Medicines & Healthcare products Regulatory Agency

**AGENDA FOR BOARD MEETING HELD IN PUBLIC**

**10:00 – 12:30 on Tuesday 19 October 2021**

**Chair: Stephen Lightfoot**

| | **AGENDA ITEM** | **PURPOSE** | **PRESENTER** |
|---|---|---|---|
| 10:00 | INTRODUCTION<br>1. What are the priorities for this meeting, how will the meeting run and who are the new Board Directors? | Information | Chair |
| | 2. Are there any Apologies or Declarations of Interest? | Information | All |
| | 3. What were the minutes & actions from last meeting? | Approval | Chair |
| | AGENCY PERFORMANCE | | |
| 10:20 | 4. What are the current issues from the CEO's point of view? | Context | June Raine |
| 10:40 | 5. What is the performance of the MHRA on the Balanced Scorecard in Month 5? | Assurance | Jon Fundrey |
| | SCIENTIFIC INNOVATION | | |
| 11:00 | 6. How is the MHRA accelerating the approval and diversification of patient recruitment for clinical trials? | Strategic Direction | Marc Bailey |
| | PATIENT SAFETY | | |
| 11:20 | 7. What assurance can be provided by the Patient Safety & Engagement Committee? | Assurance | Mercy Jeyasingham |
| | CORPORATE GOVERNANCE | | |
| 11:40 | 8. What are the mitigations for the most important risks on the Corporate Risk Register? | Assurance | Jon Fundrey |
| | EXTERNAL PERSPECTIVE | | |
| 12:00 | 9. What questions do members of the public have for the MHRA Board? | Public Engagement | Chair |
| 12:30 | CLOSE OF MEETING | - | Chair |

**Medicines and Healthcare products Regulatory Agency**

**Minutes of the Board Meeting Held in Public of 21 September 2021**

(10:00am – 12:30pm)

Round Room, MHRA, 10 South Colonnade, E14 4PU
and by Zoom Webinar

**Present:**

*The Board*

| | |
|---|---|
| Stephen Lightfoot | Chair |
| Dr June Raine CBE | Chief Executive |
| Dr Marc Bailey | Chief Science, Research and Innovation Officer |
| Dr Alison Cave | Chief Safety Officer |
| Amanda Calvert | Non-Executive Director |
| Jon Fundrey | Chief Operating Officer |
| Mercy Jeyasingham MBE | Non-Executive Director |
| Michael Whitehouse OBE | Non-Executive Director |
| Dr Junaid Bajwa | Non-Executive Director |
| Raj Long | Non-Executive Director |
| Dr Paul Goldsmith | Non-Executive Director |
| Haider Husain | Associate Non-Executive Director |

**Others in attendance**

| | |
|---|---|
| Rachel Bosworth | Director of Communications |
| Natalie Richards | Head of the Executive Office |
| Jude Thompson | Executive Assistant to the Chair |

## INTRODUCTION

### Item 1: What are the priorities for this meeting, how will the meeting run and who are the new 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.

1.2 The Chair welcomed everyone to the meeting, including a broad range of observers representing a range of patient groups, other health bodies, UK government, staff and industry.

1.3 The Chair congratulated Dr Marc Bailey, who has recently been appointed as the new Chief Science Research and Innovation Officer.

1.4 The Chair welcomed three new Non-Executive Directors: Dr Junaid Bajwa, Raj Long, and Dr Paul Goldsmith. A fourth new Non-Executive Director, Professor Graham Cooke, will also be joining from the October Board meeting onwards. The Chair then welcomed Haider Husain who has joined the Board as an Associate Non-Executive Director.

**Item 2: Are there any Apologies or Declarations of Interest**

2.1 Apologies were received from Professor Graham Cooke, Non-Executive Director; Dr Sam Atkinson, Interim Chief Quality & Access Officer; John Quinn, Interim Chief Technology Officer; and Carly McGurry, Director of Governance.

2.2 The new Non-Executive Directors announced their Declarations of Interest; these will be published on GOV.UK for transparency. A new Personal Specific Declaration of Interest was made by Amanda Calvert whose consultancy company is currently undertaking some work for a pharmaceutical company called Phoenix. An action was taken for the Governance Office to put appropriate mitigations in place for these Declarations of Interest.

***Action 56: Put appropriate mitigations in place for new Non-Executive Director Declarations of Interest*** ***Chair & Carly McGurry***

**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.

3.2 In relation to action 33, the Board noted that the Yellow Card Biobank is a new initiative to recruit patients who have submitted a Yellow Card with an Adverse Drug Reaction (ADR) of interest, for which MHRA would like to further explore the underlying mechanism of the ADR. The scoping exercise underway is looking at the legal underlying mechanisms, as well as options for legal requirements. Events held to date have indicated high support for this initiative.

3.3 In relation to action 34 regarding a new regulatory pathway for genomic medicines, there are initiatives underway to support the market introduction of new genomic medicines, including through the Innovative Licensing and Access Pathway (ILAP) and work which NIBSC is undertaking with a gene therapy manufacturing site in Sheffield. An action was taken to publish a communication on GOV.UK on how the MHRA is working to develop a pathway for new genomic products.

***Update to action 34: Publish communication on GOV.UK on the MHRA work to develop a pathway for new genomic products.*** ***June Raine***

3.4 In relation to action 55, the Board noted that recruitment to the Executive Committee has been taking place following which senior executive leadership champions will be identified for all Diversity Strands and Staff Inclusion Groups.

## GOVERNANCE

### Item 4: What are the new governance arrangements for the refreshed Unitary Board?

4.1 The Board considered a paper describing the new governance arrangements for the refreshed Unitary Board, following the recent appointment of four new Non-Executive Directors and one Associate Non-Executive Director. The Board thanked Dr Sam Atkinson, John Quinn and Dr Christian Schneider for their hard work in their interim posts while working to develop the Agency's Transformation Programme together with the Executive Committee.

4.2 The Board considered the MHRA accountability and governance structure and endorsed this. The Board reviewed the revised Agency Board Terms of Reference (TOR); with regards to the Board's role in governance and the review of its effectiveness, the Board agreed that point 2.2 should be strengthened to properly describe the Board's independence, that the ultimate responsibility for decision making lies with the CEO, and the Board's responsibility to review its own effectiveness on at least an annual basis. With this amendment the Board were content to approve the TOR.

4.3 It was noted that the MHRA/DHSC Framework Agreement will be updated to coincide with the change in the Agency's Trading Fund status on 1 April 2022.

***Action 57: Amend Board Terms of Reference with more detail on Board's role in governance and the review of its effectiveness. Chair & Carly McGurry***

***Action 58: Update MHRA/DHSC Framework Agreement to coincide with the change in Trading Fund status. Carly McGurry***

4.4 The Board considered the proposals for committee membership of each of the new Non-Executive Directors. The Board endorsed the proposal for Professor Graham Cooke to take up the post of Deputy Chair, and for Michael Whitehouse to continue as the Senior Independent Director.

4.5 The Board considered the Board Schedule of Business. It was agreed that the Patient Safety and Engagement Committee dates should be synchronised with the scheduled updates on the Independent Medicines and Medical Devices Safety Review reports. The Board agreed that the Board assurance committees should review their combined effectiveness on a periodic basis, following which a Board discussion should take place on this topic. The Board approved the schedule.

***Action 59: Board assurance committees to review their combined effectiveness and hold a board discussion on this topic. Michael Whitehouse, Mercy Jeyasingham, & Mandy Calvert***

## AGENCY PERFORMANCE

### Item 5: What are the current issues from the CEO's point of view?

5.1 Dr June Raine presented the Chief Executive's monthly report, which covered topics within the four strategic priorities:

**(i) Healthcare Access** – including latest updates on the Innovative Licensing and Access Pathway (ILAP); new product approvals; COVID-19 vaccine booster doses; COVID-19 vaccine batch testing by NISBC; COVID-19 tests; an Influenza World Health Organisation Essential Regulatory Laboratories meeting hosted by NIBSC; how MHRA has enabled wider access to oral contraception via reclassification of progesterone-only pills; the British Pharmacopoeia; supply of blood collection tubes; updated Good Practice Guides; national and international Partnerships updates on the MHRA's Clinical Trials strategy; the Access Consortium; FDA Project Orbis; inspections collaboration with the FDA; medicines and medical devices used by cosmetic practitioners;

**(ii) Patient Safety** – including updates on COVID-19 vaccines safety monitoring; valproate and the Pregnancy Prevention Programme; isotretinoin for the treatment of acne and patients' views on safety; amiodarone; contamination of ultrasound transmission gel; medicines recalls; falsified medicines; the MHRA's transitional medical devices register; and enforcement;

**(iii) Dynamic Organisation** – including updates on the Transformation Programme; the Agency's designation by UKRI with Public Sector Establishment Status; and the NIBSC 'Meet the Employer' initiative; and

**(iv) Financial Sustainability** – including updates on the Fees Policy; the British Pharmacopoeia sales; grant funding for the UK Stem Cell Bank; and the Regulators Pioneer Fund award to support Artificial Intelligence (AI) device registration.

5.2 The Board thanked Dr Raine for her report and provided comments regarding how the Agency can develop as a global player; the MHRA's work on the 100 days mission and international collaboration on Clinical Trials; development of a new guideline on AI with the FDA; the Access Collaborative; working with European colleagues particularly on safety; working with Low- and Middle-Income countries; the opportunity to develop the UK's regulatory environment; involving all staff in designing new ways of working through the transformation; and understanding staff concerns in relation to managing business as usual while also delivering the transformation. The Board noted the Executive regularly reviews areas of pressure in relation to resource deployment to carefully manage this issue.

5.3 The Board provided further comments regarding the changes which will be made to the future organisational structure following from staff comments through the consultation; staff engagement sessions on the transformation with Chief Officers; diversity and inclusion; the importance of working with other stakeholders in the healthcare system while maintaining independence of regulatory and scientific

decision making; how the ILAP system is accessible to SMEs, start-ups and academics as well as large pharmaceutical companies; and how to join up the UK's health system. The Board thanked Dr Raine for her comprehensive report.

**Item 6: What is the current performance of the MHRA on the Balanced Scorecard?**

6.1 The Board discussed the current performance of the MHRA, presented via the quarterly (Q1) Balanced Scorecard. The Board considered whether the metrics and the commentary provided appropriate assurance that current performance is on track and aligned to the Agency's strategic objectives. The Board provided comments regarding the targets and suggested – noting that some targets in the Balanced Scorecard are out of the Agency's control such as the number of applications and clinical trials – further consideration should be given to appropriate targets. It was noted that time-based targets are not appropriate. The Board noted there is a parallel piece of work ongoing regarding efficiencies.

6.2 The Board provided further comments regarding whether some of the targets are ambitious enough and how the MHRA can push these to be more ambitious; ensuring the Patient Safety and Engagement Committee is consulted for strategic input in relation to the reputational and patient engagement indices; assurance that the Agency will spend its financial reserves before the change in Trading Fund status; ensuring that underspend in projects is carefully monitored and brought back to the required level; how to change the Agency's culture through the transformation; and managing resourcing issues.

***Update to action 51: 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.*** ***Jon Fundrey***

**Item 7: What has the MHRA achieved compared to each first quarter deliverable in the Delivery Plan and how will any under-performance be recovered to avoid any impact on the overall two year Plan?**

7.1 The Board considered a report on progress against the Delivery Plan for the first quarter (Q1) of the reporting year. The Board provided comments on the new format of the report. The Board also advised caution on items which are rated as 'green' when a specific milestone has been met, but where there may be underlying problems about the future achievement of this goal or related problems elsewhere in the agency which could more broadly justify an 'amber' or 'red' rating. The Board advised that criteria could be developed to guide the RAG rating assignations. The Board also commented that information on trajectory could be included; deep dives will be undertaken by the Executive into areas of slippage or significant risk.

## PATIENT SAFETY

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

8.1 The Board considered an assurance report from the Patient Safety and Engagement Committee (PSEC). The PSEC had considered the performance of the Customer Service Centre; reviewed final feedback on the Patient and Public Involvement Strategy consultation; confirmed subjects and questions for future papers to the Committee; discussed plans to develop a reputational index; and reviewed proposals on involvement of stakeholders in the development of proposals on the Yellow Card Biobank. The PSEC also received feedback from the two Non-Executive Directors leaving the Committee, which will be considered when reviewing the PSEC TOR.

8.2 The Board provided comments regarding the process which ensures diversity in areas such as clinical trial populations; ensuring the capture of all populations of patients when considering medicines and devices safety measures; how to communicate with harder to reach populations via outreach work by the MHRA's patient engagement staff; ensuring Non-Executive Directors are involved in the transformation as well as the Executive; the Agency's role in health literacy and managing misinformation; and how the Agency can use meaningful examples to demonstrate to patients how they have influenced a key decision.

## EXTERNAL PERSPECTIVE

### Item 9: What questions do members of the public have for the MHRA Board?

9.1 The Board answered a range of questions from members of the public. Due to a technical issue the Board's answers were not broadcast via Zoom webinar to observers; an action was taken to answer all of the submitted questions directly to the members of the public who raised them.

***Action 60: Answer the questions from the public at the September Board meeting***
***Rachel Bosworth***

## ANY OTHER BUSINESS

10.1 No additional business was raised.

## ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 21 SEPTEMBER 2021

| Action Number | Action | Owner | Date | Status |
|---|---|---|---|---|
| Carried Forward from previous meetings | | | | |
| 29 | Present an Agency Laboratory Strategy to the Board as part of the Agency Science Strategy. | Marc Bailey | ~~21/09/21~~ ~~16/11/21~~ 15/03/22 | |
| 34 | The MHRA had a commitment in the Life Sciences Sector Deal 2 to publish a new regulatory pathway for genomic medicines and genomic tests by March 2021. Provide an update on progress of this commitment.<br><br>21/09/21: Publish communication on GOV.UK on the MHRA work to develop a pathway for new genomic products | June Raine | ~~18/05/21~~ ~~21/09/21~~ 19/10/21 | Verbal Update |
| 38 | PSEC and ARAC to agree how to provide assurance to the Board on the development, governance and data standards of SafetyConnect | Mercy Jeyasingham & Michael Whitehouse | ~~20/07/21~~ 15/03/22 | |
| 39 | Implement the approved Communications Strategy with particular focus on measuring trust &communication with HCPs | Rachel Bosworth | 16/11/21 | |
| 43 | A revised assurance and governance framework for the new MHRA organisation should be presented to the Board. | Carly McGurry | 15/02/22 | |
| 46 | The Board's comments on the future development &branding of ILAP, including its potential use for medical devices, should be considered so that a definitive proposal can be presented to the Board for approval. | Chief Quality & Access Officer | ~~19/10/21~~ 16/11/21 | |
| 49 | Review progress of patient recruitment for CPRD SPRINT contract as part of a paper to demonstrate how clinical trial approval and recruitment can be accelerated more widely | Alison Cave & Marc Bailey | 19/10/21 | On Agenda for October meeting |
| 50 | ARAC to review the Agency's financial performance in the first six months of 2021/22<br><br>21/09/21: Review spending of financial reserves at next ARAC | Michael Whitehouse | 16/11/21 | |

| | | | | |
|---|---|---|---|---|
| 51 | 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<br><br>21/09/21: Review the outcome measures in the Balanced Scorecard and the RAG Ratings in the quarterly Delivery Plan reports before considering the targets are ambitious enough. | Jon Fundrey | ~~19/10/21~~ 16/11/21 | |
| 52 | Review how multiple data sources including Unique Device Identifiers, Registries, NHS data and real world data can be captured and used to strengthen safety surveillance. Incorporate this into the planned review of SafetyConnect | Alison Cave | ~~16/11/21~~ 18/01/22 | |
| 53 | Develop the measures to monitor the impact of the deliverables and activities in response to the Cumberlege Review | Alison Cave | 19/10/21 | Verbal Update |
| 54 | Review the progress and impact of the short, medium and long term deliverables of the agreed Culture, Equality, Diversity and Inclusion plans | Jon Fundrey | 18/01/22 | |
| **New Actions** | | | | |
| 56 | Put appropriate mitigations in place for new Non-Executive Director Declarations of Interest | Chair & Carly McGurry | 19/10/21 | Verbal Update |
| 57 | Amend Board Terms of Reference with more detail on Board's role in governance and the review of its effectiveness. | Chair & Carly McGurry | 19/10/21 | Verbal Update |
| 58 | Update MHRA/DHSC Framework Agreement to coincide with the change in Trading Fund status. | Carly McGurry | 31/03/22 | |
| 59 | Board assurance committees to review their combined effectiveness and hold a board discussion on this topic. | Michael Whitehouse, Mercy Jeyasingham, & Mandy Calvert | 15/03/22 | |
| 60 | Answer the questions from the public at the September Board meeting | Rachel Bosworth | 19/10/21 | Verbal Update |

Medicines & Healthcare products Regulatory Agency

# BOARD MEETING HELD IN PUBLIC

**19 October 2021**

| | |
|---|---|
| **Title** | What are the current issues from the CEO's point of view? |
| **Board Sponsor** | June Raine |
| **Purpose of Paper** | Context |

# Chief Executive's Report to the Board
# 19 October 2021

**This report gives a brief overview of the Agency's current issues since the September Board meeting. The Board is asked to consider and agree the priorities.**

## 'TOP 10' HEADLINES

- Our Transformation Programme staff consultation has progressed via active engagement with the Senior Leadership Team and staff, supported by our Champions network. Feedback is being analysed and emerging themes distilled

- On 1st October, after a second round of consultation with patient groups, we finalised the Agency Strategy for Patient Involvement 2021-25, and we are now progressing implementation

- On 16th September, we launched a broad-ranging public consultation on the future legal framework for medical devices in UK, including in vitro diagnostics and innovative medical technology including software as a medical device

- The MHRA authorised three new cancer treatments and one new therapeutic indication via participation in the US FDA's Project Orbis

- We extended the Exceptional Use Authorisation for a COVID-19 sample collection swab used in the national COVID-19 testing programme and joined the COVID-19 Testing Devices Authorisation Board

- NIBSC Bacteriology Division tested and released two batches of cholera vaccine for the World Health Organisation's stockpile, used to counter outbreaks of cholera in low-and-middle-income countries

- The MHRA and NHS Digital have published the second report from the valproate registry, which has been broadened to include all antiepileptics prescribed to girls and women in England

- We took a major step towards geographical representativeness of CPRD data across the UK following acquisition of data from the third and final software supplier for primary care data

- Collaboration between the Enforcement Group and online marketplaces has resulted in the removal of just under 100 illicit adverts offering unlicensed medicines, including one advertising the supply of a Class B controlled drug

- Following publication of the British Pharmacopoeia 2022 in August, total revenue of the previous edition is up 7.5% year-on-year, showing increased uptake and use.

## HEALTHCARE ACCESS

### Innovative Licensing and Access Pathway

1. In the last month, we have received a further two applications for the Innovation Passport designation covering both common and rare diseases, with a further three expressing interest in entering the US Food and Drug Administration's (FDA) Project Orbis. There have now been a total of 59 applications for Innovation Passports. Additionally, we have received a further two requests for a Target Development Profile.

### New medicines approvals

2. We sought advice from the Commission on Human Medicines (CHM) on several novel medicines and new indications such as products for obesity and dermatological conditions. In September there were four new active substances approved: Lumykras (sotorasib) for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer, Tepmetko (tepotinib) for the treatment of adult patients with advanced non-small cell lung cancer harbouring mesenchymal-epithelial transition factor gene (MET) exon 14 (METex14) skipping alterations, and Trodelvy (sacituzumab govitecan) for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer.

### COVID-19 vaccines booster doses

3. Maintenance of the Conditional Marketing Authorisation (CMA) licences and Regulation 174 approvals of the four currently licensed COVID-19 vaccines has continued. Rolling reviews of submissions from Novavax, Valneva, Medicago and Sanofi/GSK are continuing, and are being prioritised. We continue to offer scientific advice to a number of companies concerning new COVID-19 vaccines. The Clinical Trials Unit is supporting requests for advice from companies regarding approval of a new trial (COM-COV3) of booster doses in adolescents.

### Medical device consultation

4. On 16 September, the Medical Device's Software Group published three items:
    I. A section in the Consultation on the future regulation of medical devices in the United Kingdom detailing the legislative reforms specific to software and artificial intelligence (AI). This will provide the legislative foothold to update medical device regulation, ensuring it fits software and AI.
    II. A press release announcing the intention to bring forward broader reforms, primarily in the form of guidance, processes, and wider reforms to transform medical device regulation as it applies to software and AI.
    III. A work programme detailing eleven work packages across two work streams, which seeks to ensure that medical device regulation provides a high degree of assurance for patients and public, with clear requirements and streamlined processes for industry to follow, and a 'joined-up' offer with partners such as the National Institute for Health and Care Excellence (NICE).

### Point of Care manufacture and clinical trials regulation

5. The six-week public consultation, under powers granted by the Medicines and Medical Devices (MMD) Act, on the new UK framework for Point of Care (POC) manufacture closed on the 23 September. The vast majority of responses were positive and agreed that as POC is sufficiently different from the current 'standard model' of factory-based manufacture of medicinal products, a new legal framework is required. The responses

agreed with the proposals and more details were requested on various aspects for which we will hold further stakeholder and in-house meetings to develop. A report on the consultation findings will be published, and these will inform the legal instructions to draft the new legislation and regulatory guidance documents.

6. Following the UK's departure from the European Union (EU), we have a once-in-a generation opportunity to review the clinical trials regulations to deliver simplicity, streamlining, and international interoperability, while protecting the interests of participants. We have established an Expert Working Group comprising a wide range of stakeholders to provide the MHRA with advice and input from the wider scientific and clinical trials community and patients. This Group aims to identify obstacles to innovation, ensure legislation builds international interoperability and also to ensure protection of participants remains at the heart of the new regulatory system.

**COVID-19 tests**

7. The MHRA's Target Product Profiles for COVID-19 Diagnostics have received praise from the Regulatory Horizon Scanning Council. We have recently updated our Target Product Profile for laboratory-based SARS-CoV-2 viral detection tests to accommodate novel assay formats with additional benefits including multiplexing, short turn-around times and higher throughput platforms for mass screening. The update has also strengthened the clinical performance requirements in line with the rapidly evolving state of the art and provided further guidance on their intended use, clinical performance evaluation, detection of variants of concern and requirements for next-generation sequencing.

**COVID-19 testing sample collection consumables**

8. On 30 September 2021, the MHRA extended the Exceptional Use Authorisation granted to Medline Scientific Ltd. for their oropharyngeal flocked sample collection swab for a further six months until 31 March 2022. The swab is used widely within the NHS in-hospital COVID-19 testing programme and also in the NHS Test and Trace Polymerase Chain Reaction (PCR) sample collection kits for members of the public. Medline Scientific Ltd continue to work towards UK Conformity Assessed (UKCA) and conformité européenne (CE) marking of the device.

**COVID-19 vaccine batch testing by NIBSC**

9. By the end of September 2021, NIBSC had tested and certificated 147 batches of Pfizer/BioNTech, AstraZeneca and Moderna COVID-19 vaccines, the equivalent of over 140 million doses available to UK and overseas vaccination programmes. NIBSC has received its first two batches of Janssen COVID-19 vaccine and laboratory testing is under way.

**PARTNERSHIPS NATIONAL AND INTERNATIONAL**

**FDA Project Orbis**

10. A number of innovative cancer treatments were authorised in September, including the new active substance approvals for Lumykras (sotorasib), Tepmetko (tepotinib), and Trodelvy (sacituzumab govitecan) in paragraph 2 above. A new indication was authorised for Lorviqua (lorlatinib) for the treatment of adult patients with ALK-positive advanced lung cancer where disease has progressed after other treatments.

**Access Consortium**

11. The COVID-19 Vaccines and Therapeutics Working Group of the Access Consortium (a coalition of the regulatory authorities for Australia, Canada, Switzerland, Singapore and UK) has been developing a consensus statement on authorising new COVID-19 therapeutics. The MHRA proposed a new Access Consortium clinical trials group to discuss potential future collaboration, review and approvals of clinical trials conducted in more than one of the Access countries. The opening discussion for the meeting held on 27 September shared current processes for application review. Further meetings are planned to propose next steps.

**Inspectorate international**

12. September saw publication of the Organisation for Economic Co-operation and Development (OECD) Series on Principles of Good Laboratory Practice and Compliance Monitoring Number 22; Advisory Document of the Working Party on Good Laboratory Practice (GLP) on GLP Data Integrity. The has been a significant and complex undertaking, in which MHRA GXP Data Integrity Guidance was developed into a GLP specific document for GLP facilities and regulators to use globally. The Inspectorate also held its quarterly Good Clinical Practice (GCP) meeting with US FDA and Health Canada. Compliance issues and technical knowledge associated with clinical trials and bioequivalence were shared, ensuring continued collaboration.

**British Pharmacopoeia and Lab Services**

13. The British Pharmacopoeia (BP) and United States Pharmacopeia (USP) hosted a two-day virtual workshop on the real-world application of Analytical Quality by Design and analytical procedure lifecycle management. This globally attended event showcased the BP and the MHRA as leaders in developing and influencing the global conversations and enhancing scientific and risk-based approaches and supporting innovation throughout the product lifecycle.

**COVID-19 cross-system partnerships**

14. The MHRA is joining the COVID Testing Devices Authorisation (CTDA) Board, chaired by Professor Dame Sue Hill, Chief Scientific Officer, UK Health Security Agency (UKHSA). The Department of Health and Social Care (DHSC) has developed additional criteria for manufacturers of COVID-19 tests seeking to place their devices on the UK market.

**COVID-19 international engagement**

15. We are undertaking significant engagement with US FDA regarding COVID-19 Lateral Flow Tests (LFTs). The FDA is interested in how we have established agile arrangements to respond to the numbers of LFTs entering the market and the provision we have put in place for assurance regarding Variants of Concern. A ‘round table’ discussion with colleagues from across the US FDA, MHRA, Public Health England (PHE), DHSC and NHS Test and Trace was organised to facilitate this.

16. NIBSC has joined a recently-funded consortium, “The UK International Coronavirus Network (UK-ICN)”, led by the University of Liverpool and funded by Department for Environment, Food and Rural Affairs (Defra) and Biotechnology and Biological Sciences Research Council (BBSRC). The consortium brings together a global network of laboratories to enhance knowledge of coronaviruses and inform preparedness and response strategies for future outbreaks.

**Testing cholera vaccines for WHO stockpile**

17. In September, NIBSC Bacteriology tested and released two batches of cholera vaccine for the WHO stockpile. This work, usually carried out on an annual basis, is part of the NIBSC 'technical services contract' with WHO, and NIBSC's role as a collaborating centre. The cholera vaccine stockpile is used to counter cholera outbreaks by mass vaccination campaigns in low-and-middle-income countries (LMICs). The two batches have already been used.

**NIBSC hosts external students**

18. The Divisions of Virology, Bacteriology and Infectious Disease Diagnostics at NIBSC each hosted students from Imperial College London for six-month laboratory research projects as a component of their Molecular Biology and Pathology of Viruses Masters degrees. NIBSC was also able to host a PhD student for a day visit as part of a request to the Agency from the Academy of Medical Sciences.

**NIBSC contribution to parliamentary report on Vaccine Technologies**

19. NIBSC Division of Bacteriology contributed to a Parliamentary Office of Science and Technology (POST) note entitled "Advances in vaccine Technologies". It provides an overview of vaccine development and technologies and covers opportunities and challenges in vaccine discovery and manufacture, as well as policy approaches to stimulate vaccine research and development in the UK.

**PATIENT SAFETY**

**COVID-19 vaccines**

20. By 22 September, over 360,000 Yellow Cards of UK suspected adverse reactions had been reported. For COVID-19 vaccines Pfizer/BioNTech, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna the overall reporting rate is around 3 to 6 Yellow Cards per 1,000 doses. We have undertaken specific reviews of:
    I. Delayed hypersensitivity reactions Specifically, skin reactions occurring around the vaccination site that appear a short while after vaccination and are suggestive of a delayed hypersensitivity reaction that occurs 4-11 days after vaccination. The majority of the reports have been associated with COVID-19 Vaccine Moderna, and the product information has been updated to highlight the possibility of delayed injection site reactions.
    II. Facial swelling in patients with a history of facial dermal fillers We have received Yellow Card reports for the Pfizer/BioNTech vaccine of facial swelling in people with a history of injection of facial dermal fillers. Following review of the world-wide adverse drug reaction data, the product information for the Pfizer/BioNTech vaccine has been updated to include facial swelling in those with a history of injection of facial dermatological fillers.

**Sodium valproate**

21. We continue to work closely with DHSC to ensure everyone prescribed sodium valproate always receives the statutory information. Together with NHS Digital we have published the second report from the valproate registry which now includes all antiepileptics prescribed to girls and women. Analyses of specific antiepileptics prescribed around and in pregnancy have been conducted. A decline in prescribing in females both overall and in pregnancy has occurred in the last year, but there is more to do to ensure the valproate Pregnancy Prevention Programme is always followed. In

particular using the registry capability to capture the Annual Risk Acknowledgement Form to ensure that every woman on valproate is receiving regular review of her individual needs.

**Topical steroids**

22. The MHRA has reviewed the available evidence on topical steroids and reports of a severe type of withdrawal reaction with symptoms of skin redness and burning worse than the original condition. Following CHM advice, information about these reactions is being added to the product information provided to healthcare professionals and patients. Additional materials for patients and healthcare professionals have been produced on the best way to minimise the risks of these reactions with topical corticosteroids and what to do if they occur.

**Coroners' Regulation 28 letters for medical devices**

23. Coroners' Regulation 28 letters are treated as a potential safety signal. The Devices Division has responded to four such letters requesting that we take action to prevent future deaths relating to use of a number of devices including: continuous positive airway pressure (CPAP) and alarms, ventilator breathing system filters, assistive technology hoist and sling, and polyethylene glycol containing devices. Actions taken and/or planned include issuing safety messages, communication and engagement with all relevant stakeholders, and participation and influencing of relevant standards committees to raise awareness, seek advice and implement actions to mitigate against future harm. Additionally, data collection is under way on how training regarding assistive technology is organised and managed in community settings.

**Medicines recalls**

24. The Defective Medicines Report Centre (DMRC) issued three routine medicines recalls in September. These include: Class 2 recalls for levothyroxine 50 mg tablets and Ikervis 1 mg/mL eye drops, emulsion. In both cases the risk was considered low and the recalls have been carried out as precautionary safety measures to safeguard patients. Additionally, a Class 4 Caution In Use was shared in relation to rosuvastatin 5 mg, 10 mg, 20 mg and 40 mg film-coated due to an error with the patient information leaflets (PILs) in some rosuvastatin products. This notification will only impact the stock on the market and the all stock with the company will be repackaged to ensure the correct PIL is included and the product is in compliance with its specification.

**Enforcement**

25. Interventions led by the Enforcement Group have resulted in a number of criminal threat reduction outcomes. Among these, continued collaboration with online marketplaces to remove illicit adverts offering unlicensed medicines has resulted in just under 100 listings being successfully removed from platforms, including one advertising supply of a Class B controlled drug. Analytical intelligence products have been generated to enhance our intelligence surrounding importation of unlicensed medicines, controlled drugs, and the illegal trade in falsified medicines. These products will provide the foundation for future threat reduction interventions. Intelligence of this nature continues to be shared with Police Forces and other Law Enforcement Agencies to broaden their understanding and coordinate effective responses.

26. The Enforcement Group's efforts to tackle the financial motivation for offending, alongside substantive offending against medicines regulations, resulted in a suspect being charged by the Crown Prosecution Service with money laundering under the Proceeds of Crime Act 2002. Ongoing financial threat reduction activity also continues to remove criminal profits from suspected offenders and to deter others.

**Patient and public engagement: Assistive Technology (AT) workshop**

27. On 28 September, the Devices Division delivered an online workshop with patients and patient representative groups with an interest in Assistive Technology. Most participants were members of our Patient Group Consultative Forum and they provided insightful perspectives, adding very valuable data. We sought feedback on our published information on the MHRA Assistive Technology webpage, as part of its planned update, and views on the perceptions of risks related to the appropriate road use of mobility scooters and powered wheelchairs. We will now amend our webpage information for patients and carers and encourage Yellow Card reporting.

**Clinical Practice Research Datalink (CPRD) international users group meeting**

28. Researchers who use anonymised CPRD data for public health studies comprise academics, medicines regulators and industry in over 20 countries worldwide. Each year CPRD hosts an international User Group meeting. Due to the pandemic, the 2021 CPRD User Group held in September was a virtual event. Almost 100 researchers who attended were updated on the new CPRD Aurum pregnancy register to facilitate research on pregnancy and health outcomes of newborns and the CPRD common data model to aid standardisation of analyses across diverse datasets.

**Geographical representativeness of CPRD Data**

29. Until recently, CPRD has only been able to receive anonymised primary care data from two of the three software suppliers who provide IT services to general (GP) practices. Following successful discussions, data is now flowing from TPP, the third supplier. While CPRD data is representative of age and gender of the UK population, geographical coverage in some areas of England has previously been lower due to the regional TPP dominance. This advance means that CPRD will achieve geographical representativeness across the UK. In the last month, data from GP practices using TPP software who have been waiting to join CPRD have been onboarded, with data from hundreds more TPP GP practices to be collected by CPRD in the coming months.

**DYNAMIC ORGANISATION**

**Transformation Programme**

30. Intense work on the Transformation Programme has continued. We are developing an integrated implementation plan in alignment with the Agency Delivery Plan 2021-2023 and finalising the financially sustainable operating model. A series of manager and staff engagements have been held with opportunities for discussion available through local teams and individual meetings. Our network of 'Change Champions' has provided local support to group and team discussions. The feedback from the consultation process will be used to enhance the structure proposals and the integrated implementation plan where necessary.

**Patient and public involvement**

31. On 1st October, MHRA published its first Patient Involvement Strategy. This sets out how we will engage and involve the public and patients in all our activities. The strategy was informed through consultation with patients on what was important to them. The Independent Medicines and Medical Devices Safety Review also provided clear direction on where we could improve our engagement with patients, and the resulting strategy was then approved by our Patient Safety and Engagement Committee and Agency Board. Its successful delivery now lies in the engagement and involvement of the public, patients and other health sector organisations as partners.

## FINANCIAL SUSTAINABILITY

**Spending Review**

32. We continue to work closely with DHSC on the 2021 Comprehensive Spending Review. The MHRA has submitted three bids focussing on Transition, Safety & Surveillance and Innovation. Given the challenges facing government this year, we understand that the process is very competitive. At this stage timelines are uncertain, but it is anticipated that any award will be confirmed later in October 2021.

**Finance Projects**

33. The Finance Transformation project is progressing to plan and will allow for the realisation of efficiencies and improvements to the financial control environment. The team is also managing two business critical change projects: the transition from Trading Fund Status to absorption back into DHSC's accounting boundary and the finance support for the new operating model which includes the new chart of accounts and financial information in support of the new structures.

**Fees Strategy**

34. The Fees Strategy Group has moved on from analysing the 'as is' fees environment to considering the fees structure and quantum that will be required under the new operating model. Analysis has been undertaken of each revenue line and the team is working with the business leads to determine the resource required for each service/product which will in turn determine the required fee. It is likely that this will require future discussion on which activities should be funded by fees and which by government.

**British Pharmacopoeia**

35. Following publication of the BP 2022 in August our publisher has reported that total revenue from the previous edition is the highest ever, up 7.5% year-on-year.

**New grant awarded to NIBSC for gene therapy project**

36. NIBSC was one of the organisations awarded a grant from Department for Business, Energy & Industrial Strategy (BEIS) as part of the Regulators' Pioneer Fund. The grant of £200,000 was awarded for a project on producing physical standards for adeno-associated virus (AAV) gene therapy and was one of 21 projects awarded a total investment of £3.7 million to help drive forward innovation in the public sector.

**June Raine CEO**
**October 2021**

Medicines & Healthcare products Regulatory Agency

# BOARD MEETING HELD IN PUBLIC

**19 October 2021**

| | |
|---|---|
| **Title** | What is the current performance of the MHRA on the Balanced Scorecard? |
| **Board Sponsor** | Jon Fundrey |
| **Purpose of Paper** | Assurance |

# What is the current performance of the MHRA on the Balanced Scorecard?

## 1. Executive Summary

1.1 This paper sets out commentary to support the monthly Balanced Scorecard included in the attached appendix.

1.2 The Board is asked to review the metrics and commentary before considering whether this provides sufficient assurance that the current performance of the agency is on track and aligned to our strategic objectives.

1.3 Feedback from the last meeting, involving engagement of sub-committees, review of targets and removal of non-impactful measures is being progressed for the next quarterly update.

## 2. Introduction

2.1 In recent months the MHRA has been developing a Balanced Scorecard to summarise the monthly performance of the Agency against key measures related to its strategic goals. The development work on this new reporting system is still ongoing and the latest iteration of the report is included in this paper.

2.2 This report has been updated with data for from 1 April to 31 August 2021 and compared with targets and previous periods where possible.

## 3. Commentary

### 3.1 Scientific Innovation

***Clinical Trials***

Clinical trials have seen a strong upwards trend over the last 3 months, increasing from 66 in May to 104 in August. This is due to increasing non-Covid-19 trials, as Covid-19 trials have been decreasing and now make up a small amount of the total (2-3 per month).

The increase is partially expected as we predict seasonal peaks around the summer and Christmas. It could be an indication of a backlog of demand, but clinical trials do tend to vary so we should examine over a longer term before making any conclusions.

### 3.2 Healthcare Access

**Early Access to Medicines Scheme (EAMs)**

Activity remains consistent. Three scientific opinions were published this quarter, one for the genetic disorder Pompe Disease and two for the treatment of different types of cancer.

***New Active Substances (NAS)***

NAS applications and determinations have been around the expected levels of activity. Determinations were low over July and August but as the absolute numbers are relatively small, the month-on-month changes appear relatively large. The full national applications received in the first two quarters will not reach determination until the last two quarters of the year (depending on company responses) so there will be an accumulation of in-process work during this first year of new routes to market until an equilibrium is reached. We have already seen September figures return to earlier levels.

***Innovative Licensing and Access Pathway (ILAP)***

ILAP activity continues to increase with 10 applications for Innovation Passports received during August. With wider interest in the pathway now reflected in greater application volumes the percentage of positive outcomes has decreased slightly. The 100% positive outcome seen in the first quarter was unexpected as we would anticipate receiving some applications that do not fully meet the ILAP criteria.

***Variations***

Type II variation applications received have seen a slight downward trend for the last six months, this is seen with both full national and reliance variations and is market driven. This is expected to return to normal levels in coming months.

Determinations are a little behind applications received, more so for EC Reliance applications rather than national applications which indicates that the delay is due to awaiting the EC decision documentation.

***Generics***

The number of generic applications received this quarter is lower than those seen in the first quarter of the year but is considered to be a rebalancing of the initial very high demand. Overall, applications for established medicines (including generics) remains high. MHRA has been managing significant challenges since the start of the pandemic which have required resource to support the Covid-19 vaccines and other Covid treatments as well as national applications for new medicines and the ILAP pathway. In spite of this, determinations of established medicines overall this year are 15% greater than the average for last year, but at present, the volume of determinations is not keeping pace with incoming applications. The average time to grant since January 2021 has been 222 days. In comparison, European procedures close after 210 days but they are followed by a national phase of 30 days so total timelines for most cases are comparable with EU. It is worth noting that the balance of national verses EU work has increased compared with last year with 80% of applications using the national route. However, in view of the limit on capacity, additional initiatives are needed and are being developed to mitigate a further build-up of work. These include further streamlining of low-risk work and a focus on the one third of cases where the company has responded to questions enabling these to reach a swift closure.

## 3.3 Patient Safety

***Adverse Drug Reactions (ADRs)***

ADRs continue to reduce in line with the decreasing volume of vaccinations administered. However, work remains high with ADRs still up 766% from last year despite the recent decline. Normal levels of ADRs are around 3,000 per month and it may take significant time to return to those levels.

***Patient Safety Interventions***

The August edition of Drug Safety Update was published with updates on COVID-19 vaccines for August 2021 and DHPC letters, medicines recalls and notices issued to healthcare professionals in July.

## 3.4 Financial Sustainability

***Operational Financial Surplus/Deficit***

The P5 operational surplus of £4.5m is £6.4m ahead of budget, this positive variance has decreased slightly since P4. The surplus is driven by lower operating costs than budgeted. Staff costs remain low because of vacancies across the agency as well as less usage of Covid-19 batch testing grant. The budget included agreed uplifts in Devices and IPU FTE, IPU has filled these roles effectively but Devices have a vacancy rate of 15%.

Other operating costs continue under budget, but we have seen an acceleration in spending in some vital areas. ICT is still £2.5m favourable to budget but spending has increased and we expect this variance to reduce by the end of the year. Meanwhile Accommodation and Medicines and Testing & Laboratory spend were over budget for the month, helping to move them closer to YTD budgeted spend.

***Cash Balance (scorecard metric is currently cash balance)***

The current cash balance is £82.8m but has started to reduce which we expect to continue. Current projections have a year-end cash balance of £41.5m with £19.5m of this being available reserves. In future iterations of the scorecard this metric will be updated to show only the available reserves.

## 3.5 *Dynamic Organisation*

***Full Time Equivalents (FTE)***

FTE numbers are now 6.8% below budget, compared to 3.7% this time last year, and continue to decrease due to the current recruitment freeze which is in place to protect staff displaced by the planned restructure. This has contributed significantly to the positive finance variances but is having an impact on the Agency's capacity. Targets for Q4 will be based on planned FTE following the conclusion of this phase of the Transformation Programme.

## 4. Notes

### 4.1 Devices Registrations

System was previously producing inaccurate data, this has now been addressed, data should be available in the next report

**Jon Fundrey**
**October 2021**

Medicines & Healthcare products Regulatory Agency

# Balanced Scorecard (Monthly View) v1.0



## Scientific innovation

### Clinical Trials

**Normal**

83

Target: 61

KPI ▲ Trend ↗

**Novel**

3

Target: 3

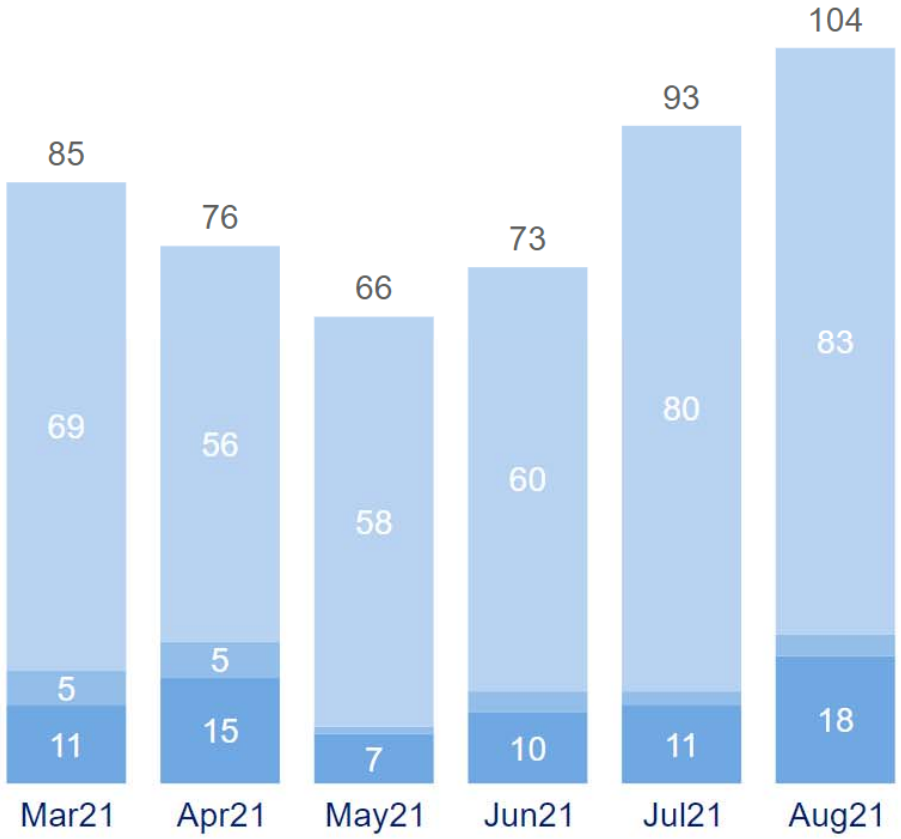
KPI ▶ Trend ↘

**FIH Approvals**

18

Target: 7

KPI ▲ Trend ↗



# Healthcare access

## EAMs - PIM-D Applications

Received

1

Target: 2

Granted

7

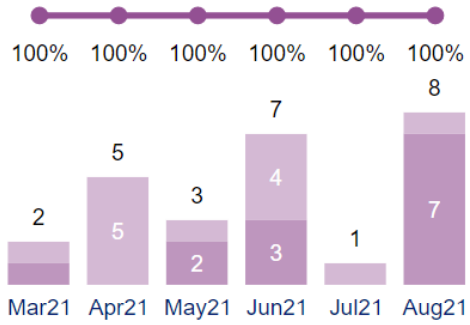
% Positive

100.0%

KPI Trend

KPI Trend

KPI Trend




## EAMs - EAMs SO Applications

Received

2

Target: 1

Granted

1

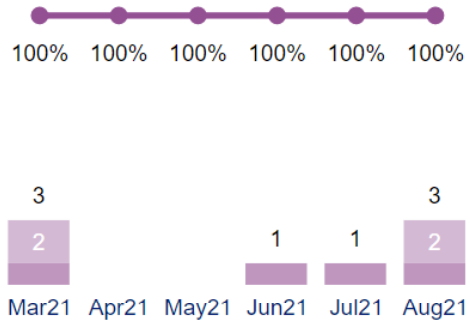
% Positive

100.0%

KPI Trend

KPI Trend

KPI Trend




## Standards Sales Volume

NIBSC (Non Flu)

6,522

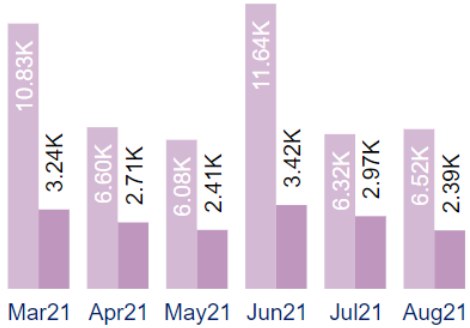
BP

2,387

Target: 2,900

KPI Trend

KPI Trend

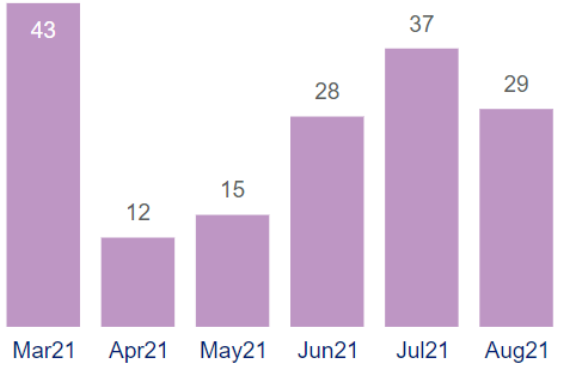



## PIPS Volume

29

KPI

Trend



Medicines & Healthcare products Regulatory Agency

# Balanced Scorecard (Monthly View) v1.0

August 2021 – 3/7

# Healthcare access

## NAS - Applications Received

National (PL-GB/PL UK)

4

Orbis/Access

1

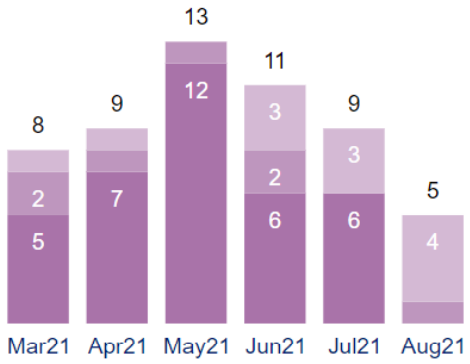
EC/MRDC Reliance

0

KPI Trend

KPI Trend

KPI Trend




## NAS - Applications Determined

National (PL-GB/PL UK)

0

Orbis/Access

0

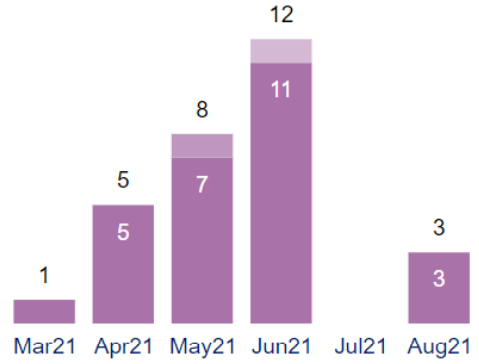
EC/MRDC Reliance

3

KPI Trend

KPI Trend

KPI Trend




## ILAP Passport Applications

Apps Received

10

Target: 3

Apps Determined

4

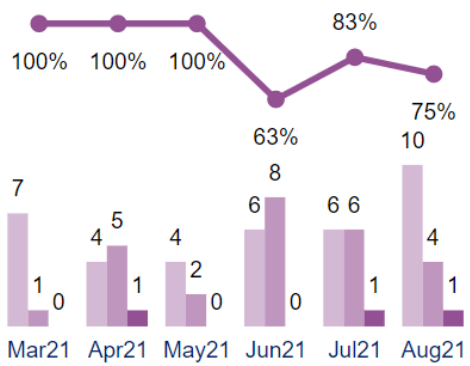
% Positive

75.0%

TDP Meeting Requests

1

Target: 2




## Device Registrations

Deadline 01/05/21

536,459

Deadline 01/09/21

117,051

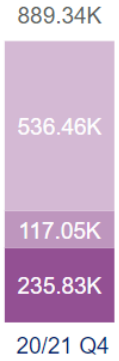
Deadline 01/01/22

235,833

KPI Trend

KPI Trend

KPI Trend



Medicines & Healthcare products Regulatory Agency

# Balanced Scorecard (Monthly View) v1.0

August 2021 – 4/7

## Healthcare access

### Variations - Applications Received

National (Std + Complex)

53

Target: 90

Type II Ext Complex

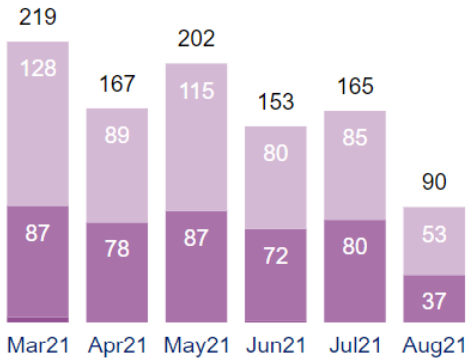
0

Type II ECDRP

37

Type II Orbis

0




### Variations - Applications Determined

National (Std + Complex)

70

Target: 63

Type II Ext Complex

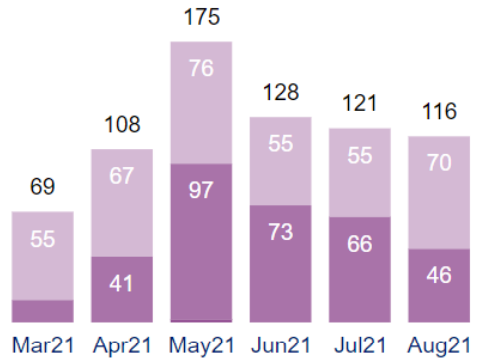
0

Type II ECDRP

46

Type II Orbis

0




### Generics - Applications Received

National MAs

51

Target: 56

KPI

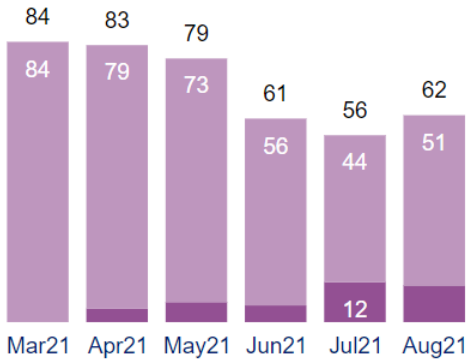
Trend

EC/MRDC Reliance

11

KPI

Trend




### Generics - Applications Determined

National MAs

29

Target: 19

KPI

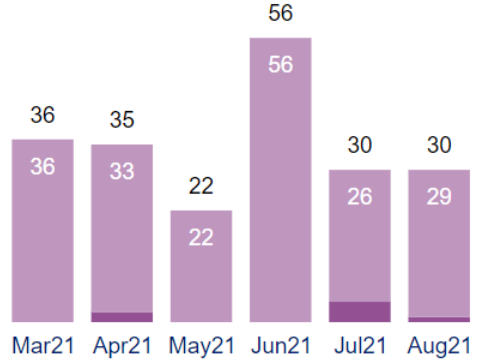
Trend

EC/MRDC Reliance

1

KPI

Trend



Medicines & Healthcare products Regulatory Agency

# Balanced Scorecard (Monthly View) v1.0

August 2021 – 5/7

# Patient safety

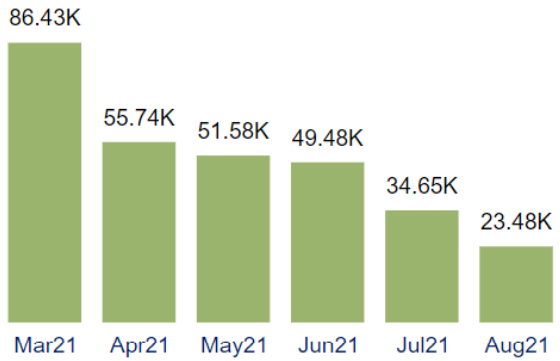
## Adverse Drug Reactions

23,476

Aug20: 2,708 (+766.91%)

KPI

Trend



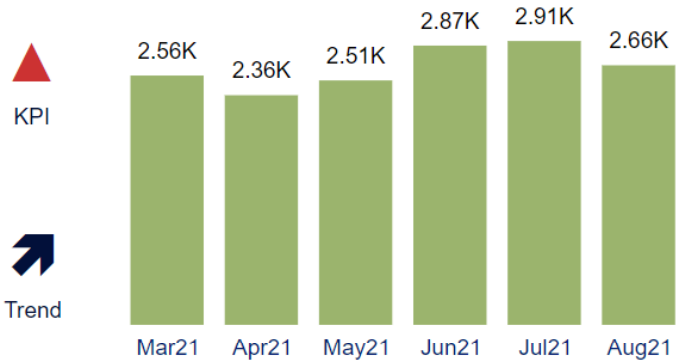

## Devices - Adverse Incidents

2,663

Aug20: 1,685 (+58.04%)

KPI

Trend



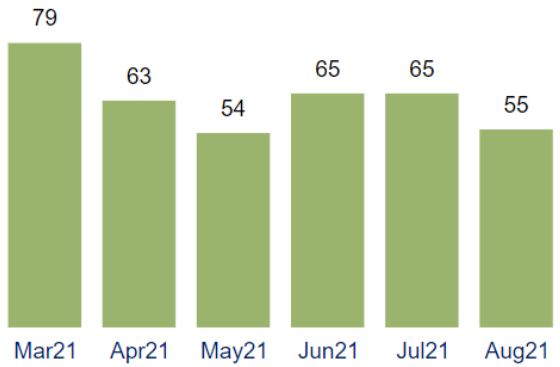

## Adverse Blood Reactions

55

Aug20: 58 (-5.17%)

KPI

Trend




## Patient Safety Interventions

Major Signals

30,083

Manuf Safety Comms

4

MHRA Safety Comms

2

KPI

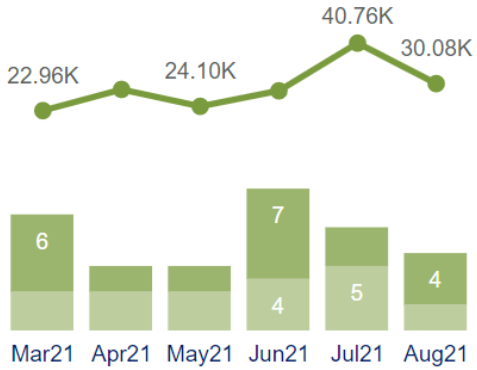
Trend

KPI

Trend

KPI

Trend



Medicines & Healthcare products Regulatory Agency

# Balanced Scorecard (Monthly View) v1.0

August 2021 – 6/7

## Dynamic organisation

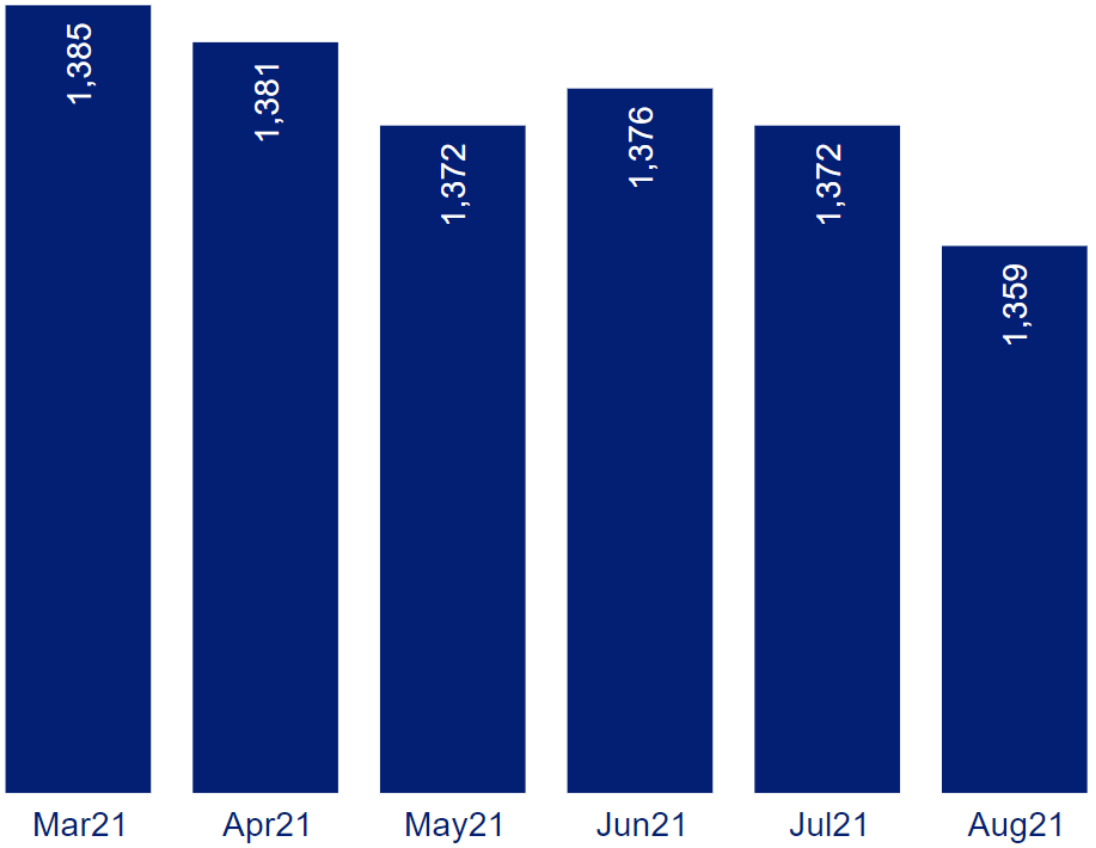
### FTE

1,359

Budget: 1,458 (-6.79%)

KPI

Trend



Medicines & Healthcare products Regulatory Agency

# Balanced Scorecard (Monthly View) v1.0

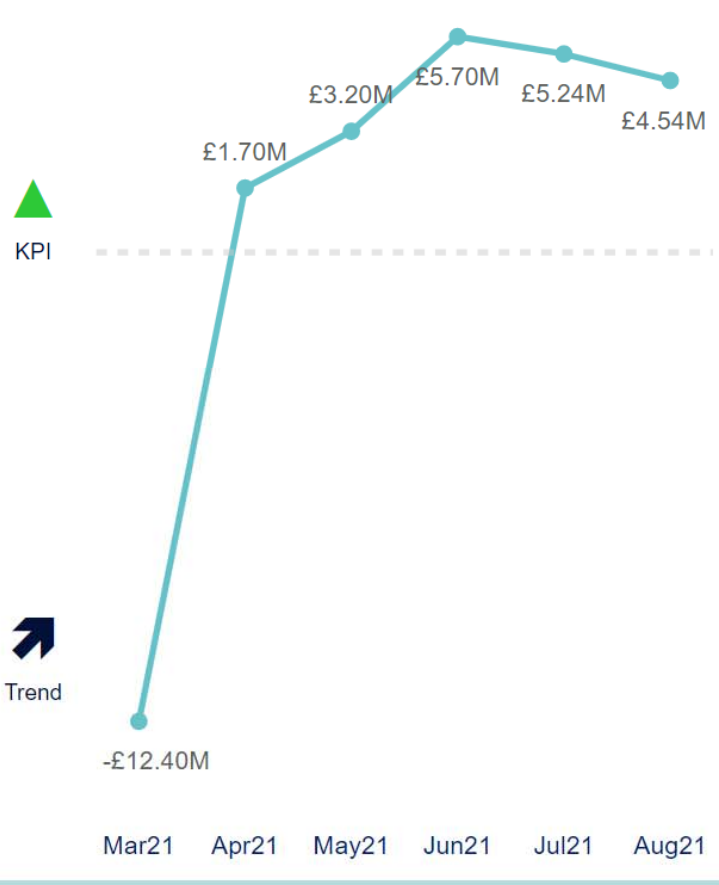
August 2021 – 7/7

## Financial sustainability

### Year To Date Operational Surplus/Deficit

**£4.54M**

Budget: -£1.93M




### Cash Balance - Available Reserve

**£82.73M**

Budget: £88.11M

Medicines & Healthcare products Regulatory Agency

# BOARD MEETING HELD IN PUBLIC

**19 October 2021**

| | |
|---|---|
| **Title** | How is the MHRA accelerating the approval and diversification of patient recruitment for clinical trials? |
| **Board Sponsor** | Marc Bailey |
| **Purpose of Paper** | Strategic Direction |

# How is the MHRA accelerating the approval and diversification of patient recruitment for clinical trials?

## 1. Executive Summary

1.1 The MHRA is working to support the Government's initiative to make the UK one of the most attractive countries for hosting clinical trials. This is helped by our reputation for timely and internationally competitive assessment decisions for clinical trials of investigational medicinal products ("CTIMPs") to facilitate innovative medicines reaching patients safely and efficiently. However, a speedy approval from one regulator has limited impact on the overall timelines for trial start and so the MHRA is looking at what other measures can be undertaken to deliver the Government's vision. This paper will focus on the improving and diversifying patient recruitment to clinical trials.

1.2 The paper discusses the most direct intervention by the Agency to date, the new tool developed by the Clinical Practice Datalink (CPRD) to use the information in the CPRD curated Patient Health Records to recruit patients to trials. The tool is in pilot so a summary of the tool is presented, and the Board asked for suggestions on how the tool can be further developed.

1.3 The MHRA currently has a limited direct role in the process of recruiting patients to trials but there is an opportunity to add guidance on patient recruitment and diversification to the changes in the clinical trials and investigations processes and guidance. The second half of the paper describes these changes and asks for input from the Board as to where more can be done

## 2. Introduction

2.1. Clinical Research in the UK utilises a collaborative system-wide approach and MHRA is an active partner in the UK-wide Clinical Research, Recovery, Resilience and Growth (RRG) programme, which brings together partners from industry, academia, charities, the NHS, regulators, patients and the public. The RRG is responsible for overseeing delivery of the UK clinical research vision - 'Saving and Improving Lives: The Future of UK Clinical Research Delivery: 2021 to 2022 implementation plan'. MHRA has specific objectives as part of the implementation of the vision to contribute to improving the speed and efficiency of study set-up, promote decentralised/remote trials, facilitate recruitment, and contribute to guidance on increasing diversity of research participants. Traditionally patient recruitment has been a concern of NIHR but recently the MHRA has developed knowledge and capability that can help this vital step.

2.2. CPRD has unrivalled access to longitudinal primary care data and an extensive network of 1 in every 5 UK GP practices, and has developed a mechanism (SPRINT) that offers the opportunity to rapidly recruit a diverse and targeted patient population from across the UK into a wide range of clinical studies using unique and innovative data enabled approaches.

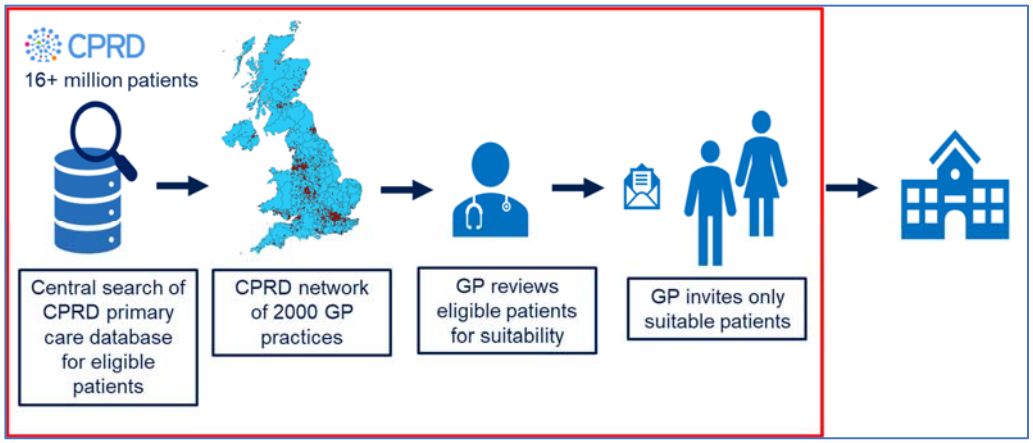
2.3. In parallel there is work on accelerating the approval of clinical trials and efforts to identify how this accelerated approval process could be exploited to facilitate the diversification of patient recruitment for clinical trials, The Board is asked for advice on how this may be done and suggestions for prioritisation of these activities.

## 3. CPRD SPRINT (Speedy Patient Recruitment INto Trials)

3.1. The CPRD is the Government's preeminent research data service, jointly supported by MHRA and the National Institute for Health Research (NIHR), providing anonymised health data and research services to support public health and clinical studies. For more than 30 years, research data services provided by CPRD have supported drug safety, use of medicines, disease epidemiology, effectiveness of health policy, health care delivery and disease risk factors studies, informing public health policy, clinical guidance and best practice. CPRD's database and services are based on anonymised longitudinal primary care data contributed by GP practices across the UK. CPRD's population coverage has increased fourfold in the past 5 years to its current coverage of 25% of the UK population, across the four UK nations. More than 1 in 5 UK GP practices now elect to contribute their anonymised data to CPRD for public health research purposes.

3.2. Recognising the imperative to rapidly locate eligible patients from a wide population pool, CPRD has harnessed its extensive GP network and Electronic Health Record (EHR) expertise to design CPRD SPRINT. The new CPRD SPRINT data-enabled recruitment service is dedicated to facilitating rapid patient recruitment into commercial sponsored phase II to IV clinical trials in any setting across the UK. Since the launch of CPRD SPRINT at an Association of the British Pharmaceutical Industry (ABPI) event in January 2021, the CPRD SPRINT service has attracted significant industry interest. The CPRD SPRINT process is illustrated in Figure 1,

**Figure 1 CPRD SPRINT rapid patient location and recruitment across the UK**




3.3. There are three essential aspects to CPRD's innovative patient recruitment and clinical trials services. The first is the ability to carry out a centralised, standardised and modifiable search of all 16 million patients in the CPRD database of near real time de-identified primary care EHR. The second is CPRD's direct relationship with an extensive network of over 2000 GP practices across the UK. The third element is CPRD's Interventional Research Services Platform (IRSP) which provides a scalable infrastructure enabling secure communication between CPRD and GP practices supporting patient consented studies.

3.4. Based on the protocol, CPRD staff carry out a search of the de-identified EHR in the CPRD database to flag potential patients who meet clinical trials inclusion and exclusion criteria. High level geo-targeted feasibility estimates can be rapidly provided to the sponsor to determine whether there are sufficient numbers of patients to carry out a trial. Once a sponsor wishes to proceed, a more detailed patient search of the database is carried out around the chosen study sites.

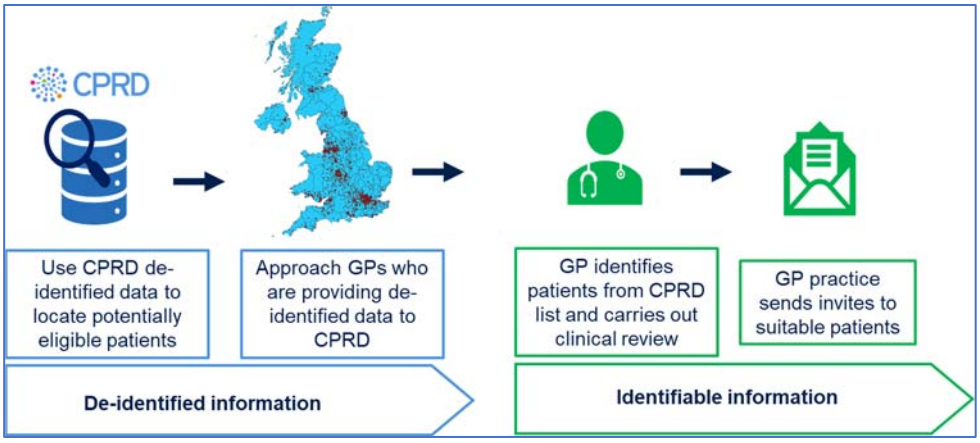
3.5. CPRD staff contact GP practices based around study sites, or any UK region for remote trials, to establish whether they want to facilitate study recruitment, or in some cases be a principal investigator for a CPRD supported trial in primary care. Overarching agreements between CPRD and GP practices are in place, with work orders specifying requirements issued for each study, which reduces start up times.

3.6. Once a GP practice agrees to take part, the list of potential suitable de-identified patients is shared with the practice. The practice is then able to identify the patients from the CPRD flagged patient list and carry out a clinical review of these patients using medical notes to which CPRD does not have access. Based on their clinical judgement, GPs send letters only to patients they believe would benefit from participating in a study. The patient then makes contact directly with the study sites.

3.7. Interaction between CPRD and GP practice staff is managed via the IRSP, which provides a safe, secure and efficient method of centrally managing and monitoring patient lists and recruitment services. Using CPRD's access to near real-time data to recruit patients from diverse populations across the UK, represents progress towards the democratisation of clinical research opportunities for patients and helps tackle health inequalities.

3.8. To date, CPRD has provided high level feasibility counts of potentially eligible patients mapped around specified trial sites for over 20 different trial protocols. One company has reported to CPRD that the UK won their bid to host clinical sites in their pending global trial, largely due to the rapid 10-day turn-around from the CPRD SPRINT patient feasibility counts. Contracts have been signed with three companies, with multiple contracts currently under negotiation covering a wide range of indications. Recruitment into the first clinical trial commenced in September 2021.

**Figure 2 CPRD SPRINT safeguarding patient confidentiality**



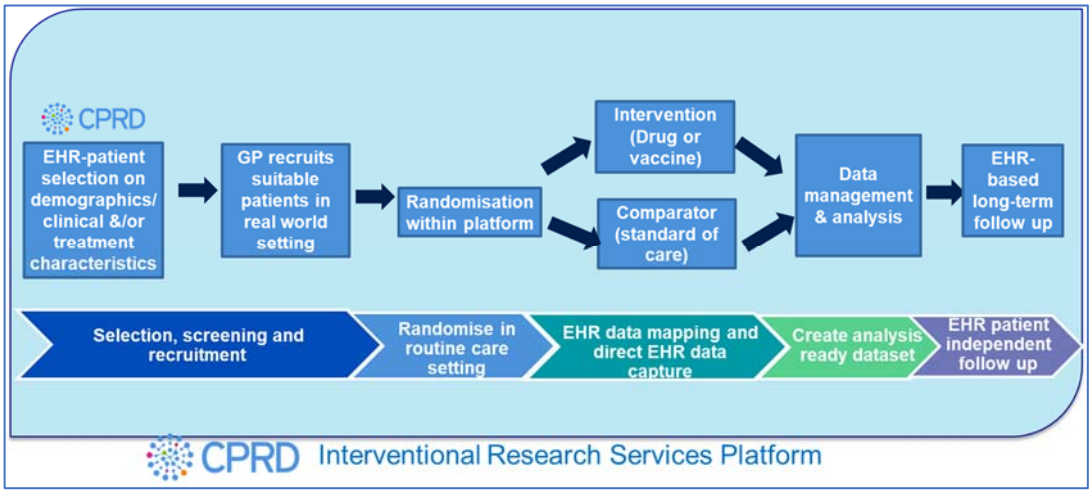

3.9. CPRD SPRINT is in pilot phase and until metrics have been collected on the first few studies supported by CPRD SPRINT, there is no data available to compare this service with other recruitment methods.

## 4. CPRD Clinical Trials Management Services

4.1. In addition to facilitating patient recruitment into clinical trials, CPRD has also developed the capability to manage Phase IV clinical effectiveness trials utilising the functionality of the IRSP. These pragmatic trials are based within primary care where the GP is the principal investigator. The process of targeted patient recruitment is as described above. Once a patient consents, the use of IRSP enables central management and monitoring of patient lists, patient recruitment, randomisation to interventions, supports safety monitoring and provides a platform where required data can be collected that is not part of the coded EHR, for example Patient Reported

Outcomes (PRO). Protocol defined outcome data and additional safety data is captured directly from the EHR into a clinical study-specific database within the IRSP. Linked data is also used for patient independent follow up. Figure 3 depicts the steps involved in patient recruitment, trial management and follow up.

**Figure 3 CPRD data enabled trial management service**




4.2. CPRD is currently providing trial management services via the IRSP for two large NIHR funded data enabled clinical effectiveness trials in atrial fibrillation (DaRe2THINK) and childhood asthma (ASYMPTOMATIC), recruiting 3000 and 2500 patients, respectively. DaRe2THINK commenced recruitment in June 2021 and ASYMPTOMATIC is due to go live in October 2021.

4.3. These pragmatic clinical effectiveness studies can demonstrate both the safety and effectiveness of medicines and devices that are newly approved or in current use in the patient population. CPRD can recruit patients at scale from all regions across the UK and from diverse socio-economic and ethnic groups, in support of the Government's agenda to tackle health inequalities. Furthermore, these studies strengthen MHRA's role in providing professional and public assurance about the safety and health benefits that can be derived from approved medical products in used by real world patients.

4.4. The Board is requested to consider what additional changes can be made to the SPRINT service to further improve the effectiveness and whether there is anything additional that can be included to ensure greater patient diversity?

**5. Ongoing initiatives to improve Clinical Trials guidance in the UK** – how these can be used to better support patient recruitment and diversification?

5.1. The MHRA is working on several initiatives that could support patient recruitment.

5.2. **Joining up trial approval with set-up and delivery**. Streamlined approval is only useful in the context of streamlined delivery of research and therefore close integration with the National Institute for Health Research (NIHR) and NHS is needed via the UK-wide clinical research Recovery, Resilience and Growth Programme. We are working with colleagues to develop a workstream that will explore how a rapid end-to-end delivery approach can be delivered sustainably and at scale. The Experimental Cancer Medicine Centre (ECMC) Network, with support from MHRA and the Health Research Authority (HRA), will deliver a pilot to accelerate the set up and delivery of Phase 1 oncology trials. The expected impact is that by expediting recruitment to Phase 1 experimental cancer trials, we will help ensure the UK remains a globally competitive location to deliver trials of innovative and experimental treatments – particularly for ground-breaking cancer research. This work is in the early stages with ECMC currently identifying sites for inclusion in the pilot. It is expected that the lessons learned from this pilot will be translatable to other areas such as trials for advanced therapy clinical trials.

5.3. **ILAP Patient and Public Reference Group and the Enhanced Patient Engagement Tool.** The Innovative Licensing and Access pathway (ILAP) includes a dedicated patient and public reference group which supports the ambition for integrating the patient voice at every stage of development. Members of this group are involved in discussions on whether a product should be awarded an Innovation Passport designation for entry into ILAP, alongside experts from the MHRA, the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC). This will build into the goal of embedding patient engagement and patient reported outcome (PRO) measures into the development programmes of ILAP medicines. The patient engagement tool will consider the patient's voice and experience from clinical design, scientific advice and all the way through to the generation of meaningful real-world data post-licensing and pharmacovigilance. It will give patients the opportunity to influence the development of products that will benefit them. A Patient Engagement Best Practice Guide for industry is being taken forward by members of the ILAP Patient and Public Reference Group. Further work is required to adapt this to support recruitment.

5.4. **Supporting the RRG Implementation plan**. A key RRG theme is patient-centred research to make access to, and participation in, research as easy as possible for everyone across the UK, including rural, diverse and under-served populations. As part of the RRG implementation plan, MHRA working with NIHR, HRA, and the devolved administrations, will expand our support for remote trials and will undertake a programme of work to assess and develop capability to support virtual and decentralised trials, including delivery of pilot projects. Action area 2 addresses this – the leads are CPRD, NHS DigiTrials and NIHR, with the RRG Programme Board working on patient registries for people to register their interest in being part of research. The expected impact is that by boosting the UK capacity to support the approval and delivery of novel study designs we will increase future system resilience and widen access to research among a broader range of prospective participants, to increase access for patients with the greatest health need.

5.5. **The MHRA Patient Involvement Strategy**. This includes a clear objective to identify stakeholders who are not active members of patient groups and create opportunities for them, as well as under-represented groups and diverse communities, to interact with us (e.g. minorities, older people, those living in poverty, those with learning disabilities, those who do not have English as their first language). This should help make trials more representative and the results from trial more generalisable to the general population. As part of our early engagement scientific and regulatory advice services the MHRA clinical trial unit will challenge sponsors where it appears that the inclusion / exclusion criteria for a trial needlessly excludes a specific group.

5.6. **Support for novel and decentralised trial designs**. MHRA support for novel trial designs has seen approvals for these types of study double from 20 to 42 in the past 3 years. Our regulatory flexibilities, published at the beginning of the COVID-19 pandemic included guidance on the remote conduct of clinical trials, for example use of telemedicine, remote monitoring and shipping of medication direct to the participant. Feedback from ABPI members showed that 87% of respondents used remote trial monitoring during COVID-19 with 74% expressing a desire to maintain this as busines-as-usual post pandemic. This guidance has not only facilitated the efficient conduct of trials for vaccines and therapeutics against COVID-19 but resulted in non-COVID-19 trials that would otherwise have stopped being able to continue, meaning that patients continued to have access to safe research (noting that many UK trials had to pause during the pandemic for other reasons).

5.7. On 8 September 2021, updated guidance on remote access to Electronic Health Records by sponsor representatives in clinical trials was published as part of our commitment to the UK Research, Recovery, Resilience and Growth programme. The guidance has been jointly developed by the MHRA and HRA, in consultation with the Information Commissioners Office (ICO), on behalf of the UK and provides practical guidance to researchers when considering management of personal data processed in relation to research.

5.8. A notable example of how using decentralised methods for trial conduct can benefit patients is the RELIEVE IBS-D study. COVID-19 restrictions meant that recruitment to the planned 28 sites was disrupted, significantly impacting the delivery of the study. Use of digital tools to aid recruitment and study conduct resulted in participation opportunities opening to people across the UK, with patients in England, Wales, Scotland and Northern Ireland taking part from the comfort of their own homes. This significantly bolstered recruitment, with a single site using the virtual method recruiting 67% faster than all 28 sites using a traditional approach.

5.9. **Legislation to support public and patient involvement**. Currently, it is an ethical expectation that researchers involve patients and the public in the design, management, conduct and dissemination of research. However, current UK legislation is silent on any requirements for public or patient involvement in trial design or conduct. The Medicines and Medical Devices Act 2021 provides us with the opportunity to embed good practice into our regulations and we plan to consult on a

potential requirement to involve people with relevant lived experience (patients, service users, carers, the public) in the design, management, conduct and dissemination of the trial, or justify to the ethics committee as part of the application, why such involvement is not appropriate for each of these trial elements.

5.10. Early engagement with patients and patient representatives has indicated support to strengthen the importance of patient and public involvement in the design, and importantly, the transparency of trials. We are working with a broad range of stakeholders to evolve potential changes to the legislation and expect the public consultation to be launched before the end of the year.

5.11. **International outlook** - Health ministers from the G7 countries have committed to a new Clinical Trials Charter which aims to accelerate the delivery of robust clinical trials through greater coordination and collaboration. Two of the charter's principles relate to clinical trials regulation: to achieve greater harmonisation and streamline regulatory process to act more proportionately to risk across the G7; and to make it easier and quicker to share results of clinical trials.

5.12. To further this work internationally, a Clinical Trials Working Group is being established by the International Coalition of Medicines Regulatory Authorities (ICMRA), co-led by the MHRA and the EMA. We are also engaged internationally via the ACCESS consortium (Australia, Canada, Singapore and Switzerland) to explore a form of co-assessment or harmonisation for clinical trials, potentially similar to the EU Voluntary Harmonisation Procedure that UK was previously involved with prior to January 2021. Our work with the ACCESS consortium will also explore ways of sharing scientific advice input to a developer. We will use these and other international fora to influence colleagues on more proportionate ways of conducting trials and to explore ways of both accelerating approvals and improving patient recruitment and diversification internationally by fostering a mechanism to take assurance from regulatory decisions made in other jurisdictions.

## 6. Recommendation

6.1. The Board is asked to provide strategic direction on prioritisation of the national and international initiatives to accelerate the diversification of patient recruitment for clinical trials and if applicable, propose other opportunities to accelerate these.

6.2. The Board is also asked to identify opportunities to support and promote CPRD's data enabled patient recruitment services.

**Marc Bailey**
**October 2021**

Medicines & Healthcare products Regulatory Agency

# BOARD MEETING HELD IN PUBLIC

**19 October 2021**

| | |
|---|---|
| **Title** | What assurance can be provided by the Patient Safety and Engagement Committee? |
| **Board Sponsor** | Mercy Jeyasingham |
| **Purpose of Paper** | Assurance |

# What assurance can be provided by the Patient Safety and Engagement Committee?

## 1. Executive Summary

1.1 The fifth meeting of the Patient Safety and Engagement Committee (PSEC) discussed scoping guidance on effective patient representation on committees and groups; the key priorities of the healthcare professionals' engagement strategy consultation; and assurances demonstrating how regulatory contribution and patient engagement/ involvement are optimised for clinical trials, in medicines development, in the UK.

1.2 The review of patient representation on committees was at a relatively early stage of development. The Committee will revisit this work to seek assurance once that work has been further developed. The consultation for healthcare professionals will also return to the Committee to provide assurance on the approach to deriving clear data from healthcare professionals. The Committee were assured good progress is being made on the involvement of patients in clinical trials in several areas including the Innovative Licensing Access Pathway, CPRD, Patient Reported Outcomes, and joint work with other research organisations.

## 2. Introduction

2.1 The fifth full meeting of PSEC was held on the 5th of October 2021. Two new non-executive Directors, Raj Long and Professor Graham Cooke, joined the Committee as members.

## 3. PSEC discussed each of the following items at the meeting on the 5 October 2021:

### 3.1 How can we ensure and support effective patient representation on Committees and Groups?

3.1.1 The Committee discussed key areas that needed to be addressed in a planned review and revision of how patients and the public are involved in the work of the MHRA expert and advisory committees and groups. The need for the review was to ensure that patient involvement is effective and consistent across the organisation.

3.1.2 The Committee reviewed several areas that were highlighted in the Patient and Public Involvement Strategy recently published by the Agency. PSEC agreed that areas such as terminology, identification of patients, training and support, tenure, payment, conflict of interest and process, as well as evaluation, all needed to be addressed by the review. As the review would cover internal as well as independent committees and groups it was important to ensure that any revisions were tailored to the role of the specific committee or group. The Committee understood that legal and other requirements would need careful thought. Some areas might be more complex, and with fewer resources than other organisations, partnership working across the sector was important.

3.1.3 Committee members made several suggestions on how this work could be developed further and will comment as the review moves forward. Issues such as barriers to involvement; how to ensure diversity of input, including views from all age groups; the difference between patient and lay perspectives, and how people are trained and supported were discussed. Different committees and groups would need different skills and levels of commitment and it was important to therefore tailor recruitment accordingly. Clarity was needed on what is expected of people, and the benefits of their contribution. The Committee was keen that involvement should make a real difference to decision making and not be tokenistic. It was also important to build into the review transparency of how input would be evaluated.

3.2 **What are the key priorities of the healthcare professionals' engagement strategy and consultation**

3.2.1 The Committee was asked for its views on the consultation themes proposed for a 12-week consultation to healthcare professionals. The proposed consultation is intended to understand healthcare professionals' interaction with the Agency including their behaviour after that interaction. The outputs will inform the development of the healthcare professionals engagement strategy and the Agency's approach to safety and risk communication going forward. It was intended that the consultation would help the Agency segment target audiences and identify additional roles individuals might have to be able to cascade safety information to others.

3.2.2 The Committee had several comments and observations on what the consultation is trying to achieve and how it could best do this. The Committee were therefore not clear who the audience for the consultation would be and this needed to be refined. Awareness of the organisation has increased but it was thought being focused on the types of healthcare professionals that need to interact with the Agency might be best instead of too wide an approach. Other suggestions included differentiating between an individual's answer and that made on behalf of an institution or organisation. The Committee were also aware that the approach used in the consultation needed to be the best use of time and effort.

3.2.3 The Committee was also interested in seeing information and evidence gleaned from audits and surveys carried out within the Agency, and from other organisations, that would not only inform consultation questions, but would also support the targeting of consultation recipients.

3.3 **What assurances can be provided to demonstrate regulatory contribution and patient engagement/involvement are optimised for Clinical Trials (medicines development) in the UK?**

3.3.1 PSEC discussed a paper on how the MHRA is contributing to patient and public involvement in clinical research. Areas included the work of the CPRD recruitment services; incorporation of patient voice in trial designs and the Innovative Licensing and Access Pathway (ILAP); support for innovative trial designs and decentralised trials that "bring the trial to the patient"; and the increasing use of patient reported outcomes throughout drug development to support market authorisations decisions.

3.3.2 The Committee noted that several initiatives were developing such as the Patient Reported Outcomes Special Interest Group within the Agency; the patient engagement tool developed by the patient reference group of ILAP; the potential to embed patient and public involvement in clinical trials in the new Medicines and Medical Devices Act 2021; and the joint declaration on public involvement with other constituent members of the UK's health and care research system. Although paediatric trials and rare diseases were not mentioned in the paper the Committee were told these areas will be addressed through upcoming meetings and workshops. There was a discussion on how to position the Agency to make it more competitive for trials and how to use global partnerships. The Committee was assured on the progress made on patient engagement in clinical trials.

## 4. Conclusion

4.1 The Committee reviewed three areas of work: representation of patients on MHRA committees and groups, the consultation on engagement with healthcare professionals, and the work to engage patients in clinical trials design and regulatory decisions. More detailed work is needed in order to ensure consistent and effective patient representation across all MHRA committees. The Committee will review this work later in the financial year to seek assurance. The Committee will receive further information on the audits and research on healthcare professionals' engagement in order to receive assurance on the consultation with healthcare professionals. The Committee were assured that the work to engage patients in different areas of trial design and regulatory decisions was progressing.

**Mercy Jeyasingham**
Chair Patient Safety and Engagement Committee
Non-Executive Director MHRA
October 2021

Medicines & Healthcare products Regulatory Agency

# BOARD MEETING
# [HELD IN PUBLIC]

**19 October 2021**

| | |
|---|---|
| **Title** | What are the mitigations for the most important risks on the Corporate Risk Register? |
| **Board Sponsor** | Jon Fundrey |
| **Purpose of Paper** | Assurance |

# What are the mitigations for the most important risks on the Corporate Risk Register?

## 1. Executive Summary

1.1. This paper provides an overview of the main mitigations in relation to some of the key corporate risks, as well as an overview of all corporate risks.

## 2. Introduction

2.1. The Agency has worked to improve its risk mitigating activities over the last quarter. This is reflected in the overview in section 3.2 and the corporate risk register overview in section 3.3.

## 3. Key strategic risks and mitigations

3.1. The Corporate Risk Register has a number of strategic risks, all of which are linked to the themes in the Agency's Delivery Plan. The risk register as a whole is owned by the Chief Executive Officer, with individual risks owned and managed by a member of the Executive Committee. The corporate risk register will be reviewed at the next ARAC meeting in November, with particular scrutiny of the risks in relation to the Future Operating Model and the new medical devices regulations, as per an action from the Board.

3.2. Currently, the key risks to the Agency relate to the following areas and a summary of all corporate risks, as well as the risk grading criteria, is included in section 3.3:

- **Risk 12: Future Operating Model not successfully implemented within expected timescales, leading to sub optimal ways of working and eroding our cost savings.**
  (Likelihood = 4, Impact = 5)
  *Mitigations:*
  - *Establish an effective programme implementation structure/governance, integrated plan and resourcing profile for delivering the operating model* - Detailed integrated planning underway. Programme resource requirements are dependent on agreeing scope and structure for implementation phase. The need for external consulting support has been identified and individuals have been appointed.
  - *Integrated comms and plan for engaging with internal and external stakeholders* - Comms strategy, including external, is being finalised and presented to Transformation Programme Board and then ExCo endorsed.
  - *Manage future financial sustainability* – This will be done through ongoing refinement of the cost and revenue model for the agency, revising agency fees structure, and submitting a bid to DHSC for Spending Review funds to address shortfall in funding in FY23/24. To date we have brought in a new version of the financial model (updated with latest data) which is providing more visibility to ExCo on sustainability scenarios; working to establish volume metrics, revenue forecasts, and cost estimates, and started the Fees Revision project.

- **Risk 2: Failure to listen to or engage with patients and partners meaningfully, especially responding to concerns, resulting in lowered public trust and confidence in the Agency.**
  (Likelihood = 4, Impact = 5)
  *Mitigations:*
  - *Patient Group Consultative Forum* - We are currently able to provide patients for workshops, although demand is increasing significantly and we will need to improve size and diversity quickly to ensure that patient input is as representative as possible. The overhaul which is currently underway will provide the dramatic increase in size and diversity required.
  - *Training programme* – This is in pilot and development stage. Everyone in the organisation will undergo training in what patient involvement means, why it is the responsibility of everyone, and how they will bring this to life in their own area.
  - *Patient and Public Involvement strategy* – This was published on 30 September 2021. Delivery dates were revised in response to feedback that our original dates were overly ambitious. Resourcing is being addressed through the Transformation Programme, but there will be a lag between appointments and impact.
  - *Customer Service Centre* - This has now been in operation for over a year dealing and resolving queries from patients and partners, despite the increased volume of queries due to COVID-19.
  - *Proactive and reactive media handling* - Resources in the media team are extremely stretched and there are recruitment challenges in this area, so reactive work has to be prioritised as necessary.

- **Risk 16: Failure to adequately prepare for transition away from Trading Fund status and to ensure that the Agency's financial culture and approach to funding are appropriately aligned to new requirements, leading to a negative impact on service delivery and utilisation of resources going forward.**
  (Likelihood = 4, Impact = 4)
  *Mitigations:*
  - *Formal project to manage the transition* – We will work with internal stakeholders (including DHSC colleagues) to ensure that the Project Plan is drafted by 31 Oct 2021. This will entail identifying changes and new key deliverables in relation to Annual Statutory Reporting, Cash Forecasting and Budgeting and Forecasting Performance; mitigating risk of non-compliance with statutory processes and reporting; and ensuring that the Framework Agreement is appropriately understood and communicated across the agency
  - *Implementation of a new governance model* - Help ensure that funding and investment decisions take place at the right level and linked to our overall objectives. This control will be further developed.
  - *Re-design Ways of working* - Aligned ways of working across the Agency, allowing for consistency of process and shared discipline. This control will be further developed.
  - *Re-design Chart of Accounts to align to FOM* - Will help ensure that reporting of financial performance allows for tracking that funds are aligned to key outcomes expected of the Agency.

Long term financial forecasting will help plan for likely future scenarios

- *Finance business partnering* - Review of effectiveness to be carried out by 30 Nov 2021. FBP portfolios to be revised in line with Size and Shape.
- *Roll out of regular forecasting* process – Will continue monthly to build Agency wide skillset. 2022/23 Design to be complete by 31/01/2022

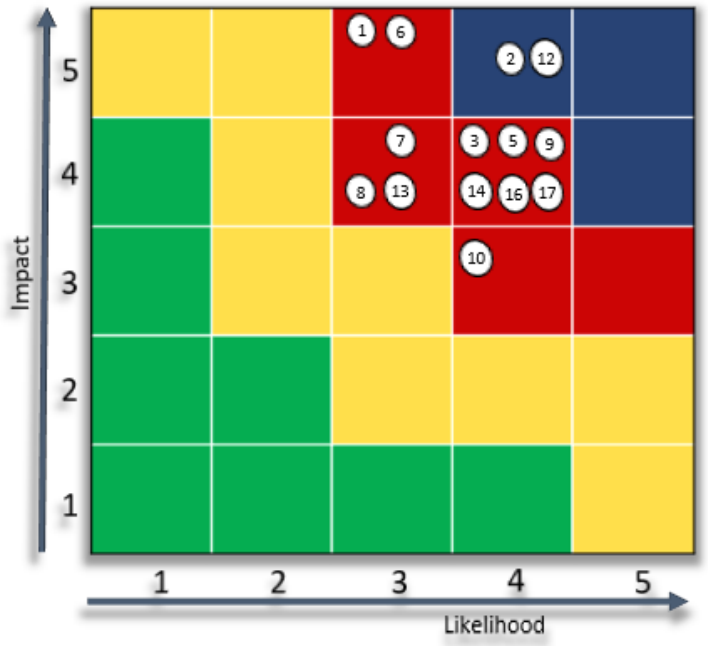
➢ **Risk 1: Failure to act on the relevant Independent Medicines and Medical Devices Safety Review recommendations in a timely manner, resulting in a negative impact on safety of medicines and devices.**
*(Note: This risk has been included because it was felt that the mitigations for this important and high profile area were not robust enough. The mitigating actions have now been strengthened).*
(Likelihood = 3, Impact = 5)
*Mitigations:*

- *Patient and public involvement* – Patient and Public Involvement Strategy objectives in place to increase the agency's focus on patient and public engagement and involvement, increasing representation on advisory committees, and the creation of a patient outcome framework to provide an experience and engagement index. Patient engagement is also central to the Delivery Plan 2021-23 with all staff having a patient engagement objective this year.
- *Device data transparency pilot project* - A one year pilot will be launched in Q4 2020-21 providing adverse incident data as an interactive report for the public. We will be seeking feedback and comment from patients and members of the public on this publicly facing platform via our patient group consultative forum and via wide use of social media channels.
- *Establishment of independent expert advice for medical devices* - The MMD Act 2021 provides powers to put independent expert advice for medical devices from the Devices Expert Advisory Committee (DEAC) and its committees onto a statutory footing. This will ensure greater involvement of independent, scientific, technical, lay and clinical experts in regulatory decision making.
- *Delivery of Safety Connect system* - Delivery of the common improved technology platform for incident management and signal detection will provide a step change, particularly for devices, to detect and respond to safety signals more quickly and comprehensively. The work will be complemented by a communications strategy to increase awareness of the Yellow Card scheme.
- *Seek external funding to deliver improvements in data capabilities* - Within the new Safety & Surveillance structure, data capabilities have been centralised into a new group called Scientific Data and Insight. Working with CPRD , the group will be responsible for the development of partnerships with NHSD, NHSX, NHSE, HDR-UK to leverage data capabilities and to seek external grant funding to develop new data capabilities. However, uncertainties around success in grant funding remain.

- A verbal update will also be provided in relation to the Technology Roadmap risk.

3.3. The corporate risk register summary below gives an overview of all strategic risks within the Agency. The risk grading criteria is also included.

# Risk Register – October 2021




(1) Current Risk Grading

| Ref | Delivery Plan Theme | Risk Description | Risk Owner | Risk Lead | Score L / I | Target score (L/I) and expected date to achieve this |
|---|---|---|---|---|---|---|
| 1 | Patient Safety | Failure to act on the relevant IMMDS Review recommendations in a timely manner, resulting in a negative impact on safety of medicines and devices. | Alison Cave | Sarah Branch / Graeme Tunbridge | 3/5 | 2/4 Sept 2022 |
| 2 | Patient Safety | Failure to listen to or engage with patients and partners meaningfully, especially responding to concerns, resulting in lowered public trust and confidence in the Agency. | Alison Cave | Rachel Bosworth | 4/5 | 2/4 Sept 2022 |
| 3 | Dynamic Organisation | Key hardware platforms supporting business systems may not recover from failure if systems are not supported due to being End of Service Life (EOSL) resulting in disruption to business. | John Quinn | Asif Rahman | 4/4 | 3/4 March 2023 |
| 5 | Financial Sustainability | Lack of a financially sustainable and agile operating model leading to inability to operate efficiently as a regulator and meet statutory duties. | Jon Fundrey | Jo Passingham | 4/4 | 3/4 Dec 2021<br>2/3 Dec 2022 |
| 6 | Scientific Innovation | Failure to implement innovative regulation leading to negative outcomes for patients and reducing the attractiveness of the UK market. | Sam Atkinson | Siu Ping Lam / Graeme Tunbridge/ Marc Bailey | 3/5 | 2/5 March 2022 |
| 7 | Dynamic Organisation | The culture of the Agency not aligned to the future challenges that the Agency will face leading to an inability to deliver key outcomes. | Jon Fundrey | Vanessa Birchall-Scott | 3/4 | 2/4 April 2022 |
| 8 | Dynamic Organisation | Failure to meet the current and future staffing, skills and capability requirements and thus unable to deliver key outcomes, including areas of statutory responsibilities. | Jon Fundrey | Vanessa Birchall-Scott | 3/4 | 2/4 April 2022 |
| 9 | Dynamic Organisation | Loss of data and/or systems failure due to a cyber attack or major data breach resulting in disruption to the core operations of the Agency. | John Quinn | Diana McAuley | 4/4 | 3/4 March 2022 |
| 10 | Dynamic Organisation | Projects fail to deliver their planned benefits within agreed cost/timescales leading to sub optimal ways of working and eroding our cost savings. | Davinder Virdi | TBC | 4/3 | 2/3 March 2022 |
| 12 | Dynamic Organisation | Future Operating Model not successfully implemented within expected timescales, leading to sub optimal ways of working and eroding our cost savings. | Davinder Virdi | TBC | 4/5 ↑ | 2/5 Sept 2022 |
| 13 | Patient Safety | Lack of resources and/or appropriate engagement with manufacturers leading to the Agency being unable to maintain COVID-19 vaccine operational delivery. | Sam Atkinson | Marc Bailey | 3/4 | 2/3 March 2022 |
| 14 | Collaborative Partnerships | Failure to address outstanding issues on the interpretation and technical implementation of the Northern Ireland Protocol (NIP) impacting on supply to NI. | Sam Atkinson | Jack Turner | 4/4 | 3/3 Jan 2022 |
| 16 | Financial Sustainability | Failure to change the Agency's financial culture and approach to funding to successfully transition away from Trading Fund Status, leading to a negative impact on service delivery and utilisation of resources going forward. | Jon Fundrey | Jo Passingham | 4/4 | 2/3 Dec 2022 |
| 17 | Patient Safety | Unable to implement new regulatory framework for medical devices & diagnostics, thus impacting on product availability and patient safety. | Sam Atkinson | Graeme Tunbridge | 4/4 | 3/3 July 2023 |

Risk rating criteria

| Scale | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| **Category** | **Insignificant** | **Minor** | **Moderate** | **Major** | **Catastrophic** |
| **Objectives** | Minor and containable impact on achievement of objective | Affects short term goals within the objective without affecting long term achievement | Significant short term damage, and important to outcome of long term objective | Significant detrimental effect on achievement of the objective in the medium or long term | Prevents the achievement of the objective or highly damaging impact |
| **Financial Performance and Control** | Financial loss or loss of funding <£0.5m in one year, or <£1.5m over SR period.<br>Insignificant fraud/loss of 3rd party monies. | Financial loss/funding loss £0.5–5m in 1 year, or £10m–£25m in SR period.<br>Minor Fraud/publicised loss of 3rd party monies. | Potential increased NAO scrutiny.<br>Financial loss/funding loss £5–10m in 1 year, or £10m–£25m in SR period.<br>Material Fraud/publicised loss of 3rd party monies. | Major NAO criticism.<br>Financial loss/loss of funding £10m–£50m in 1 year, or £25m–£125m over SR period.<br>Results in major liability requiring funding.<br>Substantial Fraud/loss of confidence re 3rd party monies | NAO qualification of accounts leading to probable PAC hearing.<br>Financial loss/funding loss> £50m in one year or >£125m over SR period.<br>Major fraud/ Loss of confidence re 3rd party monies. |
| **Reputation** | Potential for minor loss of trust at most | Some loss of trust with very limited public criticism | Some public criticism, possibly publicised at least locally | Some national level criticism<br>May require formal communication with public / stakeholders | National Media criticism<br>Requires formal communication with the public/stakeholders |
| **Compliance** | Triggers limited internal investigation and review | Potential for minor legal challenge<br>Claim relating to minor injury/minor breach | Potential for moderate legal challenge<br>Claim relating to significant injury breach | Major legal challenge<br>High likelihood that judgment will be lost.<br>Claim relating to serious injury/major breach | Substantial damages against MoJ<br>Legal challenge halts policy delivery<br>Damage to legal reputation<br>Claim following (e.g.) loss of life |
| **Management Time** | No senior management intervention | Some (<10 %) senior management time and attention needed to resolve | Moderate (10 –30 %) senior management time and attention needed to resolve | Significant (30 – 50%) senior management time and attention needed to resolve | Extensive (>50%) senior management time and attention needed to resolve |

| Scale | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| **Category** | **Remote** | **Unlikely** | **Possible** | **Likely** | **Near Certain** |
| **Frequency** | Less than once in 5 years | Once between 2 to 5 years | Once within 2 year | Once within next year | More than once within the next year |
| **Probability** | Less than 20% | Between 20% but less than 40% | Between 40% but less than 60% | Between 60% but less than 80% | Greater than 80% |

## 4. Proposal

4.1. It is proposed that the Agency build on the work over the last quarter and continue to tighten mitigating actions for corporate risks to ensure that they help manage each risk down to the target risk rating.

## 5. Recommendation

5.1. The Board is asked to consider if the proposed actions provide sufficient mitigation for the Agency's most significant risks and if any additional actions need to be taken

**Jon Fundrey**
**11 October 2021**