September 2023

Evaluation of the Data to Early Diagnosis and Precision Medicine Challenge

Final Evaluation

Final Report

SQW

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Executive Summary

1. The Data to Early Diagnosis and Precision Medicine (D2EDPM) Challenge was announced in 2017 to capitalise on opportunities for the UK to further develop world leading expertise in data driven healthcare and precision medicine. The £210m programme was launched in 2017/18 and is completing in 2023/24. It had three key strands: genomic sequencing, including the whole genome sequencing (WGS) of UK Biobank participants; digital pathology and radiology, and integrated diagnostics, including developing five Centres of Excellence; and a Digital Innovation Hub (DIH) programme. A further £50m of capital was invested by the Office for Life Sciences in three of the Centres of Excellence. This complementary programme has been evaluated separately.

2. Collectively this investment aimed to accelerate the development of precision medicines, personalised approaches and earlier diagnosis of diseases through the use of new technologies and health data informatics. The Challenge's objectives were to:

   - encourage greater adoption of precision medicines and personalised approaches, and improved or early diagnosis
   - increase the UK share of global diagnostic market from 3% to 5% over ten years
   - support the growth of UK companies and inward investment
   - develop centres of excellence/clusters of high-quality diagnostic, digital health and precision medicine focused companies
   - increase efficiency in the NHS by improving outcomes at lower cost.

3. Through the three strands, the Challenge intended to contribute to these long-term objectives through achievements across the following key elements:

   - Improved **research and innovation capacity and capability** through infrastructure (e.g. platforms and data) and data- and knowledge-sharing
   - Improved **collaboration** between academia, the NHS and industry
   - **Sector growth**, including through clusters of activity and inward investment
   - **Acceleration in developing and using new tools** in healthcare settings
   - Development of **skills, resources and trust** to implement new precision medicine approaches, products and services

4. SQW, working with PHG Foundation, Impact Data Metrics, ADL and IFF Research, was commissioned to evaluate the Challenge. The evaluation aimed to assess both the impact of the Challenge and the process through which it was delivered. This report focuses on the outcomes and impacts achieved and the lessons from delivery of the Challenge.

Headline findings

Research and innovation capacity and capability

5. The Challenge has made a significant contribution to the development of research and innovation infrastructure and capacity in precision medicine that would not have existed to the same scale or scope otherwise. This has been achieved through a mix of data curation, development of data storage and sharing infrastructure, investment in equipment, and partner engagement. Key examples are as follows:

- WGS of the UK Biobank: sequencing of the 500k participants further increased the UK's reputation as a global leader in genomics, with the UK Biobank held up as a gold standard and international exemplar.

- The Health Data Research Hubs have created important data infrastructure through a multitude of national datasets. For example, INSIGHT has published 12 platinum-rated datasets, representing the world's largest ophthalmic bioresource with over 25 million retinal images and associated clinical data; and Gut Reaction has created a lasting data resource which has the potential to provide key data to unlock personalised medicine for IBD patients.

Achievements include

- 500k Biobank participants with genomes sequenced
- 22 new data storage facilities and platforms
- 25 NHS sites using new facilities and platforms.
- 149 national datasets for major disease areas curated by DIH Hubs

- The c. 150 datasets curated by the Hubs have contributed to the Gateway, which now contains information on over 800 UK health datasets. Together with the Alliance, with over 70 partners, there is R&I infrastructure with significant potential and international recognition.

- The Centres of Excellence (CoEs) in digital pathology and radiology have created new data infrastructure such as storage facilities and platforms, and engaged NHS sites in these through new equipment, the digitisation of labs and enhanced data collection. The Centres and Integrated Diagnostics projects have supported capability development, exemplar projects and capacity that can aid future research.

6. This R&I capacity and capability has been supported by significant leveraged R&D investment as well as follow-on funding for more activity. Global pharma partners (AZ, GSK, J&J and Amgen invested £100m in the UK Biobank WGS project, investment that is unlikely to have happened without the partnership model developed for the Challenge. There has been significant match funding provided through the Centres of Excellence by key industry players such as Siemens, GE, Roche and Canon. **Across different parts of the Challenge there is evidence of industry partners having increased their R&D investment either directly or indirectly as a result of being involved in the Challenge activities**, and some projects accessing follow-on funding for successor activities. The Digipath projects secured over £40m in additional and follow-on R&D investment, and the DIH strand leveraged an extra £100m.

7. With these as long-term endeavours, it will be important to sustain the capacity and infrastructure that has been created and take advantage of new-found capabilities and knowledge. Some of the Hubs will be sustained beyond the Challenge under varying models. The English-based CoEs will see part of their activity and infrastructure integrated into the regional NHS England (NHSE) Secure Data Environments. Continuation is key to enabling a long-term effect of the CoEs through the infrastructure, teams and knowledge. This knowledge includes learning in relation to how different sectors and partners operate and their differing needs, technical aspects of data-sharing and interoperability, and the outstanding issues that need to be considered going forward.

Collaboration between academia, the NHS and industry

8. This Challenge was shaped by extensive engagement across the health and life sciences sector carried out as part of the Life Sciences Sector Deal. This has led to **significant collaboration across all parts of the sector in the delivery of ambitious projects across the three strands of the Challenge.**

9. The collaboration between global pharma and sequencing partners in the UK Biobank WGS project was a major achievement. It required significant time and effort to set up but has proven to be a successful model, with the learning from this now informing other activities that can stimulate greater private-public investment initiatives.

10. The CoEs have been successful in bringing together industry, academic, charities and NHS partners. There has been good engagement in particular between the research base and a wider range of NHS partners, including incorporating some regional hospitals not typically involved in R&D activity. In some cases the level and speed of ambition was too high and the complexities of initial contracting (particularly when dealing with large NHS Trusts) and managing such large consortia have contributed to some delays in project delivery, which has been a source of frustration for some industry partners in particular.

11. The DIH Programme has made significant progress in bringing together data custodians and data controllers through the Alliance which has over 70 member organisations. The Hubs have also strengthened and enhanced collaborations and secured over 500 contracts with a range of academic, industry and NHS clients.

Acceleration in the development and use of new products and tools

12. There is evidence of progress of numerous tools, approaches, products and services towards the market. However, the extent to which the Challenge has led to new tools with widespread clinical adoption is limited to date.

13. In the genomics strand, the UK Biobank WGS project created a world-leading dataset to enable the development of new precision medicine approaches and drug treatments over the coming years, and some CR&D projects have helped to enhance diagnostic tools.

14. Across the other strands of the Challenge there are a range of products and tools progressing towards commercialisation and adoption. The CoEs have delivered a large number of exemplar projects which have accelerated the development of new or existing products from proof of concept through to prototyping, product marking and deployment in clinical settings. Notable examples include the e-stroke suite developed through the NCIMI CoE and the Mia AI platform for breast screening developed through the ICAIRD CoE.

Achievements include

- 69 exemplar projects delivered
- 51 AI tools in development
- 18 AI tools developed
- 481 publications
- TRL progress for new tools and technologies
- 18 tools now at deployment phase TRLs 7-9

15. There have been further examples through the Integrated Diagnostics and DIH Hubs including the deployment of the Cytosponge through the DELTA project, and the development of AI tools for diagnosing eye disease through the INSIGHT Hub. Across all of these projects, the collection and analysis of new datasets has also encouraged the larger industry partners to strengthen their relationships with NHS and other industry partners. Although there continue to be issues around data access, the Challenge projects have provided the confidence that these issues can be resolved over the coming years.

16. Although all projects were impacted by the disruption caused by the COVID-19 pandemic, many projects were able to pivot their activity and expertise towards making important contributions to the pandemic response. For example in the CoEs, ICAIRD developed algorithms to identify COVID from x-rays, NCIMI used MRI scans to diagnose long COVID and the LMIAI Centre developed an AI tool to help with COVID diagnosis. In the DIH Programme,

BREATHE increased COVID-19 data access and worked on a number of projects to support the pandemic response and the Innovation Gateway held key resources relating to COVID-19, e.g. the Zoe symptom tracker database.

Skills, resources and trust to implement new approaches

17. The **CoEs have made substantial contributions to building awareness, knowledge and skills, and in doing so trust, in new approaches**. Specifically, the CoEs have had direct engagement with clinicians through exemplar projects that have been supported, enabling clinicians to take part in research projects that have tested new approaches, and to use newly installed equipment. There are ongoing opportunities with clinicians testing new technologies, tools and product suites as part of the next stage of development and validation in clinical workflows. For pathology, this is just the start of a long process as it requires a cultural shift from physical slides to digital images, and then to the use of AI tools. For radiology, where digital is the norm, the shift required is less, though still reflects an important change in practice.

18. In addition, the CoEs have provided training that will aid future adoption, for example:

- how to use new digital pathology equipment and AI imaging platforms
- understanding the opportunities (and current limitations) in relation to AI tools – e.g. AI Clinical Fellowship programme delivered through the London Centre.

Achievements include:

- 1,807 clinicians trained
- 6,926 researchers trained
- 65 PPIE events
- 46,921 PPIE participants

19. In addition to training professionals, a key part of building trust in new approaches is through patient and public involvement and engagement (PPIE). These PPIE activities have been built into projects across the Challenge and have been important to ensure wider buy-in to the use of patient data, and to the adoption of new approaches and technologies. There has also been a range of activity to encourage new people to work in the precision medicine and data driven healthcare sector. For example, the Challenge-funded Health Data Research Hubs have played an important role in delivering HDR UK's Black Internship Programme. It was widely acknowledged that there is more to do here, including in relation to ensuring that PPIE reaches under-represented groups in the pursuit of EDI objectives.

Sector growth

20. The evaluation developed a bespoke database of the precision medicine sector and used ONS datasets to assess whether engagement in the Challenge had facilitated company growth. The

evidence indicated that **the sector has grown over the period of the Challenge, both in terms of employment and turnover, and, geographically, there has been growth in different areas of the UK**. Notably, growth has occurred in parts of the North of England, Scotland and Northern Ireland as well as in London and the Greater South East. Overall, **there was insufficient evidence at this point that those businesses engaged with the Challenge had grown faster as a result of participation**. This aligned with consultation feedback that the effect of the Challenge on commercial performance was limited so far, reflecting that research and innovation activities had moved approaches and tools along towards the market, but not brought about significant adoption.

21. That said, there were individual examples of companies engaging in the Challenge that believed that they had been able to grow their business in ways that would not have been the case otherwise. This was particularly true for small companies (including start-ups) that had been able to use Challenge-funded activities as a platform to secure external investment from both private and public sources, and to grow employment and in some cases sales of their products/services. They also believed that they were now more attractive collaborators for larger companies because of the capabilities and access to data that they can bring. The wider evidence highlighted that those smaller companies engaged with the Challenge have grown both before the Challenge and afterwards at faster rates than similar smaller companies that had not engaged with the Challenge. This does not imply causality, but indicates that the Challenge has supported the sector's faster growing companies.

22. There were some examples of larger companies that reported: growth in R&D activities (i.e. investment and jobs) in the UK which were linked to the Challenge, reflecting the UK's profile in this area; and the increased ability to test further existing products in real life settings that may help lead to future commercial effects.

Key lessons

23. From the delivery of the Challenge, there are a number of important lessons:

- **Time for project investments such as these**: overall, the timescales of the projects were insufficient, even taking into account that there was a global pandemic during delivery. This was particularly an issue for the CoEs, because of the time required for set-up, including establishing project governance, memoranda of understanding, intellectual property agreements etc. and then installing and setting up data infrastructure. The result was that industry partners in particular had to wait longer than expected before exemplar projects could start. Allowing for five years or more for investments would enable more realistic timeframes for set-up and expectations for industry partners, thereby allowing more time to demonstrate commercial potential.

- **Planning for sustainability**: related to the previous point, given the time and resource that is needed to put in place data infrastructure, it is important that plans are made to

capitalise on it once developed. Developing sustainable models was an important element for the Hubs, but the CoEs faced significant uncertainty during the final year of funding. At the time of writing it was recently agreed that the English CoEs would be integrated into the subnational SDEs (Secure Data Environments). To some extent, this uncertainty reflected changes in the wider NHS landscape relating to data and digital technologies that created challenges for future planning. The key lesson here is ensuring funders and projects understand the realistic timescale to impact and the extent to which strategic investments may need follow-on support from the public sector.

- **Developing and maintaining project partnerships**: the project investments have been built around partnerships and consortia. The development of the consortium for the WGS project was impressive, bringing together a group of industry pharma partners that would not typically collaborate and with substantial industry match alongside public funding. With the arrangements in place, including preferential data access, this provides a model for future similar investments. Other projects tended to build on existing relationships, though their scale resulted in new introductions and partnerships. The downside has been that some consortia were too large, which added to the timing challenges in managing the set up process and ongoing engagement.

- **Promotion and communications**: there was insufficient attention given to the promotion of the activities of the Challenge to the wider sector. As a result, there was a lack of awareness even within the Challenge of what else was being funded and undertaken. Whilst this was remedied to some extent later on in the Challenge, this is likely to have resulted in missed connections and opportunities. Going forward, UKRI should ensure that sufficient resources are allocated for dissemination and communication, in particular where investments are seeking to raise profile and share knowledge about new areas of technology.

24. As indicated, there are a number of ongoing challenges to developing the potential of precision medicine in the UK. Going forward, actions are required in the following areas in particular:

- There is a need for **greater standardisation around storing and sharing data**. Whilst being addressed, ongoing funding is required to ensure these efforts are supported. Data needs to be seen as long-term essential infrastructure which requires ongoing maintenance. In the wider landscape, with the role of Trusted Research Environments and Secure Data Environments interoperability will be essential as part of developing and managing this infrastructure.

- **Data curation** requires appropriate resource to understand the data you are working with, define the data and data terms, standardise data and associated metadata, and address issues in quality. The specific issues depend on the nature of the data. For image data, there is a particular need to address standardisation. For NHS records, key barriers

that were highlighted were in relation to means of integrating data, and in developing solutions to address natural language or free text processing, i.e. to handle more text based data types such as free text boxes in forms or medical records.

- **Patient public, practitioner and industry perspectives will be required** to develop national and local policy on information governance. In addition, steps should be taken to tackle EDI issues, which will require gathering data from as wide a range of Trusts as possible to capture population diversity within datasets and embedding PPIE into programmes. Public involvement from diverse and representative groups in co-design of projects, including data sharing processes, is vital to this.

1. Introduction

1.1 In 2020, an SQW-led consortium was commissioned by UKRI to evaluate the Data to Early Diagnosis and Precision Medicine (D2EDPM) ISCF Challenge, and the complementary investment by the Office for Life Sciences in the Centres of Excellence.

1.2 The consortium led by SQW included PHG Foundation, Impact Data Metrics, ADL and IFF Research. The evaluation aimed to assess both the impact of the D2EDPM Challenge and the process through which it is delivered.

1.3 There were four stages to the evaluation. The first stage involved the development of an evaluation framework and was completed in February 2021. The second stage, a baseline assessment of the Challenge, reported in July 2021. The interim progress and process evaluation reported in March 2022. This report is for the final impact evaluation of the Challenge.

1.4 The evaluation of the complementary investment by the Office for Life Sciences in the Centres of Excellence is subject to separate reporting.

Final impact evaluation

Key research questions for the final impact evaluation

- To what extent has the Challenge led to new, scaled-up or different activities in the precision medicine and early diagnostics landscape? What has the Challenge funded that is different to what may have been delivered in any case?
- To what extent (and how) has the Challenge successfully strengthened the sector's R&D capacity and capability?
- To what extent (and how) have the three strands enabled the development and adoption of precision medicine approaches in diagnostics, digital pathology and radiology?
- To what extent (and how) has the Challenge enabled the development of products (that are intended to improve the health of patients and the public)?
- To what extent (and how) has the Challenge extended effective connectivity and collaboration between academic, NHS and industry researchers and innovators to increase knowledge exchange and accelerate progress of R&D?
- To what extent has the Challenge supported the UK as a world leader in early diagnostics and precision medicine?
- To what extent is there early evidence of an impact on the size of the sector?
- To what extent is there early evidence of effects on healthcare delivery that may lead to patient outcomes?

1.5 The primary research for this final phase of the evaluation was undertaken between January and April 2023, and was then followed by three stakeholder workshops which were held in May 2023 to discuss emerging findings. There was some slight variation in the timescales covered by the monitoring data provided by project managers, though most data related to the period up to March 2023. Similarly the consultation feedback from project managers and partners reflected views on activity that had taken place by early 2023, with some projects in the final stages of implementation.

Research approach

1.6 The overall approach to the final impact evaluation was a theory-based assessment, with evidence collected on different stages of outputs and outcomes expected, and the use of contribution analysis to assess the role of the Challenge in achieving effects. This approach was agreed in the evaluation framework. The final phase involved the following main tasks:

- **Bespoke database of companies involved in data driven healthcare and precision medicine** – the database was developed as part of the baseline and collected details for

over 300 Precision Medicine (PM) businesses. A further 125 companies were added when the database was updated as part of the final phase evaluation. Data was collected on location, main technology areas, investment, employment size and turnover.

- **Survey of companies from this database** – for the final phase of the evaluation, we obtained 59 responses from PM businesses, collecting data on their R&D/innovation activity over the last three years, collaborations, skills issues and views on the UK's wider innovation environment. In the baseline evaluation we obtained 80 responses from businesses.

- **Desk review of wider contextual datasets** – we carried out a desk review of secondary data relating to the life sciences sector and genomic, diagnostic and digital health sub-sectors. The aim of this review was to understand how the wider landscape has changed during the Challenge delivery period and key drivers of change, including the Challenge investments.

- **Econometric analysis** – we undertook a quasi-experimental assessment, using 'difference-in-difference' analysis, to examine whether there were any differences in performance between those businesses involved in the Challenge and other non-participating businesses in the data driven healthcare and precision medicine sector.

- **Case studies of four comparator countries** – we updated our case studies on similar programmes in the USA, Germany, Sweden and Israel to identify lessons around governance, industry engagement and supporting the growth of data driven healthcare and precision medicine sectors.

- **Stakeholder consultations** – discussions with 89 individuals from organisations that participated in projects across the three strands of the Challenge. We also collected feedback from 13 consultees involved in the governance and management of the D2EDPM Challenge through the Programme Board, Advisory Group and innovation leads responsible for managing the three strands.

  - The consultations focused on main achievements, key lessons, progress in terms of delivered outputs, outcomes and impacts from Challenge funded projects.

- **Survey of UK Biobank researchers** – the survey collected feedback from 29 researchers to discuss early views on the new datasets generated by the Whole Genome Sequencing of the 500,000 UK Biobank participants.

- **Monitoring data collection** – templates were sent out to collected data on project performance in terms of spend, activities and outputs.

Report structure

1.7 The final impact evaluation report is structured as follows:

- **Section 2** provides an overview of the D2EDPM Challenge including the context and rationale, its main objectives and a logic model for the Challenge
- **Section 3** sets out the progress in delivering the three strands of the Challenge including the main lessons, what has worked well and not so well
- **Section 4** summarises the evidence on how the Challenge activity and investments have led to changes in R&D capacity and capability
- **Section 5** presents evidence on how the Challenge has helped to progress innovations towards impacting on healthcare
- **Section 6** highlights the evidence on the Challenge's contribution to the development and growth of the data driven healthcare and precision medicine sector
- **Section 7** discusses the sustainability and legacy of the investments, and lessons for future programmes
- **Section 8** sets out the main conclusions from the final impact evaluation

1.8 Alongside the final impact evaluation report we have produced a set of evidence papers with one for each of the three individual strands of the Challenge, a paper on the international comparator research, and a paper that updates the contextual evidence that was presented in the baseline report.

2. Overview and context to the Challenge

Context and case for the Challenge

2.1 The scope of the D2EDPM Challenge investment was informed by the Life Sciences Industrial Strategy[1] and Life Sciences Sector Deal,[2] both published in 2017. These documents identified the significant opportunities for the UK to develop world leading expertise in the use of AI and big data in the life sciences sector through major precision medicine investments such as whole genome sequencing of UK Biobank participants and digital diagnostics.

Key issues and opportunities from the baseline research

- The feedback from the baseline research highlighted opportunities to fully leverage the potential of information communications technologies (ICTs) that could facilitate better access to, and storage, analysis and processing of data.
- In terms of the genomics strand, it was recognised in 2017/18 that the UK Biobank was a national asset and represented an important opportunity to generate genomic data at scale linked to existing patient data. Large-scale data linkage and analysis was seen as essential to better understand the underlying causes of disease, and allow clinical genomics precision medicine approaches.
- In 2017/18 there was significant pressure on diagnostic pathology and radiology services with increasing patient demand, skills shortages in the workforce and the need for the NHS to generate efficiencies. Around this time, there were emerging opportunities to use AI and other digital technologies to help accelerate and improve diagnostic services and the early identification of biomarkers for certain diseases.
- Another key baseline issue in 2017/18 was the fragmented health data landscape, and there was a realisation that this was holding back precision medicine and the growth of the data driven healthcare sector. Stakeholders noted the urgent need to connect and facilitate access to high quality, representative datasets to build capabilities and health data infrastructure.

SQW – Baseline evaluation evidence

2.2 Collectively, the issues highlighted above provided a strong rationale for the range of investments being funded though the Challenge. Throughout the evaluation work, we have heard from stakeholders that the case for investment is now better understood. The experience of the COVID-19 pandemic and the pressures on the health sector in its aftermath have reinforced the need to make better use of data and technology to improve and accelerate

[1] Life Sciences Industrial Strategy Board (2017), Life Sciences Industrial Strategy: A report to the Government from the life sciences sector
[2] HM Government (2017), Industrial Strategy: Life Sciences Sector Deal 1

diagnosis, and the opportunities from developing more precision medicine approaches and tools.

2.3 The period in which the Challenge has been delivered has been extremely difficult and this needs to be recognised when evaluating the programme of investment.

2.4 Prior to the pandemic, the NHS was already under major pressures from skills shortages, under-investment and general lack of capacity to engage in innovation related activity. COVID-19 exacerbated many of these issues as referrals and procedures were postponed and most NHS staff were re-allocated to dealing with the pandemic. As we will describe later the disruption across the NHS has led to major backlogs in diagnoses and treatments.

2.5 On the technology side there have also been lots of changes since the start of the Challenge in terms of the development of AI, machine learning, virtual care, the Internet of medical things and 5G. More specifically in relation to the Challenge, there have been significant developments in genomic and other omics technologies, advanced image analysis, new scanner and sequencer equipment and the interoperability of data sharing platforms.

2.6 The regulation of new healthcare devices in the UK changed at the start of 2021 after the end of the Brexit transition period and many of the evaluation consultees highlighted the ongoing uncertainty in the market. The new UK regulator MHRA was expected to introduce a new medical devices legislative regime by July 2023 but this has recently been push back by 12 months.

2.7 In response to all the changes in the NHS and across different technologies over the last few years, there have been some important policy developments which have affected the delivery of the Challenge as described in Table 2-1 below. These have provided a backdrop that aligns with the intents of the Challenge to develop the types of data-driven technologies that can support the health sector, and the nature of the benefits that are sought. The documents also point to some of the broad set of enabling factors needed, such as interoperability, security of data, fairness and workforce development.

Table 2-1: Evolving policy context

Strategy document	Summary
The future of healthcare (2018)[3]	Policy document which set out the Government's commitment to investing in more data-driven technologies such as AI and genomics to improve diagnosis and treatments of diseases
The NHS Long Term Plan (2019)	10 year NHS plan to improve health and social care. This will be achieved through providing patients with more control, greater integration of health and social care services, preventing illness and addressing health inequalities, workforce development, improving efficiency, and making better use of data and digital technology

[3] DHSC (2018), The future of healthcare: our vision for digital, data and technology in health and care

Strategy document	Summary
The Topol Review (2019)[4]	Review highlighted that the successful delivery of digital healthcare technologies (in genomics, digital medicine, AI and robotics) will require significant investment in NHS training, CPD and workforce development. Suggested three principles for the deployment of new technologies: patients need to be kept informed about new health technologies; the healthcare workforce needs the expertise and guidance to evaluate new technologies; and the adoption of new technologies should provide staff with more time for direct patient care.
Genome UK: the future of healthcare (2020)[5]	Strategy highlighted the need for earlier detection and faster diagnoses, using genomics to target interventions to specific groups of patients, and supporting patients to understand what genomics means for their health
National Data Strategy (2020)[6]	Policy paper set out how the UK can leverage existing strengths to boost the better use of data across businesses, government, civil society and individuals. The main action areas are: unlocking the value of data across the economy; securing a pro-growth and trusted data regime; ensuring the security and resilience of the infrastructure on which data relies
A plan for digital health and social care (2022)[7]	Policy paper on plans to implement digital health systems across the NHS including infrastructure and inter-operability standards for health data sharing. Includes access to health, genomic, imaging and pathology digital datasets for clinical trials and other research purposes There are commitments to 'enable researchers to access linkage-enriched genomics datasets from linked sources' and to develop a network of Trusted Research Environments across England to allow research access to 'data generated across the NHS including genomics, imaging and pathology'
Accelerating genomic medicine in the NHS (2022)[8]	New five-year strategy for embedding genomics in the NHS in England linked to delivery of wider 2020 Genome UK ten-year genomic medicine strategy. Commitments include: Developing an interoperable informatic and data infrastructure that enables the NHS to use and share genomic data; enabling the NHS to use cutting-edge analytical tools and up to date variant databases; Deliver equitable genomic testing for improved prediction, prevention, diagnosis and precision medicine.
Better, Broader, Safer: Using Health Data for Research and Analysis (2022)[9]	A review of how to improve the use of NHS data for analysis and research with a view to supporting the broader NHS Data Strategy, with recommendations to create shared infrastructure and inter-operability standards for health data sharing.

[4] NHS Health Education England (2019), The Topol Review: Preparing the healthcare workforce to deliver the digital future
[5] HM Government (2020), Genome UK: the future of healthcare
[6] Dept. for Digital Culture Media and Sport (2020), National Data Strategy
7 Dept. of Health and Social Care (2022), A plan for digital health and social care
8 NHSE (2022), Accelerating genomic medicine in the NHS
9 Goldacre, Review/ DHCS(2022). Better, Broader, Safer: Using health data for research and analysis

Strategy document	Summary
	The report calls for more investment in developing secure data platforms and the workforce needed to realise the full value of NHS data, driving research, health service improvement, and innovation.
Data saves lives: reshaping health and social care with data (2022)	Health and social care data strategy with objectives around improving patient trust, supporting health care professionals, empowering researchers, working with partners to develop innovations, and developing the right technical infrastructure Describes the 11 draft guidelines for secure data environments, based on the ONS Five Safes Framework. Highlights the Data for Research and Development programme with £200 million for NHS data infrastructure (subject to HM Treasury approval)
A pro innovation approach to AI regulation (2023)[10]	White Paper includes Framework with five principles to guide and inform the responsible development and use of AI in all sectors: Safety, security and robustness; Appropriate transparency and explain-ability; Fairness; Accountability and governance; Contestability and redress

Source: SQW desk review

Challenge aims

2.8 The original long-term aims of the D2EDPM Challenge were to:

- encourage greater adoption of precision medicines & personalised approaches, improved or early diagnosis
- increase the UK share of global diagnostic market from 3% to 5% over the next 10 years
- support the growth of UK companies and inward investment
- develop centres of excellence/clusters of high-quality diagnostic, digital health & precision medicine focused companies
- increase efficiency in the NHS by improving outcomes at lower cost.

Strand activity and objectives

2.9 The Life Sciences Sector Deal announced the £210 million investment in the D2EDPM Challenge over five years from 2017/18 to 2022/23. The Challenge has three main strands:

- Genomics: £100m UKRI investment in whole genome sequencing and linked informatics has leveraged another £150m from a consortium of industry and the Wellcome Trust,

[10] Dept. for Science, Innovation and Technology (2023), A pro innovation approach to AI regulation

allowing whole genome sequencing and informatics on all 500,000 UK Biobank participants. This strand of activity includes funding for Genomics England to support WGS in cancer trials, and six CR&D projects involving SMEs applying whole genome sequencing to cancer.

- Centres for digital pathology, radiology, AI and machine learning and enabling integrated diagnostics: £50m of UKRI investment has been used to create a network of Centres of Excellence in digital pathology and in-vivo imaging focused on the use of AI and digital systems for the benefit of industry, researchers, clinicians and the NHS. There is also £16m for integrated diagnostics CR&D projects that will challenge companies to work with the UK healthcare and research infrastructure to deliver solutions for early diagnosis and precision medicine.

- Digital Innovation Hubs: £37.5m UKRI investment in the Digital Innovation Hub Programme managed and delivered by HDR UK which is improving data discoverability, linking routine NHS and R&D data, and providing analytic tools and informatics support for businesses alongside local access to integrated UK-wide data.

2.10 Through these three strands, the Challenge intended to contribute to the long-term aims through achievements across the following key elements:

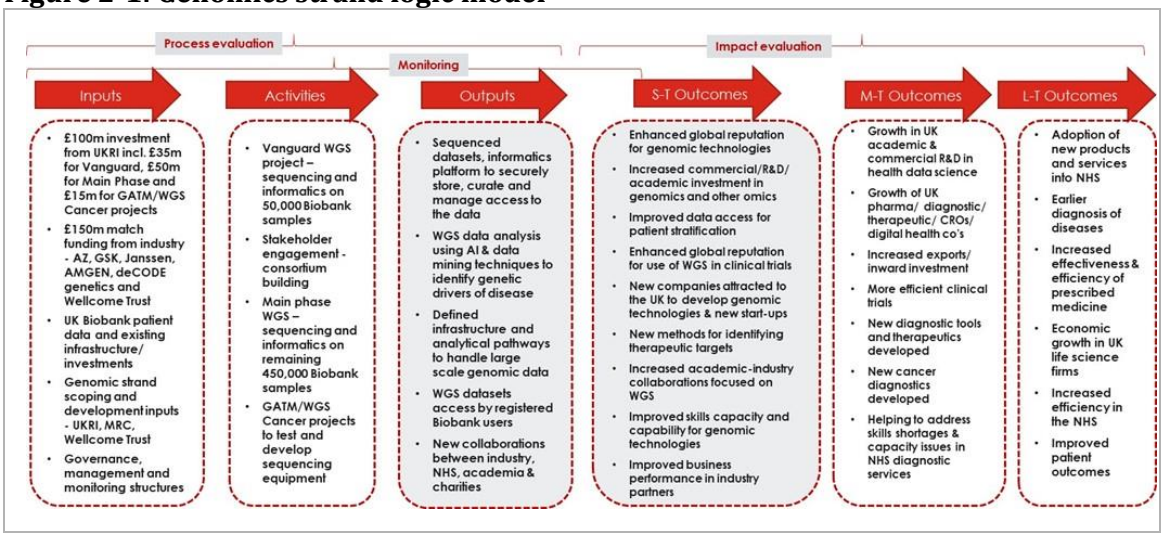
- Improved **research and innovation capacity and capability** through infrastructure (e.g. platforms and data) and data- and knowledge-sharing
- Improved **collaboration** between academia, the NHS and industry
- **Sector growth**, including through clusters of activity and inward investment
- **Acceleration in developing and using new tools** in healthcare settings
- Development of **skills, resources and trust** to implement new precision medicine approaches, products and services

Logic models

2.11 As part of developing the M&E Framework for the Challenge evaluation, we produced logic models for each of the three strands and these are shown below. These provide a summary of what the projects were expected to deliver in terms of direct outputs and then what they were expected to generate in short/ medium and longer term outcomes.

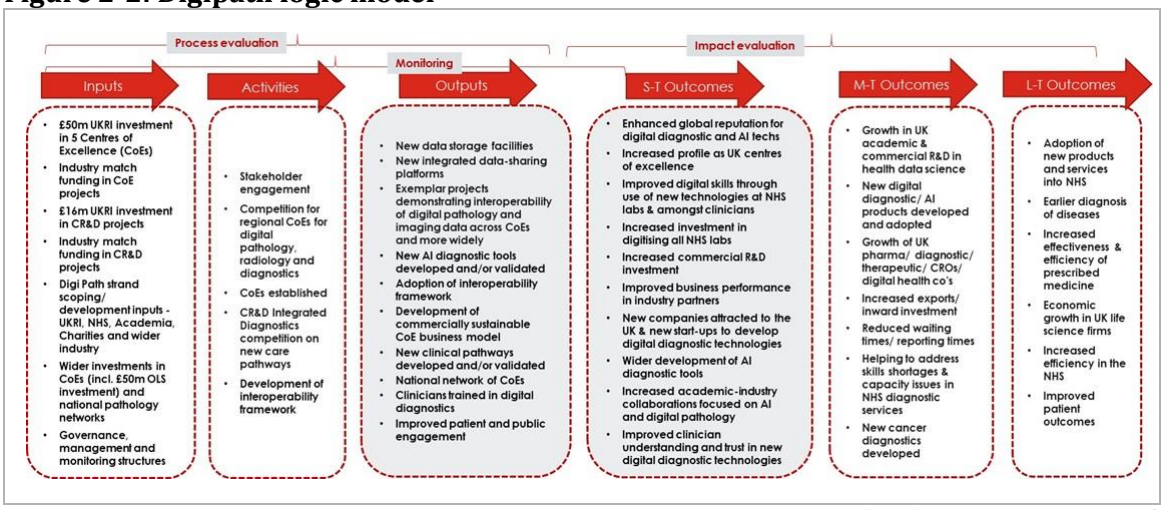
2.12 At the time of drafting the M&E Framework it was expected that all project outputs would be delivered by this stage. However, as we will go on to discuss, due to delays and project reprofiles some projects were still in the final stages of delivery at the time of evaluation.

Figure 2-1: Genomics strand logic model



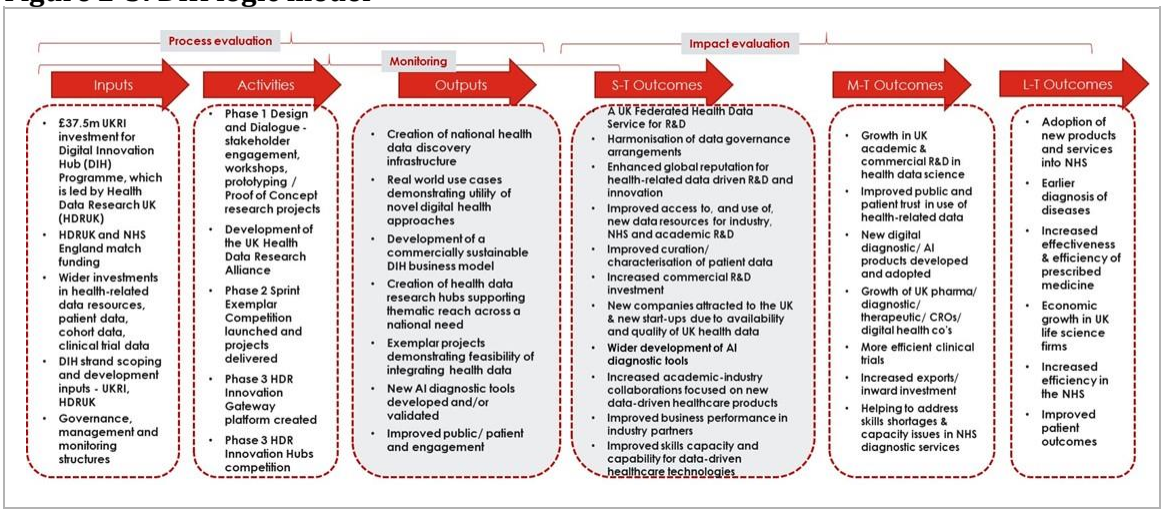
Source: SQW (2020) D2EDPM M&E Framework

Figure 2-2: Digipath logic model



Source: SQW (2020) D2EDPM M&E Framework

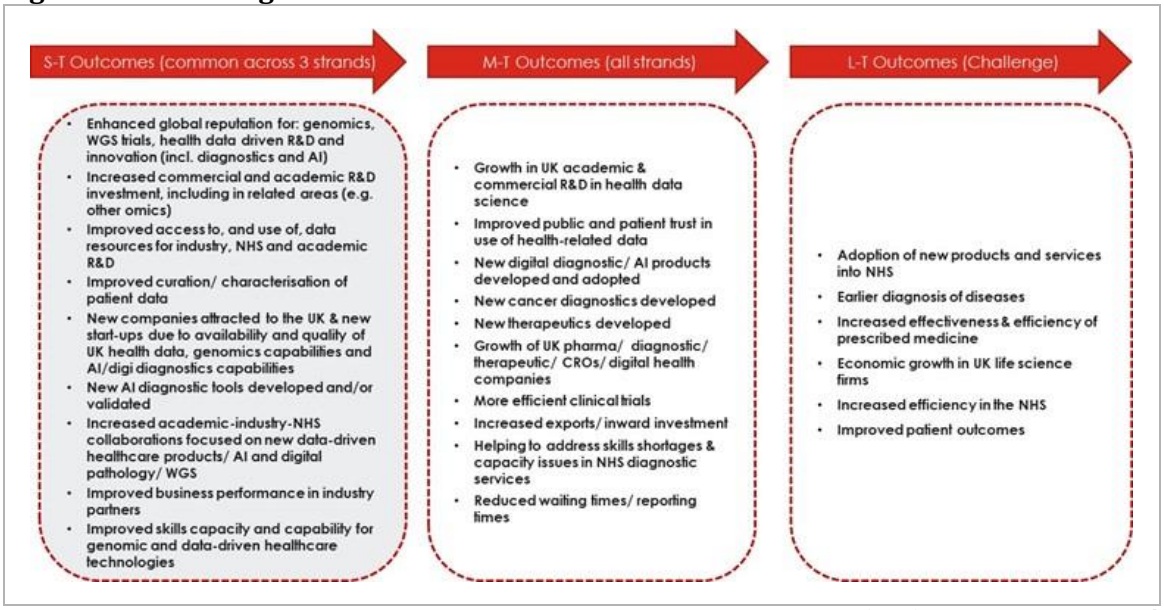
Figure 2-3: DIH logic model



Source: SQW (2020) D2EDPM M&E Framework

2.13 Figure 2-4 below draws together the key elements associated with anticipated outcomes from across the Challenge. For the purposes of this report, we have aggregated these outcomes further to provide the evidence under the following themes: R&D capacity and capability; development of healthcare innovations; and business/ commercial outcomes.

Figure 2-4: Challenge level outcomes



Source: SQW (2020) D2EDPM M&E Framework

3. Delivery progress

Spend progress

3.1 The Challenge has invested £198.0m across the three strands to date and this has been matched by £223.4m. A further £139.2m has been leveraged by project partners. Although most parts of the Challenge have completed at the time of writing there will be £8.0m in UKRI expenditure in the final months of 2023. By the end of the Challenge UKRI will have invested £206.0m across the three strands, broadly in line with the £210m announced at in 2018.

Table 3-1: Challenge spend progress

	Spend to date (as of July 2023) £m			Additional spend expected through existing project approvals	
	UKRI funding	Match-funding	Leveraged funding	UKRI funding	Match-funding
Genomics	93.73	131.61	1.56	0.93	0.05
Digipath	66.79	57.29	31.1	7.03	1.32
DIH programme	37.50	34.50	106.5	-	-
Totals	198.02	223.40	139.2	7.95	1.36

Source: SQW analysis of Challenge spend data from UKRI (DIH Programme leverage calculated by HDR UK)

Project delivery

Genomics

3.2 The UK Biobank WGS project brought together nine major industry partners (UK Biobank, GSK, AstraZeneca, Janssen/J&J, Amgen, Wellcome Sanger Institute, deCODE genetics, DNAnexus and Amazon Web Services) and successfully sequenced 500,000 Biobank participants. The successful creation of a Cloud-based Research Analysis Platform (RAP) and the public release of data from the first 200,000 genomes in September 2021 were significant milestones. The final tranche of data will be released as part of a major global launch at the end of 2023. There were technical challenges in developing the informatics platform and this caused around a nine-month delay to the project, but taking the time to solve these challenges enabled delivery of a fully functional final product.

3.3 The genomics CR&D projects were funded to use WGS to analyse cancer. The projects have all completed and have successfully delivered a range of outputs including diagnostic tools, AI tools, methods to identify therapeutic targets, publications and patents. Despite challenges

presented by the COVID-19 pandemic, particularly in terms of patient recruitment and access to sequencing capacity, the projects broadly successfully delivered their planned activities.

3.4 There have been some delays with the Genomics England (GEL) WGS in cancer trials project which aims to enhance national datasets to support research in cancer genomics as the pandemic had a major adverse effect on clinical trial recruitment. Based on the latest monitoring return the project had sequenced 1,500 cancer patients against a target of around 2,000 patients by March 2023.

Digipath

3.5 This strand of the Challenge had two main areas of activity. First there were the **five Centres of Excellence** set up to develop AI and other digital tools to improve the diagnosis of disease. Two of the Centres focused on digital pathology (NPIC and NCIMI), two aimed to develop AI tools for medical imaging (LMIAI and NCIMI) and one (ICAIRD) aimed to support the development of new tools in both digital pathology and imaging. The Centres were established in February 2019 and Challenge funding came to an end in April 2023.

3.6 Nearly 130 partners have been involved cross the five Centres, including 18 academic partners, 30 NHS organisations and 66 commercial partners (Table 3-2). Across the Centres more partners have been involved than envisaged at the outset, demonstrating the success of the projects in engaging new partners. There has been good progress in terms of creating new digital infrastructure with 22 new data storage facilities and 25 NHS sites using the new infrastructure.

3.7 There were 65 exemplar projects carried out and this figure has nearly doubled since the interim evaluation in early 2022. As a result of these exemplars, 46 AI tools were in development and 18 fully developed. There has also been significant activity in terms of research outputs with 279 publications and presentations at 325 events, including 55 overseas events.

Table 3-2: Centres of Excellence – key activities and outputs

Key activity/ output	Total for the five Centres
No. of project partners (total)	127
No. of academic partners	18
No. of NHS partners	30
No. of commercial partners	66
No. of new data storage facilities	22
No. of NHS sites using the facilities	25

Key activity/ output	Total for the five Centres
No. of fully digitalised NHS labs	8
No. digital pathology images collected (m)	1.74
No. of automated imaging reports	118,263
No. of CoE exemplar projects started	65
No. of AI tools in development	46
No. of AI tools developed	18
Training programmes developed by the CoE	14
No. of clinicians/ researchers trained	1,807
No. of PPIE events	65
No. of PPIE participants	1,168
No. of publications	279
No. of UK events to promote exemplars	270
No. of international events to promote exemplars	55

Source: SQW analysis of monitoring data from project managers

3.8 The Challenge also provided funding for **seven Integrated Diagnostics Collaborative R&D projects**. Most of these projects started in late 2020, three completed in April 2023 and the remainder will complete in late 2023 (one has been extended to April 2024). These projects have successfully developed and tested new approaches, analyses and tools to link different datasets to improve diagnostics. The main disease areas targeted by these projects have been lung disease, liver disease, different types of cancers and Crohn's disease.

3.9 The projects have involved 63 partners including 14 academic partners, 18 NHS organisations and 24 commercial partners. The remaining seven partners were charities and Academic Health Science Networks. Across the IDX Lung, ID Liver and DELTA projects there have already been nearly 8,000 patients recruited on to trials to develop new diagnostics. Although some of the projects are still live, it was reported that through the ID Liver, ACTIONED and DART projects new AI diagnostic tools have been developed. In terms of research outputs, there have been 20 publications by project partners to date.

DIH Programme

3.10 The Challenge provided funding to HDR UK to deliver the DIH Programme from September 2018 to August 2022. The aim of the Programme was to create UK-wide infrastructure for

health data research and innovation. There were three main areas of activity which have been completed in line with expectations.

3.11 The Alliance was set up in 2019 with eight founding members, the Alliance now has 75 members and brings together data providers, custodians, and curators to develop and share standards and best practice. The Innovation Gateway was launched in June 2020 as a platform to provide a central access point for researchers to access health datasets. It currently signposts 800 datasets.

3.12 The third part of the Programme was the Research Hubs. A competition was launched in 2018 to fund Research Hubs that would bring together data from "routine" NHS systems (e.g. NHS clinics, laboratories, diagnostics, primary care), and relevant registry or cohort data to curate these to provide new high value data resources for research and innovation. Five Hubs were funded through the Challenge (INSIGHT, Discover-NOW, Gut Reaction, DATA-CAN and BREATHE) and two further Hubs were funded by HDR UK (NHS Digitrials and PIONEER).

3.13 These Hubs have provided range of services including feasibility, analysis, consultancy, clinical trial design, and have focused on different disease areas including eye disease, inflammatory bowel disease, cancer and respiratory diseases. Based on HDR UK analysis, the Research Hubs (including the two HDR UK funded Hubs), have secured 200 academic and 175 commercial contracts.

3.14 Table 3-3 provides a summary of the main activities and outputs delivered through the DIH Programme. The five Hubs funded by the Challenge involved 49 partners including 20 commercial partners. They curated 149 datasets for major disease areas and delivered 138 CR&D projects. In terms of research outputs, there have been 163 publications produced by Hub partners.

Table 3-3: Health Data Research Hubs – key activities and outputs

Key activity/ output	Latest data (June 23)
No. of attendees at workshops to promote DIH programme	6,608
No. of Alliance members	75
No. of Sprint Exemplars	10
No. of partners involved in Sprint Exemplars	49
No. of commercial partners involved in Sprint Exemplars	15
No. of datasets available through the Gateway	800
Hub activities and outputs (ISCF funded)	
No. of partners involved in Research Hubs	49

Key activity/ output	Latest data (June 23)
No. of commercial partners involved in Research Hubs	20
No. of national datasets for major disease areas curated by Research Hubs	149
No. of CR&D projects delivered by Research Hubs	138
No. of data applications submitted to Research Hubs	204
No. of service users provided with advice through the DIH Hub	389
No. of individuals attending training events	6,925
No. of individuals involved in PPIE events	45,753
No. of research publications by DIH partners	162
No. of academic research contracts (incl 2 HDR UK Hubs)	201
No. of commercial research contracts (incl 2 HDR UK Hubs)	175

Source: SQW analysis of monitoring data from project managers

Delivery issues

3.15 The main delivery issues were highlighted in the process evaluation report. For the Genomics CR&D projects, data sharing and contractual issues had caused the most problems. Some projects experienced difficulties with initial data transfer and contracting arrangements with GEL. This was particularly an issue for those that did not have ethics and data sharing agreements in place. Similarly, some projects had problems with data storage and transfer from the NHS, and other consultees highlighted limited experience and expertise around IP and confidentiality agreements.

3.16 For the Centres of Excellence the main delivery issues were in relation to managing the set up and contracting phase, managing such a large number of partners and the technical challenges of integrating data from different organisations. Across all projects, there were data access issues and delays and this has been particularly for industry partners. For some of the Centres it has taken longer than expected to set up the infrastructure and data sharing processes to actually start collecting patient data from NHS partners.

3.17 In the DIH Programme, data access was also highlighted as a key challenge for the Hubs. Consultees highlighted a lack of consistency in data processes between different NHS Trusts, lack of standardisation between organisations and variable quality in the data provided which then required significant curation. Once again there was feedback from Hub partners about the reluctance to collaborate with industry, and in some cases there were misunderstandings between HDR UK and individual hubs around expectations for the project milestones.

COVID-19 disruption

3.18 The pandemic had a significant impact on the delivery of projects across the Challenge. This was not surprising given the sector and important role played by NHS partners across the Challenge. In the genomics strand, the main impact for the UK Biobank WGS project was around sequencing capacity. Fortunately for the project deCODE was able to deliver more when Sanger laboratories took on a central role in COVID sequencing. For the CR&D projects, the main challenges were delays in access to sequencing materials, samples and essential infrastructure and personnel (e.g. laboratory staff, facilities and equipment).

3.19 The lockdown measures introduced in March 2020 caused many of the Digipath project activities to be put on pause and, for the subsequent 12-18 months, there were significant delays to projects due to limited access to universities and labs, NHS staff (clinical and non-clinical) reallocated to COVID-related activities and difficulties recruiting patients for clinical trials. The disruption varied by project, for instance depending on the extent to which they were reliant on retrospective or prospective patient data.

3.20 The impact of the COVID-19 pandemic for the DIH Programme varied considerably between different Hubs, partly depending on the relevance of their clinical focus. Some of the Hubs were able to pivot to directly support the pandemic research response but this diverted attention away from original objectives. For example, one of the Hubs, BREATHE, played a key role in the COVID response but failed to deliver against the Challenge objectives. It therefore failed to pass Milestone 2 and did not receive subsequent funding.

Governance and programme management

3.21 The process evaluation considered the effectiveness of governance and programme management structure and processes across the Challenge. At the programme level the main conclusions were that the Programme Board performed well in overseeing the management of the Challenge but that the Advisory Group could have been leveraged more effectively in terms of providing advice on particular data-related issues and helping to make linkages with other parts of the health data and precision medicine landscape. Although the Advisory Group only met three times, it was reconvened in early 2023 to help UKRI and partners consider next steps in supporting the Challenge funded projects.

3.22 Under the Genomics strand, the UK Biobank WGS project was led and managed by the pharma partners. The consultee feedback across the different phases of the evaluation recognised the leadership provided by the MRC, Wellcome Trust and UKRI to manage the negotiation process with the pharma partners and two sequencing partners. Many consultees noted that the Wellcome Trust played a key convening role for the partnership prior to UKRI appointing a Challenge Director. The Challenge had two different Directors and this lack of continuity was felt to have hindered overall management.

3.23 The feedback from project leads was positive about the role of UKRI monitoring officers in tracking progress of the Collaborative R&D projects (Genomics and Integrated Diagnostics) and the Centres of Excellence. However, throughout different phases of the evaluation there has been a consistent view that the level of project management resource required for the Centres of Excellence was perhaps underestimated by the project applicants. Either projects should have built in more resource for this task or they should have focused on fewer exemplar projects. It was also suggested that UKRI should have provided more support in helping the Centres to deal with some of the challenges in working with large industry and NHS partners, and more latterly in sustainability planning.

3.24 HDR UK management of the DIH Hub programme was considered very 'hands-on' with regular informal and formal reporting and opportunities to raise and address challenges; some Hub partners referenced the informal fortnightly check-ups by HDR UK as helpful, light-touch method of keeping track. Overall consultees complimented the robust and transparent management structures and processes built into the DIH programme.

Project delivery lessons

3.25 The main lessons highlighted by Challenge funded projects are set out below.

- Contracting and setting up governance structures – the need to commit sufficient time and resource prior to application submission and then during the first few months of delivery to work through the partnership agreements, IP and contractual obligations.

- Building new platforms and data-sharing systems/ processes – for many projects this proved to be far more complicated than expected both in terms of ensuring the technical infrastructure and capability existed across NHS partners, as well as the common understanding of how data would be shared and stored.

- Ensuring sufficient capacity for storing and sharing data – some consultees highlighted the importance of having adequate physical and/or cloud-based storage not just to store data but also to enable data transfer. The costs of these, including maintenance of data, were highlighted as areas where more support was needed, with thought needed on how costs could be covered beyond completion of the project to keep data accessible.

- Improving access to high quality of data – many projects commented on the poor quality of NHS data and the amount of time and resource required for data curation. In order to develop and test new PM products, projects needed access to high quality clinically annotated datasets and effective trusted research environments.

- Creating the right size of consortium – the feedback highlighted examples of projects with potentially too many NHS partners and/or too many industry partners. These types of project should involve significant scoping to understand the right size of consortium to ensure the project can be managed and monitored effectively.

- Meeting industry data access requirements – the projects generally made progress in terms of accelerating access to patient data. However, there were some frustrations where industry partners experienced long delays in getting approvals to access data (highlighted as being a particular issue for small start-ups). There was a related lesson around managing expectations and ensuring good ongoing communication with project partners about any issues regarding data access.

- Ensuring diverse patient data – EDI was already a priority for most project delivery partners but more needed to be done to improve the diversity of patient data. For some projects the diversity of the data was determined by the profile of the samples but there was increasing awareness of the need to be able to integrate datasets to collect larger more diverse data. Our Future Health should help to improve on the lack of diversity within UK Biobank.

- Ensuring realistic timescales – even if there had been no pandemic, many projects would have struggled to generate the desired outcomes and impacts over a three year period. Many consultees suggested that investments such as the Centres, where there is an infrastructure component and complexity around partnerships and data flows, should be funded for at least 5 years.

- Building in sustainability requirements – given the focus of the projects on creating new platforms, infrastructure and capability to develop new AI tools and digital diagnostics, it was suggested that there should have been a stronger focus on how projects could build on the initial Challenge funding to progress towards sustainability to ensure a legacy for the infrastructure developed.

- More facilitation of the wider ecosystem – many consultees believed that UKRI should have been more proactive in promoting the projects, encouraging collaboration between projects and other strands of the Challenge. It was also stated that there should have been closer strategic alignment between NHSE and UKRI so that the Centres could have acted as the pilots for the new sub national SDEs (Secure Data Environments). Some of these linkages are being strengthened at the end of the Challenge funding period. For example, the English based CoEs will be integrated into the regional NHSE SDEs. The Health Data Research Hubs have also strengthened their relationships with NHSE and the Gateway will also play a key role in relation to the data catalogue function of the SDEs.

4. Development of R&D capacity and capability

4.1 This section sets out the evidence on the achievements in relation to the development of R&D capacity and capability. First, we examine the broader trends in activity in relation to research in precision medicine, and then we look strand by strand at the key evidence.

Increasing interest and activity in the wider PM sector

4.2 During the Challenge period there have been some significant changes in the R&D capacity and capability of the wider PM sector. Peer-reviewed academic publications typically precede clinical uptake of innovations and so this is a helpful proxy indicator for the research activity, interest and general awareness of PM tools and approaches. As shown in Table 4-1, there has been a major increase in the number of publications mentioning AI and Machine Learning, growing by 765% from 52 publications in 2017 to 450 in 2022. Publications mentioning Digital Pathology have grown substantially from a relatively low base, and those mentioning Precision or Personalised Medicine have more than doubled from 2017 to 2022.

Table 4-1: Number of publications relating to PM

PubMed publications search terms	2017	2018	2019	2020	2021	2022	% change
Genomics and Genetics	1278	1336	1502	1715	1911	1741	36%
AI and Machine Learning	52	105	174	254	386	450	765%
Precision or Personalised Medicine	463	586	672	879	1027	1048	126%
Pharmacogenomics or Pharmacogenetics	193	179	195	205	241	184	-5%
Digital Pathology	20	19	35	42	76	59	195%
Precision Diagnosis or Early Diagnosis	231	252	293	280	300	259	12%

Source: PHG analysis of PubMed

Genomics strand outcomes

4.3 As we summarise below, **the UK Biobank WGS project has delivered outcomes such as improved industry collaboration and improved capacity and capability** around the use of WGS. **It has also strengthened the UK's global reputation for WGS and increased the profile of the UK Biobank more generally**. The CR&D projects have delivered enhanced sequenced datasets, improved skills and experience in genomic technologies and increased collaborations across a range of partners.

UK Biobank Whole Genome Sequencing project

The project involved the whole genome sequencing (WGS) of all 500,000 Biobank participants and involved the following partners: UK Biobank, GSK, AstraZeneca, J&J, Amgen, Wellcome Sanger Institute, and deCODE genetics, with the Wellcome Trust also providing funding. The Sanger Institute and deCODE carried out the sequencing.

The data was released in two stages, with the first 150,000 sequences, together with the 50,000 sequences from the Vanguard phase, being released in 2021. The remaining data was released to industry partners in February 2023 and is due to be released to the wider UK Biobank community towards the end of the year.

Sanger and deCODE each sequenced half of the participants. deCODE sequenced more than originally planned highlighting the benefit of having two centres involved and the role of regular communication. It was highlighted that the quality and organisation of UK Biobank helped the project to be successful, as samples were of good integrity and quality, and the supporting information that came with them was accurate.

Project outcomes

The data from all 500,000 sequences was only recently released to industry partners in February 2023, and consultees stated that many of the outcomes will take many years, or even decades, to be seen. However, there were some initial outcomes beginning to emerge. Consultees stated that the WGS of the UK Biobank has increased the UK's global reputation for genomics – many stated that the UK Biobank is held up as a gold standard and international exemplar, particularly in terms of data availability and sharing policies. The successful partnership model has also influenced other major studies such as Our Future Health.

The Sanger Institute recognised the benefits of the project in terms of their sequencing capacity and capability, highlighting that they now have more robust and professionalised processes in place that enable them to take on much larger sequencing projects than previously possible. For example, improvements were made to sample management pipelines, including the adoption of barcoding, and they were able to improve the integrity of the samples via improvements in workflows. During the COVID-19 pandemic, where they were able to adapt these processes to enable sequencing of SARS-CoV-2 at scale. WSI was the central sequencing hub of the COVID-19 Genomics UK (COG-UK) consortium, which processed positive PCR samples from the Lighthouse Laboratories.

Consultees highlighted significant benefits around the collaborations and partnerships that resulted from the project. The industry partners were seen as having access to WGS data and associated expertise so were more attractive collaborators for biotech companies and others who want to make use of this. However, there were some concerns that the wider UK environment might limit future benefits. One concern was challenges getting new drugs approved for use on the NHS. Industry partners may reduce the investments made in the UK if drugs produced as a result are not approved by NICE. Another was around skill shortages in the UK.

Contribution of the Challenge

Without the Challenge, it was thought that this project would not have happened at the same scope or within the same timeframe. Interviewees thought that smaller amounts of funding might have contributed to WGS of subsets of UK Biobank participants in a

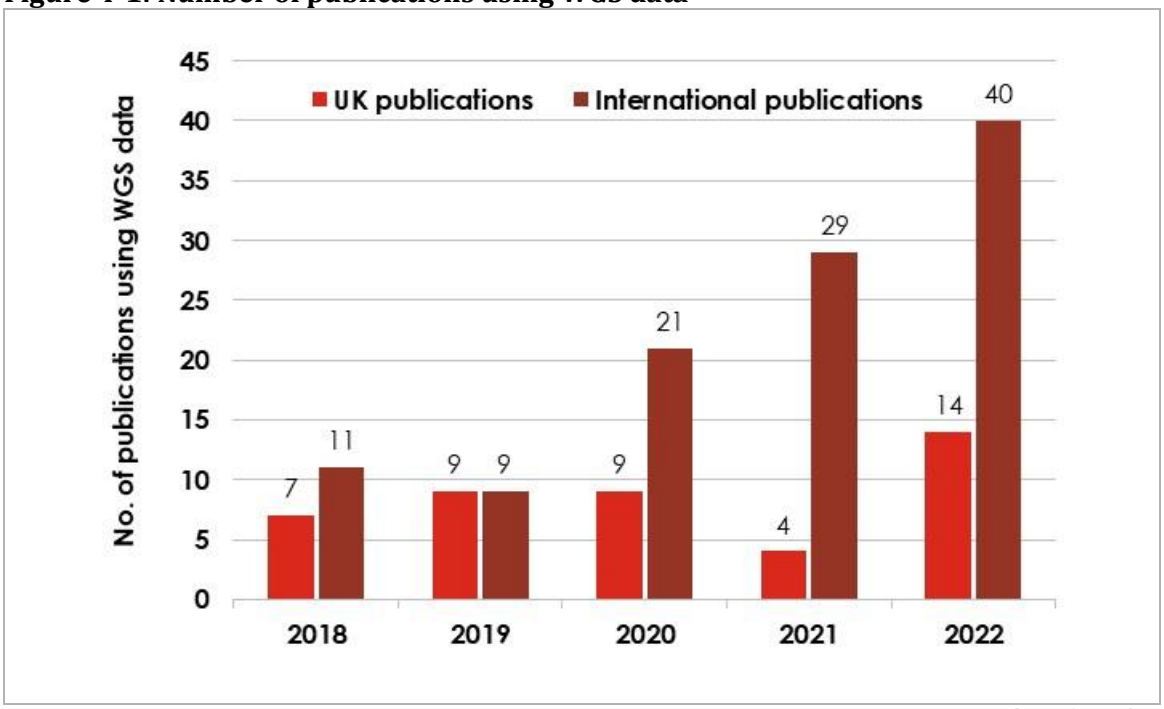
more fragmented approached, which would have made later analysis and integration of the data much more challenging.

The Challenge funding model meant that industry partners were able to contribute, as the presence of Government funding reduced the risk of investment and brought legitimacy to the project. There is not enough benefit for industry partners to undertake large population level sequencing projects, including WGS of the UK Biobank and Our Future Health, without additional funding and coordination. Involvement of UKRI also gave endorsement and quality control, enabling the bringing together of partners that might not usually collaborate.

4.4 As part of the evaluation we requested data from the UK Biobank on demand for the new WGS datasets. **The growth in the number of approved researcher registrations and the number of research projects using UK Biobank data over the past five years shows highlight an increase in demand from the research community to use UK Biobank data**. Most of the growth has come from international researchers, corroborating the perceptions around the UK's growing global profile.

4.5 A more specific indicator of how the new WGS dataset has been used so far relates to the number of publications. This has increased from 18 publications in 2018 using the WGS data (presumably from the Vanguard phase of the project) to 54 publications in 2022 after the public release of the first tranche of data (Figure 4-1).

Figure 4-1: Number of publications using WGS data



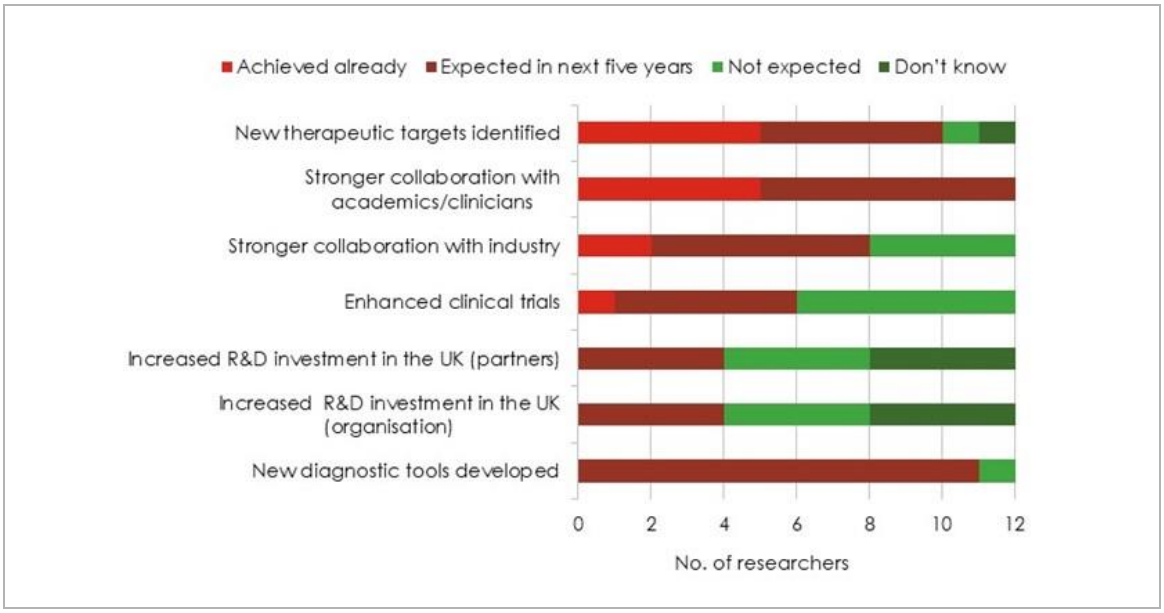
Source: SQW analysis of UKB data

UK Biobank researcher survey

4.6 The Whole Genome Sequencing (WGS) of the UK Biobank was one of the flagship projects funded through the Challenge. In addition to discussing the performance of the project with the main partners we undertook a short survey of researchers to understand the difference this new dataset is making for the wider scientific community. Based on a list of 85 researchers provided by the UK Biobank, we received feedback from 29 researchers, including 12 who had successfully accessed the WGS dataset.

4.7 Nine of the 12 researchers reported outputs from using the WGS dataset conference presentations and published research papers. Three researchers reported that, at the time of the survey, it was too early to have experienced any direct outputs. **All researchers had achieved or expected to achieve benefits from their research such as the identification of new therapeutic targets, stronger collaborations with academics/clinicians/ industry. Most of the respondents also expect to have developed new diagnostics tools over the next five years**. Around half of the researchers reported that the benefits would not be realised without the new WGS data and the other half stated the benefits would have been at a lower quality scale or they would have taken longer.

Figure 4-2: Achieved and expected benefits associated with research projects using the WGS dataset



Source: IFF/ SQW survey of UK Biobank researchers

Digipath strand outcomes

4.8 The Centres of Excellence have delivered a wide range of new infrastructure for collecting, sharing and storing data. ICAIRD, NCIMI, PathLAKE and NPIC have all successfully established new data storage facilities and platforms. LMIAI has successfully delivered and deployed two major software platforms, the Federate Learning and Interoperability Platform (for R&D) and

the AI Deployment Engine (a platform for delivery of models into clinical care). Some of the key achievements were as follows:

- 22 new storage facilities
- 25 NHS partners using the facilities
- 8 digitised labs.

4.9 As highlighted earlier the Centres of Excellence have brought together a large number of partners from academia, the NHS and industry. New relationships have been created and there were many examples of collaborations beyond the Challenge funded projects. The Centres and IDx projects have provided a catalyst for new collaborations to take forward new innovations. Many of the projects have also delivered training/ guidance for pathologists and radiologists e.g. on the use of new digital scanners and AI imaging platforms.

4.10 The case study boxes below cover two of the Centres and illustrate how digital pathology equipment and training has developed the R&D capacity and capabilities for R&D and clinical settings (NPIC) and how AI capacity development has put in place key foundations for future progress (LMIAI).

NPIC – digital pathology training

The Northern Pathology Imaging Co-operative (NPIC) was one of five Centres of Excellence and led by the University of Leeds and Leeds Teaching Hospitals NHS Trust. It also included a network of six NHS partners across West Yorkshire and Harrogate, six universities across the North and ten industry partners. The project began in February 2019 and ended in March 2023. NPIC deployed new digital pathology scanners into the partner NHS hospitals, and developed digital infrastructure to allow data to be shared more easily for both clinical and R&D purposes.

NPIC included a work package to train and support pathologists to adopt the new digital technology. The team at Leeds Teaching Hospitals published The Leeds Guide to Digital Pathology in 2018 to explain the benefits of digital pathology and provided practical information on clinical deployment based on their extensive experience and knowledge. Each of the NHS sites received training on the day-to-day deployment and use of digital pathology equipment, with more technical training for scanner operators provided by the scanner providers, including Leica Biosystems.

The adoption of digital pathology has also been supported by the development of an online screen assessment tool which allows pathologists to test whether their display is suitable to view digitised slides. This has had over 3,000 uses since it was launched in 2020. The tool allows pathologists to have the confidence to work from home because they know their screen is suitable. The assessment tool was promoted 150 attendees on a webinar which was delivered as part of the OLS scale-up NPIC.

Project outcomes

Scanners will be installed across all participating sites and connected to the digital infrastructure (for sharing files) by March 2023. Experience from Leeds Teaching Hospitals suggests that it may take 12-24 months for users to 'get comfortable' with the digital processes, and for benefits around the use of digital diagnostics for improved diagnosis to become evident.

In the shorter term, emerging benefits include an improved clinical understanding and trust in new digital diagnostic technologies and helping to address workforce challenges were reported. First, NPIC and its digital pathology training have allowed clinicians to work from home which has improved their work/life balance and promoted staff retention, including individual examples of pathologists who have stayed in the labour force for longer than might otherwise be the case. This supports levels of capacity across the NHS, thus helping to address wider workforce challenges.

Second, the digital equipment at Leeds Teaching Hospitals which was installed pre-pandemic allowed the institution to provide continuity of education to junior pathologists during lockdown. When it was not possible to access labs to use glass slides and microscopes, teaching could be done remotely via screen sharing. This supports the next generation of digital pathologists.

Role of the Challenge

The Challenge played a central role in enabling the training through providing the infrastructure and also resourcing the partners to then deliver the training. Other factors have contributed to the emerging outcomes including the NHSE investment through the Digital Diagnostics Capability Programme and also the pandemic stimulated people to think about different ways of working. Adopting a digital pathology approach is one way of offering NHS staff greater flexibility and an improved work/life balance.

LMIAI – AI capacity development and training

The London Medical Imaging & AI Centre for Value Based Healthcare (LMIAI) was a Centre of Excellence led by King's College London and the Guy's and Thomas' NHS Foundation Trust. The Centre was based within the St Thomas' Hospital MedTech Hub. The LMIAI community brought together ten NHS Trusts, four Universities, a number of multi-national industry partners (including Siemens Healthineers, NVIDIA, IBM and GSK), ten UK-based SMEs, and the Health Innovation Network. The project began in February 2019 and ended in March 2023.

At the core of LMIAI, there were a number of exemplar projects exploring medical innovation and treatment for some of the UK's most common and destructive diseases including heart disease, cancer and strokes. By March 2023, the Centre had supported a total of 13 projects, of which three had been completed, two were in clinical testing, four in development, and four had not yet begun development . The projects were all highly collaborative, with leading roles for industry alongside inputs from NHS and academic partners.

A key value proposition for the Centre was its role in facilitating access to patient data. However, setting this up took much longer than anticipated due to the complexity of the task. This meant that projects were not able to go ahead with their original plans at the

outset, with some of them adapting by revising project scope (e.g. to factor in alternative data sources) whilst others opted to pause all activity until data access was set up (which led to some delays in delivering the projects).

In addition, the Centre facilitated the Fellowships in Clinical Artificial Intelligence, a year-long programme set up to train a generation of NHS leaders to deliver the transformational power of AI in healthcare. Although the Fellowships were funded primarily by Health Education England, it would not have been possible without access to the staff and facilities funded by the ISCF Challenge.

Project outcomes

The collaborative projects have provided clinicians with opportunities to provide inputs and make sure that the technologies being developed are tailored to real clinical need. The ongoing engagement with NHS teams as part of the projects has helped to improve clinical understanding of and trust in AI-enabled technologies, including the opportunities these may bring within the NHS.

There have also been other ways in which the Centre has provided thought leadership and access to expert. For example, Guy's and St Thomas' Hospital Trust set up an AI Board in 2019 to help with the procurement of AI. The Board included people from LMIAI as expert members which gave the hospital confidence in relation to the more technical aspects.

The Fellowships were considered to have been a success, providing the first systematic route in the UK for clinicians to acquire the relevant skills in clinical AI deployment. The programme was expected to welcome its second cohort in July 2023. For Cohort 3, they are considering introducing industry placements which could involve some of the LMIAI partners.

Role of the Challenge

Consultees were clear that without funding from Challenge, none of the activity would have gone ahead. This was largely attributed to a lack of alternative funding sources that would have provided a similar level of funding over a similar time period.

DIH Programme outcomes

4.11 The DIH Programme has made significant progress in terms of trying to bring together the health data landscape.

- The Alliance has grown from eight founding members to 75 data controllers and data custodians including a range of Government bodies, NHS organisations, public sector, charities, and industry partners. This structure has helped improve understand and awareness of the key health data issues and has informed the production of lots of important guidance and policy papers.

- The Innovation Gateway provides an important platform to provide a central access point for researchers. It provides access to 800 datasets which is significant progress compared to the 18 datasets that were previously available through NIHR's Health Data Finder.

4.12 Examples of some of the important outcomes generated by the Challenge funded Hubs are provided below. Through strong and effective collaborations these Hubs have successfully collected and curated datasets which has helped improve the understanding of how to diagnose faster and then treat a range of diseases and health conditions.

Gut Reaction Research Hub

Gut Reaction is the Health Data Research Hub for Inflammatory Bowel disease (IBD) which includes Crohn's disease and ulcerative colitis. Gut Reaction provides a secure data resource designed to facilitate academic and industry research in IBD. The Hub is led by Cambridge University Hospitals NHS Foundation Trust in partnership with Crohn's and Colitis UK, NIHR BioResource, Wellcome Sanger Institute, IBD registry, Privitar and AIMES. This Hub brings together NHS trusts, industry and patients. The Hub was funded by the Challenge from 2019 to 2022.

Gut Reaction has created a secure data resource containing real-world data representing 36,000 IBD patients from 14 NHS trusts. They have data from patients with Crohn's disease and ulcerative colitis consented through the NIHR Bioresource for their data to be used in research. This data includes genomics profiles along with digital pathology, images, hospital episode statistics, and available samples for further research.

Gut Reaction is now considered to be sustainable and has been absorbed into NIHR BioResource primarily using a mix of academic, charity and industry funding. As a result, the Hub is now working at a smaller scale than during the Challenge and their focus has shifted from curating and expanding on their data resources to making the best use of their existing datasets.

Project outcomes

Gut Reaction has created a lasting data resource which has the potential to provide key data to unlock personalised medicine for IBD patients. Genomic, phenotypic and treatment data is available which can be used to identify signatures associated with disease course. While this research is in the early stages, there is enormous potential for this data to be used to develop innovations that significantly improve patient outcomes in the future. For IBD, the real value is in correlating long-term treatment outcomes and other types of longitudinal data to identify factors associated with disease course.

In a test use case, Gut Reaction collaborated with a pharma company who sought to investigate genes and clinical classifications of interest. Gut Reaction data represented a unique opportunity to use this multi-modal data to create patient digital 'fingerprints' from patient histology, genetic and laboratory test results data. This could be used to better define the sub-types of IBD leading to more accurate and speedy diagnostics of patients, unlocking personalised treatment for IBD patients instead of a 'one-size-fits-all' approach. The study with the pharma partner involved the Patient Advisory Committee agreeing to the transfer of data to the company's secure data environment (SDE). Importantly, the company was able to demonstrate that they met requirements in terms of data security, access requirements, duration data would be held for and data disposal. This experience was important for defining the regulatory and legal framework for secure data-sharing that permits data to move from the Hub's TRE to the company's SDE.

Gut Reaction put patients with IBD and the public at the centre of the Hub's work to improve treatments and outcomes for patients through responsible use of patient data. Over 1,600 patients and members of the public have attended meetings and other events

and the animation describing the programme has been viewed over 1,500 times. Five webinars involving the Patient Advisory Committee (PAC) have taken place and a number of blogs and news articles have been co-developed by PPIE representatives. Crohn's and Colitis UK have been key partners to facilitate PPI engagement and access a wider audience to recruit new members to ensure diverse views and experiences.

Role of the Challenge

The Challenge fund accelerated access to NHS data for research for this disease group and building infrastructure of this type would not have been possible otherwise. The development of the IBD Hub was significantly informed by the 'sprint exemplar' focused on rare disease and this formed the foundations of their approach to the IBD Hub.

INSIGHT Research Hub

INSIGHT is the health data research hub for eye health. This NHS-led partnership has established a process to make routinely collected eye data available for health research. INSIGHT's primary aim is to benefit patients and the NHS. They do this by making it easier for trusted organisations to undertake research using large-scale anonymous patient data. INSIGHT is a collaboration between six partners: University Hospitals Birmingham NHS Foundation Trust (DIH lead institution), Moorfields Eye Hospital NHS Foundation Trust, The University of Birmingham, Roche, Google and Action Against AMD. INSIGHT started as a research project in 2015 with DeepMind Technologies and Moorfields Eye Hospital. The Hub was funded by the Challenge from 2019 to 2022.

Project outcomes

INSIGHT has published 12 platinum-rated datasets, featured on the Innovation Gateway, representing the world's largest ophthalmic bioresource with over 25 million retinal images and associated clinical data. This rating is assessed by HDR UK. INSIGHT has extended expertise and advice, and, as of October 2022, supported the submission of 12 Data Use Applications. These applications are from multi-sector research users across the pharma and tech industries, SMEs, the charity sector, NHS and global policy. Each of these applications has progressed to different stages of access management, negotiation, data licensing and delivery. This highlights how successful INSIGHT have been establishing a data access process that works for any sector, key to harnessing data for research and development, and innovation.

In December 2021, the first Data License Agreement was agreed between Moorfields and an industry research user for the AMD dataset, securing high value return to the NHS particularly in terms of investment in advanced AMD patient services at the trust. This agreement was a cornerstone for hub sustainability for the next financial year and into 2023-24. The learnings from negotiations with industry have informed the Hub's 'industry playbook' for market engagement. INSIGHT approach this engagement from multiple angles, considering networking and marketing through to business engagement and support. Their approach is also tailored by learning and the Hub has refined their approach to SMEs.

Role of the Challenge

There was consensus between interviewees that INSIGHT would have continued to develop from foundations established in collaboration with DeepMind, but this would have been a significantly slower process. The Challenge funding in effect supercharged this hub allowing them to build this infrastructure faster and, through this collaboration, build representative datasets from two large NHS Trusts.

Summary of outcomes and Challenge contribution

4.13 Most of the evidence indicated that without the Challenge funding it would have been highly unlikely that the UK Biobank WGS project would have happened. The funding helped de-risk the industry investment and added credibility to the project. It was also seen as unlikely that NHS and academic partners could have funded the new infrastructure, facilities and equipment to produce, store and analyse the data across the Centres and IDx projects.

4.14 There was also high levels of additionality in relation to the DIH Programme in terms of the Alliance and Innovation Gateway and Hub collaborations. Many consultees highlighted that the scale of collaboration in the Challenge was significantly different to their previous R&D projects and that this scale of engagement simply could not have happened without the Challenge. It was felt that the scale of investment provided a real catalyst for collaboration.

5. Progress of innovations towards impacting on healthcare

5.1 This section provides evidence on the progress of innovations. First, we set out contextual evidence on the clinical adoption of new PM technologies and industry R&D, and then we set out evidence on the different strands of the Challenge.

Development of new PM technologies and approaches

Clinical adoption of new PM technologies

Our review of various metrics relating to the clinical adoption of PM technologies suggests there have been some improvements in the wider landscape but potentially some constraints and progress has most likely been impacted by wider factors such as Brexit and the pandemic.

The NIHR's Health Technology Assessment Programme carries out evaluations of new health technologies. Over the course of the Challenge there has been a general increase in HTA publications relating to PM technologies over though the number seems to fluctuate with a peak of 28 in 2020 and a reduction in 2022 (down to 11).

In addition the total number of PM relevant publications by NICE has generally increased over the period of the Challenge, rising for example from 22 in 2017 to 34 in 2022.

The number of genomic diagnostic tests available for use in the NHS has more than doubled over the course of the Challenge from around 1,100 in 2018 to just over 2,200. The overall number of innovations supported by the NHS Accelerated Access Collaborative (AAC) increased from around 2,700 in 2019/20 to c.3,700 in 2020/21 before falling back to 3,100 in 2021/22.

However our analysis of the ClinicalTrials.gov website shows that the number of trials involving PM has declined slightly from around or just under 40 per annum in 2017 to 2019 to around or just over 30 per annum in 2020 to 2022. This drop should naturally be viewed in the context of wider clinical trial activity in the UK over the same period, which saw a much greater fall of 41% from 2017-2021[11].

There have been lots of factors which may have contributed to more activity around PM in the UK over the last five years. This would include the setting up of the NHS National Genomic Medicine Service in 2018, the restructuring of NHSE and changes in the regulatory landscape with the MHRA taking on sole responsibility for regulation of new healthcare products.

R&D investment in PM companies

5.2 A bespoke database of data driven healthcare and precision medicine companies was developed as part of the evaluation and is described in more detail in Section 6. This database

[11] www.abpi.org.uk/publications/rescuing-the-uk-industry-clinical-trials/

contains information on Innovate UK funding and external investment (only publicly announced deals) received by companies over recent years.

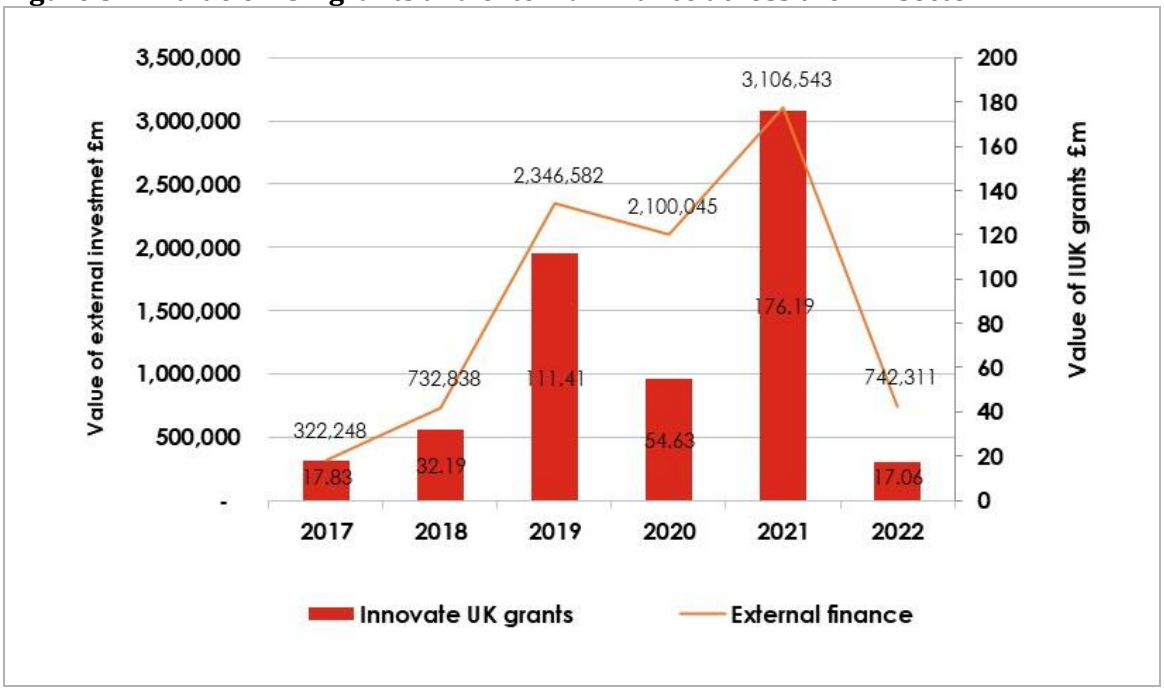
5.3 In 2017, there were 44 deals totalling £322bn (Figure 5-1). The value of external investments reached £3.1tn in 2021 but this fell back to £742bn in 2022 with 70 deals completed.

5.4 In terms of Innovate UK support, 36 businesses secured £17.8m in grant funding in 2016/17. Since then, the funding has fluctuated to £111.4m (to 110 firms) in 2018/19 and then back to £17.1m provided to 26 businesses in 2021/22.

5.5 The spike in Innovate UK grant support in 2018/19 is likely to be, in part, due to companies successfully applying for grants through the Wave 1 and Wave 2 Industrial Strategy Challenge Funds (including D2EDPM) as well as other competitions such as Precision Medicine Technologies: Shaping the Future and the Digital Health Technology Catalyst. The major increase in funding in 2021 aligns with other data highlighting record levels of investment in the UK life sciences sector.

5.6 The scale of financial support being provided to PM companies over the last five years highlights that there are other key factors driving R&D activity in the sector (i.e. from other UKRI funding in addition to the ISCF funding, and external investment from private sector sources).

Figure 5-1: Value of IUK grants and external finance across the PM sector



*Source: Impact Data Metrics * 2022 date for 9 months only*

Genomics strand outcomes

5.7 Based on data provided by four of the Genomics CR&D projects there has been some progression in the development of seven new tools developed through the Challenge funded competition. Table 5-1 highlights the median and average TRLs (Technology Readiness Level) at the start of the project and then its latest TRL.

5.8 Around £0.5m in additional and follow-on R&D investment has been secured by these four projects, with a mix of internal R&D spend and Innovate UK grants. Another £1.8m has been secured by the GEL project.

Table 5-1: Genomics CR&D projects - development status of key tools and techs

	Project 1	Project 2	Project 3	Project 4
No. of tools/tech	2	3	1	1
Median TRL – at start	2.5	1	4	3
Median TRL - latest	3.5	7	7	5
Average TRL – at start	2.5	1	4	3
Average TRL - at finish	3.5	6.33	7	5
No. now at deployment phase (TRL 7-9)	0	2	1	0
No. now at TRL9	0	1	0	0

Source: SQW analysis of monitoring data

5.9 Two of the Genomics CR&D projects are profiled below. They demonstrate some early benefits in terms of offering cancer patients additional treatment options, helping to inform the Genomic Medicine Service Test Directory, and helping to develop combined imaging and WGS products for treating cancer and COVID.

Genomics CR&D project - CUP-COMP/Roche

The project was led by Roche. A key priority of this project was to understand the comparative value of adding in liquid biopsy or WGS of solid biopsy samples in patients with cancer of unknown primary (CUP), to potentially enable faster access to a targeted therapy. A secondary objective was to see if, using multi-omic data alongside clinical information, it would be possible to determine likely responses to treatment via modelling approaches to create a predictive algorithm.

The project was in the final stages when interviews were conducted. It had received an extension from UKRI from December 2022 to March 2023 to enable recruitment

of more patients, bringing the target total to 100 to 120 patients. Progress was being made towards this goal, having recruited 93 patients by December.

The COVID-19 pandemic slowed recruitment for some time, with recruitment only just starting to return to pre-pandemic levels in early 2023. Delays were compounded as even once restrictions were lifted, patients were presenting at stages too late for treatment and clinical trial participation until the end of 2022. A shortage of bioinformaticians to analyse the sequencing data further slowed progress on the project.

By March 2023 all patients were expected to have had liquid biopsy profiles, and as many as possible to have had WGS, combined with other clinical information. Work was ongoing compiling overall data, including outcome data, for the end of the project. The first analysis of using WGS and biopsy data to develop predictive algorithms was underway, but efficacy was not expected to be known until the end of the project, and health economic work was also underway.

Project outcomes

Although it is too early to see wider impact on the healthcare sector, there have been significant benefits for individual patients by providing additional treatment options. Many patients followed different treatment pathways that had a positive impact as a result. There was also a reduction in time spent in multi-disciplinary team (MDT) discussions and decision-making, especially for more complex cancer cases.

An additional benefit for the Northwest and Northeast NHS trusts involved in this project was improvements to their referral processes, in particular for genetic testing. Clinician engagement was seen as being vital, as project 'champions' supported patient recruitment, ensuring multiple sites were able to recruit to the project.

Another benefit was contributing to the recent NHS England (NHSE) decision to introduce WGS for cancers of unknown origin in the NHS Genomic Medicine Service (GMS) National Test Directory. However, the project findings now show that liquid biopsy is more effective, as the NHS tumour biopsy tissue fresh/frozen pathway adds a lot of complexity and cost. In fact, even a simpler panel testing approach instead of WGS could have produced faster and cheaper results. Partners were in ongoing dialogue with NHSE on this issue, especially around formal commissioning of liquid biopsy for patients where tissue biopsy for WGS analysis is not possible. Additionally, discussions with Genomics England were ongoing to see whether the health economics findings from this project can inform or support an alternative lung cancer pilot.

Role of the Challenge

Without the Challenge funding the project may still have gone ahead but would have had a narrower scope, with fewer partners and fewer sites involved. Another contribution of the Challenge was that the resulting data was to be deposited in the Genomics England (GEL) dataset for use by other researchers, which otherwise might not have happened.

Genomics CR&D project - Perspectum

The primary aim of this project was to carry out the Precision One trial, with the goal of developing a liver cancer product, Hepatica. Perspectum is an imaging-based medical technology company but wanted to expand to integrate WGS into the product and diversify the information they can provide to customers. Further goals included how to offer and commercialise outcomes, while ensuring WGS as a service is clinically useful. The project was a collaboration with University of Oxford, and the trial was undertaken at Hampshire Hospitals NHS Foundation Trust.

90 samples of blood or liver tumour tissue were collected, prepared by the inhouse laboratory, and sent to partners for sequencing. A bioinformatics pipeline, set up for the project, was followed to analyse and interpret data. Interpreted data was presented to MDT meetings to evaluate the clinical usefulness of information from WGS.

Future outputs were expected to be academic papers and the development of Hepatica to include a form of genetic service. This will mean Perspectum's future service will progress from just imaging to also include genetics. One of the key reasons for success of the was that all involved were highly engaged and highly collaborative, across industry, academia, and the NHS. Partners maintained regular communication and were all working to achieve a common goal. Interviewees mentioned having seen other projects where collaborators were not as engaged, with this having a large impact and reducing success of the overall project.

Project outcomes

The clinical and industry partners had worked together previously, but the relationship has been further developed through this project. This has brought wide-reaching benefits, beyond the project itself, since the clinical collaborators were surgeons and so potential future customers for the product. Further, they can communicate within their networks about Perspectum and Hepatica to expand the potential customer base.

In terms of business benefits, Perspectum were able to upskill and diversify the work they do by adding genetic capabilities to their imaging expertise. They did not attribute any turnover for this yet but expected this to increase once the product (Hepatica) goes to market. Through the project new routes to market were opened through the new data produced and the development of an inhouse laboratory to process samples. The new laboratory enabled work that had previously been subcontracted to the University of Oxford to be carried out in-house.

The development work carried out on Hepatica also informed another product CoverScan to monitor organ function in COVID patients. The company carried out a clinical trial and it is now being rolled out to a range of NHS sites for clinical deployment.

Role of the Challenge

Without the Challenge funding, the project would not have been done to the same extent, if at all, since the company's R&D budget was not big enough to support the trial, particularly during COVID-19. The project may have been conducted further in the future but would have been in the much longer term, if or when investment made the money available. Further, being able to collaborate with academia and clinical

partners was key for the project but if funding had not been available for University of Oxford and the NHS Trusts, then this part of the project would not have happened.

Digipath

5.10 Four of the five Centres provided information on the TRL of new tools and technologies that were developed through exemplar projects. Table 5-2 highlights the median and average TRLs (Technology Readiness Level) at the start of the project and then its latest TRL. Across all the Centres they provided support to tools at different stages of the development process.

Table 5-2: Centre of Excellence – development status of key tools and techs

	ICAIRD	LMIAI	PathLAKE	NCIMI
No. of tools/technologies	11	12	9	9
Median TRL - at start	1	3	1	6
Median TRL - latest	6	6	4	9
Average TRL - at start	2.3	3	1	4
Average TRL - at finish	7.0	6	4	8
No. now at deployment phase (TRL 7-9)	5	5	1	7
No. now at TRL9	4	0	0	7

Source: SQW analysis of monitoring data

5.11 TRL data was also provided by six of the IDx projects (Table 5-3).

Table 5-3: IDx projects - development status of key tools and techs

	IDX Lung	ID LIVER	INCISE	DELTA	ACTIONED	DART
No. of tools/tech	4	2	2	2	3	5
Median TRL - at start	7	1	1	1	1	1
Median TRL - latest	7	5	2	5.5	6	2
Average TRL - at start	6.75	1	1	1	1	1.6
Average TRL - at finish	6.75	5	2	5.5	5	2.6
No. now at deployment phase (TRL 7-9)	3	0	0	1	0	0
No. now at TRL9	0	0	0	0	0	0

Source: SQW analysis of monitoring data

5.12 A range of tools developed through the Digipath strand have been certified for use in UK/EU/US markets and some were being used in the NHS at the time of the evaluation. Key examples include:

- GE Healthcare's X-ray critical care suite – NCIMI organised a reader study for the AI tool involving 9 NHS hospitals to further develop the tool
- Brainomix e-Stroke software – the deployment of this decision support tool across 37 NHS hospitals was supported by NCIMI
- Kheiron's Mia (Mammography Intelligent Assessment) tool – as part of ICAIRD, it was tested using SHAIP and evaluated in clinical practice in the Scottish Breast Screening Programme
- Bering's BraveCX AI tool for x-rays – trained using the SHAIP and achieved UKCA marking
- Brainminer's brain imaging software – at the time of the evaluation, this was under review and assessment in three NHS Trusts who were partners in the LMIAI Centre.
- Cyted's Cytosponge tool – the DELTA project has enabled the clinical testing of the assess the Cytosponge - TFF3 triage test for endoscopy to identify Barrett's oesophagus, early cancer and other oesophageal conditions.

5.13 The collaborations created by the projects have leveraged additional in-kind and cash match funding and have also led to follow-on projects with funding from a range of sources. Overall, the Centres of Excellence have leveraged around £29.3m in additional project funding and £12.1m in follow-on funding. For three IDx project that provided data, there was £1.8m in additional leveraged funding and £6.5m in follow-on investment.

5.14 The case study below focuses on the combined benefits of two projects led by the Precision Medicine Centre at Queens University Belfast. It also highlights the importance of the Challenge projects to the early growth of a QUB spin-out, Sonrai Analytics.

PathLAKE and ACTIONED – Sonrai Analytics

PathLAKE was one of the Centres of Excellence and invested in the digitisation of five major NHS laboratories, the formation of a computational pathology hub, creation of a depository of annotated digital whole slide images, as well as exemplar projects focused on AI innovation of pathology services in the UK. The project started in February 2019 and completed in March 2023.

The project consortium was led by University Hospitals Coventry and Warwickshire NHS Trust and included the Precision Medicine Centre (PMC) at Queen's University Belfast (QUB), University of Warwick, Universities and University Hospitals in Oxford and

Nottingham, Philips and various SME partners including Sonrai Analytics (a Belfast spin-out from QUB).

The **ACTIONED** project was funded through the Integrated Diagnostics CR&D competition and was a collaboration between the PMC, Roche and Sonrai. It started in February 2020 and completed in April 2023. The project involved the installation of new equipment and scanners in the PMC lab and the development of AI algorithms. Roche provided significant in-kind support with new scanners, sample processing equipment, biobank samples and also expertise from their pathology team. Sonrai's role was to develop algorithms for: the detection of tumours on glass slides and; the quantification of DNA generated in tumour samples.

Project outcomes

Both projects have played a key role in developing the PMC's new clinical laboratory which brings together high-throughput genomics, digital pathology and big data analytics in a fully integrated fashion. The PMC led exemplar in the PathLAKE project has performed well and has developed three AI algorithms to TRL 4/5. These algorithms were based on previous published research by PMC and trained on NI Biobank patient data.

The ACTIONED project has also successfully developed two algorithms, using different methods of ML/AI firstly using public data (e.g. The Cancer Genome Atlas) and then patient data (using the wet lab data). They have proved to be more accurate than similar algorithm developed in the US and will now be developed further with a view to commercialisation

The projects have started to generate benefits for the NHS in Northern Ireland in terms of upskilling and increasing awareness of new diagnostic processes. For example, the PMC has designed a genomic assay which has been validated and used in the NHS. PMC staff have also been training NHS technical staff and clinical scientists in order to roll out the service to all patients in Northern Ireland.

The main business benefits of the projects have been for Sonrai. Since the start of the Challenge they have grown from five employees to a team of more than 30. Half of the business relates to algorithm development and the experience of working with the PMC and Roche so closely over the last few years has helped to demonstrate their capabilities which has led on to follow-on R&D projects.

Although difficult to quantify an commercial benefits for Roche, the ACTIONED project has provided the company with the opportunity to develop knowledge on deploying their new digital pathology technologies in a clinical setting and strengthen relationships with leading clinicians and new start-ups.

Role of the Challenge

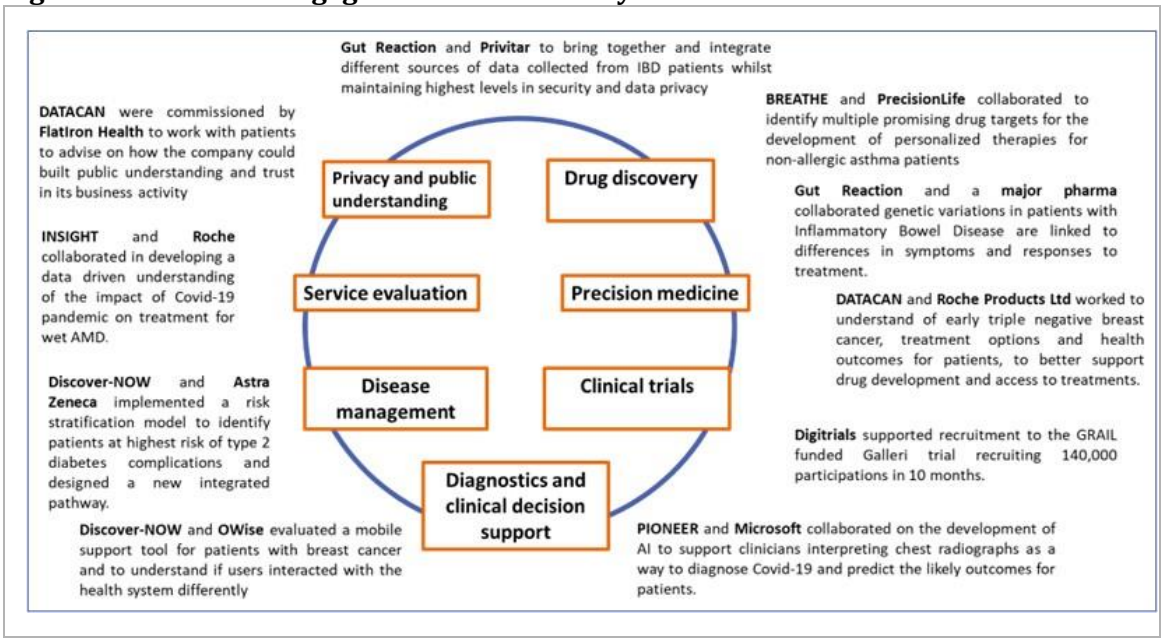
Being a partner in the PathLAKE and ACTIONED projects played a central to the growth and profile of Sonrai. The funding helped the company recruit more experience staff and the credibility of being partners in these projects helped to secure external investment to fund future growth. The Challenge projects have also played a key role in helping the PMC bring in more research funding and increased the profile of PMC as a hub for precision medicine.

DIH

5.15 Although the main focus of the DIH Programme was creating the infrastructure for collecting and curating datasets, there were examples from the Hubs where their research was influencing healthcare delivery, through the creation of datasets and trusted research environments which could support clinical trials on innovations and, notably, in terms of tools that could support the response to the pandemic.

5.16 Between 2019 and 2022, the Hubs delivered around 500 research contracts including 201 academic contracts and 175 commercial contracts. The range of industry relationships developed through the Hubs is presented in Figure 5-2. This analysis by HDR UK demonstrates how the Hubs have established themselves in the health data landscape are beginning to play an important role in shaping healthcare delivery. Table 5-2

Figure 5-2: DIH Hub engagement with industry



Source: HDR UK

5.17 A good example of the Hubs contributing to healthcare delivery is the work that was done by the BREATHE Hub to provide research support to the pandemic response.

BREATHE Research Hub

The Hub was led by the University of Edinburgh and brought together a range of academic, industry and charity partners. The aim of the BREATHE digital innovation hub was to identify datasets on respiratory data and to make these datasets more accessible to industry and other stakeholders. The goal was to achieve this by curating and linking the data within these datasets, making improvements which would support the use of

the data by industry, academia and health systems, to make best use of data that already exists, and to collect new datasets.

There was progress towards the original objectives, however work is still continuing. In terms of the original objectives, there has been some progress towards cataloguing and increasing the availability of datasets. The SAIL databank is continuing to develop the trusted research environment (TRE) for BREATHE datasets. There were some challenges in terms of the hub meeting its objectives to drive the use of health data for research and innovation. The Hub's activities were significantly impacted by the pandemic. As the hub focussed on respiratory health, BREATHE was ideally placed to support the pandemic response.

Project outcomes

The Hub played an important role in supporting the use of near real-time population data to inform the national COVID-19 pandemic response. During the pandemic, and particularly during the early stages, over 2 million people across the UK were voluntarily tracking their potential COVID-19 symptoms and daily health via the Zoe app. The app was developed by the health science company ZOE and academics and King's College London. The data provided by volunteers to the app contained vital information on the geographical distribution of COVID-19 across the whole of the UK and was one of the only population-based sources of these data. This information, including on virus 'hotspots', was necessary to inform care and ongoing public health planning. BREATHE worked with King's College London and ZOE to enable the ethical and safe use of app data by other researchers and decision-making bodies, via the SAIL databank's TRE. The TRE provided secure data access to a range of stakeholders within the health system, local authorities, public health agencies, and academia. In Wales, BREATHE anonymously linked Zoe app data with the NHS records for nearly 100,000 Welsh participants, which supported efforts to model COVID-19 prevalence and allowed analysis of app data and healthcare records in parallel.

Later in the pandemic, BREATHE supported the delivery of EAVE-II in Scotland. This project linked data from 5.4 million people (99% of the Scottish population), including from general practices to information on testing, vaccination and hospitalisation, intensive care unit and mortality data. This provided insights into the spread of COVID-19 across Scotland in near real time, and also allowed the authorities to measure the effectiveness of interventions, particularly vaccines, and to understand the impact of new variants as they emerged. For example. EAVE-II data showed that vaccination significantly reduced the risk of hospital admission due to COVID-19 in Scotland. These data were shared with bodies such as Scientific Advisory Group for Emergencies (SAGE), governments and the World Health Organization (WHO), and informed policies such as the roll out of vaccination booster programmes.

Role of the Challenge

Consultees believed the Challenge funding for the Hub helped it play a stronger role in contributing to the pandemic response.. Achievements were strengthened by the networks that were put in place, including infrastructure and clinical expertise, which meant that the hub was able to quickly provide solutions to ongoing pressing issues. For example, the pandemic was helpful in strengthening the interface between the four UK national health services, supporting the sharing of methodology and data standardisation.

Other examples of contributing to the COVID response

5.18 The project consultations highlighted many examples where projects were able to pivot some of their activity towards contributing to the pandemic response. Although these activities diverted attention away from the initial agreed projects, it enabled projects to demonstrate the early impacts of their R&D activity on healthcare delivery during the pandemic. Examples included:

- LMIAI Centre - carried out research using patients' X-ray and CT scans, triage and predictive outcomes from blood markers, and worked with the ZOE COVID study to develop an AI tool to diagnose COVID based on symptoms
- NCIMI – developed new method of diagnosing Long COVID based on MRI scans, with a new AI tool being discussed with one of the Centre's main industry partners
- ICAIRD – Bering's X-ray AI technology was adapted to help to predict COVID-19 cases which could then be confirmed using PCR testing
- INSIGHT Research Hub – the Hub provided the first reliable estimates of the scale and severity of the vision loss arising from delays in treatment for newly diagnosed wet macular degeneration (wet AMD) during the COVID-19 period
- DATA-CAN Research Hub – its research examined weekly real-time data on cancer services and compared it with pre-pandemic data, revealing a sharp drop in both urgent referrals for early cancer diagnosis.

Summary of outcomes and Challenge contribution

5.19 In this section we have highlighted examples where research studies and R&D activity have generated some early outcomes in terms of helping to shape and improve healthcare delivery. In these cases, most of evidence suggested high levels of additionality from the Challenge funding.

5.20 However, for most projects the healthcare outcomes resulting from the Challenge will be in the future. There were many examples where the Challenge has been vital to the creation and development of new tools and technologies, and the data provided on TRLs demonstrates the good level of progress that has been made over a relatively short period of time.

5.21 In some cases industry partners used the projects to test and/or refine existing products or tools and so the additionality has been more in terms of accelerating or scaling up what was already planned.

5.22 The continued testing, development and commercialisation of new technologies and products has been, and will continue to be, dependent on a range of different factors. Many project

consultees highlighted that the Challenge was critical for the first phase of development and they have subsequently secured follow-on funding from various organisations such as IUK, NIHR, Cancer Research UK.

5.23 There were also projects where the continuing clinical trials of new products will be taken forward by industry partners. It is important to acknowledge that the ability to test and then ultimately roll out new products developed from initial Challenge funding will require sufficient IT investment and capability in the NHS, continued R&D investment from public and private sources and will require all the necessary regulatory approvals.

6. Development and growth of the sector

6.1 This section sets out the key evidence on the growth of the precision medicine sector over the course of the Challenge. This draws on secondary data that has been collated into a bespoke database for the sector, and from the evaluation's own survey of businesses, which has also tracked industry perspectives on changes in the innovation environment, and the contribution of the Challenge to these. The section then sets out evidence on whether companies engaged in the Challenge have been able to grow and/or improve their performance.

Growth in the precision medicine sector

6.2 The evaluation research involved the development of a bespoke database of data driven healthcare and precision medicine companies (herein referred to as the precision medicine sector) using Impact Data Metrics' (IDM) proprietary life sciences company database, various organisation membership lists and commercial databases[12]. IDM used inhouse Iterative Folding™ AI technology to search company websites for key search terms related to data driven healthcare and precision medicine.

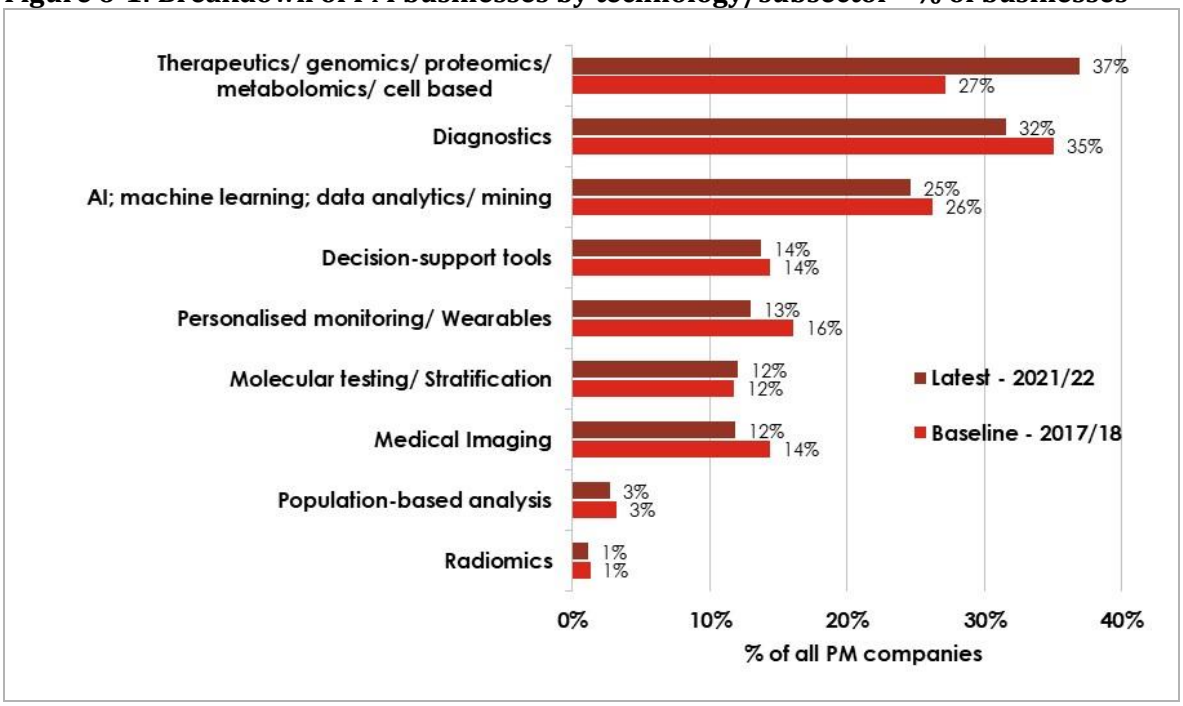
6.3 Between the baseline research (using data as at 2017/18) and the latest research (using data as at 2021/22), the number of companies active in the precision medicine sector increased from 305 to 430 (an increase of 41%).

6.4 Reflecting the early stages of this 'sector', the majority (271 firms or 63% of the 430) were created since 2012, including 25 start-ups since in 2018. Just under half (47%) of the 430 companies were micro-sized (employing fewer than 10 employees). A further 16% were small (10-49 employees), 25% were medium sized (50-249 employees) and the remaining 9% were large companies.

6.5 Based on website information, the 430 PM companies were allocated to relevant technology areas (with many firms allocated to more than one technology area). As shown in Figure 6-1, **the largest proportion of firms were involved in therapeutics and omics technologies in 2021/22 (37%), closely followed by diagnostics (32%) and AI/ Machine Learning technologies (25%).** The change in the technology profile between the original and updated version of the database highlights a notable (10 percentage points) increase in the proportion of firms involved in therapeutics and omics technologies.

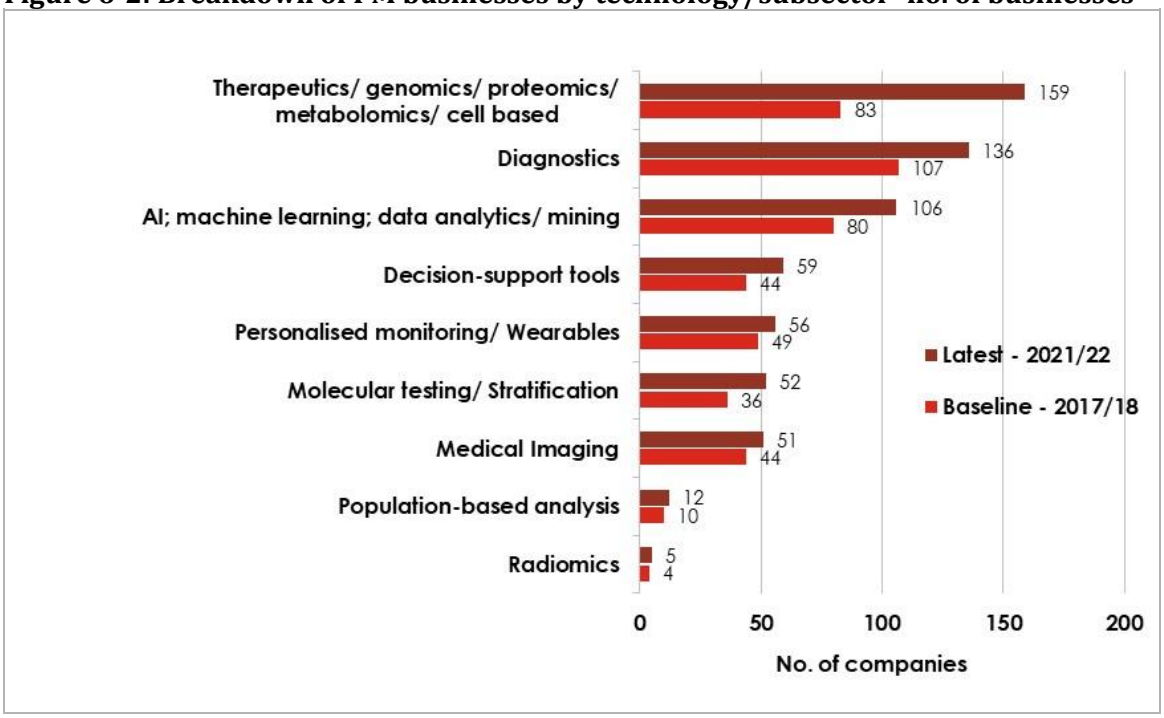
[12] IDM used inhouse Iterative Folding™ AI technology to search company websites for key search terms related to data driven healthcare and precision medicine. Defining the sectors relevant to the Challenge can be subjective and we have sought to focus on technology areas that are most relevant. For example, we have focused on 'data driven' healthcare rather than 'digital' healthcare as we are interested in the businesses developing technologies that make use of big data.

Figure 6-1: Breakdown of PM businesses by technology/subsector - % of businesses



Source: Impact Data Metrics Ltd.

Figure 6-2: Breakdown of PM businesses by technology/subsector -no. of businesses



Source: Impact Data Metrics

6.6 In geographical terms, the largest concentrations of PM companies were in London (23% of companies in 2021/22), followed by the South East (22%) and East of England (16%) – see Table 6-1. These regions have also seen substantial growth between the baseline and latest figures. There has been growth in the number of companies in other regions over the period, albeit in many cases from a low base. The map in Figure 6-3 shows, therefore, the

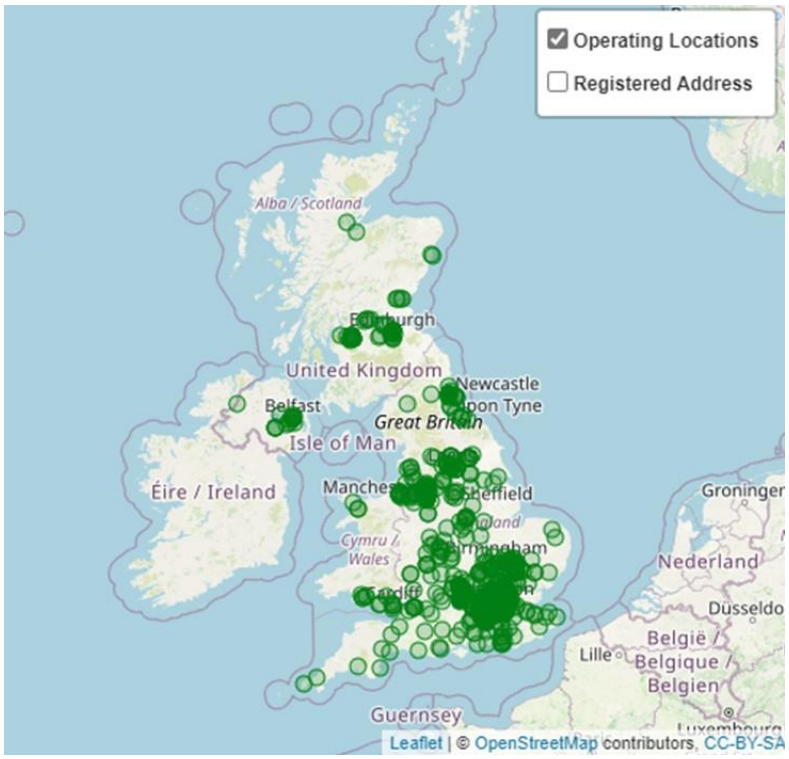
concentration of activity within the Greater South East, though with some clustering of activity elsewhere, e.g. around Manchester, Leeds, Newcastle, the central belt in Scotland and around Belfast in Northern Ireland.

Table 6-1: Location of PM companies by operating address

Operational region	2017/18 baseline	2021/22 latest	Latest % of total	% change from baseline
London	127	184	23%	45%
South East	116	176	22%	52%
East of England	80	128	16%	60%
North West	61	78	10%	28%
Scotland	42	52	7%	24%
Yorkshire and The Humber	32	49	6%	53%
South West	23	27	3%	17%
North East	21	27	3%	29%
West Midlands	16	23	3%	44%
East Midlands	14	18	2%	29%
Northern Ireland	15	17	2%	13%
Wales	13	16	2%	23%
Total	560	795	100%	42%

Source: Impact Data Metrics Ltd

Figure 6-3: Mapping the location of UK's PM businesses by operating address



Source: Impact Data Metrics

6.7 Alongside growth in the number of companies within the PM sector, the collation of data for the database has identified growth in turnover and employment. Therefore, the key metrics for the growth of the sector between 2017/18, around the time of the Challenge starting, and the latest data available (2021/22) are as follows. Two notes are important in interpreting the data:

- The employment and turnover data covers all activities of companies, and so will include non-precision medicine work. The high levels of growth, especially in turnover, are likely to be in part driven by the pandemic.

- We present employment and turnover data excluding top multi-national companies, reflecting that some of these major global companies skew the figures substantially with significant proportions of their activities likely to be outside of precision medicine.

Growth in the Precision Medicine Sector 2017/18 to 2021/22

- No. of companies active in the PM sector from 305 to 430 (increase by 41%)
- Employment in non-multinational companies from 19,800 to 23,100 (increase by 16%)
- Employment including multinational companies from 47,900 to 55,300 (increase by 15%)
- Turnover (excluding the top multinational companies) from £4.0bn to £9.2bn (increase by 129%)

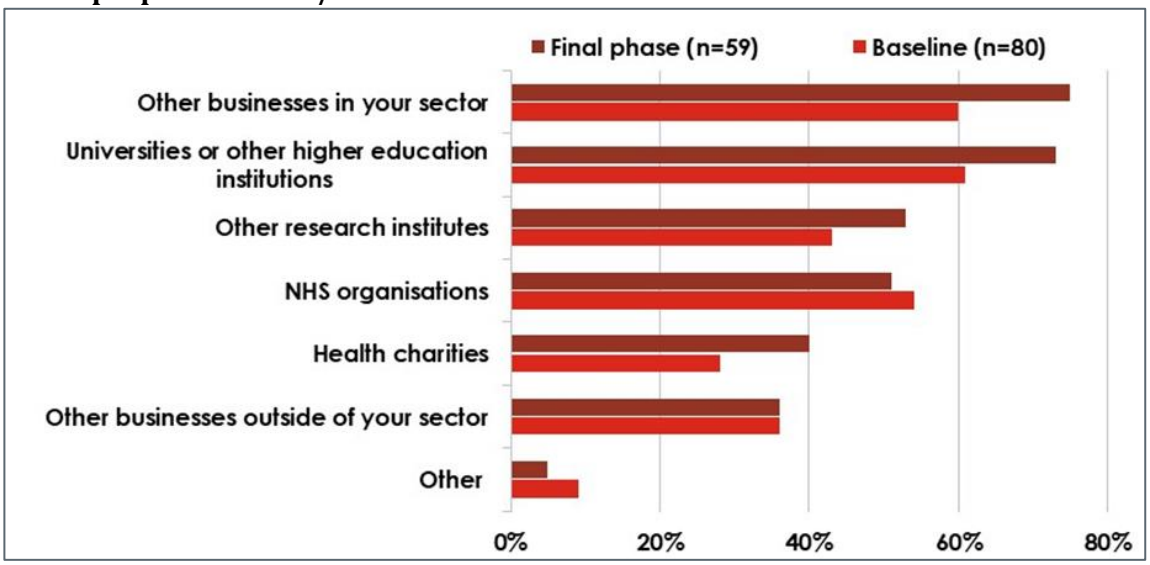
Trends in the R&D and innovation environment

6.8 In addition to the development of the database of companies, the evaluation has used a business survey, drawn from the companies identified, to track trends in R&D and innovation activity, the innovation environment, and perceptions of the UK's global reputation. The baseline survey received 80 responses and the final survey received 59 responses, so the data need to be treated with a degree of caution. The following key findings were identified.

6.9 **Most companies reported increasing their R&D investment both before and during the Challenge**. Two out of three companies said that they had increased their R&D investment in the previous three years at the baseline stage, and a similar proportion said that this was the case in the final survey. In the final survey, **12 out of 59 companies believed that the Challenge had had a positive effect on their R&D investment.**

6.10 There was **evidence of increases in collaborations between businesses and other organisations during the course of the Challenge**. In particular, more companies reported collaborating with other businesses and with universities or other higher education institutions at the time of the final survey compared to the baseline (with these increases statistically significant). The data are illustrated in Figure 6-4. **Once again, 12 companies in the sample stated that the Challenge has had a positive effect on their collaboration activity.**

Figure 6-4: In the past three years has your UK business collaborated with other orgs for the purposes of R&D/ innovation?



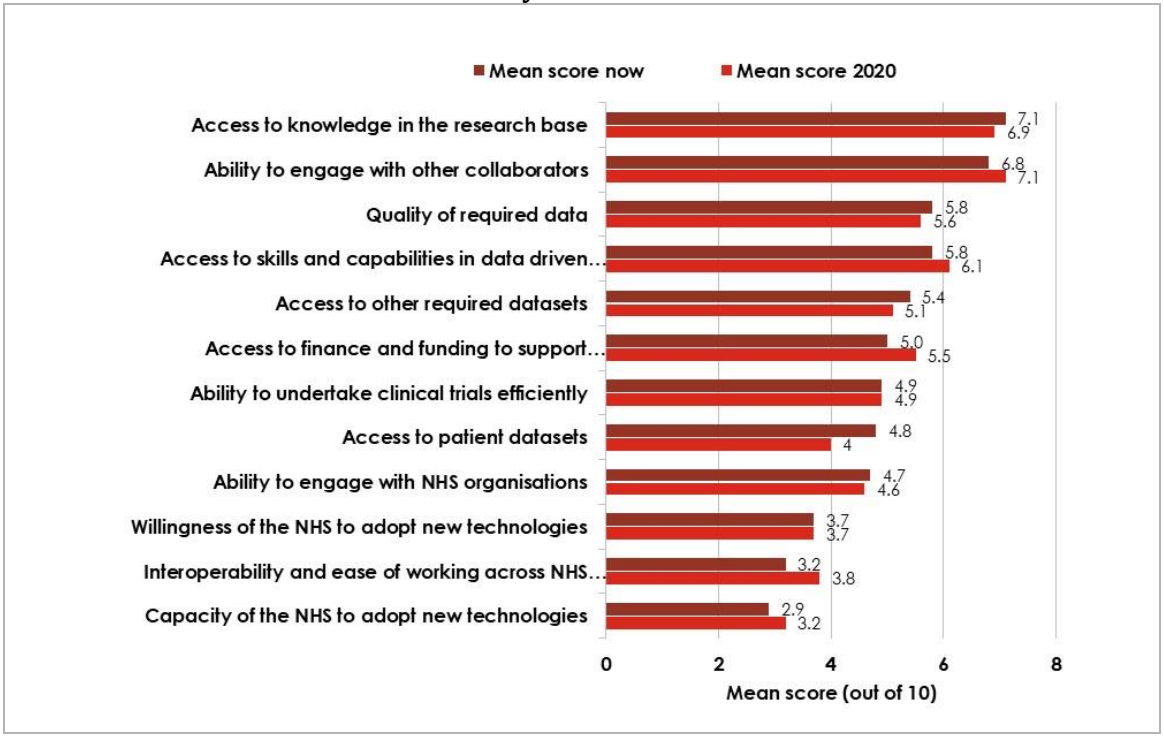
Source: IFF/SQW surveys (baseline n=80, final n=59)

6.11 Businesses were asked for their views on different elements of the innovation environment in the UK specifically related to data driven healthcare and precision medicine, now (i.e. in 2023) and three years ago (i.e. in 2020).

6.12 As shown in Figure 6-5, average scores (out of 10) remain broadly unchanged over the period, which may well reflect the short time period and the fact that this period has been unusual given the gradual returns to post-pandemic norms. **The strongest elements of the innovation environment are access to knowledge in research base (average score of 7.1) and the ability to engage with other collaborators (average score of 6.8)**.

6.13 The lowest scoring aspects related to the NHS, namely the capacity of the NHS to adopt new technologies (2.9) the interoperability and ease of working across the NHS systems (3.2), and willingness of the NHS to adopt new technologies (3.7).

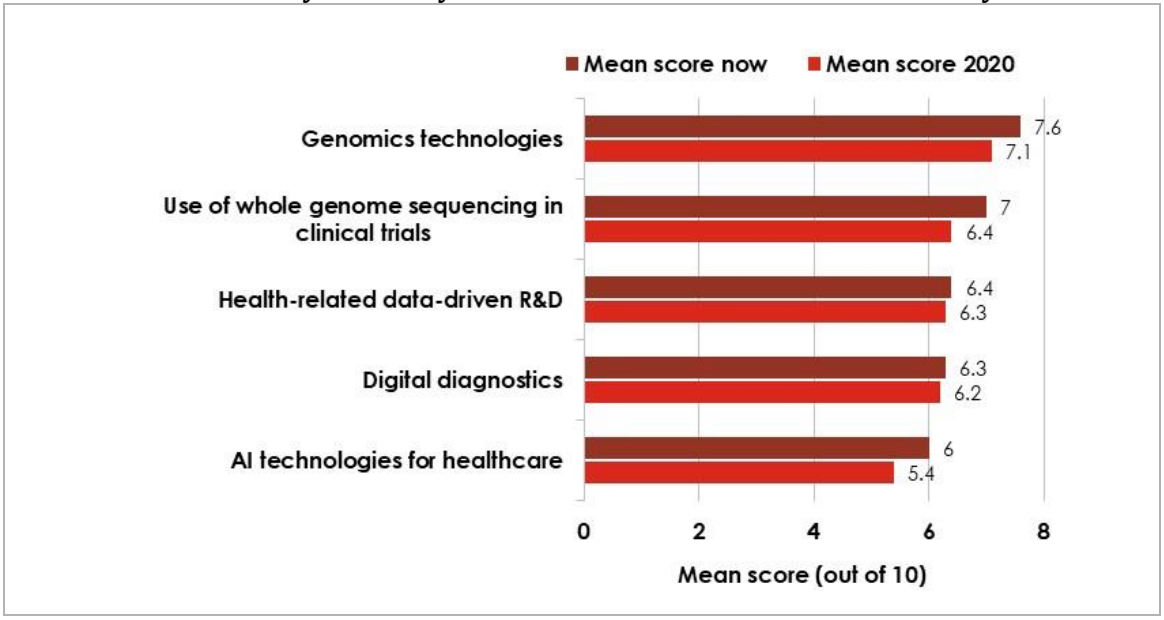
Figure 6-5: On a scale of 1-10 (where 1 is poor and 10 is excellent) how would you rate the following aspects of the environment for undertaking R&D and innovation in the UK at the current time? And in early 2020?



Source: IFF/ SQW survey 2023 (n=59)

6.14 When asked about the UK's reputation globally in key technology areas, precision medicine firms generally reported improvements since 2020, in particular for the two areas where the UK is viewed as the strongest, i.e. genomics technologies and the use of whole genome sequencing in clinical trials, and in AI technologies for healthcare – see Figure 6-6. Sixteen companies gave a score for the Challenge contribution to these changes, with 14 of these positive and two negative, indicating that the investments in research, infrastructure and collaborative projects may have made some difference to the UK's global standing.

Figure 6-6: Overall, on a scale of 1-10 (where 1 is poor and 10 is world-leading) how would you rate the UK in global terms for its reputation for the following areas at the current time? How do you think you would have rated these areas in early 2020?



Source: IFF/ SQW survey (n=59)

Growth of firms involved in the Challenge

6.15 Of course the data above on the growth of the sector provides context, but this does not mean that the Challenge itself has brought about these changes. In order to assess this, the evaluation took two different approaches:

- Econometric analysis was used to assess whether there were any differences in performance for those businesses involved in the Challenge compared to other data driven healthcare and precision medicine companies that were not engaged. This was undertaken to inform whether engagement with the Challenge had helped to improve business performance. We adopted a quasi-experimental approach known as difference-in-difference (DiD) analysis using data on employment and turnover from the Business Structure Database (BSD) accessed through the Office for National Statistics (ONS) Secure Research Service (SRS)[13].

- Survey and consultation feedback from industry representatives was used to gather, bottom-up, perspectives on whether being involved in Challenge-supported projects had led to any effects on the business, e.g. in terms of R&D investment, attracting funding or investment from other sources, or business growth (through employment or turnover).

6.16 The econometric analysis showed that the Challenge was not, so far, associated with a significant change in business growth for participating businesses both in terms of

[13] The technical aspects of the econometric analysis are described in more detail in a separate evidence paper.

employment and turnover. This finding was consistent whether we looked at the impact of the Challenge on all businesses or separately for smaller businesses involved (smaller defined as fewer than 50 employees). **Our analysis suggested that it is either too early for the Challenge to have made an impact on business growth, or that participation did not lead to a significant change in the supported businesses' growth plans and/or capacity.**

6.17 We did, however, identify that the supported businesses were significantly faster-growing businesses than other similar businesses in the precision medicine space both before and after the start of the Challenge. This finding was driven by the smaller businesses participating in the Challenge. Therefore the evidence indicates that **the Challenge has supported faster growing companies, and in particular smaller companies, in the data driven healthcare and precision medicine sector.**

6.18 The bottom up evidence from consultations indicated that, whilst in aggregate terms the Challenge is not associated with sector growth, **there have been a good number of examples where funded activities have supported individual company growth**. In Table 6-2, nine key examples of this are identified on an anonymous basis, highlighting how Challenge-funded activities have enabled the start-up, early stage development and rapid growth of some companies.

Table 6-2: Examples of where the Challenge has supported company growth

Company type	Key indicators of growth	Role of the Challenge
Early stage company (pre-revenue) at the start of the Challenge	• Secured angel investment to become a project partner • Increased employment from 0 to >10 • Now achieving sales • Secured follow-on grants and first round (£5m) of VC investment	Challenge speeded up the company's start-up and development The advice, credibility and involvement in the Challenge helped to secure further funding and investment
Early stage micro enterprise at the start of the Challenge	• Increased employment to 5, with 1 job created and 2 safeguarded due to the Challenge • Sales increased • Follow-on funding secured from UK and EU sources	Challenge activity helped to increase the firm's profile with larger companies and opened up new markets
Early stage company (pre revenue) at the start of the Challenge	• Secured over £1m in seed funding and currently in another funding round • Increased employment from 2 to over 10, with 1 directly attributable to the Challenge-funded project	Challenge helped make introductions to new partners Challenge-funded activity enabled it to test a new tool, helping to give the company credibility, e.g. with investors

Company type	Key indicators of growth	Role of the Challenge
Micro enterprise at the start of the Challenge	• Employment increased significantly from under 10 to over 30 • Revenues increased from <£50k to over £500k • VC funding secured	Around half of the growth attributed to the Challenge Challenge-funded activity enabled the company to hire better quality staff Helped to raise profile and credibility to secure funding
Small company at the start of the Challenge	• Sales increased from c. £1m to c. £4m over 4 years • Employment increased from just over 10 to nearly 20	Challenge-funded activity helped the company to develop new software, which has subsequently been sold to clients in the pharma sector
Division of a multi-national	• R&D investment increased by around £5m p.a., with one-third due to the Challenge • External funding of £2m secured, with around half of this due to the Challenge • Helped to safeguard 20 jobs in the UK	Challenge-funded project allowed the company to develop new products due to access to NHS staff and data The activities helped to influence parent company on the merits of UK location for AI development
Start-up company during the Challenge	• R&D investment up to £1m p.a. • Raised follow-on grant funding and VC funding • Employment increased from 0 to just over 20	Attributed around one-third of the investment and funding to the Challenge
Start-up company during the Challenge	• R&D investment to £100k+ p.a. • Raised VC funding • Small increase in employment (mainly contractors at this stage)	Attributed around 20% of investment and funding to the Challenge
Medium sized company	• R&D investment more or less doubled to £8m+ • Substantial series C funding round • Increase in employment from c. 100 to c. 200	Around half of the growth in R&D investment attributed to the Challenge-funded activity

Source: SQW/PHG consultation work

6.19 As can be seen in Table 6-2, several examples of company development were start-ups, early stage and other small businesses. Two case examples are set out below, illustrating the role the Challenge-funded activity has played.

Jiva.ai and ID LIVER

ID LIVER, led by the University of Manchester and Manchester University NHS Foundation Trust, was a research and innovation project which aimed to save lives by enabling earlier identification of liver disease. The partnership included further academic and clinical organisations (University of Nottingham and Nottingham University Hospitals NHS Trust) as well as two large industry partners (Roche Diagnostics and GE Healthcare) and SMEs including Jiva.ai, Perspectum and Sollis.

Jiva.ai is a Cardiff-based SME. It was founded in 2019 after one of the co-founders participated in the Innovate UK KTN's Innovation Campus process. Jiva has developed a no-code platform to rapidly prototype AI models, and has deployed this to develop predictive analytics for early disease detection.

Jiva.ai aimed to develop its AI technology in relation to liver disease detection, and in doing so to prove that Jiva.ai's approach to developing 'explainable', multimodal AI (compared to 'back box' and unimodal AI) could be successful. The company also wanted to develop relationships with the project partners to position itself for future opportunities for R&D collaboration and/or commercial activity.

The development of Jiva.ai's diagnostic was originally expected to use prospective data gathered from Liver Assessment Clinics in Manchester. However, the collection of prospective data was slower than anticipated as Covid-19 meant NHS capacity to run these clinics was limited. Instead, Jiva used retrospective data from Nottingham University to generate machine learning models.

Jiva built an AI tool based on retrospective data from Nottingham University and successfully tested it against prospective data collected in Manchester. A small scale trial of the tool was due to be undertaken after the evaluation research. After project close, partners estimate that it will take a further 18 months before there is sufficient evidence of the diagnostic's effectiveness for it to be suitably developed for adoption by the NHS. Jiva and the universities of Manchester and Nottingham all own elements of the IP within the diagnostic tool, and the most likely commercialisation scenario was reported to be via a new spin-out company which would be granted a license to use the technology.

Business outcomes

When the project began, Jiva.ai was at pre-revenue stage and had three employees. In early 2023, Jiva.ai had 12 employees, with one of the additional jobs reported to be directly attributable to ID LIVER. Whilst it is too early for ID LIVER to have had a significant impact on Jiva.ai's turnover, the project has already contributed to the company raising external finance for further R&D activity. Jiva.ai raised £1.3m in a "significantly oversubscribed" seed funding round in May 2021[14]. ID LIVER was a significant part of the pitch deck to potential investors, and the involvement in the project enhanced Jiva.ai's credibility with potential investors.

Role of the Challenge

Without grant funding from ID LIVER, Jiva.ai would have sought to access alternate grant funding but this may have been slower to secure or the alternate projects may have progressed more slowly. D2EDPM was reported, therefore, to have given timing additionality of 1-2 years to the AI diagnostic.

[14] https://jiva.ai/news/jiva-ai-completes-1-3m-seed-funding-round/

Without being part of a funded R&D project consortium, it is very unlikely that Jiva.ai would have been able to form partnerships with others, including a large global company such as Roche.

AINOSTICS and LMIAI

LMIAI, led by King's College London and the Guy's and Thomas' NHS Foundation Trust, brought together a team of artificial intelligence (AI), data science, research and clinical experts working collaboratively across industry, academia and the NHS. In total, the LMIAI community involved ten NHS Trusts, four Universities, a number of multi-national industry partners, ten UK-based SMEs, and the Health Innovation Network.

Established in 2018, AINOSTICS is an AI company working to identify the earliest biological signs of some of our society's most devastating diseases (such as Alzheimer's disease, Multiple Sclerosis, stroke and brain tumours) and therefore provide the best chance of success for potential preventions and treatments. As part of LMIAI, the company led on one of the exemplar projects looking to develop a tool for better triaging of patients suspected of dementia.

The National Institute for Health and Care Excellence (NICE) recommends the use of magnetic resonance imaging (MRI) for better diagnosis of dementia. These scans currently have to be visually assessed by clinicians, which is a time-consuming process. The Challenge-funded project in collaboration with LMIAI was seeking to address this challenge by developing a product that automates the analysis of medical images, enabling to identify subtle, early signs of neurological conditions like dementia.

The core project output was a product prototype that contributed to the company's flagship product, BR[AI]N®. This product is the first solution to be granted FDA Breakthrough Device status for the ability to accurately predict conversion to Alzheimer's disease using only structural MRI scans (the most common type of MRI scans performed in clinical practice).

Business outcomes

The ISCF-funded project helped to support the creation of jobs, with the company growing its team from zero to 13 FTE employees by Q1 2023 (of which eight jobs were considered to have been created/safeguarded as a direct result of the funding). The company had also secured a substantial amount of additional funding (attributed to the Challenge funding) and grown its turnover (of which a quarter was attributed to the Challenge).

Role of the Challenge

The ISCF funding – which came along at the earliest stages of company development – was recognised as a catalyst that helped AINOSTICS to gain necessary momentum. Without the Challenge funding, the project would have been smaller scale, taken longer and been of a lower quality.

Overall contribution of the Challenge to date

6.20 Data driven healthcare and precision medicine is a growing sector, and the key metrics presented earlier in this section highlight its development since the start of the Challenge. This, together with the role of global companies within it, can make an assessment of the difference made by the Challenge itself difficult.

6.21 The econometric analysis found no evidence at this stage that those companies from the precision medicine sector that had engaged in the Challenge had grown any significantly faster than companies that had not engaged. That said, there was evidence that companies engaged in the Challenge were faster-growing, in particular driven by fast-growing small companies – though this was the case both before and during the Challenge.

6.22 The absence of evidence of impact at the sector level aligns with the consultation and survey feedback collected as part of the evaluation. There was not widespread evidence of company and commercial effects to date. Many of those consulted reported that it was too early for such effects given the stages that project activities had reached and/or that there were numerous other factors at play, including previous R&D, subsequent funding attracted, and the requirement for further development activities (including the need for further collaborations).

6.23 Nevertheless, the consultee feedback did highlight that whilst there have not been widespread company impacts to date, there have been some important examples of how the Challenge has supported sector growth, with funded projects enabling activities to take place and growth to happen that would not have been possible otherwise or to the same speed and scale:

- There have been examples where the Challenge has helped in the start-up phase of companies, providing funding that has enabled activities of R&D intensive firms to commence – the case examples of Jiva.ai and AINOSTICS illustrate this.
- Challenge-funded activities and their outputs have helped companies in pitches for funding, including from equity investors, with the case examples also illustrating this.
- Smaller companies have drawn on the activities supported and the relationships established with larger firms to grow and access new markets.
- There has been a case where a division of a multi-national company has developed its research and product development that has helped in influencing ongoing investment decisions in the UK.

6.24 Future contributions to the growth of the sector have the potential to be achieved, in particular as project activities move onto their next stages. However, the business feedback

has pointed to broader barriers that need to be addressed in order to ensure that these are achieved. These include the following:

- Improvements that can help industry better and more easily access and use data, e.g. ensuring that data is fit for the needs of industry, availability of advice and guidance on data use, and speed and certainty of delivery.

- Engagement with the NHS, including the capacity and willingness to adopt new technologies and innovations.

- Skills and labour shortages, with nearly one-half of respondents to the business survey reporting skills gaps (increasing from around one-third at the baseline survey). AI technologies for healthcare was the most commonly reported skills gap. The potential labour supply has not been helped by Brexit, with evidence indicating a drop in the numbers of applications.

7. Legacy and development

Sustainability

7.1 Ensuring the legacy and sustainability for this type of programme, which has an emphasis on developing research and innovation infrastructure, is critical. As set out in the overarching strategic context for the programme, the first objective related to **improved research and innovation capacity and capability through infrastructure and data- and knowledge-sharing**, and the second related to **improvement collaboration between academia, the NHS and industry**.

7.2 This has manifested itself in a range of activities that have included the curation and use of datasets, development of data-sharing platforms, investment in equipment, awareness-raising and capability-building, and partnership-working. The effects of these types of activities will be achieved in the long-term and will require the maintenance of the infrastructure and will also benefit from retaining 'institutional memory' and relationships.

7.3 A key lesson from the Challenge is to build in planning for sustainability as soon as possible. This was managed well for the DIH strand of the Challenge as there was clear direction provided by HDR UK on meeting a milestone for sustainability plans. For the Centres of Excellence, the additional scale-up funding from OLS helped to provide scale and more time for three of the Centres.

7.4 However, more widely, the planning for sustainability was not built in sufficiently early. This was made difficult due to the uncertain and changing context in the NHS in relation to the plans for sub-national secure data environments (SDEs). Following the Goldacre Review, the UK Government announced £200m for the Data for R&D Programme which aims to improve access to NHS data through Secure Data Environments (SDEs) and digital clinical trial service. Work is underway to develop a national NHS SDE and 11 Sub National SDEs. They will bring together Integrated Care Boards with local universities and industry partners to build on existing collaborations and successful research partnerships.

7.5 There have been several positive examples of Challenge activity securing follow-on funding or putting in place sustainability plans, which should enable the achievement of future outcomes. These include the following:

- UK Biobank has secured £127.6m in UKRI funding to move to a new purpose-built facility at Bruntwood SciTech's Manchester Science Park. This major investment will include business incubation space where UK Biobank can work more closely with SMEs to help them leverage the WGS and other Biobank datasets for R&D

- At the time of writing, we understand that the Centres of Excellence in England will be integrated into the NHSE sub national SDEs, and part of ICAIRD was seeking integration into the NHS Scotland Regional Innovation Hubs.

- There were a range of CR&D projects across the Genomics and Integrated Diagnostics strands where project partners had secured follow-on funding, including from public sources as well as private investment.

- The DIH programme was continuing with core funding from HDR UK, and Hubs that progressed through Milestone 3 have secured future sources of funding and/or host organisations to sustain activities. For example, INSIGHT continues as a partnership with Moorfields Eye Hospital now the host institution and University Hospitals Birmingham as a partner. More broadly, University Hospitals Birmingham, which originally hosted INSIGHT and Pioneer (part of HDR UK's wider hubs programme), is now the lead organisation of the West Midlands SDE, building on the foundations that the DIH programme helped it to develop through technical and operational processes. Gut Reaction is now part of the NIHR Bioresource (coordinated by Cambridge University Hospitals NHS Foundation Trust), and Discover-NOW is part of the London SDE, along with the LMIAI Centre of Excellence.

Lessons

7.6 Lessons from the programme are split into three areas: lessons and issues from international comparator countries; the key learning from the experience of delivering the programme; and lessons around outstanding issues in the landscape. There is overlap between these areas of lessons.

International comparators lessons and issues

7.7 As part of the evaluation we produced case studies of Israel, Germany, Sweden and the USA to assess how the UK landscape compares to the international context, and identify potential lessons for the UK. The importance of securing sufficient levels of government financial support, and when at an appropriate point support to attract private investment, was consistently highlighted by consultees across the four countries. This applies at three levels.

- First, access to (grant) funding for individual research and/or commercialisation projects is often challenging due to the scale of finance required. TüCADD in Germany, for example, highlighted that it could cost around €3m to support the development of projects to 'first in man' stage. Partly in response, TüCADD has instituted an annual pitch day where projects can pitch to Venture Capitalists for funding. The time and resource required to commercialise a new product in the life sciences sector and especially in precision medicine which involves emerging technologies needs to be factored in to any support programme. There are examples from the Challenge evaluation where Hubs and Centres

of Excellence may have been better doing more to progress fewer exemplars. This would have helped to commercialise more products by the end of the funding period.

- Second, long term funding for research infrastructures is required. For example, core funding for Genomics Medicine Sweden and Sweden's Biobank is awarded for four year cycles which limits the ability of these national infrastructures to plan for the long term. This again echoes the evaluation evidence from the Challenge which highlighted the need for longer term funding for the infrastructure and data platforms that need to be built, maintained and upgraded as new technologies emerge. The Challenge evaluation also highlighted the need for longer term funding pathways to support adoption which will allow product developers to be able to test their products in the real world clinical settings.

- Third there is a need to ensure that the health system (whether national or regional, public or private) has sufficient funding to implement and adopt precision medicine approaches, e.g. purchase and installation of new equipment and associated training for medical professionals. There are parallels here with the investments made through the Challenge and OLS programme into the NHS in terms of infrastructure, skills and capability to adopt new technologies. However, the evaluation evidence suggests that there is much more to be done to address ongoing capacity and capability constraints in the NHS which is the primary domestic customer for new products. Consideration of the absorptive capacity in the market for new products and services is an important factor for any innovation programme.

7.8 .

Learning from delivery

7.9 Ensuring appropriate timescales for delivery of investments such as these is critical. As already noted above in relation to sustainability, many of the activities funded were seeking to build research and innovation infrastructure, capacity and collaborations. These take time, and as such the timescales of some of the projects were insufficient, even taking into account the fact that Covid-19 affected project delivery. The timescales were particularly an issue for the CoEs, and to some extent the DIHs, because of the preparatory work that was required in the early stages.

7.10 Effective project set-up took longer than had been anticipated, and this included aspects relating to consortium development, e.g. putting in place project governance and management procedures, and agreeing memoranda of understanding and intellectual property agreements (where required). There was also time needed for installing and setting up data infrastructure, some of which was disrupted by the pandemic. The result, for the CoEs, was that industry partners in particular had to wait longer than expected before exemplar projects could start. The key lesson for UKRI and others in the research and innovation landscape is to consider allowing longer (e.g. five years or more) for investments. This would

enable more realistic timeframes for set-up and expectations for industry partners, thereby allowing more time to demonstrate commercial potential, and then time towards the end of the cycle for sustainability planning.

7.11 There were lessons across the Challenge in developing and maintaining project partnerships, reflecting the key role in this area in relation to partnerships and consortia. The development of the consortium for the WGS project was impressive, bringing together a group of industry pharma partners that would not typically collaborate. The arrangements put in place preferential data access, and facilitated substantial industry match alongside public funding. The model could be adopted for future similar investments. CR&D projects, the CoEs and DIHs tended to build on existing relationships, though their scale and scope also meant that there were new partnerships established. In particular, there were numerous examples of smaller companies getting introductions to new partners, including larger players, that would otherwise have not been possible. The downside has been that some consortia were too large, which added to the timing challenges in managing the set up process and ongoing engagement. It also contributed to some partners not getting out as much as they expected at the outset as leads sought to manage complicated projects. We return to industry engagement in the sub-section below on issues going forward.

7.12 The Challenge has highlighted the role of variation in approaches to data curation, integration and access. This was described by some as 'burdensome', though by others as inevitable given the current nature and development of the data landscape. There are two important lessons here – first, the need to manage expectations as to data provision. Second, there is a need to build in time, resource and advice to account for the complicated nature of data sharing, in particular when working with smaller firms.

7.13 Promotion and communications have been varied across the Challenge. There was insufficient attention given to the promotion of the activities of the Challenge. As a result, there was a lack of awareness within the Challenge of what else was being delivered. Whilst this was remedied to some extent later on in the Challenge, this is likely to have resulted in missed connections and opportunities. That said, some of the later communications, including across the DIHs and CoEs, have helped to facilitate some cross-Challenge working, A lesson for UKRI is the need to have sufficient resources are allocated for dissemination and communication, in particular where investments are seeking to raise profile and share knowledge about new areas of technology.

Issues going forward

7.14 The Challenge has made substantial progress in developing new datasets, joining up the health data landscape, and providing access to valuable data for research and innovation purposes. The evaluation highlighted a number of areas of ongoing development required:

- There is a need for greater standardisation around storing and sharing data. Data needs to be seen as long-term essential infrastructure which requires ongoing maintenance and funding support.

- In the wider landscape, with the role of Trusted Research Environments and Secure Data Environments interoperability will be essential as part of developing and managing this infrastructure.

- Data curation requires appropriate resource to understand the data you are working with, define the data and data terms, and standardise data and associated metadata. In defining data needs, there are ongoing needs to address diversity issues – which Our Future Health should help to inform,

- There are issues to be addressed in data quality, with the specifics varying depending on the data concerned. For image data, for example, there is a particular need to address standardisation. For NHS records, developing solutions to address natural language or free text processing (i.e. to handle more text based data types such as free text boxes in forms or medical records) and more work on integration is required.

- Speed of data access is key, for industry partners in particular. Engagement with industry to understand needs (including in relation to support and advice on accessing and working with data), provide timelines and manage expectations will be helpful.

7.15 In responding to these data issues, engagement with patients, the wider public and industry partners will be required to develop national and local policy on information governance. As identified above, there is a need to address diversity in datasets, and steps should be taken to tackle EDI issues, which will require gathering data from as wide a range of Trusts as possible to capture population diversity within datasets and embedding PPIE into programmes. Public involvement from diverse and representative groups in co-design of projects, including data sharing processes, is vital to this.

7.16 Whilst there are many areas for progress and learning, there are now better forums and mechanisms through which to discuss and address these issues – and the Challenge has played an important role in establishing these.

8. Conclusions

8.1 In this final section we provide a ahigh level summary of the progress that the Challenge has made towards its intended outcomes (from the overarching logic model) and the answers to the key research questions for impact evaluation as set out in the M&E framework.

Progress against outcomes

8.2 As discussed in previous sections, it is relatively early to assess the achievement of intended longer-term and indeed medium-term effects. As such, the progress against outcomes needs to be viewed in this context.

8.3 Figure 8-1 provides an overall assessment, at the Challenge level, of the progress to short-, medium- and longer-term outcomes. As can be seen and as shown by the evidence, there has been significant progress in the development of, access to and use of data resources – with the genomes of 500k Biobank participants sequenced, the development of new data storage facilities, NHS sites using these facilities and data platforms, and over 100 national datasets curated by the Hubs that are in use. Many of these would not have happened to the same scale or at all without the Challenge funding. Similar is true on collaborations, with existing partnerships enhanced and new collaborations formed, especially due to new introductions for smaller, earlier stage companies.

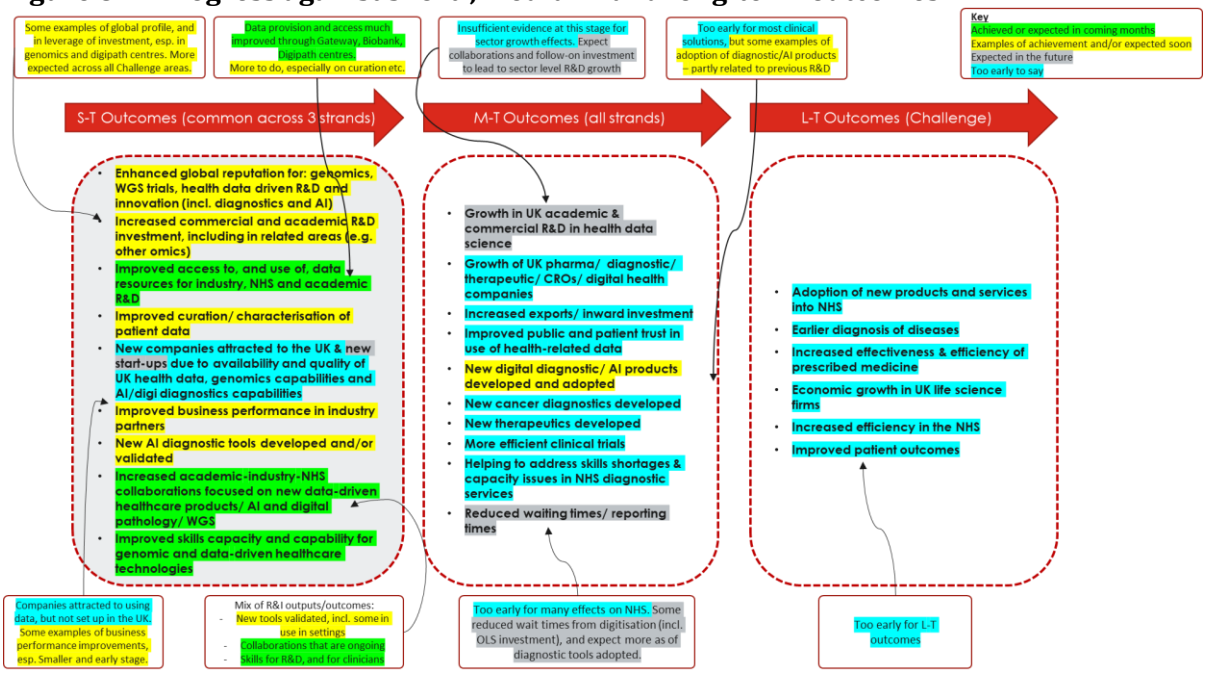
8.4 The achievement of R&I outcomes reflects the stage of innovation and that some individual projects have been able to progress more than others. Therefore, at this stage, there are numerous examples of the development of new AI diagnostic tools, with some developed and in use (in particular where the Challenge has helped to build on existing work), and with more expected over the next few years. There are longer lags for other diagnostics and therapeutics and so it is too early to say about the effects here.

8.5 In relation to sector development, there are examples of business performance improvement that the Challenge has contributed to. Section 6 identified a number of examples, especially of earlier stage companies that had grown in size in terms of employment numbers (e.g. from single figures of employees towards 20 or 30), had been able to access external finance, and in a couple of cases that had increased sales. These were examples at this stage, with there being no evidence that the Challenge had had an effect on the overall size of the sector. It is noteworthy in this context that, whilst the UK's reputation has been helped by the Challenge, it was not expected at this point to lead to substantial inward investment, in particular as datasets can often be accessed from outside the UK.

8.6 Finally, given the early stage in relation to getting tools into use, there are limited effects on NHS outcomes at this point. There were examples of reduced waiting or reporting times, in

particular in tandem with investment in digitisation that was enhanced by the OLS investment. Further outcomes are expected here as more tools are brought into use.

Figure 8-1: Progress against short-, medium- and long-term outcomes



Impact evaluation research questions

8.7 This shows that there have been high levels of additionality in relation to the funded activities, and the development of new infrastructure, datasets and equipment that have bolstered R&D capacity and capability. Whilst there were only a small number of examples of the development of new precision medicine approaches by the time of the evaluation, the Challenge has put in place the foundations for these future developments, and there was evidence of progress of new technologies. There was evidence of the strengthening of the UK's reputation and examples of sector growth, in particular for SMEs that had engaged in the Challenge. Overall, therefore, the Challenge has supported the progress of precision medicine in the UK, and there remains a case for further support to ensure that this translates into real economic and patient outcomes.

Table 8-1: Impact evaluation research questions

Research question	Findings
To what extent has the Challenge led to new, scaled-up or different activities in the precision medicine and early diagnostics landscape? What has the Challenge funded that	Levels of activity additionality were high across the Challenge. Most of the evidence indicated that without the Challenge funding it would have been highly unlikely that the UK Biobank WGS project would have happened. The funding helped de-risk the industry investment and added credibility to the project. It was also unlikely that NHS and academic partners could have funded the new infrastructure, facilities and equipment to

Research question	Findings
is different to what may have been delivered in any case?	produce, store and analyse the data across the CoEs and IDx projects – and certainly to the same kind of timeframes and scale that the Challenge was able to facilitate. There were high levels of additionality in relation to the DIH Programme in terms of the Alliance and Innovation Gateway and Hub collaborations. The evidence on the significant up-tick in datasets and Alliance members helped to corroborate the feedback from consultees.
To what extent (and how) has the Challenge successfully strengthened the sector's R&D capacity and capability?	Across the Challenge there is strong evidence of progress on R&D capacity and capability though new datasets, infrastructure and equipment.. This was supported by actual follow-on funding and R&D investment. The UK Biobank WGS project has provided world leading WGS dataset that is already generating publications and starting to inform diagnostics and therapeutic targets. The CR&D projects have delivered enhanced sequenced datasets, improved skills and experience in genomic technologies and increased collaborations across a range of partners. The Digipath strand has invested heavily in the underlying infrastructure, data sharing infrastructure and exemplar projects which are helping to develop knowledge, skills and digital diagnostic tools. Key outputs included: • 22 new data storage facilities and platforms • 25 NHS sites using new facilities, platforms And through the DIH Programme the Alliance has helped improve understand and awareness of the key health data issues, and the Innovation Gateway provides an important platform to provide a central access point for researchers, providing access to 800 datasets.
To what extent (and how) have the three strands enabled the development and adoption of precision medicine approaches in diagnostics, digital pathology and radiology?	The three strands have supported developments of precision medicine approaches, though at this stage it is too early in relation to significant adoption. The UK Biobank WGS project created a world-leading dataset to enable the development of new precision medicine approaches and drug treatments over the coming years, and some CR&D projects have helped to enhance diagnostic tools. Similarly, the datasets and collaborations in the DIH programme will help to enable development over the coming years. The CoEs have delivered a large number of exemplar projects which have accelerated the development of new or existing products from proof of concept through to prototyping, product marking and deployment in clinical settings. Key outputs across the Challenge included: • 69 exemplar projects delivered

Research question	Findings
	• 51 AI tools in development • 18 AI tools developed • 481 publications
To what extent (and how) has the Challenge enabled the development of products (that are intended to improve the health of patients and the public)?	The feedback from pharma partners and the survey of UK Biobank researchers provided evidence that the new dataset will help to create new diagnostics and therapeutic targets. It is still too early to know when these will start coming through. A range of tools developed through the Digipath strand have been certified for use in UK/EU/US markets and some were being used in the NHS at the time of the evaluation, though these were still initial examples at this point. Significant progress has been made by the DIH Hubs in collecting and curating new datasets. Although there is still some work to be done in terms of accelerating access for industry partners, the scale of engagement over the last three years indicates that these datasets will help shape new products, diagnostics and treatments.
To what extent (and how) has the Challenge extended effective connectivity and collaboration between academic, NHS and industry researchers and innovators to increase knowledge exchange and accelerate progress of R&D?	This Challenge was shaped by extensive engagement across the health and life sciences sector carried out as part of the Life Sciences Sector Deal. This has led to significant collaboration across all parts of the sector in the delivery of ambitious projects across the three strands of the Challenge. The UK Biobank WGS project has been a flagship project in the Challenge, providing an effective model for encouraging collaboration between some of the world's largest pharma partners (AZ, GSK, J&J and Amgen). The scale of the consortia developed to deliver the Centres of Excellence and IDx projects has enabled significant collaboration across industry, the NHS and academia. The DIH Programme has created new structures such as the Alliance which has helped to provide a focal point in the health date landscape and has facilitated knowledge sharing on data access, standards and interoperability. The Hubs also delivered around 500 research contracts including 201 academic contracts and 175 commercial contracts.
To what extent has the Challenge supported the UK as a world leader in early diagnostics and precision medicine?	There was evidence from across the three strands that the Challenge has helped the UK's profile internationally. The UK Biobank WGS project is regarded as the gold standard dataset and years ahead of comparable datasets such as the All of Us Programme. There has been a notable increase in international applications to use the new WGS dataset. The Centres of Excellence have been actively promoting their exemplars at international events and have seen an increase in enquiries about using their new datasets from international

Research question	Findings
	researchers. With the additional funding from delivering the DIH Programme HDR UK has also been growing its profile internationally through involvement international networks such as the European Health Data Evidence Network.
To what extent is there early evidence of an impact on the size of the sector?	The evaluation evidence suggests that the size of the data driven healthcare and precision medicine sector has grown in the UK over the last five years. The bespoke PM sector database shows that the number of businesses that are active in this space increased from 305 to 430 firms and employment in the sector (excluding the multinationals) grew from 19.8k to 23.1k. Based on feedback from businesses there has been some modest impact on growth in the sector so far. The evaluation found some examples where SMEs have benefited in the set-up process, securing external investment and creating collaborations with other industry partners as a result of being part of the Challenge. However, the econometric analysis found no evidence at this stage that those companies from the precision medicine sector that had engaged in the Challenge had grown any significantly faster than companies that had not engaged. This finding is not surprising since many projects have only recently finished and the time-lag to realise innovation and commercialisation benefits. The evidence indicated that the investments made to date will help to grow the sector over the coming years but this will be subject to continued investment in NHS infrastructure and building up the skills and capacity in the NHS as one of the key customers for these new technologies.
To what extent is there early evidence of effects on healthcare delivery that may lead to patient outcomes?	There were a small number of examples where Challenge funded projects have had an effect on healthcare delivery but for most projects where tools and products were still being developed, it is too early to comment on healthcare benefits of the Challenge. The main areas of achievement are where products have been tested in the clinic (e.g. the development of the Cytosponge in the DELTA project or the development of AI tools for diagnosing eye disease through the INSIGHT Hub). There are also projects like ID Liver where the innovative approach to recruiting of patients will lead to earlier diagnosis. Although COVID-19 caused disruption and delay to many projects it did also enable some projects, particularly the Centres of Excellence and DIH Hubs, to demonstrate at short notice how their R&D activity could improve approaches to COVID diagnosis and treatments.

Source: SQW

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