Medicines &
Healthcare products
Regulatory Agency

MHRA Transformation Programme

One Agency – Delivering for Patients

Programme Business Case

OFFICIAL SENSITIVE

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Definitions

Term	Definition
BCR	Benefit Cost Ratio
CMS	Certificate of Manufacturing Status
DbDSS	Digital by Default Service Standard
DDaT	Digital Data and Technology
DHSC	Department for Health and Social Care
EPMO	Enterprise Portfolio Management Office
GDS	Government Digital Services
Green Book Guidance	Refers to the Green Book Central Government Guidance on appraisal and evaluation
HMG	Her Majesty's Government
HMT	Her Majesty's Treasury, is the British government department responsible for developing and executing the government's public finance policy and economic policy
IAAP	Integrated Assurance and Approvals
MHRA	Medicines and Healthcare Products Regulatory Agency
MLO	Most Likely Outcome
NPSV	Net Present Social Value
PBC	Programme Business Case
PDD	Programme Definition Document
PID	Project Initiation Document
PPM	Project and Programme Management
PUS	Permanent Under Secretary
RAIDD	Risk, assumptions, issues, dependencies, decisions log
RMS	Reference Member State
RPA	Risk Potential Assessment
SCC	Strategic Change Committee
SMT	Senior Management Team
SOP	Strategic Outline Programme

SRO	Senior Responsible Officer
Technology	Technology, Data, Digital & Delivery
The programme	The programme refers to the MHRA Transformation Programme and the related activities and interventions
TMO	Transformation Management Office

1. Executive Summary

1.1 Purpose of the Document

The purpose of this Programme Business Case (PBC) is to revisit the options identified in the Strategic Outline Programme (SOP), to identify the option which optimises public value ('the preferred option') following more detailed appraisal; confirm affordability and put in place the management arrangements for the successful delivery of the programme.

This stage aligns with the Cabinet Office Gateway Review point 2 (delivery strategy) and comprises of the following business case development activities: Step 4: determining potential VfM Step 5: preparing for the potential Deal Step 6: ascertaining affordability and funding requirement Step 7: planning for successful delivery.

This Programme Business Case (PBC) builds upon the case for intervention outlined in the SOP and was approved by the MHRA Executive Committee on 12th January 2022.

The continuing justification for the programme will be monitored against this Business Case.

1.2 Approval Being Sought

The Agency is seeking approval from the DHSC Investment Committee, HM Treasury and Cabinet Office to proceed with the total transformation spending envelope of £65.2m.

The Agency wishes to gain approval for immediate year 1 (FY21/22) transformation spend (funded from the Agency cash reserves) of £27.5m with the remaining spend of £30.2m in year 2 (FY22/23) and £7.4m in year 3 (FY23/24) to be approved by an Agency spend governance model detailed in section 6.3 of the management case. These figures are correct as of November 2021.

1.3 Strategic Case

The Medicines and Healthcare Products Regulatory Agency (MHRA) is an Executive Agency of the Department for Health and Social Care (DHSC). The Agency's mission is to improve patient health through enabling the earliest access to, and high-quality supply of safe, effective, and innovative products, made available through proportionate, data-driven decisions on risks and benefits.

The SOP identified the Agency's need to rapidly respond to several key challenges it is currently facing. As of June 2021, these include:

1) **Achieving better patient outcomes in a pandemic:** The UK's Life Sciences Agenda along with the COVID-19 pandemic has increased the criticality of the MHRA's role as a regulator of vaccinations and has highlighted the importance of strong regulatory frameworks in order to proactively respond to fast-moving life science developments.

2) **Responding to the government's independent medicines and medical devices safety review:** Baroness Cumberlege exposed areas of the Agency's responsibilities which needed overhaul and highlighted a need for MHRA to address failures in listening and responding to patients.

3) **Responding to EU exit:** The United Kingdom's exit from the EU has provided an opportunity to redefine MHRA's role as a regulator and capitalise on the creation of new international regulatory relationships. However, a considerable amount of work is required to introduce a new operating model (encompassing processes and capabilities) to replace the existing regulation for medicines and medical devices that was previously conducted by the EU.

4) **Becoming financially sustainable:** The financial forecast highlights that the Agency is operating in an unsustainable cash position which requires urgent rectification. Without any cost reduction and / or restructuring action, the Agency will arrive at persistent net income gap of -£4.5m to -£7.3m per annum over the next three years.

[redacted]

6) **Operating as a siloed organisation with a structure and culture which are not fit for the future:** Operating as 3 separate and siloed divisions, the MHRA has outdated infrastructure, unclear accountability and a need to engage staff in new ways of working.

There is a clear case for an ambitious Transformation Programme to address the Agency's challenges. In addressing each of these drivers for change the proposed One Agency Transformation Programme will deliver the following:

1) **Agency Restructuring and Cost Reduction:** An Agency wide cost reduction programme targeting pay costs, non-pay costs and project spend to return the Agency to a sustainable cash position.

2) **Future Operating Model Design and Implementation:** A new, fit for purpose operating model that puts patients first, delivers critical support to UK life sciences and demonstrates a culture that positions the Agency to deliver against the MHRA 2021-2023 delivery plan.

3) **Technology Enabled Change:** A replacement of legacy systems and investment in new technology which underpin the future operating model, enabling the Agency to deliver simple, smart solutions that integrate across the health system.

4) **One Agency Culture:** A meaningful shift to the organisational culture that puts patients at the centre, drives the right behaviours across the Agency and enables new partnerships through embracing new ways of working, systems leadership and innovation.

These in turn will ensure the Agency is in a stronger position to deliver a world class service and improvements to patient health, including focussed improvements in:

1. Improving public and patient safety
2. Increasing the Agency's efficiency and effectiveness
3. Enabling innovation from science and pharmaceuticals
4. Enhancing the Agency's domestic and international reputation

1.4 Economic Case

This Economic Case details the economic appraisal of four development options for the Transformation Programme. It sets the context for the determination of these options as the 'relevant options' and considers the economic costs and benefits of each to arrive at a preferred option.

The Strategic Outline Programme (SOP) Business Case considered the long list of options and assessed these against a set of critical success factors, concluding that options 3 and 4 should be taken through to the short list for economic appraisal. The long list options were:

- **Option 1:** Business as Usual (BAU)

- **Option 2: Remove Friction –** Minor alterations to the Agency operating model with a smaller element of headcount reduction

- **Option 3: Driving Patient Outcomes across the Product life-cycle Operating Model** – Focusses the Agency's operating model around tasks that have the biggest impact on outcomes. A mid-level of legacy technology is replaced

- **Option 4: Product Lifecycle & Agile Operating Model** – Orientates the Agency organisational structure around the product lifecycle and embeds agile ways of working. The full stack of legacy technology is replaced

Economic appraisal of short list of options

Options 1-4 have been modelled using the cost benefit analysis (CBA) model to give a thorough economic appraisal of the options for the programme. Option 3 demonstrates a higher net present social value (NPSV) and benefit / cost ratio under both the 5 and 10 year timeframes:

Option	5 Year NPSV		5 Year Benefit / Cost Ratio		10 Year NPSV		10 Year Benefit / Cost Ratio	
	No OB	OB	No OB	OB	No OB	OB	No OB	OB
1	(£33.2m)	(£41.5m)	0.0	0.0	(£98.2m)	(£122.7m)	0.0	0.0
2	£10.9m	£6.7m	6.1	3.5	£26.1m	£17.7m	13.3	7.6
3	**£118.7m**	**£79.9m**	**3.5**	**2.3**	**£309.4m**	**£238.3m**	**7.5**	**5.0**
4	£75.9m	£26.4m	1.8	1.2	£266.6m	£184.9m	3.9	2.6

Figure 1: NPSV and Cost Benefit Analysis Summary (February 2022)[1]

The direct public sector benefits within this analysis (as of June 2021 and presented to the Agency board) include:

- A reduction in pay costs associated with a new operating model of up to 300 FTE fewer staff

- A reduction in accommodation non-pay costs through the reduction of space in 10 South Colonnade

- A reduction in Non-pay technology costs, focussed primarily on reducing the complexity and therefore cost of the technology estate (including utilising cheaper software/licensing products), as well as reducing reliance on third party contractors

- Increases in income to offset loss of DHSC EU exit funding & loss of EU income

- Relevant quantifiable but not monetisable benefits including reductions in adverse drug reactions (ADR) in clinical settings, and reductions in 'definitely avoidable' medication errors

[1] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

FTE reductions and associated efficiencies will be balanced together with increases in new revenue and reduction in non-pay costs. Overall FTE reductions realised may vary and therefore not reach 300 FTE. The total value of the programme's savings will be delivered by a combination of cash releasing benefits stated in the economic case.

Adjusting for risk

In line with Green Book guidance, sensitivity analysis has been applied to both benefit and cost estimations. The scenarios chosen represent scenarios that may materialise over the course of the implementation of the Transformation Programme. This includes:

- Delays in implementing FTE reduction
- Delays in Agency system replacement
- Lower than forecast reduction in FTEs

The analysis demonstrated that a significant positive NPSV is maintained for options 3 and 4 under all scenarios, with option 3 maintaining a higher NPSV under all scenarios than option 4, driven by reduced technology spend with similar achievement of the stated benefits.

In addition, Optimism Bias (OB) has been applied to the costs and benefits for each short-listed option, in order to address the historic tendency of UK Government programmes to overestimate benefits and underestimate costs. Optimism bias levels have been set using the findings of the most recent evaluation of the Agency's OB based on historical project delivery. This concludes that:

- Project costs exceed the budgeted value by 25%
- Projects underachieve on target cost reduction by 28%

Preferred Option

Option 3 (Driving Patient Outcomes across the Product life-cycle Operating Model) has been selected as the preferred option for the delivery of the Agency's Transformation Programme.

This option is clearly preferable to the long-listed options 1 and 2 that pose too high a financial and reputational risk to the Agency and do not meet sufficient critical success factors. This option is additionally preferred over short-listed Option 4, as it delivers a larger NPSV when forecast benefits and costs of the proposed Transformation Programmes are modelled. It is also more achievable in terms of the cultural change and capabilities shift.

Option 3 has additionally demonstrated that it retains a significant positive NPSV when tested under optimism bias and a number of risk conditions and scenarios

Option 3 has expected total change costs of £50.8m over years 1-3 (£63.5m inclusive of optimism bias). This option is forecast to deliver £94.3m net benefits in year 5 and c. £302.7m net benefits by year 10 (inclusive of Optimism Bias). Over a 10-year timeframe, this option has a Benefit / Cost ratio of 5.0.

Option	5 Year NPSV	5 Year Benefit / Cost Ratio	10 Year NPSV	10 Year Benefit / Cost Ratio

3	£79.9m	2.3	£238.3m	5.0

Figure 2: Option 3 NPSV and BCR ratio after OB Adjustment (November 2021)[2]

1.5 Commercial Case

The purpose of the commercial case is to provide confidence that the Agency has planned for and considered the external support it will require to carry out the Transformation Programme via the preferred Option.

The Commercial Case concludes that Agency has sufficient understanding of the requirements to engage the market and confidence that the market has the capacity to collaborate and deliver a strategic transformation partner to support the Transformation Programme.

Sourcing Options – Transformation Programme Delivery Support

The preferred option selected in the economic case is Option 3: Driving Patient Outcomes across the Product life-cycle Operating Model. The Agency recognises that delivering this Option involves significant change from current processes and ways of working and will require the Agency to work with a Strategic Transformation Partner to deliver the Programme. The proposed Programme will encompass the following four phases:

- Phase 1 – Governance Review
- Phase 2 – High Level Design
- Phase 3 – Detailed Design
- Phase 4 – Implementation

It is proposed that the Agency will use the Management Consultancy Framework 2 (or successor framework MCF3) to select a strategic transformation partner. This will require the Agency to run a competitive procurement process and will ensure it achieves value for money as:

- The Agency secures competitive market rates by consolidating public sector consultancy and audit spend.
- The Agency will have procurement options from a wide range of suppliers, from large nationals to SMEs, ensuring it can access the necessary transformation methodology and expertise
- Structured guidance is utilised throughout the procurement, covering such areas as pre-market engagement, expressions of interest, timescales and pricing models, which has been designed to help customers follow best practice.
- All potential suppliers are accredited to cyber essentials as a minimum.
- Standard terms and conditions are agreed by all suppliers on the framework

Sourcing Options – Technology

[2] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

Digital, Data and Technology delivery supporting Transformation Delivery will span both legacy and new products and the preferred option will use existing agreements, sourced through Crown Commercial frameworks and / or G Cloud where possible.

The Agency operates a multi-supplier model for provision of digital, data and technology services within an internally managed delivery framework and service, integration and management arrangement. The current sourcing and operating model comprise a mix of insourced and outsourced capabilities balanced against the forecast demand and value for money. Contracts are assured through existing pipeline assurance spend controls with DHSC, Cabinet Office & NHSX.

Services provided also support non-Transformation and business-as-usual services and projects across the Agency's complex technology estate. Existing sourcing arrangements are non-exclusive, and capability and capacity of existing arrangements will be tested at point of demand. If unable to be adequately met, the Agency will then seek competition through existing frameworks.

Selected Payment Option & Contractual Arrangements

The following payment options have been considered within the Commercial Case:

- Payments by Milestones (PbM)
- Payment by Results (PbR)
- Payments by Use (PbU)

Payment by Milestones (PbM) is recommended as the primary payment mechanism for this Transformation programme given its simplicity of use and outcome focussed nature. This approach will provide security to the Agency that payment will be directly linked to completed output, ensuring that Accountability is embedded in the Agency's relationship with its Strategic Transformation Partner. The PbM approach would also enable MHRA to request services directly from suppliers via a bespoke contract, set up in accordance with each output and agreed between MHRA and the supplier.

A Contract Manager will be appointed and will be responsible for managing the performance of a supplier. This will include agreeing and managing reporting, performance reviews and financial tracking. The Contract Manager will additionally be supported in their role by Agency commercial and financial teams as and when required over the life of the contract.

Risk Apportionment

In preparation for any potential procurement, risks to the delivery of the Transformation have been assessed and categorised into the three categories detailed below:

- **Business Risks**: These risks remain with the Agency (100%), cannot be transferred by the organisation, and include political and reputational risks
- **Service Risks**: These risks fall within the design, build, financing, and operational phases of the programme and may be shared with the others from outside of the Agency
- **External Risks**: These risks affect all society and are not connected directly with the proposal. They are inherently unpredictable and random in nature

Risks within each category have been apportioned to the party that is best placed to mitigate the risk, and each specific risk has been assigned to either the Agency, the Strategic Transformation Partner, or have been classed as shared.

1.6 Financial Case

Overview

The Financial Case assesses the affordability of the preferred option and considers the whole life costs (the Programme will be undertaken over 3 years), tying in closely with the Economic Case analysis. The analysis is based on June 2021 forecasts and assumptions.

Without a programme of transformation, the Agency is not financially sustainable. Cash reserves are reducing year on year (and will disappear entirely in FY22/23 – further detail below) and net cash generated from operations is below zero for each forecast year. This position is driven by a significant reduction in income received, primarily due to changes in post EU-exit funding agreement, alongside an increasing cost-base. The preferred option (Option 3) sets out a Transformation Programme that can move the Agency to a position of being a net positive cash generator by FY23/24, resulting in a significant improvement above the base-case scenario.

There is an additional financial imperative driven by a change in the Agency's status. MHRA currently operates as a government trading fund and therefore the Agency's finances have remained separate from its sponsor department, DHSC. The Office for National Statistics has assessed the economic status of the Agency and concluded it should now be reclassified to the central government subsector. Once the Agency's trading fund status ends on 31st March 2022 the finances will be consolidated within the DHSC, and the Agency will be subject to the DHSC financial regime. This includes a material change in that the Agency will no longer be able to carry forward reserves to future years and will need a new financial model that balances the budget in-year. This will, even more than before, require the Agency to operate on a cost-neutral basis.

Without any cost reduction and / or restructuring action, the Agency will arrive at persistent net income gap between operating costs and income throughout the 3-year transformation period forecast in the Most Likely Outcome (MLO) (all figures are cashflow items only):

£m	FY21/22	FY22/23	FY23/24
Net annual cash surplus / deficit in base case scenario	(4.5)	(5.4)	(7.3)
Net annual cash surplus / deficit – Option 3 (underlying position before Transformation costs)	(4.5)	(0.9)	9.4
Net annual cash surplus / deficit – Option 3 including Transformation costs and SR funding	(32.1)	0.0	2.0

Figure 3: Base Case & Option 3 Comparison [3]

Investing in Transformation

Option 3 provides the opportunity to invest in a transformation programme that will drive cash releasing savings in future years. Excluding non-recurrent and short-term change costs, this option is forecast to result in a positive underlying cash position from FY21/22, increasing to £21.8m per annum from FY23/24. The cost profile of the programme is detailed below:

	Financial Year			
Cost Category	21/22	22/23	23/24	Total

[3] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

Agency restructuring (£m)	(9.3)	(5.1)	-	(14.4)
FOM design and implementation (£m)	(6.2)	(3.5)	(1.6)	(11.3)
Technology spend which underpins the FOM transformation (£m)	(12.0)	(21.6)	(5.8)	(39.5)
Total Change Cost (£m)	**(27.5)**	**(30.2)**	**(7.4)**	**(65.2)**

Figure 4: Transformation Programme Cost Profile (November 2021)[4]

The Transformation programme is affordable in FY21/22 and FY23/24 from cash reserves. In FY22/23, the Agency does not have the cash reserves required to fund the programme. The Agency has therefore requested an additional £34.5m of transitional funding support in the DHSC spending review (SR) to ensure the programme can continue to be delivered. This will fully fund the Transition Programme if awarded in full, however if not fully awarded it will not be possible to implement the Transformation at the scale and pace envisaged, and the Agency will need to explore alternative options which may not bring the organisation back to a positive cash-generating position in the short to medium term.

Transformation Cash Improvements

The improvement in the financial forecast under Option 3 is driven by the achievement of a number of savings schemes:

£m	2021/22	2022/23	2023/24
Pay: Reduction of up to 300 FTE	0.0	13.3	20.1
Non-pay: Reduced accommodation costs	0.5	4.1	4.1
Non-pay: Reduced non-pay costs – Technology	0.0	0.9	5.2
Income: Increases in income to offset loss of DH EU exit funding & loss of EU income	0.0	16.4	16.4
Total savings	**0.5**	**34.7**	**45.7**

Figure 5: Option 3 Cash Releasing Benefits [5]

These savings include both cost reduction and income generation schemes and include a significant reduction in headcount of up to 300 FTE over two phases starting in FY22/23.

1.7 Management Case

The Management Case outlines the Agency's approach to manage, monitor and deliver the transformation programme. The case concludes that after detailing the processes and controls for managing the Programme, and of the proposed arrangements for delivery, the Programme can be delivered as planned.

Programme Management Arrangements

[4] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2
[5] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

Three layers of governance that will be used in the Transformation Programme and will be ultimately accountable to the CEO and ExCo. These layers are:

1) **Executive –** responsible for oversight, strategic decision making and corporate level risk

2) **Management –** responsible for enablement and execution of the programme and managing programme level risk

3) **Operational –** responsible for working through local implementation of programme and theme plans through delivery and managing operational risk

This structure has been adopted as it is easy to understand, with each layer having distinct responsibilities and audience, therefore enabling easy communication. This approach is additionally aligned to how the Agency currently works, taking into account other forums and programmes of work. The proposed structure facilitates an appropriate level of challenge and scrutiny without being burdensome on delivery, with decision making rights allocated to the most appropriate level to ensure that more senior forums are focused on items of strategic importance.

Transformation Spend Governance Model

As part of the PBC approval process, the Agency's ExCo will have approved all spend for the first year of the transformation programme which is funded from the Agency's cash reserves.

All programme spend as part of PBC's spending envelope in years 2 and 3 will need to be approved by the Strategic Change Committee (SCC) as the spend control body. As part of this approval, the SCC will conduct a risk / value assessment, and if any material impact on the business case is identified (e.g., projected overspend or lower than forecast realisation of benefits), this will be escalated for review by ExCo to determine necessary actions. ExCo will make a decision on whether the spend will be allowed to proceed and the PBC will need to be updated to reflect any differences to the forecasted spend or benefits to account for the impact of any spend changes.

Spending related to the Transformation Programme will comply with Cabinet Office spend controls: pipeline process[6] and digital and technology spend controls[7]. This will include setting up and gaining approval for a commercial spend control pipeline for all planned commercial activity above £10m.

Workstream Structure

It is proposed that the Transformation Programme will comprise three key workstreams:

- **Agency Restructuring & Cost Reduction** – This workstream will include FTE mapping to create a complete understanding of the current organisation size and shape as a financial baseline, which will then feed as an input into the Agency cost model.

- **Future Operating Model Design & Implementation** - The Future Operating Model (FOM), will cover the full Agency and key services are required to baseline the existing operating model, design a fit for purpose future operating model and then implement the model within a 3-year timeframe.

- **Technology Enabled Change** – This workstream will cover all technology implementation that specifically underpins the FOM.

[6] Source: https://www.gov.uk/guidance/commercial-spend-controls-version-5#scope-of-the-commercial-spend-controls
[7] Source: https://www.gov.uk/guidance/digital-and-technology-spend-controls-version-5

These workstreams will be supported by a Transformation Management Office (TMO) who will act as major driver in pulling together the multiple strands of delivery, whilst driving pace, rigour and excellence in implementation. The TMO will additionally take responsibility for managing a comprehensive system of reporting that will underpin delivery of the Programme.

Benefits Management and Post Project Evaluation

The tracking of benefits will also be vital to the programme. Ongoing monitoring of the programme will measure progress against plans and realisation of expected benefits, providing accurate and current information to programme stakeholders whilst enabling early interventions where required.

Benefits management will be administered by the TMO, who will own the benefits register and be responsible for supporting accountable operational owners within each workstream to track and report benefits realised over the course of the programme.

In addition to ongoing benefits tracking, an evaluation of performance will be carried out post-Programme completion and prior to BAU transition by a party selected by the Programme Board. It is proposed that interim Programme evaluations will be carried at yearly intervals, whilst post Programme evaluation will begin at the end of year FY23/24 and will be monitored 5-10 years to ensure the programme continues to deliver planned benefits listed in this business case. Monitoring will initially be undertaken by the TMO, with long term responsibility to be confirmed at a future date if the TMO function no longer exists.

2. Strategic Case

2.1 Purpose

The purpose of the Strategic Case is to:

1. Provide the strategic context, identify shortcomings of current arrangements, and summarise key business needs of the MHRA

2. Make a clear case for change in the form of an MHRA Transformation Programme

3. Provide an overview of the MHRA Transformation Programme's scope and service requirements

2.2 Strategic Context

2.2.1 Organisation Overview

The Medicines and Healthcare Products Regulatory Agency (MHRA) is an Executive Agency of the Department for Health and Social Care (DHSC). The Agency's mission is to improve patient health by enabling the earliest access and high-quality supply of safe, effective, and innovative products through proportionate, data-driven decisions on risks and benefits.

The Agency works in close partnership with other health and care bodies to provide evidence-based information, advice and guidance to government, the NHS, industry and the public on medicines, medical devices, and blood products. The organisation also focuses on conducting research (applied research projects, public health, and clinical studies), primary care data, clinical trial recruitment, developing written and physical standards and product testing.

MHRA consists of the following three divisions:

- **MHRA**: the UK's regulator of medicines, medical devices, and blood components for transfusion, responsible for ensuring their safety, quality, and effectiveness for the public. MHRA works with all elements of the UK healthcare market to protect patients' safety and ensure they are offered access to new and innovative medicines that carry societal health benefits.

- **Clinical Practice Research Datalink (CPRD):** a real-world research service supporting retrospective and prospective public health and clinical studies. CPRD collects de-identified patient data from a network of GP practices across the UK. Primary care data are linked to a range of other health related data to provide a longitudinal, representative UK population health dataset. The data encompass 50 million patients, including 16 million currently registered patients.

- **The National Institute for Biological Standards and Control (NIBSC):** plays a major national and international role in assuring the quality of biological medicines through:

- Developing standards and reference materials

- Product control testing

- Carrying out applied research

2.2.2 *Alignment to Existing Policies and Strategies*

As a medical regulator, MHRA's purpose and core delivery activities are focused on delivering key national policies in the UK life sciences sector and health service. A key government policy is the need for a regulator who safeguards the efficacy, quality, and safety of medical technologies. The government's Life Sciences Vision[8] policy paper highlights the following expectations of the Agency over the coming years. Any transformation programme will need to enable the Agency to better deliver the following policy expectations:

- For medicines, the MHRA will work with NHS partners and international regulators to **deliver the fastest regulatory assessments and decisions**. This will involve innovative regulatory models, building on the approaches developed for the Early Access to Medicines Scheme (EAMS) and the Innovative Licensing and Access Pathway (ILAP). There is a particular opportunity to support early treatment and prevention through developing innovative regulatory models for the treatment of individuals who are pre disease or have nascent disease, and for diseases (such as dementia) where there are limited or no biomarkers, and a need for surrogate markers or where impact on outcomes will not be seen for many years

- For medical devices and in-vitro Diagnostics, the MHRA will **consult with the sector on the proposed new regulatory framework** later in 2021. The UK's aim is to have a best-in-class regulatory environment for both Devices and Diagnostics. This will build on those elements of the EU's Medical Device Regulations 2017 and In-Vitro Diagnostics Regulations 2017 that work, but also aggressively explore and execute improvements that support innovation and drive patient safety. In particular, the MHRA will deliver the world's leading regulatory model for Digital Health products, which will be a key driver of innovation in the next decade and are not well regulated anywhere in the world currently – reflecting the recommendation from TIGRR and industry feedback. Delivery of the new regulatory regime for Devices and In-Vitro Diagnostics will also recognise and respond to the structure of the Sector, in which over 95% of companies are SMEs

- The MHRA will also **build on learnings from COVID-19** to refine and improve existing regulatory processes and systems. This will include early access to expertise and advice, digitisation, virtual regulatory inspections, integrated systems and use of real-world evidence

- **Take opportunities to cooperate and form partnerships** with likeminded regulators globally. The MHRA has already joined the US Food and Drug Administration (FDA) Project Orbis, which has already allowed rapid access to new cancer medicines for NHS patients, such as Tagrisso for early-stage lung cancer. In addition, the Access Consortium, will see the MHRA working together with Australia, Canada, Switzerland and Singapore to provide access to high quality, safe and effective therapeutic products across the five countries

- **Play an enthusiastic role in global standard setting forums** – shaping, driving, and promoting international best practice. The UK has joined the International Council for Harmonisation of Technical Requirements for Pharmaceutical of Human Use, the International Medical Device Regulators Forum, and the Medical Device Single Audit Programme

- **Deepen cooperation between regulators globally** through new free trade agreements and regulator to regulator agreements, including with partners such as the US Food and Drug Administration. These offer opportunities to deepen cooperation, exchange information and encourage adoption of international standards and best practice.

[8] https://www.gov.uk/government/publications/life-sciences-vision

The Agency's work directly relates to the following manifesto commitments:

- Ensuring Northern Ireland based businesses have "unfettered access" to the rest of the UK post-EU Transition
- Make the UK the leading global hub for life sciences post-EU Transition
- Develop forward-looking regulations to ensure we are first in line to develop and benefit from the technologies of the future
- Levelling up every part of the UK
- Develop new treatments for serious diseases
- Use frontline technology to improve patients' experience

2.3 Case for Change

2.3.1 Overview

There is a clear case to drive forward a substantial transformation programme and instil meaningful and purposeful change in the Agency. In part, this responds to the need to develop a new regulatory model as the UK exits the European Union (EU). But this also reflects a new focus on engaging with patients, enabling patient access to new innovative medicines and devices, and delivering a robust, intelligent, and rapid response to risks to patient safety and public health.

There are operational drivers for change too. MHRA is divided into three separate divisions, with each division functioning in a silo with individual cost and revenue management, a disjointed approach to service delivery and duplication of effort.

Underpinning this, the agency must be able to live within its financial funding envelope and therefore must address new challenges whilst reducing the costs of service delivery and placing itself on a sustainable financial footing.

The aim of the transformation programme is to move away from the current divided structure, adopt a new regulatory model and move into a single agency with a common infrastructure, strong accountability, and a vision and culture which together with the right skills, aligns with staff engagement in new and future ways of working in a financially sustainable way. This will enable the Agency to effectively respond to future opportunities and challenges and will ultimately ensure patient safety remains at the forefront of all we do.

2.3.2 Drivers for Change

An Agency business needs assessment was conducted in December 2020. This identified the Agency's need to rapidly respond to several key challenges it is currently facing:

2.3.2.1 Responding to EU Exit

The United Kingdom's exit from the EU has provided an opportunity to redefine MHRA's role as a regulator and capitalise on the creation of new international regulatory relationships. However, a considerable amount of work is required to introduce a new operating model (encompassing processes and capabilities) to replace the existing regulation for medicines and medical devices that was previously conducted by the EU.

Departure from the EU has also left the agency with a reduced level of EU-derived funding with a forecast reduction in income of 10-15% in FY22/23 and beyond.

2.3.2.2 Achieving better patient outcomes in a pandemic

The evolving nature of healthcare products and technologies presents opportunities to support the Life Sciences Strategy by creating a regulatory environment that attracts innovative products into the UK and a chance to be seen as a world-leaders in specific areas, e.g., in the regulation of combination and digital health products, uses of big data and AI, and cutting-edge advanced therapeutics.

The UK's Life Sciences Agenda along with the COVID-19 pandemic has increased the criticality of the MHRA's role as a regulator of vaccinations and has highlighted the importance to strengthen regulatory framework in order to keep abreast of fast-moving life science developments. In addition, the post-COVID-19 ways of working mean some of the work the Agency traditionally carried out will be drastically reduced and/or done in very different ways, e.g., virtual supply chain inspections.

2.3.2.3 Responding to the Government's Independent Medicines and Medical Device Safety Review

Responding to the Government's Independent Medicines and Medical Devices Safety (IMMDS) Review, in which Baroness Cumberlege exposed areas of the Agency's responsibilities which require overhaul and highlighted a need for MHRA to address failures in listening and responding to patients.

A key aim of HMG following the review is that MHRA must demonstrate that it is achieving patient centricity and ensure it can demonstrate that it is listening to the patient. In addition, the government response to the IMMDS Review[9] detailed 9 strategic recommendations and 50 "actions for improvement". Any future transformation programme will require the MHRA to create a strategic roadmap and delivery plan which can set the agency up to deliver against these recommendations.

2.3.2.4 Stop operating as a siloed organisation and adopt a structure and culture which are fit for the future

Operating as three entirely separate and independent divisions, the MHRA has outdated infrastructure, unclear accountability and a tangible need to engage staff in new ways of working. These challenges collectively distract the Agency from our primary focus of putting patient and public safety first. Patient centricity levels are varied across the three silos and the Agency's research capability is often not fulfilled to its highest potential.

Whilst an Agency-wide process architecture exists, very few Business Functions recognise or reference it as a blueprint of how their team should operate. Most Business Functions instead have disparate views of Standard Operating Procedures (SOPs), which don't appear to connect to the wider Agency process architecture. Cross Agency roles and responsibilities (RACIs) are not clearly defined which results in duplication of activities. Touchpoints across parts and functions of the Agency are undocumented and un-standardised which means effective collaboration only happens in pockets rather than being systemic.

As part of the FOM design, it is therefore essential that the Agency focuses on ensuring it has the necessary skills and capabilities to support the new ways of working. Key to this will be a strong governance capability that provides oversight and direction ensuring that the overall scientific strategy of Agency is reflected in research undertaken and standards developed, and that Agency resources are utilised efficiently. Addressing cultural change will also be critical to the success of

9 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1005847/IMMDS_Review_-_Government_response_-_220721.pdf

the Transformation Programme. Any future transformation programme will require the Agency to baseline, track and identify interventions to ensure that organisational culture supports the FOM.

2.3.2.5 Becoming financially sustainable

A review of MHRA's current cost base and forecast income is essential for increased efficiency and financial sustainability for the future.

The financial forecast highlights that the Agency is operating in an unsustainable cash position which requires urgent rectification. Compounding this, income is forecast to decrease by 10-15% in FY21/22 following departure from the EU, and at the same time operating costs are forecast to increase by £2-7m per annum. If the Agency does not address these material financial pressures, an unbudgeted funding gap will materialise from FY21/22 which will in turn increase financial pressure within central government.

There is an additional financial imperative driven by a change in the Agency's status. MHRA currently operates as a government trading fund and therefore the Agency's finances have remained separate from its sponsor department, DHSC. The Office for National Statistics has assessed the economic status of the Agency and concluded it should now be reclassified to the central government subsector. Once the Agency's trading fund status ends on 31st March 2022 the finances will be consolidated within the DHSC, and the Agency will be subject to the DHSC financial regime. This includes a material change in that the Agency will no longer be able to carry forward reserves to future years and will need a new financial model that balances the budget in-year. This will, even more than before, require the Agency to operate on a cost-neutral basis.

Without any cost reduction and / or restructuring action, the Agency will arrive at persistent net income gap between operating costs and income throughout the 3-year transformation period forecasted in the MLO (all figures are cashflow items only):

£m	FY21/22	FY22/23	FY23/24
Income	132.2	132.2	132.2
FTE costs	(92.7)	(93.6)	(95.5)
Non-pay costs	(44.0)	(44.0)	(44.0)
Non-pay TECHNOLOGY	(19.9)	(19.9)	(19.9)
Non-pay other	(24.1)	(24.1)	(24.1)
Net cash surplus / deficit in base case scenario	**(4.5)**	**(5.4)**	**(7.3)**

Figure 6: MHRA MLO Net Income Analysis (November 2021)[10]

Projected income is forecast to remain constant at £132.2m from FY21/22 to FY23/24 (all figures exclude inflation). At the same time projected operating costs are forecast to increase from £136.7m in FY21/22 to £139.5m in FY23/24. These two movements will result in a persistent net gap between income and operating costs of £4.5m for FY21/22 rising to £7.3m from FY23/24.

The Agency's negative cash position is only affordable in the very short term. On the assumption that the Agency can retain cash surpluses across years opening cash reserves of £51.5m in FY21/22 are forecast to reduce to below zero by FY22/23. From FY22/23 when the trading status of the agency changes it will not be possible to retain surpluses going forwards, reducing the opening balance of FY23/24 to £0.0m and further deteriorating the forecast cash position.

[10] Source: MHRA_Fee_Analysis_Model_20-21_SAMatrix_V.56.10.i3

£m	FY21/22	FY22/23	FY23/24
Opening cash reserves	51.5	0.0	0.0
Income	132.2	132.2	132.2
Operating Cost	(136.7)	(137.6)	(139.5)
Closing in year cash balance	**47**	**(5.4)**	**(7.3)**

Figure 7: MHRA MLO Cash Reserves Analysis (November 2021)[11]

There is therefore a clear business need to set out a financial sustainability plan which allows the Agency to operate within its agreed budget.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[11] Source: MHRA_Fee_Analysis_Model_20-21_SAMatrix_V.56.10.i3

[redacted]

2.3.2.7 Internal processes must be improved

The underlying processes associated with the Value Chain will change due to EU Exit, NI Protocol and some initiatives that are taking shape. These initiatives include ongoing project work in transforming promising innovative pathways (TPIM) which will include greater collaboration across the Agency and outside the Agency, and Safety Connect work which will bring together the work of Devices and Vigilance. The value chain is not used in the Agency. Business Functions do not tend to reference this as a blueprint of how their team operate, and the concept does not appear to be widely understood in the Agency.

Not all current operating model process maps are developed. Where these are developed, they may link to Agency SOPs (Standard Operating Procedures) (where identified), but they do not drive the SOP delivery. SOPs are frequently isolated and do not necessarily cover cross functions within the teams and across teams. SOPs are not standardised and do not always include diagrams and divisional interactions.

Key pain points of the MHRA’s process architecture include:

- Whilst an Agency wide process architecture exists, very few Business Functions recognise / reference it as a blueprint of how their team operate
- Most Business Functions instead have disparate and non-standardised views of Standard Operating Procedures (SOPs), which don’t appear to connect to the wider Agency process architecture
- Cross Agency roles and responsibilities (RACIs) are not clearly defined which results in duplication of activities
- Touchpoints across parts and functions of the Agency are undocumented and un-standardised which means effective collaboration only happens in pockets rather than being systemic

2.3.2.8 Strategic Risks Identified in the Agency Baseline

Key strategic risks have been identified as part of the Agency Baseline:

1) Despite a large cost base, most parts of the Agency believe they are under-resourced and lacking key capabilities needed for the future
2) There is a lack of documentation on who does what (capabilities, processes, RACIs) and how they deliver on Agency priorities (KPIs) and support transformation and continuous improvement
3) The Agency has not defined which services deliver patient outcomes, revenue and statutory compliance so that unnecessary services can be stopped
4) Of FY19/20’s total revenue, £27.5m per annum (18%) is not secure post EU exit
5) Even if restructuring action takes place, current cash reserves (£51.5m at beginning FY21/22) will run out in FY22/23 and there will be an investment + net income gap of £31.1m. The Agency must consider its options to fill this gap as doing nothing is not viable

6) There is alignment on patient centricity as an ambition but there is lack of clarity over actions required to achieve it, measures to track it and what it means for the Agency

2.3.3 Implementing Meaningful Change

This case sets out a preferred solution to address these key drivers for change. The proposed programme would deliver the following:

- **Future Operating Model Design and Implementation:** A new, fit for purpose operating model that puts patients first, delivers critical support to UK life sciences and demonstrates a culture that positions the Agency to deliver against the MHRA 2021-2023 delivery plan
- **Technology Enabled Change:** A replacement of legacy systems and investment in new technology which underpin the future operating model, enabling the Agency to deliver simple, smart solutions that integrate across the health system
- **Agency Restructuring and Cost Reduction:** An Agency wide cost reduction programme targeting pay costs, non-pay costs and project spend to return the Agency to a sustainable cash position
- **One Agency Culture Shift:** a meaningful shift to the organisational culture that puts patients at the centre, drives the right behaviours across the Agency and enables new partnerships through embracing new ways of working, systems leadership and innovation

2.3.4 Spending Objectives

These spending interventions will ensure the MHRA achieves the 14 objectives set out in the Agency's 2021-2023 Delivery Plan:

Cross-cutting Priority

1. Deliver better patient and public involvement to ensure the MHRA put patients first

Scientific innovation

2. Deliver public health impact, world-leading research innovation and a unique proposition

3. Overhaul the clinical trials system to support innovation and reduce time to approval

Healthcare Access

4. Develop and deliver MHRA's future strategy and approach for access to medicines and devices

5. Establish a new medical devices legislative framework to support safe innovation and ongoing access to products

Patient Safety

6. Deliver a more responsive safety surveillance and risk management system, for all medical products, to keep patients safe

7. Deliver innovative interventions to ensure the UK has a secure supply chain providing high quality products

Dynamic Organisation

8. Deliver a Transformation Programme to make the MHRA a truly world-leading, innovative regulator

9. Deliver a programme to enhance MHRA's leadership capability and to attract, retain and develop talent so that the Agency can fuel innovation and drive change

Collaborative Partnerships

10. Leverage international partnerships to drive better outcomes

11. Leverage UK healthcare system partnerships to integrate processes and drive better outcomes

12. Build public and stakeholder trust in the Agency through a programme of proactive and innovative communications

Financial Sustainability

13. Establish a new business model for the future that increases income, reduces costs, and improves productivity

14. Deliver an optimised IT infrastructure to improve our service and reduce our costs with fewer digital technologies

2.3.5 Case for Change Conclusion

In order to become fit for purpose, financially sustainable and be able to address both emerging and future challenges, the Agency requires significant transformation.

The Agency operates as three distinct organisations. This has resulted in a lack of agreement and documentation on a single future Business Model for the Agency that would usually underpin the Agency's strategic priorities.

A successful transformation programme will allow the Agency to move away from the current divided structure, adopt a new regulatory model and move into a single Agency. A unified Agency would hold a common infrastructure, strong accountability, and a vision and culture which together with the right skills, aligns with staff engagement in new and future ways of working in a financially sustainable way. This will enable the Agency to effectively respond to future opportunities and challenges and will ultimately ensure patient safety remains at the forefront of all we do.

2.4 The Agency Transformation Programme

The following sections detail the potential scope of the Agency Transformation Programme that if approved, would enable the Agency to address its critical business needs within the next 3 years.

2.4.1 Scope

The Agency Transformation Programme will include the following key workstreams:

1) Agency Restructuring and Cost Reduction

2) Future Operating Model Design and Implementation
3) Technology Enabled Change
4) One Agency Culture

The scope of each workstream is detailed below:

2.4.1.1 Agency Restructuring and Cost Reduction

The scope of this aspect of the programme will affect the full Agency and key services are required to restructure the organisation and identify efficiencies in both pay (headcount reduction) and non-pay (operating cost reduction) spend. The current FTE will need to be mapped to create a complete understanding of the current organisation size and shape as a financial baseline, which will then feed as an input into the Agency cost model.

2.4.1.1.1 Sustainability Scenario

Outcome: *A sustainable, affordable, and viable 3-year Transformation business case*

The Agency cost model will need to run several scenarios to determine the target FTE reduction, target reduction in non-pay spend and target reduction in individual project spend to return the Agency to a sustainable cash position.

The Agency cost model will need to be frequently updated with a robust set of assumptions as and when efficiencies are identified throughout the restructuring process.

2.4.1.1.2 HR Consultation Process

Outcome: *An efficient consultation with the Unions to achieve the right outcomes for the Agency and its people*

As FTE efficiencies are identified, the Agency will have to run a fair and open HR consultation process with Unions to comply with redundancy protocol. A fair and open process will be followed to identify and realise reductions in Agency headcount.

2.4.1.1.3 Benefits Realisation

Outcome: *100% of baselined Agency benefits achieved within the 3-year transformation period*

As the benefits are identified in the form of efficiency savings, these will need to be tracked to ensure successful benefits realisation of Agency's cost reductions. Support will be required on the realisation of the financial sustainability plan, working closely with in-house finance expertise and SROs to ensure full ownership within the Agency.

2.4.1.2 Future Operating Model Design and Implementation

The Future Operating Model (FOM), will cover the full Agency and key services are required to baseline the existing operating model, define the future Agency strategy and vision, design a fit for purpose future operating model and then implement the model within a 3-year timeframe.

2.4.1.2.1 Operating Model Baseline

Outcome: *A clearly defined current state assessment of the Agency's operating model*

As part of the operating model baseline, the Agency will need to develop a view of current operating model spanning the organisational structure, core capabilities and enabling processes. Pain points will also need to be identified across the current operating model to help inform the design principles of the FOM. Further analysis will need to be undertaken to understand Agency customer segments and personas, to help baseline the current patient experience.

2.4.1.2.2 FOM Options Appraisal

Outcome: *A robust appraisal of the Agency's options for a future operating model with a preferred option selected based on fit for purpose criteria*

The Agency needs to clearly define its vision and operating strategy requires a broad range of options for the FOM to be considered and assessed against a criterion which will determine the most appropriate FOM. A series of choices across each dimension of the FOM needs to be defined and structured into 3-5 high level FOM options. The Agency will need to conduct a benchmarking and impacting exercise which includes comparing current Agency costs and FTE against benchmark organisations and departments both in the UK and globally. A set of analyses against impact of high-level cost and revenue impact for each option will then help inform with FOM option can be identified as the preferred option.

2.4.1.2.3 Transformation Roadmap

Outcome: *A clear collection of desired outcomes over the next 3 years for the Agency to achieve a successful transformation*

Following these activities, the Agency will need a roadmap to cover the design and implementation of the preferred option for the FOM in conjunction with technology enabled change projects and the agency restructuring.

2.4.1.2.4 FOM Design

Outcome: *An organisation structure delivers the Agency vision of better outcomes for patients and public safety*

Once a preferred option for the FOM is identified, the Agency will need to complete a high-level design and detailed design for the FOM in conjunction with chief officers and their respective teams. As part of this process, the future organisation structure, objectives & key results, processes, and capabilities will be defined.

2.4.1.2.5 Integrated Implementation Plan

Outcome: A s*ingle, agreed, viable and affordable implementation plan that achieve the Agency's transformation objectives*

An integrated implementation plan will need to be created in conjunction with in-house HR, Finance, Transformation and Enterprise Portfolio Management Office teams to produce agreed, realistic and understandable integrated implementation plans complete with: full risk and dependencies; resourcing and spend profiles for realising efficiencies and operationalising the new operating model; agreed, timebound outcomes linked to the strategic goals and KPI's; and accountability for delivery.

2.4.1.2.6 Agency Services and Fee Structure

Outcome: A clearly defined set of Agency core services, complete with volumes, costs, and revenues.

The Agency will have to align the development of the agency fee structure to the new FOM and identify subsequent impact on the implementation of the FOM and associated opportunities. Core services will need to be defined, alongside their volumes, cost to serve, enabling processes and capabilities to enable a seamless transition into the new operating model. Further analysis on services could allow the Agency to reprioritise service delivery and identify further efficiencies within the Agency.

2.4.1.2.7 FOM Implementation

Outcome: A fit for purpose operating model that puts patients first and positions the Agency to deliver against the 2021-2023 delivery plan

The Agency will need to deliver the operating model, involving developing on assumptions and requirements across the design principle in the FOM and identifying how to successfully implement and realise agreed efficiencies during the design phase and across them to ensure the integrity of the Agency cost models.

As part of implementation, the Agency will need to identify priority actions, with supporting plans, to address and facilitate the substantial cultural shift required to ensure successful implementation and realise the benefits, efficiencies, and innovative change that the FOM enables.

2.4.1.3 Technology Enabled Change

The Agency will need to replace legacy systems that underpin the FOM in line with transformation requirements. This includes replacing the core regulatory systems with modern digital, data and technology solutions to support the transformed Agency; archive legacy data safely and securely and meet patient safety and access requirements.

A separate business case will be developed for the Application Outsourcing (AO) Tender. Whilst AO Transition is not part of this case, the technology enabled change dependent elements and replacement of our core systems are included. This project will competitively tender the outsourcing contract for Application Support and Development as per Cabinet Office and Crown Commercial requests. The new supplier will facilitate the transition of the operational support for the Agency's existing live 71 systems to a new, more flexible contract. Funding for the AO Transition project is not covered in this business case however the Transformation programme will be dependent on this project for some elements of technology delivery.

2.4.1.3.1 Digital Self-Service

Outcome: *A clean and modern front-end range of digital services that sit within the health system*

A digitally enabled, self-service "front door" will need to be designed and built to Agency specifications. This will replace the majority of the Agency's 20+ legacy websites, submission portals and access points for patients, industry, academia, and healthcare professionals in addition to its major presence on GOV.UK.

2.4.1.3.2 Regulatory Management System (RMS)

Outcome: *A robust and dynamic system that enables the Agency to meet its new obligations and strategic objectives, delivering simple, smart, solutions that integrate across the health system*

A 2-stage approach would be required to replace legacy systems with platforms and products to deliver the transformed Agency objectives:

- **Stage 1** - Building a 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. It lays the foundations to enable analytics on enterprise data. It also allows reporting across different data sources with a combined view to be able to gain insights for better decisions.

- **Stage 2 -** Building 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 [redacted] and for those legacy applications to be archived and decommissioned.

2.4.1.3.3 Legacy Management

Outcome: *A cost effective solution for storing existing data that sits on legacy systems*

The Agency needs to archive existing data held on legacy systems such as [redacted] This data should be migrated onto a read-only database, on cheaper storage rather than migrating decades of data into new systems. This is to minimise the cost and complexity of data migration and avoid continuing to run and maintain complex legacy systems indefinitely, whilst retaining critical data to meet the Agency's legislative requirements.

2.4.1.4 One Agency Culture

The Agency will need to first establish executive / senior stakeholder sponsorship for One Agency culture. This is to ensure the right values and behaviours are embraced at the top of the organisation and for there to be a clear guardian and owner for culture activity. The success and progress of these interventions and measures will be assessed against a culture dashboard which should be reviewed regularly at ExCo and as part of regular performance reporting.

2.4.1.4.1 Culture Assessment

Outcome: *A baseline of current Agency culture defined to determine the starting position for the Agency to shift towards a new way of working*

The Agency will need to review the current culture against the desired future culture to successfully deliver the new ways of working and the associated behaviours needed to achieve these. Tangible examples include the Agency becoming patient centred and breaking down siloed working. To assess the Agency's current cultural maturity, a cultural fitness diagnostic will be delivered with both quantitative and qualitative inputs required.

2.4.1.4.2 Culture Transition Plan

Outcome: *A clear plan of activities and milestones to help the Agency successfully transition to a unified "One Agency" culture*

With this baseline established, the next step will be to articulate the future state culture through co-creation activity across the Agency and other selected stakeholders, including ExCo and the identified Senior Sponsor. With the gap well understood, this will then enable a culture transition action plan to be created with clear workstreams and milestones driving meaningful activity across the Agency with clear owners.

2.4.2 Objectives

In response to the challenges and opportunities highlighted within this document, the following objectives have been set for the Agency transformation programme.

By April 2024, the Agency will:

- Establish a new operating model for the future that increases income, reduces costs, and improves productivity

- Deliver an optimised IT infrastructure by Q2 FY23/24 to improve our service and reduce our costs with fewer digital technologies

- Be a sustainable, cost-efficient, and self-funding entity that is not reliant on additional external funding to meet operational demands

- Achieve 100% of the baselined Agency benefits within the 3-year transformation period

- Embed a fit for purpose operating model that puts patients first and begins to position the Agency to deliver against the 2021-2023 delivery plan

- Become easily accessible through a clean and modern front-end range of digital services that sit within the health system

2.4.3 Strategic Benefits

A benefits appraisal of social value has been completed as part of the potential Agency Transformation programme strategic assessment. Benefits are classified as follows:

1. Cash releasing benefits (CRB)
2. Monetisable non-cash releasing (non-CRB)
3. Quantifiable but not readily monetisable benefits (Quan)
4. Qualitative unquantifiable benefits (Qual)

The proposed key programme benefit themes include:

1. Improving public and patient safety
2. Increasing the Agency's efficiency and effectiveness
3. Enabling innovation from science and pharmaceuticals
4. Enhancing the Agency's domestic and international reputation

A benefits register categorised by benefit themes for the programme is detailed below:

2.4.3.1 Improving Public and Patient safety

Benefit Classification	Description of Benefit	Beneficiary
Quantifiable but not readily monetisable	The Agency can provide early, more frequent, and intensive engagement with patients particularly around emerging trends in the safety status of products	Agency, Industry, Patients
	The Agency will be structured to deliver a more responsive safety surveillance and risk management system, for all medical products, enhancing patient safety	Agency, Industry, Patients
	Public safety will be improved through the Agency's capability to accelerate approval of clinical trials, medicines, devices, and vaccines to the market which is critical in responding to the pandemic	Agency, Industry, Patients
	The Agency will be positioned to respond to increased volumes of safety reports and signals detected across all healthcare products following the Agency's increased public profile during COVID-19	Agency, Industry, Patients
	The Agency will have an increased focus on achieving the right outcomes for patients, with patient centricity built into the heart of the Agency operating model	Agency, Industry, Patients

2.4.3.2 Increasing the Agency's Efficiency and Effectiveness

Benefit Classification	Description of Benefit	Beneficiary
Cash Releasing	A target headcount reduction of up to 300 FTE would produce a net benefit of £20.1m per annum	Agency
	A target reduction in non-pay accommodation costs which would achieve a net benefit of £4.1m per annum	Agency
	The transformation programme will enable a reduction in non-pay technology costs which would achieve a net benefit of £6.1m per annum	Agency
	The transformation programme will enable the Agency to realise increases in income of £16.4m p/a from FY22/23 to offset the loss of DH EU exit funding & loss of EU income	Agency
Monetisable non-cash releasing	The Agency's increase in efficiency will deliver a reduction in ADR's in a clinical setting	Agency, Patients
	The Agency's increase in effectiveness with result in a reduction in "definitely avoidable medication errors"	Agency, Patients
Quantifiable but not readily monetisable	The Agency will implement a set of redesigned, streamlined, automated and standardised processes which reduce the cost to serve and increase delivery efficiency	Agency, Industry, Patients
	The Agency will utilise an updated technology stack that is brought up to modern security standards, which can respond to future needs and reduces the risk of data security threats	Agency
	Be structured to deliver against the Agency's 2021-2023 delivery plan for access to medicines and devices as part of a regulatory reform	Agency, Industry, Patients
	The Agency would be positioned well to create a risk-based approach leading to more emphasis on evaluation rather than batch-testing of biological products	Agency, Industry, Patients
	The Agency can drive automation and process redesign to increase self-service in low complexity and low risk activities such as simple variations, periodic safety update reports, parallel imports, and registrations of e-cigarettes	Agency, Industry, Patients
Qualitative unquantifiable benefits	The Agency will adopt a "One Agency" culture with the breakdown of silos and clear alignment of strategy, outcomes and KPI's across the Agency	Agency
	The new structure will embed greater accountability and sense of belonging amongst MHRA employees	Agency

	A common infrastructure will be incorporated to foster collaborative working and the sharing of resources	Agency
	A more efficient organisation structure with spans and layers of the organisation set up in a way that meets operational delivery needs	Agency

2.4.3.3 Enabling Innovation from Science and Pharmaceuticals

Benefit Classification	Description of Benefit	Beneficiary
Monetisable non-cash releasing	The Agency will be positioned to proactively engage with innovators requiring scientific advice services	Agency, Industry, Patients
	The Agency will be enabled to accommodate greater volumes of innovative medicines and devices proposed for approval in line with MHRA's increased focus on a differential pathway for innovation	Agency, Industry, Patients
Quantifiable but not monetisable	The Agency will be equipped to deliver world-leading research innovation using scientific data analytics, real world data, Artificial Intelligence (AI), big data and other emerging disruptive technologies	Agency, Industry, Patients
	The Agency will develop an enhanced leadership capability that helps attract, retain, and develop talent so the Agency can fuel innovation and drive change	Agency, Industry, Patients

2.4.3.4 Enhancing the Agency's Domestic and International Reputation

Benefit Classification	Description of Benefit	Beneficiary
Monetisable non-cash releasing	The Agency would be structured to leverage international partnerships and novel clinical trial designs as the UK strategy takes shape as a global destination to develop products	Agency, Industry, Patients
Qualitative unquantifiable benefits	The Agency will build public and stakeholder trust through a programme of proactive and innovative communications	Agency, Industry, Patients
	The Agency will have a higher brand reputation as a global regulator in the industry	Agency

2.4.4 Risks

As with any large-scale transformation, there are associated risks which should be considered. Risks fall into three following classifications:

1) **Business Risks:** These risks remain with the Agency (100%), cannot be transferred by the organisation, and include political and reputational risks

2) **Service Risks:** These risks fall within the design, build, financing, and operational phases of the programme and may be shared with the others from outside of the Agency

3) **External Risks:** These risks affect all society and are not connected directly with the proposal. They are inherently unpredictable and random in nature

A risk register which details risks and potential mitigations associated with the achievement of the programme's outcomes is shown below:

Risk Category	Description of Risk	Mitigating Actions
Business Risks	There is a risk of low stakeholder availability to engage key people in the Agency throughout the lifecycle of the transformation programme There is a risk that without alignment and drive from the Executive Committee (Exco), successful execution of this transformation will not be possible	Produce a clear Case for Change narrative and communications plan early in the programme to align the business on the critically of prioritising transformation activity Establish a regular drumbeat of Exco meetings with a clear dedication to the transformation programme in order to drive the programme forward and proactively identify and address delivery risks
	There is a risk that once the new organisation structure is designed, the Agency's people won't be mobilised within the new operating model in a timely or effective manner causing a disruptive transition period	Actively monitor the FOM implementation plan, tracking progress and delivery risks / issues on a weekly basis. Escalate key barriers to FOM implementation to Exco
	There is a risk that the Agency will not be able to fund the Transformation programme from reserves and will need to obtain external funding	Explore and appraise options for external funding from DHSC as part of the spending review (SR2021) to address any funding gaps
	There is a risk that running the Transformation programme alongside BAU activities will cause significant disruption to the business and its ability to deliver a rapid response to the pandemic	A governance framework should be agreed with MHRA's CTO to enable the right level of ownership, issue resolution, engagement, and decision-making, complemented with adequate planning to minimise impact on BAU
	There is a risk of change fatigue as previous transformation programmes at the Agency have been unsuccessful	Utilise lessons learned from previous attempts at the Agency's transformation. Run a competitive tendering process to find the highest calibre of suppliers and experienced advisors to reduce the risk of an unsuccessful transformation programme. This will include post award qualitative monitoring and contract management.
	There is a risk of change resistance: Not all MHRA employees will easily adapt or agree to the FOM and will create a challenging working culture which will cause attrition	Introduce a clear comms campaign, complete with change champions. Make the restructuring process as transparent as possible with frequent all staff engagement opportunities with leadership

	There is a risk that the scale of change to be achieved within the specified 3-year timeframe is significant and potentially unachievable	Ensure a robust and efficient Transformation Management Office is established which can monitor and escalate key risks, issues, assumptions, and overall deviations from the programme plan. This includes ensuring that ownership and accountability are embedded through the programme governance structure.
	There is a risk that the Agency will be unable to source, develop and resource the necessary skills and creating the right culture	Introduce a clear business change and comms plan, complete with an active skills and recruitment campaign to build the right people and culture
	There is a risk of failure to create an appropriate and proportionate governance models for the transformation to ensure a successful transformation execution	Adopt governance best practice methodology including MSP and Agile for Technology approaches. Test and iterate the governance model to ensure it remains dynamic and evolves throughout the programme's lifecycle
Service Risks	There is a risk that the FOM design does not meet the future needs of the Agency	The Agency will work with their experienced strategic transformation partner, EY, to ensure the Agency vision, strategy and 2021-2023 delivery plan are considered as part of high level and detailed design stages of the FOM
	There is a risk that the transformation programme may run over budget and over the projected time period	Frequently track progress of supplier spends vs progress against delivering requirements. Adopt a change note contractual mechanism to limit the financial implications of any supplier cost overrun
	There is a risk that the separation of business-specific transformation requirements and technology requirements leads to a disjointed approach, duplication of effort and inadequate requirements being presented to technology with unrealistic expectations to deliver	Ensure a robust requirement gathering and prioritisation process is followed and options for technology replacement are appraised against this
External Risks	There is a risk that changes in legislation may redirect Agency effort away from the transformation programme	Assess changes as and when they occur and raise at the relevant forum to arrive at an appropriate solution
	The risk of changes in (national) policy or other grant policy direction leading to unforeseen change.	Assess changes as and when they occur and raise at the relevant forum to arrive at an appropriate solution
	Post COVID-19 impacts to other health bodies (e.g., NHSE/ I, NIPH etc) and EU-exit could continue to put pressure on MHRA	Assess changes as and when they occur and raise at the relevant forum to arrive at an appropriate solution

Risk management activities will mitigate the likelihood of risk by identifying, evaluating, and controlling potential opportunities and threats to MHRA and stakeholders in achieving the project objectives. Further consideration of risk management is detailed in the Management Case.

2.4.5 Constraints

The programme will remain flexible to accommodate changes in requirements between the submitted funding request and the programme kick-off date. At time of writing, the potential programme constraints are as follows:

2.4.5.1 Agency Trading Fund Status

The Agency ceases to be a trading fund at the end of FY21/22. At this point, the unspent financial reserves will be absorbed by HMT. This represents a constraint on the availability of funding. This change in status occurs in April 2022 which is part way through the Agency's 3-year Delivery Plan and during the process of transition from EU to sovereign Regulator which requires adjustment to the resultant changes in income, services, and workload. The Agency's Delivery Plan is focussed on achieving the necessary changes while achieving a position of net-neutral budgeting for operations (and change activities) in FY23/24, a year after the reserves are due to be re-purposed, leaving the Agency in a period of unfunded transition.

2.4.5.2 Transition funding

As the Agency will no longer be able to carry over existing cash reserves, transition funding will need to be obtained in order to continue delivering the transformation programme across its 3-year timeframe. Net-neutral financial operations cannot be achieved if the transition funding is not available. An option MHRA could explore is requesting transition funding from DHSC as part of the SR21 spending review.

2.4.6 Inter-Dependencies

The potential inter-dependencies of the transformation programme are detailed below:

2.4.6.1 Application Support and Development Contract

The Agency must replace the contract with its main Application Support and Development supplier this year. This is a major undertaking, [redacted] Until this highly complex re-tendering process is complete (intended contract signature is in March 202 – subject to HMT approval, with transition then taking 4-6 months), the Agency cannot embark upon the programme of technology work to archive the [redacted] business critical regulatory management systems and replace these with new systems, practices and services to support the future operating model. Therefore, the bulk of the technology investment cannot commence this year, when the Agency has its own reserves.

2.4.6.2 HR Consultation process

The implementation of the new FOM that is essential to the Agency transforming and becoming financially net-neutral will result in redundancies in all parts of the Agency. The staffing reduction will be aligned to the requirements & necessary capabilities of the new Agency operating model, and will be subject to a rigorous staff and trade union engagement and process run by HR. This process must run to a strict timescale, and the necessary periods of consultation form a critical path in the achievement of the new Operating Model.

2.5 Conclusion

The Agency is under a unique range of pressures that create complexity, resource and change pressures and must now respond to a once in a generation shift to redefine its role and services.

The complexity of change is significant with the requirement to transition from EU to Sovereign Regulator with significantly reduced income; to deliver the Life Science Vision with new skills and services; respond to the Cumberledge review; [redacted] to redefine the Agency's services and reduce costs by 20%; and to give up financial reserves previously assigned to fund transition as the Agency loses its trading fund status.

A case for change is clear and to respond to these challenges the Agency has scoped a Transformation programme called, 'One Agency – Delivering for Patients'. The Transformation programme will involve Agency restructuring and cost reduction, designing and implementing a future operating model, replacing legacy technology, and assessing the way forward for the Agency's site infrastructure.

A long list of options for delivering the Transformation programme are detailed in the Economic case.

3. Economic Case

3.1 Purpose

The purpose of this section is to provide an in-depth economic appraisal of the 2 options to implement the Transformation Programme and arrive at a preferred option for the programme, quantified with an NPSV value that considers programme benefits, costs, timelines and risks.

3.2 Critical Success Factors

The following critical success factors (CSFs) have been identified for the Agency transformation programme. These attributes are essential for successful delivery of the Agency transformation. Each option for delivery of the programme has been appraised against these CSFs alongside the spending objectives.

Critical Success Factors (CSF)	Description
CSF 1: Strategic fit and business needs	How well the option meets the Agency's business needs: • Achieve positive patient outcomes in a pandemic • Respond to the changes in funding and regulations as part of EU exit • Transition the Agency to becoming financially sustainable • Replace legacy technology • Operate as one Agency
CSF 2: Potential value for money	How well the option: • Optimises social value i.e., achieving better patient outcome for society • Represent VfM with a positive net present value • Optimises economic benefits against a balance of costs and risk
CSF 3: Supplier capacity and capability	How well the option: • Matches the ability of potential suppliers to deliver the required scope of the transformation • Is likely to be attractive to the supply side
CSF 4: Potential affordability	How well the option: • Can be funded from Agency cash reserves • Aligns with Agency sourcing and trading status funding constraints

CSF 5: Potential achievability	How well the option: • Can deliver the desired transformation outcomes and objectives within the 3-year transformation period • Matches the level of available skills required for successful delivery
CSF 6: Patient centricity	How well the option: • Aligns to Agency patient centricity priorities and principles
CSF 7: Brand / Reputational risk	How well the option: • Reduces the risk of damage to the perceived reputation within the health ecosystem
CSF 8: Business risk	How well the option: • Minimises disruption to the business and its ability to deliver against statutory requirements
CSF 9: Ease of implementation	How well the option: • Can deliver transformation requirements without a significant amount of new Agency capability • Minimises the degree of process change • Minimises required investment in technology and data processing

3.3 Long List Options

In addition to the four options outlined within this long list, it has been considered that to address the drivers for change (detailed in section 2.3.2) the Agency could split out or absorb its divisions into other government departments for example DHSC or other health related Agencies. This was considered in the 2015 MHRA Triennial review which concluded that the MHRA performs necessary functions and should continue to operate as an executive agency.

The following four options have therefore considered four Transformation Options whereby the Agency remains as an Executive Agency of the DHSC.

3.3.1.1 Option 1: Business as Usual (BAU)

Summary: Option 1 would do nothing to achieve the transformation outcomes the Agency is seeking, and the Agency would continue operating in its current state.

Scope:

Transformation Area	Scope Description
Agency Restructuring and Cost Reduction	Make no changes to the Agency headcount or forecast Agency spend
Future Operating Model Design and Implementation	Keep the Agency structured as 3 separate divisions with current processes and practices running as BAU
Technology Enabled Change	Focus on keeping existing systems running through remediation and re-platforming. Keep re-contracting to a minimum to deliver contractual compliance

Indicative Costs: No additional costs and benefits accrue in the BAU option.

Key Risks:

- This option leaves the Agency in a significantly unsustainable cash position with insufficient cost reduction
- The Agency's 2021-2023 delivery plan is highly unlikely to be achieved
- The organisation will not be structured to meet business needs and deliver key challenges the Agency will face over the next 3 years
- [redacted]
- It is not possible to keep some systems running indefinitely and support costs will naturally increase year on year placing the Agency in a challenging financial situation
- Re-platforming to maintain the legacy technology stack is unaffordable as this would cost in the region of £6.0-8.0m

Key Benefits: There are no benefits associated with the BAU option.

3.3.1.2 Option 2: Remove Friction

Summary: Option 2 seeks to make minor alterations to the Agency operating model with a small element of headcount reduction. Legacy technology remains in place however the Application Support and Development contract is re-procured.

Scope:

Transformation Area	Scope Description
Agency Restructuring and Cost Reduction	Minimal reductions are made to the Agency headcount and forecast Agency spend

Future Operating Model Design and Implementation	Remove friction from the current organisational structure and deliver tactical improvements
Technology Enabled Change	Focus on keeping existing systems running through remediation and re-platforming. Transition Application Support and Development to a new service in one immediate 'big bang' step

Indicative Costs: The Agency would need to spend approximately £2.3m on transformation FOM design.

Key Risks:

- This option is likely to leave the Agency in an unsustainable cash position with insufficient cost reduction
- The Agency's 2021-2023 delivery plan is unlikely to be achieved
- This option will precipitate some improvements in patient centricity but will not implement fundamental change to the way patients are involved in MHRA work
- Implementing this option alone will not provide a set up for the Agency to effectively deliver a world leading model, broadening its role working with more partners
- [redacted]

Key Benefits: This option achieves a proportion of the CRB benefits outlined in section 2.4.3 but not the full extent.

3.3.1.3 Option 3: Driving Patient Outcomes across the Product life-cycle Operating Model

Summary: Option 3 organises the Agency operating model around the product lifecycle and focuses on proactive tasks that have the biggest impact on patient outcomes. A mid-level of legacy technology is replaced which underpins the FOM.

Scope:

Transformation Area	Scope Description
Agency Restructuring and Cost Reduction	Sustainability targets are set which reduce pay costs, non-pay costs and project spend to sustainable levels. The Agency is restructured with headcount reducing based on these targets
Future Operating Model Design and Implementation	Design and implement an operating model that is organised around the product lifecycle and focuses on proactive tasks that have the biggest impact on patient outcomes

Technology Enabled Change	Replace the core regulatory systems with modern digital, data and technology solutions to support the transformed Agency; archive legacy data safely and securely and meet patient safety and access requirements. Migrate to cheaper, commodity technologies with the ability to insource elements of support

Indicative Costs: This option would include [redacted]

Key Risks:

- This option presents a medium risk of disruption to the business and its ability to deliver statutory requirements during the transformation period
- Some new capability is required to deliver this option which does not sit within the Agency
- Significant investment needs to be made in technology and data processing for commodity solutions that may not deliver all of the Agency's IT requirements as opposed to a bespoke system
- This option presents a significant change from current processes and ways of working which increases the Agency's risk of resistance to change

Key Benefits: This option could potentially realise all the transformation programme benefits listed in section 2.4.3. An economic appraisal of the benefits of this option has been detailed in section 3.5.

3.3.1.4 Option 4: Product Lifecycle and Agile Operating Model

Summary: Option 4 orientates the Agency organisational structure around the product lifecycle and embeds agile ways of working. Legacy technology is replaced with a full stack of bespoke technology solutions that underpin the FOM.

Scope:

Transformation Area	Scope Description
Agency Restructuring and Cost Reduction	Sustainability targets are set which reduce pay costs, non-pay costs and project spend to sustainable levels. The Agency is restructured with headcount reducing based on these targets
Future Operating Model Design and Implementation	Design and implement an operating model that orientates the Agency's organisational structure around the product lifecycle and embed agile ways of working
Technology Enabled Change	Replace the core regulatory systems with modern digital, data and technology solutions to support the transformed Agency; archive legacy data safely and securely and meet patient safety and access requirements. Migrate to advanced, bespoke technologies which can be designed to meet all Agency IT requirements

Indicative Costs: This option would include approximately [redacted] over the 3-year transformation period FY21/22 to FY23/24.

Key Risks:

- This option presents a high risk of disruption to the business and its ability to deliver statutory requirements during the transformation period
- Significant new capability is required to deliver this option which does not sit within the Agency
- Significant investment needs to be made in technology and data processing for bespoke IT solutions that have an increased risk of cost and time overrun due to being designed to Agency specification
- This option presents a significant change from current processes and ways of working which increases the Agency's risk of resistance to change

Key Benefits: This option could potentially realise all the transformation programme benefits listed in section 2.4.3. An economic appraisal of the benefits of this option has been detailed in section 3.5.

3.3.2 Approach to Long List Options Appraisal

Each long list option has been assessed based on the criteria in section 3.2. A summary assessment of the long list options is shown below. A more detailed appraisal, including definitions of High, Medium and Low ratings is available in Appendix D – Assessment Criteria and Appendix E - Future Operating Model Options.

Critical Success Factors	Option 1 BAU	Option 2 Remove Friction	Option 3 Product Lifecycle FOM	Option 4 Product Lifecyle Agile FOM
Strategic fit and business needs	None	Low	High	High
Potential value for money	None	Low	High	Medium
Supplier capacity and capability	None	Low	High	High
Potential affordability	None	High	High	Low
Potential achievability	None	High	High	Medium
Patient centricity	None	None	High	High
Brand / Reputational risk	High	High	Low	Medium

Business risk	High	High	Medium	High
Ease of implementation	High	High	Medium	Low
Summary	Requires appraisal but likely discount	Requires appraisal but likely discount	Preferred	Possible

3.3.3 Long List Options Appraisal Summary

On initial appraisal Options 1 and 2 are likely to have a high financial risk to the Agency and not be suitable options for the programme. However, this will be further assessed as part of the short list options appraisal.

Option 3 uses the product lifecycle operating model which appears to be a close fit for the Agency to achieve its future vision and strategic goals at this moment in time. This option has therefore been taken forward within this PBC for full economic appraisal.

Option 4 uses the product lifecycle operating model with agile ways of working embedded in the Agency. If this option is successfully implemented, it will allow the Agency to achieve each of the five strategic priorities and thrive into the world-leading, patient-centric Agency set out in its vision. However, this is an ambitious option, requiring significant investment and substantial change, which could present a risk to the business, it's brand and reputation. On this basis, this option has been taken forward for full economic appraisal within this PBC to determine whether VfM and societal value can be obtained given the balance of costs and risks involved.

3.4 Short List Options

As described within section 3.3.3, the below options have been taken forward for full economic appraisal:

- Option 1 - Business as Usual (BAU)
- Option 2 – Remove Friction
- Option 3 – Driving Patient Outcomes across the Product life-cycle Operating Model
- Option 4 – Product Lifecycle and Agile Operating Model

3.5 Short List Options Economic Appraisal

3.5.1 Approach to Determining Relevant Costs

The below tables provide a summary of the expected annual and total cost (pounds sterling) for Options 1-4 over the three-year transformation period where costs are incurred. At this stage, Optimism Bias (OB) has not been incorporated into costs displayed. This is covered separately in section 3.9.

The contributing costs detailed within the summary include:

3.5.1.1 Agency Restructuring

In line with Green Book guidance, Agency restructuring (redundancy) costs have not been included within this analysis. The rational for this approach is that while these present a cost to the Agency, when considering the overall NPSV including the payment received by relevant individuals, this has an overall net zero social impact. These costs are included in the financial case for reference.

3.5.1.2 Legal Costs

Legal costs of the transformation e.g. the redundancy process, accommodation disposal and negotiation have been estimated however these are currently built into the Agency operational budget and are therefore not considered within this case.

3.5.1.3 FOM Design and Implementation

FOM Design and Implementation costs are driven by external support to deliver the Transformation Programme and are expected to be consistent across options 3 and 4. Total costs of £6.2m are forecast for FY21/22, while £3.5m of costs are forecast in FY22/23 and £1.6m in FY23/24. FOM design cost for Option 2 is forecast at 20% of the value of Option 3 and 4, whilst Option 4 does not include any FOM design cost.

3.5.1.4 Technology Spend underpinning the FOM Transformation

This cost includes technology spend that is specifically tied to the implementation of the FOM. Any proposed cost that falls outside of the programme business case may be subject to an additional project green book business case. Option 4 includes investment in a full stack of bespoke technology solutions, which requires an additional year for full implementation over Option 3, with total expected costs of £87.1m and £39.5m for Options 4 and 3 respectively. Options 1 and 2 do not include any technology spend.

3.5.1.5 Net Deficit from Operations

Option 1 leaves the Agency in a significantly unsustainable cash position with insufficient cost reduction. As such, this option will incur the cost of a net deficit from operations annually as income is forecast to remain constant at £132.2m per annum, whilst incurring annual non-pay cost of £44m and rising pay costs. This deficit is forecast at £4.5m for FY21/22, growing to £19.3m by FY30/31. The full cost profile over a 10 year period is available in the supporting PBC economic model V1.14.

3.5.1.6 Inflation pay increase

Option 1 (BAU) includes an additional 1% inflationary pay increase over and above the 2% included in options 2-4, resulting in a total increase of 3% per annum. 3% is the typical increase as part of BAU, however as options 2-4 involve the implementation of significant cost reduction programmes, a constrained pay increase of 2% has been modelled as part of the cost saving drive. Therefore the 1% incremental uplift is only included within option 1.

3.5.1.7 Option 1 Annual and Total Cost Summary

	Financial Year			
Cost Category	**21/22**	**22/23**	**23/24**	**Total**

Additional Inflation pay increase (£m)	-	(0.9)	(1.9)	(2.8)
Net Deficit from Operations (£m)	(4.5)	(4.5)	(5.4)	(14.4)
Total Change Cost (£m)	**(4.5)**	**(5.4)**	**(7.3)**	**(17.2)**

Figure 8: Option 1 Annual and Total Cost Summary (February 2022)[12]

3.5.1.8 Option 2 Annual and Total Cost Summary

	Financial Year			
Cost Category	**21/22**	**22/23**	**23/24**	**Total**
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]

	[redacted]			
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]

		[redacted]			
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[12] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2
[13] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2
[14] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Figure 11: Option 4 Annual and Total Change Cost Summary (February 2022)[15]

3.5.2 Approach to Determining Relevant Financial Benefits

Options 3 and 4 deliver significant cash-releasing benefits to the Agency over the course of the proposed Transformation Programmes. The methodology for establishing these benefits is detailed in section 3.7.

These benefits are consistent across both options 3 and 4, which include:

- A target headcount reduction of up to 300 FTE
- A target reduction in non-pay costs – Accommodation
- A target reduction in non-pay costs – Technology
- Increases in income to offset loss of DH EU exit funding & loss of EU income

Option 1 does not generate any benefits for the Agency, whilst option 2 delivers 20% of the FTE reduction benefit realised by Options 3 and 4.

Options 2, 3 and 4 generate benefits over a multi-year time horizon. A ten-year time horizon has been selected to enable full capture of benefits delivered by the Transformation Programme.

An initial wave of FTE reduction is planned for FY22/23. Remaining FTE reductions and associated efficiencies will be achieved together with increases in new revenue and reductions in non-pay costs. Individual efficiencies and benefits may vary over the course of the Transformation, however values stated represent overall benefits sought from the combination of cash releasing benefits.

A summary of cash releasing benefits for Option 2 is displayed in the below table:

FY	Year 1 21/22 £'m	Year 2 22/23 £'m	Year 3 23/24 £'m	Year 4 24/25 £'m	Year 5 25/26 £'m	Year 6 26/27 £'m	Year 7 27/28 £'m	Year 8 28/29 £'m	Year 9 29/30 £'m	Year 10 30/31 £'m	Total £'m
Cash releasing benefits (CRB)	**-**	**2.7**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**34.8**
A target headcount reduction of c.60 FTE (20% of c.300 FTE)	-	2.7	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	34.8

Figure 12: Options 2 Cash Releasing Benefits (February 2022)[16]

[15] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2
[16] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

A summary of cash releasing benefits for Option 3 and 4 is displayed in the below table:

FY	Year 1 21/22 £'m	Year 2 22/23 £'m	Year 3 23/24 £'m	Year 4 24/25 £'m	Year 5 25/26 £'m	Year 6 26/27 £'m	Year 7 27/28 £'m	Year 8 28/29 £'m	Year 9 29/30 £'m	Year 10 30/31 £'m	Total £'m
Cash releasing benefits (CRB)	**0.5**	**34.7**	**45.7**	**46.7**	**46.7**	**46.7**	**46.7**	**46.7**	**46.7**	**46.7**	**407.6**
A target headcount reduction of up to 300 FTE	-	13.3	20.1	20.1	20.1	20.1	20.1	20.1	20.1	20.1	174.1
A target reduction in non-pay costs - Accommodation	0.5	4.1	4.1	4.1	4.1	4.1	4.1	4.1	4.1	4.1	37.4
A target reduction in non-pay costs – Technology	-	0.9	5.2	6.1	6.1	6.1	6.1	6.1	6.1	6.1	48.8
Increases in income to offset loss of DH EU exit funding & loss of EU income	-	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4	147.3

Figure 13: Options 3 and 4 Cash Releasing Benefits (February 2022)[17]

Option 1 does not deliver any benefits, whilst option 2 delivers minimal benefits related to an FTE reduction of £2.7m in FY22/23, rising to £4m p/a from FY23/24 – FY30/31.

Options 3 and 4 deliver negligible benefits in year 1. Wave 1 FTE reductions are partially implemented in year 2 and fully implemented by year 3 which enables a significant cash releasing benefit of £20.1m per annum to be realised through years 3 to 10. The office footprint reduction is partially implemented in year 1, with an associated cost saving of £0.5m. Further sustained reduction is realised in year 2, generating an associated benefit of £4.1m per annum through to FY30/31.

As a result of the transformation the Agency anticipates a reduction in technology costs. These are driven primarily by a reduction in complexity and therefore cost of the technology estate (including utilising cheaper software/licensing products), as well as reducing our reliance on third party suppliers. This saving is expected to be £0.9m in FY22/23 as new systems are developed. This saving is expected to increase to £5.2m in FY23/24, with a further increase to £6.1m from FY24/25 to FY30/31 as new systems are fully rolled out and managed within the Agency. This saving is dependent on achieving the HR critical path.

As a result of EU exit, the Agency lost a significant portion of EU income (equal to £23.6m in FY19/20, including £11.0m of DHSC Brexit funding). The shortfall in EU income is forecast to be covered by increased service fees and national applications as a result of direct licence applications to the Agency that previously would have been directed to EU regulators. The agency will additionally review fees in future to ensure that fees are set appropriately to cover the cost base of the transformed Agency. Increases in income are forecast at £16.4m p/a from FY22/23 to FY30/31.

3.5.3 Approach to Determining Relevant Non-Financial Benefits

Quantifiable but not monetisable and qualitative unquantifiable benefits are expected to be significant. The below tables provide a summary of these benefits:

[17] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

3.5.3.1 Improving Public and Patient safety

Benefit Classification	Description of Benefit	Beneficiary
Quantifiable but not monetisable	The Agency can provide early, more frequent, and intensive engagement with patients particularly around emerging trends in the safety status of products	Agency, Industry, Patients
	The Agency will be structured to deliver a more responsive safety surveillance and risk management system, for all medical products, enhancing patient safety	Agency, Industry, Patients
	Public safety will be improved through the Agency's capability to accelerate approval of clinical trials, medicines, devices, and vaccines to the market which is critical in responding to the pandemic	Agency, Industry, Patients
	The Agency will be positioned to respond to increased volumes of safety reports and signals detected across all healthcare products following the Agency's increased public profile during COVID-19	Agency, Industry, Patients
	The Agency will have an increased focus on achieving the right outcomes for patients, with patient centricity built into the heart of the Agency operating model	Agency, Industry, Patients

3.5.3.2 Increasing the Agency's Efficiency and Effectiveness

Benefit Classification	Description of Benefit	Beneficiary
Quantifiable but not monetisable	The Agency will implement a set of redesigned, streamlined, automated and standardised processes which reduce the cost to serve and increase delivery efficiency	Agency, Industry, Patients
	The Agency will utilise an updated technology stack that is brought up to modern security standards, which can respond to future needs and reduces the risk of data security threats	Agency
	The Agency will be structured to deliver against the 2021-2023 delivery plan for access to medicines and devices as part of a regulatory reform	Agency, Industry, Patients
	The Agency would be positioned well to create a risk-based approach leading to more emphasis on evaluation rather than batch-testing of biological products	Agency, Industry, Patients
	The Agency can drive automation and process redesign to increase self-service in low complexity and low risk activities such as simple variations, periodic safety update reports, parallel imports, and registrations of e-cigarettes	Agency, Industry, Patients
Qualitative unquantifiable benefits	The Agency will adopt a "One Agency" culture with the breakdown of silos and clear alignment of strategy, outcomes and KPIs across the Agency	Agency

	The new structure will embed greater accountability and sense of belonging amongst MHRA employees	Agency
	A common infrastructure will be incorporated to foster collaborative working and the sharing of resources	Agency
	A more efficient organisation structure with spans and layers of the organisation set up in a way that meets operational delivery needs	Agency

3.5.3.3 Enabling Innovation from Science and Pharmaceuticals

Benefit Classification	Description of Benefit	Beneficiary
Quantifiable but not monetisable	The Agency will be equipped to deliver world-leading research innovation using scientific data analytics, real world data, Artificial Intelligence (AI), big data and other emerging disruptive technologies	Agency, Industry, Patients
	The Agency will develop an enhanced leadership capability that helps attract, retain, and develop talent so the Agency can fuel innovation and drive change	Agency, Industry, Patients

3.5.3.4 Enhancing the Agency's Domestic and International Reputation

Benefit Classification	Description of Benefit	Beneficiary
Qualitative unquantifiable benefits	The Agency will build public and stakeholder trust through a programme of proactive and innovative communications	Agency, Industry, Patients
	The Agency will have a higher brand reputation as a global regulator in the industry	Agency

These benefits are challenging to estimate in monetisable terms due to difficulties in establishing direct linkages between the Agency's Transformation Programme and benefits delivered to patients and healthcare systems.

The full methodology used to value (in pounds sterling) quantifiable but not monetisable patient safety benefits is detailed in section 3.7. Options 1 and 2 do not deliver any significant Agency transformation and these benefits are therefore not realised for these options. The below table details these benefits which are relevant and consistent across options 3 and 4:

	FY										
	21/22	22/23	23/24	24/25	25/26	26/27	27/28	28/29	29/30	30/31	Total
	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m

Quantifiable but not monetisable benefits	**-**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**31.4**
Reduction in Adverse Drug Reactions (ADR) in a clinical setting	-	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	**27.0**
Reduction in definitely avoidable medication errors	-	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	**4.4**

Figure 14: Options 3 and 4 Quantifiable but not monetisable Benefits (February 2022)[18]

The proposed Agency Transformation covered by Options 3 and 4 includes the replacement of legacy systems with modern digital, data and technology solutions that underpin the FOM. This will unlock key benefits for the Agency once implemented, including an estimated £3.0m p/a from reductions in ADRs in clinical settings, and £0.5m p/a from reductions in definitely avoidable medication errors.

3.5.3.5 Quantifiable but not Monetisable Benefits

The proposed Agency Transformation covered by options 3 and 4 will enable the Agency to deliver the below quantifiable but not monetisable patient safety benefits outlined in section 2.4.3. Options 1 and 2 do not deliver the Agency transformation required to release this benefit.

Quantifiable but not monetisable patient safety benefits delivered:

- The Agency can provide early, more frequent, and intensive engagement with patients particularly around emerging trends in the safety status of products
- The Agency will be structured to deliver a more responsive safety surveillance and risk management system, for all medical products, enhancing patient safety
- The Agency will be positioned to respond to increased volumes of safety reports and signals detected across all healthcare products following the Agency's increased public profile during COVID-19

3.5.3.5.1 How will the Transformation Programme unlock these Benefits?

As a result of the COVID-19 pandemic, the Agency has experienced a significant increase in the number of reported suspected adverse reactions and devices adverse incidents, with 357,883 reports in the period 01/01/21 – 08/09/21. There has also been an increase awareness of the Yellow Card scheme due to it being featured in the vaccine patient information leaflet and with the heightened profile of the Agency at No.10 televised briefings.

The 2021 calendar year to date figures have been used to estimate that the total year impact on expected demand, including the COVID-19 related reports the percentage increase in reports for ADRs +1240%[19].

[18] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2
[19] See appendix C for full calculation

There has additionally been an increase in non-COVID-19 related reporting, and it is estimated that this alone has increased by 36% when modelled to show the percentage increase in yearly reports from 2019 and the expected number for 2021[20].

The proposed Agency Transformation covered by Options 3 and 4 includes the replacement of legacy systems with modern digital, data and technology solutions that underpin the FOM. This will unlock a number of benefits for the Agency, including:

1) **Increasing the ease and accuracy of reporting** – Integrated systems and development of easy-to-use front-end systems that enable first time submission of reports without follow up will increase both the volume and accuracy of reports submitted.

2) **Faster Decision making** – Data integration with National health system partners and global regulatory agencies will speed up information sharing, enabling swift decision making and improving response times.

3) **Adoption of AI and Machine learning** – Incorporation of AI and Machine learning into the reporting process will allow a significant reduction in resources required to manage report caseloads, allowing the agency to move towards a model of real time risk surveillance. This is additionally pertinent given the prolonged expected increase in reporting caseloads.

This change will enable delivery of the Agency Patient Safety benefits, with associated positive impacts on adverse events experience.

3.6 Optimism Bias

In line with Green Book guidance, OB has been applied to the costs and benefits for each short-listed option, in order to address the historic tendency of UK Government programmes to overestimate benefits and underestimate costs. Optimism bias levels have been set using the findings of the most recent evaluation of the Agency's OB based on historical project delivery. This concludes that the following uplifts should be considered, based on a weighted probability and impact of overruns:

- Project costs exceed the budgeted value by 25%
- Projects underachieve on target cost reduction by 28%

The following tables summarise the OB applied to change costs and benefits within the financial model for Options 1-4:

Change Cost	Base Cost FY21/22 – FY30/31	OB Adjustment Impact (%)	Option 1 Total Risk Impact (FY21/22-FY30/31)	Option 2 Total Risk Impact (FY21/22-FY30/31)	Option 3 Total Risk Impact (FY21/22-FY30/31)	Option 4 Total Risk Impact (FY21/22-FY30/31)
Inflation pay increase (Option 1 only)	Option 1: £17m	25% increase	(£4.2m)	n/a	n/a	n/a

[20] See appendix C for full calculation

Net deficit from operations (Option 1 only)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
FOM design and implementation	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Technology spend which underpins the FOM transformation	[redacted]	[redacted]	[redacted]	[redacted]	[redacted])	[redacted]
Total OB adjusted Costs			[redacted]	[redacted]	[redacted]	[redacted]

Figure 15: Change Cost OB Adjustments (November 2021)[21]

Cash releasing benefits (CRB)	**OB Adjustment Impact (%)**	**Option 1 Total Risk Impact (FY21/22-FY30/31)**	**Option 2 Total Risk Impact (FY21/22-FY30/31)**	**Option 3 Total Risk Impact (FY21/22-FY30/31)**	**Option 4 Total Risk Impact (FY21/22-FY30/31)**
A target headcount reduction of up to 300 FTE would produce a net benefit of £20.1m per annum	28% Reduction	n/a	(£9.7m)	(£48.7m)	(£48.7m)
A target reduction in non-pay costs - Accommodation	28% Reduction	n/a	n/a	(£10.5m)	(£10.5m)
A target reduction in non-pay costs – Technology	28% Reduction	n/a	n/a	(£13.7m)	(£13.7m)
Increases in income to offset loss of DH EU exit funding & loss of EU income	No Adjustment*	n/a	n/a	n/a	n/a
Total OB adjusted benefits		**n/a**	**£25.1m**	**£334.7m**	**£334.7m**

Figure 16: CRB OB Adjustments (February 2022)[22]

[21] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2
[22] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

*This benefit is based on Agency management account year end forecasts (FY21/22) which have been rolled forward into subsequent years. Use of this method is considered more robust than individual programme forecast benefits. OB has therefore not been applied as this is considered overly prudent.

The following table summarises the risk adjusted NPSV for options 2, 3 and 4 when accounting for OB:

Option	5 Year NPSV	5 Year Benefit / Cost Ratio	10 Year NPSV	10 Year Benefit / Cost Ratio
1	(£41.5m)	0.0	(£122.7m)	0.0
2	£6.7m	3.5	£17.7m	7.6
3	£79.9m	2.3	£238.3m	5.0
4	£26.4m	1.2	£184.9m	2.6

Figure 17: Options 2, 3 and 4 NPSV and BCR ratio after OB Adjustment (February 2022)[23]

Option 3 provides a higher NPSV than option 1,2 and 4 over both 5 and 10 year periods. In addition, Option 2 provides the highest BCR across all periods, however this option provides significantly less benefit which needs to be considered when considering this ratio.

3.7 Cost Benefit Analysis (NPSV)

3.7.1 Cost Benefit Analysis Outputs

The tables below provide a summary of the net present social value (NPSV) for options 1-4 across the 10-year time period from FY21/22 to FY30/31. In line with Green Book guidance, a discount rate of 3.5% has been applied when calculating the NPSV.NPSV and BCR values are shown with and without optimism bias (OB). The full economic model is detailed in Appendix B.

Option	5 Year NPSV		5 Year Benefit / Cost Ratio		10 Year NPSV		10 Year Benefit / Cost Ratio	
	No OB	OB	No OB	OB	No OB	OB	No OB	OB
1	(£33.2m)	(£41.5m)	0.0	0.0	(£98.2m)	(£122.7 m)	0.0	0.0
2	£10.9m	£6.7m	6.1	3.5	£26.1m	£17.7m	13.3	7.6
3	**£118.7m**	**£79.9m**	**3.5**	**2.3**	**£309.4m**	**£238.3m**	**7.5**	**5.0**
4	£75.9m	£26.4m	1.8	1.2	£266.6m	£184.9m	3.9	2.6

Figure 18: NPSV and Cost Benefit Analysis Summary (February 2022)[24]

[23] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2
[24] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

Cost Benefit Analysis Detail – Option 1

PRESENT VALUE £m	21/22	22/23	23/24	24/25	25/26	26/27	27/28	28/29	29/30	30/31	TOTAL
Total Cost	**(4.5)**	**(5.4)**	**(7.3)**	**(9.2)**	**(11.1)**	**(13.1)**	**(15.1)**	**(17.2)**	**(19.3)**	**(21.5)**	**(123.5)**
Cash Releasing Benefits (CRB)	-	-	-	-	-	-	-	-	-	-	-
Monetisable non-cash releasing (non-CRB)	-	-	-	-	-	-	-	-	-	-	-
Total Benefits	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Net Benefit / (cost)	**(4.5)**	**(5.4)**	**(7.3)**	**(9.2)**	**(11.1)**	**(13.1)**	**(15.1)**	**(17.2)**	**(19.3)**	**(21.5)**	**(123.5)**
Annual Present Value	**(4.3)**	**(5.0)**	**(6.5)**	**(8.0)**	**(9.4)**	**(10.7)**	**(11.9)**	**(13.1)**	**(14.2)**	**(15.2)**	**(98.2)**
Cumulative Present Value	(4.3)	(9.3)	(15.9)	(23.9)	(33.2)	(43.9)	(55.8)	(68.8)	(83.0)	(98.2)	

Figure 19: Option 1 Cost Benefit Analysis Detail (February 2022)[25]

[25] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

Cost Benefit Analysis Detail – Option 2

PRESENT VALUE £m	21/22	22/23	23/24	24/25	25/26	26/27	27/28	28/29	29/30	30/31	TOTAL
Total Cost	**(1.2)**	**(0.7)**	**(0.3)**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**(5.1)**
Cash Releasing Benefits (CRB)	-	2.7	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	34.8
Monetisable non-cash releasing (non-CRB)	-	-	-	-	-	-	-	-	-	-	-
Total Benefits	**-**	**2.7**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**34.8**
Net Benefit / (cost)	**(1.2)**	**2.0**	**3.7**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**32.6**
Annual Present Value	**(1.2)**	**1.8**	**3.3**	**3.5**	**3.4**	**3.3**	**3.2**	**3.1**	**2.9**	**2.8**	**26.1**
Cumulative Present Value	(1.2)	0.6	4.0	7.5	10.9	14.1	17.3	20.3	23.3	26.1	

Figure 20: Option 2 Cost Benefit Analysis Detail (February 2022)[26]

[26] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

Cost Benefit Analysis Detail – Option 3

PRESENT VALUE £m	21/22	22/23	23/24	24/25	25/26	26/27	27/28	28/29	29/30	30/31	TOTAL
Total Cost	**(18.2)**	**(25.1)**	**(7.4)**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**(50.8)**
Cash Releasing Benefits (CRB)	0.5	34.7	45.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7	407.6
Monetisable non-cash releasing (non-CRB)	-	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	31.4
Total Benefits	**0.5**	**38.2**	**49.2**	**50.2**	**50.2**	**50.2**	**50.2**	**50.2**	**50.2**	**50.2**	**439.0**
Net Benefit / (cost)	**(17.7)**	**13.0**	**41.8**	**50.2**	**50.2**	**50.2**	**50.2**	**50.2**	**50.2**	**50.2**	**388.2**
Annual Present Value	**(17.1)**	**12.2**	**37.7**	**43.7**	**42.2**	**40.8**	**39.4**	**38.1**	**36.8**	**35.6**	**309.4**
Cumulative Present Value	(17.1)	(4.9)	32.7	76.4	118.7	159.5	198.9	237.0	273.8	309.4	

Figure 21: Option 3 Cost Benefit Analysis Detail (February 2022)[27]

[27] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

Cost Benefit Analysis Detail – Option 4

PRESENT VALUE £m	21/22	22/23	23/24	24/25	25/26	26/27	27/28	28/29	29/30	30/31	TOTAL
Total Cost	**(25.9)**	**(25.0)**	**(25.3)**	**(22.2)**							**(112.8)**
Cash Releasing Benefits (CRB)	0.5	34.7	45.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7	407.6
Monetisable non-cash releasing (non-CRB)	-	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	31.4
Total Benefits	**0.5**	**38.2**	**49.2**	**50.2**	**50.2**	**50.2**	**50.2**	**50.2**	**50.2**	**50.2**	**439.0**
Net Benefit / (cost)	**(25.4)**	**13.2**	**23.9**	**28.0**	**50.2**	**50.2**	**50.2**	**50.2**	**50.2**	**50.2**	**340.6**
Annual Present Value	**(24.5)**	**12.3**	**21.6**	**24.4**	**42.2**	**40.8**	**39.4**	**38.1**	**36.8**	**35.6**	**266.6**
Cumulative Present Value	(24.5)	(12.2)	9.3	33.7	75.9	116.7	156.2	194.3	231.1	266.6	

Figure 22: Option 4 Cost Benefit Analysis Detail (February 2022)[28]

[28] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

3.7.2 Risk Adjusted Cost Benefit Analysis Outputs

Three risk conditions are outlined below that describe programme conditions that may materialise over the course of delivery of the Transformation Programme. These have been categorised as High, Central and Low Risk, and are detailed as follows:

3.7.2.1 High Risk Scenario

The High-Risk scenario represents a low benefit scenario during the delivery of the Transformation Programme. The following parameters have been modelled for this outcome:

- 6 Month technology implementation delay
- 6 Month delay in achieving FTE reduction
- Agency does not realise its forecast Non-pay Accommodation saving
- The Agency underachieves its income target by 25%

3.7.2.2 Central Risk Scenario

The Central Risk scenario represents potential delays in key aspects of programme delivery, and has been modelled to include:

- 6 Month technology implementation delay
- 6 Month delay in achieving FTE reduction
- Agency realises 50% of its forecast Non-pay Accommodation saving
- The Agency underachieves its income target by 10%

3.7.2.3 Low Risk Scenario

The Low-Risk scenario has been modelled to reflect minor impacts on programme delivery, and includes:

- 3 Month technology implementation delay
- 3 Month delay in achieving FTE reduction
- Agency realises 75% of its forecast Non-pay Accommodation saving

The below table provides a summary of adjusted NPSV and Benefit / Cost ratio under each Risk condition for Options 2-4. This analysis is not applicable to Option 1 as this option does not incorporate the relevant cost / benefit inputs. OB has been incorporated into this analysis. A full outline of OB calculation can be found in section 3.9.

	Option 2		Option 3		Option 4	
Risk Condition	**NPSV (£m) to FY30/31**	**Benefit / Cost Ratio**	**NPSV (£m) to FY30/31**	**Benefit / Cost Ratio**	**NPSV (£m) to FY30/31**	**Benefit / Cost Ratio**
High risk	16.4	7.14	178.3	4.03	125.8	2.13
Central	16.4	7.14	207.4	4.52	154.8	2.39
Low risk	17.0	7.39	228.9	4.86	175.9	2.57

Figure 23: Risk Scenario Analysis Summary (February 2022)[29]

[29] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

3.8 Assumptions for Economic Cost Benefit Analysis

3.8.1 Change Costs

The economic models for Options 1-4 (detailed fully within the economic model in Annex A) comprise the following costs (as of June 2021):

3.8.1.1 Agency Restructuring

In line with Green Book guidance, Agency restructuring (redundancy) costs have not been included within this analysis. The rational for this approach is that while these present a cost to the Agency, when considering the overall NPSV including the payment received by relevant individuals, this has an overall net zero social impact.

3.8.1.2 FOM Design and Implementation

This cost includes estimated costs for the Agency's external Strategic Transformation Partner, as well as an internal project team. This estimate will be subject to further revision as implementation costs are further defined as the programme develops. Due to the greatly reduced transformation scope, Option 2 is forecast to include 20% of the forecast FOM Design and Implementation cost of Options 3 and 4.

3.8.1.3 Technology Spend which Underpins the FOM Transformation

This cost includes only Technology spend that is specifically tied to the implementation of the FOM and is correct as of June 2021. These forecast costs are subject to the Spending Review outcome and may change if there are changes to scope before final agreement. Any proposed additional cost that falls outside of the programme business case may be subject to an additional project green book business case. In / out of scope projects have been agreed between the Transformation Programme and technology teams.

3.8.1.4 Net Deficit from Operations (Option 1)

Option 1 leaves the Agency in a significantly unsustainable cash position with insufficient cost reduction. As such, this Option will incur the cost of a net deficit from Operations annually as income is forecast to remain constant at £132.2m per annum, whilst incurring annual Non-Pay cost of £44m and rising pay costs.

3.8.2 Cash Releasing Benefits

The following section provides a breakdown of the assumptions and calculations included for cash releasing benefits detailed within the Economic Model for Options 3 and 4:

3.8.2.1 Target Headcount Reduction of up to 300 FTE

For Options 3 and 4, the future operating model sets out an efficient and financially sustainable future establishment that included up to 300 fewer FTE. The calculation is based on a bottom-up approach, but until full staff and trade union consultation has been completed, it is not possible to identify the exact number of redundancies or who they relate to. Therefore FTE reductions have been calculated on the basis that each FTE reduction is at the [redacted]. Option 2 forecasts 20% of the planned FTE reduction of Options 3 and 4 (c. 60 FTE).

An initial wave of FTE reduction is planned for FY22/23. Remaining FTE reductions and associated efficiencies will be achieved together with increases in new revenue and reductions in non-pay costs. Overall FTE reductions realised may vary and may therefore not reach 300 FTE. The total volume of savings will be delivered by the combination of cash releasing benefits.

The FTE reduction has been calculated bottom up by each function within the Agency. The breakdown of forecasted total FTE reduction by Agency function is detailed in the table below:

Portfolio	Function	Current FTE	Forecast FTE Reduction	FTE Reduction	£m Saving
Core Functions	Scientific Research & Innovation	317	247	70	4.8
	Healthcare Quality & Access	352	274	78	5.9
	Safety & Surveillance	369	287	82	5.8
Enablement	Comms	56	43	12	0.7
	Governance	29	23	6	0.4
	Transformation	13	10	3	0.2
Corporate	Commercial	13	10	3	0.2
	HR	39	30	9	0.6
	International & Partnerships	37	29	8	0.5
	Finance & Corporate Business Planning	36	28	8	0.5
Platform	Facilities & Laboratories Management	72	56	10	1.1
Total		**1378**	**1072**	306	**21.3**

Figure 24: Option 3 and 4 Forecast FTE reduction Breakdown[30]

3.8.2.2 A target reduction in non-pay costs – Accommodation

The Agency has developed plans to reduce the estates footprint as part of the Transformation Programme. This includes ceasing use of the 1st and 5th floor at our 10 South Colonnade building (£1.1m), with a part-year effect of £0.5m in FY21/22, as well as vacating 75% of the 10th floor in FY22/23 (3.0m). This reduction is only planned in Options 3 and 4 and is not included within the scope of Options 1 and 2.

[30] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

3.8.2.3 A target reduction in non-pay costs – Technology

As a result of the transformation, the Agency anticipates a reduction in non-pay Technology cost which is primarily driven by reliance on external suppliers to support Agency regulatory management systems. The below table summarises forecast reduction in non-pay technology costs as new agency systems are stood up and run through the Agency. Benefits from reduced cost are offset against the cost of additional technology staff required, with £0.9m of surge resource anticipated in FY22/23 and 23/24, falling to £27k from FY24/25 to 30/31. OB has not been applied to this analysis. This reduction is only planned in Options 3 and 4 and is not included within the scope of Options 1 and 2.

	21/22	22/23	23/24	24/25	25/26	26/27	27/28	28/29	29/30	30/31
Forecast Non-Pay Technology Cost (£m)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Annual Cost Reduction from 21/22 level of £18.3m (£m)		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Cost of Additional Technology Staff (£m)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Net Benefit (£m)		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Figure 25: Non-pay Technology Net Benefit Calculation Summary (February 2022)[31]

3.8.2.4 Increases in income to offset loss of DHSC EU exit funding & loss of EU income

As a result of EU exit, the Agency lost a significant portion of EU income (equal to £23.6m in FY19/20, including £11.0m of DHSC Brexit funding). The shortfall in EU income is forecast to be offset by a future increase in service fees and charges for national applications as a result of direct licence applications to the Agency. These fees would previously have been payable by industry to EU regulators. This benefit is forecast to be £16.4m from FY22/23 and each year thereafter. In addition, the Agency will review fees in future to ensure that they are set appropriately to cover the future cost base of the transformed Agency.

A detailed breakdown of the forecasted income increases for Options 3 and 4 is detailed in the below figure which compares forecasted FY22/23 Income to actual FY19/20 Income across MHRA business groups. FY20-22 have not been used for this comparison as they are pandemic and recovery years respectively. This benefit is not included in the scope of Options 1 and 2.

MHRA Business Group	FY19/20 Actual Income (£m)	FY22/23 Forecasted Income (£m)	Net Income Increase (£m)

[31] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

Other License Income	16.1	21.1	5.0
Service Fees	33.0	40.5	7.5
Devices	9.8	10.1	0.3
Clinical trials	3.3	3.7	0.3
British Pharmacopoeia	4.7	5.0	0.2
NIBSC	43.0	43.1	0.1
CPRD	10.2	13.1	2.9
Total	**120.2**	**136.5**	**16.4**

Figure 26: Options 3 and 4 forecasted Income Increase by MHRA[32]

3.8.3 Monetisable Non-Cash Releasing Benefits

As covered in section 3.5.3, quantifiable but not monetisable benefits are difficult to estimate due to challenges establishing direct linkages between the Agency's Transformation Programme and benefits delivered to patients and healthcare systems. The below approach has been utilised to quantify monetisable non-cash releasing benefits included within the financial model, specifically relating to its impact on:

- The reduction in ADRs in clinical settings
- Reduction in definitely avoidable medication errors

3.8.3.1 Reduction in ADRs in Clinical Setting

It is estimated that the direct cost to the NHS of hospital admissions as a result of Adverse Drug Reactions (ADRs) could total up to **£600 million** per annum[33].

A 1% reduction in the prevalence of ADRs could therefore generate up to a **£6 million** cost reduction. Although It is difficult to accurately estimate the direct impact of the Agency Transformation on the prevalence of ADR's, a prudent estimate of a 0.5% reduction in ADRs as a result of the transformation provides an estimated benefit **of £3 million p.a.**

3.8.3.2 Reduction in Definitely Avoidable Medication Errors

It is estimated that **237 million**[34] medication errors occur annually in England, with adverse effects on patients including ADRs, drug-drug interactions, lack of efficacy, suboptimal patient adherence and poor quality of life. It is estimated that costs to the NHS related to definitely avoidable medication errors are **£98 million**[35] per annum.

[32] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2
[33] Extrapolating an estimated £466 million per year from increased hospital occupancy based on data from 2004 (Pirmohamed et al. BMJ, 2004) to 2019 using data from NHS Digital, if the rate of ADR admissions remained the same
[34] From a systematic review aimed to estimate the prevalence and economic burden of medication errors in the NHS in England (Elliot et al. EEEPRU, 2018)
[35] From a systematic review aimed to estimate the prevalence and economic burden of medication errors in the NHS in England (Elliot et al. EEEPRU, 2018)

It is difficult to directly measure the impact of the Agency Transformation on Medication errors, however a 0.5% reduction in errors could provide up to **£490,000** in cost reductions to the NHS per annum.

It is important to note that it is difficult to accurately map wider economic benefits resulting from reductions in ADRs or medication errors directly to the transformation programme. However, there is clearly large potential to deliver benefits to UK healthcare systems and patients.

It is also important to consider the wider impact of these benefits, and subsequent compounding effect of benefits on the wider healthcare system e.g., a reduction is costs treating patients with co-morbidities which currently account for 7/10 pounds of overall NHS spend, and reductions in required GP visits.

3.9 Sensitivity Analysis

Sensitivity analysis has been completed to assess the impact of changes in key variables within the economic model on the NPSV of Options 2, 3 and 4. OB has been applied to all scenarios, including the base case within this analysis. This analysis has not been conducted for option 1 as the Agency is continuing with business as usual, and therefore inputs e.g. delayed technology spend or FTE reduction are not relevant. A full breakdown of optimism bias calculation can be found in section 3.9.

In line with Green Book guidance, sensitivity analysis has been applied to both benefit and cost estimations. The scenarios chosen represent scenarios that may materialise over the course of the implementation of the Transformation Programme. This includes:

- Delays in implementing FTE reduction
- Delays in Technology system implementation
- Lower than forecast reduction in FTEs

The NPSV results for each option and scenario are summarised below:

		Option 2		Option 3		Option 4	
Scenario	**Benefit sensitivity**	**NPSV to 30/31 (£m)**	**Benefit / Cost Ratio**	**NPSV to 30/31 (£m)**	**Benefit / Cost Ratio**	**NPSV to 30/31 (£m)**	**Benefit / Cost Ratio**
Base case	**Base case**	**17.7**	**7.64**	**238.3**	**4.99**	**184.9**	**2.63**
1	Redundancies delay by 3 months	17.0	7.39	235.0	4.94	181.5	2.60
2	Redundancies delay by 6 months	16.4	7.14	231.6	4.88	178.2	2.58
3	Technology implementation	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

	delay by 3 months						
4	Technology implementation delay by 6 months	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
5	Redundancies & Technology implementation delayed by 3 months	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
6	Redundancies & Technology implementation delayed by 6 months	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
7	50% of FTE reduction achieved in year 1, with further 50% achieved in year 2	7.5	3.82	187.4	4.14	134.0	2.18

Figure 27: Options 2, 3 and 4 Scenario Analysis Summary (February 2022)[36]

The analysis demonstrates that Option 2 delivers a modest positive NPSV, whilst a significant positive NPSV is maintained for options 3 and 4 under all scenarios. Option 3 maintains a higher NPSV under all scenarios than options 2 and 4. Option 3 delivers this improvement on NPSV over Option 4 through reduced Technology spend with similar achievement of the stated benefits.

3.10 Key Findings from Strategic and Economic Cases

3.10.1 Options Appraisal and Assessment against Critical Success Factors

To meet the key challenges currently facing the Agency (outlined in section 2.3.2) the Agency has set the following objectives that are to be delivered as part of the Transformation Programme:

- Establish a new business model for the future that increases income, reduces costs, and improves productivity
- Deliver an optimised IT infrastructure to improve our service and reduce our costs with fewer digital technologies
- Be a sustainable, cost-efficient, and self-funding entity that is not reliant on additional external funding to meet operational demands
- Achieve 100% of the baselined Agency benefits within the 3-year transformation period

[36] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

- Embed a fit for purpose operating model that puts patients first and begins to position the Agency to deliver against the 2021-2023 delivery plan

- Become easily accessible through a clean and modern front-end range of digital services that sit within the health system

These objectives have been translated into 9 Critical Success Factors (detailed in section 3.2). Four long list programme delivery options (see section 3.3) have been outlined within this PBC and assessed against the CSFs.

Option 1 (Business as Usual) and Option 2 (Remove Friction) were found to pose too high a financial and reputational risk to the Agency. Option 1 delivers a significantly negative NPSV that shows the unsustainable cash position the Agency would be exposed to by continuing with business as usual. Option 2, whilst delivering a limited positive NPSV, does not set the Agency up to deliver against its key strategic objectives and leaves the Agency exposed to ongoing financial sustainability risk. It is therefore recommended that these options are discounted.

Option 3 (Driving Patient Outcomes across the Product life-cycle Operating Model) and Option 4 (Product Lifecycle and Agile Operating Model) have been identified as having the potential to enable the Agency to achieve its future vision and strategic goals. Both options have therefore been short listed and subjected to full economic analysis.

Option 3 has a total change cost of £50.8m, compared to total change costs of £98.4m for Option 4 (change costs are £63.5m and £123m for both options respectively when accounting for OB). The additional spend for option 4, which is driven by increased Technology spend, does not deliver additional benefits.

Option 3 provides a higher NPSV and Benefit / Cost ratio compared to option 4 over both 5 and 10 year periods. This result is maintained when accounting for optimism bias. Additionally, both options continue to present strong positive NPSVs when subjected to both risk and sensitivity analysis (see section 3.6.2 and 3.8) which demonstrate that value will continue to be delivered for the Agency and wider society should some reasonable downside risks materialise. It is additionally important to note that strong positive NPSVs are delivered for both options, and these are primarily driven by the delivery of material cash releasing savings from operational costs, with only modest wider economic (quantifiable but not monetisable) benefits included.

3.11 Preferred Option and Conclusion

Option 3, Driving Patient Outcomes across the Product life-cycle Operating Model has been selected as the preferred option for the delivery of the Agency's Transformation Programme.

This option is clearly preferable to short listed options 1 and 2 that pose too high a financial and reputational risk to the Agency and do not meet sufficient critical success factors. This option is additionally preferred over short-listed Option 4, as it delivers a larger NPSV when forecast benefits and costs of the proposed Transformation Programmes are modelled.

Option 3 has additionally demonstrated that it retains a significant positive NPSV when tested under optimism bias and a number of risk conditions and scenarios (see section 3.6.2 and 3.8)

Option 3 provides the following NPSV after accounting for OB:

Option	5 Year NPSV	5 Year Benefit / Cost Ratio	10 Year NPSV	10 Year Benefit / Cost Ratio
3	£79.9m	2.3	£238.3m	5.0

Figure 28: Option 3 NPSV and BCR ratio after OB Adjustment (February 2022)[37]

Option 3 has expected total change costs of £50.8m over years 1-3 (£63.5m inclusive of optimism bias). This option is forecast to deliver £94.3m net benefits in year 5 and c. £302.7m net benefits by year 10 (inclusive of Optimism Bias). Over a 10-year timeframe, this option has a Benefit / Cost ratio of 5.0. A post-programme evaluation plan is included in section 6.7.1.

The Commercial Case, Financial Case and Management Case will consider the implementation of this option.

[37] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

4. Commercial Case

4.1 Purpose

The purpose of the commercial case at the PBC stage is to provide confidence that a potential deal has been considered and planned prior to approval and commencement of the Transformation Programme.

4.2 Procurement Strategy

4.2.1 Programme Procurement

If the programme requires a procurement to deliver a key component of the programme, then the Agency will adopt the following procurement cycle. Any procurement will follow the Social Value Model[38]:

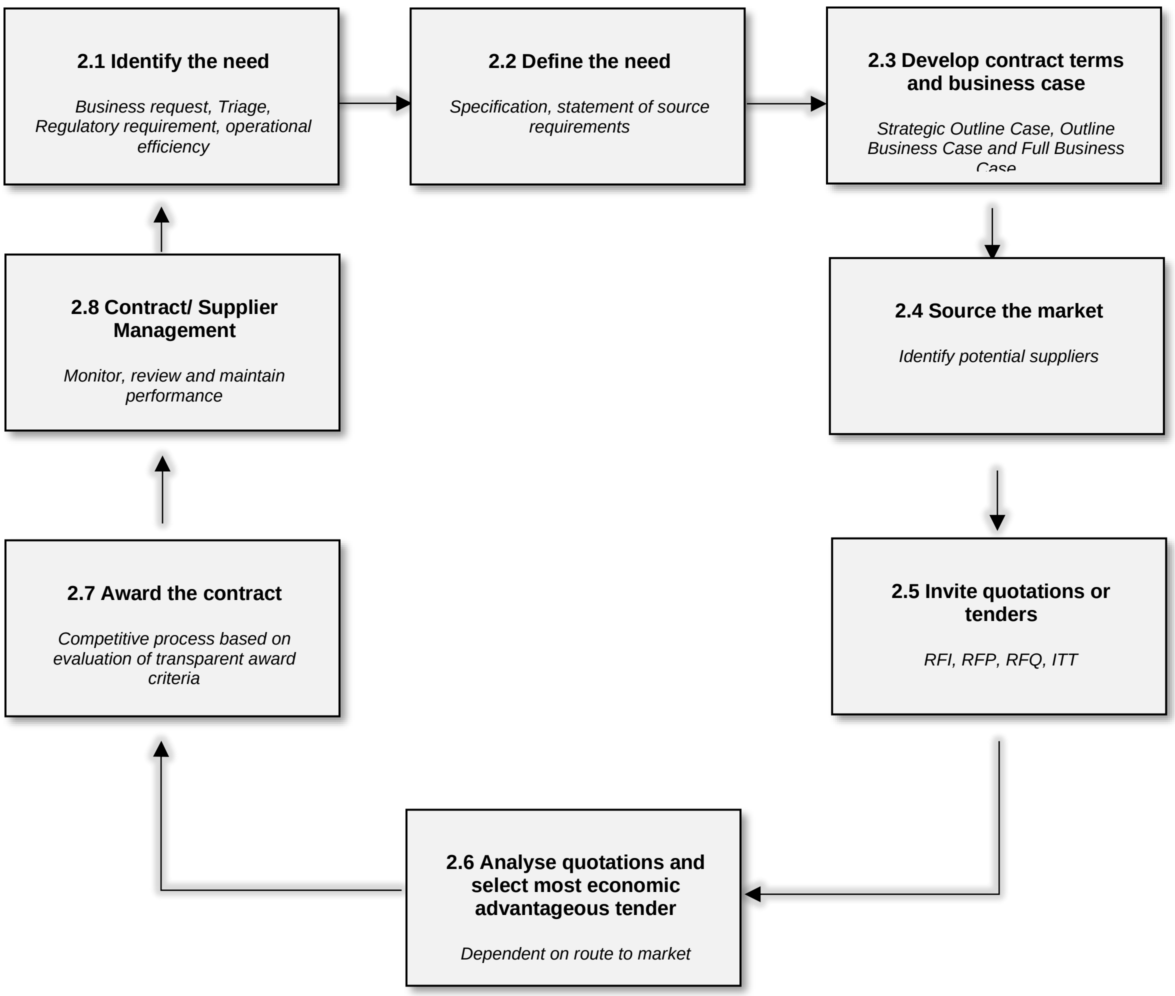

Figure 29: MHRA EPMO Procurement Cycle

[38] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940826/Social-Value-Model-Edn-1.1-3-Dec-20.pdf

4.3 Output Specification

The following high-level deliverables and actions will be required from the programme's strategic transformation partner (see section 4.4) to deliver the Transformation. This has been broken down by phase and may subject to changes agreed with the Agency's ExCo as the Programme moves through delivery.

4.3.1 Phase 1 – Agency Existing Governance Review

- Production of draft terms of reference (ToR) for the following governance bodies:
  - Board
  - Board Committees
  - Executive Committees
- Development of the initial outline of the governance handbook – a handbook that will define how governance structure will work and how committees will provide assurance to the Board
- Development of a high-level plan for implementation of the recommendations produced in the governance review
- Conduct a review of the Agencies strategic priorities

4.3.2 Phase 2 – High Level Design

- Agreement on programme governance, roles & responsibilities, progress reporting & issue / risk escalation
- Defined cost model, KPIs, existing & future revenue streams and revenue risk.
- An articulation of the MHRA future state vision and the associated change required to deliver the Future Operating Model
- Definition of MHRA's key 'Moments of Value' across the product lifecycle
- Defined design principles, assess impact of each option against assessment criteria and impact on patient experience
- Define associated high-level costs and revenue implications for each FOM option
- Write ups for 10 of 15 Agency MoVs
- Define FOM components (org, process, KPIs, capabilities, data), capability sourcing options 5-year roadmap, initiatives to implements, deliverability
- High level cost / revenue implications for FOM and initiatives
- Key risks and potential mitigations, governance model, costed resources, investment required for implementation

4.3.3 Phase 3 – Detailed Design

- Level 2 and Level 3 definition of the Future Agency's organisation structure, key capabilities, processes, objectives, key results and team governance
- A financial summary of the 3-year business case required to deliver the 3-year Transformation programme
- A single view of the Agency's initiatives required to deliver the 3-year Transformation plan

4.3.4 Phase 4 – Implementation

- Compilation of a central repository of services across the SR&I, HQA and S&S that contains detail of expected volumes, revenues, and costs where available
- An up-to-date version of the Agency-owned financial model that projects the most likely outcome of income, expenditure and change forecasts on the Agency reserves over a 3-year period of the transformation programme
- An update to FOM v1. Version 2 will capture any changes to the Level 2 and 3 definition of the Future Agency's organisation structure, key capabilities, processes, OKRs and governance based on work undertaken to date

- An approach document detailing the methodology and a phased plan to develop the Process Level 3 maps to identify areas for that could provide process efficiency benefits to the Agency through transforming, stopping or automating processes
- For process areas that have been identified as priority, newly created level 3 process maps that allow the Agency to further develop requirements and more detailed SOPS to harness efficiencies
- Paper detailing the Transformation Programme approach to governance and assurance to be approved by Agency
- Integrated delivery plan that sets out the programme workstreams, initiatives and interdependencies. This document will be maintained as a live file throughout the course of delivering the programme
- Completion of the HR redundancy process for identifying and realising FTE efficiencies.
- A culture baseline assessment and culture transition plan to help the Agency transition to the new ways of working and “one Agency” culture
- A central tracker used to measure, monitor and escalate progress against financial and non-financial benefits stated in the Green Book business case. This tracker will be updated on a periodic basis aligned to the timelines of the agencies standard financial reporting

4.4 Sourcing Options

4.4.1 Sourcing Options – Transformation Programme Delivery Support

The preferred option in the economic case is Option 3: Driving Patient Outcomes across the Product life-cycle Operating Model. This option involves a substantial transformation of the Agency’s operating model and will require significant change from current processes and ways of working. It is recognised that new capability will be required to deliver this option which does not sit within the Agency, and therefore the Agency will work with [redacted] as a strategic transformation partner to deliver the programme.

[redacted] has been selected due to their extensive experience across all sectors of transformation, from Operating Model design to implementation. This is coupled with a deep knowledge and understanding of the MHRA and wider health sector. This has been demonstrated through their extensive work with NHS England, broader regulatory industries and wider central government on the response to COVID-19, including helping to shape the operating model for the UK Health Security Agency and building strategic partnerships with NHS Digital and NHS Resolution.

The Agency utilised the Management Consultancy Framework 2 for the selection of [redacted] as strategic transformation partner. The framework is recognised as an effective, compliant route to market for a range of consultancy requirements for Government Departments. This route additionally required the Agency to run a competitive procurement process.

4.4.2 Sourcing Options – Technology

Digital, Data and Technology delivery supporting Transformation Delivery will span both legacy and new products and the preferred option will use existing agreements, sourced through Crown Commercial frameworks and / or G Cloud where possible.

The Agency has disaggregated sole supplier contracts in this area of service provision and now operates a multi-supplier model for provision of digital, data and technology services within an internally managed delivery framework and service, integration and management arrangement. The current sourcing and operating model comprise a mix of insourced and outsourced capabilities balanced against the forecast demand and value for money. Contracts are assured through existing pipeline assurance spend controls with DHSC, Cabinet Office & NHSX.

Services provided also support non-Transformation and business-as-usual services and projects across the Agency’s complex technology estate. Existing sourcing arrangements are non-exclusive, and capability and capacity of existing arrangements will be tested at point of demand. If unable to be adequately met, the Agency will then seek competition through existing frameworks.

4.4.3 Technology Procurement Strategy

Technology projects as set out in this PBC will leverage existing Agency contracts for technology delivery, managed by the TD3 team. This PBC contains a subset of technology enabled change across the Agency and will operate a multi-supplier environment that has already been subject to competitive procurement. The Agency would look to leverage existing arrangements wherever possible. All work requests for new change initiatives are currently subject to commercial, technical and compliance scrutiny through the joint pipeline process operated and attended by NHS-X, GDS, Cabinet Office, DHSC and NHS Digital. The Agency have additionally engaged this group (Digital, Data and Technology Approvals Group) around forward-looking plans in Transformation to provide a forward look subject to Transformation business case approval.

Specifically:

- **Digital Self-Service** – The Agency will leverage existing application delivery contracts. Work packages will be put forward as Change Notices / Statements of Work and proposals received, the most economically advantageous proposal will be taken forward. This will follow a standard Discovery, Alpha, Beta, Live lifecycle with the ability to change suppliers between Discovery, Alpha and Beta. Should proposals not meet quality or cost criteria we will look to engage services through existing Crown Commercial Frameworks utilising either DOS or G-Cloud.

- **RMS / Legacy Management –** The Agency will leverage the existing Application Development and Maintenance contract recent procurement where proposals around RMS and Legacy Management delivery were competitively evaluated. The contract included these as optional services. Work will be packaged as contract change requests and proposals will be reviewed. The conditions of adopting these optional services attached to the recent approval of the Application Outsourcing Transition case included providing this Transformation case to provide the strategic and wider context.

Additional supporting services for delivery are already in place in existing contracts and include:

- Infrastructure Support services
- Managed project delivery services
- Software Development services
- Enterprise Architecture services
- Infrastructure, Platform and technology services
- Testing Services
- Security Testing service

4.5 Pricing Framework and Charging Mechanisms

Payment by Milestones (PbM) is recommended as the primary payment mechanism for this Transformation programme given its simplicity of use and outcome focussed nature. This approach has been selected for the Agency's Strategic Transformation Partner [redacted] The key characteristics of the PbM approach have been outlined below, along with additional mechanisms such as Payment by Results (PbR) and Payment by Use (PbU) which have been included for the purpose of comparison but will not be the preferred mechanisms given the risks associated with them.

4.5.1 Payments by Milestones (PbM)

PbM is a payment mechanism by which payment for services are linked to specific outputs being achieved by a set time. Payment can only be made following satisfactory delivery of pre-agreed certified deliverables and signed-off by the customer.

The benefit of using PbM is that the Agency only has to pay for the service when specific outputs are completed, and it ensures there is increased accountability to deliver the service by a set time. The PbM approach would also enable MHRA to request services directly from the suppliers via a bespoke contract set up in accordance with each output and agreed between MHRA and the supplier.

The challenge with PbM is ensuring the right milestones and outputs are defined with the external supplier to ensure motivation and momentum is maintained in the programme's delivery.

4.5.2 Payment by Results (PbR)

PbR is a key payment mechanism which ensures payments for services are directly linked to specific outcomes, performance standards or in some cases, a combination of both. With this approach, value for money is maximised as payments are only disbursed based on the suppliers' ability to achieve pre-arranged specified outcomes and performance standards.

The PbR approach would enable MHRA to request services directly from the suppliers via a bespoke contract set up and agreed between MHRA and the supplier. However, there are several associated risks with this approach as outlined below:

- Complex dispute resolution
- Limited expertise on PbR across government particularly in the contract management space
- Complex payment, baseline and incentive modelling, monitoring and analytic needs
- Still novel in terms of acceptance commercially across government which introduces risks due to uncertainty
- The potential for no bids due to the inherent risks
- There are many examples of rushed implementation, a phased approach is suggested to be better
- Defining 'benefits' is needed and should sometimes be flexed to include Payment by 'findings' or payment by 'results achieved'

Additionally, from the outset of the COVID-19 pandemic, Central Government has discouraged use of this methodology as it has not been proven to be successful within the public sector. Therefore, this mechanism will not be a preferred option.

4.5.3 Payments by Use (PbU)

Departments wishing to draw down on certain services from the centre will be charged using PbU via a rate card and annual charging mechanism.

This will only work where the request is specific and measurable and a unit of use of this service can be quantified.

The benefit of using PbU is that the department only has to pay for the service as and when they use it, and the price can be directly linked to the request.

The challenge with PbU is around the uncertainty of which departments and when services will be drawn down on. Given this challenge, the PbU payment mechanism will not be a preferred option.

4.6 Risk Allocation and Transfer

Risks should be apportioned to the party that is best placed to mitigate the risk. A detailed summary of the Transformation Programmes risk identification, escalation and management approach can be found in section 6.6. The below table provides a breakdown of risk ownership by category:

Risk Category	Description of Risk	The Agency	Outsource Suppliers	Shared
Business Risks	There is a risk of low stakeholder availability to engage key people in the Agency throughout the lifecycle of the transformation programme			✓
	There is a risk that without alignment and drive from the Executive Committee (Exco), successful execution of this transformation will not be possible			✓
	There is a risk that once the new organisation structure is designed, the Agency's people won't be mobilised within the new operating model in a timely manner causing a disruptive transition period	✓		
	There is a risk that the Agency will not be able to fund the Transformation programme from reserves and will need to obtain external funding			✓
	There is a risk that running the Transformation programme alongside BAU activities will cause significant disruption to the business and its ability to deliver a rapid response to the pandemic	✓		
	There is a risk of change fatigue as previous transformation programmes at the Agency have been unsuccessful			✓
	There is a risk of change resistance: Not all MHRA employees will easily adapt or agree to the FOM and will create a challenging working culture which will cause attrition			✓
	There is a risk that the scale of change to be achieved within the specified 3-year timeframe is significant and potentially unachievable			✓
	There is a risk that the Agency will be unable to source, develop and resource the necessary skills and creating the right culture	✓		
	There is a risk of failure to create an appropriate and proportionate governance models for the transformation to ensure a successful transformation execution	✓		

Service Risks	There is a risk that the FOM design does not meet the future needs of the Agency	✓		
	There is a risk that the transformation programme may run over budget and over the projected time period			✓
	There is a risk that the separation of business-specific transformation requirements and technology requirements leads to a disjointed approach, duplication of effort and inadequate requirements being presented to technology with unrealistic expectations to deliver			✓
External Risks	There is a risk that changes in legislation may redirect Agency effort away from the transformation programme			✓
	The risk of changes in (national) policy or other grant policy direction leading to unforeseen change.			✓
	Post COVID-19 impacts to other health bodies (e.g., NHSE/ I, NIPH etc) and EU-exit could continue to put pressure on MHRA	✓		

4.7 Contract Management Approach

4.7.1 Contract Manager

A contract manager would be appointed as part of any procurement that relates to the programme. The individual nominated as the contract managed will be responsible for managing the performance of a supplier. The contract manager is to ensure that the supplier delivers the goods / services to the requisite quality levels within the agreed timescales and costs.

4.7.2 Operational Contract Manager

As well as the day-to-day management of the contract, Operational Contract Managers will work collaboratively with the contract manager ensuring minimum standards are met and relevant contract management documentation is recorded.

4.7.3 Senior Business Owner

The Senior Business Owners will act as sponsor / customer and is accountable for the management of the business activity to which the contract and management of the contract relates.

4.7.4 Commercial Lead

The Commercial Lead is responsible for sourcing, managing contract renewals and provide commercial insight and support contract management escalations. They also provide guidance on commercial legislation and marketplace insight.

4.7.5 Financial Business Partner

The Finance Business Partner will be involved on an ad hoc basis throughout the lifecycle of the contract and will attend meetings as required to support spend control, monitor expenditure and support future planning.

4.7.6 Reporting

To monitor performance, the Agency contract manager will agree an appropriate format and timescales for regular performance and financial reporting from the supplier.

While there is no mandated format for this, the programme manager will need to be able to incorporate reports into the mandated project highlight reports. All reports will be filed and accessible for future reference.

4.7.7 Performance Reviews

The contract manager will hold regular performance reviews with the supplier. Where these reviews have agendas that include commercial discussions (costs, invoicing contract changes etc) an SCM manager will be present at the meeting.

The reviews are to have formal agendas and minutes, to be kept on file within the programme's SharePoint filing structure.

4.7.8 Financial Tracking

The contract manager will keep an accurate record of all SoWs, POs and invoices associated with a suppliers' work chargeable to their projects. Where the work is being funded through a programme business case, the financial record is to be kept within the mandated programme's finance tracker.

- As part of the financial tracking, the programme manager will keep a running record of:
- Budget (agreed business case and budget per work package and per supplier)
- Committed spend (POs raised against each supplier)
- Actual spend (invoices received/paid to date against each PO, per work package and per supplier)
- Monthly burn rate (expenditure per month against each work package)
- Forecast to completion (per work package and per supplier)
- Variances:
    - Burn rate against forecast
    - Forecast to completion against SoW and PO
    - Forecast to completion against budget

The contract manager will manage performance against SoW, PO and budget and take necessary action with the supplier to remain within costs. The contract manager will pre-empt and manage any potential overspend as soon as that becomes apparent through forecasting variances.

If the contract manager is unable to resolve potential overspend or under-performance directly with the supplier, they are to escalate to the Digital & Delivery Group management, the budget holder and SCM.

4.7.9 Contractual Changes

During the life of the contract there may be a need issue a "Change Control Note" (CCN) to alter the terms or requirements of the contract to ensure it is still meeting the Agency's evolving needs. This may include unforeseen changes to contract scope, impact of regulatory changes (e.g., GDPR), or to meet recommendations (e.g., Cumberlege Review).

Furthermore, many contracts manage delivery of goods and services via "Statements of Work" (SOW).

Whichever the commercial vehicle and need for change, effective change management will help to track the nature of the changes and ensure compliance with the Public Contracts Regulations.

To manage change effectively a CCN or SOW Log needs to be kept as well as utilizing Commercial Cover Sheet to record overall impact to the contract, highlight the need for change and provide a record of all approvals.

4.8 Best Value

For any procurement falling under the Programme, the Agency will use Crown Commercial approved sourcing frameworks e.g., Management Consultancy Framework 2

These frameworks will achieve value for money due to the following:

- The Agency secures competitive market rates by consolidating public sector consultancy and audit spend.
- The Agency will have procurement options form a wide range of suppliers, from large nationals to SMEs.
- Structured guidance is utilised throughout the procurement, covering such areas as pre-market engagement, expressions of interest, timescales and pricing models, which has been designed to help customers follow best practice.
- All potential suppliers are accredited to cyber essentials as a minimum.
- Standard terms and conditions are agreed by all suppliers on the framework

4.9 Conclusion

In summary, the Agency has sufficient understanding of the requirements to engage the market and confidence that the market has the capacity to collaborate and deliver a strategic transformation partner to support the Transformation Programme. The same can be said for technology delivery partners and suppliers. Therefore, the Agency can conclude that the programme will be commercially viable should any external suppliers be appointed.

5. Financial Case

5.1 Purpose

The purpose of the Financial Case is to demonstrate the expected affordability and funding requirements for the Agency of the preferred option, Option 3. The Agency are currently transitioning to a 3 financial statement model but at present there is no Agency balance sheet or I&E forecast for the Transformation Programme. This case therefore focuses on the change in the Agency's cashflow forecast and cash balances over the course of the three-year Programme.

5.2 Forecast Cash Profile

Base case

The base case forecast highlights that the Agency is operating in an unsustainable cash position, with forecasted income now lower by 10-15% (compared to FY20/21) following departure from the EU, and operating costs forecast to increase by £2.0-3.0m per annum. If the Agency does not address these material financial pressures, the current unbudgeted funding gap will continue and worsen, which will in turn increase financial pressure within central government.

There is an additional financial imperative driven by a change in the Agency's status. MHRA currently operates as a government trading fund and therefore the Agency's finances have remained separate from its sponsor department, DHSC. The Office for National Statistics has assessed the economic status of the Agency and concluded it should now be reclassified to the central government subsector. Once the Agency's trading fund status ends on 31st March 2022 the finances will be consolidated within the DHSC, and the Agency will be subject to the DHSC financial regime. This includes a material change in that the Agency will no longer be able to carry forward reserves to future years and will need a new financial model that balances the budget in-year. This will, even more than before, require the Agency to operate on a cost-neutral basis.

Without any cost reduction and / or restructuring action, the Agency will arrive at persistent net income gap between operating costs and income throughout the 3-year transformation period forecasted in the MLO (all figures are cashflow items only):

£m	FY21/22	FY22/23	FY23/24
Income	132.2	132.2	132.2
FTE costs	(92.7)	(93.6)	(95.5)
Non-pay costs	(44.0)	(44.0)	(44.0)
Non-pay Technology	(19.9)	(19.9)	(19.9)
Non-pay other	(24.1)	(24.1)	(24.1)
Net cash surplus / deficit in base case scenario	**(4.5)**	**(5.4)**	**(7.3)**

Figure 30: Agency Base Case Cash Forecast November 2021[39]

The cash operating deficit combined with the change in trading status will reduce the Agency's cash reserves from an FY21/22 opening position of £51.5m to below zero in FY22/23 (with a resulting pressure on DHSC group accounts) and a closing position of -£7.3m in FY23/24.

[39] Source: MHRA_Fee_Analysis_Model_20-21_SAMatrix_V.56.10.i3

£m	FY21/22	FY22/23	FY23/24
Opening cash reserves	51.5	0.0	0.0
Net cash surplus / deficit in base case scenario	(4.5)	(5.4)	(7.3)
Closing Cash Reserves	**47.1**	**(5.4)**	**(7.3)**

Figure 31: Agency Base Case Cash Position Summary[40]

Investing in Transformation

Option 3 provides the opportunity to invest in a transformation programme that will drive cash releasing savings in future years. The cost profile of the preferred option for the transformation programme is detailed below:

	Financial Year			
Cost Category	**21/22**	**22/23**	**23/24**	**Total**
Agency restructuring (£m)	[redacted]	[redacted]	[redacted]	[redacted]
FOM design and implementation (£m)	[redacted]	[redacted]	[redacted]	[redacted]
Technology spend which underpins the FOM transformation (£m)	[redacted]	[redacted]	[redacted]	[redacted]
Total Change Cost (£m)	[redacted]	[redacted]	[redacted]	[redacted]

Figure 32: Transformation Programme Cost Profile (November 2021)[41]

At the end of FY21/22, the Agency is expected to lose its trading fund status and therefore any remaining cash from prior year reserves will no longer be accessible. Given this, the Agency forecasts a £31.1m cash deficit in FY22/23, and additional funding will need to be secured to fund the transformation programme during this year. A Spending Review (SR) is currently underway in which the Agency has requested an additional £34.5m of transitional funding support to ensure the programme (amongst other Agency priority activities) can continue to be delivered. This will fully fund the Transition Programme if awarded in full, however if the SR is only partially awarded, then the Agency will be required to explore options for closing the funding gap.

In FY23/24, it is forecast that the final year of the Transformation Programme costs will be fundable from net cash generated from operations.

£m	FY21/22	FY22/23	FY23/24
Opening cash reserves	51.5	0.0	0.0
Total change costs	(27.5)	(30.2)	(7.4)
Technology spend which underpins the FOM transformation	[redacted]	[redacted]	[redacted]
Redundancy cost	(9.3)	(5.1)	0.0
FOM Design & Implementation costs	[redacted]	[redacted]	[redacted]
Net cash surplus / deficit from operations	[redacted]	[redacted]	[redacted]

[40] Source: MHRA_Fee_Analysis_Model_20-21_SAMatrix_V.56.10.i3
[41] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

Closing Cash Reserves	**19.5**	**(31.1)**	**2.0**

Figure 33: Option 3 Changes in Cash Position Summary [42]

- **Redundancy costs:** Agency restructuring includes planned reductions in FTEs across two waves: 181 in FY22/23 and 98 in FY23/24. These reductions will incur redundancy costs, and these have been calculated on the basis that each FTE reduction will incur 9 months FTE cost. [redacted] (including on-costs) was used for cost calculation.

- **Transformation costs:** Forecast transformation costs relating to the design and implementation of the Transformation Programmes have been forecast over the three years. These costs include fees for project management and professional advisor (including legal) support.

- **Technology spend which underpins the FOM transformation:** A number of Technology projects will be undertaken in order to deliver the FOM as part of the Transformation Programme:

Transformation Cash Improvements

The improvement in the financial forecast under Option 3 is driven by the achievement of a number of savings schemes:

£m	2021/22	2022/23	2023/24
Headcount reduction of up to 300 FTE	0.0	13.3	20.1
Reduced accommodation costs	0.5	4.1	4.1
Reduced non-pay costs – Technology	[redacted]	[redacted]	[redacted]
Increases in income to offset loss of DHSC EU exit funding & loss of EU income	0.0	16.4	16.4
Total	[redacted]	[redacted]	[redacted]

Figure 34: Option 3 Cash Releasing Benefits [43]

These are based on the following assumptions and details:

- **Headcount:** The forecast operating model set out an efficient and financially sustainable future establishment that includes up to 300 fewer FTE. Until full consultation has been completed it is not possible to identify exact staff or roles that will be reduced, so FTE reductions have been calculated on the basis that each FTE reduction is at the Agency's [redacted]

- **Accommodation:** The Agency has developed plans to reduce the estates footprint as part of the Transformation Programme. This includes ceasing use of the 1st and 5th floor at our 10 South Colonnade building (£1.1m), with a part-year effect of £0.5m in FY21/22, as well as vacating the 10th floor in FY22/23 (£3.0m).

- **Technology:** As a result of the transformation, the Agency will reduce non-pay Technology cost through reducing reliance on external suppliers used to support regulatory management systems. These savings are profiled as follows:

£m	2021/22	2022/23	2023/24

[42] Source: MHRA_Fee_Analysis_Model_20-21_SAMatrix_V.56.10.i3
[43] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

Forecast Non-Pay Technology Cost (£m)	18.3	16.6	12.3
Impact of Transformation Programme:			
Cost Reduction (£m)		1.7	6.0
Cost of Additional Technology Staff (£m)	-	(0.9)	(0.9)
Net Benefit (£m)		**0.9**	**5.2**

Figure 35: Option 3 Non-Pay Technology Benefit Breakdown [44]

- **Income:** As a result of EU exit, the Agency lost EU funding (equal to £23.6m in FY19/20, including £11.0m of DH Brexit funding). The shortfall in loss of EU income is forecast to be offset by increased service fees and national applications as a result of direct licence applications to the Agency that previously would have been directed to EU regulators. The agency will additionally review fees in future to ensure that they are set appropriately to cover the cost base of the transformed Agency.

Return on Investment and Payback Period

Option 3 caries total change costs of £65.2m and generates 3 year cash releasing benefits of £80.9m (FY21/22 to FY22/23), with 10-year cash releasing benefits of £407.6m (FY21/22 to FY30/31). The 3 and 10 year return on investment (ROI) for option 3 is 124% and 625% respectively. The payback period for the programme is 2.66 years.

5.3 Budget Arrangements

The Transformation Programme's budget will be allocated in line with forecast change costs. A breakdown of this is provided in the table below (with further detail in the previous sub section):

£m	2021/22	2022/23	2023/24
Technology spend which underpins the FOM transformation	[redacted]	[redacted]	[redacted]
Redundancy cost	(9.3)	(5.1)	0.0
Transformation costs	[redacted]	[redacted]	[redacted]
Cost of Transformation	[redacted]	[redacted]	[redacted]

Figure 36: Option 3 Budget Allocation [45]

Change costs remain broadly consistent at [redacted] the Transformation nears conclusion.

The budget is fundable in FY21/22 using internal cash reserves, which are more than sufficient to cover the forecast costs for the year. From FY22/23 onwards the Agency will no longer retain any budget surpluses so will need to fund the transformation budget from existing cash. This will not be possible in FY22/23 without the £34.5m funding settlement that has been applied for as part of the Spending Review process. In FY23/24 the Agency will be able to fund the transformation budget using net cash generated from operations.

[44] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2
[45] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

The budget for project administration costs includes an adjustment for optimism bias to cover the risk of overspends (c.20%-25% depending on the cost type) and covers all forecast pay, non-pay and other project expenditure.

The budget for redundancy costs has been prepared on a prudent basis, assuming a payment equivalent to 9 months' salary for each post reduction, [redacted] These assumptions will allow an element of risk to be absorbed without impacting the total costs of implementing the transformation programme.

5.3.1 RDEL and CDEL Spend Allocation

The below table provides a summary of the RDEL / CDEL allocation of the Programme's change costs:

£m	RDEL / CDEL	2021/22	2022/23	2023/24
Redundancy cost	RDEL	(9.3)	(5.1)	0.0
Transformation costs	RDEL	(6.2)	(3.5)	(1.6)
Technology spend which underpins the FOM transformation	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]
Total Cost of Transformation		**(27.5)**	**(30.2)**	**(7.4)**
Total RDEL spend		[redacted]	[redacted]	[redacted]
Total CDEL spend		[redacted]	[redacted]	[redacted]

Figure 37: RDEL and CDEL Budget Allocation [46]

Redundancy and transformation costs for the Programme are classified as RDEL spend. Technology spend underpinning the FOM is split between RDEL and CDEL. The Agency has recently updated its classification guidance, and as a result the majority of technology spend will be classed as CDEL as the relevant projects within this cost category result in creating identifiable, controllable assets.

5.4 Funding Arrangements

In FY21/22, the Agency will fully fund the Transformation Programme through existing cash reserves that are £51.5m at the start of FY21/22. The Agency will additionally fund the Programme in FY23/24 through surplus net income generated from operations.

However, as mentioned in section 5.3, the Agency is forecasting a cash deficit of £31.1m for FY22/23. If fully awarded, the Agency will fund this period using funds received from the Spending Review in which the Agency has requested an additional £34.5m to ensure the programme can continue to be delivered in the FY22/23. The £34.5m requested via the SR is greater than the

[46] Source: MHRA Economic_Model>Transformation_Green_Book_Business_Case_V1.14.i.2

£31.1m required as these funds include additional elements of transformation e.g. Site Relocation / Redevelopment which are not within the scope of this PBC. If the SR is not fully awarded (i.e., less than the minimum requirement of £31.1m) it will not be possible to implement the Transformation at the scale and pace envisaged and the Agency will need to explore alternative options with DHSC which may not bring the organisation back to a positive cash-generating position in the short to medium term.

5.4.1 Source and Application of Funding

The below table provides a summary of the sources and application of funds by FY.

£m	FY21/22	FY22/23	FY23/24
Opening cash reserves	51.5	0.0	0.0
Total change costs	(27.5)	(30.2)	(7.4)
Technology spend which underpins the FOM transformation	[redacted]	[redacted]	[redacted]
Redundancy cost	(9.3)	(5.1)	0.0
FOM Design & Implementation costs	[redacted]	[redacted]	[redacted]
Net cash surplus / deficit from operations	(4.5)	(0.9)	9.4
Funding (DHSC SR 22/23)	0	31.1	0
Closing Cash Reserves	[redacted]	[redacted]	[redacted]

Figure 38: Option 3 Changes in Cash Position Summary [47]

In FY21/22, total change costs of £27.5m are funded through the use of Agency reserves (which were £51.5m at beginning FY21/22).

In FY22/23, the Agency will lose its trading fund status and no longer have access to reserves. Change costs of £30.2m and a net deficit from operations of £0.9m (total – £31.1m) are planned to be funded through use of the DHSC SR requested transition funding of £34.5m. It is important to note that the £34.5m of SR funding includes other aspects of the Agency's transformation that outside the scope of this PBC including site relocation and redevelopment. £31.1m of the £34.5m requested will fund year 2 of the programme. If the total SR requested funds are not received, the Agency will have to explore additional funding options such as obtaining permission from DHSC to carry over FY21/22 cash reserves to fund year 2 of the transformation programme.

In FY23/24, the Agency forecast to receive a net surplus from Operations of £9.4m, which will entirely fund the Transformation Programme for this FY.

5.5 Balance Sheet

The Agency are currently transitioning to a three financial statement model but at present there is no Agency balance sheet. The Agency is due to move to the new model in early 2022 where work will be undertaken to analyse the impact of capital costs and depreciation.

5.6 Conclusion

The base case forecast shows that the Agency is not currently financially sustainable. Cash reserves are reducing (and will disappear entirely in FY22/23) and net cash generated from operations is below zero for each forecast year. This position is driven by a significant reduction in

[47] Source: MHRA_Fee_Analysis_Model_20-21_SAMatrix_V.56.10.i3

income received, primarily due to changes in post EU-exit funding agreement, alongside a sustained and increasing cost-base. The preferred option (Option 3) sets out a Transformation Programme that can move the Agency to a position of being a net positive cash generator by FY23/24, resulting in a significant improvement above the base-case scenario.

£m	FY21/22	FY22/23	FY23/24
Net annual cash surplus / deficit in base case scenario	(4.5)	(5.4)	(7.3)
Net annual cash surplus / deficit – Option 3 (before Transformation costs & SR funding)	(4.5)	(0.9)	9.4
Net annual cash surplus / deficit – Option 3 including Transformation costs and SR funding	(32.1)	0.0	2.0

Figure 39: Base Case & Option 3 Comparison [48]

The Programme is financially affordable using Agency cash reserves and cash generated from operations on the condition that at least £31.1m of the full £34.5m of transitional funds requested through the Spending Review are received as planned. If not fully awarded it will not be possible to implement the Transformation at the scale and pace envisaged, and the Agency will need to explore alternative options which may not bring the organisation back to a positive cash-generating position in the short to medium term.

[48] Source: MHRA_Fee_Analysis_Model_20-21_SAMatrix_V.56.10.i3

6. Management Case

6.1 Purpose

The purpose of this section is to outline the Agency's approach to manage, monitor and deliver the programme. This builds on the management case set out in the SOP, and includes a detailed assessment for programme management, change management, risk management, programme assurance and how programme evaluation will be conducted.

6.2 Programme Management Objectives

To deliver the scope of the preferred option, the Programme will be led and supported by the following programme leadership groups:

- **Communication and Engagement:** This group will provide ongoing co-ordination support to the central team to streamline departmental engagement, capability development and provide Programme communications

- **Transformation Management Office (TMO):** This team will support to the programme management including activity reports, commercial administration and development of MI to be used at the Governance Board and to track and report on benefits

The Agency proposes to adopt the Enterprise Project Management Office (EPMO) framework to project and programme management for the Transformation programme.

6.2.1 TMO Project Management Objectives

The TMO will be responsible for driving the successful delivery of the transformation at programme level working within the wider governance and assurance structure to ensure that:

- There is clear accountability and that reporting lines are defined
- Dependencies are actively managed
- Communication to Agency employees and stakeholders is clear and instils a delivery culture that is supportive, collaborative and drives pace
- There is a shared understanding of the objectives and outcomes for transformation with a focus on benefits
- The programme delivers on time, within budget and scope
- Risks are managed across the programme with the correct level of oversight
- Escalations are managed appropriately at the right level through the governance structure
- Tracking and realisation of benefits

6.2.2 Communication and Engagement Project Management Objectives

The Communications and Engagement workstream will play a key role in supporting the central team deliver the programme, ensuring that:

- Senior leaders are aligned and engaged in the change and are committed to driving it forward within their teams

- Managers understand the importance of the change, and proactively support the leadership in driving it forward
- Employees understand what is changing and why, and have the right knowledge to successfully embrace the change

6.3 Transformation Spend Governance Model

Year 1 of transformation will be funded from Agency reserves with drawdown of funding in years 2 and 3 to follow the spend governance model detailed below.

6.3.1 Spend Governance Model

As part of the PBC approval process, the Agency's ExCo will have approved all spend for the first year of the transformation programme which is funded from the Agency's cash reserves.

All programme spend as part of PBC's spending envelope in years 2 and 3 will need to be approved by the Strategic Change Committee (SCC) as the spend control body. As part of this approval, the SCC will conduct a risk / value assessment, and if any material impact on the business case is identified (e.g., projected overspend or lower than forecast realisation of benefits), this will be escalated for review by ExCo to determine necessary actions. ExCo will make a decision on whether the spend will be allowed to proceed and the PBC will need to be updated to reflect any differences to the forecasted spend or benefits to account for the impact of any spend changes.

Spending related to the Transformation Programme will comply with Cabinet Office spend controls: pipeline process[49] and digital and technology spend controls[50]. This will include setting up and gaining approval for a commercial spend control pipeline for all planned commercial activity above £10m.

6.4 Programme Management Arrangements and Delivery

The following sections detail the potential scope of the Agency Transformation Programme that if approved, would enable the Agency to address its critical business needs within the next 3 years.

6.4.1 Programme Dependencies

The potential inter-dependencies of the Programme are detailed below. It is essential that both programmes are completed within their planned timescales in order to avoid impacting the timeliness and effectiveness of the Transformation Programme:

6.4.1.1 Application Support and Development Contract

The Agency must replace the contract with its main Application Support and Development supplier this year. [redacted]
Until this highly complex re-tendering process is complete (intended contract signature is in March 2022, with transition then taking 4-6 months), the Agency cannot embark upon the programme of Technology work to archive the legacy [redacted] business critical regulatory management systems and replace these with new systems, practices and services to support the future operating model. Therefore, the bulk of the Technology investment cannot commence until the contract is signed. In addition, there is also a substantial dependency on the Transformation timelines for the FOM and full approval of the business case from Cabinet Office/HMT.

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[49] Source: https://www.gov.uk/guidance/commercial-spend-controls-version-5#scope-of-the-commercial-spend-controls
[50] Source: https://www.gov.uk/guidance/digital-and-technology-spend-controls-version-5

6.4.1.2 HR Consultation process

The implementation of the new FOM that is essential to the Agency transforming and becoming financially net-neutral will result in redundancies in all parts of the Agency.

The Transformation Programme and subsequent organisational design process have a significant impact to the Agency's people. In this instance, any proposed impact will need to undergo both collective and individual consultation. It is expected that any consultation would cover potential voluntary and compulsory redundancy (TUPE would not apply). The Agency is committed to a full and meaningful consultation with unions and all staff.

The Agency intends to offer voluntary exit in the first instance where redundancy cannot be avoided. In the event a genuine redundancy is identified, all options to redeploy and mitigate redundancy will be explored. Compulsory redundancy would be a last resort for the Agency.

6.4.1.3 Technology Enabled FOM

The implementation of the FOM is dependent on technology projects being deployed and implemented to time and quality. The FOM will be dependent on these projects (detailed in section 2.4.1.3) in order to deliver against the new operating model's design and structure. A small proportion of headcount reduction will be dependent on technology being delivered as per the transformation roadmap.

This dependency should be closely monitored by the TMO through tracking against the transformation roadmap to ensure the relationship between TD3 and the FOM is effectively managed. If there are any delays in the technology elements of the transformation roadmap, this will be escalated at ExCo for impacting and resolution discussions.

6.4.2 Programme Governance, Organisation Structure and Roles

There are three layers of governance that will be used in the Transformation Programme and will be ultimately accountable to the CEO and ExCo. These layers are:

1) **Executive –** responsible for oversight, decision making and corporate level risk

2) **Management –** responsible for enablement and execution of the programme and managing programme level risk

3) **Operational –** responsible for working through local implementation of programme and theme plans through delivery and managing operational risk

The three layers are designed such that:

- Programme governance is easy to understand with each layer having distinct responsibilities and audience enabling easy communication

- They reflect how the Agency currently works considering other forums and programmes of work

- The governance facilitates an appropriate level of challenge and scrutiny without being burdensome on delivery. This includes decision making rights allocated to the most appropriate level to ensure that more senior forums are focused on items of strategic importance

- There is a clear route for escalation to and risk management at executive level

- Lessons learned from past programmes are carried through into operationalising the Transformation strategy with the correct oversight

6.4.3 Programme Governance Framework

The below table provides a summary of the three layers of governance that will be used in the Transformation Programme, detailing governance forums and their purpose, attendees, accountabilities, and frequencies of meetings:

Layer	Forum	Accountable to	Attendees	Headline FOM Responsibility / Purpose	Frequency
Executive	**Agency Board** (including organisation al development sub-committee)	Chair	NEDs; ExCo	Ensures strategic alignment between the Agency and external objectives and appropriate controls are in placed to manage risk. Supports the CEO by advising on strategy and deliverability of policies. Provides the leadership forum to formally approve and direct the Transformation Programme.	Monthly
	ExCo (FOM)	CEO	CEO; All Chief Officers	Governs strategy and direction of the overall FOM programme and all other change across Agency Manages corporate level risk	Weekly (moving to monthly)
	Strategic Change Committee	ExCo	CEO, COO, CTO, Transformation Director; Commercial Director Finance Director; ExCo/SRO as required, NED as required	Assures programme delivery across full remit of change programmes Takes decisions on prioritisation of change projects and programmes Allocates funding to projects based on business cases where necessary and sets expenditure controls	Monthly
	FOM Executive Change Scrum (Currently ExCo Change Scum)	ExCo	CEO; All Chief Officers and key leads from HR, Comms and Technology as required	Resolves design risk and issues and provide design direction With representation from across the Agency, change leads focus on getting the business ready to implement FOM successfully	Weekly
Management	**Transformation Programme Board**	ExCo	Transformation Director, Technology Deputy, Dep. Director of Finance, HR Director, Comms Director, Workstream or Theme Leads, TMO Lead	Responsible for supporting the SRO to deliver the timely execution and enablement of the Transformation Programme Must identify key barriers to delivery that cannot be resolved within the delegated authority of the SRO and escalate to SCC. Monitors progress and manages programme level risk including resolution of project delivery team issues Manages programme funding approved by SCC Tracks and monitors delivery of benefits	Every two weeks
Operational	**Theme / Project teams**	FOM Programme Board	Project / theme teams as structured	Manage day to day delivery and risks	Every week / two weeks

6.4.3.1 Programme Plan

The high-level programme plans in the figures below provide an indicative view of the planned activities to deliver the programme outcomes across the 4 planned phases of the transformation. This builds upon the output specification outlined in section 4.3.

The proposed activities for phase 1 and high-level plans for phases 2-4 of the Transformation Programme are detailed below:

Phase 1 – Governance Review

Phase 1 is the initial stage of the Transformation Programme, and comprises the following core deliverables and milestones:

- Draft terms of reference (ToR) for the following governance bodies:
    - Board
    - Board Committees
- Executive Committees
- Develop the initial outline of the governance handbook – a handbook that will define how governance structure will work and how committees will provide assurance to the Board
- Develop a high-level plan for implementation of the recommendations produced in the governance review
- Conduct a review of the Agencies strategic priorities

Phase 2 – High Level Design

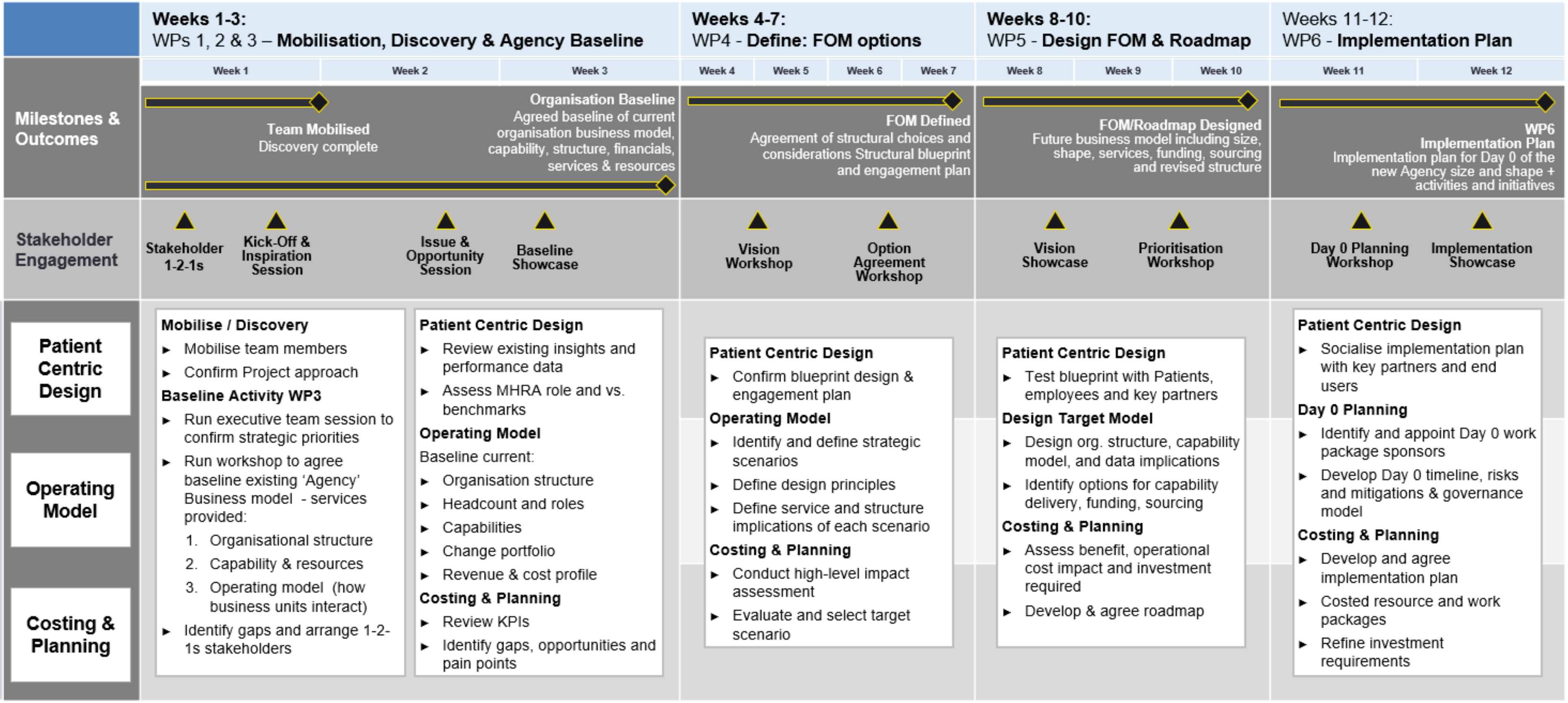


Figure 40: Phase 2 Plan[51]

[51] Source: MHRA Complex Transformation V_4

Phase 3 – Detailed Design

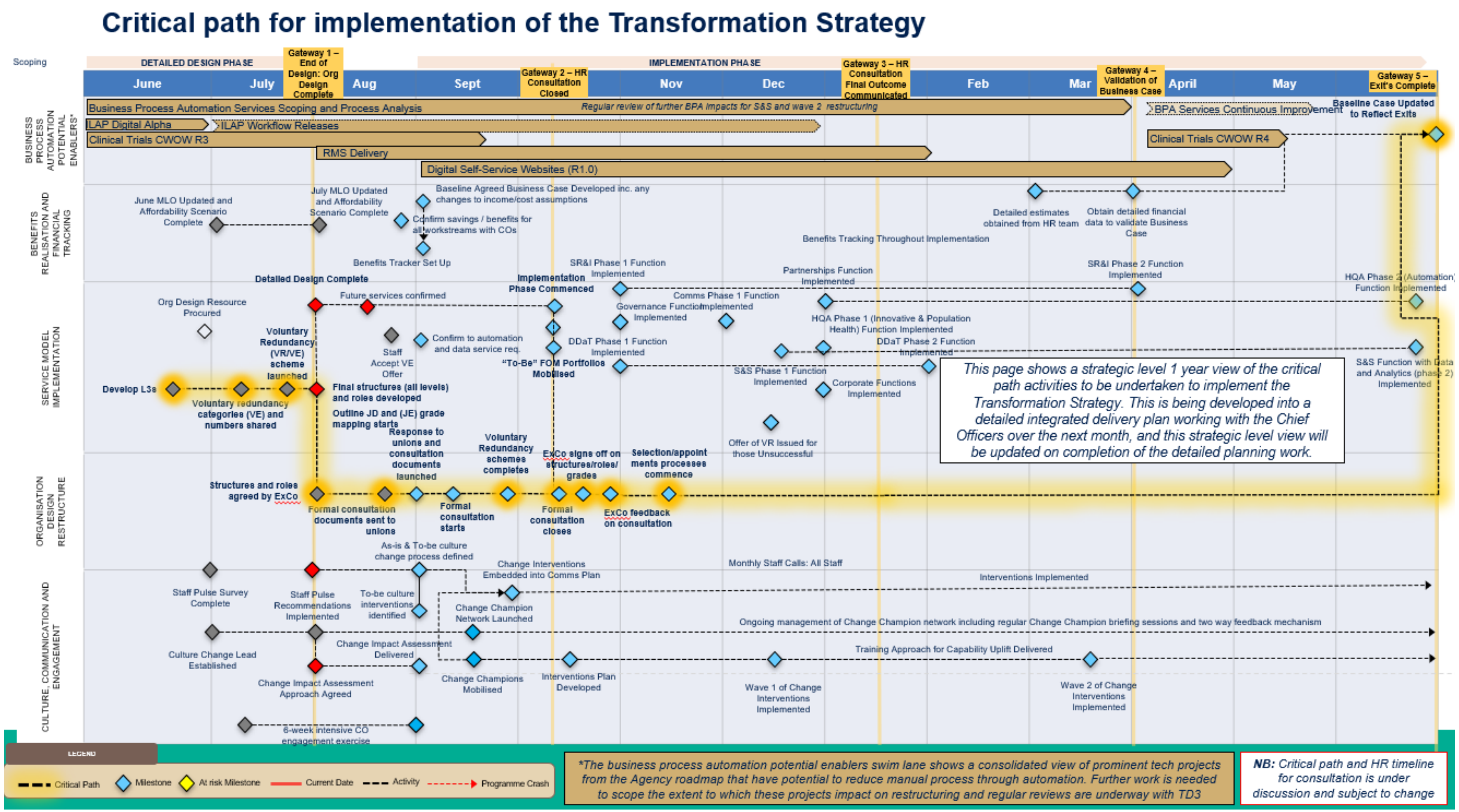


Figure 41: Phase 3 Plan[52]

[52] Source: P3 – Sprint Update – 270821 TSSG

Phase 4 – Implementation

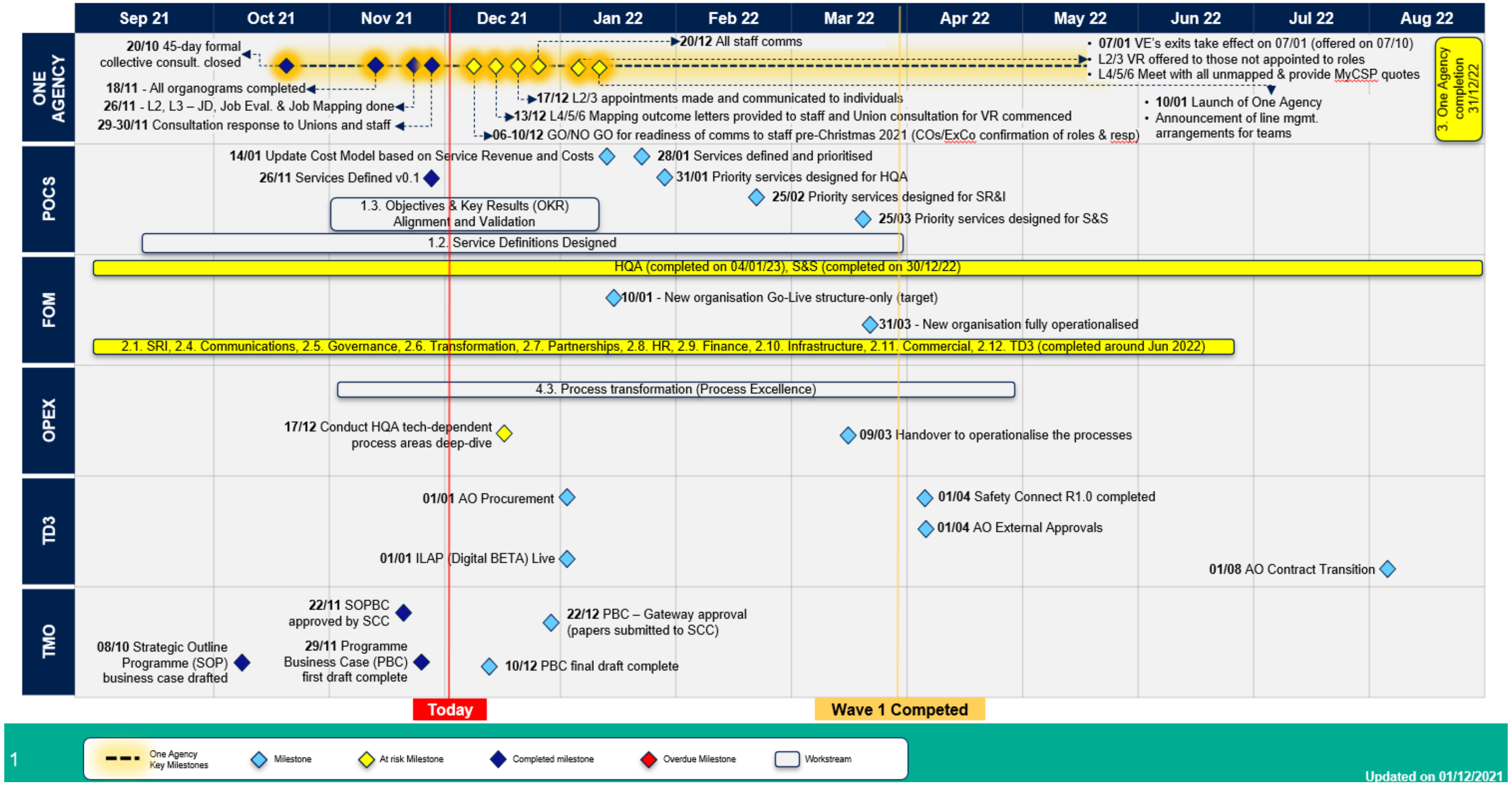


Figure 42: Phase 4 Plan[53]

A programme plan will be created and updated on a yearly basis to respond to the dynamic nature of the transformation programme. This programme plan covers the period September 21 to August 22.

[53] Source: 2021-12-02 – MHRA Transformation PoaP

6.4.4 Programme Reporting

A comprehensive system of reporting will be set up in order to deliver the Programme. TMO layers of reporting and meetings are aimed to provide a clear line of reporting and escalations through the agreed governance structure.

The below tables provide a summary of the cadence of TMO working meetings, as well as a breakdown of key documents used for programme reporting:

No	Meeting	Remit	Accountable	Input	Frequency	Output
1	Monday TMO Meeting ('Signal Session')	Align TMO to priorities for the week	Director of Transformation	Weekly report from previous week	Weekly	Receive minutes + 1 day
2	Transformation team meeting	Informal catch ups with the wider Transformation team. Providing updates on respective workstreams.	Director of Transformation	Weekly report from previous week	Weekly	
3	RAID Meeting	Manage day to day Risks, Issues, Assumptions, Dependencies.	Director of Transformation	RAID log	Weekly	Updated RAID log
4	Integrated Project Plan (IIP) Update Session	Opportunity to ensure alignment and cohesions across Workstreams.	Director of Transformation	IIP	Weekly	Updated IIP and PoaP
5	Benefit tracker meeting	Align realised benefits from implementation	Director of Transformation	PM3	Monthly	Updated Benefit tracker
6	TMO team update meeting.	Manage day by day workload	TMO Lead	Key deliverables of the week	Daily	Alignment on work priorities of the day

	Programme plan (IIP and PoaP)	RAID log	Reporting logs	Benefit tracker
What	The programme plan will capture work breakdown structure from each workstreams, key deliverables and activities. IIP is the single source of truth for the programme delivery. PoaP will reflect key milestone and key deliverables from each workstreams in a more visually representative way.	The RAID log will be used to capture Risk Action Issue and Decision coming out of the programme governance meetings.	Reporting Logs will encompass appropriate templates of programme status updates for governance meetings, including: **Agency board status report** **Transformation Programme Board status report**	Benefit tracker will capture the benefits that the programme has realised against what was baselined in business case

			Weekly reports	
How	Each workstream leads are accountable to update TMO team on any changes via Integrated Project Plan (IPP) Update Session. All the information from PoaP will be derived from IIP	Each workstream lead is accountable to update RAID log on any changes via RAID meetings.	Each workstream leads are accountable to update TMO team on any changes via Integrated Project Plan (IPP) Update Session.	Updates and discussion on benefit that has been realised will be given at the Benefit tracker meeting.
When	IIP will be refreshed following Integrated Project Plan (IPP) Update Session. This version will go to weekly status reporting. Following IIP weekly refresh, a new version of PoaP will also be produced.	The RAID log will be refreshed following weekly RAID meetings	Each reporting will follow the governance meeting cadence	Benefit tracker will be refreshed following Benefit tracker meeting. This version will go to weekly status reporting.
Where	The tools that will be used are combination of MPP and PM3 to begin with until such time that the TMO team can migrate to one tool, and that is envisaged to be PM3. Please see slide 23 for migration details. The PoaP will be in Power point.	PM3	Power point or in PM3 directly when appropriate	Excel

6.4.5 Implementation of Work Streams

6.4.5.1 Scope

The Agency Transformation Programme will include 4 key workstreams:

1) Agency Restructuring & Cost Reduction
2) Future Operating Model Design & Implementation
3) Technology Enabled Change
4) One Agency Culture

The scope of each workstream is detailed below:

6.4.5.2 Agency Restructuring and Cost Reduction

The scope of this aspect of the programme will affect the full Agency and key services are required to restructure the organisation and identify efficiencies in both pay (headcount reduction) and non-pay (operating cost reduction) spend. The current FTE will need to be mapped to create a complete understanding of the current organisation size and shape as a financial baseline, which will then feed as an input into the Agency cost model.

6.4.5.2.1 Sustainability Scenario

Outcome: *A sustainable, affordable, and viable 3-year Transformation business case*

The Agency cost model will need to run several scenarios to determine the target FTE reduction, target reduction in non-pay spend and target reduction in individual project spend to return the Agency to a sustainable cash position.

The Agency cost model will need to be frequently updated with a robust set of assumptions as and when efficiencies are identified throughout the restructuring process.

6.4.5.2.2 HR Consultation Process

Outcome: *An efficient consultation with the Unions to achieve the right outcomes for the Agency and its people*

As FTE efficiencies are identified, the Agency will have to run a fair and open HR consultation process with Unions to comply with redundancy protocol. A fair and open process will be followed to identify and realise reductions in Agency headcount.

6.4.5.2.3 Benefits Realisation

Outcome: *100% of baselined Agency benefits achieved within the 3-year transformation period*

As the benefits are identified in the form of efficiency savings, these will need to be tracked to ensure successful benefits realisation of Agency's cost reductions. Support will be required on the realisation of the financial sustainability plan, working closely with in-house finance expertise and SROs to ensure full ownership within the Agency.

6.4.5.3 Future Operating Model Design and Implementation

The Future Operating Model (FOM), will cover the full Agency and key services are required to baseline the existing operating model, define the future Agency strategy and vision, design a fit for purpose future operating model and then implement the model within a 3-year timeframe.

6.4.5.3.1 Operating Model Baseline

Outcome: *A clearly defined current state assessment of the Agency's operating model*

As part of the operating model baseline, the Agency will need to develop view of current operating model spanning the organisational structure, core capabilities and enabling processes. Pain points will also need to be identified across the current operating model to help inform the design principles of the FOM. Further analysis will need to be undertaken to understand Agency customer segments and personas, to help baseline the current patient experience.

6.4.5.3.2 FOM Options Appraisal

Outcome: *A robust appraisal of the Agency's options for a future operating model with a preferred option selected based on fit for purpose criteria*

The Agency needs to clearly define its vision and operating strategy requires a broad range of options for the FOM to be considered and assessed against a criterion which will determine the most appropriate FOM. A series of choices across each dimension of the FOM needs to be defined and structured into 3-5 high level FOM options. The Agency will need to conduct a benchmarking and impacting exercise which includes comparing current Agency costs and FTE against benchmark organisations and departments both in the UK and globally. A set of analyses against impact of high-level cost and revenue impact for each option will then help inform with FOM option can be identified as the preferred option.

6.4.5.3.3 Transformation Roadmap

Outcome: *A clear collection of desired outcomes over the next 3 years for the Agency to achieve a successful transformation*

Following these activities, the Agency will need a roadmap to cover the design and implementation of the preferred option for the FOM in conjunction with technology enabled change projects and the agency restructuring.

6.4.5.3.4 FOM Design

Outcome: *An organisation structure delivers the Agency vision of better outcomes for patients and public safety*

Once a preferred option for the FOM is identified, the Agency will need to complete a high-level design and detailed design for the FOM in conjunction with chief officers and their respective teams. As part of this process, the future organisation structure, objectives & key results, processes, and capabilities will be defined.

6.4.5.3.5 Integrated Implementation Plan

Outcome: A s*ingle, agreed, viable and affordable implementation plan that achieve the Agency's transformation objectives*

An integrated implementation plan will need to be created in conjunction with in-house HR, Finance, Transformation and Enterprise Portfolio Management Office teams to produce agreed, realistic and understandable integrated implementation plans complete with: full risk and dependencies; resourcing and spend profiles for realising efficiencies and operationalising the new operating model; agreed, timebound outcomes linked to the strategic goals and KPI's; and accountability for delivery.

6.4.5.3.6 Agency Services and Fee Structure

Outcome: A clearly defined set of Agency core services, complete with volumes, costs, and revenues.

The Agency will have to align the development of the agency fee structure to the new FOM and identify subsequent impact on the implementation of the FOM and associated opportunities. Core services will need to be defined, alongside their volumes, cost to serve, enabling processes and capabilities to enable a seamless transition into the new operating model. Further analysis on services could allow the Agency to reprioritise service delivery and identify further efficiencies within the Agency.

6.4.5.3.7 FOM Implementation

Outcome: A fit for purpose operating model that puts patients first and positions the Agency to deliver against the 2021-2023 delivery plan

The Agency will need to deliver the operating model, involving developing on assumptions and requirements across the design principle in the FOM and identifying how to successfully implement and realise agreed efficiencies during the design phase and across them to ensure the integrity of the Agency cost models.

As part of implementation, the Agency will need to identify priority actions, with supporting plans, to address and facilitate the substantial cultural shift required to ensure successful implementation and realise the benefits, efficiencies, and innovative change that the FOM enables.

6.4.5.4 Technology Enabled Change

The Agency will need to replace legacy systems that underpin the FOM in line with transformation requirements. This includes replacing the core regulatory systems with modern digital, data and technology solutions to support the transformed Agency; archive legacy data safely and securely and meet patient safety and access requirements.

A separate business case will be developed for the Application Outsourcing (AO) Tender. Whilst AO Transition is not part of this case, the technology enabled change dependent elements and replacement of our core systems are included. This project will competitively tender the outsourcing contract for Application Support and Development as per Cabinet Office and Crown Commercial requests. The new supplier will facilitate the transition of the operational support for the Agency's existing live 71 systems to a new, more flexible contract. Funding for the AO Transition project is not covered in this business case however the Transformation programme will be dependent on this project for some elements of technology delivery.

6.4.5.4.1 Digital Self-Service

Outcome: *A clean and modern front-end range of digital services that sit within the health system*

A digitally enabled, self-service "front door" will need to be designed and built to Agency specifications. This will replace the majority of the Agency's 20+ legacy websites, submission portals and access points for patients, industry, academia, and healthcare professionals in addition to its major presence on GOV.UK.

6.4.5.4.2 Regulatory Management System (RMS)

Outcome: *A robust and dynamic system that enables the Agency to meet its new obligations and strategic objectives, delivering simple, smart, solutions that integrate across the health system*

A 2-stage approach would be required to replace legacy systems with platforms and products to deliver the transformed Agency objectives:

- **Stage 1** - Building a 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. It lays the foundations to enable analytics on enterprise data. It also allows reporting across different data sources with a combined view to be able to gain insights for better decisions.

- **Stage 2 -** Building 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 [redacted] and for those legacy applications to be archived and decommissioned.

6.4.5.4.3 Legacy Management

Outcome: *A cost effective solution for storing existing data that sits on legacy systems*

The Agency needs to archive existing data held on legacy systems such as [redacted] This data should be migrated onto a read-only database, on cheaper storage rather than migrating decades of data into new systems. This is to minimise the cost and complexity of data migration and avoid continuing to run and maintain complex legacy systems indefinitely, whilst retaining critical data to meet the Agency's legislative requirements.

6.4.5.5 One Agency Culture

The Agency will need to first establish executive / senior stakeholder sponsorship for One Agency culture. This is to ensure the right values and behaviours are embraced at the top of the organisation and for there to be a clear guardian and owner for culture activity. The success and progress of these interventions and measures will be assessed against a culture dashboard which should be reviewed regularly at ExCo and as part of regular performance reporting.

6.4.5.5.1 Culture Assessment

Outcome: *A baseline of current Agency culture defined to determine the starting position for the Agency to shift towards a new way of working*

The Agency will need to review the current culture against the desired future culture to successfully deliver the new ways of working and the associated behaviours needed to achieve these. Tangible examples include the Agency becoming patient centred and breaking down siloed working. To assess the Agency's current cultural maturity, a cultural fitness diagnostic will be delivered with both quantitative and qualitative inputs required.

6.4.5.5.2 Culture Transition Plan

Outcome: *A clear plan of activities and milestones to help the Agency successfully transition to a unified "One Agency" culture*

With this baseline established, the next step will be to articulate the future state culture through co-creation activity across the Agency and other selected stakeholders, including ExCo and the identified Senior Sponsor. With the gap well understood, this will then enable a culture transition action plan to be created with clear workstreams and milestones driving meaningful activity across the Agency with clear owners.

Transformation Management Office (TMO)

These workstreams will additionally be supported by a TMO that will:

- **Engage** - Foster sustainability by managing stakeholder relationships proactively within your governance and implementation structures and track key information for your ExCo and Board.
- **Direct** - Steer the direction of programmes to ensure they are aligned, for example keeping the technology plan fully in line with your transformation programme and business case.
- **Design** - Optimise cross theme programme design and delivery plans, bringing together the requirements from multiple disciplines, unlocking the constraints and mapping out the dependencies.
- **Govern** - Ensure programme performance and quality are monitored in a consistent manner, giving your ExCo the ability to drive change while managing risks, issues and dependencies. The TMO will also embed the methodologies so that these are repeatable in future waves.

An Integrated Implementation Plan will align and integrate these themes and the corresponding workstreams and projects within them to successfully deliver the transformation. Rapid alignment will be critical to avoid delays and deliver on the commitments within this Business Case, with the TMO acting as major driver in pulling together the multiple strands of delivery, whilst driving pace, rigour and excellence in implementation.

6.4.6 Key Risks for Implementation

As the agency moves through the implementation phase of the FOM, the Transformation programme will be required to actively managing emerging challenges through the TMO and governance structure. Anticipated risks and issues can be broadly grouped as per below:

- **Technology replacement:** A significant risk to delivery and the functioning of the Agency is the technology replacement programmes within the broader Technology Roadmap. A prioritisation process will be required to be conducted to define the critical programmes, and work will be required with Chief Officers to review the full delivery ambitions of the Roadmap.

- **Funding gap:** The FY22/23 funding gap is forecast to be £31.1m. The agency has applied for £34.5m in additional transitional funds via the 2021 Spending Review, however there are a number of additional downside risks to these forecast positions.
    - The Agency may not receive the full £34.5m it has applied for via the 2021 Spending Review
    - Partial delivery of assumed savings e.g., accommodation savings
    - Increased FTE costs as a result of post staff and union consultation changes
    - Increased travel and training expenses post pandemic (above that already built into the baseline scenario)
    - Project activity increasing (more pace or increased projects) and driving costs above base case assumptions
- These risks can be partially mitigated to some extent can be mitigated by introducing controlled project delays/decommissioning, holding vacancy rates beyond 5%, additional income opportunities in late 22/23 and a reduction in contracted out services.

- **Workforce and change resistance:** Significant levels of redundancies coupled with large scale change presents risks around reducing workforce engagement, negative press attention, high turnover rates and inability to move towards new One Agency organisational culture. Key to mitigating this will be a number of key activities including designing the future culture, a consistent communications and engagement plan and narrative, building a people transition framework as staff transition into new roles, and identifying, delivering and celebrating quick wins.

- **Complex interdependencies:** There is a range of interdependencies, which if not carefully managed could impact planned financial benefits realisation. The largest of these is revision of the Technology Roadmap, with potential delays to start and end times for some items and extension of duration for others for reasons, including changing scope, external approvals process, commercial reasons, slippage in dependent projects etc. With completion of the technology prioritisation, TMO will use the Integrated Implementation Plan to surface and manage interdependencies, risks and issues.

- **External factors:** The ongoing challenge of potential post COVID-19 impacts to other health bodies (e.g., NHSE/I/ NIPH etc). To help manage and mitigate these there will be continued regular external risk scanning, and impact assessment will be undertaken within the IIP and TMO activities.

- **Delivery capacity:** Transformation at this scale, whilst maintaining full BAU places significant burden on the workforce. There is a risk if the required capacity and capability are not available to deliver at the scale and pace required alongside maintaining BAU. External capacity and capability have been secured, and any remaining gaps will be highlighted.

- **Data Management:** Data management during the headcount reduction process will be critical to ensuring the full benefits of transformation are realised. The Agency will be required to set targets and proposals on FTE reductions, and ensure there is a robust data tracking tool and process to allow reductions to be accurately tracked.

6.4.7 Communications and Stakeholder Management

The Transformation Programme will generate significant change across the Agency, and this will be implemented alongside other One Agency projects such as safety connect, accommodation, return to work, future ways of working, the culture framework and leadership work. Planning has therefore been conducted holistically to oversee all change activity and align messages as required

In addition to this challenge, COVID-19 and enforced remote working has impacted the ways the Agency has been able to communicate to date. Ongoing communication plans will therefore be required to be updated to reflect this as the situation evolves.

To meet these challenges the internal communications strategy has been developed under the following principles:

Communicate at the right time

- Develop and execute the communications plan to align with key milestones and HR critical path activities so stakeholders receive communications when they need it
- Be transparent and honest if there is nothing specific to communicate, to reduce rumours, unnecessary questions or scepticism

Communicate with the right people

- Understand key audience groups and their targeted communication needs
- Senior leaders also have a key role to play in engaging their people and must visibly lead and communicate

Communicate in the right way

- Ensure that messages are relevant and tailored to the audience group to increase engagement and commitment to the changes
- Ensure messaging is simple and uses language that is easy to understand

These principles have been translated an internal communications and engagement approach that will focus on three core areas:

1. **Transformation Strategy Programme**
    - Provide regular updates across all components of the Transformation Strategy Programme to senior stakeholders in forums such as Programme Board and Staff Partnership forum
    - Engage with Chief Officers, Directors and other key stakeholders on the detailed design of the new organisation structure
    - Introduce a new regular 'Transformation update' e-postcard / blog (content, owner and frequency to be agreed) distributed to all staff

2. **Macro Level Communications**
    - Drive Transformation messaging through current established channels owned by the Internal Communications team:
        - Directors' meetings
        - Senior Leaders meetings
        - All Staff meetings
        - Emails (Global / Manager)
        - InSite
    - Ensure that messaging is consistent across these channels and aligns to the HR critical path activities and new organisation design outputs

3. **Local Level Communications**
    - Understand local communications channels, frequency and types of content and format
    - Support local 'units' to drive Transformation messaging at the local level ensuring alignment with 'macro level' comms with the help of embedded Comms Account Directors and HR Business Partners
    - Encourage local 'units' to take ownership for 'tailored' messaging and agree process for developing content

- Provide guidance on best ways to communicate tailored content depending on message / audience

6.5 Change Management

Change management is embedded throughout the executive, management and operational layers of the governance structure as outlined in section 6.3.2 and 6.3.3. The below sections provide further detail on the specific change management role of the Transformation Programme Board and FOM Executive Change Scrum.

6.5.1 Role of the Transformation Programme Board

The Transformation Programme Board provides a key role providing oversight the Transformation programme and its constituent projects and delivery themes, as outlined in the diagram below:

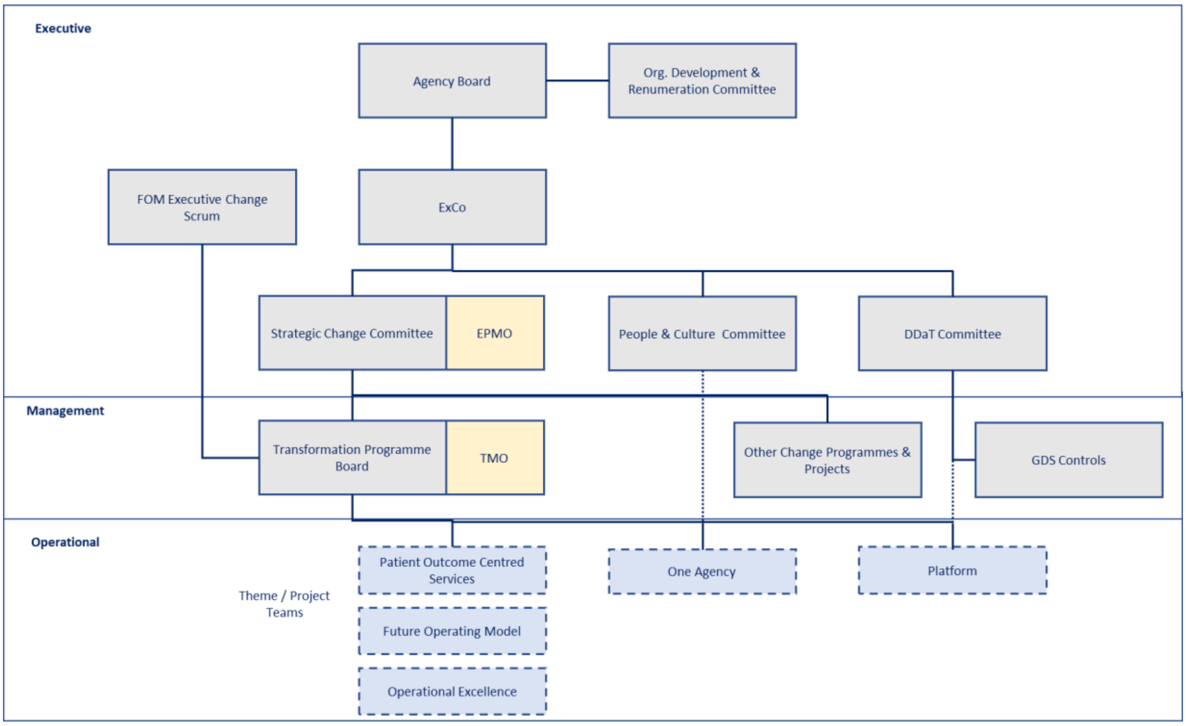


Figure 43: Programme Governance Model[54]

The Transformation Programme Board has the following specific responsibilities:

1. Coordinate implementation of the Agency's future operating model to ensure that the Transformation outputs are agreed and implemented fully.

2. Support the Director of Transformation to deliver the timely execution and enablement of the Transformation programme.

3. Prioritise and drive delivery progress against the programme plan, direct adjustments to plans and resources where required, resolve issues where possible, and agree on escalation to SCC where required.

4. Manage Transformation related spend and agree any escalations for SCC.

[54] Source: FOM Gov Assurance FINAL

5. Monitor progress, manage, and resolve key programme-level risks and issues; provide a point of escalation for unresolved issues and unmitigated risks.

6. Ensure that conflicts between change initiatives and operational/ business-as-usual activities are addressed effectively.

7. Identify key barriers to delivery that cannot be resolved within the delegated authority of the Director of Transformation and escalate to SCC.

8. Provide oversight of key Transformation programme communications and engagement activities.

6.5.2 Role of the FOM Executive Change Scrum

The FOM Executive Change Scrum has the key objective of providing expert advice and steering decision making for the Transformation Programme Board. The transformation will have to adapt to changes through the programme's lifecycle so the FOM executive change scrum will be vital for the programme's success during change.

The board, as 'Subject Matter Experts' (SMEs) are consulted in order to:

(i) Work through the implications of changes proposed by projects and determine the potential impact on service delivery
(ii) Resolve design risks and issues and provide design direction
(iii) Ensure alignment with the FOM for any proposed solutions and changes that will deliver the Agency's strategic objectives.

This approach provides early awareness of possible design impacts and how they might affect transformation and change-related risks. It will also secure strategic-level agreement on alignment of solution proposals and concepts.

The following summarises the ways of working for the FOM Executive Change Scrum:

1) The FOM Executive Change Scrum will provide formal advice, guidance, and referrals. It will provide feedback and recommendations for the FOM detailed design (for which it will be considered the "owner") to ensure alignment with the Agency's strategic vision and objectives.

2) The focus of consultation should be to seek engagement and collaboration with the FOM Executive Change Scrum members on design-related issues covering deliverability, business operations and processes, organisation design, key performance indicators (KPIs), and technology solutions.

3) FOM Executive Change Scrum members will attend key project design workshops and contribute as SMEs. Ensuring that the FOM meets all standards and approvals (both internal and external).

4) If the need to engage with the FOM Executive Change Scrum is ambiguous, then project SROs will decide in consultation with the Director of Transformation whether a project warrants further discussions and engagement with the FOM Executive Change Scrum. The FOM Executive Change Scrum will identify independencies between elements of the FOM that will need to be coordinated by the programme delivery team.

5) The intent is to minimise variance from the FOM where possible and recommend alternative solutions for consideration to maintain progress towards achieving our strategic objectives via delivery of the FOM.

6) Using judgement to identify any novel or contentious aspects of the FOM and ensuring appropriately enhanced engagement of key stakeholders on any such issues. This can include broader consultation where deemed necessary. For example, consultation on design implications with the organisation design leads appointed by Chief Officers.

7) Ensuring that the FOM remans complete, coherent, and aligned strategically. If significant divergence from the FOM is recommended by a project, the FOM Executive Change Scrum will delegate to the Transformation Programme Board for further consideration where proposals or trade-offs will have an external, strategic, or reputational impact (or which could impact the Transformation programme's agreed benefits or costs).

8) Members should act as champions for transformational change and fulfil a role as communicators of decisions from the FOM Executive Change Scrum.

6.6 Benefits Management Plan

The tracking of benefits is vital to the Programme. Ongoing monitoring of the Programme will measure progress against plans and realisation of expected benefits, providing accurate and current information to Programme stakeholders.

The Economic Case profiles four categories of benefits expected to be realised through the Transformation Programme. After allowing for optimism bias, in total the Transformation Programme is projected to deliver cash-releasing savings of c. £334.7m over three years. It is expected that quantifiable but not monetisable and qualitative unquantifiable benefits will be significant; realised through improvements in the outcomes delivered by the programme. However, as discussed in the Economic Case, these are challenging to quantify and therefore measure.

As previously discussed in section 6.3.6, the TMO will be responsible for supporting each workstream to track and report benefits realised over the course of the programme.

Additionally, it will be the responsibility of those directing and managing portfolios, programmes and projects to ensure that:

1. SROs are accountable for benefits realisation
2. Benefits should be identified, quantified, and managed
3. Wherever possible benefits should be quantifiable
4. Benefits should have a proportionate amount of time, money, resource, and activity spent on them so that adequate identification, quantification, planning and measurement can be undertaken
5. Benefits shall be specific enough and isolated enough so that their realisation can be directly attributed to the specific initiative or change claiming them
6. Benefits shall be regularly reviewed to ensure those are on track to be realised to expected levels and sense checked with stakeholders to ensure their desirability and continued value
7. Accountabilities and responsibilities for benefits management shall be defined, documented, and understood
8. Benefits management should be undertaken throughout the project lifecycle and beyond, into business-as-usual operations
9. Benefits management activities should be appropriate, scalable, and proportionate to the size of the project and the benefits
10. Benefits management shall be an evidence-based activity driven by actual and real information
11. All projects and programme are to be subject to continuing business justification to confirm benefits can be realised

6.6.1 Programme Approach to Benefits Realisation

To work within the principles and meet the standards, benefits management will be carried out consistently, using an approach appropriate to the size and nature of the programme. Benefits management will be a continuous and iterative cycle throughout the Transformation programme, and beyond into BAU operations.

The framework below will be used to manage benefits and collectively evaluate the programme as a whole:

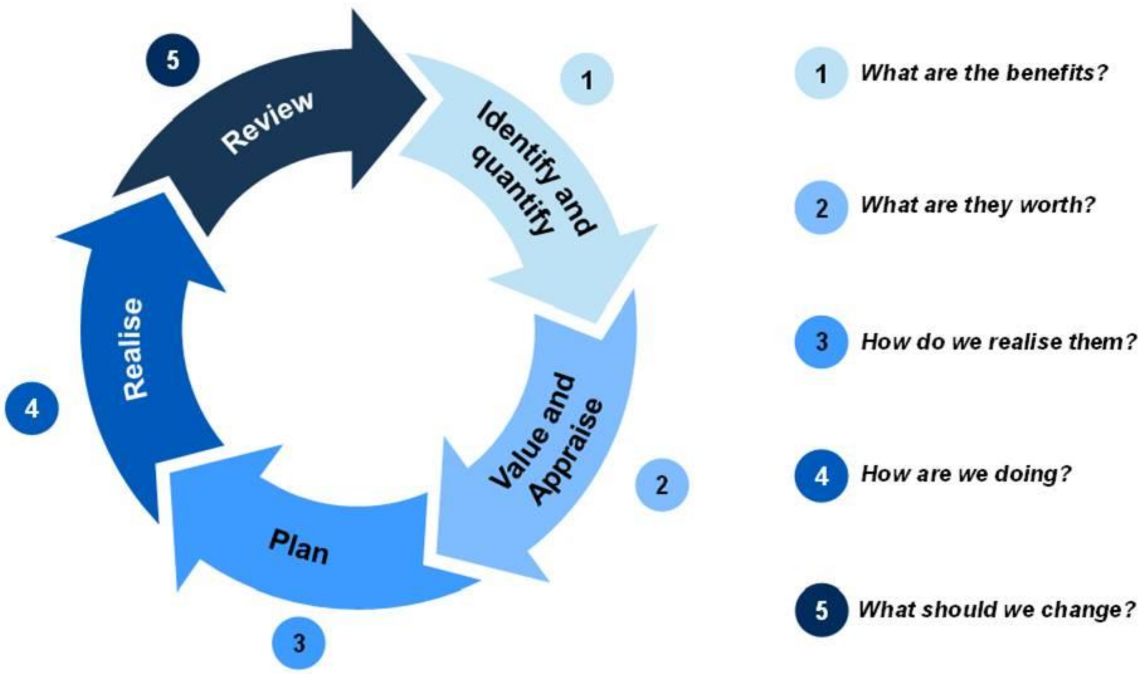


Figure 44: MHRA Benefits Management Framework

As previously discussed in section 6.3.6, the TMO will be responsible for supporting each benefit owner track and report benefits realised over the course of the programme. The TMO conduct regular check-ins with benefit owners to track progress, as well as raise and escalate issues where necessary.

Benefits will be reported through the benefits tracker. A working draft of this can be found in Appendix F.

6.7 Risk Management

6.7.1 Risk and Issue Principles

At all times, those directing the programme shall ensure:

1. Continuing business justification to confirm that benefits can be realised, and risks managed within the organisation’s risk appetite and that unjustified work is terminated

2. Governance, management frameworks and controls are proportionate and appropriate to the work and the level of prevailing risk

3. Accountabilities and responsibilities are defined, mutually consistent and traceable across all levels of management

4. Work is appropriately defined, planned, monitored and controlled, and quality actively managed to maximise the likelihood of success. Defined working methodologies are tailored for use accordingly

6.7.2 Risk and Issue Standards

Those carrying out risk and issue management for the programme shall ensure the following standards have been achieved:

1. Risks and issues should be identified, assigned an owner and evaluated, considering when the risk might be triggered (proximity)
2. Risks and issues should be responded to through mitigating or management actions to accept, eliminate, reduce or avoid consequences or reduce the possibility of occurrence (if a risk)
3. Residual risks (the elements of risk remaining even after mitigation actions have taken place) should be identified and addressed
4. Scope might be refined and clarified as work progresses to develop a plan which can be delivered at an acceptable level of risk
5. Risks and issues should be monitored to resolution and closed when no longer valid
6. Risks and issues should be reviewed to ensure any implemented risk controls are still effective
7. Risks should be managed as individual risks and not as a whole. Contingency may be retained at an appropriate level in the work hierarchy and authorised, if needed
8. Overall risk should be managed within the organisation’s risk appetite and tolerance
9. Risks and issues which cannot be resolved by an owner, or cannot be resolved at the current level (project, programme, portfolio) should be escalated or reassigned as necessary
10. Risk owners outside the formal hierarchy should be responsible to a person in the work component’s management structure
11. A Risk Potential Assessment (RPA) is carried out during the initiation stage of a Category A project or programme to fully assess risks which are envisaged to impact
12. Risks and issues should be captured and updated to reflect current status in the Agency Portfolio management tool (P3M)

6.7.3 Risk and Issue Promotion and Escalation Routes

The below table summarises the risk and issue management promotion and escalation routes, including risk and issue level categories, descriptions and relevant audiences:

Level	Description	Audience
Corporate	*Direct cross-divisional or Agency-related items that can carry financial or reputational impact on the agency. Often these will have a strategic, rather than operational, focus.*	*National Audit Office (NAO), Audit and Risk Assurance Committee (ARAC),* *Executive Committee (ExCo)*
Divisional	*Items escalated from the portfolio or other BAU department which have a wider impact or implication on a particular division and from areas affecting the operations of day-to-day business, beyond the boundaries of the portfolio.* *Divisional risks and issues may also be delegated or arising from corporate/ strategic levels.*	*Divisional Leadership Team, Risk Advisory Group*
Portfolio	*These are:* (1) escalated from projects or programmes and from areas of day-to-day/ business as usual (BAU) activities (2) impact upon the objectives of the portfolio, and/or (3) generic in that the same risk or issue is experienced by multiple projects in the portfolio *Project and programme risks that cannot be effectively managed at their originating level may be escalated to the portfolio for responses unavailable at project or programme level. Portfolio risk and issue management ensures the portfolio does not expose an organisation to too much risk.*	*Transformation Division (TD) Leadership, SCC*

Level	Description	Audience
Programme	*These are:* (1) arising from themes level which require escalation and aggregation, such as if realised may have an impact on the programme, or risks/issues that cannot be effectively managed within projects and within contingency. Escalation calls for attention and/or action within the programme. In addition, related or common risks within individual projects may be aggregated. (2) arising from the wider business and impacting business objectives. (3) impacting the programme objectives and benefits. *Programme risks and issues can also be delegated from the portfolio/ divisional/ corporate levels, as well as risks and issues arising directly at the level of the programme itself. Those are likely to focus on:* • prioritisation of programme components; • allocation of resources; • dependencies between programme components; • ability to deliver change management activities within the programme; • cumulative risks arising from combined impact of project risks.	*Transformation Programme Board, SRO*
Themes	*Individual risks and issues that will affect the project's objectives, timescales, costs, benefits or quality. Themes leads shall understand the overall project risk/issue exposure, so that this can be reported to the SRO and stakeholders.* *Risk and issue management shall be closely aligned to schedule management. Plan, cost, time and resource estimates always take risks into account. Themes leads are accountable for ensuring risk management takes place.*	*Themes meeting, SRO*

6.7.4 Risk and Issue Management Framework

The Agency's risk and issue framework comprises five elements which will be used to manage risk on the programme:

Figure 45: MHRA Risk & Issue Management Framework

6.8 Programme Review and Evaluation

The Agency will use the Framework for Benefits Management within Projects and Programmes[55] to measure benefits realisations and conduct the post-programme evaluation

6.8.1 Programme Gateway Review

In terms of assurance the Programme will have robust governance around it, which includes assurance both internally and externally. The detail of this is set out in the document 'Governance and Assurance Framework for the Transformation Programme' V1.0; approved by the MHRA's Strategic Change Committee (SCC). The Programme will comply with the MHRA's Strategic Change Assurance Governance Office (SCAO) processes and guidance. For example, the Programme will provide weekly programme updates for review to the SRO and SCAO, and monthly enterprise reporting and portfolio highlights to SCC. These reports will be made available for ExCo scrutiny on a weekly and monthly basis. The Programme will have its own monthly Programme Board chaired by the SRO which reviews the Programme and agrees necessary escalations up to SCC as a first point of escalation, and then ExCo where required.

Internally, a Programme Stage Gate is scheduled for 22nd February 2022 - this is Stage Gate B 'Delivery Strategy' - and will be held in advance of the DHSC IC meeting on 28 February where the Transformation Programme Business Case will be tabled. Internal stage gates will be scheduled in the new financial year (April 2022) and an integrated assurance and approvals plan will be developed. The Programme is expected to be subject to external assurance at the direction of DHSC. A DHSC review gateway is anticipated to be held in April 2022.

6.8.2 Post-programme Evaluation Plan

Ongoing monitoring will be embedded into regular reporting in order to assess the impact and benefits of the Programme. In addition, an evaluation of performance will be carried out post-Programme completion and prior to BAU transition by a party selected by the Programme Board to improve future Programme performance and decision making.

It is proposed that:

[55] EPMO Framework for Benefits Management within Projects and Programmes V5.0

- Interim Programme evaluations will be carried at yearly intervals
- Post programme evaluation will begin at the end of year FY23/24 and will be monitored 5-10 years to ensure the programme continues to deliver planned benefits listed in this business case

Benefit realisation will be used to assess Programme achievement

6.9 Contingency Plan

A contingency plan would be required in the event of a significant delay to the realisation of benefits, for example significant delays in reduction of FTEs or technology replacement. The contingency plan would also consider any SR settlements.

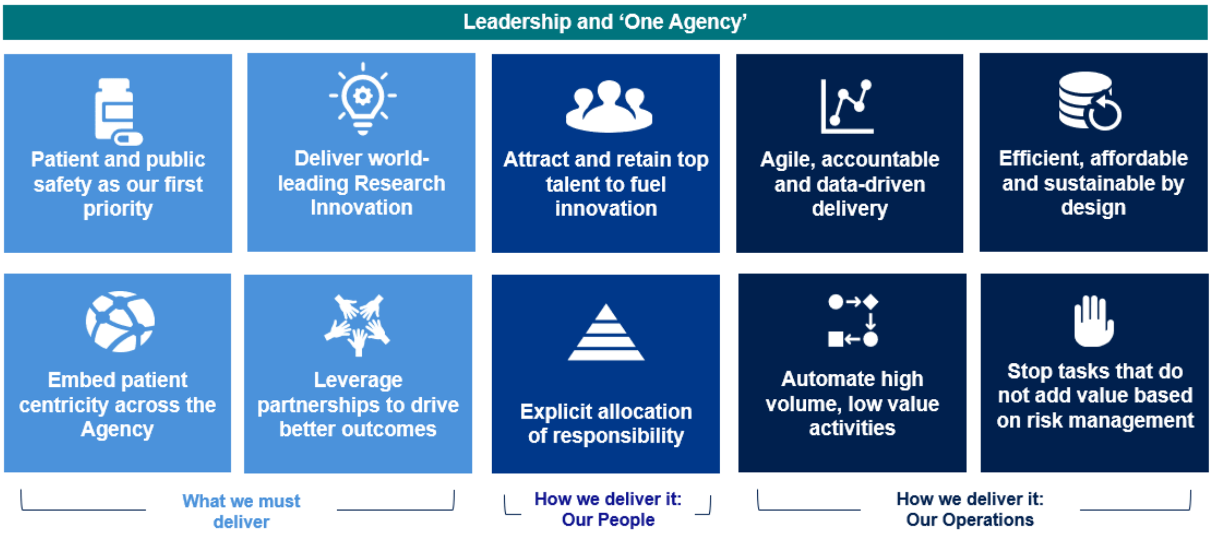
If required, triggering of a contingency plan will be conducted by ExCo, and will require approval from all key stakeholders in the transformation programme. Governance and communication activity required for the implementation on the contingency plan would use the governance model and communication channels already in place for transformation programme.

6.10 Conclusion

The Management Case concludes, after taking due consideration of the processes and controls for managing the Programme, and of the proposed arrangements for delivery, the Programme can be delivered as planned. It is important to note that additional work is required to further detail management and delivery structures within the implementation of the Transformation Programme.

7. Appendices

7.1 Appendix A – 'One Agency' Future Operating Model (FOM) Design Principles



7.2 Appendix B – Options 1-4 Full Economic Models

Description	Benefit Beneficiary	2021/22	2022/23	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30	2030/31	Total
		£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m
Costs of do nothing		**(4.5)**	**(5.4)**	**(7.3)**	**(9.2)**	**(11.1)**	**(13.1)**	**(15.1)**	**(17.2)**	**(19.3)**	**(21.5)**	**(123.5)**
Inflation pay increase		-	(0.9)	(1.9)	(1.9)	(1.9)	(2.0)	(2.0)	(2.1)	(2.1)	(2.2)	(17.0)
Net Deficit from Operations		(4.5)	(4.5)	(5.4)	(7.3)	(9.2)	(11.1)	(13.1)	(15.1)	(17.2)	(19.3)	(106.5)
DDAT spend which underpins the FOM transformation		-	-	-	-	-	-	-	-	-	-	-
Cash releasing benefits (CRB)		-	-	-	-	-	-	-	-	-	-	-
A target headcount reduction of c.60 FTE (20% of c.300 FTE) would produce a net benefit of £4m per annum	Agency											-
A target reduction in non-pay costs - Accommodation	Agency											-
A target reduction in non-pay costs - DDAT	Agency											-
Increases in income to offset loss of DH EU exit funding & loss of EU income	Agency											-
Monetisable non-cash releasing (non-CRB)		-	-	-	-	-	-	-	-	-	-	-
Quantifiable but not monetisable benefits (SB)		-	-	-	-	-	-	-	-	-	-	-
Reduction in ADR's in a clinical setting	Agency, Industry, Patients	-	-	-	-	-	-	-	-	-	-	-
Reduction in definitely avoidable medication errors	Agency, Industry, Patients	-	-	-	-	-	-	-	-	-	-	-
Qualitative unquantifiable benefits (UB)		-	-	-	-	-	-	-	-	-	-	-
Net Benefits		-	-	-	-	-	-	-	-	-	-	-
Net Costs		(4.5)	(5.4)	(7.3)	(9.2)	(11.1)	(13.1)	(15.1)	(17.2)	(19.3)	(21.5)	(123.5)
Net Cashflow		**(4.5)**	**(5.4)**	**(7.3)**	**(9.2)**	**(11.1)**	**(13.1)**	**(15.1)**	**(17.2)**	**(19.3)**	**(21.5)**	**(123.5)**

Option 1 Full Economic Model Excl. OB

Description	Benefit Beneficiary	2021/22	2022/23	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30	2030/31	Total
		£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m
Costs of do nothing		**(4.5)**	**(5.4)**	**(7.3)**	**(9.2)**	**(11.1)**	**(13.1)**	**(15.1)**	**(17.2)**	**(19.3)**	**(21.5)**	**(123.5)**
Inflation pay increase		-	(0.9)	(1.9)	(1.9)	(1.9)	(2.0)	(2.0)	(2.1)	(2.1)	(2.2)	(17.0)
Net Deficit from Operations		(4.5)	(4.5)	(5.4)	(7.3)	(9.2)	(11.1)	(13.1)	(15.1)	(17.2)	(19.3)	(106.5)
DDAT spend which underpins the FOM transformation		-	-	-	-	-	-	-	-	-	-	-
Cash releasing benefits (CRB)		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
A target headcount reduction of c.60 FTE (20% of c.300 FTE) would produce a net benefit of £4m per annum	Agency											-
A target reduction in non-pay costs - Accommodation	Agency											-
A target reduction in non-pay costs - DDAT	Agency											-
Increases in income to offset loss of DH EU exit funding & loss of EU income	Agency											-
Monetisable non-cash releasing (non-CRB)		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Quantifiable but not monetisable benefits (SB)		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Reduction in ADR's in a clinical setting	Agency, Industry, Patients	-	-	-	-	-	-	-	-	-	-	-
Reduction in definitely avoidable medication errors	Agency, Industry, Patients	-	-	-	-	-	-	-	-	-	-	-
Qualitative unquantifiable benefits (UB)		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Net Benefits		-	-	-	-	-	-	-	-	-	-	-
Net Costs		(4.5)	(5.4)	(7.3)	(9.2)	(11.1)	(13.1)	(15.1)	(17.2)	(19.3)	(21.5)	(123.5)
Net Cashflow		**(4.5)**	**(5.4)**	**(7.3)**	**(9.2)**	**(11.1)**	**(13.1)**	**(15.1)**	**(17.2)**	**(19.3)**	**(21.5)**	**(123.5)**

Option 1 Full Economic Model Inc. OB

Year >>		Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	
Description	**Benefit Benificiary**	**2021/22**	**2022/23**	**2023/24**	**2024/25**	**2025/26**	**2026/27**	**2027/28**	**2028/29**	**2029/30**	**2030/31**	**Total**
		£'m	**£'m**	**£'m**	**£'m**	**£'m**	**£'m**	**£'m**	**£'m**	**£'m**	**£'m**	**£'m**
Change Costs		**(1.2)**	**(0.7)**	**(0.3)**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**(2.3)**
Agency restructuring		-	-	-	-	-	-	-	-	-	-	-
FOM design and implementation		(1.2)	(0.7)	(0.3)	-	-	-	-	-	-	-	(2.3)
DDAT spend which underpins the FOM transformation		-	-	-	-	-	-	-	-	-	-	-
Cash releasing benefits (CRB)		**-**	**2.7**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**34.8**
A target headcount reduction of c.60 FTE (20% of c.300 FTE) would produce a net benefit of £4m per annum	Agency	-	2.7	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	34.8
A target reduction in non-pay costs - Accomodation	Agency	-	-	-	-	-	-	-	-	-	-	-
A target reduction in non-pay costs - DDAT	Agency	-	-	-	-	-	-	-	-	-	-	-
Increases in income to offset loss of DH EU exit funding & loss of EU income	Agency	-	-	-	-	-	-	-	-	-	-	-
Monestisable non-cash releasing (non-CRB)		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Quantifiable but not readily monetisable benefits (QB)		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Qualitative unquantifiable benefits		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Net Benefits		-	2.7	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	34.8
Net Costs		(1.2)	(0.7)	(0.3)	-	-	-	-	-	-	-	(2.3)
Net Cashflow		**(1.2)**	**2.0**	**3.7**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**32.6**

Option 2 Full Economic Model Excl. OB

Description	Benefit Beneficiary	2021/22	2022/23	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30	2030/31	Total
	Year >>	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	
		£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m
Change Costs		**(1.5)**	**(0.9)**	**(0.4)**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**(2.8)**
Agency restructuring		-	-	-	-	-	-	-	-	-	-	-
FOM design and implementation		(1.5)	(0.9)	(0.4)	-	-	-	-	-	-	-	(2.8)
DDAT spend which underpins the FOM transformation		-	-	-	-	-	-	-	-	-	-	-
Cash releasing benefits (CRB)		**-**	**1.9**	**2.9**	**2.9**	**2.9**	**2.9**	**2.9**	**2.9**	**2.9**	**2.9**	**25.1**
A target headcount reduction of c.60 FTE (20% of c.300 FTE) would produce a net benefit of £4m per annum	Agency	-	1.9	2.9	2.9	2.9	2.9	2.9	2.9	2.9	2.9	25.1
A target reduction in non-pay costs - Accomodation	Agency	-	-	-	-	-	-	-	-	-	-	-
A target reduction in non-pay costs - DDAT	Agency	-	-	-	-	-	-	-	-	-	-	-
Increases in income to offset loss of DH EU exit funding & loss of EU income	Agency	-	-	-	-	-	-	-	-	-	-	-
Monestisable non-cash releasing (non-CRB)		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Quantifiable but not readily monetisable benefits (QB)		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Qualitative unquantifiable benefits		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Net Benefits		-	1.9	2.9	2.9	2.9	2.9	2.9	2.9	2.9	2.9	25.1
Net Costs		(1.5)	(0.9)	(0.4)	-	-	-	-	-	-	-	(2.8)
Net Cashflow		**(1.5)**	**1.1**	**2.5**	**2.9**	**2.9**	**2.9**	**2.9**	**2.9**	**2.9**	**2.9**	**22.2**

Option 2 Full Economic Model Inc. OB

		Year >>	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	
Description		Benefit Benificiary	2021/22	2022/23	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30	2030/31	Total
			£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m
Change Costs			**(18.2)**	**(25.1)**	**(7.4)**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**(50.8)**
	Agency restructuring		-	-	-	-	-	-	-	-	-	-	-
	FOM design and implementation		(6.2)	(3.5)	(1.6)	-	-	-	-	-	-	-	(11.3)
	DDAT spend which underpins the FOM transformation		(12.0)	(21.6)	(5.8)	-	-	-	-	-	-	-	(39.5)
Cash releasing benefits (CRB)			**0.5**	**34.7**	**45.7**	**46.7**	**46.7**	**46.7**	**46.7**	**46.7**	**46.7**	**46.7**	**407.6**
	A target headcount reduction of c.300 FTE would produce a net benefit of £21.3m per annum	Agency	-	13.3	20.1	20.1	20.1	20.1	20.1	20.1	20.1	20.1	174.1
	A target reduction in non-pay costs - Accomodation	Agency	0.5	4.1	4.1	4.1	4.1	4.1	4.1	4.1	4.1	4.1	37.4
	A target reduction in non-pay costs - DDAT	Agency	-	0.9	5.2	6.1	6.1	6.1	6.1	6.1	6.1	6.1	48.8
	Increases in income to offset loss of DH EU exit funding & loss of EU income	Agency	-	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4	147.3
Quantifiable but not readily monetisable benefits (QB)			**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Monestisable non-cash releasing (non-CRB)			**-**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**31.4**
	Reduction in ADR's in a clinical setting	Agency, Industry, Patients	-	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	27.0
	Reduction in definitely avoidable medication errors	Agency, Industry, Patients	-	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	4.4
Qualitative unquantifiable benefits			**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Net Benefits			0.5	38.2	49.2	50.2	50.2	50.2	50.2	50.2	50.2	50.2	439.0
Net Costs			(18.2)	(25.1)	(7.4)	-	-	-	-	-	-	-	(50.8)
Net Cashflow			**(17.7)**	**13.0**	**41.8**	**50.2**	**50.2**	**50.2**	**50.2**	**50.2**	**50.2**	**50.2**	**388.2**

Option 3 Full Economic Model Excl. OB

Year >>		Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	
Description	Benefit Benificiary	2021/22	2022/23	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30	2030/31	Total
		£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m
Change Costs		**(22.8)**	**(31.4)**	**(9.3)**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**(63.5)**
Agency restructuring		-	-	-	-	-	-	-	-	-	-	-
FOM design and implementation		(7.7)	(4.3)	(2.0)	-	-	-	-	-	-	-	(14.1)
DDAT spend which underpins the FOM transformation		(15.0)	(27.1)	(7.3)	-	-	-	-	-	-	-	(49.4)
Cash releasing benefits (CRB)		**0.4**	**29.5**	**37.5**	**38.2**	**38.2**	**38.2**	**38.2**	**38.2**	**38.2**	**38.2**	**334.7**
A target headcount reduction of c.300 FTE would produce a net benefit of £21.3m per annum	Agency	-	9.6	14.5	14.5	14.5	14.5	14.5	14.5	14.5	14.5	125.3
A target reduction in non-pay costs - Accomodation	Agency	0.4	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	26.9
A target reduction in non-pay costs - DDAT	Agency	-	0.6	3.7	4.4	4.4	4.4	4.4	4.4	4.4	4.4	35.2
Increases in income to offset loss of DH EU exit funding & loss of EU income	Agency	-	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4	147.3
Quantifiable but not readily monetisable benefits (QB)		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Monestisable non-cash releasing (non-CRB)		**-**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**31.4**
Reduction in ADR's in a clinical setting	Agency, Industry, Patients	-	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	27.0
Reduction in definitely avoidable medication errors	Agency, Industry, Patients	-	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	4.4
Qualitative unquantifiable benefits		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Net Benefits		0.4	33.0	41.0	41.7	41.7	41.7	41.7	41.7	41.7	41.7	366.1
Net Costs		(22.8)	(31.4)	(9.3)	-	-	-	-	-	-	-	(63.5)
Net Cashflow		**(22.4)**	**1.6**	**31.7**	**41.7**	**41.7**	**41.7**	**41.7**	**41.7**	**41.7**	**41.7**	**302.7**

Option 3 Full Economic Model Inc. OB

	Year >>	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	
Description	Benefit Benificiary	2021/22	2022/23	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30	2030/31	Total
		£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m	£'m
Change Costs		**(25.9)**	**(25.0)**	**(25.3)**	**(22.2)**	-	-	-	-	-	-	**(98.4)**
Agency restructuring		-	-	-	-	-	-	-	-	-	-	-
FOM design and implementation		(6.2)	(3.5)	(1.6)	-	-	-	-	-	-	-	(11.3)
DDAT spend which underpins the FOM transformation		(19.7)	(21.5)	(23.7)	(22.2)	-	-	-	-	-	-	(87.1)
Cash releasing benefits (CRB)		**0.5**	**34.7**	**45.7**	**46.7**	**46.7**	**46.7**	**46.7**	**46.7**	**46.7**	**46.7**	**407.6**
A target headcount reduction of c.300 FTE would produce a net benefit of £21.3m per annum	Agency	-	13.3	20.1	20.1	20.1	20.1	20.1	20.1	20.1	20.1	174.1
A target reduction in non-pay costs - Accomodation	Agency	0.5	4.1	4.1	4.1	4.1	4.1	4.1	4.1	4.1	4.1	37.4
A target reduction in non-pay costs - DDAT	Agency	-	0.9	5.2	6.1	6.1	6.1	6.1	6.1	6.1	6.1	48.8
Increases in income to offset loss of DH EU exit funding & loss of EU income	Agency	-	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4	147.3
Quantifiable but not readily monetisable benefits (QB)		-	-	-	-	-	-	-	-	-	-	-
Monestisable non-cash releasing (non-CRB)		-	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**31.4**
Reduction in ADR's in a clinical setting	Agency, Industry, Patients	-	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	27.0
Reduction in definitely avoidable medication errors	Agency, Industry, Patients	-	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	4.4
Qualitative unquantifiable benefits		-	-	-	-	-	-	-	-	-	-	-
Net Benefits		0.5	38.2	49.2	50.2	50.2	50.2	50.2	50.2	50.2	50.2	439.0
Net Costs		(25.9)	(25.0)	(25.3)	(22.2)	-	-	-	-	-	-	(98.4)
Net Cashflow		**(25.4)**	**13.2**	**23.9**	**28.0**	**50.2**	**50.2**	**50.2**	**50.2**	**50.2**	**50.2**	**340.6**

Option 4 Full Economic Model Excl. OB

	Year >>	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	
Description	**Benefit Benificiary**	**2021/22**	**2022/23**	**2023/24**	**2024/25**	**2025/26**	**2026/27**	**2027/28**	**2028/29**	**2029/30**	**2030/31**	**Total**
		£'m	**£'m**	**£'m**	**£'m**	**£'m**	**£'m**	**£'m**	**£'m**	**£'m**	**£'m**	**£'m**
Change Costs		**(32.4)**	**(31.3)**	**(31.6)**	**(27.7)**	**-**	**-**	**-**	**-**	**-**	**-**	**(123.0)**
Agency restructuring		-	-	-	-	-	-	-	-	-	-	-
FOM design and implementation		(7.7)	(4.3)	(2.0)	-	-	-	-	-	-	-	(14.1)
DDAT spend which underpins the FOM transformation		(24.6)	(26.9)	(29.6)	(27.7)	-	-	-	-	-	-	(108.9)
Cash releasing benefits (CRB)		**0.4**	**29.5**	**37.5**	**38.2**	**38.2**	**38.2**	**38.2**	**38.2**	**38.2**	**38.2**	**334.7**
A target headcount reduction of c.300 FTE would produce a net benefit of £21.3m per annum	Agency	-	9.6	14.5	14.5	14.5	14.5	14.5	14.5	14.5	14.5	125.3
A target reduction in non-pay costs - Accomodation	Agency	0.4	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	26.9
A target reduction in non-pay costs - DDAT	Agency	-	0.6	3.7	4.4	4.4	4.4	4.4	4.4	4.4	4.4	35.2
Increases in income to offset loss of DH EU exit funding & loss of EU income	Agency	-	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4	147.3
Quantifiable but not readily monetisable benefits (QB)		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Monestisable non-cash releasing (non-CRB)		**-**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**31.4**
Reduction in ADR's in a clinical setting	Agency, Industry, Patients	-	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	27.0
Reduction in definitely avoidable medication errors	Agency, Industry, Patients	-	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	4.4
Qualitative unquantifiable benefits		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Net Benefits		0.4	33.0	41.0	41.7	41.7	41.7	41.7	41.7	41.7	41.7	366.1
Net Costs		(32.4)	(31.3)	(31.6)	(27.7)	-	-	-	-	-	-	(123.0)
Net Cashflow		**(32.0)**	**1.8**	**9.4**	**13.9**	**41.7**	**41.7**	**41.7**	**41.7**	**41.7**	**41.7**	**243.1**

Option 4 Full Economic Model Inc. OB

7.3 Appendix C – Quantifiable but not monetisable Benefit signals data summary

Demand Estimate Calculation for Social Patient Safety Benefits

Year	Number of AITS reports	Number of AITS reports (excluding covid related reports)	Estimated pro rata year total		Estimated percentage change from 2019	Number of Sentinel reports	Number of Sentinel reports (excluding covid related reports)	Estimated pro rata year total		Estimated percentage change from 2019	Number of AITS + Sentinel reports	Medicines and devices estimated pro rata total	Estimated percentage change from 2019
2015	16,987	16,987				38,898	38,898						
2016	17,498	17,498				42,079	42,079						
2017	19,573	19,573				43,912	43,912						
2018	20,700	20,700				42,183	42,183						
2019	22,452	22,452				43,503	43,503				65,955		
2020	22,246	21,432				40,764	38,166						
2021 (01/01 – 08/09)	20,109	18,590	**Without Covid related work**	27,141	**21%**	399,136	42,772	**Without Covid related work**	62447	**44%**	**Without Covid related work**	89,589	**36%**
			With Covid related work	29,359	**31%**			**With Covid related work**	582739	**1240%**	**With Covid related work**	612,098	**828%**
Grand Tota	139,565	137,232											

7.4 Appendix D – Option Assessment Criteria

As outlined in the table below, assessment criteria have been defined to evaluate the FOM options for potential risk, implementation complexity and alignment with Agency priorities

Despite option C being the right level of ambition, it would be the most difficult to implement – Option B balances ambition and implementation complexity

	Criteria	Description	Low Benefit / High Risk = 1	Medium Benefit / Medium Risk = 2	High Benefit / Low Risk = 3
1	Patient Centricity	Alignment to patient centricity priorities and principles	Patient voice rarely informing Agency decisions and actions	Patient voice integrated into some decisions and actions	Patient voice embedded throughout Agency decisions and actions
2	Strategic Fit	Alignment to the Agency's vision and strategic priorities	Low degree of alignment with Agency strategy	Moderate degree of alignment with Agency strategy	High degree of alignment with Agency strategy
3	Business Risk	Disruption to the business and its ability to deliver against statutory requirements	High Risk (possible disruption and inability to meet a statutory requirement)	Medium Risk (impacts on some requirements)	Low Risk (little to no disruption and impact)
4	Brand / Reputational Risk	Potential damage to reputation within the health ecosystem	No identified risk of damage to Agency's reputation	Some reputational risk to Agency (low to medium impact or likelihood)	Significant reputational risk to Agency (high impact or likelihood)
5	Ease of Implementation	Agency capability to deliver FOM option	Significant amount of new capability / outsourced capacity required	Some new capability / outsourced capacity required	No / limited amount of new capability / outsourced capacity required
		Degree of process change	Significant change in processes and ways of working	A managed degree of change in processes and ways of working	No / limited change in processes and ways of working
		Technology and data change	Significant investment in new technology and large-scale data cleansing exercise required	A managed degree of technology investment and data cleansing required	No / limited additional technology investment or data cleansing operation required
		Total			

Balanced Scorecard: Option 2 – Remove Friction

1= Low Benefit / High risk | 2= Med Benefit / Med risk | 3 = High Benefit / Low risk

	Criteria	Description	Score
1	**Patient Centricity**	• Option will precipitate some improvements in patient centricity but will not implement fundamental change to the way patients are involved in MHRA work, there will be ability to assemble around patient outcomes with a clear process and mandate.	1
2	**Strategic Fit**	• Implementing this option alone will not provide a set up for the Agency to effectively deliver a world leading model, broadening it's role working with more partners.	1
3	**Brand and Reputational Risk**	• As this option does not significantly impact the way the Agency mobilises and delivers against it's national and international responsibilities, as well as products and services, there is low risk to its standing and reputation.	1
4	**Business Risk**	• Interventions within this option will not have a significant impact on operations other than to streamline and increase efficiency, therefore reducing risk to products, services and statutory requirements.	3
5a	**Ease of Implementation:** Capability & Capacity	• Option proposed requires enhancements to capability and organisational structure (e.g. removal of silos) which presents a level of change to staff and their roles.	3
5b	**Ease of Implementation:** Process Change	• This option recommends formalisation, documentation and redesign of some processes, as well as changes to the way staff plan and conduct activities.	2
5c	**Ease of Implementation:** Technology & Data	• Technology investment is required to deploy automation and enhance technology enablement in pockets of the organisation.	2
	Overall Score	• This option involves a managed degree of change and carries reduced risk, with improvements in increased efficiency and ability to tackle new value adding tasks. • However, it does not go far enough to increase the Agency's agility and ability to focus on innovative interventions, patient experience and other ambitious strategic goals.	**13**

Balanced Scorecard: Option 3 – Driving Patient Outcomes across the Product Lifecycle

1= Low Benefit / High risk | 2= Med Benefit / Med risk | 3 = High Benefit / Low risk

	Criteria	Description	Score
1	**Patient Centricity**	• This model is organised around engagement with the end user - the patient, thereby is designed to create a patient centric organisation.	3
2	**Strategic Fit**	• This option will shift the Agency into the position it needs to be in, to become the modern, efficient, patient centric and world-leading organisation set out in its vision.	3
3	**Brand and Reputational Risk**	• This option will have significant impact on how the Agency is branded and the public's awareness of its role. With any substantial change, come an associated risk to reputation, should any challenges not be managed successfully.	3
4	**Business Risk**	• This is a highly ambitious option that will require substantial investment and significant change within the Agency, which subsequently represents a high risk to the Business.	1
5a	**Ease of Implementation:** Capability & Capacity	• The Agency in its current state does not have either the capacity or capabilities to move to the option. In areas, the capabilities do exist, but additional capacity is not currently available.	1
5b	**Ease of Implementation:** Process Change	• This option will require a substantial change to the Agency's ways of working, and implementation will likely be met with several significant challenges.	1
5c	**Ease of Implementation:** Technology & Data	• Investments in technology are required to support case management, self service and considered opportunities for automation of workflows.	1
	Overall Score	• If this option is successfully implemented, it will allow the Agency to achieve each of the 5 strategic priorities and thrive into the world-leading, patient-centric Agency set out in its vision. • However this is a highly ambitious option, requiring significant investment and substantial change, which could present a risk to the business, it's brand and reputation. At present, this would require a significant leap from where MHRA are now BUT would be a natural and manageable evolution from option B.	**13**

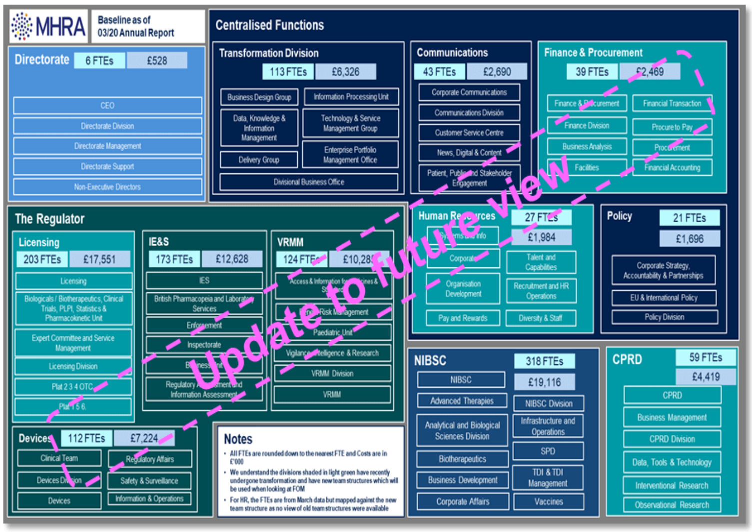
Balanced Scorecard: Option D – Product Lifecycle and Agile

1= Low Benefit / High risk 2= Med Benefit / Med risk 3 = High Benefit / Low risk

	Criteria	Description	Score
1	**Patient Centricity**	• The patient agenda is at the heart of the operations of the Agency. The pertinent points for MHRA are well understood and articulated by staff. Capability and effort is front-loaded and focussed on driving value based interventions to improve patient outcomes and public safety	3
2	**Strategic Fit**	• This model allows the full power of the strategic priorities to be distilled down into the Agency. The focus on leanness in the monitoring reduced backlog delivers efficiency and modernity whilst patient focus and international prominence are core to the model.	3
3	**Brand and Reputational Risk**	• There is some risk to the Agency's reputation as this would be an evolution of its role and value proposition within the wider health ecosystem. However, this would be a positive enhancement in line with Cumberlege requirements and could be managed with an effective strategy.	3
4	**Business Risk**	• Delivering an organisational and technological transformation of this scale risks the ongoing delivery of statutory functions. Drawing on agile, test and learn and risk management approaches should mitigate adequately.	2
5a	**Ease of Implementation:** Capability & Capacity	• Some new capability and capacity is required to deliver innovative interventions in front office and to support middle and back office transformation but additions are building on capabilities already in nascent form.	2
5b	**Ease of Implementation:** Process Change	• Medium process and operational reengineering will be required particularly to deliver middle and back office automation and efficiency opportunities. This transformation can be managed by using an agile approach.	1
5c	**Ease of Implementation:** Technology & Data	• Investment in technology and data processing is required across all three offices. This should be built on current planned IT investments such as use of AI and conducted using an agile approach.	2
	Overall Score	• This option is the closest fit for the Agency to achieve it's future vision and strategic goals at this time. • It will enable delivery of the Cumberlege agenda and equipping the Agency for a post EU-exit existence. • Whilst delivery is not without risk, these can be successfully managed by leveraging agile transformation principles.	**16**

7.5 Appendix E – Future Operating Model Options

There are three future operating model options being considered. These options represent different levels of ambition for the Agency and therefore will exhibit different features.



Option A: Remove Friction

- Remove friction from the current organisational structure (illustrated in the diagram below) and deliver tactical improvements
- One size fits all approach to removal barriers to become ‘One Agency’: optimising through small operational efficiencies

High Level Description:

- Removes key barriers to becoming ‘One Agency’, unlocking the benefits of scale and expertise across the Agency.
- Minimises the level of disruption to the business but drives greater clarity, efficiency and effectiveness.

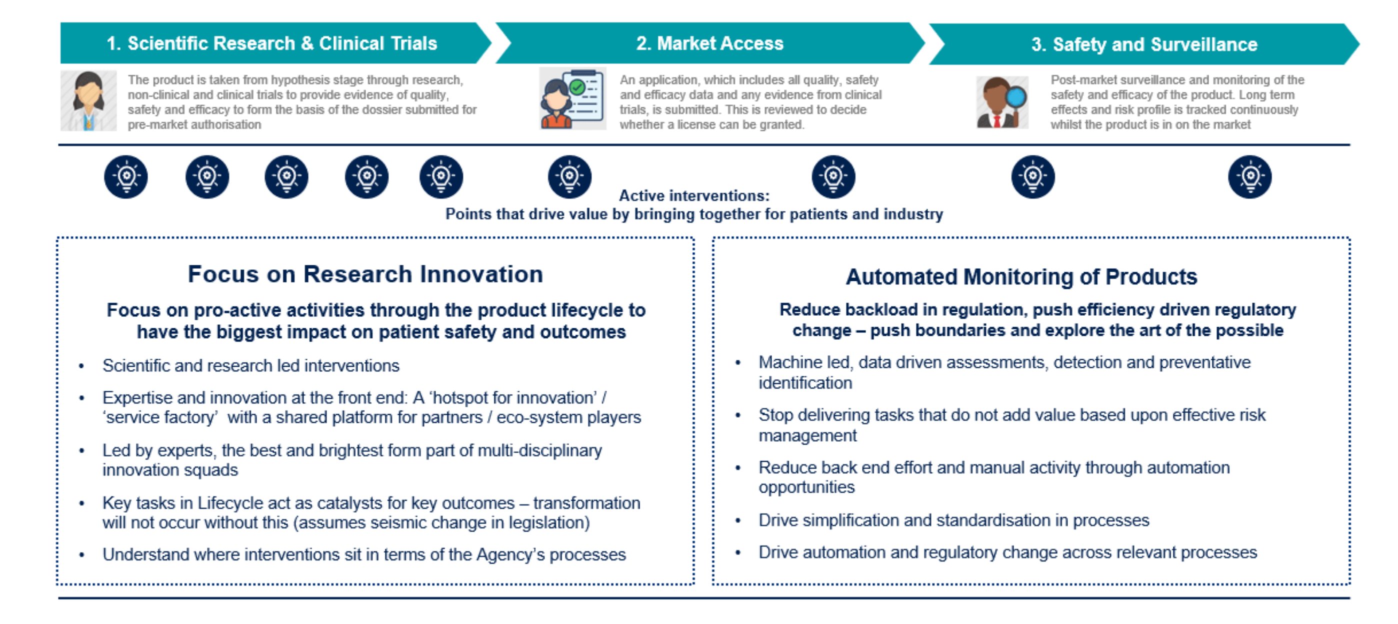
Key Objectives:

- Remove shadow functions – remove duplication of effort across and harness synergies of key centralised functions, e.g., Comms.
- Unblock conflicts of interest – enable key parts of the Agency to share key resources, e.g., data, to unlock new opportunities.
- Remove silos – breakdown organisational barriers through alignment of strategy, outcomes and KPIs.
- Improve patient engagement – involve patients more in decisions upstream and increase awareness of MHRA’s role in protecting patients and the public.

Key Features:

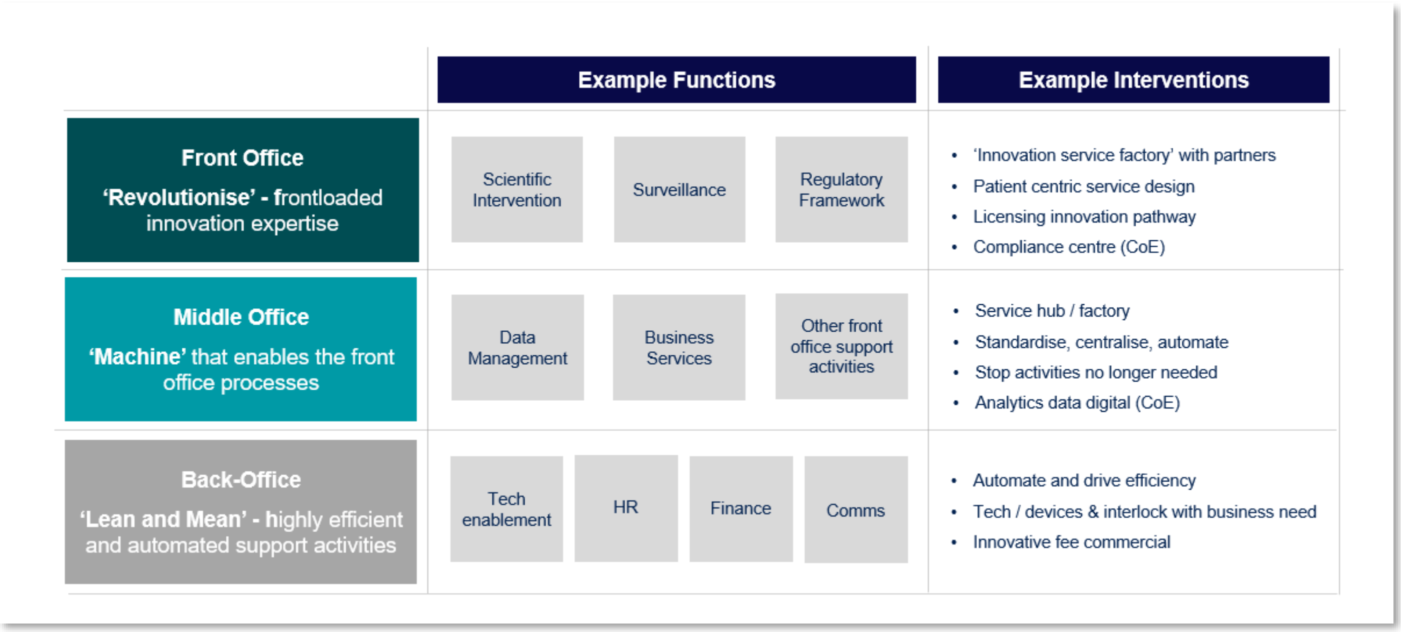
Op Model Component	Key Features
Organisation	• Removal of shadow and duplicative functions, e.g. Comms and IT. • Headcount reduction across low value, high cost activities. • Accountable officer for patient and customer experience appointed. • Workforce planning for post-Brexit in key areas of organisation only where demand is going to increase, e.g. Devices.
Capabilities	• Capability assessment for post-Brexit conducted across key areas of the organisation only. • Limited number of shared communities or pools of key expertise e.g. Data Scientists. • Enhanced patient engagement capabilities through training, education and support from line management
Processes	• Review and update MOUs between the constituent parts of the Agency. • Resolve Conflict of Interests and establish risk management approach to govern • Automate pockets of manual and repetitive processes. • Define a co-ordinated process for patient research and engagement.
KPIs	• Align Divisional outcomes and KPIs to Agency strategy, outcomes and KPIs. • Limited patient focussed individual performance metrics across engagement, research and championing.
Governance	• Limited incorporation of patient metrics into governance Terms of Reference, e.g. patient impact, benefit, satisfaction, patient research or involvement.
Technology	• Pockets of deployment of automation and AI across low value, high volume processes. • End user experience designed around patient audience where appropriate by service.
Data	• CPRD data utilised more pervasively across the Agency.

Option B: Driving Patient Outcomes across the product life cycle



Organise around the produce lifecycle (illustrated in the diagram below) and focus on proactive tasks that have the biggest impact on patient outcomes

Becoming an outcome driven Agency- what does this mean for how the Agency is organised?



Option C: Product Lifecycle & Agile

Orientate organisational structure around the product lifecycle and embed agile ways of working.

High Level Description:

- Majority of Agency (where appropriate) organised into cross-functional squads, focused on end user problems to be solved
- High capability end user engagement function empowered to shape and prioritise product and service development pipeline

Key Objectives:

- Ability to leverage industry-leading expertise and internal capabilities, responding to changing demands and external pressures
- Proactive identification of value driving activities for patients
- Embed a 'test and learn' culture and processes for continuous and optimised improvement.
- Lean business model with high volume activities fully automated through technological and data capability
- Expertise focussed and around the front end of the product lifecycle
- Embed and enhance CoE capabilities (e.g., data and analytics, compliance)

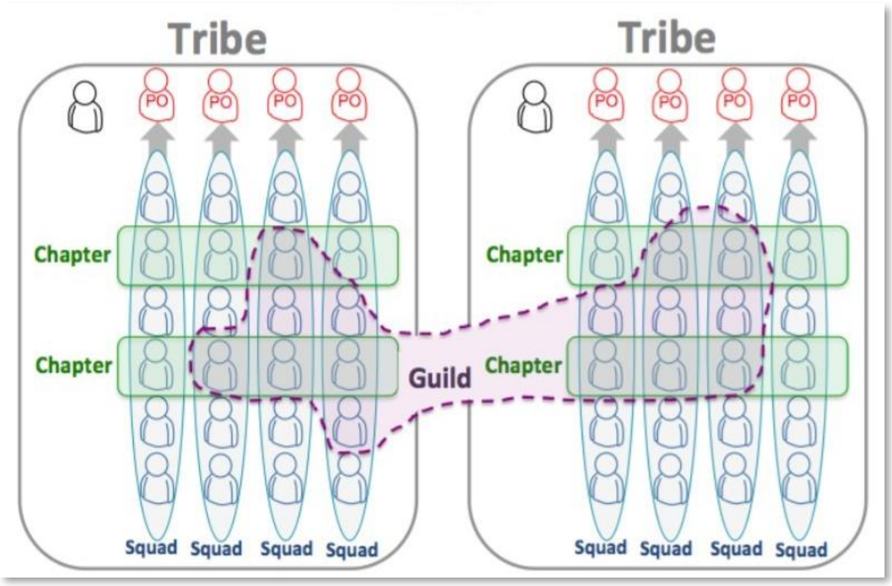


Illustration: Fully agile, matrixed model

Key Features

Op Model Component	Key Features
Organisation	• Organise functions over time around 'jobs to be done' with sub-teams focused on activities, data analysis, risk mitigation. • Lean organisation built around scientific and research specialists, fully automated processes and optimised machine learning.
Capabilities	• Agile sourcing models that readily flex to the Agency's demands and needs. • Matrix model ways of working fully deployed across the Agency where appropriate, e.g. product teams. • Teams performing rapid experimentation to test the market and growth hypotheses. • Patient research, engagement and comms capability incorporated into squads/teams, outputs and methods shard across the org.
Processes	• Lean approach to licensing and inspections through risk-based assessments, predictive analytics, automation and AR. • Activity kick off includes patient persona reviews to understand outcomes, research and engagement is planned activity with owners.
KPIs	• Patient outcome measurements and KPIs are gathered in real-time and drive planning and activity.
Governance	• Full incorporation of patient metrics into governance Terms of Reference, e.g. patient impact, benefit, satisfaction, patient research or involvement.
Technology	• Full self-service abilities across all customer products and services. • Enhanced technology and data capability enables 'case management' working where skilled resources focus on high value activities and datasets fully leveraged as an asset in the market. • Improved patient data collection integral to technology strategy.
Data	• Embed and enhance industry leading data and analytics CoE capabilities • Patient research repository leveraged to fill gaps in understanding of insight, persona, paint points.

7.6 Appendix F – Benefits Register

The benefits register maps the expected benefits of the Programme against a realisation plan with assigned owners.

A working draft of the benefits register of cash-releasing benefits is embedded below.

MHRA%20One%20A
gency%20Benefits%2