Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

10:00 am – 12:40 pm on Tuesday 15 November 2022

Chair: Stephen Lightfoot

	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 activities and priorities from the CEO's point of view?	Context	June Raine
10:35	5. How much of the MHRA Delivery Plan was delivered and what was the operational performance of the Agency in the second quarter of 2022/23?	Assurance	John Taylor Marc Bailey Laura Squire Alison Cave
	SCIENTIFIC INNOVATION		
10:55	6. How is the MHRA providing safe access to data for research?	Assurance	Alison Cave & Puja Myles
11:15	7. What are the priorities for the MHRA Science Strategy to enable scientific innovation in the UK?	Strategic Direction	Marc Bailey
	PATIENT SAFETY		
11:35	8. How will the new MHRA SafetyConnect system deliver more responsive safety surveillance?	Assurance	Alison Cave & Phil Tregunno

	DYNAMIC ORGANISATION		
11:55	9. What assurance can be provided from the Joint Organisational Development & Remuneration Committee and Audit & Risk Assurance Committee?	Assurance	Mandy Calvert
	GOVERNANCE		
12:05	10. What assurance can be provided by the Audit & Risk Assurance Committee?	Assurance	Michael Whitehouse
	EXTERNAL PERSPECTIVE		
12:15	11. What questions do members of the public have about the items on this Board Meeting Agenda?	Public Engagement	Chair
12:40	CLOSE OF MEETING	-	

Item 02

MHRA Board Declarations of Interest – November 2022

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
Stephen Lightfoot Chair of Board	NHS Sussex Integrated Care Board	Chair	Yes	Yes
	Sussex Community NHS Foundation Trust	Deputy Chair and Non-Executive Director	Yes	No
	Sussex Primary Care Limited	Chair and Director	No	No
	Gainsborough Property Development UK Limited	Director	No	No
Dame June Raine Chief Executive	World Health Organisation (WHO) Committee on Safety of Medicinal Products	Member	No	Yes
Dr Marc Bailey Chief Scientific Officer	Nokia Corporation	Ex-employee shareholder	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
	Novartis Industry Council	Advisory to UK Pharma Exec	Yes	Yes
	UCLH	Non-Executive Director	Yes	Yes
	Whittington NHS Trust	Associate Non-Executive Director	Yes	Yes
	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

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Amanda Calvert Non-Executive Director	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.	Yes	Yes
	University of Manchester digital Experimental Cancer Medicine Team	Quince Consultancy providing strategy and data protection consultancy	Yes	No
	Cambridge Judge Business School	Member of Advisory Board	No	Yes
	The Guinness Partnership Limited – Housing Association	Non-executive Director, member of Audit Committee and Chair of Health and Safety Committee	Yes	Yes
	Fennix Pharmaceuticals	Founder of this start-up company planning to develop oral chemotherapy product into Phase 2 trial. Not yet trading.	Yes	No
Dr Alison Cave Chief Safety Officer	None	N/A	N/A	N/A
Professor Graham Cooke Non-Executive Director and Deputy Chair	30 Technology Ltd	Consultant/Advisor	Yes	Yes
	DNAnudge Ltd	Consultant/Advisor	No	Yes
	Seventh Sense Biosystems	Consultant/Advisor	Yes	Yes
	Debevoise and Plimpton LLP	Consultant/Advisor in relation to COVID protocols	Yes	No
	Sanofi CoV	Chair of End Point Review Committee for vaccine trial	Yes	Yes
	WHO	Chair of Committee for Selection and Use of Essential Medicines	No	Yes
	NIHR	NIHR Research Professor	Yes	Yes
Dr Paul Goldsmith Non-Executive Director	Closed Loop Medicine Ltd	Shareholder, director & employee; ILAP applicant and user of CPRD	Yes	Yes
	Summit Inc	Shareholder	No	Yes
	Ieso Digital Health	Shareholder	No	Yes
	MDU Ltd	Director	Yes	Yes
	MDU Investments Ltd	Director	Yes	Yes
	NHS	Consultant Neurologist	Yes	Yes
	NHS	Clinical Senate Member	No	Yes
	Big Tent Foundation	Trustee	No	Yes
	Radix Group Limited	Trustee	No	Yes
	Sleepstation	Co-founder of original programme, 2012-2014	No	No
Claire Harrison Chief Technology Officer	None	N/A	N/A	N/A

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
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	Panel Chair BS30440 – Use of AI within Healthcare	No	Yes
	Dementia Carers Count	Trustee	No	Yes
	World Wars Muslim Memorial Trust	Trustee	No	Yes
	Microsoft Corp	Shareholder	Yes	Yes
	BBC	Family Member	No	Yes
	NHS Buckinghamshire, Oxfordshire and Berkshire West Integrated Care Board	Associate Non-Executive Director	Yes	Yes
Mercy Jeyasingham MBE Non-Executive Director	Royal College of Podiatry	Consultancy	Yes	No
	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
	EC IMI NEURONET EC Innovative Medicines Initiative (IMI) Non-Product	Scientist Advisory Board	No	Yes
	Gates Venture – EC Innovative Medicines Initiative (IMI) Non-Product – IMI European platform for Neurodegenerative Disorders	Advisory	Yes	Yes
	HUYA Bio	Access Advisory	Yes	No
	PAVIA – PV Africa Board (EC Funded)	Advisory Board	No	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
Laura Squire OBE Chief Healthcare Quality & Access Officer	None	N/A	N/A	N/A
John Taylor Interim Chief Finance Officer	None	N/A	N/A	N/A

Item 02

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Michael Whitehouse OBE Non-Executive Director	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	Yes
	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 20th September 2022

(14:00 – 16:00)

Round Room, MHRA, 10 South Colonnade, Canary Wharf E14 4PU

Present:

The Board

Stephen Lightfoot	Chair
Dame June Raine DBE	Chief Executive
Dr Marc Bailey	Chief Science, Research & Innovation Officer
Dr Junaid Bajwa	Non-Executive Director
Dr Alison Cave	Chief Safety Officer
Amanda Calvert	Non-Executive Director
Professor Graham Cooke	Non-Executive Director and Deputy Chair
Dr Paul Goldsmith	Non-Executive Director
Claire Harrison	Chief Digital & Technology Officer
Haider Husain	Non-Executive Director
Mercy Jeyasingham MBE	Non-Executive Director
Raj Long	Non-Executive Director
Dr Laura Squire OBE	Chief Healthcare Quality & Access Officer
John Taylor	Interim Chief Finance Officer
Dr Glenn Wells	Chief Partnerships Officer
Michael Whitehouse OBE	Non-Executive Director

Others in attendance

Carly McGurry	Director of Governance, MHRA
Rachel Bosworth	Director of Communications, MHRA
Natalie Richards	Head of the Executive Office, MHRA
Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC

INTRODUCTION

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

1.1 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.

1.2 The Chair recorded the great sadness of the nation upon the death of Queen Elizabeth II and offered his condolences on behalf of the MHRA to her family. The Chair confirmed the MHRA's commitment to His Majesty's Government, the new Prime Minister and the new Secretary of State for Health and Social Care.

1.3 The Chair introduced John Taylor who has been appointed as Interim Chief Finance Officer; and congratulated Haider Husain who has now been appointed by Ministers as a full voting Non-Executive Director. The Chair also congratulated Mercy Jeyasingham who has been reappointed as a Non-Executive Director for a second term, until August 2026.

1.4 The Chair noted with sadness the death of Dame Valerie Beral, who served as a Non-Executive Director at the MHRA for 6 years. Dame Valerie was an internationally renowned cancer expert and strong advocate of CPRD; the Chair recorded his thanks for Dame Valerie's service to the MHRA.

Item 2: Are there any Apologies or Declarations of Interest

2.1 Apologies were received from 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 for all MHRA Board members. Amanda Calvert informed the Chair of a new Declaration of Interest; Amanda has recently set up a new company called Fennix Pharmaceuticals who are looking to develop an oral chemotherapy product. The Chair noted the new declarations and was satisfied that there were no conflicts of interest preventing any of the NEDs from participating in the full agenda of this meeting.

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 and updates were provided.

AGENCY PERFORMANCE

Item 4: 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) Scientific Research and Innovation – including latest updates on polio detection in sewage samples; vaccines and therapeutics for Monkeypox; influenza vaccine requirements; control testing; the UK Stem Cell Bank; and the Innovation Accelerator;

(ii) Healthcare Access – including updates on the COVID-19 booster vaccines; Project Orbis; smoking cessation; the first designation of a new UK Approved Body; remote and hybrid inspections; and Good Manufacturing Practice inspections;

(iii) Partnerships National and International – including an update on access to medicines in Northern Ireland;

(iv) Patient Safety – including updates on Yellow Card Scheme enhancements; engagement sessions on the SafetyConnect programme; risks of nebuliser use in asthma; a mexiletine hydrochloride recall; the African Union Smart Safety Surveillance project; and criminal enforcement through Operation Pangea;

(vi) Dynamic Organisation – including updates on the Regulatory Management System; the data centre migration; and a Health and Safety inspection by the Health and Safety Executive;

(vii) Financial Sustainability – including an update on the Agency Fees consultation.

4.2 The Board thanked Dr Raine for her report and thanked all MHRA staff for the excellent work over the last month. The Board provided comments relating to taking on learnings from working with international partners to improve future work; smartphone apps linking with the Yellow Card scheme; information exchange; complementing the information from the Yellow Card Scheme with information from other data sources, and continued work with NHS Digital to enable this; the review of Agency services to optimise service delivery; the Innovative Licensing and Access Pathway; and ensuring delivery of the Regulatory Management System. The Board noted Dr Raine's report.

Item 5: How much of the MHRA Delivery Plan was delivered in the first quarter of 2022/23 and are there any risks to its completion by 31 March 2023?

5.1 The Board considered a report on Delivery Plan implementation for the first quarter (Q1; April – June 2022) of the plan's second year. The Executive Committee concluded that the Agency is in a good position overall, with some notable items completed this quarter. Handling plans for the off-track items have been scrutinised and agreed mitigations are underway; and the deliverables for the refreshed Delivery Plan are now included. The Board noted that almost everything remains due within the plan's lifetime with some (previously agreed) exceptions where elements of work will roll over into future years; the Board also noted that Q4 is now very loaded.

5.2 The Board noted the report and provided comments relating to ensuring the deliverables are closely tracked to ensure the Agency is able to deliver what has been promised in Q4. The Board noted that the issue is related to timing – it is not related to achievability of the objectives. The Board provided further comments related to securing appropriate funding for delivery of the new clinical trials regulations, and impacts from IT system dependencies with external agencies (and how to avoid these situations in future); the delay in savings from corporate costs; mapping of legacy systems to future projects; and adjusting and refining projects to ensure delivery and avoid scope creep.

5.3 The Board provided further comments relating to supporting staff to prioritise delivery of these objectives, whilst also supporting staff during the cost of living crisis; the One Agency Leadership Group; beginning time recording exercises to identify non-productive activities; ensuring continuous dialogue with staff through both a top down and bottom up mechanism; and continuous improvement. The Board noted this report with thanks.

Item 6: What was the operational performance of the MHRA in the first quarter of 2022/23?

6.1 The Board considered a report on the operational performance of the Agency in the first quarter of 2022/23. The Board considered the performance report on finance and people, and provided comments relating to financial controls over debt recovery; reporting of debt; vacancies and performance; how the Agency seems to have turned a corner in relation to integrating the different areas of the Agency in to the lifecycle model of working, and further enhancements which will continue to improve this work; culture and walking the talk; staff retention and career progression opportunities, noting that a number of internal staff have achieved promotions meaning there are still vacancies to be filled; presentation of ethnicity, diversity and inclusion metrics, and how to report on other data of protected characteristics. An action was agreed to present an Ethnicity, Diversity and Inclusion report to the Board.

Action 84: A report on Ethnicity, Diversity and Inclusion should be presented to the Board; this should be added to the Board schedule.

Chair

6.2 The Board considered the performance report on patients, public and partners, and provided comments relating to reporting on the Agency's reputational index; it was noted a procurement tender was issued but was unsuccessful. The Board recommended a survey may be useful to understand what Members of Parliament think about the MHRA.

6.3 The Board considered the performance report on Science, Research and Innovation; and provided comments relating to enabling a holistic view across the whole clinical trial system, as well as metrics that the MHRA are able to control; developing partnerships to deliver in this space; the Recovery, Resilience and Growth Initiative; it was agreed to follow up with Professor Lucy Chappell to understand how MHRA can closely work with the National Institute for Health Research (NIHR) to deliver the new Clinical Trials Legislation and guidance.

Action 85: Follow up with Professor Lucy Chappell to understand how MHRA can work closely with NIHR to deliver the new Clinical Trials Legislation and guidance

Marc Bailey

6.4 The Board considered the performance report on Healthcare Quality and Access and provided comments relating to the improving of timeliness of authorisation decisions and the work to continue improvement in this area; increasing the quality of submissions to the Agency via feedback to industry; ensuring a clear narrative to

accompany the performance reports to the Board; and managing issues relating to compliance assurance activities.

6.5 The Board considered the performance report on Safety & Surveillance and noted the number of regulatory actions being taken. The Board considered the performance report on Digital and Technology and noted the importance of including measures to provide assurance on the progression of technology projects which are fundamental to the delivery of the Agency's strategic objectives.

Further to action 51: Consider the inclusion of MP opinions on the Agency as part of the Reputation Index for future performance reports. Also develop a monthly financial and people performance report for the Board

John Taylor

PATIENT SAFETY

Item 7: How many of the key MHRA deliverables have been implemented since the Cumberlege Review was published 2 years ago and what difference have they made to patients?

7.1 The Board considered a paper describing what has been achieved so far on the Agency's planned short, medium, and long-term deliverables in response to the Cumberlege Review, and the differences these have made or will make for patients. The Board provided comments relating to the ambition of using registries for medical devices and linking patients to devices using the Unique Device Identifier (UDI); the impact on timelines due to delays to work programmes following the merger between NHS England and NHS Digital; ensuring linkages across the healthcare ecosystem; enabling stronger pre-market requirements for medical devices; SafetyConnect as an enabler to proactively identify and address safety issues; connecting with NHS medical directors to develop an ecosystem approach to patient safety; the role of the Patient Safety Commissioner; and improving how information is provided to patients. The Board noted the report for assurance.

Item 8: What assurance can be provided by the Patient Safety and Engagement Committee?

8.1 The Board considered an assurance report provided by the Patient Safety and Engagement Committee (PSEC). The PSEC discussed four areas at its meeting on the 7th of July 2022; these were the development of how the committee reviews risk/benefit from a patient's perspective; CPRD Data Governance/ Real world data and how patient input is being embedded into it; Clinical Trials Consultation response; and adding Patient Safety topics to the work programme. PSEC also held a joint meeting with the Organisation Development and Remuneration Committee (ODRC) on Equality, Diversity, and Inclusion on the 26th of July 2022. This is the first time both committees met together. The topic of Equality, Diversity and Inclusion was discussed from internal and external perspectives. The Board noted the PSEC report for assurance with thanks.

DYNAMIC ORGANISATION

Item 9: What assurance can be provided by the Organisational Development and Remuneration Committee?

9.1 The Board considered an assurance report provided by the Organisational Development and Remuneration Committee (ODRC). The ODRC met on 2nd September 2022 and discussed a review of the effectiveness of the new organisational structure and operating model; a review of the progress for developing the processes for the 4 key services that the Agency delivers to achieve its objectives; an update on the progress of the development and roll-out of the competency development framework; and an item to note the progress of the people strategy.

9.2 The Board noted the report for assurance, and provided comments relating to reverse mentoring; the importance of delivery of MHRA services and greater Chief Officer involvement with the ODRC. An action was taken to develop the ODRC work programme and share this with the Board; and to identify time for the ODRC Chair to speak with respective Chief Officers to talk through their service areas.

Action 86: Work Programme for the ODRC to be developed and shared; identify time for ODRC Chair to speak with Chief Officers about their services.

Mandy Calvert

EXTERNAL PERSPECTIVE

Item 10: What questions do members of the public have for the MHRA Board?

10.1 The Board answered a range of questions which had been submitted by members of the public before and during the meeting. An action was taken to provide a written response to a particular question asked related to debt.

Action 87: John Taylor to provide a written response to the member of public who submitted a question regarding debt at the September Board

John Taylor

ANY OTHER BUSINESS

11.1 No items of Any Other Business were raised, and the Chair closed the meeting.

ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 20 September 2022

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.	Marc Bailey	~~21/09/21~~ ~~16/11/21~~ ~~17/05/22~~ 15/11/22	Paper on agenda
43	15/06/21: A revised assurance and governance framework for the new MHRA organisation should be presented to Board.	Carly McGurry	~~15/02/22~~ ~~17/05/22~~ ~~20/09/22~~ 21/03/23	
51	20/07/21: Review Balanced Scorecard metrics and targets to provide more focus on outcomes, greater links to the Delivery Plan and (especially on innovation) and assurance that resources are available to deliver priorities 21/09/21: Review the outcome measures in the Balanced Scorecard and the RAG Ratings in the quarterly Delivery Plan reports before considering if the targets are ambitious enough. 19/10/21: Continue to evolve the Balanced Scorecard metrics to include outcome measures. Update the data set for Clinical Trials in the balanced scorecard. 16/11/21: Broaden the measures to include the impact and quality of our scientific work rather than volumes. Seek input from our customers on what MHRA services they value for inclusion in the Balanced Scorecard. 18/01/22: A new approach for Board Reporting on operational performance, risk management and opportunity progression to be recommended to the Board. 20/09/22: Consider the inclusion of MP opinions on the Agency as part of the Reputation Index. Also develop a monthly financial and people performance report for the Board.	John Taylor	~~19/10/21~~ ~~16/11/21~~ ~~18/01/22~~ ~~15/03/22~~ ~~21/06/22~~ ~~20/09/22~~ 18/10/22	New Performance Report on agenda
59	21/09/21: Board assurance committees to review their	Michael Whitehouse,	~~15/03/22~~ ~~16/08/22~~	

	combined effectiveness and hold a board discussion on this topic.	Mercy Jeyasingham, & Mandy Calvert	13/12/22	
62	19/10/21: Review the Corporate Risk Register to consider whether all strategic risks to Agency outcomes are accurately captured.	Carly McGurry	~~19/04/22~~ ~~17/11/22~~ 17/01/23	
64	16/11/21: Review opportunities for more partnership working with other regulators as part of the MHRA International Strategy	Glenn Wells	~~15/02/22~~ ~~19/04/22~~ ~~20/09/22~~ 18/10/22	Completed
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	
71	18/01/22: Using the input from the public consultation and Board discussion, develop and publish a new regulatory framework for Artificial Intelligence as a Medical Device	Laura Squire	~~21/06/22~~ ~~20/09/22~~ 21/03/22	
73	15/02/22: Develop a Sustainability Strategy	Glenn Wells	17/01/23	
79	19/04/22: Hold a discussion on the Yellow Card Biobank at an upcoming Board meeting	Alison Cave	21/03/23	
80	19/04/22: Implement the Budget as approved by the Board for 2022/23. Ensure the deficit is balanced by end of the year.	ExCo	31/03/23	
83	21/06/22: A report on stage 1 and 2 complaints will be considered by the ARAC.	Carly McGurry / Michael Whitehouse	13/12/22	
New Actions				
84	20/09/22: A report on Ethnicity, Diversity and Inclusion should be presented to the Board; this should be added to the Board schedule.	Chair	15/11/22	Completed. EDI added onto Board Schedule in January with People Strategy
85	20/09/22: Follow up with Professor Lucy Chappell to understand how MHRA can work closely with NIHR to deliver the new Clinical Trials Legislation and guidance	Marc Bailey	15/11/22	Verbal Update

86	20/09/22: Work Programme for the ODRC to be developed and shared; identify time for ODRC Chair to speak with Chief Officers about their services	Mandy Calvert	15/11/22	Verbal Update
87	20/09/22: John Taylor to provide a written response to the member of public who submitted a question regarding debt at the September Board	John Taylor	15/11/22	Verbal Update

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 November 2022

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

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

'TOP 10' HEADLINES

- On 27th October we published our refreshed Delivery Plan 2022-23, which sets out our commitment to patient involvement, healthcare equity and innovative ways of working
- We have assessed two bivalent COVID-19 booster vaccines which target two different coronavirus variants: the original Wuhan coronavirus and the Omicron BA.5 variant
- Our leading role in the development of the novel oral polio vaccine has been recognised by the World Health Organisation (WHO) Director General following the global milestone of 500 million doses
- We are developing guidelines via an NHS programme for acute myeloid leukaemia detection and better informatics tools for analysing patients' genomic data
- Our scientists are contributing to a programme focusing on developing better tools to analyse the microbiome to improve access to personalised treatments for patients
- We held a workshop on licensing electronic cigarettes as medicines, to encourage safe, high-quality and effective e-cigarette products to be made available in the UK
- On 13th October we launched a consultation exercise with healthcare professionals on how we can strengthen our communications on medicines and devices safety
- We have introduced a 12-month extension to the implementation of the future Medical Device Regulations, reflecting our commitment to ensuring the future regime is robust
- In October the British Pharmacopoeia Commission welcomed the appointment of its first female Chair in its 150-years history, Dr Anna-Maria Brady
- We have launched a recruitment campaign for a Chair and members of the Interim Devices Working Group, which will ensure we have access to high quality expert advice

SCIENTIFIC RESEARCH AND INNOVATION

Novel oral polio vaccine

1.1 Ahead of World Polio Day, and prompted by the announcement of the administration of the 500 millionth dose of nOPV2, the Director General of the WHO Tedros Ghebreyesus wrote thanking "the organization for your invaluable support of the development and rollout programme of the novel oral polio vaccine type 2 (nOPV2)", noting that since its deployment most countries that have used the vaccine have observed no further transmission of cVDPV2 (circulating vaccine-derived polioviruses). Scientists in the polio teams were instrumental in the design and testing of nOPV2 and are now leading the assessment of genetic stability data during field use. During a visit to the Agency's Laboratory Facilities at South Mimms on World Polio Day, Will Quince, UK Minister of State for Health, took time to discuss this achievement with the Head of Polio Vaccines, later tweeting about the visit.

Tuberculosis vaccine discovery work

1.2 A scientist from SR&I-R&D-Vaccines-Global Diseases participated in the 8th annual meeting of Collaboration for Tuberculosis Vaccine Discovery (CTVD) which was held at the Bill and Melinda Gates Foundation Discovery centre in Seattle, USA. The meeting was to discuss recent advances in the field of TB vaccine discovery and consider strategies for moving the field forward. A poster was presented showcasing the recent collaborative work (funded by the EC Horizon 2020 programme - TRANSVAC2 project) in TB research using novel approaches, such as mass cytometry by time of flight and serum metabolomics, in evaluating comprehensive immune responses to identify potential biomarkers in mice vaccinated with or without BCG followed by Mycobacterium tuberculosis infection.

Influencing regulatory and clinical practice

1.3 Scientists from the Biotherapeutics and Advanced Therapies team were invited to the recent global Workshop on Recent Issues in Bioanalysis. The team provided input into regulatory panels and drafting groups and delivered presentations on their research work, in particular the development of the Infliximab reference panel for anti-drug antibodies (ADA) and challenges in the standardisation of cell and gene therapies. The work will lead to publication of position papers for industry and regulators on topics which include immunogenicity of novel biotherapeutics, including multi-domain therapeutics, antibody-drug conjugates, bispecific antibodies products and cell and gene therapies. Importantly, the development of the ADA panel is an important step towards better, standardised tests for clinical monitoring of patients and if implemented in clinical practice, will result in better outcomes for the patient.

Bacterial vaccines

1.4 A member of Microbial Toxins Group of SR&I, Research and Development, and previously in the Pertussis Group of Bacteriology, NIBSC, has successfully attained the award of Doctor of Philosophy from the University of Oxford. The project was in collaboration with the Oxford Vaccine Group and involved generating viral vector-based vaccines against pertussis (whooping cough), producing a number of vaccine candidates expressing various pertussis antigens of which some proved to have protective activity in murine challenge models. Studies indicate that this technology may be suitable for the production of bacterial vaccines.

International standard for Rift Valley Fever Virus

1.5 Scientists from SRI presented the ongoing work on the development of the WHO International Standard for Rift Valley fever virus antibodies at the World Vaccine Congress, in Barcelona 11th-17th October 2022. The work is part of our partnership with CEPI on standardization of serological assay to support vaccine development.

New potency assay for Influenza vaccines

1.6 A paper describing a potential new potency assay for inactivated influenza vaccines from an all-agency research team led by the Head of Seasonal Flu and Head of Antibodies in the SRI R&D Function has been published in Vaccines. Entitled, “Development of an ELISA-Based Potency Assay for Inactivated Influenza Vaccines Using Cross-Reactive Nanobodies”, this work builds on the discovery of nanobodies that are broadly cross-reactive for influenza A virus haemagglutinin (HA) protein as described previously by our team (Hufton et al). Using

such nanobodies, scientists in Research & Development were able to develop an ELISA-based assay for measuring the amount of active HA in influenza vaccines. Further work will be necessary to expand the use of the assay to all four components of quadrivalent influenza vaccines and to optimise the use of reference reagents.

Diagnostics for clinical oncology

1.7 The Genomics team, under the Research & Development and Standards Lifecycle, is participating in the NHS for the Knowledge Transfer Partnership (KTP) Program. Particularly, it is contributing in drafting new guidelines for detection of minimal residual disease (MRD) in Acute Myeloid Leukaemia (AML) and design better informatics tools for the analysis of genomics data obtained from liquid biopsy of NHS patients. Both tasks are based on the WHO International reference materials generated within the Team. An “ad hoc” workshop held in October helped to connect MHRA to NHS members and commercial stakeholders to identify biomarkers for cancer diagnostics and prioritise the generation of reference materials. The Genomics Team also participated to the submission of a European grant to increase harmonisation of genomics testing for precision medicine.

Diagnostics and the microbiome

1.8 There is increasing recognition that the microbial communities of bacteria, viruses and fungi that live in our intestines, collectively known as the gut microbiome, impact the outcome of medical interventions. There is evidence that this gut microbiome can determine the efficacy of treatments and the development of side effects in cancer treatment with the powerful class of immunotherapeutic drugs called immune checkpoint inhibitors. In collaboration with University of Liverpool our scientists presented a scientific poster and a talk entitled “Unravelling the gut microbiome and IgA dynamics in immune related adverse events to checkpoint inhibitor therapy” at the recent Microbiome Interactions in Health and Disease Conference held at the Wellcome Genome Campus. This project is part of a programme focusing on developing better tools to harmonise the analysis of the microbiome.

WHO global polio eradication Initiative

1.9 Our scientists continue to play a pivotal role on the WHO Global Polio Eradication Initiative contributing to the development and rollout of novel vaccines and leading surveillance activities, currently monitoring an outbreak due to type 2 vaccine-derived poliovirus in London. This work has produced the first evidence of poliovirus transmission in the UK since 1984 providing essential information to the UKHSA to plan immunisation campaigns to halt the outbreak and has led to a publication in the Lancet. In addition, we had the unique opportunity to discuss our research work with Bill Gates during the Bill and Melinda Gates Foundation (BMGF) Annual Grand Challenges meeting in Brussels. The work, framed within our project ‘Innovations to improve the speed and sensitivity of polio surveillance’ is conducted in collaboration with Imperial College London and funded by BMGF alongside several other projects which altogether provide substantial funds to support our polio work.

WHO Expert Committee on Biological Standardisation

1.10 In October, scientists from the Science, Research and Innovation group presented their work to develop and produce new or replacement biological standards to the WHO Expert Committee on Biological Standardisation These projects included replacement standards for SARS-CoV-2 antibody, rabies immunoglobulin, Interleukin-6 and Factor XIII plasma, and the replacement standards will ensure continuity of International Units for the evaluation of therapeutic products or clinical responses. In addition, completed projects for new biological standards were also presented, including antibody standards for SARS-CoV-2 variants of concern and Human Papillomavirus, an antigen standard for SARS-CoV-2, a therapeutic monoclonal antibody standard for Cetuximab, gene therapy standards for Lentiviral Vector Integration Copy Number, a reference panel for Infliximab anti-drug antibodies, and reference reagents for measuring antigen content of tetanus vaccines and D-antigen content of Inactivated Poliomyelitis Virus vaccines. These new standards will facilitate the development, manufacture, regulation, control and use of biological medicines and diagnostic assays.

HEALTHCARE ACCESS

COVID-19 vaccines

2.1 We have received and assessed applications for bivalent COVID-19 booster vaccines which target two different coronavirus variants, the original Wuhan coronavirus and the Omicron BA.5 variant. We sought advice on the first BA.5 vaccine from the Commission on Human Medicines in October. We are also working with our expert committees and international partners within the ACCESS consortium (Australia, Canada, Singapore, Switzerland and UK) on the need for updates to the guideline on the general regulatory requirements for variant vaccines.

New anti-epileptic medicine

2.2 We have granted a marketing authorisation for Ontozry (cenobamate) for the adjunctive treatment of focal-onset seizures, with or without secondary generalisation. This medicine is for use in adult patients with epilepsy who have not been adequately controlled despite treatment with at least two anti-epileptic medicinal products. Cenobamate had been designated a Promising Innovative Medicine by the MHRA in 2020.

Nicotine e-cigarettes

2.3 Unlike generally available consumer products, licenced products for smoking cessation are assessed by the MHRA for their safety, quality and efficacy before they can be placed on the market. Many manufacturers of nicotine e-Cigarettes are not familiar with licensing processes. On 4th October 2022, an industry workshop on licensing electronic cigarettes as medicines was held. The workshop explained the published guidance on e-cigarettes and the quality, non-clinical, clinical and delivery device data required to support marketing authorisation applications. The workshop also provided information on how to request regulatory and scientific advice. The workshop was attended by over 100 external stakeholders, including representatives from e-cigarette companies, pharmaceutical companies, CROs, academia, and UK and non-UK government.

Lenalidomide Pregnancy Prevention Programme

2.4 Lenalidomide is an important medicine in the treatment of multiple myeloma. Good Pharmacovigilance Practice inspectors conducted the high-priority and high-risk pre-launch inspection of a lenalidomide controlled distribution and pregnancy prevention programme intended to be used as a single system for multiple generic lenalidomide products. The purpose of the inspection was to determine whether the risk management system for lenalidomide was fit for purpose and would operate in compliance with the conditions of the marketing authorisation. It is hoped that this single system for multiple generics will prove to be a safe, efficient and user-friendly system for the NHS and other users.

Remote inspections

2.5 In the light of experience during the COVID-19 pandemic, further development of remote inspection approaches has continued. Inspectors conducted the first pilot of a hybrid approach for an inspection of a clinical and laboratory facility outside of the United Kingdom. Inspectors performed several inspection activities using remote tools, before travelling to site to complete aspects the inspection which could not be performed effectively without being onsite. This initial pilot was viewed as being successful, with learnings to be applied to further trials in 2023.

Software and Artificial Intelligence (AI) as a Medical Device

2.6 On 17 October, the Software Group published the Roadmap for the Software and AI as a Medical Device Change Programme. The Roadmap details 33 deliverables across 11 work packages to reform medical device regulation for software and AI as well as further details explaining our approach and methodology. We intend to have first drafts of 5 key deliverables published before the end of 2022. The Roadmap has received favourable attention externally and further efforts to promote elements of the Change Programme will follow shortly.

2.7 On 10 October, the Software Group announced that both the MHRA and NICE have been awarded £1.8m funding over three years to explore and produce guidance on regulating digital mental health tools. With regard to guidance, we will look to clarify what qualifies as a medical device in this area, what risk classifications might apply to such tools, as well as a review of the current evidence base for these devices. The project will also draw upon robust engagement with those with lived experience of mental health conditions.

PATIENT SAFETY

Yellow Card Scheme

3.1 The annual international campaign to encourage Yellow Card reporting of suspected adverse reactions and adverse incident with medical devices '#MedSafetyWeek' ran from 7th-13th November, and we prepared a communication plan alongside regulators in 82 countries. We have been a part of the project steering group led by Uppsala Monitoring Centre, to develop two social media animations and accompanying graphics. The theme this year is "how patients and healthcare professional make safety work" and encourages everyone to play their part in report suspected side effects. Our social media campaign had the hashtag #MedSafetyWeek; we issued a press release and we secured a stand at the Royal Pharmaceutical Society annual conference where our Yellow Card team will talk to delegates

about Yellow Card, MedSafetyWeek, Drug Safety Update pharmacy alerts and the current healthcare professionals consultation on how to strengthen our communications.

Medicines safety issues

3.2 Several safety issues resulted in regulatory action:

Methylphenidate modified-release preparations and switching

A Drug Safety Update article was issued advising prescribers and dispensers to use caution if switching patients between different long-acting formulations of methylphenidate, a medicine use in the treatment of Attention Deficit Hyperactivity Disorder due to differences in formulations, as different instructions for use and different release profiles may affect symptom management.

Pholcodine and potential increased risk of anaphylaxis

We have initiated a review of the use of pholcodine and a potentially increased risk of anaphylaxis on exposure to a group of medicines used in anaesthesia (neuromuscular blocking agents). This review is in parallel with the ongoing EU referral on this topic. We are assessing all available evidence and will seek relevant expert advice, including engagement with pharmacists, anaesthetists and patients, with the aim of determining what action is appropriate in the UK regarding this potential risk.

Rucaparib – withdrawal of third-line treatment indication

The third-line treatment indication for rucaparib has been withdrawn following a review of the findings of the ARIEL-4 trial, which showed lower overall survival for rucaparib treatment versus standard chemotherapy in patients with high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer. A Drug Safety Article has been published advising healthcare professionals to inform patients already receiving rucaparib for the third-line treatment indication of the latest data and recommendations, and to consider other treatment options.

Teicoplanin batch recall

On 21 October 2022, we issued a National Patient Safety Alert to support the recall of 2 batches of the antibiotic Targocid (teicoplanin) 200mg powder for solution for injection/infusion or oral solution (batches 0J25D1 and 0J25D2; expiry 30/04/2023). This was due to out of specification results obtained for bacterial endotoxins, confirmed through testing of retained samples. This issue was observed following a medical adverse event when patients experienced a high grade of fever after approximately 3 hours after receiving teicoplanin from the impacted batches. Healthcare professionals were asked to identify any patients taking it at home to ensure they stop use.

Interim Devices Working Group

3.3 We launched a recruitment campaign for a Chair and professional and patient members of the Interim Devices Working Group (IDWG). This will conclude in November with plans to hold the first meeting in January. The IDWG will ensure we have access to high quality expert advice on the safety on medical devices. The group will meet up to 10 times per year whilst the Statutory Advisory Committee outlined in the Medicines and Medical Devices Act goes through the legislative process including public consultation.

Manufacturers' on-line reporting of device incidents

3.4 The second webinar on the replacement Manufacturer's On-line Reporting Environment was provided to medical device manufacturers and their representatives in September 2022. There were 372 attendees. The webinar provided guidance on the new system, including how to report device incidents as well as timelines and steps to take for registrations. The MORE platform subsequently went live on 13th October and we are now processing registration requests in the run up to the new safety database, SafetyConnect, going live.

Criminal Enforcement Unit (CEU)

3.5 During October, we attended the first face-to-face meeting since the start of the pandemic of the Permanent Forum of International Pharmaceutical Crime (PFIPC) which brings together international regulators, law enforcement agencies, international organisations, and industry bodies from across the globe, including the WHO, International Lab Forum for Counterfeit Medicines and Pharmaceutical Security Institute. The MHRA currently holds the Secretary position and continues to influence and drive forward the global counter-medicrime.

3.6 A CEU investigation culminated with the owner of a medicines wholesale business being sentenced at court to a term of twenty weeks imprisonment (suspended for 12 months) and 100 hours community service for illegally importing and distributing medicines valued at £2.9 million. Beyond its punitive impact, this sentencing will act as a welcome reminder to others across industry of the potential consequences of failing to comply with medicines regulations.

PARTNERSHIPS

Regulatory Reform

4.1 We continue to progress reform to the legislation that underpins our regulation of medicines, medical devices and clinical trials. Analysis has been underway of responses to our public consultations on proposals to strengthen and improve our regulatory framework for clinical trials, and to introduce a new framework for innovative medicines manufactured at the point of care. We are preparing the official government responses to those consultations, aiming to publish shortly.

4.2 We have introduced a 12-month extension to the implementation of the future Medical Device Regulations, with an aim to bring the new regulations into force by July 2024. The future Medical Device regime is a substantial reform of the current framework, and the extension reflects our commitment to ensuring the future regime is robust and reflects the detail required to avoid disruption to supplies, support innovation and enable safe access to medical devices for UK patients.

British Pharmacopoeia

4.3 In October the British Pharmacopoeia and Laboratory Services Team hosted a bilateral meeting with the United States Pharmacopoeia to agree opportunities for future collaboration and partnership. Topics included global harmonisation of standards to reduce regulatory burden, future standards for digital therapies, environmental sustainability, analytical quality by design, and enabling guidance and standards for biological medicines.

4.4 Also in October, the British Pharmacopoeia Commission welcomed the appointment of its first female Chair in its 150-years history, Dr Anna-Maria Brady. Dr Brady is a biochemist with wide-ranging research and regulatory experience, including the Veterinary Medicines Directorate. She succeeds Professor Kevin Taylor after his extended 5-year service as Chair. Dr Brady's skills and knowledge are well-placed to support our work to develop innovation enabling standards in the growing fields of personalised medicines and novel biological medicines.

Global collaboration on compliance

4.5 The PIC/S 50th anniversary meeting was held in Dublin in early October 2022. PIC/S is the leading forum for collaboration, reliance and harmonisation between GMP inspection teams globally and where MHRA has played a leading role. The PIC/S future strategic plan was confirmed which included key areas aligned with our own compliance strategy such as the use of "PIC/S reliance" and developing capability and capacity across new medicines modalities and technologies. Bilateral meetings were held with US FDA and Health Canada where opportunities for future collaboration were identified that will build on our existing strong relationship with these peer regulators.

Innovative Licensing

4.6 We contributed alongside the FDA and EMA to the TOPRA (The Organisation for Professionals in Regulatory Affairs) Human Medicines Symposium 2022 on the topic of 'Are expedited programmes delivering on the promise to accelerate drug development and patient access?' The format of the session was presentations from each jurisdiction followed by a panel session and question and answers. There was strong interest in the Innovative Licensing and Access Pathway which was held up as a good example of helping to create an end-to-end approach to patient access by including both the medicines regulator and health technology assessment bodies. Issues discussed included capacity and resourcing, future directions and opportunities to streamline approaches.

International Coalition of Medicines Regulatory Authorities (ICMRA)

4.7 The 17th annual meeting of the International Coalition of Medicines Regulatory Authorities focussed on global pharmacovigilance, opportunities and pathways for innovative products, and dealing with public health emergencies. We have worked with the Brazilian regulator ANVISA to update the ICMRA Crisis Management Protocol, which was published on 13 October 2022 to include experiences and lessons learned from COVID-19. The protocol describes types of scenarios which regulatory authorities may encounter during a public health crisis, roles and responsibilities of ICMRA members, as well as strategies for communication and international collaboration, as part of a Standard Operating Procedure.

DYNAMIC ORGANISATION

Agency data centre move

5.1 The Agency's data centre move project has commenced work to set up and commission the new site. This involves transferring the Agency's network location and is being carried out in two parts to reduce operational risk. The team is now in the final stages of the first part, setting up the network, and once complete, will start to work with all relevant stakeholders to

mobilise plans to transfer the Agency's data and services. This will start with the migration of User Acceptance Test data. This is an opportunity for the team to assess the data migration approach and make changes if required, before transferring operational Sentinel data. The project team is continuing to work closely with a cross-Agency stakeholder group to assess the operational impacts of each change and understand the implications, while also giving notice of the subsequent service outages that are planned over the coming weeks and months.

Control testing activities

5.2 The Science Research and Innovation Group has undergone its annual surveillance audit by the United Kingdom Accreditation Service (UKAS) to assess its compliance to ISO 17025 standard for our control testing activities. The audit was conducted over 6 days, with four auditors attending, looking at the overall Quality Management System and specific test methods under the scope of accreditation, including three applications for extension of the scope of accreditation which were all successful. The audit resulted in 22 findings, many of which will result in updates to processes and systems, and clarifications for changed procedures, which will require significant work. The staff dedication and skills demonstrated during the technical audits were praised by UKAS and some minor non-compliances were received for this area. The accreditation to ISO 17025 was maintained but due to the significant findings, UKAS will need to receive a detailed plan for addressing the findings and will re-assess in 6 months after which a final report will be issued.

FINANCIAL SUSTAINABILITY

Fees consultation

6.1 Our public consultation on changes to the Fees Regulations is live until 23rd November. We have had 45 responses to-date all of which are broadly in favour of all 3 proposals. A common theme of the responses is how the proposals will affect small businesses and whether the changes will support improved regulatory services.

AGENCY PRIORITIES

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

i. Progress development of the three-year Corporate Plan 2023-2025 following from workshops with the One Agency Leadership Group and the Board.

ii. Continue to move forward with implementation of our services, as part of embedding our transformed organisation, following appointment of the new Director of Delivery

iii. Work with our stakeholders to develop the future medical devices regulations and support industry through transitionary provisions, building towards the introduction of the new regulatory system

iv. Review and refresh the Innovative Licensing and Access Pathway to build on the experience of the first 20 months and optimise the potential of the end-to-end pathway from discovery of innovative medicines to deployment

v. Compete the discovery phase of the new Regulatory Management System to deliver the next generation of digital technology, enabling our patient safety focused regulatory services as a standalone regulator

vi. Develop our national and international partnerships to enable safe access and continue to make UK an attractive environment to develop and deploy healthcare products, for the benefit of patients and the healthcare system.

Dr June Raine, CEO
November 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 November 2022

Title	How much of the MHRA Delivery Plan was delivered and what was the operational performance of the Agency in the second quarter of 2022/23?
Board Sponsor	John Taylor
Purpose of Paper	Assurance

How much of the MHRA Delivery Plan was delivered and what was the operational performance of the Agency in the second quarter of 2022/23?

1. Executive Summary

- The Agency's performance versus the Delivery Plan and our Key Performance Indicators in the second quarter of 2022/23 (ie July – September 2022) has been summarised in this report.
- This quarter's report has been simplified and the measures have been prioritised to give a clearer narrative on the overall performance of the Agency.
- Future developments of this performance report will focus on trend analysis and including more comparators.

2. Recommendation

- The Board is asked to review the report and identify if it needs any more assurance on the performance of the Agency.

John Taylor
November 2022

Medicines & Healthcare products Regulatory Agency

MHRA Performance Report on Delivery Plan Progress and Operational Performance in Quarter 2 of 2022/23

November 2022

Delivery Plan – Completed Work

COMPLETED ITEMS THIS QUARTER	
Deliverable	**Summary of work**
Develop a more consistent and effective approach to public consultations by end Q3	We have made the following improvements to our consultation platform to improve our ability to get input from patients and the public: • Improving the structure to make navigation easier, including the option to jump to sections of interest rather than having to comment on everything. • Improving the language so it is more understandable to non-experts. • Maximising exposure to relevant audiences, to increase awareness. We have seen an increase in the number of people responding to recent consultations. This gives us more information to inform regulatory decisions. For example, a consultation on access to a hormone replacement therapy received 1042 responses, a level not seen before for this type of consultation.
Review teratogen use during pregnancy by end Q2, independent patient and stakeholder input in Q3 and updated guidance and action to protect public health by end Q4	We are on track to complete this by end Q4. The Q2 deliverable was a paper summarising our review of teratogenic medicines information on use during pregnancy, and planned steps for stakeholder engagement. This was presented to the Maternity and Women's Health Expert Advisory Group in September. We continue to take this work forward and the next step is stakeholder engagement during Q3. This important work will protect the public and ensure better advice for women during pregnancy.
Continued delivery of leadership development plan from Q1 to Q4 to support Delivery Plan implementation	All Q2 leadership development plan actions have been completed, including roll out of the reverse mentoring campaign and start of activity to promote Leadership in Action leadership attributes. There are several actions in the plan that span 2022/23 and the aim of the work is to increase staff capability and help deliver a more dynamic organisation.
Upgrade observational research infrastructure to enable timely and secure delivery of research data services: define requirements and commence implementation of new systems by end Q2	The upgrade of the observational research infrastructure involves the development of a Trusted Research Environment (TRE), so that we can remain compliant with national requirements and in-line with the Goldacre Review recommendations. We aim to transition to a predominantly TRE-based model of data access by end 2025/26. Our Phase 1 deliverables (i.e., the back-end technology infrastructure) have now been agreed and implemented. This work will ultimately enable more timely and secure research data services.
Improve our ability to exchange data with partners by adopting international standards; define adoption approach by end Q2; new system full implementation by end Q1, 2023/24	We have defined our adoption approach in our Data Principles document which describes our principles and meets the Government Digital Service code of practice. The principles are: data is a valued asset; data is managed; data is fit for purpose; data is standardised and linkable; data is re-used; data is available; secure data storage and transmission; and appropriate access (role based). To meet principle 4 ("data is standardised and linkable), we will use international standards for data for medicinal products, clinical data and healthcare data exchange as well as standards for date, country etc. data. This work is on track overall and will help improve our ability to work with our partners.
Launch consultation on engaging with healthcare professionals by end Q2	The consultation went out slightly after Q2 (12 Oct) but is now live. It will run for 12-weeks and will be promoted widely across registered professionals and representative organisations. The aim is to collect feedback on improving our safety communications to increase our impact and influence.
Develop, consult on (Q2) and implement a new fee structure from Q1, 2023/24	Consultation launched on 31 August and live until 23 November. It seeks views on proposals to change our statutory fees. The proposals are designed to make the Agency more financially sustainable.

Delivery Plan – Schedule Summary

	Q1 (Apr – Jun) →	Q2 (Jul – Sep) →	Q3 (Oct – Dec) →	Q4 (Jan – Mar) and beyond →
Patient and public involvement	Pilot patient "listening sessions" approach as a better method of seeking patient input, and define its role going forward by end Q1	↓ Define deliverables on Patient Reported Outcome Measures to better understand the impact of regulation on patients by end Q2 and deliver these by end Q4	Develop new process to safely and ethically expand patient engagement in our work. For example, developing training and support for patients and members of the public in contributing to our work by Q3	Tailor patient engagement guidelines to ensure the needs of different parts of the population can be included; for example, those who are already engaged with us and those who are not, by Q4
		↓ Deliver staff training and support via new "Patient Champion Network", to improve staff understanding and ability to deliver patient engagement by end Q2		Pilot new patient engagement guidelines through two patient "listening sessions" as a method of seeking patient input in an ethical, respectful and consistent manner, by Q4
		↓ Develop our understanding of patient perceptions of benefit-risk to enhance regulatory decision-making, define deliverables by end Q2 and deliver these by end Q4	Develop a more consistent and effective approach to public consultations by end Q3	Incorporate patients' views and lived experience in at least 50% of our substantial benefit-risk reviews by Q4
				Develop plans to support patient contributions to committees and groups to improve patient representation and contributions by end Q4
Equity in healthcare	Nothing scheduled in the Delivery Plan, focus on core business	↓ Improve diversity of our patient group consultative forum to enhance its contribution to regulatory decision-making by end Q2	Define deliverables for integrating our suspected side effect data with NHS healthcare records to deepen our understanding of the representativeness of our data and the impact of demographics in patient adverse drug reactions by end Q3	↓ Review women's health regulatory inequities by end Q4
				→ Improve UK medical devices legislation by requiring more representative product clinical data to increase assurance of reduced bias and appropriateness for different populations; put legislation before Parliament and publish guidance and best practice phased over mid-to-late 2023
				↑ Reform UK clinical trials legislation, including encouraging the inclusion of underserved populations and increasing diversity in clinical research; put legislation before Parliament by end Q4
				Provide translated webpages on how to engage with our Yellow Card scheme in languages other than English commonly spoken in the UK to improve inclusion and accessibility by end Q4
		↑ Review teratogen use during pregnancy by end Q2, independent patient and stakeholder input in Q3 and updated guidance and action to protect public health by end Q4	Launch a project to define a sustainable business model and commence pilot set-up activities for a service to investigate the role of genetics in the development of adverse drug and vaccine reactions by end Q3	Improve our ethnicity data by using a new algorithm and integrating a more accurate and updated ethnicity record into the anonymised patient records within our databases by end of Q4
				Develop a prototype web-based tool that detects and correct biases due to underrepresented populations for Artificial Intelligence applications by end Q4
				Improve UK regional representativeness of our clinical practice research data service to include at least 10% of GP practices across all UK regions by end Q4

KEY: Red: late or no longer possible; Amber: at risk; Green: on-track; Blue: complete (n.b. colour combinations also possible); Trend arrows: RAG change from previous quarter (↑ improved, → no change, ↓ worsened)

Delivery Plan – Schedule Summary

	Q1 (Apr – Jun) →	Q2 (Jul – Sep) →	Q3 (Oct – Dec) →	Q4 (Jan – Mar) and beyond →
Scientific Innovation	Nothing scheduled in the Delivery Plan, focus on core business	Nothing scheduled in the Delivery Plan, focus on core business	Publish new regulatory science strategy by end Q3	Work with the HRA and the NIHR Clinical Research Network to provide regulatory support for expediting delivery of defined clinical trials; support a pilot to improve set-up of phase 1 oncology trials by end Q4
				↑ Improve UK clinical trials legislation, including encouraging the inclusion of underserved populations and increasing diversity in clinical research; put legislation before Parliament by end Q4
			Risk-based approach to batch release: guidelines drafted by end Q3; implement independent testing based on risk-based strategy by end Q4	Work with our Access consortium partners to deliver a clinical trial work and information sharing mechanism, put forward proposals for a common assessment template, and associated guidance to ensure a more harmonised approach by Q4
				↑ Improve our IT platforms to support delivery of an enhanced clinical trials service by end of Q4
Embedding innovative WoW	Refresh culture action plan by end Q1 and continue driving culture change needed for new operating model	Continued delivery of leadership development plan from Q1 to Q4 to support Delivery Plan implementation	Deliver a refreshed health and safety system, including high hazard assurance monitoring, by end Q3	Implement innovative devices pathway in conjunction with innovative medicines and build foundations for collaborative approach with the Access Consortium by end Q4
		↓ Publish new people strategy by end Q2 to support the implementation of our Delivery Plan and retain our status as a world-leading regulator and employer	↓ Launch key redesigned services and supporting process and systems, including design of a refreshed underpinning quality management system, by end Q3	
		↓ Update talent management model by end Q2 to ensure we attract, develop and retain world-class scientific and regulatory capability	Embed operation of new risk proportionate established medicines pathway by end Q3 [tbc]	
		↓ Engage with staff to refresh vision statement and values and behaviours framework to align with the new operating model by end Q2	Implement new inclusive hybrid working policy by end Q3 to ensure an effective working approach that balances business and staff needs	

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Delivery Plan – Schedule Summary

	Q1 (Apr – Jun) →	Q2 (Jul – Sep) →	Q3 (Oct – Dec) →	Q4 (Jan – Mar) and beyond →
Healthcare Access	Nothing scheduled in the Delivery Plan, focus on core business	Finalise Compliance Strategy through consultation with external stakeholders by end Q2 *(n.b. strategy finalised but final approval meeting had to be postponed due to rail strike)*	Embed visual technology capabilities as a standard part of inspections by end Q3	→ Establish new devices framework to support safe innovation and ongoing access to products: lay statutory instrument and publish guidance and best practice phased over mid-to-late 2023
				↓ Lay the statutory instrument for remaining elements of the first tranche of legislative change proposals by end Q4
				↑ Deliver a set of work packages to ensure that AI as a medical device is underpinned by robust evidence to enable safer innovation by end Q4
				Ensure integrated UK regulatory pathways for products that combine medicinal products and devices; consultation by end Q4 [tbc]
Patient Safety	Nothing scheduled in the Delivery Plan, focus on core business	Upgrade observational research infrastructure to enable timely and secure delivery of research data services: define requirements and commence implementation of new systems by end Q2	Work with others in the healthcare system to implement new, strengthened safety measures for sodium valproate by end Q3, and to continue to drive down the number of exposed pregnancies	↓ Review the available evidence on pelvic mesh benefit-risk by end Q4
			Agree policy for an enhanced devices transparency regime by end Q3, with key elements delivered over 2022/23 and 2023/24	↓ Develop risk communication strategy to ensure more coordinated, pro-active communications by end Q4
			Launch a project to define a sustainable business model and commence pilot set-up activities for a service to investigate the role of genetics in the development of adverse drug and vaccine reactions by end Q3	
		↑ Review teratogen use during pregnancy by end Q2, independent patient and stakeholder input in Q3 and updated guidance and action to protect public health by end Q4	Improve model of the Devices Expert Advisory Committee: launch consultation by end Q3; and establish statutory committee by July 2023	Deliver expanded scope of NHSX-funded synthetic data research project and launch the synthetic data service by endQ4
			↑ Deliver enhanced signal detection process; roll out from Q3, 2022/23 to end of Q4	

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Delivery Plan – Schedule Summary

	Q1 (Apr – Jun) →	Q2 (Jul – Sep) →	Q3 (Oct – Dec) →	Q4 (Jan – Mar) and beyond →
Dynamic organisation	Deliver HR support and guidance to staff during restructuring throughout Q1-Q4, 2021/22	→ Deliver our Transformation Programme including a plan for optimised services benefits realisation and implement restructuring; operationalise the future operating model and redefine and optimise prioritised core services by end of Q2	Deliver our data strategy, including a data sharing strategy, underpinned with robust security standards and privacy by design by end Q3	↓ Review our use of expert and advisory committees to ensure best use of expertise, the application of consistent, high-quality standards of operation and safeguard their important independent advisory role, by Q4
	Review workforce in Q1, identify follow-up actions to ensure we embed workforce planning by Q4	↓ Fully scope what self-service functionality can be delivered via the Regulatory Management System by end Q2 and deliver the core system by end Q1, 2023/24		Review workforce in Q1, identify follow-up actions to ensure we embed workforce planning by Q4
		↓ Complete main elements of our rebranding to ensure consistency and raise our profile by end Q2		Support revised medical devices regulations, deliver the digital self-service, automation and data platforms required by early- to mid-2024
Collaborative Partnerships	Nothing scheduled in the Delivery Plan, focus on core business	→ Identify which flexibilities introduced in response to COVID-19 are safe to embed by end Q2	Consult on a national GB scheme to replace Falsified Medicines Directive safety features regulation; put legislation before Parliament as per departmental timescales; and agree position on Falsified Medicines Directive for Northern Ireland post 3-year EU derogation, by end 2023	Publish a partnerships strategy by end Q4: setting out our long-term partnerships approach and the impact that partnerships can achieve
		↓ Identify key policy areas for the second tranche of legislative change and define timescales for putting legislation before Parliament over 2022/23 and beyond by end Q1		
		Improve our ability to exchange data with partners by adopting international standards; define adoption approach by end Q2; new system full implementation by end Q1, 2023/24		
		Launch consultation on engaging with healthcare professionals by end Q2		Agree policy on reliance and recognition, for global implementation by Q4 2023/24

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Delivery Plan – Schedule Summary

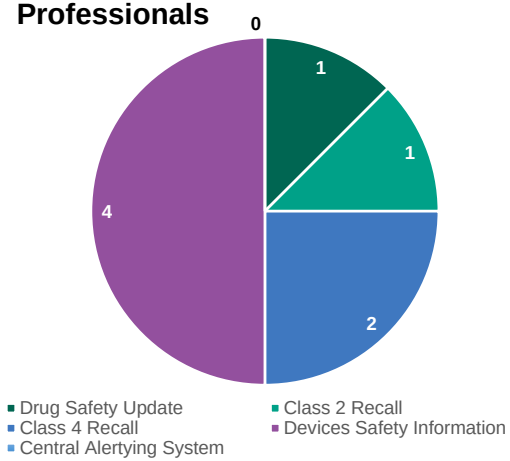
	Q1 (Apr – Jun) →	Q2 (Jul – Sep) →	Q3 (Oct – Dec) →	Q4 (Jan – Mar) and beyond →
Financial Sustainability	Finalise plan to overhaul outmoded legacy IT systems by end Q1	Develop, consult on (Q2) and implement a new fee structure from Q1, 2023/24	Nothing scheduled in the Delivery Plan, focus on core business	Implement organisational design, creating a new, leaner organisational structure and balancing costs by end Q4, 2023/24
				Reduce corporate costs including technology costs by 15% by the end of 2024/25

KEY: Red: late or no longer possible; Amber: at risk; Green: on-track; Blue: complete (n.b. colour combinations also possible); Trend arrows: RAG change from previous quarter (↑ improved, → no change, ↓ worsened)

Patients, Public, Partners and Customers

Delivery Plan Priority – Patient and Public Involvement

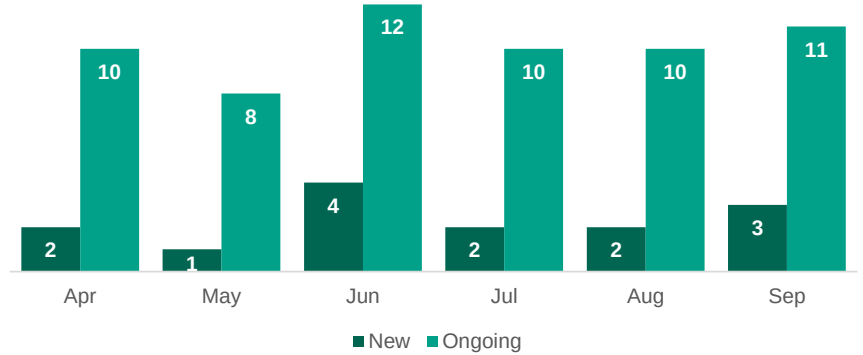
Q2 Communication to Healthcare Professionals



Patient Engagement Training Completed by Staff From Q3

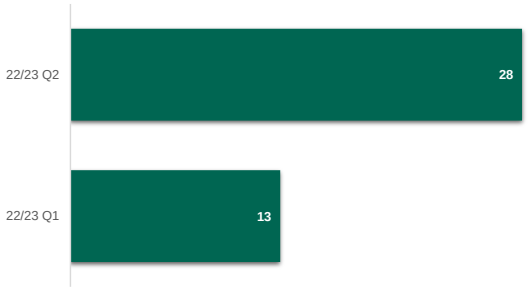
Following its launch on 25 October,76 members of staff (from across all 7 Groups) have registered and 37 have already completed through to certification. These figures are in addition to the 18 users tested who completed the product prior to launch.

Internal requests for patient engagement activities



This shows the number of new requests for patient engagement from across the agency, together with ongoing patient engagement projects across the organisation. It includes support for patient engagement relating to matters being considered by the Commission on Human Medicines and expert committees.

Scientific Papers Published



Reputational Index From Q4

Tendering process currently underway for supplier to provide this data. Procurement is due to complete by January with the aim to have the first index (baseline) in Q4.

Public Assessment Reports

- 4 PARs on self-mediation reclass procedures
- 3 on safety – (the COVID vaccine ADR public report)

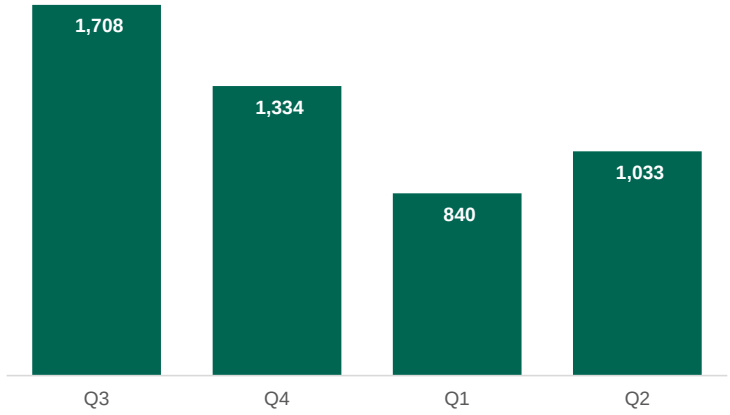
PARs published for new marketing authorisation – *(Target is 60 calendar days from licence grant, plus any clock off time)*

- Jul 22 - 40 (34; 85% completed on time)
- Aug 22 - 30 (27; 90% completed on time)
- Sep 22 - 22 (17; 77% completed on time)

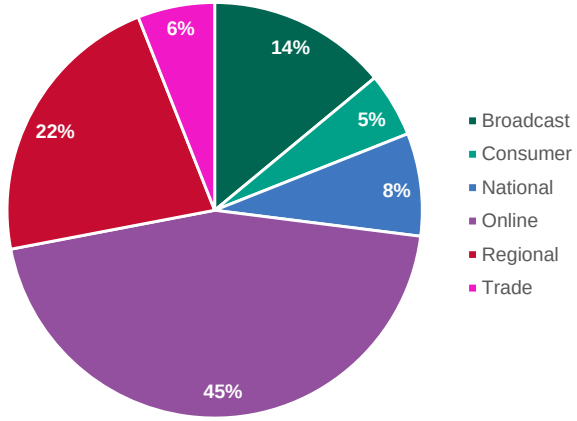
Patients, Public, Partners and Customers

Delivery Plan Priority – Patient and Public Involvement

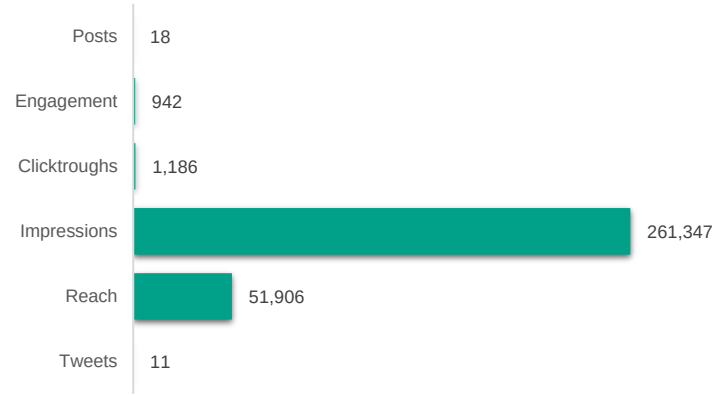
Media Article Mentions



Q2 Articles by Media Type



Social Media Reach – Month of September



MHRA was featured in 1,033 articles in Q2, reflecting a 23% increase compared with the last quarter. This quarter also saw renewed COVID-19-related coverage following the approval of the Moderna vaccine which is designed to target the original variant and Omicron. News of the approval by MHRA was covered widely by the media and appeared in prominent outlets with high eadership figures such as BBC News and Daily Mail. Dr June Raine, Chief Executive, was quoted in nearly all of the relevant articles and was Q2's most prolific agency spokesperson. Dr Raine accounted for 70% of all articles that featured a spokesperson while Laura Squire, MHRA Chief Healthcare Quality and Access Officer, was the second-highest and appeared in articles relating to the offering of a hormone replacement therapy over the counter amongst others.

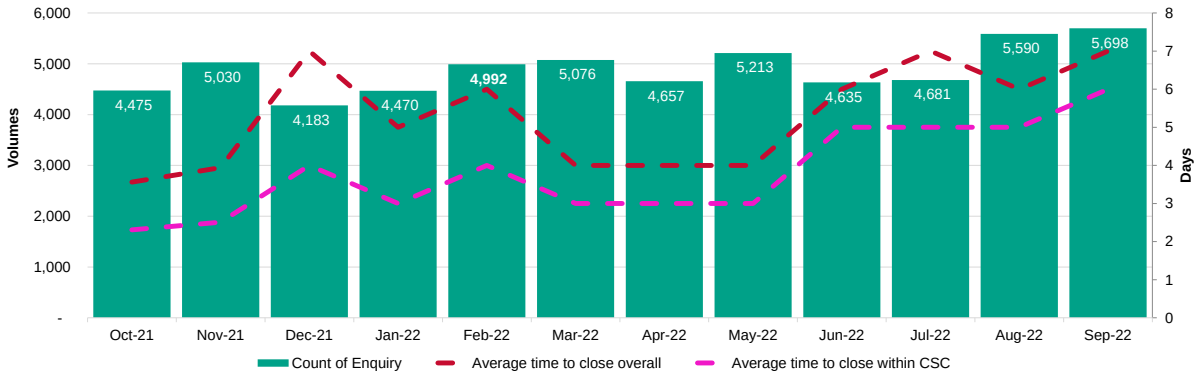
Amongst prominent non- COVID-19 coverage was news that a hormone replacement therapy (HRT) can now be sold over the counter for the first time in the UK. Articles mentioned that: "The drug was reclassified from a prescription-only medicine to a pharmacy medicine by the Medicines and Healthcare products Regulatory Agency (MHRA) earlier this year" (Independent, Sky News, The Telegraph).

In terms of social media, we had 380 new Facebook followers, 671 new LinkedIn Followers and 50 new twitter followers. Social media activity was paused for much of September because of the national mourning period.

Patients, Public, Partners and Customers

Delivery Plan Priority – Patient and Public Involvement

Customer Experience Centre – Queries per Month



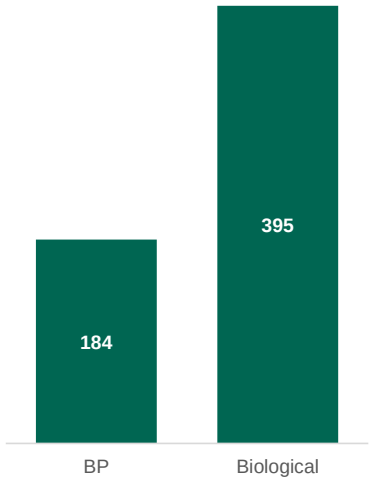
Count of enquiry refers to any telephone call, email or letter received at the Customer Experience Centre, including Freedom of Information requests and complaints.

Average time to close overall: this is the average number of days before a enquiry receives a response, including those which are answered fully within the Customer Experience Centre and those where input is sought from another team within the agency.

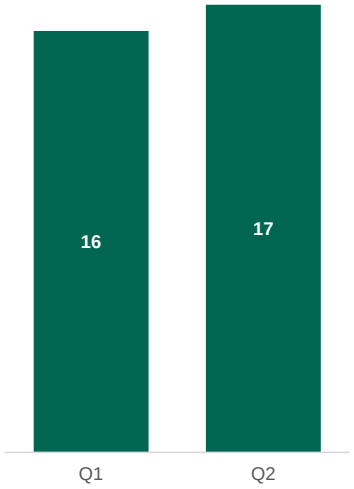
Average time to close (CEC): refers to those enquiries which are handled entirely within the Customer Experience Centre with no involvement in response from any other team within the agency.

The dip in performance in Q2 reflects the impact of Transformation and staff shortages within the Customer Experience Centre team and wider agency.

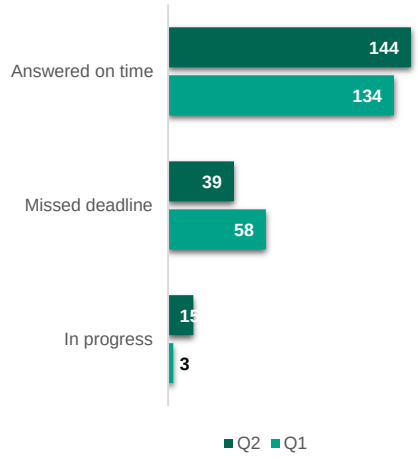
New Customers - Standards



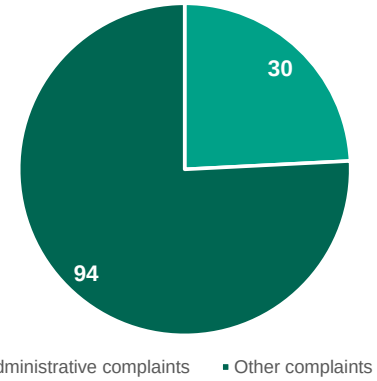
Parliamentary Questions Received



Freedom of Information requests received and responded to in 20 days



Complaints

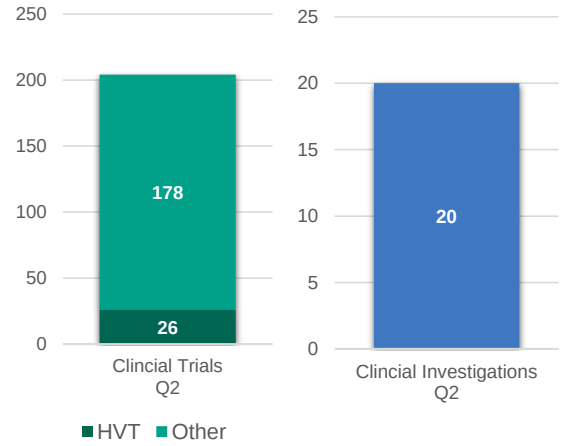


Administrative complaints are about the Agency's handling (eg: delays, whether a process has been followed) and do not include complaints or dissatisfaction about policies or regulatory decisions.

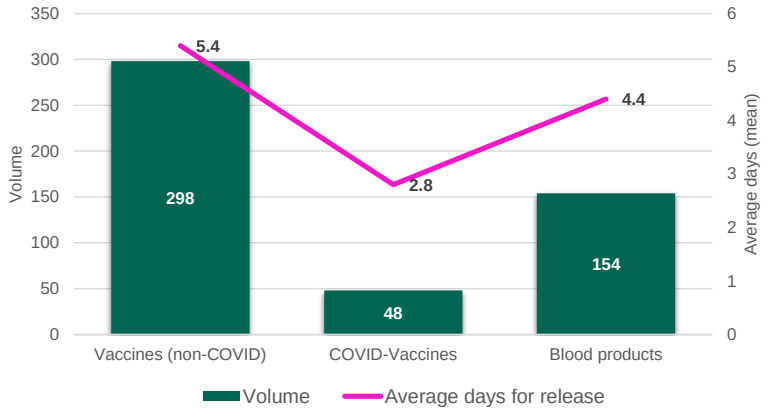
Performance – Science, Research & Innovation Group

Delivery Plan Priority – Scientific Innovation

Clinical Trials & Clinical Investigations Volumes



Q2 Control Testing Batch Releases Volume and Time



95% of vaccine batches certified within 43 days

99% of blood product batches certified within 15 days

The total number of clinical trial applications assessed in the financial year to date is 69 less than the same period last year (481 for 2021 compared to 412 for 2022). The timeline for assessment performance is slightly above target; however, this needs to be taken in context of combined review where timelines are dependent on both MHRA, HRA and also the sponsors choice of an ethics meeting date. In September, for 75% of 'overdue' trials, the ethics meetings that occurred after day 30. The (positive) overall picture remains that combined review reduces the overall time for approval significantly.

The temporary decrease in capacity of the UK's clinical research system remains and is being addressed via the "restart" initiative led by DHSC.

HVT studies are being prioritised but the internal target of 14 days cannot currently be met due to resourcing pressures. We have met with representatives of the Phase 1 community to discuss means to continue enhanced support for early phase studies.

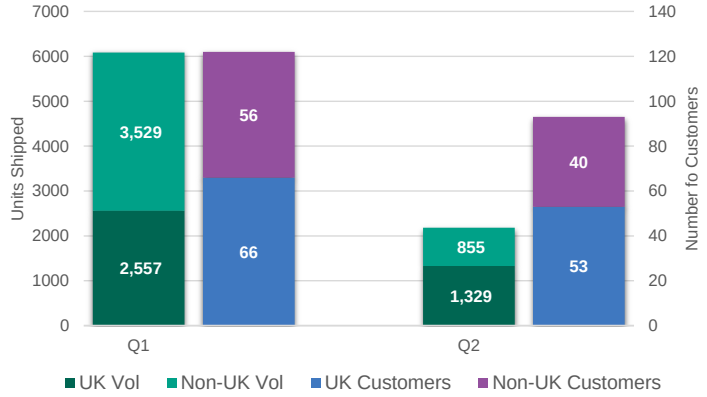
Clinical Investigation assessment performance is well within target and in line with Q2 2021-22.

Performance – Science, Research & Innovation Group

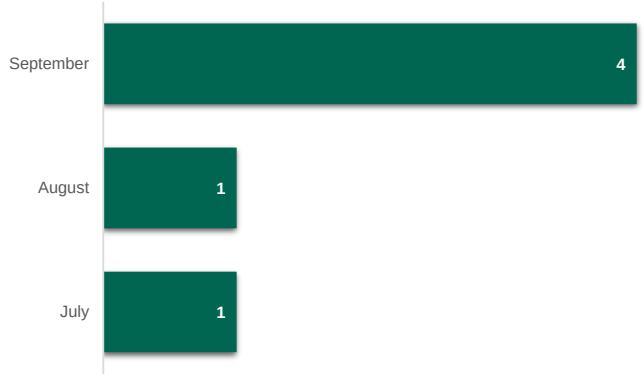
Delivery Plan Priority – Scientific Innovation

International Standards – Different Products and Customers

Diagnostic Standards – Volume Shipped and Customers



TDP Volumes



ILAP

Q2 IP applications – **13**

Q2 IP MHRA review meetings – **18**

Q2 IP approvals through the ILAP steering group – **15**

Q2 IP refusals - **1**

We measure the number of distinct customers and the number of different products in our International Standard provision that are ordered'. This is a developing metric to assess global impact of these materials. There is a slight decrease from Q1 but it is too soon to build trends.

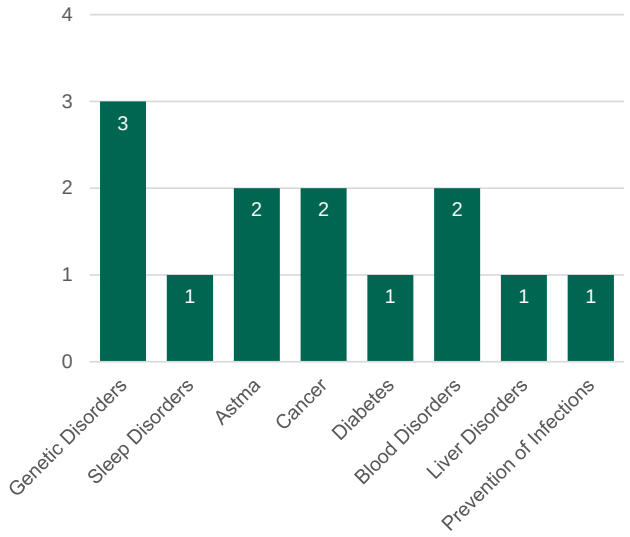
Diagnostic Standards are also an emerging metric. Q2 is significantly down on Q1. This may also be within year fluctuation or decline in covid related reference materials.

ILAP applications have been steady during the last quarter. The IA has driven a major drive to address the backlog which was due in part to double figure per month applications at the beginning of the year. It is expected that there will be no backlog by the end of the following quarter. Application approval remains around 85-90%.

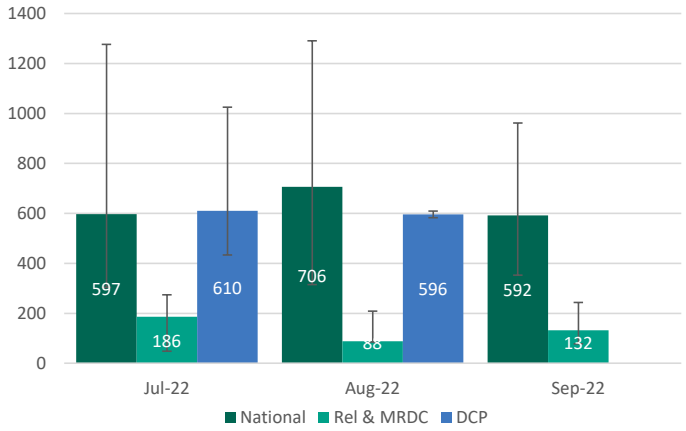
Performance – Healthcare, Quality & Access Group

Delivery Plan Priority – Healthcare Access

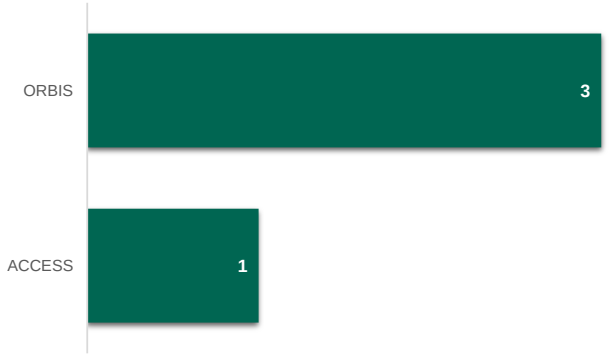
New Licences – Q2 New Active Substances



Established Medicine Initials – Median days to determination with 10% to 90% interpercentile



New licences resulting from ACCESS & ORBIS



In Q2, New Active Substance work has prioritised COVID Products, (vaccines, monoclonal antibodies and antivirals). The chart below shows that we are now broadening our coverage across therapeutic areas with medicines for treatment of cancer making up the highest proportion of the **30 new licences granted** in the second quarter of 2022/23 across 15 therapeutic areas.

Whilst total elapsed time is not entirely in the MHRA's control, it is a vital measure for patients as it represents how long they are waiting for new treatments. Work is ongoing to reduce total elapsed time by limiting rounds of Request for further information (RFIs), ensuring only decision-relevant questions are raised, and streamlining processes. RMS will also improve this.

Performance – Healthcare, Quality & Access Group

Delivery Plan Priority – Healthcare Access

Compliance

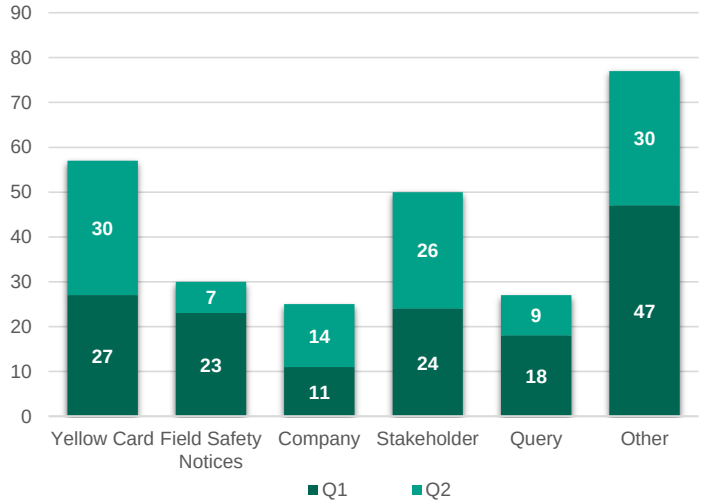
Nature of activity	How does this improve compliance?	Q 2 Performance
Initial reviews of new Approved Bodies.	Ensures bodies approved to undertake assessments of conformity against regulations for Medical Devices used in the UK meet required standards	4 reviews undertaken, 75% completed within 2 weeks - target 90%
Designation of new approved bodies.		One new approved AB in Q2 -DEKRA. 5 open applications. We are expecting 2 organisations to submit in the coming months
Inspectorate Blogs	Keeps industry up to date with latest standards and best practice, and lessons learned from inspections, ensuring they are aware of requirements.	17,298 Unique Visitors 24,184 Unique Page Views.
GXP Guide Sales		Orange Guide - £90,728 (£23,659 in Q4 21/22) Green Guide - £56,368 (£2136 in Q4 21/22)
Site Inspections	Inspections can be desk based (remote), hybrid (assisted by remote technology) or full physical inspections. Inspections detect system problems which could put patients at risk.	9 Clinical Trial sites inspected. 1 referral for critical findings. 22 Laboratories Inspected, 2 referrals for critical findings. 4 Pharmacovigilance (safety monitoring) systems inspected. 2 referrals for critical findings. 78 Manufacturers Premises Inspected, 4 referrals for critical findings. 94 Supply Chain sites inspected. 11 referrals for critical findings.

Performance – Safety & Surveillance

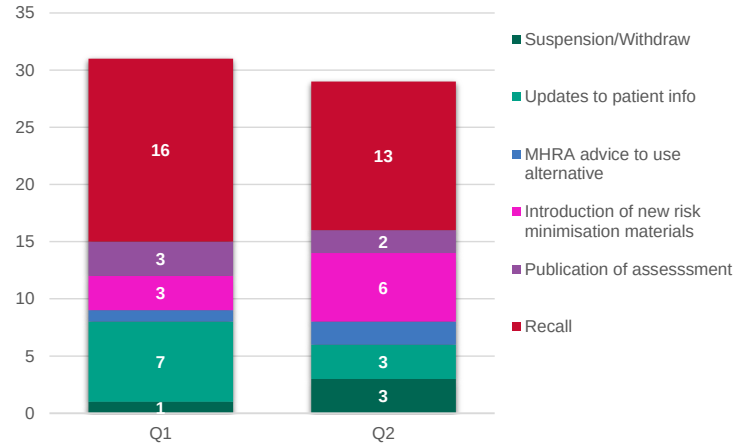
Delivery Plan Priority – Patient Safety

Yellow Card – Q2 reports

Benefit Risk Evaluation



Actions Taken to Minimise Risk to Patients*



Signal detection and assessment

<u>For medicines:</u>

The total number of drug-event combinations reviewed by S&S during Q2 was:

- Black Triangle/Additional Monitoring substances: **23,265**
- Established substances**: 51,676**

<u>The total number of new safety signals identified for further assessment*: **27**</u>

In Q2, Yellow card reporting from members of the public has decreased in relation to COVID-19 vaccines, reflecting the decreased rate of vaccination over the summer months, but increased for other substances. A further breakdown is provided.

Benefit risk evaluations include those newly identified, completed and ongoing during the period broken down by source. Each signal or issue is included only once. Ongoing safety issues include complex ongoing projects such as assessment of nitrosamine contaminants, mental health and sexual side effects with isotretinoin, review of teratogens in pregnancy etc.

Not all safety signals result in regulatory action. When measures to minimise risk are required a number of routes to manage the identified risk for patients are available.

Performance – Safety & Surveillance

Delivery Plan Priority – Patient Safety

CPRD – UK Population Coverage

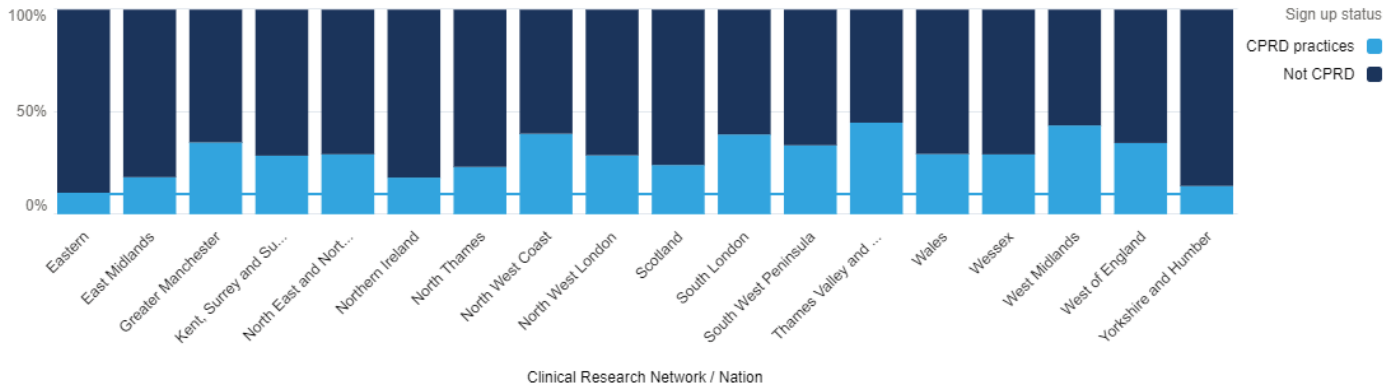
End of FY2022-23 Q2, CPRD's coverage of the UK population is:

25.06%

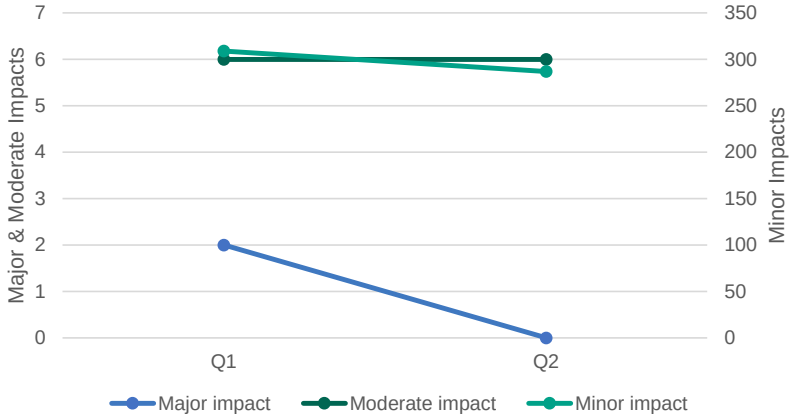
Completeness of CPRD data coverage

CPRD Aurum Oct 2022 Current Acceptable patients 13,794,796
+ CPRD GOLD Oct 2022 Current Acceptable patients 3,018,734
ONS estimates of UK population Jun 2021 67,081,000

CPRD Regional Coverage



Criminal Enforcement Unit



Target CPRD population coverage is 27% by end of 22/23, we are currently on track to achieve this.
Target regional coverage is at least 10% of GP practices in each region, currently all regional are above target except for Eastern which has 9.7% sign up.

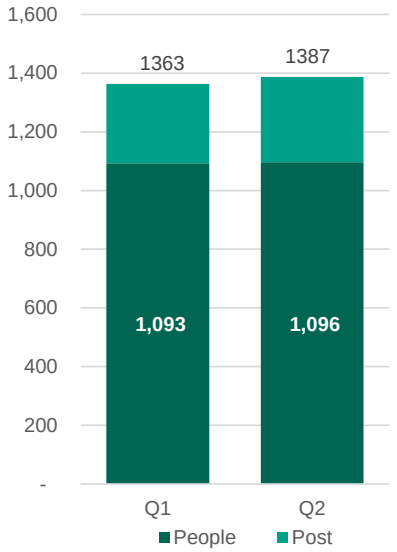
The Criminal Enforcement Unit gathers information from all sources, converts this into actionable intelligence and then uses the resulting insight to identify, prevent and disrupt the most serious criminal threats to public safety.

The number and distribution of threat reduction interventions for Q2 remains broadly consistent with that recorded in the previous quarter.

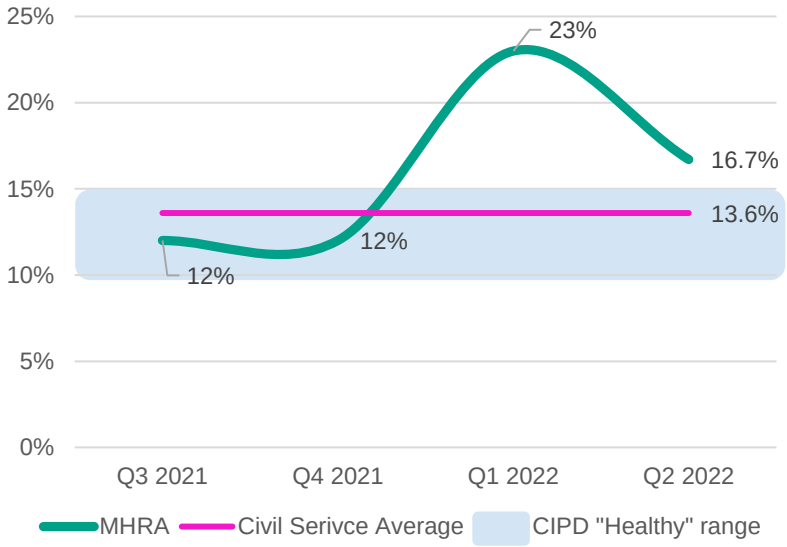
People

Delivery Plan Priority – Dynamic Organisation

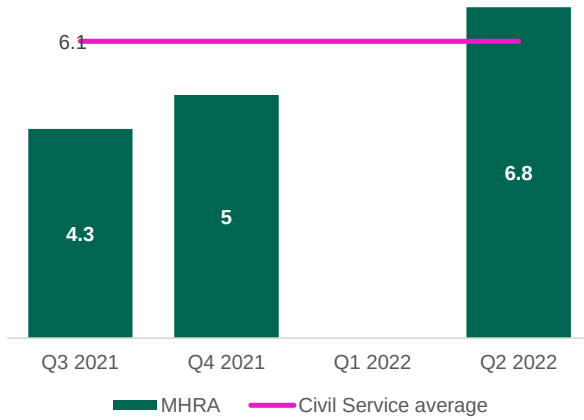
Recruitment
Posts filled v structure



Voluntary Turnover – Annualised



Sickness Absence Days – Annualised



"Posts" includes those in Digital & Technology currently filled by contractors, but intended to convert to employees. "People" excludes contractors and at risk of redundancy staff; reduced from 64 to 7 over this period.

October 2022 - 261 posts are identified to recruit to and 175 are currently in progress; a request to ExCo to initiate the remaining recruitment activities. Note onboarding times impacted by references, police checks and notice periods. Current vacancy rate is 19.7% v budget of 8%.

Turnover impacted by the major change, the "big resignation" and the current employee market. The Chartered Institute of Personal Development report a "healthy" turnover as between 10% and 15% and Civil Service average is 13.6%.

Ongoing efforts to engage with staff corporately and locally. One Agency Leadership Group review of staff PULSE feedback and related action plan published. All Staff and Group/Function staff meetings. Response rate to People Survey increased from 48% to 70% and will provide further feedback on areas for focus

Of the total figure, short term sickness absence figure is 2.5 days and itself not of concern, however long term (certificated) sickness absence takes the current figure just above the Civil Service average. Reasons for both long and short term absence continue to flag both stress and musculoskeletal diagnoses and ongoing efforts to signpost resources and provide direct support in these areas. Q1 figure unavailable due to re-build of Oracle Fusion.

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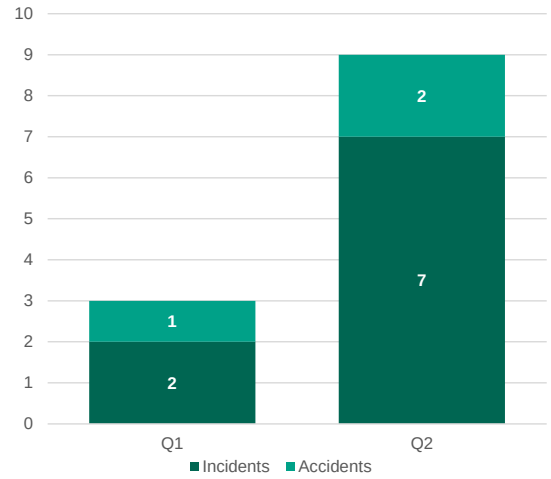
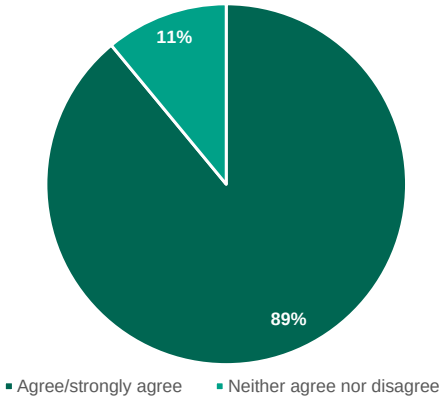
People

Delivery Plan Priority – Dynamic Organisation

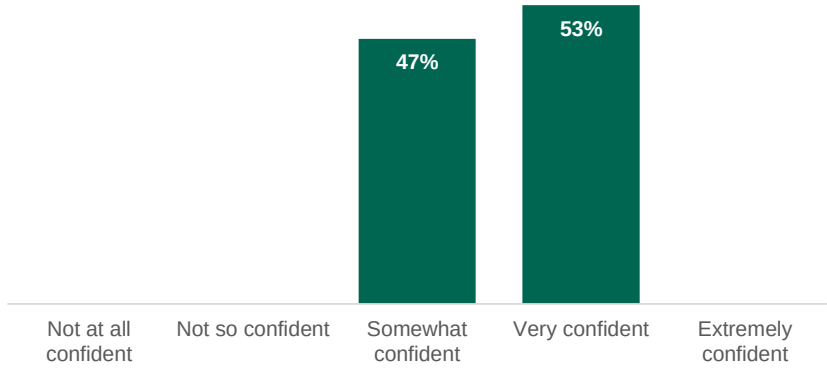
Incidents and Accidents



Training – Applicability of learning across 2022



Training – Increased Confidence



Incidents in this report refer to near misses that could have caused injury or resulted in a dangerous occurrence taking place. Accidents are recorded when actual physical harm takes place or there is an actual exposure of harmful biological agent.

There have been 726 agency developed, corporate training attendances by staff since January 2022 (some staff may have attended more than one). Please note this data does not include the majority of the training provision which is via the Government Campus (Civil Service Learning). The Government Campus provides both mandatory and a broad range of generic training and related data is currently unavailable to us for IT technical reasons; this will be included again from Q1, 23/24. Agency developed training run by Groups/Functions which has not been recorded centrally is also unavailable and there will be further efforts to capture and record this for Q1, 23/24.

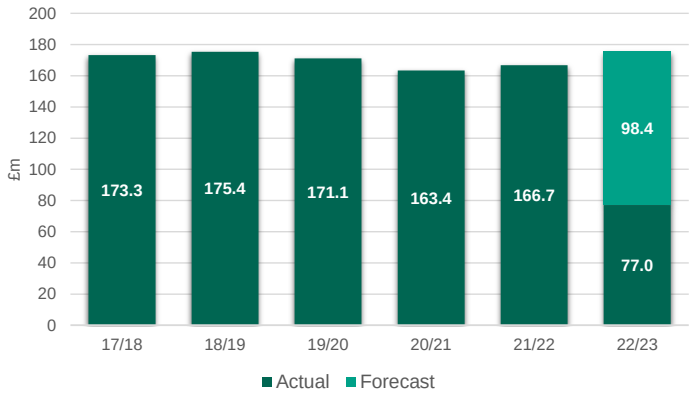
89% of corporate training participants during 2022 agree or strongly agree that the learning undertaken was applicable to their role and performance in role.

69% of L2 and 3s have attended leadership training since Jan 2022. 100% of participants report increased confidence in their leadership capability immediately post-training. Further training dates are being organised for leaders, including recent arrivals.

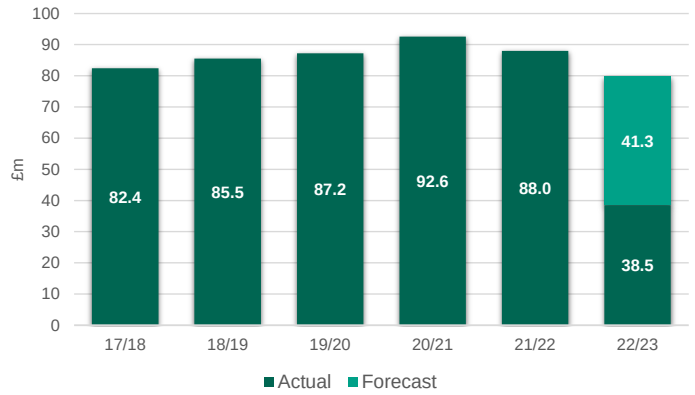
Finance

Delivery Plan Priority – Financial Sustainability

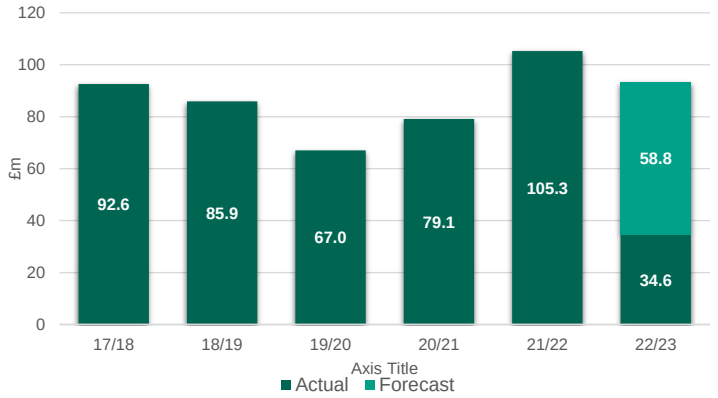
Income – 22/23 forecast **£175.4m** v budget £180.0m



Pay Costs – 22/23 forecast **£79.8m** v budget £90.5m



Non-Pay Costs – 22/23 forecast **£93.4m** v budget £89.6m



Forecast total 22/23 surplus of **£2.2m** v £0.1m budget 22/23 total deficit

Large vacancy rates (currently 20%) are leading to forecast full year staff costs being **£10.7m** under budget (12%).
This is currently being offset by **£4.6m** of reduced income (within Reagent sales and Licensing growth) and **£4.3m** of increased operating costs (majority within accommodation and depreciation).

Reagent sales income budget was set on last year, one of the highest years for sales we have had.

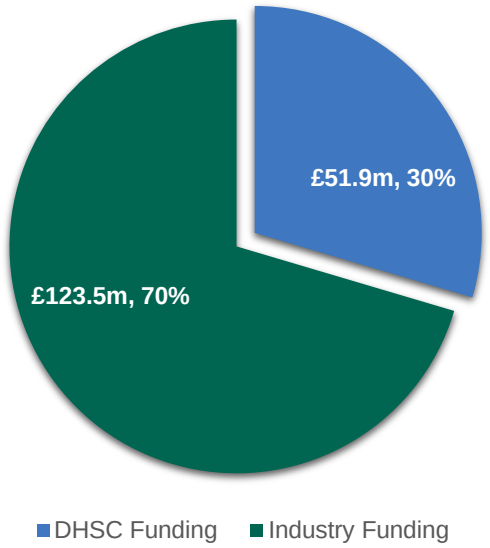
Targeted growth within Licensing was based on assumption of additional FTE, however income is being affected by the high number of vacancies we are currently experiencing.
Accommodation costs have been impacted by a delay in handover of 10SC floorspace. Deprecation has increased from prior year following a period of increased capital investment.

Change cost forecast has improved by **£0.5m** since the budget. With a £1.2m overspend in SafetyConnect being offset by £1.4m of reduced redundancy costs as well as additional small underspends on various other projects.

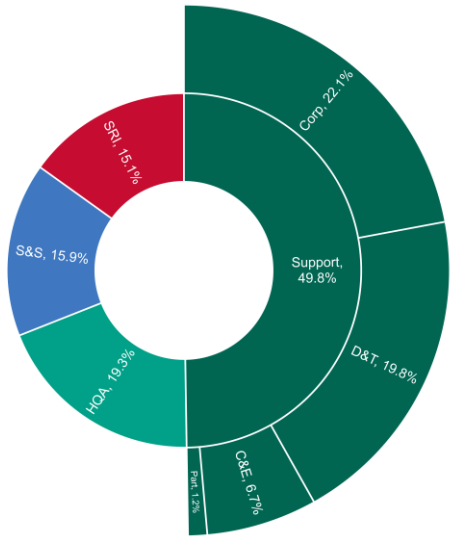
Finance

Delivery Plan Priority – Financial Sustainability

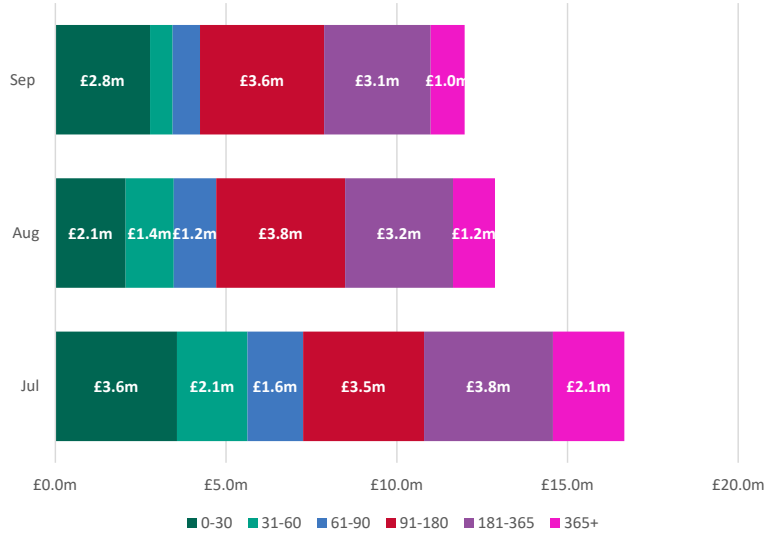
DHSC / Industry Income Split



Support Expenditure %



Debt by Days Due



The agency has an ambitions to reduce DHSC reliance and reduce relative expenditure within the support groups.
DHSC funding for 22/23 is higher than usual due to spending review funding including £9m for RMS and £1.2m for SafetyConnect. This will reduce in the future.

Currently the 49.8% of support spend is less than the 50.4% budgeted expenditure. Despite an increase in accommodation and depreciation the disproportionately large number of vacancies within partnerships and D&T more than offset this.

Debt has decreased by £0.9m since last month with the majority being due to debt aged 31-90 days.

Service fee - Towards the end of June, we issued £52.7m of invoices. We continue to receive applications for credit notes from companies who are entitled to a discount on product lines where they have sold less than the set threshold. The residual amount of potential debt has reduced from £22.165m to £18.2m at the end of September.

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 November 2022

Title	How is the MHRA providing safe access to data for research?
Board Sponsor	Alison Cave, Chief Safety Officer
Purpose of Paper	Assurance

How is the MHRA providing safe access to data for research?

1. Executive Summary

1.1 In recent years there has been a growing public awareness of data privacy and calls for greater transparency of data sharing, including assurances that healthcare data is safe, secure, and only used for its intended purposes. This has led to Trusted Research Environments (TRE) being considered the future method for access of healthcare data. TREs differ from more widely used models of data access as researchers can only access and analyse the data within the secure environment.

1.2 The MHRA's specialist real world data research service, the Clinical Practice Research Datalink (CPRD), has provided access to anonymised patient data for research for the benefit of public health for 35 years. CPRD has an excellent track record in ensuring that data is safe, secure, and only used for its intended purposes by following the Five Safes Framework, as recently validated by an external NHS Audit.

1.3 CPRD's implementation of the Five Safes Framework can be further strengthened and streamlined by the development of the CPRD TRE. This will require a combination of technology, client engagement, and collaboration with UK-wide bodies to ensure policy and strategy strikes a balance between reassuring patients that their data is safe and only used for its intended purpose, whilst ensuring the UK is a global leader in innovative public health research.

2. Introduction

2.1 In recent years there has been a growing public awareness of data privacy and calls for greater transparency of data sharing, including assurances that healthcare data is safe, secure, and only used for its intended purposes. NHS X's *"Data saves lives: reshaping health and social care with data"*, Health Data Research UK's (HDRUK) *"Principles and Best Practices for Trusted Research Environments"*, and Professor Goldacre's *"Better, broader, safer: using health data for research and analysis"* all set the future direction of travel for a strengthened and consistent management and access of healthcare data through the use of TREs.

2.2 TREs, also known as Secure Data Environments (SDE) or Data Safe Havens, are highly secure computing environments that provide remote access to data for approved researchers to use for research that makes use of sensitive and personal data. TREs differ from widely used models of data access where researchers need to download a dataset onto their computer to be able to use it for their analysis. In a TRE the data remains in a secure location, and approved researchers access it remotely, with only aggregated outputs of any analysis allowed to leave the TRE. A TRE provides enhanced patient privacy and data protection, greater assurance that data are handled securely as researchers can only access and analyse the data

within the secure environment and a central audit trail provides transparency of data manipulation and analysis. In addition, technical safeguards are applied to ensure only approved analytical results and data leave the secure environment.

2.3 In line with current UK wide direction of travel a major strategic aim for CPRD is therefore to move to a predominantly-TRE based model for data access and analysis. Most research that utilises CPRD data will take place within the TRE, but there may be limited instances, such as patient consented trials, where it will be possible for data to leave the TRE to be combined with other datasets for analysis.

3. CPRD's current approach to providing safe access of data

3.1 The MHRA's specialist real world data research service, the CPRD, has provided access to anonymised patient data for research for the benefit of public health for 35 years. As part of its data stewardship role, CPRD's current systems and processes already align with the 'Five Safes Framework' to ensure safe access to data for research.

3.2 The Five Safes Framework was developed by the UK Office for National Statistics (ONS) to help data custodians make decisions about making effective use of data which is confidential or sensitive. The Five Safes Framework proposes that data access decisions are considered using five dimensions, namely, safe data (data is treated to protect any confidentiality concerns), safe projects (research projects are approved to ensure public benefit), safe people (researchers are trained and authorised to use data safely), safe settings (a secure environment to prevent unauthorised use) and safe outputs (ensuring any research outputs are non-disclosive). The combination of the controls placed on these dimensions leads to safe use of data.

3.3 The Five Safes Framework is currently, successfully implemented via a combination of robust technical and contractual controls underpinned by a host of processes and policies including vetting of organisations wishing to access CPRD data which includes an assessment of their data security infrastructure, CPRD's research data governance (RDG) process which includes privacy risk assessments, managed release of data to only secure environments in the researchers' institutions via secure transfer methods, named nominated and authorised research users, data minimisation, small cell count suppression policies, regular audits of data users etc.

3.4 This approach has been recently audited by NHS Digital including an assessment of dataset samples provided by CPRD, by two independent disclosure risk specialists from the Office for National Statistics. The audit concluded that the disclosure risk associated with CPRD data sharing was low (this is the lowest disclosure risk rating that can be awarded in this audit). However, CPRD's implementation of The Five Safes Framework can be further strengthened and streamlined by the development of the CPRD Trusted Research Environment.

4. Proposal on the future direction of travel for data access

4.1 Technology

4.1.1 As outlined above, CPRD already has an established secure environment which is accessed only by authorised researchers to define a dataset for their study and then extract this for storage in their own approved institutional secure environment. While all organisations wishing to access CPRD data undergo a data security vetting, which sets strict minimum security requirements, we are reliant on a third party for data protection. This is enforced via contractual controls and policed via the client audit process.

4.1.2 A major strategic aim for CPRD is therefore to move to a predominantly-TRE based model of data access whereby researchers will analyse data entirely within CPRD's TRE and will only be able to download the outputs of the research in the form of aggregated data.

4.1.3 The CPRD TRE development is currently underway, and a phased approach has been taken to the development to enable iterative user testing and refining throughout the process. The first iteration of the CPRD TRE has been released with some basic tooling and sample datasets to enable feedback and suggestions from clients. The transition to a predominantly TRE-based model of data access will be completed by 2024/25.

4.2 People

4.2.1 The development of the CPRD TRE is more than a technology implementation and CPRD has already engaged with key clients and continues to do so. CPRD has held numerous briefing and feedback sessions with CPRD clients to ensure a successful transition to a TRE-based model of data access including at the annual CPRD User Group. CPRD are planning quarterly briefing and feedback sessions with clients to inform the iterative development of the TRE as well as accompanying policies / processes.

4.2.2 Patient engagement and involvement activities will also take place with reference to the Goldacre Review and the national data strategy, *Data Saves Lives* to ensure the public continue to support research by knowing that their data is safe, secure, and at low risk of disclosure.

4.3 Policy

4.3.1 In addition to working with CPRD clients, CPRD are engaging with key pan-UK stakeholder groups to ensure input and alignment with the national policy and requirements on TREs. CPRD are active participants of the following boards and groups:

- The Research Advisory Group (RAG) – co-chaired by Professor John Iredale and Professor Lucy Chappell, brings the research community together to advance the use and effectiveness of NHS Digital's data and

services. There has been a focus lately on TREs, sub-national TREs and the policy around their use.

- Health Data Research UK (HDR UK) – The UK's national institute for health data science. CPRD is a founder member and is represented on the Board. HDRUK has various policy groups, and a lot of focus has been placed on TRE design and policy, which has had some influence on NHS Digital's decision making in this area.
- Goldacre Task & Finish Group – this is led by the NHS England Transformation division and is tasked with implementing key recommendations from the Goldacre review, including TREs.
- TRE Design working group – Originally hosted in NHS X, its remit includes policy and technical standards for implementing a TRE.

4.3.2 The transition to a predominantly TRE-based model of data access needs to be complemented by a policy and operational process framework to ensure data assurance and protection. A CPRD TRE Policies and Processes Working Group has been established to address questions on this, for example:

- Consider how we best enable researchers to 'bring your own data (BYOD)' and 'bring your own algorithm (BYOA)' into the TRE as well as criteria and audit capability about data extractions for aggregated data and potentially in exceptional circumstances more granular level data. We need to ensure that restrictions do not discourage researchers from using UK data for globally leading innovative research that benefits public health.
- Undertake accreditation of the CPRD TRE as well as ensure that key data assurance (data protection impact assessment) and security controls (system level security policy) are in place and appropriate to give the public assurance that their data is safe, secure, and only used for public health benefitting research.
- How to enable CPRD TRE to communicate with other sub-national TREs or data analytics platforms for the purpose of distributed meta-analyses or to enable computationally intense and advanced AI techniques that cannot be practically supported by the TRE. This will also open the capability of linking with more NHS and other third-party datasets to further add value to CPRD's real world data offering.

4.4 Opportunity

4.4.1 The transition to a predominantly TRE-based model of data access not only further strengthens and streamlines CPRD's current business model but provides further opportunities enhancing and expanding the use of CPRD's real world data in public health benefiting research:

- Opportunities to further enhance CPRD and the MHRA's global reach perhaps through adoption of the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) to support collaboration with global initiatives, or similar US CDMs, thereby potentially enhancing the utility of CPRD data globally.

- Work with the NHS Transformation Directorate to ensure both TREs are aligned to facilitate access to additional linked data and establish an agreed framework for how this will be managed.
- Provide increased oversight to ensure the data is being used only for approved purposes though more robust audit trails.
- Conduct a review our current licensing model. The TRE model will allow CPRD to offer appropriately scaled solutions to all clients perhaps involving greater or lesser levels of computing power, or more or less workspace. Licensing models will need to reflect this flexibility in the services from client to client to ensure that CPRD is financially sustainable, and to open up different levels of services to attract established research groups as well as research groups who are not currently familiar with CPRD data.

5. Conclusion

5.1 Given the strong political support for TREs, it is most likely that TREs will be the preferred approved mechanism by which healthcare data can be made available for research. CPRD has an excellent track record in ensuring that data is safe, secure, and only used for its intended purposes by following The Five Safes Framework as validated by an external NHS Audit. Engaging with national policy discussions on the use of healthcare data in research and starting the development of the CPRD TRE in partnership with CPRD clients, will further strengthen and protect the model of providing patient healthcare data for public health benefiting research in a safe and secure manner that protects patient privacy.

6. Recommendation

6.1 The Board is asked to endorse the strategy of using a predominantly TRE-based access model for healthcare data.

Alison Cave
November 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 November 2022

Title	What are the priorities for the MHRA Science Strategy to enable scientific innovation in the UK?
Board Sponsor	Marc Bailey
Purpose of Paper	Strategic Direction

What are the priorities for the MHRA Science Strategy to enable scientific innovation in the UK?

1. Executive Summary

1.1. The MHRA has a world leading reputation as an innovator in regulation and for producing high quality science that supports the development of new regulations and regulatory decisions. This comes from its foundation of using scientific evidence as a basis of risk/benefit decisions.

1.2. The new Agency Science Strategy aims to maintain and grow this reputation for scientific excellence by both maintaining the science that is unique to the Agency, partnering with leading scientific experts and nurturing new ideas.

1.3. The UK is a leader in scientific innovation and the MHRA has a pivotal role in applying its scientific knowledge to ensure that scientific innovation in healthcare products in the UK is safely and effectively transferred into benefits for Patients and Public Health.

1.4. The Strategy must enable the Agency to identify relevant emerging and existing scientific areas that can be applied to improving regulation. The Science Strategy will support the growth and maintenance of the knowledge and expertise required to do this. The paper describes a framework within the Strategy for identifying the science to be done by the Agency in partnership with others and identifying how this science supports the application of healthcare product innovations. The Board is asked to consider the draft Strategy and provide strategic direction on its further development.

2. Introduction

2.1. The vision of the MHRA is to be a truly world-leading, enabling sovereign regulator, protecting public health through excellence in regulation and science to deliver the right outcomes for patients. Our purpose is clear: to protect and improve patient health by enabling the earliest access to, and high-quality supply of, safe, effective and innovative medical products through proportionate, data-driven assessment of risks and benefits.

2.2. The vision and purpose task the MHRA to deliver excellence in science and risk benefit decisions based on data-driven technical assessments. The Science Strategy will enable the Agency to have the scientific skills and knowledge to achieve its vision and purpose. It will balance competing needs to ensure that it has the correct balance of in-house expertise and access to external expertise to deliver and that it can engage and deliver the public health-driven research that cannot be accessed from elsewhere.

2.3. The large number of healthcare products and the regulations that ensure their safety, efficacy and suitability for patient use, require the Agency to draw on a highly diverse portfolio of scientific knowledge and activities. The main categories are:

2.3.1. Medicines (Advanced Therapies, Combination Products, Biological and Chemical entities)
2.3.2. Medical Devices
2.3.3. Vaccines and vaccinology
2.3.4. Diagnostics
2.3.5. Regulatory Science
2.3.6. Pandemic Preparedness
2.3.7. Health Data Science
2.3.8. Blood-derived products
2.3.9. Artificial Intelligence and Software
2.3.10. Human Factors (Sociology, Psychology and Behaviour Science)

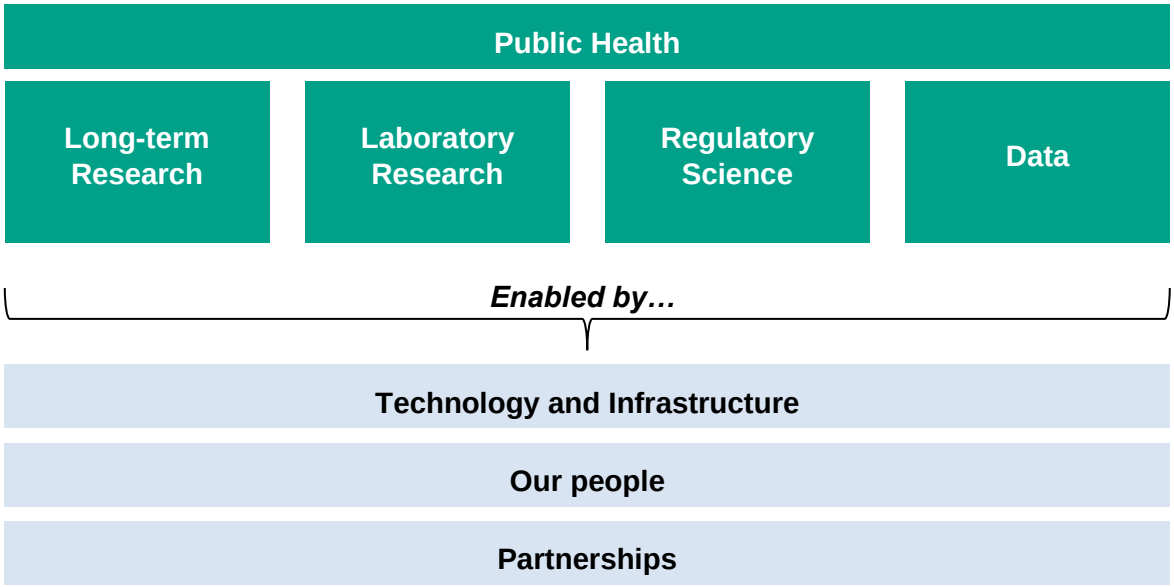
2.4. The Agency has a long tradition of creating scientific knowledge that is applied to healthcare needs and research to underpin healthcare products regulation is a statutory function. The Agency is proud of the achievements of its scientists and the impact of our science is measured by several metrics including peer-reviewed scientific publications, guidance documents and grants won. The impact of the research is frequently included in the CEO's reports to the Board and other news stories promoted by the Agency.

2.5. The science is delivered by teams distributed across the three Agency patient-supporting groups, Science, Research & Innovation (SRI), Healthcare Quality & Access (HQA) and Safety & Surveillance (S&S) with supporting activities by the Corporate functions. From a workforce of approximately 1250 staff, over 130 work full-time in research with approximately another 150 delivering science as part of their job function. Part-time activities are often applied science projects that the staff use to keep their knowledge and expertise up to date rather than delivery by the structured permanent teams found in the SRI Research and Development sub-group, but the part-time projects will include collaborations with external partners and often lead to changes in regulation and guidance. Laboratory science is delivered in the Agency laboratories at South Mimms and at collaborating laboratories, with Chemistry Services delivered by the British Pharmacopoeia using the facilities in Teddington.

2.6. The MHRA should continue to support its areas of greatest scientific strength and public health and patient impact while developing its science base to support new areas. The MHRA Science Strategy will structure the scientific work of the Agency to ensure that it delivers value to the patient and public health and that the Agency has a framework for prioritising its science. The Board is asked to consider the proposed structure of the Science Strategy and proposed mechanisms for assigning priorities

3. Proposal

3.1. The MHRA Science Strategy will adopt the structure shown below with the functions of Public Health and four partially overlapping functions of Long Term Research, Laboratory Research, Regulatory Science and Data. These are supported by three enabling activities: Technology and Infrastructure, Our People and Partnerships that are the subject of other Agency strategies.



3.2. The five functions are defined as follows

3.2.1. **Public Health**: an oversight function to manage the overall strategic direction, delivery and impact of the Science Strategy and align the science with the Agency's vision, purpose, and values. It will ensure that the science supports healthcare product innovation. The definition and measurement of the patient and public health impact of a scientific project is essential to justify why the project is led by the Agency and it requires that the Agency is continuously identifying the challenges and reviewing its responses. This will be work undertaken by the Science Research and Innovation (SRI) sub-group Innovation Accelerator.

3.2.2. **Long-term Research** is the section of the MHRA science portfolio that represents the "long term bets", scientific projects that will deliver a future public health benefit but on a longer timeframe with some of the intermediate steps yet to be defined. The Long-term Research function can overlap with the Laboratory research, Regulatory Science and Data functions as a MHRA scientific team will run multiple parallel projects. For example, the South Mimms Polio research teams have run parallel research projects that lead to the long-term benefit of the nOPV2 vaccine while delivering short term benefit through environmental surveillance for polio virus.

3.2.3. **Laboratory Research** is applied research that uses scientific theories to develop technology or techniques within the controlled environment of a laboratory or clinical setting. Examples include work to develop a biological reference material where the pathway to impact and the impact of the reference material can be defined.

3.2.4. **Regulatory Science** consists of an applied version of various scientific disciplines used in the designing and implementing the regulatory process. The outcomes are documentation-based body of knowledge as well as new written tools, standards, and approaches to assess the safety, efficacy, quality, and performance of regulated products

3.2.5. **Data** covers data science, an interdisciplinary field that uses scientific methods, processes, algorithms and systems to extract or extrapolate knowledge and insights from noisy, structured and unstructured data. This includes bioinformatics and health data sets. This area is supported by the Agency's Data Strategy, its inclusion in the Science Strategy is to provide a functional interface between the two strategies and to acknowledge that scientific progress requires data analysis.

3.3. The MHRA needs to review and respond to relevant Government and non-governmental organisation strategies to understand the public health challenges and determine those policies and strategies that are expected to have a significant effect on patient access to healthcare products. The significant recent government strategies in terms of scientific challenge for the MHRA are the Life Sciences Vision (2021), The NHS Long Term Plan and the NHS Core20PLUS5. The Life Sciences Vision sets out a growth plan for the UK Life Sciences industry and sets deliverables for the Agency that require scientific work with universities and research sponsors to ensure clinical trials are delivered in the most innovative and effective ways and support for innovation and research friendly global regulatory standards through global regulatory fora and bilateral relationships – as well as the use of novel biomarkers or surrogate markers where the impact of treatment on disease is not well understood. These deliverables are relatively straightforward, but the Agency will have tough choices to make when considering how its science can be applied to support the multiple priority areas in the three strategies

3.3.1. The Life Sciences Vision describes 7 healthcare missions: dementia, cancer, mental health, obesity, ageing, respiratory and vaccines.

3.3.2. The NHS Long Term Plan highlights cancer, cardiovascular, stroke, diabetes, respiratory disease and mental health as the major health conditions to be treated, as well smoking, obesity, alcohol, air pollution and antimicrobial resistance where more NHS action is required on prevention.

3.3.3. The NHS Core20PLUS5 priorities are maternity, severe mental illness, chronic respiratory disease, early cancer diagnosis, hypertension and smoking cessation.

3.4. The Agency can also inform its science priorities by learning from its customers. The SRI Innovation Accelerator group receives enquiries and responds with either informal scientific advice or directs the enquiry to sources of formal scientific or regulatory advice within the Agency. This advice enables innovators to improve their progress towards regulatory approval of their products. These questions are confidential but provide useful evidence of healthcare product trends. In the past ten months the Innovation Accelerator has received enquiries distributed over the following categories (not all the enquiries required scientific input to answer):

Technology Area	**Percentage**
Medical Devices and Diagnostics	35%
Chemical Entity Medicines	21%
Clinical Trials	13%
Advanced Therapies and Manufacturing	12%
Platform Technologies	9%
Biological Entity Medicines	3%
Point of Care	2%
Other	5%

3.5. The Public Health function of the Science Strategy must also enable the most important step, nurturing new ideas. The trends and information collected from different sources should inform the ideas. Very early ideas for science projects need time to develop but from the very start they should consider how the idea will result in public health benefit, patient impact and why the idea should be delivered by the MHRA. Agency staff should be encouraged to think and refine early ideas until they need resource to develop them further. At this point the Agency needs to consider how to support the early ideas for example by establishing a fund to support early projects through to proof of principle data and help then towards winning sustainable investment.

3.6. The Public Health function also needs to monitor the project metrics and their impact to ensure ongoing relevance and innovation. This requires developing an accepted definition of success.

3.7. The Strategy supports four areas for mature projects that have passed proof of principle stage and are already resourced.

3.7.1. **Long-term Research**: This supports the long-term science that is required to be an innovative regulator, that addresses scientific challenges where the MHRA has the expertise to have impact and where academic and commercial science will not lead to robust regulation. Example projects include the vaccinology projects on the development of vaccines for emerging or rare diseases where the commercial case for company driven development is too weak; the support of the WHO-endorsed system for the International Unit of biological activity; rapid development of regulatory systems for developing economies and others. Many of the current examples of such projects are supported by grants awarded based on scientific expertise unique to the

MHRA. They are expected to underpin MHRA statutory functions and services but not necessarily deliver a short-term outcome.

3.7.2. Laboratory Research: Experimental research delivered in the Agency's South Mimms and British Pharmacopoeia laboratories and/or by collaborators and partners. This research is more closely linked to the requirements for sustaining the portfolios of biological and chemical reference materials or to medicine's control testing and so supporting statutory functions of the Agency. Some projects span Long-term Research and Laboratory Research depending on their identity, others are applied science.

3.7.3. **Regulatory Research**: Agile and responsive regulation supports national and international innovation. The agency is a proven innovator in healthcare product regulation, and this supports scientific research into best methods for regulation and determining the impact of regulatory changes. The Agency is committed to delivering novel regulatory mechanisms such as an expedited access pathway (ILAP), or the integration of Clinical Investigations and Clinical Trials approvals. As these new mechanisms generate more outcome data, they and other Agency activities are the subject of research by academics and other organisations. This reactive research is useful to understanding the benefits of regulatory changes already enacted but ideally the Agency needs a mechanism to understand the impact of regulatory changes before they are enacted. The Goldacre report and the Taskforce on Innovation, Growth and Regulatory Reform (TIGRR) report both recommend the establishment of UK Centres of Excellence in Regulatory Science and these would be an excellent opportunity to develop and test new regulatory principles and systems in advance. The Agency is committed to taking a leading role in shaping the work of Regulatory Science Centres and advising on the applicability of their work. We will continue to work with such centres, if they emerge, to ensure that their outputs can be applied to UK regulation to generate value for patients and the public. This will be increasingly important as the advantages of leaving the EU are recognised, new international regulatory partnerships built, and new international comparability must be developed.

3.7.4. **Data:** The Agency increasingly uses Real World Evidence (clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of data collected from patients) to support its decisions and this in turn needs investment in Data Analysis and Data Science. This function will enable projects that draw on the principles of both Science and Data strategies for success. Examples may include the health data research performed by the Clinical Practice Research Datalink (CPRD) and research by our Medical Devices experts into the role of AI and software in healthcare products and their effectiveness.

3.8. The main sections of the Science Strategy require Enabling Activities:

3.8.1. **Technology and Infrastructure**: World-leading science requires state of the art IT technology and scientific infrastructure. Meeting these requirements requires the Science Strategy to feed into existing Agency strategies such as the Technology Roadmap and the Accommodation Strategy. It must also influence activities such as the Capital investment project to ensure that the Agency's resources are invested to give greatest value.

3.8.2. **Our People**: Training for staff in scientific skills and to gain experience in partner organisations is essential to success. The Science Strategy must influence the People Strategy to ensure that scientist career paths and training gain sufficient support and recognition.

3.8.3. **Partnerships**: Partnerships and collaboration are essential for success and the existing Agency scientific projects have partners and collaborators that number in the hundreds. Some partnerships are project-specific but many have strategic influence on multiple projects such as the work with Genomics England on the Yellow Card Biobank to develop it as a research service. The Partnership Strategy has been discussed by the Board and identifies the difference between project-specific collaborators and strategic partnerships. These principles will be applied within the Science Strategy to ensure that the partnerships deliver high quality science. Stronger strategic scientific partnerships will be required with other regulatory bodies such as the National Institute of Health & Care Research (NIHR), the Health Research Authority (HRA), the National Institute for Health & Care Excellence (NICE) and the Health Security Authority (HSA) so that the strengths of the UK Health ecosystem can be supported by scientific evidence to enable innovation.

3.9. The Agency lacks the resource to support all its scientific ideas so there must be a prioritisation system. Previous advice from the Board was to adopt best practice used by other organisations that commission and deliver scientific research. Several different bodies have been reviewed and the findings are being adapted to the MHRA circumstances.

- First, any prioritisation mechanism must be transparent, can be applied to the diversity of science described and operated in line with the principles of managing public funding.
- Second, a very successful model empowers in house experts to drive forward high-risk high reward projects with clear path to real world use and evidence. For use by the MHRA this must be tailored to defined benefit and controlled risk based on evidence, in line with the risk benefit process to support regulatory approval.
- Third, the assignment of the priorities is most successful when the evaluators have a clear understanding of the area and the breakthrough required. If they do not have that expertise, the effectiveness of the prioritisation decreases.
- Fourth the mechanism can be biased towards short term effects whereas a successful portfolio of science has short- and long-term benefits defined.

A set of prioritisation criteria have been developed and applied to a pilot set of projects. The pilot has shown more work is required on the evaluation stage and this is under way. Evidence that the science will support patients, public health and UK innovation will be significant criteria.

4. Recommendation

4.1. The Board is requested to consider the outline of the Agency Science Strategy under development, confirm the direction of travel and provide strategic input.

4.2. The Board's advice is sought on the mechanisms described for identifying priorities and for supporting them with new areas of Agency science.

4.3. Further strategic input is requested on mapping mature projects to agreed priorities to ensure that the outputs support innovation.

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Marc Bailey
November 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 November 2022

Title	How will the new MHRA SafetyConnect system deliver more responsive safety surveillance?
Board Sponsor	Alison Cave
Purpose of Paper	Assurance

How will the new MHRA SafetyConnect system deliver more responsive safety surveillance?

1. Executive Summary

1.1. The paper summarises progress and next steps with the SafetyConnect programme. The Board is asked to note enhancements that have been delivered to date and advise as to whether this provides sufficient assurance of progress towards the vision of a more responsive safety surveillance system for all medical products.

2. Introduction

2.1 In the Independent Medicines and Medical Devices Safety (IMMDS) Review, Baroness Cumberlege highlighted areas of vigilance which need strengthening and gaps in the health system but most important of all, a failure to listen to and respond to patients. Recommendation six of the IMMDS Review states: *The MHRA needs substantial revision, particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public protection roles and to ensure that patients have an integral role in its work.*

2.2 The MHRA is undertaking a major investment programme to upgrade its safety reporting systems. MHRA's SafetyConnect programme is using new technology to improve its responsiveness to patients and a new modern vigilance database using artificial intelligence to support the more rapid identification of safety signals and product quality defects across medicines, medical devices and blood/ blood components. Throughout the development of the new system, we have engaged with patients and the public directly, as well as healthcare professionals and the industry to gain user feedback and perceptions on the system via user needs sessions.

2.3 The SafetyConnect programme is among the highest priorities of the Agency, the programme is split into multiple project areas including:

i. Yellow Card and Vigilance Hub;
ii. Core technology for safety case management;
iii. Signal detection;
iv. Business intelligence and reporting;
v. Common integrated vigilance team.

The project is being delivered in phases with the first phases of work on Yellow Card already deployed earlier in the year with upcoming releases of technology and services across the rest of the programme over the coming months.

2.4 SafetyConnect is delivering numerous improvements to the patient journey, starting with the enhancement of Yellow Card reporting described in this paper. These changes also enable the reporting system to be embedded into other external systems, improving access, while patients will also benefit from improved information provision from the regulatory system including news, incident reports and information about products of interest to them or that they have reported previously.

2.5 The enhancements to the patient journey will be facilitated by replacement of the internal case management systems with a highly automated platform that utilises embedded artificial intelligence to deliver higher quality data to signal detection faster. The signal detection and management software is also replaced to enable us to implement novel analytical techniques which have been researched over the last 18 months, meaning that signal detection approaches can be customised to the product or class of interest.

2.6 The new Yellow Card website went live in February 2022, replacing the legacy system that was launched in 2008, based on modern technology to improve accessibility, scalability and adaptability. The SafetyConnect programme will continue to enhance our safety service over the coming months.

2.7 The new website built on the improvements made through the Coronavirus Yellow Card site that was deployed in May 2020 and enhanced throughout the pandemic. The improvements deployed through the Coronavirus Yellow Card site enabled us to process the reports received more quickly and efficiently, for faster and more effective safety signal detection for patient safety.

2.8 The first of a series of enhancements were deployed in May including over 100 individual improvements. These included commitments to the Independent Medicines and Medical Devices Safety Review (IMMDSR) such as:

- Ability to allow registered users to update their submitted reports for medicines and vaccine reports (with devices to follow in a future release), from within the website or app
- Ability to allow attachments for medicines and vaccine reports (deployed in an earlier release for devices)
- Improvements in data collection for device incidents
- Support for smart forms based on conditional logic
- Support for automated follow-up
- General bug fixes to improve the user experience and reduce manual processing by the MHRA team
- Further enhancements will be delivered for release in November and December

2.9 This improves our ability to conduct responsive safety surveillance in response to an emerging issue; an example of how this capability might be used is showed in Annex 1, showing how additional questions could be asked in response to a specific safety concern.

2.10 These changes also enable integration of Yellow Card into other services such as the NHS App. The website has been made easier to use with new search and help functions as proposed by patients. There is also a new “News Feed” area so users can keep up to date with the latest research and analysis coming from the Yellow Card data. We are continuing to use patient feedback to add new features such as enabling provision of attachments and will deploy further enhancements by the end of 2022 and through 2023.

2.11 The creation of common teams combining expertise across all medical products for the delivery of our safety services associated with the collection, management and signal detection & assessment of adverse incident data for all product types has been realised now through the delivery of the Transformation Programme, the design work and benefits modelling being part of early SafetyConnect work. The benefits of the new team structures will be fully realised as the roll-out of SafetyConnect Core Technology Programme progresses.

3. Next steps

3.1 Deployment of the core technology programme has been separated into different phases, with the safety database, data platform and enhanced industry incident reporting systems for medical devices going live in late November. This phase will fully integrate the new Yellow Card with the safety database and enhance two-way communication between the MHRA and device manufacturers on individual incidents. The safety database, HALO, goes live on November 21st for medical devices safety data, replacing Lotus Notes. HALO will use Artificial Intelligence and automation to assist in case processing, building on the experience the Agency has gained using such technology during the pandemic. Medicines and vaccines will be moved from Sentinel to HALO in February 2023.

3.2 In December we will deploy the first phase of enhanced data visualisations of incident reports into the Yellow Card platform (Annex 2). This will initially deliver improvements in format, accessibility and data protection whilst allowing individuals to access more granular data than has been published to date. Further enhancements to the public data visualisation platform will be made during 2023, as the technology will be rolled out across all medicinal products and devices and fully linked to the new data platform.

3.3 During the first quarter of 2023 we will complete the development of the core technology programme for medicines and deploy enhanced signal detection capabilities. This will build on the signal detection research project that has been assessing different methodologies and approaches to identify safety issues and enable different methods to be deployed for different types of products. Those enhanced signal detection capabilities will then be extended to medical devices by summer 2023.

3.4 The new signal detection functionality will enable automation of different signal detection approaches for medical devices, using the same robust signal management capability as for medicines. For the first time we will be able to assess safety at different levels of the Global Medical Device Nomenclature (GMDN), and automatically flag patterns of reporting in relation to both medical device problems and associated health effects.

3.5 The future vigilance of both medicines and devices will be significantly enhanced by these new capabilities which will facilitate a genuinely responsive safety surveillance system, which can be adapted depending on the surveillance needs of the product and situation.

3.6 The combination of smart forms and follow-ups (Annex 3) within the Yellow Card platform will over the coming months offer a spectrum of vigilance options, from passive spontaneous surveillance to active monitoring, which when combined with flexible methods afforded through the new signal detection tools and used alongside linked electronic healthcare record data from the Clinical Practice Research Datalink (CPRD) will offer substantial improvements to the vigilance system.

3.7 Application of this functionality could support newly licenced products, such as black triangle products, where collecting fast, real-time data would be highly desirable. In this setting we could either choose to recommend/require that individuals are signed up to active monitoring, ask conditional questions at the point of initial reporting or actively follow-up spontaneous reporters for further information, as necessary.

3.8 A key foundation of the smart forms and follow-ups described above is conditional logic to deliver a smart surveillance system. We are exploring how we can expand the use of conditions to set rules in other areas of this surveillance platform, for example, for communication of tailored safety information to registered users tailored safety information based on the outputs of our signal detection system.

4. Recommendation

4.1 The Board is asked to note the progress to date and next steps of deployment of the programme.

4.2 The Board is asked to advise on which third party patient focused platforms should be targeted to embed Yellow Card reporting and to comment on the areas where the responsive safety surveillance might have most impact.

4.3 The board is asked to advise on additional areas where the flexibility offered by conditional logic could be applied and on mechanisms to determine the impact of the improvements to be provided by Safety Connect.

Alison Cave
November 2022

Annex 1: Opportunity for use of smart questions in the new Yellow Card

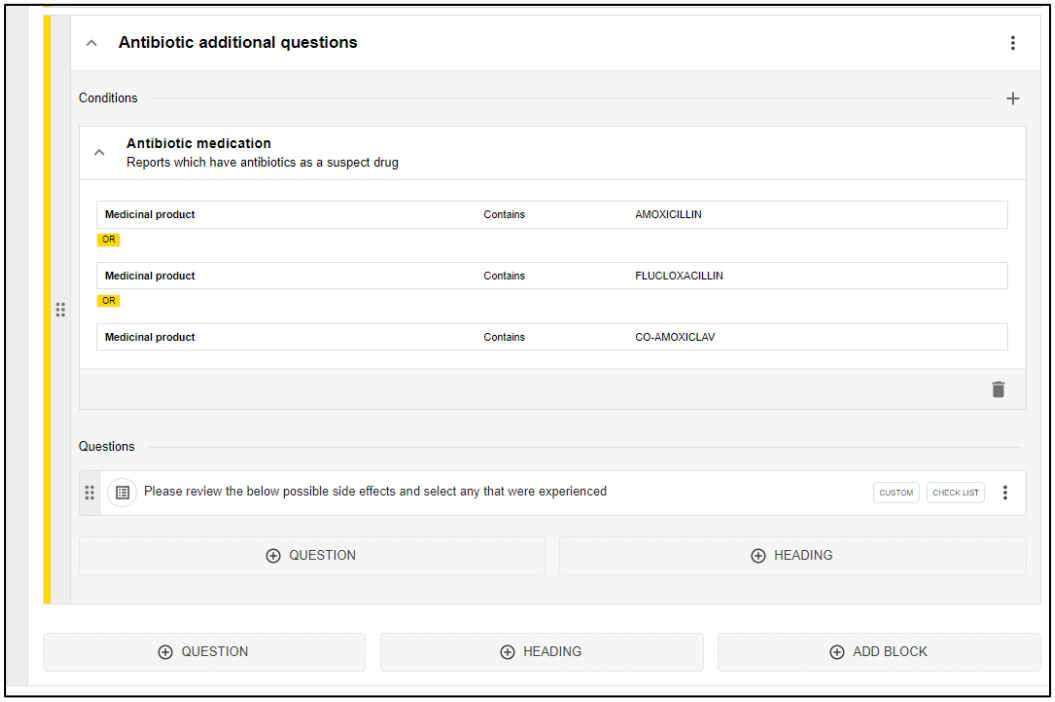


Figure 1: An example of a 'condition' where a rule has been defined to identify those reporting side effects to an antibiotic

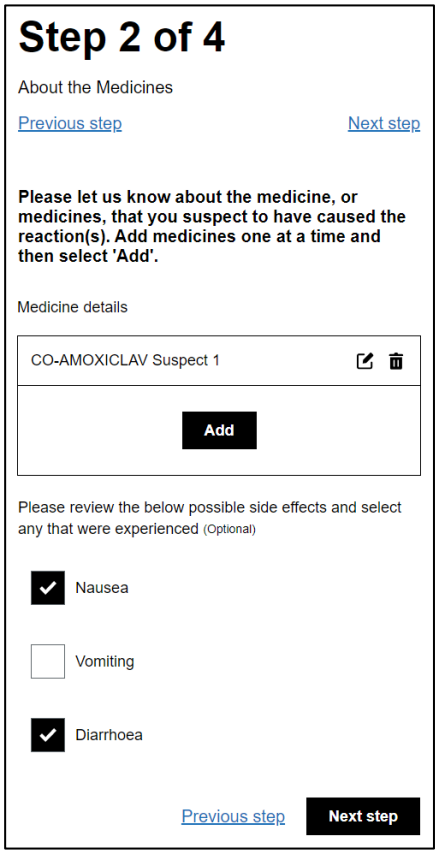
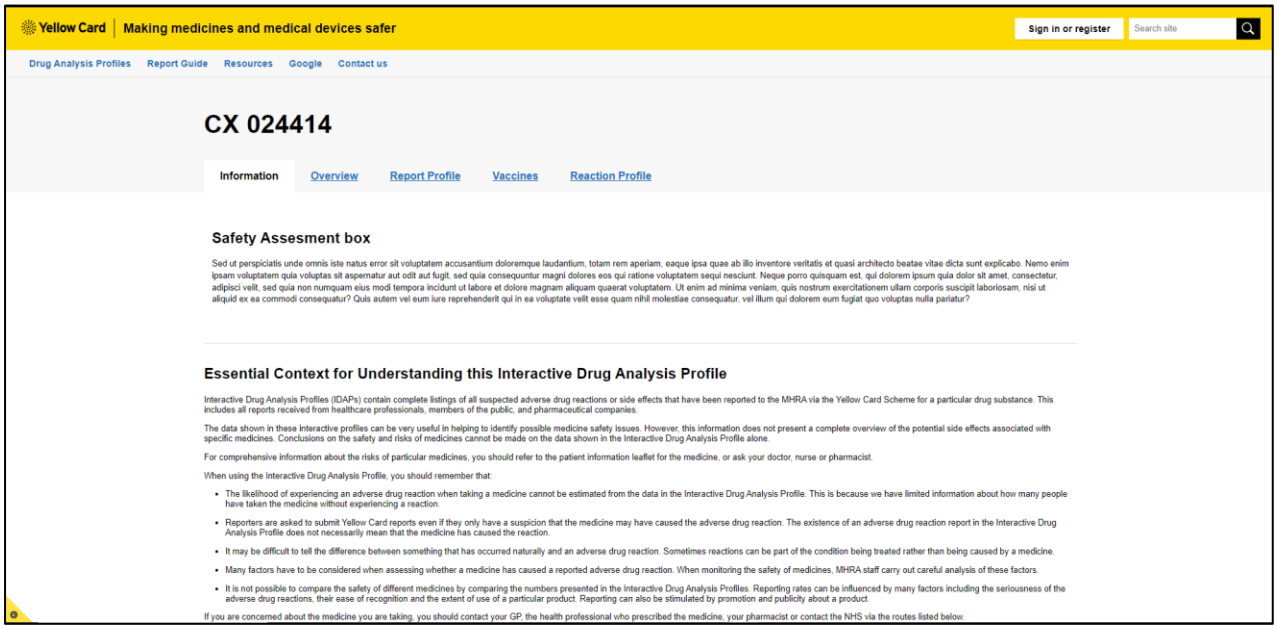
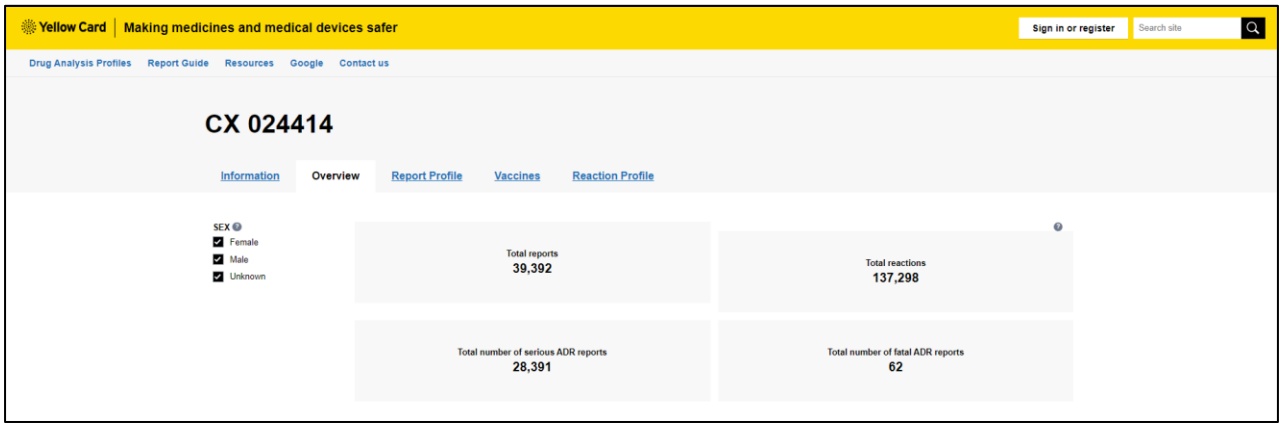


Figure 2: An example of how the conditions implemented into the Vigilance Hub could be presented to a Yellow Card reporter on the website, this is an example for demonstration purposes only

Annex 2: Enhanced data visualisation





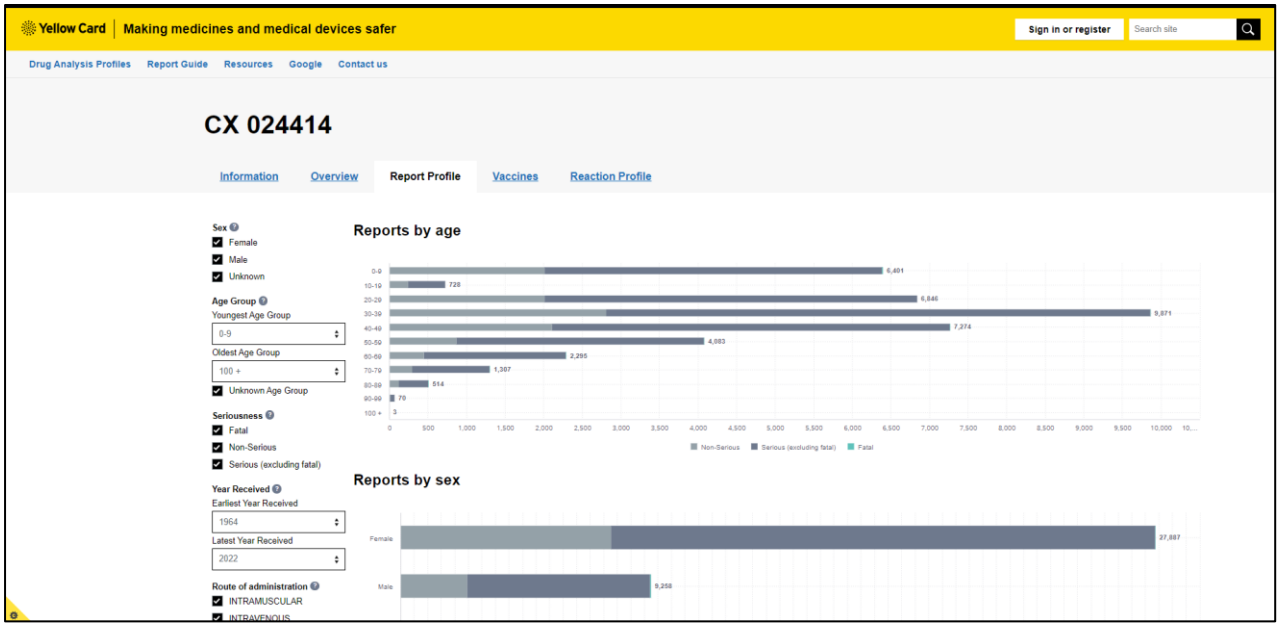


Figure 3: Early development of enhanced data visualisation within the Yellow Card platform.

Annex 3: Smart follow up

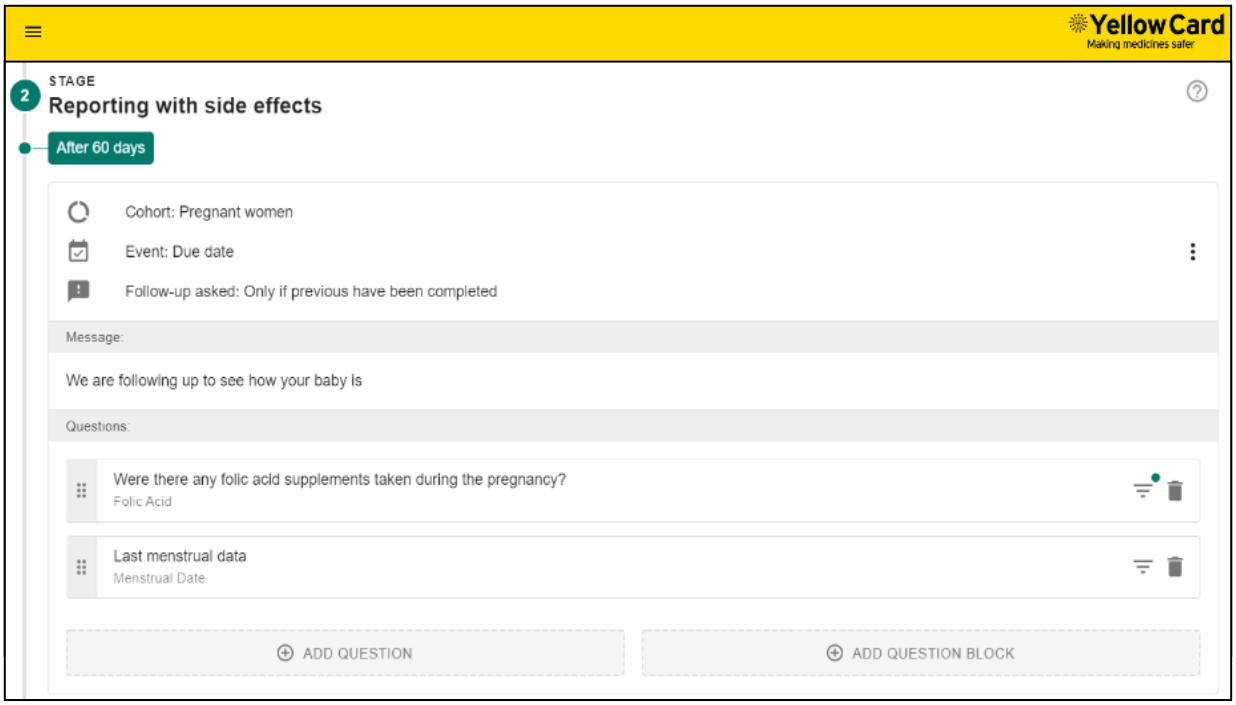


Figure 4: An example of the ability scheduled follow up for a cohort enabled by the enhancements

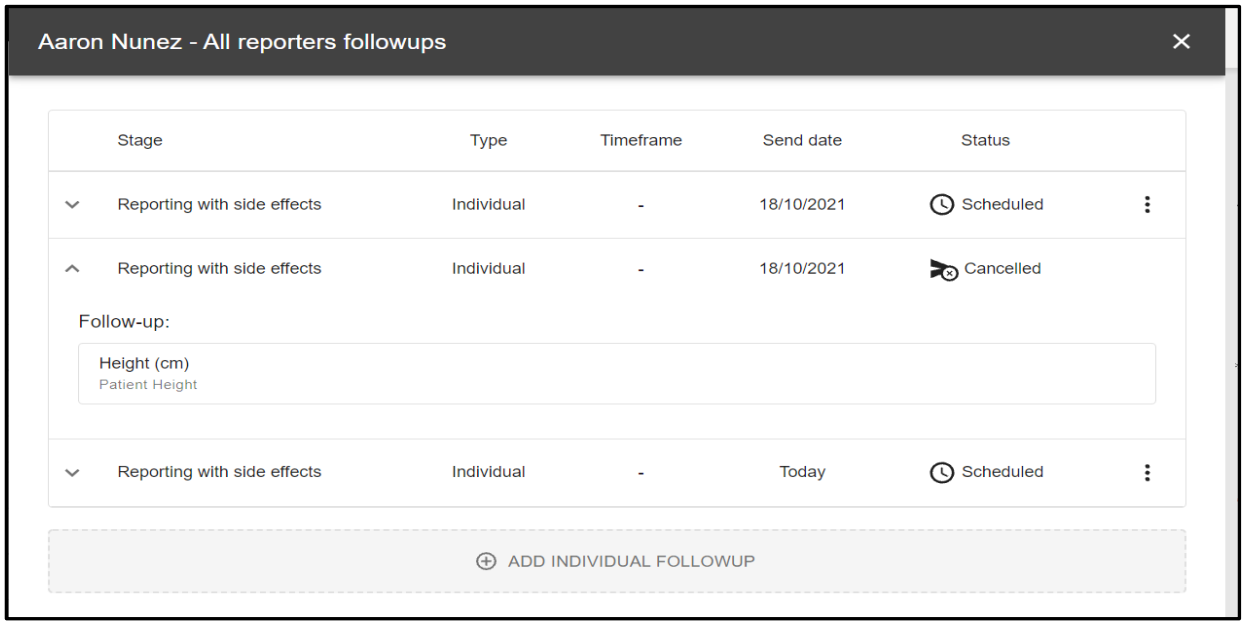


Figure 5: An example showing what follow ups have been scheduled for an individual reporter. Follow ups can be cancelled, amended or rescheduled if necessary.

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 November 2022

Title	What assurance can be provided from the Joint Organisational Development & Remuneration Committee and Audit & Risk Assurance Committee?
Board Sponsor	Amanda Calvert
Purpose of Paper	Assurance

What assurance can be provided from the Joint Organisational Development & Remuneration Committee and Audit & Risk Assurance Committee?

1. Introduction

The Organisation Development & Remuneration Committee (ODRC) and Audit & Risk Assurance Committee (ARAC) met on 12th October 2022 with the following objectives:

- Review progress and plans for implementation of the Regulatory Management System (RMS) project
- Understand how the RMS will enable delivery of key regulatory services
- Understand the data strategy for RMS
- Discuss the risks and dependencies for the project

2. Current status of the RMS project and the forward plan

2.1. Laura Squire, Chief Healthcare Quality & Access Officer has been appointed as Senior Responsible Officer (SRO) for the RMS programme and is working closely with Claire Harrison, Chief Digital & Technology Officer, to ensure that the technology solution and business processes are aligned to meet the needs of the Agency.

2.2. They lead an RMS project board that meets monthly to track progress and resolve issues. The project discovery phase is currently on plan.

2.3. The project is in discovery phase which is working with users and process owners to define the technology requirements and is on track to deliver a basic technology solution, the Minimal Viable Product (MVP), by June 2023.

2.4. Two current issues have been identified for further investigation:

- The future requirements for Device Devices Regulation are changing but the current Lotus Notes system is not fit for purpose.
- There needs to be a strategy for legacy data to ensure that it can be made available when required but does not “clog up” the new system.

2.5. The cross-Agency working and collaboration appears to be working effectively at this stage of the programme.

3. How the RMS will enable the delivery of key regulatory services

3.1. The Agency is in the process of defining the services that it will deliver. The RMS will support the efficient and effective delivery of regulatory services for medicines and devices.

3.2. Assessors will be key users of the system and are working as part of the discovery team. Their knowledge and expertise are key to identifying efficiencies such as the ability to automate administrative tasks so that they can spend more time on assessing high risk activities, where their expertise adds most value.

3.3. The introduction of any new system will change the way people within the agency undertake their roles and deliver services and good communication, training and leadership are as important as the technology itself.

3.4. The joint committee members supported the inclusion of medical devices in the MVP. It recognised that there is uncertainty associated with this approach as the future regulations for devices are not yet fully defined.

3.5. Workflow and case management is key information for customers. The MVP will provide information for users so that they will be able to track progress which aims to reduce the time spend answering routine queries.

3.6. The system will be designed to allow it to be modular and flexible to address the changing regulatory landscape.

3.7. The discovery phase will articulate the design principles that will form the basis for the full business case and for the design and implementation of the MVP due for delivery in June 2023.

3.8. The RMS will seek to pull in data from other sources such as safety monitoring and post-market surveillance.

4. Data Strategy for RMS

4.1. The data strategy is key for the success of the project. The system will adopt the ISO IDMP data standards which will facilitate sharing of data with other organisations globally. An implementation plan needs to be developed for this.

4.2. There are large amounts of data in legacy systems. Only a minimum set of data in addition to Master Data will be transferred to the RMS. All historical data will be transferred to a fully searchable legacy archive.

4.3. ARAC asked for clear visibility of the data architecture map and the data governance structure that is being developed. This will give assurance that the data standards, architecture and governance are fit for purpose. The Committees were given assurance that there were data architects working in the project team and guidance from data.gov.uk on how to delivery of open and common data standards was being followed.

4.4. The data and systems architecture will evolve from the MVP to both ensure that it is fit for purpose and can incorporate user experience improvements and regulatory legislation changes into future developments but also to get the new system up and running as quickly as possible for the lowest possible cost.

5. What is the Scope of the Minimum Viable Product?

5.1. The discovery phase will be completed by the end of October and the first version of the RMS, denoted the Minimum Viable Product (MVP), is planned for delivery in June 2023. There are choices to be made in terms of what services will be included.

5.2. The Strategic Change Committee will review the business case developed by the project team on the scope of what can be delivered by June 2023. If this is acceptable, the funding will then be released, and the MVP delivery phase will commence.

5.3. The project team were asked to share the scope of the MVP with ARAC and the Board and to highlight the business benefits that will be delivered.

5.4. The MVP will be the first phase of the programme and needs to deliver substantial benefit to the Agency. Additional phases should be planned as early as possible to secure funding and resources. ARAC and the Board will be kept updated on progress.

6. Ongoing Development and Governance of RMS

6.1. This is recognised as a complex programme of work which requires close collaboration with external suppliers who will be delivering and maintaining the technology. The meeting was assured that they are being managed effectively, delivering value for money and the Agency is not embedding dependence on them. This will be subject to ongoing review by the project team working with legal and commercial teams.

6.2. Assurance was given that the business case will include resourcing to ensure that the appropriate Agency resources are put in place to ensure that the role of suppliers is governed effectively.

6.3. Whilst the project requires good collaboration with suppliers, there are regular meetings with the supplier CEO's and the Agency's Chief Digital & Technology Officer as well as formal contractual meetings.

7. Risks and Dependencies

7.1. There is a robust risk management framework being used by the project team to manage the project risks. The project board and governance office have oversight of the risks and there is evidence that risks are being escalated appropriately. There are both internal and external risks requiring mitigation.

7.2. Risks are being managed effectively but focus on the scope of the MVP delivery in June 2023 will require constant assessment and mitigation of the current risks.

7.3. ARAC and ODRC will continue to review the risks and the plan for delivery of the MVP.

8. Concluding Remarks

8.1. This was the first joint meeting of ARAC and ODRC. Both committees have assurance responsibilities that are dependent upon the successful implementation of the Regulatory Management System, and this was an excellent opportunity to review progress together.

8.2. We were encouraged by the progress that is being made. There is close collaboration at leadership level and across the different parts of the Agency. The definition of the new services and ways of working did not reach the level of maturity hoped for in the transformation programme but are now being defined in the RMS project discovery process. The importance of designing the processes and systems to meet future needs is understood by the team and the RMS remains a cornerstone for the delivery of the One Agency strategy and business plan.

8.3. There are strong governance processes in place both within the project team and through the Project Board and Strategic Change Committee processes.

8.4. The delivery of the MVP will be challenging as there is much to do, but the plans look realistic, and the programme is currently on plan and budget at this stage. Resourcing remains a key risk to the programme and is under constant review.

8.5. ARAC and ODRC will continue to seek assurance that the programme is progressing to plan and will report to the Board periodically.

Amanda Calvert – Chair of Organisational Development & Remuneration Committee
Michael Whitehouse – Chair of Audit & Risk Assurance Committee
November 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 November 2022

Title	What assurance can be provided by the Audit & Risk Assurance Committee?
Board Sponsor	Michael Whitehouse
Purpose of Paper	Assurance

What assurance can be provided by the Audit and Risk Assurance Committee?

1. Executive Summary

1.1 The Audit & Risk Assurance Committee (ARAC) met formally on Monday 31 October 2022. We received a presentation on how the Agency is responding to an inspection by the Health and Safety Executive (HSE). We reviewed progress in implementing the National Audit Office's (NAO) recommendations. We discussed the next steps and timetable for revising the Agency's Risk Register and considered the Agency's financial performance. Finally, we received an update on Internal Audit's work and reviewed the Agency's approach to responding to complaints.

1.2 ARAC met informally on 26 September 2022 together with the Chairs of the Patient Safety & Engagement Committee (PSEC) and the Organisational Development & Remuneration Committee (ODRC) to consider medium to longer term issues (horizon scanning) which could influence the Agency's work and performance.

1.3 ARAC and ODRC held a joint meeting on 12 October 2022 to consider progress with the Agency's strategically important RMS project and how the associated risks are being managed. The outcome of this meeting is reported separately to the Board by the Chair of ODRC.

2. Health and Safety

2.1 We received a comprehensive presentation on the current issues which the Agency is addressing to strengthen health and safety. These arise from a Health and Safety Executive (HSE) inspection and cover three areas: ensuring that changes such as the Agency's recent organisational transformation do not result in gaps in safety critical roles; demonstrating that policies and procedures which are essential to maintaining health and safety resilience remain embedded and adhered to as the Agency's transformation is implemented; and addressing four incidents notified to the HSE under the Reporting of Injuries Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR). The Agency is also preparing its submission for the renewal of its licence for critical work under the Specified Animal Pathogens Order (SAPO) 2008.

2.2 We were assured that the Agency is focused on remedying the issues that the HSE has identified. Staff vacancies in critical roles has been a significant issue and while we understand positions are now being filled, work pressure on existing staff has intensified and is not sustainable. It will inevitably take some time for new staff to become fully competent in their new roles and we agree with the Executive that health and safety should be included in the Agency's strategic risk register.

2.3 We sought assurance that the Agency is investing enough resources in health and safety. We were told that the Health and Safety Team's budget is sufficient to fund the key safety roles that are needed. Once all of these roles are filled, resilience should be strengthened. We recommend, however, that assurance would be enhanced if the time and resources

devoted to health and safety in critical activities across the Agency was more transparent and periodically reviewed by the Executive Committee. We were told that the Agency's new time recording system should make this possible.

2.4 Health and Safety is now reinstated as a standing agenda item for every ARAC meeting. In addition, the Committee will continue to consider the Agency's Annual Health and Safety Report. We have also asked for a progress report at our meeting in January on the implementation of actions underway to address issues identified by the HSE, including the RIDDOR cases, and progress in renewing the MHRA's SAPO licence.

3. Financial Performance

3.1 We covered three areas: progress in implementing the NAO's recommendations; implications for the MHRA's financial statements for 2022/23 now the Agency is no longer a Trading Fund; and mid-year financial performance.

NAO Recommendations

3.2 We were assured that all of the specific recommendations that arose from the NAO's audit of the MHRA's 2021/22 Annual Report and Financial Statements have or are being implemented. The Agency and ARAC does need, however, further assurance that the problems encountered with the finalisation of the 2021/22 Financial Statements will not be repeated for 2022/23.

3.3 We endorse a number of actions intended to mitigate this risk. The Deputy Director of Finance will lead a short review of Finance's capability using the Cabinet Office's functional capability standard. Internal Audit will provide independent assurance on this to the Agency and report to ARAC. The NAO will focus on a number of the issues which arose last year during its interim audit and highlight any remaining or new risks. This will only provide partial assurance as many of the 2021/22 issues arose from end of year reconciliations but will be supplemented by more in-depth work and preparation by Finance at the interim stage. ARAC will dedicate more time to review progress and provide assurance to the Board.

Financial Statements 2022/23

3.4 Finance provided a paper which set out the changes required to the MHRA's financial statements now it is no longer a Trading Fund. The main change is how funding from the Department is disclosed and which will likely show the Agency in deficit. We agreed this will require careful explanation in the supporting narrative in the Annual Report.

3.5 We discussed and were assured that the Agency has a clear budgetary framework underpinning its financial management with senior responsible officers having specific financial accountabilities. We emphasised the importance of the Agency's governance framework for financial decision making and accountability being closely aligned to all income and expenditure. We also recommend that total expenditure on corporate costs is consolidated and reported as such so that total corporate costs are more transparent and that the Board can be assured that these represent value for money.

Mid-year financial performance

3.6 We considered the Agency's financial performance for the first six months of 2022/23 and the projected position at the year-end. This was a draft paper as it had yet to be considered by the Executive. As discussed at the recent Board, the main issues are the under-spend on staffing as the Agency has a significant number of vacancies and the priority to continue to drive down debt (ARAC will continue to seek assurance on the latter).

3.7 In respect of the likely end year position, we discussed a number of risks which the Agency is aware of. While finance has stress tested the financial projections and underlying assumptions, the risk of optimisation bias remains which could result in a substantial underspend.

3.8 Where there are difficulties in recruiting staff it is understandable to substitute either interims or consultants to maintain service levels and deliver priority programmes. Interims and consultants are likely to be more expensive in the medium term. The level of additional cost which the Agency is incurring from having to rely on consultants and interims is not transparent from the financial report nor is the real level of vacancies. We concluded that both these merit further investigation by Finance and HR before consideration by the Executive Committee.

4. Risk Management

4.1 Following the Board's consideration of key strategic risks, we sought assurance on the timetable for translation of these into a new Risk Register. The Agency has appointed a full-time Risk Manager who is in post and the intention is that a revised draft Risk Register will be developed for consideration by ARAC in December and subsequently presented to the Board in January. The Committee is encouraged by the progress being made. We advised that it would be helpful if the Risk Register could be presented to the Board together with the Agency's Risk Appetite Statement and plans for embedding risk management in the Agency. We emphasised that as well as helping to mitigate adverse consequences, risk management should help support a culture of innovation to ensure that the MHRA realises its full potential as a standalone sovereign regulator.

5. Internal Audit

5.1 Three Internal Audit reports which ARAC planned to consider were delayed. These are: the Innovative Licensing and Access Pathway (ILAP) - delayed from Spring 2022; Payroll Controls and Financial Control (we understand that this will be broadly positive). Some of the delay is attributable to the availability of Internal Audit resources, but timely engagement by the Agency was also a significant factor. ARAC recognises that shortages mean that Agency staff are under pressure and have to prioritise. Nevertheless, Internal Audit's work is a critical component of the Agency's governance and the independent assurance it provides to the Accounting Officer and the Board. The insights which Internal Audit can provide through its wider cross government perspective also have real potential to add value to the MHRA, but realisation of this requires more active engagement with Internal Audit by all levels in the Agency.

5.2 We understand that the outstanding reports will be finalised in the next week. We will convene an additional ARAC meeting in December to consider these.

5.3 The Committee briefly discussed progress in implementing Internal Audit's recommendations. We support the Executive's decision to strengthen governance so that progress in implementing recommendations is more transparent. We will consider the new reporting arrangements at our January meeting. To ensure that we can be confident about the added value of the recommendations we have asked Internal Audit, in consultation with the Executive, to draw attention in their annual report to specific outcomes which can be attributed to their work.

5.4 We endorsed some changes to Internal Audit's 2021/22 work programme. These are: deferring the further work on HR processes including recruitment; and substituting some assurance on the Agency's revised Risk Register together with additional assurance work on Information Governance. We agreed to convert the planned work on business planning into a two-stage approach over 24 months. The first will be supporting the Agency in advising on good practice as it develops its new business planning and performance management. The second (delivery 2023/24) will be providing assurance on the implementation of new business planning.

5.5 Internal Audit assured us that the revised programme, if completed as planned, would provide sufficient evidence for their annual assurance to the Accounting Officer on controls. We emphasised the importance of Internal Audit providing sufficient substantive evidence and our support for adjusting the programme should this be needed.

6. Governance – complaints handling and error

6.1 We were assured by a comprehensive presentation that the Agency's approach to handling complaints from the public was reliable. We discussed if complaints had increased as a consequence of COVID and there is no discernible evidence.

6.2 We asked that the number of complaints received be routinely reported to ARAC at each of its formal meetings and that a short annual report be produced each Spring on overall performance, any emerging themes and how the Agency is responding to these. This report should be shared with the Patient Safety & Engagement Committee.

6.3 We received the routine report on non-regulatory fraud and error. Seven incidents were recorded of which one was classified as a near miss fraud. In respect of the latter, we asked for confirmation at our next meeting that the Agency's procurement procedures require contractors to certify if they are working for other public bodies. Four of the six reported errors related to pay roll, which has been a regular occurrence in error reports to ARAC. We intend to explore this further when we receive Internal Audit's report on Payroll.

6.4 No instances of whistle blowing were brought to our attention.

Michael Whitehouse
Chair, Audit & Risk Assurance Committee
November 2022