EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Technology Capability Investment Plan

Becoming the digital hub for the European Medicines Regulatory Network

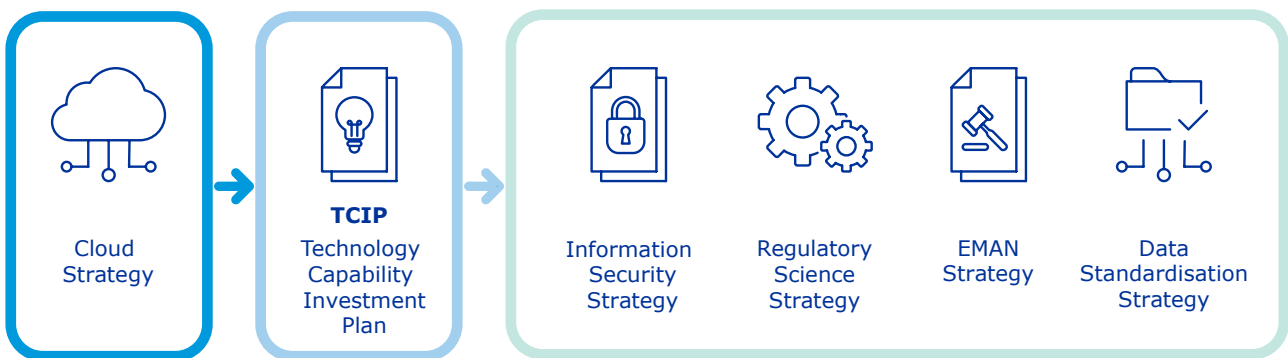Investment focus 2022-2025

Contents

1. Introduction

The Technology Capability Investment Plan provides strategic guidance for meeting the digitalisation objectives of the European Medicines Regulatory Network and its stakeholders, addressing emerging information management needs driven by new legislation and enabling 'the Network' as a data-driven, knowledge and information-based entity.

The main drivers of the Technology Capability Investment Plan (TCIP)

1. The need to accelerate digital business transformation and enable an agile operating model
2. Increasing business demand and new legislative requirements, requiring higher and faster throughput of the delivery pipeline
3. Aging technology landscape, bespoke and disparate databases and systems that become increasingly difficult and costly to maintain
4. The need to increase productivity through automation and data integration
5. New business opportunities coming from novel technologies and the need to support innovation

Figure 1.   TCIP builds on the Cloud Strategy to enable the business strategies of the Network

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

This document is intended for the European Medicines Regulatory Network (EMRN), stakeholders, and Network IT community to clarify:

• How we will drive the modernization of EMA's technology capabilities to enable public and animal health objectives

• How we will improve our operating model to be customer-centric, agile and innovative

The TCIP builds on the EMA Cloud Strategy from 2022 and its fundamental purpose is to establish the necessary technology and agile delivery foundation to support the implementation of the Regulatory Science Strategy, European Medicines Agencies Network (EMAN) Strategy, EMA Security Strategy, EMRN Data Standardization Strategy as well as to enable the efficient and effective delivery of the EMA multi-annual work programme.

For more information please do not hesitate to contact the CIO Office in I-Division: CIO-Office@ema.europa.eu

1.1. Technology vision for the Agency

EMA's vision is to enable an all-digital, modern, efficient and data-driven Network of regulatory Agencies of the future and to establish the EMRN as a global reference authority. From an Information Management perspective, our goal is to become a digital hub providing high-quality data and information services by enabling a connected, interoperable medicines regulatory platform for the Network and its stakeholders.

Various external and internal factors are influencing the EMA technology vision. The Agency must continue to implement legislations (such as Veterinary Medicines, Clinical Trials Regulations and Extended Mandate) while preparing to address needs of the new initiatives, such as European Health Union, Network Data Standardisation Strategy, and addressing needs from the Network. At the same time, internally, the Agency will need to future-proof the Agency's technology landscape to cope with increasing business needs, unlock business value of new technologies and drive cost and organisational efficiencies.

Main elements of implementing this vision are:

To move away from the historical operating model of developing bespoke applications in isolation as this has led to a proliferation of information silos, unnecessary duplication of information and business processes, and is increasingly expensive to support; further build up the organisational change capacity and do more with the same; improve quality of delivery; modernise data management, collaboration and advanced analytics capabilities; continue migrating regulatory scientific procedures onto strategic platforms, and transition legacy systems to a secure and data protection compliant cloud-native enterprise architecture; use standard (cloud-enabled) technologies to the best of their strengths.

On this journey we will focus on the following pillars for success:

Maximising customer success

We aim to enable success of the European Medicines Regulatory Network and maximise business impact through customer focus. We operate in a diverse internal and external stakeholder landscape which requires a well-coordinated demand management process so Information Management can fully contribute to the success of each stakeholder. Our aim is to be recognised as a trusted partner for our stakeholders' information service needs and to play an integral part in achieving EMRN's mission. We will enable this by having customer-focused, multidisciplinary teams with the right level of business understanding and technology expertise, demonstrating a customer-centric, can-do and agile attitude delivering business value incrementally and quickly.

A modernisation mindset

We will strategically focus on innovating IT capabilities and transforming how we deliver IT to our customers. We will introduce and foster best-in-class technology ecosystems leveraging best-of-breed, standard technologies where possible, adapting our processes to the strengths of the technologies. We will provide opportunities for staff to grow and be proficient in emerging technologies and empower them to recommend the right technologies for the right use cases. We will continue the journey to bring data together and make it actionable. We will enable the re-design of key business processes by migrating to strategic platforms and transform legacy to secure and cost-efficient cloud infrastructure. We will collaborate with stakeholders to enable interoperability of data and business processes.

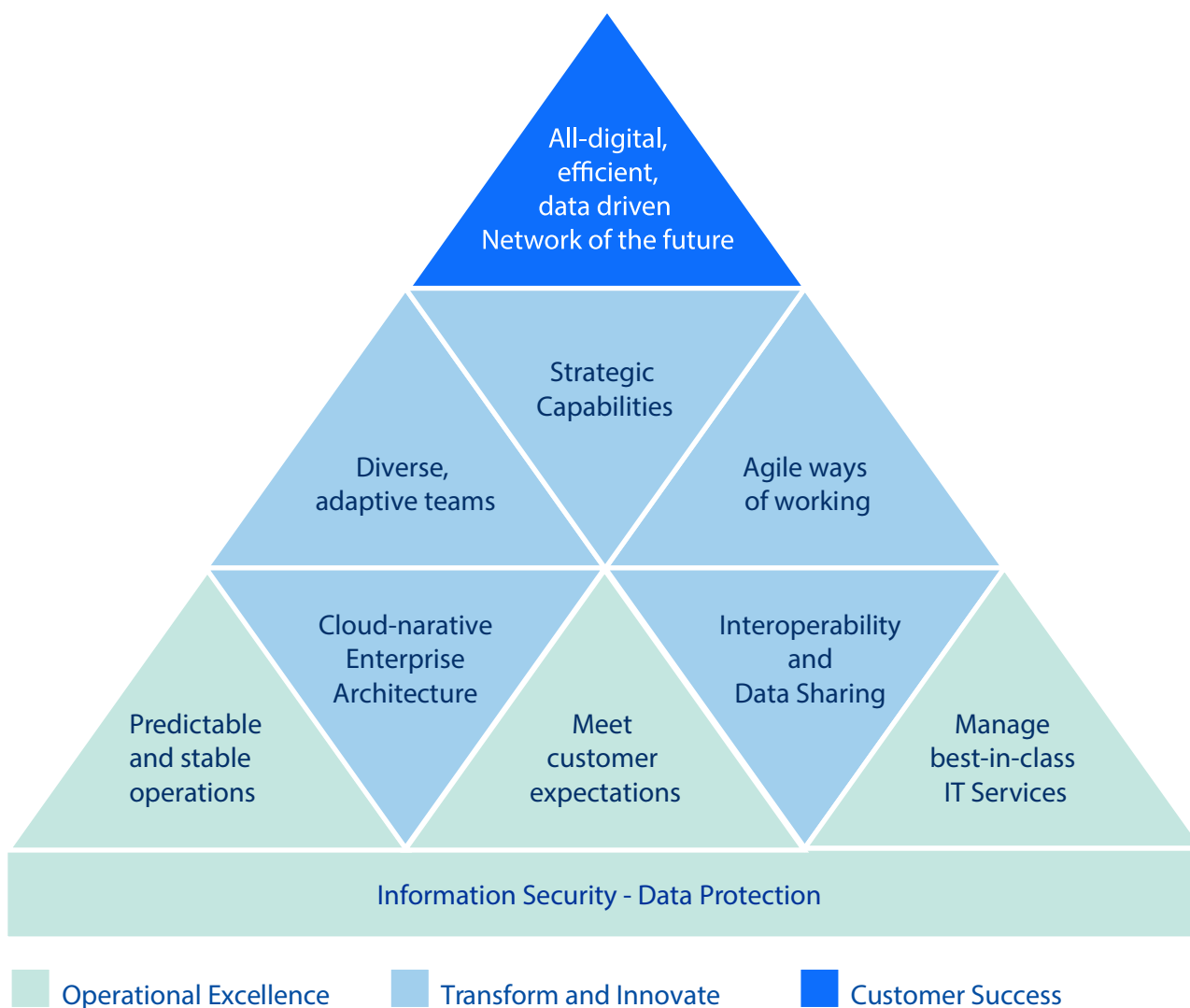### Operational Excellence and Information Security

Operational Excellence and Information Security are the foundations for well-run IT operations. We will continuously enhance information security and data protection compliance and will assess progress based on best practices and frameworks. We work to enhance performance and responsiveness of our systems. We will apply a risk-based approach to ensure focus where it is needed the most first and leverage cloud-enabled services to enhance security monitoring and threat protection using latest technologies supported by Artificial Intelligence and Machine Learning.

We will meet customers' expectations through Service Level Agreements that are fit for purpose and provide services in accordance with

Procurement functions, IM will pursue a flexible, scalable IT sourcing contract portfolio that covers the breadth of skills and profiles required to optimize delivery and address growing business demand. This is achieved through establishing capability-based IT sourcing contracts that incentivize vendors to provide high quality products efficiently and drive continuous improvement. The planning function will be further matured to coordinate and manage these contracts.

Figure 2.   Overview of pillars and associated capabilities to implement the Technology Vision

All-digital, efficient, data driven Network of the future

Strategic Capabilities

Diverse, adaptive teams

Agile ways of working

Cloud-narative Enterprise Architecture

Interoperability and Data Sharing

Predictable and stable operations

Meet customer expectations

Manage best-in-class IT Services

Information Security - Data Protection

Operational Excellence   Transform and Innovate   Customer Success

1.2. Target Operating Model and Supporting Organisation

The IM organization went through a major future-proofing effort in 2020 to become more customer-focused, agile, integrated and innovative.

As a result, a new client-facing organisational structure has been put in place to align better with the customers of IM, improve communication and planning and promote the use of standard, shared enterprise technologies and services and to maximize benefits:

• **Customer Advocacy** builds client relationships and manages business demand from stakeholder groups for IT services. It ensures that the potential business value of the services is captured, optimised and recognised. It also makes sure that business strategies fully leverage IT capabilities. A key focus is to align requirements to common capabilities, instead of implementing in silos. Focus on domain expertise and solution architecture and addressing customers' needs holistically.

• **Strategic Platforms** responds to demands for IT, evaluates and proposes technology options and opportunities, drives innovation, and

focuses on consistency, service availability and resilience, integration and optimising technology. Focus on application and platform architecture of sustainable platforms and meeting customer needs at the operational level.

• **Core Services** focuses on providing best-in-class service management for digital workplace, infrastructure and regulatory data management. Core Services is leading the way to the cloud, provides state-of-the-art collaboration and communication tools and manages the core regulatory data for the Network.

• **Office of the CIO** is responsible for the operational and strategic management of IT services and comprises sourcing, planning, governance and assurance, communications and enterprise IT architecture functions supporting strategic planning, road mapping, and application portfolio optimisation.

Benefits

To fully realize the benefits of the new IM organization it is critical to implement the Technology Capability Investment Plan as it provides the foundation for long-term success.

Figure 3. New IM Organisation since 2020
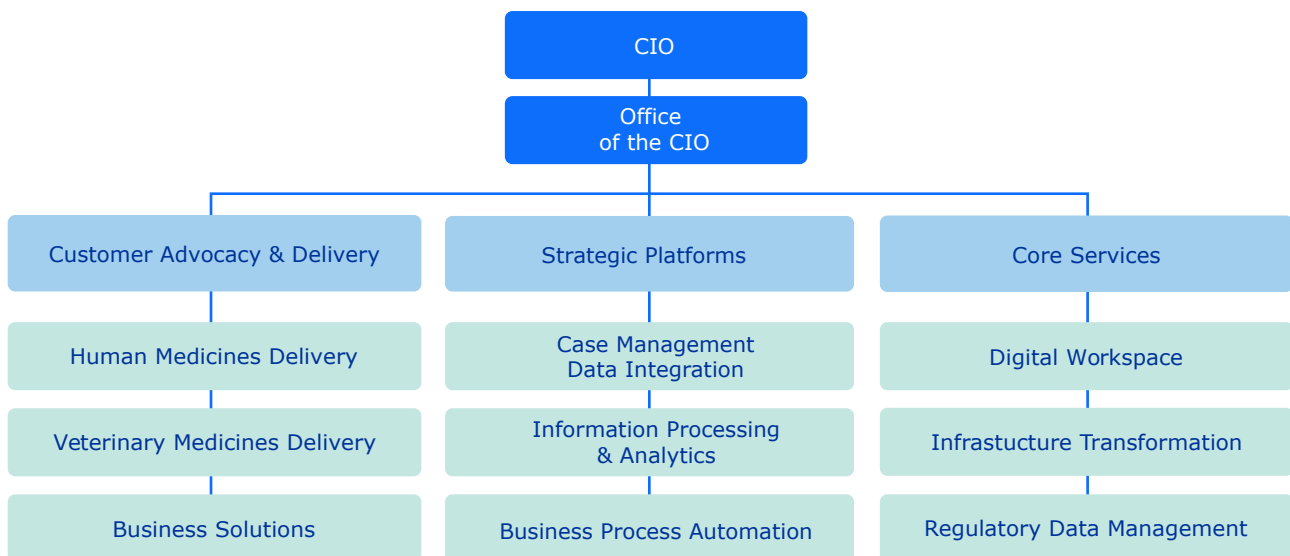
2.   Maximising Customer Success

The Agency provides services to European and international regulatory authorities, and our stakeholders which include patient organisations, healthcare professionals, academia and the pharmaceutical industry.

Understanding the different needs of stakeholders and addressing it in a sustainable and strategic way is key to enable internal and external stakeholders in meeting our shared public and animal health mission.

2.1.   Business-IT partnership

EMA is operating in a dynamic stakeholder field consisting of the Member States and National Competent Authorities, patient consumers,

industry, academia and healthcare professionals that bring specific expectations to EMA. On the legislative side mandatory requirements enter EMA's systems due to the Clinical Trials Regulation, Veterinary Regulation and very recently the Extended Mandate.

These (individual and collective) expectations and must-do requirements need to be considered against the COVID19 evolution and EMA's resources. EMA business specific activities that had been suspended during the peak of COVID19 outbreak are ramping up again, as has 'regular' human and veterinary product-related activities – together absorbing a majority of staff resources.

The aim for Information Management at the EMA is to bring transparency in the priority setting of all different expectations and requirements, and to establish a jointly agreed portfolio roadmap supporting the partnership between IT and the Network based on transparency and open dialogue.

> Operating in a diverse internal and external stakeholder landscape requires a well-coordinated demand management process to ensure Information Management can contribute to the success of each stakeholder to the fullest extent possible.

2.2.   Delivery through Value Streams

In order to shift focus towards value, the Agency is transitioning from a short-to-medium-term project/programme approach to establishing long-lived Value Streams.

Value Streams represent the series of steps that an organisation uses to implement solutions that provide a continuous flow of value to a customer (scaledagileframework.com). The portfolio will be organized around five Value Streams, each of which is dedicated to build and support a set of solutions, which are the products, services, or
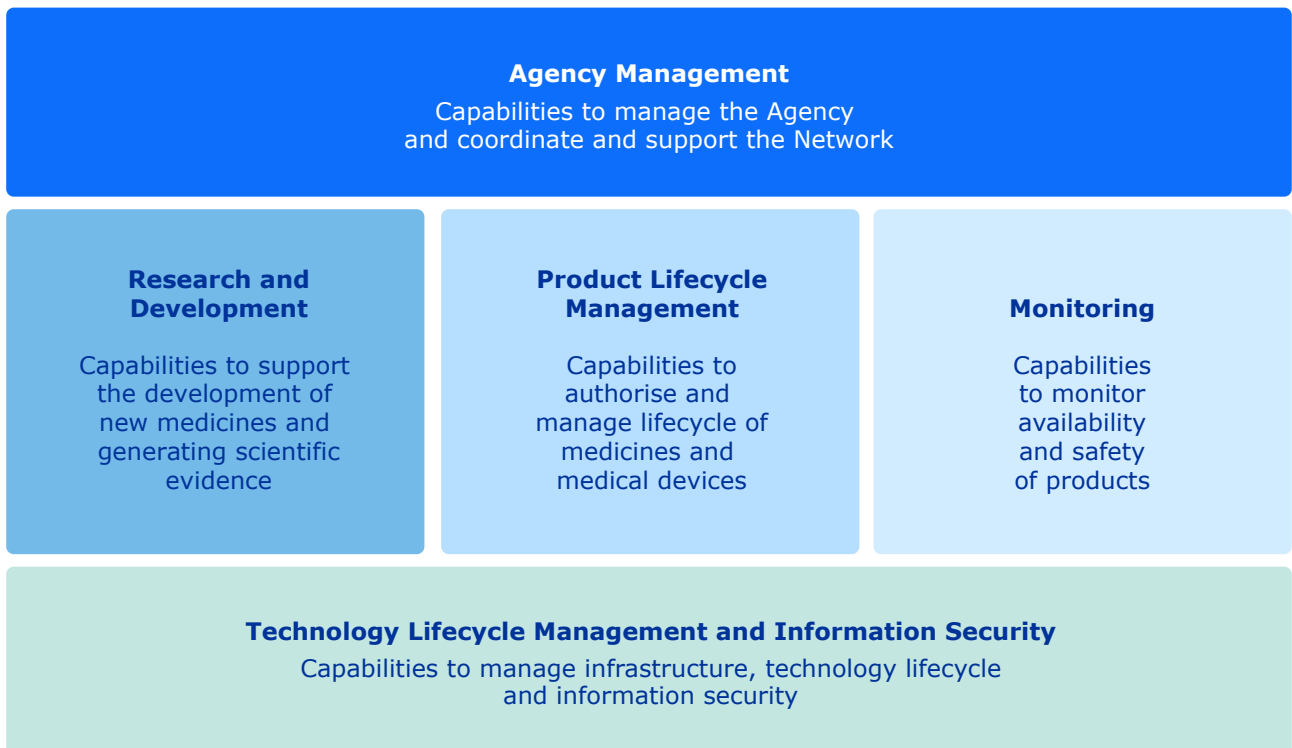
systems delivered to the different internal and external customers.

The following are specific considerations and criteria in the definition of the Value Streams, to ensure that they optimally support the delivery of the Network IT portfolio:

- Value Streams must be long-lived and focus on end-to-end value delivery, instead of short-term focus on individual programmes/projects and task completion.

- Value Streams need to reflect the fundamental purpose of the European Medicines Regulatory Network and align to the overall value we provide such as ensuring safe and effective medicines for the public.

- Value Streams must be designed to overcome organisational silos and drive synergies.

- Value Streams must have fixed budgets and resources to provide stability and allow teams to focus on continuous delivery and to optimise the "IT factory".

- Value Streams have business owners who collectively make up the Portfolio Board and shape the portfolio objectives and portfolio roadmap.

Figure 4. The Agency is transitioning from project approach to long-lived Value Streams

Agency Management
Capabilities to manage the Agency
and coordinate and support the Network

Research and Development
Capabilities to support the development of new medicines and generating scientific evidence

Product Lifecycle Management
Capabilities to authorise and manage lifecycle of medicines and medical devices

Monitoring
Capabilities to monitor availability and safety of products

Technology Lifecycle Management and Information Security
Capabilities to manage infrastructure, technology lifecycle
and information security

# 3. Transform and Innovate

3.1. Strategic capabilities

The future Information Management landscape aims at reducing complexity and streamlining how scientific and regulatory knowledge is provided to the stakeholders to enable good decision-making.

The logical target state follows the principles of a layered architecture with distinct business capabilities that are connected through an integration layer enabling seamless workflows and a consistent, simplified way for external stake–holders and partners to engage with the agency.

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 and as such 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.

Figure 5. **Streamlining scientific and regulatory knowledge to the stakeholders through distinct business capabilities**
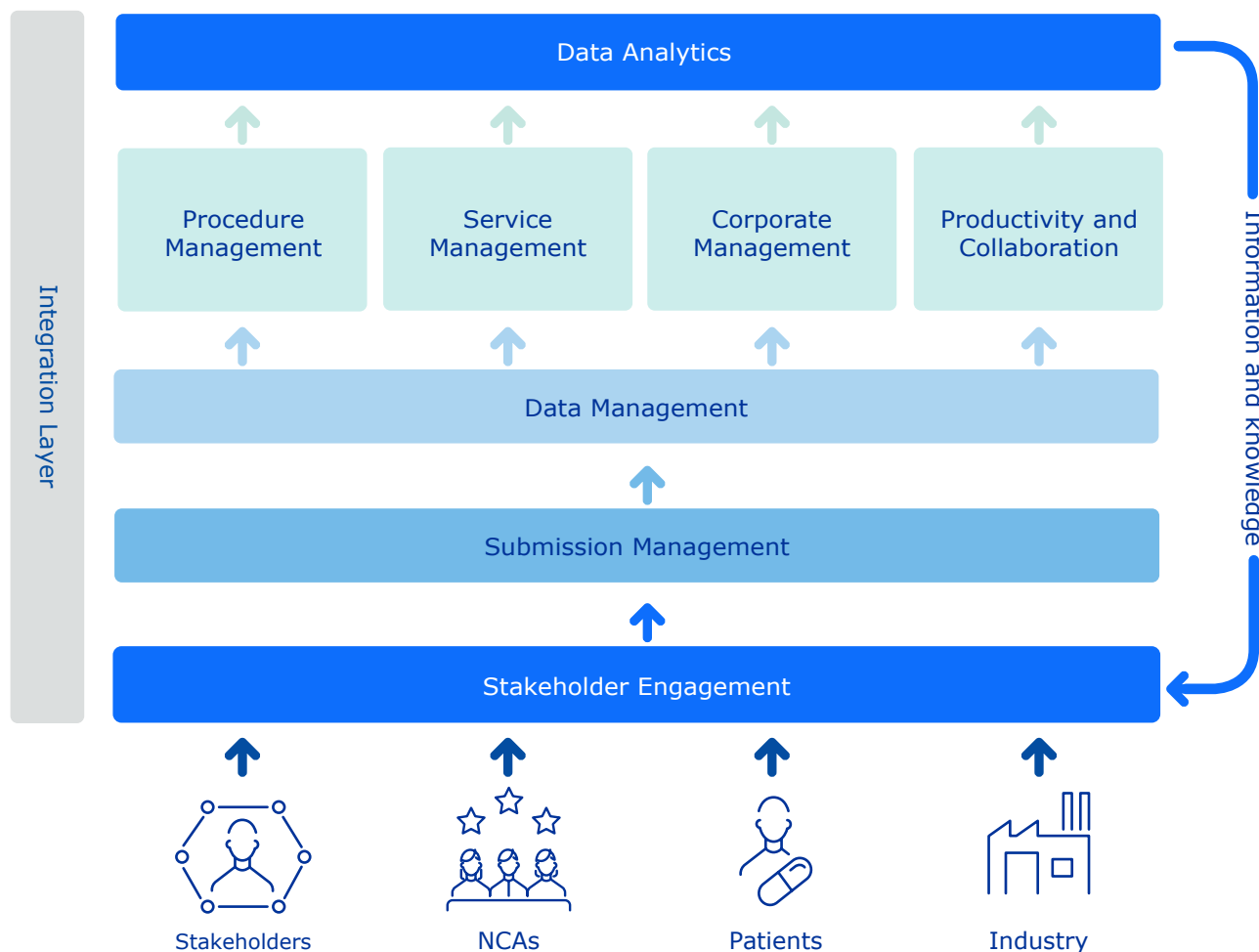
The following table provides examples for major business capabilities required for the functioning of the Agency that must be enabled by standard technology platforms:

Context	Where we want to be	How to get there
Stakeholder Engagement		
• We are striving for a unified, consistent user experience for partners, stakeholders and the general public who need to interact with the EMA systems.	• A one-stop-shop user experience for all stakeholders that need to interact and communicate with the Agency.	• Transition to a layered architecture with technology selection for the front-end stakeholder engagement capability.
Submission Management		
• There is an ambition to move towards a more integrated submission management platform for the Network that facilitates centralised and national procedures.	• A modern, secure, integrated submission management platform that allows the Network to process, validate, access and view regulatory submission without the need to duplicate submissions in local repositories.	• Evolve target architecture and tool set as part of the eCTD v4 transition with the ultimate goal of implementing global cloud-based exchange of regulatory information.
Data Management		
• Major progress has been made on creating a common data foundation for the Network for all core regulatory data. This work needs to continue to unlock the full potential of using shared, reusable data across the Network.	• There is a single source of truth for all regulatory data across the Network. • Data management services are regarded as critical and foundational prerequisites for any data exchange between EMA and partners. • Data management is performed according to agreed data governance policies and in a user friendly, efficient and secure manner. • Clear reporting on data management activities and clear measures on data quality have been established.	• Continue the systemic roll out across all regulatory data domains following best practices and internationally agreed data standards and identify target cloud-native target architecture. • Streamline data management services by adopting best-in-class service management tools.

Context	Where we want to be	How to get there
Procedure Management		
• A cloud-based case management platform has been adopted for some regulatory procedures and the ambition is to complete the modernisation of all regulatory procedures across the Agency in the coming years.	• Full adoption of the platform for all centralized procedures simplifying the work of the scientific committees and NCA experts.	• Accelerate the systemic implementation of all regulatory procedures in the new platform.
Service Management		
• A service management platform has been identified to support IT service management, risk management which can be leveraged for use cases requiring robust workflows and reporting. This capability is intended to be used for non-procedure related workflows. Currently this capability is considered to support workflows related to the expert management system.	• Fully integrated service management platform that can support many administrative processes and back-office workflows.	• Develop expertise in this new platform, mature the operations and establish adequate use cases and target architecture.
Corporate Management		
• EMA's finance management system (SAP FI) is nearing its end-of-life. Upcoming changes to the Fees Regulation will impact the accounts receivable processes and financial systems. • Opportunities to share common systems for procure-to-pay processes are being explored with the European Commission.	• The Agency operates modern, cloud-based Human Resources and Financial management solutions driving resource efficiencies and better decision-making through automation and real-time reporting.	• Clarify the key supplier strategy and conduct a technology selection procedure. Align the regulatory scientific procedures with the updated Fees Regulation. • Align the Procure to Pay technology selection procedure with the key supplier strategy and financial landscape renewal. • Leverage off-the-shelf-solutions and platform ecosystems. Join Commission tooling for identified solutions (e.g. procurement).
Productivity & Collaboration		
• Expanding capabilities for advanced collaboration will drive efficiencies and quality improvements in our work with partners and stakeholders.	• In the new normal, a mobile workforce is enabled to work securely, efficiently, and effectively from anywhere and from any device.	• Invest in seamless integration of working from home and in the office. • Enable a user-friendly way to comply with records management

Context	Where we want to be	How to get there
		policies and safeguard our records.
		• Learn from Bring Your Own Device (BYOD) pilot to understand user needs and productivity needs.
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.	• Move to cloud based modern platform and offer state-of-the-art analytics services that are monitored, auditable, reliable and in line with ethical considerations. • Provide analytics capabilities that help to drive insights from large volumes of real-world health care data, aligned with the goal of creating a European Health Data Space set out in the European Strategy for Data. • Establish a data lake for all regulatory data and enterprise search capabilities bridging the gap between structured and unstructured data. • Enable self-service business intelligence capabilities through a modern, state-of-the art Business Intelligence platform. Empower EMA and its stakeholders to take evidence-based decisions based on analytical, transactional, raw, clinical & non-clinical data. • Drive insights from large amounts of unstructured data using AI/ machine learning capabilities where appropriate.

Strategic capabilities

The Agency needs to establish a set of strategic capabilities that can be configured to address a wide range of business needs and systemically invest in re-platforming its substantial amount of legacy technologies.

3.2. Diverse and adaptive teams

People are the foundation of our strategy. We want Information Management to be a place where staff is given the opportunity to lead, learn and grow.

Context	Where we want to be	How to get there
• We want to maximise the potential of our staff by promoting flexibility and creating a culture where staff is encouraged to take initiative.	• Maximise our talent and create an environment where the change is embraced and staff is given the opportunity to lead, learn and grow.	• Influence and leverage organisational culture to become better equipped to swiftly react to and implement change at the individual and team levels. • Empower staff to step up to the next level of responsibility. Foster a safe environment for risk taking where people are allowed to make mistakes, fail fast and learn. • Promote collaboration as well as strategies for communication.
• Flexibility is essential and we need to transform the way we organize, lead, interact, and drive the change continually.	• Teams have the ability to adapt and transform in a fluid, dynamic world.	• Build competencies that enable successful teams to deal with unexpected changes: robustness, resilience, planning, agility and versatility. Composite diverse teams with the right capabilities synergy.
• The new approach requires us to move away from teams with a historically quite technical skillset towards diverse, multi-competency teams where team members complement each other and multiply the teams' impact.	• Diverse people in teams with a good balance of technical and leadership skills to drive dynamic problem-solving and decision-making.	• Recruit people with different background (culture, studies). Balance recruiting from other public institutions with candidates from private sector.
• We need to build capabilities that enable an innovation mindset and out-of-the-box thinking.	• Effectively manage modern business/IT teams both in technical and behavioural competencies.	• Focus the training curriculum on skills related to growth mindset, leadership and people skills. • Standardise the way teams interact with the customer through use cases / storyboarding that is valid across all capabilities and platforms.

3.3. Agile ways of working

We want to deliver business value early and continuously. We want to have lean governance for EMA-specific and Network-wide initiatives.

Context	Where we want to be	How to get there
• We are transitioning from traditional programme and project approach towards continuous delivery of business value via products and value streams.	• Continuous and sustainable value delivery by long-living value stream and platform/service teams. • Continuous value delivery: short jobs with high business value are delivered first. Value delivery always takes less than 12 months.	• Transform the Agency thinking from project based to product based, using platform teams to accelerate value delivery. • Transform all programme/project portfolio items to agile delivery model, using one prioritised backlog of items to be delivered by a fixed capacity.
• We have established an Agile governance model. Through the agile ceremonies we will ensure transparency, appropriate delegation of authority and effective decision-making.	• One way of working delivering on solutions that benefit the Network.	• Operationalise agile portfolio management, value streams and products to enable EMA together with the Network to deliver on its mission.
• Overcoming the separation of business vs. IT through multifunctional agile teams is of paramount importance to maximize value delivery.	• Business and IT colleagues are assigned to agile roles across multiple products to ensure more business value through alignment, collaboration and efficiency gain.	• Introduce and implement agile roles and ceremonies. Train personnel for different agile role types. Actively support the change from old to the new role concept.
• We implement Agile at the Enterprise level. Agile is a business change, it is not just about how IT works.	• Agile is how we work as an organisation and agile teams are jointly accountable to deliver business outcomes. Agile as a mindset that that involves understanding, collaborating, learning, and staying flexible to achieve high-performing results.	• Promote agile mindset beyond IT delivery across the division and Agency. Provide coaching at leadership and operational level.

3.4. Interoperability and data sharing

We want to be the EU digital hub on medicinal products. We want to enable European interoperability for all data we manage.

Context	Where we want to be	How to get there
• Aligning medicinal product and substance data across the Network has been a common objective for EMA and its stakeholders and partners. There is a need for an agreed operating model to ensure data quality and stewardship.	• A data foundation for all pharmaceutical products and substances in Europe and harmonizing product data submission over the medicine's lifecycle. • Enable interoperability with the master data systems managed by the EC (European database on medical devices and economic operators (EUDAMED) for medical devices and European Business Registry Information System (BRIS) for organisations).	• Collaborate with business (including taskforces) to create an integrated data operating model for human and veterinary medicines and medical devices. • Enable the first use cases to utilise the current European database on authorised medicinal products, complying with the Regulation (EC) No. 726/2004 (Art57 DB) based datasets through Product Management Service (PMS). Kick off data operating model epics to clarify business processes and interfaces to improve data quality. Use agile ways to incrementally improve data quality.
• The Aency and Network have adopted various semantic and technical interoperability standards.	• A one-stop-shop for all EMA data services through an Application Programming Interface (API) portal. • Submissions to be compliant with recognised international data standards, technical specifications and reports published by Standards Developing Organisations (SDOs) (e.g., International Organization for Standardization (ISO), Health Level 7 (HL7), Clinical Data Interchange Standards Consortium (CDISC)) and International Council for Harmonisation (ICH), and as laid down by the regulatory guidelines. • Data should be submitted once and used by many; enable and support harmonisation of data to reduce the administrative efforts currently required to receive, process, make available and reuse scientific data throughout the EU as well as in the global life science industry.	• Utilise data governance to coordinate and align data standardisation activities across Business, IT and the Network. • Implement the data standardisation recommendations set by the EMA Data Standardisation Strategy (DSS), focusing at the four identified domain areas, namely: medicinal product, submissions, safety & risk management, healthcare & study data). • Further develop the HL7 Fast Healthcare Interoperability Resources (FHIR) infrastructure aiming at making FHIR a common standard for digital submissions. • Organise and coordinate international data standardisation events focusing on regulatory space and business cases, as they are set by the Agency in collaboration with EMRN the Network and our stakeholders.

Context	Where we want to be	How to get there
	Create the foundations for exchanging medicinal product and substance related information for global regulatory and healthcare use cases. Demonstrate the results through pilots and information systems.	• Streamline the exchange of regulatory information with industry while adopting eCTD v4.0. • Follow the general provisions and requirements related to data sharing, re-use and data privacy laid out in the draft EU Data Governance Act.
• New initiatives like DARWIN EU and the EU health data space drive the need for interoperability at all levels. The agency identified the need for a comprehensive data strategy to guide data related initiatives in coming years.	• The Agency shares open data with data ecosystems and consumes data provided by the ecosystem partners. • The Agency shall deliver IM services that comply with the European Interoperability Framework (EIF) and Reference Architecture (EIRA).	• Collaborate with business to create a holistic data ecosystem strategy. • Continue connecting with data ecosystem European Health Data Space. Additional value adding data ecosystems have been identified: SRS Network (EMA/ EU-FDA-WHO), European Medicines Verification System, eHealth Digital Service Infrastructure, and various public-private initiatives such as Gravitate Health.

3.5. Cloud-native enterprise architecture

We want to fully adopt and benefit from the potential of cloud-based technologies. We want to transform our business applications and systems to cloud native architectures.

Context	Where we want to be	How to get there
• Rapidly increasing expectations regarding demand, capabilities and business interactions. • Complex and costly to maintain hybrid environments of selected cloud options and on-premises data centres. • At the same time, modern cloud solutions provide opportunities for built-in security and easy access to innovative technologies like AI and machine learning.	• A full transition to the cloud by 2025 to leverage cloud-native innovations (machine learning, AI, big data) and efficiencies (scalability, elasticity). • Being able to respond to rapidly increasing demand stemming from a variety of sources, such as legislation, public health emergencies and emerging technologies and advances in science.	• Implement EMA's Cloud Strategy (2021-2025) to strategically unlock cloud capabilities. • The new strategy provides the agency with the principles and approach to fully adopt and benefit from the potential of cloud-based technologies. • It contains a built-in focus on information security and data protection compliance, which will be embedded in both existing and new solutions by design, and can be elevated to new levels with the help of state-of-the-art solutions powered by the cloud. It minimises vendor lock-in by embracing a multi-cloud environment following a best of breed approach. Improved scalability, cost efficiency and information security.
• Enterprise architecture for legacy environments impair the ability to adopt modern cloud capabilities and to drive value from data (data architecture). • Traditional architectural models require lengthy processes, full stack hosting environments, and high consumption of internal resources for maintenance and operations.	• Service and business applications that are built on a cloud native enterprise architecture.	• Adopt and enforce 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.

Context	Where we want to be	How to get there
		• The Enterprise Architecture will provide guidance to domain architecture, platform and solution architectures ensuring alignment of architectural principles across all levels of IT delivery.

4. Operational Excellence

4.1. Meeting customer expectations through agreed service levels

We want to align service levels with business expectations and empower the customer to resolve their issue in the most efficient and quick way.

Context	Where we want to be	How to get there
• Aligning service levels with the expectations of agency staff, partners and stakeholders is critical to ensure continuity and efficiency in day-to-day business operations.	• Service Level Agreements (SLAs) are clearly defined, agreed, communicated and monitored in close collaboration with the business. • IT operations meeting the customer's expectations and needs based on SLAs. • We provide services in accordance with recognized quality standards.	• Review, update, and align SLAs with business needs as part of the new tender for a managed service desk. • Selection of the new service desk provider with updated SLAs to address the agency's needs. • Alignment with Operational Level Agreements. • Enforce and automate escalation of tickets to continuously meet and exceed SLAs.
• Customers frequently need help outside of business hours and need flexibility for getting help when and how they need it. We want to provide a cost-effective, customer-oriented, and tailored support model that puts the needs of the customer first.	• Customer can interact with the service desk in his/her preferred way to resolve issues most efficiently and quickly	• A broad range of access to service desk and support options via self-service portals, knowledge articles, chat, phone, VIP service, 24x7 coverage and a best-in-class service management tooling.

4.2. Predictable and stable operations

We want to minimise the number of major incidents.

Context	Where we want to be	How to get there
• The agency operates and maintains 150 bespoke applications that become increasingly difficult and costly to run. The mean time between major incidents has been drastically reduced in 2021 through concerted stabilization efforts.	• No major incidents over 12-month period.	• Decrease the number of incidents and avoid repeating incidents by applying root cause analysis methodologies to identify resolutions and permanent fixes. • Proactive maintenance plan and release management. • Phase out legacy solutions and related cross-dependencies by moving to modern (cloud-based) solutions based on a clear target enterprise architecture optimized for data.
• Uptime and performance monitoring capabilities are covering more and more business-critical applications.	• Performance and availability will be defined and monitored based on KPIs, driving predictable and stable IT operations.	• Invest in monitoring capabilities to measure uptime and performance of business-critical applications and services. • Standardize and leverage industry best practices for Information Technology Service Management delivery (ITSM) (Information Technology Infrastucture Library (ITIL) framework for Incident, Problem, Service Request, Knowledge, Change Management and Continuous Service Improvement).

4.3. Managing best-in-class IT services

We want to provide best-in-class applications and services to address the business needs in the best way, balancing functional fit, technical fit and cost.

Context	Where we want to be	How to get there
• Current contract portfolio is not suitable to deliver on the IT promise (increase business delivery in agile way, move to cloud, exploit novel technologies).	• Flexible, scalable IT sourcing contract portfolio that covers the breadth of skills and profiles required to optimize delivery and address growing business demand. • Capability-based contracts that incentivize vendors to provide high quality products efficiently and drive the best value for our customers. • Partnerships with leading and renowned vendors who represent the best of their domains.	• Completion of the transition to capability-based contracts. The next generation platform contracts will be aligned with the strategic capabilities mentioned in chapter 3 and enable the agile way of working: vendors work in agile teams, attend joint agile ceremonies, and are capable of scaling up and down their agile teams based on business need. • In order to implement the cloud strategy, contracts will need to be in place for IaaS, PaaS, and SaaS platform providers and vendors providing consultancy services for the plan, build, and run of these services. • A new contractual vehicle to make full use of emerging technologies needs to be established. • Strengthen the vendor management and contract management capabilities within EMA, increasing the strategic vendor relationships based on mutual trust.

5. Information security and data protection

We want to minimise the number of major incidents and downtime cost of technology. We want to ensure that the information security and data protection are foundational aspects of the service design and delivery.

Context	Where we want to be	How to get there
• In 2021 the Information Security Strategy has been approved, with the Information Security Steering Committee (established under business sponsorship) overseeing its implementation. • A Data Protection Awareness Programme has been established. • Separation of roles and responsibilities for oversight and operations is in progress.	• A security mindset: Information Security and Data Protection principles are fully embedded in system development and IT operations. • Staff is continuously trained and updated in security operations and engineering. A security certification programme exists. • EMA is supported by state-of-the-art Security Operations Center to provide monitoring and proactive threat prevention. We have the right technologies to proactively monitor, detect and respond to cybersecurity threats and potential security incidents. • Strong collaboration and communication with EMA Information Security Office while applying best practices of separation of duty between Information Security and Security Operations.	• Set up IT security capability in line with the Information security strategy. • Implement Security Operations Center with external provider to detect, contain and respond to information security incidents. • Establish cross-agency Information Security Task Force to support the implementation of the EMA's Information Security Strategy. • Data loss prevention policies and capabilities, and data protection impact assessments are integrated as security by design and part of day-to-day operations. • A secure use and centralized management of laptops, virtual desktops, bring your own device, and phones or tablets. • Session recording platform to elevate the security of contractors being connected to our systems and making changes. • Strengthen data protection and information security through cloud-native capabilities. • Roles and responsibilities are documented between Information Security and Information Management.

Context	Where we want to be	How to get there
• Transition to access management based on the need-to-know principle is in progress.	• A clearly defined set of baseline roles (access policies with sets of privileges based on job tasks) where user accounts can be mapped against. • These roles can be assigned and re-used across EMA's application and data landscape. • Modifications and additional access rights are based on "need to know" principle. • Centralized access management is in place.	• In alignment with the "Zero-Trust" principles as part of EMA's Information Security Strategy, define baseline roles for Access Management, and processes to grant access rights based on "need to know" principles. • Technologies for centralized access management are adopted.
• The agency needs to prioritise applications for upgrade to multi-factor authentication in order to comply with new security standards as established in the information security strategy.	• User accounts (internal and external) shall be managed and monitored through a centralized, robust platform that meets that agency's high requirements for secure authentication and authorization leveraging concepts such as federation with trusted sources, multi-factor authentication, and passwordless technologies.	• Establish and adopt a cloud-native target platform (Azure Active Directory) through governance process (i.e. Enterprise Architecture Board), and redevelop the applications to be compliant with the new access management platform legacy systems to new identify and access management platform. • For external user accounts, work with EMA partners (NCAs, Industry, EU Agencies) to white-list domains, and federate identity management systems to avoid duplication of identities and switching of identities.
• A technology lifecycle management value stream has been established to ensure visibility and planning for all activities required for technology refresh and upkeep.	• EMA is supported by their vendors systems and technologies. • EMA has established a lifecycle management process that will foresee any issues coming from end of support systems/ technologies and acts proactively to upgrade them before becoming unsupported.	• All legacy applications and technology should be re-developed or re-built using supported technology that will be compliant with the Security Strategy, following security best practices. • The new applications and adopted technology should be compliant with the Security Operations Center solution to be monitored.

Context	Where we want to be	How to get there
• The agency is revamping its risk management processes and is implementing best practices and tools to facilitate effective risk management.	• EMA has established an Information Security Risk Management process based on a recognized framework across the relevant organisational entities.	• A complete Configuration Management Database (CMDB) should be created with relationships and dependencies. • An evaluation of all assets (tangible and intangible) should be conducted. • All identified vulnerabilities and issues will be recorded and evaluated as risks impacting specific assets.
• Scenarios for potential disruptions need to be reviewed to ensure that the scenarios are still accurate and the capabilities in place are still relevant. • Disaster Recovery capabilities in place need to be periodically tested to validate effectiveness.	• Disaster Recovery capabilities are fully aligned to meet business needs. • Disaster recovery capabilities include protection against evolving information security threats. • Modern (cloud native) concepts of resilience implemented and adopted by design.	• The Cloud Strategy and Cloud native enterprise architecture include security / disaster recovery / scalability / elasticity by design to address disaster recovery requirements. • Audit and information security assessments will verify and validate plans and capabilities.

6. Architecture Principles

The Technology Capability Investment Plan will inform the evolution of the enterprise architecture through the following principles that will guide recommendations about technology selection, technology adoption and the target enterprise architecture:

1. Cloud first (SaaS over PaaS over IaaS) – cloud-native architecture
2. Use of multiple cloud service providers as a choice to prevent vendor lock-in
3. Preferred use of best-of-breed, cloud-native, standard technologies
4. Procure services, not assets
5. Capability-based, layered architecture
6. Information Security and Data Protection by design
7. Simplification over sophistication
8. Interoperability based on international exchange standards, combined with open standards where applicable
9. All systems have a common/shared data architecture

7. Roadmap and key milestones

Based on the strategic pyramid from section 1, the TCIP will follow below timeline and key milestones to establish the necessary technology and agile delivery foundation to support the implementation of the Regulatory Science Strategy, European Medicines Agencies Network Strategy, EMA Security Strategy as well as the EMRN Data Standardization Strategy.

Figure 6.   Roadmap and key milestones
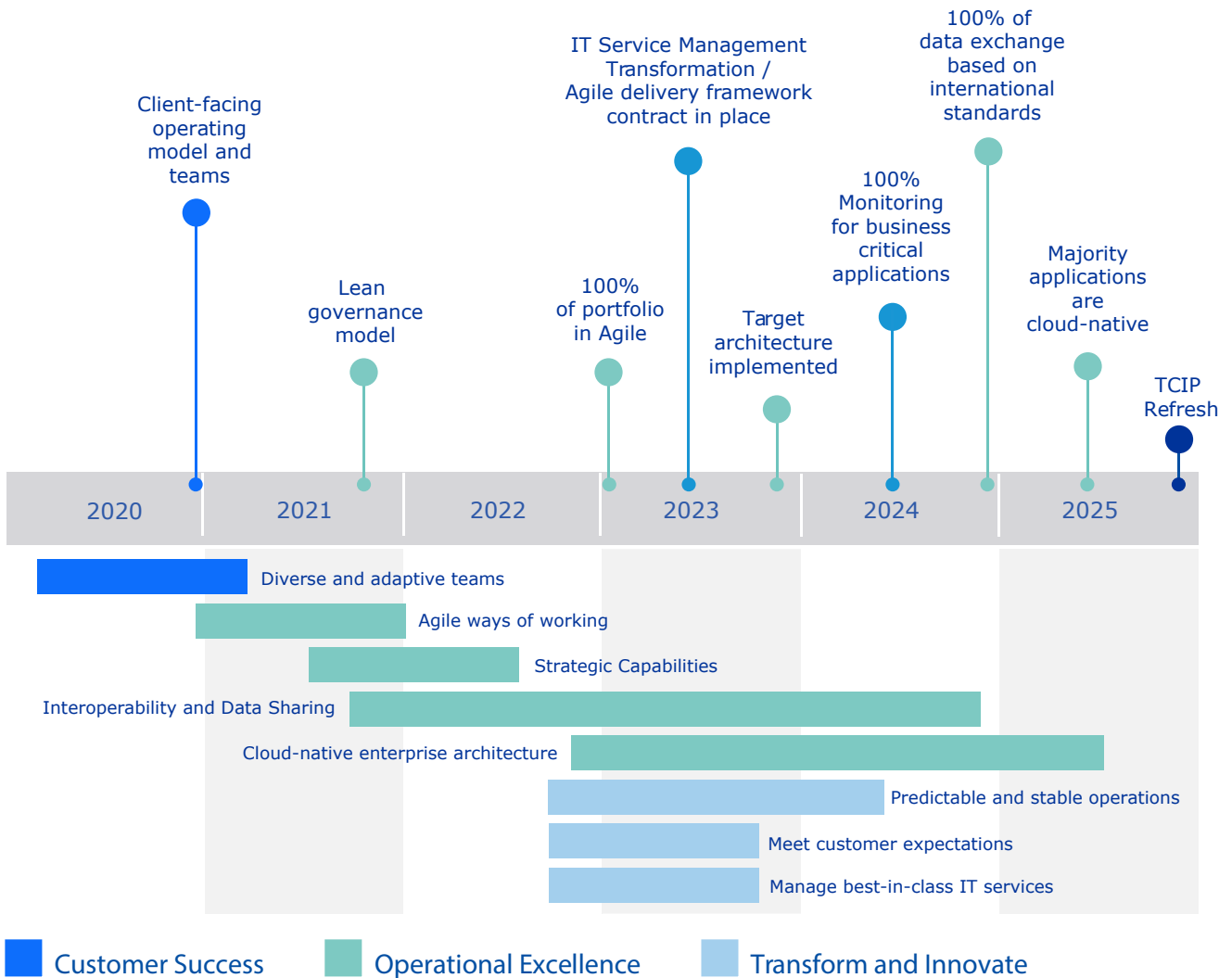
Acronym key and glossary terms

aPaaS Application Platform as a Service

API Application Programming Interface

BPM Business Process Management

CDISC Clinical Data Interchange Standards Consortium

CMDB Configuration Management Database

CRM Customer / Stakeholder Relationship Management

EAB Enterprise Architecture Board

EMA European Medicines Agency

HL7 Health Level 7 (standards)

IaaS Infrastructure as a Service

ICH International Council for Harmonisation (of Technical Requirements for Pharmaceuticals)

IM Information Management

IS Information Security

ISO International Organization for Standardization

ITIL Information Technology Infrastructure Library

ITSM Information Technology Service Management

KPI Key Performance Indicator

OLAs Operational Level Agreements

PaaS Platform as a Service

SaaS Software as a Service

SDOs Standards Development Organisations

SLA Service Level Agreement

SOC Security Operations Center

TCIP Technology Capability Investment Plan

Annexes

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

B.09_EMA Cloud Strategy 2022
EMA/686675/2021
https://www.ema.europa.eu/en/about-us/how-we-work/information-management#it-cloud-strategy-(new)-section

European medicines agencies network strategy to 2025
https://www.ema.europa.eu/en/documents/report/european-union-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf

Regulatory science strategy
https://www.ema.europa.eu/en/about-us/how-we-work/regulatory-science-strategy#regulatory-science-strategy-to-2025-section

EMA Data Standardisation Strategy
EMA/447502/2021
https://www.ema.europa.eu/en/documents/other/european-medicines-regulatory-network-data-standardisation-strategy_en.pdf

EU Data Strategy
https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-data-strategy_en