30 September 2014
EMA/289808/2014

EU Telematics Strategy 2014-2016

Endorsed by EMA Management Board in June 2014 and Heads of Medicines Agencies in July 2014

The Vision for EU Telematics

'A European IT collaboration that will deliver a broad range of cost-effective, efficient and inter-operable services to the European Medicines Regulatory Network and to its stakeholders that improve the quality and effectiveness of their business activities.'

Table of contents

1. Introduction

Since the introduction of harmonised European legislation governing many aspects of the regulation of medicinal products, both the European Medicines Agency (EMA) and National Competent Authorities (NCAs) have engaged in a variety of technology initiatives. In order to build on success, and mitigate risks associated with inefficient utilisation of resources, the European Medicines Regulatory Network (the Network[1]) has developed the shared vision for the future of IT services at pan-European level that is presented in this strategy. The Network has responsibility for overseeing the safe and effective use of human and veterinary medicinal products at national and EU level. This vision ensures alignment of EU Telematics with international standards and is created in recognition of the major role that IT systems play in underpinning the work of the Network. Following an independent review commissioned on behalf of the EMA management Board, starting in 2013, new governance structures were put in place to address the varying level of success of previous EU Telematics programmes. The new structure is designed to increase cooperation within the Network, thereby ensuring effective governance of telematics programmes both in terms of delivering new functionality and in ensuring that existing systems are appropriately maintained.

This strategy takes into account the lessons learnt to date within the Network regarding the development of national and EU telematics systems and aims to:

- ensure EU Telematics projects address clear business needs and drivers and that the governance and processes that deliver this strategy promote a close and continuous alignment between business needs and IT solutions;
- recognise the complexity of the regulatory environment governing medicinal products within the EU and at international level;
- promote simplification wherever possible and avoid over-complicated solutions;
- differentiate clearly functionality that is put in place directly to address a requirement in EU legislation (e.g. the European Medicines Web Portal) from functionality designed to increase the efficiency or effectiveness of the operation of the Network (e.g. e-submission Gateway);
- introduce a gated management system and strict change control systems to prevent scope creep in projects and programmes with consequential impacts on cost, timelines and feasibility;
- put in place a structured collaboration/communication/cooperation between EMA and National Competent Agencies and provide appropriate access for stakeholders to information held by regulatory authorities;
- ensure systems are designed to optimise inter-operability and with future technology change in mind;
- ensure close alignment between IT projects and the high level objectives of the Network by maintaining this strategy as a 'living' document.

A key component in this new approach to EU Telematics is the preparation of this Strategy endorsed by both the HMA and EMA. This strategy provides a high-level ambition for a variety of

[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.

IT solutions to be delivered, with a particular focus on areas of common interest to EMA, the European Commission and HMA.

One of the notable challenges in engaging with, and endorsing, a shared strategy for IT is the common alignment of IT deliverables to support both the EMA and HMA organisational strategies, particularly in the area of prioritisation of resources. In many cases the National Competent Authorities 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 with these obligations, resource allocation to undertake IT activities at 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 underpin the fulfilment of the legislative mandate and that 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 and those which are included within the remit of EU Telematics on the basis of agreement within the Network that they underpin the efficient operation of the Network's activities as a whole. There is pressure throughout the network to deliver cost-effective IT solutions that promote efficiency.

To be successful the EU Telematics Strategy must acknowledge the mandates of the NCAs and EMA, each respecting the others' role, 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 and, when feasible and appropriate, integrated.

2. Vision and Strategy

The vision for EU Telematics is:

'A European IT collaboration that will deliver a broad range of cost-effective, efficient and inter-operable services to the European Medicines Regulatory Network and to its stakeholders that improve the quality and effectiveness of their business activities.'

This vision will be realised by developing a range of **services** that meet strategic **business goals**. A **governance structure,** including a gated programme and project management framework, has been devised and put in place to ensure the timely delivery within the next three years (2014-2016) of the **objectives** necessary to achieve these business goals. The continued relevance of this vision and strategy at EU and international level will be monitored by a rolling **environmental analysis**.

3. EU Telematics Governance Structure

The delivery of the EU Telematics Strategy is overseen by the new telematics governance structure, as detailed in Appendix 1. This structure replaces the former EU Telematics structure and provides a number of constructs to inform decision making on project prioritisation, potential technologies, terminologies and data standards. The principal purpose of the governance structure is to oversee the delivery of cost-effective IT solutions that support the regulatory process and the implementation of legislative changes within the network. In addition, the governance structure seeks consistency for shared delivery models, for example the use of E2B standards for exchanging safety data; makes recommendations for the adoption of data standards, for example,

ISO-IDMP; and, considers common approaches for working with stakeholders, particularly the human and animal healthcare industries. The structure provides a framework for prioritisation of IT initiatives within its scope throughout the governance chain, and puts in place a planning and reporting structure for the various work programmes underway. The governance structure recognises the heterogeneous nature of the partners within the Network and seeks to ensure a fair representation of this diversity at all levels (e.g. small, medium and large agencies; human, veterinary and joint agencies; national and EU agencies and the European Commission). Furthermore, recognising that not all services will be relevant for all partners, the recommendations made by the telematics governance structure are not binding on NCAs or EMA, unless agreed otherwise, and the governance will operate on a consultative and collaborative basis. The governance is therefore essentially a 'coalition of the willing' and decisions will be based on consensus wherever possible. The operations of EMA internal management systems and NCA internal management systems are considered outside the scope of the governance structure. NCAs are represented at all levels within the new governance structure, with the Telematics Management Board (TMB) advising EMA Management Board and HMA on IT related topics. Stakeholders also have defined roles within the governance structure.

As this EU Telematics Strategy evolves, with support from the new governance structure, it will be carefully monitored by both HMA and the EMA Management Board.

4. Strategic Business Goals

The high-level business goals for the EU Telematics strategy are:

	Business Goals
SG1:	Seek opportunities for technology to support efficiency in regulatory process that will benefit both partners within the Network and their stakeholders
SG2:	Seek opportunities to avoid duplication of resource(s) and ensure 'value for money' in the development and on-going usage of systems across the Network
SG3:	Optimise existing IT assets in use across the Network, including knowledge sharing, analytical and reporting capability; best-practice capability and interoperability of solutions, where feasible
SG4:	Promote alignment with other regions to ensure relevance in the context of global pharmaceutical regulation, where feasible (US; Japan, BRIC countries)
SG5:	Promote sharing and open access to data repositories, interfaces, technologies, controlled terms, data dictionaries, reference terminologies etc. that can be utilised throughout the Network and make them available to stakeholders, as appropriate
SG6:	Support timely delivery of IT systems, including those required by legislation, ensuring that the solutions should seek to meet the basic needs of the Network, without introducing unnecessary complexity or additional cost to the Network or its stakeholders

The most effective way to support these business objectives within the Network is to share information on existing or planned developments and experience, to share costs and services where appropriate, to explore IT-operational and overall organisational impact of IT solutions and to consider the broader use of technological solutions in the planning phase. Open and structured collaboration, communication and cooperation between EMA, the European Commission and NCAs are key success factors. There is potential to develop and publish best practises for application development e.g. common standards, also common approaches in database design, interfaces and

security aspects. There is also potential to develop common systems and data repositories to be shared by EMA, the European Commission and those NCAs that wish to use them, thereby avoiding overlapping investments.

All development and implementation should be based on a solid business case with comprehensive 'end to end' regulatory impact analyses for those developments impacting on the Network. This can lead to IT solutions delivering benefit to EMA, the European Commission and NCAs, and can also provide opportunities for collaboration between a subset of EU Member States where this is a necessity to support particular business requirements. The IT Strategy also acknowledges existing differences in national legislation, internal processes, security policies and archiving, yet endeavours to harmonise them wherever possible. 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 and to their stakeholders to maximise the transparency and availability of the information held.

5. Services to be developed as a result of this strategy

This strategy will result in the development, supply and maintenance of a range of services to the Network. The main services to be developed in period 2014-2016 are:

- Development, adoption and maintenance of standards for common medical and regulatory terminologies to enable harmonised implementation of technology solutions across the regulatory network and enhanced data exchange opportunities;
- Delivery of data stores (e.g. on substances, products, organisations and referentials such as units of measure, dosage form, species);
- Adoption of common electronic formats and standards to support electronic provision of submissions for EU licensing activities;
- Delivering submission planning and tracking information for shared procedures/activities;
- Providing a single point of entry to enable industry to submit dossiers directly to all Network parties, for all regulatory activities;
- The EMA will provide on-line tools to allow an appropriate level of access to information held by the EMA to the stakeholders of the Network For those dossiers held within the EMA Common Repository, the provision of open interfaces to support the automated download of data sets from this repository to the national systems in accordance with established criteria;
- Information provision to partners and stakeholders such as meeting agendas, minutes, guidelines, policies, information related to medicinal products (e.g. SmPCs and leaflets), safety information, etc. appropriate to their role (partner, stakeholder, EMA, NCA, European Commission, healthcare professionals, patients and other members of the public).

These services should benefit both the partners within (the European Commission, EMA, NCAs), and the stakeholders of, the Network, namely sponsors of clinical trials, marketing authorisation applicants and holders, healthcare professionals, veterinarians, breeders, patients, consumers, national governments and health authorities, international medicines regulatory bodies as well as health technology assessment bodies. The relevant domains include both human and veterinary medicinal products.

This approach also provides sufficient flexibility to enable EMA and NCAs to share or develop common systems[2] supporting a single European platform. Irrespective of the source of the solution or the host for the service, all services supplied to the Network shall comply with appropriate standards, where these have been defined, in terms of security and access control. These security and access control measures will be agreed between the provider(s) of the solution and the solution users. Delivery and maintenance of an agreed level of performance for all Telematics solutions and services shall be monitored through the appropriate channels of the Network governance model.

6. Environmental analysis

As part of the continuous EU Telematics Strategy development, the EU Telematics Management Board should also seek to ensure that IT developments are consistent with future needs and, where possible, explore the potential for introducing new technologies to enhance the telematics services to stakeholders.

Examples of the evolving environment include:

- HMA & the International Coalition of Medicines Regulatory Authorities (ICMRA);
- EMA and NCA roles and responsibilities in the context of future changes to EU legislation governing human and veterinary medicinal products;
- Terminology usage in delivery of healthcare services, for example, the use of clinical terminologies such as SNOMED-CT versus regulatory terminologies such as MedDRA, and the emerging roles of e-health records and e-prescribing;
- International harmonization initiatives such as ISO-IDMP and GInAS;
- Trend towards mobile computing, overall digitisation and potential benefits to the Network;
- Emerging 'best practice' for security and confidentiality of data within the Network;
- Convergence of information technology and medicinal products;
- The overall evolution towards Digital Enterprises;
- Public interest in greater transparency.

EU Telematics should seek opportunities to collaborate on initiatives that will enhance or inform the development of new or improved services.

7. Objectives 2014-2016

In order to attain the strategic goals as outlined above, and in recognition of existing, on-going initiatives together with evolving needs, the focus for 2014-2016 for this IT Strategy is achieving the following objectives. It is not the purpose of this document to determine the detailed technical solutions, but to state the Network's ambition for technology over the coming 3 year time frame. These objectives have all been selected on the basis of their high strategic priority. Objectives are ordered as close as possible in line with the life-cycle of medicinal products and not with respect to their relative priority. Where appropriate, the Network will develop subsidiary strategies to this overarching EU Telematics Strategy giving more detail on the approach to be adopted in particular

[2] For example, document management and workflow systems like Pharos in Austria, Sentinel in the UK, RIO/Nimbus in Ireland and ICI in the Netherlands.

areas covered by one or more of the Objectives below. To date, such strategies have been developed for eSubmissions and Veterinary IT & Data, and a Network Data Strategy is under development. Where there are links to other strategies, this is mentioned in the description of the respective objective.

Objective	Deliverables	Timeframe
Objective 1:	Successful implementation of the EU Telematics Governance Structure	*2014*
Objective 2:	Develop solutions to support the implementation of the new Clinical Trials Regulation, encompassing the Member State (Ethics Committee and NCA (Human), EMA and European Commission roles)	*2015*
Objective 3:	Agree on the use of identified standards to support the full implementation of electronic submission of applications for EU procedures (submission format, e-forms, lifecycle management) taking account of both the veterinary & human domains	*2014-2017*
Objective 4:	Deliver a single submission portal that supports both the submission of applications for centralised procedures to the EMA Central Repository via the EMA gateway, using, as appropriate, the eSubmission Gateway with the Common Repository and CESP (human & veterinary). The ultimate objective is to deliver a single integrated, consistent and standardised way to submit applications for all procedures across the regulatory network	*2014- -2015*
Objective 5:	Deliver a comprehensive data strategy to determine the appropriate standards, referentials and terminologies for data managed and stored across the Network, together with proposed timelines for implementation, and therefore enhance opportunities for interoperability and data sharing. Recommendations for 'best practice' on topics such as security are also envisaged (human & veterinary)	*2014-2016*
Objective 6:	Deliver and make public a common European database of veterinary medicinal products that will enable the development of an EU wide integrated veterinary pharmacovigilance system. By making available in one place information on all veterinary products authorised within the EU the creation of this common database will also promote availability of veterinary medicinal products at a European level and the use of the prescribing 'cascade'	*2014-2016*
Objective 7:	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	*2014-2016*
Objective 8:	Deliver improved on-line services to stakeholders at the EMA by supplying effective electronic tools in the context of evaluation procedures, in particular submission and sharing of documents and information related to procedures within the centralised authorisation procedure across the network of National Competent Authorities, European Commission and the EMA	*2014-2016*

Objective	Deliverables	Timeframe
Objective 9:	Agreement on, and implementation of, solutions to satisfy the current pharmacovigilance legislative requirements for human medicinal products (as adopted by the EMA Management Board in December 2013)	*Ongoing-2016*
Objective 10:	Develop a detailed plan for the delivery of the EU telematics infrastructure that will be necessary to underpin the effective functioning of the revised legislation governing veterinary medicinal products on which proposals from the European Commission are expected in 2014. Translation of this plan into tools and services for the network and stakeholders will start during the lifetime of this strategy	*2014-2016*

Objective 1: Implementation of the EU Telematics Governance

The new governance structure is designed to service the IT ambition of the Network. It is critical that its implementation is achieved as rapidly as possible and that the implementation delivers benefit to the IT developments across the Network. It is expected that the structure will be fully operational in 2014. The structure contains sufficient flexibility to adapt a common framework to the needs of the particular domain or project where it is applied. It will be important that this flexibility is utilised to accommodate the differing drivers and needs of the various different stakeholders including regulators and industry in both the human and veterinary domains. The EU Telematics Management Committee will keep the new structure under review, particularly during the first year of operation, and will authorise any changes that may be required.

Objective 2: Supporting technology to the revision of legislation related to clinical trials

The EU Clinical Trial Regulation has been adopted by Parliament and Council in April 2014 and will come into force no earlier than 2 years later and then only when the EMA Management Board has declared, following an audit, that the EU Clinical Trial Portal and Database meet the functional specifications to be prepared by the EMA, in consultation with the Network, for submission of one application form and dossier for clinical trial authorisation regardless of the number of member states involved, and management of the trial authorisation throughout its lifecycle, and for the delivery of a single decision per Member State on the authorisation of each trial.

The key deliverables are:

- Functional specifications for the design (and audit) of the EU Clinical Trial Portal and Database. Plans and processes for transition between the current EudraCT and EUCTR systems established under the old clinical trial directive, and the new Union Portal and Database. Member States' implementation plan for their use of these systems;
- Workspace (non-public) collaboration tools, workflow and document/message storage for Member States (NCAs and Ethics Committees);
- Transparency on the authorisation and conduct of each trial, and on their results;
- Central electronic safety reporting to the EudraVigilance clinical trial module, and electronic reporting of Annual Safety reports to a central repository at the Agency including data

warehouse and reporting tools, to support analysis of safety and/or clinical trial information from the EU database;

- EU dictionary of investigational medicinal products (substances and products) as part of the EU Medicinal Product (Article 57) dictionary.

This objective will be delivered to the greatest extent possible using solutions and technologies that have already been developed or are in development.

Objective 3: Identification and agreement of Electronic submissions standards

A separate eSubmission Strategy has been developed and will be approved by the EU Telematics Management Board in 2014. The eSubmission strategy elaborates in more detail Objectives 3 and 4 which are summarised in this wider EU Telematics Strategy. The eSubmission strategy explains how interoperability across and between the stakeholders and the Network is enhanced by the adoption and implementation of appropriate standards. In recent years, the network has advanced its thinking on the use of eCTD versus NeeS for human medicinal products. Similarly there is a clear requirement for continued usage of VNeeS for veterinary medicinal products, at least until human and veterinary standards may eventually merge in the long term (RPS). The agreement of a timeline for the mandatory use of eCTD and VNeeS is encouraged and it is the ambition of the Network that this can be implemented over the lifetime of this strategy.

The decision on the adoption and timeline for implementing the IDMP standard for human medicinal products information is also a prerequisite for many other projects. Likewise, there is a need to define the extent and nature of appropriate referential standards that should apply for interchange of information related to veterinary submissions. Wider usage of electronic forms is also a consideration under this objective.

Objective 4: Single submission portal

The ambition is that a single submission portal can be delivered that enables usage of CESP and the EMA Gateway with the Common Repository by 2015. This initiative would build on existing success and demonstrate a cohesive working relationship between the NCAs and EMA to their stakeholders.

In the event that such a solution can be identified, the resulting portal should preferably be mandated for all stakeholders for human and veterinary medicinal products in a timeframe to be agreed by the Network in consultation with these stakeholders.

The ultimate objective is to deliver an integrated, consistent and standardised way to submit applications for all procedures across the regulatory network. However this may not be achieved within the lifetime of this current strategy.

Objective 5: Data strategy

Interoperability is considered necessary to the future development of telematics within the Network. Key to interoperability will be the development of a EU Telematics Data Strategy. Within this strategy the following key initiatives will be developed:

- Identify the most appropriate data standards (e.g. ISO IDMP), data model, the necessary terminologies to support the exchange and analysis of information, with the potential to provide referential data, where appropriate. In terms of veterinary medicinal products, identify

the shared elements with the human data model and encompass those elements that are unique to veterinary medicinal products (e.g. species, MRL);

- Identify unambiguous definition and description of medicinal products in the context of EU projects like eHealth, ePrescription and Horizon 2020. The publication of Article 57 product data should also be considered as part of this process with the potential to allow sharing of the common data within the Network;
- The identification and/or development of a substance master data for the Network is also considered a key deliverable over the life of the strategy. Such an initiative should take account of developments (e.g. GInAS) within other regions (USA, Japan etc.) particularly in the context of globalisation and the requirement for data sharing among regulators;
- Recommend "best practices" for security and privacy policies to protect data assets in accordance with the EU legislation, as transposed by the EU Member States, and in line with the opinions and guidance adopted by the Article 29 Working Party and the competent authorities of the EU Member States;
- Ensure that tools are in place to support the analysis and reporting of data.

Objective 6: A common European database of veterinary medicinal products

A specific Veterinary IT and Data Strategy has been developed and approved by the EU Telematics Management Board that provides detail on how the overall objectives within this wider EU Telematics Strategy will be adapted to the particular nature and requirements of the veterinary domain. Within this veterinary strategy, the development of a common European database of veterinary medicinal products is seen as the single highest priority in terms of EU telematics in the veterinary domain. Such a database will allow a step change in veterinary pharmacovigilance and will enable the subsequent development of systems to provide access to high quality, pan-EU data on adverse events as well as EU wide signal detection and management.

In addition, access to this database by veterinary surgeons will greatly facilitate use of the prescribing 'Cascade', thereby promoting the availability of veterinary medicine.

Objective 7: Develop and launch an extranet

The Extranet project will deliver a new information-sharing and collaboration platform hosted by EMA for the benefit of partners within the Network, namely the NCAs of the Member States (for both delegates participating in the Agency's work at the EMA premises, and NCAs' staff working at the Member States' premises) and the European Commission.

The aim is to improve collaboration, ideas and knowledge sharing for the EU Regulatory Network staff participating in the EMA work, thereby creating a closer relationship with delegates and better supporting the work of the delegate community. Regular satisfaction surveys with the delegate community will be held to measure progress made. Securing 'buy-in' from the delegate community with respect to the advantages of the collaborative features (such as workspace functionalities, discussion forums, etc.) and the novel knowledge sharing tools, compared to current working practices, will be critical.

Objective 8: Improved services to stakeholders

The successful achievement of the objectives detailed within this strategy will deliver improved services to the stakeholders of the Network in both the human and veterinary domains. New, on line information delivery mechanisms will be deployed by the EMA to raise the service level, to provide appropriate levels of access to information held by 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. During the period covered by this strategy, working with partners in the Network and with industry stakeholders, the EMA will identify those additional services that can be provided through its website for the benefit of National Competent Authorities in their role as the source of expertise for the centralised procedure and for industry as the beneficiary of this procedure.

Objective 9: Implement solutions to support pharmacovigilance legislation for human medicinal products

New pharmacovigilance legislation explicitly foresees technology-based solutions and business processes to provide:

- An enhanced EudraVigilance system including capacity and tools for patient reporting, forwarding of reports to Member States, extensive data access including for industry and data provision to WHO;
- Literature monitoring by EMA on behalf of industry to enter cases into EudraVigilance;
- A repository for Periodic Safety Update Reports (PSURs) and their assessments including their collection, storage, retrieval and evaluation;
- The EU medicinal products web-portal linked to national web-portals;
- An auditable system for tracking drug safety signals (signal detection) and other pharmacovigilance issues;
- A database of medicinal products (Article 57 database).

Objective 10: Technology to support the revision of the veterinary legislation

The framework for the veterinary medicines legislation is foreseen to change substantially during the next few years as a result of the publication in 2014 of proposals from the European Commission. The Veterinary IT and Data Strategy takes account of these developments and their timescale by limiting the projects to be run in the period 2014-2016 to those that will deliver functionality that will be required by the Network irrespective of whatever changes are introduced in the revised legislation.

During the period 2014-2016, the veterinary strategy foresees that a comprehensive plan will be prepared for the delivery of the IT tools necessary to underpin the effective functioning of the new legislation. The plan will present a number of programmes and projects with defined timelines, budgets and accountability for delivery. It is envisaged that delivery will take place through collaborative working within the Network utilising existing technologies and solutions wherever possible and desirable. A high priority will be given within the plan to developing the next generation of tools for veterinary pharmacovigilance based around the common European database. The development of certain elements of these new tools, such as the data warehouse for pharmacovigilance reports and associated signal detection tools, can be developed in advance

of the new legislation whereas other functionality cannot be planned until the requirements of the new legislation are known.

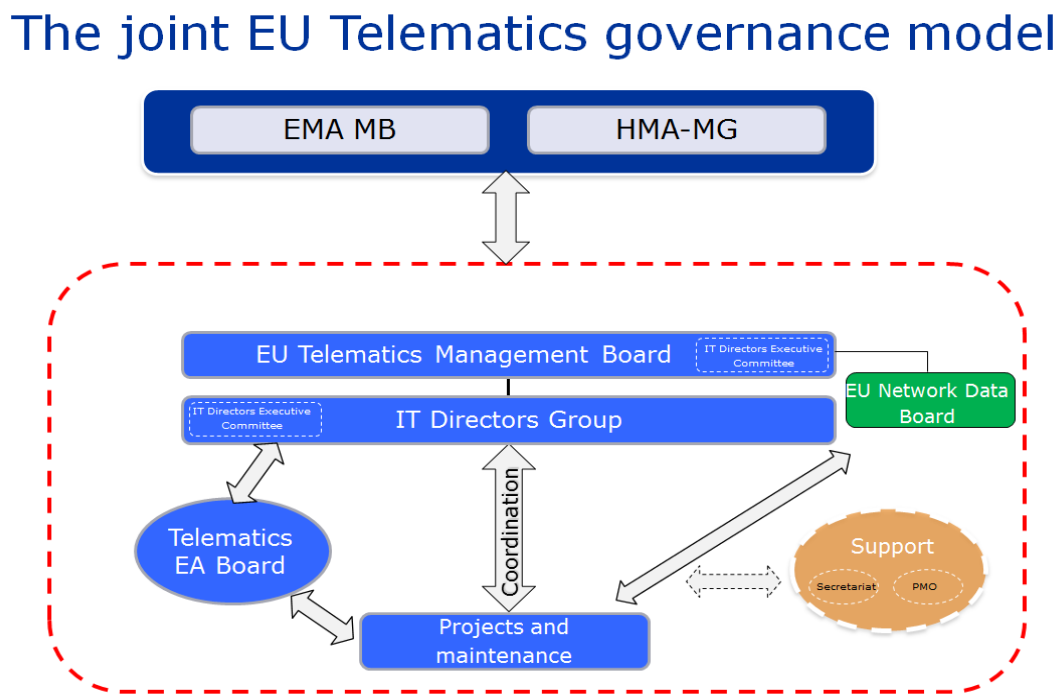
Other areas covered by the Veterinary Strategy that will be delivered in the period 2014-2016 include the veterinary-specific elements of the projects listed in this EU Telematics Strategy that are common between human and veterinary domains, such as eSubmission, data integration and the supply of services by the EMA to partners and stakeholders of the Network.

Annex 1 – Outline of the governance structures

The EU Telematics Governance structure has three layers: (1) The EMA Management Board and the HMA Management Group (2) the EU Telematics Management Board (EUTMB), (3) the IT Directors Group and its Executive Committee. The EMA Management Board and the HMA (and its Management Group) define the strategic direction and parameters within which the EU Telematics Programme will operate. The EUTMB is principally responsible for establishing the EU Telematics Strategy and then providing strategic governance as to its implementation. The EUTMB has membership from EMA, NCAs, the European Commission and patients and comprises senior staff from both the business and IT domains. The IT Directors Group is composed of the EMA and NCAs' heads of IT mandated to agree and implement the EU Telematics Strategy through a series of programmes and projects. The IT Directors group appoints an Executive Committee of EMA and NCA representatives to plan and manage execution of the strategy and to interlink between the EUTMB and IT Directors.

The Telematics Enterprise Architecture Board develops and manages the EU telematics enterprise architecture and the information architecture. It sets standards and provides advice to partners within the Network intended to promote adoption of a common architecture where possible or at least inter-operability where integration is not possible or desirable. The Data Board is responsible for data related standards, including alignment with international standards, and the quality of master referential data (SPOR).

Careful consideration has gone into the composition of the various layers of governance to ensure that representation covers the full diversity of the partners within the Network and their differing needs. Close alignment between business needs and IT solutions is ensured through business representation in the EUTMB, the Data Board and throughout the organisational structures for project management and system maintenance.



i) Project Structures

Approved projects will be run by project teams, populated mainly by EMA and NCA resources and supported by external resources as required. The Project Management Office (PMO) assists the project team while the IT Directors Executive Committee supervises and approves the plans for delivery of all projects. For this reason, the terms of reference of the IT Directors Group emphasise the need for IT Directors to be familiar with the business needs of their agencies and to be mandated to make decisions related to EU Telematics projects on behalf of their agency.

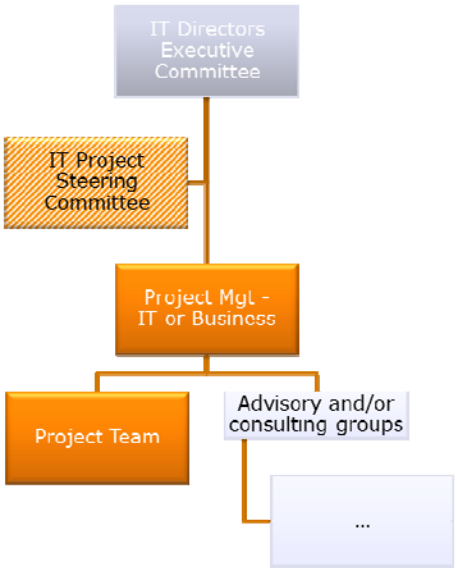
Specific projects may be initiated either to implement parts of this Telematics Strategy or may be initiated at the request of partners or stakeholders following approval at an appropriate level of the governance structure, depending on the size of the project. All projects must be operated in accordance with the strategy objectives and governance structure.

The 'generic' project structure is shown in the diagram below. The involvement of both business and IT experts occurs at all level. Engagement, and involvement, of stakeholder is foreseen for all projects. The mechanisms for engagement of stakeholders within projects will differ depending on the extent and nature of their involvement in the activity concerned.

Project Governance Structure

All project structures are based on the common project structure template

- The IT Directors Executive Committee approves each project structure and acts as the IT Programme Board for Telematics
- Project may have a Steering Committee chaired by the Business Owner and an IT Director, ensuring direction and issue resolution
- Day-to-day project management is carried out by either an IT or business project manager, depending on the project
- The project team delivers the solution
- Advisory and/or consulting groups provide input from stakeholders and others on requirements and support implementation

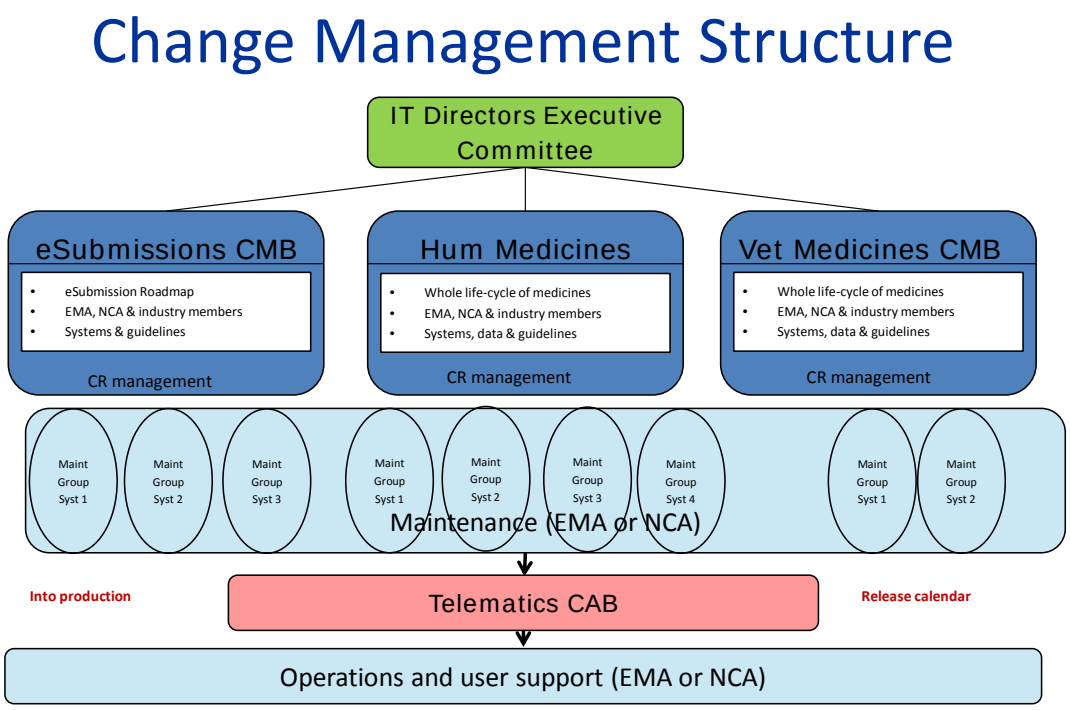


ii) Maintenance Structures

Once a project has been completed the resulting system will be handed over to a Change Management Board for maintenance. There are three Change Management Boards, one for e-submissions, one for human medicinal products and one for veterinary medicinal products. They are populated mainly by EMA and NCA resources, and they are responsible for maintenance and change management of telematics systems. They receive change requests from stakeholders and decide on implementation. In case of major changes they propose a project.

Change Management Boards have system specific teams and a Telematics Change Advisory Board to assist them in practical matters. The Telematics Change Advisory Board is the interface to implementation and operations within the various organisations of the Network.

The following life cycle model describes the delivery and reporting of EU Telematics programmes and projects.



The number of Change Management Boards (CMBs) that are required will depend on the number and relationship between the EU Telematics systems in operation at any one time.

Annex 2 - Glossary of abbreviations and terms

Term / abbreviation	Definition
Article 57 product 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
BRIC countries	In economics, BRIC is a grouping acronym that refers to the countries of Brazil, Russia, India and China, which are all deemed to be at a similar stage of newly advanced economic development
CESP (human & veterinary)	Common European Submission Portal
Clinical Trials Regulation	Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use
CMBs	Change Management Boards
Common standards	Best practises for application development
Digital Enterprises	A digital enterprise is an organization that uses technology as a competitive advantage in its internal and external operations
E2B standards	Standards for reporting by electronic transmission
eCTD	Electronic Common Technical Document
eHealth	Healthcare practice supported by electronic processes and communication
EMA	European Medicines Agency
EMA Common Repository	Open interfaces to support the automated download of data sets
EMA MB	EMA Management Board
ePrescription	Computer-based electronic generation, transmission and filling of a medical prescription
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
EU Member States	A member state of the European Union is a

Term / abbreviation	Definition
	state that is party to treaties of the European Union (EU) and thereby subject to the privileges and obligations of EU membership
EU Telematics	EU Telematics aims to put in place and maintain common information-technology (IT) services to implement European pharmaceutical policy and legislation
EU TMB	European Union Telematics Management Board
EUCTR	European Union Clinical Trials Register
Eudra	European Union Drug Regulatory Authorities
EudraCT	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
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 (EEA)
European Medicines Regulatory Network (The Network)	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
European Medicines Web Portal	Provide access to information on medicines through a single search interface, concerning product information, reports, clinical trials, protocols and results summaries, safety announcements and news items
GInAS	Global Ingredient Archival System
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. Abbreviated as HMA
Horizon 2020	The EU Framework Programme for Research and Innovation
ICMRA	International Coalition of Medicines Regulatory

Term / abbreviation	Definition
	Authorities
ISO-IDMP	Identification of Medicinal Products (MPID)
MedDRA	Medical Dictionary for Regulatory Activities (MedDRA) is a clinically validated international medical terminology dictionary (and thesaurus) used by regulatory authorities in the pharmaceutical industry
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 medicine
NCAs	National Competent Authorities - Medicines regulatory authority in a European Union Member State
NeeS (VNeeS)	Non-eCTD electronic submissions (Veterinary)
Pan-EU data	European-wide data
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
Pharmacovigilance	Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem
PMO	Project Management Office
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
RPS	Regulated Product Submission; a standard for the electronic submission of documents and data related to regulated products, including medicines

Term / abbreviation	Definition
SmPCs	Summary of Product Characteristics - A document describing the properties and the officially approved conditions of use of a medicine. Summaries of product characteristics form the basis of information for healthcare professionals on how to use the medicine safely and effectively
SNOMED-CT	Systematized Nomenclature of Medicine Clinical Terms (SNOMED-CT) is a systematically organized computer processable collection of medical terms providing codes, terms, synonyms and definitions used in clinical documentation and reporting.
SPOR	Substance, Product, Organisation and Referential
Stakeholders	External parties with which the network interacts: the general public, health professional organisations, Council and European Parliament, Pharmaceutical industry
Telematics Enterprise Architecture Board	The European Union Telematics Enterprise Architecture Board is the information technology architecture governance body that operates on behalf of the European Medicines Regulatory Network
Third Health Programme 2014-2020	The Programme aims to support Member States' action to improve people's health and reduce health inequalities, by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting EU citizens from serious cross-border health threats
WHO	World Health Organization
Working Party	A group of European experts that can be consulted by the European Medicines Agency's committees on scientific issues in their area of expertise. Working parties are often given tasks linked to the evaluation of applications and the drafting or revision of guidance