

ISO-IDMP und Terminologien im Arzneimittelbereich

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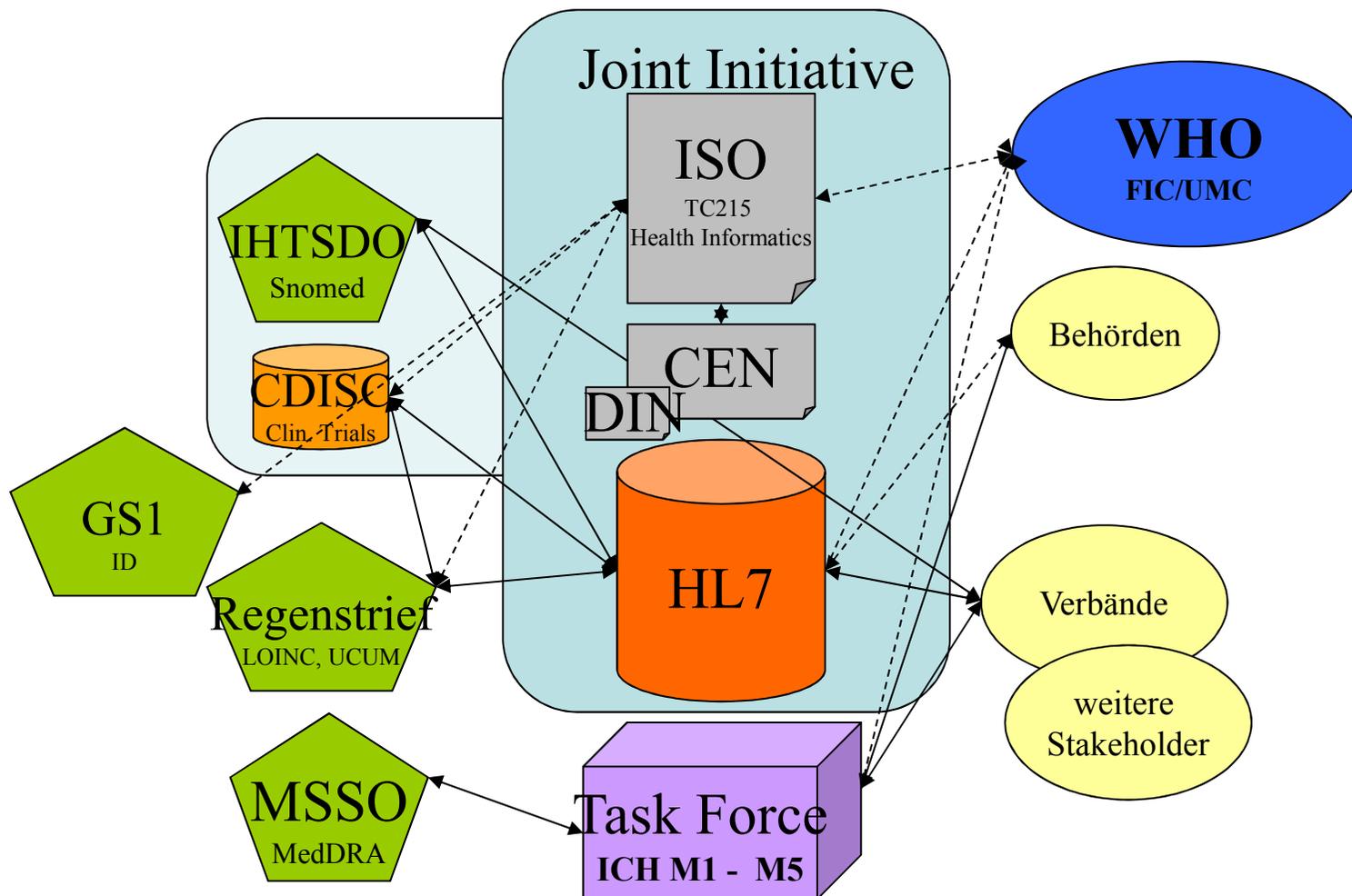
ISO-IDMP

ECKSTEIN FÜR EIN INTERNATIONALES ARZNEIMITTELREGISTER

Die Idee in einem globalen Umfeld ...

- Datenaustausch und Bereitstellung von Arzneimitteldaten zwischen Behörden in einheitlicher Struktur
- Verbesserung der Arzneimittelsicherheit (Datenaustausch international, Identifikation betroffener Arzneimittel)
- Harmonisierte Struktur für ein (europäisches) Arzneimittelregister

Die Beteiligten ...



Core Principles for Maintenance of Identifiers and Terms
DTR 14872

IDMP

Identification of Medicinal Products
Data elements and structures
for the unique identification and exchange

DTS 19844 + GInAS

EN ISO 11238

Substances

Regulated information on substances

Defines Substances by their main, general characteristics and Specified Substances (which are more granular, specific descriptions of a substance, e.g. including manufacturing information, purity, grade). Substances can have different roles in medicinal products (e.g. active, adjuvant, basis of strength, excipient). The standard also allows for the specification of multiple component substances ("Intermediate Products").

DTS 20440 + EDQM

EN ISO 11239

Dose forms, etc.

Regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging

Identifies and defines concepts for each of the above. For example, in dose forms: "injection solution", "injection suspension" (or a less granular regional term linked to these)

DTS 20443

EN ISO 11615

MPID

Regulated medicinal product information

Defines, characterizes and uniquely identifies regulated medicinal products for human use during their entire life cycle (development, authorization, post-marketing and renewal or withdrawal from the market) by describing the detailed data elements and their structural relationships that uniquely identify a medicinal product.

HL7 Common Product Model



EN ISO 11240

Units of measurement

Units of measurement

Specifies rules for the usage of units of measurement for IDMP; defines requirements for traceability to metrological standards; establishes reference code system for units; provides structures and rules for mapping between different unit vocabularies and language translations, linking to existing systems, dictionaries and repositories

DTS 20451

EN ISO 11616

PhPID

Regulated pharmaceutical product information

Pharmaceutical Product Identification (PhPID) uniquely identifies a generic (pharmaceutical) representation of a medicinal product at various levels, based on the following subset of elements

- Substance(s)/Specified Substance(s)
- Strength(s) - Strength units (units of measurement and/or unit of presentation)
- Reference Strengths
- Administrable Dose Form

HL7 Regulated Reporting (Safety)



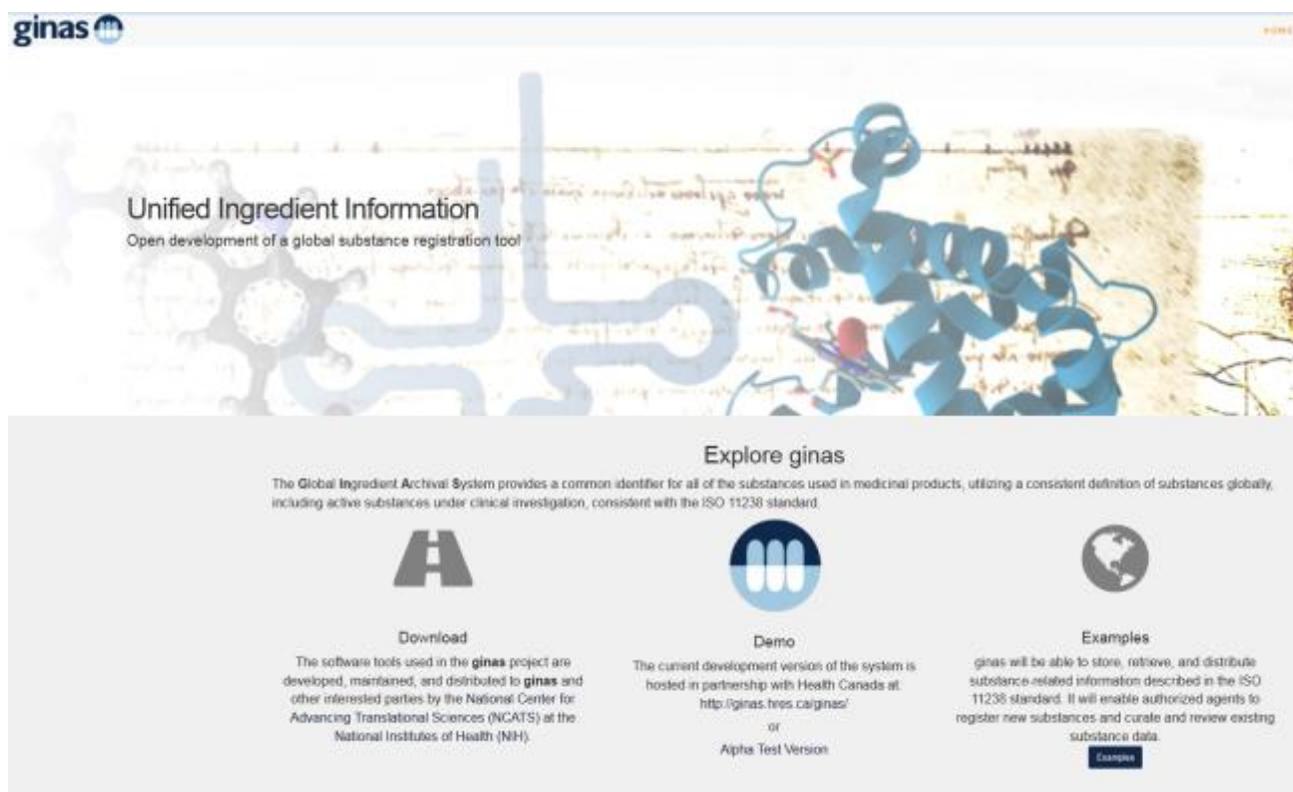
Umsetzung von ISO-IDMP

Substanzen
Standard Terms
Maßeinheiten

Global Substance registration Tool

<https://tripod.nih.gov/ginas/>

- Technische Plattform für ein globales „Substance Master File“
- Zuordnung eines (im regulativen Bereich) globalen Identifiers



ginas

Unified Ingredient Information
Open development of a global substance registration tool

Explore ginas
The Global Ingredient Archival System provides a common identifier for all of the substances used in medicinal products, utilizing a consistent definition of substances globally, including active substances under clinical investigation, consistent with the ISO 11238 standard.

Download
The software tools used in the **ginas** project are developed, maintained, and distributed to **ginas** and other interested parties by the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH).

Demo
The current development version of the system is hosted in partnership with Health Canada at: <http://ginas.hres.ca/ginas/> or Alpha Test Version

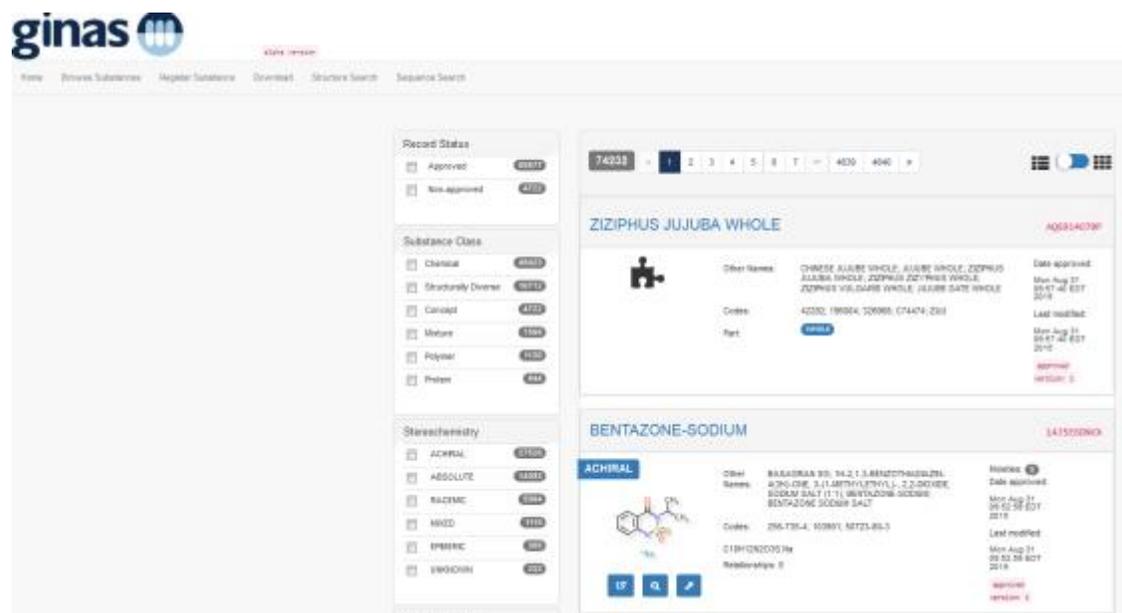
Examples
ginas will be able to store, retrieve, and distribute substance-related information described in the ISO 11238 standard. It will enable authorized agents to register new substances and curate and review existing substance data.

[Example](#)

Substance Maintenance

→ Gesucht: Maintenance Organisation zur fachlichen Betreuung und Hosting des OpenSource Systems

- Interessent: WHO Monitoring Centre in Uppsala
www.who-umc.org
 (Betreibt Vigibase zur Erfassung von Arzneimittelrisikomeldungen)
- Regionale bzw. Nationale Subsysteme in Planung (z.B. in D beim BfArM), Kooperation mit pharmazeutischer Industrie

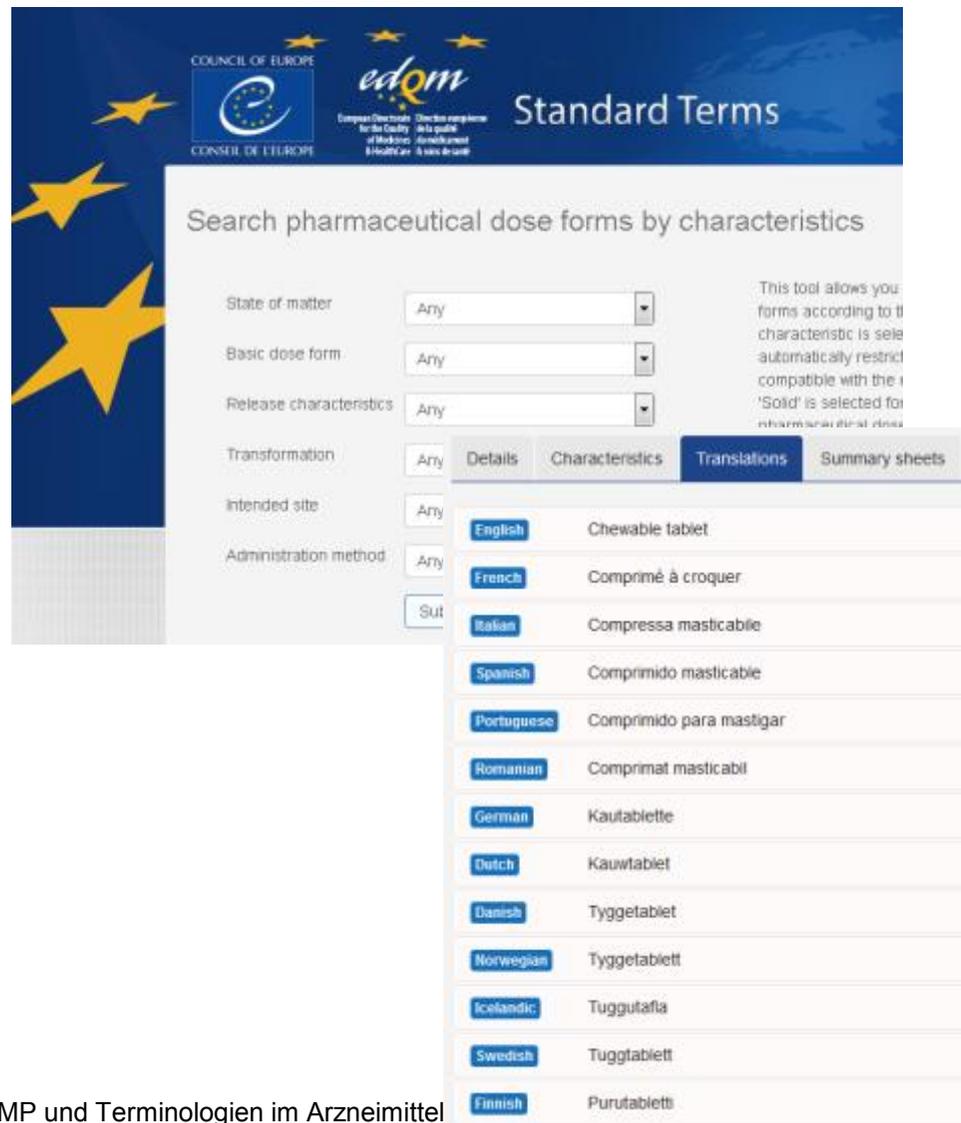


The screenshot displays the GINAS web application interface. On the left, there are filters for Record Status (Approved: 4087, Not approved: 417), Substance Class (Clinical: 4860, Structurally Diverse: 4072, Concept: 472, Mixture: 439, Polymer: 432, Protein: 484), and Stereochemistry (ACHIRAL: 4150, ABSOLUTE: 4080, RACEMIC: 4094, MIXED: 4110, ENANTIOMERIC: 405, ENDOGEN: 402). The main content area shows two substance records:

- ZIZIPHUS JUJUBA WHOLE** (A03B1AC39P): Includes other names like CHINESE JUJUBE WHOLE, JUJUBE WHOLE, ZIZIPHUS JUJUBA WHOLE, ZIZIPHUS JUJUBA WHOLE, ZIZIPHUS JUJUBA WHOLE, JUJUBE SATE WHOLE, codes 4232, 19824, 20990, 67424, 233, and a last modified date of Mon Aug 27 09:47:46 EDT 2014.
- BENTAZONE-SODIUM** (J41S029X3): Includes other names like BENTAZONE SODIUM, BENTAZONE SODIUM, BENTAZONE SODIUM, BENTAZONE SODIUM, BENTAZONE SODIUM, BENTAZONE SODIUM, codes 294, 7354, 10881, 10723, 853, and a last modified date of Mon Aug 27 09:52:58 EDT 2014.

ISO - Standard Terms (EDQM)

- Umsetzung der durch den ISO-Standard vorgegebenen Rahmenbedingungen (fachliches Modell) durch EDQM
- Mapping internationaler Begriffe in Arbeit
- Verpflichtende Nutzung im Zulassungsantrag in Europa → in jedem Beipackzettel, Fachinformation, auf der Packung aufgedruckt
- Übersetzt in alle europäischen Sprachen
- <https://standardterms.edqm.eu/> (nach Registrierung)



The screenshot shows the EDQM Standard Terms search interface. The header includes the Council of Europe logo and the EDQM logo. The main heading is "Standard Terms". Below this, there is a search form titled "Search pharmaceutical dose forms by characteristics". The form has several dropdown menus for "State of matter", "Basic dose form", "Release characteristics", "Transformation", "intended site", and "Administration method", all currently set to "Any". To the right of the form, there is a text box explaining that the tool allows users to search for forms according to their characteristics and that selecting "Solid" restricts results to solid oral dosage forms. Below the search form, there are tabs for "Details", "Characteristics", "Translations", and "Summary sheets". The "Translations" tab is active, showing a list of translations for "Chewable tablet" in various European languages.

Language	Translation
English	Chewable tablet
French	Comprimé à croquer
Italian	Compressa masticabile
Spanish	Comprimido masticable
Portuguese	Comprimido para mastigar
Romanian	Comprimat masticabil
German	Kautablette
Dutch	Kauwtablet
Danish	Tyggetablet
Norwegian	Tyggetablett
Icelandic	Tuggutafli
Swedish	Tuggtablett
Finnish	Purutabletti

Maßeinheiten

- Basieren auf UCUM-Notation
 - Im pharmazeutischen Bereich zahlreiche „Arbitrary Units“ {..}
 - 50% Embryo Infective Dose*
 - allergy unit(s)*
 - billion colony forming units*
 - Notwendigkeit der Darstellung „komplexer“ Maßeinheiten im Sinne der Usability
 - percent weight/volume*
 - millilitre(s)/square cm*
 - Gleichzeitig Normierung für Datenaustausch erforderlich
 - 0,5 g = 500 mg*
- Maintenance Organisation für {Arbitrary Units} gesucht!
Kandidat BfArM (D)



Die Umsetzung von ISO-IDMP in Europa

**XEVMPD und Art. 57 Register
ISO-IDMP Task Force (SPOR)
EUTCT und Webservice**

Art. 57 Register / XEVMPD

The screenshot shows the EMA website interface. At the top, there is the EMA logo and the text 'EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH'. To the right, there is a search bar and social media links. The main navigation bar includes 'Home', 'Find medicine', 'Human regulatory', 'Veterinary regulatory', 'Committees', 'News & events', 'Partners & networks', and 'About us'. The 'Human regulatory' section is active. The main content area is titled 'Data submission on medicines' and contains the following text:

All holders of marketing authorisations for medicines in the European Union (EU) and the European Economic Area (EEA) must submit information to the European Medicines Agency (EMA) on authorised medicines and keep this information up-to-date. This is a legally binding requirement from the EU pharmaceutical legislation. The Agency uses this information to support the analysis of data, regulatory activities and communication.

The aim of the submission of data is to establish a complete inventory of all medicines authorised for use in the EU and EEA, including medicines authorised centrally via the EMA and those authorised at national level.

The Agency plans to use this information for a range of purposes. These include:

- performing data analysis, including:
 - analysis of data in EudraVigilance and signal management;
 - reporting and coding of individual case safety reports;
 - data analytics and business intelligence;
- facilitating medicines regulation and fulfilling regulatory actions and legal obligations, such as:
 - coordination of regulatory actions to safeguard public health, including referral procedures, establishment of a repository of periodic safety update reports (PSURs) and literature monitoring;
 - supporting the calculation of fees for pharmacovigilance;
- strengthening communication with stakeholders by means of:
 - establishing the European medicines web portal;
 - granting proactive and reactive access to EudraVigilance data;
 - exchanging data within the EU and internationally;
 - supporting communication between the Pharmacovigilance Risk Assessment Committee (PRAC) and marketing-authorisation holders.

Legal background

The submission of data on medicines by marketing-authorisation holders is a **legal requirement** from the 2010 pharmacovigilance legislation.

Marketing-authorisation holders (MAHs) were initially required to submit information on medicinal products for human use to the European Medicines Agency (EMA) using the electronic format referred to as Article 57 format or extended EudraVigilance Product Report Message (XEVPRM) format by 2 July 2012.

On the right side of the page, there are sections for 'Related documents', 'Related content', 'Related EU legislation', 'External links', and 'Contact point'.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000496.jsp&mid=WC0b01ac058078fbe0

EMA Master Data Management

Master Data Management Concepts

EUROPEAN MEDICINES AGENCY

Master Data:

- Basic business data used across multiple systems, applications, and/or processes. Represents key business entities such as customers and products in all the necessary detail (e.g., for customers: number, name, address, and date of account creation).
- Can in itself contain reference data.
- Typical examples of Master data are: Products; Substances; organisations; people.

Reference Data:

- Set of permissible values to be used by other (master or transaction) data fields.
- Typical examples of reference data are: Units of measure; Country codes; Dosage Form.

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<https://tripod.nih.gov/ginas/docs/Wednesday/EMA%20activities%20-%20Current%20status%20and%20next%20steps%20-%20Ginas.pdf>

Referentials

<http://eutct.ema.europa.eu/>

<http://eutct.eudra.org/eutct/lists>

EUTCT

Welcome to EUTCT

The European Union Telematics Controlled Terms (EUTCT) System is a 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).

For more information on EUTCT click [here](#)

Guest User access to EUTCT

EUTCT You are logged in as: Guest User [Log In](#)

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Controlled Term Lists 258 Lists found Page 1 of 4 Lists per page 20

List Identifier	List Name	List Version	List Information	List Attributes
100000155046	Applicants Submission Unit Type		List Information	List Attributes
100000116040	Application Legal Status		List Information	List Attributes
100000075859	Application Recipient		List Information	List Attributes
100000154440	Application Reference Reason		List Information	List Attributes
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100000075861	Clinical Trial Inspection Scope		List Information	List Attributes
100000075902	Clinical Trial Inspection Status		List Information	List Attributes
100000075903	Comparator Type		List Information	List Attributes

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amendmenttype.xml.zip	1072	2011-02-21T23:55:03
applicantsubmunittype.txt	2310	2013-11-15T01:00:00
applicantsubmunittype.txt.zip	838	2013-11-15T01:00:00
applicantsubmunittype.xml	14606	2013-11-15T01:00:13
applicantsubmunittype.xml.zip	1471	2013-11-15T01:00:13
applicrecipient.txt	1707	2014-05-05T01:00:03
applicrecipient.txt.zip	709	2014-05-05T01:00:03
applicrecipient.xml	6120	2011-02-21T23:55:06
applicrecipient.xml.zip	1173	2011-02-21T23:55:06
applicrefreason.txt	1459	2014-04-18T01:00:00
applicrefreason.txt.zip	675	2014-04-18T01:00:00



Bedeutung für Daten zu Arzneimitteln im regulativen Bereich

Arzneimitteldaten im regulativen Bereich

- Pharmazeutische Unternehmen in Europa müssen ihre Arzneimittel IDMP-konform in ein zentrales Arzneimittelregister laden.
- Alle inhaltlichen Aktualisierungen müssen innerhalb 15 Tagen an das Register gemeldet werden.
- Eingriff in die Datenstruktur und Workflow in vielen Bereichen eines Unternehmens (Mapping der internen Quellen auf Datenmodell und Semantik).
- Behördensysteme sollten (müssen) kompatibel sein.

Arzneimitteldaten im regulativen Bereich

- Ca. 500.000 Basisdaten für Arzneimittel in Europa
- Enthalten die wichtigsten Elemente in strukturierter Form [Darreichungsform, Anwendungsart, Zusammensetzung, ATC-Codes, Indikationen (MedDRA codiert)], Ca. 500 Datenfelder, davon ca. 1/3 strukturiert
- Jedes Produkt bekommt einen europaweit (weltweit) einheitlichen Schlüssel.
- Alle Basisdaten liegen in Englisch vor.
- Zu jedem Arzneimittel liegt die Fachinformation (SmpC) in der Originalsprache vor.
- Darauf basierend sollen Risikomeldungen weltweit strukturiert ausgetauscht werden können.



Bedeutung für die Arzneimittelversorgung

- Crossborder Directive**
- ePrescription Guideline**
- Projekte zur „Machbarkeit“
epSOS und EXPAND
OpenMedicine**



Grenzüberschreitende Gesundheitsversorgung

- Richtlinie 2011/24 /EU über die Ausübung der Patientenrechte in der **grenzüberschreitende Gesundheitsversorgung**
<http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=celex:32011L0024>
- Durchführungsrichtlinie 2012/52/EU mit Maßnahmen zur Erleichterung der **Anerkennung** von in einem anderen Mitgliedstaat ausgestellten **ärztlichen Verschreibungen**
<http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX:32012L0052>
- Guidelines on **ePrescriptions dataset for electronic exchange** under Cross-Border Directive 2011/24/EU
http://ec.europa.eu/health/ehealth/docs/eprescription_guidelines_en.pdf



Umsetzung Crossborder ePrescription

Grundlage für Crossborder ePrescription in Europa, basierend auf Ergebnissen von epSOS:

Identifizier	<input checked="" type="checkbox"/> Identifizier des Art. 57 Registers / EMA
Zentrales Register mit Metadaten	<input checked="" type="checkbox"/> Art. 57 Register / EMA
Ingredient	<input checked="" type="checkbox"/> GInAS / WHO
Strength	<input checked="" type="checkbox"/> UCUM / BfArM
Pharmaceutical Form	<input checked="" type="checkbox"/> Standard Terms / EDQM
Route of Administration	<input checked="" type="checkbox"/> Standard Terms / EDQM



<http://www.theuropean.de/anke-domscheit-berg/12008-digitale-weiterentwicklung-der-demokratie>