S ACRONY

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	

GLOSSARY OF TERMS

Whenever possible, definitions are taken directly, or derived from, official sources such as ICH, Health Canada regulations, FDA regulations, Tri

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 Modification(s)

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.

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

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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.

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

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.

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.

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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 di1iem(ci)2 ()d9at04 Tc -10 (10 Whad

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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

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

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REVISION HISTORY

Effective Date	Summary of Changes