



## Speaking the Same Language

### Introduction

Developing streamlined province-wide processes requires the use of consistent terminology.

The glossary and common terminology:

- Includes acronyms and classification systems
- Improves communication by ensuring shared understanding of concepts for discussion and measurement
- Improves clarity and reduces delays by avoiding confusion and misunderstanding

The common terminology is integrated into the ACRC processes, tools, templates, and training opportunities. Clinical researchers, service departments, study staff, and institutions are encouraged to adopt the terminology.

This glossary is part of the [ACRC strategic priority #3](#) to “**develop provincial standards and opportunities for clinical research training**”. It contributes to a set of tools and training opportunities which incorporate best practices and applicable guidelines, created by the ACRC. Through these efforts, it is anticipated that the quality and efficiency of clinical research in the province will be enhanced.

### Alberta Clinical Research Consortium (ACRC)

The ACRC is a provincial initiative that involves academic and community-based researchers and administrators working together to achieve the vision of “high quality, integrated and efficient clinical research in Alberta”.

From study start-up to close in all phases and disease areas, the ACRC is simplifying and harmonizing administrative processes across the province. High quality clinical research standards are upheld through the incorporation of best practices and applicable guidelines. The goal is to enhance quality clinical research that will improve patient outcomes in the province.

For the latest version,

Visit the ACRC Webpage at:

<http://www.aihealthsolutions.ca/initiatives-partnerships/acrc-alberta-clinical-research-consortium/>

#### ACRC Partner Organizations

Alberta Health Services

Alberta Innovates

College of Physicians &  
Surgeons of Alberta

Covenant Health

University of Alberta

University of Calgary

©Alberta Innovates

Suite 1500, 10104 - 103 Ave NW

Edmonton, Alberta, Canada T5J 0H8

Phone: 1-877-423-5727

Fax: (780) 429-3509

ISBN (Print): 978-1-894927-85-7

ISBN (Online): 978-1-894927-86-4

1 May 2017

Funding provided by:



## TABLE OF CONTENTS

TABLE OF CONTENTS .....	3
METHOD.....	4
ACKNOWLEDGEMENTS.....	4
ACRONYMS .....	5
ORGANIZATIONS .....	5
TERMS .....	6
CLASSIFICATION .....	8
CIHR CATEGORIES OF RESEARCH.....	8
STUDY ORIGINS .....	8
FUNDING SOURCES .....	8
PHASES OF CLINICAL RESEARCH.....	8
METHODS OF RESEARCH.....	8
STUDY PHASES.....	8
STUDY STATUSES.....	8
PARTICIPANT STATUSES .....	8
TYPES OF INVESTIGATOR / RESEARCH ROLES .....	8
STUDY DESIGNS.....	8
ALBERTA-SPECIFIC TERMINOLOGY .....	9
DEFINITIONS FOR CLINICAL (HEALTH) RESEARCH .....	9
ADMINISTRATIVE DEFINITION FOR CLINICAL (HEALTH) RESEARCH .....	9
DETERMINING WHETHER YOUR QI OR PROGRAM EVALUATION STUDY HAS A CLINICAL (HEALTH) RESEARCH COMPONENT.....	10
PARTICIPANT VERSUS SUBJECT .....	10
GLOSSARY.....	11
BIBLIOGRAPHY .....	61
TABLE 1: COMPARISON OF CLINICAL RESEARCH AND TRIAL DEFINITIONS.....	62

## METHOD

The *Glossary and Common Terminology* is developed from existing documents and primary sources (ie. TCPS2, Health Canada, FDA). The *Strategic Priority #3 - Glossary and Common Terminology Working Group* reviews each term in consultation with the ACRC partner organizations. Terms are defined, and where necessary refined, to the Alberta context. The Glossary is reviewed annually and revised as necessary.

Occasionally there are changes in terminology, names of committees, groups, etc. Terms no longer in use will refer to the new term for a period of one year, after which the old term will be removed.

Please submit comments to [acrc@albertainnovates.ca](mailto:acrc@albertainnovates.ca).

## ACKNOWLEDGEMENTS

The ACRC gratefully acknowledges the assistance of the *Strategic Priority #3 – Glossary and Common Terminology Working Group*: Mary-Ann Clarkes (Covenant Health/CHRC); Ronda Danchak (AI/ACRC); Troy Hamilton (The Bailey Clinic); Trina Johnson (AI/ACRC); Tammy Mah-Fraser (AI/ACRC).

Additionally, Lori Anderson, Liza Chan, Marilyn David, Mary Hodges, Audrey Hollingshead, Scott Jamieson, Lissa Jutras, Nicky Kopac, Shane Lacusta, Carlos Miranda, Rachel Syme and Elizabeth Watts.

### ACRC Related Resources & Websites:

[The ACRC](#)

[The Inaugural Strategic Plan Consultation \(2011\)](#)

[The ACRC Inaugural Strategic Plan \(2012\)](#)

[Strategic Plan At-A-Glance 2012-2013](#)

[ACRC Research Toolbox](#)

[CITI-Canada Training](#) and [CITI-Training ACRC Instruction Manual](#)

## ACRONYMS

### ORGANIZATIONS

AbSPORU	<a href="#">Alberta SPOR Support Unit</a>	EC	<a href="#">European Commission</a>
ACCT	<a href="#">Alberta Cancer Clinical Trials</a>	EMA/EMEA	<a href="#">European Medicines Agency</a>
ACRC	<a href="#">Alberta Clinical Research Consortium</a>	EU	<a href="#">European Union</a>
ACHRI	<a href="#">Alberta Children's Hospital Research Institute</a>	FDA	<a href="#">Food &amp; Drug Administration (US)</a>
ACRO	<a href="#">Association of Clinical Research Organizations</a>	GoA	<a href="#">Government of Alberta</a>
ACRP	<a href="#">Association of Clinical Research Professionals</a>	HC (SC)	<a href="#">Health Canada / Santé Canada</a>
AH	<a href="#">Alberta Health</a>	HPFB	<a href="#">Health Products &amp; Food Branch</a>
AHRQ	<a href="#">Agency for Healthcare Research &amp; Quality</a>	HPFBI	<a href="#">Health Products &amp; Food Branch Inspectorate</a>
AHS	<a href="#">Alberta Health Services</a>	HREB	<a href="#">Health Research Ethics Board (AHS, Covenant Health, UofA)</a>
AI	<a href="#">Alberta Innovates</a>	HREBA	<a href="#">Health Research Ethics Board of Alberta</a>
ANSI	<a href="#">American National Standards Institute</a>	HREBA-CC	<a href="#">Health Research Ethics Board of Alberta-Cancer Committee</a>
APCR	<a href="#">Academy of Physicians in Clinical Research</a>	HREBA-CHC	<a href="#">Health Research Ethics Board of Alberta- Community Health Committee</a>
ARECCI	<a href="#">Alberta Research Ethics Community Consensus Initiative</a>	HREBA-CTC	<a href="#">Health Research Ethics Board of Alberta- Clinical Trials Committee</a>
AU	<a href="#">Athabasca University</a>	HREH	<a href="#">Health Research Ethics Harmonization initiative</a>
BGTD	<a href="#">Biologics and Genetic Therapies Directorate</a>	IATA	<a href="#">International Air Transportation Association</a>
CASRAI	<a href="#">Consortia Advancing Standards in Research Administration Information</a>	ISO	<a href="#">International Organization for Standardization</a>
CCCR	<a href="#">Calgary Centre for Clinical Research</a>	MHRA	<a href="#">Medicines and Healthcare Products Regulatory Agency</a>
CDC	<a href="#">Centers for Disease Control and Prevention (US)</a>	N2	<a href="#">Network of Networks</a>
CDISC	<a href="#">Clinical Data Interchange Standards Consortium</a>	NACTRC	<a href="#">Northern Alberta Clinical Trials Research Centre</a>
CHLA	<a href="#">Canadian Health Libraries Association</a>	NICHSR	<a href="#">National Information Center on Health Services Research and Health Care Technology</a>
CHRC	<a href="#">Covenant Health Research Centre</a>	NIH	<a href="#">National Institute of Health</a>
CHREB	<a href="#">Conjoint Health Research Ethics Board (UofC)</a>	NLM	<a href="#">National Library of Medicine</a>
CIHR	<a href="#">Canadian Institutes of Health Research</a>	NSERC	<a href="#">National Sciences &amp; Engineering Research Council of Canada</a>
CITI	<a href="#">Collaborative Institutional Training Initiative</a>	OIPC	<a href="#">Office of the Information and Privacy Commissioner</a>
CMPA	<a href="#">Canadian Medical Protective Association</a>	PHEN	<a href="#">Provincial Health Ethics Network</a>
CONSORT	<a href="#">Consolidated Standards of Reporting Trials</a>		
CPSA	<a href="#">College of Physicians &amp; Surgeons of Alberta</a>		

PhRMA	<a href="#">Pharmaceutical Research and Manufacturers Association</a>	TPD	<a href="#">Therapeutics Product Directorate</a>
QMCR	<a href="#">Quality Management in Clinical Research</a> (UofA)	UofA	<a href="#">University of Alberta</a>
SCDM	<a href="#">Society for Clinical Data Management</a>	UCalgary	<a href="#">University of Calgary</a>
SCNs	<a href="#">Scientific Clinical Networks</a>	UofL	<a href="#">University of Lethbridge</a>
SOCRA	<a href="#">Society of Clinical Research Associates</a>	US	<a href="#">United States of America</a>
SSHRC	<a href="#">Social Sciences and Humanities Research Council of Canada</a>	WCHRI	<a href="#">Women &amp; Children's Health Research Institute</a>
SPOR	<a href="#">Strategy for Patient Oriented Research</a>	WHO	<a href="#">World Health Organization</a>
		WMA	<a href="#">World Medical Association</a>

## TERMS

21 CFR	Title 21 of the Code of Federal Regulations (CFR)	CTCAE	<a href="#">Common Terminology Criteria for Adverse Events</a>
ADME	<a href="#">Absorption, distribution, metabolism, and excretion</a>	CTMS	<a href="#">Clinical trial management system</a>
AE	<a href="#">Adverse event</a>	CTSI	<a href="#">Clinical trial site information</a>
AESI	<a href="#">Adverse events of special interest</a>	CV	<a href="#">Curriculum vitae</a>
ALCOA	Attributable, Legible, Contemporaneous, Original, Accurate (FDA)	DIN	<a href="#">Drug identification number</a>
ALCOAC	Attributable, Legible, Contemporaneous, Original, Accurate, Complete (ICH E6[R2])	DSMB	<a href="#">Data safety monitoring board</a>
AR (ADR)	<a href="#">Adverse reaction</a> /Adverse drug reaction	EDC	<a href="#">Electronic data capture</a>
ARO	<a href="#">Annual Report Online</a> (UofA)	EDTA	<a href="#">Ethylenediamine tetra-acetate</a>
AUC	Area under curve	EDR	<a href="#">Emergency drug release</a>
BID	Twice a day (Latin: bis in die)	eCRT	<a href="#">Electronic case report tabulation</a>
CDA	<a href="#">Confidentiality disclosure agreement</a>	ePRO	<a href="#">Electronic patient reported outcome</a>
CDASH	Clinical Data Acquisition Standards	ERC	<a href="#">Ethics review committee</a>
CDM	Clinical Data Management	F,D&C (FDCA) (FFDCA)	<a href="#">Food, Drug and Cosmetics Act (US)</a>
CMAx	Concentration maximum	FAQs	Frequently Asked Questions
CMIN	Concentration minimum	FOIP	Freedom of Information and Protection of Privacy Act
CRA	<a href="#">Clinical research associate</a>	GCG	Global cooperation group
CRC	<a href="#">Clinical research coordinator</a>	GCP	<a href="#">Good clinical practice</a>
CRF	<a href="#">Case report form</a>	GDP	Good documentation practice
CRIO	<a href="#">Collaborative Research and Innovation Opportunities</a>	GLP	<a href="#">Good laboratory practice</a>
CRO	<a href="#">Contract research organization</a>	GMP	<a href="#">Good manufacturing practice</a>
CRU	Clinical research unit	HIA	<a href="#">Health Information Act</a>
CSA	<a href="#">Clinical study agreement</a>	HIA s.54	<a href="#">HIA Research Agreement</a>
CSR	<a href="#">Clinical study report</a>	HL7	<a href="#">Health Level 7</a>
CTA	<a href="#">Clinical trial agreement</a> or <a href="#">Clinical trial application</a>	HTA	<a href="#">Health technology assessment</a>
CTA-A	<a href="#">Clinical trial application – Amendment</a>	IB (IDB)	<a href="#">Investigator brochure</a> /Investigator's drug brochure
		ICAC	<a href="#">Independent Central Adjudication Committee</a>
		ICF	<a href="#">Informed consent form</a>
		ICH	<a href="#">International Council on Harmonization</a>

IDE	<a href="#">Investigational Device Exemption</a>	QD	Every day
IDMC	<a href="#">Independent data-monitoring committee</a>	QI	<a href="#">Qualified investigator</a>
IND	<a href="#">Investigational new drug</a>	QI	<a href="#">Quality improvement</a>
IRB	<a href="#">Institutional review board</a>	QID	Four times daily
ISF	<a href="#">Investigator site file</a>	QIU	<a href="#">Qualified investigator undertaking</a>
ITA	<a href="#">Investigational Testing Authorization</a>	QMS	Quality management system
IVRS	<a href="#">Interactive voice response system</a>	QoL	<a href="#">Quality of life</a>
KT	<a href="#">Knowledge translation</a>	RBM	Risk-based monitoring
MAA	<a href="#">Marketing Authorization Application</a>	REB	<a href="#">Research ethics board</a>
MedDRA	<a href="#">Medical Dictionary for Regulatory Activities</a>	REBA	<a href="#">Research Ethics Board Attestation</a>
MSDS	<a href="#">Material safety data sheets</a>	RNase	<a href="#">Ribonuclease</a>
MTD	<a href="#">Maximum tolerated dose</a>	SAE	<a href="#">Serious adverse event</a>
NCR	<a href="#">No carbon required</a>	SAR	<a href="#">Serious adverse drug reaction</a>
NDA	<a href="#">New drug application</a>	SD	<a href="#">Source documents</a>
NOA	<a href="#">Notice of authorization</a>	SDV	<a href="#">Source document verification</a>
NOC	<a href="#">Notice of compliance</a>	SEM	<a href="#">Standard error of the mean</a>
NOL	<a href="#">No objection letter</a>	SIF	Site investigator file (See related “ <a href="#">ISF</a> ”)
NON	<a href="#">Notice of non-compliance</a>	SIV	<a href="#">Site initiation visit</a>
NSN	<a href="#">Not satisfactory notice</a>	SMO	<a href="#">Senior Medical Officer</a>
ODM	Operational Data Model	SMO	<a href="#">Site management organization</a>
OTC	Over the counter	SNOMED CT	<a href="#">Systematized Nomenclature of Medicine Clinical Terms®</a>
PIPEDA	<a href="#">Personal Information Protection and Electronic Documents Act</a>	SOCs	System Organ Classes (from MedDra)
PCERT	<a href="#">Pre-Clinical and Clinical Evaluation Report Template</a>	SPC	<a href="#">Summary of product characteristics</a>
PE	<a href="#">Program evaluation</a>	SUSAR	<a href="#">Suspected unexpected serious adverse reaction</a>
PFCC	Patient and family centered care	SOPs	<a href="#">Standard operating procedures</a>
PHN	<a href="#">Personal Health Number</a>	TA	Therapeutic area
PI	<a href="#">Principal Investigator</a>	TCPS2	<a href="#">Tri Council Policy Statement</a> (2 <sup>nd</sup> Edition)
PIA	<a href="#">Privacy Impact Assessment</a>	TDG	Transportation of dangerous goods
PK	Pharmacokinetic	TID	Three times daily
PMA	<a href="#">Pre-market approval</a>	TMF	<a href="#">Trial master file</a>
POR	<a href="#">Patient-oriented research</a>	UAT	<a href="#">User acceptance testing</a>
PRBC	Packed Red Blood Cells	ULI	<a href="#">Unique Lifetime Identifier</a>
PREMs	Patient reported experience measures	WHMIS	<a href="#">Workplace hazardous material information system</a>
PRIHS	<a href="#">Partnership for Research and Innovation in the Health System</a>	WHO ART	World Health Organization Adverse Reaction Terminology
PRN	As needed	WHO Drug	World Health Organization Drug Dictionary
PRO	<a href="#">Patient-reported outcomes</a>		
PSEAT	<a href="#">Protocol safety and efficacy assessment template</a>		
QA	<a href="#">Quality assurance</a>		
QC	<a href="#">Quality control</a>		

## CLASSIFICATION

### CIHR CATEGORIES OF RESEARCH

- [Biomedical](#)
- [Clinical Research](#)
- [Health Services Research](#)
- [Social, Cultural, Environmental and Population Research](#)

### STUDY ORIGINS

- [Cooperative group](#)
- [Industry-initiated](#)
- [Investigator-initiated](#)

### FUNDING SOURCES

- [Cooperative group](#)
- [Industry-sponsored](#)
- [Grant](#)
- [In-kind contribution](#)
- [Internal and/or contingency funding](#)

### PHASES OF CLINICAL RESEARCH

- [Pilot](#)
- [Phase I](#)
- [Phase II](#)
- [Phase III](#)
- [Phase IV](#)

### METHODS OF RESEARCH

- [Chart review](#)
- [Interventional clinical research](#) ([Drug](#), [Treatment](#), [Device](#))
- [Epidemiological](#)
- [Applied health research](#)
- [Outcomes research](#)
- [Procedure](#)
- [Qualitative](#)
- [Quantitative](#)
- [Technology assessment](#)

### STUDY PHASES

- [Pre-study phase](#)

- [Clinical phase](#)
- [Post-study phase](#)

### STUDY STATUSES

- [Pending](#)
- [Approved](#)
- [Closed to accrual / Enrollment closed](#)
- [Completed](#)
- [Terminated](#)
- [Withdrawn](#)

### PARTICIPANT STATUSES

- [Pre-screened](#)
- [Eligibility assessment](#)
- [Screened / Consented](#)
- [Eligibility assessment – eligible, ineligible](#)
- [Accrued / Enrolled](#)
- [On protocol / Active treatment](#)
- [On follow-up](#)
- [Termination/Withdrawn](#)
- [Lost to follow-up](#)

### TYPES OF INVESTIGATOR / RESEARCH ROLES

- [Qualified investigator](#)
- [Sponsor-investigator](#)
- [Co-Investigator](#)
- [Sub-investigator](#)
- [Clinical research associate](#)
- [Clinical research coordinator](#)

### STUDY DESIGNS

- [Controlled clinical trial](#)
- [Uncontrolled clinical trial](#)
- [Prospective study](#)
- [Retrospective study](#)
- [Cross-sectional studies](#)
- [Randomized clinical trial](#)
- [Cross-over design](#)
- [Parallel study design](#)
- [Double-dummy technique](#)



## ALBERTA-SPECIFIC TERMINOLOGY

### DEFINITIONS FOR CLINICAL (HEALTH) RESEARCH

To facilitate research administrative processes in Alberta, the following operational definitions are given for clinical health research/trial, clinical trial and investigator-initiated trial which are derived from NIH, TCPS2, and WHO.

([Table 1 p.62](#))

**Clinical (health) research/trial:** Clinical research has the goal of improving the diagnosis, prevention and treatment (including rehabilitation and palliation) of disease and injury, and improving and evaluating the health and quality of life of individuals. Clinical research is conducted on or for the treatment of human subjects. Clinical research includes living human participants, human tissues, human remains, cadavers, biological fluids, embryos, fetuses and patient information. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. This includes clinical trials on patients, epidemiological and behavioral studies, outcomes research, health services research and population health studies, typically falling under the CIHR rubric of pillars 2, 3 & 4.

**Clinical trial:** A type of [clinical \(health\) research](#) that is designed to assess the effect of a biomedical intervention (e.g. drug, device, cognitive-behavioural, process, diagnostic test, etc.). Clinical trials can take the form of a prospective cohort study, a prospective case-control study or a randomized controlled trial. Clinical trials are incorporated into and an inextricable part of advanced clinical care.

**Investigator-initiated clinical trial:** A trial where the academic investigator generates the research question(s) and study design, controls the content and conduct of the research protocol and has ultimate and final responsibility for making changes to the same protocol, and for analyzing data and reporting results. The Investigator and institution holds the intellectual property to the project and its results. Investigator-initiated protocols are not defined by the source of funding.

---

### ADMINISTRATIVE DEFINITION FOR CLINICAL (HEALTH) RESEARCH

As described in [clinical health research/trial](#), [clinical trial](#), or [investigator-initiated clinical trial](#), and

- requires approval by the relevant human ethics board<sup>1</sup>. Clinical research and the subset of clinical trials are not defined by the source of funding.
- may include the collection and bio-banking of human tissues, human remains, cadavers, biological fluids, blood, embryos, fetuses and other bio-samples. Research on these samples is considered clinical if the research includes linking of the material to patient clinical information, such as demographics, baseline clinical history, clinical interventions or outcomes. Research on these samples is considered basic research if the samples cannot be linked by the researcher to a living individual and does not involve any use of patient clinical information, such as demographics, baseline clinical history, clinical interventions or outcomes.

---

<sup>1</sup> Per TCPS2, human participant research requiring ethics review is research involving:

- a) living human participants (or their data) and
- b) human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

---

## **DETERMINING WHETHER YOUR QI OR PROGRAM EVALUATION STUDY HAS A CLINICAL (HEALTH) RESEARCH COMPONENT**

A project that has the primary purpose to improve practice or service delivery within your organization or setting, is site or program-specific, or targets a service or process improvement may be either a [quality improvement](#) (QI) or [program evaluation](#) study.

In an effort to use an objective (though not definitive) standard to facilitate considerations of clinical research applicability, it is recommended that researchers/project leads run their project through the [ARECCI Ethics Screening Tool](#). The distinction is made primarily based upon the intended use of the results despite similarities in methodology. Receiving a competitive research grant award indicates that the project is research (per item #1 on the ARECCI Screening Tool). Of note, QI/PE studies which include a clinical research component must have the clinical research portion reviewed by the relevant REB.

For projects that are categorized as QI or evaluation, researchers/project leads can use the [ARECCI Ethics Guidelines](#) to help identify and integrate the appropriate ethics consideration into the project. Consultation with expertise in project ethics is recommended and should be done prior to involving participants as ethics approval cannot be granted for research already undertaken. This expertise may include:

- a. the REB to confirm if the project falls outside the REB's mandate or should be submitted for REB review, or
- b. QI and evaluation consultants with projects ethics review training to confirm if the project requires that type of review.

For additional guidance refer to:

[TCPS2](#): Chapter 2, Scope and Approach, and in particular Article 2.5

[HIA](#): Section 27 and Section 50

---

## **PARTICIPANT VERSUS SUBJECT**

In referring to individuals who take part in clinical studies, the preferred term in Alberta is “participant” over “subject”.

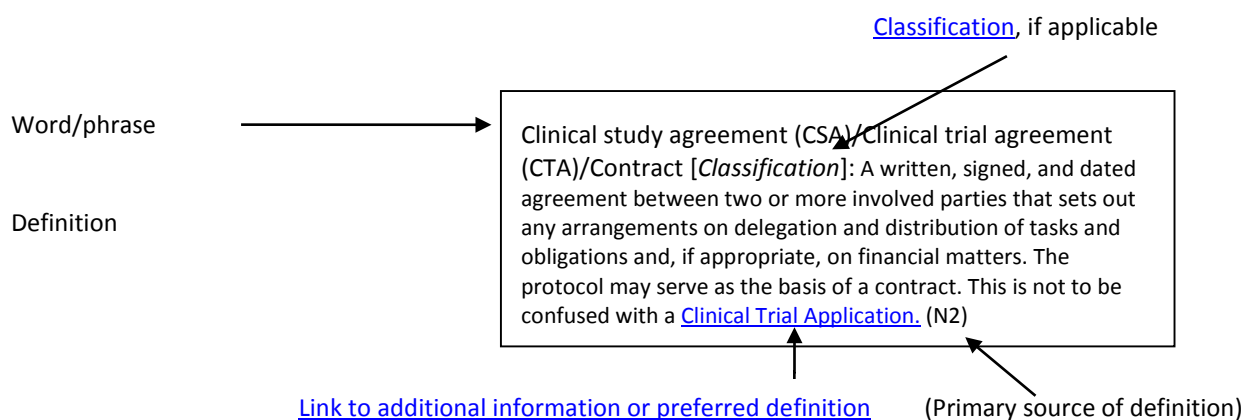
## GLOSSARY

This glossary uses provincial and Canadian terms related to clinical research.

- Additionally, terms from other sources are cross referenced to the equivalent Canadian term.
- There are several terms that can be used interchangeably, thus both terms are indicated with a slash "/" in between (e.g. closed to accrual/enrollment closed).

The primary source(s) of the definitions are indicated in parentheses after each term, for example: (HC). Some of the definitions have been modified for consistency.

### Anatomy of a definition:



**510(k):** The medical device marketing clearance application made on a predicated device.

**1572 (FDA Form 1572):** The Statement of Investigator which is an agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic. (FDA)

**Abbreviated protocol:** A brief summary of the protocol that may be used for planning and implementation. For example, an initial discussion document with a prospective principal investigator, or a reference to solicit internal approval to start the planning phase of a study.

**Abnormality:** Any sign, symptom, or test result that is outside the standard reference or acceptable range for a population or group.

**Aboriginal peoples:** Persons of Indian (First Nations), Inuit, or Métis descent, regardless of where they

reside and whether or not their names appear on an official register. In the international context, the term comparable to Aboriginal peoples is Indigenous peoples. (TCPS2)

**Absolute risk reduction:** A measure of risk reduction which answers the question, "Out of X number of people, how many more are saved by this treatment compared to no treatment?" (CIHR) See related "Relative risk reduction".

**Absorption:** The process by which medications reach the blood stream when administered other than intravenously, for example, through nasal membranes. (CDISC) See related "Absorption, distribution, metabolism, and excretion (ADME)" (pharmacokinetics).

**Absorption, distribution, metabolism, and excretion (ADME):** The disposition of a pharmaceutical compound within an organism.

**Academic freedom:** The collective freedom of faculty and students to conduct research, and to

disseminate ideas or facts without religious, political, or institutional restrictions. It includes freedom of inquiry, freedom to challenge conventional thought, freedom to express one's opinion about the institution, its administration, or the system in which one works, and freedom from institutional censorship. (TCPS2)

**Accrued/Enrolled** [*Participant status*]: Individual has signed consent form and then is randomized/registered. (HC, ACCT)

**Action letter:** The letter from the Food and Drug Administration (FDA) to the sponsor in response to an application submission to do a clinical trial. It may be an "[Approval letter](#)" with some minor modifications recommended or a letter indicating that changes will be needed before the application can be considered. (Weiser)

**Active treatment:** Use "[On protocol](#)".

**Ad hoc advisor:** A person with relevant and competent knowledge and expertise consulted by a research ethics board for a specific research ethics review, and for the duration of that review. The ad hoc advisor is not a member of the research ethics board. (TCPS2)

**Administrative approval:** The final step before a clinical study can commence. At this point, all required documentation for the study, such as contracts, operational, ethics and regulatory approvals, has been reviewed by appropriate administrative personnel and approved. (ACRC)

**Admission criteria:** Basis for selecting target population for a clinical trial. Participants must be screened to ensure that their characteristics match a list of admission criteria and that none of their characteristics match any single one of the exclusion criteria set up for the study. (CDISC) See related "[Inclusion criteria](#)", "[Exclusion criteria](#)".

**Adverse drug experience:** Use "[Adverse drug reaction](#)".

**Adverse drug reaction (AR) (ADR):** In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic doses may not be established: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase 'responses to a medicinal product' means that a causal relationship between a medicinal product and an [adverse event](#) is at least a reasonable possibility; i.e., the

relationship cannot be ruled out. For marketed medicinal products: a response to a [drug](#) which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function. (N2)

**Adverse event (AE):** Any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. (N2)

**Adverse events of special interest (AESI):** Any specific [AE](#) that has been identified at the project level as being of particular concern for prospective safety monitor and safety assessment with a particular protocol. Usually based on AE knowledge from other compounds in the same class of drugs. AESIs are reported to Pharmacovigilance with the same timeframes/urgency as [SAEs](#). (ACRC)

**Adverse experience:** Use "[Adverse event](#)".

**Adverse reaction:** Use "[Adverse drug reaction](#)".

**Agencies:** Refers to Canada's three federal research agencies: the Canadian Institutes of Health Research (CIHR); the Natural Sciences and Engineering Research Council of Canada (NSERC); and the Social Sciences and Humanities Research Council of Canada (SSHRC)

**Aim of study:** The overall purpose of the study, also known as objective. Normally, each study will have only one main objective but can have several secondary objectives.

**Alpha error:** The likelihood that a relationship observed between two variables is due to chance. The probability of a [Type 1 error](#). (CDISC)

**Alpha-testing:** the in-house testing phase of the commercial product, which is the first step in the commercialization phase of product development. (GoA)

**Amendment:** Any changes and/or additions to an existing document, i.e. protocol, contract or clinical trial agreement, clinical trial application.

**Analysis dataset:** An organized collection of data or information with a common theme arranged in rows and columns and represented as a single file; comparable to a database table. NOTE: Standardizing analysis datasets is intended to make review and assessment of analysis more consistent. (CDISC)

**Analysis set:** A set of participants whose data are to be included in the main analyses. This should be defined in the statistical section of the protocol. NOTE: There are a number of potential analysis sets, including, for example, the set based upon the intent-to-treat principle. (CDISC)

**Analysis variables:** Variables used to test the statistical hypotheses identified in the protocol and analysis plan; variables to be analyzed. (CDISC) See related "[Variable](#)".

**Anonymized:** Personal data which have been processed to make it impossible to know the person with whom the data are associated. Applicable particularly for secondary use of health data. (CDISC) See related "[De-identified](#)".

**Appeal:** A process that allows a researcher to request a review of a research ethics board (REB) decision when, after reconsideration, the REB has refused ethics approval of the research. (TCPS2)

**Appeal mechanism:** A procedure established by an institution to promptly handle a researcher's appeal of a research ethics board (REB) decision. An ad hoc or permanent appeal committee, which reflects a range of expertise and knowledge similar to that of the REB, is established or appointed by the same authority that established the REB. (TCPS2)

**Applicable regulatory requirements:** Any laws and or regulations addressing the conduct of clinical trials of investigational products. (N2)

**Applied health research** [*Method of research*]: A type of [clinical health research](#) that includes: physiotherapy, acupuncture, psychosocial interventions, rehabilitation measures, training or diet. (NACTRC, ARO)

**Approached patients/participants:** Patients/participants who have been identified for a study, who have had the [informed consent](#) process initiated, have been given a consent form and have been invited to participate in the clinical trial. (N2)

**Approvable letter:** US term, equivalent to "[Clarifax](#)".

**Approval (in relation to research ethics boards):** The affirmative decision of the [REB](#) that the trial has been reviewed and may be conducted at the institution site, after also obtaining institutional approval, within the constraints set forth by the REB, the institution, [good clinical practice](#) (GCP), and the [applicable regulatory requirements](#).

**Approval letter:** An official communication from FDA to inform an applicant of a decision to allow commercial marketing consistent with conditions of approval. (CDISC)

**Approved** [*Study status*]: All applicable approvals have been obtained and the study can begin recruiting participants. (ACCT)

**Archiving of clinical trial data:** Long-term storage of clinical trial data upon study closure.

**Area under curve (AUC):** The area under the concentration versus time curve. The AUC symbol may be qualified by a specific time (e.g., 72 hours, or AUC<sub>0-72h</sub>), time of last quantifiable concentration (AUCT), or infinity (AUCI). In clinical pharmacology, it is the plot of plasma concentration of drug against time after drug administration. The AUC is a good way of comparing the [bioavailability](#) profiles of the same drug made by different companies.

**Arm:** A planned sequence of elements, typically equivalent to a [treatment group](#). (CDISC)

**Ascending doses:** Participants are dosed with increasingly higher doses of a drug until the maximum tolerated dose is reached. (Weiser)

**Assent:** Process whereby minors (i.e. below the age of majority) or individuals who do not have the [capacity](#) to provide consent may agree to become a participant in a research study. See related "[Informed consent](#)".

**Attribute:** 1. a quality or feature regarded as a characteristic or inherent part of someone or something. 2. In data modeling, refers to specific items of data that can be collected for a [class](#). (CDISC)

**Attributable:** A quality by which records and data can be traced back to the participant to whom they pertain, as well as to those persons who have acted on the records. (CDISC)

**Attribution assessment:** Use "[Causality assessment](#)".

**Audit:** A systematic and independent examination of trial related activities and documents to determine

whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's [standard operating procedures](#) (SOPs), [good clinical practice](#) (GCP), and the [applicable regulatory requirement](#)(s). (N2)

**Audit certificate:** A declaration of confirmation by the auditor that an [audit](#) has taken place. (N2)

**Audit report:** A written evaluation by the auditor of the results of the [audit](#). (N2)

**Audit trail:** Documentation that allows reconstruction of the course of events. (N2)

**Authorization:** The process of giving someone permission to do or have something. In multi-user computer systems, a system administrator defines for the system which users are allowed access to the system and what privileges of use are permitted. (CDISC)

**Authorized third party:** Any person with the necessary legal authority to make decisions on behalf of a prospective participant who lacks the capacity to consent to participate, or to continue to participate, in a particular research project. In other policies/guidance they are also known as "authorized third party decision makers." (TCPS2)

**Autonomy:** The capacity to understand information and to be able to act on it voluntarily; the ability of individuals to use their own judgment to make decisions about their own actions, such as the decision to consent to participate in research. (TCPS2)

**Award:** Direct salary support to individual research personnel or stipend support to individual research trainees. (CIHR)

**Back translation (natural language):** The process of translating a document that was translated from one language to another back to the original language. Used to ensure that consent forms, surveys, and other clinical trial documents will be clear and accurate in the translated form. (CDISC)

**Balanced study:** A trial in which characteristics of the participants are equally represented in each group. For example, each group may contain 75% female and 25% male participants or it may have the same number of patients in each group. (Weiser, ACRC)

**Bar code:** A pattern of black vertical lines with information coded in the relative widths of the black lines. Bar codes can be used to identify clinical trial

supplies and [case report forms \(CRFs\)](#) for individual patients. The use of bar codes can improve the tracking of clinical trial supplies and CRFs. (Weiser)

**Baseline:** Measurements that are taken at the beginning of a study to serve as a reference. (ACRC, Weiser)

**Baseline characteristics:** Demographic, clinical, and other data collected for each participant at the beginning of the trial before the intervention is administered. (CDISC)

**Baseline imbalance:** Systematic error in creating intervention groups, such that they differ with respect to prognosis. That is, the groups differ in measured or unmeasured baseline characteristics because of the way participants were selected or assigned. NOTE: Also used to mean that the participants are not representative of the population of all possible participants. (CDISC)

**Batch:** An item/product that is prepared under defined criteria and certain conditions (e.g. controlled materials/ingredients, controlled temperature, for a controlled time frame, quantity, volume or time period).

**Bayesian statistics:** A system for describing epistemological uncertainty using the mathematical language of probability. In the 'Bayesian paradigm,' degrees of belief in states of nature are specified; these are non-negative, and the total belief in all states of nature is fixed to be one. Bayesian statistical methods start with existing 'prior' beliefs, and update these using data to give 'posterior' beliefs, which may be used as the basis for inferential decisions. (Spiegelhalter & Rice, 2009)

**Beta error:** Probability of showing no significant difference when a true difference exists; a false acceptance of the null hypothesis. (CDISC) See related "[Type 2 error](#)".

**Beta-testing:** This is software second phase internal testing, a critical stage in commercialization in that the company tests its product with end users. (GoA)

**Bias:** An error that distorts the objectivity of a study. It can arise if a researcher doesn't adhere to rigorous standards in designing the study, selecting the participants, administering the treatments, analyzing the data, or reporting and interpreting the study results. It can also result from circumstances beyond a researcher's control, as when there is an uneven distribution of some characteristic between groups as a result of randomization (CIHR).



**Bio-analysis:** The measurement of a drug level in a biological sample. Bio-analysis quantifies the drug and its major metabolites in samples collected from cell culture media, plasma, serum, urine, or other human biological matrix. (N2)

**Bioavailability:** The rate and extent of absorption of a drug into the systemic circulation. It is most frequently assessed by serial measurements of the drug in the systemic circulation. These serial measurements provide a plasma, serum or whole blood concentration time profile from which a number of important pharmacokinetic parameters can be calculated, including the [area under the curve](#) (AUC). (HC)

**Biobank:** A collection of [human biological materials](#). It may also include associated information about individuals from whom biological materials were collected. (TCPS2)

**Bio-equivalence:** A high degree of similarity in the [bioavailabilities](#) of two pharmaceutical products (of the same galenic form) from the same molar dose, that are unlikely to produce clinically relevant differences in therapeutic effects, or adverse effects, or both. (HC)

**Biologic:** A [drug](#) that is prepared using a biological starting or source material (e.g. derived from a microorganism, virus, animal, human, or plant), and using for example, either conventional manufacturing methods, recombinant DNA technology, and/or other novel approaches. Some examples of biologics include vaccines, blood and its derivatives, cells, tissues and organs, including xenografts (living cells, tissues and organs from animal sources), certain hormones and enzymes, recombinant DNA products, gene therapies, and transgenics, viral and bacterial vaccines. Biologics make up one large category of drugs; the other major category of drugs is pharmaceuticals; synthetic drugs made from chemicals. (N2)

**Biological marker:** Use "[Biomarker](#)".

**Biological product:** A product that is derived from living organisms and that is used to prevent, treat or diagnose disease in human beings or animals or for development, experiment or investigation purposes. (Transport Canada, N2)

**Biological samples:** Use "[Human biological materials](#)".

**Biological sampling:** Collecting, processing and analyzing of biological samples. (N2)

**Biologics and Genetic Therapies Directorate (BGTD):** is the Canadian federal authority that regulates biological drugs (products derived from living sources) and radiopharmaceuticals for human use in Canada, whether manufactured in Canada or elsewhere. Some of the products regulated by BGTD include: blood and blood products, hemostatic agents, bacterial and viral vaccines, hormones, enzymes, cytokines, monoclonal antibodies, allergenic extracts, gene and cell therapies, tissues, and organs. The BGTD also oversees the activities of the blood establishments. (HC)

**Biologics Licensing Application (BLA):** An application to FDA for a license to market a new biologic product in the United States. (CDISC)

**Biomarker:** A characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention. (CDISC)

**Biomedical research** [*CIHR category of research*]: Research with the goal of understanding normal and abnormal human functioning, at the molecular, cellular, organ system and whole body levels, including development of tools and techniques to be applied for this purpose; developing new therapies or devices that improve health or the quality of life of individuals, up to the point where they are tested on human participants. Studies on human participants that do not have a diagnostic or therapeutic orientation. (CIHR)

**Biometric signature:** A signature based on the verification of an individual's identity, based on measurement of the individual's physical feature(s) or repeatable action(s), where those features and/or actions are both unique to that individual, and measurable. (CDISC)

**Biospecimen:** All biological material of human origin, including organs, tissues, bodily fluids, blood, teeth, hair and nails, and substances extracted from such material such as DNA and RNA. Synonyms: sample, biological specimen, human biological material, biomaterial. (OTRN/OICR) See related "[Human biological materials](#)".

**Biostatistics:** The application of statistics that deals with error and probability in biological systems. (Weiser)

**Blind review:** Checking and assessing data prior to breaking the blind, for the purpose of finalizing the planned analysis. (CDISC)

**Blinded (masked) medications:** Use "[Placebo](#)"

**Blinded study:** A study in which the participant, the investigator, or anyone assessing the outcome is unaware of the treatment assignment(s). (CDISC) See related "[Blinding](#)", Masking, "[Double-blind](#)" study, "[Single-blind study](#)", "[Triple-blind study](#)", "[Open-label](#)" or "[Unblinding](#)".

**Blinding:** A procedure to limit bias by preventing participants and/ or study personnel from identifying which treatments or procedures are administered, or from learning the results of tests and measures undertaken as part of a clinical investigation. The term masking is often preferred to blinding in the field of ophthalmology. (CDISC) See related "[Double-blind](#)" "[Open-label study](#)", "[Unblinding](#)", "[Triple-blind study](#)".

**Block randomization:** In a comparative multicenter study, participants are randomly allocated to their investigational product. Commonly, the treatments are randomly organized in blocks so that an equal number of patients in each block will receive treatment A and treatment B. The purpose of blocking studies is to ensure that an approximately equal number of participants receive each of the study treatments even if every investigator does not reach their full quota of participants. (Weiser, ACRC)

**Branch:** Point within a study design where there is an allocation of participant subsets to particular [procedures](#) or [treatment groups](#). (CDISC) See related "[Arm](#)".

**Brand name (Food and Drug Regulations):** With reference to a drug, the name, whether or not including the name of any manufacturer, corporation, partnership or individual, in English or French: a. that is assigned to the drug by its manufacturer; b. under which the drug is sold or advertised; and c. that is used to distinguish the drug. Synonym: proprietary name. (HC)

**Buffy coat:** White blood cells found in peripheral blood. When whole blood is fractionated, the buffy coat layer is usually the middle, thin, white layer. (OTRN/OICR)

**Canadian Medical Protective Association (CMPA):** The CMPA is a mutual defense organization for physicians who practice in Canada. (N2)

**Capacity:** The ability of prospective or actual participants to understand relevant information presented (e.g. purpose of the research, foreseeable risks, and potential benefits), and to appreciate the potential consequences of any decision they make based upon this information. (TCPS2)

**Carryover effect:** Effects of treatment that persist after treatment has been stopped, sometimes beyond the time of a medication's known biological activity. (CDISC)

**Case-control studies:** Studies that examine a disease in an attempt to identify risk factors. Two groups are identified. Everyone in one group has a particular condition and no one in the other group has that condition (e.g., heart disease). Both groups are studied to see if more people in one group have a particular event or behaviour in their history that could be associated with either causing the disease or protecting against it (e.g., smoking, exercise). (CIHR)

**Case history:** An adequate and accurate record prepared and maintained by an investigator that records all observations and other data pertinent to the investigation on each individual administered the investigational drug (device or other therapy) or employed as a control in the investigation. (CDISC)

**Case record form:** Use "[Case report form](#)".

**Case report:** Detailed presentations of a single case or a handful of cases. They represent an important way in which new or unfamiliar diseases, or manifestations or associations of disease are brought to the medical community. (Fletcher, Fletcher, & Wagner, 1996)

**Case report form (CRF):** A printed, optical, or electronic document designed to record all of the [protocol](#) required information to be reported to the sponsor on each trial participant. (N2)

**Case report form (CRF) (paper):** Case report form in which the data items are linked by the physical properties of paper to particular pages. See related "[Case report form](#)", "[eCRF](#)". (CDISC)

**Case report form (CRF) data:** Subset of clinical trial data that are entered into fields on a [CRF](#). (CDISC)

**Case report tabulations (CRT):** In a paper submission, listings of data that may be organized by domain (type of data) or by participant. See related "[eCRT](#)". (CDISC)



**Categorical data:** Data evaluated by sorting values (for example, severe, moderate, and mild) into various categories. (CDISC)

**Category A substance (IATA definition):** An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. (IATA)

**Category B substance (IATA definition):** An infectious substance which does not meet the criteria for inclusion in Category A. (OTRN/OICR)

**Causality:** The cause of exposure and effect of disease or death. In clinical trials, the known relationship between the adverse experience/event and the investigational product in terms defined in the protocol.

**Causality assessment:** An evaluation performed by a medical professional concerning the likelihood that a therapy or product under study caused or contributed to an [adverse event](#). (CDISC)

**CDISC Standard (The):** CDISC term for a proposed uniform CDISC standard intended to address the full life-cycle of a clinical trial including protocol representation, capture of source data, submission, and archiving using a set of fully integrated and consistent models, terms, and controlled vocabularies derived from the current set of CDISC standards. (CDISC)

**Certificate of destruction:** A document that lists the study items and method of destruction – e.g. drugs, batch numbers, and the quantity destroyed on a given date.

**Certified copy:** A copy (irrespective of the type of media used) of original information that has been verified as an exact copy, having all of the same attributes including data that describe the context, content, and structure as the original. The copy may be verified by dated signature or by a validated electronic process. A certified copy of a source document may serve as a source for a clinical investigation. (CDISC/ICH E6[R2]) See related [“Source data”](#).

**Chart review [Method of research]:** Consists of retrospective method of collecting data that involves reviewing medical records. (NACTRC, ARO)

**Chemical name:** The chemical name of a drug provides an unambiguous picture of a molecule so

that a trained chemist can use it to draw its structure if required {i.e., 4-(4-Chlorophenyl)-1-[3-(4-fluorobenzoyl) propyl]-piperidin-4-ol: 4-[4-p-Chlorophenyl]-4-hydroxypiperidino]-4-fluorobutyrophenone is the chemical name for Haloperidol}. (HC)

**Citizen:** Encompasses interested representatives of the general public, consumers of health services, patients, caregivers, advocates and representatives from affected community and voluntary health organizations. (CIHR)

**Citizen engagement:** The meaningful involvement of citizens in its activities, from agenda-setting and planning to decision making, implementation and review. (CIHR) See related [“Patient engagement”](#).

**Clarifax:** A request sent to a manufacturer by Health Canada, requesting clarification during the screening and review of an application.

**Class:** A definition of objects with properties (attributes, methods, relationships) that all objects in the class have in common. In data modeling, a class defines a set of objects that share the same [attributes](#), relationships, and semantics. A class is usually an entity that represents a person, place, or thing. (CDISC)

**Class I Device:** These devices present the lowest potential risk in Health Canada’s device categorization and do not require a licence (e.g. thermometer). (HC)

**Class II Device:** These devices require the manufacturer’s declaration of device safety and effectiveness. They require a Health Canada licence before selling or advertising. Annual licence renewals are required. (e.g. pregnancy test kits). (HC)

**Class III Device:** Present a moderate potential for risk and are subject to in-depth regulatory scrutiny before licensing and sale. Annual licence renewals are required (e.g. orthopedic implants). (HC)

**Class IV Device:** present a greater potential for risk and are subject to in-depth regulatory scrutiny before licensing and sale. Annual licence renewals are required (e.g. pacemaker). (HC)

**Clean database (or file):** A database from which errors have been eliminated. (N2) See related [“Clean file”](#), [“Database lock”](#).

**Clean file:** When all data cleaning is completed and database is ready for quality review and unblinding. (CDISC)

**Clinical clarification:** A [query resolution](#) received from the sponsor staff (medical monitors, DSMB monitoring board, etc.). (CDISC) See related "[Query](#)".

**Clinical data:** Data pertaining to the medical well-being or status of a patient or participant. (CDISC)

**Clinical development plan:** A document that describes the collection of clinical studies that are to be performed in sequence, or in parallel, with a particular active substance, device, procedure, or treatment strategy, typically with the intention of submitting them as part of an application for a marketing authorization. (CDISC) See related "[Development plan](#)".

**Clinical efficacy:** Power or capacity to produce a desired effect (i.e., appropriate pharmacological activity in a specified indication) in humans. (CDISC)

**Clinical encounter:** Contact between participant/patient and healthcare practitioner/researcher, during which an assessment or activity is performed. Contact may be physical or virtual. (ACRC, CDISC)

**Clinical equipoise:** The existence of a genuine uncertainty on the part of the relevant expert community about what therapy or therapies are most effective for a given condition. (TCPS2)

**Clinical (health) research [Alberta-specific terminology]:** Clinical research has the goal of improving the diagnosis, prevention and treatment (including rehabilitation and palliation) of disease and injury, and improving and evaluating the health and quality of life of individuals. Clinical research is conducted on, or for the treatment of human subjects. Clinical research includes living human subjects, human tissues, human remains, cadavers, biological fluids, embryos, fetuses and patient information. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. This includes clinical trials on patients, epidemiological and behavioral studies, outcomes research, health services research and population health studies, typically falling under the CIHR rubric of pillars 2, 3 & 4.

**Clinical pharmacology:** Science that deals with the characteristics, effects, properties, reactions, and uses of drugs, particularly their therapeutic value in humans, including their toxicology, safety,

pharmacodynamics, and pharmacokinetics (ADME). (CDISC)

**Clinical phase of a study:** The period between study initiation and study close at the investigating site. It represents that period of the clinical trial in which the investigator is actively involved in recruiting, treating, and monitoring trial participants. (Weiser)

**Clinical research associate (CRA):** Person may be employed by a third party, CRO, SMO, who monitors the progress of investigator sites participating in a clinical study. At some sites (primarily in academic settings), [clinical research coordinators](#) are called CRAs. See related "[Monitor](#)". (CDISC, ACRC)

**Clinical research coordinator (CRC):** Person who handles most of the administrative responsibilities of a clinical trial on behalf of a site investigator, acts as liaison between investigative site and sponsor, and reviews all data and records before a monitor's visit. Synonyms: trial coordinator, study coordinator, research coordinator, clinical coordinator, research nurse, protocol nurse. (CDISC)

**Clinical research manager:** A person who typically has the budget and project responsibility for a clinical trial program. This individual may also be responsible for the activities of a number of clinical research staff. (Weiser)

**Clinical significance:** Change in a participant's clinical condition regarded as important whether or not due to the test article. Some statistically significant changes (in blood tests, for example) have no clinical significance. The criterion or criteria for clinical significance should be stated in the protocol. (N2)

**Clinical study/trial [Alberta-specific terminology]:** A type of clinical health research that is designed to assess the effect of a biomedical intervention (e.g. drug, device, cognitive-behavioural, process, diagnostic test, etc.). Clinical trials can take the form of a prospective cohort study, a prospective case-control study or a randomized controlled trial. Clinical trials are incorporated into and an inextricable part of advanced clinical care.

**Clinical study agreement (CSA)/ Clinical trial agreement (CTA)/Contract:** A written, signed, and dated agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may

serve as the basis of a contract. Not to be confused with a [Clinical Trial Application](#). (N2)

**Clinical study materials:** Complete set of supplies provided to an investigator by the study sponsor. (N2)

**Clinical study report (CSR):** A written description of a study of any therapeutic, prophylactic, or diagnostic agent conducted in human participants, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report. (N2)

**Clinical trial agreement (CTA)/Contract/Clinical study agreement (CSA):** See "[Clinical study agreement \(CSA\)/Clinical trial agreement \(CTA\)/Contract](#)".

**Clinical Trial Application (CTA):** An application to Health Canada for approval to run a clinical trial according to Division 5 of the Food and Drug Regulations Amendment. Not to be confused with [clinical trial agreement](#). (N2)

**Clinical Trial Application Amendment (CTA-A):** A submission to Health Canada requesting approval for a change to a study which is running under a [Clinical Trial Application](#) (CTA). (N2)

**Clinical trial data:** Data collected in the course of a clinical trial. (CDISC) See related "[Clinical trial information](#)".

**Clinical trial information:** Data collected in the course of a clinical trial or documentation related to the integrity or administration of that data. A superset of clinical trial data. (CDISC)

**Clinical trial management system (CTMS):** A software system used to manage clinical trials in clinical health research. The system maintains and manages planning, performing and reporting functions along with participant contact information, tracking deadlines and milestones. (ACRC)

**Clinical trial materials:** Complete set of supplies provided to an investigator by the trial sponsor. (CDISC)

**Clinical trial site:** The location where clinical trial-related activities are performed. (HC)

**Clinical Trial Site Information (CTSI):** A form detailing site information, required by Health Canada for all trials that are subject to Division 5 of the Food and Drug Regulations Amendment. This is a post-authorization requirement. (HC)

**Clinical trial status report / management report:** A report giving the current status of a particular trial including information on the following: enrollment statistics (i.e. recruited, enrolled/accrued, currently active, complete, withdrawn etc.) number of serious adverse events to date, the total amount of research funds that have been paid to the investigator to date. If the study is multicenter then this information is provided for each investigator and then combined to provide the overall status of the study. Contents of the report may vary and is driven by the end-use. (Weiser, ACRC)

**Clinical trial supplies:** Any material (i.e. drug/device, collection kits, case report forms, shipping boxes, etc.) which are required to undertake a particular clinical trial.

**Clinician:** A physician or other practitioner who is involved in the treatment and observation of patients, as distinguished from one engaged in research.

**Clinician reported outcome:** Clinician assessment of patient outcomes, based on objective or subjective data evaluated by the clinician. (CDISC)

**Clinician-scientist:** A physician or other practitioner who has undertaken additional training in health research or basic science. (RCPSC)

**Closed to accrual/Enrollment closed [Study status]:** Date identified in letter from sponsor (or to sponsor) when no more patients can be accrued /enrolled. (ACCT)

**Code breaker:** A sealed envelope or label that contains the identity of the test agent for each of the study participants and should be opened only in an emergency or unusual circumstances, as specified by the protocol and the sponsor. (Weiser)

**Coded data (de-identified):** Single code: A participant's data are assigned a random code. Direct identifiers are removed from the dataset and held separately. The key linking the code back to direct identifiers is available only to authorized members of the research team. Double or multiple codes: Two or more codes are assigned to the same participant's data held in different datasets (e.g. health administrative data, clinical data, genetic samples and data). The key connecting the codes back to participants' direct identifiers is held by a third party (such as the data holder) and is not available to the researchers. Coded data refers to data that are at least single coded. (*Adapted from*

*CIHR Best Practices for Protecting Privacy in Health Research – September 2005*) (N2)

**Codelist:** Finite list of codes and their meanings that represent the only allowed values for a data item. A codelist is one type of controlled vocabulary. (CDISC) See related "[Controlled vocabulary](#)".

**Coding:** In clinical trials, the process of assigning data to categories for analysis. (CDISC)

**Coercion:** An extreme form of undue influence, involving a threat of harm or punishment for failure to participate in research. (TCPS2) See related "[Undue influence](#)".

**Cohort:** 1. A group of individuals who share a common exposure, experience or characteristic. 2. A group of individuals followed-up or traced over time in a cohort study. (CDISC)

**Cohort study:** Study of a group of individuals, some of whom are exposed to a variable of interest, in which participants are followed over time. Cohort studies can be prospective or retrospective. (CDISC) See related "[Prospective study](#)".

**Co-investigator** [*Type of investigator*]: An individual involved with the [principal investigator \(PI\)](#) in the scientific development or execution of a project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered "key personnel". The designation of a co-investigator, if applicable, does not affect the PI's roles and responsibilities.

**Collaborative research:** Research that involves the cooperation of researchers, institutions, organizations and/or communities, each bringing distinct expertise to a project, and that is characterized by respectful relationships. (TCPS2) See related "[Community-based research](#)" and "[Participatory research](#)".

**Collected:** Information that is recorded and/or transmitted to the sponsor. This includes data entered by the site on CRFs/eCRFs as well as vendor data such as core lab data. Synonym: "captured". (CDISC)

**Combination product:** 1. A product comprising two or more individual products. 2. Two or more separate products packaged together in a single

package or as a unit. 3. A product that is packaged separately but is used only with another product. (CDISC)

**Commercial invoice:** A legal document between the supplier and the customer to describe the details of a certain commodity. The commercial invoice is needed for all international non-document shipments, and is used for the customs in the country of destination to determine the customs value. (OTRN/OICR)

**Common name (Food and Drug Regulations):** With reference to a drug, the name in English or French by which the drug is: a. commonly known; and b. designated in scientific or technical journals, other than the publications referred to in Schedule B to the Act. (HC)

**Common Technical Document (CTD):** A format agreed upon by ICH to organize applications to regulatory authorities for registration of pharmaceuticals for human use. (CDISC)

**Community:** A group of people with a shared identity or interest that has the capacity to act or express itself as a collective. A community may be territorial, organizational, or a community of interest. (TCPS2)

**Community-based research:** Research conducted at a community site that focuses not only on individuals but on the community itself. Community-based research may be initiated by the community independently or in collaboration with a researcher. (TCPS2) See related "[Collaborative research](#)" and "[Participatory research](#)".

**Community engagement:** A process that establishes an interaction between a researcher (or a research team) and a community with regard to a research project. It signifies the intent of forming a collaborative relationship between researchers and communities, although the degree of collaboration may vary depending on the community context and the nature of the research. (TCPS2)

**Comparative bioavailability:** The [bioavailability](#) of a drug compared to a reference product.

**Comparative study:** One in which the investigative drug is compared against another product, either active drug or placebo. (CDISC)

**Comparator (product):** An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical study. (N2)

**Compassionate use/emergency drug release (EDR):**

Circumstances under which the use of an investigational agent for a single patient may be allowed. (Weiser)

**Complete file:** File for which all data cleaning is complete and database is ready for quality review and unblinding. (CDISC) See related "[Database lock](#)" and "[Frozen](#)".

**Completed** [*Study status*]: Date when all study related activity is completed at the site; the study may still be open at other sites. Trial is completed – no patients on active treatment or follow-up. Letter has been sent to [REB](#). All trial activity has been completed (data analysis, finances, etc.). (ACCT) Synonym: 'end of a trial' (CIHR)

**Completion:** 1. Participant completion: the case where a participant ceases active participation in a trial because the participant has, or is presumed to have, followed all appropriate conditions of a protocol. 2. Study completion: according to the study protocol, the point at which all protocol-required activities have been executed. (CDISC)

**Compliance:** The state of conformity of a regulated party or a product with a legislative or regulatory requirement or a recognized standard. (OTRN/OICR)

**Compliance (in relation to studies):** Adherence to all the study-related requirements, [good clinical practice](#) (GCP) guidelines, and the [applicable regulatory requirements](#). (N2)

**Complications:** An unanticipated problem that arises following, and is a result of, a procedure, treatment, or illness.

**Computer system:** The set of computer hardware or other similar device by or in which data are recorded or stored and any procedures related to the recording or storage of the study database. For example, a computer system may be a mainframe, server, virtual server, workstation, personal computer, portable device or a system of computers arranged as a network. (N2)

**Concern for welfare:** A core principle of TCPS2 that requires researchers and research ethics boards to aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks associated with the research. (TCPS2) See related "[Risk](#)" and "[Welfare](#)".

**Concomitant medication:** Medication taken by a participant, in addition to the investigational

product. A concomitant medication can be another prescription drug that is prescribed by the investigator or it may be an over the counter preparation including herbal products taken during the trial period. Typically, the protocol outlines allowable concomitant medications. (Weiser, ACRC)

**Concomitant treatment:** Treatment that is undertaken by the participant at the same time as the investigational product (e.g. physiotherapy, diet). The use of concomitant treatment is in instances where it does not interact with the investigational product and if it does not affect any of the assessments, observations or measurements that are undertaken as part of the study. Sometimes, study groups are stratified into those who receive concomitant treatment and those who do not. (Weiser)

**Confidence intervals:** The range of values within which the population mean is likely to lie. Usually 95% confidence limits are quoted which means that there is a 95% probability that the true population mean will lie somewhere between the upper and lower limits. (Weiser)

**Confidentiality:** Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a participant's identity. (N2)

**Confidentiality disclosure agreement (CDA):** A legal agreement used with an outside organization to enter into collaborations or have confidential discussions leading to collaborations. (FDA)

**Confirmatory trial:** Phase 3 trial during which the previously revealed actions of a therapeutic intervention are confirmed. (CDISC) See related "[Exploratory study](#)".

**Conflict of interest:** The incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the ethical conduct of research, such that one cannot be fulfilled without compromising another. (TCPS2)

**Consent:** An indication of agreement by an individual to become a participant in a research project. The term "consent" means "free (also referred to as voluntary), informed and ongoing consent". (TCPS2)

**Consent form:** Use "[Informed consent form](#)".

**Consented participant:** Use "[Accrued/Enrolled](#)".



**Consignee:** An individual agency, institution, or organization that receives specimens and assumes responsibility for storage, dispensing and tracking the disposition of specimens. Synonym: Receiver. (OTRN/OICR)

**Container (for diagnostic substances):** Container designed, constructed, filled, closed, secured and maintained so that under normal conditions of transport, including handling, there will be no accidental release of dangerous goods that could endanger public safety. (OTRN/OICR)

**Content validity:** The extent to which a variable (for example, a rating scale) measures what it is supposed to measure. Evidence from qualitative research demonstrating that the instrument measures the concept of interest, including evidence that the items and domains of an instrument are appropriate and comprehensive, relative to its intended measurement concept, population, and use. (CDISC)

**Continuing research ethics review/Continuing ethics review:** Any review of ongoing research conducted by a research ethics board (REB) occurring after the date of initial REB approval and continuing throughout the life of the project to ensure that all stages of a research project are ethically acceptable in accordance with the principles in the Policy. (TCPS2)

**Contract/Clinical study agreement (CSA)/Clinical trial agreement (CTA):** See "[Clinical study agreement/Clinical trial agreement/Contract](#)".

**Contract research organization (CRO):** A person or an organization (commercial, academic, or other) contracted by the [sponsor](#) to perform one or more of a sponsor's study-related duties and functions. (N2)

**Contraindication:** A condition in which it is recommended that a drug/medication not be administered. (Weiser)

**Control (of electronic records):** To prepare and maintain case histories and other records for regulated clinical investigations. (CDISC)

**Control group:** A group of participants receiving the standard of care or treatment or a placebo whose results will be used as a comparison against the results of the participant group receiving the investigational treatment. (Weiser)

**Controlled clinical trial [Study design]:** A type of clinical trial in which observations made during the trial are compared to a standard (called the control). The control may be observations from a group of participants in the same trial or observations from outside the trial (for example, from an earlier trial, called a "historical control"). (clinicaltrials.gov)

**Controlled terminology/vocabulary:** A finite set of values that represent the only allowed values for a data item. These values may be codes, text, or numeric. See related "[Codelist](#)".

**Controlled variable:** Something that does not change, for example, the number of times per day that each participant is expected to take the trial medication. (CIHR) See related "[Analysis variables](#)", "[Dependent variable](#)", "[Independent variable](#)".

**Cooperative group [Study origin; Funding source]:** A large network of researchers, physicians, and health care professionals at public and private institutions across the countries who are members of the group involved in [clinical research](#) funded externally; for example National Cancer Institute of Canada (NCIC-CTG), Radiation Therapy Oncology Group (RTOG), Children's Oncology Group (COG), International Cancer Research Group (ICRG), VIGOUR. (NACTRC, ARO)

**Coordinating committee:** A committee that a sponsor may organize to coordinate the conduct of a multi-centre study. (N2)

**Coordinating investigator:** An [investigator](#) assigned the responsibility for the coordination of investigators at different centres participating in a multicentre study. (N2)

**Core principles:** The three core principles of the TCPS2 Policy that together express the overarching value of respect for human dignity: Respect for Persons, Concern for Welfare and Justice. (TCPS2) See related "[Respect for persons](#)," "[Concern for welfare](#)" and "[Justice](#)".

**Correlation:** The degree to which two or more variables are related. Typically the linear relationship is measured with either Pearson's correlation or Spearman's rho. NOTE: Correlation does not necessarily mean causation. (CDISC)

**Covariate (prognostic):** Factor or condition that influences outcome of a trial. (CDISC)

**Critical inquiry:** The analysis of social structures or activities, public policies, or other social phenomena for research purposes. (TCPS2)

**Cross-over design:** A study design that has each participant in two or more treatments in a specified order.

**Cross-sectional studies:** (Prospective or retrospective) observational study in which a group is chosen (sometimes as a random sample) from a certain larger population, and the exposures of people in the group to an intervention and outcomes of interest are determined for a specific point in time. (NIH)

**Cryogenic freezer:** A cryogenic vessel used for storing samples at the collection centre. Samples should be stored in the vapour phase of liquid nitrogen to preserve the samples at a low temperature of -196°C. (OTRN/OICR)

**Cryopreservation:** A process for storing biological material at very low temperatures for lengthy periods of time. (OTRN/OICR)

**Cryovial:** A screw-capped 2mL specimen container used to store aliquots of tissue and fractionated blood. (OTRN/OICR)

**Cultural heritage:** A dynamic concept which includes, but is not limited to, First Nations, Inuit and Métis peoples' relations with particular territories, material objects, traditional knowledge and skills, and intangibles that are transmitted from one generation to the next, such as sacred narratives, customs, representations or practices. (TCPS2)

**Curriculum vitae (CV):** Document that outlines a person's educational and professional history. (CDISC)

**Custodian:** An organization or individual in the health system who receives and uses health information and is responsible for ensuring that it is protected, used and disclosed appropriately. (HIA)

**Custodianship:** Individual/organization responsible for safe keeping of tissue samples and associated data and control of their use and eventual disposal in accordance with the terms of the consent given by the participant and as regulated by the regulatory requirements. Custodianship implies some rights to decide how the samples are used and by whom, and also responsibility for safeguarding the interests of donors. (OTRN/OICR)

**Cyber-material:** Documents, images, audio or video recordings, records, performances, or on-line archival materials available in digital form on the Internet. (TCPS2)

**Dangerous goods:** A product, substance or organism included by its nature or by the regulations in any of the classes listed within the act (Classes 1 to 9):

Class 1: Explosives

Class 2: Gases: Compressed, deeply refrigerated, liquefied or dissolved under pressure.

Class 3: Flammable and combustible liquids

Class 4: Flammable solids; substances liable to spontaneous combustion; substances that on contact with water emit flammable gases

Class 5: Oxidizing substances; organic peroxides

Class 6: Poisonous (toxic) and infectious substances

Class 7: Nuclear substances that are radioactive or radioactive materials

Class 8: Corrosives

Class 9: Miscellaneous products, substances or organisms considered to be dangerous to life, health, property or the environment when handled or transported (N2)

**Dangerous goods safety mark:** Means a label, placard, orange panel, sign, mark, letter, word, number or abbreviation that is used to identify dangerous goods and to show the nature of the danger posed by them. (N2)

**Data:** The information reported about a participant in a study. (AHRQ)

**Data acquisition:** Capture of data into a structured, computerized format without a human-to-computer interface (i.e., from another measuring instrument or computerized source). (CDISC) See related "[Data entry](#)", "[Electronic data capture](#)".

**Data capture:** Use "[Data entry](#)".

**Data clarification:** Answer supplied by the investigator in response to a query. NOTE: The investigator may supply a new data point value to replace the initial value or a confirmation of the queried data point. (CDISC)

**Data clarification form:** A form used to query an investigator and collect feedback to resolve questions regarding data. (CDISC)

**Data cleaning:** The process of dealing with errors and omissions in a set of data; ensuring that measurements are given in the same units and to the same degree of accuracy. (Weiser)

**Data collection:** Information about each patient that is collected during the course of a study. This information is usually recorded in a [case report form](#) (CRF) that is designed for each study. (Weiser)

**Data collection instrument:** A tool (either electronic or paper) used to record, transcribe, or collect clinical data. (CDISC)

**Data dictionary:** The repository for all the required objects for creating and maintaining data collection, validation, and extraction operations. (N2)

**Data entry:** Human input of data into a structured, computerized format using an interface such as a keyboard, pen-based tablet, or voice recognition. (CDISC) See related [“Data acquisition”](#), [“Data collection”](#), [“Electronic data capture”](#), [“Direct entry”](#).

**Data integrity:** A dimension of data contributing to trustworthiness and pertaining to the systems and processes for data capture, correction, maintenance, transmission, and retention. Key elements of data integrity include security, privacy, access controls, a continuous pedigree from capture to archive, stability (of values, of attribution), protection against loss or destruction, ease of review by users responsible for data quality, proper operation and validation of systems, training of users. (CDISC) See related [“Data quality”](#).

**Data integrity verification:** Process of manually supervised verification of data for internal consistency. (CDISC)

**Data interchange:** Transfer of information between two or more parties, which maintains the integrity of the contents of the data for the purpose intended. (CDISC)

**Data linkage:** The merging or analysis of two or more separate data sets (e.g. health information and education information about the same individuals) for research purposes. (TCPS2) See related [“Data set.”](#)

**Data listing:** Set of observations organized by domain.

**Data management:** Tasks associated with the entry, transfer, and/or preparation of source data and derived items for entry into a clinical trial database. NOTE: Data management could include database

creation, data entry, review, coding, data editing, data QC, locking, or archiving; it typically does not include source data capture. (CDISC)

**Data management conventions:** Procedures and policies for data management (e.g., documented procedure(s) for resolving self-evident changes). (CDISC) See related [“Self-evident change”](#).

**Data management system (DMS):** A software platform for collaborating on gathering, sharing, and using analytical data. (OTRN/OICR)

**Data model:** Unambiguous, formally stated, expression of items, the relationship among items, and the structure of the data in a certain problem area or context of use. A data model uses symbolic conventions agreed to represent content so that content does not lose its intended meaning when communicated. (CDISC)

**Data monitoring:** Process by which clinical data are examined for completeness, consistency, and accuracy. (CDISC)

**Data monitoring committee (DMC):** Group of individuals with pertinent expertise that reviews on a regular basis accumulating data from an ongoing clinical trial. The DMC advises the sponsor regarding the continuing safety of current participants and those yet to be recruited, as well as the continuing validity and scientific merit of the trial. (CDISC) See related [“Data safety monitoring board”](#).

**Data quality:** A dimension of data contributing its trustworthiness and pertaining to accuracy, sensitivity, validity, and suitability to purpose. Key elements of data quality include attribution, legibility (decipherable, unambiguous), contemporaneousness, originality (i.e., not duplicated), accuracy, precision, completeness, consistency (logical, not out of range), and those who have modified the data. (CDISC) See related [“ALCOA”](#), [“Data integrity”](#).

**Data query:** A request for clarification of information received, often by the data entry group, monitor, or data manager. See related [“Query”](#).

**Data safety monitoring board (DSMB):** A multi-disciplinary, expert advisory group established by a research sponsor, that is responsible for safeguarding the interests of participants by reviewing emerging data, assessing the safety and efficacy of clinical trial procedures, and monitoring the overall conduct of a trial. (CDISC) See related [“Data monitoring committee”](#).



**Data security:** Degree to which data are protected from the risk of accidental or malicious alteration or destruction and from unauthorized access or disclosure. (CDISC)

**Data selection criteria:** The rules by which particular data are selected and/ or transferred between the point of care and the patient record; subsequently, from the patient record to the database; and from database to inclusion in subpopulation analyses. (CDISC)

**Data set:** A collection of information to be used for research purposes, including [human biological materials](#). (TCPS2)

**Data storage:** To maintain data by placing the data, or a copy of the data, onto an electronically accessible device for preservation (either in plain-text or encrypted format).

**Data transformations:** Algorithmic operations on data or data sets to achieve a meaningful set of derived data for analysis. (CDISC) See related "[Derived variable](#)".

**Data type:** Data types define the structural format of the data carried in the attribute and influence the set of allowable values an attribute may assume. (CDISC)

**Data validation:** 1. Checking data for correctness and/or compliance with applicable standards, rules, and conventions. 2. Process used to determine if data are inaccurate, incomplete, or unreasonable. The process may include format checks, completeness checks, check key tests, reasonableness checks, and limit checks. (CDISC)

**Data verification:** the process of verifying the accuracy of the data that has been collected and recorded for each participant.

**Database:** Applies to all computer software which is used to format, manipulate or control storage of the electronic data for the study. This may be one computer file or a system of files which are maintained as the study database. (N2)

**Database lock:** Action taken to prevent further changes to a clinical trial database. NOTE: Locking of a database is done after review, query resolution, and a determination has been made that the database is ready for analysis. (N2)

**Database set-up:** A collection of data entry screens that defines, through data management software, the database structure. The database set-up will be

defined according to the study protocol. For paper based [case report form](#) (CRF), the database set-up will be defined according to the CRF and the study [protocol](#). (N2)

**Database unlock:** When write-access is granted to a designated individual(s) in order to allow a modification(s) to the data. The modification(s) is approved prior to unlocking the database. (N2)

**Debriefing:** The full disclosure of the research purpose and other pertinent information to participants who have been involved in research employing partial disclosure or deception. Debriefing is typically done after participation has ended, but may be done at any time during the study. (TCPS2)

**Decision rule:** Succinct statement of how a decision will be reached based upon the expected foreseen clinical benefits in terms of outcomes of the primary endpoint. (CDISC)

**Declaration of Helsinki:** A set of recommendations or basic principles that guide medical doctors in the conduct of biomedical research involving human participants. It was originally adopted by the 18th World Medical Assembly (Helsinki, Finland, 1964) and recently revised (52nd WMA General Assembly, Edinburgh, Scotland, October 2000). (CDISC)

**De-identified:** Removal of elements connected with data which might aid in associating those data with an individual. Examples include name, birth date, social security number, home address, telephone number, e-mail address, medical record numbers, health plan beneficiary numbers, full-face photographic images). (CDISC) See related "[Anonymized](#)".

**Delegated research ethics board (REB) review:** The level of REB review assigned to minimal risk research projects. Delegated reviewers are selected from among the REB membership, with the exception of the ethics review of student course-based research which can be reviewed by delegates from the student's department, faculty, or an equivalent level. (TCPS2)

**Delegation log:** The document that indicates the legal delegation of study- specific responsibilities. It records the tasks delegated from the [Qualified investigator](#) to other study team members, appropriate to skill set, and is signed and dated by the Qualified investigator and the individual to whom the functions were delegated.

**Demographic data:** Characteristics of participants or study populations, which include such information as age, sex, family history of the disease or condition for which they are being treated, and other characteristics relevant to the study in which they are participating. (CDISC)

**Deoxyribonuclease (DNase):** is a type of enzyme that catalyzes the degradation of DNA into smaller components. (OTRN/OICR)

**Dependent variable:** A variable over which the experimenter has no control, but that is expected to change in a systematic way, depending on the independent variable. The change in the dependent variable is what gets recorded as data in a research study. (CIHR) See related "[Analysis variables](#)", "[Controlled variable](#)", "[Independent variable](#)".

**Deployment:** Readyng an electronic clinical trial system for field use by providing or disseminating capture devices, tokens, or passwords for users of an activated system. (CDISC)

**Derived:** Derived refers to information that is not directly entered into the specific data field by the investigator site or by a core lab. This category includes auto-encoded data, calculated data and similar electronically generated data, but not pre-populated fields. (CDISC)

**Derived variable:** New variable created as a function of existing variables and/or application of mathematical functions. (CDISC) See related "[Raw data](#)", "[Variable](#)".

**Development plan:** An ordered program of clinical trials, each with specific objectives. (CDISC) See related "[Clinical development plan](#)".

**Development process:** Use "[Drug development](#)".

**Device [Method of research]:** A clinical trial utilizing a medical device, which includes any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in:

- diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- restoring, correcting or modifying a body function or the body structure of human beings or animals,
- the diagnosis of pregnancy in human beings or animals, or

- the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring. (NACTRC/ARO)

Health Canada categorizes devices as Class I, II, III, or IV, based on the risks associated with their use, including the degree of invasiveness, duration of contact with the patient, energy transmission hazard, and consequences of device malfunction or failure. (HC)

**Diagnostic specimen:** Human material including blood and its components, tissue and tissue fluids that is offered for transport for the purpose of diagnosis, analysis or testing. (OTRN/OICR)

**Digital image:** Electronic data file specifying the histological image of a representative tumour section. (OTRN/OICR)

**Digital signature:** An electronic signature, based on cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters, such that the identity of the signer and the integrity of the data can be verified. (CDISC)

**Direct access:** Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical study. Any party (e.g., domestic and foreign regulatory authorities, sponsor's monitors and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of participants' identities and sponsor's proprietary information. (N2)

**Direct entry:** Recording of data by human or automated action where an electronic record is the original means of capturing the data into an electronic records system without a paper source document. Examples are an individual keying original observations into a system or the automatic recording into the system of the output from measuring devices such as a balance that measures participant's body weight or an ECG machine. (CDISC) See related "[Data acquisition](#)", "[Data entry](#)".

**Direct identifiers:** These are variables such as name and address, health insurance number, etc., that provide an explicit link to a respondent. (CIHR *Best Practices for Protecting Privacy in Health Research – September 2005*). (N2)

**Dirty database/file:** A [database](#) from which errors have not been eliminated. (N2)

**Discipline:** A field of study. (CASRAI)

**Disclosure:** To make the information available or to release it to another health information custodian or to another person. (N2)

**Discontinuation:** The act of concluding participation, prior to completion of all protocol-required elements, in a trial by an enrolled participant. NOTE: Four categories of discontinuation are distinguished: a) dropout: Active discontinuation by a participant (also a noun referring to such a discontinued participant); b) investigator initiated discontinuation (e.g., for cause); c) loss to follow-up: cessation of participation without notice or action by the participant; d) sponsor initiated discontinuation. Note that participant discontinuation does not necessarily imply exclusion of participant data from analysis. “Termination” has a history of synonymous use, but is now considered nonstandard. (CDISC) See related “[Withdrawal](#)”.

**Disease:** Any deviation from or interruption of the normal structure or function of a part, organ, or system of the body as manifested by characteristic symptoms and signs. (CDISC)

**Distribution:** 1. In statistics, a group of ordered values; the frequencies or relative frequencies of all possible values of a characteristic. 2. In pharmacokinetics, the processes that control transfer of a drug from the site of measurement to its target and other tissues. (CDISC) See related “[Absorption, distribution, metabolism and excretion \(ADME\)](#)”.

**Documentation:** All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a study, the factors affecting a study, and the actions taken. (N2)

**Donor:** Refers to a participant whose information has been recorded into a biorepository data base and/or samples have been collected and stored. (OTRN/OICR)

**Dosage:** The amount of drug administered to a patient or test participant over the course of the clinical study; a regulated administration of individual doses. (CDISC)

**Dosage 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) See related “[Drug \(product\)](#)”.

**Dosage regimen:** The number of doses per given time period; the elapsed time between doses (for example, every six hours) or the time that the doses are to be given (for example, at 8 a.m. and 4 p.m. daily); and/or the amount of a medicine (the number of capsules, for example) to be given at each specific dosing time. (CDISC)

**Dosage strength:** 1. Proportion of active substance to excipient, measured in units of volume or concentration. 2. The strength of a drug product tells how much of the active ingredient is present in each dosage. (CDISC)

**Dose:** The amount of drug administered to a patient or test participant at one time or the total quantity administered. (CDISC)

**Dose-ranging studies:** A study designed to evaluate the effect and/or safety of different doses of an investigational product. (Weiser)

**Double-blind:** A type of masking in which two or more parties involved with the clinical trial do not know which participants have been assigned which interventions. Typically, this includes the investigator and participant. (clinicaltrials.gov)

**Double-dummy technique:** A technique for retaining the blind when administering supplies in a clinical trial, when the two treatments cannot be made identical. Supplies are prepared for Treatment A (active and indistinguishable [placebo](#)) and for Treatment B (active and indistinguishable placebo). Participants then take two sets of treatment; either A (active) and B (placebo), or A (placebo) and B (active). (CDISC)

**Drop-out:** A participant in a clinical trial who for any reason fails to continue in the trial until the last visit or observation required of him/her by the study protocol. (CDISC)

**Drug (product):** Traditional pharmaceuticals in addition to biologic products, or those derived from living sources. (HC)

**Drug trial/study** [*Method of research*]: A clinical trial utilizing an investigational product (including [biologics](#), [radiopharmaceuticals](#) or [natural health product](#)). Includes any substance or mixture of substances manufactured, sold or represented for use in:

- diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- restoring, correcting or modifying organic functions in human beings or animals, or
- disinfection in premises in which food is manufactured, prepared or kept. (NACTRC, ARO, N2)

**Drug accountability:** The process of being responsible for the investigational product by following safe pharmaceutical practices. The investigator is responsible for investigational product(s) accountability at the study site(s). (N2)

**Drug development:** The program for advancing an investigational product from preclinical studies through approval for marketing following review by regulatory agencies.

**Drug free period:** A period during which no study drug is taken. Drug free periods can occur during the [run-in](#) phase for a study (when the participant's current medication has been stopped) or it may occur during a [washout period](#) between two periods of active treatment. (Weiser)

**Drug identification number (DIN):** A number assigned by Health Canada to a drug product prior to being marketed in Canada. (N2)

**Dry ice:** The solid phase of carbon dioxide, which is particularly useful for keeping samples frozen because of its very cold temperature of -78.5°C. (OTRN/OICR)

**Duration of the study:** The period from the start of a clinical project to its completion.

**Duration of treatment:** The treatment period for each participant in the study (i.e. if the treatment period is six weeks per participant then the duration of treatment is six weeks). (Weiser)

**eCertified copy:** A copy of an electronic record that is created through the application of a process validated to preserve the data and metadata of the original and where the validation of the process is certified by the dated signature of an authorized person. (CDISC)

**eClinical trial:** Clinical trial in which primarily electronic processes are used to plan, collect (acquire), access, exchange, and archive data required for conduct, management, analysis, and

reporting of the trial. Synonyms: eClinical study, eClinical investigation. (CDISC)

**Edit check:** An auditable process, of assessing the content of a data field against its expected logical, format, range, or other properties that is intended to reduce error. NOTE: Time-of-entry edit checks are a type of edit check that is run (executed) at the time data are first captured or transcribed to an electronic device at the time entry is completed of each field or group of fields on a form. Back-end edit checks are a type that is run against data that has been entered or captured electronically and has also been received by a centralized data store. (CDISC) (N2)

**Effect:** An effect attributed to a treatment in a clinical trial. In most clinical trials, the treatment effect of interest is a comparison (or contrast) of two or more treatments. (CDISC) See related "[Treatment effect](#)".

**Effectiveness:** The desired measure of a drug's influence on a disease or condition as demonstrated by substantial evidence from adequate and well-controlled investigations. (CDISC)

**Efficacy:** The capacity of a drug or treatment to produce beneficial effects on the course or duration of a disease at the dose tested and against the illness (and patient population) for which it is designed. (CDISC)

**Electronic case report form (eCRF):** 1. Auditable electronic record designed to capture information required by the clinical trial protocol to be reported to the sponsor on each trial participant. 2. A [CRF](#) in which related data items and their associated comments, notes, and signatures are linked electronically. NOTE: eCRFs may include special display elements, electronic edit checks, and other special properties or functions and are used for both capture and display of the linked data. (CDISC)

**Electronic case report tabulation (eCRT):** CRTs provided in electronic format for eSubmissions (electronic regulatory submissions).

**Electronic data capture (EDC):** The process of collecting clinical trial data into a permanent electronic form. NOTE: Permanent in the context of these definitions implies that any changes made to the electronic data are recorded with an audit trail. EDC usually denotes manual entry of [CRF](#) data by transcription from source documents. The transcription is typically done by personnel at

investigative sites. (CDISC) See related "[Data acquisition](#)", "[Data entry](#)", "[Direct entry](#)".

**Electronic Health Record (EHR):** An electronic record for healthcare providers to create, import, store, and use clinical information for patient care, according to nationally recognized interoperability standards. (CDISC)

**Electronic Medical Record (EMR):** An electronic record for healthcare providers within one healthcare organization to create, store, and use clinical information for patient care. An electronic record derived from a computerized system used primarily for delivering patient care in a clinical setting. (CDISC)

**Electronic record:** Any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system. (CDISC)

**Electronic signature:** A signature that consists of one or more letters, characters, numbers or other symbols in digital form incorporated in attached to or associated with an electronic document. (Statutes of Canada 2000, PIPEDA, N2)

**Electronic source data (eSource data):** Source data captured initially into a permanent electronic record used for the reconstruction and evaluation of a clinical study. NOTE: "Permanent" in the context of these definitions implies that any changes made to the electronic data are recorded via an audit trail. (CDISC) See related "[Permanent data](#)", "[Source data](#)".

**Eligible participant:** These are participants who meet the inclusion and exclusion criteria defined in the protocol. An eligible participant is not necessarily the same as an entered patient as the patient may not consent to take part in the study. (Weiser)

**Eligibility assessment** [*Participant status*]: Looking at eligibility of a participant for a study. (HC)

**End-point:** An indicator (e.g. disease, symptom, sign, or laboratory abnormality) measured in a participant or biological sample to assess safety, efficacy, another trial objective or a predetermined event (i.e. MI, death, etc.) as defined in the protocol, and may also refer to any disease or sign that motivates the withdrawal of that individual from the trial.

**Enrolled/Accrued:** See "[Accrued/Enrolled](#)".

**Enrollment closed/Closed to Accrual:** See "[Closed to accrual/Enrollment closed](#)".

**Entered participant:** Use "[Accrued/Enrolled](#)".

**Epidemiological** [*Method of research*]: A study of the patterns of determinants and antecedents of disease in human populations utilizing biology, clinical medicine, and statistics in an effort to understand the etiology (causes) of illness and/or disease. (NACTRC, ARO)

**Electronic Patient Reported Outcome (ePRO):** Patient reported outcome (PRO) data initially captured electronically. NOTE: Usually ePRO data is captured as eSource. (CDISC) See related "[eSource](#)", "[Patient reported outcome \(PRO\)](#)".

**Equipose:** A state in which an investigator is uncertain about which arm of a clinical trial would be therapeutically superior for a patient. NOTE: An investigator who has a treatment preference or finds out that one arm of a comparative trial offers a clinically therapeutic advantage should disclose this information to participants in the trial. (CDISC)

**Equivalence trial:** A trial with the primary objective of showing that the response to two or more treatments differs by an amount that is clinically unimportant. NOTE: This is usually demonstrated by showing that the true treatment difference is likely to lie between a lower and an upper equivalence margin of clinically acceptable differences. (CDISC)

**eSignature:** Use "[Electronic signature](#)".

**eSource:** Source record that is electronic. See related "[Electronic record](#)", "[Source](#)". (CDISC)

**eSource data:** Use "[Electronic source data](#)".

**eSource document:** The electronic record used to aggregate a particular instance of eSource data items for capture, transmission, storage, and/or display, and serving as a source document for a clinical investigation. NOTE: Electronic source documents are recorded in electronic systems according to conventions (such as those for PDF documents) that ensure that all the fields of eSource data and associated contextual information (e.g., time of capture, time zone, authorship, signatures, revisions) are linked to each other in a particular structure for presentation. The encoded specifications in the electronic record thus serve the same role as have the physical properties of paper (binding items together). eSource documents are subject to regulations and guidance that apply to



source documents. (CDISC) See related "[Source documents](#)".

**Ethylenediamine tetra-acetate (EDTA):** The EDTA binds calcium ions thus blocking the coagulation (clotting) cascade. Erythrocytes, leucocytes and thrombocytes are stable in EDTA anti-coagulated blood for up to 24 hours. (OTRN/OICR)

**Ethics committee:** Use "[Research ethics board \(REB\)](#)" or "[Institutional review board \(IRB\)](#)". (US)

**Ethics review board (ERB):** Use "[Research ethics board \(REB\)](#)" or "[Institutional review board \(IRB\)](#)". (US)

**Ethics review committee (ERC):** Use "[Research ethics board \(REB\)](#)" or "[Institutional review board \(IRB\)](#)". (US)

**Ethnicity:** Denotes social groups with a shared history, sense of identity, geography, and cultural roots. (CDISC)

**Essential documents:** Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. (N2, GCP)

**Evaluable participant:** A participant in a clinical study who has satisfied all of the protocol requirements and whose collected data may be evaluated for safety and efficacy in the final analysis.

**Evaluation:** The careful and complete collection of information about a program or process in order to determine whether it achieved its goal. Both research and evaluation have features that center on answering a question but the purpose of evaluation is essentially to improve an existing program, while research is intended to provide support for a theory or hypothesis. (CIHR)

**Exclusion criteria:** A list of criteria, any one of which, if crossed, excludes a potential study participant from participation in a study. (N2) See related "[Inclusion criteria](#)".

**Excretion:** The act or process of eliminating waste products from the body. (CDISC) See related "[Absorption, distribution, metabolism, and excretion](#)".

**Expanded access:** A means by which manufacturers make investigational new drugs available, under certain circumstances, to treat a patient(s) with a serious disease or condition who cannot participate in a controlled clinical trial. (NIH)

**Experiment:** A study in which a researcher has control over some of the study's conditions and over some aspects of the independent variables being studied. (McGraw-Hill Concise Dictionary of Modern Medicine, 2002)

**Expiry date:** The established date by which a product or a batch of material has reached its approved life span (e.g. clinical trial supplies or dip-sticks used to assess the presence of protein or blood in urine etc.) (Weiser)

**Exploratory IND study:** A clinical study that is conducted early in Phase 1; involves very limited human exposure and has no therapeutic or diagnostic intent (e.g., screening studies, microdose studies) (CDISC) See related "[Phase 0](#)".

**Exploratory study:** Phase 1 or 2 study during which the actions of a therapeutic intervention are assessed and measured. NOTE: Procedures in exploratory studies may appropriately be altered to expand the scope or method of investigation. (CDISC) See related "[Confirmatory study](#)".

**External audit:** Audits that are carried out by an external body at clinical trial sites and at the offices of the sponsor (or CRO). The purpose of the audit is to ensure that a study has been conducted to GCP standards (and in accordance with the sponsor's standard operation procedures and applicable regulations) and that all CRFs and trial documentation comply with these standards. (Weiser)

**Final monitoring visit:** The last monitoring visit at the end of the study, at which all used and unused materials are collected from the study site by the sponsor (or the CRO). All remaining CRFs are collected after all outstanding errors have been corrected. The investigator is reminded of his/her obligations, including the archiving of all correspondence and copies of the CRFs following the sponsor's and institution's archiving policies. (Weiser)

**Final study report:** A complete and comprehensive description of the study upon its completion; including a description of experimental materials and methods, a presentation and evaluation of the results, statistical analyses, and a critical and clinical evaluation. (Weiser)

**Financial agreement:** This may be a formal document or a letter stating the financial arrangements associated with the provision of

research funds by the sponsor to an investigator who has agreed to participate in a clinical study. The agreement should include the following: the number of patients to be recruited, the schedule and amount of each payment, basis for payments (e.g. number of patient visits vs. number of patients completed). The financial agreement may include an up-front payment for study set up, special equipment, etc. (Weiser)

**Federal Food, Drug and Cosmetics Act (FD&C; FDCA and FFDC) (US):** A set of laws passed in 1938. It ensures the safety of all food except for meat, poultry and some egg products; ensures the safety and effectiveness of all drugs, biological products (including blood, vaccines and tissues for transplantation), medical devices, and animal drugs and feed; and makes sure that cosmetics, medical and consumer products that emit radiation do no harm. (FDA)

**Field:** Locus on a data collection instrument (usually a case report form) for recording or displaying a data element. (CDISC)

**Field of application:** The specific area within a discipline. (CASRAI)

**File Transfer Protocol (FTP):** A standard protocol for exchanging files between computers on the Internet. (CDISC)

**First participant/subject in (FSI/ FPI):** The date and time the first participant is enrolled and randomized into a study. The participant will have met the inclusion/exclusion criteria to participate in the trial and will have signed an informed consent form. Synonym: first patient in. (CDISC)

**First participant/subject screened:** First participant who signs the informed consent form and is screened for potential enrollment and randomization into a study but has not yet been determined to meet the inclusion/exclusion criteria for the trial. (CDISC)

**First participant/subject treated:** First participant who receives the test product or placebo in a clinical investigation. (CDISC)

**First patient, first visit (FPFV):** Use "[First participant/subject in](#)".

**First-in-humans study:** The first Phase 1 study in which the test product is administered to human beings.

**First-in-man study:** Use "[First-in-humans study](#)". (CDISC)

**Food and Drug Administration (FDA):** The Food and Drug Administration is a consumer protection agency of the government of the United States of America. The United States regulatory authority charged with, among other responsibilities, granting [Investigational New Drug \(IND\)](#) and [New Drug Application \(NDA\)](#) approvals. (N2)

**Formalin-fixed paraffin embedded (FFPE):** Refers to a tissue block which contains tissue which was fixed in formalin and then embedded in paraffin for long term storage at room temperature. (OTRN/OICR)

**Fraud:** The deliberate falsification or forgery of clinical study data. E.g. include nonexistent participant being entered into clinical trials or a deceased participant being recruited into studies. (Weiser, ACRC)

**Frequentist methods:** Statistical methods, such as significance tests and confidence intervals, which can be interpreted in terms of the frequency of certain outcomes occurring in hypothetical repeated realizations of the same experimental situation. (CDISC)

**Frozen:** Status of a database, file, or element that has been presumed to be in its final state pending "lock" and where further editing is prevented without "unfreezing." NOTE: Freezing and unfreezing are usually formalized in audit trails and differ from "locking" and "unlocking" only in the degree of approval required. (CDISC) See related "[Database lock](#)".

**Full research ethics board (REB) review –** The level of REB review assigned to above minimal risk research projects. Conducted by the full membership of the research ethics board, it is the default requirement for the ethics review of research involving humans. (TCPS2)

**Gender:** Refers to the socially constructed roles, behaviors, expressions and self-identities of girls, women, boys, men, and gender diverse people. Gender is usually conceptualized as a binary (girl/woman and boy/man) yet there is considerable diversity in how individuals and groups understand, experience, and express it. (CIHR, ACRC) See related "[Sex](#)".

**Generalizability:** The extent to which the findings of a clinical trial can be reliably extrapolated from the participants in the trial to a broader patient

population and a broader range of clinical settings. (CDISC)

**Generic name:** The generic or non-proprietary name describes the drug substance. International Nonproprietary Names are created to identify generic names as unique, universally applicable and accepted names. A generic name is the proper name of an ingredient, or the common name if the ingredient has no proper name. (HC)

**Good clinical practice (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical studies that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of study participants are protected. (N2)

**Good clinical research practice (GCRP):** Term sometimes used to describe GCP. (CDISC) Use "[Good clinical practice](#)".

**Good laboratory practice (GLP):** A set of regulations to establish standards for the conduct and reporting of nonclinical laboratory studies that are intended to assure the quality and integrity of safety data submitted to the regulatory authority (ies). (N2)

**Good manufacturing practice (GMP):** Part of pharmaceutical quality assurance which ensures that products are consistently produced and controlled in accordance with quality standards appropriate for their intended use and as required by the product specification. (Weiser)

**Grant [Funding source]:** Support for the direct costs of research projects including for the training of researchers and/or activities that support the translation of research findings, conducted by either an investigator working alone or by a group of investigators working together. (CIHR)

Includes Awards, Foundation Grants, Peer-Reviewed Grants, CIHR and NIH Grants. (NACTRC, ARO)

**Granularity:** Refers to the size of an information unit in relation to a whole. NOTE: Structuring "privileges" in electronic systems is said to be highly granular when each of many roles can differ in their capacity to act on electronic records. (CDISC)

**Group sequential design:** A trial design that allows a look at the data at particular time points or after a defined number of patients have been entered and followed up based on formulating a stopping rule derived from repeated significance tests. (CDISC)

**H + E Stain:** Hematoxylin and eosin is used for routine staining of tissue sections on microscopic slides. (OTRN/OICR)

**Half-life (drugs):** The time taken to eliminate half the active metabolite of the drug present in the body. It is often expressed as the time taken for the plasma concentration to fall by 50% when absorption and distribution have been completed. (Weiser)

**Handling:** Loading, unloading, packing or unpacking dangerous goods in a means of containment for the purposes of, in the course of or following transportation and includes storing them in the course of transportation. (OTRN/OICR)

**Health Canada / Santé Canada (HC/SC):** Federal government agency that oversees health and food products. (N2)

**Health Information Act (HIA):** An Act passed by the Legislative Assembly of Alberta in 1999, which sets out rules regarding the collection, use and disclosure of health information. Alberta Health or the HIA provides individuals with the right to request access to health records in the custody or under the control of custodians, while providing custodians with a framework within which they must conduct the collection, use and disclosure of health information. (OIPC)

**Health Information Act (HIA) s.54 Research**

**Agreement:** A mechanism that binds the researcher to meet the requirements of the Health Information Act. It includes provisions regarding use, publication, contact with patients and the right to inspect. (AHS)

**Health Level 7 (HL7):** An ANSI accredited Standards Developing Organization (SDO) operating in the healthcare arena. NOTE: Level 7 refers to the highest level of the International Standards Organization's (ISO) communications model for Open Systems Interconnection (OSI), the application level. The application level addresses definition of the data to be exchanged, the timing of the interchange, and the communication of certain errors to the application. Level 7 supports such functions as security checks, participant identification, availability checks, exchange mechanism negotiations, and, most importantly, data exchange structuring. (CDISC)

**Health Products and Food Branch (HPFB):** The division within Health Canada with the mandate to take an integrated approach of the management to the risks and benefits to health, related to health products and food by minimizing health risk factors



to Canadians while maximizing the safety provided by the regulatory system for health products and food, and by promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. The [Therapeutic Products Directorate](#) (TPD) is a division of HPFB. (N2)

**Health Products and Food Branch Inspectorate (HPFBI or the inspectorate):** The Inspectorate responsible for the management of inspection, investigation, monitoring activities and enforcement strategies related to the fabrication, packaging/labeling, testing, importation, distribution and wholesaling of regulated health products for human and veterinary use. (N2)

**Health services research [CIHR category of research]:** Research with the goal of improving the efficiency and effectiveness of health professionals and the health care system, through changes to practice and policy. Health services research is a multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviours affect access to health care, the [quality](#) and cost of health care, and, ultimately, Canadians' health and well-being. A CIHR theme. (CIHR)

**Health technology:** Any intervention that may be used to promote health, prevent, diagnose or treat disease, or for rehabilitation or long-term care. The intervention can be a test, device, medicine, vaccine, procedure, program or system. (HTA Glossary/ EUnetHTA)

**Health technology assessment (HTA):** The systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies. (WHO)

**Healthcare provider:** 1. One who directly or indirectly administers interventions that are designed to improve the physical or emotional status of patients. 2. A person licensed, certified, or otherwise authorized or permitted by law to administer healthcare in the ordinary course of business or practice of a profession, including a healthcare facility. (CDISC)

**Healthy volunteer:** Participant (not a patient) in a clinical trial. NOTE: Usually healthy volunteers serve as participants in [Phase 1](#) trials. (CDISC)

**HIA s.54 Research Agreement:** Use "[Health Information Act \(HIA\) s.54 Research Agreement](#)"

**Human biological materials** – Materials originating from human bodies for research. (OTRN/OICR)

- **Identified human biological materials** – The materials are labeled with a direct identifier (e.g. name, personal health number). Materials and any associated information are directly traceable back to a specific individual.
- **Coded human biological materials** – Direct identifiers are removed from the materials and replaced with a code. Depending on access to the code, it may be possible to re-identify specific individuals (e.g. a principal investigator retains a key that links the coded material with a specific individual if re-linkage is necessary).
- **Anonymized human biological materials** – The materials are irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.
- **Anonymous human biological materials** – The materials never had identifiers attached to them and risk of identification of individuals is low or very low. (TCPS2)

**Human subject:** Use "[Participant](#)"

**Hypothesis:** The proposition that a study sets out to support (or disprove); for example, "blood pressure will be lowered by [specific endpoint] in participants who receive the test product." A scientific hypothesis must explain all of the results of a study, and be testable, repeatable, and refutable (capable of being proven wrong). (CDISC, CIHR) See related "[Null hypothesis](#)".

**IATA:** Use "[International Air Transportation Association](#)".

**Identifiable data:** Any element or combination of data elements that allows direct or indirect identification of an individual (i.e. via direct identifiers or indirect identifiers). (*Adapted from CIHR Best Practices for Protecting Privacy in Health Research – September 2005*) (N2)

**Identifiable information** – Information that may reasonably be expected to identify an individual, alone or in combination with other available information. See related "[personal information](#)".

- **Directly identifying information** – The information identifies a specific individual through direct identifiers (e.g. name, social insurance number, personal health number).
- **Indirectly identifying information** – The information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g. date of birth, place of residence, or unique personal characteristic).
- **Coded information** – Direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g. the principal investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary).
- **Anonymized information** – The information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.
- **Anonymous information** – The information never had identifiers associated with it (e.g. anonymous surveys) and risk of identification of individuals is low or very low. (TCPS2)

**Immunohistochemistry (IHC):** the process of detecting antigens (e.g., proteins) in cells of a tissue section by staining with antibodies which specifically bind to antigens in biological tissues. Immunohistochemical staining is widely used in the detection of abnormal cells such as those found in cancerous tumors. (OTRN/OICR)

**Impartial witness:** A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the participant or the participant's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the participant. (N2)

**In-kind contribution** [*Funding source*]: In-kind (cash equivalent) contributions provided by a partner that:

- are generally entirely relevant and central to the research (such judgment may be referred to peer review) for leveraging by CIHR; and
- would have to be purchased by the recipient if they were not provided by a partner. (CIHR)

In-kind contribution does not include any form of cash funding. It does include donations of devices, drugs, products or supplies. (NACTRC, ARO)

**Incentive:** Anything offered to participants, monetary or otherwise, to encourage participation in research. (TCPS2)

**Incidence rate:** The rate of occurrence of new cases of a disease, adverse reactions, or other events in a given population at risk. (Weiser)

**Incidental findings** – Unanticipated discoveries made in the course of research that are outside the scope of the research. (TCPS2)

**Inclusion criteria:** The criteria that prospective study participants must meet to be eligible for participation in a study. (N2) See related "[Exclusion criteria](#)".

**Indemnification:** Legal clause(s) indicating protection or exemption from liability for compensation or damages from a third party. It outlines the legal and financial coverage by which one person or organization agrees to secure another against undesirable events from specific liabilities i.e. claims by a participant. (Weiser, ACRC)

**Independent central adjudication committee:** A committee blinded to the study intervention assignments, that assesses study endpoints/events.

**Independent data-monitoring committee (IDMC):** Use "[Data safety monitoring board \(DSMB\)](#)".

**Independent ethics committee:** Use "[Research ethics board \(REB\)](#)".

**Independent variable:** A factor in the experiment that is manipulated by the experimenter. An example could be three dose levels of the same drug. (CIHR) See related "[Analysis variables](#)", "[Controlled variable](#)", "[Dependent variable](#)".

**Indication:** A health problem or disease that is identified as likely to be benefited by a therapy being studied in clinical trials. NOTE: Where such a benefit has been established and approved by regulatory

authorities, the therapy is said to be approved for such an indication. (CDISC)

**Indirect identifiers:** These are variables such as date of birth, sex, initials, marital status, area of residence, occupation, type of business, etc. that, in combination, could be used to identify an individual. (*CIHR Best Practices for Protecting Privacy in Health Research – September 2005*) (N2)

**Industry-initiated** [*Study origin*]: A [clinical research study](#) designed and funded by a pharmaceutical company, biotech or other private entities. Must have a [clinical trial agreement](#) with the institution and is subject to Overhead Policy. (NACTRC, ARO)

**Industry-sponsored** [*Funding source*]: Funding is provided through unrestricted or non-peer reviewed industry grants, awards, gifts or similar. (NACTRC, ARO)

**Ineligible participants:** Participants who do not meet the inclusion criteria or who fulfill any exclusion criteria, as defined in the study, cannot be enrolled into the study.

**Infectious substance:** A substance known or reasonably expected to contain viable micro-organisms that are known or reasonably expected to cause disease in human beings or animals. (e.g. micro-organisms such as bacteria, viruses, parasites, or fungi) (N2)

**Informed consent:** A process by which a participant voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate. (N2) See related "[Consent](#)".

**Informed consent form (ICF):** A written form that provides the study participant with information essential to making an informed decision about participating in a clinical investigation. The signature of the study participant or the participant's legally authorized representative on the ICF indicates the intent of the participant or the participant's legally authorized representative to give [informed consent](#). (N2)

**Innovation:** Introduction of a new method, idea or product.

**Inspection:** The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical trial

and that may be located at the site of the trial, at the sponsor's and/or [contract research organization's](#) (CROs) facilities, or at other establishments deemed appropriate by the regulatory authority(ies). (N2)

**Institution:** Any public or private entity or agency of medical or dental facility who the agreement/contract is entered with. (HC)

**Institution, medical:** Any public or private entity or agency or medical or dental facility where clinical trials are conducted. (N2)

**Institutional review board (IRB):** Commonly used in the U.S. Use "[Research ethics board](#)" (REB)

**Intention-to-treat:** The principle that asserts that the effect of a treatment policy can be best assessed by evaluating the basis of the intention to treat a participant (i.e., the planned treatment regimen) rather than the actual treatment given. NOTE: This has the consequence that participants allocated to a treatment group should be followed up, assessed, and analyzed as members of that group irrespective of their compliance with the planned course of treatment. The principle is intended to prevent bias caused by loss of participants that may reflect non-adherence to the protocol and disrupt baseline equivalence established by random assignment. (CDISC)

**Interaction (qualitative and quantitative):** The situation in which a treatment contrast (e.g., difference between investigational product and control) is dependent on another factor (for example, the center). A quantitative interaction refers to the case where the magnitude of the contrast differs at the different levels of the factor; for a qualitative interaction, the direction of the contrast differs for at least one level of the factor. interim analysis(es). Analysis comparing intervention groups at any time before the formal completion of the trial, usually before recruitment is complete. (CDISC)

**Interactive voice response system (IVRS):** An automated telephone system that can read a combination of voice and touch tone input. It gives users the ability to access a database of information by phone.

**Interim analysis:** An analysis performed before all participants have completed the study. The timing of such analyses is pre-determined during protocol development. These analyses are to evaluate for early efficacy, and can lead to terminating the trial

early if the result is favourable or unfavourable. Termination should be done with due care and consideration for the study participants. (Weiser)

**Interim analysis schedule:** The time/information points at which interim analyses are planned. (CDISC)

**Interim clinical trial report:** A report of intermediate results and their evaluation, based on analyses performed during the course of a trial. (N2)

**Internal and/or contingency funding** [*Funding source*]: Includes funding from investigator contingency accounts and all Faculty and Departmental internal funds. Does not include investigator's personal sources. (NACTRC, ARO)

**International Air Transportation Association (IATA):** is an international industry trade group of airlines with the mission to represent, lead, and serve the airline industry. (OTRN/OICR)

**International Council on Harmonization (ICH):** A joint initiative involving both regulators and industry as equal partners in the scientific and technical discussions of the testing procedures which are required to ensure and assess the safety, quality and efficacy of medicines. (N2)

**Interpretation:** The process whereby the clinical meaning or significance of data, after it has been statistically analyzed, is determined. (Weiser)

**Inter-rater reliability:** The property of scales yielding equivalent results when used by different raters on different occasions. (CDISC)

**Intervention:** The drug, device, therapy, 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). Synonyms: therapeutic intervention, medical product. (CDISC) See related: "[Combination product](#)", "[Device](#)", "[Drug \(product\)](#)", "[Investigational product](#)".

**Interventional clinical research** [Method of research]: A research investigation involving human participants that is designed to answer specific questions about the safety and efficacy of a biomedical intervention (drug, treatment, device) or new ways of using a known drug, treatment, or device.

Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical

procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). (NACTRC, ARO)

**Invasive procedure:** Any procedure that breaks the skin or enters into a body cavity of a participant. Such a procedure requires the participant's consent before it is undertaken. Examples of invasive procedures include injections, endoscopy and catheterization.

**Investigational Device Exemption (IDE) Application:** An application which provides information to the FDA on device design and qualification, as well as on the study protocol.

**Investigational New Drug (IND):** A new drug, antibiotic drug or biological drug that is used in a clinical investigation. It also includes a biological product used *in vitro* for diagnostic purposes. The FDA equivalent to the [Clinical Trial Application \(CTA\)](#).

**Investigational product:** A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. (N2)

**Investigational site:** Use "[Clinical trial site](#)".

**Investigational product accountability:** Use "[Drug accountability](#)". (N2)

**Investigational Testing Authorization (ITA):** ([Clinical Trial Application](#) equivalent for devices): Documentation that is required to obtain an authorization for the sale of a device for investigational testing, under the *Medical Devices Regulations*. (HC)

**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 a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. (HC) Types of investigators include: (a) [Qualified investigator/Principal Investigator](#), (b) [Sponsor-investigator](#), (c) [Co-investigator](#), and (d) [Sub-investigator](#)

**Investigator agreement:** Use "[Clinical study agreement \(CSA\)/Clinical trial agreement \(CTA\)/Contract](#)".

**Investigator brochure (IB) or Investigator’s drug brochure (IDB):** A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the [investigational product\(s\)](#) in human participants. (N2)

**Investigator-initiated clinical trial** [*Alberta-specific terminology*]: A trial where the academic investigator generates the research question(s) and study design, controls the content and conduct of the research protocol and has ultimate and final responsibility for making changes to the same protocol, and for analyzing data and reporting results. The Investigator and institution holds the intellectual property to the project and its results. Investigator-initiated protocols are not defined by the source of funding.

**Investigator meeting:** A meeting organized by the sponsor to bring together all of the Investigators and Study Coordinators conducting the clinical trial and the sponsor representatives such as the Project Manager and [clinical research associates](#) assigned to the study. (N2)

**Investigator Site File (ISF):** Essential Documents held by the Investigator. NB on occasion the [group/institution] may also hold the Sponsor's Essential Documents in a Trial Master File, where the Principal Investigator (PI) assumes a Sponsor-investigator role. See related "[Trial Master File](#)".

**Justice:** A core principle of the TCPS2 that refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it. (TCPS2)

**Knowledge translation (KT):** a process connecting contextualized knowledge with its application to improve health and wellness.

**Label:** Description of a drug product/ device that includes: the indication, who should use it, adverse events, instructions for use, and safety information. NOTE: Labels must be approved by regulatory authorities. Synonyms: package insert, patient package leaflet. (CDISC)

**Labeling** (of clinical trial material): The requirements for drug product labeling should comply with the regulations of the country where the clinical trial will

be conducted and in Canada. The labels on drug products to be used in clinical trials should comply with Section C.05.011 of the *Food and Drug Regulations*. The following information shall be included on labels in both official languages:

- a statement indicating that the drug is an investigational product to be used only by a qualified investigator; (Similar wording may be used, such as "for clinical trial use only".)
- the name, number or identifying mark of the drug;
- the expiration date of the drug; (See below section.)
- the recommended storage conditions for the drug;
- the lot number of the drug;
- the name and address of the sponsor;
- the protocol code or identification; and
- if the drug is a radiopharmaceutical as defined in Section C.03.201 *Food and Drug Regulations*, the information required by subparagraph C.03.202(1(ICH, N2)b)(vi).

If stability studies to support expiry dating for a clinical trial drug are still ongoing at the time of labelling, alternate approaches to providing information regarding expiry dating can be considered. Regardless of the approach taken, data should be in place at all times to support the ongoing suitability of the clinical trial drug at the time of use. (HC)

**Laboratory certification/accreditation:** A certificate that is issued to the laboratory after appropriate inspection indicating that it is qualified to perform all of the indicated tests.

**Last participant/subject out/complete (LPC/ LSC or LPO/LSO):** 1. The date and time when the last participant has reached a planned or achieved milestone representing the completion of the trial. 2. The last participant to complete a trial. Synonym: [last patient last visit \(LPLV\)](#). (CDISC) See related "[Completion](#)".

**Last participant/patient/subject in (LPI/LSI):** Date and time when the last participant to participate in a clinical trial is enrolled. (CDISC) See related "[Enrolled](#)", "[Site initiation visit](#)". Synonym: [last patient first visit](#) (LPFV).

**Last patient first visit (LPFV):** "Use [Last participant/patient/subject in](#)".



**Last patient last visit (LPLV):** Use "[Last participant/subject out/complete](#)".

**Legal authentication:** A completion status in which a document has been signed manually or electronically by the individual who is legally responsible for that document. (CDISC)

**Legally acceptable representative:** An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective participant, to the participant's participation in the clinical trial. (N2)

**Letter of Information:** May refer to any one of the following: participant informed consent, information given to participants prior to signing a short form informed consent. (ACRC)

**Liability:** The state of being legally obliged or liable. (Weiser)

**Loading dose:** The initial dose that is larger than the maintenance dose to ensure that drug levels in the blood reach therapeutic levels quickly. (Weiser, ACRC)

**Longitudinal study:** Investigation in which data are collected from a number of participants over a long period of time (a well-known example is the Framingham Study). (CDISC)

**Loss to follow up:** The circumstance that occurs when researchers lose contact with some participants and thus cannot complete planned data collection efforts. A common cause of missing data, especially in long-term studies. (CONSORT)

**Lot number:** The unique letters and numbers used to identify the manufacture, processing, packing and/or distribution of a particular medicinal product. The lot is a subset of a [batch](#) and there can be many lots in a batch.

**Marketing Authorization Application (MAA):** An application requesting marketing authorization in the European Community. The application is made to a Regulatory Authority and should contain information on the chemical, pharmaceutical, biological and clinical data. (Weiser)

**Masking:** Use "[Blinding](#)". (N2)

**Matched-pair design:** a type of parallel trial design in which investigators identify pairs of participants who are "identical" with respect to relevant factors, then randomize them so that one receives treatment a

and the other treatment b. (CDISC) See related "[Pairing](#)".

**Matching:** Use "[Pairing](#)".

**Material Safety Data Sheets (MSDS):** Printed material that provides detailed hazard and precautionary information about hazardous materials. (N2)

**Material Transfer Agreement (MTA):** A contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives. (OTRN/OICR)

**Maximum tolerated dose (MTD):** The highest dose of a drug that can be given to a participant without unacceptable side effects. (Weiser)

**Mean:** A statistical measure of the average of a sample of observations formed by summing the values and dividing by the number of observations. (Weiser)

**Median:** A statistical measure determined by ordering a set of data from the smallest to the largest value. For data with an odd number of values the median is the value that lies at the centre of the ordered values. For data with an even number of values, the median is the simple arithmetic mean of the two "middle" values. In a true normal distribution, the mean and the median are the same value. (Weiser)

**Medical Dictionary for Regulatory Activities (MedDRA):** a clinically validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry throughout the entire regulatory process, from pre-marketing to post-marketing activities, and for data entry, retrieval, evaluation, and presentation. Used to standardize adverse events, serious adverse events and medical conditions (Historical/concomitant) (OTRN/OICR, ACRC)

**Medical history:** Any general health problems that the patient has experienced during his/her lifetime. Particular emphasis is placed on the history of the condition that is being studied.

**Medical monitor:** A sponsor representative who has medical authority for the evaluation of the safety aspects of a clinical trial. (CDISC)

**Medical records:** In general practice, these are the patient’s visit and test results; in hospitals the medical information related to patients are contained in a hospital record file (with each patient having a unique hospital number). (Weiser)

**Medicines and Healthcare products Regulatory Agency (MHRA):** The UK government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. (CDISC)

**Memorandum of Understanding (MOU):** A formal agreement between the Food and Drug Administration (FDA) and federal, state, or local government agencies; academic institutions; and other entities. NOTE: The MOU constitutes an understanding between the parties but is a nonbinding agreement.

**Meta-analysis:** A way of statistically analyzing the results of a [systematic review](#). In a meta-analysis, the participant populations of all similar studies are combined, giving much more statistical power to the result than any individual study would have on its own. It can also show the degree of similarity (homogeneity) or difference (heterogeneity) in the studies included. If the studies being combined are very different, the overall result is less trustworthy, but an examination of the data might show what particular feature of a subset of the data makes it different. (CIHR)

**Metabolism:** The biochemical alteration of substances introduced into the body. (CDISC)

**Metadata:** Data that describe other data, particularly XML tags characterizing attributes of values in clinical data fields. (CDISC)

**Missing data:** Blank entries in the [CRF](#). Data may be missing because, e.g. a test or an assessment was not done, entry was missed, equipment was broken, and samples may have been damaged during transit or analysis. (Weiser, ACRC)

**Mode:** The most frequently occurring value in a data set. (CDISC)

**Monitor:** Person employed by the sponsor or CRO who is responsible for determining that a trial is being conducted in accordance with the protocol and GCP guidance. NOTE: A monitor’s duties may include but are not limited to helping to plan and initiate a trial, assessing the conduct of trials, and assisting in data analysis, interpretation, and extrapolation. Monitors work with the clinical research coordinator to check all data and

documentation from the trial. (CDISC) See related [“Clinical research associate \(CRA\)”](#).

**Monitoring:** The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, [standard operating procedures](#) (SOPs), [good clinical practice](#) (GCP), and the [applicable regulatory requirement](#)(s). (N2)

**Monitoring plan:** A document that describes the strategy, methods, responsibilities, and requirements for monitoring the trial. (ICH/GCP)

**Monitoring report:** A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor’s [SOPs](#). (N2)

**Monitoring visit:** A visit to a study site to review the progress of a clinical study and to ensure protocol adherence, accuracy of data, safety of participants, and compliance with regulatory requirements and good clinical practice guidelines. (CDISC)

**Multi-centre trial:** A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator. (N2) See related [“Multi-site”](#).

**Multi-jurisdictional [Alberta-specific terminology]:** A study that falls under the authority of two or more health information act (HIA) designated Alberta Research Ethics Boards. (HREH)

**Multi-site [Alberta-specific terminology]:** A research study that will be accessing participants from, or using the resources of more than one location/site/facility within the province. (HREH) See related [“Multi-centre trial”](#).

**N-of-1 study:** A trial in which an individual participant is administered a treatment repeatedly over a number of episodes to establish the treatment’s effect in that person, often with the order of experimental and control treatments randomized. (CDISC)

**Natural Health Product (NHP):** A substance such as a plant, vitamin, amino acid, essential fatty acid, mineral or probiotic, or combination of these substances, a homeopathic medicine, or a traditional medicine, that is manufactured, sold or represented for use in

- diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;

- restoring or correcting organic functions in humans; or
- modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health (NACTRC, ARO, N2)

**Negative results:** The results of trials in which the test drug proved to be no better or even worse than the comparator drug. (Weiser, ACRC)

**New Drug Application (NDA):** An application to FDA for a license to market a new drug in the United States. (CDISC)

**New Drug Submission:** The application that a sponsor files to the [TPD](#) when they would like to market a drug in Canada. This contains information and data about the drug's safety, effectiveness and quality. It includes the results of the preclinical and clinical studies, details regarding the production of the drug, packaging and labelling details, and information regarding therapeutic claims and side effects. (HC)

**New safety information:** with respect to a drug, information derived from a clinical trial, an adverse event report, a post-approval study, or peer-reviewed biomedical literature; data derived from the post-market risk identification and analysis system (REMS); or other scientific data regarding: (a) a serious risk or unexpected serious risk associated with use of the drug since the drug was approved, since the REMS was required or last assessed (b) the effectiveness of the approved REMS for the drug obtained since the last assessment of such strategy. (CDISC)

**No carbon required (NCR) paper:** paper that is used to produce multiple copies of each page in a CRF. E.g. usually three copies are produced. When each page is completed (with any required corrections) the top two copies are retrieved by the CRA and sent to the sponsor (or CRO). The bottom copy is left on site as the investigator's copy of the data. (Weiser)

**No Objection Letter (NOL):** A letter issued by Health Canada when a [Clinical Trial Application](#) has been deemed satisfactory. (N2)

**Nonclinical study:** [Biomedical](#) studies not performed on human participants. (N2)

**Non-evaluable participant:** A participant whose study data cannot be included in the efficacy analysis for any of the following reasons: did not meet the

inclusion/exclusion criteria, did not take the medication as directed, did not return for assessments, or received another medication which was disallowed in the study protocol which invalidated the assessments. (Weiser)

**Non-interventional trial:** A study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorization. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data. (CDISC)

**Non-invasive procedure:** A procedure that does not break the skin or enter into a body cavity of a participant. The measurement of blood pressure using an ordinary sphygmomanometer is an example of a non-invasive procedure.

**Non-therapeutic trial:** A trial in which there is no anticipated direct clinical benefit to the participant. (N2)

**Normal distribution:** The histogram of a continuous variable derived from single measurements using different patients will have a characteristic "bell shaped" distribution. (Weiser)

**Not approvable letter:** An official communication from FDA to inform a sponsor of a marketing application that the important deficiencies described in the letter preclude approval unless corrected. (CDISC) US term, equivalent to [Not Satisfactory Notice](#) (HC)

**Notice of authorization (NOA):** A letter issued by the Natural Health Products Directorate when a Clinical Trial Application has been deemed satisfactory. (N2)

**Notice of compliance (NOC):** A Notice of Compliance is a notification issued to a manufacturer following the satisfactory review of a submission.

**Notice of compliance with conditions (NOC/c):** The authorization to market a drug intended for the treatment, prevention, or diagnosis of serious, life threatening, or severely debilitating illnesses or conditions, with the condition that the manufacturer undertake additional studies to verify the clinical benefit. (N2, HC)



**Notice of non-compliance:** A notice from Health Canada, on completion of review of a New Drug Submission, that the submission is deficient. The sponsor has an opportunity to respond to this notice. If the response is insufficient, a Notice of Non-Compliance/Withdrawal (NON/W) is issued. (HC)

**Not Satisfactory Notice (NSN):** A letter issued by Health Canada when a [Clinical Trial Application](#) submission is deficient or a timely response to queries is not received by Health Canada. (N2)

**Null hypothesis:** The null hypothesis,  $H_0$ , default position is that there is no relationship or the potential medical treatment has no effect. It may or may not be rejected as a result of a hypothesis test.

**Numeric signature:** Use "[Electronic signature](#)".

**Nuremberg Code:** Code of ethics, set forth in 1947, for conducting human medical research. (CDISC)

**Objective:** The reason for performing a trial in terms of the scientific questions to be answered by the analysis of data collected during the trial. NOTE: The primary objective is the main question to be answered and drives any statistical planning for the trial (e.g., calculation of the sample size to provide the appropriate power for statistical testing). Secondary objectives are goals of a trial that will provide further information on the use of the treatment. (CDISC)

**Observation:** 1. An assessment of patient condition or analysis of data collected on an individual patient or group of patients. 2. A discrete piece of information collected during a study. 3. A deviation or deficiency noted by an inspector/auditor during an inspection/audit. (CDISC, N2)

**Observational clinical research:** A type of study in which individuals are observed or certain outcomes are measured. There is no attempt to affect the outcome (for example, no treatment is given). Synonym: non-experimental, non-interventional research. (NACTRC, ARO)

**Observer assessment:** An assessment of patient condition made by an observer (investigator, nurse, clinician, family member, etc.). NOTE: Distinguished from self-assessment. The observer relies on his or her judgment to assess the participant. An interviewer simply capturing participant self-assessments is not making an observer assessment. (CDISC) See related "[PRO](#)", "[Proxy](#)".

**On follow-up** [*Participant status*]: Participant is no longer receiving active treatment intervention, but is still being followed (HC, ACCT)

**On protocol:** [*Participant status*]: Participant is receiving active treatment (surgery, oral or intravenous medications, respiratory therapy, etc.) / as per protocol. (HC, ACCT)

**Ongoing research:** Research that has received REB approval and has not yet been completed. (TCPS)

**Open-label study:** A trial in which participants and investigators know which product each participant is receiving; opposite of a blinded or double-blind study. (CDISC) See related "[Blinding](#)".

**Open to enrollment:** The status of a study such that a participant can be enrolled into that study. NOTE: Registry terminology in common use is "open to recruitment"; however, recruitment can begin upon IRB approval of the site; whereas enrollment requires availability of study supplies, participant informed consent, etc., to allow participation of eligible individuals. (CDISC)

**Operational approval:** Impact of the clinical study / trial on departments within an institution/organization (e.g. pharmacy, nursing, medical imaging, laboratory, etc.). (ACRC)

**Origin:** Use "[Source](#)".

**Original data:** Use "[Source data](#)".

**Outcome:** A result, condition or event associated with individual study participants, and used to assess efficacy and/or safety.

**Outcomes research** [*Method of research*]: Research studying the benefits, financial costs, healthcare system usage, risks, and quality of life as well as their relation to therapeutic interventions. (NACTRC, ARO)

**Outliers:** Values outside of an expected range. (CDISC)

**Package insert:** A leaflet that is included with a marketed pharmaceutical product. It gives prescribing information for the drug and also the contraindications and precautions which must be undertaken when using the drug. See related "[Product monograph](#)".

**Pairing:** A method by which participants are selected so that two participants with similar characteristics (for example, weight, smoking habits) are assigned to a set, but one receives Treatment A and the other

receives Treatment B. (CDISC) See related "[Matched-pair design](#)".

**Paraffin block:** formalin-fixed paraffin-embedded tissue within a cassette. (OTRN/OICR)

**Parallel study design:** A study design where participants are randomized to one treatment plan for the duration of the trial. (Weiser)

**Parallel trial:** Participants are randomized to one of two or more differing treatment groups (usually investigational product and placebo) and usually receive the assigned treatment during the entire trial. Synonyms: parallel group trial, parallel study design trial. (CDISC)

A clinical trial in which two or more groups of participants are randomized to receive different interventions. Other study conditions are similar such that the groups proceed through the trial "in parallel".

**Partial responder:** A participant who does not show a complete response to a particular drug. E.g. Many cancer study participants may be classed as partial responders when they show partial remission of their disease. (Weiser, ACRC)

**Participant:** An individual who volunteers to participate in a research study of any kind (called in other documents a subject or trial subject.) (N2)

**Participant record:** A file containing demographic and medical information about a participant, e.g. copies of a medical record, a consultation record, or a special participant file.

**Participant information:** Study-specific information given to a participant, i.e. instructions given to patients for the administration of an investigational product.

**Participant number:** the number allocated to participants taking part in a clinical study.

**Participant registry:** An organized collection of data on humans within a particular disease group or other special group (e.g., cancer, pregnancy, birth-defect, organ transplant, and serious skin disease registries). (HC) See related "[Trial registry](#)".

**Participant screening log:** A log of all participants potentially eligible for a clinical trial.

**Participatory research:** Research that includes the active involvement of those who are the subject of the research. Participatory research is usually action-oriented, where those involved in the research

process collaborate to define the research project, collect and analyze the data, produce a final product and act on the results. (TCPS2) See related "[Collaborative research](#)" and "[Community-based research](#)".

**Patient:** Person under a physician's care for a particular disease or condition. NOTE: A participant in a clinical trial is not necessarily a patient, but a patient in a clinical trial is a participant. See related "[Participant](#)", subject, trial subject, "[Healthy volunteer](#)". Although often used interchangeably as a synonym for participant, a healthy volunteer is not a patient. (CDISC)

**Patient engagement:** Meaningful and active collaboration in governance, priority setting, conducting research and knowledge translation. Depending on the context, patient-oriented research may also engage people who bring the collective voice of specific, affected communities. (CIHR)

**Patient/Participant file:** One that contains demographic, medical, and treatment information about a patient or participant, respectively. It may be paper- or computer-based or a mixture of computer and paper records. (CDISC)

**Patient-oriented research:** A continuum of research that engages patients as partners, focusses on patient-identified priorities and improves patient outcomes. This research, conducted by multidisciplinary teams in partnership with relevant stakeholders, aims to apply the knowledge generated to improve healthcare systems and practices. (CIHR)

**Patient-reported outcome (PRO):** Information coming directly from patients or participants through interviews or self-completed questionnaires or other data capture tools such as diaries about their life, health condition(s), and treatment. NOTE: PROs are used to assess outcomes involving the participants' perceptions, symptoms, satisfaction with treatment, adherence to prescribed regimens. PROs include outcomes recorded by interviewers transcribing the views expressed by the patient, but the term does not apply to outcomes recorded by observers who rely on their own judgment. A PRO is usually a subjective assessment of feeling or function distinguished from a self-reported objective measurement such as body weight. Synonym: subject-reported outcome (SRO). (CDISC) See related "[Outcome](#)", "[Patient](#)".

**Patient specimen:** Specimens collected directly from humans or animals, including but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention. (OTRN/OICR)

**PBS:** Use "[Phosphate buffered saline](#)".

**PCR:** Use "[Polymerase chain reaction](#)".

**Peer review:** The review of the study (typically a grant or publication) by other experts in the field. (ACRC)

**Pending:** Pre-study approval is being obtained. (ACCT)

**Per-protocol analysis set:** The set of data generated by the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit the effects of treatment according to the underlying scientific model. (CDISC) See related "[Intention-to-treat](#)".

**Performed activity:** Clinical trial events as they actually occurred (as compared with events planned in the protocol). (CDISC)

**Period effect:** An effect occurring during a period of a trial in which participants are observed and no treatment is administered. (CDISC)

**Permanent data:** Data that become or are intended to become part of an electronic record in relation to a regulatory submission. NOTE: Any changes made to such permanent data are recorded via an audit trail so that prior values are not obscured. (CDISC)

**Permissible values:** Limited universe of options for data items. (e.g., dropdown menus, codelists, pick lists). (CDISC)

**Personal health information:** Certain information about an individual, whether living or deceased and whether in oral or recorded form. It is information that can identify an individual and that relates to matters such as the individual's physical or mental health, the providing of health care to the individual, payments or eligibility for health care in respect of the individual, the donation by the individual of a body part or bodily substance and the individual's health number. (N2)

**Personal Health Number (PHN):** Identifier issued to Albertans who are eligible for basic coverage with the Alberta Health Care Insurance Plan. This number

is the same as the Unique Lifetime Identifier ([ULI](#)) - if applicable. (AH)

**Personal information:** Information that may reasonably be expected to identify an individual, alone or in combination with other available information. This may include name, address, age, birthdate, ethnicity, social insurance number, educational background, employment history, life experience, religion, or social status. (TCPS2)

**Personal Information Protection and Electronic Documents Act (PIPEDA):** A Canadian Federal Act (Bill C6) to support and promote electronic commerce by protecting personal information that is collected, used or disclosed in certain circumstances, by providing for the use of electronic means to communicate or record information or transactions. (N2)

**Pharmaceutical trial:** A clinical trial designed to test the safety and/or efficacy of a pharmaceutical product. (TCPS2)

**Pharmacodynamic (PD) sample:** A sample used to study the biochemical and physiological effects of drugs on the body and the mechanisms of drug action and the relationship between drug concentration and effect. (OTRN/OICR)

**Pharmacodynamics (PD):** Branch of pharmacology that studies reactions between drugs and living structures, including the physiological responses to pharmacological, biochemical, physiological, and therapeutic agents. (CDISC)

**Pharmacoeconomics:** Branch of economics that applies cost-benefit, cost-utility, cost-minimization, and cost-effectiveness analyses to assess the utility of different pharmaceutical products or to compare drug therapy to other treatments. (CDISC)

**Pharmacoepidemiology:** The study of the use of the drugs in the general population and in specific group types. (Weiser)

**Pharmacogenetic test:** An assay intended to study inter-individual variations in DNA sequence related to drug absorption and disposition or drug action. (CDISC) See related "[Pharmacogenomic test](#)".

**Pharmacogenetics:** Study of the way drugs interact with genetic makeup or the study of genetic response to a drug. (CDISC)

**Pharmacogenomic (PG) sample:** A sample used to study the effects of genetic variation on drug response in patients by correlating gene expression

or single-nucleotide polymorphisms with a drug's efficacy or toxicity. (OTRN/OICR)

**Pharmacogenomic test:** An assay intended to study inter-individual variations in whole genome or candidate gene maps, biomarkers, and alterations in gene expression or inactivation that may be correlated with pharmacological function and therapeutic response. (CDISC) See related "[Pharmacogenetic test](#)".

**Pharmacogenomics:** Science that examines inherited variations in genes that dictate drug response and explores the ways such variations can be used to predict whether a person will respond favorably, adversely, or not at all to an investigational product. (CDISC)

**Pharmacokinetic (PK) sample:** A sample used to study the mechanisms of absorption and distribution of an administered drug, the rate at which a drug action begins and the duration of the effect, the chemical changes of the substance in the body, and the effects and routes of excretion of the metabolites of the drug. (OTRN/OICR)

**Pharmacokinetics:** Study of the processes of bodily absorption, distribution, metabolism, and excretion ([ADME](#)) of medicinal products. (CDISC)

**Pharmacology:** Science that deals with the characteristics, effects, and uses of drugs and their interactions with living organisms. (CDISC)

**Pharmacovigilance:** Term used for adverse event monitoring and reporting. (CDISC)

**Phase:** One in a set of successive stages in a progression or sequence such as 1. a step in the progression of a therapy from initial experimental use in humans to post-market evaluation. 2. a stage in the conduct of a clinical trial. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. For meaning 1, see Phase 0–5. (CDISC)

**Phase 0:** First-in-human trials, in a small number of participants, that are conducted before Phase 1 trials and are intended to assess new candidate therapeutic and imaging agents. The study agent is administered at a low dose for a limited time, and there is no therapeutic or diagnostic intent. (CDISC)

**Phase 1** [*Phase of clinical research*]: (Phase 1 is sometimes written as Phase I.) Phase of clinical trials

which establish the basic clinical pharmacology (drug biochemistry or pharmacokinetics) of the drug and biological effects of the drug or device. These studies are done in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g. determine a safe dosage range, and identify side effects). (NIH)

**Phase 2** [*Phase of clinical research*]: Phase 2 is sometimes written as Phase II. Phase of clinical trials which usually involve participants who have the disease or condition under investigation. Normally participants are randomly assigned to groups or conditions, with one condition being the treatment (program, drug, etc.) under consideration, and at least one comparison condition. Phase 2 studies involve a limited number (e.g., 100-300) of closely monitored participants. These trials are done to determine how effective is the drug or device as a therapeutic agent (pharmacodynamics), and what dose of the drug is needed. (NIH)

**Phase 2A:** Controlled clinical studies that occur after the completion of Phase 1 studies and the first set of exposure-response studies in patients, and before beginning Phase 2B (i.e., patient dose-ranging trial) and Phase 3 clinical efficacy-safety studies. (CDISC)

**Phase 3** [*Phase of clinical research*]: Phase 3 is sometimes written as Phase III. Phase of clinical trials which are done to study the efficacy of the biomedical or behavioral intervention in large groups of human participants (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely. Usually, these trials involve multiple sites. (NIH)

**Phase 3B:** A subcategory of Phase 3 trials done near the time of approval to elicit additional findings. (CDISC)

**Phase 4** [*Phase of clinical research*]: Phase 4 is sometimes written as Phase IV. Phase of clinical trials which are done after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use. For example, the drug will be used in patients with additional diseases, and in patients who do not comply with the correct dosing. Post-

marketing surveillance of a new drug or device can involve 10,000 patients worldwide. Phase 4 Trials provide the most effective means of identifying and quantifying potential but rare toxic effects of new drugs, including the recognition of low frequency adverse events. (NIH)

**Phase 5:** Post-marketing surveillance is sometimes referred to as Phase 5. (CDISC) See related "[Outcomes research](#)".

**Phosphate buffered saline (PBS):** A water-based salt solution commonly used in biological research to help maintain a constant pH. (OTRN/OICR)

**Pilot [*Phase of clinical research*]:** Phase of clinical trials which are exploratory studies limited in size and scope that give insight into the actions, efficacy, and safety of a drug or device before beginning the trial. These trials cannot provide definitive support for specific mechanistic or therapeutic claims. The objectives of a clinical pilot trial typically include assessing feasibility (e.g., preliminary device performance), exploring eligibility criteria and their practical application for the pivotal randomized controlled trial, ascertaining potential harm (preliminary safety evaluations), studying drug mechanism, validating a method for determining an outcome measure, using a defined drug mechanism to validate a surrogate outcome measure, and evaluating the logistics of pivotal trial performance.

**Pilot phase:** Phase of device trial which establishes safety and assists in design of the pivotal trial.

**Pilot-testing:** In device trials, external/real-world testing.

**Pivotal phase trial:** A device trial which generates data that defines patient populations in which use of the device is safe and effective.

**Pivotal study:** A study which is conducted to GCP standards and which is subjected to intensive monitoring to ensure the validity of that study. A pivotal study provides fundamental information to the regulatory authorities about the safety and efficacy of the new drug. See related "[Supportive study](#)".

**Placebo:** A pharmaceutical preparation that contains no active agent. In blinded studies, it is generally made with the same outward physical appearance as the active product. (N2)

**Placebo-controlled:** A comparative study comparing the new drug against placebo. This may be

conducted as a parallel group or as a crossover study.

**Placebo effect:** The perceived beneficial effect of taking a placebo medication.

**Plasma:** Blood fraction remaining after red blood and white blood cells are removed from whole blood. When whole blood is fractionated, the plasma layer is usually the upper, pale yellow layer. (OTRN/OICR)

**Polymerase chain reaction (PCR):** A biochemical technology in molecular biology to amplify a single or a few copies of a piece of DNA across several orders of magnitude, generating thousands to millions of copies of a particular DNA sequence. (OTRN/OICR)

**Population:** Any finite or infinite collection of participants from which a sample is drawn for a study to obtain estimates for values that would be obtained if the entire population were sampled. (CDISC)

**Post marketing surveillance:** After a drug/device comes to market, the sponsor is responsible for monitoring and evaluating the drug for adverse events in a large number of patients.

**Post study phase:** That phase of a study which occurs after the end of the clinical phase. It includes data entry, statistical analysis, final report and publication of the study results. (Weiser)

**Power:** The power of a statistical test is a measure of a study's ability to detect a statistically significant difference between the results of the intervention group and the control group in a randomized controlled trial (RCT). A difference is considered statistically significant when it is highly unlikely to have occurred by chance. A study's power is partly determined by the size of the difference in scores between the groups, but it is also affected by how many people are included in the study and how much variation there is within each of the groups. For example, if there are too few people in the study, even a large difference may not produce a statistically significant result. (CIHR)

**Pragmatic trial:** Term used to describe a clinical study designed to examine the benefits of a product under real world conditions. (CDISC)

**Pre-clinical and Clinical Evaluation Report Template (PCERT) [*Participant status*]:** This is a submission rationale and brief summary that is required as part



of a [Clinical Trial Application \(CTA\)](#) to Health Canada. (N2)

**Preclinical studies:** Those studies done prior to human clinical trials and designed to establish information about a new drug such as absorption, distribution, metabolism, elimination and toxicity. Preclinical studies may also continue after trials in humans are underway. (Weiser) See related "[Phase](#)".

**Pre-commercial product sales (devices):** When a company sells beta or noncommercial grade products (beta) to customers for testing or for research and development purposes only. (GoA)

**Pre-market approval (PMA):** FDA evaluation of safety and effectiveness of Class III medical devices. Analogous to the drug [NDA](#).

**Pre-product testing (devices):** Pre-product testing and animal testing involve a series of experiments and modifications to the prototype to evolve the technology to commercial application. (GoA)

**Pre-screened:** Very quick surface look for potential patients (HC, ACCT)

**Pre-screening period:** The portion of the recruitment process prior to the patient/participant signing the consent form. (N2)

**Pre-study phase:** That phase of a trial which precedes the clinical phase. It comprises pre-study planning, the preparation of the study protocol, the design of the CRFs, ordering of clinical supplies, the selection and recruitment of investigators and regulatory and ethics approval. (Weiser)

**Pre-study visit:** A visit that is made to a potential site to determine whether the centre has the experience, equipment and resources to undertake a proposed clinical study. (Weiser) See related "[Site selection visit](#)".

**Prevention:** Action so as to avoid, forestall, or circumvent a happening, conclusion, or phenomenon (disease prevention). (Stedman's Medical Dictionary, 2006)

**Primary objective:** Use "[Objective](#)".

**Primary prevention:** Preventing a disease before it occurs. An example would be a healthy person with a family history of heart disease taking a blood pressure reducing medication to prevent a heart problem in the future. (CIHR) See related "[Prevention](#)", "[Secondary prevention](#)", "[Tertiary prevention](#)".

**Primary variable:** An outcome variable specified in the protocol to be of greatest importance to the primary objective of the trial, usually the one used in the sample size calculation.

**Principal investigator (PI):** The leader of a research team who is responsible for the conduct of the research, and for the actions of any member of the research team. (TCPS2) See related "[Investigator](#)" and "[Qualified investigator](#)".

**Privacy:** An individual's right to be free from intrusion or interference by others. (TCPS2)

**Privacy breach:** Involves improper or unauthorized collection, use, disclosure, retention or disposal of personal information. (GoC)

**Privacy Impact Assessment (PIA):** A process that reviews the impact a new practice (or change in practice) may have on individual privacy. This process includes an analysis of risks and the measures put in place eliminate these risks. (ACRC)

**Privacy risks:** The potential harms that participants, or the groups to which they belong, may experience from the collection, use and disclosure of personal information for research purposes. (TCPS2)

**Probability:** A measure of the chance of a particular event occurring. For example, the probability of selecting, at random, a person with a particular property from a population is simply the proportion of people in the population with that property. (Weiser)

**Procedure** [*Method of research*]: Clinical trial studying or evaluating a medical or surgical procedure. (NACTRC, ARO)

**Product monograph:** Use "[Package insert](#)".

**Prognosis:** A medical prognosis is a prediction of the course of a disease and likelihood of recovery, disability, or death, based on medical expertise. It includes factors such as the patient's medical history, the course of treatment being followed, and the statistical likelihood of the outcome of the disease in other people. (CIHR)

**Program evaluation (PE):** The systematic collection and analysis of information about program activities, characteristics, and outcomes to make judgments about the program, improve program effectiveness, and/or inform decisions about future programming. (ARECCI)



**Proper name:** C.01.001.(1) of the Food and Drug Regulations states that a "proper name" means, with reference to a drug, the name in English or French (I) assigned to the drug in section C.01.002, (ii) that appears in bold-face type for the drug in these Regulations and, where the drug is dispensed in a form other than that described in this Part the name of the dispensing form, (iii) specified in the Canadian licence in the case of drugs included in SCHEDULE C or SCHEDULE D to the Act, or (iv) assigned in any of the publications mentioned in SCHEDULE B to the Act in the case of drugs not included in subparagraphs (I), (ii) or (iii) of this paragraph. For products with multiple ingredients, there is no proper name for the product but there is a proper name for each ingredient. (HC)

**Proprietary name:** Use "[Brand name](#)".

**Prospective consent:** Consent obtained from a participant prior to initiating any research activities or interventions. Generally used for surgical/invasive studies.

**Prospective study:** A prospective study watches for outcomes, such as the development of a disease, during the study period and relates this to other factors such as suspected risk or protection factor(s).

**Protocol:** A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments. (N2)

**Protocol amendment:** A written description of a change(s) to, or formal clarification of a [protocol](#). (N2)

**Protocol deviation:** An incident involving non-compliance with the protocol that may or may not have a significant effect on the patient's rights, safety or welfare, or on the integrity of the data. NOTE: Good clinical practice recommends that deviations be summarized by site and by category as part of the report of study results so that the possible importance of the deviations to the findings of the study can be assessed. (CDISC) (N2) See related "[Protocol violation](#)".

**Protocol Safety and Efficacy Assessment Template (PSEAT):** This is a summary of safety and efficacy information completed by the sponsor in clinical trial

protocols filed with Health Canada. It replaces the [Pre-clinical and Clinical Evaluation Report Template \(PCERT\)](#). (HC)

**Protocol violation:** An event occurring in a study that is not in compliance with the protocol and for which an exception has not been approved by the sponsor. For example, the recruitment of patients into the study with ages outside the range specified in the protocol.

**Proxy (as an origin of outcome measures):** A proposed standardized qualifier variable to describe the origin of observations of the Findings class resulting from outcomes measures. Proxy describes outcome data furnished by someone other than the patient and distinguishes the origin of the outcome from a self-report ([PRO](#)) directly from the patient. NOTE: The term proxy helps qualify outcomes measures that record feelings and symptoms reported by the patient but not recorded directly. (CDISC) See related "[Observer assessment](#)".

**Proxy respondent:** Someone other than the patient who is responding about the patient on behalf of the patient, not as an observer. (CDISC) See related "[Observer assessment](#)".

**Psychometric reliability:** The degree to which a psychometric "instrument" is free from random error either by testing the homogeneity of content on multi-item tests with internal consistency evaluation or testing the degree to which the instrument yields stable scores over time. NOTE: Reliability pertains to questions concerning whether an instrument is accurate, repeatable, sensitive. Reliability is distinguished from validation, which answers whether the instrument (e.g., questionnaire) actually measure the selected "construct" (latent variable). (CDISC) See related "[Psychometric validation](#)", "[Validation](#)".

**Psychometric validation:** The specialized process of validating questionnaires used in outcomes research to show that they measure what they purport to measure. NOTE: Several types of validity are distinguished. For example, face validity means that an assessment instrument appears by inspection and consideration of the semantic content of items in it to be measuring what it is supposed to measure. Construct validity means that a scale based on one or more items measures an unobservable psychological construct (e.g., "distress") that it is proposed to measure. Construct validity is usually tested by measuring the correlation in assessments

obtained from several scales purported to measure the same construct. (CDISC) See related [“Psychometric reliability”](#), [“Validation”](#).

**Psychometrics:** The science of assessing the measurement characteristics of scales that assess human psychological characteristics. (CDISC)

**Psychotherapy trial:** A clinical trial testing the safety and/or efficacy of one or more psychotherapeutic approaches to behavioral disorders or other mental illness. (TCPS2)

**Publicly available information:** Any existing stored documentary material, records or publications, which may or may not include identifiable information, and that has no restrictions on its use or distribution, or that may be released under certain legal conditions. (TCPS2)

**Publicly declared emergency:** An emergency situation which, due to the extraordinary risks it presents, has been proclaimed as such by an authorized public office (in accordance with legislation and/or public policy). Publicly declared emergencies are extraordinary events that arise suddenly or unexpectedly, and require urgent or quick responses to minimize devastation. Examples include hurricanes and other natural disasters, large communicable disease outbreaks, catastrophic civil disorders, biohazardous releases, environmental disasters, and humanitarian emergencies. (TCPS2)

**P-value:** Study findings can also be assessed in terms of their statistical significance. The p-value represents the probability that the observed data (or a more extreme result) could have arisen by chance when the interventions did not differ. (CDISC)

**Qualified investigator (QI)** [*Type of investigator*]: The person responsible for the conduct of the clinical trial at a clinical trial site, who is entitled to provide health care under the laws of the province where the clinical trial site is located, and who is:

- In the case of a clinical trial respecting a drug to be used for dental purposes only, a physician, dentist and a member in good standing of a professional medical or dental association,
- In any other case, a physician and a member in good standing of a professional medical association. (HC)

See related [“Investigator”](#), [“Principal investigator \(PI\)”](#).

**Qualified investigator undertaking (QIU):** A post authorization form required by Health Canada which must be completed by the qualified investigator responsible for the conduct of the clinical trial at the specified site.

**Qualitative** [*Method of research*]: The purpose of a qualitative analysis is to get a range of responses on an issue from a variety of perspectives, valuing unique responses as much as consistent ones. Investigative methodologies included ethnographic, naturalistic, anthropological, field, focus groups, or participant observer research. It emphasizes the importance of looking at variables in the natural setting in which they are found. In general, qualitative research develops theory through rigor in interpretation of observations. (NACTRC, ARO, ARECCI, CIHR)

**Qualitative variable:** One that cannot be measured on a continuum and represented in quantitative relation to a scale (race or sex, for example). Data that fit into discrete categories according to their attributes. (CDISC)

**Quality assurance (QA):** A process in which activities are systematically monitored and evaluated. These planned and systematic actions are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with [good clinical practice \(GCP\)](#) and the [applicable regulatory requirement\(s\)](#). Quality Assurance can identify trends and issues through systematic monitoring. (N2, ARECCI)

**Quality control (QC):** The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled. (N2)

**Quality improvement (QI):** Projects that apply scientific methods, project management and group process tools to analyze data and improve all aspects of service delivery with particular focus on eliminating waste, reducing variation, and improving reliability. (ARECCI) See related [“Health Services Research”](#).

**Quality of life (QoL):** A broad multidimensional concept that usually includes subjective evaluations of both positive and negative aspects of life. (WHO, CDC)

**Quantitative** [*Method of research*]: Research projects that are directed by specific hypotheses or

research questions that guide the selection of the scientific design of the specific study, including the analysis methods. In general, quantitative research tests theory through the measurement of key variables. Statistical analyses applied to quantitative data define exactly how likely a result is to have occurred by chance alone, which helps the user understand how representative the results are of the population as a whole. (ARECCI, CIHR)

**Quantitative variable:** One that can be measured and reported numerically to reflect a quantity or amount, ideally on a continuum. (CDISC)

**Query:** A request for clarification on a data item collected for a clinical trial; specifically a request from a sponsor or sponsor's representative to an investigator to resolve an error or inconsistency discovered during data review. (CDISC)

**Query management:** Ongoing process of data review, discrepancy generation, and resolving errors and inconsistencies that arise in the entry and transcription of clinical trial data. (CDISC)

**Query resolution:** The closure of a query usually based on information contained in a data clarification.

**Radiopharmaceuticals:** Include drugs either of chemical or biological origin which are intentionally made radioactive for the purpose of diagnosing illness, as well as kits that are used for the preparation of radiopharmaceutical and radionuclide generators. Radiopharmaceuticals are used as diagnostic or therapeutic agents and are always prepared and administered by health care professionals; they are never self-administered.

**Random allocation:** Assignment of participants to treatment (or control) groups in an unpredictable way. NOTE: In a blinded study, assignment sequences are concealed, but available for disclosure in the event a participant has an adverse experience. (CDISC) See related "[Randomization](#)".

**Random number table:** Table of numbers with no apparent pattern used in the selection of random samples for clinical trials. (CDISC)

**Random sample:** Members of a population selected by a method designed to ensure that each person in the target group has an equal chance of selection. (CDISC)

**Randomization:** 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. (N2)

**Randomization code:** A record of the treatment that has been allocated to each patient in a study. In an emergency (e.g. if a SAE has occurred) the investigator may need to break the code to discover which treatment the patient had been receiving. See related "[Code breaker](#)".

**Randomized controlled trial/Randomized clinical trial:** A prospective experiment in which investigators randomly assign an eligible sample of patients to one or more treatment groups and a control group and follow patients' outcomes. (NICHSR)

**Raw data:** Data as originally collected. Distinct from derived. Raw data includes records of original observations, measurements, and activities (such as laboratory notes, evaluations, data recorded by automated instruments) without conclusions or interpretations. Researcher's records of participants/patients, such as patient medical charts, hospital records, X-rays, and attending physician's notes. NOTE: These records may or may not accompany an application to a Regulatory Authority, but must be kept in the researcher's file. (CDISC) See related "[eSource](#)", "[Source data](#)", "[Source documents](#)".

**Reciprocal REB review:** An official agreement between two or more institutions, in which they accept, with an agreed level of oversight, the research ethics reviews of each other's REBs. (TCPS2)

**Recruitment:** The processes and activities used to identify patients/participants for clinical trials, from a base population through to enrolment into the study. (N2)

**Recruitment log:** The form/spreadsheet used to record patient/participant pre-screening and screening activities.

**Recruitment period:** Total period of time from initiation of recruitment activities until all participants have been enrolled into a study. (N2)

**Recruitment target:** Number of patients/participants that must be recruited into a study to meet the requirements of the study protocol. (N2)

**Reference interval:** Use "[Reference ranges/Normal ranges](#)".

**Reference/Normal ranges:** The range of normal values provided by laboratories for each test. Ranges are specific to each laboratory.

**Registry:** Use "[Participant registry](#)" and "[Trial registry](#)".

**Regulatory affairs:** In the healthcare industry, a profession which has responsibility for making sure their organizations comply with regulations and laws pertaining to safety and efficacy of products, as well as working with [regulatory authorities](#) on specific issues and advising their organizations on regulatory matters.

**Regulatory authorities:** Bodies having the power to regulate. In the ICH [GCP](#) guideline the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections. (N2)

**Reimbursement:** Payment to participants to ensure that they are not put at a direct, or indirect, financial disadvantage for the time and inconvenience of participation in research. Direct expenses refer to the costs incurred, and indirect expenses refer to losses that arise, because of research participation. (TCPS2)

**Relative risk reduction:** A measure of [risk reduction](#) which answers the question "Out of X number of people, what percentage more are saved by this treatment compared to having no treatment?" (CIHR) See related "[Absolute risk reduction](#)".

**Remote data entry:** A system in which clinical data from the [CRFs](#) are entered directly into the computer or server. The CRFs and the computer data are often compared during monitoring to ensure data integrity.

**Repeat rule:** Guide for repeating activities specified in protocol, including such features as the number of cycles and the criteria for stopping. (CDISC)

**Replacement:** The act of enrolling a clinical trial participant to compensate for the withdrawal of another. (CDISC)

**Rescue/Escape medication:** The additional medication provided to a participant to treat the disease condition being studied which is not being controlled despite the use of the investigational product.

**Research:** An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation. (TCPS2)

**Research agreement:** A document that serves as a primary means of clarifying and confirming mutual expectations and, where appropriate, commitments between researchers and communities. (TCPS2)

**Research directive:** Written instructions used to express an individual's preferences for participation in future research, in the event that the individual loses capacity. It is intended to guide the individual's authorized third party in deciding whether or not to give substitute consent for the individual to participate in research. (TCPS2)

**Research ethics:** The application of ethical principles to the planning, conducting, and reporting of research.

**Research ethics approval:** The process of reviewing a study protocol plus associated materials (i.e. Participant information sheet, participant consent form, any advertisement) by a duly constituted research ethics board. The purpose of the review is to ensure that the integrity and rights of any patients participating in the study are not violated. Written confirmation of ethics approval (with clear identification of the study being approved) is required before allowing an investigator to start entering patients (or participants) into a clinical study. (Weiser)

**Research ethics board (REB):** A body that is not affiliated with the sponsor, and the principal mandate of which is to approve the initiation of, and conduct periodic reviews of biomedical research involving human participants in order to ensure the protection of their rights, safety and well-being. (N2)

#### Health Information Act designated REBs in Alberta

Health Research Ethics Board of Alberta	<a href="#">Cancer Committee</a>
	<a href="#">Community Health Committee</a>
	<a href="#">Clinical Trials Committee</a>
University of Alberta Health Research Ethics Board (HREB)	<a href="#">Biomedical Panel &amp; Health Panel</a>
University of Calgary	<a href="#">Conjoint Health Research Ethics Board (CHREB)</a>

**Research Ethics Board Attestation (REBA):** A post-authorization form required by Health Canada, which attests that the membership of this Research Ethics Board complies with the membership requirements for research ethics boards defined in Part C Division 5 of the *Food and Drug Regulations*; that the REB carries out its functions in a manner consistent with Good Clinical Practices, and that the Research Ethics Board has reviewed and approved the clinical trial protocol and informed consent form for the trial which is to be conducted by the qualified investigator at the specified clinical trial site. (HC)

**Research ethics education and training:** The provision of materials and corresponding instruction by an institution to research ethics board (REB) members or researchers with regard to the core principles and understanding of the Tri Council Policy, basic ethics standards, applicable institutional policies, and legal or regulatory requirements. This term also includes an understanding of the role and mandate of REBs and responsibilities of REB members. (TCPS2)

**Research involving partial disclosure of deception:** A type of research, in which the participant may not know that they are part of a project until it is over or is not informed of the true purpose of the research in advance. (TCPS2) Use "[Debriefing](#)".

**Research nurse:** A nurse who is involved in the research study activities. See related "[Clinical research coordinator](#)".

**Research Output:** Publications, products or services directly generated from the activities of clinical health research. (ACRC)

**Research records:** Materials recorded by or for a study to document, reconstruct, evaluate, and validate research results and events and processes leading to the acquisition of those results. Research records may include laboratory notebooks, diaries, surveys, questionnaires, interview notes, transcripts, machine-generated data, recruitment material, consent forms, correspondence, approvals, computer files, audio or video recordings, photographs including negatives, slides, x-ray films, samples, organisms and components of organisms.

**Respect for persons:** A core principle of the Tri-Council Policy that recognizes the intrinsic value of human beings and the respect and consideration that they are due. It incorporates the dual moral obligations to respect autonomy and to protect

those with developing, impaired, or diminished autonomy. (TCPS2)

**Response option:** One of several choices to be available for selection in response to a prompt, question or instruction in a [PRO](#) item. (CDISC)

**Result synopsis:** The brief report prepared by biostatisticians summarizing primary (and secondary) efficacy results and key demographic information. (CDISC)

**Retrospective:** Capture of clinical trial data is retrospective when it is recalled from memory rather than captured contemporaneously in real-time. NOTE: Retrospective capture is important in [PROs](#) because of "recall bias" and other errors documented in psychological research comparing contemporaneous self-reported assessments and those that rely on recall from memory. (CDISC)

**Retrospective consent:** Retrospective consent is obtained after the patient has undergone surgery or other invasive procedure for usual patient care. (OTRN/OICR)

**Retrospective study:** A study in which investigators select groups of patients that have already been treated and analyze data from the events experienced by these patients. These studies are subject to bias because investigators can select patient groups with known outcomes. (NICHSR)

**Ribonuclease (RNase):** A type of enzyme that catalyzes the degradation of RNA into smaller components. (OTRN/OICR)

**Risk:** The possibility of the occurrence of harm. The level of foreseeable risk posed to participants by their involvement in research is assessed by considering the magnitude or seriousness of the harm and the probability that it will occur, whether to participants or to third parties. (TCPS2)

**Risk/benefit ratio:** Assessing whether the benefits of the study intervention outweighs the risk to the participant. The risk/benefit ratio may differ depending on the condition being treated.

**Risk reduction:** A measure of how successful an intervention is, when compared to patients not receiving the intervention, in reducing the risk of a negative health outcome such as death, stroke, or bleeding. There are two measures of risk reduction – [absolute](#) and [relative](#). (CIHR)

**Route of administration:** The path by which a drug is taken into the body: oral, topical, rectum,



intravenous, intra-arterial, intradermal, intramuscular, etc. The route of administration for a particular drug will depend upon the characteristics of the compound.

**Run-in period** (of a study): Period before a clinical trial is commenced when no treatment is given. The clinical data from this stage of a trial can serve a role in screening out ineligible or non-compliant participants, ensuring that the participants are in a stable condition and in providing baseline observations.

**Safety and tolerability:** The safety of a medical product concerns the medical risk to the participant, usually assessed in a clinical trial by laboratory tests (including clinical chemistry and hematology), vital signs, clinical adverse events (diseases, signs, and symptoms), and other special safety tests (e.g., ECGs, ophthalmology). The tolerability of the medical product represents the degree to which overt adverse effects can be tolerated by the participant. (CDISC)

**Sample size:** 1. A subset of a larger population, selected for investigation to draw conclusions or make estimates about the larger population. 2. The number of participants in a clinical trial. 3. Number of participants required for primary analysis. (CDISC)

**Sample size adjustment:** An interim check conducted on blinded data to validate the sample size calculations or reevaluate the sample size. (CDISC)

**Schedule of assessments:** A tabular representation of planned protocol events and activities, in sequence. (CDISC) See related "[Study design schematic](#)".

**Scientific review:** review of a study protocol by a department or organization to ensure the trial is of high scientific merit and appropriately designed.

**Screen failure:** Potential participant who did not meet one or more criteria required for participation in a trial. (CDISC) See related "[Screening](#)".

**Screened / Consented** [*Participant status*]: Consent has been signed and patient data is being collected. (HC, ACCT)

**Screening:** 1. A process in which an investigator reviews patients for possible entry into a clinical study. If the patient is eligible for the study, he/she may be approached to participate in the study. 2. A method of [secondary prevention](#). Screening

programs check large numbers of individuals who are otherwise healthy for known symptoms before a disease is established. Screening is presently offered through programs such as mammography for breast cancer or skin examinations for melanoma. (CIHR)

**Screening (of sites):** Determining the suitability of an investigative site and personnel to participate in a clinical trial. (CDISC)

**Screening trials:** Trials conducted to detect persons with early, mild, and asymptomatic disease. (CDISC)

**Script:** A program or a sequence of instructions that are interpreted or carried out by another program or by a person.

**Secondary objective:** Use "[Objective](#)".

**Secondary prevention:** Preventing a worsening or future occurrence of a disease after evidence of the disease has already been found. An example would be a doctor removing a suspicious growth before it becomes cancerous and spreads. (CIHR) See related "[Prevention](#)", "[Primary prevention](#)", "[Tertiary prevention](#)".

**Secondary use:** The use in research of information or [human biological materials](#) originally collected for a purpose other than the current research purpose. (TCPS2)

**Security:** Measures taken to protect information. It includes physical, administrative, and technical safeguards. (TCPS2)

**Self-evident change:** A data discrepancy that can be easily and obviously resolved on the basis of existing information on the CRF (e.g., obvious spelling errors or the patient is known to be a male and a date of last pregnancy is provided). (CDISC) See related "[Query](#)".

**Senior Medical Officer (SMO):** A scientific or medical officer residing in Canada, representing the sponsor, who is responsible for providing an attestation with respect to the [Clinical Trial Application \(CTA\)](#) or [Clinical Trial Application-Amendment \(CTA-A\)](#) at the time of filing. (HC)

**Serious adverse drug reaction (SAR):** An [adverse drug reaction](#) that requires in-patient hospitalization or prolongation of existing hospitalization, that causes congenital malformation, that results in persistent or significant disability or incapacity, that is life threatening or that results in death. (N2)



**Serious adverse event (SAE):** An untoward experience that is fatal, life-threatening, disabling or which results in in-patient hospitalization or prolongation of hospitalization. In addition, congenital anomaly and occurrence of malignancy are always considered a Serious Adverse Event.

**Serious adverse experience:** Any experience that suggests a significant hazard, contra-indication, side effect or precaution. (CDISC) See related "[Serious adverse event](#)".

**Serious unexpected adverse drug reaction:** A [serious adverse drug reaction](#) that is not identified in nature, severity or frequency in the risk information set out in the investigator's brochure or on the label of the drug. (N2)

**Sex:** Phenotypic expression of chromosomal makeup that defines a study participant as male, female, or other. (CDISC) See related "[Gender](#)".

**Shall** (when used in policies such as [TCPS2](#)): Indicates a mandatory provision. (TCPS2)

**Should** (when used in policies such as [TCPS2](#)): Indicates guidance for the interpretation of the core principles. (TCPS2)

**Side effect:** Any effect that is secondary to the one that is intended resulting from therapeutic treatment or intervention. (CDISC) See related "[Adverse drug reaction](#)", "[Adverse event](#)".

**Significance level:** The probability of rejecting a true null hypothesis in a statistical test. This is usually set at the 5% level.

**Signature sheet:** Use "[Delegation log](#)".

**Single-blind study:** A study in which one party (i.e. either the patient or the investigator) is unaware of what medication the patient is taking. (Weiser)

**Single-masked study:** Use "[Single-blind study](#)".

**Site:** 1. Use "[Clinical trial site](#)". 2. Specific part of the body

**Site audit:** An audit conducted at a clinical study site. This may be conducted by the internal (i.e. the Sponsor or CRO auditor), external audit staff or inspectors from the various regulatory authorities. (Weiser)

**Site closeout:** Process of completing a clinical study at a trial site.

**Site initiation visit (SIV):** The visit at which the sponsor's monitor/CRA delivers all the clinical trial

materials to the clinical trial site. A meeting will be held with the investigator and his/her team. The sponsor CRA will ensure that everyone is familiar with the protocol, the CRFs and the study procedures. Any outstanding pre-study paperwork is collected and often at the end of the visit the investigator can begin recruitment. (Weiser)

**Site 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 a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. (CDISC) See related "[Investigator](#)".

**Site management organization (SMO):** Organization that provides clinical trial related services to a principal investigator or clinical site.

**Site number:** A unique clinical trial number that identifies the study site. This number may appear on documents (e.g. protocol, CRFs, clinical trial supplies, consent form, financial agreements, ethics and regulatory approvals, etc.).

**Site selection visit:** The process of interviewing and selecting a potential investigator about a clinical study and discussing the aims of the study and the number of participants that the investigator is expected to recruit. The time frame and the financial funding available for the study would also be discussed.

**Site visit log:** A log kept in the investigator's study file that is signed and dated by any member visiting from outside of the site clinical research staff.

**Social, cultural, environmental and population research [CIHR category of research]:** This research works to enhance the health of Canadian populations (or subpopulations, such as those from a particular region or ethnic group) by understanding how social, cultural, environmental, work-related, and economic factors affect people's health. It also involves the evaluation of certain health interventions such as the effect of tobacco control programs on populations. (CIHR)

**Soft lock:** Use "[Frozen](#)".

**Source:** 1. The specific permanent record(s) upon which a user will rely for the reconstruction and evaluation of a clinical investigation. 2. Sometimes used as shorthand for source documents and/or source data. NOTE: Accuracy, suitability, and trustworthiness are not defining attributes of "source". The term identifies records planned

(designated by the protocol) or referenced as the ones that provide the information underlying the analyses and findings of a clinical investigation. (CDISC) See related "[Certified copy](#)", "[Source data](#)".

**Source data:** All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies). (N2)

**Source data verification:** The process of ensuring that data that have been derived from source data accurately represent the [source data](#). (CDISC)

**Source documents:** Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, participants' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm, or magnetic media, x-rays, participant files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial). (N2)

**Source document verification (SDV):** Comparison of the source document with the CRF to verify the accuracy of the recorded data.

**Special populations:** Subsets of study populations of particular interest included in clinical trials to ensure that their specific characteristics are considered in interpretation of data (e.g., geriatric). (CDISC)

**Sponsor:** An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial. (ICH)

**Sponsor-investigator** [*Type of investigator*]: An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a participant. The term does not include any person other than an individual (e.g. it does not include a corporation or an agency). The obligations of sponsor-investigator include both those of a sponsor and those of an investigator. (HC)

**Staging:** Categorizing the extent or severity of a disease. Knowing the stage of disease helps determine the treatment plan and estimate prognoses.

**Standard:** Criterion or specification established by authority or consensus for 1. measuring performance or quality; 2. specifying conventions that support interchange of common materials and information. NOTE: CDISC standards exist to support the exchange of clinical data, for example, at both the syntactic and semantic levels. (CDISC)

**Standard deviation:** A statistical measure of the spread of the study data that is based on averaging the distances of the data from the mean value. It is the square root of the variance. (Weiser)

**Standard error of the mean (SEM):** The precision with which a population's mean is estimated is measured by the standard deviation of the mean. It is calculated by dividing the standard deviation by the square root of the number of participants. (Weiser, ACRC)

**Standard of care:** The treatment currently being used to treat a disease or condition that is accepted and considered to be effective.

**Standard operating procedure (SOP):** Detailed, written instructions to achieve uniformity of the performance of a specific function. (N2)

**Standard operating procedure (SOP) authorized signatory:** An investigator or research team member qualified by experience, skills and training to provide final approval of [SOPs](#). (N2)

**Standard operating procedure (SOP) committee:** A group of clinical research individuals responsible for the development, revision, review and approval of SOPs. The committee should include a [Qualified Investigator](#) and a [clinical research coordinator](#) (CRC). (N2)

**Standard treatment:** Use "[Standard of care](#)".

**Statistical method/methodology:** The particular mathematical tests and techniques that are to be used to evaluate the clinical data in a trial. (CDISC)

**Statistical plan:** The statistical analysis that is planned to be undertaken on the data collected in a clinical study. The statistical plan will be included in the statistical section of the protocol. (Weiser)

**Statistical significance:** The probability that an event or difference occurred by chance alone. The level of statistical significance depends on the number of participants studied and the observations made, as well as the magnitude of differences observed. (Weiser) See related "[p-value](#)".

**Stochastic:** Involving a random variable; involving chance or probability. (CDISC)

**Stopping rules:** Statistically significant end points and safety considerations for a clinical trial that are determined in advance, and, once reached, dictate that the trial must be terminated. (TCPS2)

**Storage requirements** (for investigational product): Outlines the specific storage conditions to which the article may be subjected.

**Stratification:** Grouping defined by important prognostic factors measured at baseline. (CDISC)

**Study:** Use "[Clinical trial](#)".

**Study arm:** One part, segment, or specific treatment group of a study. (Weiser)

**Study coordinator:** Use "Clinical research coordinator ([CRC](#))".

**Study database manual:** The repository of information concerning the study data base. (N2)

**Study design schematic:** Schematic diagram (not tabular) of study design, procedures, and stages. (CDISC) See related "[Schedule of assessments](#)".

**Study description:** Representation of key elements of study (e.g., control, blinding, gender, indication). (CDISC, ACRC)

**Study design:** A specific plan for conducting a study. Examples of various designs that can be used are; [parallel study](#), [crossover study](#), randomized study.

**Study drug:** Use "[Investigational product](#)".

**Study feasibility:** The evaluation of factors (e.g. protocol, study team, budget, operational components) involved in conducting a clinical study in a particular institution/region and assessment of probability of successfully completing the project. (ACRC)

**Study number:** A unique clinical trial number that identifies the study. This number should appear on all key documents (e.g. protocol, CRFs, clinical trial supplies, consent form, financial agreements, ethics and regulatory approvals, etc.).

**Study population:** The group of individuals in a study, defined by protocol inclusion/exclusion criteria. (ACRC)

**Study procedures manual:** A document that describes the practical guidelines for conducting a

particular clinical trial while adhering to the terms of the protocol. (Weiser)

**Study protocol:** Use "[Protocol](#)".

**Study records:** Use "[Research Record](#)".

**Study report:** A full description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human participants, in which the clinical and statistical description, presentations, and analysis are fully integrated into a single report. (ICH) See related "[Interim clinical trial report](#)".

**Study site.** Use "[Clinical trial site](#)".

**Study status:** Description of specific study stages. i.e. closed to accrual, completed. (ACCT)

**Study supplies/materials:** Use "[Clinical trial supplies](#)".

**Study treatment:** Use "[Intervention](#)".

**Sub-investigator** [Types of investigator]: A qualified member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions – usually a licensed physician, associate, resident, or research fellow. (N2)

**Sub-site:** A site that is participating in a clinical trial under the administration of the primary site.

**Subject identification code:** A unique identifier assigned to each research subject/participant to protect the participant's identity and used in lieu of the participant's name when the investigator reports adverse events and/or other trial related data. (N2)

**Subject** [*Participant status*]: Use "[Participant](#)".

**Subject-reported outcome (SRO):** Use "[Participant reported outcome \(PRO\)](#)".

**Summary of Product Characteristics (SPC):** A description of a medicinal product, in terms of its chemical/pharmaceutical characteristics and its intended use. (European) See related "[Investigator brochure](#)".

**Superiority trial:** A trial with the primary objective of showing that the response to the investigational product is superior to a comparative agent (active or placebo control). (CDISC)

**Supportive study:** A study that is not subjected to intensive monitoring. The FDA will not evaluate efficiency data from a supportive study although the

safety data will be admissible as part of a regulatory submission.

**Surrogate marker:** A surrogate endpoint or marker is some change that is easy to measure and is expected to correlate with a more meaningful endpoint, although the actual relationship between the marker and event may not be known. (CIHR)

**Surrogate variable:** A variable that provides an indirect measurement of effect in situations where direct measurement of clinical effect is not feasible or practical. (CDISC)

**Survey:** Any means (e.g., questionnaire, diary, focus group, personal interview, group of items) that is used to collect [PRO](#) data. NOTE: Survey refers to the content of the group of items and does not necessarily include the training and scoring documents generally not seen by respondents. (CDISC, ACRC)

**Suspected unexpected serious adverse reaction (SUSAR):** Use "[Serious unexpected adverse drug reaction](#)".

**Surgical trial:** A clinical trial which compares the safety and/or efficacy of different surgical techniques. (TCPS2)

**Symptoms:** Any departure from normal function or feeling felt by the patients. It is often subjective and the presence of symptoms usually prompts patients to seek a consultation with a physician.

**Synopsis:** Brief overview prepared at the conclusion of a study as a routine part of a regulatory submission, summarizing the study plan and results; includes numerical summary of efficacy and safety results, study objective, criteria for inclusion, methodology, etc. (CDISC)

**Systematic review:** A type of research study that attempts to collate all empirical evidence that fits pre-specified eligibility criteria to answer a specific research/clinical question. A systematic review uses explicit and systematic methods with the aim of minimizing bias, thus providing more reliable findings that could help with decision making. (Cochrane) See related "[Meta-analysis](#)".

**Target enrollment:** The number of participants in a class or group (including the total for the entire trial) intended to be enrolled in a trial to reach the planned sample size. Target enrollments are set so that statistical and scientific objectives of a trial will have a likelihood of being met as determined by

agreement, algorithm, or other specified process. (CDISC)

**Target study population:** Demographic and health condition of the population to be included in a clinical study. (CDISC)

**Technology assessment** [*Method of research*]: [Clinical research](#) studying or evaluating new technologies (for example; medical equipment, biologic specimen/sample or testing with no direct patient contact). Biologic specimens and samples are/can be obtained from human participants. (NACTRC)

**Terminated** [*Study status*]: Trial is closed prior to anticipated end date. (ACCT)

**Termination of a study:** Premature discontinuation of a trial prior to plan. (CDISC)

**Termination/withdrawal of a study participant** [*Participant status*]: The participants who are withdrawn from a clinical study by the investigator due to the presence of intolerable adverse effects, lack of efficacy or poor compliance with the study protocol, development of any exclusion criteria (e.g. pregnancy or an intercurrent illness which affects the study), study has been terminated for safety reasons or lack of efficacy. Participants who are withdrawn may be replaced by new patients to ensure that the correct numbers of patients are entered into the study; must be specified in the protocol sample size. (Weiser, ACRC) See related "[Discontinuation](#)".

**Tertiary prevention:** Treatment for an ongoing disease. This type of prevention could include reducing the effect of symptoms, slowing the progress of the disease, or taking steps to cure the disease. (CIHR) See related "[Prevention](#)", "[Primary prevention](#)", "[Secondary prevention](#)".

**Therapeutic intervention:** Use "[Intervention](#)".

**Therapeutics Product Directorate (TPD):** When a product is offered for sale in Canada to treat or prevent diseases or symptoms, it is regulated as a drug under the Food and Drugs Act. Health Canada's TPD is responsible for evaluating and monitoring the safety, effectiveness and quality of pharmaceutical drugs and other therapeutic products available to Canadians. Health Canada's Therapeutic Products Directorate is the Canadian federal authority that regulates pharmaceutical drugs and medical devices for human use. Prior to being given market authorization, a manufacturer must present

substantive scientific evidence of a product's safety, efficacy and quality as required by the Food and Drugs Act and Regulations. (N2)

**Therapeutic misconception:** A misunderstanding, on the part of participants, of the purpose, benefits, and/or risks of clinical trials. Often participants do not understand that research is aimed primarily at producing knowledge and may not provide any therapeutic benefit to them. (TCPS2)

**Therapeutic window/therapeutic ratio:** This term applies to the difference between the minimum and the maximum doses that may be given to a patient to obtain an adequate clinical response while avoiding unacceptable toxic effects. (Weiser)

**Tissue micro array (TMA):** Consists of paraffin blocks in which up to 1000 separate tissue cores are assembled in array fashion to allow multiplex histological analysis, such as immunohistochemistry and fluorescent in situ hybridization. (OTRN/OICR)

**Tissue processor:** Mechanical device that facilitates processing of formalin-fixed tissue by embedding in paraffin. It automatically removes the water from formalin-fixed tissues and replaces it with a series of solutions resulting in the impregnation of the tissue with paraffin wax. The firmness of the paraffin wax enables the tissue to be sectioned into microscope slides. (OTRN/OICR)

**Tolerability:** The ability of a participant to tolerate any intervention for the duration of the period of the study.

**Tolerance:** A reduction in the therapeutic response to a drug in a patient who has been treated continuously with the medication. This should not be confused with tolerability. (Weiser)

**Topic:** In relation to research classification, a specific concentration in the field of application. (CASRAI)

**Toxicity:** Any adverse effect produced by a drug that is detrimental to the patient's health. The level of toxicity associated with a drug will vary depending on the condition that the drug is used to treat. (Weiser)

**Toxicology:** The study of the toxic pharmacology of a compound. (Weiser)

**Traditional knowledge:** The knowledge held by First Nations, Inuit and Metis peoples, the Aboriginal peoples of Canada. Traditional knowledge is specific to place, usually transmitted orally, and rooted in the experience of multiple generations. It is

determined by an Aboriginal community's land, environment, region, culture and language. It may also refer to new knowledge transmitted to subsequent generations. (TCPS2)

**Transcription:** Process of transforming dictated or otherwise documented information from one storage medium to another. NOTE: often refers explicitly to data that is manually transcribed from source docs or measuring devices to CRFs or to eCRFs. (CDISC)

**Translation:** Converting information from one natural language to another while preserving meaning. Compare with mapping. (CDISC)

**Translational research:** A process of transforming scientific discoveries found in the laboratory, or through clinical and population studies, into interventions or treatments that will reduce morbidity and mortality from disease as well as provide prevention programs to improve the health of the general population. It includes two interrelated processes:

- Bench and preclinical studies that inform and shape studies and trials in humans
- Studies and trials in humans that leads to adoption of best practices in clinical practice and in the community including cost-effectiveness of prevention and treatment strategies.

Translational research can be defined through its operational areas T0-T4. (Blumberg, 2012)

T0 Research incorporates a broad area of pre-clinical approaches designed to inform an investigator about a pathway, pathophysiology, or treatment approach. (Basic and applied science research.)

T1 Research translates discoveries made at the bench to first testing in humans. (Phase 1 and 2 clinical trials).

T2 Research is the second phase of the translation process and builds on the clinical efficacy work conducted in the first phase of the translation process (T1). (Phase 2 and 3 clinical trials.)

T3 Research is the third phase of the translation process and builds on the clinical efficacy work conducted in the second phase of the translation process (T2). It translates results from T2 research into clinical practice. (Phase 4 clinical trials.)

T4 Research is the fourth phase of the translation process and builds on the results of third phase of



the translation process (T3). T4 Research will help identify the best approach to reach clinicians and patients nationwide so that they not only understand the new treatment but will start to use it. (Tufts)

**Transmit:** To transfer data, usually electronically.  
NOTE: In eClinical investigations data are commonly transmitted from participants to clinical study sites, within or among clinical study sites, contract research organizations, data management centers, and sponsors, or to regulatory authorities. (CDISC)

**Treatment effect:** An effect attributed to a treatment in a clinical trial. In most clinical trials the treatment effect of interest is a comparison (or contrast) of two or more treatments. (CDISC)

**Treatment-emergent adverse event:** An event that emerges during treatment, having been absent pretreatment, or worsens relative to the pretreatment state. (CDISC)

**Treatment group:** The group of participants receiving the experimental treatment regime. (Weiser)

**Trial coordinator:** Use "[Clinical research coordinator](#)".

**Trial design model:** Defines a standard structure for representing the planned sequence of events and the treatment plan of a trial. (CDISC) See related "[Study design](#)".

**Trial master file (TMF):** A file containing the essential documents for the operation of a clinical trial. A TMF should be kept on file at the investigator/institution's site and at the sponsor's office (ICH-GCP). (Weiser)

**Trial registry:** A data bank containing information about each trial sufficient to inform interested participants (and their healthcare practitioners) how to enroll in the trial. (CDISC) See related "[Participant registry](#)".

**Trial statistician:** A statistician who has a combination of education/ training and experience sufficient to implement the principles in the ICH E9 guidance and who is responsible for the statistical aspects of the trial. (CDISC)

**Trial subject:** Use "[Participant](#)".

**Tri-Council Policy Statement (TCPS2):** The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS or the Policy) is a

joint policy of Canada's three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC), or "the Agencies". The Agencies have adopted the TCPS2 as a benchmark for the ethical conduct of research involving humans. As a condition of funding, the Agencies require that researchers and their institutions apply the ethical principles and the articles of this Policy and be guided by the application sections of the articles. (TCPS2)

**Triple-blind study:** A study in which knowledge of the treatment assignment(s) is concealed from the people who organize and analyze the data of a study as well as from participants and investigators. (CDISC)

**T-test:** A statistical test used to compare the means of two groups of test data. (CDISC)

**Type 1 error:** The error of rejecting the null hypothesis when it is actually true. Synonym: false positive. (CDISC).

**Type 2 error:** The error of not rejecting the null hypothesis when the alternate hypothesis is true. Synonym: false negative.

**Type 3 (or Type III) error:** Some statisticians use this designation for an error made when calling the less effective treatment the more effective one. (CDISC)

**Type of comparison:** How treatment arms will be compared (e.g., Safety, Efficacy, PK/PD). May also include comparison to data from other studies or sources (e.g., historical control). (CDISC)

**Unanticipated issues:** Issues that: occur during the conduct of research; may increase the level of risk to participants or have other ethical implications that may affect participants' welfare; and were not anticipated by the researcher in the research proposal submitted for research ethics review. (TCPS2)

**Unblinding:** Identification of the treatment code of a participant or grouped results in studies where the treatment assignment is unknown to the participant and investigators. (CDISC)

**Uncontrolled clinical trial:** When there is no control arm to a study against which to compare the investigational treatment arm. (Weiser)



**Undue influence:** The impact of an unequal power relationship on the voluntariness of consent. This may occur when prospective participants are recruited by individuals in a position of authority over them (e.g. doctor/patient, teacher/student; employer; employee). (TCPS2)

**Unexpected adverse drug reaction:** An [adverse drug reaction or event](#), the nature or severity of which is not consistent with the applicable product information (e.g., [Investigator brochure](#) for an unapproved investigational product or package insert/summary of product characteristics, e.g. Product Monograph for an approved product). (N2)

**Unexpected serious risk:** A serious adverse drug experience that is not listed in the labeling of a drug, or that may be symptomatically or pathophysiologically related to an adverse drug experience identified in the labeling, but differs because of greater severity, specificity, or prevalence. (CDISC)

**Unique Lifetime Identifier (ULI):** A unique and permanent number assigned to all persons who receive Health Services in Alberta. Unique Lifetime Identifiers are assigned to all Alberta residents, residents of other provinces/territories or other countries. This number changes to a Personal Health Number ([PHN](#)) when patients have Alberta Health Insurance Plan coverage. (AH, AHS)

**User acceptance testing (UAT):** A formal means by which one verifies that the system meets the required business functions by emulating normal use conditions. (N2)

**User site testing (UST):** Any testing that takes place outside of the developer's controlled environment. NOTE: Terms such as beta test, site validation, user acceptance test, installation verification, and installation testing have all been used to describe user site testing. User site testing encompasses all of these and any other testing that takes place outside of the developer's controlled environment. (CDISC)

**Validation:** 1. Process of establishing suitability to purpose. 2. For software and systems, establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes. NOTE: Validation is accomplished by planning how to measure and/or evaluate suitability to purpose; then executing the plan and documenting the results. (CDISC)

**Validation of computerized systems:** A process of establishing and documenting that the specified requirements of a computerized system can be consistently fulfilled from design until decommissioning of the system or transition to a new system. The approach to validation should be based on a risk assessment that takes into consideration the intended use of the system and the potential of the system to affect human participant protection and reliability of trial results. (ICH E6[R2])

**Validation of data:** 1. A process used to determine if data are inaccurate, incomplete, or unreasonable. The process may include format checks, completeness checks, check key tests, reasonableness checks and limit checks. 2. The checking of data for correctness or compliance with applicable standards, rules, and conventions. NOTE: Meaning 1 is not "data verification" but meaning 2 could be. (CDISC) See related "[Source document verification](#)".

**Validity:** Use "[Validation](#)".

**Variable:** 1. Any entity that varies; any attribute, phenomenon, or event that can have different qualitative or quantitative values. (CDISC) See related "[Analysis variables](#)", "[Endpoint](#)".

**Variance:** The measure of the spread of a distribution about its expected value.

**Verification:** 1. The act of reviewing, inspecting, testing, checking, auditing, or otherwise establishing and documenting whether items, processes, services, or documents conform to specified requirements. 2. (of software). Provides objective evidence that the design outputs of a particular phase of the software development life cycle meet all of the specified requirements for that phase. NOTE: 2. Software verification looks for consistency, completeness, and correctness of the software and its supporting documentation, as it is being developed, and provides support for a subsequent conclusion that software is validated. Verification is used in the sense of matching elements of a report or results of system testing to individual requirements. (CDISC) See related "[Validation](#)" where suitability to purpose is also established.

**Verification of data:** Use "[Source document verification \(SDV\)](#)", "[Data verification](#)".

**Violation:** Use "[Protocol deviation](#)".

**Visit:** A clinical encounter that encompasses planned and unplanned trial interventions, procedures, and assessments that may be performed on a participant. A visit has a start and an end, each described with a rule. (CDISC)

**Vulnerable subjects:** Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent. (N2)

**Vulnerability:** A diminished ability to fully safeguard one's own interests in the context of a specific research project. This may be caused by limited capacity or limited access to social goods, such as rights, opportunities and power. Individuals or groups may experience vulnerability to different degrees and at different times, depending on their circumstances. (TCPS2) See related "[Autonomy](#)".

**Warning Letter:** A written communication from FDA notifying an individual or firm that the agency considers one or more products, practices, processes, or other activities to be in violation of the Federal FD&C Act, or other acts, and that failure of the responsible party to take appropriate and prompt action to correct and prevent any future repeat of the violation may result in administrative and/or regulatory enforcement action without further notice. (CDISC)

**Wash-out period:** A period in a clinical study during which participants receive no treatment for the indication under study and the effects of a previous treatment are eliminated (or assumed to be eliminated). (CDISC)

**Welfare:** The quality of a person's experience of life in all its aspects. Welfare consists of the impact on individuals and/or groups of factors such as their

physical, mental and spiritual health, as well as their physical, economic and social circumstances. (TCPS2)

**Withdrawal:** The participant-initiated act of discontinuing participation in a clinical study. NOTE: Withdrawal can range from the participant's complete withdrawal from study procedures and follow-up activities, to the participant's withdrawal from study-related interventions while the participant permits continued access to his/her medical records or identifiable information. Note that according to FDA regulations, when a participant withdraws from a study, the data collected on the participant to the point of withdrawal remain part of the study database and may not be removed. (CDISC) See related "[Discontinuation](#)".

**Weighting:** An adjustment in a value based on scientific observations within the data. (CDISC)

**Well-being (of the trial participants):** The physical and mental integrity of the participants in a clinical trial. (CDISC)

**WHO Drug Dictionary:** An international classification of medicines created by the WHO Programme for International Drug Monitoring that is used by pharmaceutical companies, clinical trial organizations, and drug regulatory authorities for identifying drug names in spontaneous Adverse Drug Reaction reporting and pharmacovigilance in clinical trials. (OTRN/OICR)

**Withdrawn [Study status]:** Site withdraws participation in a study. (ACCT)

**Workplace hazardous material information system (WHMIS):** Canada's national hazard communication standard. (HC)

## BIBLIOGRAPHY

Blumberg, R. S. (2012). Unraveling the Autoimmune Translational Research Process Layer by Layer. *Nature Medicine*, 35-41.

Fletcher, R. H., Fletcher, S. W., & Wagner, E. H. (1996). *Clinical Epidemiology The Essentials*. Philadelphia: Lippincott Williams & Wilkins.

Guyatt, G., & Rennie, D. (2002). *Users' Guides to the Medical Literature: A Manual for Evidence-based Clinical Practice*. Chicago: AMA.

*McGraw-Hill Concise Dictionary of Modern Medicine*. (2002). Retrieved December 15, 2015, from <http://medical-dictionary.thefreedictionary.com/experiment>

Spiegelhalter, D., & Rice, K. (2009). *Bayesian statistics*. Retrieved 12 15, 2015, from Scholarpedia: [http://www.scholarpedia.org/article/Bayesian\\_statistics](http://www.scholarpedia.org/article/Bayesian_statistics)

*Stedman's Medical Dictionary*. (2006). Lippincott Williams & Wilkins.

**TABLE 1: COMPARISON OF CLINICAL RESEARCH AND TRIAL DEFINITIONS**

	National Institute of Health (NIH)	Tri-Council Policy Statement – 2 <sup>nd</sup> Edition (TCPS2)	World Health Organization (WHO)
<b>Clinical Research</b>	<p>Research with human subjects that is:</p> <ol style="list-style-type: none"> <li>1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: <ul style="list-style-type: none"> <li>o mechanisms of human disease</li> <li>o therapeutic interventions</li> <li>o clinical trials</li> <li>o development of new technologies</li> </ul> </li> <li>2. Epidemiological and behavioral studies.</li> <li>3. Outcomes research and health services research.</li> </ol> <p>Studies falling under 45 CFR part 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition.</p>		
<b>Clinical Trial</b>	<p>A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective.</p> <p>Biomedical clinical trials of an experimental drug, treatment, device, or behavioral intervention may proceed through four phases:</p> <p><b>Phase I.</b> Tests a new biomedical intervention in a small group of people (e.g. 20-80) for the first time to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects).</p> <p><b>Phase II.</b> Study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and further evaluate safety.</p> <p><b>Phase III.</b> Study to determine efficacy of the biomedical or behavioral intervention in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely.</p> <p><b>Phase IV.</b> Studies conducted after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.</p>	Any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes.	Any research project that prospectively assigns human participants or groups to one or more health-related interventions to evaluate the effects on health outcomes.