UNICOM

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[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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0.1	11.01.2021	Initial Draft	Sean d'Art / Mark Kelly
0.2	21.01.2021	Revised draft with implementation details and executive summary.	Sean d'Art / Mark Kelly
0.9	25.01.2021	Final version	Sean d'Art / Mark Kelly
1.0	29.01.2021	Review and submission	EMP

Deliverable abstract

As part of its participation in UNICOM WP4, the HPRA has committed to progressing ISO IDMP implementation through a combination of business process and IT systems changes.

The implementation of IDMP at the Health Products Regulatory Authority (HPRA) involves reviewing and amending business processes, training users in new processes, mapping and changing data in core case management systems, refactoring information technology applications to handle IDMP requirements, and develop automated system interfaces to access and synchronise with SPOR data on an ongoing basis.

The HPRA's primary case management application used for the management of data and processes for human and veterinary product authorisation and licensing is EOLAS. EOLAS provides data feeds to other HPRA information technology systems and public web sites/extranets referenced by national eHealth providers and other external stakeholders.

The database structure of EOLAS was designed with IDMP compliance in mind, given the information available in respect of IDMP when the system was commissioned several years ago. EOLAS provides a common repository for both Human and Veterinary for case management with shared information across both regulatory domains.

Significant effort is also required by the organisation to map local data to SPOR to deliver IDMP compliance.

Keywords: HPRA, ISO IDMP, SPOR, RMS, OMS

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List of abbreviations

Abbreviation	Complete form
EOLAS	Case management system in use at the HPRA
HPRA	Health Products Regulatory Authority
IDMP	Identification of Medicinal Products
MAH	Marketing Authorisation Holder
OMS	Organisation Management System
RMS	Referential Management System
SMS	Substance Management System
SPOR	EMA data service for substances, products, organisations, referentials
UI	User Interface
UX	User Experience
WinPure	Application used for cleansing of data

1   Executive summary

The Health Products Regulatory Authority (HPRA) is the Irish state agency whose role is to protect and enhance public and animal health by regulating medicines, medical devices and other health products. The health of people and animals is at the core of everything the organisation does. Using scientific and clinical expertise, the organisation assesses, regulates and monitors health products available in Ireland or exported abroad.

The HPRA will review and amend as required both business processes and IT systems to progress towards IDMP compliance. This will include the analysis and redesign of existing business process, refactoring of IT systems, developing IT system interfaces to SPOR, data mapping to align with the new standards, and comprehensive testing of both data and systems changes.

EOLAS is the HPRA's primary information technology platform, custom built using SharePoint technology, and is used for medicinal and veterinary product authorisation and licensing, and for the overall management of the medicinal product lifecycle. A significant programme of work is underway to on-board the HPRA's other functions onto the system. EOLAS provides data feeds to other HPRA information technology systems and public web sites/extranets that are referenced by national eHealth providers and other external stakeholders. EOLAS supports a number of online services for external stakeholders to digitise collaboration between external stakeholders and the agency.

This work package will ensure the IT system EOLAS, its data and data feeds to external national eHealth providers, and external stakeholders are IDMP compliant, and EOLAS can utilise SPOR services as an integral part of the data management process.

The focus of activities to date has been in the following four areas:

- Promoting awareness in the organisation of IDMP and the changes required.
- Conducting a gap analysis on processes and systems.
- Planning and progressing mapping of data to align with IDMP requirements
- Developing an understanding of the technical and operation requirements and changes for the integration of SPOR.

The promotion of IDMP has been primarily through information technology channels whereas there is significant change required in the day-to-day regulatory operations of the organisation. Promoting awareness to a resource constrained organisation has been an essential step.

Changes, both process and data, will be required to EOLAS. An initial gap analysis identified a number of changes and data cleansing/mapping initiatives that will be required in order to align with IDMP and enable integration with the SPOR database.

Application changes are being specified, and will signed off by a joint working group and development will be progressed. System data controls are being introduced to ensure data integrity for the future. Development teams have access to the SPOR API with initial work has been done integrating (read only) with SPOR API for an existing project. Learnings will be utilised for integrating SPOR with EOLAS, with changes being subject to extensive testing before being deployed.

Both Human and Veterinary share EOLAS as a common case management application and data repository. Significant work has been done by joint teams reviewing the data mapping requirements and on progressing data cleansing, concentrating to date on Referentials. Although Organisation data is not directly related to IDMP compliance, due to data dependencies, cleaning of Organisational data is integral to progressing the HPRA towards IDMP compliance.

2 HPRA

The Health Products Regulatory Authority (HPRA) is a state agency of the Republic of Ireland, its role is to protect and enhance public and animal health by regulating medicines, medical devices and other health products. The HPRA is also responsible for monitoring the safety of cosmetics.

The HPRA puts the health of people and animals at the core of everything it does. It uses scientific and clinical expertise to review and monitor health products available in Ireland or exported abroad. The HPRA's aim is to make sure that health products it regulates are as safe as possible and do what they are intended to do.

The HPRA's broad regulatory remit includes;

- Human medicines
- Veterinary medicines
- Clinical trials
- Medical devices
- Controlled drugs
- Blood and blood components
- Tissues and cells
- Cosmetic products
- The protection of animals used for scientific purposes
- Organs intended for transplantation

2.1 Deliverable 4.5 – Ireland Progress Report on Implementation

Deliverable 4.5 is a progress report on the implementation of the work described in task 4.6 below.

2.2 Task 4.6 - Progressing ISO IDMP Implementation at HPRA

The HPRA will review and then amend both business processes and IT systems. This will include analysis of business process, refactoring of IT systems and IT system interfaces, data extraction, data transformation and data migration exercises, system testing and documentation.

EOLAS is the HPRA' s primary IT system that is used for medicinal product authorisation and licensing, and as part of the medicinal product lifecycle, EOLAS provides data feeds to other HPRA IT systems and public web sites/extranets that are referenced by national eHealth providers and other external stakeholders. EOLAS supports several online services for external stakeholders to digitalise the collaboration between external stakeholders and the agency.

This work package will ensure the IT system EOLAS, its data and data feeds to external national eHealth providers, external stakeholders are ISO IDMP compliant, and EOLAS can utilise EMA's SPOR services as part of the data management process.

2.3 Authorship and responsibilities

The Project Coordinator is responsible of 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 and 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 of 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 Implementation Approach & Progress

3.1 Overview

Both the Human and Veterinary Medicines Departments use the HPRA's core case management system, EOLAS. The structure of substance, organisational, referential and medicinal product data is common between the two departments, as is much of the referential, organisational and substance data itself.

As such, adapting EOLAS to the IDMP data standards has impacts on both departments and requires a cross-departmental approach to requirements analysis, change control and the impact analysis of any needed changes.

Therefore, a significant focus during the reporting period has been on establishing a cross-departmental data and process governance group to understand IDMP and agree changes needed to both systems and data.

3.1.1 Organisation

At the outset of the UNICOM project, awareness and understanding of the IDMP data standards was limited, both the regulatory/scientific teams and within the ICT and Business Services department.

As part of a discovery phase, a senior database engineer conducted an initial review of IDMP related documentation including the EMA's EU IDMP Implementation Guide and subsequently performed a GAP analysis between the IDMP standard and the data model in EOLAS.

This analysis resulted in a prioritised list of areas of focus for progressing the project and formed the basis of a draft project plan. At this point it became apparent that business owners were required to progress much of the work associated with UNICOM WP4. The ICT and Business Services team presented a summary of findings to directors and section managers from the HPRA's various functional departments and requested nominated business owners to support the project.

Since then, business owners from the relevant departments have been identified for Referential and Organisational data. These business owners have begun to develop an understanding of the IDMP standards and have begun detailed analysis of specific areas including Pharmaceutical Product, and Dose Form.

3.1.2 System

Organisations Related Systems Changes:

There is a significant level of duplication in EOLAS Organisational data. These duplicate organisations will need to be removed in order to enable mapping to organisations in OMS. The process for removing these duplicates is underway and is described in more detail in section 3.1.3 of this document.

While cleansing of existing organisational data is underway, it will also be necessary to make changes to EOLAS in order to prevent creation of further duplicates moving forward. Analysis of both the business process for organisation creation as well as the EOLAS UI/UX which enables organisation creation revealed a number of characteristics in the system which essentially encourage users to create duplicate organisations.

Currently there are no organisation types in EOLAS. Additional functionality is required to capture organisation types. These organisation types will be used to filter organisations in dropdowns or search boxes used for Authorisation holder, Manufacturer, Contact organisation and regulatory contact organisations in EOLAS cases.

Organisation related system changes are described in more detail below. As of January 2021, these changes have been developed and integration tested but not deployed to production. These changes

will be deployed to production as and when organisation data cleansing, patching and mapping activities have completed.

Organisation Type

A new reference data table is required to store the following organisation types:

► Authorisation holder
► Regulatory contact
► Case contact
► Manufacturer

An organisation can have more than one organisation type. A new organisation-to-organisation type relationship table is required in the data model to link organisation with organisation types.

Changing organisation type

Changing an organisation's "Organisation type" should only be allowed if the organisation is not assigned as that "Organisation Type" in any case.

► Add validations so that Organisations need to be approved (have a master data status of "Current") before being used in a case.
► Add a "Deleted flag" column to the "Organisation" table to identify deleted records after organisation data cleansing.
► Organisation validations should be updated to eliminate duplicates.
► Add validations so that "Organisation name" and "address" cannot be duplicated.

Changes in EOLAS Case UI

Authorisation Holder

The „Add Authorisation holder" option should be removed from the right hand menu of the core information page.

Figure 1 - Core Information Screen - Authorisation Holder

The „Add new authorisation holder'" option should be removed from the „Add product" UI.

Searching for an authorisation holder should only return organisations with organisation type "Authorisation holder" and Master data status "Current".
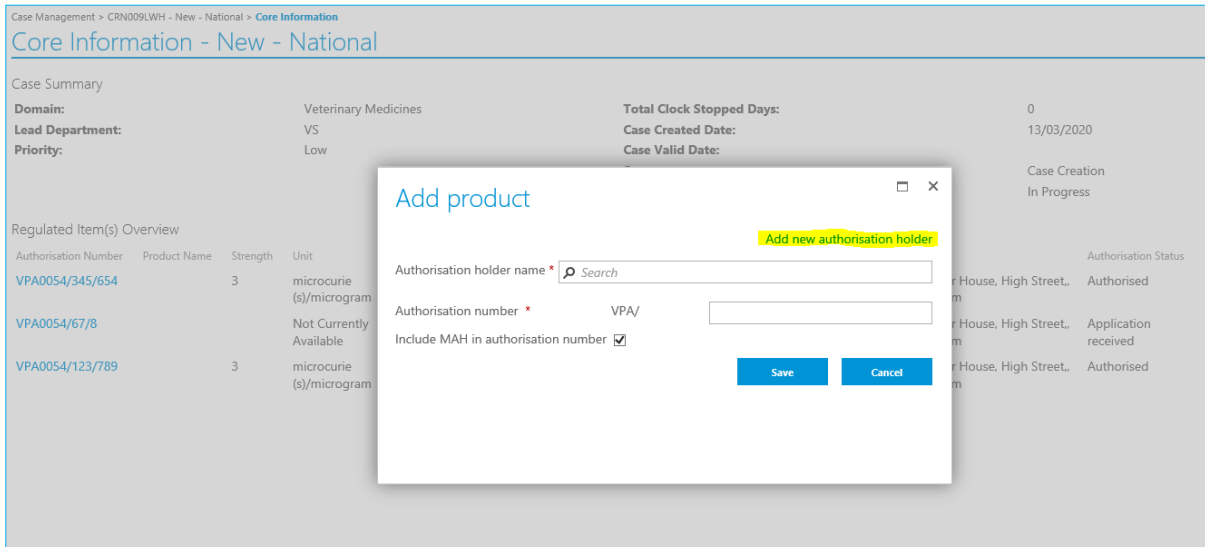
Figure 2 - Add Product Screen - Add New Authorisation Holder

Manufacturing information

The „Add manufacturer" option should be removed from "Manufacturing Information" UI.
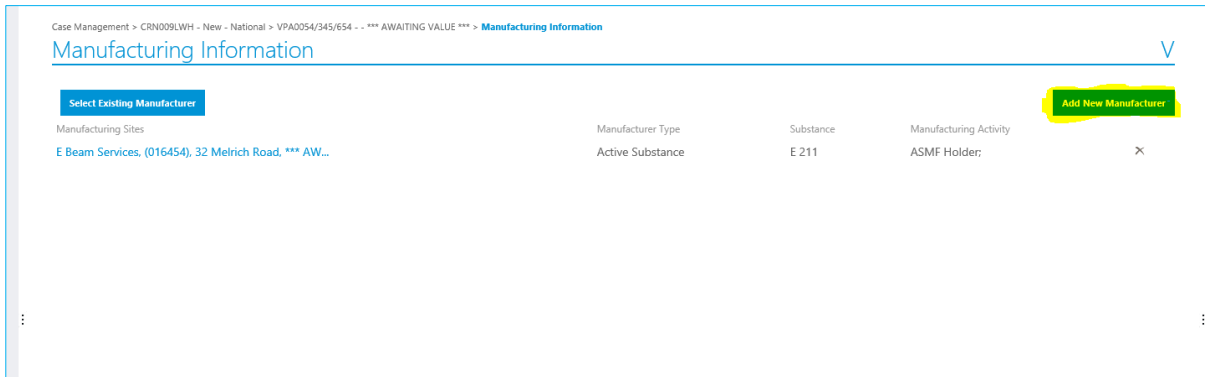

Figure 3 - Manufacturing Information - Add New Manufacturer

The „Select existing manufacturer" search should only return organisations with organisation type "Manufacturer" and master data status "Current".

Figure 4 - Manufacturing Information - Select Existing Manufacturer

Regulatory Contacts

Remove „add new contact" option from the „regulatory contacts" and „Authorisation holder" screens.

Figure 5 - Regulatory Contacts - Add New Contact

The „Add existing contacts" option should only return organisations with type „regulatory contacts" or „Authorisation holder" and master data status "Current".
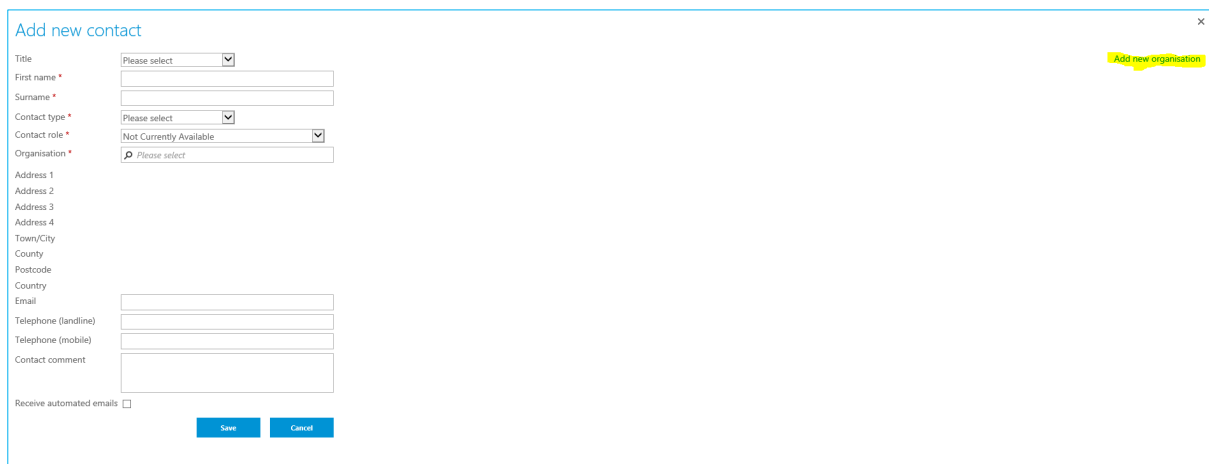
Figure 6 - Add Existing Contact - Organisation Search

Case Contacts

Remove the "Add organisation" option from „case contacts" screens.

Figure 7 - Case Contacts - Add Organisation

The „Organisation search" functionality in the „add new contact" screen should only list organisations with organisation type "Case contacts" and master data status "Current".

Figure 8 - Add New Contact - Organisation Search

The „Existing contacts search" functionality should only return contacts from organisations with organisation type "Case contacts" and master data status "Current".

Figure 9 - Add Existing Contact - Existing Contacts Searc

Other changes

- Add validation for new contact: „First name + surname + organisation + email" should be unique.
- „Add existing contact" should list email address of the contact. Currently the contact list is only showing 5 per page, it should be increased to 15.

Figure 10 - Add Existing Contact Screen

- Archived organisation functionality should be used for case contacts. Currently case contacts are not archived and any update for organisation or contact changes details in closed cases.
- Automated email functionality should work if the check box ("receive automated emails") is selected for a contact.

Figure 11 - Add New Contact Screen - Automated Emails

Referentials Related Systems Changes

Systems changes related to capturing data for Pharmaceutical Product are drafted but not finalised.

An area of initial focus was on capturing "strength" in a manner which is compatible with SPOR and IDMP. EOLAS currently captures Pharmaceutical Product Strength as a combination of a free text quantity and a drop down for "unit of measurement".

Analysis suggests EOLAS will need to be adapted to capture Strength as a combination of free text numerical fields for both 'Numerator' and 'Denominator' in combination with new dropdowns for 'Unit of Measurement' and 'Unit of Presentation' as presented in Figure 1 below.

In the event the user selects 'Range' from the 'Operator' dropdown, both the 'From' and 'To' values for strength will need to be represented by the new 'Numerator', 'Operator', 'Unit of Measurement' and 'Unit of Strength' fields.
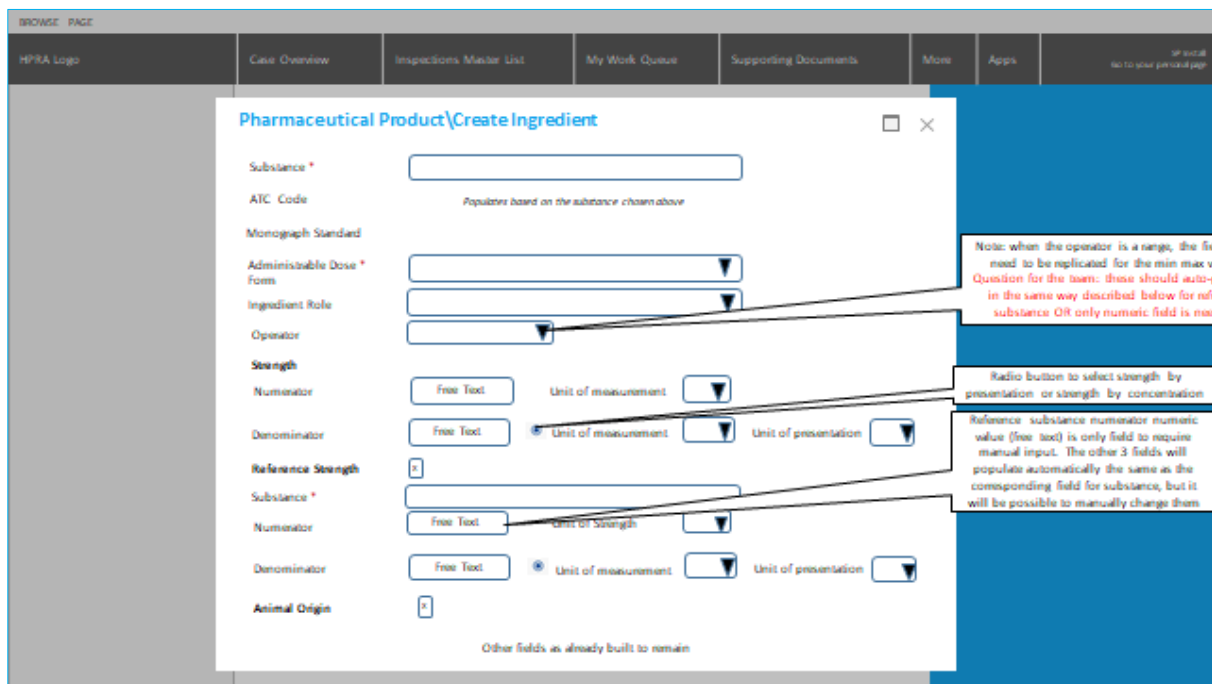
Figure 12 - Pharmaceutical Product Screen - Strength Changes Mockup

The impact of the changes described above requires further analysis as information which is published to the HPRA website is populated from elsewhere in the UI, specifically in the 'Product Information' screen represented in Figure 2 below.

The 'Strength' field in the 'Product Information' page may need to be configured to auto populate from the "Pharmaceutical product strength" which is defined in the screen in the mock up in Figure 1 above.
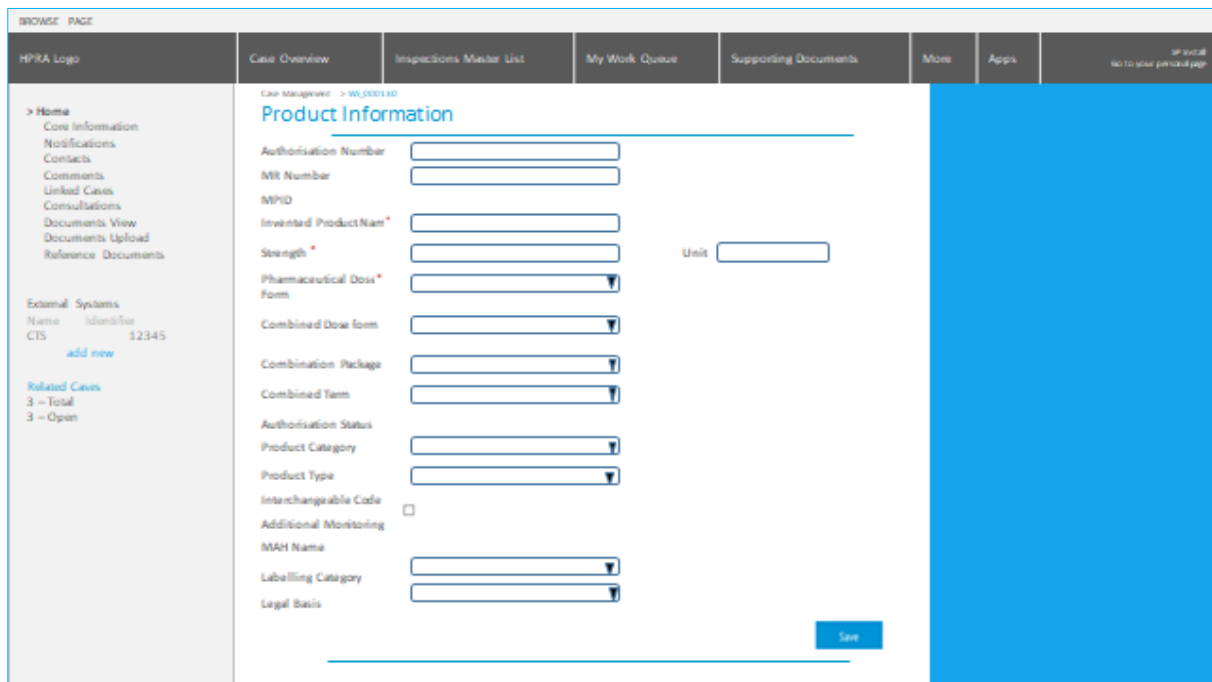
Figure 13 – Current EOLAS Product Information Screen

3.1.3   Data

Organisation Data Cleansing and Mapping

An initial technical review of data structures and quality revealed a significant level of duplication in EOLAS organisational data which will need to be resolved before mapping to Organisations in OMS can happen.

Further analysis of both the business process for organisation creation as well as the EOLAS UI/UX which enables organisation creation reveals a number of flaws in the system which essentially incentivise users to create duplicate organisations.

The HPRA's approach to resolving this is two-fold:

1. Cleansing of legacy organisational data needs to take place to remove existing duplicates.
2. Code changes are required to optimise the UI/UX with respect to organisation creation so that users are no longer incentivised or allowed to create duplicate organisations. These code changes are described in more detail in section 3.1.2 of this document.

Figure 3 below illustrates the level of duplication among MAH type organisations in EOLAS. Manufacturer type organisations are more numerous and are subject to similar levels of duplication.

Table 1 - EOLAS MAH Data Duplication

	Total MAH	Duplicates
Human MAH only	2763	252
VET MAH only	564	53
MAH that have Human and Vet Products	139	29
Total	**3466**	**334**

In order to remedy this issue, organisational data owners have been identified and a data analysis tool called WinPure has been acquired. WinPure has enabled us to automatically identify some of the duplicates but business owners are still ultimately responsible for reviewing lists of organisations and signing off on those which are duplicate. The HPRA's approach has been to conduct this exercise in a step-wise fashion, starting with MAH (a relatively short list) before moving on to Manufacturers.

Referentials Data Cleansing and Mapping

EOLAS referential data is of a higher quality than organisational data but presents unique challenges in that it is common between the human and veterinary medicines departments. As such, changes must be agreed across both domains.

An example of some of the work underway in relation to 'Unit of Measurement' is described below.

Unit of Measurement

As discussed in section 3.1.2, changes to the way in which Pharmaceutical Product Strength is captured have been drafted and include the use of new 'Numerator' and 'Denominator' free text numerical fields in combination with new drop downs for 'Unit of Measurement' and 'Unit of Presentation.

EOLAS contains a total of 545 unique terms for 'Unit of Measurement'. Of these, 283 terms are an exact match with RMS terms and can therefore be mapped without much effort.

Of the remaining 262 terms, approximately 50 are not associated with any Human or Veterinary Medicinal Products, it is expected that these can be ignored or deleted.

This leaves approximately 210 terms for 'Unit of Measurement' which will need to undergo manual review. It is anticipated that some of these terms can be mapped to RMS terms while some will need to be split into separate values for 'Unit of Presentation'.

84 of these terms are specific to the Veterinary department and another 70 are used by both Human and Veterinary and will require cross-departmental agreement on mappings.

Other Data Related Activities

EOLAS substance data appears to be subject to a degree of duplication but detailed analysis of substance data has been de-prioritised pending availability of SMS.

Once data has been cleansed and mapped, the HPRA have identified a requirement to address gaps between EOLAS data and data in SPOR. Gaps in referential data are understood to be addressable by means of submission of change requests to the EMA. Gaps in organisational data will likely be addressed by contacting organisations which do not exist in OMS and requesting that they register. Specifics in relation to the change request process are not yet understood and require further investigation.

Specifics in relation to the ongoing synchronisation of data between EOLAS and SPOR have not been defined and more substantive testing and familiarisation with the SPOR API is scheduled to take place in Q1 2021.

3.2   Delivery Approach & Schedule

The HPRA initiated its work on UNICOM WP4 with a technical review of the EMA's EU IDMP Implementation Guide, documentation around the IDMP data standards and a subsequent high level GAP analysis between EOLAS' data model and the IDMP standards.

An initial analysis document was drafted which outlined at a high level the work which would need to take place in order to align EOLAS to IDMP and integrate with SPOR.

This initial document served as the basis of a more detailed planning exercise that took into account resource requirements and likely activity durations in order to create of a more detailed project plan. This project plan was then adapted to take into consideration an existing, programme of work that was already underway to on-board Scientific Animal Protection, Clinical Trials, Medical Devices and Compliance teams and processes into the EOLAS case management system.

A consolidated plan for EOLAS was created and has served as the guiding document for the project through the latter half of 2020 and into 2021. While there is a high degree of confidence in the accuracy of the activities and dependencies which have been identified, uncertainty around the actual capacity within the HPRA's various departments to perform these activities creates uncertainty as to the likely timeline for completion of the project.
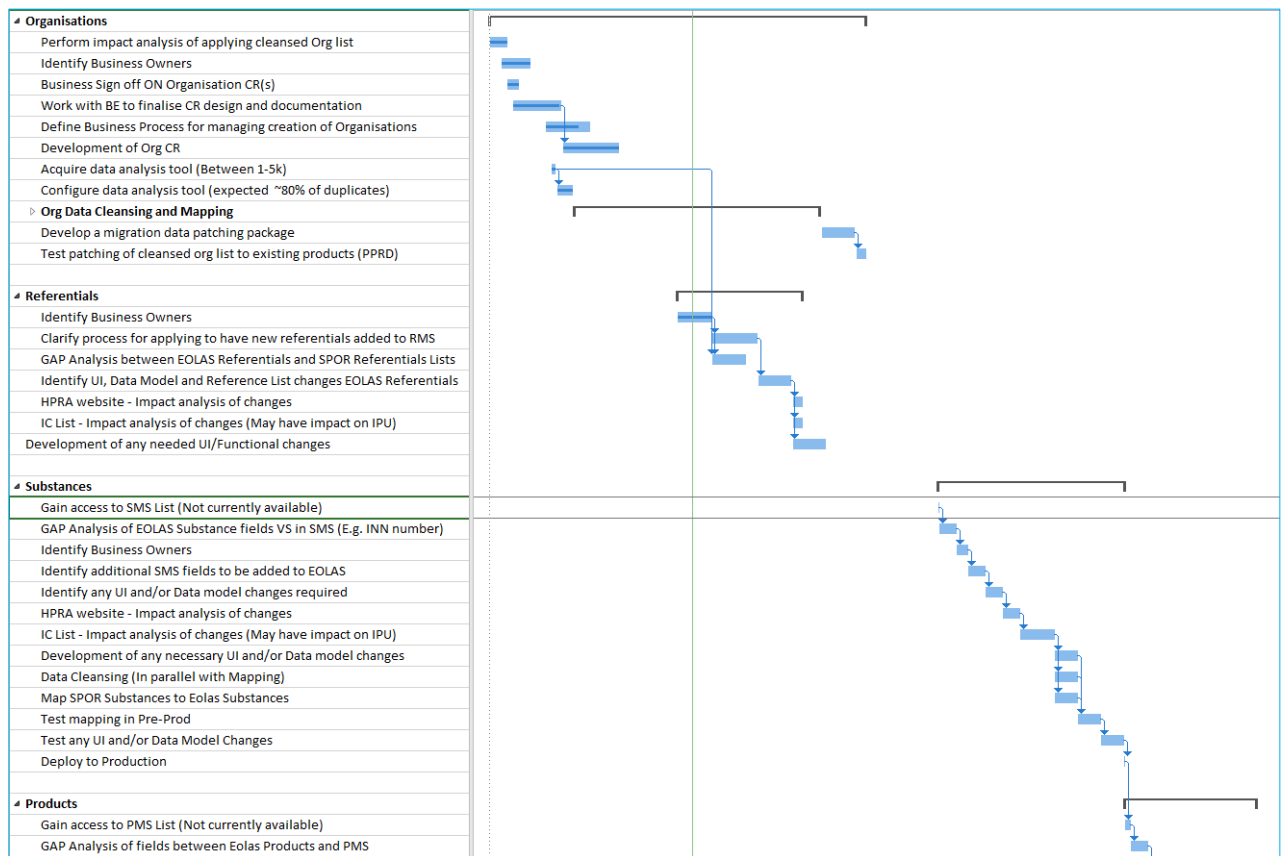
Figure 14 - HPRA WP4 Project Plan

3.2.1   Project Organisation

The HPRA's UNICOM WP4 Project team is multi-disciplinary, consisting of business owners from both the Human and Veterinary Medicines departments alongside technical resources including Database engineering, Business Analysis, QA Testing and Software Development.

The project is managed and co-ordinated by a Project Manager within the ICT and Business Services Department reporting to the ICTBS director. The Human Medicines Director sponsors the project.

Project progress is reported to the entire HPRA Management Committee through the PMO and at regular Management Committee and ICT Steering Committee meetings.

Figure 15 - HPRA WP4 Project Organisation Structure

3.3 Dependencies
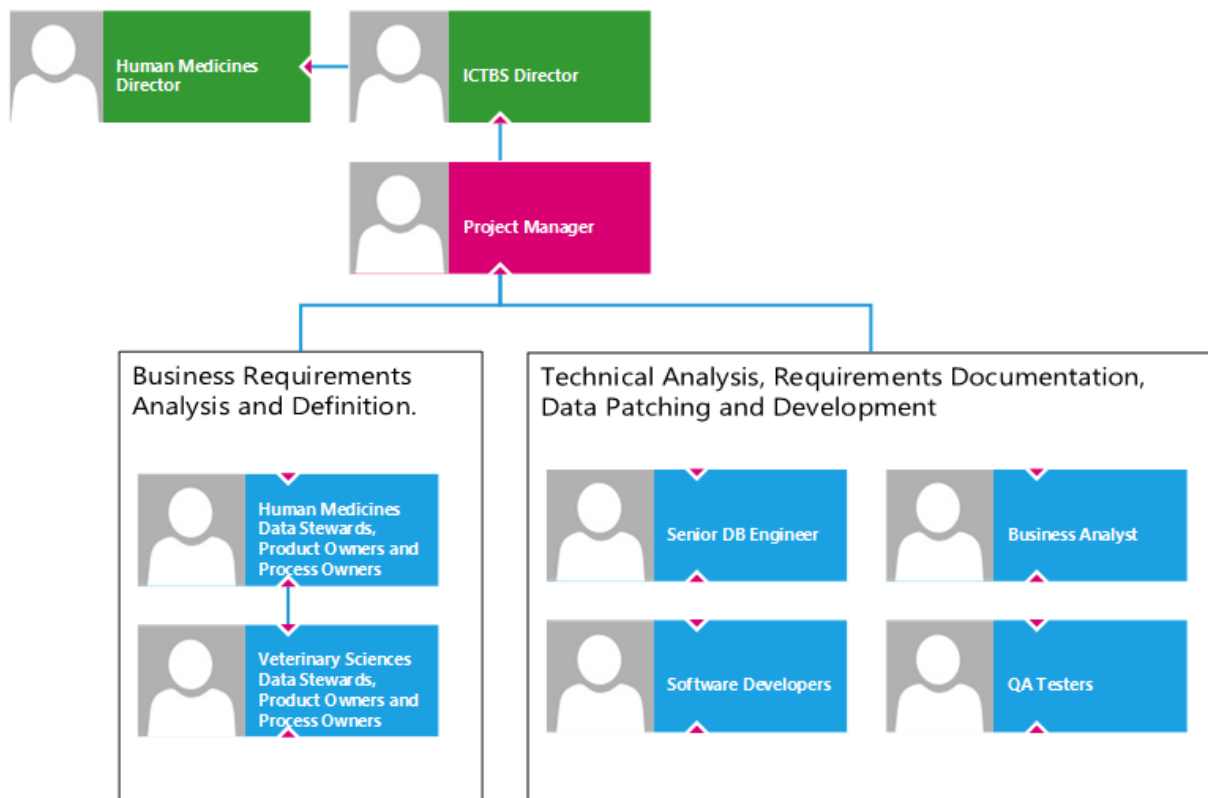
Human and Veterinary share common data sets, processes and user interface requiring extensive planning and testing for changes to any aspect of the application.

In addition to IDMP changes underway at the HPRA for this work package, the EOLAS system and data is being modified to support the implementation of the NVR (New Veterinary Regulations) and interfacing to the Union Product Database. Significant dependencies exist and close coordination of activities is required between the two programmes of work.

3.4 Risks

The project faces a range of risks that will potentially influence activities and schedules, although not impact the overall deliverable of the work package. A significant programme of work is currently underway at the HPRA with significant commitments from both information technology and business staff.

Risks management is coordinated by the project team through periodic reviews where risks are identified, classified, recorded. Risks are reviewed on an ongoing basis by the project team, with mitigating actions taken to ensure risks do not materialise. Categories of risks identified by work package activities generally fall into three broad categories:

- Resources risks: due to availability of staff, across different functions within the organisation, and supplemental external to support work stream activities. This risk specifically includes the availability of staff with the process knowledge to understand the implications of changes.
- Requirements risk: due to completeness and stability of requirements and guidance as defined in the implementation guides.

- Data risks: due to complexity of changes required due to underlying product data structures, and ensure the preservation of published legacy regulatory data.
- System risks: due to complexity, time and cost required to refactor the primary application EOLAS and the extensive testing required to ensure integrity of system and data.
- Integration risks: due to coordinating the activities across projects requiring changes to common processes, data and systems.

A further general category of risk is that the project is being advanced substantially as an information technology project, with limited understanding of the benefits of IDMP and the consequent commitment required to effect the transition. Communications have been undertaken to address this risk.

Table 2. WP4 Work stream Risks

Risk Category	Description
Resource	The organisation capacity is directed towards critical activities including managing the introduction of COVID-19 vaccines, and supporting other organisations in the Irish health service. This limits the organisation resource available to support work stream activities.
Resource	The organisations capacity is being directed towards mitigating the impact of Brexit
Requirements	The requirements are incomplete and subject to change, specifically completion of Referential and Substance information. Creates a degree of uncertainty in planning IDMP adoption at a national level, and presents a risk to the quality of the work being undertaken and the necessity for rework.
Resource	UNICOM related data cleansing and mapping activities will create a significant demand in terms of both human and financial resourcing.
Data	Different parts of the organisation share common repositories of integrated data.
Resource	There is a risk that non-availability of key resources will delay the adoption of IDMP standards or that UNICOM work will delay other needed business and ICT activities.
Resources	Staff from business and technology functions are required to support work package activities. In particular, where data remapping is required, decision makers are required from the organisation to assist in this process, so subsequently data changes can be identified and agreed.
Integration	Significant parallel and related projects (NVR) are facing urgent deadline for the submission of legacy veterinary medicinal product data. EOLAS is used by both Veterinary and Human Medicines functions, necessitating that the Human medicines department accelerate their own timelines in respect of data cleansing and mapping.