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WP4 IDMP implementation at National Drug Agencies

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[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

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0.2	22.12.2020	Draft for internal Fimea review	Mika Kuivamäki (Fimea), Sofia Lahtonen (Fimea), Markus Mäkelä (Fimea), Harri Nurmi (Kela)
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1.0	29.01.2021	Final review and submission	EMP

Deliverable abstract

This report describes the activities conducted towards the IDMP implementation in Finland during the first 12 months of the project, and the outputs achieved.

At the Finnish Medicines Agency (Fimea), we have designed, implemented, tested and launched a new marketing authorization and medicines register Saga that replaced the old iRis system in November 2020. In addition, 14 data integrations of iRis have been reconstructed to be compatible with Saga's data model. Moreover, we have completed the migration and cleansing of the legacy data between the two systems as well as initiated the creation of data connections to the EMA's SPOR. Initial planning of a pilot for IDMP compliant pharmaceutical register has started with the Social Insurance Institution of Finland (Kela).

In 2021, we continue the work by gradual implementation of the remaining data model changes, e.g. RMS terms and OMS information, and by completing the SPOR integration. The planning of the pharmaceutical register pilot continues with Kela in Q1/2021.

This report contains 17 pages. The representatives of two UNICOM partners, namely EESAM (Estonia) and AGES (Austria), and the UNICOM coordinator Empirica (Germany), have reviewed the report prior to its submission to the European Commission.

Keywords: UNICOM, Fimea, Kela, ISO IDMP, SPOR, RMS, OMS

TABLE OF CONTENTS

LIST OF FIGURES

List of abbreviations

Table 1	
Abbreviation	**Complete form**
API	A set of routines, protocols and tools for building software applications, OR a software component in terms of its operations, inputs/outputs and underlying types
eAF	Electronic Application Form
EMA	European Medicines Agency
FIMEA	Finnish Medicines Agency
IDMP	Identification of Medicinal Products
iRis	Integrated Regulatory Information System (Fimea's old medicines registry)
KELA	Social Insurance Institution of Finland
MP	Medicinal Product
MPID	Medicinal Product Identification
NCA	National Competent Authority
OMS	Organisation Management Services
PhPID	Pharmaceutical Product Identification
PMS	Product Management Services
RMS	Referentials Management Services
Saga	Name of Fimea's new medicines registry (Seer goddess in Scandinavian mythology)
sFTP	Secure Shell File Transfer Protocol
SMS	Substance Management Services
SPOR	EMA's quality data management services for substances, products, organisations and referential (SPOR) to power EU regulatory activities
THL	The Finnish Institute for Health and Welfare

1   Executive summary

This document describes the Finnish medicines agency's (Fimea) tasks and achievements in the UNICOM project during the first 12 months of the project.

As a partner in the UNICOM project, Fimea aims on:
  ➢ renewing its marketing authorization and medicines register iRis to be compatible with IDMP
  ➢ migrating and cleansing of the legacy data
  ➢ creating the necessary data connections to the EMA's Substance, Product, Organisation and Referential (SPOR) data
  ➢ piloting, in co-operation with the Social Insurance Institution of Finland (Kela), of the data transfer from the medicines register to the national pharmaceutical database
  ➢ supporting IDMP implementation in the national eHealth context, in co-operation with Kela

In the first 12 months of the project, Fimea has performed the following tasks:

Renewal of marketing authorization and medicines register: Fimea has been able to design, implement and launch the first version of new marketing authorization and medicines register, named Saga. After an intense testing phase, the new Saga system replaced the old iRis in November 2020. In addition, Fimea has reconstructed 14 data integrations of iRis to be compatible with Saga's data model.

In the next phase, we will focus to data structures related to substances and product information.

Work on migration and cleansing of the legacy data from the legacy register and the new Saga register has been completed. Migration and cleansing of the legacy data between Saga and SPOR has started. At this phase, Referentials Management Services (RMS) and Organisation Management Services (OMS) related data model changes have been performed while the Substance Management Services (SMS) and Product Management Services (PMS) related changes are awaiting publication of EMA's implementation guideline. To help and speed up this process, procurement process for purchase of a cleaning and mapping tool (Sporify) has been started.

In the next phase, we continue the data cleansing and mapping of the legacy data.

Creation of the necessary data connections to the EMA's SPOR: SPOR integration has started and access to SPOR test API has been established.

The work continues with building the access to production API.

Piloting the data transfer from the medicines register to the national pharmaceutical database: The data model work for the pilot is in its early phases but the possible structures have been taken into account in the design of Saga database. The method for transferring the pilot data from Fimea to Kela has been discussed. The plan is to continue with existing data transportation method.

In the next phase, we will complete the design of the new data model and data transfer schema, create term lists and map to medicines, and create a test version of the pharmaceutical register.

Creation of support for eHealth implementation: The work has been started by planning the transfer to the national code service and discussing with the national actors (Fimea, Kela and THL) about the use of the national code service in distributing the terms. Initial agreement has been made to publish the terms but no official decision nor documentation have been created yet.

In the next phase, we will document and describe use of the national code server as the national distribution source of RMS lists, and move to the implementation of codes/ term transfers of pharmaceutical forms, routes of administration, containers, and active substances.

2   Description of the responsible partner Fimea

The Finnish Medicines Agency Fimea is the national competent authority for regulating pharmaceuticals. As a central administrative agency operating under the Ministry of Social Affairs and Health it promotes the health and safety of the population by regulating medicinal, blood and tissue products, and by developing the pharmaceuticals sector.

Fimea's organisation is structured around three core processes: enforcement and inspections in the pharmaceuticals sector, regulating medicinal products, and the evaluation of pharmacotherapies. The organisation is supported by a process of internal services.

Fimea's aim is to improve the pharmaceutical service for the population and the safety, appropriateness and economy of pharmacotherapy. Fimea also enhances and provides the general population and other interested parties with impartial information on medicinal products. Fimea works in a close cooperation with relevant parties and stakeholders in the pharmaceutical field.

Fimea maintains and provides a public register for medicinal products containing medicinal products with marketing authorisation and products with a temporary special permit in Finland. The public register for medicinal products includes information for example on the identification, classification and packaging details and information about the medicinal substance, the required codes for prescription terms and conditions, ATC classification, pharmaceutical form and storage container. The register is primarily intended for the use of health care organisations responsible for the acquisition, distribution and sales of medicinal products. It is also a primary source (master) for the national for the national eHealth services that are provided by the Finnish Social Insurance Institution Kela.

Fimea transfers a set of the medicinal product registry to Kela, which then loads it to the national pharmaceutical database. Kela enriches the data with nationally relevant information, such as the price information for pharmacies or conditions for reimbursement amongst others. The pharmaceutical database acts as medicinal data's master database for the Finnish eHealth and health care.

3 Deliverables, tasks, task management and risks

3.1 Deliverables

Table 2				
Deliverable Number	Deliverable Title	Type	Dissemination level	Due date (in months)
D4.3	Finland: Progress report on implementation	Report	Public	14

3.2 Tasks

Task 4.4 Progressing ISO IDMP implementation at FIMEA in Finland. Lead: FIMEA (M1-M48)

Fimea will work on renewing its marketing authorization and medicines register iRis to be compatible with IDMP, migration and cleansing of the legacy data and creating the necessary data connections to the EMA's SPOR. Fimea and Kela will also pilot the data transfer from the medicines register to the national Pharmaceutical database to support IDMP implementation in the national eHealth context.

3.3 Task management

At Fimea project management is included in managerial and operational processes, which are described as codes of conduct and standard operational procedures. The project team composed of substance experts and project manager who all participate in the project work. The financial services unit is responsible for matters related to project's resourcing planning and monitoring, accounting and contract management.

The project manager reports work progression and resourcing status to the steering group in accordance with a pre-approved annual plan. The steering group provides project's performance monitoring reports to the Fimea management in connection with the management review.

Project working time and expenditure are monitored using Fimea's administrative software; all project personnel have been instructed to log daily project working hours to the system on a weekly basis. Once a month the project manager reports the cumulative hours to the WP4 lead.

3.4 Risks

The risk management is performed to identify, assess and monitor risks in operations that may have an impact on the realization of the project strategic and financial objectives or on work continuity. Risk management is part of Fimea's normal, day-to-day working and integrated into the management system.

Soon after the start of UNICOM project the COVID-19 pandemic began, which caused an urgent need for prioritizing personnel and financial resources to disease counter measures across the world. In the UNICOM project, the situation caused delays in work progression that due to the WP interdependencies affected the whole consortium. At Fimea, we estimate that the cumulative delay is ca. 4,5 months due to the triggering of risks 3, 5, 6 and 7 (Table 3). Selected risk-mitigation measures, such as increased alignment efforts between the WPs, are in use.

Table 3		
Risk number	**Description of risk**	**Proposed risk-mitigation measures**
1	Low availability of IDMP and NCA/EMA experts. (M)	Intensive collaboration with consortium partners and, if needed, with external experts to clarify relevant topics.
2	Data migration towards IDMP delayed or scope must be reduced. (M-H)	Adapt the scope of IDMP data migration to a minimum, which is defined by the needs of the data consumers.
3	Due to national prioritisations and internal dependencies implementation of national tasks slows down or benefits from more financial resources. (M-L)	Contribution monitoring of progress and consumption at NCA level. Possible reallocation of funding between tasks (NCA's) to mitigate risk and enhance progress where possible.
4	The high number of beneficiaries increases cross-WP communication efforts and alignment needs between the partners. (M)	Shift resources from technical tasks to WP coordination. Optimise links and cross communication between WPs.
5	ISO IDMP identifiers needed for the univocal identification of medicinal products that depend on EMA publication and maintenance are not available. (M-H)	Find replacement for these identifiers through direct collaboration with Drug NCAs of countries involved; substitute with MP data of repository piloted in WP9.
6	Different work packages are not aligned or progress at different paces thus affecting the outcome of WP4. (M)	Increase alignment efforts between work packages. Regular - monthly - review meetings of timetable and progress.
7	COVID-19 related tasks at the NCA are prioritized and require temporarily input from project team. (M)	If the situation persists new personnel is recruited allowing the project team to focus on its tasks.
8	No partner for cross-border piloting is obtained due to scheduling and resourcing matters. (L)	Discussion within the consortium and possible reallocation of funding between partners to mitigate the risk.

4 Progress in the national implementation of IDMP

4.1 Renewal of Fimea's marketing authorization and medicines register for IDMP compliance

4.1.1. Aim

The aim of the task is to renew Fimea's marketing authorization and medicines register iRis with a IDMP compatible Saga system. The task includes the following sub-tasks:

- ➢ Plan and design the IDMP compliant medicines register
  - o Gap analysis of current data model against the IDMP implementation guide
  - o Identify needed changes
  - o Design the new phase I data model
- ➢ Plan implementation and data migration
- ➢ Implementation of the new medicines register
- ➢ Data migration
- ➢ Cleansing of the legacy data

4.1.2. Work performed and current status

The work started by designing a new IDMP compatible system to replace the 20-year old marketing authorization and medicines register (iRis). The whole infrastructure of iRis, including the database, software and servers, needed to be replaced by a new open-source register architecture (Saga) based on microservices that are operated in containers (Figure 1).

At the beginning of the UNICOM project, not all necessary building blocks for IDMP implementation nor the EU IG V2 implementation guideline were available for the partners. Therefore, construction of the Saga system was decided to be made in stages. First, the evaluation and gap analysis of the current data model was done against the ISO IDMP standard documentation. At this phase, RMS and OMS related data model changes were performed but elements that were related to parts still missing from SPOR data, as for example SMS and PMS related changes, were left untouched. Due to the several data model changes, the conversion of the legacy data required substantial amount of work. For example, some of the data in the iRis system was contained in documents and csv-files that needed to be converted into a form compatible with the Saga database (Figure 2).

In Finland, the marketing authorization and medicines register serves as the master data source of medicines and, importantly, is also utilized by many national applications. This translates to 14 data integrations that had to be redesigned and reconstructed to be compatible with Saga's data model.

In summary, we built the foundation of the new Saga registry during the first year of the project. The Saga was launched in November 2020 after an intense testing phase and it immediately replaced the iRis. When the implementation guideline becomes available, the work continues by gradual implementation of the remaining data model changes (SMS and PMS) and mapping the legacy data with the RMS terms and the OMS information.
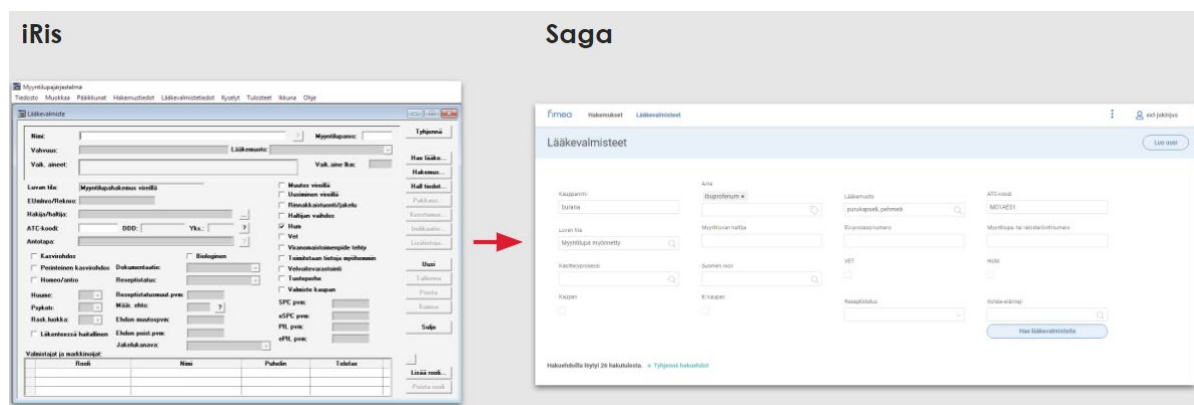
Figure 1. Replacement of the 20-year old marketing authorization and medicines register iRis with a new IMPD compatible Saga system. Illustration of the change in user interface between the old client-based registry and new browser-based system.
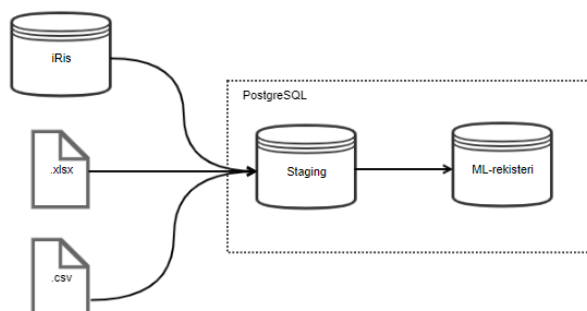

Figure 2. Legacy data migration from the old iRis registry and file formats to the new Saga system.

4.1.3 Plan forward

In the next phase towards the IDMP compliant medicines register, Fimea will continue the work with data structures related to substances and product information. The tasks include the following:

- ➢ Gap analysis of current data model against the IDMP implementation guide
- ➢ Identify needed changes
- ➢ Design the phase II data model
- ➢ Plan implementation and data migration
- ➢ Implementation of the phase II version of the medicines register
- ➢ Data migration
- ➢ Cleansing of the legacy data

Following information is needed in order to perform remaining tasks:

- New UNICOM compatible Electronic Application Form (eAF) schema (WP3)
- SPOR implementation guideline v2
- SPOR SMS

4.2 Create the necessary data connections to the EMA's SPOR

4.2.1 Aim

The aim of the task is to create integration between Fimea's new marketing authorization and medicines register and create functions to update and maintain the terms in the national register. Furthermore, there are several terms that are used in the cross-border ePrescription system that need to be mapped and cleansed against the RMS terms, which is a prioritized task in the UNICOM project.

4.2.2 Work performed and current status

SPOR integration has started and access to SPOR test API has been established. Work continues with building the access to production API. In addition, the required update and maintenance user interfaces for Saga need to be defined, designed and implemented.

Work with the SPOR lists has also been started. First, we focus on the RMS lists, especially those needed for the ePrescription and importing the eAF data to the national register. The essential RMS lists, terms and other information have been identified and prioritized. The next step is to get these items translated and mapped. To help and speed up this process, purchase of cleaning and mapping tool (e.g. Sporify) is planned and procurement process has been started.

The structure of the data in the OMS was different from the old national register. In the iRis, all the organizations and locations were saved as separate units. The structure of the OMS was taken into account in the design and implementation of the new register, but cleansing of the organization data is still needed for the register.

The OMS data is maintained and updated by the marketing authorization holders, but since some of the changes are done with variation applications, OMS data cannot be directly updated from SPOR to the national register. Therefore, the process for keeping the OMS data frequently updated needs to be reviewed and implemented.

4.2.3 Plan forward

We continue the work with data cleansing and mapping.

The next tasks include the following:

- ➢ Completing the SPOR integration
- ➢ Define, design and implement the required update and maintenance user interfaces
- ➢ Creation of the remaining SPOR connections
  - o RMS
    - o Translations and mapping of the terms
  - o OMS (will be updated through variation forms by MA's
    - o Cleansing the existing (registered) OMS data (removing duplicates and fixing the data to match new structure
  - o SMS (awaits WP2)
  - o PMS (awaits EMA)
  - o Completion of the procurement process of Sporify for cleansing RMS-terms

4.3 Pilot the national IDMP compliant pharmaceutical register

4.3.1 Aim

The aim of the task is to create a pilot for IDMP compliant pharmaceutical register. Fimea will provide the base information to Kela from Fimea's new medicines register Saga. Together, Fimea and Kela will design and create a new IDMP compatible pharmaceutical register. The pharmaceutical register is distributed to all prescription systems in Finland. This project will pilot the new format of the pharmaceutical register without making changes to the production register.

4.3.2 Work performed and current status

Fimea and Kela have started to work on the following tasks where possible.

➢ Designing the data model for the pharmaceutical register

> The data model work for the pilot is in its early phases but the possible structures have been taken into account when designing Saga's database.

➢ Design and pilot the data transfer from the medicines register to the national pharmaceutical database

> The method for transferring the pilot data from Fimea to Kela has been discussed. The plan is to continue with existing data transportation method, which is Secure Shell File Transfer Protocol (sFTP). Forming the data happens in the Saga registers backend and is then transferred via sFTP to Kela.

> Designing the actual dataset and its schema has not been started as the Saga registers data model is not yet fully in its final IDMP form. When the final structure of Fimea's register is designed, the work to set the schema for the pharmaceutical registers data transfer can be done.

➢ Create needed term lists and map to medicines

> This task has started by defining the RMS terms that are crucial in the ePrescription and the national healthcare context. In this task, Fimea will go through and review all the lists required in the UNICOM scope and will make sure that all the essential data is translated, mapped and aligned between SPOR and the national register.

> The first SPOR list that has been used as a template for the following is the Routes and Methods of Administration (Figure 3). Additional SPOR lists and terms to add and map to the national register at this phase are Packaging list and its terms for containers and closures, Pharmaceutical Dose Form and Legal Status for the Supply (Figure 4). Terms and classifications are also needed for Active substances and Drug classifications.

> The terms mapped to additional national codes, list and the data format have been evaluated to ensure the data format equivalence with the national Code Service (Figure 5). Terms for Routes and Methods of Administration are currently registered only for veterinary medicines but will be added also to human medicines later on.

Figure 3. Current Routes and methods of administration is Saga. An example screen capture from the Saga's Route of administration template.

Figure 4. Newly designed contents of the Routes and methods of administration. An example screen capture is shown.

Figure 5. National Code Service is used for evaluation of SPOR lists and terms data format equivalence. An example screen capture of the Code Service is shown.

4.3.3 Plan forward

To move forward with the task, remaining changes to Fimea's medicinal registry need to be done. To do this, SPOR SMS and PMS information as well as the EMA's implementation guideline are needed.

Next steps are to:

- ➢ Designing the data model for the pharmaceutical register
- ➢ Design the schema of the data transferred to the national Pharmaceutical database
- ➢ Implement the data transfer from the medicines register to the national Pharmaceutical database
- ➢ Create term lists and map to medicines
- ➢ Create a test version of the pharmaceutical register
- ➢ Plan and implement the pilot of the pharmaceutical register

4.4   Create support for eHealth implementation

4.4.1 Aim

The aim of the task is to support prescription system providers and healthcare actors in the implementation of the new IDMP compliant pharmaceutical register. The task includes, publishing terms in the national health care code service to harmonize the use of standard terms in the healthcare and pharmacy systems, and providing implementation guidelines to stakeholders on term usage and eHealth / prescription systems.

4.4.2 Current status

The work has been started by planning the transfer to the national code service and discussing with the national actors (Fimea, Kela and THL) about the use of the national code service in distributing the terms. Initial agreement has been made to publish the terms but no official decision nor documentation have been created yet. However, Routes and methods of administration has already been approved by the national code server coordination group and the list is already used in the current version of the national Code Service.

4.4.3 Plan forward

The next steps with the task is to:

- ➢ Document and describe the use of the national code server as the national source of RMS lists
- ➢ Code/term transfer implementation to the national code service (pharmaceutical forms, routes of administration, containers)
- ➢ Code/term transfer implementation to the national code service (active substances)
- ➢ Start writing the implementation guidelines

Following information is needed in order to perform remaining tasks:

- Active substances with their SMS identifiers.

5 Lessons learned

Renewing entire marketing authorization and medicines register and altering its data model requires substantial amount of work from IT- and domain experts. Marketing authorization processes are very complex and there are numerous rules to take into account when implementing the system. As the register provides data for many healthcare IT-systems, changes to the data and data model reflect in the data connections that also needed to be updated. This link to healthcare systems requires a substantial coordination effort with the stakeholders. Furthermore, creating and aligning national term lists with RMS term lists as well as term mapping requires a lot of effort by the domain experts.

We came to realize that the initial plan, to cover all changes at once, was not possible in Finland and continuing with the original plan would have led to delays as guidelines and other information was missing. As hindsight, dividing the work into even smaller parts and deliverables, in which the interdependencies would been better accounted for, would have been helpful at the beginning of the project.

Clear instructions on project resourcing for the personnel and frequent follow up / reminders are essential for accurate financial management.