



Official - Sensitive
Medicines and Healthcare products Regulatory Agency (MHRA)
Transformation Programme
Gate 0

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Senior Responsible Owner (SRO):	[REDACTED]
Programme or Project Title	MHRA Transformation Programme
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About this report

This report is an evidence-based snapshot of the programme's/project's status at the time of the review. It reflects the views of the independent review team, based on information evaluated over the review period, and is delivered to the SRO immediately at the conclusion of the review.



This assurance review was arranged and managed by:

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<https://www.gov.uk/government/organisations/infrastructure-and-projects-authority>



1. Stage Gate Assessment (DCA)

Delivery Confidence Assessment
Amber
<p>The Delivery Confidence Assessment is rated Amber because successful delivery appears feasible but significant issues exist requiring management attention.</p> <p>The MHRA has completed a major restructuring exercise including a reduction in headcount. The Agency has begun its ambition of creating an integrated and patient-focussed “One Agency”. However, in order to meet expectations set out in the Programme Business Case, agreement on the scope and management of the next phase of the Transformation Programme needs to take place. There was a widespread recognition that current governance structures were not clear. Roles, responsibilities, reporting mechanisms and decision making all need to be more transparent. Transformation will require changes to the way the Agency carries out its business. Interviewees agreed that efficiencies and improvements could be achieved through business process redesign but this has not been incorporated into a clear Transformation Plan and needs to be agreed and shared. The challenge of filling job vacancies remains. A shared vision of what transformation means needs to be agreed and shared with staff.</p> <p>Transformation is a considerable challenge but the Agency has identified many positive opportunities as they redefine themselves as a patient-centric sovereign regulator that puts public health first.</p>



2. Summary of concerns, evidence and recommendations

Priority	Recommendation	Risk* and Issue Identified with Evidence	Classification Insert Reference Number	Critical, Essential, Recommended
1	The Transformation Programme Board should agree the scope of its responsibilities and revise its Terms of Reference accordingly.	There is a risk that without clear governance the programme will not meet its aims.	1. Governance	Critical
2	Clarify the relationship between each of the governance structures as they relate to the next phase of the Transformation Programme and communicate this clearly within the Agency.	There is a risk that without clear governance the programme will not meet its aims.	1. Governance	Critical
3	A programme plan showing all Transformation Programme deliverables needs to be produced and maintained.	There is a risk that a lack of clarity on scope could lead to programme failure.	3. Programme and Project Management	Critical
4	A Benefits Realisation Plan needs to be developed to reflect agreed metrics on benefits.	There is a risk that without a Plan, benefits will not be measured and delivered.	6. Benefits management and realisation	Essential (within three months)
5	The Risk Register needs to be updated and active risk management processes put in place.	Without a register and proper processes, risks may not be appropriately managed.	9. Risk, issues and dependency management	Essential (within three months)
6	There is an urgent need to agree, articulate and share a clear and	There is a risk that without this engagement with the programme will be sub-optimal.	8. Context, aim and scope	Critical



	visionary end-state for the Transformation Programme.			
7	In developing a new communications and engagement strategy for the next phase of transformation, the Agency should focus on enthusing, engaging and explaining clearly to staff and stakeholders what is happening next to build positive momentum.	There is a risk that without this, stakeholders will not support the delivery of the next phase.	13. Other (communications)	Recommended

**Risk denotes risks, issues, concerns and key dependencies*

All recommendations should be categorised as Critical, Essential or Recommended:

- **Critical (Do Now):** To increase the likelihood of a successful outcome it is of the greatest importance that the programme/project should take action immediately.
- **Essential (Do By):** To increase the likelihood of a successful outcome the programme/project should take action in the near future. *[Note to review teams – whenever possible Essential risk based recommendations should be linked to programme/project milestones e.g. before contract signature and/or a specified timeframe e.g. within the next three months.]*
- **Recommended:** The programme/project should benefit from the uptake of this recommendation. *[Note to review teams – if possible Recommended risk based recommendations should be linked to programme/project milestones e.g. before contract signature and/or a specified timeframe e.g. within the next three months.]*

3. Blockers to delivery

Ref No	Blocker	Describe specific nature of blocker	Consequence if not resolved
1	Recruitment	High levels of vacancies exist, methods of recruitment currently have long lead times and	The full range of transformation activities will not be delivered in a timely manner.



		challenges remain in attracting high calibre staff.	
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4. Comments from the SRO

SRO Comments
<p>I would like to thank the Review Team for the work they carried during a busy week with many stakeholder interviews covering a range of functions in the agency and Trade Union and industry representatives.</p> <p>I welcome the recommendations in this report and view them as providing extremely useful guidance on establishing a positive way forward as we move our Transformation Programme into its next phase.</p> <p>Work has already begun on reviewing the role of the Transformation Programme Board and where it sits in the agency's wider governance structure. This governance structure is also under review.</p> <p>The need for a new programme plan has been identified and work is underway to clearly identify future milestones. The need for clear and effective communications on the aims of the new phase of the programme is well noted.</p> <p>The recommendations on the need for an updated Risk Register and for a Benefits Realisation Plan are also well noted and will be delivered through the update of the Programme Business Case which is due to get underway shortly.</p> <p>Once again I would like to thank the Review Team for the report and their support.</p>



5. Review Team findings and recommendations

1. Governance

Strong governance is critical to the success of any Transformation Programme in terms of assurance and accountability. The Review Team heard that, at present, there is a lack of clarity around the governance structures associated with the MHRA Transformation Programme in relation to their roles, responsibilities and relationship to each other. These structures are the Transformation Programme Board, the Strategic Change Committee, and ExCo. It was described to the Review Team that ExCo is a pinchpoint in relation to decision making, that its agendas are long with items often rolling over to future meetings and that it meets multiple times. Moving forward, more focus should be given to these issues. There does not appear to be a clear escalation pathway between the governance structures and the ability to make decisions would seem to have not been delegated to structures other than ExCo.

The impact of what the Review Team heard in relation to governance of the Transformation Programme is that decisions get delayed, when they are made, they are not recorded or communicated effectively and that many of the same people meet on multiple occasions to discuss the same papers. This is not a good use of senior leaders' time. The Review Team understands that some work has commenced on revising the governance structures, including committees, and this is to be welcomed.

The role of the Transformation Programme Board (or its successor) must be very clear in terms of what is expected of it, what it is and is not responsible for (e.g. is it leading on culture or is that HR/OD?), how it manages interdependencies and how it reports into the other structures. The SRO is currently looking at revising the terms of reference for the Programme Board. The Transformation Programme covers many activities that will be not be delivered by the Transformation Team but will need to be tracked by them. The scope of work of the Transformation Board and its responsibilities regarding all activities need to be made clear in revised Terms of Reference. The SRO should then be issued with his internal SRO appointment letter.

RECOMMENDATION 1: The Transformation Programme Board should agree the scope of its responsibilities and revise its Terms of Reference accordingly.

The current Transformation Programme Board is part of a governance structure that is unclear in terms of roles and responsibilities particularly regarding escalation, authority and decision making. While the Review Team saw evidence that a



governance structure does exist it was not evident that it worked effectively in practice or was fully understood.

RECOMMENDATION 2: Clarify the relationship between each of the governance structures as they relate to the next phase of the Transformation Programme and communicate this clearly within the Agency.

The Review Team was presented with documents regarding a number of Pathfinder projects from Phase 3 of the Programme but it was not clear from the documentation provided, what the outcome and way forward for these were. This was not helped by the absence of minutes or record of action from meetings. Clear auditable trails of decision making need to be available so that there is clarity about where decisions were taken, what action points were agreed and who is responsible for them. While recognising that patient safety is of the highest importance, the Review Team heard of a desire for much quicker decision making, delegated to the most appropriate level. The current Highlight Report is quite lengthy and the Review Team were informed that different reports were required for different governance boards creating an unsustainable overhead on the team. The Review Team would encourage the SRO to review how papers, including (shorter) Highlight Reports, are presented for decision making so that those making the decisions have clear and timely evidence and the appropriate level of detail to allow informed decisions to be taken.

2. Plans for Next Phase

Interviewees gave different responses when asked about the aims and vision for the Transformation Programme. These ranged from seeing Transformation as merely about the restructure and cost savings (and hence already delivered), to a vision for a fully integrated, innovative organisation capable of responding rapidly and efficiently to new opportunities. Moving forward, a high-level statement of the purpose of the Programme needs to be agreed and communicated so that all staff are aware of the need for, and potential benefits of, transformation.

A Transformation Plan was provided to the Review Team for the period to March 2023, however, this did not include any activity on business process redesign which will be essential to delivering the benefits outlined in the Business Case. The Review Team was presented with a document from the November ODRC which described the agreed four priority areas of work for process redesign with the specific “Products” or services listed under each area. It was not clear how these products were agreed but the Review Team was informed that they were due to be reviewed and potentially revised during the week of this Review.



The need to produce a programme plan with a critical path for all Transformation Programme activities (irrespective of where delivery responsibility for these activities lies) is urgent. Without such a plan, it is not possible to determine whether the programme is on track and how benefits will be delivered.

RECOMMENDATION 3: A programme plan showing all Transformation Programme deliverables needs to be produced and maintained.

The SRO has been tasked with updating the Programme Business Case. The Business Case included sections on benefits but work is now needed to develop meaningful measurements and baseline metrics so that these can be monitored. This work will also help staff understand the rationale for the work on process change that they will need to deliver. The Business Case referred to reductions in posts of up to 300. The Review Team were informed that following the restructure, posts have been reduced by 120 and that there was a shortfall in savings from accommodation reductions. That said, an increase above forecast levels in income has placed the Agency in a stable financial position.

RECOMMENDATION 4: A Benefits Realisation Plan needs to be developed to reflect agreed metrics on benefits.

Most interviewees commented on the high level of vacancies being carried. Figures of between 16% and 20% were given across the Agency but much higher in some areas. Interviewees stated that this was acting as a real blocker to considering further change at the same time as meeting the requirements of the day job. The length of time recruitment was taking was also raised. There will clearly be a variety of reasons for this including, the need to agree job descriptions in a changing environment, pay levels in what is a highly competitive sector, security clearances, notice periods etc. However, some questioned whether HR policies were contributing to this. For example, where and how advertisements are placed and the restrictions of only recruiting to a London location. The Agency may wish to consider if there is a need for a more radical approach to current policies and whether lessons on recruitment can be learned from delays that have been encountered.

The Programme has a Risk Register which was reviewed and updated in September. It was not clear how risks are currently managed. The risk register needs to be reviewed and each risk given an owner. The Transformation Programme Team then need to ensure that risks are actively managed and an escalation route for critical risks agreed.

RECOMMENDATION 5: The Risk Register needs to be updated and active risk management processes put in place.



The Review Team understands that the SRO is Director of Delivery. Given opinions expressed to the Review Team, this may cause some difficulties and misunderstandings as other teams and individuals are also responsible for delivery within the Agency.

3. Communications/Culture

The Review Team heard how the Agency is at a critical stage in its evolution post-EU Exit, Cumberlege and COVID-19. Restructuring is largely complete and existing staff have moved into their new roles.

The impacts from the staff restructure are still evident and some hearts and minds have been lost in the process. The Review Team heard that many people think of the Transformation Programme as being the staff restructure. This has negative connotations and is linked to difficult decisions about job losses and restructuring of job roles and responsibilities which has been uncomfortable for many staff. The Review Team heard that restructuring and persistent job vacancies have placed many staff under significant and sustained pressure affecting well-being and organisational resilience.

The Review Team heard how the creation of 'One Agency' and a new culture remains an abstract concept to many. A strong new culture will take time to build but the detail needs to be developed in partnership with staff as organisational design changes take root and people settle into their new roles. A common understanding needs to be reached in terms of the language used to describe what is being delivered and why. In particular, the Agency needs to define a clear and visionary end-state for transformation setting out the Agency's future direction of travel and the many opportunities which lie ahead. There is much to be excited about as the Agency moves into a new phase of delivery. A critical part of this will be articulating what a 'patient centric' organisation means in practice. The Review Team heard different versions of this but there needs to be a single, agreed definition of this and how it fits into the new 'One Agency' culture.

RECOMMENDATION 6: There is an urgent need to agree, articulate and share a clear and visionary end-state for the Transformation Programme.

Chief Officers need to set the tone for the next phase and build service-redesign into peoples' day jobs. This message needs to be reinforced regularly at senior level and throughout the Agency so it is fundamental to staff roles as the Agency moves forward. The Review Team understand this may be challenging in practice while vacancy rates remain high but believe this is the only way to create the pace needed on the mission-critical service design work.



The Review Team believes that a communications and engagement strategy for the next phase of transformation is vital in the period ahead. The Transformation Programme needs to develop a new narrative going forward which sets it apart from the restructuring which is now complete. This narrative should engage, enthuse and explain to staff and stakeholders what will happen and when as the Agency moves forward, with key messages to underpin it. It should be clear when and where there is space for staff engagement and set out how that engagement will happen. The engagement should be real and not tokenistic. There should be a regular rhythm of communication and engagement and ExCo need to agree it and commit. Messages need to be embedded in wider Agency communications so it is part of the everyday narrative of the organisation from now on, and not an 'add-on'. The people communicating should be equipped to do so clearly and with confidence. This includes everyone from ExCo down to junior managers and those who are less familiar or comfortable giving messages about change. This is vital to help build the new Agency culture from the ground up and to foster an environment where regular dialogue and working in partnership are central to the way the Agency operates.

The Review Team believes that a review of the lessons learned from past change programmes should inform the handling of the next phase of transformation. This should include what could have been done better or differently when handling the recent staff restructure.

RECOMMENDATION 7: In developing a new communications and engagement strategy for the next phase of transformation, the Agency should focus on enthusing, engaging and explaining clearly to staff and stakeholders what is happening next to build positive momentum.

6. Areas of good practice

Commending delivery of	Describe specific details of successful delivery
2. Stakeholder Engagement	The Review Team heard of very positive collaborative early engagement with industry in relation to process redesign.



**2. Stakeholder
Engagement**

The Review Team heard that a good working relationship between HR and Trade Union contacts was maintained during the restructure exercise.

7. Acknowledgement

Review Team Acknowledgement

The Review Team would like to thank the Project/Programme Team for their support and openness, which contributed to the Review Team's understanding of the Programme and the outcome of this review. In particular, thanks to [REDACTED] for logistical support in organising this review.

8. Next Assurance Review

Next Assurance Review

A repeat gate 0 should take place in approximately one year in line with good practice.



ANNEX A – Stage Gate Assessment (SGA) Descriptions

From 1 April 2021, the IPA has moved to a 3 tier SGA RAG status (Red, Amber, Green). The SGA will be based on the following definitions:

Colour	Criteria Description
Green	<p>Successful delivery of the programme/project to time, cost and quality appears highly likely and there are no major outstanding issues that at this stage appear to threaten delivery.</p> <p><i>Recommendation: The programme/project is ready to proceed to the next stage.</i></p>
Amber	<p>Successful delivery of the programme/project to time, cost and quality appears feasible but significant issues already exist requiring management attention. These appear resolvable at this stage and, if addressed promptly, should not present a cost/schedule overrun.</p> <p><i>Recommendation: This programme/project can proceed to the next stage with conditions but the programme/project must report back to the IPA and HMT on the satisfaction of each time bound condition within an agreed timeframe.</i></p>
Red	<p>Successful delivery of the programme/project to time, cost and quality appears to be unachievable. There are major issues which, at this stage, do not appear to be manageable or resolvable. The programme/project may need re-baselining and/or its overall viability re-assessed.</p> <p><i>Recommendation: This programme/project should not proceed to the next phase until these major issues are managed to an acceptable level of risk and the viability of the project/programme has been re-confirmed.</i></p>



ANNEX B - Terms of Reference for Hybrid Review

This is a Gate 0 assurance (Strategic Assessment).

The purpose of the Gateway 0 Review is to:

- Review the expected outcomes, objectives and benefits for the project (and the way they fit together) and confirm that they make the necessary contribution to the overall strategy of the organisation and its senior management;
- Ensure that the project is supported by key stakeholders;
- Confirm that the programme's potential to succeed has been considered in the wider context of Government policy and procurement objectives, the organisation's delivery plans and change programmes, and any interdependencies with other programmes or projects in the organisation's portfolio and, where relevant, those of other organisations;
- Review the arrangements for leading, managing and monitoring the project as a whole and the links to individual parts of it (e.g. to any existing projects in the programme's portfolio);
- Review the arrangements for identifying and managing the main project risks (and the individual project risks), including external risks such as changing business priorities;
- Check that provision for financial and other resources have been made for the project (initially identified at project initiation and committed later) and that plans for the work to be done through to the next stage are realistic, properly resourced with sufficient people of appropriate experience, and authorised;
- After the initial Review, check progress against plans and the expected achievement of outcomes.
- Check that there is engagement with the market as appropriate on the feasibility of achieving the required outcomes;
- Where relevant, check that the project takes account of joining up with other programmes, internal and external; and
- Evaluation of actions taken to implement recommendations made in any earlier assessment of deliverability.

Specific issues and lines of enquiry

Aside from the areas to probe at Gateway 0 assurance, the programme has also asked for scrutiny in some specific areas:

- There is a risk that the prioritised services may not deliver against the full scope of Agency services and Moments of Value identified across the core areas of the Agency (Science Research & Innovation, Healthcare Quality & Access, Safety & Surveillance).



ANNEX C - Background

Question	Answer
Describe the aims of the project/ programme	<p>The Transformation Programme aims to deliver the following in the programme lifecycle:</p> <ol style="list-style-type: none">1. Agency Restructuring and Cost Reduction: An Agency wide cost reduction targeting pay costs, non-pay costs and project spend to return the Agency to a sustainable cash position2. 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 plan3. Technology Enabled Change: A replacement of legacy systems and investment in new technology which underpin the future operating model.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 <p>The above programme objectives are underpinned by the Agency's ambitious roadmap for Change as outlined in the Agency Delivery Plan 2021 – 2023 "Putting patients first – A new era for our agency".</p> <p><u>The current priorities and workstreams of the Transformation programme</u></p> <p>The organisational restructure is complete and the new One Agency structure is fully operational, restructuring no longer reports to Transformation and ongoing recruitment activities have transitioned to business as usual.</p> <p>The Pathfinder project during the Detailed design phase of the programme (February 2021 – September 2021) progressed initiatives required to deliver on our commitments as set out in the Agency Delivery Plan and to build momentum in delivering the Transformation Programme. Some pathfinders included identifying cost saving opportunities such as reducing Accommodation footprint at 10 South Colonnade, reducing non-pay costs (also being partly delivered by Digital and Technology group to reduce non-pay technology costs), integration of Clinical Trials and Investigations and integration of signal detection teams, to deliver Transformation benefits in the form of efficiencies, savings, and/or improved services. The pathfinder projects are complete and ongoing activities have transitioned to business as usual. Realisation of these benefits are being monitored by Transformation with benefit owners, Chief Officers and their Senior Management Teams on a frequent basis.</p> <p>At present, we are finalising the structure, design and priorities of Transformation following completion of the organisational restructure, with a focus on delivering key services for the agency, effectively managing change and ensuring patient needs and outcomes drive our implementation and ways of working.</p>



Transformation is delivering across the following key areas:

- 1) Transformation - Oversee and drive the people related transition to the operating model, including impacts on structure, size and shape of future teams in terms of their design, roles and capabilities. Deliver Transformation programme activities, including the governance and assurance of the programme and management of risks, issues, dependencies and realisation of benefits. Workstreams include:
 - Benefits
 - Change Management
 - Transformation Management Office/ Governance
- 2) One Agency - Embed the One Agency culture and Ways of Working in alignment with the operating model. Workstreams include:
 - Culture
 - Leadership & High Performance Team
- 3) Service Redesign - Drive, support and coordinate the delivery of the future operating model and associated transformed services across the Agency, ensuring patient needs and outcomes drive our implementation and ways of working.
- 4 services areas prioritised by the Executive Committee for process optimisation and delivery are:
 - Established Medicines - Speedy risk proportionate approval of well-known products facilitating access by the NHS.
 - Integrated Pathway (Innovative Licencing and Access Pathway and Innovative Devices Access Pathway) - Premium fast-stream service for innovative products based on early dialogue and targeted development integrated with HTA (and NHS)
 - Safety Signalling - To be the premium global surveillance service based on state-of-the-art responsive ADR reporting, real time proactive vigilance, innovative analytics, patient engagement and excellent prospective studies.
 - Compliance - To ensure risk-proportionate compliance across the product lifecycle to enable secure patient access to medicines.
- 4) Agency platform - Ensuring that our technology and data platforms enable the future operating model and associated transformed services.

Reasons for the project/ programme's

There are 4 key factors driving the MHRA Transformation programme:

1. **UK's Life Sciences Agenda** - The UK's Life Sciences Agenda along with the COVID-19 pandemic has increased the criticality of the MHRA's role as a regulator



<p>existence, by type and description</p>	<p>of vaccinations and has highlighted the importance of strong regulatory frameworks in order to proactively respond to fast-moving life science developments.</p> <ol style="list-style-type: none"> 2. Independent Medicines and Medical Devices Safety Review - Baroness Cumberlege exposes areas of vigilance which need strengthening, gaps in the health system, but most important of all, a failure to listen to and respond to patients. 3. UK’s exit from the European Union - We have the opportunity to re-define MHRA’s role as a regulator and capitalise on the creation of new international regulatory relationships. 4. Finances - Create an Agency with a financially sustainable future in preparation for the end of the Agency operation as a Government Trading Fund on 31 March 2022, address changes to income from fee generating activities following Brexit, and invest in ageing IT infrastructure to improve efficiencies.
<p>The impact if the project/programme fails to deliver e.g. any risks to or any material impact on civilians/citizens:</p>	<p>The Agency transformation will improve capability within overall parameters of the existing public health protection remit and supports delivery of the current Agency Delivery Plan (2021 – 2023). Potential impact if the programme fails to deliver its benefits include:</p> <ul style="list-style-type: none"> • One Agency culture - The new organisational structure is established and operational, however challenges are ongoing to recruit to the new structure. Risk captured of potential negative impact on statutory functions performance during implementation and embedding new Ways of Working. • Financial sustainability - Significant cost reductions have been realised and the Agency is currently operating at a balanced budget. There is potential financial impact on the Agency if cash-releasing benefits are not continued to be realised. In addition to this, significant non-pay cost savings are dependent on the successful delivery of the technology change. These savings would be at risk if the programme fails to deliver its benefits. • Patient safety - Programme benefits include delivering a more responsive safety surveillance and risk management system for all medical products, to enhance patient safety and position the Agency to respond to increased volume of safety reports and signals detected across all healthcare products. If not achieved, there’s potential impact on the Agency’s ability to identify and respond effectively to safety issues and mitigate associated impact on citizens/patients/industry. • Public safety and access to healthcare products - programme benefits include improving the Agency's capability to accelerate approval of clinical trials, medicines, devices, and vaccines to the market which is/has been critical in responding to the pandemic. If not realised, there’s potential delays to public access to healthcare products. • Technology enabled change which underpins the future operating model - If technology change is not delivered, there’s potential impact on the Agency’s ability to respond to future needs and reduce the risk of data security threats as per modern security standards.
<p>Project/programme link to departmental</p>	<p>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 policy paper highlights the following expectations of the Agency over the coming</p>



**or government
strategies or policies:**

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



	<p>deepen cooperation, exchange information and encourage adoption of international standards and best practice.</p> <p>The Agency's work directly relates to the following manifesto commitments:</p> <ul style="list-style-type: none"> • 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
<p>Projects/programme interdependencies [if applicable]:</p>	<ul style="list-style-type: none"> • There are interdependencies on the Transformation programme with technology projects which underpin the future operating model such as the Regulatory Management System (RMS), Innovative Licensing and Access Pathway, Appian, SafetyConnect and Digital Self Service. • There is a risk of a lack of resource required for implementation due to capacity gap across the Agency. Successful delivery of transformation is dependent on sufficient capacity from Transformation team and supporting functions such as HR, Finance, D&T and core areas (Healthcare Quality & Access, Science Research & Innovation, Safety & Surveillance).
<p>Has the SRO's Osmotherley letter (letter of appointment) been approved at the appropriate levels?</p>	<p>No.</p> <p>The programme is not on the Governments GMPP and therefore an Osmotherley appointment letter has not been issued or approved. A new SRO has recently been appointed to the programme and an internal SRO appointment letter has been drafted. This has not been issued to the SRO as the strategic direction of the programme under the new SRO is under review. The outcome of this review is not fully agreed and will influence the content of the internal SRO appointment letter. Once known the SRO appointment letter will be updated and issued to the SRO.</p>
<p>The procurement / delivery status:</p>	<p>Procurement for the 4 Phases of Transformation Consultancy of the programme as outlined in the Programme Business Case was developed in accordance with best practice and within applicable controls. Commercial outcomes were driven by business requirements and tenders being fulfilled by Crown Commercial Services Management Consultancy Frameworks. Please note all corresponding contracts are now complete/closed.</p>



- Procurement for Phase 1 – Governance review
- Procurement for Phase 2 – High Level Design
- Procurement for Phase 3 – Detailed Design
- Procurement for Phase 4 – Implementation

Technology procurement within the scope of the Transformation Programme Business Case

- **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.
 - The RMS main procurement was undertaken as an OJEU tender using the Competitive Dialogue procedure and concluded with an award in Feb 2020. The requirements for this tender were derived from user needs and organisational objectives. The team engaged with DHSC, Cabinet Office, and Treasury to ensure all external approvals were gained.

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



Funding / Business Case:	<p>The Transformation programme is fully funded for its current phase by a combination of funds received from DHSC, as well as funding the transformation from its own operations. DHSC will provide a portion of the funding for the 2022/23 and 2023/24 financial years. The rest of the funding for those and subsequent years is covered by the Agency's operations.</p> <p>The Transformation programme has a Strategic Outline Case approved internally by the MHRA Executive Committee and a Transformation Programme Business Case approved by DHSC Investment Committee.</p>
Integrated Assurance and Approval Plan (IAAP):	<p>An IAAP is currently not in place for the Transformation programme as is not a mandatory requirement for internal MHRA governance.</p> <p>We have a document which acts as an equivalent, the Governance and Assurance Framework Transformation programme v1.0 which has been approved by the Agency's Strategic Change Committee shared with the independent review team.</p>
Programme/Project plan:	<p>Yes, however the programme plan is under review.</p> <p>Yes, the programme plan was reviewed/signed off by the Transformation Programme Board.</p>
Current position regarding previous IPA assurance reviews:	<p>Not Applicable.</p>



ANNEX E – List of Interviewees

The following stakeholders were interviewed during the review:

Name	Organisation and role
[REDACTED]	SRO Director of Delivery
[REDACTED]	Director of HR
[REDACTED]	Head of Project Management in Digital and Technology Group
[REDACTED]	Chief Executive Officer/Accounting Officer
[REDACTED]	Head of Business Analysis and Design Service
[REDACTED]	Chief Safety Officer
[REDACTED]	Director of Communications and Engagement
[REDACTED]	Head of Strategic Change Assurance in Governance Office
[REDACTED]	Non-Executive Director (Organisational Development and Remuneration Committee (ODRC) chair)
[REDACTED]	Chief Partnerships Officer
s40(2) FOIA [REDACTED]	Device Data Specialist (Trade Union representation – main contact)
s40(2) FOIA [REDACTED]	Deputy Director Finance/Business Case Manager
S40(2) FOIA [REDACTED]	Head of Organisational Development
S40(2) FOIA [REDACTED]	Technical Director, British Generic Manufacturers Association (BGMA)
[REDACTED]	Chief Healthcare Quality and Access Officer
[REDACTED]	Chief Science Research and Innovation Officer
[REDACTED]	Chief Digital and Technology Officer



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Social Care



ANNEX F – Recommendation Classifications and Priority Order

There are 13 classifications in the classification set, Review Teams are asked to record the classification reference number of each recommendation as per the table below.

#	Classification	Definition
1	Governance	Recommendations related to the oversight, structure and decision making of a project/ programme. This theme also includes recommendations relating to alignment with pan-government priorities, strategies and controls.
2	Stakeholder Management	Recommendations related to relationships with all parties with an interest in the outcome of the project/programme, whether internal to the agency, internal to government or external.
3	Programme and Project Management	Recommendations related to all aspects of project, programme and portfolio management, but excludes recommendations on Risk, Issues and Dependency Management (Theme 9) and Resource Management (Theme 10)
4	Change Management & Transition	Recommendations related to the Management of Business Change – all the work required with and in the business and with the customer to make ready for the initiative, in terms of changes to business processes including: business continuity planning, changes to work processes and resourcing, changes to organisational structures and staffing to support transformational or process changes to business delivery to ensure a smooth transition to BAU It does not include Technology Readiness for Service (Theme 12).
5	Financial Planning and Management	Recommendations related to financial planning, organising, directing and controlling of financial activities.
6	Benefits Management & Realisation	Recommendations related to the identification, ownership, measurement and realisation of benefits and dis-benefits. Benefits can be either financial or non-financial.



7	Commercial Strategy & Management	Recommendations related to the end-to-end procurement process including: Procurement strategy and planning, Approaches to the market, Contract negotiation and Contract management.
8	Context, Aim & Scope	Recommendations that are aimed at the clarity of the change to be implemented. It covers alignment to vision, strategy and policy; the purpose, objectives, justification and description of the change; and the determination of success and the necessary environment to ensure success.
9	Risk, Issues & Dependency Management	Recommendations related to the identification, analysis, impact assessment, response and the on-going review and management of Risks, Issues and Dependencies (i.e. outputs that are required by a project to succeed, but which will be delivered by parties not under the direct control of the project).
10	Resource & Skills Management	Recommendations related to all aspects of the identification, supply, optimisation, prioritisation and maintenance of resources and appropriate skills.
11	Knowledge Management	Recommendations related to the process of capturing, developing, sharing, and effectively using organizational knowledge. It includes sharing knowledge and experiences or Lessons Learnt.
12	Technology	Recommendations related to all technology issues, including the alignment of the technology solution to the technology and business strategy, the integration of one or more technology solutions, the operational readiness of the solution (including testing of the solution), and all aspects of security relating to the technology solution.
13	Other	To be used only when other classifications do not apply.

Each risk-based recommendation will be recorded as Critical / Essential or Recommended:

- **Critical (Do Now):** To increase the likelihood of a successful outcome it is of the greatest importance that the programme/project should take action immediately.



- **Essential (Do By):** To increase the likelihood of a successful outcome the programme/project should take action in the near future. [Note to review teams – whenever possible Essential risk-based recommendations should be linked to programme/project milestones e.g. before contract signature and/or a specified timeframe e.g. within the next three months.]
- **Recommended:** The programme/project should benefit from the uptake of this recommendation. [Note to review teams – if possible Recommended risk-based recommendations should be linked to programme/project milestones e.g. before contract signature and/or a specified timeframe e.g. within the next three months.]