

Terminology Management: Value Set Catalogues

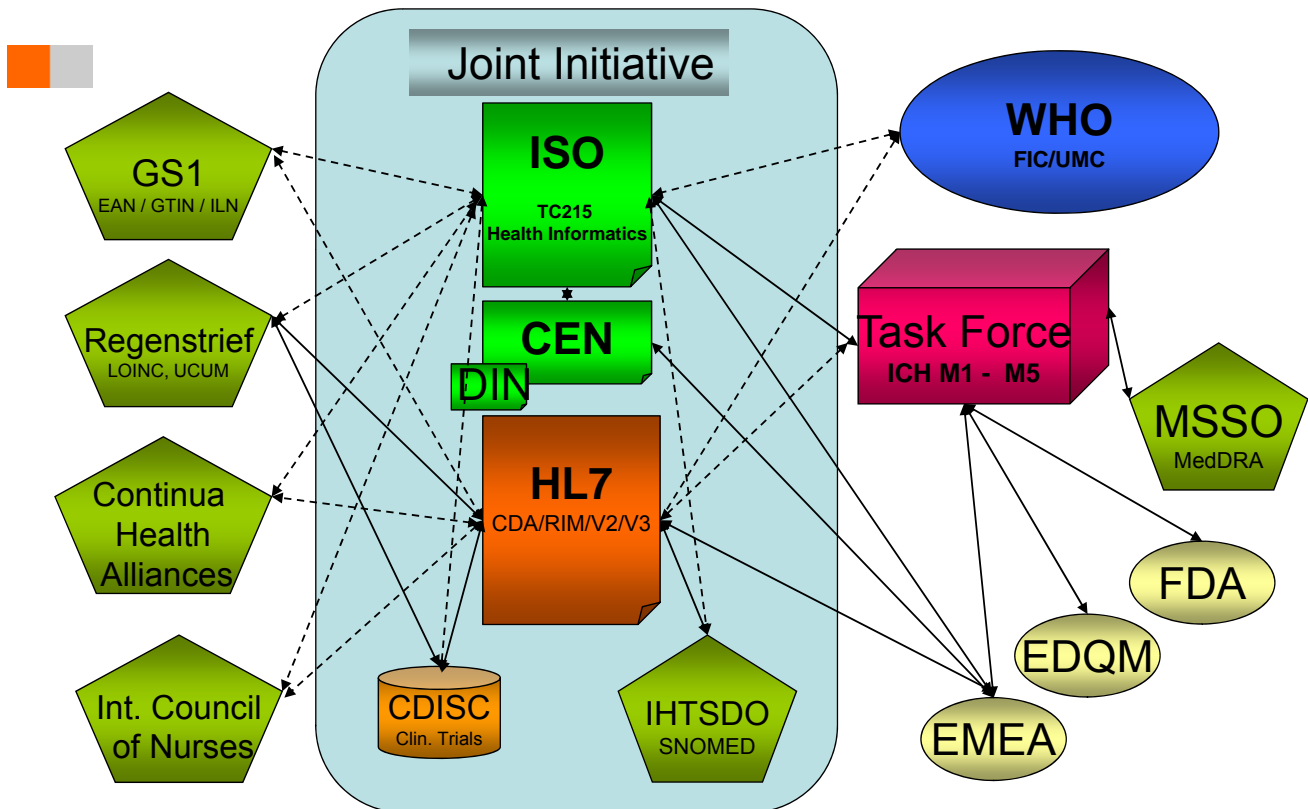
Dr. Sylvia Thun, DIMDI

3rd CALlepSO Workshop on
Open Semantic Services



Agenda

1. Int. standardisation of eHealth terminologies
2. Responsibilities: epSOS vs. national centers
3. Copyrights and licensing
4. Methodology
5. Code systems & value sets

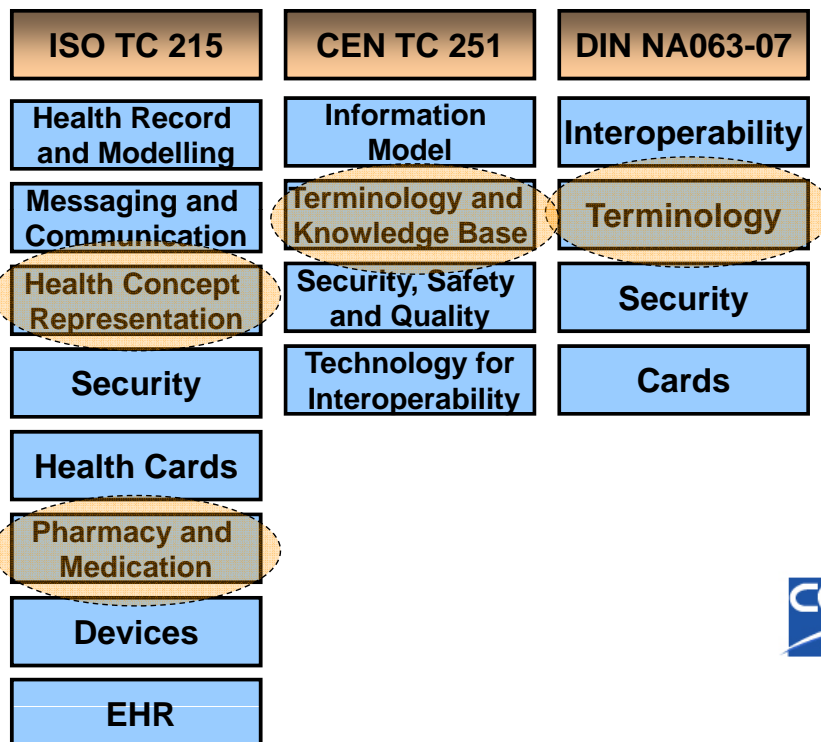


Joint Initiative on SDO Global Health Informatics Standardization

1. A mutually agreed upon and used decision process for international standardization needs;
2. Coordinated standards strategies and plans, with the future goal of making all standards available through ISO;
3. An integrated work program; and
4. Focused, specific resolution of overlapping or counteracting standards within the participating SDOs' existing work programs.

Projects:

- Common Terminology Services
- Electronic Health Record
- Common Glossary
- Terminologies: Drugs, Diagnosis, Devices,...
- ...



European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

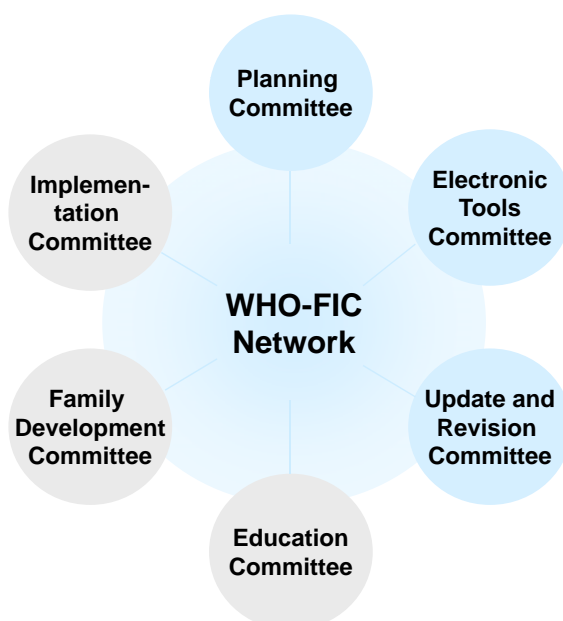


WHO-Collaborating centers





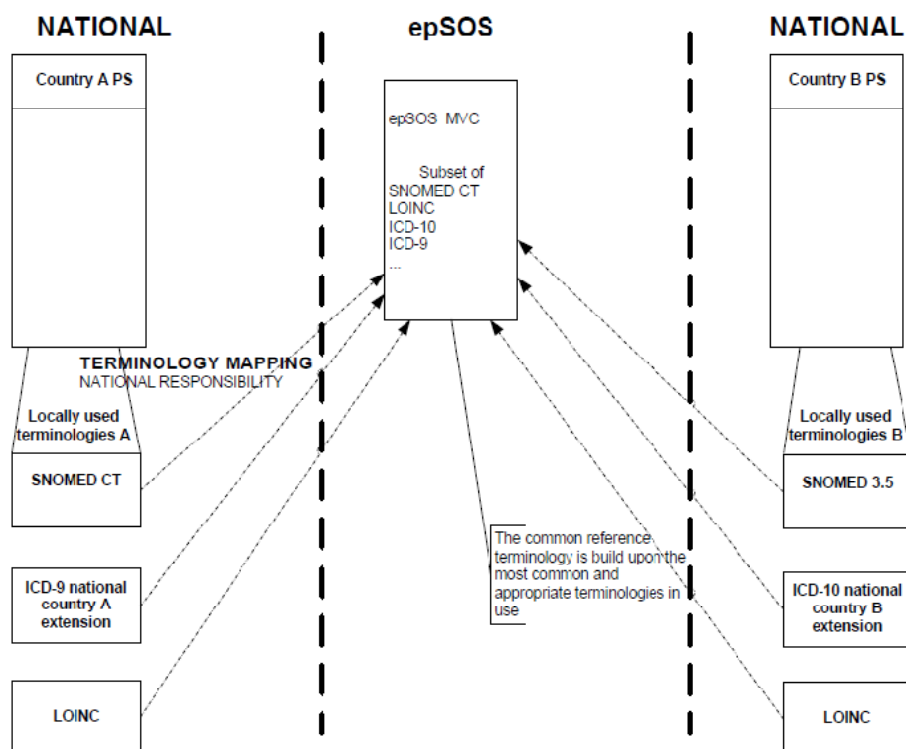
WHO – FIC



SemanticHEALTH Report January 2009, EC

- Enable the safe, **meaningful** sharing and combining of health record data between heterogeneous systems
- Enable the **consistent use of modern terminology systems** and medical knowledge resources
- Enable the integration and safe use of computerised protocols, alerts and care pathways by EHR systems
- Link EHR data to explanatory and educational materials to support patient and family engagement and professional development
- Ensure the necessary data quality and consistency to enable rigorous secondary uses of longitudinal and heterogeneous data: public health, research, health service management.

Semantic Services in epSOS



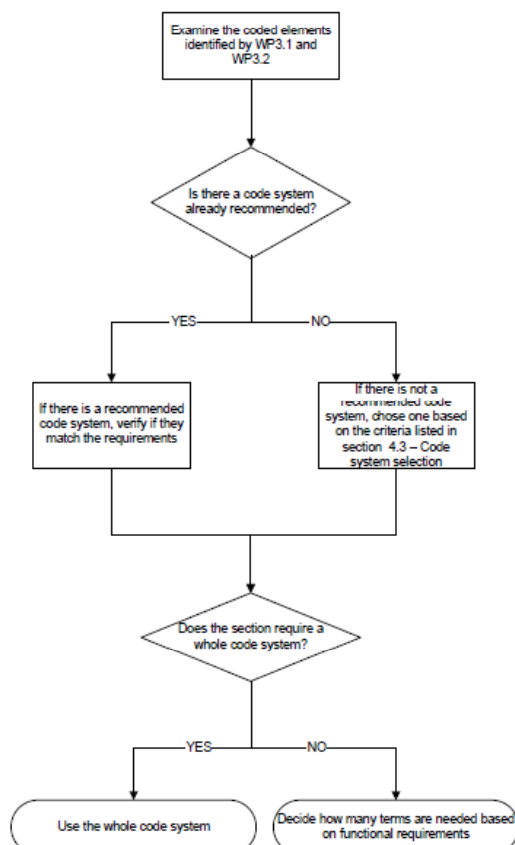
Responsibilities

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Methodology epSOS Master Value Sets → epSOS Ontology → Semantic Services

1. Definition and Concept Domain -Binding to CDA upon requirements of WP3.1 & WP3.2
2. Selection of concepts (in english) upon requirements of WP3.5A
 - Selection of value sets/coding systems on defined criteria
 - Analysis of Pre-assigned value sets /coding systems
 - constraining
 - add concepts
3. Coding with International Terminologies
 - Guidelines for mapping and coding
4. Creating the epSOS Ontology
5. Translation & Mapping to member states languages/coding systems
 - Guidelines for translation
6. Quality assurance
7. Evaluation by medical doctors and pharmacists
8. Versioning and Publication

Methodology MVC



Criteria for selection of terms and coding systems

- | | |
|---|---|
| 1. <i>International standard</i> | 9. <i>Frequency of use</i> |
| 2. <i>In Use</i> | 10. <i>Severity</i> |
| 3. <i>Existence of transcoding systems / services</i> | 11. <i>Content evaluation and acceptance</i> |
| 4. <i>Cost of licences, of implementation and maintenance</i> | 12. <i>Syntactical and orthographical rules of each language have to be held.</i> |
| 5. <i>Implementable</i> | 14. <i>Reconcilability</i> |
| 6. <i>Relevancy to scope documents</i> | 15. <i>Unambiguity</i> |
| 7. <i>Information sufficient for clinical decision</i> | 16. <i>Clinical acceptability</i> |
| 8. <i>Information systems behind</i> | 17. <i>Consistency and systematic order</i> |

Selection of 8610 concepts using intern. terminologies

IHTSDO – Snomed CT

WHO-FIC – ICD 10

WHO-FIC - ATC

HL7 – HL7 V3 CDA, Vocab

IHE – Profiles with Value Sets

Regenstrief Institute – LOINC & UCUM

EDQM – Standard Terms

Challenges

- CAVE : Copyrights and licenses
- selecting value sets
- selecting terminologies
- e.g. allergies:

Allergy Display Name	Allergies and Other Adverse Reactions Section 1.3.6.1.4.1.19376.1.5.3.1.3.13	Allergy & Intolerance Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root="2.16.840.1.113883.10.2027"]/entryRelationship[@typeCode="SUBJ"]/observation[templateId/@root="2.16.840.1.113883.10.20.1.13"]/entryRelationship[@typeCode="MFST"]/observation[templateId/@root="2.16.840.1.113883.10.20.1.54"]/code/@displayName	NS / NS / RNFA	CD	epSOSReactionAllergy 1.3.6.1.4.1.12559.11.10.1.3.1.42.11
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Requirements

Active ingredient or name of the medicinal product	Strength of the medicinal product (dose/unit)	Medicinal product package	Pharmaceutical dose form
Paracetamol	500 mg	30	capsules
Atropine	5 mg/ml	10ml	Eye drops

ATC WHO Anatomical Therapeutic Chemical classification system

- Copyright & Issuer: WHO Collaborating Centre for Drug Statistics
- Languages & Localization: English, Spanish, German, Italian
- Various manifestations: ATC-WHO, ATC-GM (Germany), ATC-WIDO (Germany), ATC Vet, ATC Herbal
- International non-proprietary names (INN) are used. If INN names are not assigned, USAN (United States Adopted Name) or BAN (British Approved Names) names are usually chosen.
- Fields of application: In the ATC-classification pharmacological substances are divided into different groups according to the organ or organ system which they affect and their chemical, pharmacological and therapeutic properties.
- Number of entries: 5597 Codes
- **epSOS substances**

European Directorate for the Quality of Medicines



- Publication of the European Pharmacopoeia
 - Certification of pharmaceutical substances
 - European network of Official Medicines Control Laboratories (OMCLs)
 - Standard Terms:
 - Route of Administration
 - Pharmaceutical Form
 - Containers
- **mandatory in regulatory transactions**
- **epSOS routes, dosage forms, container**

<http://www.edqm.eu/StandardTerms/>

EDQM StandardTerms

Search... all languages StandardTerms Search

Standard Terms

- Dosage forms
 - oral preparations-liquid and semi-solid forms
 - oral preparations-solid forms
 - oromucosal preparations
 - preparations for dental use
 - cutaneous and transdermal preparations
 - eye preparations
 - Eye cream
 - Eye gel
 - Eye ointment
 - Eye drops, solution
 - Eye drops, emulsion
 - Eye drops, suspension
 - Eye drops, powder and solvent for solution
 - Eye drops, powder and solvent for suspension
 - Eye drops, solvent for reconstitution
 - Eye drops, prolonged-release
 - Eye lotion
 - Eye lotion, solvent for reconstitution
 - Ophthalmic insert
 - Ophthalmic strip
 - ear preparations
 - nasal preparations
 - vaginal preparations
 - rectal preparations
 - preparations for inhalation
 - parenteral preparations
 - implants
 - preparations for dialysis
 - preparations for intravesical and urethral use
 - tracheopulmonary preparations
 - endocervical preparations
 - intramammary preparations
 - intrauterine preparations
 - environmental preparations
 - medicinal gases
 - miscellaneous
- Short Terms
- Routes
- Containers
- Combined Terms

Language	Term	Revised
ID number	10601000	
English	Eye cream	
French	Crème ophtalmique	
Italian	Crema oftalmica	
Spanish	Crema oftálmica	
Portuguese	Crema oftálmico	
Romanian	Crema oftalmică	
German	Augencreme	
Dutch	Oogcrème	
Danish	Øjencreme	
Norwegian	Øyeskrem	
Icelandic	Augnkrem	
Swedish	Ögonkräm	
Finnish	Silmävoide, creme	
Estonian	Silmakreem	
Turkish	Göz kremi	
Hungarian	Szemkrém	
Czech	Oční krém	
Slovak	Očný krém	
Slovenian	Krema za oko	
Croatian	Krema za oko	
Serbian	Krem za oči	16/03/2006
Polish	Krem do oczu	
Lithuanian	Akių kremas	
Latvian	Acu krēms	
Russian		
Bulgarian	Крем за очи	
Macedonian	Крем за око	
Greek	Οφθαλμική κρέμα	
Albanian		
Maltese	Krema għall-ghajnejn	
Chinese	眼用乳膏	23/02/2007
Ph. Eur. monograph	1163	

In 31 languages reference to Ph. Eur

UCUM (Unified Code for Units of Measure)

- UCUM: · Copyright & Issuer: Regenstrief Institute, Indiana
- Languages & Localisation: English
- Fields of application: UCUM is a system of codes for unambiguously representing measurement units to both humans and machines.
- Number of entries: 556
- **epSOS units e.g. ml**

ICD-10 WHO International Statistical Classification of Diseases and Related Health Problems

- Copyright & Issuer: WHO
- Languages & Localization: ICD-10 is available in the six official languages of WHO (Arabic, Chinese, English, French, Russian and Spanish) as well as in 36 other languages.
- Localizations have been made mainly for reimbursement purposes
- Fields of application: The ICD is the international standard diagnostic classification of diseases (signs, symptoms, conditions) for all general epidemiological, health management and statistics (death) and clinical use (health records). These include monitoring of the incidence and prevalence of diseases and other health problems.
- Number of entries: 1734 3-digit codes
- **epSOS: Diagnosis, Illnesses, Problems (Allergies)**

Snomed CT Systematized Nomenclature of Medicine-Clinical Terms

- Copyright & Issuer: IHTSDO – International Health Terminology Standards Development
- Organization, a non-for-profit association based in Denmark.
- Languages & Localization: English (US, UK), Spanish, Danish.
- Translations to French and Swedish are currently taking place. Translation into Lithuanian are also taking place but only on a small-scale.
- Fields of application: SNOMED CT is a comprehensive terminology, created to cover the whole patient record and medical documentation.
- Number of entries: **310.000 active concepts**
- Cross-map to other international standards is not officially available.
- It has been announced the creation of a joint working group between IHTSDO and WHO to develop an official cross-reference between SNOMED-CT and ICD-10 (ICD-11).

Use of Snomed CT in epSOS

- Adverse Event Type (drug, food, substance)
- Allergies
- Blood group
- Vaccination
- Medical devices
- Procedures
- Social history

LOINC (Logical Observation Identifiers names and codes)

Copyright & Issuer: Regenstrief Institute, Indiana

Languages & Localization: English, Spanish, Chinese, German (Users guide), Estonian, Italian

Number of entries: 53,344

Scope: Laboratory test results, Clinical findings

epSOS Sections, Blood pressure, pregnancy information

Structure:

- **Component** (analyte) - e.g., potassium, hemoglobin, hepatitis C antigen.
- **Property** measured - e.g., a mass concentration, enzyme activity (catalytic rate).
- **Timing** - i.e., whether the measurement is an observation at a moment of time, or an observation integrated over an extended duration of time - e.g., 24-hour urine.
- **The type of sample** - e.g., urine, blood.
- The type of **scale** - e.g., whether the measurement is quantitative (a true measurement) ordinal (a ranked set of options), nominal (e.g., E. coli; Staphylococcus aureus), or narrative (e.g., dictation results from x-rays).
- Where relevant, the **method** used to produce the result or other observation

HL7 Vocab

- Other catalogues
 - Timing event
 - Telecommunication
 - Address
 - Personal relationship
 - Participation
 - Null flavor
 - Confidentiality
 - Gender
 - Act encounter

IHE Value Sets

Since the syntax used in the pivot document is based on the IHE PCC specifications, there are some specific code systems defined by IHE such as IHEActCodeVocabulary or IHERoleCodeVocabulary.

These are necessary for the implementers and are part of the coding specifications.

Functional Requirements

- Additions: Registered users can add new concepts, representations, relationships, and mappings.
- Deletions/modifications: Registered users can identify invalid and obsolete concepts. Concepts that have been assigned and ID codes are never deleted. Instead, the status of concepts can be set to be inactive or obsolete.
- Creating categories: Registered users can create new categories and subcategories.
- Creating links: Registered users can create meaningful named relationships among concepts.

WP3.2 Patient Summary Emergency Data Set ISO21549

ICD-10-GM	ICD-10 WHO	Snomed CT	ATC	German	English (Snomed CT)	Slovak
J45.-	J45.-	195967001		Asthma bronchiale	asthma	Astma
E10-E14	E10-E14	73211009		Diabetes mellitus	diabetes mellitus	Diabetes mellitus
E27.1	E27.1	363732003		Morbus Addison	Addison's disease	Addisonova choroba
B99	B99	40733004		Infektionskrankheit	infectious disease	Infekčná choroba
Z94.-	Z94.-	316053009		Zustand nach Transplantation	transplanted organ or tissue	Stav po transplantácii
Z71.4	Z71.4	233985008		Bauchortenaneurysma	abdominal aortic aneurysm	Aneurysma brušnej aorty
		372695000	C03	Diuretika	diuretic	Diuretiká
		280110009	C01DA	Organische Nitrate	nitrate agent	Blokátory vápnikových kanálov
		372603003	C03DA	Aldosteron-Antagonisten	aldosterone antagonist	Antagonisty aldosterónu
		84812008	B01AB	Heparin	heparin	Heparín
		372765004	N07AA	Cholinesterasehemmer	anticholinesterase agent	Inhibitory cholinesterázy

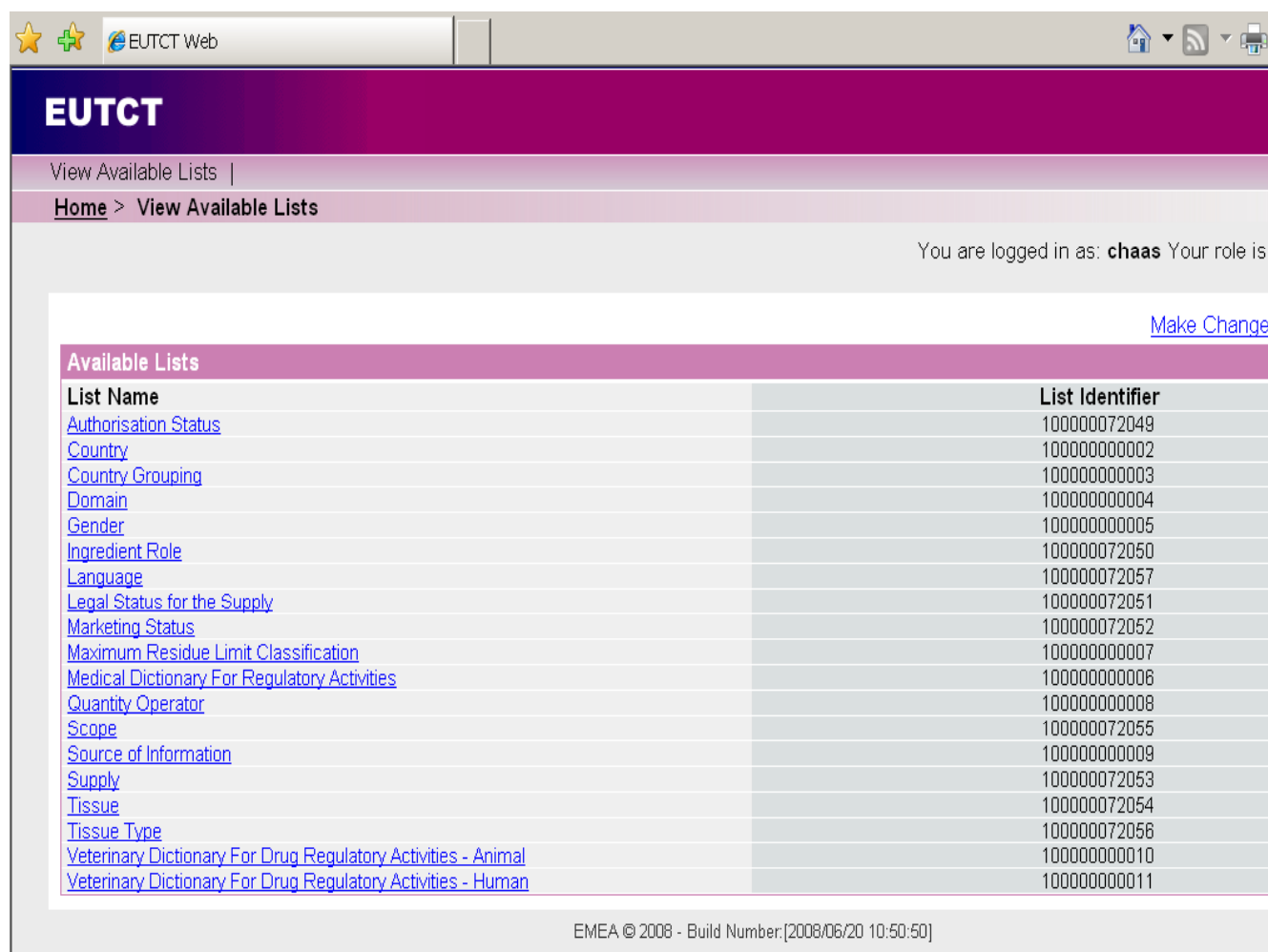
Outlook: EU Telematics Controlled Terms (EUTCT)

EU Telematics

- Founded in May 2005
- Controlled Terms for the European Regulatory Network
- Linking the European Databases

→ Intended to be mandatory in regulatory transactions

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



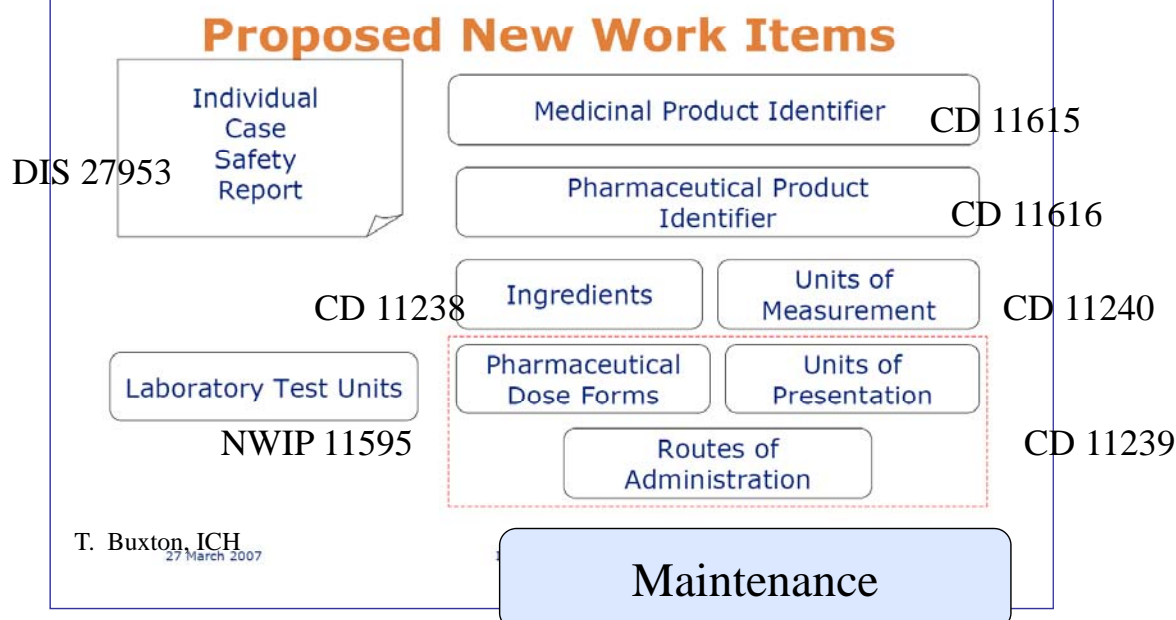
The screenshot shows the EUTCT Web application interface. The browser window title is "EUTCT Web". The page has a purple header with "EUTCT" in white. Below the header, there is a navigation bar with "View Available Lists" and "Home > View Available Lists". A message on the right says "You are logged in as: chaas Your role is:". A link "Make Change" is visible. The main content area is titled "Available Lists" and contains a table with two columns: "List Name" and "List Identifier". The table lists various controlled terms and their corresponding identifiers.

List Name	List Identifier
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Country Grouping	100000000003
Domain	100000000004
Gender	100000000005
Ingredient Role	100000072050
Language	100000072057
Legal Status for the Supply	100000072051
Marketing Status	100000072052
Maximum Residue Limit Classification	100000000007
Medical Dictionary For Regulatory Activities	100000000008
Quantity Operator	100000000008
Scope	100000072055
Source of Information	100000000009
Supply	100000072053
Tissue	100000072054
Tissue Type	100000072058
Veterinary Dictionary For Drug Regulatory Activities - Animal	100000000010
Veterinary Dictionary For Drug Regulatory Activities - Human	100000000011

EMEA © 2008 - Build Number: [2008/06/20 10:50:50]

View : Federal Republic of Germany	
Term Identifier	100000000403
Term Name	Federal Republic of Germany
List Name	Country
List Identifier	100000000002
Operational Attributes	Creation 12/09/2007 16:51:47 by kogbe Modification 29/02/2008 11:46:10 by kogbe Revision number 2
Term Name: en Federal Republic of Germany Translation Status: CURRENT Modified On: 20/08/2007+14:41 Modified By: secretariat	
Short Name: en fr bg cs da de el es et fi hu is it lt lv mt nl no pl pt ro sk sl sv Germany Translation Status: CURRENT Modified On: 20/08/2007+14:41 Modified By: secretariat	
Controlled Term Status Modified By: secretariat Status Code: CURRENT Modified On: 20/08/2007+14:41	
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Controlled Term Mappings Source ID: 1000000000023 (3-digit ISO 3166-1 Codes for the representation of names of countries and their subdivisions - ISO 3166-1 numeric) Source Term ID: 276	

ISO Task Force Identification of Medicinal Products and Pharmacovigilance



Identification of Medicinal Products

☑ NWIP 11615 Data elements and structures for the exchange of regulated product information for drug dictionaries

Structures and controlled vocabularies for

☑ NWIP 11616 pharmaceutical product identifiers

☑ NWIP 11238 ingredients and substances

☑ NWIP 11239 dosage forms, units of presentation and routes of administration

☑ NWIP 11240 units of measurement

Ingredients and Substances (INN/ATC/UNII)s (ISO 11238)



Source: www.natureplan.com/images/pulver.jpg

- human, veterinary
- Active ingredient, excipient
- Authorized, investigational

- Chemicals
- Biologicals
- Gene products
- Cell and Tissue products
- Homeopathics
- Herbals, Botanicals
- Animal preparations
- Radiochemicals
- Food, feed additives
- Cosmetics

Units of Measurement (ISO 11240)



Source: <http://www.netzausfall.de/wp-content/gewichte.jpg>

100 mg
100 IE / ml
1000 KBE ...

- Units of measurement / Units of presentation
UCUM
- EN 12435
- ISO/IEC 99:2007
- EN1614

Dosage form (ISO 11239)



- Tablet, coated tablet
...
- Solid, liquid, semi-solid ...

- Standard Terms by
EDQM
- ...

Source: http://www.kvb.de/servlet/PB/show/1002748/Arzneimittel_neu.jpg

Route of Administration (ISO 11239)



- Oral, i.v., parenteral ...
- Ocular use, inhalational use ...

- Standard Terms of **EDQM**
- ICH Draft
- ...

Source: <http://www.pw1.tsn.at/schueler/pirpamer/111Spritze%20gross.jpg>

Thank you for your attention

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Medical Classification Sector

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