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EU Telematics Strategy and Implementation Roadmap 2015 – 2017

Endorsed by Heads of Medicines Agencies in July 2015 and EMA Management Board in August 2015

Table of contents

1. Executive summary

Since the introduction of harmonised European legislation governing many aspects of the regulation of medicinal products, the European Medicines Agency (EMA) and National Competent Authorities (NCAs) have engaged in a variety of technology initiatives. In order to build on past successes and mitigate risks, the European Medicines Regulatory Network (the Network[1]) has developed and is progressing with a shared vision and strategy for the future of IT services at a pan-European level. The EU Telematics strategy provides a goal for a variety of IT solutions to be delivered, with a particular focus on areas of common interest to the EMA, the European Commission and NCAs. It is created in recognition that IT systems underpin the work of the Network with wide-reaching impacts on stakeholders, patients, healthcare professionals, the pharmaceutical industry and international partners. The strategy ensures alignment of EU Telematics with legislation, international standards, and other EU initiatives such ISA programme (Interoperability solutions for European Public Administration).

One of the notable challenges is the common alignment of IT deliverables to support both the EMA and NCA strategies, particularly in the area of prioritisation of resources. Another notable challenge, a paramount prerequisite for the development, alignment, quality and effectiveness of IT deliverables is achieving information standardisation. In many cases NCAs have a variety of obligations outside the pharmaceutical regulatory domain, for example, medical devices, pricing and reimbursement, patient engagement and support services to national human and animal health care professionals, government and industry. In accordance to these obligations, resource allocation to undertake IT activities at a national level is driven by public health priorities, mandated legislative deliverables and economic realities. As a networking agency, the EMA has a different remit in the context of EU Telematics. This remit is focussed on building and providing access to IT systems that enable legislative mandates to be fulfilled and promote effective cooperation between the different parts of the Network. This remit therefore includes systems which the legislation specifically requires the EMA to build and manage as well as those which are included within the remit of EU Telematics as agreed by members of the Network based on their importance to the efficient running of the Network's operations as a whole.

To be successful, the EU Telematics strategy must acknowledge the mandates and respective roles of the EMA and NCAs, and accordingly seek to deliver solutions in areas of common interest and priority. The purpose of the EU Telematics strategy is to build on the substantial competence that already exists within the Network to ensure that future developments are legally, socially, economically and technically feasible in the context of the Network's broad remit. IT solutions should be interoperable, cost-effective, promote efficiency and, when feasible and appropriate, integrated.

[1] In the context of this document 'the Network' comprises the EU national competent authorities with responsibility for regulation of human and/or veterinary medicinal products as represented by the Heads of Medicines Agencies, the European Medicines Agency and relevant services of the European Commission. The Network has responsibility for overseeing the safe and effective use of human and veterinary medicinal products at national and EU level.

2. Purpose of document

The purpose of this document is to outline the EU Telematics strategy and its implementation from 2015 to 2017. The document describes the vision and strategy, which will be delivered through a related set of programmes and projects, which, combined, will address the IT needs arising from European pharmaceutical policy and legislation.

Significant progress has been made since the EU Telematics Strategy 2014- 2016[2] was endorsed by the EMA Management Board and Heads of the Medicines Agencies in mid-2014 and it is planned that the present document will be updated periodically to reflect programme advancements and the changing regulatory environment. This strategy document is intentionally high-level and provides an overall framework. It is not the purpose of this document to determine the detailed project charters or technical solutions, but to state the Network's roadmap for information technology. Where appropriate and required, subsidiary strategies to this overarching EU Telematics strategy have been developed and now incorporated into the Telematics strategy, providing more detail on the approach to be adopted in the following areas:

- HMA eSubmission Roadmap[3]: offers a timeline for EMA, NCAs and industry activities that aim to establish secure, consistent and efficient electronic submission processes for medicinal products for human and veterinary use across the Network;
- Veterinary IT and Data Strategy, Roadmap and Management Overview[4]: identifies and develops, from a veterinary medicines perspective, common standards and service components that promote further integration and involves developing a set of programmes and projects with defined budgets and timelines for delivery;
- European Medicines Agency (EMA) Master Data Management Roadmap[5]: communicates the approach taken by EMA to enhance the quality, consistency and availability of medicinal product data used by the EMA, the EU Regulatory Network, industry and the wider stakeholder community. This is central to achieving excellence in the evaluation and supervision of medicines. This will enable the Network to more effectively exchange data and simplify processes, thereby improving operational efficiency.

3. Telematics Vision and Strategy

3.1. Vision for EU Telematics

> *"A European IT collaboration that will deliver a broad range of cost-effective, efficient and interoperable services to the European Medicines Regulatory Network and its stakeholders, ultimately improving the quality and effectiveness of their business activities."* ***- The vision for EU Telematics***

[2,4,5]http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000116.jsp&mid=WC0b01ac0580028c2b

[3]http://esubmission.ema.europa.eu/tiges/docs/eSubmission%20Roadmap%20v%201%200_Nov%202014_final_adopted.doc

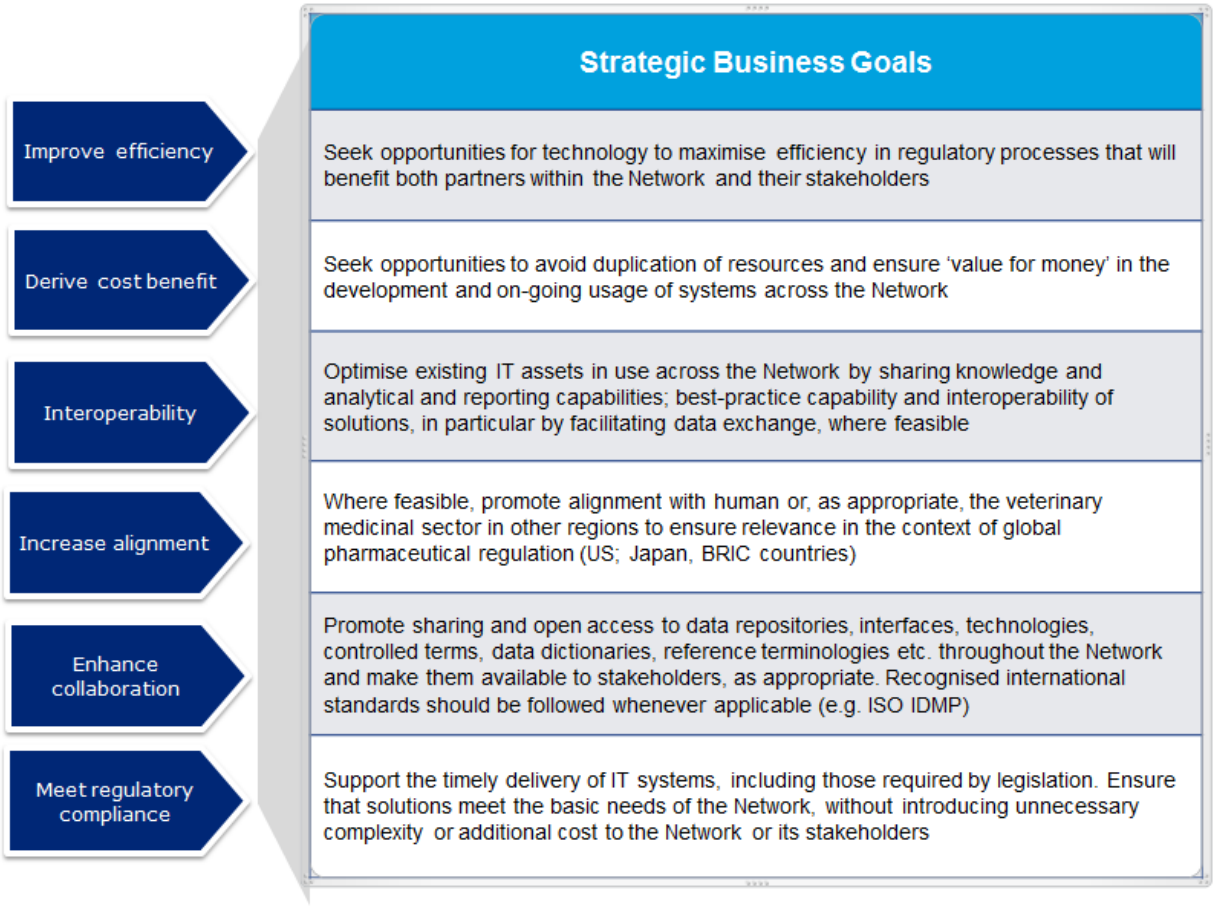
This vision will be realised by developing a range of services that meet strategic business goals. A governance structure has been devised and put in place to ensure the timely delivery of the objectives necessary to achieve these business goals. The continued relevance of this vision and strategy at European and international level will be monitored by a rolling environmental analysis.

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

3.2. Strategic business goals

The most effective way to support the Telematics programme's business objectives within the Network is through open and structured collaboration, communication and cooperation between the EMA, the European Commission and NCAs. It is vital for the Network to share information on existing or planned developments and experience, to share costs and services where appropriate, to explore the operational and overall organisational impact of various IT solutions, and to consider the broader use of technological solutions in the planning phase. There is potential to develop and publish best practices for application development e.g. common standards, also aligned approaches in database design, interfaces and security aspects. There is also potential to develop shared systems and data repositories to be shared by the EMA, the European Commission and those NCAs that wish to use them, thereby avoiding redundant investments.

The high-level business goals for the EU Telematics strategy are outlined in the diagram below.



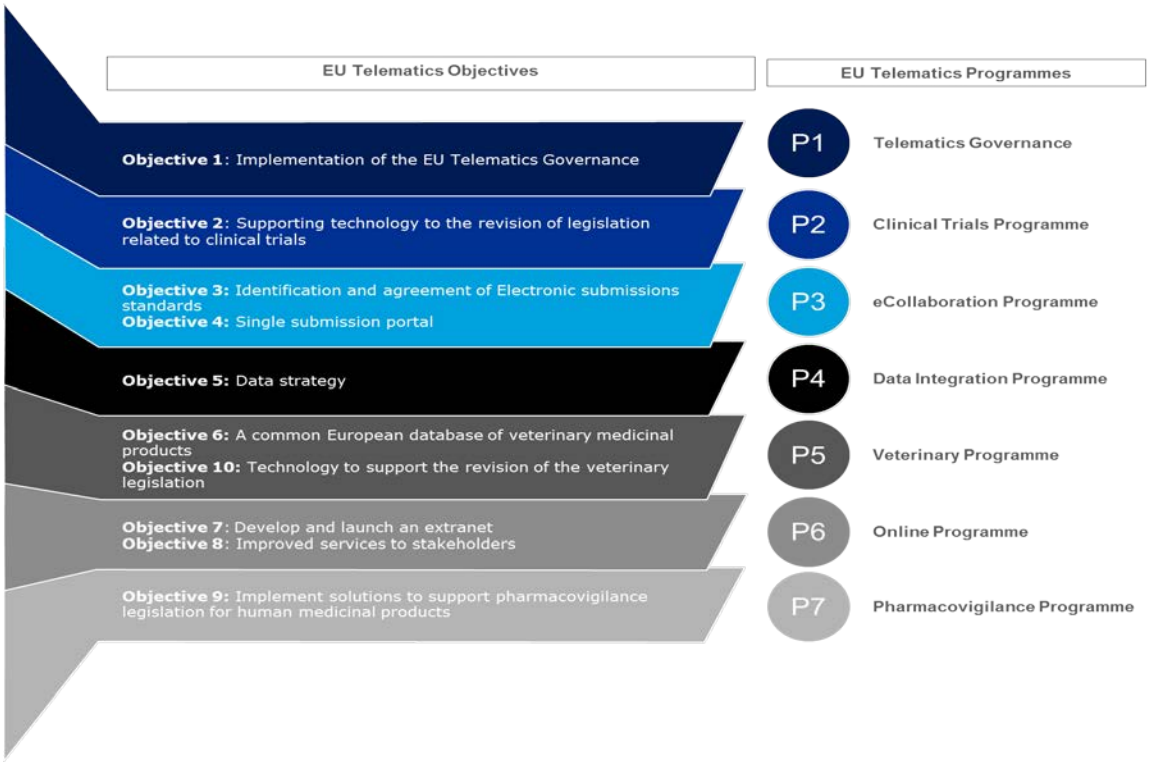
All development and implementation should be based on solid business cases with comprehensive 'end-to-end' regulatory impact analyses for those developments impacting on the Network. This can

lead to IT solutions delivering benefits to the EMA, European Commission, NCAs and pharmaceutical industry, and can also provide opportunities for collaboration between a subset of EU Member States where this is a necessity to support particular business requirements. It will also make best-use of available competencies within the Network. The IT strategy also acknowledges existing differences in national legislation, internal processes, IT infrastructure, security policies and archiving. Due to this the IT strategy has to be flexible promoting the development of interfaces that guarantee the interoperability between national and EU systems, providing at the same time, built-in systems that give response to NCAs without national solutions in place. It yet endeavours to harmonise the differences wherever possible as well as encourage federated usage. One of the most important priorities for the Network is to develop a common data model for medicinal products, thereby improving information sharing and consistency. Particular attention will be focussed on the need, where possible and appropriate, to provide tracking, analysis and reporting tools available to both members of the Network as well as to their stakeholders to maximise the transparency and availability of the information held. Nevertheless, when needed, Telematics solutions will need to take due account of the different business and IT environments in which NCAs operate, e.g. by providing access via a Graphic User Interfaces (GUI) and via Application Programming Interfaces (API) for machine-to-machine data exchange.

4. Programmes and projects 2015 – 2017

4.1. Addressing Telematics strategic objectives

The EU Telematics Strategy 2014-2016 highlighted ten key objectives. These objectives had been selected on the basis of their high strategic priority. In 2014, these objectives were progressed and are now being executed as a series of programmes and projects. As accomplishments have been made, the ten objectives defined have been consolidated into seven key programmes to manage project interdependence and to clarify benefits and impacts for end users.

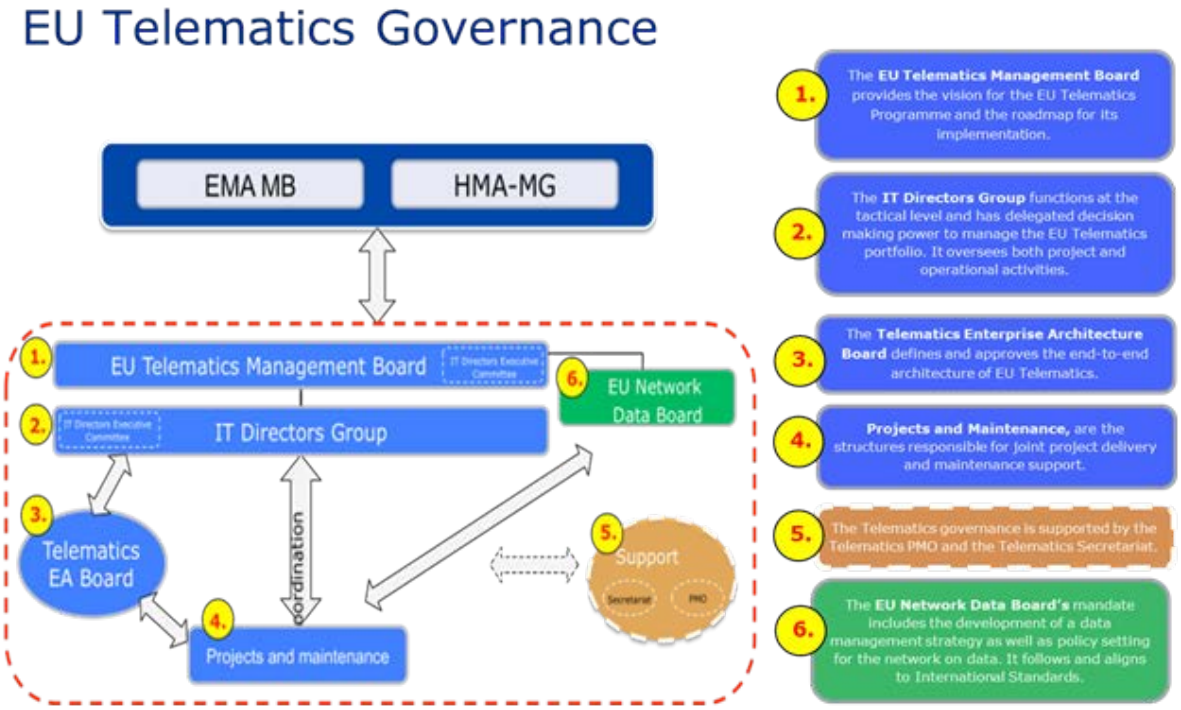


4.2. Description and scope of programmes

4.2.1. Programme 1: Telematics Governance

Goal: Successful implementation of the EU Telematics governance structure.

The new governance structure is designed to service the IT ambition of the Network and contains sufficient flexibility to adapt a common framework to the needs of the particular domain or project where it is applied. It is important that this flexibility is utilised to accommodate the differing drivers and needs of the various stakeholders, including regulators and industry, in both the human and veterinary domains. The new governance structure became fully functional in 2014. The EU Telematics Management Board will keep the new structure under review, and will authorise any changes that may be required.



EU Telematics governance has the ambition to:

- Foster collaboration across the Network by setting up and maintaining a coalition that is willing to develop, implement and maintain the common information technology services that are effective, value-adding and clearly help to optimise support to the Network in the regulation of medicinal products for the protection of human and animal health;
- Maximise efficiency in communication around the development and operation of IT for the Network;
- Over time become a common platform for the Network IT activities;
- Define approach to benefits realisation to support NCAs in evaluating that potential benefits arising from Telematics programmes are actually realised and justify investments in financial and human resources.

EU Telematics governance intends to promote collaboration in IT development and operations and to support well-informed decision making at the right levels.

Recognising the significant impact of EU Telematics on the pharmaceutical industry, the EU Telematics Management Board will invite industry stakeholders' participation at a strategic level and at an operational level via working groups for projects or maintenance activities as appropriate.

4.2.2. Programme 2: Clinical Trials

Goal: To develop solutions to support the implementation of the new Clinical Trials Regulation involving Member States, European Commission, EMA, Ethics Committees and NCAs (Human), and sponsors (industry and academia).

The EU Clinical Trial Regulation was adopted by Parliament and Council in April 2014 and will become applicable no earlier than 28 May 2016 (2 years after its publication). According to the Regulation, the Agency has the responsibility, in collaboration with Member States and the Commission, to set up and maintain the EU Portal and EU Database. The EU Portal and EU Database will be subject to an audit, after which the EMA Management Board will decide whether or not the EU Clinical Trial Portal and Database meet the functional specifications prepared by the EMA in consultation with the Network. Once the EMA Management Board concludes that the EU Portal and EU Database have achieved full functionality and the systems meet the agreed functional specifications, it will inform the Commission, which will then publish a notice to that effect. The Regulation becomes applicable 6 months after the publication of this notice. The EU Portal will be used as a single entry point for the submission, authorisation and supervision of trials in the EU. Data and information submitted through the EU Portal will be stored in the EU Database which will serve as the source of public information on the clinical trial applications assessed, and all clinical trials conducted in the EU.

In addition to the EU Portal and EU Database, the Clinical Trials Programme will develop other systems which are needed for the full implementation of the provisions of the Clinical Trial Regulation.

The collection of projects that constitute the Clinical Trials programme include:

1. **EU Portal and Database**: this project will develop a Portal at Union level which will be used as a single entry point for the submission of data and information relating to clinical trials in accordance with the Regulation, throughout the life cycle of a trial including planning and outcome of inspections. Data and information submitted through the EU portal will be stored in an EU Database. The database will be publicly accessible, unless, for all or part of the data and information, confidentiality is justified on any of the grounds established by the Regulation. In addition, the project will implement workspace collaboration tools, workflow and document management capabilities to be used by Member States.

Domain: Human

Legal reference:

- Regulation (EU) No. 536/2014 – Art. 80 EU Portal, Art. 81 EU Database, Art. 82 Functionality of the EU Portal and the EU Database
- Regulation (EC) No. 726/2004 – Art. 57 (EU Medicinal Product Dictionary)

2. **Safety Reporting**: this project will deliver the upgraded EudraVigilance clinical trial module, for the electronic reporting of suspected unexpected serious adverse reactions (SUSARs) and an electronic reporting system for annual safety reports (ASRs) to a central repository at the Agency including storage of related assessment reports and actions. Additionally, tools such as the data warehouse and other reporting tools will be developed to support the analysis of safety and/or clinical trial information from the EU-CT and EV database. It will also deliver the functionality for forwarding SUSARs and ASRs to the member States concerned.

Domain: Human

Legal reference:

- Regulation (EC) No. 726/2004 – Art. 24, Art. 40
- Regulation (EU) No. 536/2014 – Art. 40, Art. 42, Art. 43, Art. 44

3. **Legacy EudraCT and EU-CTR**: EudraCT will co-exist with the EU Portal and Database during a transition period established by the Clinical Trial Regulation. Public and non-public legacy data will have to be handled after new data is no longer accepted in EudraCT. Plans and processes for the transition between the current EudraCT and EUCTR systems and the new EU Portal and EU Database will be developed as part of this project.

Domain: Human

Legal reference:

- Regulation (EU) No. 536/2014 – Art. 98
- Directive 2001/20/EC
- Regulation (EU) No. 726/2004, Art. 57 1L
- Regulation (EU) No. 1901/2006, Art. 41, 45 & 46

The objectives of the projects within the Clinical Trial Programme are to develop the systems required for the implementation of the Clinical Trial Regulation which aims to simplify and harmonise the authorisation and supervision of clinical trials in the EU and increase transparency on the authorisation and conduct of each trial and on each trial result.

Integration with essential master databases such as Product and Substance dictionaries will be included and interfaces to Member State systems will be provided.

4.2.3. Programme 3: eCollaboration

Goal: To develop and enhance existing capabilities for the management and processing of electronically submitted applications for the marketing authorisation of human and veterinary medicinal products as well as other procedure types.

A HMA eSubmission Roadmap has been developed and endorsed by the EU Telematics Management Board in 2014. The eSubmission roadmap explains how interoperability across and between the stakeholders and the Network is enhanced by the adoption and implementation of appropriate standards. The roadmap includes a number of initiatives such as dossier formats, portal solutions, and application forms.

The programme is based on multiple projects which, when fully realised in the longer term, will harness operational effectiveness and efficiencies for the EMA, NCAs and the pharmaceutical industry.

The individual projects that currently constitute the eCollaboration programme are centred around eSubmissions and the Single Submission Portal and include:

1. **The Common Repository:** a single, common storage place for human Centralised Procedure (CP) eCTD submissions. Under this system, all CP submissions are sent to the EMA only and all NCAs retrieve the submissions via the Common Repository and make them available in their own review systems. The NCAs can access the repository via a User Interface (UI) or an Application Programming Interface (API) for automated downloads. Therefore, all regulators will have the same, validated submissions at the same time. Submissions for Centrally Authorised Products (CAPs) to the Common Repository must be made in the Electronic Common Technical Document (eCTD) format using the eSubmission Gateway or the Web Client. The current Common Repository is envisaged to be further enhanced and developed so that it will enable all EMA-run procedures to be submitted in all formats (including the veterinary format VNeeS) and be stored in the repository.

   Domain: Human and Veterinary

2. **The PSUR Repository**: since January 2015 the PSUR Repository has been available for human medicinal products, offering a secure electronic submission point for Marketing Authorisation Holders (MAHs), streamlining the Periodic Safety Update Report (PSUR) submissions for the pharmaceutical industry on the human side. Based on the independent audit report confirming that the PSUR repository met the functional specifications as agreed in the 'PSUR Repository functionalities to be audited' document, it was concluded and endorsed in April 2015 by the PRAC confirming that the repository had achieved its full functionality as required in the 'auditable functionalities' document. The PRAC also recommended the EMA Management Board to announce in June 2015 that the use of the repository will be mandated from mid-2016. The PSUR repository acts as a common storage place for PSURs, PSUR Assessment Reports (ARs), comments and final outcomes including Commission Decisions, with a secure access for NCAs and the European Commission. NCAs can access the PSUR repository via a User Interface (UI) or via an API (Application Programming Interface) to be delivered by the end of 2015 for automated downloads. The PSUR Repository supports both the PSUR Single Assessment Procedure (PSUSA) and the single pure National Authorised Products (NAP) procedures where the active substance is authorised in one Member State only. All PSUR submissions are sent to EMA only and all NCAs can search, query and retrieve the submissions via the PSUR Repository to make them available in their own systems if required. All PSURs, supplementary information submissions, Assessment Reports, comments and final outcomes are available via the PSUR repository for CAPs, NAPs included in the EU Single Assessment procedures, products approved via MRP/DCP and also for single pure NAPs. The NCAs are able to upload assessment reports in the repository for single NAPs. All regulators have the same, validated submissions at the same time so there will be no need for manual reconciliation of submissions.

Domain: Human

Legal reference:

- Regulation (EC) No. 726/2004 – Art. 25a
- Regulation (EC) No. 1235 /2010

3. **eCTD v4.0:** for applications of medicinal products for human use, eCTD v4.0 will be the future submission format standard which will replace the current eCTD format in use for electronic

submissions within the Network. It is envisaged that the new format will improve the functionality and usability of eCTD submissions for Human submissions. The use of eCTD v4.0 does only apply to human medicinal products. Although concepts of the underlying HL7 submission standard may also be suitable for veterinary submissions, there are currently no plans to transit from the existing VNeeS format to eCTD v4.0 as the business case to support such transition has not yet been identified. The new standard will introduce a new, lighter folder structure and simpler folder naming conventions. It allows the reuse and sharing of documents across products and submissions, hence enabling submissions to be grouped as well. Two-way communication between MAHs and regulators can also be enabled. The EU is developing the standard together with other ICH regions.

Domain: Human

4. **Electronic Application Form (eAFs):** eAFs have been made available for Human and Veterinary procedures in addition to the Word and simple PDF versions published in the Notice to Applicants (NtA). The eAFs now leverage technology not previously available in the Word version. They enable use of PDF technology to capture and validate information and XML import/export technology to transfer the information enabling automation of data output/input to industry and national Member State systems and databases. From July 2015 onwards, the eAFs will be the only accepted format for Centralised Procedures and from January 2016, they will be the only accepted format for all other European procedures. Word application forms will no longer be accepted for any procedures and will therefore no longer be published by the EU Commission. Harmonising the format and common usage of the eAF across the network will, for example, reduce the need for specific national portals for submission. Inbuilt validation rules and use of controlled vocabularies (CVs) will improve data quality and reduce the number of issues found during business content validation. As outlined in the eSubmission roadmap, the longer term goal will be for the eAF to be further integrated with the Single Submission Portal and be linked to procedure management systems via the use of an alternative technology so that information that is already held by regulators does not need to be resubmitted.

Domain: Human and Veterinary

Legal reference:

- "The rules governing medicinal products in the European Union" - Notice to Applicants, mid-2015

5. **Single Submission Portal:** presents a single submission channel for all procedure types for all submissions across the network (human and veterinary submission). The vision for the Single Submission Portal is to integrate the electronic Application Forms (eAFs) and to link masterdata and datasets provided in previous submissions, thereby reducing the need for industry to resubmit information already held by the regulators. The vision for the regulators could include support for fully automated handling of the submissions via e.g. an electronic and structured cover letter. The future version is expected to become available in 2018. Plans are to incrementally include requirements for the single submission portal into the Common European Submission Portal (CESP).

Domain: Human and Veterinary

4.2.4. Programme 4: Data Integration

Goal: To deliver a comprehensive data strategy determining the appropriate standards, referentials and terminologies for data managed and stored across the Network. Through the implementation of this strategy, opportunities for interoperability and data sharing will be created and recommendations for 'best practice' on topics such as data security in both human and veterinary contexts will be provided.

Interoperability is crucial for the future development of Telematics within the Network. The Data Integration programme exists to identify the most appropriate data standards (ISO IDMP), data model and terminologies to support the exchange and analysis of information.

An unambiguous definition and description of medicinal products and substances will be developed. Where appropriate, elements shared between veterinary and human data as well as those unique to veterinary medicinal products (e.g. MRLs) will be identified. These efforts will take into account EU projects including eHealth, ePrescription, Horizon 2020, anti-falsification initiatives as well as initiatives within other regions such as the development of the Global Ingredients Archival System (GInAS). The programme will recommend "best practices" for security and privacy policies to protect data assets in accordance with the EU legislation adopted by the EU Member States, and in line with the opinions and guidance adopted by the Article 29 Working Party and the NCAs of the EU Member States. In order to ensure the right tools are in place to support the analysis and reporting of data, the following projects have been advanced:

1. **ISO IDMP**: The project aims to finalise the implementation guides to support the adoption of the ISO standards for the Identification of medicinal products (IDMP). ISO IDMP implementation is being coordinated by the International Organisation for Standardisation (ISO), resulting from a joint initiative between members of the International Conference on Harmonisation (ICH). The IDMP has been built on Health Level 7 (HL7) approaches with regard to data models and messaging specifications, as well as other ISO standards. The geographic reach of the IDMP extends far beyond that of the XEVMDP (eXtended EudraVigilance Medicinal Product Dictionary), which affects only companies with products in the EU. The IDMP is currently in development and will be adopted by ISO countries. EU Implementation guides for ISO IDMP are expected at the end of Q2 2016.

   The EU ISO IDMP Task Force was set up in 2015 to prepare for ISO IDMP implementation and consists of representatives from the EMA, NCAs, industry and software vendors. This group will define the number of iterations, their scope (i.e. the set of mandatory data elements/physical data models) and planning to support ISO IDMP implementation deadlines. This exercise will strive to find a balance between what is achievable with minimum effort versus what data elements support the biggest number of business cases and therefore represent the highest business value.

   The legislation requires compliance with IDMP for Pharmacovigilance purposes by July 2016 and the work of the ISO IDMP Task Force will focus on the gap analysis between the current XEVMPD and the minimum core of fields required to meet IDMP standards. The deadline and scope for implementation of ISO IDMP will be communicated in July 2015 and an implementation roadmap will be communicated thereafter.

   The implementation of the ISO IDMP standards will support master data management for the EU regulatory network. Master data management (see next section) involves the establishment of a single authoritative source for specific source of information (i.e. SPOR). The information will not be data solely but will be used to facilitate Pan-European activities and data sharing.

Although it is acknowledged that the potential use of the IDMP stretches across the life cycle of a product to include clinical trials, scientific assessment, paediatric use, inspections, etc., the ISO IDMP Task Force will consider the potential use of IDMP standards on these regulatory areas at a later stage. Likewise for veterinary products, the feasibility and opportunity to comply with ISO IDMP will need to be evaluated at a later stage (see Programme 5). The use of IDMP has potentially greater reach beyond regulatory processes. Projects are being initiated by the European Commission (e.g. eHealth, falsified medicines) and it is highly likely that IDMP will play a role in those endeavours.

Domain: Human

Legal reference:

- Regulation (EU) No. 520/2012 – Art. 25, 26 & 40

2. **Master Data Management (MDM) services:** will develop processes and technological capabilities for registering and maintaining access to and exchange of master data. A customer service will be established to support all stakeholders consuming these services. The core master data domains are defined as substances, products, organisations and referentials (collectively referred to as "SPOR"). The implementation of MDM will take a Network-wide approach to data management, integrating data, processes and systems. This will enable the Network to meet legal requirements within the context of Pharmacovigilance activities as well as broader strategic goals. Furthermore, MDM will support the implementation of ISO IDMP standards across the EU Network and industry.

   All SPOR projects will take an iterative and incremental service delivery approach.

   – Referential Management Service (RMS): acquisition, installation and configuration of a Master Data Management tool and setting up of a Referentials Management Service.

   – Organisation Management Service (OMS): the full implementation of an Organisation Management Service will require a number of different sub-projects. The initial project will implement Master Data Management services around registration and maintenance of organisation data and the provision of an organisation dictionary via system and web user interfaces. The organisation master data will be made available in this dictionary incrementally throughout the project. Examples of organisation data include: Marketing Authorisation Holders (MAHs), Marketing Authorisation Applicants (MAAs), Sponsors and Manufacturers. A new centralised organisation/person registration process is expected to be in place as part of the initial iterations.

   – Substance and Product Management Services (SMS/PMS): the projects are intended to put in place an IDMP compliant solution that will provide centralised substance and product data management services. The scope of these projects and iterations of delivery are dependent on input from the EU ISO IDMP Task Force.

The EMA will use GInAS/G-SRS software and will be the European maintenance organisation for Substance data in collaboration with a European Substance Advisory Board comprising experts from NCAs.

To maximize the benefits of the new SPOR MDM services, all the Telematics systems will have to be reviewed and adapted to the common EU data model using these services as they are deployed.

Domain: Human and Veterinary

4.2.5. Programme 5: Veterinary Programme

Goal: To develop an IT- and systems-based solution that is fit for purpose, cost-effective and that will a) further establish and evolve the key operational data-systems on product data and pharmacovigilance data and b) position the Regulatory Network to respond effectively to the revised veterinary legislation in the coming three to four years through a specific Veterinary Change Programme.

A veterinary IT and Data Strategy was published in May 2014 and provides detail on how the overall objectives within the wider EU Telematics Strategy will be adapted to the particular nature and requirements of the veterinary domain. High priority will be given to developing the next generation of tools to enable veterinary pharmacovigilance based around a common European database. Certain elements of these new tools, e.g. the database for veterinary medicinal products, data warehouse for pharmacovigilance reports and related signal detection tools, can be developed in advance of the new legislation, whereas other functionalities cannot be planned until the requirements of the new legislation are known. Re-use of existing systems and standards will be the first approach when reviewing the requirements for the new legislation.

The veterinary programme is subdivided into two project areas: EU Veterinary Medicinal Product Database and Veterinary Infrastructure.

1. **EU Veterinary Medicinal Product Database**: the EU Veterinary Medicinal Product Database (based today on the EudraPharm model) was released in February 2015 and will enable the development of an integrated, EU-wide veterinary Pharmacovigilance system. At release, the database contains the product data from a limited number of Member States. The first phase of the Veterinary product data management services project, which will establish the processes to support the transfer of product data by most NCAs, will be delivered by the end of 2015. At the same time, requirements gathering will be initiated within 2015 together with the Network towards the rebuilt and integration of the database into the network's overall SPOR model. This will include an assessment of the impact on existing data in the EU Veterinary Medicinal Product Database and a feasibility study and impact analysis of compliance with relevant parts of the ISO IDMP standard. Work will continue to engage and support regulatory authorities in planning and providing data for products authorised by the DCP, MRP and national procedures in the local language to the EU Veterinary Medicinal Product Database via EudraPharm in order to allow surveillance of Pharmacovigilance data on an EU scale using the data warehouse.

Domain: Veterinary

Legal reference:

- Regulation (EC) No. 726/2004 – Art. 57. 1. L
- Proposal for Revised legislation 2014/0257 (COD) – Art.51

2. **Veterinary Infrastructure**: Veterinary infrastructure encompasses all the projects that will be required to ensure that the regulatory Network can work efficiently from an IT integration point of view in support of the revised legislation that is expected to come into force sometime after 2019. The new legislation places great reliance on an increased use of IT to improve the efficiency of the operation of the Network with respect to veterinary medicines. Furthermore, the legislation governing veterinary medicines will diverge from that for human medicines where this is required to meet the particular requirements of the sector. There will therefore be a need carefully to examine the impact that this divergence will have on the business requirements in the veterinary

domain. For example, the initial EudraPharm database will be developed into a full service model to ensure that all business requirements foreseen in the future revised veterinary legislation can be met including signal detection for all products authorised in the EU. It will be important to strive to harmonise human and veterinary IT solution and data structures as far as possible where this reduces cost and increases efficiency. The legislation also foresees enhanced IT support in the areas of pre- and post- marketing authorisation procedures, manufacturing and wholesale dealing authorisations, and coordination of inspections.

Veterinary infrastructure can be viewed as a sub-programme due to its wide remit, and will require updating the current IT roadmap together with the Network. Several aspects relevant for veterinary products will be covered by other programmes mentioned above, e.g. VNeeS (under eCollaboration) or Master Data Management services (under Data Integration). The Veterinary Infrastructure sub-programme will be implemented in a step-wise fashion. The first step will be to conduct a detailed requirements analysis of the new legislation that will form the basis for a gap analysis against current and planned EU telematics services. The sub-programme will then be developed to fill these gaps either by adapting existing systems to veterinary needs or developing veterinary-specific solutions where necessary. The sub-programme will therefore be implemented by a combination of including veterinary requirements within common programmes where possible and launching veterinary-specific projects where necessary.

Domain: Veterinary

Legal reference:

- Proposal for revised legislation Regulation (EC) No. 726/2004 –A revised legislation is expected to be in place as soon as 2019
- Proposal for Revised legislation 2014/0257 (COD)

4.2.6. Programme 6: Online

Goals: To create a multi-lingual website giving access to information on authorised medicines, irrespective of the licensing route. Also, to develop an extranet at the EMA to support the partners within the Network and enable greater knowledge sharing, collaboration and cooperation within a secure online environment. The extranet is, however, considered as a lower priority initiative and is no longer included in the EU Telematics implementation roadmap.

1. **EU Medicines Web portal**: the EU Medicines Web Portal for human medicinal products will be a free, unbiased, scientifically-valid source of medicinal product information on the internet. The primary target audiences are patients, consumers, carers, and health care professionals. The portal will replace EudraPharm human and provide a EU-wide view of a medicinal product's lifecycle, including CAP and NAP product information, EU-level ADR data, searchable EU dictionaries of substances and products, and clinical trial summaries. The European medicines web portal supports other high-level EU initiatives, such as eHealth Action Plan, EU open-data agenda, and the Digital Agenda for Europe. New, online information delivery mechanisms will be deployed by the EMA to raise the service level, to provide appropriate levels of access to information held by the EMA in relation to the central authorisation procedure and to provide a greater degree of transparency on the progress of applications through the regulatory procedures.

Domain: Human

Legal reference:

- Regulation (EC) No. 726/2004, as amended by Regulation (EU) No 1235/2010, Art. 26 (1)
- Regulation (EC) No. 726/2400 – Art. 83

4.2.7. Programme 7: Pharmacovigilance

Goal: To deliver the IT systems needed to support the business activities of the revised EU Pharmacovigilance Legislation for human medicinal products and to change the relevant business functions to maximise the benefits from these new systems.

The new EU Pharmacovigilance Legislation has been operational since July 2012. The legislation foresees various information systems to enhance pharmacovigilance, particularly to support the collection, management and analysis of data, information and knowledge. These systems will contribute to public health through optimisation of the safe and effective use of medicines. They should also facilitate pharmacovigilance, delivering rationalisation and efficiency gains, involving the processes and systems of EMA, NCAs and MAHs.

The individual projects that constitute the Pharmacovigilance Programme include:

1. **Medical Literature Monitoring (MLM):** there is a legal requirement for EMA to monitor selected medical literature for reports of suspected adverse drug reactions containing certain active substances and to enter Individual Case Safety Reports (ICSRs) into the EU adverse reaction database (EudraVigilance, EV). To facilitate this function, the EMA will make enhancements to the EV system and provide associated services. This will improve safety monitoring of medicines through better quality of safety information and simultaneously reduce the administrative burden on MAHs for the relevant substances.

Domain: Human

Legal reference:

- Regulation (EC) No. 726/2004

Article 57 (Art. 57): a European list of all medicinal product information. The purpose of the database is to deliver structured and quality-assured information on medicinal products authorised in the EU that can support, EU terminologies of products, substances and organisations used to power pharmacovigilance and regulatory systems in the EU. These data are already used in EU pharmacovigilance systems (e.g. EudraVigilance, PSUR repository, referrals, PASS, pharmacovigilance fees). They will constitute version one of the content of the ISO IDMP / SPOR terminologies and transition over time to more complete ISO IDMP data elements and adopted processes for SPOR. The optimal approach to engage National Competent Authorities in the quality assurance of Article 57 product submissions received by EMA will be explored within the Network.

Domain: Human

Legal reference:

- Regulation (EC) No. 726/2004/EU
- Art. 57 1(l) and paragraph 2, 2nd sub paragraph
- Legal Notice on the Implementation of Art. 57(2), Regulation (EC) No. 726/2004

2. **EudraVigilance Auditable Requirements (EV-ADR):** An enhanced adverse reaction collection and management system (EudraVigilance) that will deliver better health protection through simplified and centralised reporting, better quality data and improved searching, analysis and tracking functionalities. Enhanced detection of new or changing safety issues allows more rapid action to protect public health.

Domain: Human

Legal reference:

- Regulation (EC) No. 726/2004/EU Art. 24
- Commission Implementing Regulation No. 520/2012 – Art. 25, 26 and 40
- Transitional provisions until 6 months after Management Board decision that EudraVigilance functionalities are delivered

3. **EudraVigilance (Signal Management) Critical Requirements (EV-SM):** the project will deliver tracking of the signal detection process and entire signal management from detection through to recommendation for labelling change. In order to deliver a streamlined, end-to-end process for tracking, the project may deliver enhanced data analysis tools for signal detection.

Domain: Human

Legal reference

- Regulation (EC) No. 726/2004 Art. 24
- Commission Implementing Regulation No. 520/2012 Art. 24

5. Benefits and impacts of programmes to stakeholders

5.1. Approach to understanding benefits and impacts

This section outlines the benefits of all the programmes within scope and the associated impacts to the NCAs and industry. The table below represents a summary of the opinions and feedback across all the programmes which have been gathered through consultation with partners of the Network via an EU Telematics workshop regarding this EU Telematics strategy. Since benefits and impacts depend highly on the business processes and IT solutions and are infrastructure specific to each organisation, this information can only be considered as an average view.

Across all the programmes there are common themes, with overall benefits being:

- Improve efficiency in all regulatory procedures by making best use of IT
- Reduce duplication and cost of developing and maintaining local IT systems
- Optimise value of existing IT systems by improving interoperability of IT systems
- Provide a unified way for Industry to interact with regulators in the EU and reduce cost for Industry
- Increase regulatory quality by facilitating sharing of high quality data within the EU and globally
- Meet timely regulatory compliance

As the EU Telematics strategy is implemented there will be various impacts affecting the EMA, NCAs and industry. The EU Telematics governance will maintain engagement and collaboration with the Network and industry stakeholders, and will help them to understand key impacts in order for them to plan ahead with foresight. Most of the programmes will require changes which will necessitate investments in IT and process adaptation, and which in the longer term will provide simplification of processes and a realisation of the benefits listed. It is the ambition of the Programme 1, Telematics Governance, to provide clarity over the benefits realisation.

In the following table, benefits are meant to apply to all stakeholders, except where specifically labelled as “For NCAs” or “For industry”.

5.2. Benefits and impacts of projects

5.2.1. Programme 1: Telematics Governance

Project	Benefits	Impacts on NCAs	Impacts on industry
Periodic Review of Governance Structure	• Reduced overlap of governance across the leadership framework, introducing greater clarity of responsibility and having a lean effective governance • Separated functions of strategic, tactical, development, maintenance and architecture • Enhanced participation of the different stakeholders at various levels in the governance structure • Improved communication and information dissemination to the stakeholders	• Requires dedicated resources to work with the bodies of the Telematics governance structure	• Requires resources to feed into the programmes and projects and maintenance groups

5.2.2. Programme 2: Clinical Trials

Project	Benefits	Impacts on NCAs	Impacts on industry
EU Portal and Database	• A single interface allows improved submission, assessment, monitoring and supervision of CT • Provides a platform to facilitate multistate assessment of clinical trials, fostering effective collaboration and communication between NCAs and with sponsors • Information is processed in a coordinated, non-duplicative manner	• Requires process tuning and it may require significant changes to the national systems. • Will require training of staff and adaptation of processes	• Industry and academia need to reorganise and centralise application and surveillance processes

Project	Benefits	Impacts on NCAs	Impacts on industry
	• Increased transparency of CT information • Improvements in data quality. Less errors thanks to automatic data entry • Improvements in visibility and transparency through less misdirection of documents, and in the ability to track procedures at all stages • Reduction of duplication as part of a clinical trial application will be achieved as the system will permit cross-referencing between CTAs • EU Portal and Database will drive compliance with assessment timelines thus providing greater certainty for the CTA assessment process • For NCAs: provide faster and easier exchange of information between NCA and EU databases • For MSs: facilitate interaction between NCAs and Ethics Committees. Outputs for multistate trials become a single input decision of one MS • For industry: simplifies CT application submission procedures i.e via use of an eAF for submission of standardised data and reuses master product and substance data captured by the regulators in other contexts (Art. 57) • For industry: ability for information to be submitted once only and referenced/accessed in relation to		

Project	Benefits	Impacts on NCAs	Impacts on industry
	further CT applications without submission		
CT Safety Reporting (SUSARs and ASRs)	• Facilitate the reporting of SUSARs submission as sponsors will be able to use a simplified web-based form to submit SUSARs to EV CTM (significant benefit in particular for non-commercial sponsors) • For MSs: MSs will be able to cooperate more closely in the assessment of the safety information • For NCAs: streamlines and facilitates the flow and assessment of clinical trial safety information between Member States • For NCAs: standardised and harmonised solution across all NCAs by means of a central repository • For industry: facilitates and streamlines reporting of ASRs (single electronic submission) and SUSARs • For industry: ASRs will be stored in a common repository accessible to all NCAs, reducing the number of submissions	• Processes to be modified to allow for the simplified submission procedure of ASRs	• Process changes required to convert ASR submissions to an electronic format and submit to a single repository
EudraCT & EU-CTR Legacy	• Allows the transition measures defined in the CT Regulation to be implemented in a controlled manner • Allows for the legacy data from EudraCT and EU-CTR data to be preserved and made available	• Need to access two systems during the transition period	• Need to access two systems during the transition period

5.2.3. Programme 3: eCollaboration

Project	Benefits	Impacts on NCAs	Impact on industry
eAF	• Increased automation accelerates processing and harnesses system efficiencies both at the industry end and at the regulators' end (NCAs, EMA) • An integrated eAF would enable the EMA and stakeholders to better reuse data and result in uniform presentation of the information received • In-built validation rules and use of controlled vocabularies improve data quality and reduce issues found during business content validation such as inconsistencies and errors • Workflow re-engineering and electronic workflow integration will support the processing of incoming electronic application forms and introduce an end-to-end paperless process • For industry: filling out application forms will become less time-consuming and error-prone in the long term • For industry: automatic generation of the eAFs with data directly from sponsor/CRO systems and databases will result in saving of resources. This would be in part achieved through the necessary alignment between IDMP and the eAFs	• eAF must be linked with EUTCT or similar such as SPOR, which will be ISO-IDMP compliant, and provide sufficient XML data to populate local marketing authorisation system in terms of applicant, application, substance and medicinal product data. Only one 'full' eAF will be submitted and this will be the basis for prepopulating the other eAFs • Systems should be in place with sufficient capacity to support response times similar to the benchmarked response times published on the eAF web page • If data are to be automatically consumed by the NCAs, then systems for data loading and validation of data would be needed	• May cause additional work and longer application creation time in the interim • Some additional resources required at the outset • Need for training of applicants • Requirement to adapt current processes and practices • Bigger companies will want to automate creation, eliminating manual steps to complete the form as the data usually lies in their existing electronic systems

Project	Benefits	Impacts on NCAs	Impact on industry
		• NCAs need to be IDMP-compliant in a later step to make use of the provided data	
Single Submission Portal	• Streamlining of submission channels currently offered, providing significant cost savings by removing paper-based processes • Improved data quality and integration to local case management applications by means of eAF integration • Replacing eAF with an online data set makes the creation of submissions faster and more reliable • Reduce duplicative efforts currently experienced by industry and NCAs by obviating the need to resubmit information already held by the regulators • Increased transparency, ability for document tracking and abidance to procedural deadlines • For NCAs: all NAP, DCP and MRP submissions will be re-routed to concerned NCAs via the Portal while CAP submissions will be found in the Common Repository • For industry: removes the need to use separate submission transfer mechanisms for different procedures	• Investments required in the optimisation of business processes and in setting up receiving systems on the NCA side of the portal • Process changes will need to adapt to a mandatory electronic only submission form. This includes process changes to handle eSubmissions without the need for additional submission of any paper (e.g. wet signatures)	• Resources to take part in the project • Need for training of applicants • Requirement to adapt current processes and practices • Bigger companies will want to automate creation, eliminating manual steps to complete the form as the data usually lies in their existing electronic systems
PSUR Repository	• Provides a secure electronic submission point and common storage place for PSURs, PSUR Assessment	• Investments in training and process adaptation required	• More work may be required initially to create and submit PSURs before the use of the

Project	Benefits	Impacts on NCAs	Impact on industry
	Reports (ARs), comments and final outcomes • Eliminates duplicative efforts and mistakes in terms of PSUR processing • For NCAs: the functionality and data content of the portal and database should be so comprehensive that local systems are no longer needed. Hence, the need to store/archive PSUR submissions locally will be minimised but might still be needed for many NCAs due to local archiving laws or for business needs • For industry: the simplified PSUR submission procedure does not require submission to NCAs and will reduce process lead times	• Investments by NCAs (where needed) in amending the NCA's IT system in order to automatically down- and upload using the API • Need to set up (harmonised) business rules for handling of "missing" eCTD sequences of the NAP dossier (including MRP and DCP) in the NCA's dossier repositories	repository becomes mandatory
Common Repository	• Efficiency improvements for internal EMA processes by automating several manual registration processes • For NCAs: all previously submitted sequences are permanently available to all NCAs • For NCAs: submissions can be downloaded ad hoc, allowing NCAs to retrieve only those documents/submissions/dossiers that are needed at any point in time. This is beneficial to NCAs with limited storage capabilities • For NCAs: possible savings in human resources, in both business and IT functions, depending on local archive laws and NCA business needs	• Investments for interfacing with the Common Repository needed • Will require investments in training • Increased online traffic as a result of downloading may require bandwidth upgrade • Investments by NCAs (where needed) in amending the NCA IT system in order to automatically download using the API (especially since the	• Not applicable

Project	Benefits	Impacts on NCAs	Impact on industry
	• For industry: a simplified, single submission channel for CAP dossiers eliminates the need to submit separately to all concerned MSs	CR interface is not designed to support full assessment online)	
eCTD v4.0	• Increases effectiveness and efficiency of the submissions received in the regulatory agencies • Improves the quality and accessibility of data • Single electronic exchange message for regulatory information complying to regulatory standards • Two-way communication could be enabled between industry and regulatory authorities • Streamlining of life-cycle management of submissions • Reducing the number of paper-based submissions • Allowing reuse/sharing of documents across products and submissions hence enabling 'grouping' of submissions	• eCTD v.4.0 format will in the long run replace the current eCTD v3.2 and NeeS formats • eCTD validation and review software that support v4.0 and is available for use by the full network before the format is accepted for submissions in any procedure • No conversion of old dossiers is required. The old version will be supported during the transition to allow smooth parallel use of old and new versions • A significant amount of new skills and an update of integration with the local licensing system are required • Assessment of technological requirements must be performed; investments into review systems and training needed • VNeeS format for veterinary submissions need to be continuously supported until or unless a viable alternative is developed	

5.2.4. Programme 4: Data Integration

Project	Benefits	Impacts on NCAs	Impact on industry
MDM SPOR	• Provides a single authoritative view, (“one source of truth”) for SPOR data to support	• A standard web service interface to MDM is needed	• Data exchange based on structured and standardised data will require new data management processes,

Project	Benefits	Impacts on NCAs	Impact on industry
	regulatory activities • Reliable and re-useable data will enable data consumers to make better decisions more quickly • Increases accuracy of reporting and data analysis • Supports continuous improvement of data consistency and quality • Promotes a collaborative approach between the Agency and stakeholders by facilitating sharing of information and resources • Simplified implementation of the regulatory framework • Harmonises critical data items and improves their consistency and quality • Facilitates sharing of information and resources across EMA and NCAs	• Successful synchronisation of data between MDM and NCA systems requires executive buy-in, sponsorship and investment • Referential data should be used as the sole source of EU controlled terminologies in the European network. However national vocabularies will still need to be maintained for things not covered by EU-wide needs • Need to ensure interoperability and interaction of processes and systems • Interfaces will need to be ISO IDMP compliant and enable data exchange and integration across systems • Data exchange based on structured and standardised data will require new data management processes, and improvements in data quality	and improvements in data quality • Early engagement with the EMA for change management activities during the development of MDM services is recommended • For reading/querying data, web services may require consumers to provide security credentials and adapt systems to make use of the new message format (HL7 v3). • The read/query functionality is exposed through a User Interface (UI), enabling users to query directly or embed into existing application UIs • Security credentials are essential for users to author data or submit change requests. Functionality will also be exposed through a User Interface. • A representative or small user group should be appointed as liaison for training, communication, and general support throughout the transition • Develop data strategies and

Project	Benefits	Impacts on NCAs	Impact on industry
			implementation plans for the consolidation of medicinal product data in a format compliant to ISO IDMP
ISO IDMP	• Influence the ISO and HL7 fora in order to have ISO Implementation Guides, Technical Reports and HL7 messaging specifications that are compatible as much as possible with the data needs and processes identified through collaboration with the EU stakeholders (NCAs and MAHs) and with the EU legal framework • Normalisation of the definition of product and substance concepts facilitating the identification and exchange of such information in EU by means of the adoption of a single set of standards for the unique identification of medicinal Products (including substances and referential) leading to efficiency gains in data and process integration for regulators and industry • Enhanced relationship with NCAs through collaboration in the process to produce the EU implementation guides • Improved quality of data to support decision	• Need to contribute to discussions on the ISO/EU implementation guides and HL7 message specifications to include their requirements in the discussion • Need to start planning changes to their IT infrastructure and product/substance database models in order to receive, store and exchange electronically medicinal product information compliant with the EU ISO IDMP implementation guides and via HL7 messages • Small agencies may not have enough experienced experts to contribute to the ISO IDMP standardisation activities • Need to acquire expertise in HL7 messaging •	• Need to start planning changes to their IT infrastructure and product/substance database models in order to structure, store and exchange electronically medicinal product information compliant with the EU ISO IDMP implementation guides and via HL7 messages • Many ISO IDMP data elements are only available in unstructured format (e.g. Dossier) so retrieval and codification of such information will be time/efforts consuming • Need to foster closer collaboration within different business areas • Need to migrate from Art57 data structure to a more complex ISO IDMP data structure • Need to acquire expertise in HL7 messaging

Project	Benefits	Impacts on NCAs	Impact on industry
	making • Reinforce the Agency's position as a leader in the definition of standards for medicinal product information • Simplification of the exchange of information between regulatory authorities across the World and within different business domains (e.g. PhV, cross-border ePrescription, anti-falsification, product traceability, etc)		

5.2.5. Programme 5: Veterinary Programme

Project	Benefits	Impacts on NCAs	Impact on industry
EU Veterinary Medicinal Product Database	• Provides consistent master data for veterinary medicinal products and signal detection of adverse reactions across all EU products • As the database matures, it will evolve into a full service model to support the functionality agreed in the revision of the veterinary legislation. Under the current European Commission proposal this includes support to regulatory processes (e.g. procedure management, including referrals) and the supply of information to veterinary healthcare professionals (use of products under the "prescribing cascade") and the general public	• A compromise solution will need to be found. For NCAs that deal with both human and veterinary medicinal products, separate medicinal product databases for each may cause extra administrative burden, whereas for NCAs dedicated to Veterinary medicinal products only, the implementation of "human database compliant" systems	• Eventually, eSubmission data will be directly integrated with the product database and hence this may require mandating MAHs to adhere to agreed standards • The potential impact of the implementation of ISO IDMP standards must be analysed to see whether it is a desirable and viable option

Project	Benefits	Impacts on NCAs	Impact on industry
	• A single source of information on veterinary products will reduce duplication and improve consistency of data across the Network	may be too costly • Requirements gathering will require considerable input from the network as well as agreements on data quality compliance for which NCAs will need to consider planning for the review and update of their local data systems • The potential impact of the implementation of ISO IDMP standards must be analysed to assess whether it is a viable option	
Vet infrastructure	• Allows the revised veterinary pharmaceutical legislation to be efficiently implemented • Enables adherence to international standards that take into account the constraints of the veterinary pharmaceutical and regulatory environment • Creates fit-for-purpose, fully integrated solutions that foster interoperability • For NCAs: As far as possible, single EU veterinary service modules should become available, allowing for the reduction of system and resource costs	• Set up of veterinary specific systems should only be needed when proven cost-effective and required by legislation	• Analysis will need to be carried out with the veterinary industry to determine what benefits could arise from the centrally available service modules. There is potential to further limit the need of specific systems

5.2.6. Programme 6: Online

Project	Benefits	Impacts on NCAs	Impact on industry
European Medicines Web Portal	• Provides a free, unbiased, trustworthy, scientifically-sound source of medicinal information that is publicly available on the Internet • Provides a unique, pan-European view of the lifecycle of a medicine including CAP and NAP product information, EU-level ADR data, searchable EU dictionaries of substances and products, and clinical trial summaries • Supports the European eHealth and open-data agenda • Demonstrates compliance with legislative requirements by EU bodies • For NCAs: raises visibility of NCAs and the European regulatory network	• Validating the information and keeping it valid may be an issue • Multiple data sources may be problematic; CAP data from EMA, NAP data from NCAs • Requires NCA resources and readiness to populate and maintain local data	• Provides information for consumption by healthcare professionals, patients and other stakeholders

5.2.7. Programme 7: Pharmacovigilance

Project	Benefits	Impacts on NCAs	Impact on industry
Article 57	• Supports the product index for EudraVigilance and thus identification of products and substances in Individual Case Safety Reports • Provides EMA with the capability to support PV Procedures (PSUR /Referrals / PASS) that facilitate	• NCAs will have to adapt their business processes to align with new EMA processes relating to the requests for information on the urgent	• MAHs will have to maintain their own business process and allocate resources to comply with the legal obligations of:

Project	Benefits	Impacts on NCAs	Impact on industry
	the coordination of regulatory decisions and actions to safeguard public health • Strengthens transparency and communication with EMA stakeholders by granting access to safety data, efficiently exchanging data within the EU Network and international partners, and supporting communication between the Agency's committees and the pharmaceutical industry • Supports reduction of duplication of encoding and maintenance of the same information on medicines, thus reducing time requirements and associated costs • For MSs: Member States will have access to quality controlled, structured data on all authorised medicines in the EU • For NCAs: Full Article 57 database implementation will ultimately reduce workload in relation to the responses requested on the urgent safety issues, non-urgent information and information to be provided for Annex I (referrals)	safety issues, non-urgent information and information to be provided for Annex I (referrals) • NCAs may wish to use the product and substance data for their systems • NCAs will use the Qualified Persons for Pharmacovigilance (QPPV) and the Pharmacovigilance System Master File (PSMF) in Article 57 as their reference sources	– Maintaining the structured information on medicines in Art. 57 and notifying the EMA of any variation to the terms of marketing authorisation within 30 days of the date of approval of the changes – Submitting information on new MAs granted in the EEA within 15 calendar days from the date of notification of the granting of the MA by the Regulator • MAHs will receive information on PRAC discussions on safety issues relating to the MAs they hold • MAHs will stop submitting administrative variations (i.e. changes to QPPV and PSMF) as NCAs will rely on Article 57
Medical Literature Monitoring (MLM)	• Improved safety monitoring of medicines through better data quality in EV	• ICSRs will still reach NCAs, through the EMA for the	• MAHs may choose to review and revise contracts with their current literature

Project	Benefits	Impacts on NCAs	Impact on industry
	• Development of detailed EU guidance on literature monitoring provides an opportunity for international harmonisation of literature monitoring (e.g. through ICH). If realised, this could deliver simplification and resource savings for industry. • For NCAs: The MLM service aims at reducing the burden of processing literature cases for industry, and for NCAs reducing the number of duplicate reports, reducing correspondence with MAHs and removing the requirement to submit these cases to the EMA • For NCAs and MAHs: It is anticipated that the quality and consistency of the ICSR will be improved based on clearly defined data entry and coding principles, thus reducing duplication of efforts • For MAHs (with substances covered by the EMA service): reduction in resource requirements and associated costs due to the reduction of literature monitoring activities • For MAHs: access to up-to-date results of MLM activities and ICSRs generated allows MAHsto repost ICSRs to other regulatory bodies outside the EU in a timely fashion	scope of the MLM services • Individual journal articles will need to be purchased if required by the NCA • Internal procedures relating to case processing will need to be updated to take into account the changes in receipt, review and submission of these cases • NCA systems will require changes to the current auto forwarding rules. Member States should not re-submit the ICSRs resulting from the MLM service to EudraVigilance	monitoring service providers • MAH systems will require changes to the current auto forwarding rules. Concerned MAHs should not re-submit the ICSRs resulting from the MLM service to EudraVigilance or to the concerned NCAs in the EEA • Industry will need to continue reporting and undertaking data entry activities for all non-serious cases, as this will not be under the EMA'sremit until 2017
EudraVigilance Auditable Requirements	• Data in ISO format will be of higher quality, improving searchability and analysis efficiency	• Initially, NCAs may require additional resources to implement the new standard	• Initially, MAHs may require additional resources to implement the new standards

Project	Benefits	Impacts on NCAs	Impact on industry
(EV-ADR)	• Simplified reporting will be delivered (MAHs report to the NCAs through EudraVigilance) • Compliance with international data standards (and future compatibility with ISO IDMP standards based on Art. 57 data) including Backwards Forwards Conversion Tools for E2B(R2)/(R3) messages • All EU reports of suspected ADRs delivered electronically to WHO through EudraVigilance • For NCAs: enhanced detection of new or changing safety issues which allows for more rapid action to protect public health • For NCAs: thanks to centralised reporting, NCAs will no longer need to re-route data to MAHs, which for NCAs without fully automated processes will allow a re-allocation of finances and resources • For NCAs and MAHs: enhanced signal detection and data analysis tools to support safety monitoring provided to member states and MAHs • IT functionalities are provided and thus where NCAs decide that the data provided is adequate to meet their national requirements they will use provided facilities rather than their own, resulting in potential long-term cost-savings for these NCAs. • For NCAs: the new aggregated data reports (PhV Data, Art. 57 data, eRMR for MAH, data quality	and support the receipt of R3 messages. A EU Backwards Forwards Conversion Tool will be made available by the EMA • Will need to review their business processes for ICSR management	and support the receipt of R3 messages. EU Backwards Forwards Conversion Tool will be made available by the EMA • A new IT process is to be established to retrieve data directly from EV • MAHs will need to change their business processes as centralised reporting will no longer require NCAs and EMA to re-route the information • MAHs will need to undertake their own manual searches for accessing ADR cases in Eudravigilance. MAHs to notify validated signals from the EudraVigilance data

Project	Benefits	Impacts on NCAs	Impact on industry
	reports) will be generated and become accessible • For industry: the new, aggregated data reports (eRMR in EVDAS) will be generated and become accessible; MAHs will need to introduce safety monitoring (signal detection)		
EudraVigilance Signal Management (EV-SM)	• Robust and automated signal detection, improved tracking and management processes, replacement of manual, labour-intensive processes • Efficiency gains achieved that will enable the handling of the expected significant increase in signals from increased ICSR reporting and the introduction of industry signal detection • Improves integration of systems across signal life cycle		• Business process for reporting validated signals will change

6. Critical Success Factors

6.1. Critical Success Factors Impacting the EU Telematics Strategy

Critical success factors are key variables or conditions that are important for the overall success of the Telematics strategy. These factors act as a common point of reference and must be effectively evaluated and managed throughout implementation. Over time, these factors will adapt and change in terms of importance and priority, and as a result must be regularly adjusted for optimal performance.

Critical Success Factor	Description of Factor
Effective governance and oversight	The new EU Telematics governance is designed to address business needs and service the IT ambition of the Network. It will promote and foster a highly collaborative coalition and will be flexible to differing drivers as they unfold. Effective governance will be essential for decision making and direction setting. The governance structure will be reviewed periodically and changes will be authorised as needed to suit the changing environment.
Availability of skills, capabilities human and financial resources	Successful implementation of the Telematics strategy will require a plethora of skills and capabilities from across the Network. It is essential that organisations and resources with the right skills and capabilities are leveraged. Successful implementation will also require significant financial investments and sufficient financial resources will also be required for the maintenance of Telematics systems.
Effective collaboration and communication	Ongoing collaboration and effective communication is essential to the implementation of this strategy. Communication channels and access to information for relevant stakeholders must continue to be made available.
Programme and project management	The strategy is made up of a series of programmes and projects. To ensure successful implementation across all initiatives, a strengthened project management capability is necessary. A rigorous gate management system will strictly control potential scope, costs and timelines.
Business and IT alignment	This strategy is built upon key business drivers around implementation of pharmaceutical policy and legislation. IT plays a key role in enabling technology simplification and optimisation of existing and new procedures. It is essential to ensure close alignment between the high-level objectives and business needs of the network and IT projects.
Understanding the complexity	The regulatory environment is complex; business needs are to be clear, coherent and effectively translated into tangible and pragmatic solutions which add value to the network.
Understanding the critical path	Projects should not be run independently in silo; interdependencies between and within programmes must be recognised. At times, one programme will be dependent on another for the progression of certain milestones. It is critical that these are well understood and managed, and the critical path of the overall portfolio is defined and agreed on.

7. EU Telematics Implementation Roadmap 2015 - 2017

The EU Telematics implementation roadmap provided in Annex 1 is intended to give an indication of the implementation of EU Telematics projects over the coming three years, from 2015 to 2017. The roadmap is accurate as of the date of publication of this document. However, due to the mutable nature of many of the projects, the timelines provided here are subject to change as further developments become more mature. It is therefore recommended to use the timelines in this roadmap as a point of reference only.

As far as it is known, the roadmap shows when projects are in one of the three key phases of project delivery:

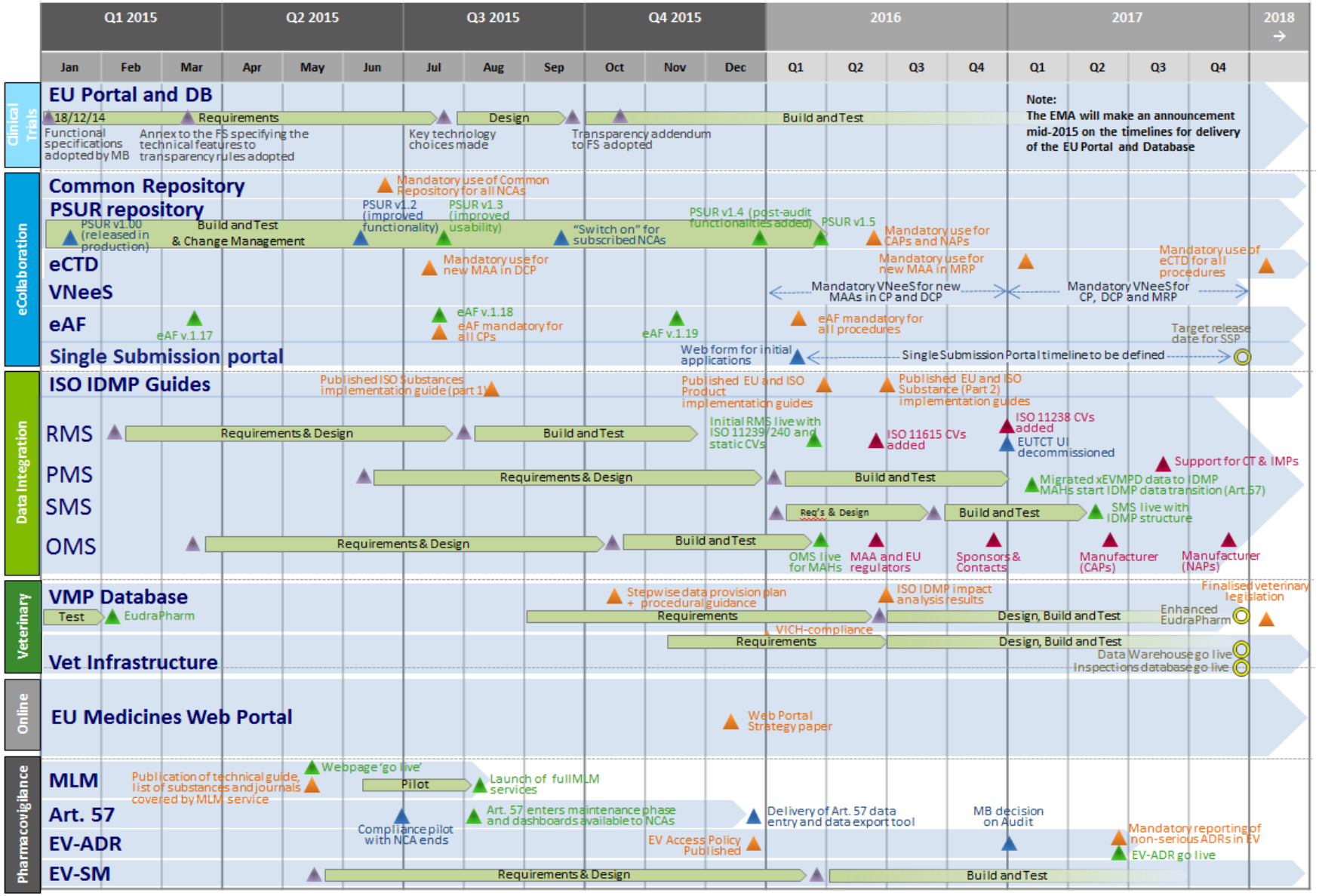
- Requirements phase: the gathering of high-level requirements;
- Design: the gathering of detailed requirements and the design of the IT solution;
- Build and Test: the delivery of the IT solution and testing, including User Acceptability Testing on which the decision for "go live" of the system is decided.

Milestones in 2015 are of higher certainty than milestones from 2016 onwards. Where a time period for implementation is known but a specific point in time cannot be pinpointed, a double-headed arrow with dotted lines has been used. Where a milestone is highly tentative, a yellow ring has been used.

Interdependencies between projects need to be carefully analysed and managed. For instance, to deliver their full functionalities, most projects rely on the availability of a trusted source of master data for the identification of medicinal products and organisations delivered by the master data management services (Data Integration programmes). The level of dependency will to a great extent depend on agreed processes and technical solutions that will be implemented by the various Telematics projects. Architectural considerations will need to be weighed against the need to meet legislative timelines or realise benefits as soon as possible and cost or human resource constraints. Such priorities may justify reducing dependencies by delivering interim solutions, which will later be improved once other projects deliver their component of the Telematics systems landscape so as to optimise interoperability between systems. Project interdependencies (or 'critical path') as far as known will be identified by the EU Network Data Board and Telematics Enterprise Architecture Board and presented to the EUTMB with recommendations on cross-project sequencing of milestones documented in the roadmap which will then be updated as required to optimise project delivery.

This EU Telematics implementation roadmap will be updated as and when project plans evolve to reflect the progress of implementation with due consideration of the impact on NCAs, industry and other stakeholders. Any updates will be communicated to NCAs, industry and other stakeholders.

Annex 1 – EU Telematics Implementation Roadmap 2015 – 2017



Disclaimer: The roadmap shown is a draft version, and is subject to further change

** The timelines for the S&P project are indicative at this stage because they are based on a preliminary analysis; they will be revised during the approval process for the S&P project and they will be influenced by both the development of the ISO IDMP technical specifications*

Key

- Pre-go live milestones
- Publication of guides or legal requirement dates
- Project go live
- Project milestones
- Functionality upgrade
- Tentative milestones
- Tentative timeline

Abbreviations found in roadmap

The following abbreviations are found in the roadmap, and have are listed here for ease of reference. A full glossary can be found in Annex 2, where some abbreviations are accompanied by a more detailed explanation.

ADR – Adverse Drug Reaction, **Art. 57 –** Article 57, **ASR** – Annual Safety Report, **CAP** – Centrally Authorised Product, **CRO** – Contract Research Organisation, **CT**- Clinical Trial, **CVs**-controlled vocabulary, **DCP** – Decentralised Procedure, **eRMR** – electronic Reaction Monitoring Report, **EUTCT** – European Telematics Controlled Terminology, **EV** – EudraVigilance, **EV-ADR** – EudraVigilance Auditable Requirements, **EV-SM** – EudraVigilance Signal Management, **IAM** – Identity and Access Management, **MAA** – Marketing Authorisation Applicant, **MAH** – Marketing Authorisation Holder, **MB** – Management Board, **MDM** – Master Data Management, **MLM** – Medical Literature Monitoring, **MRP** – Mutually Recognised Product, **NAP** – Nationally Authorised Product, **OMS** – Organisation Management Service, **S/PMS** – Substance/Product Management Service, **QPPV** - **RMS**- Referentials Management Service, **SPOR** – Substances, Products, Organisations, Referentials, **SUSAR** – Suspected Unexpected Serious Adverse Reaction, **VICH** – Veterinary International Conference on Harmonisation, **VNeeS** – Veterinary Non-eCTD Electronic Submissions, **VPM** – Veterinary Medicinal Product, **XEVMPD** – Extended EudraVigilance Medical Product Dictionary

Explanation of key milestones

The following table provides annotations to the roadmap. A selection of the key milestones that appear in the roadmap have been elaborated on. For a full description of each project and what services their delivery aims to provide, please see section 4.2 Description and scope of projects.

Project	Milestone	Description
P2: Clinical Trials		
EU Portal and Database	*To be defined*	*Announcement to be made mid-2015 on the timelines for delivery of the EU Portal and Database.*
P3: eCollaboration		
PSUR Repository	PSUR v1.0	First release in production; non-mandatory usage of the PSUR repository fulfilling only legislative requirements. The repository is used in pilot with participating NCAs and industry stakeholders.
PSUR Repository	PSUR v1.2	A release to improve functionality and implement improvements following an independent audit of the repository.
PSUR Repository	PSUR v1.3	A release to improve functionality to support 'switch on' for NCAs.
PSUR Repository	"Switch on" for NCAs	NCAs that have signed up to the switch on will undergo a change management programme supported by the EMA up until the PSUR Repository becomes mandatory for all NCAs. The "switch on" allows all PSURs to be accessed via the repository while PSURs continue to be submitted to NCAs (i.e. the repository is not mandatory). This allows NCAs to gradually become accustomed to the use of the repository and correct issues.
PSUR Repository	PSUR v1.4	A release to implement post-audit functionalities; in

		particular to make available an application program interface) (API) to those NCAs that require it, allowing automatic download of PSURs from the repository to NCA systems.
PSUR Repository	PSUR v1.5	A final release to address outstanding issues after which the project will be closed and the repository will be continuously maintained.
PSUR Repository	Mandatory use for CAPs and NAPs	The repository must be used for all PSURs by industry and NCAs. Submission to NCAs is no longer required and NCAs rely on the PSUR repository.
Common Repository	*To be defined*	*Pending detailed implementation plans.*
eCTD	*To be defined*	*Pending detailed implementation plans.*
VNeeS	*To be defined*	*VNeeS submission will be required for all Veterinary applications in the EU from 2016 onwards.*
Electronic Application form (eAF)	eAF v1.18	Prioritised change requests.
Electronic Application form (eAF)	eAF mandatory for all CPs	The use of eAF is mandatory for all central applications for initial MAA, line-extensions, variations and renewals.
Electronic Application form (eAF)	eAF v1.19	Prioritised change requests.
Electronic Application form (eAF)	eAF mandatory for all procedures	The use of eAF is mandatory for all central and non-central applications for initial MAA, line-extensions, variations and renewals.
Single Submission Portal (SSP)	*To be defined*	*Pending detailed implementation plans.*
P4: Data Integration		
ISO IDMP	Indicative milestones for implementation guides	The deadline and scope for implementation of ISO IDMP in the EU will be decided and roadmap and implementation plans published. Implementation guides are drafted and published.
ISO IDMP	Substances (part 1) published	Publication of the technical specifications for the following substance classes: chemical, nucleic acid, protein and herbal.
ISO IDMP	Substances (part 2) published	Publication of the technical specifications for the following substance classes: polymer, homeopathic, allergens, vaccines, biologics and advanced therapy.
IDMP Implementation (RMS)	Initial RMS live with ISO 11239/240 and static CVs	The service for managing referential data is available for ISO 11239 (Pharmaceutical dose forms, units of presentation, routes of administration and packaging) and ISO 11240 (Units of Measure).
IDMP Implementation (RMS)	ISO 11615 CVs added	The RMS is extended to also cover ISO 11615 (Regulated medicinal product information).
IDMP Implementation (RMS)	ISO 11238 CVs added	The RMS is extended to also cover ISO 11238 (Regulated information on substances).
IDMP Implementation (RMS)	EUTCT UI decommissioned	The User Interface (UI) of the RMS replaces EUTCT (European Union Telematics Controlled Terms System).

IDMP Implementation (SMS)	SMS live	The ISO IDMP 11238 EU technical specifications will provide information on the storage and exchange of substance data, and the extent of enrichment will be determined during the project analysis and design phase
IDMP Implementation (PMS)	PMS live for authorised products	The initial iteration for the PMS will contain data elements available in the Article 57 format and minimum required IDMP elements to assign and maintain identifiers for authorised medicinal products and support product life cycle management (MPIDs, PCIDs and PhPIDs) within an IDMP compatible structure. It is expected that the current Article 57 operating model is continued for this iteration.
IDMP Implementation (PMS)	PMS live for investigational medicinal products to support Clinical Trials	Data extended to include elements required to support investigational medicinal products.
IDMP Implementation (OMS)	OMS live for MAHs	The provision of data on organisations will be delivered in iterations. This first iteration includes a dictionary of organisations and contacts, which will be extended to include additional organisations to support more business activities as part of the subsequent iterations.
IDMP Implementation (OMS)	MAA data released	The OMS will manage and make available data on market authorisation applicants.
IDMP Implementation (OMS)	Sponsor data released	The OMS will manage and make available data on Sponsors including CROs.
IDMP Implementation (OMS)	Manufacturer (CAPs/NAPs) data released	The OMS will manage and make available data on manufacturers.
P5: Veterinary		
Veterinary Medicinal Products (VMP) Database	Enhanced Eudrapharm	*The decision for whether the data stored in this database will need to be ISO IDMP compliant is yet to be determined. The veterinary legislation that is expected to come into force in 2019 - 2020 will clarify this.*
Veterinary Infrastructure	*To be defined*	*An analysis of the business requirements contained in the veterinary legislative proposal will be carried out followed by a gap analysis against existing or planned telematics systems to identify those needs that can be incorporated into other programmes from those that require specific projects to be initiated and run within the veterinary programme.*
P6:Online		
EU Medicines Web Portal	*To be defined*	*Pending detailed implementation plans.*
P7: Pharmacovigilance		
MLM	Launch of full MLM services	The EMA provides medical literature monitoring for suspected adverse drug reactions for certain active substances.

Article 57	Art. 57 enters maintenance phase and dashboards available to NCAs	Initial validation of product completed.
Article 57	Delivery of Art.57 data entry and data export tool	The data entry tool (aka. EVWEB) allows users to visualise the differences between versions. The data export tool allows for the retrieval of the latest version of the validated product.
EV-ADR	EV-ADR go live	The module for Adverse Drug Reactions of EudraVigilance goes live and includes: • Switch on eRMR; • Agency moves to centralised reporting; • EV System able to accept R3 messages; • ADR dashboards available; • Data submission to WHO (by the EMA).
EV-SM	*To be defined*	*Pending detailed implementation plans.*

Annex 2 – Glossary of abbreviations and terms

Term / abbreviation	Definition
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: EMA to publish the format for the electronic submission of information on medicinal Products for human use by 2 July 2011; 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; 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
Article 57 data	Database developed by the EMA in compliance with Article 57 of Regulation (EC) 726/2004 and comprising a database of all human medicinal products authorised within the European Union
ASR	Annual Safety Report
CAP	Centrally Authorised Product
CESP	Common European Submission Portal
Common Repository	Open interfaces to support the automated download of data sets
CRO	Contract Research Organisation. An organisation that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
CT	Clinical Trial
CVs	Controlled vocabulary
DCP	Decentralised Procedure. The procedure for authorising medicines in more than one EU MS in parallel
E2B standards	Standards for reporting by electronic transmission
eCTD	Electronic Common Technical Document
eHealth	Healthcare practice supported by electronic processes and communication

Term / abbreviation	Definition
EMA	European Medicines Agency
EMA MB	EMA Management Board
ePrescription	Computer-based electronic generation, transmission and filling of a medical prescription
eRMR	Electronic Reaction Monitoring Report. A report extracted from EudraVigilance which provides an overview of the ICSRs transmitted to EV over a defined period of time
eSubmission	The receipt/processing of electronic applications for marketing authorisation
eSubmission Gateway	The European Medicines Agency's Gateway and the Submission Web Client are electronic submission channels that allow the applicants to submit documents supporting all types of applications for human medicines to the Agency
ESVAC	The European Surveillance of Veterinary Antimicrobial Consumption. This project was launched in 2009, following a request from the European Commission to the European Medicines Agency to establish a surveillance program for the collection of harmonised data on the sales of veterinary antimicrobial agents in the European Union
EUCTR	European Union Clinical Trials Register - provides public access to information from the European Union Clinical Trial Database (EudraCT)
Eudra	European Union Drug Regulatory Authorities
EudraCT	European Union Clinical Trials Database. A database that includes information on clinical trials taking place in the European Union and clinical studies conducted worldwide in accordance with a pediatric investigation plan. A subset of the data is publicly accessible via the European Clinical Trials Register
EUNDB	The European Union Network Data Board
EUTCT	European Union Telematics Controlled Terms
EU TMB	European Union Telematics Management Board
EV	Eudravigilance. A centralised European database of suspected adverse reactions to medicines that are authorised or being studied in clinical trials in the European Economic Area

Term / abbreviation	Definition
EV-ADR	Eudravigilance Auditable Requirements
EV-SM	Eudravigilance Signal Management
GInAS	Global Ingredient Archival System. Provides a common identifier for all of the substances used in medicinal products, utilizing a consistent definition of substances globally, including active substances under clinical investigation, consistent with the ISO 11238 standard
GSIS	Global Substance Formation System software. An application for the maintenance and sharing of substance data in compliance with the ISO IDMP standards
HMA	Heads of Medicines Agencies. The network of the heads of the regulatory authorities responsible for the regulation of human and veterinary medicines in the European Economic Area
Horizon 2020	The EU Framework Programme for Research and Innovation
IAM	Identity and Access Management. A security discipline that enables the right individuals to access the right resources at the right times for the right reasons
ICH (VICH)	International Conference on Harmonisation (Veterinary). This organisation makes recommendations on how to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration, thereby reducing or eliminating duplication of testing carried out during the research and development of new human medicines
ICSR	Individual Case Safety Report. A report documenting an adverse event for an individual patient
IDMP	Identification of Medicinal Products
ISO	International Organisation for Standardisation
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
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.
MRL	Maximum Residue Limit. The maximum concentration of a medicine residue that is considered acceptable in food produced from an animal that has been treated with that

Term / abbreviation	Definition
	medicine
MRP	Mutual Recognition Procedure.Based on the principle of the mutual recognition by EU Member States of their respective national marketing authorisations
NAP	Nationally Authorised Product
NCA	National Competent Authority. The medicines regulatory authority in a European Union Member State
NeeS (VNeeS)	Non-eCTD electronic submissions (Veterinary)
NtA	European Commission Notice to Applicants
Partners	Regulatory partners of, and within, the Network including the European Commission, European Medicines Agencies, EMA Management Board, National Competent Authorities, Heads of Medicines Agencies, and International partners
PSURs	Periodic Safety Update Reports. A report prepared by the marketing authorisation holder describing the worldwide safety experience with a medicine at a defined time after its authorisation
PV	Pharmacovigilance
QPPV	Qualified Person for Pharmacovigilance
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	A set of managed business services supported by systems and data that will be built around the four main types of structured data: Substance, Product, Organisation, and Referential data (considered to be “master data”.) Substance: the ingredients of a medicine Product: the medicinal product itself Organisation: organisational data, e.g. Pharmaceutical industry, their addresses, their plants, distribution centres, the regulatory agencies, and persons related to these organisations. Referential: Reference lists such as dosage, forms, country codes, package codes, weight codes, etc.

Term / abbreviation	Definition
Stakeholders	External parties with which the Network interacts. This includes: the European Council, the European Parliament, the pharmaceutical industry, healthcare professionals and providers, the general public
SUSARs	Suspected Unexpected Serious Adverse Reaction
TEAB	Telematics Enterprise Architecture
VMP	Veterinary Medicinal Product
WHO	World Health Organisation
XEVMPD	Extended Eudravigilance Medical product Dictionary - database designed to support the collection, reporting, coding and evaluation of medicinal product data in a standardised and structured way