

EUTCT

Glossary

1.14, CURRENT

CONTENTS

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A

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| Term, acronym | Definition |
|--|--|
| Actor | An actor (also business actor) means the role someone, or something plays while interacting with the business. |
| Applicant | Replaced by: Change Requestor |
| Accepted | Replaced by: Approved |
| Activity Diagram | Activity diagrams show the sequence the activities occur and are used as a tool in the analysis |
| Anatomical Therapeutic Chemical Classification System with Defined Daily Doses Index | The ATC/DDD system classifies therapeutic drugs. The purpose of the ATC/DDD system is to serve as a tool for drug utilization research in order to improve quality of drug use. Contains the ATC Codes and the Defined Daily Dose. |
| Approved | The approval of a new Controlled Term or a controlled term list - The use of Approved implies evaluation has been completed |
| ATC Codes | An Anatomical Therapeutic Chemical (ATC) classification system. The purpose of the ATC system is to serve as a tool for drug utilization research in order to improve quality of drug use. One component of this is the presentation and comparison of drug consumption statistics at international and other levels. The drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. This Controlled Term List/ Controlled Vocabulary is supplied by the WHO: http://www.whocc.no/atcddd/ |
| ATC/DDD Index | <i>Anatomical Therapeutic Chemical Classification System with Defined Daily Doses Index</i> |
| ATCvet | The basis for the ATCvet classification system is the ATC (Anatomical Therapeutic Chemical) classification system for human medicines |

| | |
|------------|--|
| Herbal ATC | <p>For various reasons it has been deemed impractical to incorporate hundreds of herbal remedies in the regular ATC classification. However, experience from the ATC system - particularly in connection with the monitoring of adverse effects of drugs - has shown that such a system would also be suitable for herbal remedies.</p> <p>In 1998, De Smet proposed a system for ATC classification of herbal remedies which is fully compatible with the regular system. With a few modifications this system has now been adopted and is given in the WHO's published guidelines. If you are interested in these publications, please contact info@who-umc.org.</p> |
|------------|--|

B

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| Term, acronym | Definition |
|-------------------------------|--|
| BUC | <i>Business Use Case</i> (Rational Unified Process term) |
| Business Entity | Within the Rational Unified Process, Business Entities are artefacts used by the business to undertake work |
| Business Object Model | Describes the business entries and the business workers interaction to provide the functionally described on the business use case (Rational Unified Process term) |
| Business Rule | A rule that is used to define process flow and validation - declaration of policy or conditions that must be satisfied |
| Business Use Case Model | A model of the business functionality as defined by the BUCs and business actors |
| Business Worker | A business worker represents an abstraction of a human that acts within the business |
| Business Actor | The role that someone or something plays while interacting with the business |
| Business Use Case | A business use case defines a sequence of actions a business performs that yields an observable result of value to a particular business actor. A business use case class contains all main, alternate workflows related to producing the "observable result of value to the <i>Business Actor</i> ". A business use case defines what should happen in the business when it is performed; it describes the performance of a sequence of actions that produces a valuable result to a particular <i>business actor</i> . |
| Business Use Case Realisation | A business use case realisation describes how the workflow of a particular business use case is realised within the <i>business analysis model</i> , in terms of collaborating business objects (<i>Business Worker</i> and <i>Business Entities</i>) |

C

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| Term, acronym | Definition |
|-----------------------------------|--|
| CA | <i>Competent Authority</i> |
| CAS | <i>Chemical Abstracts Service</i> |
| CAP | <i>Centrally Authorised Product(s)</i> |
| CEN | <i>Comité Européen de Normalisation</i> |
| Centrally Authorised Product(s) | A medicinal product authorised by EMA |
| Change Requestor | The term used for the person requesting a change to a Controlled Term within the EUTCT Project. The term Applicant was not used as it could be confused with the applicant for a marketing authorisation. |
| Change Request - Approval Process | The process the EUTCT Terminology Evaluation Group use to approve a Change Request to a Controlled Terms List in accordance with the EUTCT Standard Change Request Process. |
| Change Request Status | <p>A valid Change Request status can be:</p> <ul style="list-style-type: none"> • APPROVED: The Change Request has gone through the EUTCT process and has met all criteria in order to be included in the EUTCT system. • REJECTED: The Change Request does not meet the criteria to be included in the EUTCT system. This could be because the request itself was not deemed to need to be included. <p>INVALIDATED: The Change Request does not meet the criteria to be included in the EUTCT system. This could be because the Change Request was incorrectly formulated (not enough supporting information, etc.)</p> |
| Chemical Abstracts Service | CAS is a division of the American Chemical Society which produces Chemical Abstracts and related products. CAS provides databases of publicly disclosed and searchable chemical and related scientific information. |
| ClaML | <i>Classification Markup Language</i> |
| Classification Markup Language | This is an XML application designed for the exchange of classifications. It is currently a CEN Technical Specification (TS14463). |

| Term, acronym | Definition |
|---|---|
| Comité Européen de Normalisation | CEN, the Comité Européen de Normalisation (European Committee for Standardisation), is a private non-profit organisation whose mission is to foster the European economy in global trading, the welfare of European citizens and the environment by providing an efficient infrastructure to interested parties for the development, maintenance and distribution of coherent sets of standards and specifications. |
| Competent Authority (also National Competent Authority) | An authority in an EEA Country responsible for the authorisation and supervision of medicinal products. Abbreviation: NCA |
| Constraint | A restriction on the degree of freedom we have in providing a solution or enacting the process |
| Consumer (role) | The Consumer roles allow the users to consume something from the EUTCT system by viewing, searching or downloading. They include: <ul style="list-style-type: none">- General User Role- Licensed User Role |
| Consumers' systems | The EU Telematics System that acts as a consumer by viewing, searching or downloading information from EUTCT |
| Contributor (role) | The Contributor roles allow the users to add something to the EUTCT system. The roles include: <ul style="list-style-type: none">- Change Requestor Role- List Requestor Role- TC Member Role- TEG Member Role- Translator Role |
| Controlled Term | An element of structured information. In the context of the EUTCT application, this refers to the actual Controlled Term itself and is the text the EUTCT system will display. |
| Controlled Term Description | The detailed, concise and accurate description of the Controlled Term. |
| Controlled Term Domain | The Domain Identifier from the Domain Controlled Term List which indicates the area of use of a Controlled Term |
| Controlled Term Identifier | This is an agreed European identifier, a unique sequential 12-digit number across all Controlled Term Lists for each Controlled Term within the system. |
| Controlled Term List | A list of structured and maintained information. Can be externally, internally or shared (i.e. both) managed. |
| Controlled Term Revision number | A number representing how many times the Controlled Term has been revised. |

| Term, acronym | Definition |
|----------------------------|---|
| Controlled Term Term Name | This is the official full name of the Controlled Term in English. |
| Controlled Term Short Name | The first or principle shortened, acronym or abbreviated name of the Controlled Term. |
| Controlled Term Source | Details the source from which the Controlled Term originates and, as such, is only present for Controlled Terms from external Controlled Term Lists. |
| Controlled Term Status | The status of the Controlled Term in the Controlled Term List. the status can be one of the following five values: <ul style="list-style-type: none">- Current- Provisional- Non-Current- Nullified- Under Consultation |
| Controlled Vocabulary | A list of structured and maintained information. Controlled Vocabulary is the term used by ICH for a Controlled Term List. Within the EUTCT project the standardised term Controlled Term List should be used to avoid any confusion. |
| CSV or .csv | The CSV ("Comma Separated Value") file format is often used to exchange data between disparate applications. The file format dates back to the days of mainframe computing. For this reason, amongst others, CSV files are common across all computer platforms. |
| CT | <i>Controlled Term</i> |
| CTL | <i>Controlled Term List</i> |
| Current (Term Status) | The status given to a Controlled Term to indicate that it is a term approved for use in new applications/records. |
| CV | <i>Controlled Vocabulary</i> (ICH term) |

D

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| Term, acronym | Definition |
|------------------------------|---|
| Dictionary | Reference table of standard terms and their translations, a Controlled Term List (CTL) or Controlled Vocabulary (CV). Replaced by Controlled Term List within EUTCT project. |
| Data Council | Obsolete – Replaced by Terminology Committee |
| Dosage Form | The form of the completed pharmaceutical product, e.g. tablet, capsule, injection, elixir, suppository |
| DES | Data Exchange Standards. An agreed structure to enable electronic data to be held and transmitted from sender to receiver, mainly linked to the electronic exchange of structured information. |
| Delete (Controlled Term) | No Controlled Term will be physically deleted from a Controlled Term List. Instead it will have its status changes to “non-current” to indicate that is not a term in current use and should not be used. |
| DIA | <i>Drug Information Association</i> |
| DIMDI | Deutschen Institut für Medizinische Dokumentation und Information – German Institute of Medical Documentation and Information |
| DTD | The Document Type Definition (DTD) is used to validate an SGML or XML document. DTDs are used to support and effectively describe XML file structures, providing the vocabulary and allowable structure of the elements in an XML document. |
| Drug Information Association | <p>DIA is a professional association of approximately 20,000 members worldwide who are involved in the discovery, development, regulation, surveillance, or marketing of pharmaceuticals or related products.</p> <p>DIA is committed to the broad dissemination of information among its members, with continuously improved professional practice as the goal. DIA serves its members in a neutral, global environment that operates independent of the influence of any one organization or authority. For more information, see http://www.diahome.org/en/aboutdia/overview/aboutdia</p> |

E

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| Term, acronym | Definition |
|------------------------------|---|
| Executive Sub-Group | Obsolete – Replaced by: Terminology Evaluation Group (with qualifier for the type of Controlled Term List, e.g. “Terminology Evaluation Group on ATC Codes”) |
| EC | <i>European Commission; European Community</i> |
| ECD | <i>Eudra Common Directory</i> |
| ECDM | <i>Eudra Common Directory Manager</i> |
| EDMS | The internal Electronic Document Management System, based on Documentum used by the EMEA. |
| EDQM | <i>European Directorate for the Quality of Medicines and Healthcare</i> Manages the standard terms for: <ul style="list-style-type: none"> - Dosage Forms - Routes of Administration - Containers |
| EEA | <i>European Economic Area</i> |
| EFPIA | <i>European Federation of Pharmaceutical Industry Associations</i> |
| EFPMA | <i>European Federation of Pharmaceutical Manufacturers' Association</i> |
| EMA | <i>European Medicines Agency</i> . The New name for the European Medicines Evaluation Agency (http://www.ema.europa.eu/) |
| EMEA | <i>European Medicines Evaluation Agency</i> . Now European Medicines Agency (http://www.ema.europa.eu/) |
| EMA Rational Unified Process | RUP@EMA is the customisation of the Rational Unified Process used by the EMEA. It consists of processes, templates and guidelines for software development at the EMA. |
| EMRN | <i>European Medicines Regulatory Network</i> |
| EMRN users | Users who are from the EMRN (NCAs). |
| EMRN users (external) | Users who are not from the EMRN (the public or industry). |

| Term, acronym | Definition |
|--|---|
| EM CTLs | <i>Externally Managed Controlled Term List</i> |
| End-users | The users of the EUTCT system. These users are assigned roles and therefore can act as Guest, Licensed, Change Requestor and Secretariat. |
| ETL | Extract, Transform and Load |
| EUDRA | European Union Drug Regulatory Authorities |
| Eudra Common Directory | A contacts database administrated by EMA containing details of employees and contractors of EMA, NCAs and the Pharmaceutical Industry |
| Eudra Common Directory Manager | Tool for the administration and updating of the Eudra Common Directory |
| EudraCT | Computer System for the management of a registry of Clinical Trials, developed as specified in Directive 2001/20/EC, and operated by the EMA |
| EudraNet | <i>European Union Drug Regulatory Authorities Network</i> |
| EUP | EMA Unified Process (a customised version of the Rational Unified Process), the systems development process applied by the EMEA for EU Telematics projects |
| European Commission | The "civil service" of the European Union. Its full name is the Commission of the European Communities; however, it is usually simply known as the Commission. It is the executive organ of the European Union. It proposes Community policy and legislation, implements the decisions taken by the Council of Ministers and supervises the day-to-day running of Commission policies. It is the "guardian" of the Treaties and can initiate action against Member States that do not comply with EC rules. |
| European Economic Area | The EEA includes all the EU Member States, plus Iceland, Liechtenstein and Norway |
| European (Terms) | The Controlled Term is approved for use in European Union and European Economic Area Member States. |
| European Union Drug Regulatory Authorities Network | The computer network infrastructure connecting the NCAs, the EMAEMAEMA and the EC |

| Term, acronym | Definition |
|--|--|
| European Union Telematics Controlled Terms | The full name of the EUTCT project. EUTCT is concerned with the development of a central hub providing agreed and authoritative look-up information for medicinal products in the 23 EEA languages including English. It is intended that this hub will be maintained centrally, and will serve not only all the EU Telematics systems but, as far as is possible, the entire regulatory community for pharmaceutical industry. The hub will also act as a medicinal products dictionary for use in validating information submitted to the Eudra applications electronically, for identification purposes. |
| EuroPharm | Obsolete: The original name for EudraPharm |
| EudraGMP | EudraGMP will be the European Community database of manufacturing authorisations and of certificates of good manufacturing practice. The system will support the legal requirements on reporting, storing and dissemination of information on manufacturing authorisations and the results of GMP inspections. |
| EudraPharm | EudraPharm is a database of information on all medicinal products, for human or veterinary use, authorised in the European Union. EudraPharm has been established to fulfil Articles 57 1 (l) and 57 2 of Regulation 726/2004. |
| EudraVigilance | EudraVigilance will now support the Pharmacovigilance activities in the pre- and post- authorisation phase. Therefore, EudraVigilance contains two reporting modules: The EudraVigilance Post-Authorisation module (EVPM) designed for post-authorisation ICSRs as required by Council Regulation No. 2309/93/EEC, as amended (to be replaced by <u>Regulation (EC) No 726/2004</u> in November 2005), Directive 2001/83/EC, as amended, and Volume 9 of the "Rules Governing Medicinal Products in the European Union". The EudraVigilance Clinical Trial (EVCTM) module designed for pre-authorisation SUSARs as required by Directive 2001/20/EC. |
| EUTCT | <i>European Union Telematics Controlled Terms</i> |
| EUTCT Project | The European Union Telematics Controlled Terms (EUTCT) project addresses the interoperability between Systems via the establishment and maintenance of a centralised set of Controlled Terms for the ongoing exchange of data between EU Telematics applications, the EMA and National Competent Authorities (NCAs). |
| EUTCT System | The EUTCT System is a European Community repository and provider of controlled terms in multiple languages for the ongoing exchange of data between information systems and applications throughout the European Medicines Regulatory Network (EMRN). |
| EU Telematics | EU Telematics is the collective term for the systems in the EMRN. |
| EU Telematics systems | See EU Telematics. |

| Term, acronym | Definition |
|---|--|
| External CT List Manager | An External CT List Manager is an organisation external to the EMA that manages Controlled Term Lists (CTLs). Examples are: EDQM, ICH, ISO, MSSO and WHO. |
| Externally Managed Controlled Term List | An Externally Managed Controlled Term List contains Controlled Terms that are managed and maintained by organisations outside the EUTCT system. Examples are MedDRA from MSSO, ATC codes from the WHO. |

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| Term, acronym | Definition |
|--------------------------|--|
| GUI | <i>Graphical User Interface</i> |
| Graphical User Interface | An onscreen user interface which allows the user (a person) to interact with a computer or application which employs graphical icons, special graphical elements called "widgets", as well as text labels or text navigation to represent the information and actions available. Interaction is usually undertaken by direct manipulation of the graphical elements using a mouse (or other pointing device) and a keyboard. |

H

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| Term, acronym | Definition |
|---------------|--|
| HMA | <i>Heads of Medicines Agencies</i> Has three groups: HMA-Joint, HMA-Human and HMA-Vet |
| HTML/html | HTML is the family name for the group of languages that form the lingua franca of the World Wide Web. The HTML Working Group is chartered to evolve HTML into an XML-based markup, modularise it to make it easier to combine with other markup languages, and correct the problems still known to exist in areas such as internationalization, accessibility, device independence and forms processing. |

I

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| Term, acronym | Definition |
|-------------------------------------|--|
| ICH | <i>International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use</i> |
| IATE | <i>Inter-Active Terminology for Europe</i> |
| IM CTLs | <i>Internally Managed Controlled Term List</i> |
| Inter-Active Terminology for Europe | <p>Inter-Active Terminology for Europe is the EU inter-institutional terminology database. IATE has been used in the EU institutions and agencies since summer 2004 for the collection, dissemination and shared management of EU-specific terminology.</p> <p>The project partners are:</p> <ul style="list-style-type: none"> ▪ European Commission ▪ Parliament ▪ Council ▪ Court of Justice ▪ Court of Auditors ▪ Economic & Social Committee ▪ Committee of the Regions ▪ European Central Bank ▪ European Investment Bank ▪ Translation Centre for the Bodies of the EU <p>The project was launched in 1999 with the objective of providing a web-based infrastructure for all EU terminology resources, enhancing the availability and standardisation of the information.</p> <p>IATE incorporates all of the existing terminology databases of the EUs translation services into a single inter-institutional database. The IATE web site is administered by the Translation Centre for the Bodies of the European Union in Luxembourg on behalf of the project partners. Questions or feedback may be sent to: iate@cdt.europa.eu.</p> <p>Note: This terminology project is not intended to contain product specific information.</p> |
| Invalidate (change request) | A Change Request in EUTCT might be 'invalid' because it has insufficient information or has been submitted on the wrong form |
| INN | <i>International Non-proprietary Names</i> |

| Term, acronym | Definition |
|---|---|
| International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use | A program of conferences in which representatives from regulatory authorities and trade associations in the European Union, the United States, and Japan meet to develop common standards and approaches to various aspects of pharmaceutical regulation, classified by topics under either Quality (Q), Safety (S, non-clinical), Efficacy (E) or Multidisciplinary (M). 6 conferences have already taken place, the last one in 2003 in Osaka. |
| International Non-proprietary Names | International Non-proprietary Name is the official non-proprietary or generic name given to a pharmaceutical substance, as designated by the World Health Organization (WHO). This is a list managed by the WHO and is used in the ATC/DDD index. |
| Internally Managed Controlled Term List | <p>An Internally Managed Controlled Term List contains Controlled Terms that are managed and maintained within the EUTCT system using the standard EUTCT process.</p> <p>Examples are:</p> <ul style="list-style-type: none"> - Authorisation status - Status legal supply - Procedure type - Medicinal product type - Age Range (formerly known as Target (population)) - Domain indication - MRL species - MRL tissue - Tissues - Manufacturer type - Manufacturer (site)? - Drug Substances - not active |
| ISO | <p>International Organization for Standardization</p> <p>http://www.iso.org/iso/en/aboutiso/introduction/index.html</p> |
| ISO codes | <p>Agreed specifications and criteria to be applied consistently in the classification of materials, in the manufacture and supply of products, in testing and analysis, in terminology and in the provision of services.</p> <p>In this way, International Standards provide a reference framework, or a common technological language, between suppliers and their customers - which facilitates trade and the transfer of technology.</p> |

| Term, acronym | Definition |
|--|---|
| ISO 3166 alpha-2 | <i>(Referenced documents)</i> Country - ISO Code. As defined and recommended by EU in European Union, 'EU-25 and candidate countries', countries, languages and currencies: names, codes and listing order (Development project for point 7 of the Interinstitutional style guide - Rev. 6 / 6.3.2006) |
| ISO codes 639-1 in force, alpha-2 code | <i>(Referenced documents)</i> Language - ISO Code. As defined and recommended by EU in European Union, 'EU-25 and candidate countries', countries, languages and currencies: names, codes and listing order (Development project for point 7 of the Interinstitutional style guide - Rev. 6 / 6.3.2006) |
| ICSR | <i>Individual Case Safety Report</i> |

J

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| Term, acronym | Definition |
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| Term, acronym | Definition |
|---------------|--|
| Legacy data | Legacy data is data/information being used in active historical records, electronically or otherwise, that are required for either Clinical Trials, Marketing Authorisation, Pharmacovigilance or any other regulatory purposes. |

M

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| Term, acronym | Definition |
|---------------|--|
| MedIDs | Medicinal Product Identifiers – part of the ICH Implementation of Controlled Vocabularies. Note that within EUTCT Controlled Vocabularies are known as Controlled Terms Lists. |
| MedDRA | MedDRA or Medical Dictionary for Regulatory Activities is 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. In addition, it is the adverse event classification dictionary endorsed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). MedDRA is used in the US, European Union, and Japan. Its use is currently mandated in Europe and Japan for safety reporting. |
| MSSO | Maintenance and Support Service Organisation (MSSO). The third party commercial organisation that supplies and maintains MedDRA. MSSO reports to the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). |
| MAA | <i>Marketing Authorisation Application</i> Across all European markets, plus Australia, New Zealand, South Africa, and Israel (exceptions amongst major markets include USA, Canada, China and Japan), the Marketing Authorisation Application (MAA) is a common document used as the basis for a marketing application (an application for approval to market the product based on a full review of all quality, safety, and efficacy data, including clinical study reports). In the USA, the New Drug Application (NDA) is the MAA equivalent. In Canada, the New Drug Submission (NDS) is the MAA equivalent. An MAA is comprised of 4 parts: Part 1: Summary of the Dossier includes application forms, summary of Product Characteristics, packaging, Expert Reports. Part 2: Chemical, Pharmaceutical, and Biological Documentation: drug substance and drug product. Part 3: Pharmacological and Toxicological (Preclinical) Documentation is a report of all animal pharmacology, toxicology, and pharmacokinetics studies. Part 4: Clinical Documentation is a report of all Phase I, II, III, IV, V clinical studies conducted up to the time of submission. |
| MAH | <i>Marketing Authorisation Holder</i> |
| Manufacture | All operations of purchase of materials and products, production, quality control, release, storage, distribution of medicinal products and the related controls |

| Term, acronym | Definition |
|--------------------------------|--|
| Manufacturer | Holder of a Manufacturing Authorisation as described in Article 40 of Directive 2001/83/EC for human products and Article 44 of Directive 2001/82/EC for veterinary products |
| Manufacturing Authorisation | Required prior to the commencement of production – application triggers a GMP inspection |
| Marketing Authorisation Holder | Marketing Authorisation Holder is a person or entity, who has applied and received a Pan EEA right to market and sell a product in a pharmaceutical form or a set of pharmaceutical forms. |
| MIA | Manufacturing / Importers Authorisation |
| Medicinal product | Any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances, which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product. |
| Member State | A country member of the European Union |
| MR | <i>Mutual Recognition.</i> A community registration procedure described by Council Directive 75/319/EEC (as amended) for the authorisation of medicinal products. Mutual Recognition Procedure: One of the routes for seeking regulatory approval in the European Union. A submission is first made to an EU Member State authority that assesses, grants a national approval and prepares an assessment report. This report is circulated by the initial authority to the other (concerned) Member States who are expected to recognize this decision and grant their own national authorisation within a period of 90 days following the initial approval. The 90-day period is used to resolve any issues between Member States. If serious objections are raised then the application is referred to the CHMP for arbitration leading to a binding decision. Note: Concerned Member State: A Member State that is concerned (i.e. included in the mutual recognition phrase) with an application for Mutual Recognition, and expected to recognize the initial approval of the Reference Member State. |
| MRA | <i>Mutual Recognition Agreement</i> |
| MRA countries | Australia, Switzerland, New Zealand, Canada and Japan |
| MS | <i>Member State</i> |
| MSCA | <i>Member State Competent Authority</i> Now replaced by National Competent Authority |

| Term, acronym | Definition |
|------------------------------|---|
| Mutual Recognition Agreement | An agreement between two regulatory agencies to recognise the regulatory assessment or inspection of a site (for GMP compliance) or review (pharmaceutical devices) conducted by one another. |

N

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| Term, acronym | Definition |
|------------------------------|--|
| National Competent Authority | An authority in an EEA Country responsible for the authorisation and supervision of medicinal products. |
| National Specific (Terms) | The Controlled Term is approved for use in the identified Member State(s) and reflects the specific jurisdictional particularity of this Member State. Its use in exchange of information is envisaged to cover National requirements. |
| NCA | <i>National Competent Authority</i> |
| Non-Current (Term Status) | The status given to a Controlled Term to indicate that the Controlled Term is not approved for use in new applications/records. The Controlled Term is not physically removed from the system and is maintained to cover legacy data. |
| Nullified (Term Status) | The status given to a Controlled Term to indicate the Controlled Term has been published in error and needs to be removed. |

O

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| Term, acronym | Definition |
|---------------|---|
| Orphan Drugs | A drug for the treatment of a Rare disease or for a disease not likely to generate sufficient profit to justify Research & Development costs. |
| OWL | <i>Web Ontology Language</i> The OWL Web Ontology Language is designed for use by applications that need to process the content of information as well as simply presenting information to humans. |

P

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| Term, acronym | Definition |
|-----------------------------------|--|
| PDSG | Process Definition Sub Group – one of the 2 business sub groups set up by the EUTCT Umbrella Group, in line with its Terms of Reference. |
| PhPID | Pharmaceutical Product Identifier |
| Pharmaceutical Product Identifier | The PhPID is the Pharmaceutical Product ID which uniquely identifies any pharmaceutical product worldwide. |
| Pilot | <p>A system developed to verify that the developed solution fully supports the business processes. The implementation will generally be limited to a restricted user base with a view to migrating to full production after the pilot phase.</p> <ul style="list-style-type: none"> • The system should be built to design documentation • The system should be fully tested and documented • The system runs in the production environment • Support is provided by IT Operations with backup as necessary from the project team • The system contains production data |
| PIM | <p>PIM (Product Information Management) is a system introduced by the EMA as a means of:</p> <p>a) increasing the efficiency of the management and exchange of product information (Summary of Product Characteristics, package leaflet and labelling) by all parties involved in the evaluation process through the structuring of the information and its exchange by electronic means;</p> <p>b) improving the quality and consistency of the published product information.</p> |
| PoC | <i>Proof of Concept</i> |

| Term, acronym | Definition |
|---------------------------|---|
| Proof of Concept | <p>A system developed to check whether an idea or concept can be used by the business to support their processes.</p> <ul style="list-style-type: none"> • The development of the system can be discarded if the concept does not work • The system should be built to design documentation • The system should be tested • The system runs in the development or test environments • Support is provided by the project team • The system never contains production data |
| Prototype | <p>A system developed to check whether a technology or architecture can be used to implement a solution.</p> <ul style="list-style-type: none"> • The development of the system can be discarded if the technology does not work • The system should be built to design documentation • The system runs in the development or test environments • Support is provided by the project team • The system never contains production data |
| Provisional (Term Status) | The status given to a Controlled Term to indicate that it has been entered into the system after the initial sign-off of the Controlled Term List, but prior to approval by the Terminology Evaluation Group (TEG).. Note that this may not be used in every Controlled Term List. |
| PoC1 | The scope of the PoC1 is contained within the EUTCT EU level of the project and is documented in the project Software Architecture document |
| PoC2 | The scope of the PoC2 was agreed at the ICH meeting in June 2006. This PoC2 involves the EUTCT project at an EU level but was successfully conducted at a global level for the ICH M2/M5 groups in October/November 2006 |
| PDF | Pharmaceutical Dosage Form |
| PDF | <i>Portable Document Format</i> |
| PhV | <i>Pharmacovigilance</i> |

| Term, acronym | Definition |
|--------------------------|---|
| Pharmaceutical Form | <p>The Pharmaceutical Form is the combination of the form in which a medicinal product is presented by the manufacturer (form of presentation) and the form in which it is administered including the physical form (form of administration). The pharmaceutical forms should be included in the "List of pharmaceutical forms by the European Pharmacopoeia of the Council of Europe- European Directorate for the Quality of Medicines (List of Standard Term, Introduction and Guidance for use - 2002 Edition)".</p> <p>Pharmaceutical form is for example tablet, capsule, solution for injection, oral solution, suspension for injection etc. WHO refers to them as dosage forms. The EMA certifies only one pharmaceutical form per certificate e.g. tablet. The certificates issued per pharmaceutical form include all authorised strengths.</p> <p>Pharmaceutical form is also known as Dosage Form.</p> |
| Pharmacovigilance | System for collecting spontaneous reports on adverse reactions, assessing causality and risks. EudraVigilance is one such system in the EMA. |
| Portable Document Format | Portable Document Format (PDF) is a file format created by Adobe Systems in 1993 for desktop publishing use. PDF is used for representing two-dimensional documents in a device independent and display resolution independent fixed-layout document format. |
| Post Conditions | The status of the environment after a process step or action has taken place (+/- outcomes) |
| Pre Conditions | A set of criteria that must be true before the process step or action can take place |
| Production | All operations involved in the preparation of a medicinal product, from receipt of materials, through processing and packaging, to its completion as a finished product |

Q

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| Term, acronym | Definition |
|---------------|------------|
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R

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| Term, acronym | Definition |
|--------------------------|---|
| Rare disease | Defined in the EU as a condition that affects not more than 5 in 10,000 persons in the Community and in the USA as a condition affecting fewer than 200,000 people in the USA |
| Reject Change Request | Rejecting a proposed change implies that the proposed change has been validated and is of insufficient quality. The Reject Change status must be supported by a reason why the change was rejected. For example, 'Rejected due to insufficient supporting documentation', or 'Rejected because synonym for term X'. |
| Requirement | 1. A capability need by a user to solve a problem or achieve an objective. 2. A capability that must be met or possessed by a system or component to satisfy a contract, standard, specification or other formally imposed documentation. |
| Rights | Privileges assigned to a user who controls that user's access to and visibility of information stored within the EUTCT system. |
| RoA | <i>Routes of Administration</i> |
| Routes of Administration | Controlled Term List to hold the multilingual routes of administration values |
| Reclassification | The process by which a Controlled Term from outside EUTCT is categorised within EUTCT or a Controlled Term within EUTCT is re-categorised, after discussion within the EUTCT Terminology Sub Group. |

S

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| Term, acronym | Definition |
|--------------------------------------|--|
| Service Level Agreement (SLA) | A service-level agreement (SLA) is a negotiated agreement between two parties where one is the customer and the other is the service provider. |
| Shared Managed Controlled Term Lists | A Shared Managed Controlled Term List contains Controlled Terms that are managed and maintained by both EUTCT and organisations outside the EUTCT system. These lists are usually maintained by organisations outside the EUTCT system, but for use within the EMRN these lists are adapted or modified by EUTCT to suit EMRN needs. |
| SM CTLs | <i>Shared Managed Controlled Term Lists</i> |
| SOP | <i>Standard Operating Procedure</i> Detailed, written instructions to achieve uniformity of the performance of the special functions. These provide a general framework enabling the efficient implementation and performance of the functions and activities for a particular process. |
| Stakeholder | Any person or organisation who could be materially affected by the implementation of a new system/application |
| SDO | <i>Standards Development Organisation</i> |
| Standard Term | Used by EDQM as the name for what is known within the EUTCT project as a 'Controlled Term'. |
| SUSAR | <i>Suspected Unexpected Serious Adverse Reaction</i> |
| System entities | An entity represents a significant and persistent piece of information (e.g. a document) that the actors manipulate. |
| System Roles | Roles that actors can play. Some examples are: administrator, guest, secretariat, and translator. |
| System-Specific | The Controlled Term is approved for use in the identified System(s) and reflects the specific jurisdictional particularity of this System. Its use in exchange of information is envisaged to cover specific business requirements. |

T

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| Term, acronym | Definition |
|------------------------------|--|
| TMC | <i>Telematics Management Committee</i> |
| Term ID | The text identifier for an element within a schema |
| Terminology Committee | <p>The Terminology Committee contains representation from all NCAs and other identified stakeholders of the EUTCT system acting as observers. These include EDQM, ICH, WHO, MSSO, etc.</p> <p>It meets twice yearly and provides:</p> <ul style="list-style-type: none"> - Approval of the translations of the Controlled Terms - Acts as the Steering Committee for the EUTCT process - Decides which new lists are to be used, which organizations to approach, etc - Provides the point for final appeal in the case of the Change Requestor not agreeing with the decision of the Terminology Evaluation Group <p><i>Formerly known as the Data Council (EUTCT Project).</i></p> |
| TEG | <i>Terminology Evaluation Group</i> |
| Terminology Evaluation Group | This group comprises of experts in its field, the name of the group is qualified with the area of expertise it addresses e.g. for ATC codes. |
| Third-countries | Any country that is not a Member State of the EU. |
| ToR | Terms of Reference for the EUTCT Umbrella Group adopted by the TSC - Terms of Reference - Dictionaries Group approved by the TSC (<i>Referenced documents</i>) |
| TSG | Terminology Sub Group - one of the 2 business sub groups set up by the EUTCT Umbrella Group, in line with its ToR. |

U

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| Term, acronym | Definition |
|--------------------|---|
| Under consultation | The Controlled Term is being made available for the consultation process on the content of the Controlled Term Lists. This usually applies to full lists that are not in use yet and have not undergone any approval process, therefore are not perceived to cover any urgent situations. |

V

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| Term, acronym | Definition |
|---------------|---|
| Vision | The user's or customer's view of the product or service to be developed, specified at the level of key stakeholder needs and features of the system. The business defining the boundaries of the system. The agreed version of the Vision document (click to view) is published on the under Publications in the Library section of EUTCT website: http://euteleproj.eudra.org/hor/eutct/library.htm |

W

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| Term, acronym | Definition |
|-----------------------------|--|
| Web Ontology Language (OWL) | The OWL Web Ontology Language is designed for use by applications that need to process the content of information as well as simply presenting information to humans |
| WHO | <i>World Health Organization</i> The World Health Organization, which came into being on 7 April 1948, is an agency of the United Nations. The objective of the WHO is the attainment by all peoples of the highest possible level of health. The World Health Assembly is the policy-making body of the WHO. |
| WHO-CC | The WHO-CC (World Health Organization Collaborating Centre for Drug Statistics Methodology) manages the ATC/DDD and ATCvet Controlled Term Lists |

X

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| Term, acronym | Definition |
|---------------|--|
| XML | <i>eXtensible Mark-up Language</i> A hypertext document format |
| XSD | XML Schema Definition. XML data that describes the relationship between elements and attributes in some other class of XML data. A schema may or may not include data type representations. XML schemas are a more advanced alternative to DTDs. |
| XSL | A standard developed by the World Wide Web Consortium (W3C) defining a language for transforming and formatting XML documents |

Y

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| Term, acronym | Definition |
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DOCUMENT INFORMATION

Open issues

(None)

Document location

This document is stored in the EMA's Electronic Document Management System (EDMS), in the User Documentation subfolder of the project folder for EUTCT, within a folder named Glossary.

Document id

EMA/72102/2006

Referenced documents

| Doc ID | Title |
|---|--|
| TSC - 05 - 2005 - 011 | Terms of Reference - Dictionaries Group approved by the TSC |
| EMA/46652/2006 | PDSG – adopted Modus Operandi |
| EMA/135660/2006 | TSG – To be finalised and adopted at meeting 27/04/2006 - Modus Operandi |
| http://publications.eu.int/code/pdf/370000en.htm | EU 1 May 2004 guidance and ongoing direction (Development project for point 7 of the Interinstitutional style guide - Rev. 6 / 6.3.2006) Including Country and Language codes (ISO 3166 ALPHA-2 and ISO codes 639-1 in force, alpha-2 code) |
| EMA/78295/2006 | EUTCT Software Architect Document |

Document history

| Version | Who | When | What |
|---------|-----|------|------|
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|---------------|---------------|------------|---|
| 0.1 | Mb | 27/02/2006 | Created for EUTCT based on EudraGMP |
| 0.2 | Mb | 13/04/2006 | Updated based on input from the PDSG & TSG |
| 0.3 | Mb | 13/04/2006 | Updated with specific project information ICH and EUTCT related |
| 0.4 | Neil Cordwell | 19/04/2006 | Updated with changes from the Business Use Case Report |
| 0.5 | Neil Cordwell | 04/05/2006 | Updated following requests at the Process Definition and Terminology Sub-Group meetings |
| 0.6 | Mb | 15/06/2006 | Updated SDO |
| 0.7 | JL | 06/06/2007 | Reviewed, amended and updated against EUTCT draft schema 0.2 document. |
| 0.8 | JL | 07/06/2007 | General review/edit of the Glossary |
| 0.9 | JL | 08/06/2007 | Continued general review/edit of the Glossary |
| 0.10 | JL | 08/06/2007 | Continued general review/edit of the Glossary |
| 0.11 | JL | 12/06/2007 | Completed general review/edit of the Glossary |
| 0.12 | Mb | 13/06/2007 | General review/edit. Final version to be created for publishing on the EU Telematics website by Technical Author. |
| 1.0 | JL | 13/06/2007 | Version 1 for publication on Telematics website. |
| 1.1 | JL | 14/06/2007 | Approved version. |
| 1.2 | JL | 15/06/2007 | Version number in footer manually updated. |
| 1.3 | JL | 02/07/2007 | Added acronym and definition for IATE. |
| 1.4 | | 04/04/2008 | |
| 1.5 | LC | 24/09/2009 | Updated Glossary terms to match EUTCT Memorandum of Understanding (MoU) |
| 1.6 | LC | 28/09/2009 | Updated Glossary after review and comment. |
| 1.7 | LC | 09/11/2009 | Added alphabet hyperlinks and accepted all changes in document. |
| 1.8 | LC | 09/11/2009 | Updated document history. |
| 1.9 | LC | 09/11/2009 | Minor changes to document |
| 1.10 | LC | 09/11/2009 | Minor changes to document |
| 1.11 | JL | 25/11/2009 | Updated document header and footer to EUTCT project from EMEA ready for . |
| 1.12 | LC | 25/11/2009 | Changed header format from portrait to landscape. |
| 1.13 | JL | 09/12/2009 | Replace all references to EMEA and full name version with EMA / European Medicines Agency in line with the Agency's rebranding of 08/12/2009. |
| 1.14, CURRENT | JL | 09/12/2009 | Version for publication in EUTCT Documentation page and on EU Telematics website. |

