04 October 2018

EMA/456818/2018

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| EU Telematics Strategy 2020 – 2025 Concept Paper  European collaboration for providing efficient and high-quality information services to the European Medicines Regulatory Network and its stakeholders |
| Endorsed by Heads of Medicines Agencies in July 2018 and EMA Management Board in October 2018 |

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1. Introduction

* 1. Purpose of the Concept Paper
* The concept paper outlines the content of the future Telematics strategy 2020 – 2025.
* Its purpose is to assure that there is adequate top-down strategic direction for the development of the strategy and that all relevant strategic aspects are addressed.
* The concept paper, once approved by HMA and the EMA Management Board, will serve as direction for bottom-up consultation and as a foundation for developing the Telematics strategy 2020-2025.
  1. Need for the Telematics strategy 2020-2025
* The current Telematics strategy covers the period from 2015 to 2017;
* The current Telematics implementation roadmap will continue throughout 2018 and 2019, in part driven (and impacted) by the relocation of the Agency;
* The [EU Medicines Agencies Network Strategy to 2020](http://www.hma.eu/fileadmin/dateien/HMA_joint/02-_HMA_Strategy_Annual_Reports/08_HMA_Publications/2015_12_Adopted_EU_Medicines_Agencies_Network_Strategy_to_2020.pdf) is not reflected in the current strategy and provides guidance on the strategic business priorities of the European medicines regulatory network (‘the Network’); and
* As a result, and taking into account planning and budget cycles, the Network should now start developing a new Telematics strategy beyond 2019 to ensure that the vision for information management and technology is clearly described and appropriately represents the business needs of the Network.
  1. Process for developing the Telematics strategy

The process for updating the Telematics strategy:

1. HMA and EMA Management Board adopts the concept paper (the paper outlines the content of the future Telematics strategy);
2. Bottom-up consultation led by the EUTMB and ITDEC on the basis of the concept paper involving the following groups within the Network:

* CMDh, CMDv and EMA’s scientific committees to ensure regulatory science needs are adequately covered;
* Regulatory optimisation group (ROG) to ensure that the priorities in terms of process optimisation are understood;
* HMA Task Force on Big Data to ensure that Telematics builds the required data analytics capabilities;
* Telematics Change Management Board to ensure that the strategy takes into account the needs for continuous improvement of existing Telematics systems;
* The IT Directors Group to ensure technology and IT budget constraints are taken into account;
* The European Commission to ensure the Telematics strategy is future proof with respect to the evolution of EU legislation.

1. Consultation of stakeholders (e.g. pharmaceutical industry);
2. Following the consultation, the EUTMB assesses business priorities in light of the strategic direction defined in the concept paper;
3. On the basis of business priorities, Telematics Enterprise Architecture Board in collaboration with the EU Network Data Board review and finalise the information and technology contributions proposed initially in the concept paper;
4. EUTMB with help of ITDEC draft the Telematics strategy including a model for the funding of and human resource contribution to the Telematics programme;
5. Consultation on the Telematics strategy via IT Directors Group, Industry stakeholders, HMA and EMA Management Board;
6. Endorsement by HMA and EMA Management Board;
7. EUTMB with help of ITDEC develop the Telematics strategy implementation plan (i.e. roadmap) including financial and human resource plans;
8. Once endorsed by HMA and the EMA Management, the Telematics strategy implementation plan will serve as the basis for updating any required more detailed roadmaps and plans (e.g. eSubmission roadmap).

2. Business Context for the future Telematics strategy

* The European Medicines Regulatory Network (the Network) continues to be a unique collaborative model with over fifty national regulatory authorities for both human and veterinary medicines;
* The implementation period of the current Telematics and Network strategies will likely see the UK leave the EU and thus the Network and the relocation of the European Medicines Agency;
* The implementation period will cover the implementation of the new Veterinary Regulation and the Implementation of the new Medical Device Regulation (MDR);
* Following this period of change the Network will emerge having maintained and enhanced its capabilities (current Network/Telematics strategy), for example delivering towards the objective of support for patient-focussed innovation through its implementation of the Clinical Trials regulation, but also facing new challenges and operational constraints;
* It is likely that a number of programs started by the Telematics strategy 2015-2017 will be carried forward into the future strategy with clear plans for transition and evolution; and
* The Network will continue to face emerging business operational and regulatory challenges, for example the implementation of further legislative or regulatory changes, limited capacity of the Network in the face of increasing complexity of regulatory decision-making, the continuous need for better and safer new medicines, and maintaining trust of patients and healthcare professionals in times of increasing information – and mis-information – about treatments and medicines.

3. Lessons Learned from the current Telematics strategy

The future strategy should be based on what was achieved by the EU Telematics strategy and implementation roadmap for 2015 – 2017 and address the top lessons learned from this implementation which are:

* The heterogeneity of the Network results in complex and extensive requirements that need to be implemented resulting in costly solutions to satisfy needs of all NCAs, i.e. NCAs in charge of human medicines, NCAs in charge of veterinary medicines, NCAs in charge of both human and veterinary medicines, small and large NCAs, different national legislations, different mandates of NCAs (e.g. some NCAs are also in charge of medical devices), etc. Complex solutions increase timeframes, costs and risks of delivering Telematics solutions. Business process alignment is difficult or does not happen requiring local solutions on top of Telematics solutions. It also makes understanding of what are the right common Network requirements difficult.
* There are significant differences in business and IT capacity and capability across the Network of NCAs so that not all NCAs can equally engage in and support Telematics initiatives and business and IT experts involved do not have the knowledge and authority to represent the Network for defining requirements and making decisions.
* Telematics initiatives are mostly funded by EMA or by single NCAs who can only recoup their investments once the services are available via payments by individual Agencies. The lack of Network funding for Telematics requires over-reliance on EMA. Except for IT required to operate the pharmacovilance legislation for which the EMA can charge a fee, Telematics initiatives are funded from EMA’s overall income.

4. Business strategy of the Network and priorities

To effectively respond to the Network’s challenges and building on the [EU Medicines Agencies Network Strategy 2020](http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000292.jsp&mid=WC0b01ac05800293a4), the three top strategic business objectives of the Network identified by the EU Telematics Management Board following the think tank workshop on the Network business needs are:

* Better and more effective regulatory decision making in the Network;
* Facilitate research and development (R&D) in Europe;
* Build trust in medicines by empowering patients, animal owners and healthcare professionals.

Telematics is a key enabler to deliver these Network objectives which will have to be reviewed in light of future updates of the Network Strategy. In this context the Network’s vision is that EU Telematics is the 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.

5. Strategic choices: business and Telematics changes

To determine how Telematics can contribute effectively to the Network’s strategic objectives, it is important to first decide which business activities of the Network will need to be maintained, grown and reinforced to meet the Network’s objectives. To be undertaken, activities typically require a combination of resources, competencies, processes, information, and technology: all these elements need to be taken into account when defining the required business and Telematics changes.

Additionally, these existing business activities will be strongly impacted by a number of events in the coming years and this should also be considered. In particular, the Network will need to complete investment in operationalising the requirements of new or revised legislation for Clinical Trials, Pharmacovigilance, Veterinary medicines, fees and medical devices. It will need to invest in optimising business processes by maximising the benefits that can be gained from better use of information and technology, as well as becoming more agile and collaborative in order to cope with the demand of doing more with the same amount of resource.

The following table describes how Network business activities will need to be changed and improved.

| **Strategies Business Objectives** | **Network activities[[1]](#footnote-1)** | **Essential Business changes to achieve the strategic business objectives** |
| --- | --- | --- |
| Better and more effective regulatory decision making in the Network | Coordinate the Network  Manage Business change & shared initiates  Manage Data & Provide Data Services  Authorise Human & Veterinary Medicines  Assure Safety & Efficacy of Medicines  Assess & Enforce Compliance and Standards  Provide Information, Training & Guidance | * Achieve more consistent regulatory decisions by enabling more effective access to past, relevant material and decisions and through increasing use of shared data. * Strive for more consistent quality in the initial assessment reports by increasing scientific expertise through training and by shifting from administrative work to more assessment work. * More efficient and effective allocation of experts to assessment work for which their expertise is required. * Become able to do more with the same number of people through reducing administrative work and streamlining activities by optimising processes with use of process support systems and by considering a possibility of outsourcing ancillary processes to third party suppliers, if necessary, to free up internal resources. * Reduce duplication across the network by increasing collaboration and sharing of information and data, but not by focusing on processes. * Optimise work by taking a risk based/outcome based approach to prioritising work and activities, where appropriate, instead of increasing staff (or making other investments) |
| Facilitate Research and Development (R&D) in Europe | Enable & Foster Research and Development | * Develop multiple approaches for supporting research and development; such support and ease of access to it should be adapted to whether R&D is for commercial or academic purpose and public health priorities (e.g. rare diseases). * Facilitate the conduct and transparency of multi-centric trials in Europe. * Share and make better use of the data available at EMA and NCAs and improve analytics capability of the Network to support regulatory science activities. * Define strategic goals for the utilisation of real world evidence and artificial intelligence. * Foster the sharing of standardised anonymised R&D data by companies in pre- or non-competitive areas to reduce duplication and facilitate R&D. * Make anonymised data held by Agencies publicly available to support R&D. * Facilitate networks of investigators across Member States. * Simplify requirements to reduce animal testing and increase ability to extrapolate data obtained in animals to humans. * Facilitate enrolment of individuals in clinical trials |
| Build trust in medicines by empowering patients, animal owners and healthcare professionals | Provide Information, Training & Guidance  Engage & Manage Stakeholders | * Improve the quality of product information. * Provide timely access to comprehensive, quality, tailored and targeted information on medicines and their availability * Provide contextual information on associated regulatory science concepts and methodologies. * Provide timely information and reliable information in emergency situations (e.g. shortages, public and animal health threats). * Provide information on the grounds for regulatory decisions in a transparent manner using communication channels and formats adapted to the target audience. * Strengthen the Network’s capability to engage in a coordinated and collaborative manner. * Increase efficiently the ability to involve stakeholders in decision making. |

The following table describes how Telematics contributes to the business changes. These contributions are a combination of delivery of actual information and technology services (bold), principles of delivery and capability building activities.

| **Strategic business objectives** | **Business changes** | **Information and Telematics Contribution**  **(in order of priority)** |
| --- | --- | --- |
| Better and more effective regulatory decision making in the Network | * Achieve more consistent regulatory decisions by enabling more effective access to past relevant material and decisions and through increasing use of shared data. * Strive for more consistent quality in the initial assessment reports by increasing scientific expertise through training and by shifting from administrative work to more assessment work. * More efficient and effective allocation of experts to assessment work for which their expertise is required. * Become able to do more with the same number of people through reducing administrative work and streamlining activities by optimising processes with use of process support systems and by considering a possibility of outsourcing ancillary processes to third party suppliers, if necessary, to free up internal resources. * Reduce duplication across the network by increasing collaboration and sharing of information and data, but not by focusing on processes. * Optimise work by taking a risk based/outcome based approach to prioritising work and activities, where appropriate, instead of increasing staff (or making other investments) | 1. Continue to build **Master Data Management services** [[2]](#footnote-2)delivering open and quality data services on Substances, Products, Organisations and Referentials with agreed level of data scope, quality and standardisation.    1. Support data consistency by ensuring that EMA and NCA IT systems and processes are compliant to agreed standards, including security standards. 2. Provide ways for **sharing assessment reports**. 3. Make collaboration easier and more streamlined by introducing modern collaboration tools (e.g. replace EudraLink) 4. Reduce administrative burden by promoting the functionality of existing IT systems [training]. 5. Support the Network when new standards need to be implemented, such as e.g. eCTDv4 or when existing standards should be expanded to cover additional domains (e.g. Veterinary or Human).  (a) Impact analysis for regulators and taking into account feedback from industry; and  (b) providing reliable implementation timelines and implications 6. Introduce technical standards to facilitate automated data and document exchange to reduce administrative burden on data management. |
| Facilitate Research and Development in Europe | * Develop multiple approaches for supporting research and development; such support and ease of access to it should be adapted to whether R&D is for commercial or academic purpose and public health priorities (e.g. rare diseases). * Facilitate the conduct and transparency of multi-centric trials in Europe. * Share and make better use of the data available at EMA and NCAs and improve analytics capability of the Network to support regulatory science activities. * Define strategic goals for the utilisation of real world evidence and artificial intelligence based on strategic goals. * Foster the sharing of standardised anonymised R&D data by companies in pre- or non-competitive areas to reduce duplication and facilitate R&D. * Make anonymised data held by Agencies publicly available to support R&D. * Facilitate networks of investigators across Member States. * Simplify requirements to reduce animal testing and increase ability to extrapolate data obtained in animals to humans. * Facilitate enrolment of individuals in clinical trials. | 1. Deliver, maintain and improve the **Clinical Trials system**. 2. Make **anonymised safety data from Eudravigilance** more publicly available. 3. Develop the Network’s skills (by running proofs of concept) on big data and artificial intelligence for data analysis based on agreed areas if application (e.g. safety of medicines). 4. Agree principles of ‘open data’ and the use of global data standards to facilitate sharing R&D data. 5. Provide access to complete **analytics solutions** allowing the Network to store, share and analyse large datasets; consider Cloud solutions for this purpose. |
| Build trust in medicines by empowering patients, animal owners and healthcare professionals | * Improve the quality of product information. * Provide timely access to comprehensive, quality, tailored and targeted information on medicines and their availability * Provide contextual information on associated regulatory science concepts and methodologies. * Provide timely information and reliable information in emergency situations (e.g. shortages, public/veterinary health threats). * Provide transparently information on the grounds for regulatory decisions using communication channels and formats adapted to the target audience. * Strengthen the Network’s capability to engage in a coordinated and collaborative manner. | 1. Continue to build **Master Data Management services**[[3]](#footnote-3) delivering open and quality data services on Substances, Products, Organisations and Referentials with agreed level of data scope, quality and standardisation.    1. Deliver the European Medicines Web Portal. 2. Support the business by providing more digital ways of managing electronic product information. 3. Provide services for sharing high quality authoritative information on medicines in structured and standardised open formats so that it can be consumed by other systems for further processing, distribution and for providing value adding services. 4. Provide data services related to emergency situations (e.g. shortages, public and veterinary health threats) in structured and open formats so that it can be consumed by other systems for further processing, distribution and for providing value adding services. 5. Provide ways for the Network to have access and ability to collaborate on the latest correct information on medicines (e.g. recalls, shortages, safety alerts.). 6. Provide services to the Network with technology that provides more effective **ways of engaging stakeholders**. |

6. Telematics collaboration

Success of the Telematics strategy will require:

* Making transparent contributions to business cases and cost and resource implications of Telematics changes also taking into account the diversity of the Network.
* Ensuring that Telematics initiatives deliver end-to-end business change.
* Ensuring that Telematics initiatives deliver business outcomes, making sure that processes work end-to-end.
* Commitment from all NCAs that they will use Telematics systems that are agreed to be developed and contribute to the improvements/development of Telematics systems which requires financial investments and human resources;
* Greater commitment and adherence to Telematics Governance (e.g. provide dedicated resources to work with the bodies of the Telematics governance structure); Raising awareness and enhancing understanding of Telematics to partners and stakeholders to support a better integration of business and IT;
* A review of the way the Network delivers and maintains Telematics services: in terms of:
  + How the Network runs projects: governance, execution (outsourcing (e.g. EMA responsible to engage with service suppliers), security, etc.)
  + Developing a funding model which allows co-financing (EMA and NCA) of Telematics systems. This may imply the creation of a Telematics fund managed by a portfolio body.
  + Selecting appropriate platforms and architecture (service provider vs. SaaS)
* Consultation and involvement of stakeholders outside the Network so they are able to rely on Telematics services to support initiatives such as e-prescription or cross border eHealth.

Therefore, in addition to pursuing the realisation of business objectives, this strategy will also pursue the objective of establishing Telematics as a key enabler of the strategy:

|  |  |  |
| --- | --- | --- |
| Strategic Telematics objective | Telematics collaboration changes | Contribution of the Telematics governance |
| EU Telematics as a key enabler | * Support the optimisation and standardisation of business processes across the Network so that they can be effectively supported by Telematics systems. * Ensure EU Telematics implementation projects are defined to be able to meet functional and non-functional requirements, timelines and budget constraints. * The EU Telematics strategy is a guideline for NCA and EMA to define national IT strategies. * Harmonise and optimise the EU Telematics system landscape. * Make transparent contribution to business cases and cost and resource implications of Telematics changes also taking into account the diversity of the Network. * Ensure that Telematics initiatives deliver end-to-end business changes. * Ensure access to Telematics systems and information by providing both human interfaces and application programming interfaces. | * Optimise the model for governance, funding, implementation, maintenance and operation of EU Telematics services to support the strategic goals. * Provide guidance and advice to inform the definition and agreement of legislation and implementing acts so that implementation can more effectively be supported by Information and Technology to meet required timelines and within budget constraints. |

7. Strategic principles, risks and metrics

7.1 Principles

The Telematics strategy will define a number of strategic principles to guide decision-making and governance to ensure that the Telematics strategy remains on track to deliver business objectives. Such principles will in particular guide decisions on project approach, scope and design for the delivery and provision of Telematics solutions.

7.2 Strategic metrics

The Telematics strategy will define key metrics to track execution of the strategy and measure the contribution of Telematics to achieving the strategic objectives. For instance: ‘better and more efficient regulatory decision making in the Network’ could be measured in terms of reduction in FTEs required to execute a volume of regulatory applications.

Strategic metrics are high level metrics and complemented by more specific project benefit realisation metrics defined in the context of specific Telematics projects (e.g. process efficiency metrics).

7.3 Risks

Potential barriers to successful delivery of the strategic business objectives are:

| **Business vision** | **Risks (consolidated across the 2 workstreams aiming to focus on most critical risks)** | **Risk response** |
| --- | --- | --- |
| Better and more effective regulatory decision making in the Network | Lack of participation and collaboration | - Identify all actors  - Improve Communication  - ROI / Demonstrable benefits  - Optimise governance  - Conclusive results through small steps |
| Lack of strategic alignment and diverging national goals | Define areas of responsibilities  Describe opportunities for NCAs |
| Lack of :  - Alignment of practices  - Data standardisation  - Data quality | - Identify relevant information  - Focus on essential information  - Enforce standards |
| Lack of competences in the Network | - Reinforce training  - Work with externals teams  - Identify required competence  - Use NCA cluster of competences and use both IT and Business experts |
| Build trust in medicines by empowering patients, animal owners and healthcare professionals | Different expectations and goals with poor alignment and understanding of patients’ needs | - Engage stakeholders to understands their needs  - Targeted communication |
| Facilitate research and development (R&D) in Europe | Unclear scope (too complex for industry/academia) | Efficient stakeholder management |
| Data protection and data access | Seek to influence national legislation |
| Telematics as a key enabler | Lack of human and/or financial resources in the Network | Establish and manage a Telematics fund |

Annex I

The Heads of Medicines Agencies consultation on the EU Telematics strategy 2020-2025 Concept Paper resulted in comments from MHRA (UK), FIMEA (Finland), AEMPS (Spain) and BVL (Germany). These additional considerations, summarised below, will be taken into account while developing the EU Telematics strategy 2020-2025 and its implementation plan.

**Telematics strategy**

* Define governance and funding model (e.g. how Telematics changes will be funded) as well as the delivery and sourcing approach in the sense that different participants of the Network may deliver individual services.
* Consider level of ambition (is it too ambitions/not ambitions enough) and provide specific examples in either direction.
* Involve pharmaceutical industry in the strategy development.

**Implementation plan**

* Visualise what the implementation plan is intending to deliver.
* Categorise activities into non-discretionary (e.g. legislation driven activities or external commitments already made), discretionary (e.g. building the capability of the Network), and essential and major maintenance activities.
* Consider residual impact of the EMA relocation in 2020 and beyond.

**Telematics services**

* Consider whether Telematics services should be enriched centrally or whether standardised APIs should be provided to allow enrichment of data locally.
* Promote providing of well-defined standard interfaces to facilitate the interoperability between Telematics and national systems.
* Consider whether sharing of technology and technology experiences should continue and should be increased and facilitated.

1. Although synergies exist across activities, priorities are mapped to the business capabilities where there is most impact. [↑](#footnote-ref-1)
2. Master data management (MDM) provides a single location for managing master data (i.e. the four SPOR domains) that are critical to EU regulatory network processes. SPOR data is stored, shared, analysed, transformed and consumed by different business processes as a service. SPOR data alone has limited business benefits, unless if it is integrated with business processes (e.g. ROG recommendation for simplification of type IA variations, signal detection in Pharmacovigilance). [↑](#footnote-ref-2)
3. Master data management (MDM) provides a single location for managing master data (i.e. the four SPOR domains) that are critical to EU regulatory network processes. SPOR data is stored, shared, analysed, transformed and consumed by different business processes as a service. SPOR data alone has limited business benefits, unless if it is integrated with business processes (e.g. ROG recommendation for simplification of type IA variations, signal detection in Pharmacovigilance). [↑](#footnote-ref-3)