Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

10:00 am – 12:30 pm on Tuesday 9 July 2024

Chair: Professor Graham Cooke

	AGENDA ITEM	**PURPOSE**	**PRESENTER**
10:00	INTRODUCTION		
	1. What is the purpose of this meeting, who are the Board Directors and are there any absences?	Information	Chair
	2. Are there any new Declarations of Interest?	Information	All
	3. What were the minutes and actions from the last meeting?	Approval	Chair
	AGENCY PERFORMANCE		
10:15	4. What are the most important current activities and priorities from the CEO's point of view?	Context	June Raine
10:30	5. What was the financial and people performance of the MHRA for this year up to 31 May 2024?	Assurance	Rose Braithwaite
10:45	6. How well does the 2023/24 Annual Report and Accounts reflect the performance, governance and financial results of the MHRA over the last year?	Approval	Carly McGurry & Rose Braithwaite
	PATIENT SAFETY		
11:05	7. How will the MHRA implement the recommendations of the Infected Blood Inquiry?	Assurance	Alison Cave & Rachel Bosworth
	DATA STRATEGY		
11:25	8. How can the Data Strategy provide important value for the Agency's services and regulatory science?	Strategic Direction	Alison Cave & Claire Harrison
	GOVERNANCE		
11:45	9. What will the Board effectiveness review cover in the upcoming review?	Discussion	Carly McGurry

	ASSURANCE		
12:00	10. What assurance can be provided by the Organisational Development and Remuneration Committee?	Assurance	Amanda Calvert
12:15	11. Audit and Risk Assurance Committee Annual Report	Assurance	Michael Whitehouse
12:30	CLOSE OF MEETING		Chair

MHRA Board Declarations of Interest – July 2024

The MHRA Board is responsible for advising and agreeing the strategic direction of the Agency, endorsing the Agency's recommendations to Ministers on key financial and performance targets, and advising on and monitoring plans to ensure those targets are met.

The Board supports the Chief Executive Officer in the effective delivery of services and overall performance by providing leadership, developing strategy, advising on the delivery of policies, maintaining high standards of corporate governance, scrutinising performance and ensuring that controls are in place to manage risk.

The Board and its Non-Executive Directors have no involvement in any regulatory decisions affecting medicines, medical devices or any other products or services delivered by the Agency. These decisions are the responsibility of the Chief Executive Officer, supported by the Executive Committee.

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Professor Graham Cooke Non-Executive Director & Interim Co-Chair	Imperial College NHS Trust and Chelsea & Westminster NHS Foundation Trust	Honorary NHS Consultant	Yes	Yes
	NERVTAG	DHSC NERVTAG committee member	No	Yes
	NIHR	NIHR Research Professor	Yes	No
	NIHR	Influenza platform trial in the UK	Yes	Yes
	NIHR	Chair DSMB (PROTECT-V trial)	No	Yes
	Pfizer	Pneumonia study with Imperial College Healthcare Partners	Yes	No
	30 Technology Ltd	Consultant/Advisor	Yes	Yes
	DNAnudge Ltd	Consultant/Advisor	No	Yes
	Seventh Sense Biosystems	Consultant/Advisor	Yes	No
	Sanofi CoV	Chair of End Point Review Committee for vaccine trial	Yes	Yes
	WHO	Member of Committee for Selection and Use of Essential Medicines	No	Yes
Dame June Raine Chief Executive	World Health Organisation (WHO) Committee on Safety of Medicinal Products	Member	No	Yes
Dr Junaid Bajwa Non-Executive Director	Microsoft	Employed (Chief Medical Scientist at Microsoft Research), Shareholder	Yes	Yes
	Merck Sharp and Dohme	Ex-employee shareholder	No	Yes
	Ondine biomedical	Non-Executive Director	Yes	Yes
	UCLH	Non-Executive Director	Yes	Yes
	Whittington NHS Trust	Non-Executive Director	Yes	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
	NHS	GP, Physician (Sessional)	Yes	Yes
	Nuffield Health	Governor (NED)	Yes	Yes
	Nahdi Medical Corporation	Non-Executive Director	Yes	Yes
	DIA Global	Board Member	No	Yes
	HDR UK	Trustee	No	Yes
Julian Beach Interim Lead, Healthcare Quality & Access	None	N/A	N/A	N/A
Liz Booth Chief People Officer	None	N/A	N/A	N/A
Rose Braithwaite Chief Finance Officer	Mental Health Foundation	Treasurer	No	No
Amanda Calvert Non-Executive Director & Interim Co-Chair	Astrazeneca	Ex-employee shareholder Immediate family member	No	Yes
	Quince Consultancy Ltd	Provides consultancy services including companies in the healthcare sector.	Yes	Yes
	Athenex Pharma	Quince Consultancy providing strategic consultancy on oral oncology chemotherapy platform. ILAP applicant and Marketing Authorisation applicant.	No	No
	Cambridge Judge Business School	Member of Advisory Board	No	Yes
	Duke Street Bio	Advisory / Consultant	Yes	Yes
	Fennix Pharmaceuticals	Founder of start-up company planning to develop oral chemotherapy product into Phase 2 trial. Not yet trading.	No	No
	High Value Manufacturing Catapult	Non-Executive Director	Yes	Yes
Dr Alison Cave Chief Safety Officer	None	N/A	N/A	N/A
Dr Paul Goldsmith Non-Executive Director	Closed Loop Medicine Ltd	Shareholder, director & employee; MA submission	Yes	Yes
	Lanthor Ltd	Book publishing and medico-legal reports	Yes	Yes
	Ieso Digital Health	Shareholder	No	Yes
	Institute of Global Health Innovation (IGHI), Imperial College, London	Visiting Professor	No	Yes
	MDU Ltd	Director	Yes	No
	MDU Investments Ltd	Director	Yes	No
	NHS	Consultant Neurologist	Yes	Yes
	NHS	Clinical Senate Member	No	Yes
	Radix Big Tent Foundation	Trustee	No	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
	Sleepstation	Co-founder of original programme, 2012-2014	No	No
Claire Harrison Chief Digital & Technology Officer	None	N/A	N/A	N/A
Haider Husain Non-Executive Director	Healthinnova Limited	Chief Operating Officer	Yes	Yes
	Milton Keynes University Hospital NHS Foundation Trust	Non-Executive Director	Yes	Yes
	British Standards Institute	Chair – TC304 Healthcare Organisation Management Committee	No	Yes
	Madad UK	Trustee	No	Yes
	World Wars Muslim Memorial Trust	Trustee	No	Yes
	Microsoft Corp	Ex-employee shareholder	No	Yes
	BBC	Family Member	No	Yes
	NHS Buckinghamshire, Oxfordshire and Berkshire West Integrated Care Board	Digital and Data Advisor / Member of the System Productivity Committee	Yes	Yes
Mercy Jeyasingham MBE Non-Executive Director	NHS South West London Integrated Care Board	Non-Executive Member	Yes	Yes
Raj Long Non-Executive Director	Gates Foundation	Employee – Deputy Director	Yes	Yes
	Bristol-Myers Squibb	Ex-Employee Shareholder	Yes	Yes
	RESOLVE (Sustainable solutions to critical social, health, and environmental challenges)	Scientific Advisory	No	Yes
	Novartis	Ex-Employee Shareholder	Yes	Yes
	BioNTech Global Health (non-profit)	Strategic Advisory for only Sub-Saharan Africa Public Health for Equitable Access	Yes	Yes
	Gates Venture – EC Innovative Medicines Initiative (IMI) Non-Product – IMI European platform for Neurodegenerative Disorders	Advisory	Yes	Yes
	WHO – Sustainable COVAX Manufacturing Strategy for Regional Health Security	Advisory Expert	No	Yes
	UK Health Security Agency	Associate Non-Executive Board Member	Yes	Yes
	EU Innovative Health Initiatives (IHI)	Advisory Expert for this EU public-private partnership funding health research and innovation funded by European Commission	Yes	Yes
Nicola Rose	None	N/A	N/A	N/A

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Interim Executive Director, Science and Research				
Laura Squire OBE Chief Healthcare Quality & Access Officer	None	N/A	N/A	N/A
Michael Whitehouse OBE Non-Executive Director & Interim Co-Chair	South East Coast Ambulance Services NHS Foundation Trust	Deputy Chair & Senior Independent Non-Executive Director Chair of Audit Committee Chair of Charities Committee	Yes	Yes
	Cruse Bereavement Charity	Trustee Chair of Finance and Audit Committee	No	No
	Republic of Ireland Audit Office	Member of Audit Committee	No	No
	National Audit Office	Board Member and Chief Operating Officer until 17 April 2017	No	No
Glenn Wells Chief Partnerships Officer	None	N/A	N/A	N/A

Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public on 21 May 2024

(10:00 – 12:00)

NIBSC, Blanche Lane, South Mimms

Present:

The Board

Professor Graham Cooke	Non-Executive Director & Interim Co-Chair
Dr June Raine DBE	Chief Executive
Dr Junaid Bajwa	Non-Executive Director
Liz Booth	Chief People Officer
Rose Braithwaite	Chief Finance Officer
Amanda Calvert	Non-Executive Director & Interim Co-Chair
Dr Alison Cave	Chief Safety Officer
Dr Paul Goldsmith	Non-Executive Director
Claire Harrison	Chief Digital & Technology Officer
Haider Husain	Non-Executive Director
Mercy Jeyasingham	Non-Executive Director
Nicola Rose	Interim Executive Director, Science and Research
Dr Laura Squire	Med Tech Regulatory Reform Lead (Chief Healthcare Quality and Access Officer) (for items 9 and 10)
Dr Glenn Wells	Chief Partnerships Officer
Michael Whitehouse OBE	Non-Executive Director & Interim Co-Chair

Others in attendance

Rachel Bosworth	Director of Communications and Engagement, MHRA
Carly McGurry	Director of Governance, MHRA
Mick Foy	Director of Delivery, MHRA
Natalie Richards	Head of the Executive Office, MHRA
Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC
Joseph Burt	Head of Diagnostics, MHRA (for items 9 and 10)
Andy Morling	Deputy Director, Criminal Enforcement, MHRA (for item 8)

INTRODUCTION

1. Item 1: What is the purpose of this meeting and who are the Board Directors?

1.1. Professor Graham Cooke opened the meeting. The Chair set out his expectations and priorities for this Board meeting held in public which was being live streamed to the registered audience and recorded. The Chair welcomed everyone to the meeting, including a broad range of observers including patients and members of the public, representatives of patient groups, healthcare professionals, government officials, industry, media and MHRA staff.

2. Item 2: Are there any Apologies or Declarations of Interest?

2.1. Apologies were received from Raj Long, Non-Executive Director; Julian Beach, Interim Executive Director, Healthcare Quality & Access; Alison Strath, Chief Pharmaceutical Officer for Scotland; Greig Chalmers, Head of Chief Medical Officer's Policy Division in the Scottish Government; and Cathy Harrison, Chief Pharmaceutical Officer for Northern Ireland.

2.2. The Board reviewed the Declarations of Interest (DOIs) for all MHRA Board members. Dr Junaid Bajwa declared that he has been appointed as a trustee of HDR UK. The Chair reviewed the DOIs and was satisfied that there were no conflicts of interest preventing any Board Member from participating in the full agenda of this meeting.

3. Item 3: What were the minutes and actions from the last meeting?

3.1. The Board reviewed the minutes and actions from the last meeting. No comments were received. The minutes were accepted as an accurate record of the last meeting.

INFECTED BLOOD INQUIRY

3.2. Dr Raine gave a statement regarding the Infected Blood Inquiry, the report of which was published on Monday 20th May. The Board noted that the government will study the report and its recommendations in great detail, before returning to parliament with a full and considered response.

Action 121: Review the recommendations from the Infected Blood Inquiry and consider how the Agency can take action on these recommendations.

ExCo

AGENCY PERFORMANCE

4. Item 5: What are the most important current activities and priorities from the CEO's point of view?

4.1. Dr June Raine presented the Chief Executive's monthly report, which covered the following:

(i) **Science, Research and Innovation** – including updates on Control testing for blood safety; antimicrobial resistance; pandemic preparedness; a golimumab international standard; reference materials; quality assurance of biological medicines; the NHS Chief Scientist Office Knowledge Transfer Partnership; metrology in chemistry and biology; the microbiological society; Next Generation Organ-on-a-Chip Technologies grant funding; cell therapies; the UK Stem Cell Bank; and quality management systems;

(ii) **Healthcare access** – including updates on Cabotegravir for PrEP; fosdenopterin for molybdenum cofactor deficiency; established medicines performance; the International Recognition Procedure; borderlines; the MHRA's strategic approach to AI; Digital Mental Health Technologies; and in vitro diagnostics;

(iii) **Patient Safety** – including updates on montelukast and neuropsychiatric adverse reactions; finasteride and psychiatric and sexual side effects; Hormone Replacement Therapy; Patient Safety Monitoring; Benefit Risk Evaluation; Safety enquiries; and the Clinical Practice Research Datalink;

(iv) **Partnerships** – including updates on the Clinical Trials Regulations; Point of Care Manufacture; the Windsor Framework; and National and international liaison;

(v) **Patient involvement** – including an update on cancer immunotherapy vaccines;

(vi) **Digital and technology** – including updates on cyber security; RegulatoryConnect; and knowledge and information management;

(vii) **Dynamic organisation** – including updates on the Business Plan 2024/25; Return to Green; the MHRA core performance script; Freedom of Information requests; and

(viii) **Financial sustainability –** including an update on the new Public Contract Regulations training.

4.2. The Board thanked Dr Raine for her report and provided comments relating cancer vaccines; the AI strategy; new regulations; the Infected Blood Inquiry; antimicrobial resistance; feeding back to Yellow Card reporters; and transparency of communications.

5. Item 6: What was the financial and people performance of the MHRA for this year up to 31 March 2024?

5.1. The Board considered a report describing the financial and HR performance of the MHRA for this year up to 31 March 2024. The Board noted the report and provided comments relating to optimism bias; delivery of core deliverables; strategic workforce planning; Return to Green; resourcing; and the Agency's scientific advice model.

Action 122: Present the Agency's strategic workforce plan to the Board.
Liz Booth

Action 123: Prepare an update for the Board on scientific advice activities around the Agency. ***Julian Beach***

6. Item 7: How effectively is the MHRA addressing performance on established medicines, and how will a sustainable established medicines function be established?

6.1. The Board considered a paper describing how the Agency is addressing performance on established medicines. Progress had been made to clear backlogs, review resource requirements and amend processes. The Board noted the progress made with thanks, and provided comments related to resourcing; flexibility of the workforce; and recruitment.

PATIENT SAFETY

7. Item 8: What is the Criminal Enforcement Unit's approach to identification, prioritisation and reduction of the threat posed by the illegal trade in human medicines?

7.1. Andy Morling joined the meeting in person and presented a paper describing the Criminal Enforcement Unit (CEU)'s approach to identification, prioritisation and reduction of the threat posed by the illegal trade in human medicines. The Board considered the paper and provided comments related to the availability of medicines online; use of technology to address this issue; Artificial Intelligence; working across government to understand these threats; working with the National Cyber Security Centre; communication; working with international partners; and development of a global solution.

SCIENCE, RESEARCH & INNOVATION

8. Item 9: How will the new legislation strengthen the safety of medical devices?

8.1. Dr Laura Squire and Joseph Burt joined for this and the following agenda item. The Board noted that the MHRA is delivering a programme of changes to the Medical Device Regulations of 2002. This will take the form of a series of statutory instruments, in parallel with stakeholder engagement, as set out in

our recently published Roadmap. This will strengthen the safety of medical devices. The Board considered the paper and provided comments relating to the importance of traceability of devices; improving the data quality of electronic patient health records; working with other international regulators; and international recognition.

9. Item 10: How will the regulation of in vitro diagnostics change to support safe access to these innovative products and how will wider engagement take place?

9.1. The Board considered a paper describing how the MHRA is addressing the particular challenges of regulating in-vitro diagnostics (IVDs); and the Agency's IVD Strategy, which describes the Agency's approach to exploiting the strengths of the UK diagnostics sector to facilitate access to high quality IVDs for patients and the public.

9.2. The Board provided comments relating to the importance of demographics and genetics in AI in relation to medical devices and machine learning; application of responsible AI frameworks; applying an appropriate level of regulation and use of guidance to avoid over-regulation leading to stifling of innovation; the wellness field; intended purpose; education for patients and healthcare professionals; the UK's capacity for batch testing; and utilisation of trusted advisor groups. The Board thanked Dr Squire and Mr Burt for this important work.

ASSURANCE

10. Item 11: What assurance can be provided by the Patient Safety and Engagement Committee?

10.1. The Board considered an assurance report from the Patient Safety and Engagement Committee (PSEC). The PSEC met on 9 May 2024 and discussed the findings from the evaluation of the Patient Involvement Strategy, and how the Agency is going to effectively contribute to the UK Electronic Patient Information (ePI) Task Force. The Board considered the report and provided comments relating to the MHRA website noting that this is causing an issue; digitisation; issuing regulatory information; and the NHS app. An action was taken to review the MHRA website and options to improve this. The Board noted the report for assurance with thanks.

Action 124: Bring an update to the Board on the MHRA website and options to improve this. ***Rachel Bosworth***

11. Item 12: What assurance can be provided by the Audit & Risk Assurance Committee?

11.1. The Board considered an assurance report from the Audit and Risk Assurance Committee (ARAC). The ARAC met on 24 April 2024 for assurance

that all the necessary work needed to ensure that the Agency submits its annual report and financial statements to Parliament in accordance with the statutory timetable is progressing as planned. The Board noted the report for assurance with thanks.

EXTERNAL PERSPECTIVE

12. Item 13: What questions do members of the public have for the MHRA Board?

12.1. The Board answered a range of questions which had been submitted by members of the public before and during the meeting. These questions concerned the Clozapine safety review; and the MHRA's performance in relation to clinical trials.

ANY OTHER BUSINESS

13.1 No items of other business were raised and the Chair closed the meeting.

ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 21 May 2024

The actions highlighted in red are due this month

Action Number	Action	Owner	Date	Status
Carried Forward from previous meetings				
29	16/03/21: Present an Agency Science Strategy to the Board. 15/11/22: Revise the Science Strategy to include clear prioritisation; and greater inclusion of in-house expertise on behavioural science with a complementary expert group. Include vaccines work as a specific area of expertise, alongside biologics and the UK Stem Cell Bank, to create a distinctive offering to make the UK an internationally recognised centre of excellence in this field. A review of scientific committees should also be undertaken. Present a further update to the Board in March 2023. 21/03/2023: Science Strategy to be presented to the Board in July. 11/07/23: Present an update to the Board on progress against each of the themes in the Science Strategy at the end of 2023.	~~Marc Bailey~~ Nicola Rose	~~21/09/21~~ ~~16/11/21~~ ~~17/05/22~~ ~~15/11/22~~ ~~21/03/23~~ ~~11/07/23~~ ~~12/12/23~~ 17/09/24	
70	18/01/22: Develop and present a Data Strategy to the Board.	Alison Cave & Claire Harrison	~~17/05/22~~ ~~18/10/22~~ ~~15/11/22~~ ~~18/04/23~~ ~~12/12/23~~ ~~19/03/24~~ 09/07/24	
73	15/02/22: Develop a Sustainability Strategy.	Glenn Wells	~~17/01/23~~ ~~16/01/24~~ ~~19/03/24~~ 09/07/24	
101	11/07/23: Action: Present an update to the Board on the performance and proactive communications and engagement activities related to clinical trials which will maintain	Marc Bailey	~~21/11/23~~ ~~16/01/24~~ 09/07/24	

	trust in the Agency from industry and research customers. 19/09/23: Provide an update to the Board in November 2023 on the progress of the new clinical trial process pilot. Prepare a plan for training and upskilling of staff to increase resilience across the Agency. 21/11/23: Provide the Board with an update on the new proposed Clinical Trials process. Undertake a review of any other backlogs in the Agency. 16/01/24: Present a paper to the Board containing operational detail including a clearly defined budget; how this is resourced (skill and headcount); and demand estimation over the next year and beyond. 19/03/24: Explore developing a model for a clinical trial hub and lead coordinator.			
104	19/09/23: Develop a reputation strategy for the Agency with reputation index measures.	Rachel Bosworth	~~21/11/23~~ ~~19/03/24~~ 09/07/24	
106	21/11/23: Provide the Board with an update on the work of the Criminal Enforcement Unit. 16/01/24: The enforcement strategy should be reviewed in light of the Windsor Framework and the Falsified Medicines Directive.	Alison Cave	21/05/24	On agenda
108	21/11/23: Provide the Board with an update on the Trusted Research Environment	Alison Cave	~~19/03/24~~ 09/07/24	
110	21/11/23: Provide a further update on the progress of the Health, Safety & Wellbeing Strategy to the Board.	~~Marc Bailey~~ Nicola Rose	21/05/24	
111	16/01/24: The budget and financial reporting should be linked to the Agency's statutory functions in the Performance Report. Provide the Board with further details on the decrease in CPRD income.	Rose Braithwaite	21/05/24	On agenda

114	19/03/24: Deliver an operating model for established medicines which will deliver sustained performance.	Julian Beach	21/05/24	On agenda
117	19/03/24: Provide an update on innovation pathways to future Board meeting.	James Pound	09/07/24	
118	19/03/24: Additional work on Raising Concerns Champions to be carried out with Mercy Jeyasingham.	Liz Booth	21/05/24	
119	19/03/24: Undertake a review of long-term sickness rates.	Liz Booth	21/05/24	
120	19/03/24: Create a feedback survey for Board effectiveness, including external stakeholders.	Liz Booth	09/07/24	
New Actions				
121	21/05/24: Review the recommendations from the Infected Blood Inquiry and consider how the Agency can take action on these recommendations	ExCo	18/06/24	
122	21/05/24: Present the Agency's strategic workforce plan to the Board	Liz Booth	18/06/24	
123	21/05/24: Prepare an update for the Board on scientific advice activities around the Agency	Julian Beach	17/09/24	
124	21/05/24: Bring an update to the Board on the MHRA website and options to improve this.	Rachel Bosworth	09/07/24	

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

09 July 2024

Title	**What are the most important current activities and priorities from the CEO's point of view?**
Board Sponsor	June Raine
Purpose of Paper	Context

What are the most important current activities and priorities from the CEO's point of view?

'TOP 10' HEADLINES

- Eliminating the original backlog of established medicines applications at present progress is expected to be achieved by end of September, and variations by December
- A new regulatory pathway for individualised medicines for rare diseases and cancers is in preparation, with draft guidance and a consultation on our approach by end of 2024
- We continue to share data with partners including the National Institute for Health and Care Excellence (with permission) to ensure speedier access to medicines for patients
- Following Infected Blood Inquiry recommendations, we plan to promote the Yellow Card Scheme facilitating patients to report adverse events for biologicals and blood products
- Following a review of Nordic data, the migraine and antiseizure medication topiramate must no longer be prescribed to women unless on a Pregnancy Prevention Programme
- Following the launch of the regulatory sandbox for AI, the Agency is working with international regulators to inform the guiding principles for transparency in the use of AI
- As a result of a Criminal Enforcement Unit investigation a defendant was sentenced to imprisonment for their part in the supply of unauthorised medicinal products
- Strengthening Health and Safety provisions remains a priority - we provided the Health and Safety Executive with full information on the actions taken in response to their letter
- Work is progressing on updating guidance following the passing of the Windsor Framework, with the implementation of the framework due at the beginning of 2025
- The Agency's annual culture and pulse survey is under way to help us understand the impact of current activities to shape an enabling culture, and what else needs to happen.

SCIENCE AND RESEARCH

Pandemic preparedness

1.1 A new Coalition for Epidemic Preparedness Innovations (CEPI) service order has been signed to support the storage and distribution of a new adjuvant library. The establishment of the CEPI adjuvant library is in support of the achieving the 100 Days Mission goals and aims to enable match making of optimal adjuvants for vaccines candidates and to facilitate their availability. This library will be managed by the research reagent repository at the MHRA Science Campus initially for 2 years and will be key to generate new combinations of adjuvants and immunogens which will be assessed by vaccine manufacturers and animal testing facilities, through compatibility and immunogenicity studies.

Centre for Infectious Diseases Reagents

1.2 A grant agreement has been signed with the UK Vaccine Network (UKVN) to establish the Centre for Infectious Diseases reagents (CIDR). This initiative, supported by UKVN for the next 4 years, will be built as an expansion of the current research reagent repository at the Science Campus (the Centre for AIDS Reagents) and covers new emerging viral pathogens in order to increase pandemic and epidemic preparedness.

Quality assurance of biological medicines

1.3 The Control Testing team presented at the Windsor Framework Engagement meeting that was organised by the Partnerships team in June. A guidance document for manufacturers of biologicals has been written and cleared. The Control Testing guidance will be amongst the first Windsor Framework documents to be published by the Agency. From January 2025, the implementation of the Windsor Framework will result in more vaccines, blood products and plasma pools requiring independent control testing and certification.

Assay development and harmonisation

1.4 Our scientists led a joint WHO-MHRA-Imperial College London training workshop for Direct Detection and Nanopore Sequencing, held at the Science Campus. This was attended by representatives of WHO Polio Laboratories from Ukraine, France, Netherlands, Italy, France and Germany. This is part of our work funded by a grant from the Bill and Melinda Gates Foundation (BMGF) aimed at reducing the time between a clinical/environmental sample reaching a WHO laboratory and a poliovirus sequence being determined so we can respond to polio outbreaks quicker and help completing global polio eradication. Our scientists often travel to WHO laboratories around the world to help in establishing this technology locally.

Multiplex immunoassay study

1.5 A paper has been published on an Interlaboratory comparison of a multiplex immunoassay that measures human serum IgG antibodies against six-group B streptococcus (GBS) polysaccharides. The study was funded by the BMGF to the GBS Consortium, of which MHRA is a member, for the development of sero-correlates of protection assays to be used to facilitate the licensing of GBS vaccines for pregnant women, in order to protect newborns against GBS diseases. The MHRA team was responsible for preparing and qualifying the GBS polysaccharides-Polylysine conjugates that were used as the antigens in the assay.

Crimean-Congo Haemorrhagic Fever Virus

1.6 Crimean-Congo Haemorrhagic Fever Virus (CCHFV) causes haemorrhagic fever with a high fatality rate. CCHFV is a WHO priority pathogen and there are currently no approved vaccines. This study used convalescent serum to investigate protective serum responses. Further characterisation of the serological reactivities within these samples will establish their value as reference materials to support assay harmonisation and accelerate vaccine development for CCHFV.

Health and Safety

1.7 The new Health and Safety Executive inspector for the South Mimms site attended a those in support roles. Staff working in the biocontainment laboratories at the Science Campus introduced themselves and provided an overview of their work. The Inspector found the day to be very useful and gained a wider understanding of the Science Campus activities and the layout of the facility.

Freeze driers

1.8 Projects are under way to address the cyber risk associated with the computational interface on our freeze driers. Phase I addressed a single freeze drier in the year 2023/24. Phase II mitigates cyber risk on the interface of the remaining freeze-driers. The tender for this work closed in June with the project on track.

Visiting students

1.9 The Science Campus hosted a visit by medical students from Birmingham University and their professor. Following an introductory talk on the role of Science & Research in the MHRA by the Interim Executive Director, the students visited various laboratory facilities across the site, where they engaged with scientific staff to find out about their regulatory science activities including biological standards with reference to emerging diseases and pandemic response; antimicrobial resistance; the role of the MHRA WHO laboratory for influenza; the UK Stem Cell Bank and the physico-chemical analysis of biologicals. Colleagues from HQA gave a talk and held an engaging Q&A session on the future medical device regulations.

HEALTHCARE ACCESS

Established medicines

2.1 Sustained progress continues to be made to reduce the backlog of marketing authorisation applications for established medicines. This comprises applications under a range of legal bases, approximately 60% of which are generic applications. The clearance trajectory has been replanned and reflects elimination of the overall backlog by the end of December 2024 latest. This month the focus is on completing first assessments to ensure that sufficient work is moving through the system to achieve clearance of the original backlog by the end of September 2024. As of 1st July, Type 1B variations outside statutory timelines are expected to be cleared by the end of July 2024. For Type II variations outside statutory timelines, the expected clearance date for these is the end of December 2024 as these involve greater complexity. Key interventions include reallocation of designated resources supported by regular ‘clinic’ meetings and offering assessors overtime. Work is underway to make use of existing professional services.

International recognition procedure

2.2 Applications via the International Recognition Procedure (IRP) continue to successfully meet statutory timeframes, with decisions on Route A applications being determined at a median of 57 days. We have approved three Route B applications involving non-EU regulators, none of which has required referral for CHM advice. An internal audit is currently under way to review the IRP process. Initial findings from the audit have highlighted the critical importance of closely monitoring the time from validation to allocation. The audit report is scheduled for completion by the end of July and will include suggestions for process improvement.

Personalised medicines

2.3 A number of highly personalised therapies are under development for cancer and very rare diseases. Each medicine is matched to the patient’s individual genetic profile, presenting new regulatory challenges. A platform approach is envisaged whereby an approval is granted for the proprietary product platform, supported by quality, safety and efficacy data. Initially the focus will be on individualised mRNA cancer immunotherapies (known as ‘cancer vaccines’) which are in late-stage clinical development, and this work lays important groundwork for rare disease therapies. We aim to consult stakeholders on draft guidance for developers by the end of 2024. This will cover regulatory classification, tumour sampling, mutation selection,

manufacturing, batch testing, non-clinical and clinical data requirements, risk management and post-marketing safety surveillance. We have convened the Highly Personalised Medicines Expert Working Group to provide advice on the scientific aspects.

International Council for Harmonisation

2.4 During June 6 MHRA representatives supported the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, developing standards in critical areas which the Agency will use in topics ranging from Clinical Trial Design, and Pharmaceutical Development to Real World Data. Our application to join the ICH Management Committee of the organisation received broad support from all regulators but was ultimately unsuccessful as we had not attended sufficient meetings in person. We believe our input was instrumental in all the topics under discussion, in reaching pragmatic guidance for development and implementation.

Machine learning medical devices

2.5 Our series of trilateral publications with MHRA, the US FDA and Health Canada continues this month with our publication on the guiding principles for Transparency for machine learning (AI) enabled medical devices.

In Vitro Diagnostics

2.6 The International Medical Device Regulators Forum (IMDRF) working group for Clinical Evidence of In Vitro Diagnostics (IVDs) was launched during June. The working group brings together several regulators and the WHO to harmonise and update the definitions, approaches and evidence required for clinical evaluation studies of IVD devices. The UK and EU are co-chairs of the working group. Through this working group, harmonised guidance will be updated that enables regulators to assess clinical evidence required for IVD performance studies across country jurisdictions, especially for studies that cross multiple regulatory jurisdictions.

PATIENT SAFETY

Topiramate and harms in pregnancy

3.1 A review into the safety of topiramate, an antiseizure medicine also indicated for migraine, has found that the use of topiramate during pregnancy is associated with significant harm to the unborn child. Harms included a higher risk of congenital malformation, low birth weight and a potential increased risk of intellectual disability, autistic spectrum disorder and attention deficit hyperactivity disorder in children. Topiramate is therefore now contraindicated in pregnancy and in women of childbearing potential unless the conditions of a Pregnancy Prevention Programme are fulfilled. Patients and healthcare professionals are encouraged to report suspected adverse drug reactions associated with topiramate to the Yellow Card scheme.

Topical Corticosteroids and withdrawal reactions

3.2 Following our previous review in 2021 we continue to receive reports and concerns from patients regarding reactions associated with topical corticosteroids and their withdrawal, particularly when used to treat eczema. We have reviewed information received since the last review and sought advice from the Commission on Human Medicines, with clinical experts in dermatology and representatives from dermatology charities being included in these discussions. We communicated on this in the May edition of Drug Safety Update and information on the potency of the topical steroid is now being introduced onto the product information to support the correct use of these medicines.

SafetyConnect system

3.3 On 28th May the second phase of the SafetyConnect programme went live, including our case management system. Reporting using the data platform went live on 22nd May for legacy data. This substantial milestone included complex activities to ensure backward-forward conversion between legacy and current ICH standards, interoperability with pharmaceutical industry systems and data migration activities for over 12.5 million cases and associated documents. These systems provide a platform to significantly enhance our vigilance capability for all medicinal products, both medicines and medical devices, now and into the future.

CPRD ethnicity records uptake

3.4 The CPRD Ethnicity Records were launched in May 2023 and comprise a single derived ethnicity category for each patient. The CPRD Ethnicity Records draw ethnicity data from the primary care databases and, for linkage eligible patients, Hospital Episode Statistics datasets. Since May 2023 they have been released quarterly in September 2023, December 2023, March 2024, and June 2024 and have been requested in 79 research protocols (some of which are currently under review) and released for 36 studies. These are currently our most requested algorithm-derived data.

Fastest CPRD validation study

3.5 The CPRD interventional research (IR) team has just completed the fastest ever PROVE study using IR digital platforms. This was a GP validation study which used our IR services and the new DART platform to invite GPs to validate diagnoses of narcolepsy and obstructive sleep apnoea recorded in the electronic health records as part of a wider observational study. The target of 242 responses was reached in 9 weeks from the first practice being activated and involved 73 GP practices out of the 100 practices initially invited to participate. The speed of response was also helped by incentivising practices for completion. For comparison, previous PROVE studies typically ran for 14 weeks and frequently did not hit target number of responses.

Criminal Enforcement Unit interventions

3.6 Following a Criminal Enforcement Unit (CEU) investigation and subsequent trial at Southwark Crown Court, a defendant was sentenced to imprisonment for their part in the supply of unauthorised medicinal products and the possession of Class C Controlled Drugs with the intent to supply. The defendant was found guilty on 16 related indictments. Working in partnership with the UK Border Force, the month of June saw two periods of intensification of tackling medicines trafficking at UK ports. These operations resulted in the seizure of almost 200,000 doses of illegally traded medicines, a new criminal investigation and valuable intelligence. This partnership working included a deployment at Dover ferry port, a first for the CEU which enabled the gathering of valuable strategic intelligence into the importation of medicines through such routes.

Criminal enforcement IT system

3.7 The CEU's new intelligence and case management solution, Clue, has now fully transitioned into the live state. All teams are using the system effectively and positive feedback has been received from users. A monthly stakeholder group chaired by the CEU Business Lead has now been established to track post implementation progress and assess and approve any future changes to the system. The group includes the Clue Customer Success Manager who will work with the MHRA to ensure continued success in the post implementation phase.

PARTNERSHIPS

Data sharing

4.1 We continue to share information with NICE and other health system partners (with permission) in order to minimise delays in patient access to new treatments by facilitating partners' processes, leading to better access for patients. This supports the MHRA commitments to the Life Sciences missions, particularly on new innovative drugs. The team is also working with the Innovative Licensing Access Pathway (ILAP) project to ensure that best practice on information sharing is spread throughout MHRA activities.

International partnerships

4.2 The International Team provided extensive support for the Access Consortium Heads of Agencies' Annual Meeting (Australia, Canada, Singapore and Switzerland). The MHRA has established a new working group on Clinical Trials with the aim of developing common approaches to key aspects with the potential for a joint scientific advice offer. The MHRA has also developed a new website for the Consortium and further work is to be done to improve its usability.

General election planning

4.3 Our regulatory policy team has had to pivot away from activities such policy development and pushing forward our regulatory reform programme, and instead provide support to election planning activities working closely with DHSC teams.

Windsor framework

4.4 We have continued to engage with DHSC and the pharmaceutical industry on the implementation of the Windsor Framework by January 2025. Work is progressing on the Windsor Framework across the Agency, reviewing and updating all guidance, with significant updates in the areas of licensing, pharmacovigilance, labelling, wholesale dealing, distribution and falsified medicines.

DIGITAL AND TECHNOLOGY

Cyber security

5.1 The MHRA's latest cyber audit has just been completed. The Data Security and Protection Toolkit is a mandatory annual audit set out by the DHSC and NHSE Joint Security Unit. This year's rating for our cyber security is 'moderate'. The MHRA has close relationships with the National Cyber Security Centre (NCSC), the DHSC/NCSC Joint Cyber Unit, and the NHSE Cyber Operations Team; and liaises frequently with these bodies. Since early 2024 we have also regularly liaised with cyber departments in international organisations.

Clinical Trials

5.2 In addition to RegulatoryConnect, work is progressing on Clinical Trials. The team is focussing on the Regulations and Guidance and implications for business processes which will drive out the requirements needed for a change request. Engagement continues with the Health Research Authority to manage dependencies and user experience. In addition, the team is developing AI 'use cases' to optimise efficiency for the business. The work to embed query tools to support performance reporting will be instrumental in being able to readily share and respond to performance data.

RegulatoryConnect

5.3 We continue to work with the Programme team to support the replanning activities and options analysis for Release 2 of RegulatoryConnect. This includes input into the scope and plans needed for a fully costed delivery of the licensing pathway and data migration. We are also currently evaluating the feasibility of an in-house development of the RegulatoryConnect functionality in support of Release 2 delivery.

Hemovigilance

5.4 Following testing, the integration work is now progressing on the Hemovigilance system. Once this work has concluded, data migration can commence. Demonstrations continue to take place with the business and a further demonstration of the Vigilance Hub is to be scheduled over the coming weeks. User Acceptance Testing is expected to start on 3rd July, with the data migration happening in parallel on 10th July. The current Go Live date is planned for 13th August 2024.

DYNAMIC ORGANISATION

Return to Green

6.1 The Return to Green Programme continues to monitor progress with clearance of backlogs and identify business process changes. The last month has seen a steady decrease in backlogs in line with plans. We continue to look for interventions as to how clearance dates may be brought forward. All new work in the variations area is meeting statutory timelines. Plans are also being developed to address backlogs in key areas of scientific advice. A business case for additional resource to support clearance plans and how these might be escalated is in development.

All Staff Meeting

6.2 Following on from our People Survey Action Plan, our recent All Staff Meeting focussed on wellbeing and how to raise concerns. Our wellbeing lead reminded colleagues of the variety of excellent wellbeing support we have, including a new additional counselling service, and reflected on the early feedback from our quarterly wellbeing survey which will be considered by the Executive Team in August. The profile of our 'raising concerns' scheme was raised by Mercy Jeyasingham who, as Champion, also filmed a short video to highlight the importance of speaking up. Colleagues asked a wide variety of questions, from office attendance to the redevelopment of the Science Campus. The increasing number and range of questions for the Executive team in this forum is welcomed.

One Agency Leadership Group

6.3 At our One Agency Leadership Group (OALG) meeting, which is the senior leadership of the organisation, our DHSC sponsor gave some insight and reflections on the impact of the General Election and its aftermath on the delivery of civil service business and answered a range of questions from colleagues. We followed this with a brief discussion session about the likely impacts on the MHRA of the various political manifestos. Our technical update this month was on the challenges of regulating mNRA cancer therapies.

Culture survey

6.4 This month we launched our culture survey, which will give us fresh data to gauge how the People Survey action plan and culture action plan are impacting on colleague engagement. The results of the survey will be considered by OALG once available.

AGENCY PRIORITIES

In summary, the current priorities for the Agency are to:

I. Maintain the Agency's overarching focus on delivering its core business activities, meeting targets for all key services and ensuring risk proportionality via new ways of working

II. Further develop our sustainable business model through revision of our fees based on the results of activity recording

III. Continue to invest in our technology systems to improve the tools used by our staff and the services for our customers and patients

IV. Focus on optimising the Health and Safety measures for our staff undertaking laboratory work at the Science Campus, and ensure the appropriateness of the H&S 'model' as our science strategy is implemented

V. Continue to collaborate with our national partners in healthcare and with international regulators, in particular on our approaches to new regulatory frameworks.

Dr June Raine, CEO
July 2024

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

9th July 2024

Title	What are the financial and people performance of the MHRA in May 2024?
Board Sponsor	Rose Braithwaite
Purpose of Paper	Assurance

What was the financial and people performance of the MHRA in May 2024?

1. Executive Summary

1.1 The Agency finished May (Period 2) with a small year-to-date (YTD) resource surplus of £1.2m compared to budget, driven by underspends in pay and non-pay costs making up for slightly below budget income in month. Capital spend was £0.3m behind profiled budget.

1.2 While the YTD results show a small resource surplus, it is usual for costs to be lower at the start of the year and then increase towards budget later in the year. This means that lower trading income could be an emerging risk for the Agency's overall financial position and will need to be monitored closely. The Q1 forecast planned for July will be an important exercise to firm up our view of the full year's operating position, and to consider saving and spending decisions to ensure the Agency stays within its financial envelope.

2. Introduction and Background

AGENCY PERFORMANCE – RESOURCE

Income

2.1 The Agency receives most of its funding from trading income realised in the performance of its Regulatory obligations, supplemented by direct funding from its sponsor department, the Department for Health and Social Care (DHSC).

2.2 The YTD trading income position is £0.5m (3%) under budget. Although some of this may be recovered in future months we will monitor it closely. A clearer position will emerge from the Q1 forecast after three months' worth of data is available.

2.3 In May, HQA Licensing income was slightly above budget, which is encouraging given the higher budget set that reflect the aimed reductions of backlogs and deferred revenue. Innovation and Compliance income was under budget because of low Inspections income, which tends to be low at the beginning of a quarter as invoicing and income recognition peaks at the end of a quarter.

2.4 Trading income in Safety and Surveillance was slightly lower than budget. Science and Research was significantly below budget because of a slower than anticipated start in the sale of standards during the flu season and low grant income.

Table 1 - Agency Financial performance to the end of May 2024

Finance Report — May 2024

May 2024 Resource	Period Actual £M	Period Budget £M	Variance vs Budget % / £M	YTD Actual £M	YTD Budget £M	Variance vs Budget % / £M	Full Year Budget £M
Trading Income	8.7	8.6	2%	16.5	17.0	(3%)	100.5
Service Fee Income	3.8	3.8	0%	7.5	7.5	0%	45.0
Grant Income	0.3	0.6	(52%)	0.5	1.1	(58%)	5.9
Staff Costs	8.1	8.3	2%	15.9	16.6	4%	103.5
Operating Costs	5.2	5.4	4%	9.5	11.2	16%	68.8
Operating Net Position	**(0.6)**	**(0.9)**	**0.2**	**(0.8)**	**(2.2)**	**1.3**	**(20.9)**
Staff Costs	0.2	0.1	(23%)	0.3	0.3	12%	1.8
Projects Costs	0.7	0.9	15%	1.8	1.6	(12%)	11.8
Projects Net Position	**(0.9)**	**(1.0)**	**0.1**	**(2.1)**	**(1.9)**	**(0.2)**	**(13.6)**
Agency Resource Net Position	**(1.5)**	**(1.9)**	**0.3**	**(2.9)**	**(4.1)**	**1.2**	**(34.5)**
DH RDEL Operational Funding	2.9	2.9	0%	5.8	5.8	0%	34.5
Total RDEL	**1.4**	**1.0**	**0.3**	**2.8**	**1.7**	**1.2**	**0.0**

Staff Costs

2.5 Staff costs in May were £8.1m, £0.2m (2%) behind budget. Although a number of roles, either approved in the 2024/25 budget or in the baseline remain vacant, the vacancy rate assumption means the overall underspend is small. We expect the underspend to disappear as joiners fill vacant roles.

Non-Pay Costs

2.6 Spend on other operating costs in May was £5.2m, £0.2m (4%) lower than the £5.4m monthly budget. The YTD position shows a higher underspend of £1.7m (16%). Areas of material underspend are contracted-out services in HQA, which has a dedicated budget for external support to reduce backlogs, and accommodation costs in Corporate. Both of these are expected to increase spend over the coming months which should drive overall non-pay costs towards budget.

Project Resource Expenditure

2.7 May project costs were slightly above budget because of an overspend in the Regulatory Connect project. The project team is reviewing plans to make sure that monthly budget profiles and spend classifications (resource v capital spend) are correct.

AGENCY PERFORMANCE – CAPITAL

Table 2 – Capital spend to the end of May 2024

May 2024 Capital	Period Actual £M	Period Budget £M	Variance vs Budget % / £M	YTD Actual £M	YTD Budget £M	Variance vs Budget % / £M	Full Year Budget £M
Projects Costs	1.1	1.8	38%	2.9	3.4	16%	19.5
CDEL Operational Costs	(0.2)	0.1	241%	0.4	0.1	(191%)	6.0
Agency Capital Net Position	**(0.9)**	**(1.9)**	**1.0**	**(3.3)**	**(3.6)**	**0.3**	**(25.5)**
DH Capital Funding	1.4	1.9	(25%)	3.6	3.6	0%	25.5
Total CDEL	**0.5**	**0.0**	**0.5**	**0.3**	**0.0**	**0.3**	**0.0**

2.8 All of the capital budget has to be provided either by DHSC or from other Government Departments via the Commissioner Pays model which allows for the transfer of capital budget between departments. The Agency has a full year capital budget of £25.5m. Although capital spend in May was significantly under budget, the YTD position is a small £0.3m underspend.

2.9 The largest capital project is Regulatory Connect, with a budget of £14.1m. Spend in May was considerably behind budget and drives the overall May result.

2.10 The South Mimms Capital Programme is the second largest capital investment area for the Agency, with a budget of £6m. Spend in South Mimms is planned for later in the year.

3 People Performance May 2024

3.1 We had 1,311.77 people in post at the end of May 2024 (FTE, permanent, fixed term and PhD students covering established posts). Of this number, 157.25 were fixed term, an increase of 6 FTE on April.

Turnover

3.2 Turnover of staff has fallen marginally at 7.8% from 7.9% reported for April. Whilst this rate is comparatively low, it is reflective of the large number of relatively new joiners the Agency has welcomed in the last two years in particular and brings much needed stability to our Groups and Functions

3.3 Despite a challenging employment market for all sectors, we continue to see an increase in the number of joiners versus leavers, reflected in our turnover. We welcomed 19 new starters to the Agency in May versus 11 voluntary leavers.

3.4 The Board asked in June about the grades of leavers. The following table shows joiners and leavers over the first two month of the financial year by grade to provide this information.

Grade	Starters v Leavers	April 2024	May 2024
AO	Starters	1	0
	Leavers	**0**	**1**
EO	Starters	7	5
	Leavers	**4**	**2**
HEO	Starters	3	1
	Leavers	**2**	**2**
SEO	Starters	5	5
	Leavers	**0**	**3**
G7	Starters	5	6
	Leavers	**2**	**1**
G6	Starters	2	1
	Leavers	**2**	**1**
SCS1	Starters	2	1
	Leavers	**0**	**1**
Total	Starters	25	19
	Leavers	12	11

Vacancies

3.5 In respect of our 137 ‘vacancies’ (an increase on the 109 reported for April) these are split by Group as follows:

Group	Vacancies	% vacancies FTE
Corporate	8	7.3%
D&T	16	14.4%
Enablement	11	11.6%
HQ&A	42	10.9%
Partnerships	2	7.2%
S&S	26	8.7%
SR&I	32	10.8%
Total	**137**	**10.4%**

3.6 True vacancies will include any role in Oracle Fusion that is pending recruitment. Where staff have one month’s notice (grades up to SEO) this can mean a gap/vacancy pending the recruitment of a replacement. Grades G7 and above have a three month notice period, reducing the potential gap between leaver and new joiner, and this will be reflected in our vacancy calculation.

3.7 Sickness absence (annualised) has decreased to 5.7 days per FTE compared to 6.3 reported for April. Typically, we would expect to see fluctuations in absence levels over the winter and spring months, and level off as summer approaches. Civil service absence statistics reported in February 2024 reported average absence to be 8.1 days.

3.8 Absence related to stress/depression remains the highest reported reason at 34% of all absence in the Agency. Civil Service statistics report that mental

health related absence in the wider civil service is the largest cause of long-term absence, at 45%. Lowest levels of absence are reported for London, and it should be noted that just under half of civil servants (49%) took no absence at all.

3.9 By Group the sickness absence data is as below:

Group	Average days by FTE
Corporate	9.1
D&T	4.1
Enablement	6.8
HQ&A	5.3
Partnerships	2.1
S&S	5.3
SR&I	6.0
Total	**5.7**

3.10 Corporate Group continues to report the highest levels of absence in the Agency, which includes the Commercial, Finance, HR and Infrastructure & Laboratory Services functions. Absence has fallen in all Groups except Enablement (Communications and Engagement, Governance and Strategic which saw an increase compared to April, and D&T, which has remained the same. The long and short term split by Group is not given as it could inadvertently identify colleagues, particularly in the smaller Groups or where absence is attributable to one person. Particularly in the smaller Groups and in Functions, the long-term absence of one person can skew the absence rates significantly.

4 Group Performance

Science and Research

£'000s	Period			YTD			Full Year
	Actual	Budget	Variance	Actual	Budget	Variance	Budget
Trading Income	2,020	2,466	(446)	3,815	4,789	(974)	25,052
Staff Costs	1,347	1,244	(103)	2,661	2,488	(173)	15,542
Non-Staff Costs	428	614	187	1,002	1,236	235	6,205
Operating Position	**246**	**608**	**(362)**	**151**	**1,064**	**(913)**	**3,305**

4.1 The overall operating position shows a YTD deficit of £0.9m, which is driven by low Trading income. Income is low in the Sale of Good and Products as Flu standard sales have not performed to budget, either because orders arrived earlier than expected and fell in the last financial year, or because of lower demand in this flu season. These are high value / low volume orders so changes in the number of orders have a material effect on income. Grant income is also significantly under budget because of slow recruitment and procurement spend, which is reflected in lower costs. We expect to recover some ground on grants later in the year.

4.2 Staff costs are slightly over budget but well within the vacancy rate. Non-Pay are below budget because of lower spend in Lab costs. These are lumpy, so we should see costs increase towards budget later in future months.

HQA

£'000s	Period			YTD			Full Year
	Actual	Budget	Variance	Actual	Budget	Variance	Budget
Trading Income	3,618	3,356	262	7,421	6,712	710	40,270
Staff Costs	1,910	1,987	77	3,675	3,974	299	24,888
Non-Staff Costs	233	672	439	257	1,343	1,087	4,477
Operating Position	**1,475**	**697**	**778**	**3,490**	**1,395**	**2,095**	**10,904**

4.3 HQA has YTD Trading income 11% above budget. This is good news for the Agency considering the ambitious budgets set to match the efforts to reduce backlogs. Areas where we have seen the most income generated include Complex and Standard National Applications, where much of our deferred revenue sits, and in Authorisation Lifecyle such as Labels and Leaflets and Tobacco products. However, two areas with slightly weaker performance are Variations and Major National Applications.

4.4 Staff costs are below budget as expected as a material element of the budget relates to new roles that need to be recruited.

4.5 Non staff costs are significantly underspent because of slower than budgeted spend for external contractors to help reduce backlogs. This is a timing variance as a number of spend commitments have now been agreed, so we expect spend to increase significantly over the next months. Overall, the non-pay underspend contributes to a positive operating position of £2m against budget.

Innovation and Compliance

£'000s	Period			YTD			Full Year
	Actual	Budget	Variance	Actual	Budget	Variance	Budget
Trading Income	1,295	1,600	(305)	2,560	3,199	(639)	20,799
Staff Costs	988	1,231	243	1,947	2,461	514	15,476
Non-Staff Costs	707	508	(198)	649	1,017	368	6,010
Operating Position	**(399)**	**(139)**	**(260)**	**(36)**	**(278)**	**243**	**(687)**

4.6 The overall operating position is positive. YTD trading income, however, is 20% behind budget. Most of the negative variance is from Inspections income, which tends to be low in the middle months of a quarter because of the invoicing schedule. GMP income is also forecast to be lower than budget because of loss of resource. We should see a more accurate picture of inspections income at the end of Q1.

4.7 Pay and non-Pay costs are significantly behind budget, more than making up for the loss in income. The Pay underspend is driven by vacancies. The Non-Pay underspend is a result of slower contracted-out spend in CIT and the Innovation Accelerator, but which should increase towards budget as the year progresses, and lower T&S costs in the Inspectorate.

Safety and Surveillance

£'000s	Period			YTD			Full Year
	Actual	Budget	Variance	Actual	Budget	Variance	Budget
Trading Income	1,931	1,572	359	2,977	3,144	(167)	18,865
Staff Costs	1,728	1,773	45	3,475	3,547	72	22,029
Non-Staff Costs	1,002	696	(306)	1,528	1,395	(133)	8,503
Operating Position	**(799)**	**(897)**	**98**	**(2,026)**	**(1,798)**	**(228)**	**(11,668)**

4.8 Although Safety and Surveillance's operating position is showing a small negative variance, this is probably a timing variance that will be corrected in future months. Trading income is only very slightly behind budget because of lower PL Variations income. CPRD Observational income is also behind budget, but income is projected to increase to budget later in the year. Other CPRD income lines and Grant income are performing well.

4.9 In terms of costs, there is a small pay underspend which should disappear later in the year as roles are filled. Non-Pay costs are slightly above budget, but again this is a timing variance in the use of contracted-out services. Overall costs should remain around budget.

Non-fee earning groups

4.10 We have a number of non-fee earning groups which directly support our fee-earning areas. These include Partnerships, Digital & Technology, Corporate and Enablement Groups. These form the basis of Agency corporate charges that, as in each year, will be shared across Agency operational areas to recognise where costs should be borne. Corporate allocations for 2024/25 are to be finalised for the Q1 report as we improve the allocation of costs per function.

4.11 Financial performance for each of the non-fee earning group is shown in the table below.

4.12 Enablement is operating under budget because of lower non-pay costs, such as Seminar, Advertising and Promotion and Committee costs. Spend across these categories tends to be lumpy so we expect these to be timing variances and that spend will increase to budget.

4.13 Partnerships has no income stream of its own. Costs are at budget with only small variances across pay and non-pay categories. The distribution of CERSI funds is expected later in the year.

		Period			YTD			Full Year
Corporate Overhead groups	**May-24**	**Actual**	**Budget**	**Variance**	**Actual**	**Budget**	**Variance**	**Budget**
Enablement	Trading Income	(16)	0	(16)	(9)	0	(9)	0
	Spend	627	950	323	1,581	1,901	320	**11,677**
	Operating Position	**612**	**950**	**307**	**1,572**	**1,901**	**311**	**11,677**
Partnerships	Trading Income	0	0	0	0	0	0	0
	Spend	114	186	72	382	373	(9)	**2,313**
	Operating Position	**114**	**186**	**72**	**382**	**373**	**(9)**	**2,313**
Corporate	Trading Income	3,757	3,754	3	7,501	7,508	(7)	45,054
	Spend	1,682	1,518	(164)	2,750	3,036	286	**19,122**
	Operating Position	**2,075**	**2,236**	**(161)**	**4,751**	**4,472**	**279**	**25,932**
D&T	Trading Income	116	117	(1)	214	233	(19)	1,400
	Spend	2,568	2,342	(225)	5,416	4,987	(429)	**36,092**
	Operating Position	**2,684**	**2,459**	**(226)**	**5,630**	**5,220**	**(448)**	**(34,692)**

4.14 Corporate has a small operating underspend because of lower accommodation costs. The periodic fee, which is the biggest single income stream, is being recognised in the management accounts in line with the budget. We have changed the process for collecting the periodic fee this year and invoicing under the new process will happen in later months. Accommodation costs are lower than budget in South Mimms because of utilities and building repairs and maintenance. These will mostly be timing variances as we tend to spend more on gas and electricity during winter months.

4.15 Digital and Technology's operating position is 9% overspent because of higher contracted-out services and IT Costs. Most of these are because of projects approved to be funded from the 2023/24 underspend, but which run over into the new year. These should be finished soon, so we expect D&T to perform to budget in future months.

5 Recommendations

5.1 The Board is asked to consider the assurance it gains from the financial data, in particular the income meeting budget levels, in the second month of the new financial year given the pressure within the budget.

5.2 The Board is asked to consider the HR data and the assurance that it provides on the resourcing of the Agency.

Rose Braithwaite
27th June 2024

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

9 July 2024

Title	**How well does the 2023/24 Annual Report and Accounts reflect the performance, governance and financial results of the MHRA over the last year?**
Board Sponsor	Carly McGurry
Purpose of Paper	Approval

How well does the 2023/24 Annual Report and Accounts reflect the performance, governance and financial results of the MHRA over the last year?

1. Executive Summary

1.1 The annual report and accounts for the Agency have been prepared in accordance with the relevant requirements and are subject to audit by the National Audit Office (NAO). The Executive Committee (ExCo) and the Audit and Risk Assurance Committee (ARAC) have both reviewed and approved the documents (on the 2 July 2024 and 5 July 2024 respectively). The Board is asked to approve the draft and advise the CEO as Accounting Officer to sign the report and accounts, prior to submission to the NAO for certification.

2. Introduction

2.1 Every year, MHRA, in keeping with other government bodies, has to lay an annual report and audited accounts in Parliament, in order to set out our performance throughout the year and account for our use of public funds (including those arising from charges to service users).

2.2 Over recent years, we have embarked on a programme of improvement to our annual report and accounts, to ensure that the report fulfils our obligation in a way that is transparent and user friendly, whether to a member of parliament or a member of the public, and that it gives a full account of all that the Agency has achieved over the last twelve months. Compilation of the document together is a significant undertaking, begun in December, and reliant upon all areas of the Agency to contribute the required content.

2.3 Board members will recall that last year the draft report came to the Board in full for approval, for the first time in many years, supported by the prior approval of ARAC. This year we are also pleased to be able to follow this same approval process, with the improved timelines enabling us to bring the designed version of the report for approval by the Board. ExCo agreed the report on 2 July 2024 and ARAC approved the report at its meeting held on 5th July, as detailed in the ARAC assurance report.

3. Proposal

3.1 We are subject to strict controls over what must be included in the report, how it must be presented and where in the document it is positioned. This can sometimes mean that elements of the report can appear repetitive, but we have worked closely with Communications colleagues and taken advice from NAO colleagues on how best to provide and cross-reference material. The accounts are also subject to a detailed audit by the National Audit Office, who will take a close interest in the governance statement and will check for a balanced and consistent report throughout.

Performance

3.2 The performance section is the first half of the report (pages 6 to 63). We have worked hard to capture all that has been achieved by the Agency, including but not limited to objectives set out in the Corporate and Business Plan. We have also included the

updated key performance indicators which we set last year (pages 34 to 46) and then added the eight new KPIs established in year by the Performance Lead and ExCo (page 47). We have acknowledged the under-performance in some areas of the Agency's services and set out the steps that we are taking to return to full and sustained performance.

Governance

3.3 The governance statement (pages 78 to 90), and in particular the statement on internal controls (page 85) seeks to set out our improvements and challenges this year in the context of a longer, multi-year journey to bring our governance and controls up to the right level. This area of the report also contains the Head of Internal Audit's opinion on the Agency this year (page 88). While there are clearly identified areas for continued improvement within the statement, it also recognises the positive trajectory that we are on.

Finance

3.4 The Remuneration and Staff Report (page 91) and the Financial Statements (page 117) are subject to small changes while the financial audit is ongoing, but we are not expecting these to be substantial. We are not expecting any material changes to the narrative of the report from this version.

3.5 The Parliamentary and Accountability Report (page 112) is provided once the audit has closed and the report therefore currently contains holding pages.

Approval of the Annual Report and Accounts

3.6 Due to tight timelines required for agreeing and finalising the content of the annual report and the comprehensive approval process, the Board is receiving a version of the report which is in PDF and is not yet designed to review ahead of the meeting. The design company (Health Unlimited) is currently creating a designed version of this report for approval, which includes the same content as this PDF version. We will share the designed version as soon as we receive it ahead of the meeting.

3.7 Please note that the photographs of Board members will be edited and added to the designed version. Also, the lists of numbers in the performance report under SR&I, HQA and S&S will be used to create callout boxes for "our year in numbers" for each operational group.

3.8 If there are any narrative / content changes from this version these will be collated and submitted to the designers as one final submission in time for creation of the print copy of the report for laying in Parliament. ExCo, ARAC and the Board will be alerted to any material changes to the final version.

4. Recommendation

4.1 The Board is asked to approve the draft annual report and accounts and advise the Accounting Officer to sign and submit them to the Comptroller and Auditor General for his approval, prior to laying them in Parliament ahead of summer recess.

Carly McGurry
July 2024

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

July 2024

Title	**How will the MHRA implement the recommendations of the Infected Blood Inquiry to improve our responsiveness and patient safety?**
Board Sponsor	Alison Cave
Purpose of Paper	Strategic Direction

How will the MHRA implement the recommendations of the Infected Blood Inquiry to improve our responsiveness and patient safety?

1. Executive Summary

1.1. The Infected Blood Inquiry (IBI) was established in July 2017. Chaired by Sir Brian Langstaff, a retired High Court judge, it was tasked to examine the circumstances that led to individuals being given contaminated blood and blood products in the UK in the 1970s, 1980s and 1990s. As a consequence of the IBI findings the MHRA have been tasked with implementing recommendation 10a (v) - **"**steps be taken to give greater prominence to the online Yellow Card system to those receiving drugs or biological products, or who are being transfused with blood components".

1.2. The Board is asked to consider the proposed actions in response to the Infected Blood Inquiry (IBI) recommendation 10a (V) which are as follows**.**

1.2.1. Establish and run Blood transfusion workshops across the UK with the Serious Hazards of Transfusion (SHOT) Team who MHRA collaborate closely with in delivering haemovigilance activities across the UK. This will complement and enhance the current webinars that the MHRA Haemovigilance Team produce in collaboration with SHOT. These initiatives will also be included in the UK MSc in biomedical science where the Haemovigilance Team contribute. In addition, the Haemovigilance Team already consult with the Institute of Biomedical Science (IBMS) and as part of that consultation will investigate the addition of enforcing the importance and function of the BSQR and Yellow Card (YC) reporting into the biomedical Science portfolios.

1.2.2. Consider adding additional data reporting form to the YC platform to capture blood, blood component transfusion and blood donation incidents to enhance messaging and awareness of this subject with appropriate calls to action should incidents be identified.

1.2.3. Use the 60th anniversary of the YC scheme to seek opportunities to raise awareness and enhance education about the YC scheme with the public, patient organisations, clinical professional bodies and other healthcare partners and Royal Colleges.

2. Introduction and background

2.1. The Infected Blood Inquiry (IBI) was established in July 2017. Chaired by Sir Brian Langstaff, a retired High Court judge, it was tasked to examine the

circumstances that led to individuals being given contaminated blood and blood products in the UK in the 1970s, 1980s and 1990s.

2.2. The wider recommendations and impact of the IBI is expected to have a bearing on our work. This will be considered further when information from leads on the other IBI recommendations is received.

2.3. The delivery of the proposed actions will keep in mind listening to and acting on patient voices; cross system join up and responsiveness; and embodying the civil service values of transparency and candour.

2.4. The IBI has allocated the following recommendation to the MHRA for action: **Recommendation 10a (v)**, that steps should be taken to give greater prominence to the online Yellow Card (YC) system to those receiving drugs or biological products or who are being transfused with blood components.

2.5. The IBI highlighted that the MHRA YC system deserves greater publicity and needs to play a prominent part in listening to what patients have to say. In addition, the IBI noted the need for patient feedback following a report. It is the responsibility of local Trusts and blood establishments to provide feedback to the patient as they have all of the relevant clinical details regarding the treatment the patient received. Under the BSQR, as part of the regulatory inspection framework, the MHRA inspects hospital blood banks and blood establishments feedback mechanisms. Any deficiencies to these feedback mechanisms would be raised at inspection against the relevant organisation and could only be closed once appropriate feedback is provided. Any persistent deficiencies regarding the management of these patient feedback mechanisms would also be raised with CQC. We will ensure inspections have appropriate focus on this area and any deficiencies are robustly addressed.

2.6. A blood product is any therapeutic substance derived from human blood and plasma-derived medicinal products (PDMPs). These are regulated under the Human Medicines Regulation 2012. Incidents involving Blood Products are reported through the YC system.

2.7. Blood and blood components are defined as transfusable components that can be derived from donated blood and include red cell concentrates, Platelets, plasma, cryoprecipitate, and granulocytes and are regulated under the Blood Safety and Quality Regulations (BSQR) (2005 as amended) and are mandated to be reported through the Serious Adverse Blood Reactions and Events (SABRE) platform. Blood, blood components and blood products are therefore regulated under completely different regulations.

2.8. The BSQR was introduced in 2005 and MHRA became the Competent Authority in April 2005. The BSQR is used to regulate Hospital Blood Banks (HBB) and Blood Establishments (BE) Quality Management Systems (QMS) for blood transfusion processes and procedures. It makes a provision for HBB and BEs to provide haemovigilance data on serious adverse reactions and events. Haemovigilance is defined as a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors. These events and reactions are reported through the MHRA SABRE platform and analysed by the Haemovigilance Team for significant untoward trends, effective root cause analysis and corrective and preventative action to avoid incident reoccurrence. The MHRA do not have clinical consultant expertise so, since 2005, the MHRA have collaborated with SHOT to access clinical consultant input for serious adverse reactions to ensure they are classified effectively and for tracking and trending purposes. This data is published in an annual summary produced by SHOT in collaboration with the MHRA Haemovigilance Team.

3. Proposed actions to address the recommendation

3.1. Establish and run Blood Transfusion Workshops across the UK with the MHRA Haemovigilance Team and the mandated best practice body SHOT with whom the MHRA collaborates closely to deliver haemovigilance initiatives. The proposed curriculum will include Haemovigilance reporting, learning from incidents including near misses, application of Hereditary hemochromatosis in transfusion, transfusion IT related issues, donor screening, understanding the regulatory and mandated best practice framework, patient engagement, the role and purpose of YC reporting and protecting the UK blood donor supply (Rapid Alerting system). The target audience will be Health Care professionals (HCP), patient bodies and representatives. It is intended to run five events, in the Southeast, Southwest, Midlands, North and Scotland initially however this is dependent on budget. Repeat workshops will depend on feedback from participants and identifying emerging trends from the haemovigilance data collected. An online seminar will be created so that the workshop will be available to those interested or cannot attend. This will complement and enhance the current webinars that the MHRA Haemovigilance Team produce in collaboration with SHOT. These initiatives will also be included in the UK MSc in biomedical science which the Haemovigilance Team actively supports. In addition, the Haemovigilance Team already consult with the Institute of Biomedical Science (IBMS) and will investigate whether inclusion of the importance and function of the BSQR and Yellow Card (YC) reporting can be included within the biomedical Science portfolios.

3.2. Part of the IBI recommendation is for patients and HCPs to be able to receive guidance on incidents involving the transfusion of blood components and or donations. Currently the YC platform does not provide this. The reporting of Blood and blood component incidents is regulated under the BSQR where Hospital Blood Banks and Blood Establishments are mandated to report these events to the competent authority through SABRE. Reporters may not be aware of this regulated function. Therefore, to ensure compatibility of the IBI recommendation, with the different legislative requirements, we will consider the best way to appropriately route patients and HCPs to the correct reporting form with appropriate messaging, to guide the reporter as to the correct organisation to report their concern to. This may require a project plan to understand patient response and impact.

3.3. Use the 60th anniversary of the YC scheme to seek opportunities to raise awareness and enhance education about the YC scheme with the public patient organisations, clinical professional bodies and other healthcare partners and Royal Colleges.

4. Associated risks with the proposal

4.1. Assess the impact on the re configuration of YC scheme – An addition of a reporting form and the creation of a linked message which outlines to the reporter guidance on what next steps would be needed. This will enable reporters to be directed to the appropriate place to report their concerns i.e. NHSBT. This needs to be scoped for cost and an assessment of the wider impact across the YC platform.

4.2. Patient engagement – Patients may not engage with the YC message for incidents involving transfusion with blood components and donations therefore we will need to carefully draft patient guidance such as links to relevant organisations if needed or required. The MHRA will work to ensure there are links in place to enable reporting and location of the YC scheme when patients require it. For example, if a patient wishes to raise a complaint against a Trust or Health Board then, under the BSQR, we can review complaints as part of the blood inspection process.

4.3. Resources and available budget – Additional budget would be required for the YC reconfiguration and the blood workshops. The cost to the MHRA for operating the system for receiving and assessing reports of serious adverse events and reactions is set at £967 per SABRE registered organisation and we have 308 registered organisations that are mandated to pay this fee. These funds can be used to support costs associated with the delivery of the haemovigilance function. As these fees are regulated under Section 22 of the BSQR it can be justified, dependant on cost, for these fees to be used to

address the IBI recommendation. That said careful costing of both recommendations will be required. SHOT will be approached for a budget and resource contribution to delivering the blood workshops.

4.4. Conflicts of interests (COI) with the regulatory blood inspection process – The Haemovigilance Team conduct blood inspections on behalf of the blood inspectorate. Any perceived COI can be managed by ensuring that the Haemovigilance Team do not advise on the blood inspection issues.

5. Recommendation

5.1. That the Board agrees with the following initiatives to address the IBI recommendation:

5.1.1. Establish and run Blood Transfusion Workshops across the UK. In collaboration with the mandated best practice body SHOT.

5.1.2. Consider adding an additional reporting form to YC to reports to improve visibility of reporting of blood, blood component transfusion and blood donation incidents.

5.1.3. Use the 60th anniversary of the YC scheme to seek opportunities to raise awareness and enhance education about the YC scheme with all relevant stakeholders.

Alison Cave
Chief Safety Officer
27-06-2024

Medicines & Healthcare products Regulatory Agency

MHRA BOARD MEETING HELD IN PUBLIC

9 July 2024

Title	How can the Data Strategy help improve the Agency's services and strengthen regulatory decisions?
Board Sponsor	Alison Cave & Claire Harrison
Purpose of Paper	Strategic Direction

How can the Data Strategy help improve the Agency's services and strengthen regulatory decisions?

1. Executive Summary

1.1 We have committed within the BP 24/25 to publish a Data Strategy by the end of Q2.

1.2 A draft of the MHRA's Data Strategy was presented to the Executive Committee in February and May 2024, and as a Board Seminar in May 2024.

1.3 An external engagement programme was conducted in March/April 2024, and extensive constructive feedback was received.

1.4 The MHRA Data Strategy to be refined and developed in response to feedback.

1.5 The MHRA Data Strategy (Annex A) and deliverables mapping (Annex B) is presented for review and comment.

2. Introduction

2.1 Data and digital technologies have had a revolutionary impact across the broader economy and have been compared to a 'fourth industrial revolution'.

2.2 Our ability to proactively regulate, enable innovation, and safeguard public health depends upon an agile, responsive, and forward-looking approach to data.

2.3 There is significant interest within industry in the use of Real-World Data (RWD) to support medical product development through innovative evidence generation approaches, for example the use of external control arms, causal inference methodologies, and computational modelling and simulation.

2.4 These approaches span the product lifecycle and have potential to enhance regulatory decision-making in both the pre- and post-authorisation phases.

2.5 Improving our access to a wide range of data should support more timely, transparent, and predictable decision-making whilst maintaining our reputation for scientific rigour. Data-driven insights may also facilitate earlier access to innovative products for patients especially those with unmet medical need, by reducing ambiguity and enabling more proactive approaches to post-authorisation surveillance.

2.6 The data landscape is increasingly multi-modal, complex, and heterogeneous. For example, conventional sources of RWD such as EHRs and registries are now complemented by molecular data (e.g. genomics, proteomics), image data (e.g. pathology, radiology), and near-continuous read-out data (e.g. wearable, IoT devices). Data, such as patient-reported outcome measures, can also improves our ability to determine the impact of therapies on clinically meaningful measurements of how a patient feels and functions. However, there remains

significant uncertainty around best practice for integration and evaluation of these datasets across the spectrum of regulatory decisions.

2.7 There are significant challenges within the broader UK health data ecosystem, in particular siloing and fragmentation. This is particularly relevant for regulatory decision-making in relation to a lack of information on secondary care prescribing (e.g. isotretinoin) and implantable medical devices (e.g. pelvic mesh). Whilst the MHRA, can articulate these issues and identify opportunities for improvement, responsibility to address these sits with other organisations and requires an ecosystem-wide approach.

2.8 Our stakeholders in industry require clarity from us to enable them to adopt innovative methodological approaches to Real-World Evidence generation, including dataset choice, use of analytical and computational techniques, and endpoint selection, at multiple points throughout the product lifecycle. This is necessary to instil confidence that such methodologies can contribute to regulatory decision-making.

2.9 MHRA's Data Strategy aims to articulate our vision for data, digital technologies, and real-world evidence for the coming three years. Delivery of this strategy should facilitate earlier access to innovative products through proactive approaches to surveillance and support the broader UK life science sector by providing increase clarity of regulatory expectations for evidence generation.

2.10 A number of comparable organisations both within the UK and internationally have published stand-alone strategic documents highlighting their commitments in areas such as data, digital technology, and RWE. These strategies provide visible thought leadership and support stakeholder confidence in these organisations' approaches to emerging tools and technologies.

2.11 Context for the MHRA's Data Strategy is provided by several recent reviews including Cumberlege, Goldacre, McLean, O'Shaughnessy, and Whitehead, and by current NHS England activities in developing Secure Data Environments.

2.12 MHRA's Clinical Practice Research Datalink (CPRD) remains one of the most highly regarded sources of RWD globally, due its robust approach to data quality and the longitudinality of primary care records. However, the broader health data ecosystem is increasingly competitive and CPRD is facing challenges including linkage and cost-recovery within a future TRE-based operating model. CPRD an essential component of the implementation of this Data Strategy.

2.13 Professor Cathie Sudlow, Chief Scientist at HDR UK, was commissioned in 2023 by Professor Sir Chris Whitty, Dr Timothy Ferris, and Professor Sir Ian Diamond to conduct an independent review of the UK health data landscape, entitled 'Unifying Health Data in the UK'. The Sudlow Review, expected in 2024, will provide an important overview of the broader UK health data ecosystem and the MHRA has contributed to this review.

2.14 Additional context is provided by the Life Science Vision and the Agency's Corporate Plan and its companion pieces, particularly the Science Strategy within which Data Science features as one of five core themes. However, the scope of the Data Strategy is significantly broader than data science and encompasses *inter alia* digital technologies, real-world evidence, and data management and architecture. The Data Strategy also provides a key touchpoint for the Agency's

Technology Roadmap, which lays out the tools and technologies required to enable and catalyse the deliverables of the Data Strategy.

3. Proposal

3.1 The MHRA Data Strategy currently includes sections covering Executive Summary, Context, Mission, Lay Summary, Digital & Technology, and Five Core Themes.

3.2 The Lay Summary has been added in response to previous feedback at Board and the patient and public health impact has been illustrated in relevant sections.

3.3 A production version of the Data Strategy is presented in Annex A for consideration by Board.

3.4 The MHRA Data Strategy will be structured upon 5 cores themes, with each of these underpinned by specific deliverables.

3.5 The proposed 5 key priorities are:

3.3.1. Support data-driven innovation, early access, and interdisciplinary data science to underpin our regulatory framework.
3.3.2. Enable effective, timely, and proportionate regulatory decision-making through real world evidence.
3.3.3. Develop, extend, and integrate our capabilities in data and digital technologies.
3.3.4. Establish, embed, and expand synergistic partnerships across the data ecosystem.
3.3.5. Safely and responsibly harness the potential of artificial intelligence and advanced analytics throughout the product lifecycle.

3.6 As a key deliverable within our Data Strategy, we propose a RWE Scientific Dialogue Programme which will consolidate and extend our thought leadership in this space and support a broad base of regulatory data science to ensure we can make robust regulatory decisions in the context of uncertainty and ambiguity. From this, we will also subsequently develop a Data, Methodology, and Endpoints Qualification framework. These programmes should provide clarity of regulatory expectations for innovators, potentially facilitate earlier access to novel products, and will support the broader UK life science sector to efficiently develop novel medical products.

3.7 Capability building, including our people, skills, tools, and technologies, is an essential component which will require investment to bring the strategy to life.

3.8 Leveraging our network of Centres of Excellence in Regulatory Science and Innovation (CERSI) to deliver progress on data and data science is an additional critical deliverable within the Data Strategy and should position us competitively with programmes led by other global regulators including the USA's Sentinel and EU's DARWIN. Strengthening our partnerships across the ecosystem, including

academic collaborations in regulatory science, will be integral to the success of the CERSI mission.

3.9 A programme of external engagement has been completed as follows:

3.4.1. Trade Associations and Industry Representatives on 25 March 2024
3.4.2. Research Funders and HDRUK on 27 March 2024
3.4.3. Cross-HMG stakeholders including DHSC, ALB, DA Representatives on 3 April 2024

3.10 A deliverables mapping is provided in Annex B in response to previous feedback at Board. This mapping relates deliverables to the 24/25 BP where appropriate and gives consideration to anticipated resource requirements.

3.11 There are risks associated with this strategy. A risk of not publishing and implementing this strategy is lost opportunity for impact, reduced thought leadership in this space, and the possibility of falling behind global peers. However, an opposing risk is that the expectations set within the strategy will not be achieved, leading to reputational damage and reduced credibility. This is a non-trivial risk since many of the deliverables will require additional resourcing (see Annex B) and many of these activities will require cross-functional expertise which needs to be considered in light of core operational pressures. Furthermore, as with all activities, there is an associated opportunity cost, and the Data Strategy activities will need to be weighed against alternative opportunities for investment.

4. Recommendation

4.1. Board is asked to comment on the Data Strategy and the deliverables mapping.

4.2. Board is asked to consider the risks associated with the Data Strategy as described in Section 3.11 and comment on these.

4.3. Board is asked to advise on next steps to progress the Data Strategy towards publication and implementation.

Alison Cave & Claire Harrison
July 2024

Medicines & Healthcare products Regulatory Agency

MHRA Data Strategy

2024 to 2027

Our vision for data, digital technology, and real-world evidence to enable innovation and safeguard public health.

Contents

Executive Summary

I am delighted to introduce the MHRA's first Data Strategy at a moment of profound change and opportunity. We are seeing data and digital tools transform almost every aspect of our work and our lives. Big data, advanced analytics, and emerging digital technologies have been compared to a 'fourth industrial revolution', whilst artificial intelligence and machine learning have been likened to 'the new electricity'.

Never before has science and technology converged with such velocity and potential for tangible impact across a range of clinical conditions and medical products. It is therefore timely that we have reflected upon the opportunities and challenges we face in relation to digital, data, and technology both within our organisation and across the broader health data ecosystem.

Having considered this landscape, we have developed a strategy which defines our vision for data, digital technology, and real-world evidence over the coming years. In doing so, we have sought to differentiate our strategy, recognising the highly specialist and in some cases unique aspects of our organisation, as a sovereign regulator of medical products and a hub for regulatory science and innovation. Our Data Strategy is based on five core themes, each underpinned by specific deliverables.

Running through fiscal years 2024 to 2027, the MHRA's Data Strategy looks outwards, seeking to optimise our offering for our stakeholders and our customers, and enable innovation throughout the ecosystem. Our approach aspires, wherever it is possible and appropriate, to use data to streamline, deduplicate, and harmonise our regulatory processes and procedures.

By delivering this strategy, working in close collaboration with partners both within the UK and internationally, we will use data to deliver timely, proportionate, and scientifically robust regulatory decisions which facilitate early access to medical products and safeguard public health.

Dr June Raine DBE
Chief Executive Officer

Context

Data and digital technologies have transformed our society and continue to touch upon almost every aspect of our lives. Innovations in data science offer opportunities to support and improve our regulatory decisions across the medical product lifecycle.

However, significant challenges exist particularly relating to data access and linkage, uncertainty around data quality, integration of heterogenous data sources across care systems, and implementation of modern tools upon underlying legacy technology stacks. For example, barriers exist to routinely linking primary and secondary care data, and reliably identifying medical devices which limits our ability to consistently generate robust evidence in certain contexts.

These challenges are neither new nor unique to MHRA but impact upon the entire health data ecosystem and require a cohesive, collaborative, and unified approach to develop the capabilities required to achieve data-driven innovation, improve evidence generation, and support sustainable healthcare and clinical research.

Both in the UK and globally, the data landscape is complex, multi-modal and continuously growing. Conventional Real-World Data (RWD), acquired in the context of healthcare delivery and outside of the randomised controlled trials (RCT), such as electronic health records (EHR) and registry data are now being complemented by 'omics' modalities such as genomics, transcriptomics, proteomics, metabolomics, as well as biomedical images, and near-continuous monitoring from wearables and Internet of things (IoT) devices. We also recognise the critical importance of quality-of-life measurements including patient-reported outcomes to support the ambition of a more personalised regulatory framework.

While the promise of a cradle-to-grave patient record should be achievable given the UK health system, siloing and fragmentation across the health data ecosystem are a persistent and significant obstacle. Addressing these issues, improving data quality and fitness-for-purpose, and effectively integrating evidence from across the four nations of the UK, will be critical to effective and equitable solutions to the most pressing public health needs including precision medicine, long-term conditions, and rare diseases.

Context

This Data Strategy capitalises upon our new One Agency structure and defines our approach to harnessing the potential of data and digital technologies across the medical product lifecycle. Realising our ambitions, will require us to extend and diversify the data we draw upon to inform our decisions, optimise and integrate our own data assets, and embrace novel analytical and methodological approaches.

The strategy recognises the vital public service we provide to patients and other stakeholders, including academia, industry, and the third sector, and considers how delivery of this service will be optimised by effective, collaborative, and proactive approaches to data and technology.

Mission

The vision of our Strategy is to enable an agile, responsive, and forward-looking approach to ensure we continue to regulate proactively, enable innovation, and safeguard public health. To achieve this, our Data Strategy will identify the opportunities and challenges for data and technology both within our organisation and from the broader ecosystem.

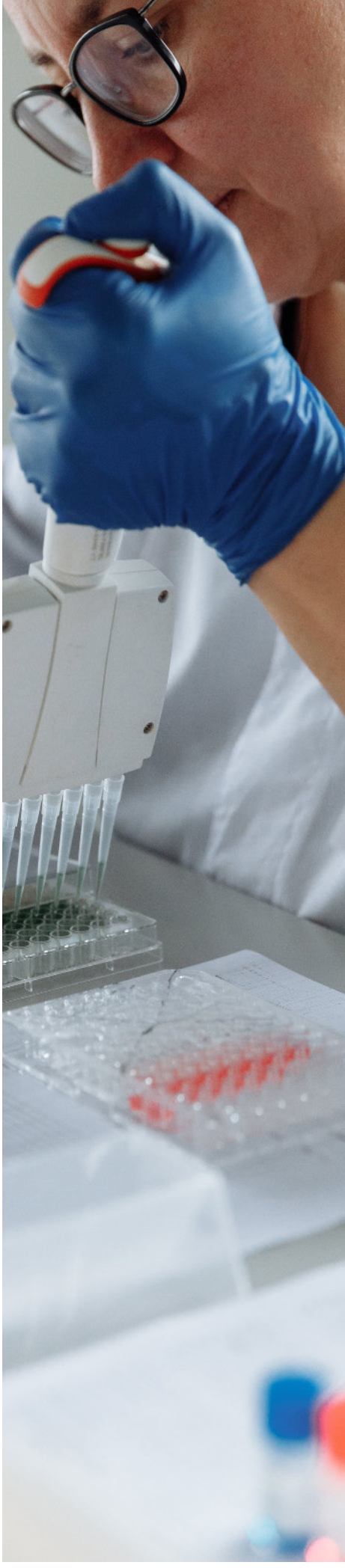
Our Data Strategy is contextualised by several recent reports including Cumberlege (2020), Goldacre (2022), McLean (2023), and Whitehead (2024), in addition to the Life Science Vision (2021), Department of Health Social Care (DHSC) 'Data saves lives: reshaping health and social care with data' policy paper, and our own Corporate Plan 2023 – 2026.

Our Science Strategy identifies Data Science as one of five key themes. This Data Strategy consolidates and builds upon the scientific deliverables placed under that theme. Support for a Centre of Excellence in Regulatory Science is a critical deliverable within this Data Strategy, and the launch of our regulatory science and innovation network funding call with Innovate UK and Office of Life Sciences (OLS) exemplifies our commitment to driving innovation in this space.

An overarching goal of this Strategy is to ensure we develop the infrastructure, architecture, and expertise to deliver timely access to Real-World Data (RWD) which can in turn result in actionable Real-World Evidence (RWE), and leverage this to support a broad base of regulatory data science including methodology development. This should ensure the evidence generated is sufficiently rigorous to support scientifically-robust regulatory decisions across the product life cycle in the context of uncertainty and ambiguity.

Key to delivering our ambitions will be the development of our people, skills, tools, and technologies to ensure that we can access, integrate, and interrogate data for maximal impact. Capability building is therefore a core element of our Strategy.

Finally, our Data Strategy will drive forward our ambitions to capitalise on artificial intelligence and advanced analytical methodologies to both streamline our business activities and generate actionable insights which support our regulatory mission.



Lay Summary

As the regulator of medicines, medical devices, and blood products, decision-making is at the heart of our organisation. This document sets out our plans to improve the ways in which we use data to make these decisions. In particular, this strategy will support us to draw upon the wide range of data sources from across the United Kingdom and beyond and help us to enable earlier access to innovative products through proactive approaches to monitoring safety after authorisation. Another key objective is to improve our operational performance by harnessing the potential of data to enhance the timeliness, transparency, and predictability of our regulatory processes. Patient safety and public health are central to this plan and we will ensure that progress is communicated to all of our stakeholders as we move to delivering this strategy.

Digital & Technology

Our core approach to digital and technology underpins, enables, and catalyses the deliverables within our Data Strategy. The approach is centred upon the application of innovative technologies across the organisation, eradication of legacy applications, and embedding a robust and sustainable approach to cybersecurity.

We recognise the importance of novel technologies as a catalyst and driver for change and creating new opportunities to improve our operational performance. Integrating automation and AI tools should improve the timeliness and predictability of our services.

We will seek wherever possible to democratise our solutions across the organisation for example by establishing a self-service-based infrastructure and procuring low- and no-code solutions to enable greater productivity. Effectively delivering this will require us to modernise our core technology stack for example by migration from bespoke to standardised platforms and embracing cloud-based infrastructure aiming to improve our resilience and sustainability.

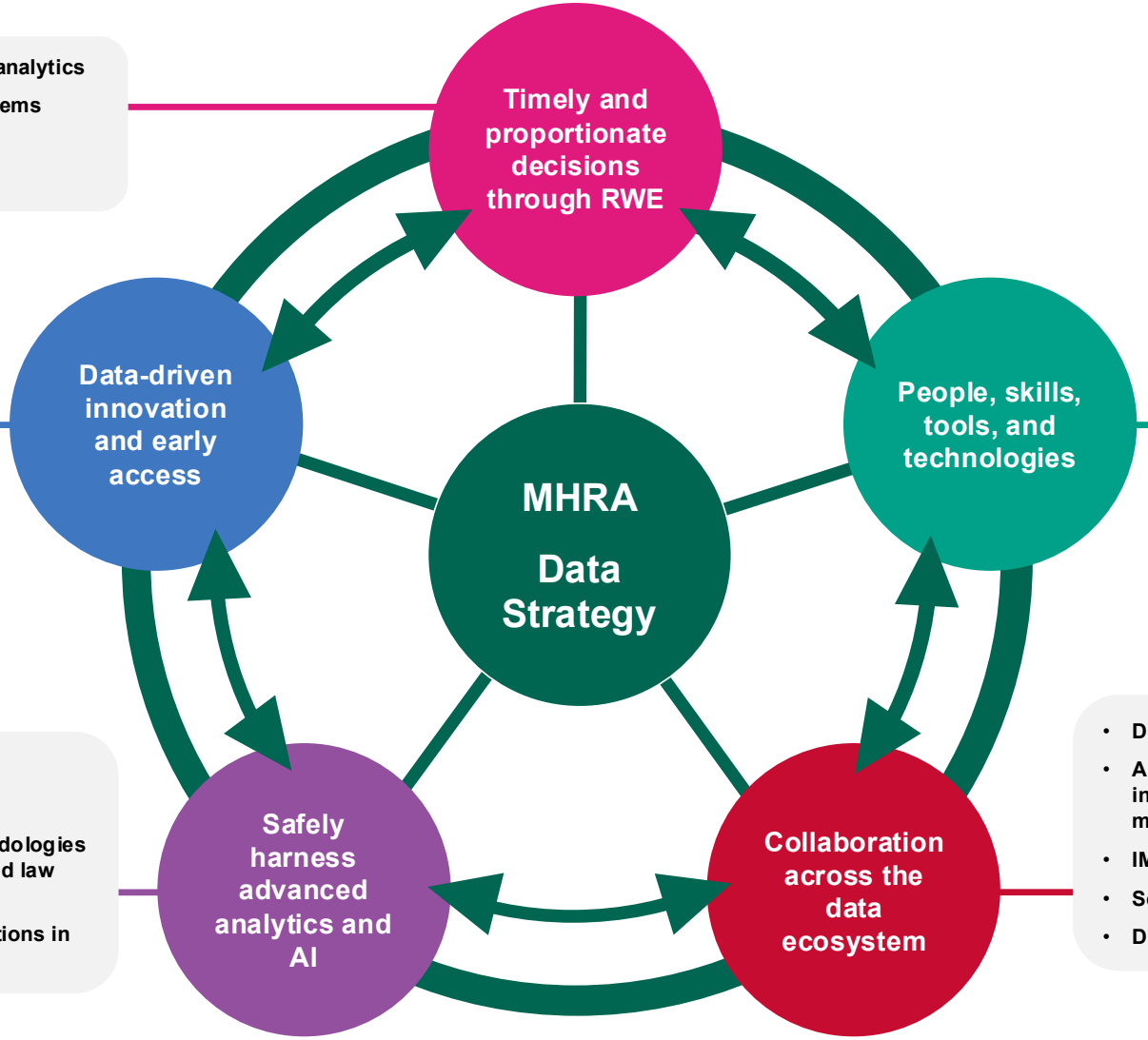
Cybersecurity is a critical component of our strategy and, recognising the significant threats we and comparable organisations face, will be based on a 'zero-trust' paradigm. We will establish a Cyber Security Operations Centre and deliver an application portfolio which is 'secure-by-design' - underpinned by automated solutions, global gold standards, and cyber-AI.

Partnership working, both nationally and internationally, is a prerequisite for the effective delivery of data, digital, and technological use-cases across the organisation. We will therefore work proactively with the technology industry, with partners and stakeholders from across HM Government, and with our global regulatory peers, to deduplicate wherever possible and ensure our approach is aligned to international best practice.

Strategic Themes

1. Support data-driven innovation, early access, and interdisciplinary data science to underpin our regulatory framework
2. Enable effective, timely, and proportionate regulatory decision-making through Real-World Evidence
3. Develop, extend, and integrate our capabilities in data and digital technologies
4. Establish, embed, and expand synergistic partnerships across the data ecosystem
5. Safely and responsibly harness the potential of artificial intelligence and advanced analytics throughout the product lifecycle

Data Strategy On A Page



- Common data models and federated analytics
- Data linkage across settings and systems
- Device and outcome registries
- Unique device identification

- RWE Scientific Dialogue Programme
- Data, Methodology, and Endpoint Qualification
- Early access RWE tools
- RWE guideline series
- Equitable representation in clinical research
- Workshop series and reflection papers on in silico trials, synthetic data, CM&S

- Cross-MHRA LLM/GenAI task force
- NLP in safety monitoring
- Advanced analytics and novel methodologies in signal detection, RWD analysis, and law enforcement
- Datathons and data science competitions in RWE and ADR predictions

- Prototyping technological use cases e.g. clinical trials and licensing
- Cross-MHRA data science network and Cross-HMG communities of practice
- Data science graduate placements and apprenticeships
- CDDO Data Maturity Assessment
- Internal data architecture, infrastructure and platforms
- RegulatoryConnect and SafetyConnect
- Trusted Research Environment for CPRD

- Data Science CERSI
- Academic partnerships in causal inference, machine learning, and methodologies for RWD
- IMDRF adverse event terminology
- Scan4Safety medical device traceability
- Device registration data sharing

1. Support data-driven innovation, early access, and interdisciplinary data science to underpin our regulatory framework

The Pro-innovation Regulations of Technologies review (2023) articulated the critical role of the MHRA within the broader life science ecosystem. Harnessing the potential of data, digital tools, and evidence generation is key to enabling innovation at multiple points in the medical product lifecycle, from initial discovery and development through to post-market surveillance and lifecycle management.

The UK's strengths are exemplified by our rich health data landscape, extensive capabilities in genome sequencing and interpretation, research-intensive higher education institutions, and collaborative approach to inter-disciplinary science.

Randomised clinical trials (RCT), though the gold standard for demonstration of efficacy, often do not yield representative information about the effectiveness and safety of products across all potentially exposed patients under real-world conditions. We increasingly recognise the synergy and complementarity of Real-World Evidence (RWE), derived from analysis of Real-World Data (RWD) with randomised studies. These types of approaches can streamline and enhance product development, reduce ambiguity, and potentially enable earlier access by facilitating a more proactive approach to post-authorisation surveillance.

1. Support data-driven innovation, early access, and interdisciplinary data science to underpin our regulatory framework

Box 1: Challenges in evidence generation for our stakeholders

- Characterising benefit/risk profiles whilst also achieving timely market access in the context of unmet medical need
- Harmonising studies for regulatory requirements and health technology appraisal across multiple territories
- Minimising study burdens on participants, investigators, and sites
- Situations where randomisation is unethical or unfeasible, including certain rare diseases or conditions which result in irreversible morbidity and/or mortality
- Ensuring equity of access to participation in clinical research
- Generalisability and external validity of clinical trials
- Ensuring endpoints robustly predict clinically-meaningful measurements of how patients feel, function, and survive
- Characterisation of safety, in particular long-latency and rare adverse events
- Stratifying patients according to prediction of efficacy and toxicity, including precision medicine and pharmacogenomics
- Delivering proactive vigilance and risk management in the real-world setting

This Strategy aims to identify opportunities to consolidate and harmonise our approach to evidence generation and encourage the uptake of novel methodologies where appropriate, with the aim of promoting efficient and patient-centric approaches to product development. By optimally deploying these methodologies and tools across well-considered hypotheses, investigators should be able to mitigate biases and deliver relevant, actionable evidence for the evaluation of benefits and risks across the spectrum of patients who use the product.

1. Support data-driven innovation, early access, and interdisciplinary data science to underpin our regulatory framework

Box 2: Opportunities for RWD throughout the product lifecycle

- Defining disease epidemiology including incidence and prevalence e.g. for orphan designation
- Understanding natural history and disease heterogeneity
- Characterising treatment patterns and standard of care
- Identification and validation of surrogate endpoints
- Pragmatic trials
- External control arms
- Identification and recruitment of potential clinical trial participants
- Informing clinical trial design
- Development and validation of predictive models including training of AI/ML
- Pharmacogenomic and precision medicine approaches
- Product utilisation studies
- Signal detection, contextualisation, and validation
- Post-authorisation safety and effectiveness studies
- Evaluating the impact of risk minimisation measures

We recognise that innovators require clarity from the regulator to enable them to develop and apply novel approaches to evidence generation.

Early dialogue and engagement are being embraced by other global regulators, for example through the US FDA's Advancing RWE Program .Through the deliverables underpinning Theme 1, we will support innovators in their evidence generation strategies by establishing a Scientific Dialogue Programme to provide support on protocol development for real world studies and subsequently introduce a Data, Methodology, and Endpoints Qualification process. This process should place the patient perspective at the heart of the development process and ensure that studies capture meaningful measurements of how patients feel and function.

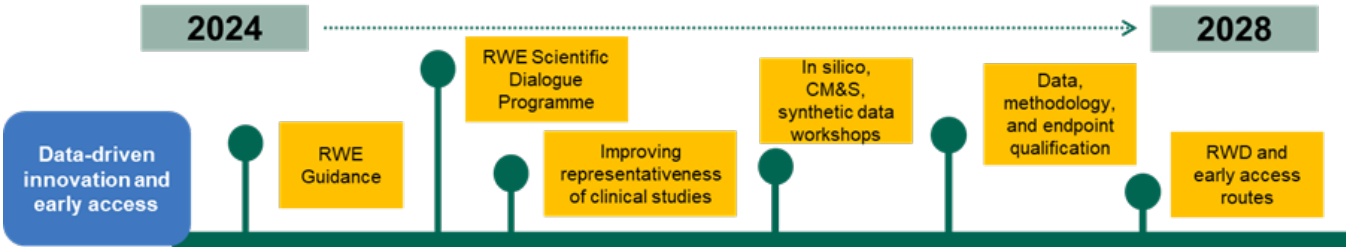
Our ambition here is to deliver system-wide global thought leadership and enable innovators to embark on novel evidence generation strategies with a clear view of how these methodologies may support regulatory decision-making underpinned by trustworthy and compliant data.

To achieve this, we will pro-actively engage with our stakeholders to ensure a shared vision for evidence generation across the product life cycle, and to work with ecosystem partners, such as the Health Technology Appraisal bodies, NHS and Devolved Nations.

1. Support data-driven innovation, early access, and interdisciplinary data science to underpin our regulatory framework

To deliver Theme 1, we will:

- Continue our series of guidance documents on RWD/RWE and engage with stakeholders and global regulators to improve international harmonisation.
- Develop a Scientific Dialogue Programme for RWD/RWE to improve clarity around regulatory expectations for innovative approaches to evidence generation.
- Understand and describe patterns of underrepresentation in clinical research, thereby defining a harmonised view of inclusivity to improve generalisability and equity of access.
- Develop principles and exemplars on the regulatory acceptability of computational modelling and simulation; in silico trials; and synthetic data.
- Pilot a Data, Methodology, and Endpoints Qualification process to support innovative evidence generation strategies across the product lifecycle.
- Identify opportunities and deliver clear routes for real-world data to support early access to innovative medicines and devices whilst upholding safety through proactive surveillance in market.



2. Enable effective, timely, and proportionate regulatory decision-making through Real-World Evidence

The Independent Medicines and Medical Devices Safety Review (2020) provides a strong and clear frame of reference for this Data Strategy. The deliverables are fundamental to our ambitions to be an integral component of a healthcare system which learns and continuously improves, thus ensuring the public trusts our decisions and the patient voice is central.

Fulfilling our role as sovereign regulator requires us to make timely and scientifically-robust regulatory decisions which carefully balance the potential benefits and risks of medical products in the context of uncertainty and ambiguity. We must also detect signals of adverse events rapidly and accurately, then contextualise and validate these signals to determine the need for regulatory action. These decisions are reliant on the application of specialist expertise and judgement, underpinned by a comprehensive review of the available scientific evidence.

Evidence generation depends on high-quality, relevant data to enable an unbiased decision on whether the product is safe and effective. Where regulatory interventions are made, we need to be able to monitor the consequences and effectiveness of such actions in real-world clinical practice.

The data ecosystem which can support this is complex, distributed, and heterogeneous. Vast quantities of data, across many modalities, are potentially available – but must be linked, evaluated, and interrogated, to generate trustworthy and actionable evidence.

To fully harness this potential, we need to consider both the data architecture within our organisation and the broader ecosystem, evaluating how we utilise our own data assets, identifying our data needs and proactively address these requirements. In doing so, we recognise the critical importance of data governance to uphold trust in the robustness of our processes and systems, ensuring confidence in decisions we make.

2. Enable effective, timely, and proportionate regulatory decision-making through Real World Evidence

Box 3: Requirements for RWD to support regulatory decision-making in benefit risk-evaluation

- Timely access with predictable timelines and governance requirements
- Adequately characterised data quality enabling assessment of fitness-for-purpose
- Harmonised standards and ontologies permitting interoperability
- Data which is representative of the UK population
- Capture of data over a sufficient time course to address the scientific and regulatory questions of interest
- Linkage and integration of data generated in different care settings and systems
- Adequate capture of medical product exposure, clinically meaningful outcomes, and relevant covariates including potential confounders

UK health data is an unparalleled potential resource in terms of its scale, diversity, depth, longitudinality, and longevity – however, addressing key challenges around quality, linkage, and interoperability will be key to capitalising on this potential.

Considerations for medicines and medical devices are likely to be distinct and therefore require specific and strategic approaches. For example, traceability of medical devices and linkage to long-term outcomes is a persistent challenge which should be addressed by unique device identification and integration of this information in a structured way into longitudinal records. Adequately understanding safety signals for medical devices also requires additional contextual information about the user, operator, and procedure.

Access to secondary care prescribing is limited in some areas and this presents an obstacle to understanding the impact and consequences of regulatory action for specific issues.

Other leading global regulators have established initiatives to access RWD for regulatory decision-making and in some cases to generate a broader resource to support public health and wider evidence generation activities. A key element of using such data to generate informative and reliable evidence is consistently and thoroughly evaluating the data's relevance, quality, and fitness-for-purpose.

Establishment of a federated clinical data network within the UK would support evidence generation for regulatory decision making at scale and at pace but should be built in such a way to leverage ongoing initiatives and deliver outputs relevant across health system partners.

2. Enable effective, timely, and proportionate regulatory decision-making through Real World Evidence

Box 4: Challenges in the UK Health Data Landscape

- Siloing and fragmentation of data across systems, healthcare settings and regions, with many subnational and disease area specific data sources
- Large number of disparate initiatives delivering distinctive offerings using inconsistent approaches
- Regional variation leading to limited generalisability and perpetuation of health inequalities
- Distinctive approaches across the four nations limiting UK-level analysis
- Lack of consistent data standards and format limiting interoperability
- Variability in data platforms and infrastructure creating challenges for end-users
- Variable data quality and limited transparency around fitness-for-purpose of datasets
- Limited opportunities to link data and integrate multiple data modalities
- Complex and varying approaches to data governance leading to long-lead times for access and a lack of predictability
- Specific problems with certain classes of products such as traceability of medical devices and certain care settings such as prescribing in secondary care and the private sector

MHRA's **Clinical Practice Research Datalink** is a critical component of the UK health data ecosystem

The Clinical Practice Research Datalink (CPRD) is our RWD research service. CPRD makes available anonymised patient data from a UK-wide network of GP practices for research benefiting public health. Access to data is controlled via a robust data governance framework and secure research environments.

CPRD currently encompasses 65 million patients from all four nations of the UK, including 19 million currently registered patients. Primary care data are linked to a range of other health related data to provide a longitudinal, representative UK population health dataset, with 25% of patients having at least 20 years of follow-up time.

CPRD data have been critical for the monitoring of medical product safety by the MHRA for over 35 years. A key strength of the CPRD databases is that they have been specifically created with research and regulatory requirements in mind. This means that CPRD has a documented data quality strategy, rigorous data quality checks, timestamping of data with no overwriting, metadata, versioning, archiving, and value-added data variables and algorithms.

2. Enable effective, timely, and proportionate regulatory decision-making through Real World Evidence

CPRD is increasingly used in clinical trial recruitment and in support of primary care led decentralised trials. The Data Analytics Recruitment Tool (DART) is a delivery platform to support patient recruitment for this innovative work.

An independently validated Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) version of the larger primary care databases is also available along with the Observational Health Data Science and Informatics (OHDSI) Atlas tool for federated analyses. CPRD has also undertaken mapping and conversion of its primary care data into the Sentinel CDM.

CPRD has developed both high and medium-fidelity synthetic datasets that can be used for a variety of purposes including training and validation of machine learning algorithms. CPRD has also been supporting the MHRA's regulatory science ambitions by validating applications of high-fidelity synthetic data for sample size boosting and as external control arms.

In line with the Goldacre Review recommendations, CPRD aims to move to a predominantly trusted research environment (TRE) based model of data access by the end of fiscal year 2024/2025. This is a major change to CPRD's model of data access that requires careful consideration of archiving, provisioning of storage and compute, interoperability, linkages, and affordability.

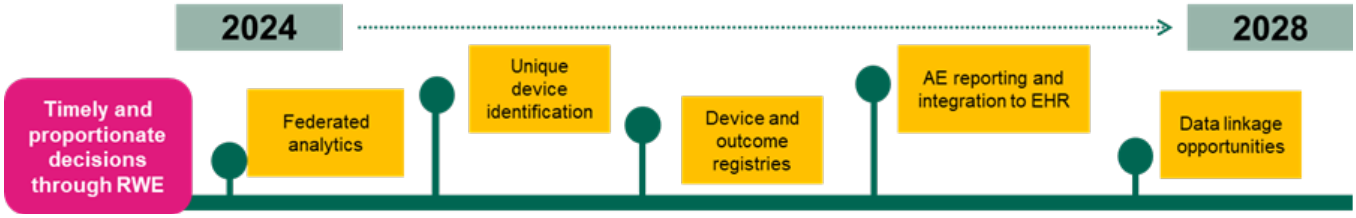
While CPRD data have been invaluable for both the MHRA and the wider research community, the primary care data alone provide only a partial picture of the patient care pathway. This makes linkage to secondary care and other health-related datasets critical. CPRD currently is linked to secondary care, death registration and cancer registry data, but the frequency and timeliness of linked data updates need to be increased.

Expanding the programme of linkage will vastly increase the public health utility and impact of CPRD data, but this will only be feasible in partnership with NHS England and equivalent bodies in the devolved nations. Additionally, from a safety surveillance perspective, there are some key data gaps that could be addressed via new linkages e.g. secondary care prescribing.

2. Enable effective, timely, and proportionate regulatory decision-making through Real World Evidence

To deliver Theme 2, we will:

- Evaluate the role of common data models and federated analytics to generate RWE within the UK data ecosystem for both medicines and medical devices to address regulatory questions in a timely and scientifically robust manner.
- Deliver the necessary secondary legislation and associated guidance around medical device identification to support traceability across the medical device lifecycle.
- Map, evaluate, and strategically engage with major device and outcome registries, and with NHS England's Outcomes Registry Platform programme, identifying opportunities to enhance our safety activities by leveraging RWD from across the UK.
- Engage with stakeholders to establish the potential value of and address key governance elements required for linkage of Yellow Card spontaneous adverse event reports to routine electronic health records.
- Explore opportunities to expand and improve linkage between primary and secondary care settings to generate actionable regulatory evidence for medicines and medical devices.



3. Develop, extend, and integrate our capabilities in data and digital technologies

Our Data Strategy provides an opportunity to identify and address the challenges we face in ensuring we have the requisite capabilities to realise the full potential of data and digital technologies.

A broad range of capabilities will be required to deliver our ambitions for data science and evidence generation. We will develop our people and skill mix to ensure we have the specialist expertise to address requirements across data architecture, software engineering, analytics, data science, and machine learning. Key to achieving this will be embedding a culture of collaboration, inter-connectedness, and shared best practices.

3. Develop, extend, and integrate our capabilities in data and digital technologies

Box 5: Core priorities for technological capabilities

- Cloud-based infrastructure
- Eradication of legacy applications and technical debt
- Cybersecurity
- Information governance
- Process automation
- Innovative tools including AI
- Environmental sustainability

HM Government's Digital, Data and Technology (DDaT) approach and the Open Data Institute (ODI) Data Skills Framework will support us to develop a resilient, capable, and multidisciplinary data workforce. Drawing upon the considerable external expertise in the broader ecosystem will also support our ambitions and ensure our strategic direction is appropriate and consistent.

Like many comparable organisations we are faced with legacy systems, technical debt, and data islands which may limit our scope for achieving operational efficiency and constrain innovation. We are proactively addressing this through investment in legacy eradication and architecture development.

Establishing a robust organisation-wide data model, underpinned by our RegulatoryConnect system, should deliver a secure and trustworthy 'single point of truth', minimise duplication, and prevent siloing. Development of a rich suite of tools and technologies is an additional critical capability which will be required, recognising that this will require us to refresh and realign our underlying systems.

The development of a modern, flexible and modular architecture will underpin these capabilities and be supported by secure cloud-based solutions. This architecture will facilitate the operationalisation of systems, such as our new vigilance platform SafetyConnect, which will consolidate and extend our capability to deliver proactive and agile safety decisions.

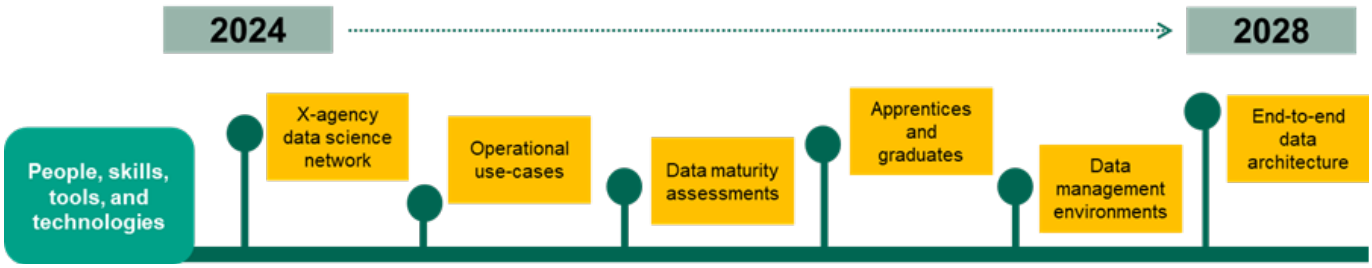
Secure integration of our systems with appropriate third-party solutions will provide additional opportunities to improve our responsiveness. Underpinning this, an organisation-wide data governance framework will be essential in ensuring the appropriate utilisation of our data assets.

Taking the steps required to drive theme 3, will benefit patients and stakeholders by ensuring that our people and our digital tools are able to deliver in a timely, predictable, and transparent manner.

3. Develop, extend, and integrate our capabilities in data and digital technologies

To deliver Theme 3, we will:

- Establish a Cross-Agency Data Science network to share expertise, encourage collaboration and foster innovation.
- Strengthen our involvement with the Apprenticeship scheme and Graduate Programme, proactively identifying opportunities for digital and data focussed placements.
- Participate in communities of practice across government, sharing knowledge, developing skills, and identifying opportunities to collaborate.
- Conduct a Data Maturity Assessment programme to evaluate our internal data assets from across the organisation, aligning with the CDDO framework.
- Implement an Agency-wide data architecture based on the principle of 'collect once, use many times' to enable us to gain a comprehensive and end-to-end view of any specific medical product.
- Operationalise data management environments to productionise our data using best practices for data stewardship.



4. Establish, embed, and expand synergistic partnerships across the data ecosystem

The UK has a diverse and flourishing life science ecosystem including academia, industry, the third sector, and public institutions. Our goal is to engage effectively and constructively with partners and stakeholders, aligned on a shared purpose of population health and wellbeing.

The Goldacre review affirmed the vital importance of partnership working, both within the UK and globally. We will further develop an outward-facing and proactive approach to engagement, seeking wherever possible to streamline, de-duplicate, and align our ambitions through a harmonised national and international approach.

We will establish synergistic partnerships and collaborations needed to achieve the goals set out within this strategy. Partnering with academic institutions should support our ambitions for a pipeline of data talent and enable us to collaborate on methodological research which underpins key regulatory priorities.

Opportunities also exist for using the agency's data knowledge to support international collaboration especially in vigilance. Building on the knowledge and work done to date through SafetyConnect, there are further opportunities to support safety signalling in low- and middle-income countries (LMIC).

Centres of Excellence in Regulatory Science and Innovation

Delivering this ambitious programme of regulatory science will require extensive collaboration across the broader ecosystem. To enable this, we will work with our network of Centres of Excellence in Regulatory Science and Innovation to deliver tangible progress in data science for regulatory needs.

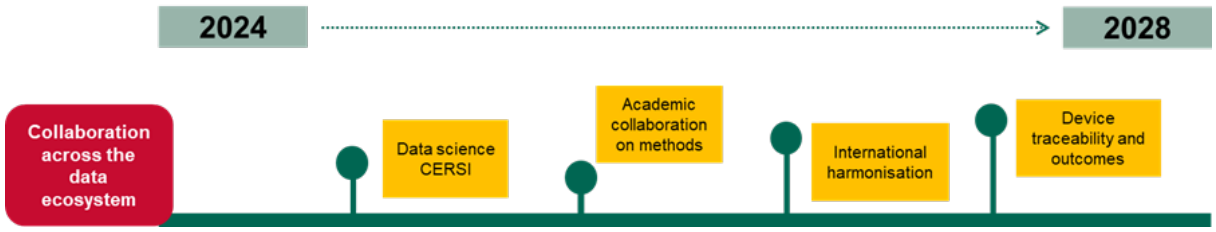
Over recent years, regulators worldwide have recognised that access to new data sources and associated analytical methodologies offer unparalleled opportunities to manage uncertainty through better evidence generation. Examples of such programmes include the European DARWIN and FDA Sentinel initiatives.

The network should provide MHRA with decision-ready evidence and methodology development to contextualise and validate signals of adverse events, reduce ambiguity in benefit-risk evaluation, enable timely and proportionate regulatory decisions, and facilitate monitoring of the consequences and impact of regulatory intervention such as risk minimisation measures. Collectively this effort should enable innovative product development and early market access through proactive approaches to safety and surveillance.

4. Establish, embed, and expand synergistic partnerships across the data ecosystem

To deliver Theme 4, we will:

- Leverage our Centres of Excellence in Regulatory Science and Innovation to deliver tangible progress in data science for regulatory needs.
- Support international harmonisation of terminology, nomenclature, and data standards by working collaboratively with partners such as ICH and IMDRF.
- Establish academic partnerships which will develop and apply novel analytical methodologies to improve the benefit-risk evaluation of medical products.
- Collaborate with partners across the UK to ensure collection and integration of decision-ready regulatory medical product data.



5. Safely and responsibly harness the potential of artificial intelligence and advanced analytics throughout the product lifecycle

Artificial intelligence and machine learning (AI/ML), alongside advanced analytical techniques such as modelling and simulation, are revolutionising our ability to make data-driven decisions across multiple sectors, creating opportunities for scientific discovery, and promising system-wide improvements in efficiency, productivity, and safety. These tools can sift vast quantities of heterogeneous data, discover unexpected patterns and associations, and integrate diverse data modalities which would previously have required distinct analytical approaches.

While there are considerable opportunities to apply and refine the more established AI/ML approaches, such as supervised and unsupervised learning, novel technologies, such Generative AI and Large Language Models (LLMs), are also subject to substantial current interest and the Central Data and Digital Office has recently published a Generative AI Framework for HM Government.

AI/ML approaches offer us tantalising possibilities to extract actionable insights from the wealth of data produced across the health ecosystem. They may also enable us to streamline our processes, improve our operational performance, and innovate across our digital estate.

Nevertheless, these promising tools require a thoughtful and considered approach to their application, particularly in a regulatory and evidence generation context. Quality and representatives of the underlying data used to train and evaluate AI/ML models is critical, and this will be a key area of focus.

5. Safely and responsibly harness the potential of artificial intelligence and advanced analytics throughout the product lifecycle

Box 6: Key issues in AI/ML for medical product development and regulation

- Data – quality, representativeness, and fitness for purpose
- Ethical development and application
- Intended purpose and context-of-use
- Model training and validation best practices
- Bias/variance trade-off: overfitting and underfitting
- Performance evaluation
- Reproducibility
- Uncertainty quantification
- Generalisability and subgroup performance
- Interpretability and explainabilility
- Distribution drift and continuous learning
- Human/AI interface
- Regulatory compliance
- Cybersecurity and resilience
- Governance and oversight

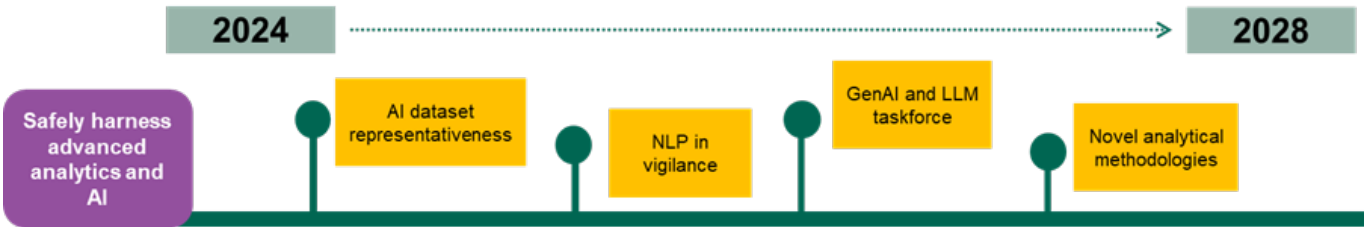
We will be mindful of the importance of fairness, consistency and trust, all of which underpin the application of novel technologies. Following Dame Margaret Whitehead's review of equity in medical devices, we will ensure that clear frameworks are in place to support the validation of AI/ML performance across the patient groups which will be affected by them.

It is critical with all analytical methodologies, but particularly so for AI/ML, that the uncertainty and reproducibility is considered and quantified. We will consider how these tools can be best integrated with human expertise and judgement, ensuring that there is clear accountability where such tools are utilised in product development and across multiple regulatory touchpoints.

5. Safely and responsibly harness the potential of artificial intelligence and advanced analytics throughout the product lifecycle

To deliver Theme 5, we will:

- Support UK-wide efforts to improve the representativeness of AI training datasets with a focus on equity, diversity, and fairness.
- Evaluate the use of natural language processing to improve our pharmacovigilance systems and operations.
- Establish a cross-functional task force to explore the operational potential of Generative AI and LLMs to augment our processes.
- Investigate the role of advanced analytical methods, including causal inference and AI/ML, for the analysis of RWD and generation of RWE to reduce ambiguity in benefit-risk evaluation.
- Evaluate the potential of novel methodologies analytical approaches to adverse event signal detection for both medicines and medical devices.
- Investigate the potential of advanced analytical approaches in support of the prevention, detection and investigation of threats to the UK public from medicines crime.



Abbreviations

AI/ML	Artificial Intelligence / Machine Learning
CDM	Common Data Model
CDDO	Central Digital and Data Office
CERSI	Centre of Excellence in Regulatory Science and Innovation
CM&S	Computational Modelling & Simulation
CPRD	Clinical Research Practice Datalink
DART	Data Analytics and Recruitment Tool
DARWIN	E.U. Data Analysis and Real-World Interrogation Network
DDaT	Digital, Data, and Technology
DHSC	Department of Health and Social Care
EHR	Electronic Health Record
FDA	U.S. Food & Drug Administration
GenAI	Generative Artificial Intelligence
HTA	Health Technology Appraisal
LMIC	Low- and Middle-Income Countries
LLM	Large Language Model
MHRA	Medicines and Healthcare products Regulatory Agency
NLP	Natural Language Processing
ODI	Open Data Institute
OHDSI	Observational Health Data Sciences and Informatics
OLS	Office for Life Sciences
OMOP	Observational Medical Outcomes Partnership
RWD	Real-World Data
RWE	Real-World Evidence
TRE	Trusted Research Environment
UKRI	United Kingdom Research and Innovation

Contact us

If you are a patient, member of the public, healthcare professional, or work in the sectors we regulate and would like more information on our work, please contact us.

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ANNEX B				
Deliverable	**Description**	**FY**	**BP 24/25 mapping**	**Anticipated resourcing**
1a	Continue our series of guidance documents on RWD/RWE and engage with stakeholders and global regulators to improve international harmonisation.	24/25 and ongoing	1.2, 3.1, 3.2, 3.4	Existing resource
1b	Develop a Scientific Dialogue Programme for RWD/RWE to improve clarity around regulatory expectations for innovative approaches to evidence generation.	24/25 and ongoing	1.2, 2.2, 3.1, 3.2, 3.4	Funded for 24/25, interim additional resource needed, and will aim to become fee earning
1c	Understand and describe patterns of underrepresentation in clinical research, thereby defining a harmonised view of inclusivity to improve generalisability and equity of access.	24/25 and ongoing	1.3, 3.1	Existing resource
1d	Develop principles and exemplars on the regulatory acceptability of computational modelling and simulation; in silico trials; and synthetic data.	25/26 and 26/27	N/A	Potential CERSI
1e	Pilot a Data, Methodology, and Endpoints Qualification process to support innovative evidence generation strategies across the product lifecycle.	26/27 and ongoing	N/A	Interim additional resource needed, and will aim to become fee earning
1f	Identify opportunities and deliver clear routes for real-world data to support early access to innovative medicines and devices whilst upholding safety through proactive surveillance in market.	26/27	N/A	Interim additional resource needed, and will aim to become fee earning

2a	Evaluate the role of common data models and federated analytics to generate RWE within the UK data ecosystem for both medicines and medical devices to address regulatory questions in a timely and scientifically robust manner.	24/25 and ongoing	1.3, 2.1, 3.1	Potential CERSI
2b	Deliver the necessary secondary legislation and associated guidance around medical device identification to support traceability across the medical device lifecycle.	24/25	3.1, 3.2	Existing resource
2c	Map, evaluate, and strategically engage with major device and outcome registries, and with NHS England's Outcomes Registry Platform programme, identifying opportunities to enhance our safety activities by leveraging RWD from across the UK.	24/25	2.1, 3.1	Existing resource
2d	Engage with stakeholders to establish the potential value of and address key governance elements required for linkage of Yellow Card spontaneous adverse event reports to routine electronic health records.	25/26	N/A	Existing resource
2e	Scope opportunities to expand and improve linkage between primary and secondary care settings to generate actionable regulatory evidence for medicines and medical devices and implement through driver projects.	25/26	N/A	Additional resource required, academic partnerships and grant applications
3a	Establish a Cross-Agency Data Science network to share expertise, encourage collaboration and foster innovation.	24/25	3.1, 4.1, 4.2, 4.3	Existing resource

3b	Strengthen our involvement with the Apprenticeship scheme and Graduate Programme, proactively identifying opportunities for digital and data focussed placements.	24/25 and ongoing	3.1, 4.1, 4.2, 4.3	Existing resource
3c	Participate in communities of practice across government, sharing knowledge, developing skills, and identifying opportunities to collaborate.	24/25 and ongoing	3.1, 4.1, 4.2, 4.3	Existing resource
3d	Conduct a Data Maturity Assessment programme to evaluate our internal data assets from across the organisation, aligning with the CDDO framework.	25/26	N/A	Existing resource
3e	Implement an Agency-wide data architecture based on the principle of 'collect once, use many times' to enable us to gain a comprehensive and end-to-end view of any specific medical product.	24/25 – 26/27	2.3, 3.1	Additional resource required
3f	Operationalise data management environments to productionise our data using best practices for data stewardship.	24/25 – 26/27	2.3, 3.1	Additional resource required
4a	Establish a Centre of Excellence in Regulatory Science and Innovation focussed on Data Science.	24/25 and ongoing	3.1	Existing resource
4b	Support international harmonisation of terminology, nomenclature, and data standards by working collaboratively with partners such as ICH and IMDRF.	24/25 and ongoing	3.1, 3.4, 4.1, 4.3	Existing resource

4c	Establish academic partnerships which will develop and apply novel analytical methodologies to improve the benefit-risk evaluation of medical products.	24/25 and ongoing	2.1, 3.1, 3.4, 4.1, 4.3	Existing resource
4d	Collaborate with partners across the UK to ensure collection and integration of decision-ready regulatory medical product data.	24/25 and ongoing	3.1, 3.4	Additional resource required
5a	Support UK-wide efforts to improve the representativeness of AI training datasets with a focus on equity, diversity, and fairness.	24/25 and ongoing	1.3, 3.1	Existing resource
5b	Evaluate the use of natural language processing to improve our pharmacovigilance systems and operations.	25/26 and ongoing	N/A	Additional resource required
5c	Establish a cross-functional task force to explore the operational potential of Generative AI and LLMs to augment our processes.	24/25 and ongoing	2.3, 3.1	Existing resource
5d	Investigate the role of advanced analytical methods, including causal inference and AI/ML, for the analysis of RWD and generation of RWE to reduce ambiguity in benefit-risk evaluation.	24/25 and ongoing	2.1, 3.1, 3.4, 4.1, 4.3	Existing resource and grant applications
5e	Evaluate the potential of novel methodologies analytical approaches to adverse event signal detection for both medicines and medical devices.	24/25 and ongoing	2.1, 3.1, 3.4, 4.1, 4.3	Existing resource and grant applications
5f	Investigate the potential of advanced analytical approaches in support of the prevention, detection and investigation of threats to the UK public from medicines crime.	26/27 and ongoing	N/A	Additional resource required

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

09 July 2024

Title	What will the Board effectiveness review cover in the upcoming evaluation and how will the results strengthen how the Board works?
Board Sponsor	Carly McGurry
Purpose of Paper	Approval

What will the Board effectiveness review cover in the upcoming evaluation and how will the results strengthen how the Board works?

1. Executive Summary

1.1. This paper sets out the proposed focus of the Board effectiveness evaluation for approval and considers how the results may be used, including by a new Chair when appointed, to strengthen the operation of the Board.

2. Introduction and Background

2.1. In line with best practice, the Agency Board Terms of Reference include a commitment to an annual review of the Board's effectiveness. This provides an opportunity for all members of the Board to reflect on what is working well and what could be improved or changed to better support the Agency in achieving its objectives. Such a review is normally led by the Chair, utilising anonymous feedback. As the Agency has been without permanent Chair for the last year, we had placed this exercise on hold pending the new Chair's appointment. However, we have come to the view that we should not delay further and as such below is a proposal for the topics to be covered by a survey to all members of the Board.

2.2. The proposed survey questions below align closely with the last set of survey questions developed by the previous Chair, based on NAO best practice guidance. Using an aligned survey set will allow us to see how perceptions of the Board's effectiveness have developed over time and to reflect on whether our previous interventions were successful. We are proposing however not to include any questions on the effectiveness of the chairing of the Board at this point, given the role has been covered on an interim basis for much longer than was initially expected. Finally, the proposed question do include an additional free text question seeking views on the priorities for a new Chair once a permanent appointment is made.

2.3. The results of this survey will be analysed by the Interim Co-Chairs in the first instance, to identify key themes for areas of improvement, for discussion by the Board. Once the new Chair is in post, the results of this survey will be shared with them and a plan for further discussion/review will be agreed. That plan will also include external review by an independent reviewer at an appropriate point, as per best practice.

3. Recommendation to the Board

3.1. The Board is asked to agree the proposed survey questions and approach, and to highlight any additional areas that should be considered. The Board is also asked to consider the intended approach to reviewing results and agreeing improvements.

Carly McGurry
2 July 2024

Annex A

Proposed survey questions, to be rated from 1 – strongly disagree to 5 – strongly agree.

Strategy

1. The Board sets the strategic direction for the agency with clear strategies, plans and objectives to fulfil its statutory duties.
2. The Board ensures that the agency has the financial and human resources in place to meet its strategic objectives.
3. The Board updates the agency's strategy to reflect any changes in the external operating environment and/or Government policy.
4. The Board ensures that all significant internal programmes and projects are aligned to the agency's strategy.

Leadership

5. The Board creates a positive and motivational organisational culture for our staff to thrive and deliver the agency's strategic objectives.
6. The Board acts as role models in engaging staff, making decisions, communicating clearly and leading by example.
7. The Board understands the UK health eco-system, the international regulatory environment and the opportunities for the MHRA to excel.
8. The Board develops productive working relationships with the agency's partners, stakeholders and DHSC sponsors.

Performance

9. The Board reviews the achievement and key outcomes from the agency's strategy on a regular basis so that plans can be updated.
10. The Board reviews the agency's operational performance on a regular basis to ensure that it is meeting external expectations.
11. The Board gets early warning of any problems that will adversely impact on the agency's ability to deliver its strategic or operational objectives.
12. The Board has collective accountability for the performance of the agency.

Risk Management

13. The Board Assurance Committees have sufficient expertise, support and access to key staff to discharge their oversight roles effectively.
14. The Board has a robust process to review the agency's principal risks and the mitigations to minimise their impact on a regular basis.
15. The Board is assured that all requirements of Managing Public Money are being satisfied.
16. The Board receives regular and insightful reports on internal controls to provide assurance on the effectiveness of the agency's governance.

Board dynamics

17. The Board has the right blend of diverse skills, expertise and thinking styles to address current and future opportunities and challenges.
18. The Board has developed the necessary trust and working relationships to support and challenge each other constructively.
19. All Board Members make valuable contributions at every meeting in line with the behaviours of the Board Charter agreed in September 2021.
20. The expertise of all Board Members is utilised in the development of new agency plans and partnerships outside Board Meetings.

Board meetings

21. The Board has the appropriate frequency, purpose and duration of meetings to fulfil its statutory responsibilities.
22. The Board has the opportunity to provide input into the Board's forward schedule of business.
23. The quality and availability of Board papers enables the Board to debate the issues on its meeting agendas effectively.
24. The Board Meetings add value to the strategic direction, leadership and governance of the agency.

Proposed open text questions

What are the Board's biggest development needs?
What are the Board's greatest strengths?
What do you consider the [top three/five] priorities for the new Chair once appointed?
Space for any additional commentary

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

9 July 2024

Title	**What assurance can be provided following the meeting of ODRC 10th May 2024**
Board Sponsor	Amanda Calvert
Purpose of Paper	Assurance

What assurance can be provided from the meeting of ODRC?

1. Introduction

The Organisation Development and Remuneration Committee (ODRC) met on 10th May 2024

- To review the progress on the Return to Green Programme with focus on the clearance of backlogs
- To review how quality will be embedded into the ways of working for the delivery of future services
- To discuss the scope and priorities for the MHRA Workforce Plan

2. Regulatory Connect

Release 1 was successfully delivered and there has been positive feedback from both internal and external users.

Release 2 has the bigger impact the service delivery teams across the Agency. Whilst an extensive "discovery" process has been undertaken, there is still a need to simplify the processes that will be used in the future rather than replicate the processes that are currently being used which are embedded in the current IT systems. The committee strongly supported using the revised processes, that have been developed through the RtG deep dives, as the basis for the design of the IT system in Release 2. There is a risk to the November 2024 delivery date for release 2. This is being mitigated through the establishment of a war-room to bring together the Digital, Change and Service delivery teams. The committee encouraged the team to use the deep dive and discovery data as part of the input to develop streamlined processes that would be fit for the future.

2. Review of progress of the Return to Green (RtG) programme and timelines for elimination of backlogs

Since December 2023 when the committee last met, a holistic programme "Return to Green" has been established under the leadership of Mick Foy to improve operational performance and embed sustainable changes to the way that services are delivered. The RtG programme is focusing on 5 key areas:

- Licensing – including Established Medicines, Innovative Medicines and Variations
- Safety Amendments
- Inspections
- Scientific advice – including scientific advice meetings and the Innovative Licensing Access Pathway (ILAP).
- Clinical Trials with a focus on sustainability of current performance

- **Approach –** The team reported that they had completed deep dives using a root cause analysis approach to understand the causes of backlogs and to develop sustainable processes for the future. The team have established a Terms of Reference for the RtG programme and have established formal governance and reporting processes. Dedicated project resources have been allocated to all RtG projects.

- **Progress –** The committee welcomed the summaries presented for each RtG project status. The monthly data for April was presented and discussed. Monthly data is presented to the board and executive and will not be discussed in detail here. The team is developing trajectory models for the clearance of all backlogs.

- Established Medicines (EM) - The committee were assured that the target of September for clearance of the EM backlog was credible. Process changes were required as well as recruitment and training of additional staff to achieve this goal.

- Clinical Trials – No backlog. All applications are being cleared within statutory timelines. Additional changes to improve resilience are being agreed with ExCo.

- Innovative Medicines and Licencing variations – Improvements in processes and additional resources have been secured to deal with the backlogs in these areas and plans for clearance of backlogs will be available soon.

- Inspections – Redeployment of resources, better triaging and planning and some contingent labour will be used to address immediate backlogs. More radical options are being developed to establish a more sustainable solution.

- Scientific Advice – Work is in progress to establish the root cause of issues and planning for a more sustainable solution for the future.

- **Assurance –**

3. Quality and Sustainable Services

Whilst the Agency operates to a number of quality management standards in different areas, there has been no aligned approach to quality and governance across the Agency. An external review has been undertaken to understand the governance framework required to support oversight and give assurance to the quality of the decisions and services that the Agency is responsible for and whether a peer review model would be appropriate.

The committee welcomed this approach as it sought assurance regarding the Agency's approach to quality. This is important both for patients and for staff at all levels across the organisation.

The committee discussed and supported the three main recommendations:

- Development of a quality and governance strategy for the MHRA owned by ExCo
- Incorporation of quality into the RtG process improvements to deliver improved and sustainable performance. This will give confidence about the "what" as well as the "how"
- Explore the benefits of peer review to strengthen complex decision-making and to support staff to work to their full potential.

4. **Workforce Planning**

Work is starting on the development of a workforce plan for the Agency. It was noted at Board that effective resourcing and workforce planning is the pre-eminent reason cited when performance issues arise. Recognising the challenges of pulling together a workforce plan, the committee offered support and experience of what they would expect to see within the plan and sought to gain assurance that the HR team were sufficiently resourced and supported to deliver the plan.

There was some discussion on the work that had been done to date that had identified a strong "expert culture" and that many key positions were still filled with people on very short term contracts (contingent labour).

It was agreed that the RtG programme was an opportunity to change some of the cultural practices that were no longer appropriate and to move towards a more quality and process driven culture rather than one that relied too heavily on individual experts.
It was agreed that there needed to be a talent acquisition strategy that allowed more flexible approaches to acquiring, training and using talent. The committee offered support and experience to the team responsible for developing the plan.

5. Concluding Remarks

- The Agency has sustained its performance with assessing clinical trial applications within statutory timelines throughout 2024. The ODRC were assured that changes had been embedded to sustain this performance.
- The RtG team under the leadership of Mick Foy is making positive progress to address the state of all backlogs and share learning between teams to establish processes that are fit for purpose and sustainable. The plan for eliminating the Established Medicines backlog by September looks robust.
- It is encouraging to see that there are much improved volume metrics for all the major services and this is enabling more accurate resourcing plans to be developed.
- The quality assurance and governance review undertaken by EY provides data and recommendations that can help address some of the cultural issues that the Agency has faced when undertaking change programmes to improve performance.
- The RtG programme is an opportunity to build the quality principles into the improved business processes through establishing consistent ways of working, adherence to standards and transparency in reporting and providing clarity on governance and decision-making processes.
- Phase 1 of Regulatory Connect was delivered on time in March 2024 and has delivered the improvements to staff ways of working and tools for customers. This is a significant milestone.
- The delivery date of November 2024 for Phase 2 of Regulatory Connect is at risk. Whilst extensive work has been undertaken in the “discovery” phase, there has been less focus on the improved processes required to deliver services. The work being done by the RtG team to design sustainable processes to deliver statutory obligations will form the bedrock of the system design for Phase 2.
- To be effective the Agency requires a highly trained, talented and flexible workforce to meet the challenges of new scientific innovations in medicines and devices and changes to the patient populations and economic environments that we work within. In the past we have relied heavily on expertise built over many years. Going forward we will need to be more responsive to change and the workforce plan is a vital tool to address this shift.
- The quality of our decisions and the services we deliver is built from many factors that were reviewed at this meeting; The revised business processes that are being developed, understanding the workload and capacity requirements (RtG), the technology required to support these processes (Regulatory Connect) and the people with the talent and expertise (Workforce Plan) working within a culture that is supported by governance and quality frameworks (Quality and Governance Standards) led by senior management team. The challenge is to bring all these strands together.

Amanda Calvert – Chair of Organisational Development and Remuneration Committee
June 2024

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

9 July 2024

Title	**AUDIT AND RISK ASSURANCE COMMITTEE (ARAC) Annual Report 2023-24**
Board Sponsor	Michael Whitehouse
Purpose of Paper	Assurance

Medicines & Healthcare products Regulatory Agency

Audit and Risk Assurance Committee Annual Report 2023-24

1. Executive Summary

1.1. This report provides the Board with an annual review of the Committee's work to provide assurance on the effectiveness of the MHRA's governance, risk management, financial and internal control arrangements over the last 12 months.

1.2. The Board is asked to receive the report and to note in particular the Committee's assessment of the work undertaken in 2023-24 (paragraphs 3.1 to 3.29) and the anticipated challenges for the coming year (section 4).

2. Introduction

2.1. The Committee's primary role is to provide the Board with an independent and objective view of the adequacy and effectiveness of the MHRA's governance arrangements, systems of internal controls, financial control, and the management of risk.

2.2. To discharge this function the Audit and Risk Assurance Committee (ARAC) prepares an annual report for the Board and the Accounting Officer. In addition, throughout the year after each Committee meeting the Board receives a short report summarising its discussion and highlighting any assurance issues to bring to the Board's attention.

2.3. Membership of the Committee remained unchanged throughout the year and no change is anticipated over the next twelve months. The Committee was pleased to welcome Sharon Mcarthy as independent adviser who has attended meetings since February 2024. No members declared any conflicts of interests for any agenda item during the year.

2.4. The Committee met seven times in 2023-24. All our meetings were quorate We were pleased to have input from the Chair of the Agency's Patient Safety and Engagement Committee at several of our meetings when we were considering risk or issues where both Committees had a remit. This approach is intended to strengthen governance through a focus on cross cutting issues and good practice.

2.5. The Committee held two horizon scanning meetings to help identify new emerging risks. One of which involved external partner organisations including NICE and the UK Health Security Agency.

3. Proposal

Audit and Risk Assurance Committee's assessment

3.1. The assessment of the Committee, based on the totality of the work presented to it, including; but not exclusively; internal and external audit work, is that is that financial controls are well designed and managed. The Committee has seen significant improvements in the Agency's approach to risk management and as confirmed by Internal Audit's independent review. A robust framework for identifying and managing risk is now in place. The challenge going forward is to ensure that the approach is fully and consistently embedded across the Agency and used effectively in decision making.

3.2. On wider governance and internal control, the Agency recognises that it has more to do as reflected in the Limited annual opinion awarded by Government Internal Audit Agency for 2023-24 (paragraph 3.7). Over the last 2-3 years the Agency has undergone significant change. This has set the requirement for major internal redesign of processes and investment in new technology. Agency staff are having to adapt to new ways of working. The Agency's "Return to Green" programme is now beginning to have an impact in ensuring that key processes are fit for purpose. More recent internal audit reviews have provided Moderate assurance reflecting the improvement journey which the Agency is on.

3.3. Over the next twelve months the Agency needs to have a plan to return to an annual Internal Audit Moderate opinion. Implementation of the plan needs to result in a body of evidence to demonstrate that the MHRA's internal governance framework is consistently operating effectively. The Committee received the plan at its July meeting. This is comprehensive and if implemented as intended should address the thematic issues identified by Internal Audit. We are pleased that the plan has dedicated senior executive leadership. The Committee will monitor progress and report to the Board accordingly.

Information supporting the Committee's opinion.

3.4. Summarised below are the key sources of assurance that the Committee has relied upon in formulating its opinion:

- **Internal Audit**

3.5. The MHRA's internal audit service is provided by the Government Internal Audit Agency (GIAA). ARAC can, should the need arise, commission private or specialist firms to perform discrete audits or investigations. There was no requirement to do this during 2023-24. All work was performed by GIAA which utilised its own specialists.

3.6. MHRA's head of Internal Audit during the year was Stephen Wright. The Committee agreed an annual work programme for internal audit at the beginning of the year. This was made up of 13 substantial reviews. These are set out below together with the period when they were delivered, and the assurance rating awarded. Annex A explains the ratings.

Audit Title	Timing	Rating
Data Security Protection Toolkit	Quarter 1	Unsatisfactory
Cyber Security	Quarter 1	Limited
Medical Devices Incident Reporting	Quarter 2	Substantial
Strategic and Business Planning and Performance Management	Quarter 2	Advisory
International Recognition Procedure	Quarter 2	Moderate
RMS Reset/Recovery	Quarter 2	Limited
Key financial controls	Quarter 3	Moderate
Recruitment Processes	Quarter 3	Limited
End of Life Systems / Technical Debt	Quarter 3	Moderate
Health and Safety Management	Quarter 3	Moderate
Backlogs	Quarter 4	Substantial
Business Continuity Planning	Quarter 4	Moderate
Risk Management	Quarter 4	Substantial

3.7. These audits informed the head of Internal Audit's annual opinion which the Committee reviewed in draft at its April meeting, receiving the final version at its July meeting. An opinion of Limited assurance was issued for the year ending 31 March 2024.This is the third consecutive year of Limited assurance.

3.8. The number of internal reports receiving moderate or substantial assurance has increased from five in 2022-23 to eight in 2023-24 which is good progress. Internal Audit recognised this and commented positively that there is evidence of embedding and further maturing of centrally orchestrated governance and that oversight processes are on a positive trajectory and are strengthening the organisation.

3.9. In order complete this transition, Internal Audit concluded that more substantive evidence is needed to be confident that performance is consistently resilient. Internal Audit identified four areas of systemic focus which the Agency should continue to prioritise. These are:

- Digital control environment
- Operational performance
- Corporate functions
- Change management.

3.10. The Committee considers that the Agency's new recently enhanced assurance mapping (paragraph 3.21) has good potential to provide more substantive evidence of progress in these key areas.

- **External Audit**

3.11. MHRA is subject to external audit by the National Audit Office (NAO). In respect of the Agency, the NAO currently subcontracts its audit to KPMG. The responsibility for recommending the audit opinion to the Comptroller and Auditor General (C&AG) is retained by the NAO. The opinion covers whether the accounts are a true and fair view of the financial affairs of the MHRA and whether its funds have been applied for the purposes intended by Parliament.

3.12. In support of the external audit process the Committee reviewed the Agency's accounting policies, the draft financial statements and draft annual report and on behalf of the Board provided the necessary assurances required by external audit.

3.13. The Committee is pleased to report that the NAO will be recommending that the C&AG gives a clear unqualified opinion on the MHRA's financial statements.

3.14. The NAO's Engagement Director and Engagement Manager attend each Audit Committee meeting together with KPMG. As external auditor of all Department of Health Arm's Length Bodies (ALBs) the NAO provides the Committee with useful comparative insights from across the sector and more widely from across central government.

- **Fraud, bribery and corruption**

3.15. All health ALBs are required to comply with the Government's Functional Standard GovS 013: Counter Fraud. MHRA's counter fraud, bribery and corruption strategy, policy and response plan is aligned to the Functional Standard. Fraud prevention both internal to the Agency and externally in the unregulated medicines supply chain are standing items on ARAC's agenda. In 2023-24 the Agency was peer assessed as fully meeting the requirements of the Counter Fraud Functional Standard.

3.16. They were no incidents of fraud, bribery or corruption detected during 2023-24 financial year.

Whistle blowing

3.17. There were no formal whistleblowing cases in 2023-24.

Information Governance

3.18. The Committee received two specific Internal Audit Reports on information governance (paragraph 3.6). We were also kept informed about the extent of the Agency's alignment with the National Cyber Security Centre's Cyber Assessment Framework. At our July 2024 meeting we received Internal Audit's most recent assessment of the Agency's performance using the Data Security Protection Toolkit. This received a Moderate opinion, demonstrating a significant improvement since the previous assessment in July 2023 which received an Unsatisfactory opinion. MHRA recognises that it has more to do to strengthen its cyber security and in particular resolving digital legacy risks. The Committee will continue to seek evidence to provide assurance that controls are effective.

Assurance Framework

3.19. The Committee has oversight of the operation of the MHRA's internal control and assurance arrangements. These arrangements include the:

- identification of corporate risks linked to business objectives
- assessment and management of high and medium level risks
- monitoring of the effectiveness of internal controls
- monitoring of financial controls and exception reporting
- considering of any instances of non-compliance with laws or regulations
- review of independent assurance reports.

3.20. We comment specifically on risk management in paragraphs 3.23-3.26.

3.21. A significant positive development is the detailed assurance mapping which was completed in the last quarter of 2023-24. This should help in determining whether the internal control environment is resilient and in identifying sufficiently early any emerging gaps which need to be addressed. The Committee will seek assurance on compliance with controls set out in assurance map over the next 12 months drawing on Internal Audit's independent scrutiny.

3.22. We considered reports from the Health and Safety Executive (HSE) on the Science Campus at South Mimms. The Board has been kept informed and remedial action is being implemented to resolve the safety issues identified by HSE. The establishment of a separate Health and Safety subcommittee of the Board from 2024-25 should strengthen governance.

Risk Management

3.23. The Risk Management Framework (RMF) sets out the MHRA's approach to risk management. It defines risk, outlines roles and responsibilities, explains how risk governance operates generally. Risk appetite is now defined. The risk approach aligns with the principles and concepts set out in HM Treasury's Orange Book: Management of risk.

3.24. The ExCo management committee - Risk and Assurance Group, was refreshed in 2023. This group meets monthly and supports the Executive Team and the Accounting Officer by ensuring effective management of risks, issues and opportunities across the Agency, enabling the successful delivery of Agency objectives. The Group is chaired by the Director of Governance. Membership is from across the organisation. The MHRA's risk management was reviewed by Internal Audit in the last quarter of 2023-24 and received a Substantial assessment indicating that management and control is adequate and effective.

3.25. The Committee reviews the risk register at each of its meetings reporting any emerging control issues as appropriate to the Board and ExCo. The Committee also held two risk horizon scanning meetings and undertakes periodic deep dives into risks such as cyber resilience.

3.26. The Committee has seen considerable strengthening of the Agency's risk identification and management over the last two years.

- **Governance and Management Reporting.**

3.27. The Committee received a range of assurance reports from management throughout the year. These included: losses and write offs, waivers, management of complaints and declarations of interest and conflicts of interest management. There were no material issues in 2023-24 to bring to the Board's attention.

- **Effectiveness of the Audit and Risk Assurance Committee**

3.28. ARAC effectiveness has been assessed using the National Audit Office questionnaire which measures it against six areas of: Membership, Skills & Experience, Roles & Responsibilities, Scope, Communication & Reporting and Continual Improvement. The assessment has been completed by ARAC members as well as internal and external audit teams. The analysis of the responses demonstrate that the Committee meets the essential requirements in most areas. The following three areas from the essential requirements have been highlighted for further improvement:

- Whistleblowing practices
- Assurance on the risk and control environment encompassing services outsourced to external providers, including shared service arrangements, and the wider supply chain.
- Consideration of key judgements in preparing the accounts

3.29. No specific audit and risk training was held last year but a training seminar is being planned for the autumn of this year. Managing the climate change and Environment, Sustainability Governance (ESG) risks has been particularly recommended in the assessment to excel the ARAC effectiveness.

4. Recommendation

Challenges and risks for 2023-24

4.1. In the coming year we will continue to review the range of strategic risks facing the MHRA, consider the controls in place and assess their effective management. In terms of focus, we are conscious of the following six issues and key risks facing the MHRA which will guide our work:

4.1.1. **Supporting "Route To Moderate" programme**. Strengthening the four systemic areas highlighted by Internal Audit is a high priority for the Agency. For each of the four areas: digital control environment; operational performance; corporate functions; and change management we will seek evidence of progress.

4.1.2. **Cyber security and resilience**. All organisations face this risk which is escalating in scale. Internal Audit's reports in 2023-24 have identified that the Agency has more to do to strengthen its digital control environment. The Committee will expect to see more empirical evidence to demonstrate progress and to provide assurance that as best it can; the Agency has in place resilient cyber security.

4.1.3. **Skills and capabilities**. As the Agency continues to transform its processes it is having to recruit new people and enhance its skill base. This needs to be guided by a medium to longer term plan together with greater transparency over the Agency's efficiency and productivity. The Agency is committed to developing productivity measures which strengthen both its ability to deploy staff and financial budgeting. Internal Audit will be reviewing progress and as part of its 2024-25 programme. The Committee will report the outcome of this work to the Board.

4.1.4. **Integration**. The Agency is making good progress in redesigning how it delivers its regulatory responsibilities. As this work is brought to fruition in 2024-25 it will be important that the Agency's new way of working - in essence its operating model, is integrated and underpinned by good system alignment. This will help strengthen resilience and support strong performance and efficiency if staff can be more easily deployed. Corporate services need also to be delivered in a more integrated way.

4.1.5. **Risk Management**. The MHRA has made considerable progress in strengthening its risk management and a key milestone recently has been the definition of the Agency's risk appetite. This is also potentially a key enabler of the cultural change which the organisation is seeking to achieve particularly in realising opportunities to support innovation which has good potential to benefit patients. The Committee will continue to support the Agency in realising the significant benefits of its enhanced risk management approach.

4.1.6. **Health system alignment**. In getting medicines and medical devices to patients to improve health outcomes the MHRA is one of many key organisations. The Agency's effectiveness depends on how well these organisations all work together as part of the wider health ecosystem. The Committee will continue to seek assurances on the effectiveness of joint working where this is relevant.

4.2. While all of the above are largely internally focused on governance issues, they are key enablers of ensuring that the MHRA is a consistently high performer Regulator which ultimately benefits patients in enhancing access to medical products in a safe and effective way.

4.3. The Committee wishes to say tremendous thanks for the support it has received from the Governance team over the last year. We also appreciate the work and insights of both Internal Audit and the NAO which have been invaluable. Finally, we thank the MHRA executive and their colleagues for the positive way in which they have responded to our scrutiny.

Michael Whitehouse,

Annex A : GIAA classification systems