Medicines & Healthcare products Regulatory Agency

# BOARD SEMINAR

**18 May 2021**

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| **Title** | What is the Technology Roadmap to enable the Future Operating Model, improve our services and reduce our costs with fewer digital technologies? |
| **Board Sponsor** | John Quinn |
| **Purpose of Paper** | Approval |

# What is the Technology Roadmap to enable the Future Operating Model, improve our services and reduce our costs with fewer digital technologies?

## 1. Executive Summary

1.1 Technology underpins our One Agency operating model. It enables us to provide services for our customers; reduces cost through automation; gives us insights and information to make better decisions; supports our response to emerging challenges and enables us to work anywhere.

1.2 Significant progress has been made in recent years on the underpinning technology estate by implementing modern technology platforms and replacing legacy systems and services.

1.3 However, requirements have changed significantly, objectives are clearer, and direction has been set through the Agency's two-year Delivery Plan. To reduce the costs of our operations *and* the cost of change, we must build on our modern digital platforms, but taking a radically different approach to that of the past.

1.4 This paper proposes a series of difficult but necessary decisions. It proposes investing in strategically important safety systems; deleting all the Sentinel and Lotus Notes systems; standardising on simple, common and reusable platforms and solutions; and implementing a new agile delivery model built around an in-house delivery centre of excellence, managing our products to deliver maximum value, building our capability and capacity for a sustainable Technology, Digital, Data and Delivery (TD3) operation.

1.5 Trade-offs will be necessary. There are tensions between implementing the Agency's two-year Delivery Plan, reducing operating cost, reducing investment costs and keeping systems and Agency services running safely and securely. This paper proposes how we intend to balance these tensions to deliver the optimum set of outcomes for the Agency.

1.6 The prize is significant. If we get this right, we will have reduced cost in two years by 21 per cent, taking out £4.03M annualised savings, and delivering within a £54M budget over two years. We will have played a significant part in securing the financial stability of the organisation. We will have delivered revolutionary safety systems, built our internal capacity and capability to deliver change ourselves, and we will have created stable and secure platforms for the future.

1.7 **Our strategy is *Simple Smart Solutions.***

1.8 The Board is asked to approve the proposed solutions.

## 2. Introduction and Background

### Current estate

2.1 The Agency's current technology estate is complex - 432 applications and 563 servers supporting the delivery of services. These range from modern applications that have just been released through to legacy applications that are over 22 years old.

2.2 These applications are split across our core services of Scientific Research and Innovation; Healthcare Quality and Access; Safety and Surveillance; Corporate; Platform IT and Core IT.

2.3 Of the total number of applications, 27 per cent require some form of intervention to keep them running, supportable or secure within the next two years. These applications take up a disproportionate share of operational cost, taking over 38 per cent of non-pay support, maintenance and service costs, but also underpin critical Agency services and regulatory functions.

**Changing scope**

2.4 We have many of our core target platforms in place and have been implementing business solutions on them to enable new ways of working and services, without which we could not have delivered our exit from the European Union or the integrated Clinical Trials services with the Human Research Authority (HRA).

2.5 However, the approach has been slow as we have had to transfer large volumes of data and manage the transition from existing processes across into each new service. We have also, in the case of the European systems, had to integrate both old and new. While this brings stability, continuity and control, it also increases complexity, time and cost. Building on old ways of working the investment has only perpetuated the status quo. Now we need a different approach.

2.6 The Agency's structure and focus has shifted as we move towards our Future Operating Model and successfully implement our two-year Delivery Plan that will ensure we put patients first, become a truly world-leading, enabling regulator and that we protect public health through excellence in regulation and science.

2.7 Whilst the high-level structure and focus has been agreed, many of the lower level requirements, policies and legislation that would enable us to build new systems to support new ways of working have yet to be decided or defined.

**Meeting targets**

2.8 We had previously been planning on a cost reduction target of 15% for our technology operations over 2 years, and an estimated investment budget of £40M for IT replacement, with an additional estimated £21M set aside for Safety Connect, NIBSC digital investment and CPRD investments.

2.9 In the past 2 weeks the analysis of the Agency finances has identified a further gap, now clarified as addressing four interrelated targets:

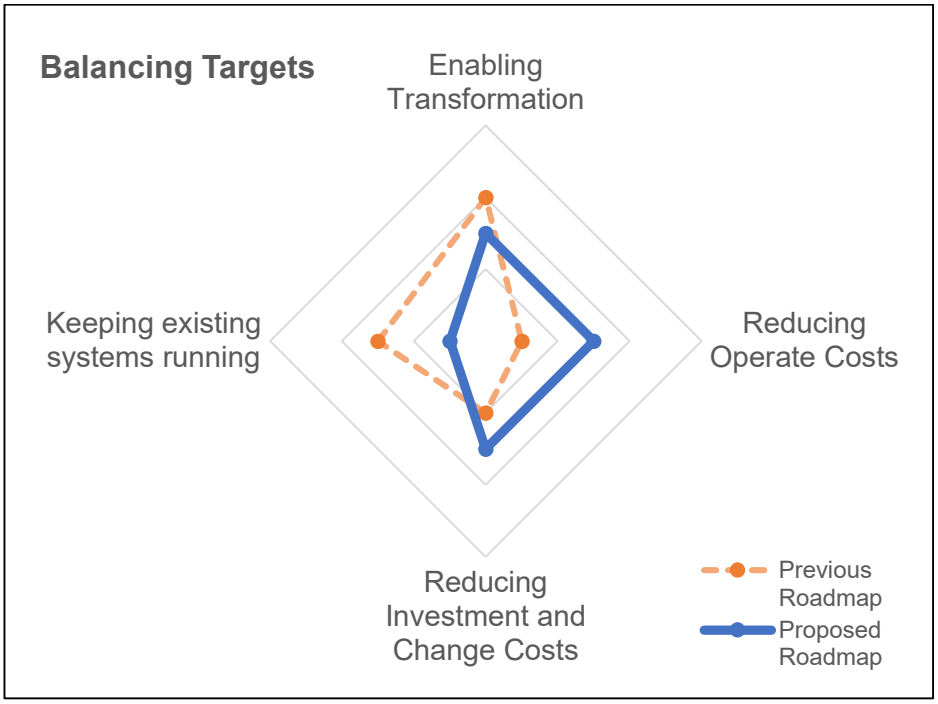
a. deliver the Agency strategy as outlined in the two-year Delivery Plan;
b. reduce the Agency technology operational cost in two years by a minimum of 21 per cent;
c. deliver all technology enabled change within a three-year budget of £54M
d. continue to manage our core operations through this transition safely.

2.10 This tighter position has required a further replan in the past week. It requires a more radical approach than we had previously considered.

2.11 The previous technology roadmap presented to ExCo and the Agency Board was focused on meeting the investment cost challenge and proposed investing in legacy systems to extend their lifespan, giving us longer to migrate away from them. This increased period of time where old and new systems would co-exist inevitably increased operating cost.

2.12 Our analysis shows that in order to take out cost, we need earlier investment, and we propose an investment of £54M over 2 years.

2.13 This new technology roadmap proposes a better balance between these targets and takes account of the Agency's financial challenges but still requires trade-offs and difficult decisions to be made.




2.14 To begin to address the **cost reduction targets**, we met with Chief Officers and their leadership teams to present information on the attributed corporate cost of running their systems. Our aim was to identify areas where costs could be reduced, and whether their future operating model intent would deliver a 20 per cent cost reduction on their systems.

2.15 To support this discussion, we allocated the non-pay Technology, Digital, Data and Delivery ($TD^3$) costs based on financial year FY2019/20 across all our applications, working with nominated portfolio representatives to understand which applications were still used, by how many and for what purpose. The following table provides a summary of the total number of systems and approximate costs:

| Portfolio | No. of applications | Application portfolio cost approx. p.a. |
|---|---|---|
| Scientific Research and Innovation | 90 | £3,272,712 |
| Healthcare Quality and Access | 156 | £6,283,486 |
| Safety and Surveillance | 61 | £2,532,106 |
| Corporate | 55 | £1,926,422 |
| Platform IT | 31 | £2,101,434 |
| Core IT | 30 | £1,329,532 |
| Unattributed infrastructure/software | N/A | £1,752,677 |
| **Grand Total** | **423** | £19,198,369 |

2.16 While more detailed analysis is needed as we go through the process of delivery and recognising that different approaches are required for each portfolio, there was not an immediate opportunity to significantly reduce the cost of operations and change.

2.17 While more analysis will bring greater depth to the discussions, it will not achieve a breakthrough on cost in the timescales we require. Analysis therefore, should be done 'inflight' leading to 'course correction' once the directional decisions are made.

2.18 The objectives in the two-year Delivery Plan **enabling transformation** that relate specifically to the technology roadmap are as follows, although significant other objectives are enabled by Digital, Data and Technology (DDaT) solutions.

| Objective | Deliverable |
|---|---|
| **Delivering for Patients** | |
| 1. Deliver better patient and public involvement to ensure we put patients first | • Implementing an enhanced and more responsive reporting system (objective 6).<br>• New digital self-service platform that will improve the service patients and customers receive (objective 14). |
| **Scientific Innovation** | |
| 3. Overhaul clinical trials system to support innovation and reduce time to approval | • Integrate with HRA and National Institute for Health Research Clinical Research Network to provide a fast track approval for defined clinical trials - criteria approval agreed by end Q2, 2021/22 |
| **Healthcare Access** | |
| 4. Develop and deliver the agency's future strategy and approach for access to medicines and devices | • Promote the Innovative Licensing and Access Pathway (ILAP) Novel Trial Design Tool in partnership with the wider health ecosystem by Q2, 2022/23.<br>• |
| **Patient Safety** | |
| 6. Deliver a more responsive safety surveillance and risk management system for all medical products to keep patients safe | • Deliver enhanced signal detection process for medicines and devices by Q4, 2021/22; service enhancement and international opportunities to defined in Q4, 2021/22 and delivered in 2022/23. |

| Objective | Deliverable |
|---|---|
| **Collaborative Partnerships** | |
| 10. Leverage international partnerships to drive better outcomes | • Improve ability to capture and exchange data with partners by adopting international standards including "Identification of Medicinal Products" regulations by Q2, 2022/23.<br>• Engage with Access Consortium and define options for approach to information sharing, joint inspections, interoperability of systems standards by Q3, 2021/22 for delivery in 2022/23 (exact timings dependent on ongoing negotiations). |
| 11. Leverage UK healthcare system partnerships and integrating process to drive better outcomes | • Deliver Agency data sharing strategy across the health sector, underpinned with robust security standards and privacy by design by Q3, 2021/22. |
| **Financial Sustainability** | |
| 13. Establish a new business model for the future that increases income, reduces costs and improves productivity | • Reduce corporate costs by 15 per cent by end 2022/23.<br>• Reduce non-pay costs of £60M by £6M per year through contract renegotiation and contract management by end 2022/23. |
| 14. Deliver an optimised IT infrastructure to improve our service and reduce our costs with fewer digital technologies | • Finalise plan to overhaul costly legacy systems by Q3, 2021/22 and start to deliver improved service and savings from Q4, 2021/22, and to have a new regulatory management core system in place by Q3, 2022/23.<br>• New digital self-service platform delivered in beta by Q4, 2021/22 and live in Q1, 2022/23 that will improve the service patients and customers receive.<br>• To support the revised regulations around medical devices, deliver the digital self-service, automation and data platforms required by Q3, 2022/23.<br>• Work with the HRA to deliver an enhanced clinical trials service by Q4 2022/23. |

2.19 Our proposed roadmap delivers against these objectives.

## 3. Proposal

3.1 Below, we have broken the proposal into sections. The solutions we propose to the objectives laid out in the introduction; the technology roadmap to show the planned activity, with the accompanying finances; and the benefits and risks associated with this proposed approach.

## A. Solutions

3.2 Below are the proposals against the five portfolios. While there will be granular options and a desire for further analysis, time and cost pressures mean that we are at a point where decisions are required to allow us to act or we will fail to implement the two-year Delivery Plan, fail to reduce investment and operate costs and be unable to provide stable and secure Agency services.

3.3 The table below summarises the key proposals:

| Portfolio | Proposal | Current Annual Cost | Cost impact | New Annual Cost |
|---|---|---|---|---|
| Scientific Research and Innovation | • Centralise distributed teams and platform ownership to deliver efficiency<br>• Review each scientific system against the new FOM to take out cost | £3,272,712 | 21 per cent reduction | £2,585,443 |
| Healthcare Quality and Access | • Delete Sentinel and Lotus Notes over next two years<br>• Deliver simple services on core platforms | £6,283,486 | 25 per cent reduction | £4,712,615 |
| Safety and Surveillance | • Invest in SafetyConnect<br>• Remove legacy | £2,532,106 | 30 per cent increase | £3,291,737 |
| Corporate/ Enablement | • Re-platform and remove local bespoke systems with in-house teams<br>• Take a risk or buy a service on some core systems | £1,926,422 | 21 per cent reduction | £1,521,874 |
| Platform (Including Core IT) | • Insource into a Delivery Centre<br>• Reduce service to match the fewer number of staff we will be supporting, | £3,430,966 | 28 per cent reduction | £2,470,296 |
| Unattributed infrastructure /software | • Infrastructure decommissioning<br>• Software reduction | £1,752,677 | 66 per cent reduction | £584,000 |
| **TOTAL** | | **£19,198,369** | **21 per cent reduction** | **£15,166,712** |

## Scientific Research and Innovation

3.4 The corporate systems that support the Scientific Research and Innovation portfolio are a mix of software to support scientific research and standards principally at NIBSC, and the data platforms and services that support CPRD.

3.5 At the highest level these systems have been run in a distributed way, with a rough split of basic infrastructure managed by $TD^3$ and strategy, solutions and software decisions run locally in the teams. This is largely due to historical structures, but there are benefits and risks to distributed control. At its best it can bring flexibility. However, it can lead to misalignment, inefficient use of resources, greater cost, lack of interoperability and greater levels of cyber risk.

3.6 Through our analysis, we did not find any immediate or significant cost savings to be found in the science domain. Scientific systems require software, and the answer to reduction will be a mix of decisions around the future operating model, and belt tightening with a system by system review. It may also be necessary to accept risk of failure on some systems.

3.7 In the area of CPRD, we believe there is an opportunity to deliver Agency savings of between 15 and 20 per cent through centralisation and direct management and control, by embedding the CPRD Data, Tools and Technology team within the central Technology, Digital Data and Delivery ($TD^3$) Division. We understand that this is a contentious proposal and that providing a service back to CPRD could appear to reduce control of this important Agency service. However, we believe that there will be efficiencies through re-use and we believe an enhanced service will be provided to the whole of the Scientific Research and Innovation portfolio as a result.

3.8 Given that the CPRD teams have not yet been engaged in this proposal at this stage, we believe this is a priority area to address and engage with the teams to assess the opportunity. We must take out 20 per cent cost, and at present we cannot see a way that we can afford distributed capability and capacity. The next steps will be to consult the Organisation Design Specialist to assess roles, and for a platform and plan review to assess cost savings. If savings cannot be found through centralisation, cost reduction in Scientific Systems may be necessary.

**3.9 We believe that with these actions we can target operating cost reductions of 21 per cent in two years and reduce the cost of change to work within £54M investment.**

## Healthcare Quality and Access

3.10 The corporate systems that support Healthcare Quality and Access portfolio are principally the Sentinel and Lotus Notes legacy platforms. They are out of support, overly complex, subject to unsustainably high maintenance and infrastructure costs, are at increasing risk of cyberattack and data loss and locks us in to processes that our Agency Future Operating Model seeks to change.

3.11 Our original proposal was to limit our investment to prolong the life of these systems while we developed cheaper, simpler systems in parallel to support the new operating model. While the investment would be limited, it reduced the cost of transferring processes and data given the budget and time constraints and allowed for a longer transition and investment period.

3.12 However, with the clarification of cost reduction targets in the past 2 weeks, it means we cannot reduce the cost of our operations to meet the 21 per cent target with this approach.

3.13 All efforts to reduce the cost cannot be delivered because of the high degree of integration of the systems and licensing and support costs. In simple terms, switching off parts of systems does not take out cost – if areas of the business continue to use these legacy systems, the cost remains high. We therefore propose to delete Sentinel and Lotus Notes over the next two years. We will explore taking a limited amount of data out and into a data store in the cloud at low cost to meet any regulatory needs, and based on work underway for Safety Connect, we would estimate 30% of data would need to be retained in low cost archived storage.

3.14 To enable delivery of the Future Operating Model within the cost envelope, we propose putting in place robust and simple workflow and case management solutions, configuring them on our cloud-based platform that currently has Clinical Trials, Customer Contact Management and Devices Registration services. To reduce these costs further, we propose a fast-paced delivery with a hybrid in-house development and supplier team during the first two years to ensure legacy systems can be deleted whilst maintaining services.

3.15 Interoperability will be a requirement for all new systems and improve our ability to capture and exchange data with partners in varying formats. By working with partners across the health sector to develop shared standards, and embedding international standards including “Identification of Medicinal Products” regulations we will ensure that we are able to support a range of processes e.g. ILAP and Project Orbis.

**3.16 We believe that with these actions we can target operating cost reductions of 25 per cent in two years and reduce cost of change to work within the available budget.**

**Safety and Surveillance**

3.17 The corporate systems that support the Safety and Surveillance portfolio are principally a mix of Sentinel for medicines, Lotus Notes for Devices, some specialist software, and web-based Yellow Card services. The cost of operating the current services outside of Sentinel and Lotus Notes are relatively low.

3.18 We have made the strategic decision to invest in safety systems to enable the Future Operating Model of bringing devices and medicines together into a common integrated vigilance service. The programme intended to deliver these benefits is SafetyConnect by:

- enhancing how patients report suspected adverse incidents to us and how we engage and provide feedback;
- introducing new cutting-edge technology for all our incident management and signal detection utilising automation and machine learning; and
- creating a new world leading vigilance service by introducing common ways of working across all vigilance activities and medical products.

3.19 The competitive tender for the core vigilance technology is nearing completion and it is clear that this will be a major investment as it replaces the Agency's vigilance systems used for case management, the detection of signals, analytics and reporting. A large proportion of the programme costs (£10.6M) is being used to replace the vigilance technology and the associated change and data management activities needed to do this. Of these costs, £5M is to procure the core vigilance systems which have an initial implementation cost of £2M and an increase to the corporate IT costs of £750k each year.

3.20 There are significant benefits associated with this programme of work with it contributing to improving public health and reducing preventable harm. The improvements will help the Agency detect safety signals quicker, increase reporting and the data available and utilise automation so our experts' focus is on activities which have the greatest public health benefit.

3.21 **We believe it is therefore not possible to reduce the overall operating costs and they will increase by 30 per cent. By transferring historical data out of Sentinel, it will enable the benefits to be achieved from deleting it when complete.**

**Corporate and Enablement**

3.22 Corporate and Enablement costs are principally associated with the cloud-based Oracle Fusion services that underpin HR, Finance and Commercial Management. We have explored the opportunity of taking shared services from other organisations, but the offer is yet to mature and the cost of such a move is not currently affordable. We believe there is some limited opportunity to take out cost that we will explore with providers through the Application Outsource (AO) procurement. We believe the functionality we have gained from our move to Oracle Fusion, forms part of the answer to cost savings and control overall that we require.

3.23 However, there are a large number of local and bespoke systems that create software licence, infrastructure and support costs. Alongside the systems that support enablement, and the opportunity to go after residual legacy systems, there is an opportunity to target savings that will reduce operational costs by 21 per cent.

3.24 Delivering within the budget constraints of investment will not be possible by outsourcing this work to suppliers. We believe this will be achieved by using new in-house civil servant teams configuring our existing low-code cloud platforms, reusing our existing licences and reducing the number of technologies we currently pay for and support. We have proved this model can work through our delivery of the Customer Contact Centre application.

3.25 The Common Alerting System (CAS) that provides an alerting service across the healthcare system was tactically replaced in 2016 but no longer meets the needs of the Agency or wider system. We receive no funding for operating this service but alerting our customers is an important regulatory function. The cost of developing a bespoke service is not achievable within the current cost envelope. We do not yet have an answer for this problem, and need to explore how it can be resolved; whether there are similar services in government we could re-use; whether there is off the shelf limited functionality from our existing platforms; whether there are cascade processes where we ask other organisation to disseminate our information; or whether a charging model can be implemented to allow us to extend. We propose revisiting previous analysis and undertaking new investigations with cost being the defining factor in the ultimate decision.

3.26 **We believe that with these actions we can target operating cost reductions of 21 per cent in two years and reduce the cost of change within a total financial investment of £54M.**

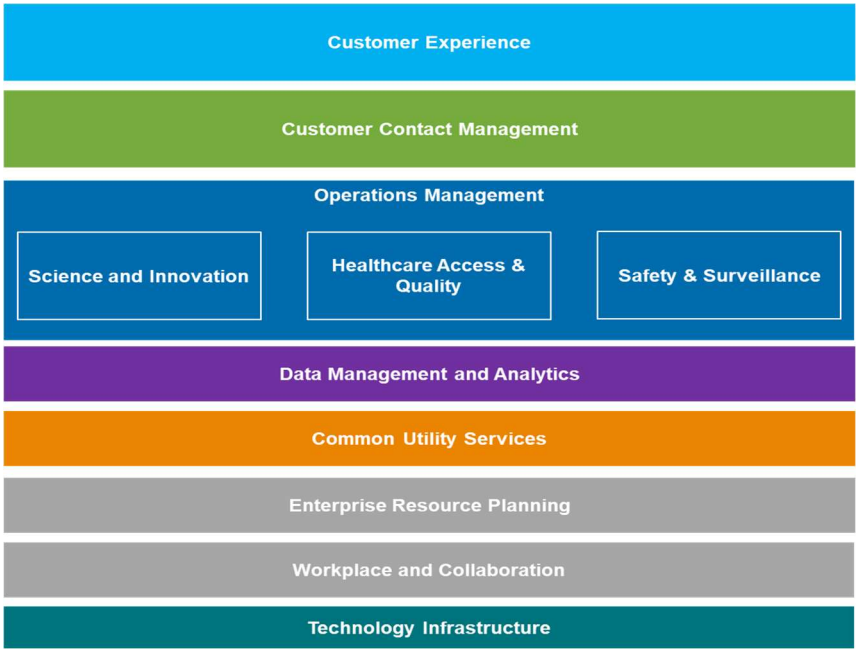
## Platforms

3.27 Delivering the new services and reducing operating costs outlined above are fundamentally linked to the following platform proposals. Without implementing the following recommendations, delivering the cost reductions in operations and change will not be possible.

3.28 There are three integrated components to this proposal that will enable us to deliver our ambition for Simple Smart Solutions.

### I. Common Technology Platforms

3.29 We propose adopting a platforms and component approach to technology across the Agency. New simple systems will be assembled from the layers of platform technology below, from reusable common components. It will simplify and reduce our technology estate, enabling us to develop skills in fewer modern technologies.




### II. Core IT

3.30 Core IT covers the provision of infrastructure on which our services reside, the service management and operational management of those services. It includes devices like laptops, computers, monitors and keyboards; the helpdesk; our networks and server estate; and supplier provisioned management services.

3.31 Over the past three years we have progressively modernised our core IT, enabling us to reduce costs and improve services. If we had not done so the Agency would not have been able to move to remote working seamlessly during the pandemic or been able realise the £4.78M annual cashable benefits per year already delivered.

3.32 The scope for reduction is more limited as a result but we can contribute to savings once we reduce the number of staff in the Agency requiring software licences, laptops and equipment. There is a clear dependency on reducing headcount, but we are assuming this will lead to savings that we have now included in our model.

3.33 As we move to cloud-based computing, and enabled by the decision to move away from our legacy over the next two years, the ability to reduce these costs will grow and be dependent on how willing we are to allow use of personal devices. Homeworking means a lower requirement for office support and for example reducing office printers to a total of one or two machines would contribute further savings.

### III. TD$^3$ Delivery Centre

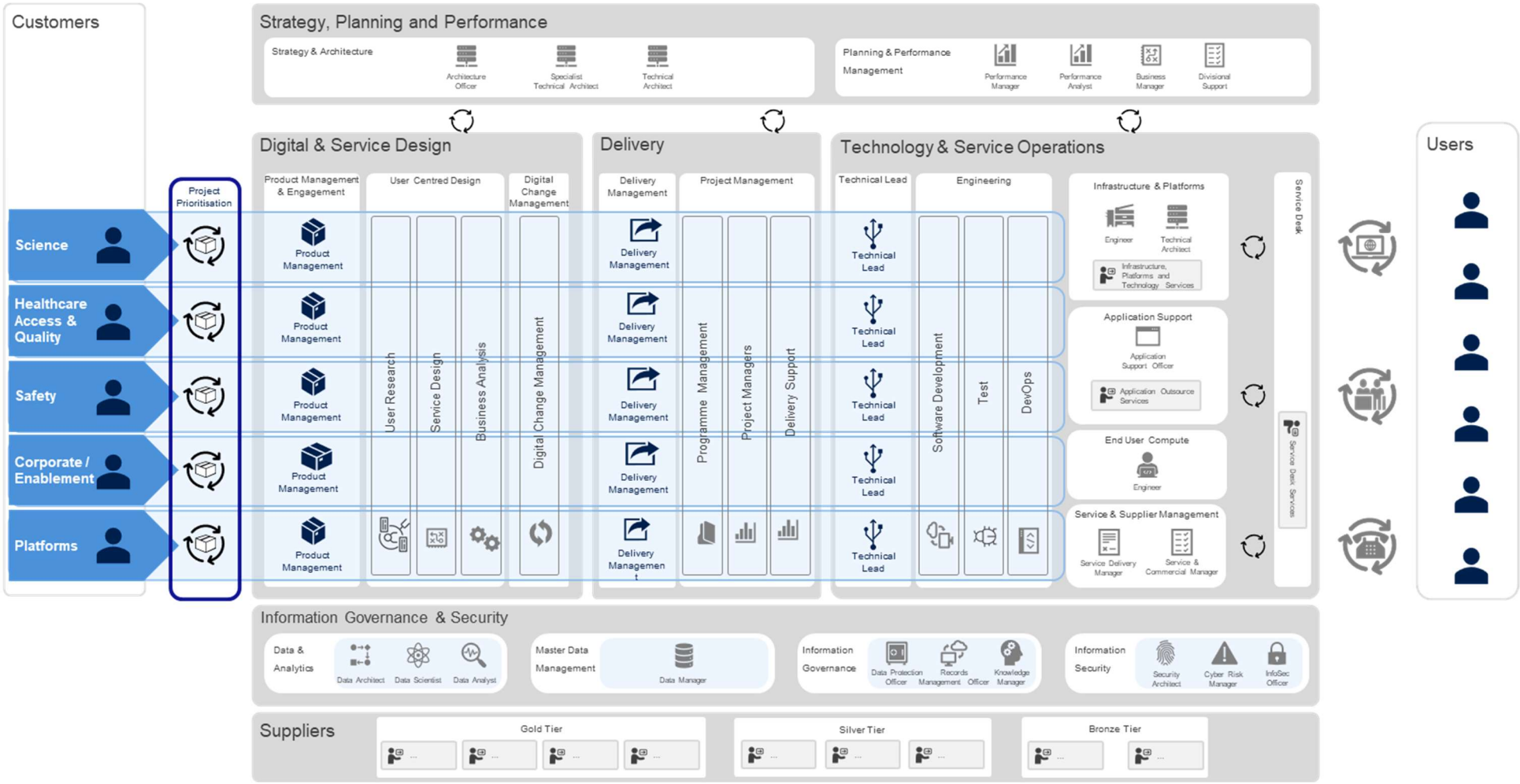
3.34 We propose consolidating distributed digital, data, technology and delivery teams into one team, creating cross functional delivery teams aligned to the new Agency portfolios, and matrix managed to align to priorities. Fundamentally this puts the customers at the heart of design, working alongside delivery teams to give them what they want. Combined with a usability labs approach with patients, we believe this will act as an engine room for delivering the agency technology enabled changes. See the new TD$^3$ Delivery Centre Operating Model on the following page.

3.35 This will enable us to reduce costs through efficiencies, create expertise in fewer technologies, build career pathways based on professional standards outlined by the Digital, Data and Technology (DDaT); Project Delivery (PD); Government Knowledge and Information Management (GKIM); and Cyber Security professions.

3.36 We have revisited how we resource the TD$^3$ Delivery Centre. Our aim in 2021/22 is to deliver a mixed model of inhouse, insourced people at cheaper rates than suppliers, to create a sustainable model delivering and managing simple systems.

3.37 We are currently procuring a replacement contract that is 20 years old managing our applications, where we will seek cost reductions and cross training for our own teams.

# TD³ Delivery Centre



3.38 At this stage we have primarily addressed the operating cost target. However, there are also significant potential reductions to be made to the cost of implementing projects over the next two years. While we do not propose to hire permanent civil service staff which would increase our operating costs for the majority of change, we believe we can take on fixed term posts, fast streamers, redeployed and trained internal staff and apprentices to reduce the dependence on suppliers.

3.39 Based on the current portfolio of change projects initial modelling demonstrates that it would be possible to replace around £4M of external spend with a team of around 25 appropriately skilled DDaT specialists at a cost of £2.1M per annum – a saving of almost £1.9M or nearly 50 per cent. We will model this into the delivery costs and report through to the Transformation Board where the opportunities reside.

3.40 **We believe with these actions we can target operating cost reductions of 28 per cent in two years, and reduce the cost of change within a total financial investment of £54M.**

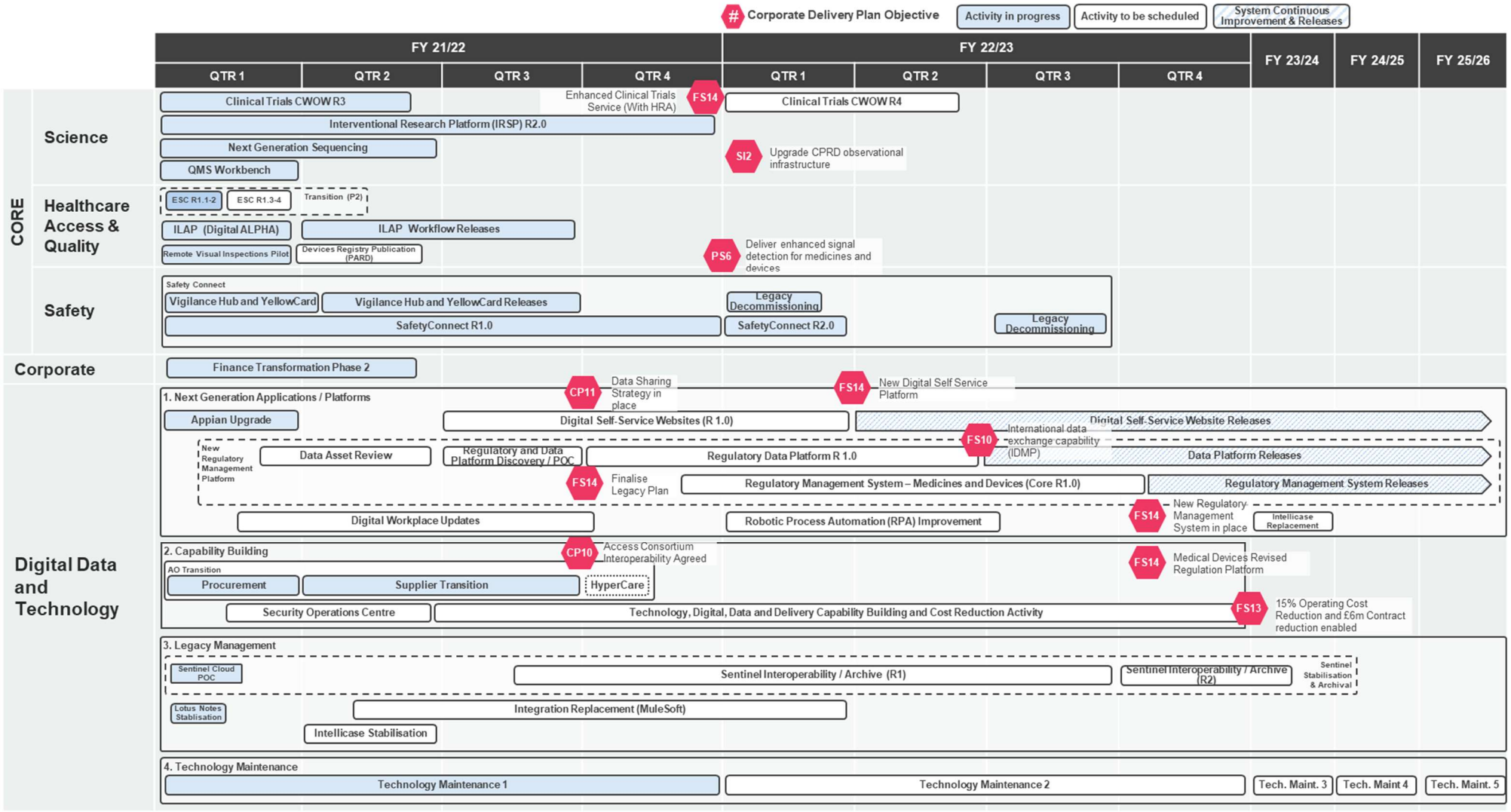
## B. Roadmap

3.41 To provide a balanced response and to support the required approach to cost reduction, more emphasis and investment has been proposed for next generation applications and platforms with a significant reduction in focus on legacy management.

3.42 The sequencing and timing of projects is important and is aligned to minimise potential dependencies, rework, slippage and congestion. The two-year Delivery Plan objectives that are enabled or delivered are highlighted.

3.43 The plan works on the assumption of continued funding beyond March 2022, but we recognise that our funding regime will change, and there is a risk that funding may not be available.

3.44 Our plan is designed to put in place the core capabilities in the current financial year to enable change by building in house capability to implement services. The risk will be to operational benefits in such an eventuality, where we would not be able to decommission our legacy at our preferred rate.


# Corporate Delivery Plan Objective
Activity in progress
Activity to be scheduled
System Continuous Improvement & Releases
FY 21/22
FY 22/23
FY 23/24
FY 24/25
FY 25/26
QTR 1
QTR 2
QTR 3
QTR 4
CORE
Science
Clinical Trials CWOW R3
Enhanced Clinical Trials Service (With HRA)
FS14
Clinical Trials CWOW R4
Interventional Research Platform (IRSP) R2.0
Next Generation Sequencing
QMS Workbench
SI2
Upgrade CPRD observational infrastructure
Healthcare Access & Quality
ESC R1.1-2
ESC R1.3-4
Transition (P2)
ILAP (Digital ALPHA)
ILAP Workflow Releases
Remote Visual Inspections Pilot
Devices Registry Publication (PARD)
PS6
Deliver enhanced signal detection for medicines and devices
Safety
Safety Connect
Vigilance Hub and YellowCard
Vigilance Hub and YellowCard Releases
Legacy Decommissioning
SafetyConnect R1.0
SafetyConnect R2.0
Legacy Decommissioning
Corporate
Finance Transformation Phase 2
Digital Data and Technology
1. Next Generation Applications / Platforms
CP11
Data Sharing Strategy in place
FS14
New Digital Self Service Platform
Appian Upgrade
Digital Self-Service Websites (R 1.0)
Digital Self-Service Website Releases
FS10
International data exchange capability (IDMP)
New Regulatory Management Platform
Data Asset Review
Regulatory and Data Platform Discovery / POC
Regulatory Data Platform R 1.0
Data Platform Releases
FS14
Finalise Legacy Plan
Regulatory Management System – Medicines and Devices (Core R1.0)
Regulatory Management System Releases
Digital Workplace Updates
Robotic Process Automation (RPA) Improvement
FS14
New Regulatory Management System in place
Intellicase Replacement
2. Capability Building
CP10
Access Consortium Interoperability Agreed
FS14
Medical Devices Revised Regulation Platform
AO Transition
Procurement
Supplier Transition
HyperCare
Security Operations Centre
Technology, Digital, Data and Delivery Capability Building and Cost Reduction Activity
FS13
15% Operating Cost Reduction and £6m Contract reduction enabled
3. Legacy Management
Sentinel Cloud POC
Sentinel Interoperability / Archive (R1)
Sentinel Interoperability / Archive (R2)
Sentinel Stabilisation & Archival
Lotus Notes Stablisation
Integration Replacement (MuleSoft)
Intellicase Stabilisation
4. Technology Maintenance
Technology Maintenance 1
Technology Maintenance 2
Tech. Maint. 3
Tech. Maint 4
Tech. Maint. 5

3.45 The breakdown of projects is shown below:

| Portfolio | | Group | Impact and Rationale |
|---|---|---|---|
| **Core** | **Science** | Clinical Trials | Work with Health Research Authority (HRA) to enable straight through processing of cases from HRA self-service websites. In Release 4, implement Clinical Investigations (Devices) to harmonise onto same strategic target platform and enable decommissioning of Lotus Notes Clinical Investigations legacy system.<br>This moves Clinical Trials to product status meaning incremental changes going forward. Further development will still require funding. |
| | | Interventional Research Platform (IRSP) | Complete two-step migration to new IRSP. Disentangles intellectual property from hosting provider and rebuilds in the Agency's strategic target hosting platform. |
| | | Next Generation Sequencing | Replaces legacy and approaching end of life high performance compute platform located at NIBSC South Mimms and migrates to cloud platform. Allows increase in capacity and performance on demand depending on service and research demands rather than having a fixed on-premise capacity at a much lower level of performance. Aligns technology and skills required with broader life sciences community which will help with talent attraction, retention and support for the platform. Decommission problematic legacy high performance computing cluster. |
| | | QMS Workbench | Migrate from standalone quality management system (QMS) document management solution to Agency-wide SharePoint, reducing licence cost and aligning with strategic target platform. |
| | **Healthcare Access & Quality** | Transition (ESC) | Complete minimum required transitional activities to ensure compliant EU Exit. |
| | | ILAP | Implement basic digital service. Further refinements on workflow should be considered post-Agency size and shape and be aligned to the future Regulatory Management System (RMS) development to avoid rework. |
| | | Remote Visual Inspections Pilot | Pilot to establish remote visual inspections. |
| | | Public Access Registration Database (PARD) | To be confirmed pending Agency Size and Shape. Publication of registration information to public facing website (Product Information Portal) and improving searchability and accessibility. |
| | **Safety** | SafetyConnect | Replaces significant portions of legacy applications within Devices (Lotus Notes) and medicines (Sentinel) safety and surveillance functionality. |

| Portfolio | Group | | Impact and Rationale |
|---|---|---|---|
| | | | Programme will implement target safety platforms. Migrate required data, integrate with legacy where required by the product lifecycle and decommission legacy systems. This includes front end Yellow Card and Vigilance Hub all the way through adverse reaction/incident handling, signal detection and management and including underlying hardware and infrastructure. |
| **Corporate** | Finance Transformation Phase 2 | | Upgrades existing interfaces between financial systems to allow improved debt management; replaces legacy application (TAS Books) with strategic Ingenica platform for ordering and stock control for British Pharmacopeia standards; implements new invoice matching software; and implements finance and budget planning software. |
| **Platforms (DDaT)** | 1. Next Generation Applications / Platforms | Replacing legacy systems with platforms and products enabling the transformed One Agency services and user needs. These projects are creating the future platforms of the Agency aligned to new ways of working and the new services we will be providing. | |
| | | Digital Self Service & Websites | Provide front door gateway for customers to actively engage and self-serve. This will look to consolidate our entry point for customers, provide a single user account across all services, implement a new e-Commerce and content management system and provide a consistent look and feel for all stakeholders with the ability to personalise and tailor content. |
| | | Data Asset Review | Review legacy data assets, allocate ownership and establish business criticality of assets to inform future data architecture requirements, data archival requirements and support legacy management decision making. |
| | | Regulatory Data Platform | Builds core regulatory data platform covering structured and unstructured data and including handling master (party and product) and reference data. This platform will enable data to be better accessed and maintained at a higher level of quality. Lays the foundations to enable analytics on enterprise data. Reporting across different data sources with the combined view to be able to gain insights for better decisions. First step in addressing legacy RMS issues and replacing Sentinel. |
| | | Regulatory Management System (Medicines | Builds core functional platform for regulatory activity. This application will build on top of the data platform and provide the Agency with a new regulatory management platform to allow migration of functions from Lotus Notes and Sentinel and for those legacy applications to be archived and decommissioned. |

| Portfolio | Group | | Impact and Rationale |
|---|---|---|---|
| | | and Devices) Core | This will be built to a Minimal Viable Product (MVP) level and will require continual improvement and investment at a lower level over its life. |
| | | Digital Workplace Updates | Provides access to the continuously improving tools agency needs to work securely and effectively wherever they are to meet future remote and hybrid working requirements. Builds capability to replace existing smaller Corporate applications to reduce subscription and software costs. |
| | | Intellicase Replacement | Replacing our enforcement solution. |
| | 2. Capability Building | Building capability and capacity to successfully deliver the Corporate Plan including internal capability to reduce future change costs and improve sustainability. | |
| | | Applications Outsourcing Transition | Building internal capability to reduce future change costs and improve sustainability. |
| | | TD[3] Capability Building and Cost Reduction | Implements capability building and cost reduction measures outlined in this paper. |
| | 3. Legacy Management | Building the legacy archival and decommissioning solution and making select legacy software and systems last longer whilst maintaining agreed standards of security to give us more time to replace them or confirm we no longer need them (Upgrade, Accept Risk, Retire). | |
| | | Sentinel Interoperability / Archive | Considers a cheap data archival solution to enable decommissioning of Sentinel, Lotus Notes and other legacy applications. |
| | | Robotic Process Automation (RPA) Re-platform | Re-platforming our RPA solution that automates high volume and repetitive activities. There is increased appetite for automation and this will provide part of the solution for the Business Process automation centre. The current solution's vendor has been taken over and this requires us to move to the new standardised vendor offering. |
| | | Lotus Notes decommission | Move Lotus Notes to a staging area to extract the data as we look to decommission the platform over the next two years in-line with Safety Connect and RMS. This work will also move the applications to the cloud, removing the need to continuously replace hardware and enabling us to close a legacy data centre to reduce cost. |

| Portfolio | Group | | Impact and Rationale |
|---|---|---|---|
| | | Integration Replacement | Replacing existing integration technology (MuleSoft) with a more sustainable and cheaper solution that will reduce our annual operating software licence costs. |
| | 4. Technology Maintenance | Keeping the lights on and what we have running by delivering the continued service and operation of the Agency's infrastructure, technology systems and platforms, ensuring that they are fit for purpose, secure, supported and cost efficient.<br>Key deliverables for FY21/22 include:<br>• Security enhancements<br>• Network upgrades<br>• Laptop refresh<br>• Replacing defunct hardware | |

**C. Benefits and Risks**

3.46 The benefits of implementing these proposals are significant. Throughout the paper we demonstrate how the proposals support the Agency two-year Delivery Plan. In so doing it will reduce our operational and change implementation costs, but critically develop an in-house capability to manage ongoing change that will be necessary to create an agile organisation that can adapt to evolving patient needs.

3.47 The core focus on reducing costs by 21 per cent in two years, whilst building in capability for delivering agile solutions in the future, and making provision for a strategic investment in the Safety portfolio is an ambitious agenda, but one that is required by the Agency.

3.48 There are a number of key risks relating to this approach, at both a strategic and an operational level. A full risk assessment will be developed for the strategy once approved, but the risks we would rate as high are as follows:

| | Category | Risk description | Mitigation |
|---|---|---|---|
| 1 | Strategic | Systems which have reached End of Service Life (EOSL) may not recover in the event of failure leading to the Agency not being able to perform its regulatory function. | Agency decision making and governance to support early decision making is required to reduce our reliance on these systems and prioritise investment in support for those we maintain. |
| 2 | Strategic | Loss of data and/or system failure caused by a cyberattack or major data breach impacting on the operation of the Agency causing reputation damage | Reduction in number of platforms and systems requiring support<br>Reduction in number of 3rd parties accessing Agency systems |
| 3 | Strategic | Agency IT infrastructure and software does not meet the needs of customers, patients, and the public | Strengthened focus on Agency portfolios through new Operating Model<br>Shift to product focus and agile development framework |
| 4 | Operational | Internal resistance to the proposals either delay or block the required changes. | Workshops with key stakeholders to understand and address their concerns and secure buy-in |
| 5 | Operational | We are not able to recruit civil servants with the right skills within planned timescales | Savings profile has assumed the application of GDS benchmarked rates for relevant posts |
| 6 | Operational | Resistance from suppliers to new ways of working | Early engagement with suppliers as part of supplier management |
| 7 | Commercial | The Agency is unable to find a supplier able to fulfil the delivery roadmap and willing to work in partnership as we build internal capability and capacity | Application Outsource (AO) procurement is underway and has adopted a competitive dialogue approach ensuring that as our requirements firm-up we can continue to use them supplier selection criteria. |

## 4. Recommendation

4.1 The Board is asked to approve the proposed solutions to enable the Future Operating Model, improve our services and reduce our costs with fewer digital technologies.

**John Quinn**
**May 2021**