Glossary of Terms

ACRONYMS

English Acronyms	Significations/Meaning
ADR	Adverse Drug Reaction
AE	Adverse Event
CAPA	Corrective and Preventive Action
C.c	Code civil du Québec
CDISC	Clinical Data Interchange Standards
CRF	Case Report Form
CRO	Contract Research Organization
CTD	Common Technical Document
CTSI	Clinical Trial Site Information Form
DMP	Data Management Plan
DMS	Data Management System
DSMB	Data Safety Monitoring Board
FDA	Food & Drug Administration (US)
GCP	Good Clinical Practices
HPFB	Health Products & Food Branch
ICF	Informed Consent Form
ICH	International Council for Harmonisation
IDMC	Independent Data-Monitoring Committee
IEC	Independent Ethics Committee
IRB	Institutional Review Board
ITA	Investigational Testing Authorization
IVDD	*In vitro* diagnostic device

English Acronyms	Significations/Meaning
IVRS/IWRS	Interactive Voice/Web Response System
LAR	Legally Authorized Representative
MDR	Medical Device Regulations
NHP	Natural Health Product
OM	Operating Manual
REB	Research Ethics Board
ROEB	Regulatory Operations and Enforcement Branch
SADR	Serious Adverse Drug Reaction
SDM	Substitute Decision Maker
SOPs	Standard Operating Procedures
TCPS	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

Acronymes français	Significations/Meaning
ACEP	Action Corrective et Preventive
BPC	Bonnes pratiques cliniques
C.c	Code civil du Québec
CCDS	Comité de controle de données de sécurité
CEE	Comité d’examen de l’établissement
CEI	Comité d’éthique indépendant
CER	Comité d’éthique à la recherche
CICD	Comité indépendant de contrôle des données
CIH	Conseil internationale sur l’harmonisation
DGPSA	Direction générale des produits de santé et des aliments

Acronymes français	Significations/Meaning
EPTC	Énoncé de politique des trois Conseils: Éthique de la recherché avec des êtres humains
FCE	Formulaire de consentement éclairé
FEC	Formulaire d'exposé de cas
FRSQ	Fonds de la recherche en santé du Québec
IDIV	instrument diagnostique *in vitro*
IT	Incident thérapeutique
L.S.S.S.S.	Loi sur les services de santé et les services sociaux
MON	Mode opératoire normalize
ORC	Organisme de recherche sous contrat
RIM	Réaction indésirable à un médicament
RIGM	Réaction indésirable grave à un médicament

GLOSSARY OF TERMS

Whenever possible, definitions are taken directly, or derived from, official sources such as ICH, Health Canada regulations, FDA regulations, Tri-Council guidelines, PIPEDA, etc.

Adverse Drug Reaction (ADR): In the pre-approval clinical experience with a new medicinal/natural health 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/natural health product 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. Marketed medicinal/natural health products: a response to a drug/natural health product 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.
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 (AE) can therefore be any unfavourable 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.
Annotation (of the CRF/eCRF): A representation of the variables and tables in the paper CRF or data entry screens.
Applicable Guidance: Any guidance or policies addressing the conduct of human participant research (e.g., ICH GCP, etc.). Ethics guidance addresses ethical oversight of human participant research (e.g., TCPS, etc.).
Applicable Regulatory Requirements: Any laws and or regulations addressing the conduct of clinical trials of investigational products.
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.
Approval (in relation to Research Ethics Boards (REBs)): The affirmative decision of the REB that the trial has been reviewed and may be conducted at the institution site within the constraints set forth by the REB, the institution, Good Clinical Practice (GCP), and the applicable regulatory requirements.

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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).
Audit Certificate: A declaration of confirmation by the auditor that an audit has taken place.
Audit Report: A written evaluation by the sponsor's auditor of the results of the audit.
Audit Trail: Documentation that allows reconstruction of the course of events.
Authorized Third Party: An individual who may consent on behalf of a participant who is not competent to provide their own consent. This may include a legally authorized representative (LAR) or a substitute decision maker (SDM).
Bioanalysis: The measurement of a drug level in a biological sample. Bioanalysis quantifies the drug and its major metabolites in samples collected from cell culture media, plasma, serum, urine, or other human biological matrix.
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, certain hormones, and enzymes, recombinant DNA products, gene therapies, and transgenics. Biologics make up one large category of drugs; the other major category of drugs is pharmaceuticals - synthetic drugs made from chemicals.
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)
Biological Sampling: Collecting, processing and analyzing of biological samples.
Blinding/Masking: A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the participant (s) being unaware, and double-blinding usually refers to the participant(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

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Calibration: A set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards. a) The result of a calibration permits either the assignment of values of measure and adds to the indications or the determination of corrections with respect to indications. b) A calibration may also determine other metrological properties such as the effect of influence quantities. **c)** The result of a calibration may be recorded in a document, sometimes called a calibration certificate or a calibration report.
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.
Causality/Attribution Assessment: In the case of clinical studies with an investigational product, the investigator determines, according to their clinical judgment, if there is a reasonable doubt as to causal relationship. Attribution may be related, not related, or unknown. Adverse events that have been judged to have at least a possible relationship with the investigational product are called Adverse Reactions (ARs).
Certified Copy: A paper or electronic copy of the original record that has been verified (e.g., by a dated signature) or has been generated through a validated process to produce an exact copy having all of the same attributes and information as the original.
Certified Translator/Interpreter: an individual who has knowledge of a language, based on being a native speaker and/or extensive training/experience in using the specified language(s), especially in the required area (e.g., medical terminology), and who has a certification/designation, as granted by the provincial regulatory bodies for these professions. This is not the same as a qualified translator or qualified interpreter, who has no professional title/designation.
Clean Database (or File): A database from which errors have been eliminated.

Clinical hold: An order issued by FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. The clinical hold order may apply to one or more of the investigations covered by an IND. When a proposed study is placed on clinical hold, participants may not be given the investigational drug. When an ongoing study is placed on clinical hold, no new participants may be recruited to the study and placed on the investigational drug; patients already in the study should be taken off therapy involving the investigational drug unless specifically permitted by FDA in the interest of patient safety.
Clinical Research: A systematic investigation to establish facts, principles or generalizable knowledge involving living human participants, human remains, cadavers, tissues, biological fluids, embryos or foetuses.
Clinical Research Associate (CRA): Also called a monitor. Person employed by the sponsor, or by a contract research organization (CRO) acting on a sponsor's behalf, who is responsible for determining that a trial is being conducted in accordance with the protocol at the site. 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 site's clinical research coordinator (CRC) to review all data and documentation pertinent to the trial.
Clinical Research Coordinator (CRC)/Clinical Research Personnel (CRP): A nurse, health professional, or other qualified clinical research team member who handles most of the administrative responsibilities and day-to-day activities of a clinical trial. The CRC acts as liaison between the investigative site and the sponsor, and ensures review of all data and records before a monitor's visit and performs designated participant assessments. Synonyms: trial coordinator, study coordinator, research coordinator, clinical coordinator, research nurse, protocol nurse.
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.
Clinical Study Agreement (CSA)/Clinical Trial Agreement (CTA): See Contract
Clinical Study Materials: Complete set of supplies provided to an investigator by the study sponsor.
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.

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Clinical Trial Application (CTA): An application to Health Canada for approval to run a clinical trial according to Divisions 5 of the Food and Drug Regulations Amendment.
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).
Clinical Trial/Study: Any investigation in human participants intended to discover or verify the clinical, pharmacological and/ or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous. Note: A clinical study may also involve a device, observation, questionnaires, interviews or diagnostic tests.
Clinical Trial Site Information Form (CTSI): Required by clinical trial sponsors prior to initiating a protocol or protocol amendment at a clinical trial site. There is one site per form.
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*)
Common Technical Document (CTD): Standard format prescribed by ICH for the submission of information to regulatory authorities.
Comparator (Product): An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical study.
Compliance (in relation to studies): Adherence to all the study-related requirements, Good Clinical Practice (GCP) guidelines, and the applicable regulatory requirements.

Computer system: The term computer system applies to 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.
Confidentiality: Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a participant's identity.
Consent: See Informed Consent
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. Also known as Clinical Trial Agreement (CTA). The protocol may serve as the basis of a 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.
Coordinating Committee: A committee that a sponsor may organize to coordinate the conduct of a multicentre study.
Coordinating Investigator: An investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre study.
Corrective and Preventive Action (CAPA): A series of actions taken to resolve a compliance issue and to prevent recurrence. First step is to identify the issue, then correct it and finally prevent it from occurring again.
Corrective maintenance: It is sometimes called "repair" or "condition-based maintenance," and is conducted to get equipment working again.
Dangerous Goods Safety Mark: This 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.
Database: The term 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.
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.

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Database set-up: A collection of software data fields defined within a database structure and set-up according to the requirements of the DMP, study protocol and CRF/eCRF.
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.
Data dictionary: The repository for all the information, relationships and formats required for creating and maintaining data collection, validation, usage and extraction operations.
Data Safety Monitoring Board (DSMB): See Independent Monitoring Committee
Diagnostic Specimen: Human material, including excreta, secreta, blood and its components, tissue and tissue fluids, that is offered for transport or transported.
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.
Direct identifiers: 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*)
Dirty Database (or File): A database from which errors have not been eliminated.
Disclosure: To make the information available or to release it to another Health Information Custodian or to another person.
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.
Drug (Investigational Product): A drug for human use that is to be tested in a clinical study.
Drug (Investigational Product) 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).

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Drug Identification Number (DIN): A number assigned by Health Canada to a drug product prior to being marketed in Canada.
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. For example, time-of-entry edit checks are 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 are run against data that has been entered or captured electronically and has also been received by a centralized data store. (*CDISC*)
Electronic Signature: (aka, numeric 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.
Essential Documents: Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.
Exclusion Criteria: A list of criteria, any one of which, [if crossed], excludes a potential study participant from participation in a study. Also see inclusion criteria.
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.
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.
Good Documentation Practice (GDP): A standard for the effective control and management of documentation following the guidance of ALCOA+ principles: Attribuable, Legible, Contemporaneous, Original, Accurate. (+= Complete, Consistent, Enduring and Available).
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).
Health Canada (HC/SC): Federal government agency that oversees health and food products.

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.
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*)
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.
Importer (medical device): A person other than the manufacturer of a device whose establishment is in Canada, who causes the medical device to be brought into Canada from foreign manufacturers or distributors, for sale in Canada.
Inclusion Criteria: The criteria that prospective study participants must meet to be eligible for participation in a study. See also exclusion criteria.
Independent Data-Monitoring Committee (IDMC): Also called Data and Safety Monitoring Board, Monitoring Committee, Data Monitoring Committee. An independent data-monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical study, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a study.
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*)
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. (Examples: micro-organisms such as bacteria, viruses, parasites, or fungi)

Informed Consent: A process by which a participant voluntarily confirms their 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.
Informed Consent Form (ICF): (also called a consent form) 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.
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). Note: Some regulatory agencies and regulations (particularly FDA), may use 'audit', and particularly 'inspection' or "investigation" in a broader sense, or interchangeably.
Institution (medical): Any public or private entity or agency or medical or dental facility where clinical trials are conducted.
Interactive Voice/Web Response System: System that can be accessed via telephone or web for clinical trial site staff to obtain screening numbers, randomization numbers and assignment of IP. The system allows sponsors to proactively manage the enrollment, randomization, dosing, IP inventory, unblinding etc.
Interim Clinical Trial/Study Report: A report of intermediate results and their evaluation, based on analyses performed during the course of a trial.
International Council for Harmonization (ICH): ICH is 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. They develop ICH guidelines. Mission is to achieve greater harmonisation worldwide to ensure that safe, effective and high quality medicines are developed, registered and maintained in the most resource efficient manner whilst meeting high standards.
Interpreter: Interpreters and translators perform similar tasks, but in different settings. While an interpreter converts any spoken material from one language (the source language) into a different language (the target language), a translator converts written material in the same manner.

Investigational Product: Also known as study drug or study medical device or study natural health product. A pharmaceutical form of an active ingredient or placebo, or a medical device, or a natural health product, 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.
Investigational Product Accountability: The process of being responsible for the investigational product by following safe pharmaceutical/medical device/natural health product practices. The investigator is responsible for investigational product(s) accountability at the study site(s).
Investigational Testing Authorization (ITA): Required for all unlicensed class II, III and IV medical devices that will be imported and/or sold in Canada for the purpose of investigational testing involving humans.
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 or qualified investigator.
Investigator Brochure (IB): 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.
Investigator-Initiated Study: A research study that is developed, initiated and conducted by an investigator. The obligations of the investigator in this case include both those of a sponsor and those of an investigator.
Investigator-Sponsored Trial (medical device): Where an investigation is initiated by a clinician or health care facility, not the device manufacturer, this is considered an investigator-sponsored trial. In this case, the data generated in the investigation are not intended to support a licence application or a new marketing claim.
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.
***in vitro* diagnostic device (IVDD):** A medical device that is intended to be used *in vitro* for the examination of specimens taken from the body.
Legally Acceptable Representative (LAR): 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.

Manufacturer (medical device): A person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.
Manufacturer-Sponsored Trial (medical device): A clinical investigation initiated by the manufacturer, that involves either an unlicensed device, or a licensed device with unlicensed indications.
Material Safety Data Sheets (MSDS): Printed material that provides detailed hazard and precautionary information about hazardous materials.
Medical Device: A device within the meaning of the Food and Drugs Act, but does not include any device that is intended for use in relation to animals.
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).
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.
Multicentre 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.
Natural Health Product: As defined by Health Canada Natural Health Products regulations, Interpretation and Part 4 Clinical Trials involving Human participants.
Nonclinical Study: Biomedical studies not performed on human participants. (ICH GCP 1.41)
Non-therapeutic Trial: A trial in which there is no anticipated direct clinical benefit to the participant.
No Objection Letter (NOL): A letter issued by Health Canada when a Clinical Trial Application has been deemed satisfactory.
Notice of Compliance (NOC): A Notice of Compliance is a notification issued to a manufacturer following the satisfactory review of a submission. (Health Canada Web Site)

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.
Numeric Signature: (aka, 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)
Observation (i.e., audit observation): A deviation or deficiency noted by an inspector/auditor during an inspection/audit.
Operating Manual (OM): A manual issued by the manufacturer usually accompanying a technical device explaining how to install, operate and maintain the equipment and manufacturer's contact information.
Participant (or Trial/Study Participant): An individual (patient or healthy volunteer, if applicable) who participates in a clinical study, either as a recipient of the investigational product(s) or as a control. (The terms study patient, study participant, and research participant are sometimes used interchangeably).
Participant Identification Code: A unique identifier assigned to each research 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.
Pharmaceutical Drugs Directorate (PDD): Formerly the Therapeutic Products Directorate (TPD). Canada's regulator of prescription pharmaceutical drugs for human use. 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 PDD is responsible for evaluating and monitoring the safety, effectiveness and quality of pharmaceutical drugs and other therapeutic products available to Canadians. Health Canada's PDD 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
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.
Pre-approval Inspection (PAI): FDA inspection carried out during New Drug Application (NDA) review, usually to confirm data validity.
Pre-clinical and Clinical Evaluation Report Template (PCERT): This is a submission rationale and brief summary that is required as part of a Clinical Trial Application (CTA) to Health Canada.

Pre-Screening Period: The portion of the recruitment process prior to the patient/participant signing the consent form.

Preventive (Preventative) Maintenance: The institution (Qualified Investigator/Sponsor) shall determine, provide, and maintain the infrastructure needed to achieve conformity to product requirements which includes process equipment. Preventative maintenance of process equipment can be described as maintenance of equipment or systems before fault occurs. It can be divided into two subgroups:

- Planned maintenance and
- Condition-based maintenance.

The main difference between subgroups is determination of maintenance time or moment when maintenance should be performed. Preventative maintenance is conducted to keep equipment working and/or extend the life of the equipment.

Principal Investigator (PI): See “Investigator” and “Qualified Investigator”; primarily US terminology.

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.

Protocol Amendment: A written description of a change(s) to or formal clarification of a protocol.

Protocol Deviation/Violation: 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.

Qualified Investigator (QI): (as defined by Health Canada) The person responsible to the sponsor 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 that 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 or 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.

There can only be one QI per study per Canadian study site.

Qualified Translator/Interpreter: an individual who has knowledge of a language, based on being a native speaker and/or extensive experience in using the specified language(s), especially in the required area (e.g., medical terminology). This is not the same as a certified translator or certified interpreter, whose title/designation is granted by the provincial regulatory bodies for these professions.
Quality Assurance (QA): All those planned and systematic actions that 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 requirements(s).
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.
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.
Recruitment: The processes and activities used to identify patients/participants for clinical trials, from a base population through to enrolment into the study.
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.
Recruitment Target: Number of patients/participants that must be recruited into a study to meet the requirements of the study protocol.
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.
Regulatory Operations and Enforcement Branch (ROEB) : 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.
Research Ethics Board (REB): (Also see Independent Ethics Committee) 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.

Serious Adverse Drug Reaction (SADR): An adverse drug/natural health product 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. Also referred to as Serious Adverse Event (SAE).
Serious Unexpected Adverse Drug Reaction: A serious adverse drug/natural health product 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/natural health product. Also referred to as Suspected Unexpected Serious Adverse Reaction (SUSAR).
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).
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).
Sponsor: An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.
Sponsor/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 a sponsor/investigator include both those of a sponsor and those of an investigator.
Standard Operating Procedure (SOP): Detailed, written instructions to achieve uniformity of the performance of a specific function.
Standard Operating Procedure (SOP) Authorized Signatory: An investigator or research team member qualified by experience, skills and training to provide final approval of SOPs.

Glossary of Terms

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).
Study Database Manual: The repository of information concerning the study data base.
Study Site: The location(s) where trial-related activities are actually conducted.
Sub-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.
Therapeutics Product Directorate (TPD): Now called the Pharmaceutical Drugs Directorate (PDD).
Translator: Interpreters and translators perform similar tasks, but in different settings. While an interpreter converts any spoken material from one language (the source language) into a different language (the target language), a translator converts written material in the same manner.
Trial/Study Participant (or Participant): An individual (patient or healthy volunteer, if applicable) who participates in a clinical study, either as a recipient of the investigational product(s) or as a control. (The terms study patient, study participant, and research participant are sometimes used interchangeably).
Unexpected Adverse Drug Reaction: An adverse reaction, 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).
User Acceptance Testing (UAT): A formal means by which end users verify that the database is complete, set-up is correct, and it meets the required business functions by emulating normal use conditions.

Vulnerable participants**:** 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 participants 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.

REVISION HISTORY

Effective Date	Summary of Changes
15-May-2017	original version
15-May-2019	Added definitions for: Certified Copy; Importer (Medical Device); Investigator Sponsored Trial (Medical Device); Manufacturer Sponsored Trial (Medical Device); Natural Health Product. Clarified the following definitions: Investigational Product; Investigational Product Accountability; Investigator; Serious Adverse Drug Reaction; Serious Unexpected Adverse Drug Reaction. Minor typos corrected.
15-May-2021	Corrected ICH to be “Council” not “Conference” Changed all occurrences of “subject” to “participant”. Minor typos corrected. A few definitions added: Corrective and Preventive Action (CAPA); Good Documentation Practice (GDP); Participant; Participant Identification Code; Pre-Approval Inspection (PAI); Regulatory Operations and Enforcement Branch (ROEB). ICH definition expanded to include Mission.
31-May-2023	Split acronym list into 2 lists – one for English acronyms and one for French acronyms. Added the following definitions: • Applicable Guidance • Authorized Third Party • Clinical Research Personnel (under Clinical Research Coordinator) • Clinical Trial Site Information Form (CTSO) • Common Technical Document (CTD) • Interactive Voice/Web Response System • Investigational Testing Authorization (ITA) • Pharmaceutical Drugs Directorate ICH corrected to International Committee for Harmonisation from “of”.