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

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

D4.11: Portugal: Progress report on implementation

Version: 1.0
Status: Final
Dissemination Level¹: PU
Due date of deliverable: 31.01.2021
Actual submission date: 26.02.2021
Work Package: WP4: IDMP implementation at National Drug Agencies
Lead partner for this deliverable: INFARMED, I.P.
Partner(s) contributing: INFARMED, I.P.
Deliverable type²: R

Main author(s):
Rui Vilar INFARMED, I.P.
Nuno Lopes INFARMED, I.P.

Other author(s):
João Figueira INFARMED, I.P.

Resource consumption estimate: Person months
INFARMED 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

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Changes made</th>
<th>Author(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1</td>
<td>20.12.2020</td>
<td>First draft</td>
<td>Rui Vilar</td>
</tr>
<tr>
<td>0.2</td>
<td>28.12.2020</td>
<td>Review and comments</td>
<td>Nuno Lopes / João Figueira</td>
</tr>
<tr>
<td>0.3</td>
<td>15.01.2021</td>
<td>Peer Review</td>
<td>Sanja Grčić Plečko</td>
</tr>
<tr>
<td>0.4</td>
<td>20.01.2020</td>
<td>Review and comments</td>
<td>Nuno Lopes / João Figueira</td>
</tr>
<tr>
<td>0.5</td>
<td>25.01.2021</td>
<td>Review</td>
<td>Rui Vilar</td>
</tr>
<tr>
<td>1.0</td>
<td>26.01.2021</td>
<td>Final check and submission</td>
<td>EMP</td>
</tr>
</tbody>
</table>

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This deliverable contains original unpublished work except where clearly indicated otherwise.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

INFARMED is a government agency accountable to the Health Ministry, which evaluates, authorises, regulates and controls human medicines as well as health products, namely, medical devices and cosmetics for the protection of Public Health.

During the first year of UNICOM, first steps were taken towards refactoring of INFARMED’s system into an ISO IDMP compliant model. In particular, these concerned ongoing data mapping and cleansing activities, simultaneously with gap analysis between current system and ISO IDMP.

Keywords: Infarmed, Portugal, UNICOM, SPOR, 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
List of abbreviations ................................................................................................................................. 5
1 Executive summary .......................................................................................................................... 6
2 About INFARMED ............................................................................................................................ 7
3 IDMP implementation at INFARMED ............................................................................................... 8
   3.1 Context .................................................................................................................................... 8
   3.2 COVID-19 pandemic impact on task 4.12 progress ................................................................. 8
   3.3 Progress on IDMP implementation .......................................................................................... 9
       3.3.1 Procurement ................................................................................................................ 9
       3.3.2 Data ................................................................................................................................ 9
       3.3.3 RMS mapping and data cleansing .............................................................................. 9
       3.3.4 OMS mapping and data cleansing ............................................................................. 11
       3.3.5 SMS mapping and data cleansing .............................................................................. 11
       3.3.6 Gap analysis .............................................................................................................. 11
4 Summary and outlook .................................................................................................................... 12

LIST OF FIGURES

Figure 1. Routes and Methods of Administration: screenshot of the mapping table. ......................... 10
Figure 2. Packaging: screenshot of the mapping table. ..................................................................... 10
Figure 3. ATC: screenshot of the mapping table............................................................................... 11
## List of abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Complete form</th>
</tr>
</thead>
<tbody>
<tr>
<td>INFARMED, I.P.</td>
<td>National Authority of Medicines and Health Products, I.P.</td>
</tr>
<tr>
<td>UNICOM</td>
<td>Up-scaling the global univocal identification of medicines¹</td>
</tr>
<tr>
<td>WP</td>
<td>Working package</td>
</tr>
<tr>
<td>SPOR</td>
<td>EMA service delivering quality data management services for substances, products, organisations and referentials (SPOR) to power EU regulatory activities.</td>
</tr>
<tr>
<td>ISO IDMP</td>
<td>International Organization for Standardization Identification of Medicinal Products</td>
</tr>
<tr>
<td>ATC</td>
<td>Anatomical Therapeutic Chemical (ATC) Classification</td>
</tr>
<tr>
<td>EMA</td>
<td>European Medicines Agency</td>
</tr>
<tr>
<td>OMS</td>
<td>Organisation Management Services</td>
</tr>
<tr>
<td>PMS</td>
<td>Product Management Services</td>
</tr>
<tr>
<td>RMS</td>
<td>Referentials Management Services</td>
</tr>
<tr>
<td>SMS</td>
<td>Substance Management Services</td>
</tr>
</tbody>
</table>
1 Executive summary

The pandemic had a severe impact on task 4.12 (Progressing ISO IDMP implementation at INFARMED in Portugal) progress, resulting in an overall project delay. In order to address and prevent any further delays, the project plan is currently under review.

Procurement for business analysis and solution architecture teams is concluded, procurement for a development team will be brought forward to prevent additional delays.

Data mapping and cleansing activities are ongoing for the RMS lists, to be followed by OMS related lists. PMS and SMS related lists will be mapped when available from EMA.

Gap analysis for RMS begun in November and is ongoing, expected to be concluded before the end of the first quarter 2021. OMS gap analysis to follow.
2 About INFARMED

INFARMED is a government agency accountable to the Health Ministry, which evaluates, authorises, regulates and controls human medicines as well as health products, namely, medical devices and cosmetics for the protection of Public Health. Amongst its attributions, Infarmed provides medicinal product master data to the national eHealth agency to support the national e-prescription/e-dispensation system. Therefore, implementation of ISO IDMP at Infarmed is a cornerstone for the global univocal identification of medicines for cross-border prescription in Portugal.

The tasks it pursues stem from its mission: to regulate and supervise the sectors of human medicines and health products, according to the highest standards of public health protection, and to ensure access for health professionals and citizens to quality, effective and safe medicines and health products.

The Institute's main goal is to ensure the quality, safety and efficacy of medicines authorised for marketing in Portugal, and the quality, safety and performance of health products in order to avoid the risks of their use while ensuring adequate standards of public health and consumer's protection.

Amongst Infarmed top activities the regulation and supervision of medicinal and health products from research up to their use by healthcare professionals and patients is of particular importance.

As a national agency that is responsible for the authorisation and regulation of medicinal products, Infarmed delivers national supporting data on medicines for e-prescription and e-dispensing, as well as identification of medicinal products in all national supply chain activities. Therefore, Infarmed will support within UNICOM the development and implementation of ISO-IDMP and supply ISO-IDMP compliant data for e-prescription and e-dispensing systems.
3 IDMP implementation at INFARMED

3.1 Context

The work to be reported upon is part of UNICOM workpackage 4 “IDMP implementation at National Drug Agencies.” The Commission Implementing Regulation (EU) No 520/2012 (articles 25 and 26) states that European Union (EU) Member States, marketing authorisation holders and EMA shall make use of the ISO IDMP standards. NCAs at national level are responsible to maintain medicinal product data, and in many members states NCAs also provide medicinal product master data to eHealth providers. In order to implement ISO IDMP at national level, preparatory work on IT systems and medicinal product data repositories is necessary. This is also a prerequisite to provide ISO IDMP compliant data to eHealth organisations. It is key to implement the standards in a unified way to enable data exchange between NCAs and other essential partners (eHealth, ePrescription, cross-border-prescription) of the system, and software used for tracking regulatory activities (CTS).

The Communication and Tracking System (CTS) is the system used by the National Competent Authorities (NCAs) involved in the licensing of human and veterinary medicinal products via the mutual recognition and decentralised procedures. CTS supports the co-ordination and tracking of marketing authorisation, post-licensing and work sharing procedures as monitored by the Coordination Groups for Mutual Recognition and Decentralised Procedures for Human (CMDh) and Veterinary medicines (CMDv). The system serves as data provider for other applications. Owned by the Heads of Medicines Agencies, management responsibility for the CTS has been given to the CMDs.

Implementation of ISO IDMP at NCAs is performed in national implementation projects where the funding by UNICOM is a financial contribution in addition to the national investments (an estimated total of more than 20 Million Euros at 11 NCA’s). The participation in the project enables faster national implementation and supports necessary collaboration. Objectives of WP 4 are, inter alia, to progress essential tasks to provide ISO IDMP-compatible IT-systems based on national implementation plans, to support legacy data migration towards ISO IDMP based on national migration plans, and to progress essential tasks on data connectivity to EMA’s SPOR services based on national implementation plans.

In this context, task 4.12 concerns “Progressing ISO IDMP implementation at INFARMED in Portugal.” INFARMED will refactor the national medicinal product database to become ISO IDMP compliant, migrate legacy data into the new ISO IDMP compliant model while continuing to implement the data connection to EMA’s SPOR services where appropriate, support automation of data entry into internal databases, and interoperability between internal and EMA systems. Infarmed will also develop a prototype of an IDMP compliant data feed to the national ePrescription system and other systems in the national eHealth context.

3.2 COVID-19 pandemic impact on task 4.12 progress

The main activities planned for 2020 were as follows:

► Procurement for the Business Analysis and Solution Architecture – Q1;
► RMS mapping and data cleansing – Q2 to Q4;
► SPOR API: access request and specification analysis – Q4;
► Gap analysis:
  ▪ RMS – Q2 to Q3;
  ▪ OMS – Q4 to Q1 2021

Unfortunately, the pandemic had a severe negative impact on most of these activities, particularly on procurement activities and the INFARMED business experts’ availability for planning of overall work across departments, resulting in an overall project delay.

In order to address and prevent any further delays, the project plan is being reviewed taking in consideration the following mitigation measures:

► When possible, anticipating the start date for procurement procedures, in order to account for the currently extended timelines of this process;
To reinforce the business expert/business analysis and development team capacities, in order to recuperate some of the delay;

Whenever possible, consider the lessons learned shared by the other Unicom partners.

3.3 Progress on IDMP implementation

3.3.1 Procurement

Procurement for the Business Analysis and Solution Architecture teams have been concluded in late October 2020, in spite of the severe delays in the process caused by the pandemic situation.

The team members have been onboarded in November and are currently working on the gap analysis activities to be detailed below.

As a way to minimize further impact on the project due to the delay in procurement activities, the procurement for the development team will be brought forward a few months from the initially planned starting date in order to be concluded in time.

3.3.2 Data

Data mapping and cleansing activities between Infarmed’s system and EMA’s SPOR data bases have been postponed to begin in June of 2020, albeit with limited business resources.

3.3.3 RMS mapping and data cleansing

Mapping and data cleansing activities will take place in the following order:

1. Pilot Data lists to be used by the xBorder prescription pilot:
   - EDQM Lists:
     ▶ Pharmaceutical Dose Form and related lists;
     ▶ Routes and Methods of Administration;
     ▶ Packaging;
     ▶ Units of Presentation;
     ▶ Units of Measurement;
     ▶ ATC;
     ▶ Legal Status for the supply;
     ▶ Special precaution for storage;
     ▶ Country;
   2. Remaining RMS lists;
   3. OMS related lists;
   4. SMS related lists (when available);
   5. PMS related lists (when available).

Mapping activities entail mapping of national term lists with SPOR lists, cleansing of national lists, transfer of SPOR terms that do not exist in national lists, and change requests to SPOR in case of national term in use inexistent in SPOR.

The mapping of the first batch of lists is still mostly ongoing, but has been concluded for the following lists:

   ▶ Routes and Methods of Administration;
   ▶ Packaging;
   ▶ ATC.
Figure 1. Routes and Methods of Administration: screenshot of the mapping table.

Figure 2. Packaging: screenshot of the mapping table.
Figure 3. ATC: screenshot of the mapping table.

Priority, inclusion and exclusion of lists for mapping and translations will be under continuous scrutiny depending on project needs for the xBorder prescription pilot.

The knowledge achieved with mapping activities includes a better knowledge of the various categories of lists that exist in SPOR, their relationship with national lists, and with corresponding fields in national databases. Although at an initial stage, the mapping activities, have already identified some potential issues such as the existence of SPOR lists that are currently stored as unstructured data.

3.3.4 OMS mapping and data cleansing

OMS mapping and data cleansing will begin when the RMS activities are concluded, currently estimated for the second quarter 2021.

3.3.5 SMS mapping and data cleansing

SMS / PMS activities planning is currently under review.

3.3.6 Gap analysis

In the Gap analysis phase, we will compare Infarmed’s current data model against the ISO IDMP model and define the activities needed to reach the final model.

The Gap analysis model will follow the same order used for the data mapping and cleansing activities:

1. RMS;
2. OMS;
3. SMS & PMS.

The Gap analysis for RMS begun in November and is ongoing, expected to be concluded before the end of the first quarter 2021.

Gap analysis timeline for the next phases (OMS, SMS & PMS) is currently being reviewed.
4 Summary and outlook

Unfortunately, the COVID-19 pandemic had a strong negative impact in the first year of the project.

From planned activities, the ones that could be ensured were ongoing data mapping and cleansing of RMS lists, with three lists concluded, and start of RMS gap analysis expected to be concluded before the end of the first quarter 2021.

Mitigation measures were put in place that should have a positive effect on the project in 2021: review of project plan, consider the lessons learned shared by the other Unicom partners, anticipation of procurement procedures, reinforce business experts and develop team capacities.

Experience in first year has led to a better understanding that IDMP/SPOR has a profound direct impact on INFARMED business processes besides being a technological project. It is necessary to secure a bigger involvement of business experts and their education and training about IDMP/SPOR.

Work to increase experience and knowledge about IDMP/SPOR, already started, is expected to develop significantly in early 2021.

Gap analysis for RMS is ongoing and should be shortly followed by OMS gap analysis.

Data mapping and cleansing activities will create a significant search for human resources. The search for software to speedup these activities is ongoing.