This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Grant Agreement No. 875299

Project acronym: UNICOM
Project full title: Up-scaling the global univocal identification of medicines in the context of Digital Single Market strategy
Call identifier: H2020-SC1-DTH-2019

Deliverable D4.17: Gap analysis report on CTS

Version:	1.0
Status:	Final
Dissemination Level[1]:	PU
Due date of deliverable:	31.01.2022
Actual submission date:	31.01.2022
Work Package:	WP4: IDMP implementation at National Drug Agencies
Lead partner for this deliverable:	BfArM
Partner(s) contributing:	INFARMED
Deliverable type[2]:	R

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Resource consumption estimate:	
BfArM	0.2 Person months (for writing the report)

[1] Dissemination level: PU: Public; CO: Confidential, only for members of the consortium (including the Commission Services); EU-RES: Classified Information: RESTREINT UE (Commission Decision 2005/444/EC); EU-CON: Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC); EU-SEC Classified Information: SECRET UE (Commission Decision 2005/444/EC)

[2] Type of the deliverable: R: Document, report; DEM: Demonstrator, pilot, prototype; DEC: Websites, patent fillings, videos, etc.; OTHER; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot

Revision history

Version	Date	Changes made	Author(s)
0.1	08.11.2021	Added content to the document	BfArM
0.5	01.12.2021	Review and improvements	BfArM
1.0	18.01.2022	Final submitted to Coordinator	BfArM

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

Deliverable abstract

Within this task a gap analysis on the IDMP compliance of CTS shall be provided. Starting from the targeted aim, a short description on the historical and current status is provided followed by the activities to reach the goal of IDMP compliance.

Keywords: IDMP; CTS; gap analysis.

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List of abbreviations

Abbreviation	Term
ATC	Anatomical Therapeutic Chemical classification
CTS	Communication and Tracking System
DADI	Digital Application Dataset Integration
EUTCT	European Union Telematics Controlled Terms
FHIR	Fast Healthcare Interoperability Resources
HMA	Heads of Medicines Agencies
INN	International Non-proprietary Name
MRI	Mutual Recognition Information
NCA	National Competent Authority
PMS	Product Management Services
RMS	Referential Management Service
SmPC	Summary of Product Characteristics
SMS	Substance Management Service
SPOR	Substances, products, organisations and referentials

1 Executive summary

The document outlines the steps required for an IDMP compliant Communication and Tracking System (CTS). As a system used for the tracking of regulatory authorisation and post-authorisation procedures for medicinal products in the decentralised/mutual recognition system, compliance with IDMP is needed for the identification of the product(s) subject to the regulatory procedure and provision of data elements related to the procedure. However, this could be achieved by implementing an interface to import product data from FHIR messages and export respective (partial) FHIR messages.

With implementing an IDMP compliant database schema in addition, full value could be taken from CTS with the possibility to keep track of 'draft' products, create and update product information (SmpC, PL and labelling) at the end of the regulatory procedures.

In its current state CTS records certain data elements for the identification of the medicinal product. The structure of the database schema used to store this data is largely deviant from the conceptual IDMP data model. The attribute values, despite some are selected from referential lists, are not IDMP compliant either with regard to terms or data composition.

To achieve IDMP compliance in CTS, a new database schema for products, implementing the conceptual IDMP model and EU Implementation Guides, as well as interfaces to read from and create FHIR messages is proposed. The proposal fully depends on the availability of products in the Product Management System (PMS) within SPOR or corresponding data from a DADI dataset. Migration of the current CTS products into the new database schema is not foreseen. Product data will be assigned with new procedures coming in. However, efforts to map PMS products to CTS products based on the procedure/product identifier will be undertaken.

2 IDMP Compliance for CTS

The Communication and Tracking System (CTS) is owned by all European National Competent Authorities (NCAs) under the responsibility of the Heads of Medicines Agencies (HMA), a network of NCAs whose organisations are responsible for the regulation of medicinal products for human and veterinary use in the European Economic Area. BfArM is hosting, maintaining and developing CTS on behalf of the HMA. The system is used for tracking and co-ordinating the pre- and post-licensing regulatory processes for human and veterinary medicinal products authorised via mutual recognition and decentralised procedures – as defined in European legislation. In addition, CTS transfers data to the Mutual Recognition Information (MRI) Product Index (aka MR-Index) for the human and veterinary domain, available to prescribers and patients/consumers. As a consequence of implementing an IDMP compliant CTS, information displayed in MRI may benefit from having IDMP data in CTS. The implementation of the ISO IDMP standards based on the European implementation guides and SPOR is crucial for having the system ready for all ongoing challenges like the cross-border identification of the same medicinal product.

2.1 Purpose of IDMP Compliance for CTS

CTS core feature is the tracking of the European part of regulatory authorisation and post-authorisation procedures. Having said that, it needs to be added that keeping track of the national phase - issue and date of licenses, product information translated into national languages - is outside the scope of CTS, despite that data fields to enter this information in CTS are provided.

Core data recorded in CTS, as timetables and contact details during procedures, is not a part of IDMP. However, certain aspects of the regulatory activity in CTS as e.g., the marketing authorisation procedure, procedure identifier and more can be found in the 'Marketing authorisation information' entity provided by IDMP.

Within CTS IDMP compliance is needed for:

- Identification of the medicinal product concerned by the regulatory procedure.

  In this narrower scenario, there is no strict requirement for CTS to implement an IDMP compliant database schema.
  The basic information to identify the product(s) being used in a CTS procedure could easily be retrieved from FHIR message having the complete product data and mapped into the existing data model using a software adapter.
  The Medicinal product identifiers as defined in the EU Implementation guides could be equally read from the same file and be used as reference to the product in data exported from CTS to other parties. However, until it will be possible to update individual data elements in the PMS, CTS will not be able to add information to the PMS, e.g., specific regulatory data for the marketing authorization and associated entities. Neither could any update of a product be processed via CTS nor product information be kept as draft for new products not present in PMS.
  The product data read from FHIR messages can be used to improve the data quality in the (V)MRI, in particular of the CMS for a product.

- Creating or amending details of a product

  Within a wider scope, full compliance with IDMP to the level of the EU Implementation guides in CTS is considered advantageous to enable keeping and updating product data for newly applied products received via DADI, not present in PMS. Capability to provide fully IDMP compliant products may be used to create first versions of products required at the end of a Marketing Authorisation Application procedure, to be complemented by NCAs later.
  Likewise, CTS would be able to keep track of information amended for the product(s) during a procedure and update the product data upon finalisation of the procedure.

2.2 Historical / current status

Historically the need to identify the medicinal products being subject to the regulatory procedure has been met by recording attributes considered most relevant. Strictly speaking, this set of data based on information representing details from the RMS does only represent common data of the concrete medicinal products authorized by each participating RMS/CMS. As visible common identifier for these products the Product Number is defined:

Attribute	Entry Type	Reference	Conformance
Name of the Medicinal product	free text	none	Mandatory
Marketing authorisation holder (in the RMS)	free text, multiline	none	Mandatory
Active substance, INN name // name	catalogue	EUTCT-List / legacy data /	Mandatory

Active substance, salt	catalogue	EUTCT-List / legacy data /	optional
Unit	catalogue assisted free text	EUTCT-List/Legacy data	Mandatory
Pharmaceutical (dose) form	catalogue	SPOR: R	Mandatory
ATC-Code	catalogue	SPOR: R	Mandatory
Additionally for each MS			
Product name in MS	free text	none	Optional
National reference Number	free text	none	Optional

Some further data elements related to the Regulatory procedure are not listed.

This ‘product’ data set has been considered sufficient for the identification of the Medicinal product within a concrete regulatory procedure by the MSs.

As information has to be manually entered by an end user, data updates are provided only if the user at the end of the procedure identified discrepancy against the initially entered data. This led to a mixed state with regard to the data quality: Mandatory fields have a sufficient data quality while optional fields in general are of low data quality. However, some member states also maintain optional data in CTS.

The above data is stored as part of the procedures in CTS. In 2009, a construct for a ‘product’ that includes the above data elements has been introduced. A workflow to update the product information upon finalization of procedures was put into place. However, database wise these 'products' have not been separated as extension of the data scheme, but have been included as a ‘procedure type’. These ‘products’ were found of sufficient data quality to serve as data source for the (Veterinary) Mutual Recognition Index ((V)MRI), a web front end providing to the public basic details on the medicinal products authorized via Mutual Recognition or Decentralised procedures, the Product Information agreed and the (English) Public Assessment Report.

From the above stated –no separate database scheme exists for products – it is obvious, that no IDMP compliant structure is present in the current CTS.

With regard to terminology used, some attributes as pharmaceutical dose form and ATC-Code (also certain procedural data as countries and sites) are based on SPOR referential lists. To utilize SPOR data, tables have been added to the database scheme, being synchronized daily.

However, some legacy data that could not be mapped has been flagged and added to the internal SPOR Tables. Though this data is referred to in historical procedures/ products only and for new records only Terms from the SPOR referential lists are used, this overall reduces the compliance with IDMP terminology.

Other data as e.g., Marketing Authorisation Holder and ProductName do not comply with the structure foreseen in IDMP and thus are considered non-compliant. (Note: SPOR OMS data is used in a certain CTS component, but only as source list for manufacturers (batch release, finished product). For the name of active substances currently a mixture of WHO and substances from EUTCT is used.). Taken altogether the CTS data model and data can be stated being non-compliant with IDMP.

2.3 Approach to achieve IDMP compliance

Considering the present situation in CTS there is no easy 'migration' that could be applied to the existing system. To achieve the goal of IDMP compliance in CTS the following action is foreseen. A prerequisite for this approach, however, is availability of product data from PMS or DADI with respective FHIR messages allowing the exchange of this data:

- Establish an IDMP compliant data schema for products
  At level of the database, a data schema based on the conceptual IDMP data model outlined in the IDMP ISO norms (mainly 11615, 11616) is to be created. The entities, data extensions and attributes will be aligned to those defined per EU Implementation guides.
  In its first iteration, this will be limited to a schema supporting the Product data as defined for veterinary medicinal products in the context of the UPD. The second iteration foresees extending the scheme to fully align with the PMS, including potential deviations between veterinary and human products. Product data as defined in PMS foresees certain data to be retrieved from SMS, in particular in relation to the Ingredient resource. Limited to the data needed to describe substances in the context of the product, integration of SMS data will be undertaken.

- Build programming interfaces for the import and export of medicinal product data
  Based on the FHIR specification (Rx?) the possibility to import product data from a FHIR Message and persist information into a product according to the above database scheme is to be developed.
  Basically, two sources for this FHIR Message import are foreseen: from the SPOR PMS or from a DADI dataset, expected to provide the same FHIR structure and content as the SPOR V2 API.
  To support the use case of CTS updating product data upon finalisation of procedures, also a mechanism to create a FHIR message applying changes to the product that may have been retrieved via an updated DADI message or by manual edit of a user during the procedure is foreseen.
  Any information from the regulatory process that does not amend the description of the medicinal product, but e.g. applies to the Marketing authorisation information, will be added to such an export FHIR message as well.

- Terminology
  To guarantee correct terminology, the SPOR lists as referred to in the EU implementation guides will be locally stored and regularly synchronized. Any potential amendment of data has to use a valid term from these lists.

- Data generation
  The above concept is based on availability of medicinal product data in the format of a FHIR message. At no point, it is foreseen that a product is manually 'created' by a user in CTS.
  The 'product' database scheme will be populated from one of the two data sources: PMS or DADI.
  New Marketing Authorisation Application procedures (DCP, MRP) will use a 'draft product' imported from a DADI dataset.
  When a new application is made for a product already existing in PMS, an automated mapping of a product based on the product and procedure identifier from DADI will be tried. If no product in the PMS can be matched, the user responsible for the procedure is requested to assign a PMS product using a GUI to search in the PMS.

It is not intended to 'migrate' the product data existing in CTS into the new 'product' schema. For the legacy products in CTS, an automatic mapping based on the procedure / product ID is provided, but this is not systematically tracked if a product cannot be matched.

Upon successful assignment of a product to a CTS procedure/product, data from the newly imported PMS/ DADI product is superseding the historical data in CTS.

- Product reference
  For the export of procedural data from CTS using the CTS-API, reference to the product is made by using the unique product identifiers as defined in the EU implementation guidelines. In addition, same product data as hitherto will be included in the export. Optionally, a FHIR message with the complete product data can be added to an export.