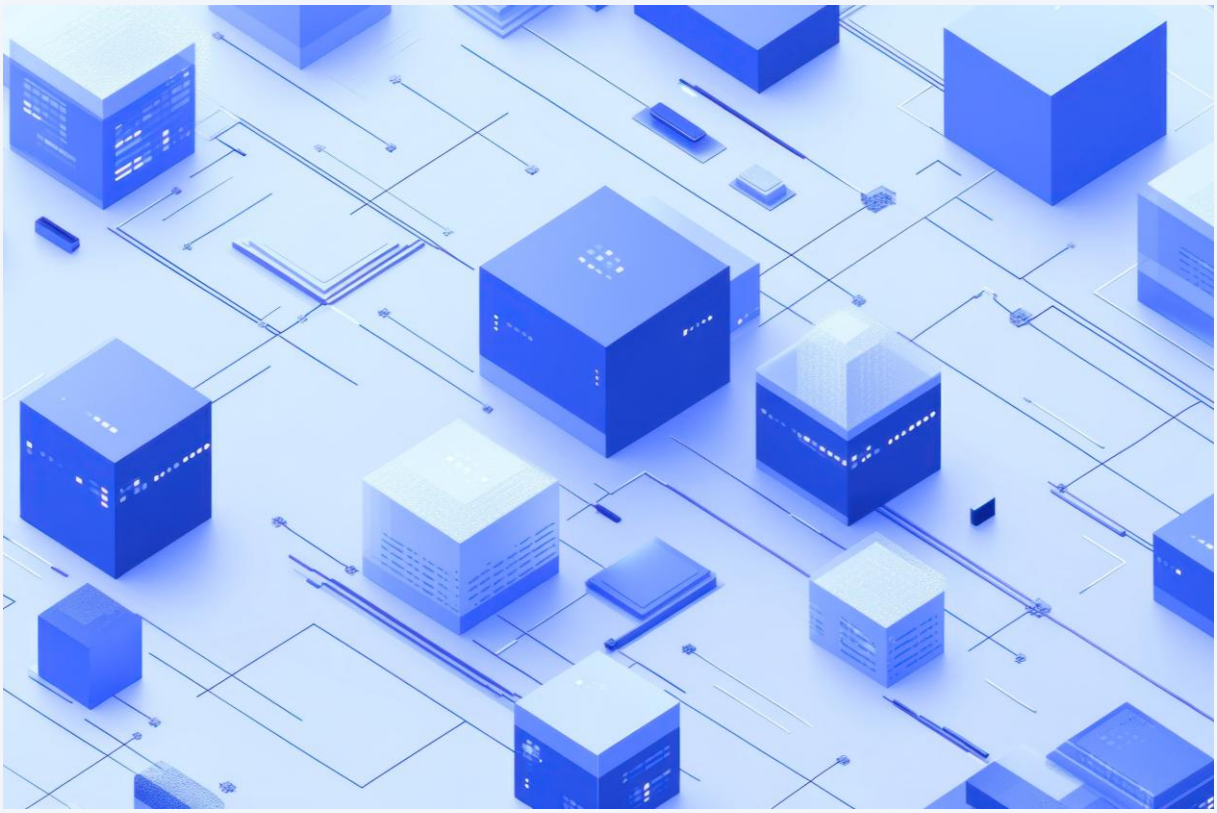
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



Technology Capability Investment Plan

Becoming the digital hub for the European Medicines Regulatory Network

Investment focus to 2028

An agency of the European Union

Table of contents

1. Introduction

The Technology Capability Investment Plan (TCIP) offers strategic direction to achieve the digitalisation objectives of the European Medicines Regulatory Network and its stakeholders. It addresses emerging information management needs arising from new legislation and supports the development of a fully digital, efficient, and data-driven Network for the future.

EMA is at a critical point, balancing the need to meet growing demand for new digital capabilities, with the goal of simplifying and modernising its IT landscape. The key drivers behind this transformation are:

- **Rising business demands:** EMA must adapt swiftly to evolving legislative requirements, particularly in preparation for the forthcoming pharmaceutical legislation, ensuring compliance and operational readiness.
- **Maximising digital investments:** EMA is moving beyond basic digitalisation, preparing for digital transformation by reimagining business models, enhancing customer experiences, and strengthening internal capabilities through digital technologies.
- **Simplifying and modernising IT landscape:** The Agency is proactively transforming its IT environment by streamlining and consolidating legacy, bespoke, and fragmented systems. This strategic modernisation will enhance operational efficiency, reduce costs, and create a more agile and scalable technology foundation to support future innovation and growth.
- **Driving innovation:** EMA is committed to accelerating the adoption of cutting-edge technologies such as artificial intelligence to transform regulatory operations and enhance decision-making processes.

This document focuses on the strategic direction for the next 3 years, resulting in key operational and technology investments to achieve it. The TCIP will serve as a guideline for the EMA Architecture Board to make recommendations regarding technology selection, technology adoption and target enterprise architecture.

This document is designed for the European Medicines Regulatory Network (EMRN), its stakeholders, and the Network IT community to provide clear insights into:

- **Driving technology modernisation:** How we will advance EMA's technology capabilities to strengthen the protection of public and animal health.
- **Enhancing the IT operating model:** How we will evolve to become more customer-centric, agile, and innovative in delivering our mission.

The Technology and Capability Implementation Plan plays a pivotal role in executing both the Agency's and Network's strategic objectives. It ensures the efficient and effective delivery of EMA's multi-annual work programme, empowering the Network to meet current and future challenges with confidence and agility.

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1.1. EMA's technology vision

EMA envisions an all-digital, modern, efficient, data-driven network of regulatory agencies, enabling seamless regulatory operations and collaboration across the EMRN. Our goal is to become a digital hub providing high-quality data and information services through a connected, interoperable regulatory platform. This vision will enable seamless interactions across agencies and ensure that stakeholders have access to the regulatory information they need.

Key influences on EMA's technology vision

- **Network interoperability:** The EMA is advancing network interoperability in line with legislative requirements, building a cohesive data-sharing environment that strengthens accessibility and ensures the effective use of health data across Europe.
- **Transition to Cloud:** EMA is modernising its legacy systems by moving to a cloud-native architecture. Through this transition, EMA is improving scalability and flexibility while reducing the costs and complexities of maintaining on-premises infrastructure.
- **Process optimisation:** The EMA is leveraging AI for breakthrough gains in efficiency and effectiveness. By embedding AI at the core of its operations, EMA can automate routine tasks, enhance decision-making processes, and improve the accuracy of regulatory assessments.
- **Data security:** The Agency is strengthening the protection of confidential and personal data as it becomes increasingly data-driven. By implementing robust security measures, the EMA is safeguarding health data against data breaches and cyber threats while ensuring the highest standards of privacy.
- **Vendor independence:** The EMA is developing a strategy to reduce the risk of vendor lock-in. By adopting open standards and interoperable solutions that prevent dependency on a single vendor, EMA is ensuring flexibility and long-term sustainability across its digital ecosystem.

Core elements of implementation

- **Integrated IT environment:** EMA is moving away from isolated bespoke applications to eliminate information silos and duplication, creating a more cohesive and connected IT landscape.
- **Platform strengthening:** The Agency is strengthening its IT platform approach to improve quality of delivery. By standardising platforms, EMA is streamlining operations, reducing technical complexity, and enhancing overall system performance. A data platform strategy is currently being adopted to make full use of advanced analytics, enabling the EMA to realise the full potential of its data, generating actionable insights and fostering collaboration among regulatory agencies.
- **Cloud migration:** EMA is continuing to migrate procedures to strategic platforms while transitioning legacy systems to a cloud-native architecture. This ensures that EMA's systems remain secure, modern and capable of meeting future demands.

- **Product-oriented organisation:** EMA is evolving from a service-based to a product-based delivery model by using proven, standard technologies to their full potential. This approach enables EMA to deliver high-quality products that better meet the needs of its stakeholders.
- **AI at scale:** The Agency is working towards integrating Artificial Intelligence across all its operations to enhance efficiency and accuracy in regulatory processes.

Strategic pillars for success

Maximising customer success

The EMA is enabling the success of the European Medicines Regulatory Network (EMRN) by focusing on stakeholder needs and delivering value more quickly through multidisciplinary, customer-centric teams. The EMA is committed to being a trusted partner for stakeholders' information service needs, ensuring reliable, timely, and relevant data is always accessible.

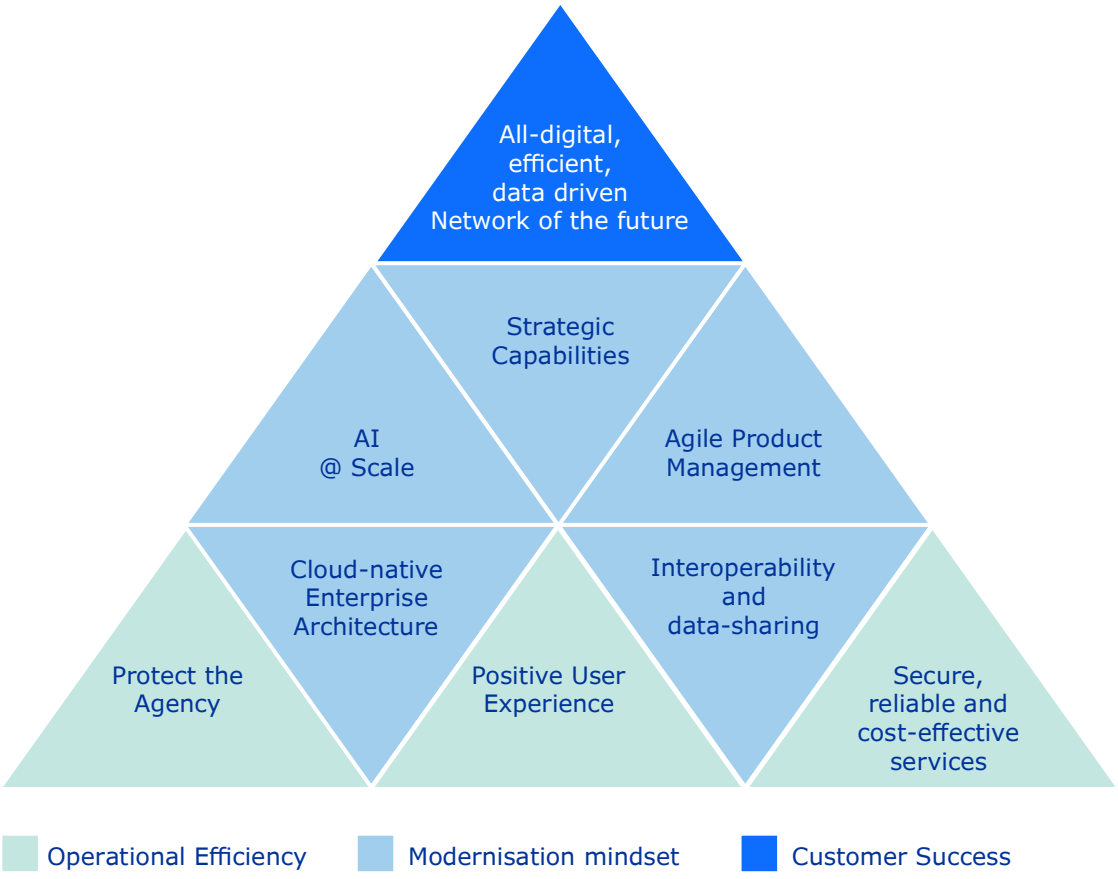
Modernisation mindset

The EMA is fostering a modernisation mindset by focussing on technology innovation and transforming delivery methods. Key processes are being migrated to secure, cost-efficient cloud platforms. Staff are being empowered to work on emerging technologies, and data-driven services are being promoted. This modernisation will strengthen EMA's agility and responsiveness to emerging challenges and opportunities.

Operational efficiency and information security

The EMA is enhancing information security, strengthening data protection compliance, and improving system performance. By applying a risk-based approach, the EMA is focussing on critical areas first, leveraging cloud services for security monitoring, demonstrating cost transparency, and strengthening critical capabilities needed in an outsourced IT delivery model. By prioritising operational efficiency, EMA is safeguarding the reliability and integrity of its digital services.

Figure 1. Overview of pillars and associated capabilities to implement the technology vision



2. Transform and innovate

2.1. Strategic capabilities

EMA provides services for the European medicines and medical device industry and regulators, and we are therefore operating within a complex, rapidly changing technology landscape. Established in 1995, the Agency has accumulated nearly 30 years of legacy IT systems and data. Many of these legacy systems are now outdated and are often no longer actively supported or developed, increasing operational risks, for example through the discontinuation of security patches. In addition, the lack of integration and standardisation across the IT landscape hampers business agility, making it more difficult to rollout new business solutions efficiently. To address these challenges, EMA is expanding the scope of its Data Analytics Platform towards a Data (Integration) Platform that will include all data, positioning the Agency to be ready for real-world data sharing and reuse of use cases as mandated by legislation and in support of data-sharing across the Network.

This chapter describes our technology and architecture vision aimed at delivering modern, secure, interoperable services to support our stakeholders as well as internal operations.

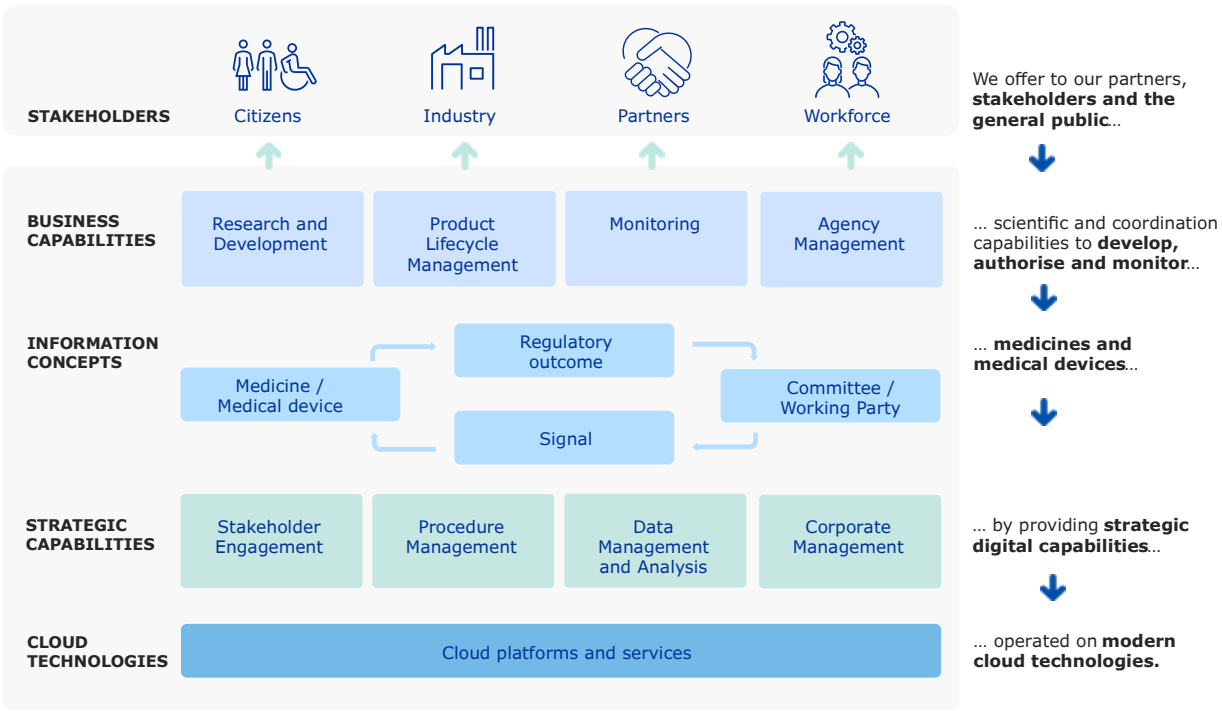
The future Information Management landscape aims at reducing complexity and streamlines how scientific and regulatory knowledge is provided to stakeholders, while supporting effective decision-making. The target architecture is based on a layered model: external stakeholders interact through the Stakeholder Experience capability, which provides user-facing interfaces.

Behind these interfaces, loosely coupled services provide secure access to data, whilst case management engines orchestrate core business processes.

Fee-generating business processes are integrated with financial services. Core business processes manage and reuse master data. Various scientific and administrative analytics services enhance decision-making, leveraging AI-services. Productivity and collaboration services provide a digital workspace for staff, contractors, and experts to create content and communicate. Finally, IT Operations underpin the entire landscape and contain systems to manage information service delivery.

The diagram below illustrates the overall target architecture.

Figure 2. Target architecture



Business capabilities

Research and Development capabilities enable early phases of the medicine or device lifecycle. Product Lifecycle Management capabilities are needed for regulatory procedure management, as well as data submission and reuse, while monitoring capabilities are ensuring medicinal products surveillance in the post authorisation phase of the product lifecycle. Agency management capabilities enable all administrative support functions.

Information concepts

The EMA provides services of different nature based on a regulatory and scientific framework to its stakeholders.

Strategic capabilities

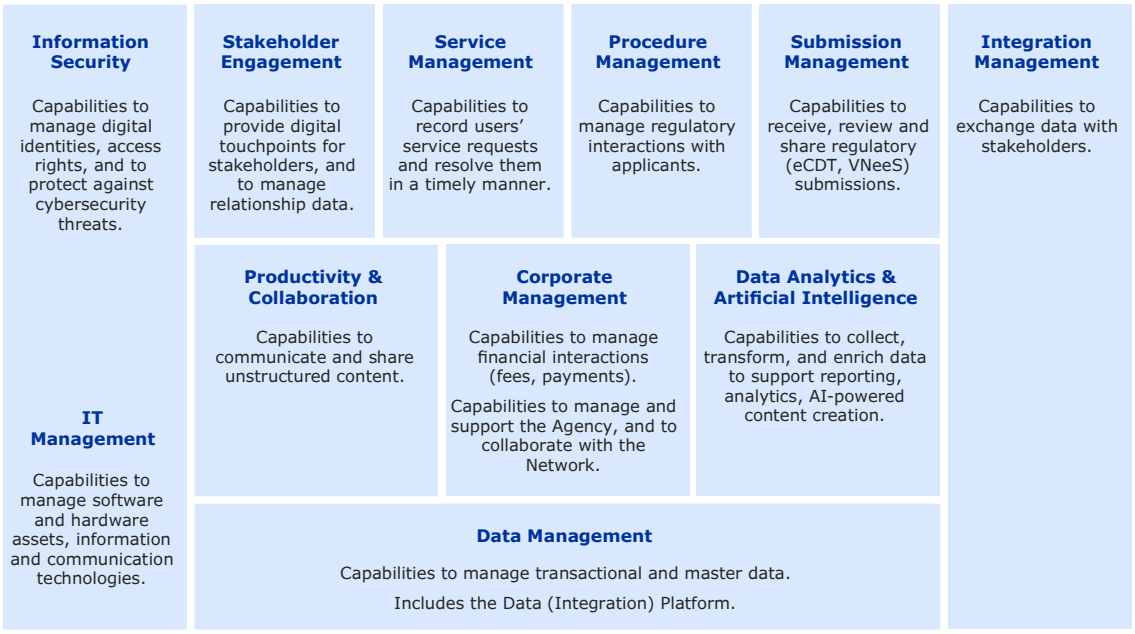
Strategic capabilities will be delivered through a set of standard, industry-leading technologies and tools that provide distinct business value that can be easily scaled and adopted across the enterprise. Strategic capabilities are not static and will evolve over time hence tools will be added, consolidated, and removed as the software market evolves. We will strive to match the process design to the technology in an efficient manner, working to the strengths of the technology.

Cloud Technologies

We leverage cloud technologies, prioritising cloud software services (SaaS) over cloud components (PaaS) over cloud servers (IaaS). Cloud services are ready to use, with providers handling maintenance and updates, so that teams focus on business goals rather than on technology. For each solution it is crucial to evaluate how it meets our specific requirements and security needs.

The overview below shows the target strategic capabilities.

Figure 3. Target strategic capabilities



The following table provides more detail on the evolution of the capabilities required for the functioning of the Agency that must be enabled by standard technology platforms:

Context	Where we want to be in 2028
Stakeholder engagement • Our current system features a variety of touchpoints and interaction methods through purpose-built portals, each utilising different technologies and user interfaces. This fragmented approach makes it challenging to gain a comprehensive view of interactions with individual stakeholders or stakeholder groups, thereby limiting our ability to effectively target specific audiences. We must advance our engagement strategies to deliver a unified, consistent user experience for national competent authorities, industry stakeholders, healthcare professionals, patients, and the public who interact with the EMA.	• We will enhance our customer relationship management (CRM) capabilities to provide a unified and consistent user experience for stakeholders engaging with EMA through its various portals and data services. Where feasible, we will leverage our current investments and technologies, maximising their benefits while consolidating and replacing legacy systems that support fragmented processes and interactions with various stakeholders. Our CRM capabilities will seamlessly integrate with our service management and procedure management capabilities, providing a 360 degree view on each stakeholder and ensuring a smooth and consistent user journey.

Context	Where we want to be in 2028
Procedure Management • Procedure management offers comprehensive capabilities for overseeing regulatory processes and interactions with applicants. Significant advancements have been achieved during the period 2022-2025 of the previous TCIP, bringing us to the cusp of the final phase. This progress paves the way for ongoing transformation and the ability to meet new legislative mandates. A multitude of regulatory procedures are now fully integrated into the platform, resulting in a unified and efficient method for managing regulatory processes and data.	• We will pursue the transition of all regulatory procedures into an integrated management platform, decommissioning legacy systems and moving from a complex transitional architecture to the target state. Additionally, we will enhance automation and incorporate embedded AI technologies to drive business transformation.
Service Management • Service management is used to manage short-term interactions with industry stakeholders, sponsors, experts, national competent authorities, and employees. Its purpose is to ensure that users' service requests are resolved in a timely manner. Currently the platform supports expert management as well as multiple IT and business processes, and it acts as a master data system for security incidents and the configuration management database (CMDB) containing key information about all systems, software and hardware assets.	• Many administrative processes and back-office (short-term) workflows can be implemented on the platform. We can use the platform when a case/workflow is not related to applicants or regulatory procedures. The vendor has a strong application marketplace; when feasible we prefer commercial out-of-the-box applications to custom implementations.
Submission Management • Submission management provides capabilities to receive, review, and share human and veterinary medicine submissions. Europe is planning to adopt eCTD v4 for human medicines. While the upgraded standard provides significant efficiency improvements for the Network, it also introduces interoperability challenges.	• We aim to provide a single submission portal for all European submissions to EMA. A modern, secure, integrated submission management platform that allows regulatory agencies to process, validate, access and view regulatory submission without the need to duplicate submissions in local repositories. This will facilitate sharing documents across dossiers and introduce shared eCTD v4 capabilities to the National Competent Authorities (NCAs).

Context	Where we want to be in 2028
Corporate Management • The corporate management capability comprises the systems and processes that support efficient and effective corporate support functions. Central to this capability are resource and financial management, complemented by facilities management as well as the coordination of events and meetings, which also encompasses visitor management at EMA.	• EMA is committed to modernising its corporate systems leveraging experience from Commission tooling, complemented by the selective adoption of cloud-based SaaS solutions where appropriate. The overarching goal is to reduce the total cost of ownership and increase automation, particularly in key areas such as Human Resources and Fees Management. • This vision will be further realised through the planned replacement of the financial system within the next five years, aligning with EMA's broader business transformation and digitalisation objectives.
Productivity & Collaboration • EMA has transformed its digital workplace through cloud-native technologies and SaaS solutions, modernizing document management and collaboration tools for internal staff and external stakeholders including experts, assessors, and NCAs. • Employee AI is emerging, and pilot initiatives on AI-assisted productivity tools for document drafting, meeting summarization, and data analysis have been explored.	• Recent initiatives have reshaped information flow and decision-making. The ongoing records management system replacement enables automated retention policies and modern governance while addressing regulatory compliance and user experience needs. • The next focus is on external collaboration, which requires secure access with information boundaries, standardized communication channels, and audit trails while accommodating diverse technical capabilities and security clearances. • The Agency pursues integration across productivity tools and service platforms to ensure consistency. This includes stakeholder-specific training and intuitive interfaces to maximise adoption, creating a connected ecosystem where teams and partners co-create value seamlessly while maintaining security and compliance.
Data Analytics • Data Analytics capabilities are critical for the Agency's ability to harvest knowledge and drive insights from a vast amount of scientific and regulatory information.	• The Agency is a credible, authoritative source of regulatory information and knowledge for partners, stakeholders, and patients. • The Agency can build on the historic knowledge and data insights to guide consistent regulatory decision-making. • By safely making available critical data sets and providing a common set of analytical tools to data scientists in the Network, we will move from collecting insights to providing process impact.

Context	Where we want to be in 2028
Data Management • Major progress has been made in the previous period on creating a common data foundation for the Network for all core regulatory data (master data). This work needs to continue to unlock the full potential of using shared, reusable data across the Network.	• The Network and the Agency now have a consistent source of truth for all regulatory master data and crucial data assets. Data management services are vital for any data exchange between EMA and its partners. These services follow established data governance policies and are designed to be user-friendly, efficient, and secure. Reports on data management activities and data quality measures are clearly documented. Data is catalogued with specified quality levels and made accessible as needed. Open standards, like FHIR and VICH, are used for exchanging common data assets. Additionally, efforts are ongoing to provide modern and scalable API interfaces that support seamless communication between EMA systems and across the Network.
Integration Management • Contains capabilities to enable technical interoperability. These capabilities manage the lifecycle of Application Programming Interfaces (providing data models for others to use) and capabilities to integrate independently designed systems together by orchestrating multiple APIs.	• EMA currently has multiple cloud-specific API gateways and integration platforms. We will set up an API Management Platform and integrate operational practices to DevSecOps processes. We will provide transparency for stakeholders regarding planned API changes. The API management platform will also provide gateways or submission portals to receive regulatory submissions.
Information Security and IT Management • EMA has established robust monitoring with real-time threat scanning. The recently updated cybersecurity strategy aims to enable a secure digital transformation. We are adopting a Zero Trust security architecture and enhancing the security culture. The focus is on continuous improvement and adaptation to emerging threats and technologies. • We have worked to establish a continuous management of our technology lifecycle, and have established the foundations by analysing the existing legacy landscape and planning for a modernisation roadmap. The methodology has been adopted and an architectural runway established which will facilitate for	• Our goal is to implement the adopted cybersecurity strategy to further elevate the security posture of EMA. The focus will be on enhancing cybersecurity measures and integrating security into all digital initiatives. This involves designing a comprehensive security assurance process to ensure that all systems and processes meet stringent security standards. This will require embedding security practices into the Agency's operational framework. This will be achieved through expanding continuous logging and real-time monitoring, as well as policy implementation, tool adoption and improvement of security measures. The Agency will proceed with the modernisation of the Identity and Access Management processes and tools, to include Role Based Access Policy and its implementation. • To effectively manage platforms and applications lifecycle, we will focus on continuous improvement of software development practices, ensuring that technology capabilities and operations are optimised. This includes the continued establishment of the multi-cloud strategy to

Context	Where we want to be in 2028
the execution of this roadmap based on value delivery and continuity of operations.	enhance flexibility and resilience. Instilling a product lifecycle culture is essential for managing technical debt, which involves identifying and categorising technological debt per platform. The adoption of Site Reliability Engineering (SRE) methods will help maintain system reliability and performance. Removing outdated and vulnerable technological components is crucial for maintaining security and efficiency. Managing the catalogue of risks in an updated Configuration Management Database (CMDB) will ensure that all risks are documented and addressed systematically. This will assist in prioritising and mitigating potential issues, ensuring that the EMA's digital transformation goals are met effectively and securely. This comprehensive approach will support the EMA's mission to enhance its digital capabilities and provide a secure and optimised user experience.

2.2. AI at scale

At EMA, we aim to support the use of artificial intelligence (AI) in regulatory systems across the European Union (EU) while carefully managing its potential risks. As interest and experimentation with AI continue to grow, transitioning from AI Proof of Concepts to wider and impactful production deployments remains the challenge. To realise the value of these early AI pilots, EMA is defining a business value proposition, ensuring alignment with strategic goals, assessing user readiness, providing training and establishing a risk management framework.

In addition, to be able to scale AI initiatives effectively, EMA's Information Management team is working to address a number of technical challenges and goals:

Infrastructure and modern technologies to enable AI

To support the development and deployment of AI, EMA is investing in the latest cloud-based versions of its strategic platforms. By maintaining a modern, cloud-based infrastructure, we ensure access to the scalability, computational power, and specialised tools and services needed for effective AI implementations. AI infrastructure also includes orchestration and automation platforms to streamline the deployment of AI models into production environments. This infrastructure is designed to support both traditional AI development, which is focused on the generation of valuable insight based on data, as well as the establishment of agentic AI, which enables the automation of complex tasks.

AI embedded in enterprise architecture and design of existing and new products

EMA has defined three types of AI solution models across its Enterprise Architecture and strategic platforms: Out-of-the box AI, low-code AI and custom developed AI solutions. These AI capabilities are embedded and ready to be used within existing live systems or can

be swiftly integrated into new product development. Together with our product vendors we are working to clarify and expand the AI offerings within the out-of-the box AI category and work with them on low code AI use cases tailored to EMA's needs. For custom developed solutions we have established analytics and data platforms with integrated AI Cloud services which are accessible via a standard API framework. Keeping AI experimentation and development close to the strategic platforms technology and products will guarantee more successful and faster scale up and deployment of AI systems.

Secure and responsible use of AI tools and data

Public AI tools are increasingly being used within the EMA workplace to enhance productivity, automate routine tasks, and generate creative content. To mitigate potential risks such as data privacy or security breaches, EMA will provide a safe and secure internal suite of generic AI solutions (Microsoft Copilot) for all EMA staff. In parallel, as we develop custom AI solutions, we are committed to adhering to responsible AI development principles, ensuring that all development and implementation is ethical, transparent, and accountable.

AI in IT service management and software delivery

We are encouraging our technology delivery partners to leverage AI in software delivery for coding, testing and detection with to the aim of boosting productivity and to redirect resources toward product quality and value delivery. The application of artificial intelligence will also improve various aspects of IT and security service management at EMA by enabling task automation and improved IT knowledge management.

2.3. Agile product management

As agile software delivery matures, focus shifts from simply adopting agile practices to integrating them deeply within operational and organisational structures. The need for adaptive and responsive product management has become crucial for improving delivery efficiency and realising greater business value. This shift is changing not only how we prioritise and plan but also how we organise operational delivery and foster strategic partnerships with our vendors.

Future strategic planning and IT portfolio prioritisation is moving away from project or epic level planning towards a new top-down approach. Major business objectives will be met through a multi-year product roadmap, ensuring stable and continuous delivery capacity across defined, key investment areas. Agile product management will play a vital role in bridging the gap between strategic and operational teams, ensuring that the product vision aligns with demand and business objectives and removing the need for heavy operational governance.

To support the shift towards product roadmap delivery, the current horizontal Information Management Division operating model and organisational structure will partly transform to a more vertical structure, organising teams around specific products or services. This shift aims to improve alignment, speed, and customer value by bringing together the necessary skills and expertise within dedicated product-focused teams. These product teams will be responsible for the full lifecycle of a product, creating greater ownership and accountability. Agile product teams will emphasise the use of metrics and clearly defined KPIs to ensure efficiency and data-driven decision-making on product level.

Mature agile product management will utilise new product teams to drive innovation and expand the value proposition to meet both current and future business needs. Innovation and experimentation will become core components of product and service delivery. These product teams will ensure higher efficiency and better delivery quality through expanded use of modern technologies and AI in code development. They will also actively maximising the use of strategic platforms by incorporating native AI capabilities and compatible low-code solutions to fast-track value delivery and meet business goals.

As the IT portfolio expands to deliver more integrated and complex solutions, the need for collaboration across products and portfolio is increasing. Traditional product management within the boundaries of individual value streams is no longer sufficient as solutions are built across different technologies and include both new and existing integrated products. To address this, we will focus on cross-portfolio collaboration and management as part of the agile IT delivery model, supported by centralised budget and contract management. Critical capabilities needed in an outsourced IT delivery model like vendor management will need to be strengthened.

2.4. Cloud-native enterprise architecture

Building on the Agency's successful transition of its workload to the cloud, the next phase is to move towards a cloud-native enterprise architecture. This next step involves a strategic shift focused on leveraging microservices, containers, and automated Continuous Integration/Continuous Deployment pipelines to enhance flexibility, scalability, and operational efficiency. The key objectives of this transition include accelerating time-to-market, improving system resilience, optimising costs through dynamic resource allocation, and enabling rapid innovation aligned with evolving business needs.

The next step in our transformation journey is to progressively transform the existing IT landscape towards services and business applications that are built on a cloud-native enterprise architecture.

We will achieve this by adopting and enforcing cloud-native enterprise architecture models and principles such as:

- SaaS over PaaS over IaaS
- Buy before Build
- Cloud-native security by design (including Zero Trust)
- Automation, DevOps, Agile, Microservices, Container, Serverless
- Manageability, observability, elasticity, and resilience
- Refresh the Enterprise Architecture in terms of data management, cloud and strategic vendor choices – taking into account domain specific knowledge and business process architecture where applicable.

When developing new systems or modernising legacy applications, our goal is to make decisions that benefit the entire organisation. This means that we want to focus on long-term value and organisation-wide priorities.

To maximise the value of existing investments, we will consistently reuse established platforms and technologies across the entire organisation. This approach promotes

consistency, reduces costs, and accelerates development. Designing cost-efficient solutions is key: we aim to avoid sub-optimisation by using the existing assets to avoid unnecessary expenditure. We want to empower staff citizen developers across the organisation will be able to use guard-railed low-code services on approved platforms. This will enable exploration and higher pace of digital transformation.

Furthermore we want to design IT solutions with reuse and modularity in mind so that internal teams, NCAs or other EU health policy agencies will be able reuse our building blocks.

The Agency has already taken a key step by rehosting applications to a software-defined cloud infrastructure.

The structured implementation of a comprehensive modernisation roadmap will be a major enabler for EMA's transition to a cloud-native organisation. Going forward, there are two key strategies to modernise the IT landscape:

- **Re-platforming and refactoring:** Moving applications to new platforms without changing their external behaviour while minimising software changes. EMA will utilise established technologies to re-platform (and re-factor) systems that are not impacted by business process (re-)design.
- **System replacement and strategic rebuild:** Replacing legacy IT systems with a new commercial solution or rebuilding the application on a strategic cloud-native technology platform. This may require significant business process re-design and new development.

Building on the success of the marketing authorisation procedures transformation, EMA will migrate the remaining procedure management applications onto its strategic platform while ensuring its sustainability through the introduction of appropriate technical guardrails.

EMA will establish a comprehensive data solution (Data Platform) aimed at:

- Enhancing the data lifecycle from gathering to analysis and publication
- Streamlining and standardising data integration methods across various systems
- Strengthening stakeholder trust by delivering reliable, high-quality data
- Implementing transparent and responsible AI functionalities
- Adopting a factory approach to create a sustainable data ecosystem focused on value

By introducing a CRM-platform we aim to consolidate stakeholder data and make it actionable, replacing current fragmented and outdated applications.

Legacy applications will largely be replaced with modern cloud-native technology, thereby improving security posture, adaptability, and overall cost structure. By identifying common patterns and accelerators, access to native cloud technologies will be democratised, enabling a factory style model to reduce the time and effort required for development.

Furthermore, we aim to advance our cloud strategy execution by:

- Shifting from infrastructure-centric models (IaaS) to modern architectures leveraging PaaS, SaaS, and serverless technologies. This transition supports agility, scalability, and alignment with our vision for digital innovation in regulatory science.

- Streamline our multi-cloud ecosystem by strengthening vendor convergence through Growth Shaping and fully integrated landing and partner zones. This enables secure, efficient, and policy-compliant traffic flow across cloud service providers, supporting interoperability and strategic vendor alignment.
- Accelerate innovation enablement by expanding automation capabilities, including Infrastructure as Code, account provisioning, and a standardised service catalogue. These foundations foster faster time-to-value for cloud-native solutions and reinforce operational efficiency.
- Demonstrate cloud maturity by embedding optimisation practices and eliminating waste across all deployments. These efforts directly support our sustainability ambitions, ensuring that every resource is aligned with efficiency, accountability, and long-term impact.

2.5. Interoperability and data-sharing

EMA Data Management and Platform Strategy

The European Medicines Agency (EMA) manages complex data sets, including submissions, medicinal products, healthcare studies, safety, risk, and administrative data. EMA is committed to continuous improvement in data management, focusing on process optimization, technology advancement, skill development, and collaboration.

Key objectives include:

- Transitioning all regulatory procedures to a unified management platform, decommissioning legacy systems for streamlined operations across EMA and National Competent Authorities (NCAs).
- Maintaining and enhancing a unified data foundation for the Network, covering all core regulatory master data on Substances, Products, Organisations, and Referentials (SPOR) to support regulatory activities.

This approach aligns with EMA's long-term vision of enabling efficient, standardized regulatory processes and decision-making. Significant progress has been made in establishing a unified data foundation, with the Product Management Service (PMS) positioned as the primary reference for medicinal product data in the European Economic Area (EEA).

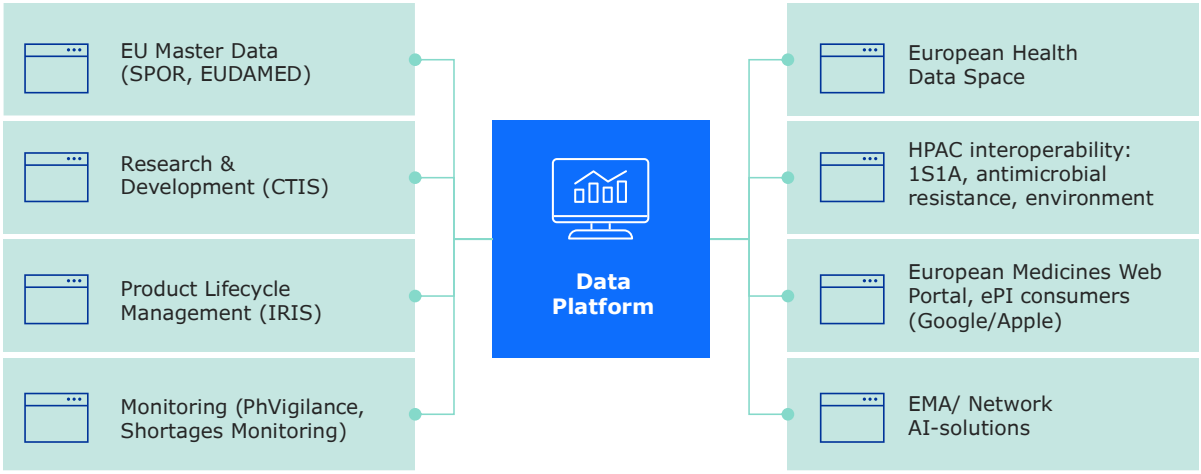
The Network serves as a single source of truth for regulatory master data and critical assets. Data management services ensure secure, efficient, and user-friendly exchanges between EMA and partners, adhering to governance policies. Reporting mechanisms and data quality measures provide accessible, catalogued data with transparent quality levels. Adoption of open standards (e.g., FHIR, VICH) and scalable API interfaces supports seamless data exchange within EMA and across the Network.

The data platform is designed to:

- Simplify data sharing and serve as a central access point for EMA data.
- Initially support internal consumers, with plans to extend access to external stakeholders.

- Enable public-facing solutions, such as the European Medicines Web Portal, and controlled access to electronic health datasets in compliance with European Health Data Space regulations.
- Enhance data sharing among EU Health Agencies, supporting initiatives like One Substance, One Assessment, joint antimicrobial resistance reporting, and environmental impact reporting.
- Support the transition from paper-based to electronic product information through AI-powered data pipelines.
- Implement modern API interfaces and an API management platform for transparent, efficient communication and stakeholder engagement.

Figure 4. Illustrative target architecture of the Data Platform



Technical and Operational Challenges

- A recent survey among NCA's has shown that from a technological perspective, we are not set up to work seamlessly across the Network. For example, collaboration is hindered by incompatible office software versions across the Network.
- While each NCA and the EMA pursue similar objectives, multiple systems with overlapping functions result in duplicated efforts as NCAs develop localised capabilities.
- EMA's Technology Capability Investment Plan prioritizes technical interoperability.
- Alignment with open interoperability standards and investment in a common technology foundation by EMA and NCAs is essential.

3. Operational efficiency

3.1. Protect the agency

In today's rapidly evolving digital landscape, safeguarding the Agency's digital assets, data, and infrastructure is paramount. This section outlines the strategic initiatives and investments required to enhance our cybersecurity posture and ensure the resilience of our operations against emerging threats.

Objectives

Enhance cybersecurity measures	Implement advanced security protocols to protect against cyber threats.
Data protection and privacy	Ensure the confidentiality, integrity, and availability of all data stored and processed by EMA according to their classification.
Infrastructure resilience	Strengthen and harden, according to the best practices, our IT infrastructure (cloud) to withstand and recover from attacks.

Key initiatives

1. Advanced threat detection and response

- Invest in AI-driven threat detection systems to identify and mitigate potential security breaches in real-time.
- Enhance the capabilities of the Agency's Security Operations Center (SOC) to monitor and respond to incidents 24/7.
- Strengthen secure application design, development and deployment processes (DevSecOps pipeline) to minimise security risks and vulnerabilities.
- Increase the efficiency of vulnerability management with particular focus on zero-day vulnerabilities at system level.

2. Data encryption and access control

- Implement end-to-end encryption for all data transmissions and storage according to their classification level.
- Finalise the adoption of a zero-trust architecture by deploying robust access control mechanisms to ensure that only authorised personnel can access sensitive information.
- Converge to a single authentication system for all systems, solutions and services. Furthermore, continuously adjust authentication methods to respond to newly introduced threats.

3. Centralised management of cybersecurity activities

- Consolidate all cybersecurity activities across the Agency into a single task force for improved coordination, unified control enforcement, and optimal resource utilisation.
- Define advanced cybersecurity requirements and incorporate them into service and vendor contracts.
- Enforce additional cybersecurity requirements through established decision-making bodies.
- Enhance the ability to provide security consultancy across all epics within the value streams, ensuring that security is considered right from the outset.

Services from various Agency areas complement the achievement of the Agency's security objectives, including:

- "Regular Security Audits and Compliance",
- "Employee Training and Awareness Programs"
- A detailed and up to date "Disaster Recovery and Business Continuity Planning".

Investing in robust cybersecurity measures is essential to protect the Agency from potential threats and ensure the continuity of our operations. By implementing these initiatives, we aim to safeguard our digital assets, maintain stakeholder trust, and uphold our commitment to security and resilience.

The European Union is facing unprecedented threats – from geopolitical tensions and conflicts, cybersecurity and information manipulation risks, to climate change and increasing risks of natural hazards.

Information Management plays a vital role in protecting the Agency against unpredictable events. Business continuity planning is a proactive process aimed at identifying and mitigating key risks to the Agency's core business capabilities. While business teams are responsible for business continuity planning, Information Management drives a future-proof and low-risk technology strategy and implements technical disaster recovery mechanisms. Together with its strategic partners, EMA will build on technology and data sovereignty.

3.2. Positive user experience

IT and information security operations have direct touchpoints with various stakeholders: users' access EMA's services and require support; partners and industry seek an integration with EMA's systems; and IT-related financial decision-making must be transparent, compliant and smart.

Recognising that customers frequently require support outside of standard business hours, we will provide a cost-effective, customer-oriented, and tailored support model that puts the needs of the customer first. We will align service levels with business expectations and empower the customer to resolve their issue quickly and efficiently. We will establish Service Level Agreements (SLAs) that are clearly defined, agreed, communicated, and monitored in close collaboration with relevant business teams. And finally, we will enforce and automate the escalation process to continuously meet and exceed agreed SLAs.

3.3. Secure, reliable and cost-effective services

One of EMA's key objectives is to provide secure, reliable and cost-effective services.

Security is a fundamental component of any service and EMA is committed to strengthening it through the following steps:

- **Optimise the "Security by Design" approach:** Enhance the security of provided services by incorporating advanced security requirements and controls within the Secure Software Development Lifecycle (SSDLC) framework.
- **Mitigate service unavailability risks:** Implement and align technical requirements derived from the continuously updated "Disaster Recovery and Business Continuity Planning" to further reduce the risk of service disruptions.
- **Enhance security controls:** Adopt the security measures outlined in the "Protect the Agency" section of this strategy document.

The Agency operates and maintains over 100 business applications that are becoming increasingly complex and costly to maintain. We want to progress towards increased cost transparency for our business users, providing insight in the total cost of ownership of services (on both cloud and non-cloud costs) considering development, maintenance and hosting costs. We will utilise concepts such as cost transparency and financial operations) (FinOps) to implement this ambition.

4. Key objectives for the strategy period

The ambition outlined in this document for the period until and including 2028 is reflected in the following objectives:

4.1. Objectives

Assessment and Planning	• Align resources and technology capabilities with a defined **portfolio vision** and roadmap. • Establish a comprehensive **legacy modernisation plan** with prioritised initiatives and clear timelines.
Technology Adoption	• Migrate to fully **cloud-native infrastructure** services leveraging a best-of-breed multi-cloud approach. • **Scale up AI capabilities** to enable automation and analytics at the enterprise level.
Simplification Initiatives	• **Define an Enterprise Architecture Roadmap** guided by simplification principles • **Rationalise and consolidate** applications leveraging a set of scalable, fit-for-purpose technology platforms while **decommissioning outdated hardware and software.**
Transforming Operational Model	• Enable an agile **product-based delivery** model to enhance lifecycle management and drive innovation. • **Develop critical capabilities needed in an outsourced IT delivery model** and excel in contract management and technology oversight competencies
Secure and Cost-effective Services	• **Provide cost transparency** and drive KPI improvements (FinOps). • Continuously enhance the monitoring and **prevention of cyber-attacks.**

4.2. Key results

The implementation of the strategy will be tracked through below KPI's.

- Percentage of legacy systems successfully modernised
- Reduction in overall IT operational costs
- Time-to-market for launching new digital services
- Percentage of digital services provided through target enterprise architecture
- Number of processes automated
- Percentage reduction in identified vulnerabilities

Glossary

API	Application Programming Interface
EMA	European Medicines Agency
IaaS	Infrastructure as a Service
IM	Information Management
PaaS	Platform as a Service
SaaS	Software as a Service
SLA	Service Level Agreement
TCIP	Technology Capability Investment Plan

Annexes

Annex 1. Supplementary material

This section contains supplementary material that supports statements made in the main document.

EMA Cloud Strategy 2022

European medicines agencies network strategy to 2028

EMA Data Standardisation Strategy

EMA Network Data Strategy

European Medicines Agency

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