EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management Division

Information Management Strategy 2019-2021

EMA's strategy for providing high-quality information services to staff, partners and stakeholders

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See the appendix 8.1 for an explanatory note on the structure of this strategy document.

1. Executive Summary

- This strategy is intended as a short, high-level and business-oriented description of how EMA will achieve its mission and business objectives for the protection of human and animal health through the use of information and technology. The document covers a period of three years and full delivery of the strategy is expected to take 5-7 years. It will be adjusted annually to respond to EMA's changing and evolving environment.
- It is a progression of the *'EMA Information Management strategy'* endorsed in 2015 by the EMA Executive Board and the EMA Management Board.
- Although it is presented as a self-standing document, the relevant information in this document is integrated into EMA multiannual work programme and any other EMA business strategy documents.
- EMA's relocation outside the United Kingdom and accompanying loss of staff – and therefore capacity, skills and knowledge – constitutes a considerable risk to the realisation of this strategy, potentially delaying significantly the timeframe for realisation of business benefits.
- The scope of information services provided by EMA is growing with new legislation. This is an issue of increasing importance since the budget and staff required to maintaining the growing IT and data services are considerable and in the long term this situation must be addressed.
- The strategy:
    - aims at maintaining operational stability of EMA's core activities and services while relocating the Agency and its data centre outside of the United Kingdom;
    - seeks to minimise change during and around relocation;
    - aims to upgrade EMA's IT underpinning core regulatory and administrative activities to ensure that the Agency can continue to fulfil its duties and support the Network in a sustainable manner, to enable process optimisation and to meet higher technical and information security standards;
    - attempts to solve IT resource constraints through making use of cloud services and through moving from time and means contracts to outcome-based fixed price contracts;
    - implements new legislative requirements such as data protection regulation and, subject to the limits of the resource and financial constraints that are set for the Agency, the clinical trial, the pharmacovigilance, fees, veterinary, and medical devices legislations;
    - enables the business to benefit from process optimisation by putting in place a platform on which to bring together business processes and related data including scientific knowledge;
    - enables digital ways of working, better collaboration and information security through putting in place a single collaboration platform that integrates what is delivered today via multiple solutions;
    - puts in place Master Data Management to support initiatives like data integration at EMA and Telematics; and
    - puts in place better data analytics to enable more data-driven decisions in the EMA committees and in the management of the Agency and seeks to benefit from the opportunity of the EU environment of real-world data.

2. Business context and the operating environment

The European Medicines Agency (EMA) promotes and protects public and animal health in EU Member States, as well as the countries of the European Economic Area, by ensuring that all medicines available on the EU market are safe, effective and of high quality. EMA serves a population of approximately 500 million citizens living in the EU.

EMA operates at the heart of the European medicines regulatory network (the Network) a unique collaborative model between over fifty national regulatory authorities for both human and veterinary medicines in the European Economic Area, EMA and the European Commission. This Network has access to thousands of experts from Member States across Europe, allowing it to source the best possible expertise for the scientific evaluation and regulation of medicines in the European Union (EU). In this collaborative model, EMA provides essential information services – so called Telematics services. As such, EMA operates as a provider of information services to the Network. As the scope of these information services grows with new legislation, increasingly, this is reflected in EMA's expenditures on information services in proportion to the overall budget of the EMA.

EMA also operates in a constantly changing and evolving environment. Factors such as developments in the pharmaceutical industry, globalisation, the growing complexity of medicines development, digital transformation of society and regulation, stakeholder requirements for transparency, legislative changes and resource constraints on EU institutions all impact how the EMA works. Furthermore, work of the EMA-HMA Joint Big Data Task Force and on the EMA Regulatory Science Strategy has demonstrated the huge potential role of big data, including real-world data, in support of regulatory decision-making. Given this dynamic and fluid operating environment, EMA needs to regularly review existing plans and recalibrate its priorities, objectives and operating model to meet emerging needs.

Relocation of EMA

Following the triggering of Article 50 by the United Kingdom in 29 March 2017, EMA will relocate to a temporary building and then to a final building in Amsterdam in 2019. During and around the period of relocation EMA is required to ensure continued delivery of its mission despite likely significant loss of staff and expertise during the relocation period. In this context relocating EMA's IT infrastructure within tightly set timelines and maintaining continued secure IT services will be a major challenge. Priority given to business continuity in the absence of additional human resources will significantly delay delivery of the IT components of new legislation and EMA's IM strategy.

Operational constraints

EMA oversees an ever-growing list of often complex business processes. In addition, it provides IT and data services to support business processes across the Network. As such there is a desire internally and among the Network and stakeholders to standardise sometimes disparate business processes and to bring data and information together and make it available in a more actionable way. There is also an increased expectation among users to have services that are easy-to-use and constantly available.

At the same time, EMA will be understaffed during its relocation while continuing to operate in a zero growth environment with an increased focus on value for money. EMA has been and is significantly constrained in recruiting the necessary number of highly skilled IT and data professionals to fulfil business demand and adequately manage the growing complexity of IT and data services it provides. The budgetary and staff required to maintain and grow IT and data services is considerable and in the long term, is considered unsustainable. Therefore, while recruitment of additional talent is necessary the EMA has also to consider adapting to new technologies and new IT delivery options such as cloud services in order to leverage greater efficiencies with available resources.

3. EMA strategic priorities for information management

From the perspective of information management, and while it will continue to strive to pursue its role in delivering the Network strategy to 2020 and strategic priorities as described in its work programme, EMA's business strategy is to:

1. Successfully **relocate EMA's operations** outside the United Kingdom while assuring business continuity in carrying out its mission to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health.

2. **Maintain and improve operational excellence** as a recognised reference medicines regulatory authority with a focus on efficiency in light of EMA's staff capacity and particular emphasis on:

    - **Fulfilling legislative obligations in the context of evolving workload and increasingly complex environment.** EMA is a demand-driven organisation and a main driver is the flow of new or revised EU legislation. Its continually growing portfolio of activities and products as a result of legislation translates into additional workload in post-authorisation, pharmacovigilance and supervision activities.

        - The priority will increasingly become investing in and optimising the Agency so that it continues to be able to accommodate existing obligations in a sustainable manner, and depending on an increase in capacity also new obligations, in the context of evolving workload and an increasingly complex environment.

        - During relocation of the Agency, delivery of legislative requirements that the Agency has already committed to will remain a priority. However, the Agency has put some initiatives, such as the European Medicines Web Portal on hold as part of its published business continuity plan.

    - **Stakeholder involvement and transparency.** EMA has formal frameworks in place to foster interaction and involvement of stakeholders in its regulatory processes.

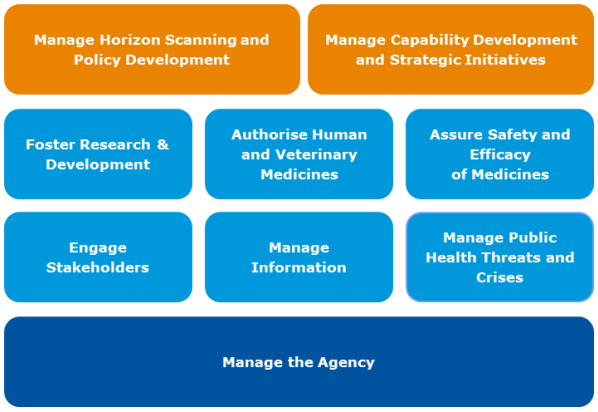
3. **Deliver, upgrade and maintain effective and secure information services.** Information Management is an essential capability for the efficient and effective undertaking of virtually all regulatory activities by the European Medicines Regulatory Network (NCAs, EMA and EC) and for managing and sharing information on medicines to promote and protect public and animal health. The Network relies on IT services provided by EMA to support activities related to the authorisation and supervision of human and veterinary medicines in the EU. In this context, EMA operates a unique collaborative model focussed on building and providing access to IT systems that enable legislative mandates to be fulfilled and promoting effective cooperation between the different parts of the Network (e.g. by reducing duplication and cost of developing and maintaining local IT systems) and stakeholders (e.g. by providing a unified way for industry to interact with regulators in the EU). To date, EMA is the main provider of these information services and is responsible for ensuring availability and usability of these services to the Network and stakeholders. To ensure sustainability of the information services it provides as well as its operations, it is essential that EMA has and dedicates the necessary resources to upgrading the information services it provides to meet required technical and information security standards. This will also benefit public and animal health by enabling data and information managed by EMA to be leveraged by the network for better decision-making.

4. Strategic choices

4.1. Business capabilities

To determine how EMA needs to evolve in order to achieve its strategic objectives and therefore how information and technology need to develop to support this, it is important to consider the Agency's business capabilities.

Business capabilities are the combination of resources, competencies, information, technology, processes and their environments. The EMA business capability model[1] identifies a number of key business capabilities defined in the graphic below (see also Appendix 9.2 for additional descriptions):



The EU Medicines Regulatory Network is the cornerstone of the Agency's work and thus an integral part of all the Agency's business capabilities.

In order to achieve EMA's strategic priorities described in the previous chapter as well as the demands of the relocation, EMA business capabilities will need to be maintained, grown and reinforced.

Additionally, these existing business capabilities will be strongly impacted by a number of events in the coming years and this should also be considered.

During the relocation period, maintaining operational stability of EMA's core activities will be the priority. The Agency will need to improve its ability to attract and recruit new staff since significant recruitment activity is necessary as a consequence of the relocation.

Furthermore, subject to the limits of the financial resource constraints set for EMA, EMA will need to invest in operationalising the requirements of new or revised legislation for Clinical Trials, Pharmacovigilance including the European Medicines Web Portal, fees, the new Veterinary medicines, medical devices legislations. 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 table on pages 8 and 9 describes how these nine business capabilities will need to be changed and improved.

[1] This is EMA's current business capability model, which may need to evolve as EMA adapts to an ever-changing business environment.

4.2. Information and technology

EMA information and technology investments fall into three broad categories of activity. In order of priority these are to:

1. **deliver external commitments**, for example implementing new legislative requirements;
2. **maintain operational stability** and to continue to be able to deliver on existing commitments, for example maintaining and upgrading technology underpinning current regulatory processes;
3. **build the capability of EMA**, for example investing in technology that enhances the Agency's ability to deliver on its commitments, and thereby the capabilities of the Network.

Through the disciplines of enterprise architecture and portfolio management, EMA will strive to invest strategically and find commonality across categories of initiatives. It will continue to rationalise business applications into a set of re-usable information services and enable this by putting in place a set of flexible technology platforms.

Recognising that EMA has limited resources, the Agency will seek to leverage economies of scale and the predictable, repeatable nature of commodity cloud services to enable it to better meet demand. EMA's cloud strategy is to adopt Software as a Service (SaaS) opportunistically where there is value and where the right controls are in place and, over the longer term will transition application and infrastructure platform services to a cloud-based provisioning model. By doing this, EMA will become a broker of information services: some provided through internal IT operations, some provided by public or private cloud providers and some provided by the European Commission or via the Member States of the European medicines regulatory network.

During and around the relocation period, the priority will be to: support the relocation of EMA data centre facilities, support the work to equip the new premises, upgrade technology to meet required technical and information security standards, improve internal communication and collaboration, and reconfigure existing business applications and services to cater for the new composition of the European Union.

To ensure sufficient capacity prior to the relocation, only essential maintenance will be undertaken on legacy business applications. In addition, existing investments will continue and new investments will be made to support legislative requirements to which EMA has already committed to and to build the capabilities of EMA. Investments in new technology will be aligned with the EMA cloud strategy and post-relocation cyclical maintenance will also be aligned with the cloud and data centre strategies.

During these years of innovation and renovation, EMA will continue to improve existing services by working closely with business owners and user communities on identifying enhancements and opportunities, and improving usability. It will continue to work with the Network and stakeholders including suppliers to protect its systems, networks and data from malware and other cybersecurity threats by strengthening existing measures and providing best practice advice to users. Such collaborative work will also ensure that the Agency is informed and ready to address the opportunities provided by big data including real world data. Finally, work will continue on building strong relationships within the Telematics bodies in order to ensure that Telematics services meet the needs of the Network.

The table on page 9 outlines the investments in information and technology capabilities required to ensure that EMA's business capabilities can effectively deliver the business strategy. These changes will introduce new ways of working within EMA and with partners and stakeholders.

Business Strategies	Business Capability[2]	Changes and improvements
Support to innovation and addressing scientific advancement Timely access to promising medicines Veterinary medicines	Foster Research & Development Authorise Human and Veterinary Medicines Assure Safety & Efficacy of Medicines	• Invest in EMA's ability to **foster research and development** of medicines in Europe • Build the **Network's capacity** by supporting training of experts • **Harmonise and simplify business processes** for more efficient ways of working and more flexibility in resourcing for EMA and NCAs • **Improve collaboration** internally and externally through more digital ways of working • **Invest in core regulatory processes** in order to facilitate better and more secure sharing of information across the lifecycle of medicines, break down data silos and increase flexibility in sharing resources across regulatory activities • Continue to facilitate access to data relevant to regulatory decision-making and improve business intelligence and **data analysis capabilities** for data-driven decision-making, scientific assessment and insight into regulatory processes. • Improve EMA's ability to **coordinate monitoring of safety and efficacy of medicines** manufactured and tested in Europe and internationally. Specifically through investing in the EMA's ability to **manage and coordinate inspections** and verifying compliance
Enhancing international cooperation	Manage Horizon Scanning & Policy Development	• Strengthen EMA's capability **to engage strategically and in a coordinated manner** with external stakeholders to develop policies, strategies and standards
Addressing public and animal health priorities	Manage Public Health Threats & Crises	• Continue EMA's work on **managing public health threats** and crises and invest in its capability to coordinate activities and collaborate with partners in Europe and internationally
Fulfilling legislative obligations in the context of evolving workload and increasingly complex environment	Manage Capability Development & Strategic Initiatives	• **Deliver the legislative requirements** of the Clinical Trials, Pharmacovigilance, fees legislations, data protection and, resource-permitting, the Veterinary and medical devices legislations
	Manage the Agency	• Successfully **relocate EMA**, ensuring minimal disruption in services and to staff, assuring information security and adapting the Agency and the Network to the new reality • Improve EMA's ability to **retain and attract staff** • Become **more agile and adaptable**, ranging from products and services to business and operating model • Strengthen relevant **governance processes** and **compliance with IT Service Management processes** and controls to enable a culture of continuous improvement
Stakeholder involvement and transparency	Engage Stakeholders	• Provide **location-agnostic ways of collaborating online** • Develop data validation processes to enable sharing and **re-use of referential, organisation, product and substance data product data across the Network** • Hold dialogue with stakeholders on **big data, real world data and artificial intelligence** to ensure EMA is informed on opportunities for collaboration and able to facilitate data access and analytics
	Manage Information	• Develop and implement **targeted communication frameworks**

[2] Although synergies exist across capabilities, priorities are mapped to the business capabilities where there is most impact.

Business Strategies	Business Capability	Information and Technology Contribution
Support to innovation and addressing scientific advancement Timely access to promising medicines Veterinary medicines	Foster Research & Development Authorise Human & Veterinary Medicines Assure Safety & Efficacy of Medicines	• Deliver the **Clinical Trials** system • Deliver a more integrated and modern **Productivity and Collaboration platform** to provide more digital ways of working and more secure ways of sharing information • Deliver a **Customer Relationship Management platform** to replace aging technology supporting procedures and to link together all partners and stakeholders and product-related activities and data providing a comprehensive view of the state and status of a product, company, organisation or person • Continue to build **Master Data Management services** delivering quality data services on Substances, Products, Organisations and Referentials to power EU regulatory information and data analysis • Strengthen the Business Intelligence and Analytics services and establish an Analytics Competency Centre to build the Agency's capabilities in advanced analytics, AI and robotics • Continue delivery towards one Pharmacovigilance platform supporting Human and Veterinary domains and, subject to the availability of resources, the Veterinary legislation
Enhancing international cooperation	Manage Horizon Scanning & Policy Development	• Integrate **IT and business strategic planning** and **improve Telematics planning** in the context of emerging EU legislation and the EMA Regulatory Science Strategy
Addressing public and animal health priorities	Manage Public Health Threats & Crises	• Deliver a **Productivity and Collaboration platform** to provide more digital ways of working
Fulfilling legislative obligations in the context of evolving workload and increasingly complex environment	Manage Capability Development & Strategic Initiatives	• Deliver **information services** to meet security and legislative requirements. • Meet business demand for technology change through the use of **cloud services** and transition to **new sourcing models** • Continue to actively participate in **developing and maintaining international standards for data exchange**
	Manage the Agency	• Enable the **relocation of EMA**: relocating the Data Centre, IT helpdesk, application maintenance, equipping EMA's new premises, upgrading IT systems, introducing technology for communications • **Reconfigure existing services** to cater for the departure of the UK • Undertake only **essential maintenance prior to and during relocation** and align with the EMA cloud strategy subsequently • Further **strengthen the Telematics governance processes**
Stakeholder involvement and transparency	Engage Stakeholders	• Deliver a **Productivity and Collaboration platform** to provide more digital ways of working • Deliver **improved identity and access management** for Information Services and in particular Telematics Services • Deliver **Application Programming Interfaces** (APIs) based on international standards to facilitate data exchange, and make data available to other digital platforms
	Manage Information	• Deliver a modern platform to underpin EMA's online presence, including the EU Medicines Web Portal, and deliver relevant **digital websites and workspaces** • Deliver EU data standard for electronic Product Information (ePI)

4.3. People and culture

This section provides an explanation of any changes in business capabilities, including within the information and technology landscape, which may have an impact on people and culture at EMA.

Organisational impact

Managers and staff will need to critically examine current ways of working in order to identify alignments across business areas, seek out simplification of processes and embrace the concept of enterprise-wide ways of working. Senior management and staff will need to embrace the opportunities for improved regulatory decision-making presented by analysis of real world data. Senior management and staff will need to embrace business simplification and the enterprise culture. This will require a shift in corporate culture and behaviour.

Reorganising, rebuilding and realigning the EMA's information management landscape will take time and resource. While implementation of the strategy will see regular year-on-year delivery and associated benefits, full delivery is expected to take 5-7 years. EMA will be required to keep focus despite environmental and political disruptions such as relocation outside of the UK, the appointment of a new Executive Director in 2020 and fluctuating budgets.

The introduction of improved collaborative working will enable more openness and effective feedback loops which in turn can lead to better decision-making and innovation. While technology can enable the shift to a more collaborative, open and information-sharing business culture, EMA management will need to support the change and agree to unified requirements across business areas. In addition, awareness activities promoting the benefits and goals of information sharing as well as the responsibilities and challenges of this shift in business behaviour should also be organised with staff.

Approach to innovation and change

The strategy implies a multiannual programme of work which will touch the professional life of every staff member. The focus of the business priorities on simplification, data use and sharing and collaboration is accompanied by deep technology change. Staff may be involved in project work such as requirements gathering or content migration or simply as end users needing to retrain on a new application. In whichever capacity they are involved, embracing a culture of continuous improvement, resilience to change and positive acceptance of technology change as a feature of working life at EMA will be an important factor in the successful delivery of this strategy. EMA will also need to further develop and strengthen its change management practices within programmes and projects to ensure that change is delivered effectively.

Becoming an increasingly data-driven organisation will mean growing the analytical competencies of staff which will require different types of skills. EMA will need to increase investment and organise accordingly. Equally, an objective of new technology adoption is to significantly reduce administrative and repetitive tasks such as rekeying, thereby freeing up resource for differentiating regulatory and scientific activities, compared to other organisations i.e. activities that make a medicines regulatory agency unique such as data analysis and scientific assessment. Again staff will need to be upskilled accordingly.

With the introduction of increased dissemination and sharing of data and documentation, EMA will need to further tighten its information management policies, procedures and governance to ensure that permissions-based access by EMA staff and non-EMA staff is workable against EMA's systems and applications. A move to permissions based systems access means that staff use of permission-setting and the rules governing this will need to be clearly communicated and effectively supervised.

Technology competencies are becoming core to the business and in some cases will no longer be just uniquely the responsibility of the IT organisation. This will also require training and acquiring new competencies among staff such as the ability to evaluate and respond to emerging technologies, in big data, artificial intelligence and robotics, as well as the ability to on-board and consider technology more strategically in the way EMA delivers its mission.

4.4. Ecosystem

This strategy will require a change in the way EMA approaches the European medicines regulatory network and external stakeholders including suppliers selected through procurement procedures.

In order to better serve the needs of the Network and to better coordinate and execute strategic initiatives across the Network a number of changes will be required:

- strengthening the use of existing Telematics governance processes to better enable the Network to prioritise, coordinate and realise initiatives in-line with stated strategies and priorities including more closely and robustly tracking and monitoring benefits realisation;
- better strategic planning with the Network to ensure solutions are complementary across Telematics and Member state initiatives and that they track to business needs and to move to a more integrated portfolio;
- closer monitoring of the EU legislative pipeline in order to track more closely key legislative developments and to, at an earlier stage, assess the potential impact on the Network with a view to influence the legislative process where appropriate; and
- leveraging the Network more in order to work more closely on identifying trends (including industry trends such as use of artificial intelligence and robotics) and business drivers and to develop ways of working that will allow sharing of not only scientific resources but also Information Technology resources.

The Agency will continue to work with the pharmaceutical industry through the existing structures that have been setup for these purposes.

In order to strengthen the capabilities of the Network, EMA will continue to evolve as a provider of information services by further evolving its end-user and Application Programming Interfaces (API) services through initiatives such as implementing the Clinical Trials legislation, delivering master data services for substance, product, organisation and referential data and through further development of existing services, such as the Common Repository of dossiers.

In addition, stakeholders outside of the immediate regulatory network will be able to rely on EMA services to support related regulatory initiatives such as the medical devices regulation, e-Prescription and cross border eHealth. By engaging with such stakeholders EMA will be well placed to make the case for data standards and for regulatory access to key data sources in the EU such as aggregated data from electronic health records.

In essence the EMA will increasingly be viewed as a data services provider as part of its core European regulatory role.

Suppliers

When engaging with suppliers of information and technology services, EMA will continue to transition from a strategy of contracting consultants on a 'time and means' basis to a strategy of sourcing more services via outcome-based contracts. To maintain adequate control over advice by consultants and

delivery by contractor and suppliers, EMA will continue to re-inforce its technical competence in data management, information technology, IT processes, and ability to manage contractors and service providers external to the EMA. In full compliance with procurement rules, EMA will also look to form more strategic partnerships with suppliers enabling not only improvement in delivery of services over time but also in innovation where this is of shared value.

5. IT Principles

The IT principles are informed by EMA's strategic choices for information and technology and will guide decision-making and governance to ensure that the IT strategy remains on track.

Deliver services that meet minimal requirements – then improve them

To reduce delivery risk, EMA will first deliver solutions that meet minimum requirements and that work well. Then, through incremental iterations, EMA will provide continuous improvements to these solutions. Whether driven by EU legislation or other needs EMA will always seek to deliver cost-efficient, usable services that provide clear benefits for the Network, partners and stakeholders.

Shift from isolated, process specific solutions to shared information services

As solutions are delivered, EMA will continue to establish a set of sustainable services and shift to increasingly funding continuous improvement of these services rather than projects which implement new isolated solutions. Existing, isolated solutions will be transformed and moved onto these shared services as cyclical maintenance activities become necessary, thus rationalising and modernising EMA's application landscape. Services will be based on robust information service management processes to ensure quality, continuity and sustainability.

Collaborate for the delivery and maintenance of services

EMA's iterative service-centred approach aims to establish a common shared centralised EU information technology infrastructure where components are delivered and maintained both by EMA and by EU medicines agencies. EMA will make use of solutions made available by the European Commission or established by the network of EU decentralised Agencies where these are available and where there is a good fit. The Agency will focus on those services where it has legal responsibility and where investments have demonstrated tangible value such as the Common Repository or which hold great promise for added value at EU level such as advanced data analytics and artificial intelligence. In sharing delivery and making use of shared services, EMA will optimise use of its own resources and contribute to investments in common services being of value.

To procure services at the highest level of outcome by default and that is appropriate

Since services must benefit the largest number of customers who have diverse needs, EMA will keep customisation to a minimum. This will allow leveraging ready-made and cloud solutions that require little adaptation and thereby increase certainty of delivery and reduce maintenance efforts. In adopting cloud solutions, EMA will closely monitor the European Commission's cloud adoption strategy. The Agency will provide standardised application program interfaces (API) to allow partners and stakeholders to automatically exchange information with its systems.

Maximise the intellectual capital of the EMA in support of core regulatory scientific activities

The EMA will deliver solutions that allow information to be brought together and made actionable in business processes. EMA will establish systems and processes to ensure appropriate data quality, increase the use of business intelligence and structured data to provide the right information at the

right time across the regulatory lifecycle thereby maximising the use of knowledge within the Agency, its committees and experts. The Agency will standardise the management of documents by introducing tools to automate regulatory processes and allow users to have the right process in place for the content that needs to be managed. EMA will increase the use of analytics to support data-driven decision-making at all levels of the organisation. This will include facilitating regulatory access to real world data, investing in technological and human capability and capacity to manage and analyse data and ensure that such analytics support better decision-making at EMA committees.

Optimise infrastructure and increase security

EMA will build a robust infrastructure by rationalising and modernising existing technology. The Agency will aim to reduce its infrastructure footprint, simplify the application landscape and, where possible, opt for out of the box solutions or solutions based on open source and open standards to foster interoperability. It will continuously improve information security to protect EMA's information assets, safeguard personal data and commercially confidential information, ensure compliance with legal requirements and guarantee business continuity.

6. Metrics

The Agency will develop appropriate metrics to ensure that information technology is delivering business objectives effectively. These may include key indicators around IT service incidents, project delivery milestones and frequency of security assessments and are reported in the Agency's annual report.

7. Risks and issues

Risks

In the area of risk management, EMA is following widely-recognised best practices including the Risk Management Standard[3] and the COBIT IT governance and control framework[4]. Major IT risks are aligned with EMA's strategic business objectives and relate to activity areas such as programme and project delivery, IT operations and service delivery and IT benefit/value enablement. EMA recognises some risks as a threat and others as an opportunity. For each strategic risk a mitigation plan is developed and implemented in order to ensure that the benefits of the Information Management strategy are successfully delivered.

EMA's relocation outside the United Kingdom and accompanying loss of staff – and therefore capacity, skills and knowledge – constitutes a considerable risk to the realisation of this strategy, potentially delaying significantly the timeframe for realisation of business benefits.

Issues

EMA does not provide information services for its own operations but operates as a provider of information services to the EU medicines regulatory network. As the scope of these information services grew with new legislation, IT systems grew independently of each other without an integrated approach to manage information, leading to a number of silo systems unable to exchange data and to

[3] https://www.theirm.org/knowledge-and-resources/risk-management-standards/irms-risk-management-standard/
[4] http://www.isaca.org/Knowledge-Center/COBIT/Pages/Overview.aspx

significant unaddressed technical debt[5] leading to yearly increase in IT operational costs. Increasingly, this is reflected in EMA's expenditures on information services in proportion to the overall budget of the EMA. The budget and staff required maintaining and growing IT and data services are considerable and in the long term, this situation is considered unsustainable.

Therefore, while recruitment of additional talent is necessary the EMA has also to consider i) adapting to new technologies and new IT delivery options such as cloud services in order to leverage greater efficiencies with available resources; ii) making investments to address the technical debt (i.e. "IT updgrade"); iii) reviewing the funding model of IT and data services; iv) ensuring the EMA is aware of new technology and methodology for collecting, connecting, managing and analysing data to support decision-making.

[5] Technical debt is the deviation of a system from any of its nonfunctional requirements. All systems carry technical debt. The gradual accumulation of technical debt leads to a level of suboptimal performance, such that there will be significant and measurable negative impact on business performance. Therefore, it is necessary to make continuous investments to contain technical debt.

8. Appendices

8.1. Structure of this strategy

The development of this strategy and hence this document is organised as follows:

- **Chapter 2 - Business context and operating environment:** summarises key macro-level drivers and conditions which impact Agency operations;
- **Chapter 3 - EMA strategic priorities:** describes the Agency's business priorities as understood by the Information Management Division. These inform and justify strategic choices the Agency must make for the organisation to be successful;
- **Chapter 4 - Strategic choices:** outlines:
    - the EMA **business capabilities** specifically the Agency's core activities and how these will require change and improvement to ensure business success in the coming years;
    - how **information and technology** will specifically contribute to achieve business success;
    - what the implications on **people and culture** will be as a consequence of business changes; and
    - what the approach will be towards EMA's **ecosystem** of the European medicines regulatory Network and stakeholders such as pharmaceutical industry.
- **Chapter 5 - IT principles:** outlines the principles that will guide day-to-day decision-making to ensure that information and technology will successfully enable the business strategy;
- **Chapter 6 - Metrics:** outlines how the contribution of IT to business outcomes will be measured;
- **Chapter 7** - **Risks and issues**: outlines the potential barriers to successful delivery of the information and technology solutions.

8.2. Description of EMA's business capabilities

The following table provides a description of EMA's business capabilities.

	Core Business Capability	Description
Management	Manage horizon scanning & policy development	Monitor the external environment, interpret how changes may impact EMA and the Network and, where appropriate, develop policies and strategies in anticipation of change.
	Manage capability development & strategic initiatives	Continually being able to optimise the operation of EMA and the Network, building scientific and regulatory capability and execute strategic initiatives in response to policies and strategies.
Core Regulatory science	Foster Research & Development	Provide scientific and regulatory guidance and support to human and veterinary medicine development and to ensure the European Union remains an attractive place to undertake research and develop new medicines.
	Authorise Human and Veterinary Medicines	Coordinate the scientific evaluation of marketing authorisation applications and variations for human and veterinary medicines.
	Assure safety & efficacy of medicines	Manage and coordinate pharmacovigilance activities, including risk management planning for human and veterinary medicines; coordinate inspections and process referrals.
	Engage stakeholders	Manage engagement with other regulatory authorities globally, industry, partners and other stakeholders.
	Manage information	Manage shared information on medicines for Europe for both human and veterinary medicines. Provide information on medicines to the public and to other stakeholders.
	Manage public health threats & crises	Effectively managing and coordinating the response to public health threats and crises.
Enabling	Manage the Agency	Manage human resources, finance, sourcing and procurement, facilities, legal, and other services necessary to run the Agency and to successfully participate in the EU Medicines Regulatory Network. Communication of EMA's activities.