EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management Division

# European Medicines Agency (EMA) Master Data Management Roadmap

## Substance, Product, Organisation and Referential data

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# Table of Contents

# 1. Executive summary

This report outlines an EMA multi-year programme which defines a Master Data Management (MDM)[1] strategy for the use of medicinal product data specifically related to Substance, Product, Organisation and Referential (SPOR) data. MDM is a technology-enabled discipline in which business and IT work together to ensure the uniformity, accuracy, and consistency of medicinal product data which supports key business processes and is a strategic asset for EMA. This EMA driven initiative will seek to address opportunities in optimising and building upon the current data governance, business processes and technology platforms principally in place at the EMA, whilst simultaneously considering wider stakeholder data needs.

The EMA executed a process of stakeholder interviews to understand the current situation and requirements for MDM services, including an assessment of data governance, management processes, business and technology-based solutions. The roadmap also considers inputs received from pharmaceutical industry associations and the wider stakeholder network. The key business drivers have been defined in alignment with the EMA goals and roadmap vision, and clearly linked to the expected benefits for all stakeholders.

As a result of this strategic exercise this roadmap proposes the following key conclusions and expected results:

A collaborative approach will be taken to data management which will seek to benefit all parties, including industry with respect to product data submission obligations relating to Article 57 of the Pharmacovigilance legislation.

An integrated MDM solution will be implemented, which will deliver ISO IDMP[2] standards compliant SPOR master data.

The approach for the implementation of MDM services will be iterative and gradual focusing on supporting the EMA high priority business activities first with the view of incrementing these services to support all EMA processes in the future. It is important to start with tactical projects to set up the foundation which are aligned with an overall strategy for MDM.

The MDM solution will be implemented in phases to support different areas of SPOR data. The Referential MDM will deliver the first services which will lay the groundwork for the following Substance, Product and Organisation MDM implementations.

The proposed roadmap recommendation considers a conservative approach to minimise exposure to risk, protect investment and address stakeholder concerns.

The EMA will adapt and replace its business processes and systems over an ongoing period but simultaneously will maintain the current interfaces at least until an agreed time period with stakeholders to ensure a smooth transition and avoid disruptions.

The transformation programme will be supported by a set of foundation capabilities to ensure continuous alignment with our stakeholders through the appropriate use of tools such as change management and governance.

In conclusion, it is believed that through this EMA transformation programme, a catalogue of data services will be provided to the EU network and industry. The services provided will be supported by

[1] See 'Master data' in the Glossary.
[2] ISO standards for the Identification of Medicinal Products. Refer to the Glossary for further details regarding the standards and their scope.

high quality, consolidated medicinal product data. Such enhancements once used under a continuous improvement culture, will enable EMA to simplify processes and improve operational efficiency.

The roadmap will be updated in the future at regular intervals in order to reflect environmental and regulatory changes, and adapted according to the pace of implementation progress.

# 2. Background

Over the years EMA has overseen the implementation of a range of IT solutions to support the ever growing range of business services provided to EU Member States, the pharmaceutical industry as well as the broader stakeholder community including the general public. In common with many organisations, both the scope and number of business processes and systems supporting these processes have increased, in some cases resulting in data duplication across systems with data managed in isolation. This data duplication and differing approaches to data management across the organisation can result in a reduction in data quality and inefficiencies in general. A key example being the way industry submits product data to EMA in differing formats in support of different EMA procedures, or the lack of appropriate data/information analytics which can lead to inappropriate business decisions.

All these factors lead to serious data quality problems thereby negatively impacting the EMA's ability to make strategic investment and resourcing decisions, maintain adequate governance, run efficient processes, mitigate risks and provide accurate and timely compliance reports.

The new ISO IDMP standards being introduced will provide an international framework for consistent documentation, coding and exchange of product information between partners such as, global regulators and pharmaceutical industry. In general it will help enable the unique identification of Medicinal Products and will allow the reliable exchange of information in a consistent manner when communicating with partners throughout the entire product lifecycle. Development of an MDM framework will provide the platform for the provision of processes and enabling technologies will support the collection, aggregation, alignment, consolidation, data quality and distribution with respect to the ISO IDMP and the wider SPOR data sets.

Following recommendations from an internal EMA driven assessment, EMA has reviewed the approach to data management and is implementing a data management strategy. Within this strategy it has been identified that medicinal product master data relating to Substances, Products, Organisations and Referential (SPOR) data currently maintained in numerous systems should be maintained within an MDM service to ensure data quality and to provide the basis for new stakeholder services enabling them to benefit from EMA's investment in this area.

In addition to the system and process changes required to implement recommendations, the primary systems managing medicinal product data are subject to significant change to align with the ISO IDMP standards and ensure compliance with the Pharmacovigilance and clinical trials legislation. The scale of these changes and the impact within EMA and with our stakeholders requires the development of a shared plan for implementation and transition covering the different perspectives of stakeholders.

The adoption of ISO IDMP presents a significant opportunity to improve the efficiency of SPOR data management between industry and regulators on a global basis. The true extent of these benefits can be more effectively realised through the use of the proposed MDM services rather than perpetuating the current situation which does not allow for greater data and process integration.

The implementation of MDM should support an enterprise approach to data governance at EMA and integration of data, processes and systems will enable the realisation of this benefit. Transitional stages will be necessary throughout the implementation of SPOR MDM.

The outcome of this is to develop a roadmap to address these issues and lay the foundations for benefits to EMA and stakeholders to be realised.

The result of following the roadmap will be the gradual implementation of MDM business services aligned to EMA's regulatory needs and delivering value to stakeholders through new master data services.

# 3. Roadmap Vision, Goals and Scope

## *3.1. EMA Mission*

The mission of the European Medicines Agency (EMA) is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health.

EMA is the European Union body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and Pharmacovigilance of medicinal products. EMA provides the Member States and the institutions of the EU the best-possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

## *3.2. Vision for the Roadmap*

The vision of this roadmap is to enhance the quality, consistency and availability of medicinal product data used by EMA, the EU Regulatory Network, industry and the wider stakeholder community. This is central to achieving excellence in the evaluation and supervision of medicines. Through such enhancements our stakeholders will be able to more effectively exchange data and simplify processes facilitating improved operational efficiency.

To communicate the approach taken in the delivery of these enhancements to support EMA's stated Mission, EMA has developed this master data roadmap for Substance, Product, Organisation and Referential data (SPOR). Implementation of MDM is a pre-requisite for EMA to provide future services around master data, and enable the benefits to be realised through delivering value to stakeholders.

This Roadmap has a broad scope which is defined by the goals described in the following section.

## *3.3. Goals*

The vision provides the direction which is cascaded here into goals with clearly defined tangible outcomes and benefits to be achieved by the implementation of this roadmap:

1. Implement an integrated and harmonised MDM solution which will deliver standards compliant master data for Substances, Products, Organisations and Referentials (SPOR).
2. Data will be collected, managed and made available to the network, industry and wider stakeholder community, in compliance with legislative requirements and relevant standards for privacy, data protection and security.

3. Implement a new portfolio of services which will be supported by standardised data governance and lifecycle management.
4. Maximise the benefits realised throughout the implementation of the roadmap by involving and engaging effectively with stakeholders, leading to operating model simplification and efficiency improvements.

## *3.4. Scope*

In alignment with the goals of this roadmap, the scope includes the following:

***Goal 1:*** *Implement an integrated MDM solution which will deliver standards compliant master data for Substances, Products, Organisations and Referentials (SPOR).*

- Implementation of an MDM solution for the SPOR master data required to fulfil the regulatory and scientific role of EMA
- Review, integration and improvement of the following processes in alignment with the implementation of the MDM solution:
    - Marketing authorisation procedures (from pre-authorisation to post-authorisation activities) and pre-submission activities (e.g. Orphan, Paediatrics and Scientific Advice) for human and veterinary medicinal Products
    - Pharmacovigilance
    - Clinical Trials (for authorised and development Substances and Products)
- Implementation of:
    - Substance and product data exchange and storage in compliance with the ISO IDMP standards.
    - Additional data requirements to support the full product lifecycle
    - A standard data model to register and manage veterinary medicinal products and substances
    - A standard organisations data model (aligned with ISO IDMP) supporting human and veterinary processes
    - Substance and medicinal product related referential data with consistent access mechanisms and where required the definition or implementation of a standard for data exchange
- Definition of the enterprise architecture for business processes, data, applications and technology within a chosen reference architecture.

***Goal 2:*** *Data will be collected, managed and made available to the network, industry and wider stakeholder community, in compliance with legislative requirements and the relevant standards for privacy, data protection and security.*

- Ensure compliance with legal obligations for data protection, privacy, confidentiality and implement the data access policy including data classification, and standards for security and privacy

- Publication mechanisms for data supporting interactive user requests and system interfaces (on-demand or automatic notification).

**Goal 3:** Implement a new portfolio of services which will be supported by standardised data governance and lifecycle management.

- Implementation of full-lifecycle governance processes with the definition and assignment of roles and responsibilities, data quality controls and monitoring to facilitate continuous improvement
- Definition of how business applications will interact with the MDM solution and will support MDM.
- Development of services to support master data registration and maintenance, access to master data and 'customer service' approach to support all stakeholders consuming these services.

***Goal 4:*** *Maximise the benefits realised throughout the implementation of the roadmap by involving and engaging effectively with stakeholders, leading to operating model simplification and efficiency improvements.*

- Identify system, process and application dependencies and opportunities for alignment and integration
- Articulate the relationship between stages of the roadmap and foreseen stakeholder benefits
- Clear, consistent and timely communications to support stakeholder engagement and their planning.

## *3.5. Out of scope*

The roadmap is limited to addressing the processes, data and systems required for the maintenance of SPOR master data. This, for example, does not necessarily include transactional data or adapting all systems to use the new services. The exclusions listed below are not intended to be exhaustive but to provide an indication of the scope boundary:

- The implementation of the solutions related to the management of 'unstructured data'. A separate roadmap covering the implementation of solutions to manage unstructured data will be developed in the future.
- Development of the Business Intelligence and Data Analytical capabilities on the SPOR master data. The plan to deliver these services will be defined in a separate roadmap to be in the future.
- The management of Clinical Trials data which is not SPOR master data.
- The management of EMA regulatory procedural data which is not SPOR master data.
- The management of the Pharmacovigilance Art. 57 and Individual Case Safety Report (ICSR) data which is not SPOR master data.
- Implementation and support for processes which do not serve SPOR MDM.

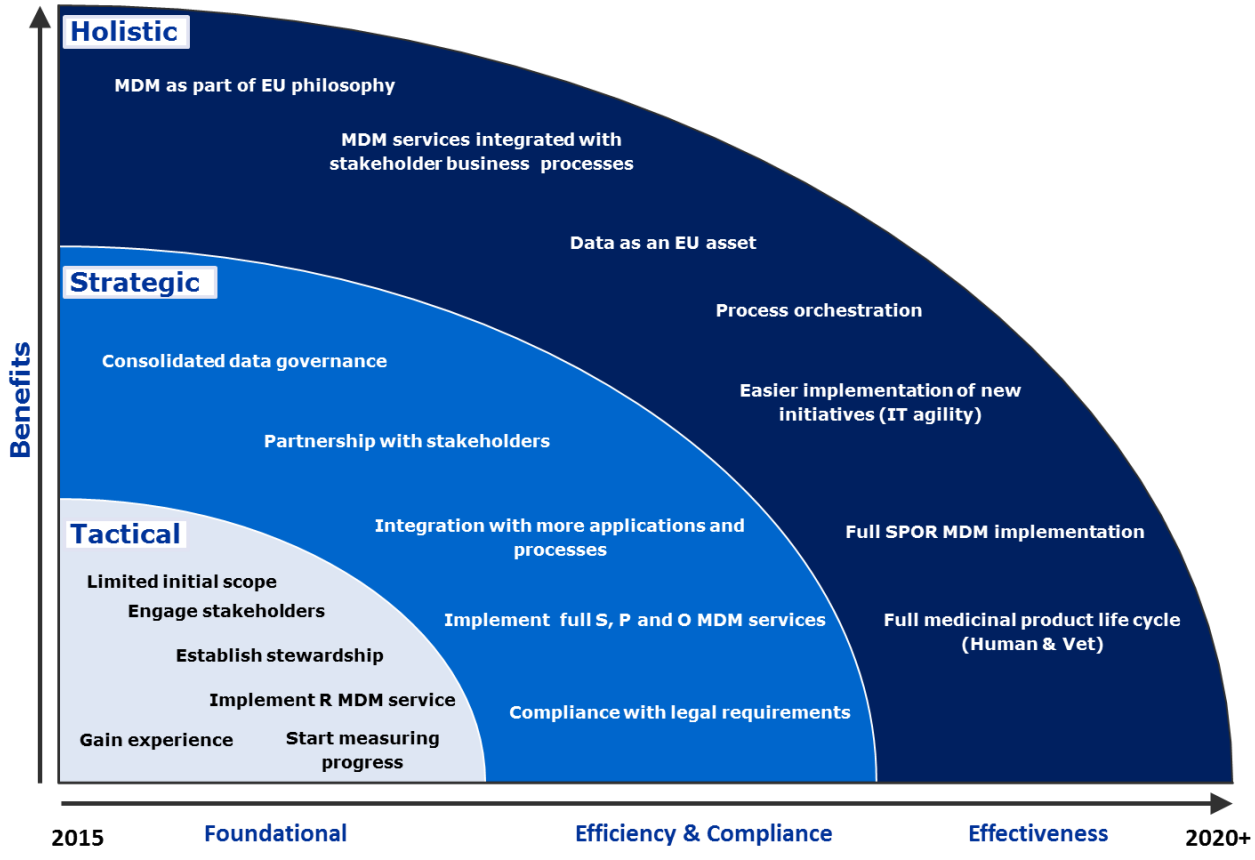
- Implementation of the ISO IDMP data model outside EMA.
- Implementation of IT solutions and processes outside EMA.

# 4. Business benefits and risks

The integration of SPOR data stored across multiple systems into a single MDM solution will enable the provision of high-quality, consistent and reliable data for stakeholders. Improved decision-making on business and IT programmes and projects to define and implement the SPOR master data solution can be supported by a clear understanding of the benefits, connected to business drivers.

*Table 1* describes the proposed MDM services to be provided, and *Table 2* proposes key factors for stakeholder readiness to consume MDM services. *Table 3* outlines the key business drivers underlying this roadmap, and makes an explicit link to the expected benefits for all stakeholders. A summary diagram (*Figure 1*) shows the expected benefits by stages of SPOR MDM implementation. The initial, foundational stage enables the efficient and compliant delivery of services and effective engagement with stakeholders. The later stages deliver on the vision of the roadmap, providing increased value to stakeholders. Enhanced SPOR MDM services will support all core business processes relating to medicinal product lifecycle support across human and veterinary areas. The implementation of the roadmap recommendations will facilitate greater integration between the EMA, EU network partners and industry.

**Figure 1.** Expected benefits by stage of SPOR MDM roadmap implementation



## *4.1. MDM services to business areas and stakeholders*

The motivation for developing this roadmap is to address areas that in some cases relate to current data management challenges and regulatory compliance and in others, capitalising on the opportunity to improve the operations of EMA whilst also delivering new services to our stakeholders. Greater consistency in the way medicinal product data is managed across the European and global stakeholder communities has the potential to improve efficiency and reduce costs for all parties. The implementation of this roadmap will enable EMA to continue improving the efficiency and effectiveness of data management, which will be necessary to be in the position to further support the EU network and global partners by the provision of a set of MDM services.

**Table 1.** Proposed MDM services related to SPOR

| Services | Description |
|---|---|
| **Registration and maintenance of master data** | Establishment of the processes and technology capability for EMA and relevant stakeholders to participate in the registration and maintenance of the master data i.e. validating mastering new data or changes to the existing master data.<br><br>The service provided will need to be based on the agreed operating model within the EU as well as the EMA. |
| **Access and exchange of data** | Stakeholders will require the right services to access master data to support a number of business processes. Access to data may be provided systematically via system interfaces, or via web user interfaces. The interfaces developed will need to be ISO IDMP compliant to enable data exchange and integration across systems. |
| **Customer services** | Stakeholders consuming these EMA MDM services will require support in the form of guidance documentation, training and direct helpdesk support when problems arise in using these services or to recommend changes for future improvements. |

### 4.1.1. Stakeholder readiness to consume MDM services

**Table 2.** Consuming MDM services

| Area | Description |
|---|---|
| **Technology** | Services may be delivered via a web-based Graphical User Interface (GUI) or through a system interface. Service users will require the right interfaces to make use of the new services. In the case of the GUI, no significant IT changes should be required.<br><br>Establishing system interfaces may require the adaptation or development of compatible and ISO IDMP compliant system interface. Partnering with the EMA at an early stage of roadmap implementation to gather requirements will ensure the sustainability of the MDM solution through future technology |

| Area | Description |
|---|---|
| | transformations and upgrades. |
| **People** | Organisations or individuals consuming the EMA services must establish the necessary process or/and technical know-how. It would be advisable to appoint a representative or a small user group to closely liaise with the EMA on training, communication (with regards to business and technical matters) and general support throughout the transition. Service users will need to be aware of new policies, service level agreements, and processes put in place as part of the service provisioning and consumption. |
| **Processes** | New processes will be established to deliver and consume the MDM services. Early engagement with EMA to be part of the change management process during the development of these services is recommended. EMA will have a point of contact for communication and interaction with future service users. |

## *4.2. Business drivers and expected benefits*

**Table 3.** Business drivers and expected benefits

| Business drivers | Description | Expected business benefits |
|---|---|---|
| *Compliance with legal requirements* | EMA and stakeholders must ensure that legislative requirements are met. Legal obligations have been considered in this roadmap, including ISO IDMP implementation relating to Pharmacovigilance and Clinical Trial legislation or data protection legislation to mention some. | • Supports the role assigned to EMA as a regulator of medicines.<br>• Ensures privacy, confidentiality and to prevent unauthorised inappropriate use of data.<br>• Data exchange based on structured and standardised data will enable data management process efficiencies, improvements in data quality and simplified implementation of the regulatory framework. |
| *Data Integrity* | Maintenance and assurance that the data is accurate, high quality and consistent over the entire information life-cycle. Data integrity is a critical facet to the design, implementation and usage of any processes e.g. pharmacovigilance and clinical trial activities, MA regulatory submissions and the respective technologies which store or retrieve data. | A single, well-controlled, and well-defined MDM solution promotes:<br>• Increased reporting and data analytical accuracy<br>• Improves quality of evaluation of MA applications and subsequent decisions<br>• Enables data consumers to make better decisions more |

| Business drivers | Description | Expected business benefits |
|---|---|---|
| | | quickly<br>• Reliability of data<br>• Re-usability of data<br>• Avoidance of duplication of data and services |
| *An integrated data management system* | Complexities in the current management of SPOR data require significant resources and restrict the ability to effectively support the medicinal product lifecycle activities. An integrated data management system would provide a single point of reference for medicinal Product information and also allow the direct identification of the stage at which the medicinal product is within the product lifecycle. | • Simplifies the data operating model for EMA and harnesses operational efficiencies.<br>• Will promote and enable cross-functional data management and processes, and thus, break down the organisational silos<br>• Provides a single authoritative view, one source of the truth of the SPOR data/information.<br>• Enables a consistent interaction between systems within EMA and outside.<br>• Supports the implementation of the *'one-stop-shop'* approach to medicinal product data management at EMA, especially during the pre-submission phase. |
| *Stakeholder value* | The value of the implementation of this roadmap will be maximised if the services implemented around the SPOR MDM are fit for purpose for EMA and external stakeholders. This will be realised by the continuation of the collaborative culture across the EU network and pharmaceutical industry.<br><br>Longer term cost savings are expected to be realised as close co-operation between stakeholders helps reduce inefficiencies by sharing resources. | The EMA will provide a range of services to the EU network and industry whom will benefit via:<br><br>• Standardisation of reference data of high quality, sharing and reuse of data<br>• Increased interoperability and integration of processes and systems<br>• Sharing of resources with European regulatory partners<br>• Efficiency savings can ultimately benefit the public through improvements in EU-wide medicinal product data quality and accessibility. |
| *Operational excellence* | Service users will be able to leverage a catalogue of services to support their | • Enable EMA and their stakeholders to share SPOR |

| Business drivers | Description | Expected business benefits |
|---|---|---|
| | scientific and regulatory activities such as accessibility of the SPOR master data service and registration services.<br><br>Standardised processes and integrated systems to manage and exchange data, including SPOR master data, can enable organisations to manage their data more cost effectively. EMA goals include the reduction of operating costs and increasing the effectiveness and quality of services. | master data in support of regulatory and scientific activities<br>• Improved support for simplified and coherent processes which involve pharmaceutical industry, EMA and other regulators to exchange medicinal product related data.<br>• Clear point of contact for stakeholders with regards the SPOR master data.<br>• Enhances EMA's capabilities to provide better services to the network and industry |
| *Enhanced human capital* | People with data management expertise, and especially in MDM, can provide the level of service that delivers value to the stakeholders.<br><br>The success of the implementation of this roadmap, and future improvements on servicing the stakeholders regarding SPOR MDM will be achieved if the people involved have adequate competency levels. | • Increases EMA's ability to deliver value in support of their scientific and regulatory activities.<br>• Ensures that EMA will be able to continue providing the services under their remit in the future.<br>• Increases productivity levels throughout the organisation.<br>• Helps EMA to build a service oriented culture within and outside the organisation. |

## *4.3. Risks*

**Table 4.** Risks which may affect the roadmap implementation

| Risk | Description |
|---|---|
| Lack of EU/global governance models for SPOR data management | The implementation of MDM will need to be fit to support the EMA business processes. Many of these processes are dependent on external processes which are yet to be defined, especially in the areas of substance, product and organisation data. Delays in defining the EU operating and data governance models can also delay the delivery of the projects.<br><br>The governance model will also need to define the authority body(ies) responsible to register and maintain referentials, substances, products and organisations in Europe and globally. |
| Delays in developing the EU Technical specification guides for ISO IDMP | The implementation of substance and medicinal product master data services will need to be compliant with data formats and data models described by these documents. Public consultation and subsequent |

| Risk | Description |
|---|---|
| | adoption of the specification guides may therefore result in delays to the projects. |
| Difficulties in gathering information to enrich substance and product data to make it ISO IDMP compliant | ISO IDMP data format for substance and product has more attributes than data formats currently used at EMA. During the data migration processes for substances and products, data enrichment will be required from the current data into an ISO IDMP compliant master data. It is yet to be defined where the missing data will be sourced and whether the data provider will be able to supply all the required data. The extent of missing and incomplete data is currently an unknown quantity. |
| Non-awareness of new MDM services and benefits by stakeholders | Stakeholders may not be aware of the planned implementation of MDM services, and the benefits they will provide. This could prevent or delay adoption of the services. A comprehensive stakeholder communication, change management and support plan is required to ensure awareness. |
| Lack of acceptance of MDM services by stakeholders | MDM services must provide business value to the service users. If the services are not consumed, the business benefits of the investment will be reduced or not realised.<br><br>The lack of adoption of the MDM services may be due to their non-suitability, or that stakeholders do not have the capacity to start consuming these services or a lack of understanding of the benefits of using these services to mention some. |
| Implementation difficulties due to dependencies on other projects | The implementation of this roadmap will require other EMA projects such as the Identity and Access Management (IAM) and the eSubmission, as examples, will be required to deliver their services/functionality. Without it, the business value of the MDM services may be decreased considerably. |
| Inadequate resourcing to oversee and execute all SPOR projects in parallel | There may be a need for additional qualified and experienced resources to augment the existing team to manage a programme of this scale involving multiple parallel projects alongside change management and stakeholder engagement activities. The required projects to implement MDM services may often need to utilise the same resources within EMA. Resource allocation will be challenging with multiple and concurrent SPOR projects dependant on the same human resources. |
| Low level of data integration | The implementation of MDM should support an enterprise approach to data governance at EMA and integration of data, processes and systems will enable the realisation of this benefit.<br><br>Transitional stages will be necessary throughout the implementation of SPOR MDM. There is a risk of extending this transition state which may introduce low level of integration and higher maintenance costs for longer periods of time than anticipated. |

# 5. Roadmap Recommendation

The results of the analyses led to the conclusion that in order to best provide services around medicinal product master data to all stakeholder groups, a staged approach beginning with the implementation of a strong foundational MDM service must be established. In the context of this roadmap, the provision of Referential master data sets the foundation for the subsequent master data services for substance, product and organisations.

The logical order of implementation of services around SPOR master data is based on the inherent dependencies between the use of Products, Substances, Referential and Organisation data by core business processes. At a fundamental level, referential data is needed to allow the consistent definition of values for the implementation of master data for substances, products and organisations.

Although the referential MDM may be the project which will deliver the initial services around master data at EMA, projects implementing master data for organisations, substance and products will start enhancing these services soon after.

The implementation of SPOR master data integrating many of the core EMA systems and processes with the MDM is envisaged to take a number of years. Multiple projects will be necessary, not only to implement, substance, product, organisation and referential together but also for each of these four domain areas. The activities defined in this roadmap can be undertaken with the initial projects which are expected to take a phased and incremental approach, where smaller iterations will begin to deliver a suite of services on limited master data and functionality and always supported by adequate change management. As additional iterations or phases are completed, stakeholders should expect new or enhanced services.

The advantages for the EMA and stakeholders of this approach are as follows:

- The establishment of a referential MDM first enables the delivery of master data services earlier, increasing trust in the capability of EMA to provide future services.
- Starting with referential data services enables the EMA to build on the capability via less complex, lower-risk projects before undertaking more complex projects for the implementation of Substance, Product and Organisation MDM solutions.
- It enables EMA to prepare for the implementation of the Pharmacovigilance and Clinical Trial legislation to receive and exchange SPOR data in an ISO IDMP compliant format.
- Provides a platform for master data service delivery based on a reduced risk approach and stakeholder impact with small but incremental changes.
- Allows gradual knowledge build up for the delivery of new services around SPOR MDM between EMA and stakeholders.

# 6. High level MDM implementation roadmap

The projects for the implementation of SPOR master data are envisaged to start during the first half of 2015. The approach for implementation of master data services will be iterative. *Figure 2* depicts the high level activities which will take place as part of multiple projects. The milestones for new MDM services indicate the planned delivery time for SPOR. The enhancements of these services will continue

on an incremental approach to be defined at the start of the respective projects. Organisation MDM implementation highlights the iterative approach, showing a sequence of analysis followed by design, build and test cycles. Delivery of Organisation MDM services is divided into iterations as shown in *Figure 2*. Each iteration includes detailed analysis and design for the efficient delivery of the next iteration, in parallel with the implementation work. A dictionary of organisations will be made available as part of iteration 1, which will be extended to include additional organisations to support more business activities as part of the subsequent iterations. This iterative approach will be followed for all SPOR projects, incrementally delivering MDM services to stakeholder groups using a lower-risk, transitional method.

Referential MDM services will provide data from EUTCT initially, and subsequent iterations will adapt the Controlled Vocabularies to meet ISO IDMP specifications.

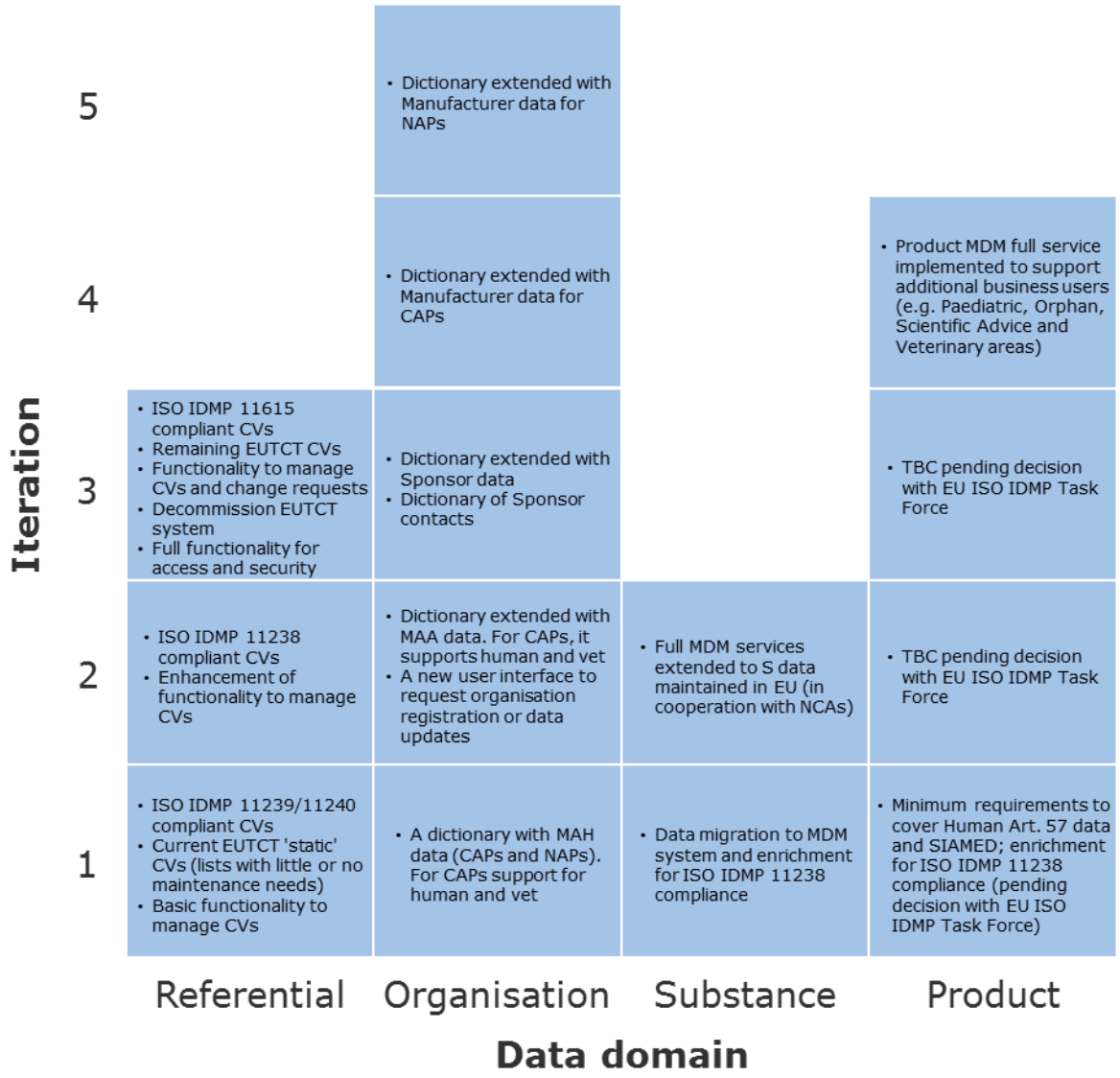
Substance MDM services will be provided based on data sourced from EudraVigilance - Human Art. 57 data in xEVMPD format. As the xEVMPD data format stores only a subset of data attributes required by the ISO IDMP standard, the xEVMPD data migrated to the MDM systems will require data enrichment. Data structures for storage and exchange of substance data in the MDM system will be based on the ISO IDMP 11238 EU technical specifications, and the extent of data enrichment will be determined during the project analysis and design phase.

The initial iterations of Product MDM services will be provided based on data sourced from EudraVigilance (Human Art. 57 data in xEVMPD format) and Siamed (Centralised medicinal product data for MA procedures). The data migrated to the MDM system will be enriched to meet new ISO IDMP 11615 EU technical specifications. The scope of the iterations for the implementation of Product MDM services is to be further defined during the project inception phase.

A number of key dependencies on other projects or external initiatives will need to be monitored closely to ensure that the delivery of the SPOR master services takes place in agreed timelines and in alignment with the EU Roadmap. The EU Roadmap is expected to define the EU operating models for the registration and maintenance of SPOR master data and the overall data governance needs.

The implementation of this roadmap requires a multiyear plan. *Figure 2* outlines the initial project for all SPOR data domains, giving an indicative view of the scope of each iteration. These high level activities for the initial projects will need to be followed by new projects in the future to further implement the full scope of the SPOR MDM roadmap including the extension of services to Orphan, Paediatrics and Scientific Advice activities in support of the full product lifecycle and also veterinary activities.

**Figure 2.** Indicative scope of SPOR project iterations

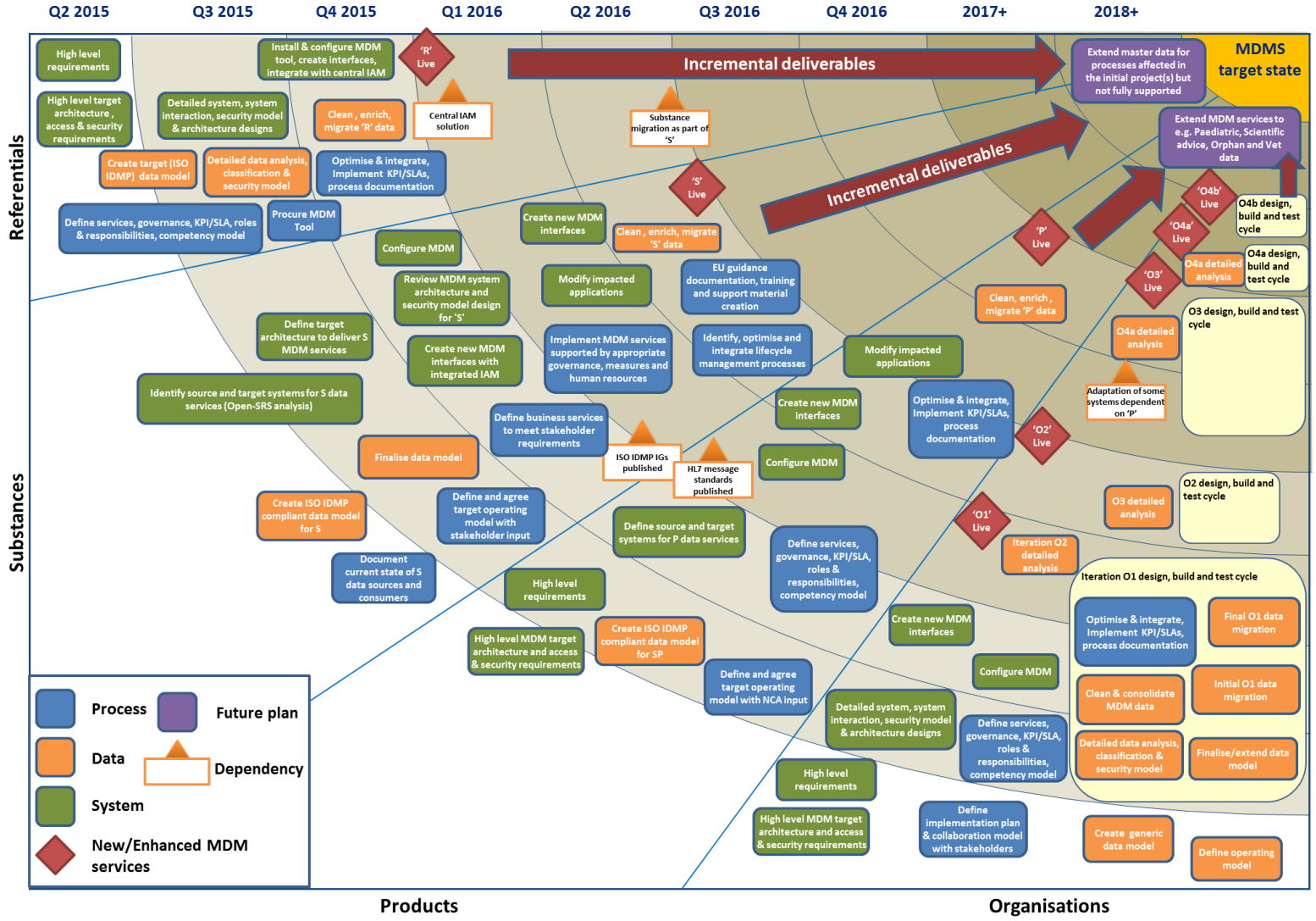



A change management process will underpin the high level activities described in *Figure 3*, which will be implemented through a number of different projects. The change management activities such as communication, training and customer support should seek to engage all stakeholders throughout the life of the projects and beyond.

It should be noted that adopting an MDM strategy for the implementation of SPOR master data would require process change and impact the day-to-day workings of many people within and outside the EMA. Bringing this change to the EU network requires careful planning and well-thought-out processes to manage the change mind-set and effort. Solid governance, visible leadership involvement and commitment, in addition to regular communication, training, and detailed progress monitoring are critical to ensure the necessary momentum is maintained. Continued buy-in is only possible by documenting, promoting and evangelising successes, ensuring MDM projects remain on track (from benefits value, budget, resources, scope and timeline perspectives), and MDM stakeholders remain accountable.

The roadmap will be updated in the future at regular intervals in order to reflect environmental and regulatory changes, and adapted according to the pace of implementation progress.

**Figure 3.** SPOR master data management service implementation roadmap



# 7. Document history

| Version | Date | Action | Authors |
|---|---|---|---|
| V0.1 draft | 19/11/2014 | Document created to present a proposal for the high level SPOR projects sequence approach to EUNDB and internally at EMA. | Kepa Amutxastegi, Pedro Pina Ferreira, Richard Fautley, Marek Lehman, Ray Power, Adam Stiling |
| V0.2 draft | 18/03/2015 | Draft roadmap consolidated for presentation and endorsement internally at EMA. | Kepa Amutxastegi, Richard Fautley, Marek Lehman, Ray Power, Adam Stiling |
| V1.0 draft | 17/04/2015 | Draft roadmap finalised for publication on the external EMA website. | Kepa Amutxastegi, Richard Fautley, Marek Lehman, Ray Power, Adam Stiling |

# Glossary

## *Key Terms*

| Term | Description |
|---|---|
| Article 57 / Art. 57 | The submission of data on medicines by marketing-authorisation holders is a legal requirement from the 2010 pharmacovigilance legislation. Article 57(2) of Regulation (EU) No 1235/2010 requires:<br>1) EMA to publish the format for the electronic submission of information on medicinal Products for human use by 2 July 2011; 2) marketing-authorisation holders to submit information to EMA electronically on all medicinal Products for human use authorised in the European Union (EU) by 2 July 2012, using this format; 3) marketing-authorisation holders to inform EMA of any new or varied marketing authorisations granted in the EU as of 2 July 2012, using this format. |
| eSubmission | The EMA system that manages receipt/processing of electronic applications for marketing authorisation. |
| ICSR | Individual Case Safety Report. A report documenting an adverse event for an individual patient. |
| IDMP | Identification of Medicinal Products. A set of standards agreed within ISO comprising:<br>ISO prEN 11615, Data elements and structures for unique identification and exchange of regulated medicinal Product information<br>ISO prEN 11616, Data elements and structures for unique identification and exchange of regulated pharmaceutical Product information<br>ISO prEN 11238, Data elements and structures for unique identification and exchange of regulated information on Substances<br>ISO prEN 11239 Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging<br>ISO prEN 11240 Data elements and structures for unique identification and exchange of units of measurement |
| ISO | The short name for "International Organization for Standardization". |
| Master Data | Business data entities used across multiple systems, applications, and/or processes.<br>Master data within the EMA is considered to include the primary attributes used to describe Substances, Products, Organisations and Referential data (SPOR) which are required to support multiple business processes. |
| Master Data Management (MDM) | The processes, governance, policies, standards and tools that consistently define and manage the master data providing a single, trusted point of reference. |
| 'One-stop-shop' approach | In the context of this roadmap: an holistic approach to MDM service provision which provides a single, |

| Term | Description |
|---|---|
| | comprehensive source of data via one service. |
| Referentials/Reference Data | Lists of data used to ensure consistency in describing master data. Examples being country codes, routes of drug administration as well as more structured lists such as MedDRA. |
| SPOR | Substance, Product, Organisation, and Referential data considered to be "master data".<br>Substance: the ingredients of a medicine<br>Product: the medicinal product itself<br>Organisation: organisational data, e.g. Pharmaceutical companies, their addresses, their plants, distribution centres, the regulatory agencies, and persons related to these organisations.<br>Referential: Reference lists such as dosage, forms, country codes, package codes, weight codes, etc. |