



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

WP4 IDMP implementation at National Drug Agencies

D4.2: ESTONIA: Progress report on implementation

Version: 1.0
Status: Final
Dissemination Level¹: PU
Due date of deliverable: 31.01.2021
Actual submission date: 31.01.2021
Work Package: WP4: IDMP implementation at National Drug
Agencies
Lead partner for this deliverable: EESAM
Partner(s) contributing:
Deliverable type²: R

Main author(s):

Toomas Silla EESAM
Triin Mäesalu EESAM
Raheeli Mirzojev EESAM

Resource consumption estimate:	Person months
EESAM	1

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 filings, videos, etc.; OTHER; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot

Revision history

Version	Date	Changes made	Author(s)
0.1	17.12.2020	Initial draft	Toomas Silla
0.2	21.12.2020	Abstract and Executive Summary	Toomas Silla
0.3	21.12.2020	Quality check, refinement	Triin Mäesalu
0.4	22.12.2020	Refinement for WP4 internal review	Toomas Silla, Triin Mäesalu, Raheeli Mirzojev
0.5	26.01.2021	Quality check, refinement after review by AT and PT	Toomas Silla, Triin Mäesalu
1.0	27.01.2021	Formatting and final checks	EMP

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This deliverable contains original unpublished work except where clearly indicated otherwise.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

Task 4.3 foresees ISO IDMP implementation at Estonian State Agency of Medicines (EESAM) by refactoring its SamTrack database to ISO IDMP standard.

To this end, we have started mapping and cleansing of the medicinal product data in the current SamTrack database and development of new SamTrack II IT system.

Our mapping and cleansing activities have been mainly focused on organisations and referentials lists. We have mapped and cleansed all active marketing authorisation holders and national competent authorities (NCAs) in our database. We have finished mapping of several referential lists and reported quality issues to EMA.

The development of the new drug information database SamTrack II started on 18 April 2020. The development has started successfully and is progressing according to the plan.

Keywords: EESAM, ISO IDMP

This document contains material, which is the copyright of the members of the UNICOM consortium listed above, and may not be reproduced or copied without their permission.

The commercial use of any information contained in this document may require a license from the owner of that information.

This document reflects only the views of the authors, and the European Commission is not liable for any use that may be made of its contents. The information in this document is provided “as is”, without warranty of any kind, and accept no liability for loss or damage suffered by any person using this information.

© 2019-2023. The participants of the UNICOM project.

TABLE OF CONTENTS

Revision history	2
Deliverable abstract.....	3
List of abbreviations.....	5
1 Executive summary	6
2 Authorship and responsibilities	7
3 EESAM, Estonian State Agency of Medicines	8
4 Task 4.3: Progressing ISO IDMP implementation at SAM in Estonia.....	9
4.1 Progress in migration of legacy data	9
4.2 Progress in SamTrack database refactoring	10
4.3 Progress in ISO IDMP compatible data feed.....	10
4.4 Dependencies and relationships	11
4.5 Risks and mitigations.....	11
4.6 Further plan	12
4.7 Lessons learned	12

List of abbreviations

Abbreviation	Complete form
EESAM	(Estonian) State Agency of Medicines
UNICOM	Up-scaling the global univocal identification of medicines
SPOR	EMA service delivering quality data management services for substances, products, organisations and referentials (SPOR) to power EU regulatory activities. The four SPOR data management services are: SMS, PMS, OMS, RMS
SMS	Substance Management Services
PMS	Product Management Services
OMS	Organisation Management Services
RMS	Referentials Management Services
NCA	National Competent Authority
eAF	Electronic Application Form
CTS	Communication and Tracking System
IDMP	Identification of Medicinal Products
EMA	European Medicines Agency
WP	Work package
PPL	Pilot Product List
SamTrack	EESAM's IT system/database for drug data

1 Executive summary

In order to implement ISO IDMP standards at NCAs level, preparatory work on IT systems and existing medicinal product data repositories is necessary. This preparation is a prerequisite to be able to provide ISO IDMP compliant data to Health Service providers, including eHealth organisations.

Relevant implementation tasks are carried out in Work package (WP) 4 related tasks, in which 11 national competent authorities have setup local implementation projects to implement new IDMP compatible systems or to refactor existing software systems towards IDMP.

As part of Task 4.3 EESAM will refactor its SamTrack database, which is used for medicinal product marketing authorisation and licensing. SamTrack is also a central database that provides data flows to other IT systems used by national Health Service providers.

Prerequisite to database refactoring is migration of the national legacy data to ISO IDMP/SPOR compatible data. We started our mapping and cleansing activities on organisations and referential lists, as Organisations Management Service (OMS) and Referentials Management Service (RMS) are currently two live SPOR services.

We have mapped and cleansed all active marketing authorisation holders and NCAs in our current database. This work included submitting several change requests to change the names and addresses of Estonian companies as well reporting data discrepancies through the EMA service desk.

We have finished mapping of several referentials lists (e.g., Pharmaceutical Dose Form, Combined Pharmaceutical Dose Form, Combination Package, Combined Term, Country, Special Precaution for Storage) and reported found quality issues to EMA. To make other WP4 members aware of the issues found, we have created an Excel list accessible to all WP4 NCAs to collect and report RMS data quality issues.

The development of the new SamTrack II drug information database started on April 18, 2020 after the signing of the framework agreement. First stage of the development consists developments of marketing authorisations functionalities including data delivery to Medicinal Product Registry, automation of functionalities for consumption of eAF data, integration with SPOR and CTS. By now, we have completed the analysis of business processes and established SPOR and CTS API connections.

EESAM is one of the WP4 NCAs responsible for providing ISO IDMP data feeds for cross border pilots, which is part of the deliverable D4.14 "Delivery of selected ISO IDMP medicinal product data for cross border pilots". In collaboration with WP9 representatives we have analysed Pilot Product List (PPL) data fields and made initial draft of ISO IDMP compatible PPL.

The next updates of this document are expected in month 26; 38 and 48.

2 Authorship and responsibilities

The Project Coordinator is responsible for submitting the deliverables in accordance with the timing and conditions set out in the DoA.

The leader of the Work Package to which the deliverable is assigned is responsible of reporting to the Project Coordinator about the progress, completion of the output and the document, to ensure that it has the required quality.

The lead beneficiary of each deliverable, as identified in the Description of the Action (DoA), is responsible for editing the document. For that purpose he or she may count with the contribution of other partners. All authors that have made significant contributions to the deliverable shall be listed in the table contained in the second page of the template.

3 EESAM, Estonian State Agency of Medicines

EESAM is a governmental agency under the Ministry of Social Affairs with the aim to:

- ensure that medicines approved for use in Estonia for the prevention, treatment and diagnosis of human and animal diseases are proven to be efficacious, of high quality and safe;
- promote the rational use of medicines;
- ensure the protection of the safety and rights of the clinical trial participants in Estonia;
- ensure that cells, tissues and organs used in the treatment of humans in Estonia are proven to be safe and of high quality;
- ensure that narcotic and psychotropic substances and their precursors are used appropriately and in accordance with international conventions.

4 Task 4.3: Progressing ISO IDMP implementation at SAM in Estonia

EESAM will refactor its SamTrack database based on ISO IDMP standard. SamTrack database is the primary source of medicinal product information for the Medicinal Product Registry and Health Service providers.

EESAM will implement data connections to EMA's SPOR services where appropriate, to support automation of data entry into internal databases, and support interoperability between internal and EMA systems.

This task also includes migration of the national legacy data to ISO IDMP/SPOR compatible data. The data fields needed for the e-Prescription and e-Dispensation will be the starting points for data migration of legacy data towards IDMP. In addition, a prototype of an IDMP compatible data feed of Medicinal Product Registry which is used by the e-Prescription system and pharmacies in Estonia will be presented.

4.1 Progress in migration of legacy data

We have hired a new specialist to work exclusively on Unicom activities. So far, she has mainly worked on organizing and mapping legacy data.

Regarding mapping and cleansing of the medicinal product data in the current SamTrack IT system/database to ISO IDMP/SPOR, we have:

- OMS
 - started organisation mapping by merging duplicates and mapping them to OMS IDs.
 - submitted several change requests via EMA's Service desk to amend names and addresses of Estonian companies.
 - mapped all NCA organisations in our database. We found discrepancies between the data published in OMS/RMS list EU Territorial Authority/HMA website.
 - mapped and cleansed all active Marketing Authorisation Holders entries
 - amended our standard operating procedures (SOPs) to ensure data consistency

- RMS
 - done: lists for (Authorised) pharmaceutical forms: Pharmaceutical Dose Form, Combined Pharmaceutical Dose Form, Combination Package, Combined Term, Routes and Methods of Administration, Country, Special Precaution for Storage, Manufacturing activity (on parent term level).
 - found several RMS data quality issues. We have set up excel list accessible to all WP4 NCAs to collect and report RMS data quality issues. Currently we have reported 7 issues of which two have been solved by EMA and five are still pending.

- SMS
 - Not started data cleansing

- PMS
 - Analysis of SamTrack II data model completed, started SamTrack I pre-migration analysis.

4.2 Progress in SamTrack database refactoring

The development of the new SamTrack II drug information database is outsourced. On April 18, 2020, a new framework agreement for the development of the IT system SamTrack II was signed. Samtrack II uses state-of-the-art tools and system architecture is based on microservices (Figure 1). Development is divided into three stages (4 years project). Stage one consists of development of Marketing authorisations functionalities including data delivery to Medicinal Product Registry, automation of functionalities for consumption of eAF data, integration with SPOR and CTS. Until progress report submission, we have:

- Created a draft of ISO IDMP compatible data model
- Established SPOR API v.1 (RMS and OMS) connection, performed tests and analysed query results
- Analysed of RMS/OMS data usage processes
- Decided the RMS lists of which a local copy will be made and synchronised, which attributes to display etc
- Concluded business processes analysis
- Started and concluded portion of UI/UX designs
- Established CTS API CTreST v4 connection and performed initial tests

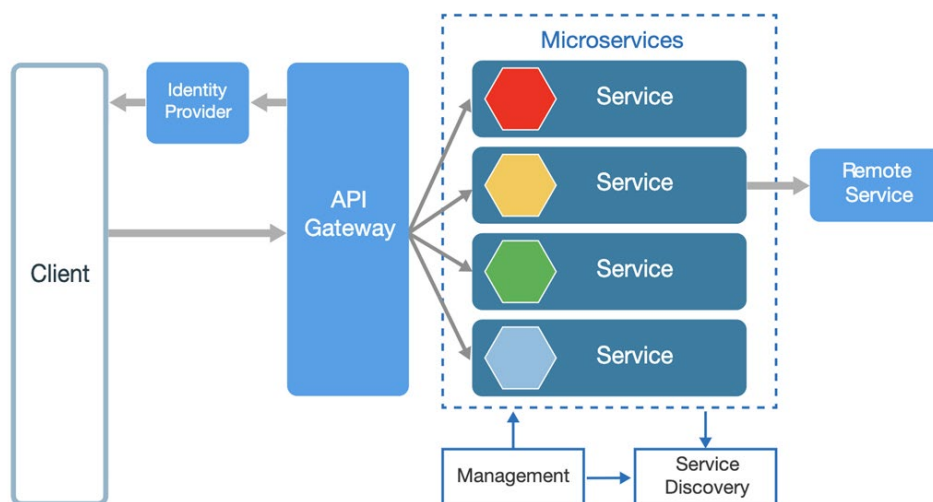


Figure 1. Architectural overview of the new IT system Samtrack II

4.3 Progress in ISO IDMP compatible data feed

This part of the deliverable is connected to the deliverable D4.14 “Delivery of selected ISO IDMP medicinal product data for cross border pilots” and has strong dependencies to other UNICOM tasks and WPs (illustrated on Figure 2).

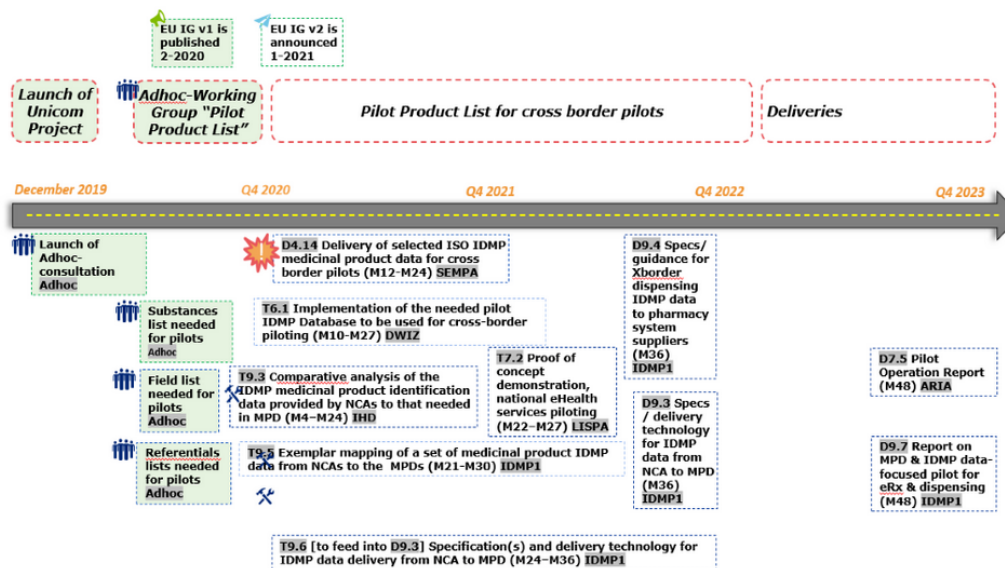


Figure 2. Deliverable D4.14 “Delivery of selected ISO IDMP medicinal product data for cross border pilots” dependencies with other tasks and WPs (figure is adapted from WP9).

EESAM is one of the WP4 NCAs responsible for providing ISO IDMP data feeds for cross border pilots. Until progress report submission, we have:

- organized (24.11.20) D4.14 kick-of meeting.
- In collaboration with WP9 representatives analysed PPL data fields

4.4 Dependencies and relationships

EESAM deliverables are strongly dependent on SPOR data management services SMS, PMS, OMS and RMS progression. So far only OMS and RMS services are live and SMS, PMS are not activated yet. During the mapping exercise, creating ISO IDMP data model and working on PPL we have faced several issues:

- OMS – guidance on deviations due to standardisation, manufacturer data quality
- SMS – Clear guidance on substance data mapping is needed. Synchronization via API connection planned, waiting for information on API Access from EMA
- RMS – We have identified several RMS issues that EMA needs to address in a timely manner
- PMS – EMA contact for practical questions on PMS LDM/IDMP implementation is needed

In addition, EESAM is working closely with:

- WP1 – participating in ISO IDMP related trainings
- WP2 – actively participating in discussions/workshops, including EU-SRS meetings
- WP9 – working on PPL for cross border pilots

4.5 Risks and mitigations

Table1. Task 4.3 related main risks and their mitigation

Risk	Mitigation	Level
All EESAM's IT systems belong to the Health and Welfare Information Systems Centre (TEHIK), an	Inclusion of TEHIK to the UNICOM Consortium. Process has initiated and	High

agency under the supervision of the Estonian Ministry of Social Affairs, develops and manages ICT services in the fields of health, social security and work. TEHIK also organize IT development project management and organize procurement. Thus, TEHIK is a legal entity for the procurement of developments for EESAM's SamTrack IT system, which must be refactored to complete Task 4.3 of WP4.	project PCC will make decision on 23.12.2020	
Delays in IT development	Special attention from the developer and the NCA to project management and manpower	High
Different WPs are not aligned	Increase alignment efforts by regular meetings	Moderate

4.6 Further plan

EESAM next steps for months 13-24:

- Analysis of data migration from SamTrack I to Samtrack II (M13 – M16)
- Analysis data flow from SamTrack II to Medicinal Products Register and eHealth system, interdependencies with cross-border ePrescription (M13 – M16)
- Finish Samtrack II first stage development (M24)
- Continue with mapping and cleansing activities (M13 – M24)
- In cooperation with WP9, work will continue on PPL for cross border pilots (M13 – M24)

4.7 Lessons learned

EESAM was one of the NCAs who hosted “Best practice and lessons learned” session for other WP4 members. Our lessons learned are described in D4.15 annual report.