

Glossary of terms

510(k): Pre-market notification for medical devices in the US. The 510(k) procedure is used for class II devices that are subject to the general controls of class I devices but also require special controls.

AE (adverse event): An undesirable experience associated with the use of a medical product. Also called a side effect.

ASR (analyte specific reagent): Defined by the FDA as “antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reactions with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens.”
[<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=864.4020>]

BGTD (Biologics and Genetic Therapeutics Directorate): The division of Health Canada responsible for regulating biologic drugs including blood and blood products, cells, tissues, organs, xenografts, and viral and bacterial vaccines.

CBER (Center for Biologics Evaluation and Research): A division of the FDA responsible for assessing the safety, efficacy and quality of biological products.

CDER (Center for Drug Evaluation and Research): A division of the FDA responsible for assessing the safety, efficacy and quality of pharmaceutical products.

CE marking: In Europe, the CE marking symbolizes the conformity of a medical device to the EU’s requirements.

CHMP (Committee for Medicinal Products for Human Use): The committee responsible for preparing the EMA’s opinions on all questions concerning medicinal products for human use.

Clarifax: A faxed letter from Health Canada with minor requests for clarification on a submission.

CLIA (Clinical Laboratory Improvement Amendments of 1988): Establishes quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed.

Clinical hold: An order issued by the FDA to a sponsor to delay or suspend an investigation.

CMC (chemistry, manufacturing and controls): The procedures and specifications related to the manufacturing of a therapeutic.

CMS (Centers for Medicare and Medicaid Services): The US federal agency that administers Medicare and Medicaid services.

CRO (contract research organization): A company that provides services to the pharmaceutical industry such as clinical research, non-clinical research and data management.

CTA (Clinical Trial Application): An application for approval to start a clinical trial.

Drug: Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals. [*Federal Food, Drug, and Cosmetic Act*, <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChaptersIandIIShortTitleandDefinitions/ucm086297.htm>]

EMA (European Medicines Agency): The body responsible for the protection and promotion of public and animal health through the evaluation and supervision of medicines for human and veterinary use.

EudraCT: A database of all clinical trials occurring in Europe.

FDA: US Food and Drug Administration, the agency that regulates drugs in the United States.

GMP (or cGMP): Good Manufacturing Practice, or Current Good Manufacturing Practice (cGMP).

GNA (Grounds for Non-Acceptance): A letter issued by UK regulators indicating that a clinical trial is not authorized to commence.

GLP (Good Laboratory Practice): The quality standards by which non-clinical studies should be conducted.

IB (Investigator's Brochure): A summary of all that is known about a drug that is provided to an investigator (physician) participating in a clinical trial.

ICH (International Conference on Harmonisation): A multinational committee of regulators and industry professionals that establishes consistent guidelines for the efficacy, safety and quality of new therapeutics.

IDE (Investigational Device Exemption): An application to the FDA to conduct a clinical trial on a medical device in the US.

IND (Investigational New Drug): An application to the FDA for the authorization to conduct a clinical trial on a drug in the US.

IVD (*in vitro* diagnostic): Defined by the FDA as "those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body." [<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=809.3>]

IVDMIA (*in vitro* multivariate index assay): The FDA definition of an IVDMIA is a device that

- combines the value of multiple variables using an interpretation function to yield a single, patient-specific result that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease
AND
- provides a result whose derivation is non-transparent and cannot be independently derived or verified by the user

LDT (laboratory-developed test): A test developed by a single clinical laboratory for use only in that laboratory.

MAA (Marketing Authorization Application): An application for marketing authorization of a new drug in the EU.

MHRA (Medicines and Healthcare products Regulatory Agency): The regulatory authority that governs therapeutics in the UK.

NDA (New Drug Application): An application for marketing authorization of a new drug in the US.

NDS (New Drug Submission): An application for marketing authorization of a new drug in Canada.

NHPD (Natural Health Products Directorate): The division of Health Canada responsible for regulating natural health products.

NOC (Notice of Compliance): A letter from Health Canada that indicates a New Drug Submission has been approved.

NOC/c (Notice of Compliance with conditions): A letter from Health Canada that indicates a New Drug Submission has been approved but there are certain conditions a company must meet.

NOD (Notice of Deficiency): A letter from Health Canada that indicates the review of a New Drug Submission

cannot continue due to deficiencies or significant omissions in the file.

NOD/w (Notice of Deficiency - Withdrawal): A letter from Health Canada that indicates the response to an NOD is inadequate and that the company must withdraw the submission.

NOL (No Objection Letter): A letter issued by Health Canada that indicates there are no objections to a Clinical Trial Application, and a clinical trial can commence.

NON (Notice of Non-compliance): A letter from Health Canada that indicates the review of a New Drug Submission is complete and that the submission is deficient or incomplete.

NON/w (Notice of Non-compliance - Withdrawal): A letter from Health Canada that indicates the response to a NON is inadequate and that the company must withdraw the submission.

PDUFA: *Prescription Drug User Fee Act*

PDUFA-date: The date by which the FDA is expected to complete its review of a marketing application of a new drug.

PMA (Pre-Market Approval): The PMA is the FDA process of pre-market scientific and regulatory review to evaluate the safety and effectiveness of class III medical devices in the US.

POC (point of care): Usually refers to a test that is done in the doctor's office rather than being sent to a laboratory for analysis.

Priority NDA: A priority NDA is a new drug application that is designated as a priority. An application is eligible for priority review if the drug provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease.

Rapporteur: The rapporteur is a country-specific regulatory authority within the EU.

REB (research ethics board): A committee that reviews a clinical trial and either grants or denies ethics approval for a study to start at a particular site.

RUO (research use only): Usually refers to a diagnostic device that is being tested for research purposes.

SAE (serious adverse event): An undesirable experience associated with the use of a medical product that is life-threatening or results in death, hospitalization or disability, or it requires intervention to prevent impairment or damage.

SmPC (Summary of Product Characteristics): A document that summarizes the key aspects of a medical product that has been approved for marketing in the EU.

Standard NDA: A new drug application that has not been designated as a priority.

SUSAR (suspected unexpected serious adverse event): A SUSAR is similar to a serious adverse event.

TPD (Therapeutic Products Directorate): The division of Health Canada responsible for regulating medical devices, and prescription and non-prescription drugs.

TPP (target product profile): The desired characteristics and attributes of a new therapeutic in development that a company aims to demonstrate.