218694	Amendment Details		A written message within the study protocol that describes the amendment details, especially as to whether the protocol has been amended previously.	Protocol Amendment Details
C218695	Amendment Scope Enrollment Definition		The enrollment description as to whether the amendment scope applies globally, locally, or per cohort across the trial.	Amendment Scope Enrollment Description
C42581	Amendment Summary		A short description describing the changes introduced in the current version of the protocol.	Summary
C218478	Approximately <#/%> enrolled		The value (expressed either numerically or as a percentage) for the estimated number of participants enrolled at the time of the protocol amendment.	Approximate Participant Enrollment At Time of Sponsor Approval
C181233	Brief Rationale for Change		The brief reason for the change introduced in the current or prior version of the protocol.	Brief Rationale for Protocol Change
C218701	Briefly Explain Substantial Impact on Data		A short descriptive account of any substantial impacts on the reliability and robustness of the data generated in the clinical trial due to the protocol amendment.	Brief Explanation of Substantial Impact on Study Data
C218699	Briefly Explain Substantial Impact On Safety		A short descriptive account of any substantial impacts on the safety or rights of the participants due to the protocol amendment.	Brief Explanation of Substantial Impact on Participant Safety
C218483	Description of Change		A description of the change introduced in the current or prior version of the protocol.	Description of Protocol Change
C218700	Is this amendment likely to have a substantial impact on the reliability and robustness of the data generated in the clinical trial?		An indication as to whether the amendment likely to have a substantial impact on the reliability and robustness of the data generated in the clinical trial.	Amendment Impacts Reliability and Robustness of Data Indicator
C218698	Is this amendment likely to have a substantial impact on the safety or rights of the participants?		An indication as to whether the amendment is likely to have a substantial impact on the safety or rights of the participants.	Amendment Impacts Participant's Safety or Rights Indicator
C218696	Primary Reason for Amendment		The rationale of greatest importance for the protocol amendment.	Primary Reason for Protocol Amendment
C218697	Secondary Reason for Amendment		Additional rationale for the protocol amendment that is not considered the primary rationale.	Secondary Reason for Protocol Amendment
C218479	Section # and Name		The protocol section number and name containing the change introduced in the current or prior version of the protocol.	Protocol Change Section Number and Name

ICH M11 Section Title Page Terminology (ICH M11 Section Title Page Terminology)

NCI Code: C217356, Codelist extensible: No

C217356	ICH M11 Section Title Page Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218477	Amendment Identifier		A sequence of characters used to uniquely identify a protocol amendment.	Amendment Identifier
C218673	Amendment Scope		A description as to whether the amendment scope applies globally across the trial.	Amendment Scope Global Applicability Indicator
C132352	Approval Date		The date that the sponsor approved a version of the protocol.	Protocol Approval by Sponsor Date
C218679	Co-Sponsor Legal Address		The legally registered address of the trial co-sponsor.	Co-Sponsor Legal Address
C218678	Co-Sponsor Name		The literal identifier (i.e., distinctive designation) of the trial co-sponsor.	Co-Sponsor Name
C20108	Country Identifier		A sequence of characters used to identify and/or name the country.	Country Code
C218683	Device Manufacturer Legal Address		The legally registered address of the device manufacturer.	Device Manufacturer Legal Address
C218682	Device Manufacturer Name		The literal identifier (i.e., distinctive designation) of the organisation defined as being responsible for creating the device as stated on the package in which the product is supplied.	Device Manufacturer Name
C218684	EU CT Number		A sequence of characters used to identify a clinical trial, as assigned by the Clinical Trials Information System (CTIS) of the European Medicines Agency.	EU Clinical Trial Register Number
C218685	FDA IND Number		A sequence of characters used to identify a clinical trial under an Investigational New Drug (IND) application, as assigned by the US Food and Drug Administration.	US FDA Investigational New Drug Application Number
C132346	Full Title		The formal descriptive name for the protocol that contains key elements of the study. (CDISC)	Official Protocol Title
C218686	IDE Number		A sequence of characters used to identify a clinical trial under an Investigational Device Exemption (IDE) application, as assigned by the US Food and Drug Administration.	US FDA Investigational Device Exemption Application Number
C218687	jRCT Number		A sequence of characters used to identify a clinical trial, as assigned by the Japan Registry for Clinical Trials (JRCT) of the Ministry of Health, Labour and Welfare (MHLW) in Japan.	Japan Registry for Clinical Trials Number
C218681	Local Sponsor Legal Address		The legally registered address of the sponsor's legal representative at a geographical region within which the sponsor has no legal presence.	Local Sponsor Legal Address
C218680	Local Sponsor Name		The literal identifier (i.e., distinctive designation) of the sponsor's legal representative at a geographical region within which the sponsor has no legal presence.	Local Sponsor Name
C218693	Medical Expert contact information (as designated by sponsor)		The contact information for the sponsor's representative who can advise on specific trial-related medical questions or problems.	Designated Medical Expert Contact Information
C172240	NCT Number		A sequence of characters used to identify a clinical trial, as assigned by the protocol registration and results (PRS) system of the US National Library of Medicine.	Clinicaltrials.gov Identifier
C218688	NMPA IND Number		A sequence of characters used to identify a clinical trial under an Investigational New Drug (IND) application, as assigned by the Chinese National Medicinal Products Administration (NMPA).	NMPA IND Number
C97054	Nonproprietary Name(s)		Drug name that is not protected by a trademark, usually descriptive of its chemical structure, and sometimes a public name.	Generic Name
C218672	Original Protocol Indicator		An indication as to whether the protocol document reflects the original version of the protocol.	Original Protocol Indicator
C218690	Other Regulatory or Clinical Trial Identifier		A sequence of characters assigned by a regulatory agency or other health authority that is used to identify a clinical trial, and that is different than the one(s) previously specified or mentioned.	Other Regulatory or Clinical Trial Identifier
C71898	Proprietary Name(s)		A commercial name granted by an authority for use in marketing/registering a product.	Proprietary Name
C218674	Region Identifier		A sequence of characters used to identify and/or name the region.	Region Identifier
C83081	Site Identifier		A sequence of characters used to identify and/or name the study site.	Study Site Identifier
C181236	Sponsor Confidentiality Statement		A written message within the study protocol that asserts a statement of non-disclosure, such that information contained within the protocol document may only be shared with authorised parties.	Protocol Confidentiality Statement
C218677	Sponsor Legal Address		The legally registered address of the trial sponsor.	Sponsor Legal Address
C222495	Sponsor Name		The literal identifier (i.e., distinctive designation) of the trial sponsor.	Trial Sponsor Name
C132351	Sponsor Protocol Identifier		A sequence of characters assigned by the sponsor that uniquely identifies a specific protocol.	Sponsor Protocol Identifier
C222014	sponsor signatory (e.g., name, title, signature and date)		A block of text containing the name and signature of the sponsor's signatory, along with the signature date.	Sponsor Signatory
C218675	Sponsor's Investigational Product Code(s)		A symbol or combination of symbols that are assigned by the sponsor to uniquely identify an experimental intervention.	Sponsor's Investigational Product Code
C222063	state location where Medical Expert contact information can be found		The physical or virtual location of the medical expert (as designated by the sponsor) contact information.	Location of Medical Expert Contact Information
C218484	State location where sponsor approval information can be found		The physical or virtual location of the date on which the sponsor approved the current version of the protocol.	Location of Sponsor Approval Date
C222064	state location where sponsor signatory information can be found (e.g., electronic signature)		The physical or virtual location of the sponsor signatory information.	Location of Sponsor Signatory Information
C94108	Trial Acronym		Acronym or abbreviation used publicly to identify the clinical trial.	Study Protocol Version Acronym
C48281	Trial Phase		A stage in the clinical research and development of a therapy from first-in-human to post-approval clinical trials.	Trial Phase
C94105	Trial Short Title		The short descriptive name for the trial.	Study Protocol Document Version Public Title
C93813	Version Date		The date on which the document is versioned.	Document Version Date
C181232	Version Number		A string of alphanumeric characters that uniquely identifies a specific version of a study protocol.	Study Protocol Version Number
C218689	WHO/UTN Number		A sequence of characters used to identify a clinical trial, as assigned by the World Health Organisation's International Clinical Trial's Registry Platform (ICTRP).	WHO/UTN Number

Independent Committee Name Response Terminology (Independent Committee Name Response Terminology)

NCI Code: C217282, Codelist extensible: No

C217282	Independent Committee Name Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C215671	Dose Escalation Committee		A type of safety monitoring committee that monitors dose escalation activities in first-in-human trials.	Dose Escalation Committee
C78726	Endpoint Adjudication Committee		An external committee whose purpose is to evaluate study data and decide whether a study endpoint or other criterion has been met.	Adjudication Committee
C142578	Independent Data Monitoring Committee		A committee established by the sponsor to assess at intervals the progress of a clinical trial, safety data, and critical efficacy variables and recommend to the sponsor whether to continue, modify, or terminate the trial.	Independent Data Monitoring Committee
C41132	None		No person or thing, nobody, not any.	None
C17649	Other		Different than the one(s) previously specified or mentioned.	Other

Intervention Model Response Terminology (Intervention Model Response Terminology)

NCI Code: C217277, Codelist extensible: No

C217277	Intervention Model Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C82637	Cross-over		Participants receive one of two or more alternative intervention(s) during the initial epoch of the study and receive other intervention(s) during the subsequent epoch(s) of the trial.	Crossover Study
C82638	Factorial		Two or more interventions, each alone or in combination, are evaluated in parallel against a control group. This study design allows for the comparison of active drug to placebo, presence of drug-drug interactions, and comparison of active drugs against each other.	Factorial Study
C17649	Other		Different than the one(s) previously specified or mentioned.	Other
C82639	Parallel Group		Participants are assigned to one of two or more treatment groups in parallel for the duration of the study.	Parallel Study
C142568	Sequential		Groups of participants are assigned to receive interventions based on prior milestones being reached in the study.	Group Sequential Design
C82640	Single Group		All trial participants are assigned to a single treatment group for the duration of the study.	Single Group Study

Intervention Type Response Terminology (Intervention Type Response Terminology)

NCI Code: C217284, Codelist extensible: No

C217284	Intervention Type Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C15184	Behavioural		A technique used to change the behavior of a participant (e.g., psychotherapy, lifestyle counseling, or hypnosis).	Behavioral Intervention
C307	Biologic		A product of biological origin applicable to the prevention, treatment, or cure of a disease or condition, for example: virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product.	Biological Agent
C54696	Combination Product		A product composed of two or more different types of medical products (i.e., a combination of a drug, device, and/or biological product with one another and are referred to as "constituent parts" of the combination product). (CDISC Glossary)	Combination Product
C18020	Diagnostic		Any procedure or test to diagnose a disease or disorder.	Diagnostic Procedure
C1505	Dietary Supplement		Preparations containing ingredient(s) intended to supplement the diet.	Dietary Supplement
C1909	Drug		An active natural, synthetic or semi-synthetic ingredient including endogenous body substance that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient.	Pharmacologic Substance
C15238	Genetic		Introduction of genetic material into cells in order to correct or treat an inherited or acquired disease.	Gene Therapy
C16830	Medical Device		Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for, one or more specific medical purpose(s). (CDISC Glossary)	Medical Device
C218507	Non-Surgical Procedure		A medical procedure that produces an effect, or that is intended to alter the course of a disease in a patient or population, which is not considered a surgical procedure.	Non-Surgical Procedure
C15313	Radiation		Use of targeted or whole body radiation to treat a disease.	Radiation Therapy
C15329	Surgery		A diagnostic or treatment procedure performed by manual and/or instrumental means, often involving an incision and the removal or replacement of a diseased organ or tissue; of or relating to or involving or used in surgery or requiring or amenable to treatment by surgery.	Surgical Procedure
C923	Vaccine		A medicinal product inducing immunity against disease, most often to prevent occurrence of a disease, (e.g., a preventative vaccine against infectious disease), but also to treat a disease, (e.g., a therapeutic vaccine against cancer). (CDISC Glossary)	Vaccine

Intervention Use Response Terminology (Intervention Use Response Terminology)

NCI Code: C217285, Codelist extensible: No

C217285	Intervention Use Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C207614	Additional Required Treatment		A medicinal product that must be administered along with the experimental treatment (e.g., drug studies wherein opioid blockers are administered to prevent overdose).	Additional Required Medicinal Product
C165822	Background Treatment		Medicinal products that are administered to each clinical trial participant, regardless of randomisation group, a) to treat the indication which is the object of the study, or b) required in the protocol as part of standard care for a condition that is not the indication under investigation, and is relevant for the clinical trial design. (CDISC Glossary)	Background Treatment
C158128	Challenge Agent		A non-investigational medicinal product (NIMP) given to trial participants to produce a physiological response that is necessary before the pharmacological action of the investigational medicinal product can be assessed. (CDISC Glossary)	Challenge Agent
C18020	Diagnostic		Any procedure or test to diagnose a disease or disorder.	Diagnostic Procedure
C41161	Experimental Intervention		The drug, device, therapy, procedure, or process under investigation in a clinical study that is believed to have an effect on outcomes of interest in a study (e.g., health-related quality of life, efficacy, safety, pharmacoeconomics). (CDISC Glossary)	Protocol Agent
C753	Placebo		A pharmaceutical preparation that does not contain the investigational agent and is generally prepared to be physically indistinguishable from the preparation containing the investigational product.	Placebo
C165835	Rescue Medicine		Medicinal products identified in the protocol as those that may be administered to participants when the efficacy of the investigational medicinal product (IMP) is not satisfactory, the effect of the IMP is too great and is likely to cause a hazard to the patient, or to manage an emergency situation. (CDISC Glossary)	Rescue Medications

Investigational Intervention Sourcing Response Terminology (Investigational Intervention Sourcing Response Terminology)

NCI Code: C217052, Codelist extensible: No

C217052	Investigational Intervention Sourcing Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C215659	Centrally Sourced		An indication that the entity is obtained from a central source.	Centrally Sourced Indicator
C215660	Locally Sourced		An indication that the entity is obtained from a local source.	Locally Sourced Indicator

Investigational Medicinal Product Indicator Response Terminology (Investigational Medicinal Product Indicator Response Terminology)

NCI Code: C217286, Codelist extensible: No

C217286	Investigational Medicinal Product Indicator Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C202579	IMP		A medicinal product which is being tested or used as a reference, including as a placebo, in a clinical trial.	Investigational Medicinal Product
C156473	NIMP		A medicinal product that is related to the specific needs of the clinical trial as described in the protocol, but not as an investigational medicinal product. (CDISC Glossary)	Auxiliary Medicinal Product

No Yes Response Terminology (No Yes Response Terminology)

NCI Code: C217046, Codelist extensible: No

C217046	No Yes Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C49487	No		The non-affirmative response to a question.	No
C49488	Yes		The affirmative response to a question.	Yes

Population Type Response Terminology (Population Type Response Terminology)

NCI Code: C217278, Codelist extensible: No

C217278	Population Type Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218503	With Disease		An indication that the individual or group of individuals has been diagnosed with the disease of interest or under study.	With Disease
C218504	Without Disease		An indication that the individual or group of individuals has not been diagnosed with the disease of interest or under study.	Without Disease

Protocol Section Name and Number Response Terminology (Protocol Section Name and Number Response Terminology)

NCI Code: C217272, Codelist extensible: No

C217272	Protocol Section Name and Number Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218514	1 PROTOCOL SUMMARY		Section 1 of the ICH M11 Protocol standard, PROTOCOL SUMMARY.	ICH M11 Protocol Section 1 PROTOCOL SUMMARY
C218515	1.1 Protocol Synopsis		Section 1.1 of the ICH M11 Protocol standard, Protocol Synopsis.	ICH M11 Protocol Section 1.1 Protocol Synopsis
C218516	1.1.1 Primary and Secondary Objectives and Estimands		Section 1.1.1 of the ICH M11 Protocol standard, Primary and Secondary Objectives and Estimands.	ICH M11 Protocol Section 1.1.1 Primary and Secondary Objectives and Estimands
C218517	1.1.2 Overall Design		Section 1.1.2 of the ICH M11 Protocol standard, Overall Design.	ICH M11 Protocol Section 1.1.2 Overall Design
C218518	1.2 Trial Schema		Section 1.2 of the ICH M11 Protocol standard, Trial Schema.	ICH M11 Protocol Section 1.2 Trial Schema
C218519	1.3 Schedule of Activities		Section 1.3 of the ICH M11 Protocol standard, Schedule of Activities.	ICH M11 Protocol Section 1.3 Schedule of Activities
C218625	10 STATISTICAL CONSIDERATIONS		Section 10 of the ICH M11 Protocol standard, STATISTICAL CONSIDERATIONS.	ICH M11 Protocol Section 10 STATISTICAL CONSIDERATIONS
C218626	10.1 General Considerations		Section 10.1 of the ICH M11 Protocol standard, General Considerations.	ICH M11 Protocol Section 10.1 General Considerations
C218647	10.10 Multiplicity Adjustments		Section 10.10 of the ICH M11 Protocol standard, Multiplicity Adjustments.	ICH M11 Protocol Section 10.10 Multiplicity Adjustments
C218648	10.11 Sample Size Determination		Section 10.11 of the ICH M11 Protocol standard, Sample Size Determination.	ICH M11 Protocol Section 10.11 Sample Size Determination
C218627	10.2 Analysis Sets		Section 10.2 of the ICH M11 Protocol standard, Analysis Sets.	ICH M11 Protocol Section 10.2 Analysis Sets
C218628	10.3 Analyses of Demographics and Other Baseline Variables		Section 10.3 of the ICH M11 Protocol standard, Analyses of Demographics and Other Baseline Variables.	ICH M11 Protocol Section 10.3 Analyses of Demographics and Other Baseline Variables
C218629	10.4 Analyses Associated with the Primary Objective(s)		Section 10.4 of the ICH M11 Protocol standard, Analyses Associated with the Primary Objective(s).	ICH M11 Protocol Section 10.4 Analyses Associated with the Primary Objective(s)
C218630	10.4.1 Primary Objective		Section 10.4.1 of the ICH M11 Protocol standard, Primary Objective.	ICH M11 Protocol Section 10.4.1 Primary Objective
C218631	10.4.1.1 Statistical Analysis Method		Section 10.4.1.1 of the ICH M11 Protocol standard, Statistical Analysis Method.	ICH M11 Protocol Section 10.4.1.1 Statistical Analysis Method
C218632	10.4.1.2 Handling of Data in Relation to Primary Estimand(s)		Section 10.4.1.2 of the ICH M11 Protocol standard, Handling of Data in Relation to Primary Estimand(s).	ICH M11 Protocol Section 10.4.1.2 Handling of Data in Relation to Primary Estimand(s)
C218633	10.4.1.3 Handling of Missing Data in Relation to Primary Estimand(s)		Section 10.4.1.3 of the ICH M11 Protocol standard, Handling of Missing Data in Relation to Primary Estimand(s)	ICH M11 Protocol Section 10.4.1.3 Handling of Missing Data in Relation to Primary Estimand(s)
C218634	10.4.1.4 Sensitivity Analysis		Section 10.4.1.4 of the ICH M11 Protocol standard, Sensitivity Analysis.	ICH M11 Protocol Section 10.4.1.4 Sensitivity Analysis
C218635	10.4.1.5 Supplementary Analysis		Section 10.4.1.5 of the ICH M11 Protocol standard, Supplementary Analysis.	ICH M11 Protocol Section 10.4.1.5 Supplementary Analysis
C218636	10.5 Analyses Associated with the Secondary Objective(s)		Section 10.5 of the ICH M11 Protocol standard, Analyses Associated with the Secondary Objective(s).	ICH M11 Protocol Section 10.5 Analyses Associated with the Secondary Objective(s)
C218637	10.5.1 Secondary Objective		Section 10.5.1 of the ICH M11 Protocol standard, Secondary Objective.	ICH M11 Protocol Section 10.5.1 Secondary Objective
C218638	10.5.1.1 Statistical Analysis Method		Section 10.5.1.1 of the ICH M11 Protocol standard, Statistical Analysis Method.	ICH M11 Protocol Section 10.5.1.1 Statistical Analysis Method
C218639	10.5.1.2 Handling of Data in Relation to Secondary Estimand(s)		Section 10.5.1.2 of the ICH M11 Protocol standard, Handling of Data in Relation to Secondary Estimand(s).	ICH M11 Protocol Section 10.5.1.2 Handling of Data in Relation to Secondary Estimand(s)
C218640	10.5.1.3 Handling of Missing Data in Relation to Secondary Estimand(s)		Section 10.5.1.3 of the ICH M11 Protocol standard, Handling of Missing Data in Relation to Secondary Estimand(s).	ICH M11 Protocol Section 10.5.1.3 Handling of Missing Data in Relation to Secondary Estimand(s)
C218641	10.5.1.4 Sensitivity Analysis		Section 10.5.1.4 of the ICH M11 Protocol standard, Sensitivity Analysis.	ICH M11 Protocol Section 10.5.1.4 Sensitivity Analysis
C218642	10.5.1.5 Supplementary Analysis		Section 10.5.1.5 of the ICH M11 Protocol standard, Supplementary Analysis.	ICH M11 Protocol Section 10.5.1.5 Supplementary Analysis
C218643	10.6 Analyses Associated with the Exploratory Objective(s)		Section 10.6 of the ICH M11 Protocol standard, Analyses Associated with the Exploratory Objective(s).	ICH M11 Protocol Section 10.6 Analyses Associated with the Exploratory Objective(s)
C218644	10.7 Safety Analyses		Section 10.7 of the ICH M11 Protocol standard, Safety Analyses.	ICH M11 Protocol Section 10.7 Safety Analyses
C218645	10.8 Other Analyses		Section 10.8 of the ICH M11 Protocol standard, Other Analyses.	ICH M11 Protocol Section 10.8 Other Analyses
C218646	10.9 Interim Analyses		Section 10.9 of the ICH M11 Protocol standard, Interim Analyses.	ICH M11 Protocol Section 10.9 Interim Analyses
C218649	11 TRIAL OVERSIGHT AND OTHER GENERAL CONSIDERATIONS		Section 11 of the ICH M11 Protocol standard, TRIAL OVERSIGHT AND OTHER GENERAL CONSIDERATIONS.	ICH M11 Protocol Section 11 TRIAL OVERSIGHT AND OTHER GENERAL CONSIDERATIONS
C218650	11.1 Regulatory and Ethical Considerations		Section 11.1 of the ICH M11 Protocol standard, Regulatory and Ethical Considerations.	ICH M11 Protocol Section 11.1 Regulatory and Ethical Considerations
C218663	11.10 Protocol Deviations		Section 11.10 of the ICH M11 Protocol standard, Protocol Deviations.	ICH M11 Protocol Section 11.10 Protocol Deviations
C218664	11.11 Early Site Closure		Section 11.11 of the ICH M11 Protocol standard, Early Site Closure.	ICH M11 Protocol Section 11.11 Early Site Closure
C218665	11.12 Data Dissemination		Section 11.12 of the ICH M11 Protocol standard, Data Dissemination.	ICH M11 Protocol Section 11.12 Data Dissemination
C218651	11.2 Trial Oversight		Section 11.2 of the ICH M11 Protocol standard, Trial Oversight.	ICH M11 Protocol Section 11.2 Trial Oversight
C218652	11.2.1 Investigator Responsibilities		Section 11.2.1 of the ICH M11 Protocol standard, Investigator Responsibilities.	ICH M11 Protocol Section 11.2.1 Investigator Responsibilities
C218653	11.2.2 Sponsor Responsibilities		Section 11.2.2 of the ICH M11 Protocol standard, Sponsor Responsibilities.	ICH M11 Protocol Section 11.2.2 Sponsor Responsibilities
C218654	11.3 Informed Consent Process		Section 11.3 of the ICH M11 Protocol standard, Informed Consent Process.	ICH M11 Protocol Section 11.3 Informed Consent Process
C218655	11.3.1 Informed Consent for Rescreening		Section 11.3.1 of the ICH M11 Protocol standard, Informed Consent for Rescreening.	ICH M11 Protocol Section 11.3.1 Informed Consent for Rescreening
C218656	11.3.2 Informed Consent for Use of Remaining Samples in Exploratory Research		Section 11.3.2 of the ICH M11 Protocol standard, Informed Consent for Use of Remaining Samples in Exploratory Research.	ICH M11 Protocol Section 11.3.2 Informed Consent for Use of Remaining Samples in Exploratory Research
C218657	11.4 Committees		Section 11.4 of the ICH M11 Protocol standard, Committees.	ICH M11 Protocol Section 11.4 Committees
C218658	11.5 Insurance and Indemnity		Section 11.5 of the ICH M11 Protocol standard, Insurance and Indemnity.	ICH M11 Protocol Section 11.5 Insurance and Indemnity
C218659	11.6 Risk-Based Quality Management		Section 11.6 of the ICH M11 Protocol standard, Risk-Based Quality Management.	ICH M11 Protocol Section 11.6 Risk-Based Quality Management
C218660	11.7 Data Governance		Section 11.7 of the ICH M11 Protocol standard, Data Governance.	ICH M11 Protocol Section 11.7 Data Governance
C218661	11.8 Data Protection		Section 11.8 of the ICH M11 Protocol standard, Data Protection.	ICH M11 Protocol Section 11.8 Data Protection
C218662	11.9 Source Records		Section 11.9 of the ICH M11 Protocol standard, Source Records.	ICH M11 Protocol Section 11.9 Source Records
C218666	12 APPENDIX: SUPPORTING DETAILS		Section 12 of the ICH M11 Protocol standard, APPENDIX: SUPPORTING DETAILS.	ICH M11 Protocol Section 12 APPENDIX: SUPPORTING DETAILS
C218667	12.1 Clinical Laboratory Tests		Section 12.1 of the ICH M11 Protocol standard, Clinical Laboratory Tests.	ICH M11 Protocol Section 12.1 Clinical Laboratory Tests
C218668	12.2 Country/Region-Specific Differences		Section 12.2 of the ICH M11 Protocol standard, Country/Region-Specific Differences.	ICH M11 Protocol Section 12.2 Country/Region-Specific Differences
C218669	12.3 Prior Protocol Amendment(s)		Section 12.3 of the ICH M11 Protocol standard, Prior Protocol Amendment(s).	ICH M11 Protocol Section 12.3 Prior Protocol Amendment(s)
C218670	13 APPENDIX: GLOSSARY OF TERMS AND ABBREVIATIONS		Section 13 of the ICH M11 Protocol standard, APPENDIX: GLOSSARY OF TERMS AND ABBREVIATIONS.	ICH M11 Protocol Section 13 APPENDIX: GLOSSARY OF TERMS AND ABBREVIATIONS
C218671	14 APPENDIX: REFERENCES		Section 14 of the ICH M11 Protocol standard, APPENDIX: REFERENCES.	ICH M11 Protocol Section 14 APPENDIX: REFERENCES

C217272	Protocol Section Name and Number Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218520	2 INTRODUCTION		Section 2 of the ICH M11 Protocol standard, INTRODUCTION.	ICH M11 Protocol Section 2 INTRODUCTION
C218521	2.1 Purpose of Trial		Section 2.1 of the ICH M11 Protocol standard, Purpose of Trial.	ICH M11 Protocol Section 2.1 Purpose of Trial
C218522	2.2 Assessment of Risks and Benefits		Section 2.2 of the ICH M11 Protocol standard, Assessment of Risks and Benefits.	ICH M11 Protocol Section 2.2 Assessment of Risks and Benefits
C218523	2.2.1 Risk Summary and Mitigation Strategy		Section 2.2.2 of the ICH M11 Protocol standard, Risk Summary and Mitigation Strategy.	ICH M11 Protocol Section 2.2.1 Risk Summary and Mitigation Strategy
C218524	2.2.2 Benefit Summary		Section 2.2.1 of the ICH M11 Protocol standard, Benefit Summary.	ICH M11 Protocol Section 2.2.2 Benefit Summary
C218525	2.2.3 Overall Risk-Benefit Assessment		Section 2.2.3 of the ICH M11 Protocol standard, Overall Risk-Benefit Assessment.	ICH M11 Protocol Section 2.2.3 Overall Risk-Benefit Assessment
C218526	3 TRIAL OBJECTIVES AND ASSOCIATED ESTIMANDS		Section 3 of the ICH M11 Protocol standard, TRIAL OBJECTIVES AND ASSOCIATED ESTIMANDS.	ICH M11 Protocol Section 3 TRIAL OBJECTIVES AND ASSOCIATED ESTIMANDS
C218527	3.1 Primary Objective(s) and Associated Estimand(s)		Section 3.1 of the ICH M11 Protocol standard, Primary Objective(s) and Associated Estimand(s).	ICH M11 Protocol Section 3.1 Primary Objective(s) and Associated Estimand(s)
C218528	3.1.1 Primary Objective		Section 3.1.1 of the ICH M11 Protocol standard, Primary Objective.	ICH M11 Protocol Section 3.1.1 Primary Objective
C218529	3.2 Secondary Objective(s) and Associated Estimand(s)		Section 3.2 of the ICH M11 Protocol standard, Secondary Objective(s) and Associated Estimand(s).	ICH M11 Protocol Section 3.2 Secondary Objective(s) and Associated Estimand(s)
C218530	3.2.1 Secondary Objective		Section 3.2.1 of the ICH M11 Protocol standard, Secondary Objective.	ICH M11 Protocol Section 3.2.1 Secondary Objective
C218531	3.3 Exploratory Objective(s)		Section 3.3 of the ICH M11 Protocol standard, Exploratory Objective(s).	ICH M11 Protocol Section 3.3 Exploratory Objective(s)
C218532	3.3.1 Exploratory Objective		Section 3.3.1 of the ICH M11 Protocol standard, Exploratory Objective.	ICH M11 Protocol Section 3.3.1 Exploratory Objective
C218533	4 TRIAL DESIGN		Section 4 of the ICH M11 Protocol standard, TRIAL DESIGN.	ICH M11 Protocol Section 4 TRIAL DESIGN
C218534	4.1 Description of Trial Design		Section 4.1 of the ICH M11 Protocol standard, Description of Trial Design.	ICH M11 Protocol Section 4.1 Description of Trial Design
C218535	4.1.1 Stakeholder Input into Design		Section 4.1.1 of the ICH M11 Protocol standard, Stakeholder Input into Design.	ICH M11 Protocol Section 4.1.1 Stakeholder Input into Design
C218536	4.2 Rationale for Trial Design		Section 4.2 of the ICH M11 Protocol standard, Rationale for Trial Design.	ICH M11 Protocol Section 4.2 Rationale for Trial Design
C218537	4.2.1 Rationale for Estimand(s)		Section 4.2.1 of the ICH M11 Protocol standard, Rationale for Estimand(s).	ICH M11 Protocol Section 4.2.1 Rationale for Estimand(s)
C218538	4.2.2 Rationale for Intervention Model		Section 4.2.2 of the ICH M11 Protocol standard, Rationale for Intervention Model.	ICH M11 Protocol Section 4.2.2 Rationale for Intervention Model
C218539	4.2.3 Rationale for Control Type		Section 4.2.3 of the ICH M11 Protocol standard, Rationale for Control Type.	ICH M11 Protocol Section 4.2.3 Rationale for Control Type
C218540	4.2.4 Rationale for Trial Duration		Section 4.2.4 of the ICH M11 Protocol standard, Rationale for Trial Duration.	ICH M11 Protocol Section 4.2.4 Rationale for Trial Duration
C218541	4.2.5 Rationale for Adaptive or Novel Trial Design		Section 4.2.5 of the ICH M11 Protocol standard, Rationale for Adaptive or Novel Trial Design.	ICH M11 Protocol Section 4.2.5 Rationale for Adaptive or Novel Trial Design
C218542	4.2.6 Rationale for Interim Analysis		Section 4.2.6 of the ICH M11 Protocol standard, Rationale for Interim Analysis.	ICH M11 Protocol Section 4.2.6 Rationale for Interim Analysis
C218543	4.2.7 Rationale for Other Trial Design Aspects		Section 4.2.7 of the ICH M11 Protocol standard, Rationale for Other Trial Design Aspects.	ICH M11 Protocol Section 4.2.7 Rationale for Other Trial Design Aspects
C218544	4.3 Trial Stopping Rules		Section 4.3 of the ICH M11 Protocol standard, Trial Stopping Rules.	ICH M11 Protocol Section 4.3 Trial Stopping Rules
C218545	4.4 Start of Trial and End of Trial		Section 4.4 of the ICH M11 Protocol standard, Start of Trial and End of Trial.	ICH M11 Protocol Section 4.4 Start of Trial and End of Trial
C218546	4.5 Access to Trial Intervention After End of Trial		Section 4.5 of the ICH M11 Protocol standard, Access to Trial Intervention After End of Trial.	ICH M11 Protocol Section 4.5 Access to Trial Intervention After End of Trial
C218547	5 TRIAL POPULATION		Section 5 of the ICH M11 Protocol standard, TRIAL POPULATION.	ICH M11 Protocol Section 5 TRIAL POPULATION
C218548	5.1 Description of Trial Population and Rationale		Section 5.1 of the ICH M11 Protocol standard, Description of Trial Population and Rationale.	ICH M11 Protocol Section 5.1 Description of Trial Population and Rationale
C218549	5.2 Inclusion Criteria		Section 5.2 of the ICH M11 Protocol standard, Inclusion Criteria.	ICH M11 Protocol Section 5.2 Inclusion Criteria
C218550	5.3 Exclusion Criteria		Section 5.3 of the ICH M11 Protocol standard, Exclusion Criteria.	ICH M11 Protocol Section 5.3 Exclusion Criteria
C218551	5.4 Contraception		Section 5.4 of the ICH M11 Protocol standard, Contraception.	ICH M11 Protocol Section 5.4 Contraception
C218552	5.4.1 Definitions Related to Childbearing Potential		Section 5.4.1 of the ICH M11 Protocol standard, Definitions Related to Childbearing Potential.	ICH M11 Protocol Section 5.4.1 Definitions Related to Childbearing Potential
C218553	5.4.2 Contraception Requirements		Section 5.4.2 of the ICH M11 Protocol standard, Contraception Requirements.	ICH M11 Protocol Section 5.4.2 Contraception Requirements
C218554	5.5 Lifestyle Restrictions		Section 5.5 of the ICH M11 Protocol standard, Lifestyle Restrictions.	ICH M11 Protocol Section 5.5 Lifestyle Restrictions
C218555	5.5.1 Meals and Dietary Restrictions		Section 5.5.1 of the ICH M11 Protocol standard, Meals and Dietary Restrictions.	ICH M11 Protocol Section 5.5.1 Meals and Dietary Restrictions
C218556	5.5.2 Caffeine, Alcohol, Tobacco, and Other Restrictions		Section 5.5.2 of the ICH M11 Protocol standard, Caffeine, Alcohol, Tobacco, and Other Restrictions.	ICH M11 Protocol Section 5.5.2 Caffeine, Alcohol, Tobacco, and Other Restrictions
C218557	5.5.3 Physical Activity Restrictions		Section 5.5.3 of the ICH M11 Protocol standard, Physical Activity Restrictions.	ICH M11 Protocol Section 5.5.3 Physical Activity Restrictions
C218558	5.5.4 Other Activity Restrictions		Section 5.5.4 of the ICH M11 Protocol standard, Other Activity Restrictions.	ICH M11 Protocol Section 5.5.4 Other Activity Restrictions
C218559	5.6 Screen Failure and Rescreening		Section 5.6 of the ICH M11 Protocol standard, Screen Failure and Rescreening.	ICH M11 Protocol Section 5.6 Screen Failure and Rescreening
C218560	6 TRIAL INTERVENTION AND CONCOMITANT THERAPY		Section 6 of the ICH M11 Protocol standard, TRIAL INTERVENTION AND CONCOMITANT THERAPY.	ICH M11 Protocol Section 6 TRIAL INTERVENTION AND CONCOMITANT THERAPY
C218561	6.1 Description of Investigational Trial Intervention		Section 6.1 of the ICH M11 Protocol standard, Description of Investigational Trial Intervention.	ICH M11 Protocol Section 6.1 Description of Investigational Trial Intervention
C218580	6.10 Concomitant Therapy		Section 6.10 of the ICH M10 Protocol standard, Concomitant Therapy.	ICH M11 Protocol Section 6.10 Concomitant Therapy
C218581	6.10.1 Prohibited Concomitant Therapy		Section 6.10.1 of the ICH M10 Protocol standard, Prohibited Concomitant Therapy.	ICH M11 Protocol Section 6.10.1 Prohibited Concomitant Therapy
C218582	6.10.2 Permitted Concomitant Therapy		Section 6.10.2 of the ICH M10 Protocol standard, Permitted Concomitant Therapy.	ICH M11 Protocol Section 6.10.2 Permitted Concomitant Therapy
C218562	6.2 Rationale for Investigational Trial Intervention Dose and Regimen		Section 6.2 of the ICH M11 Protocol standard, Rationale for Investigational Trial Intervention Dose and Regimen.	ICH M11 Protocol Section 6.2 Rationale for Investigational Trial Intervention Dose and Regimen
C218563	6.3 Investigational Trial Intervention Administration		Section 6.3 of the ICH M11 Protocol standard, Investigational Trial Intervention Administration.	ICH M11 Protocol Section 6.3 Investigational Trial Intervention Administration
C218564	6.4 Investigational Trial Intervention Dose Modification		Section 6.4 of the ICH M11 Protocol standard, Investigational Trial Intervention Dose Modification.	ICH M11 Protocol Section 6.4 Investigational Trial Intervention Dose Modification
C218565	6.5 Management of Investigational Trial Intervention Overdose		Section 6.5 of the ICH M11 Protocol standard, Management of Investigational Trial Intervention Overdose.	ICH M11 Protocol Section 6.5 Management of Investigational Trial Intervention Overdose
C218566	6.6 Preparation, Storage, Handling and Accountability of Investigational Trial Intervention		Section 6.6 of the ICH M11 Protocol standard, Preparation, Storage, Handling and Accountability of Investigational Trial Intervention.	ICH M11 Protocol Section 6.6 Preparation, Storage, Handling and Accountability of Investigational Trial Intervention
C218567	6.6.1 Preparation of Investigational Trial Intervention		Section 6.6.1 of the ICH M11 Protocol standard, Preparation of Investigational Trial Intervention.	ICH M11 Protocol Section 6.6.1 Preparation of Investigational Trial Intervention
C218568	6.6.2 Storage and Handling of Investigational Trial Intervention		Section 6.6.2 of the ICH M11 Protocol standard, Storage and Handling of Investigational Trial Intervention.	ICH M11 Protocol Section 6.6.2 Storage and Handling of Investigational Trial Intervention
C218569	6.6.3 Accountability of Investigational Trial Intervention		Section 6.6.3 of the ICH M11 Protocol standard, Accountability of Investigational Trial Intervention.	ICH M11 Protocol Section 6.6.3 Accountability of Investigational Trial Intervention

C217272	Protocol Section Name and Number Response Terminology			
NCI Code	ICH Preferred Term	ICH Synonym	ICH Definition	NCI Preferred Term
C218570	6.7 Investigational Trial Intervention Assignment, Randomisation and Blinding		Section 6.7 of the ICH M11 Protocol standard, Investigational Trial Intervention Assignment, Randomisation and Blinding.	ICH M11 Protocol Section 6.7 Investigational Trial Intervention Assignment, Randomisation and Blinding
C218571	6.7.1 Participant Assignment to Investigational Trial Intervention		Section 6.7.1 of the ICH M11 Protocol standard, Participant Assignment to Investigational Trial Intervention.	ICH M11 Protocol Section 6.7.1 Participant Assignment to Investigational Trial Intervention
C218572	6.7.2 Randomisation		Section 6.7.2 of the ICH M11 Protocol standard, Randomisation.	ICH M11 Protocol Section 6.7.2 Randomisation
C218573	6.7.3 Measures to Maintain Blinding		Section 6.7.3 of the ICH M11 Protocol standard, Measures to Maintain Blinding.	ICH M11 Protocol Section 6.7.3 Measures to Maintain Blinding
C218574	6.7.4 Emergency Unblinding at the Site		Section 6.7.4 of the ICH M11 Protocol standard, Emergency Unblinding at the Site.	ICH M11 Protocol Section 6.7.4 Emergency Unblinding at the Site
C218575	6.8 Investigational Trial Intervention Adherence		Section 6.8 of the ICH M11 Protocol standard, Investigational Trial Intervention Adherence.	ICH M11 Protocol Section 6.8 Investigational Trial Intervention Adherence
C218576	6.9 Description of Noninvestigational Trial Intervention		Section 6.9 of the ICH M11 Protocol standard, Description of Noninvestigational Trial Intervention.	ICH M11 Protocol Section 6.9 Description of Noninvestigational Trial Intervention
C218577	6.9.1 Background Trial Intervention		Section 6.9.1 of the ICH M11 Protocol standard, Background Trial Intervention.	ICH M11 Protocol Section 6.9.1 Background Trial Intervention
C218578	6.9.2 Rescue Therapy		Section 6.9.2 of the ICH M11 Protocol standard, Rescue Therapy.	ICH M11 Protocol Section 6.9.2 Rescue Therapy
C218579	6.9.3 Other Noninvestigational Trial Intervention		Section 6.9.3 of the ICH M11 Protocol standard, Other Noninvestigational Trial Intervention.	ICH M11 Protocol Section 6.9.3 Other Noninvestigational Trial Intervention
C218583	7 PARTICIPANT DISCONTINUATION OF TRIAL INTERVENTION AND DISCONTINUATION OR WITHDRAWAL FROM TRIAL		Section 7 of the ICH M11 Protocol standard, PARTICIPANT DISCONTINUATION OF TRIAL INTERVENTION AND DISCONTINUATION OR WITHDRAWAL FROM TRIAL.	ICH M11 Protocol Section 7 PARTICIPANT DISCONTINUATION OF TRIAL INTERVENTION AND DISCONTINUATION OR WITHDRAWAL FROM TRIAL
C218584	7.1 Discontinuation of Trial Intervention for Individual Participants		Section 7.1 of the ICH M11 Protocol standard, Discontinuation of Trial Intervention for Individual Participants.	ICH M11 Protocol Section 7.1 Discontinuation of Trial Intervention for Individual Participants
C218585	7.1.1 Permanent Discontinuation of Trial Intervention		Section 7.1.1 of the ICH M11 Protocol standard, Permanent Discontinuation of Trial Intervention.	ICH M11 Protocol Section 7.1.1 Permanent Discontinuation of Trial Intervention
C218586	7.1.2 Temporary Discontinuation of Trial Intervention		Section 7.1.2 of the ICH M11 Protocol standard, Temporary Discontinuation of Trial Intervention.	ICH M11 Protocol Section 7.1.2 Temporary Discontinuation of Trial Intervention
C218587	7.1.3 Rechallenge		Section 7.1.3 of the ICH M11 Protocol standard, Rechallenge.	ICH M11 Protocol Section 7.1.3 Rechallenge
C218588	7.2 Participant Discontinuation or Withdrawal from the Trial		Section 7.2 of the ICH M11 Protocol standard, Participant Discontinuation or Withdrawal from the Trial.	ICH M11 Protocol Section 7.2 Participant Discontinuation or Withdrawal from the Trial
C218589	7.3 Management of Loss to Follow-Up		Section 7.3 of the ICH M11 Protocol standard, Management of Loss to Follow-Up.	ICH M11 Protocol Section 7.3 Management of Loss to Follow-Up
C218590	8 TRIAL ASSESSMENTS AND PROCEDURES		Section 8 of the ICH M11 Protocol standard, TRIAL ASSESSMENTS AND PROCEDURES.	ICH M11 Protocol Section 8 TRIAL ASSESSMENTS AND PROCEDURES
C218591	8.1 Trial Assessments and Procedures Considerations		Section 8.1 of the ICH M11 Protocol standard, Trial Assessments and Procedures Considerations.	ICH M11 Protocol Section 8.1 Trial Assessments and Procedures Considerations
C218592	8.2 Screening/Baseline Assessments and Procedures		Section 8.2 of the ICH M11 Protocol standard, Screening/Baseline Assessments and Procedures.	ICH M11 Protocol Section 8.2 Screening/Baseline Assessments and Procedures
C218593	8.3 Efficacy Assessments and Procedures		Section 8.3 of the ICH M11 Protocol standard, Efficacy Assessments and Procedures.	ICH M11 Protocol Section 8.3 Efficacy Assessments and Procedures
C218594	8.4 Safety Assessments and Procedures		Section 8.4 of the ICH M11 Protocol standard, Safety Assessments and Procedures.	ICH M11 Protocol Section 8.4 Safety Assessments and Procedures
C218595	8.4.1 Physical Examination		Section 8.4.1 of the ICH M11 Protocol standard, Physical Examination.	ICH M11 Protocol Section 8.4.1 Physical Examination
C218596	8.4.2 Vital Signs		Section 8.4.2 of the ICH M11 Protocol standard, Vital Signs.	ICH M11 Protocol Section 8.4.2 Vital Signs
C218597	8.4.3 Electrocardiograms		Section 8.4.3 of the ICH M11 Protocol standard, Electrocardiograms.	ICH M11 Protocol Section 8.4.3 Electrocardiograms
C218598	8.4.4 Clinical Laboratory Assessments		Section 8.4.4 of the ICH M11 Protocol standard, Clinical Laboratory Assessments.	ICH M11 Protocol Section 8.4.4 Clinical Laboratory Assessments
C218599	8.4.5 Pregnancy Testing		Section 8.4.5 of the ICH M11 Protocol standard, Pregnancy Testing.	ICH M11 Protocol Section 8.4.5 Pregnancy Testing
C218600	8.4.6 Suicidal Ideation and Behaviour Risk Monitoring		Section 8.4.6 of the ICH M11 Protocol standard, Suicidal Ideation and Behaviour Risk Monitoring.	ICH M11 Protocol Section 8.4.6 Suicidal Ideation and Behaviour Risk Monitoring
C218601	8.5 Pharmacokinetics		Section 8.5 of the ICH M11 Protocol standard, Pharmacokinetics.	ICH M11 Protocol Section 8.5 Pharmacokinetics
C218602	8.6 Biomarkers		Section 8.6 of the ICH M11 Protocol standard, Biomarkers.	ICH M11 Protocol Section 8.6 Biomarkers
C218603	8.6.1 Genetics, Genomics, Pharmacogenetics and Pharmacogenomics		Section 8.6.1 of the ICH M11 Protocol standard, Genetics, Genomics, Pharmacogenetics and Pharmacogenomics.	ICH M11 Protocol Section 8.6.1 Genetics, Genomics, Pharmacogenetics and Pharmacogenomics
C218604	8.6.2 Pharmacodynamic Biomarkers		Section 8.6.2 of the ICH M11 Protocol standard, Pharmacodynamic Biomarkers.	ICH M11 Protocol Section 8.6.2 Pharmacodynamic Biomarkers
C218605	8.6.3 Other Biomarkers		Section 8.6.3 of the ICH M11 Protocol standard, Other Biomarkers.	ICH M11 Protocol Section 8.6.3 Other Biomarkers
C218606	8.7 Immunogenicity Assessments		Section 8.7 of the ICH M11 Protocol standard, Immunogenicity Assessments.	ICH M11 Protocol Section 8.7 Immunogenicity Assessments
C218607	8.8 Medical Resource Utilisation and Health Economics		Section 8.8 of the ICH M11 Protocol standard, Medical Resource Utilisation and Health Economics.	ICH M11 Protocol Section 8.8 Medical Resource Utilisation and Health Economics
C218608	9 ADVERSE EVENTS, SERIOUS ADVERSE EVENTS, PRODUCT COMPLAINTS, PREGNANCY AND POSTPARTUM INFORMATION, AND SPECIAL SAFETY SITUATIONS		Section 9 of the ICH M11 Protocol standard, ADVERSE EVENTS, SERIOUS ADVERSE EVENTS, PRODUCT COMPLAINTS, PREGNANCY AND POSTPARTUM INFORMATION, AND SPECIAL SAFETY SITUATIONS.	ICH M11 Protocol Section 9 ADVERSE EVENTS, SERIOUS ADVERSE EVENTS, PRODUCT COMPLAINTS, PREGNANCY AND POSTPARTUM INFORMATION, AND SPECIAL SAFETY SITUATIONS
C218609	9.1 Definitions		Section 9.1 of the ICH M11 Protocol standard, Definitions.	ICH M11 Protocol Section 9.1 Definitions
C218610	9.1.1 Definitions of Adverse Events		Section 9.1.1 of the ICH M11 Protocol standard, Definitions of Adverse Events.	ICH M11 Protocol Section 9.1.1 Definitions of Adverse Events
C218611	9.1.2 Definitions of Serious Adverse Events		Section 9.1.2 of the ICH M11 Protocol standard, Definitions of Serious Adverse Events.	ICH M11 Protocol Section 9.1.2 Definitions of Serious Adverse Events
C218612	9.1.3 Definitions of Product Complaints		Section 9.1.3 of the ICH M11 Protocol standard, Definitions of Product Complaints.	ICH M11 Protocol Section 9.1.3 Definitions of Product Complaints
C218613	9.1.3.1 Definitions of Medical Device Product Complaints		Section 9.1.3.1 of the ICH M11 Protocol standard, Definitions of Medical Device Product Complaints.	ICH M11 Protocol Section 9.1.3.1 Definitions of Medical Device Product Complaints
C218614	9.2 Timing and Procedures for Collection and Reporting		Section 9.2 of the ICH M11 Protocol standard, Timing and Procedures for Collection and Reporting.	ICH M11 Protocol Section 9.2 Timing and Procedures for Collection and Reporting
C218615	9.2.1 Timing		Section 9.2.1 of the ICH M11 Protocol standard, Timing.	ICH M11 Protocol Section 9.2.1 Timing
C218616	9.2.2 Collection Procedures		Section 9.2.2 of the ICH M11 Protocol standard, Collection Procedures.	ICH M11 Protocol Section 9.2.2 Collection Procedures
C218617	9.2.3 Reporting		Section 9.2.3 of the ICH M11 Protocol standard, Reporting.	ICH M11 Protocol Section 9.2.3 Reporting
C218618	9.2.3.1 Regulatory Reporting Requirements		Section 9.2.3.1 of the ICH M11 Protocol standard, Regulatory Reporting Requirements.	ICH M11 Protocol Section 9.2.3.1 Regulatory Reporting Requirements
C218619	9.2.4 Adverse Events of Special Interest		Section 9.2.4 of the ICH M11 Protocol standard, Adverse Events of Special Interest.	ICH M11 Protocol Section 9.2.4 Adverse Events of Special Interest
C218620	9.2.5 Disease-related Events or Outcomes Not Qualifying as AEs or SAEs		Section 9.2.5 of the ICH M11 Protocol standard, Disease-related Events or Outcomes Not Qualifying as AEs or SAEs.	ICH M11 Protocol Section 9.2.5 Disease-related Events or Outcomes Not Qualifying as AEs or

C217272	Protocol Section Name and Number Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
				SAEs
C218621	9.3 Pregnancy and Postpartum Information		Section 9.3 of the ICH M11 Protocol standard, Pregnancy and Postpartum Information.	ICH M11 Protocol Section 9.3 Pregnancy and Postpartum Information
C218622	9.3.1 Participants Who Become Pregnant During the Trial		Section 9.3.1 of the ICH M11 Protocol standard, Participants Who Become Pregnant During the Trial.	ICH M11 Protocol Section 9.3.1 Participants Who Become Pregnant During the Trial
C218623	9.3.2 Participants Whose Partners Become Pregnant During the Trial		Section 9.3.2 of the ICH M11 Protocol standard, Participants Whose Partners Become Pregnant During the Trial.	ICH M11 Protocol Section 9.3.2 Participants Whose Partners Become Pregnant During the Trial
C218624	9.4 Special Safety Situations		Section 9.4 of the ICH M11 Protocol standard, Special Safety Situations.	ICH M11 Protocol Section 9.4 Special Safety Situations
C222770	Amendment Details		Amendment Details Section of the ICH M11 Protocol standard, Amendment Details.	ICH M11 Protocol Section Amendment Details
C222769	Title Page		Title Page Section of the ICH M11 Protocol standard, Title Page.	ICH M11 Protocol Section Title Page

Reason for Amendment Response Terminology (Reason for Amendment Response Terminology)

NCI Code: C217276, Codelist extensible: No

C217276	Reason for Amendment Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C218497	Change In Standard Of Care		A change in the standard of care necessitates a change(s) to, or formal clarification of, the protocol.	Change in Standard Of Care Amendment Reason
C218496	Change In Strategy		A change in the study purpose or intent of the scientific plan necessitates a change(s) to, or formal clarification of, the protocol.	Change in Strategy Amendment Reason
C218495	IMP Addition		The addition of an investigational medicinal product to a clinical trial design necessitates a change(s) to, or formal clarification of, the protocol.	IMP Addition Amendment Reason
C218501	Inconsistency And/Or Error In The Protocol		An error or inconsistency in the protocol necessitates a change(s) to, or formal clarification of, the protocol.	Inconsistency and/or Error in the Protocol Amendment Reason
C218499	Investigator/Site Feedback		Feedback from the investigator or study site necessitates a change(s) to, or formal clarification of, the protocol.	Investigator/Site Feedback Amendment Reason
C218492	IRB/IEC Feedback		Feedback from the institutional review board or independent ethics committee necessitates a change(s) to, or formal clarification of, the protocol.	IRB/IEC Feedback Amendment Reason
C218494	Manufacturing Change		A change to manufacturing processes of the study agents necessitates a change(s) to, or formal clarification of, the protocol.	Manufacturing Change Amendment Reason
C218498	New Data Available (Other Than Safety Data)		Previously unavailable data (other than safety data) becomes available, which necessitates a change(s) to, or formal clarification of, the protocol.	New Data Available (Other Than Safety Data) Amendment Reason
C218491	New Regulatory Guidance		A regulatory agency has published a guidance document that necessitates a change(s) to, or formal clarification of, the protocol.	New Regulatory Guidance Amendment Reason
C218493	New Safety Information Available		Previously unavailable safety data becomes available, which necessitates a change(s) to, or formal clarification of, the protocol.	New Safety Information Available Amendment Reason
C48660	Not Applicable		Determination of a value is not relevant in the current context.	Not Applicable
C17649	Other		Different than the one(s) previously specified or mentioned.	Other
C218502	Protocol Design Error		A protocol design error necessitates a change(s) to, or formal clarification of, a document.	Protocol Design Error Amendment Reason
C218500	Recruitment Difficulty		Challenges with participant recruitment necessitates a change(s) to, or formal clarification of, the protocol.	Recruitment Difficulty Amendment Reason
C218490	Regulatory Agency Request To Amend		A regulatory agency has expressed a need for a change(s) to, or formal clarification of, the protocol.	Regulatory Agency Request to Amend Amendment Reason

Trial Arm Type Response Terminology (Trial Arm Type Response Terminology)

NCI Code: C217283, Codelist extensible: No

C217283	Trial Arm Type Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C174267	Active Comparator Arm		An arm describing the active comparator.	Active Comparator Arm
C174226	Control Arm		An arm describing the intervention or treatment plan for a group of participants in the study receiving a control. The control may comprise a non-investigational product (active control) or regimen, placebo, or no treatment.	Control Arm
C174266	Experimental Arm		An arm describing the intervention or treatment plan for a group of participants in the study receiving test product(s).	Investigational Arm
C174270	No Intervention Arm		A study arm without an intervention or treatment.	No Intervention Arm
C174268	Placebo Comparator Arm		An arm describing the placebo comparator.	Placebo Control Arm
C174269	Sham Comparator Arm		An arm describing the sham comparator.	Sham Comparator Arm

Trial Blinding Role Response Terminology (Trial Blinding Role Response Terminology)

NCI Code: C217281, Codelist extensible: No

C217281	Trial Blinding Role Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C17445	Care Provider		The primary person in charge of the care of a patient, usually a family member or a designated health care professional.	Caregiver
C25936	Investigator		A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at the trial site, the investigator is the responsible leader of the team and may be called the principal investigator.	Investigator
C48660	Not Applicable		Determination of a value is not relevant in the current context.	Not Applicable
C207599	Outcomes Assessor		The individual who evaluates the outcome(s) of interest.	Outcomes Assessor
C142710	Participant		A member of the clinical study population from whom data are being collected. (CDISC Glossary)	Study Participant
C70793	Sponsor		An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical study. (CDISC Glossary)	Clinical Study Sponsor

Trial Blinding Schema Response Terminology (Trial Blinding Schema Response Terminology)

NCI Code: C217051, Codelist extensible: No

C217051	Trial Blinding Schema Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C15228	Double Blind		A study in which neither the participant nor the study personnel interacting with the participant or data during the study knows what intervention a participant is receiving.	Double Blind Study
C187674	Observer Blind		A study in which the study personnel who measure, record, or assess the participant do not know which intervention the participant is receiving or, in the context of observational studies, do not know the external factors to which a participant has been exposed.	Observer Blind Study
C49659	Open Label		A study in which participants and study personnel know which intervention each participant is receiving.	Open Label Study
C28233	Single Blind		A study in which one party, either the participant or study personnel, does not know which intervention is administered to the participant.	Single Blind Study

Trial Intervention Assignment Method Response Terminology (Trial Intervention Assignment Method Response Terminology)

NCI Code: C217280, Codelist extensible: No

C217280	Trial Intervention Assignment Method Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C222801	No Intervention Assignment Method		No specific methodology is used to assign trial participants to treatment or control groups.	No Intervention Assignment Method
C17649	Other		Different than the one(s) previously specified or mentioned.	Other
C25196	Randomisation		The process of assigning trial participants to treatment or control groups using an element of chance to determine the assignments in order to reduce bias. (CDISC Glossary)	Randomization

Trial Phase Response Terminology (Trial Phase Response Terminology)

NCI Code: C217045, Codelist extensible: No

C217045	Trial Phase Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C54721	Early Phase 1		Exploratory clinical trials, in a small number of participants, that are conducted early in Phase 1. The investigational trial intervention is administered at a low dose for a limited time. Early Phase 1 trials provide insights into a variety of parameters such as pharmacokinetic, pharmacodynamic, and other biomarkers. They involve limited human exposure, have no therapeutic or diagnostic intent, and are not intended to assess clinical tolerability.	Early Phase 1 Trial
C15600	Phase 1		Exploratory clinical trials that may be first-in-human, conducted in a small number of patients or healthy volunteers to evaluate clinical safety, tolerability, or therapeutic intent (pharmacokinetics and pharmacodynamics) of an investigational trial intervention.	Phase I Trial
C15693	Phase 1/Phase 2		A single clinical trial that combines elements of Phase 1 and Phase 2 trials, which may begin as a Phase 1 trial and transition into Phase 2 based upon predetermined criteria.	Phase I/II Trial
C198366	Phase 1/Phase 2/Phase 3		A single clinical trial that combines elements of Phase 1, Phase 2, and Phase 3 trials, which may begin as a Phase 1 trial and transitions through Phase 2 and Phase 3 based upon predetermined criteria.	Phase I/II/III Trial
C198367	Phase 1/Phase 3		A single clinical trial that combines elements of Phase 1 and Phase 3 trials, which may begin as a Phase 1 trial and transition into Phase 3 based upon predetermined criteria.	Phase I/III Trial
C15601	Phase 2		Exploratory trials conducted to evaluate the safety and efficacy of the investigational trial intervention in patients with the disease or condition. Objectives may include, but are not limited to, clinical pharmacology, dose-ranging (dose-response, frequency of dosing), type of patients, or other characteristics of safety and efficacy.	Phase II Trial
C15694	Phase 2/Phase 3		A single clinical trial that combines elements of Phase 2 and Phase 3 trials, which may begin as a Phase 2 trial and transition into Phase 3 based upon predetermined criteria.	Phase II/III Trial
C217024	Phase 2/Phase 3/Phase 4		A single clinical trial that combines elements of Phase 2, Phase 3, and Phase 4 trials, which may begin as a Phase 2 trial and transitions through Phase 3 and Phase 4 based upon predetermined criteria.	Phase II/III/IV Trial
C15602	Phase 3		Confirmatory trials conducted to demonstrate safety, efficacy and tolerability of the investigational trial intervention in patients with the disease or condition. Their objectives are to evaluate the overall benefit-risk relationship and may provide substantial evidence for regulatory approval and product information.	Phase III Trial
C217025	Phase 3/Phase 4		A single clinical trial that combines elements of Phase 3 and Phase 4 trials, which may begin as a Phase 3 trial and transition into Phase 4 based upon predetermined criteria.	Phase III/IV Trial
C15603	Phase 4		Post-approval (or post-marketing) trials conducted to further evaluate the safety and efficacy of an investigational trial intervention in its approved indication and may be conducted to address a regulatory requirement. These studies may explore use of the investigational trial intervention in the real-world setting of clinical practice and may also inform health economics and health technology assessments.	Phase IV Trial

Trial-Related Safety Event Type Response Terminology (Trial-Related Safety Event Type Response Terminology)

NCI Code: C217287, Codelist extensible: No

C217287	Trial-Related Safety Event Type Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C41331	Adverse Event		Any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.	Adverse Event
C222331	Drug/Device Combination Product Complaint		Any concern about the safety, quality, and/or performance of a trial-related drug-device combination.	Drug-Device Combination Product Complaint
C218510	Lactation Event		Any event that occurs when the participant is lactating.	Lactation Event
C218513	Not Reportable Adverse Event of Special Interest		An adverse event of special interest (serious or non-serious) is one of scientific and medical concern specific to the sponsor's product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor could be appropriate, and which is deemed to be not reportable to the appropriate regulatory authority.	Not Reportable Adverse Event of Special Interest
C17649	Other		Different than the one(s) previously specified or mentioned.	Other
C218511	Post-Partum Event		Any event that occurs when the participant is in the stages of recovery post pregnancy and birth event.	Post-Partum Event
C218509	Pregnancy Event		Any event that occurs when the participant or participant's partner becomes pregnant or is pregnant.	Pregnancy Event
C218512	Reportable Adverse Event of Special Interest		An adverse event of special interest (serious or non-serious) is one of scientific and medical concern specific to the sponsor's product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor could be appropriate, and which is deemed to be reportable to the appropriate regulatory authority.	Reportable Adverse Event of Special Interest
C41335	Serious Adverse Event		Any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or any other medically significant event that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed in the definition.	Serious Adverse Event
C218508	Trial Intervention Complaint		Any concern about the safety and/or quality of any trial-related interventions.	Trial Intervention Complaint

Trial Site Distribution Response Terminology (Trial Site Distribution Response Terminology)

NCI Code: C217049, Codelist extensible: No

C217049	Trial Site Distribution Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C217005	Multicentre		A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.	Multicenter Study
C217004	Single-Centre		A clinical trial that is conducted at a single site.	Single-Center Study

Trial Site Geographic Scope Response Terminology (Trial Site Geographic Scope Response Terminology)

NCI Code: C217050, Codelist extensible: No

C217050	Trial Site Geographic Scope Response Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C217007	Multiple Countries		Of, or pertaining to, an occurrence in more than one country.	Multiple Countries
C217006	Single Country		Of, or pertaining to, an occurrence in one country.	Single Country

Unit of Measure Terminology (Unit of Measure Terminology)

NCI Code: C217048, Codelist extensible: No

C217048	Unit of Measure Terminology			
NCI Code	**ICH Preferred Term**	**ICH Synonym**	**ICH Definition**	**NCI Preferred Term**
C25301	Days		A unit of measurement of time equal to 24 hours.	Day
C25529	Hours		A unit of measurement of time equal to 60 minutes.	Hour
C29846	Months		One of the 12 divisions of a year as determined by a calendar. It corresponds to the unit of time of approximately to one cycle of the moon's phases, about 30 days or 4 weeks.	Month
C29844	Weeks		Any period of seven consecutive days.	Week
C29848	Years		The period of time that it takes for Earth to make a complete revolution around the sun, approximately 365 days; a specific one year period.	Year