EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CTIS Training

List of Acronyms

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What you will find

- Acronyms and definitions of the key terms regarding CTIS.

The European Medicines Agency developed this training material to enhance public access to information on the Clinical Trial Information System (CTIS). This material describes a preliminary version of CTIS and may therefore not entirely describe the system as it is at the time of use of this material. The Agency does not warrant or accept any liability in relation to the use (in part or in whole) or the interpretation of the information contained in this training material by third parties.

CTIS Acronyms

Acronym	Term	Definition
API	**Application Programming Interface**	Intermediary software that allows two applications to exchange data or communicate with each other. An API will allow Member States to interact with the Clinical Trials Information System (CTIS) and their own systems, if applicable.
ASR	**Annual Safety Reporting**	Functionality that allows sponsors to submit the annual reports on the safety status of investigational medicinal product used in a trial, and Member States to assess the content of the ASR and adequately monitor the safety profile of the investigational drug.
ATC code	**Anatomical Therapeutic Chemical code**	International classification system for medicines that is maintained by the World Health Organisation (WHO). Users can use the ATC code in the Clinical Trials Information System (CTIS) as, for example, a filtering criterion in the advanced searches located in the Annual safety reporting tab and the Ad hoc assessment tab.
BI	**Business Intelligence**	Functionality that allows users to obtain reports and statistics based on the clinical trial data contained in CTIS.
CRO	**Clinical Research Organisation**[1]	A contract research organization, also called a clinical research organization is a service organization that provides support to the pharmaceutical and biotechnology industries in the form of outsourced pharmaceutical research services (for both drugs and medical devices).
CSR	**Clinical Study Report**	Report of an individual study of an investigational medicinal product, in which the clinical and statistical description, presentations, and analyses are integrated[2].

[1] European Medicines Agency, *EudraCT Glossary.* Available at: https://eudract.ema.europa.eu/help/Content/Glossary.htm
[2] European Medicines Agency, *ICH Topic E 3 Structure and Content of Clinical Study Reports*, July 1996,. Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-3-structure-content-clinical-study-reports-step-5_en.pdf

CT	**Clinical Trial**	Clinical study which fulfils any of the following conditions: "(a) the assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within the normal clinical practice of the Member State concerned; (b) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study; or (c) diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects." *(Article 2(2) (1 and 2) of the Clinical Trials Regulation [3]).*
CTA	**Clinical Trial Application**	A request (made by the sponsors) for the authorisation (by the Member States concerned), to perform an action related to clinical trials conducted in the EU. These actions can include a request to start a clinical trial, the extension of a clinical trial to another MSC territory and subjects, or to perform an important modification to an already started CT.
CTIS	**Clinical Trial Information System**	Single entry portal for submitting clinical trials information in the EU with the highest standards of safety for participants, from the entry into application of Regulation[4](EU) No 536/2014 (Clinical Trials Regulation). It will support the day-to-day business processes of authorities and sponsors throughout the life-cycle of a clinical trial through collaboration and communication tools between sponsors and authorities and among authorities; workflow capabilities, and document management and reporting capabilities. CTIS will also support the transparency of data regarding clinical trials conducted in the EU for the general public through a public website.
DAR	**Draft Assessment Report (Part I)**	Preliminary assessment made by the RMS of the scientific documentation of the application dossier. It is circulated to all the MSCs. The Draft Assessment Report for Part I is composed of seven parts that offer a preliminary assessment of Part I of the application dossier. These parts are: the introduction, quality assessment, pre-clinical assessment, clinical assessment, statistical methodological assessment, regulatory assessment, and the conclusion. The RMS can decide which parts to complete and share with the MSCs.

[3] European Commission, *Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC*, EU Official Journal L158. 16 of April 2014. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

[4] European Commission, *Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC*, EU Official Journal L158. 16 of April 2014. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

	Draft Assessment Report (Part II)	Preliminary assessment by the MSC of the regulatory aspects of the clinical trial application. The Draft Assessment Report for Part II is not shared with the rest of MSCs. It is an internal task that will be performed outside of CTIS and will be uploaded ultimately in CTIS.
EC	**Ethics Committee**	Independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations. *(Article 2(2)(11) of the Clinical Trials Regulation [5]).*
EC	**European Commission**	User group of the European Commission that perform Union Controls activities in CTIS.
EEA	**European Economic Area**	Economic area composed of Member States of the European Union (EU) and three countries of the European Free Trade Association (EFTA) (Iceland, Liechtenstein and Norway; excluding Switzerland)[6]. Sponsors shall indicate details of trials being conducted outside of the EEA.
EU CT number	**European Union Clinical Trial number**	Trial identifier code, unique to each clinical trial conducted in CTIS.
FAR	**Final Assessment Report (Part I)**	Final Assessment Report for Part I that provides the final assessment of the scientific documentation of the application dossier. It includes a part on the quality documentation and a part concerning the rest of the documentation
	Final Assessment Report (Part II)	Final Assessment Report for Part II that provides the final assessment of the regulatory documentation of the application dossier.
IAM	**Identity Access Management**	User registration system that provides individuals with access to the applications that are managed by EMA. To enable access to CTIS, users need to obtain profiles via IAM. IAM records roles and permissions only for administrator users.
IMP	**Investigational Medical Product**	A medicinal product which is being tested or used as a reference, including as a placebo, in a clinical trial. *(Article 2(2)(5) of the Clinical Trials Regulation[7]).*

[5] Idem.
[6] Eurostat, *Glossary:European Economic Area (EEA)*. Available at: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:European_Economic_Area_(EEA)
[7] European Commission, *Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014*

IMPD	**Investigational Medical Product Dossier**	Dossier that provides information related to the quality of an IMP(IMPD-Q), and to the Safety and Efficacy (IMPD S and E).
MA	**Marketing Authorisation**	The approval granted by the Regulatory Authority to market a specific product in a particular country[8].
MAH	**Marketing Authorisation Holder**	The company named on the Marketing Authorisation for a specific product in a particular country[9].
MSC	**Member State Concerned**	A Member State that has received an application which concerns a CT intended to be conducted in its territory, or a modification of a previously submitted application for its assessment, and therefore is responsible for the evaluating the feasibility of conducting that clinical trial.
NCA	**National Competent Authority**[10]	National regulatory agency in an EU Member State.
NOA	**National Organisation Administrator**	Medium-level administrator for the Member States user group. It operates as the administrator of a Member State organisation, different from the one of the Member State Admin (such as Ethics Committees).
Non-SM	**Non-Substantial Modification**	A change implemented to a Clinical trial with the purpose of correcting information that is not expected to have a substantial impact on the safety or rights of the subjects or on the reliability and robustness of the data generated in the Clinical trial. (e.g. correction of typographical errors, update of contact details, etc.). (*Article 81(9) of the Clinical Trials Regulation*[11]*).* It is not considered an application type under the Clinical Trials Regulation as it is not subject to evaluation by the Member State concerned. However, it is important to consider that non-SMs are accompanied by a document explaining the non-subtantial changes made to the CT, and the non-SMs submitted will be listed in the clinical trial page, along with the in the clinical trial applications.
OMS	**Organisation Management Service**	System managed by EMA which provides a single source of organisation data for CTIS, such as organisation names and location addresses. CTIS can also push information to this database when new organisations are created directly by the CTIS users.

on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, EU Official Journal L158. 16 of April 2014. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

[8] European Medicines Agency, *EudraCT Glossary.* Available at: https://eudract.ema.europa.eu/help/Content/Glossary.htm

[9] Idem.

[10] Idem.

[11] European Commission, *Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC*, EU Official Journal L158. 16 of April 2014. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

RFI	**Request for Information**	Functionality in CTIS listing the requests from Member States to sponsors to add a MSC, provide additional information in the context of validation and assessment of a CTA, ad hoc assessments, corrective measures and Annual Safety Reporting (ASR).
RMS	**Reporting Member State**	Member State Concerned with a leading role during the clinical trial lifecycle that performs several tasks including the lead assessment (or creating the draft assessment report), raising and consolidating considerations during the validation and Part I assessment phases, and including conclusions on Part I.
SM	**Substantial Modification**	Any change to any aspect of a clinical trial, which is made after the notification of a decision on a previously submitted application and which is likely to either: Have a substantial impact on the safety or rights of the subjects; On the reliability and robustness of the data generated in the CT. In all cases, a modification is regarded as 'substantial' when one or both of the above criteria are met. In principle, it is the responsibility of the sponsor to judge whether a modification is to be regarded as 'substantial' or not. This judgement is to be made on a case-by-case basis. *(Article 2(13) of the CT Regulation[12]).*
XEVMPD	**eXtended EudraVigilance Medicinal product data dictionary**	Data base that stores and provides quality data on authorised or investigational medicinal products to CTIS. This information is requested to sponsors when filling out a clinical trial dossier/application.

[12] European Commission, *Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC*, EU Official Journal L158. 16 of April 2014. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

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Clinical Trials Information System (CTIS).

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