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SCIENCE MEDICINES HEALTH

Update on SPOR

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SPOR vs IDMP

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- **ISO IDMP standards** (five standards) define the rules that uniquely identify medicinal product and the relevant elements to identify them
- Commission Implementing Regulation (EU) No 520/2012 (articles 25 and 26) obliges European Union (EU) Member States, marketing authorisation holders and EMA to **make use of the ISO IDMP standards**.
- The **SPOR projects** implements the ISO IDMP standards as well as the processes to **manage** four domains of data (**master data**) in pharmaceutical / regulatory industry:
  - **S**ubstance Management Services (SMS) – ISO 11238
  - **P**roduct Management Services (PMS) – ISO 11615, 11616
  - **O**rganisation Management Services (OMS)
  - **R**eferentials Management Services (RMS) – ISO 11239, 11240
- **Delivery of SPOR is phased**
  - RMS and OMS services were delivered in June 2017
  - Delivery of PMS and SMS will follow
- **SPOR applies to both domains Human & Veterinary**

What will SPOR deliver?

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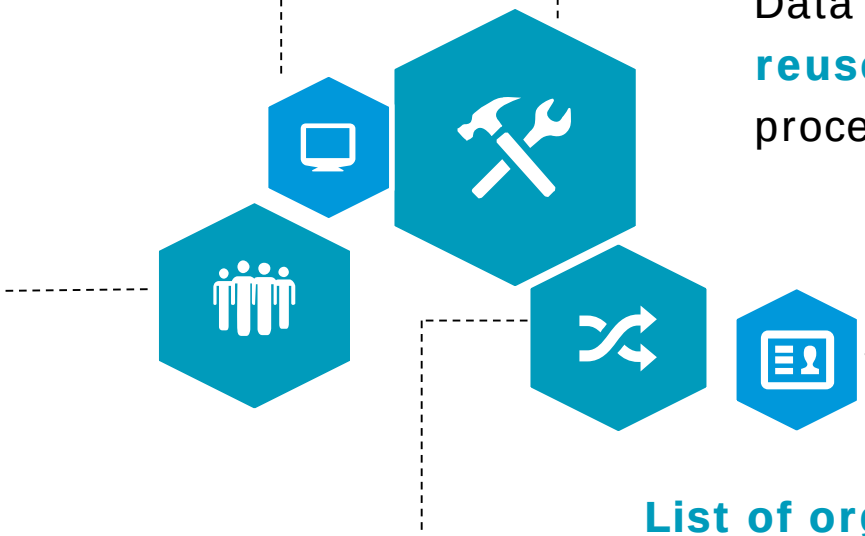
SPOR data is accessible via the **SPOR web portal** and **SPOR API** (Application Programming Interface)

New process for industry and NCAs to **pre-register**/update SPOR data before submitting regulatory applications. Data is **entered once and reused** in different processes

A specialised team of **EMA data stewards** will manage SPOR data and provide support to stakeholders



New **data management** approaches for industry, NCAs and the EMA:
- Data synchronisation on an ongoing basis
- Possible need for data transformation/enrichment

List of organisations (OMS dictionary), Referentials Lists / Terms and Substances for stakeholders to use in EU regulatory activities

SPOR Achievements & Benefits

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June 2017: RMS went live and **replaced EUTCT** as preferred source of regulatory referential data.

June 2017: OMS went live and manages regulatory organisation data. **NCA content** is available. Industry content will be made available throughout 2017-2018.

June 2017: NCA users on-boarding **Dec 2017: Industry** user on-boarding

July 2017: Initial schedule for P&SMS communicated to SPOR Task Force

Integrate RMS & OMS with CT Portal

Integrate RMS & OMS with CESSP (MAA)

Integrate RMS & OMS with Article 57/xEVMPD

ISO IDMP compliant SPOR data services

Q4 2017: Integrate OMS with ECD

Q4 2017: Integrate OMS with eAF; RMS already integrated with eAF

June 2017: RMS implements **ISO11239** and **ISO11240 standards**; makes EMA **regulatory compliant.**

2017: Users start using SPOR Target Operating Model for **pre-registration of master data** to improve regulatory submissions

2017: ECD organisation data will be corrected by master OMS organisation data

2018: RMS & OMS master data is entered once and reused across business processes.

Incremental delivery of Products and Substance Services.

Referentials Management Services (RMS)

What will RMS deliver

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- Reference data is the data used to categorise other data within applications and databases, typically these are referred to as **vocabularies or lists**
- **RMS** implements **ISO IDMP 11239 and 11240 standards** and provides Lists and Terms of Referentials
- **RMS replaces EUTCT** and will provide a centralised and **single source of referential data** to be used across the EU Regulatory Network and Pharmaceutical industry.
- RMS **went live in June 2017** and provides a **backward compatible API that mimics EUTCT**.

What will RMS deliver

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- RMS will contain **Lists from different maintenance organisations** such as EDQM standard terms (dosage forms, routes of administration, packaging); WHO (ATC Human, ATC Vet, INN); MSSO (MedDRA) as well as some internally managed lists (target species, manufacturing activities, special precautions for storage, legal basis etc.). The lists are intended to support all regulatory processes

- EMA will act as data broker, liaising with maintenance organisations and data owners to consolidate **Referentials Lists** into a single place and in a **common format** and facilitating **requests for new / updated terms**

What will RMS deliver

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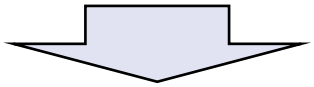
- There will be a **common process** which requires industry and other parties to request **pre-registration of new Terms or updating of existing Terms** in the **RMS system** before submitting any regulatory application to the relevant NCA
- Registration of a new **PROVISIONAL** Term takes **2-5 working days**
- In addition there is an **approval process** to determine the final term naming conventions, depending on the List owner it can take from **1 month to 1 year**
  - When terms are approved their status becomes CURRENT (approved)
  - When terms are rejected their status becomes NULLIFIED (rejected) or NON-CURRENT (used but no longer recommended) => *use a CURRENT Term instead*



Example:

- Industry can submit MA applications to the relevant NCA using **PROVISIONAL or CURRENT TERMS**
- Before finalising the assessment NCAs **should** check the Term status and only **approve MA applications using Terms which are "CURRENT"**

Organisation Management Services (OMS)

What will OMS deliver

- OMS will provide a central source of organisation data **(OMS dictionary)** which consists on a list of **organisations** with associated **physical locations** to be used as a reference and in support of EU regulatory activities

- The initial content of the OMS dictionary will derive from **Telematics systems** i.e. **xEVMPD – Art.57**, EudraGMDP and other EMA corporate systems.
  - The Dictionary is expected to expand throughout 2017, 2018 and beyond.
  - In the future new sources may be identified and Organisation data included in the OMS dictionary (e.g. CESP, EV vet, NCA systems, etc.)

- Organisation data will be structured with unique IDs (**Organisation_ID and Location_ID**) and mapped to records loaded from source systems, e.g. xEVMPD or EudraGMDP organisation IDs.

What will OMS deliver

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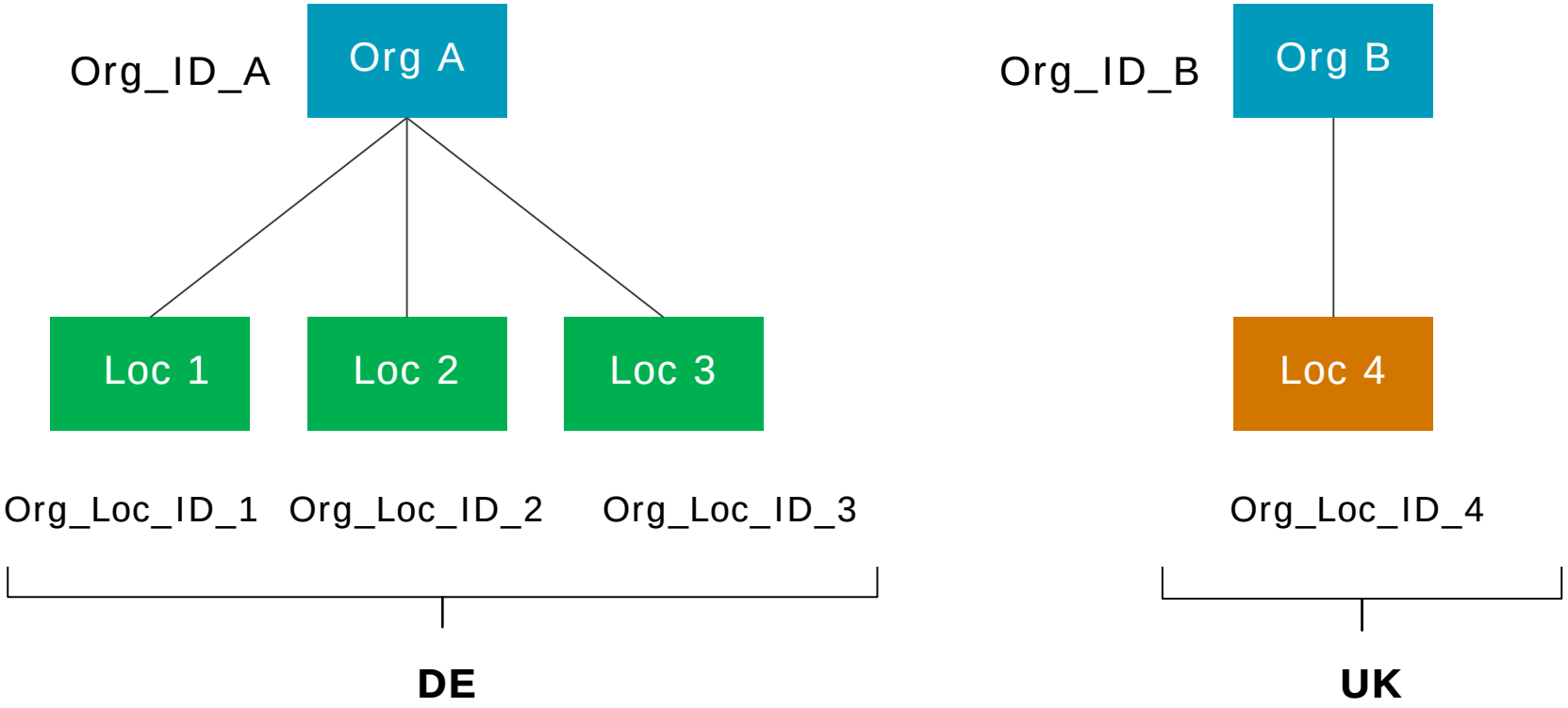
- An **organisation**, as a legal entity, groups all its physical locations within a **jurisdiction / country**
- The **Location_ID** will be unique and will **not change** even after moving the location under another organisation
- In the OMS there will be **no differentiation between an organisation** created in the context of a **human** medicinal product **versus** a **veterinary** medicinal product
- OMS **will not define which role(s) the organisation performs** since this depends on the context in which the data will be used, e.g. in theory an organisation can act as an MAH in the context of one medicinal product but as a sponsor or manufacturer for another medicinal product
- Organisations are categorised by **Type**: 'Industry', 'Regulatory authority', 'Educational institution', 'Health care', etc. or by **Size:** not SME or SME as 'Micro', 'Small' or 'Medium'
- OMS data will be hosted by EMA, accessible to and used throughout EMA and by external stakeholders

Org_ID versus Org_Loc_ID

Note: Org A name can be the same as Org B name



OMS Content Plan Q3 2017 – 2018

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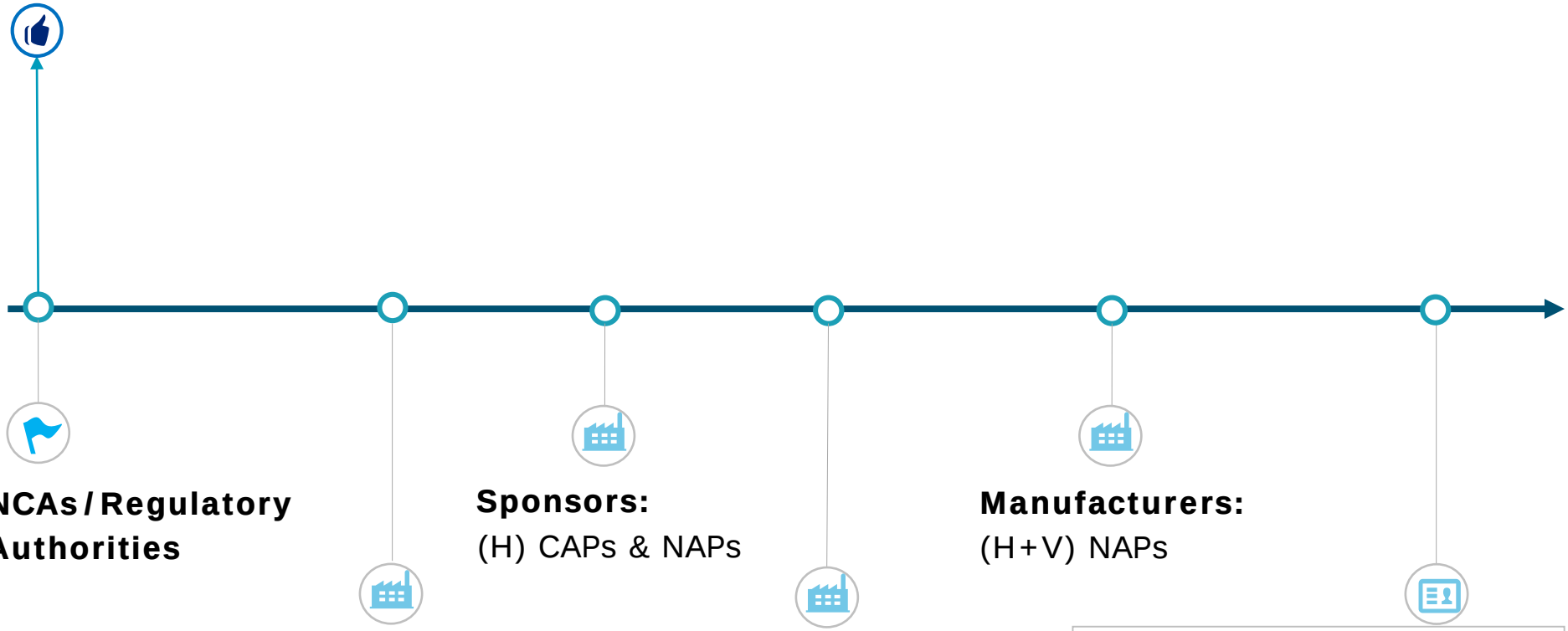
Key

Points at which new organisation data set is published / completed in OMS. Communication will be provided closer to the publication of the data set

OMS go-live
June 2017



NCAs / Regulatory Authorities

Sponsors:
(H) CAPs & NAPs

Manufacturers:
(H+V) NAPs

- **MAHs:** (H+V) CAPs & (H) NAPs
- **MAAs:** (H+V) CAPs
- **MRL applicants** (Vet)

Manufacturers:
(H+V) CAPs

Additional Organisation data will be added in future, its prioritisation will be defined at a later stage

What will OMS deliver

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- There will be a **common process** which requires industry and other parties to request **pre-registration of new Organisations/Locations or updating of Organisations/Location** before submitting an application to the relevant NCA
  - **Industry and NCAs alike can request updates** of the OMS dictionary, e.g. NCAs may request registration of organisation data or an update in the OMS for the preparation of an inspection
  - **Any User can request a change** providing they have the documentation to support the request
- **Registration/Approval** of a new **Organisations/Location** takes **2-5 working days**

Example:

- Industry can submit MA applications to the relevant NCA using **requested/valid** Organisations/Locations
- Before finalising the assessment NCAs should check the Organisation request status and only **approve MA applications with valid Organisations/Locations (published in OMS with IDs)**

SPOR Data Management Services portal

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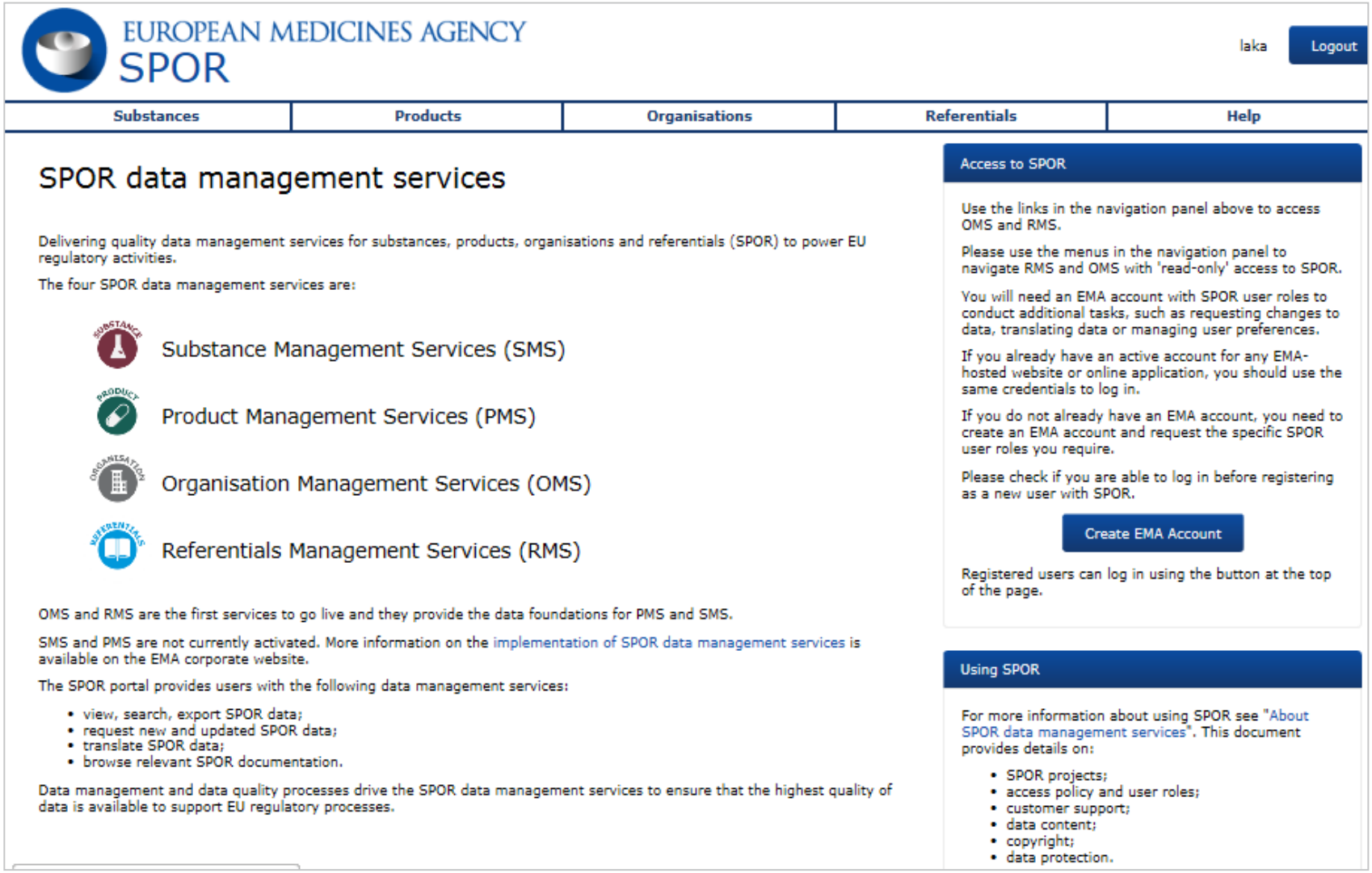
http://spor.ema.europa.eu/sporwi/



SPOR portal is compatible with web browsers Internet Explorer (version 10 and above) and Chrome (version 58 and above)

Glossary

Backward compatibility	Capability of a new solution to successfully interface/work with previous versions of software/hardware.
CESSP	The Common European Single Submission Portal (CESSP) is an ongoing Telematics programme that aims to integrate the electronic Application Form (eAF) data sets in to CESP. CESP is the current submission channel for all procedures (not technically integrated with eAF).
Controlled vocabularies	(aka Referentials) are lists of terms that refer to attributes of medicinal and pharmaceutical products e.g. dosage form, route of administration, unit of measurement.
CT Portal	(aka EU Portal and Database) will be the upgraded version of Eudra CT enabling a single entry point for submission and assessment of clinical trial applications at an EU level.
eAF	The eAF is a collection of Application Forms that facilitate electronic submission of data relating to Renewals, Variations, Marketing Authorisation Applications (Human & Vet).
Eudra CT	The existing platform for submitting and viewing information relating to regulatory activities relating to Clinical Trials.
EUTCT	A repository and provider of controlled terms (or controlled vocabularies) in multiple languages. It is the predecessor of RMS. RMS will replace EUTCT with regards to management of controlled vocabularies. EUTCT can only be fully replaced after SMS implementation as it also contains substances.
Unique identifiers	The ISO IDMP standards outline a set of attributes/data elements that make up a **unique identifier** . This enables the creation of a unique record for each medicinal product, packaged product, pharmaceutical product, substance and referential.