

# **ISO-IDMP und Terminologien im Arzneimittelbereich**

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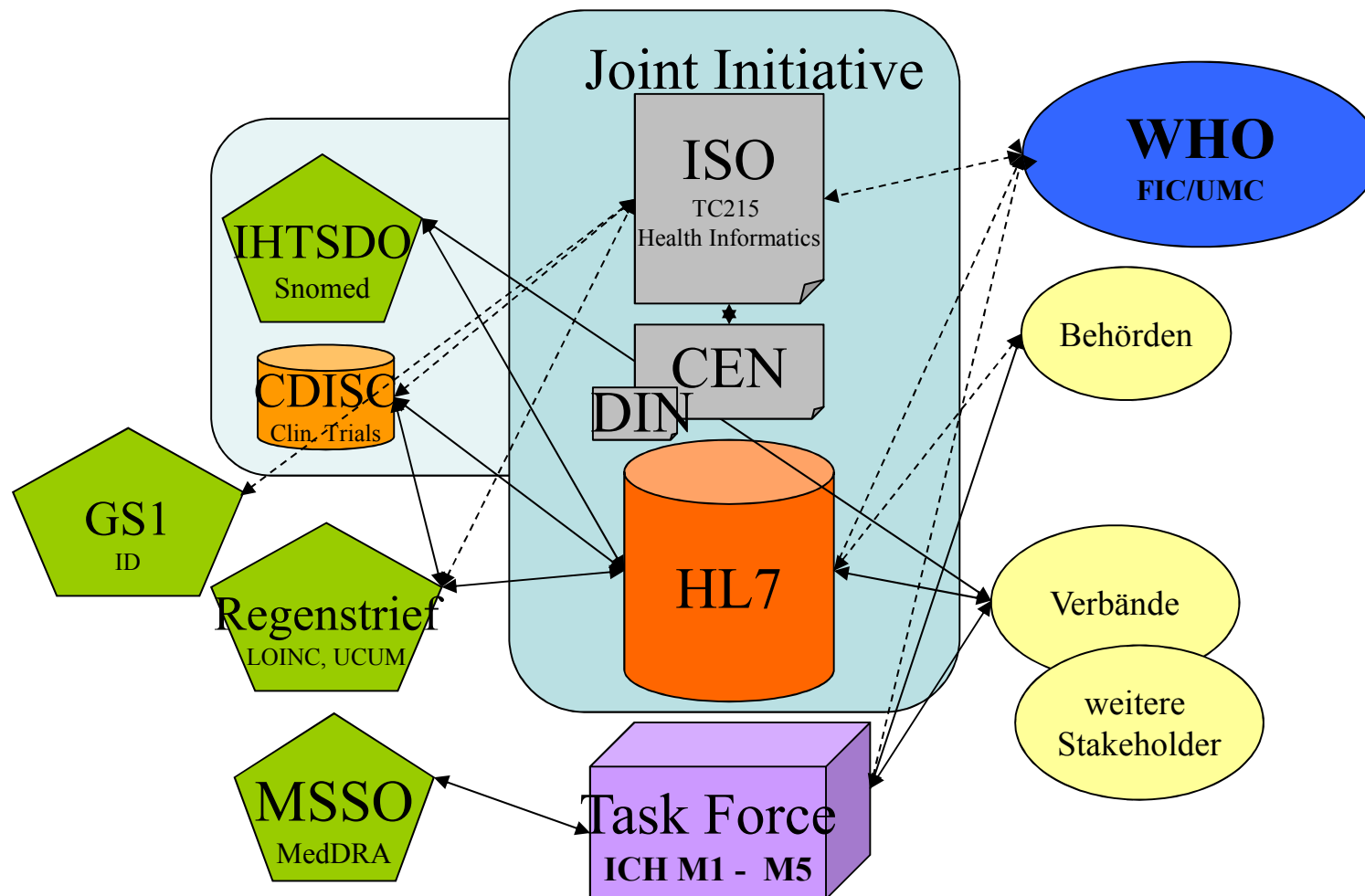
# ISO-IDMP

# 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)

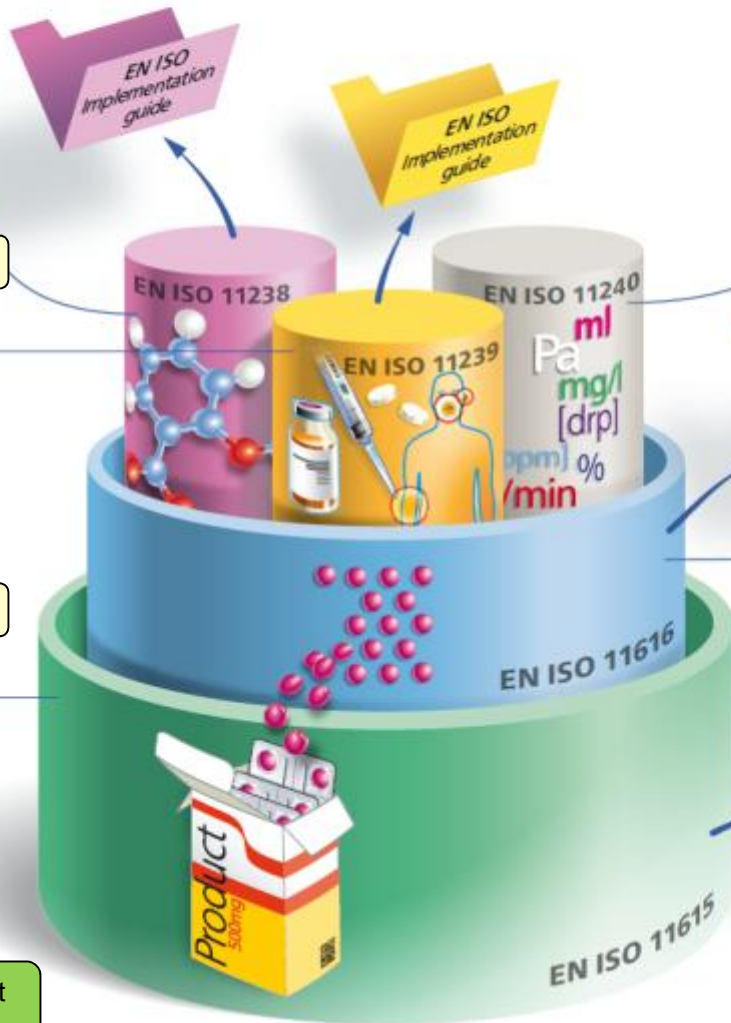
DTS 20443

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)



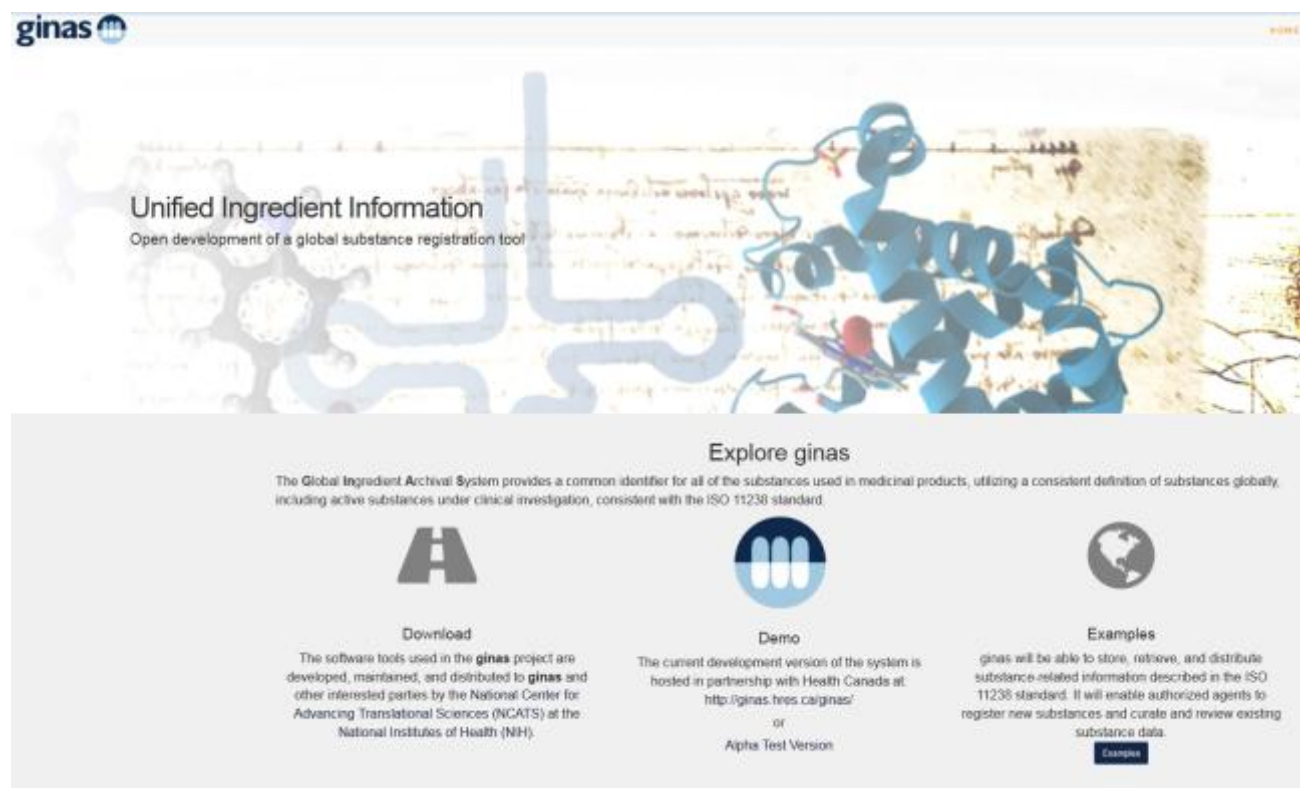
# Umsetzung von ISO-IDMP

**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

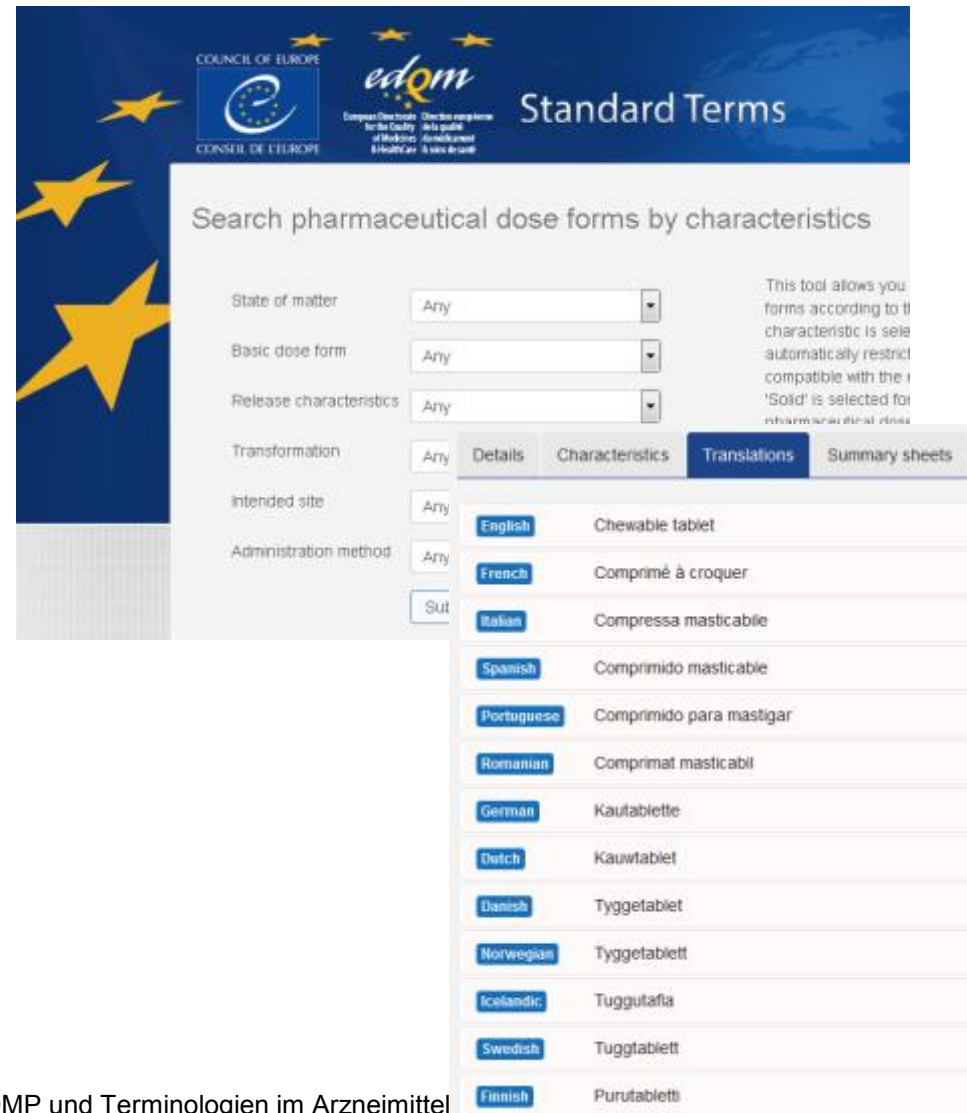






# ISO - Standard Terms (EDQM)

- 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)



Search pharmaceutical dose forms by characteristics

This tool allows you to search for dose forms according to the characteristics selected. The search results are automatically restricted to those compatible with the 'Solid' characteristic if 'Solid' is selected for the 'State of matter' characteristic.

State of matter: Any

Basic dose form: Any

Release characteristics: Any

Transformation: Any

intended site: Any

Administration method: Any

Translations

Language	Term
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 with 'Site-wide search' and a 'GO' button, along with social media icons for Twitter, Facebook, and YouTube. Below the search bar is a navigation menu with 'Home', 'Find medicine', 'Human regulatory' (highlighted), 'Veterinary regulatory', 'Committees', 'News & events', 'Partners & networks', and 'About us'. The main content area is titled 'Data submission on medicines' and includes a breadcrumb trail: 'Home > Human regulatory > Data submission on medicines'. The page contains several sections: a main text block starting with '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...', a list of purposes for data submission, a 'Legal background' section, and sidebars for 'Related documents', 'Related content', 'Related EU legislation', 'External links', and 'Contact point'.

Home > Find medicine > **Human regulatory** > Veterinary regulatory > Committees > News & events > Partners & networks > About us

Pre-authorisation  
Post-opinion  
Post-authorisation  
Product information  
Scientific advice and protocol assistance  
Scientific guidelines  
Innovation Task Force  
SME office  
Paediatric medicine  
Geriatric medicine  
Orphan designation  
Herbal products  
Referral procedures  
Article 58 applications  
Compassionate use  
Pharmacovigilance  
**Data submission on medicines**  
Reporting requirements for authorised medicines  
Implementation of ISO IDMP standards  
Registration  
Training

Text size: A A A Site-wide search GO  
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Home > Human regulatory > Data submission on medicines

## Data submission on medicines

Email Print Help Share

**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.

**Related documents**

- [Data submission of authorised medicines in the European Union: Outlines on Article 57\(2\) of Regulation \(EC\) No 726/2004 \(23/02/2015\)](#)

**Related content**

- [Pharmacovigilance](#)

**Related EU legislation**

- [Regulation \(EU\) No 1235/2010](#)


**External links**

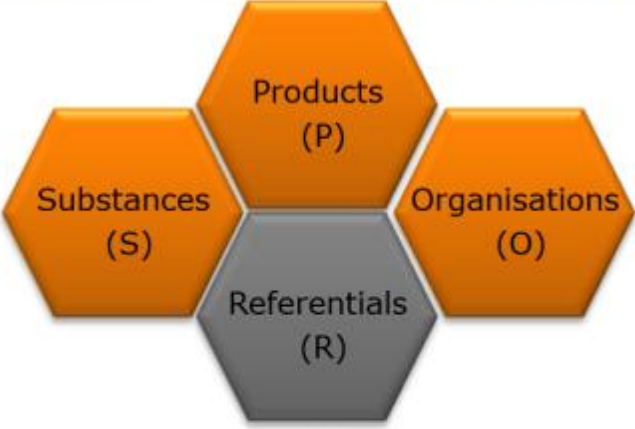
- [EudraVigilance](#)

**Contact point:**  
E-mail: [art57@ema.europa.eu](mailto:art57@ema.europa.eu)  
Tel: +44 (0)20 3660 7010

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000496.jsp&mid=WC0b01ac058078fbe0](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](#)

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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		<a href="#">List Information</a>	<a href="#">List Attributes</a>
100000116040	Application Legal Status		<a href="#">List Information</a>	<a href="#">List Attributes</a>
100000075859	Application Recipient		<a href="#">List Information</a>	<a href="#">List Attributes</a>
100000154440	Application Reference Reason		<a href="#">List Information</a>	<a href="#">List Attributes</a>
100000150688	Application Submission Type		<a href="#">List Information</a>	<a href="#">List Attributes</a>
100000072049	Authorization Status		<a href="#">List Information</a>	<a href="#">List Attributes</a>
100000033473	Central Technical Facility Duty		<a href="#">List Information</a>	<a href="#">List Attributes</a>
100000076890	Clinical Trial Inspection Outcome		<a href="#">List Information</a>	<a href="#">List Attributes</a>
100000076861	Clinical Trial Inspection Scope		<a href="#">List Information</a>	<a href="#">List Attributes</a>
100000076802	Clinical Trial Inspection Status		<a href="#">List Information</a>	<a href="#">List Attributes</a>
100000075803	Comparator Type		<a href="#">List Information</a>	<a href="#">List Attributes</a>

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<a href="#">amendmenttype.xml.zip</a>	1072	2011-02-21T23:55:03
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<a href="#">applicrecipient.txt.zip</a>	709	2014-05-05T01:00:03
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<a href="#">applicrecipient.xml.zip</a>	1173	2011-02-21T23:55:06
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# **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](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>