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Data to Early Diagnosis and Precision Medicine ISCF Challenge Evaluation

Progress and Process Evaluation Report

FINAL

SQW

Contents

Contact:
John Nolan
Tel: 0131 243 0727
email: jnolan@sqw.co.uk

Approved by:
Jonathan Cook
Director
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Executive Summary

1. In 2020, an SQW-led consortium was commissioned by UKRI to evaluate the Data to Early Diagnosis and Precision Medicine (D2EDPM) Industrial Strategy Challenge Fund programme. The evaluation aims to assess both the impact of the D2EDPM Challenge and the process through which it is delivered.

2. There are 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. This Summary presents the key findings of the third stage of the study, an interim progress and process evaluation. The final stage, the impact evaluation, will report in spring/summer 2023.

3. This third stage is based on evidence provided by monitoring returns from project managers and consultations with 69 stakeholders involved in managing and delivering the Challenge. Most of the data related to the period up to June/July 2021, and the feedback from stakeholder consultations focused mainly on the performance of the Challenge up to late summer 2021.

Progress evaluation

4. This Challenge is a complex and ambitious programme of investment that is seeking to accelerate the use of data and new technologies in the diagnosis of disease and adoption of precision medicine. This is a fast-changing landscape and the context has clearly been impacted significantly by the COVID-19 pandemic. Measuring progress of this £210m investment is not straightforward given the number and variety of projects that have been supported under the three strands of the Challenge (Genomics, DigiPath and the Digital Innovation Hubs, DIH). As highlighted in the M&E framework there are different routes and timescales to impact, and the investments made by the Challenge have started at different points over the last three years.

Overall progress towards Challenge objectives

5. The objectives of the D2EDPM Challenge are to: encourage greater adoption of precision medicines including through earlier diagnosis; increase the UK share of global diagnostic market; 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; and increase efficiency in the NHS. As identified in the M&E framework these objectives will take at least five to 10 years to come through. However, there are shorter term outcomes that can be assessed to demonstrate progress towards these longer-term objectives and these are set out in Table 1.

6. Based on the evidence in the progress evaluation, the evaluators expect that the Challenge will meet its target budget and outputs by the time of the final phase of the evaluation in 2023.

The research also indicates that progress is starting to be made against the shorter-term outcomes, and examples are provided in the Table below – albeit that there is more to do. Taking into account the inevitable time-lag for many of the Challenge outcomes and the fact that some projects have been delayed, the evaluators believe that the progress made to date is largely where it should be at this stage of implementation. This is particularly true for the Genomics and DIH strands. The DigiPath strand needs to progress more quickly going forward in order to make up on some of the delays encountered. UKRI acknowledged this and provided costed extensions to the Centres of Excellence.

7. Most of the delays have been in some way related to the pandemic, but the Centres of Excellence have also been delayed by issues specifically related to the Challenge – primarily through applicants and UKRI underestimating the complexity of delivering the Centres together with project administration issues.

Table 1: Emerging Challenge outcomes

	Key evidence on progress to date
Enhanced global reputation for: genomics, WGS trials, health data driven R&D and innovation (incl. diagnostics and AI)	• Due to its scale, ambition and level of collaboration between key industry partners, the UK Biobank Whole Genome Sequencing project was viewed as a flagship project globally and regarded as the gold standard for population genetics research. The profile generated by the investment has started to escalate following the first public release of sequenced data. • The digital pathology and radiology Centres of Excellence have increased their national profile through research papers on the Challenge funded activity and delivered national events. Over 100 publications have already been produced by partners involved at the Centres. There have also been international events, though there is work to do to translate this into global profile.
Increased commercial and academic R&D investment, including in related areas (e.g. other omics)	• The Challenge has successfully attracted funding from partners, as demonstrated by the figures below. In addition, there are already examples of the Challenge leading to subsequent/related research investments. • £150m in match funding leveraged through the UK Biobank WGS project. Across the GEL and CR&D projects, there was nearly £1m in match funding for the Genomics CR&D projects which will increase to £3.7m by the end of the projects. • £14.5m in match funding for the Centres of Excellence to date (which will rise to £43.3m) and £4.2m for the Integrated Diagnostics CR&D projects (increasing to £14.2m). £21.3m in match funding to date for the Health Data Research Hubs in the DIH Programme which will increase to £36.2m.
Improved access to, and use of, data resources for industry, NHS and academic R&D	• The data resources are being made available, though more evidence is required, at the final stage, to demonstrate widespread use across different stakeholder groups.

	Key evidence on progress to date
	• For example, Health Data Research Innovation Gateway was launched in June 2020 and now signposts to 699 datasets, some of which are visible exclusively via the Gateway - the target is to include 2,000 datasets by 2023
Improved curation/ characterisation of patient data	• The Health Data Research Hubs have so far made 100 datasets discoverable and, in meeting 'Milestone 2', they have demonstrated data improvement and improved accessibility.
New companies attracted to the UK & new start-ups due to availability and quality of UK health data, genomics capabilities and AI/digi diagnostics capabilities	• Limited evidence of this happening to date. • Whilst there is confidence this will start to happen as new technologies funded by the Challenge start to be adopted by the NHS, it is noted that presence in the UK is not necessarily a requirement to take advantage of the data resources on offer (e.g. through the UK Biobank).
New AI diagnostic tools developed and/or validated	• Across the Centres, there are 37 exemplar projects being delivered, four AI tools have already been developed and a further 28 AI tools are currently in development. By this point of the evaluation, this is encouraging, and we expect much more progress by the time of the final evaluation.
Increased academic-industry-NHS collaborations focused on new data-driven healthcare products/ AI and digital pathology/ WGS	• This is a key area of achievement by the Challenge with new collaborations evident across all strands of the Challenge. For example, by the end of 2021, the Health Data Research Hubs had secured over 500 contracts with a range of academic, industry and NHS clients.
Improved business performance in industry partners	• It is perhaps too early for substantial evidence of this outcome. There are nevertheless some early individual examples of industry partners reporting business benefits from being part of the Centres of Excellence. However, most benefits will come in the coming years from successful commercialisation, e.g. of new AI tools.
Improved skills capacity and capability for genomic and data-driven healthcare technologies	• Improved skills and capability for genomic technologies reported by pharma partners involved in the UK Biobank WGS projects, and this is expected to evolve further as researchers from other sectors begin to use the new data. • There are also examples from the digital pathology and radiology Centres of Excellence. ICAIRD and PathLAKE reported improved skills amongst clinicians trained using the new digital diagnostics. NPIC expect that once the scanners are installed and in use, this will help improve digital skills clinician understanding and trust in digital diagnostic technologies.

Source: SQW

Genomics

8. Most progress in terms of investment has been in the Genomics strand where over £100m of UKRI's investment has already been made and this has leveraged a further £150m in match funding from the four pharma partners and Wellcome Trust. The WGS UK Biobank project has progressed significantly, making some real accomplishments in the provision of genomics data. It means that in 2022, 500,000 whole genome sequences will be available to UK Biobank users, with an informatics platform for the storage, curation and analysis of the data.

9. Although the utility of the sequenced data will be tested by the pharma partners and wider research community over the coming 12 months, the evaluation found that the project has already increased the UK's profile and reputation for whole genome sequencing and is expected to help deliver better and more targeted medicines over the next 10 years. The evaluation also found qualitative evidence that the project is starting to generate benefits through increased investment in genomics and other omics research, skills and capability development, and improved industry-academic collaboration.

10. There are also emerging benefits under this strand from the GEL and Genomics CR&D projects, which are developing new WGS related technologies. Around £2m in UKRI funding had been spent on these projects by summer 2021 out of an allocation of £11m. There was nearly £1m in match funding from industry spent by summer 2021 which will increase to £3.7m by the end of the projects. Early benefits from these projects include new cross-sector collaborations (between academia, the NHS, charities and industry) new products or new evidence to validate or enhance existing tools or technologies.

11. At this stage, the strand is on track to deliver the types of outcomes expected, including investment in research, cross-sector collaboration, and capability and capacity development for innovation and research. If research and investment prove successful, then business and health benefits would be expected to follow. The early indications suggest that the investment in the UK Biobank has aided the UK's reputation internationally, though it is not clear at this point whether this will lead to inward investment and attraction of companies – reflecting the nature of the asset, which can be accessed from anywhere in the world.

12. The Challenge funding, and the inferred government commitment to the UK Biobank as a national research resource, was key to the additionality of the activities, i.e. making the genomic sequencing work and infrastructure development possible, and generating essential match funding from industry.

DigiPath

13. The progress of the digital pathology and radiology Centres of Excellence has undoubtedly been delayed, partly due to the disruption caused by the pandemic but there have been other factors which resulted in a slower start than planned. Around £25.2m of UKRI funding had been spent by summer 2021 (out of an allocation of £59m) with £14.5m in match funding spent to date (versus a total commitment of £43.3m).

14. As a result, the evidence at this stage is focused on the delivery of key outputs, with the five Centres having made good progress in setting up the infrastructure and facilities and delivering the exemplar projects. Some are also starting to develop the AI tools and diagnostic technologies for use in the NHS. The evaluation found some early evidence of increased profile for the Centres of Excellence in a UK and international context, increased commercial R&D investment, improved digital skills amongst clinicians and indirect business benefits (e.g. examples of early stage companies being able to more readily attract investment, partly aided by involvement in the Challenge). If these early individual cases of outcomes continue and spread, then this strand is well-placed to achieve its intended effects; though we caution that at this point of the evaluation, most of the outcomes will be achieved in the future. Although the requirements around interoperability were not well understood at the start, consultees reported that some progress is now being made through the eight workstreams led by the Centres with support from UKRI.

15. Despite initial delays caused by the pandemic, most Integrated Diagnostics CR&D projects are now making progress. Around £4m of UKRI investment had been spent by summer 2021, out of an allocation of £16m. Around £4.2m in match funding has been spent out of a total commitment of £14.2m.

16. The evaluation found high levels of additionality in terms of what has been funded and what has been achieved to date in terms of outputs and emerging outcomes. The funding was seen as the catalyst for investing in new equipment, recruiting additional staff and securing the buy-in from industry partners.

DIH

17. By December 2021 around £26m had been spent in UKRI funding on the Digital Innovation Hub programme out of a total of £37.5m. As part of the investment to date, £16.3m of UKRI funding had been spent on the five DIH Hubs and these had also leveraged £21.3m in match funding. The DIH programme which was delegated to HDR UK has three main areas of activity. The Health Data Research Alliance has grown from eight founding members to a total of 61 data controllers and data custodians. The Health Data Research Innovation Gateway was launched in June 2020 and now signposts to 699 datasets, some of which are visible exclusively via the Gateway- the target is to include 2,000 datasets by 2023. The Hubs have made 100 datasets discoverable through the Gateway– the uptake will be assessed in the final evaluation.

18. The Research Hubs have all passed Milestone 2 which confirms that they have demonstrated data improvement and improved accessibility. Consultees reported that the Hubs are making good progress in terms of creating TREs, improving access to health data and increasing collaboration and engagement with industry, NHS trusts and academia. There have been some strong early examples of impacts by the Hubs, such as in generating commercial interest and investment, and through outputs such as academic papers. Again, these need to continue to and spread for the strand to achieve its intended effects.

19. Once again, the evaluation found high levels of additionality in terms of what has been achieved by Challenge funding for the DIH programme to date. Consultees indicated that the Challenge support has accelerated the process and improved the quality and scale of new structures and systems for improved data integration and access. The Challenge is felt to have enabled the involvement of a wider range of stakeholders than would otherwise have been likely, and encouraged people to work outside the 'bubble' of academia.

Process evaluation

20. The M&E framework set out the key research questions for the process evaluation. The table below summarises the key findings in relation to each of these questions.

Table 2: Key process evaluation questions

Research question	Evaluator response
Did the programme meet its target budget and outputs efficiently and effectively?	• Overall, the Challenge is slightly behind schedule on expenditure mainly due to the delays in the DigiPath strand where costed extensions were approved for the Centres of Excellence. Although there has been some slippage, the evaluators expect that the Challenge will meet its target budget and outputs by the time of the final phase of the evaluation in 2023. This should be regarded positively given the context in which the Challenge has been delivered, and the complex nature of many of the activities.
To what extent did the governance, monitoring, management, and communications (internal and to external participants) enable programme delivery?	• The D2EDPM Programme Board has generally been effective in providing oversight on progress, and consultees believed that the structures and systems are comparable with other similar Government programmes. • There is good cross sector representation on the Challenge Advisory Group from relevant organisations - academia, NHS, the Royal Colleges of Pathologists and Radiologists, and industry (LifeArc and ABPI) - but this external expertise needs to be leveraged more effectively by UKRI to maximise the impact of the Challenge investments. • Across all strands of the Challenge, there would appear to be robust management structures in place to ensure effective delivery of projects for the remainder of the Challenge. • The evaluators believe that additional support and guidance on sustainability should be provided to the Centres of Excellence. A new set of interoperability workstreams have been established by UKRI to encourage more joint thinking and collaboration across the Centres on issues such as deidentification, data transfer standards and TREs. This additional support has been broadly welcomed. • Although there were cases of individual projects promoting their activity, the evidence indicates that there has been little or no external promotion of the Challenge, and this will limit the potential effects of the Challenge if not addressed. The evaluation feedback indicated the need for more promotion of the Challenge and its achievements to ensure the R&D projects across the three strands can influence wider policy and leverage further investment in the UK's data driven healthcare and precision medicine sector.

Research question	Evaluator response
How effective were risk management strategies in anticipating and mitigating risks?	• Risk management strategies have been built into the different levels of governance and management structures from the Programme Board down to local project management teams. • The UKRI monitoring officers meet quarterly with the Genomics CR&D projects, Centres of Excellence and the Integrated Diagnostics CR&D projects to track progress, assess key risks to project delivery and to identify mitigation of these risks. These processes were seen to be working effectively, and project leads valued the input from the monitoring officers in helping to keep projects on track. • In the DIH programme, HDR UK has put in place a milestone performance management structure to track progress of the Hubs, which has helped address risks to progress. For the UK Biobank WGS project the collaborative approach and project level governance has been effective in responding to issues and risks. As part of this, the regular and ongoing meetings have enabled partners to address technical challenges.
Was monitoring effective in keeping the programme on track?	• The monitoring and reporting produced for the Programme Board is generally fit for purpose with appropriate summaries provided by UK Biobank and the sequencing partners on the UK Biobank WGS project, and HDR UK in reporting progress on the DIH programme. • For the Genomics CR&D projects, Centres of Excellence and Integrated Diagnostics CR&D projects UKRI employ monitoring officers to meet project managers on a quarterly basis to review progress against spend and project milestones. The feedback from projects highlighted that these meetings are helpful to review progress. • However, there were some elements of management by Innovate UK that have not worked well. First, in some cases, claims processes were considered to be prohibitively slow. Second, the claims portal introduced in August 2020 was deemed ineffective by some project consultees. The evaluators understand that improvements have been made to the new claims system. Any outstanding issues should be discussed with projects and resolved as soon as possible.
Were there barriers or enablers for the programme?	• The main barrier to delivery to date has been the COVID-19 pandemic which has caused disruption and delays across the three strands of the Challenge due to problems with staff availability, project teams reallocated to pandemic response, restricted access to labs and supplies, and patient recruitment. • The pandemic has generated some positive wider effects in terms of: increased capacity and profile for whole genome sequencing; the data, helping to accelerate analysis and new tools developed by some of the DIH Hubs to support the pandemic response; and the increased awareness of what Centres of Excellence are seeking to deliver. • The complexity of partnership working was another key barrier. The evaluation has highlighted various examples where the process of setting up projects and finalising governance and contractual arrangements has taken longer than expected and has required significant project management resource.
To what extent has the D2EDPM Challenge	• There was a good awareness of EDI issues across the Challenge, and a recognition that UKRI has been promoting

Research question	Evaluator response
ensured that equality, diversity and inclusion is achieved by broadening sector engagement and embracing differences	this more as the Challenge has progressed. All the main partners highlighted their individual organisations' commitments to EDI, and the Centres of Excellence and DIH Hubs confirmed that they have PPIE activities built into their Challenge projects. The evaluation found examples of patient groups being consulted, lay representation on project committees and some outreach activity to promote better understanding of how patient data is being used
To what extent has the programme's design and delivery enabled it to meet its objectives?	• As reported in the Baseline report, the design and set-up stage was viewed as effective, notably in relation to securing industry investment and engagement, and in designing in additionality. In addition to the traditional approach to CR&D competitions, UKRI co-developed and directly funded the UK Biobank WGS project and sub-contracted delivery of the DIH Programme to HDR UK. This mix of approaches has been appropriate given the unique roles of the pharma partners, UK Biobank and HDR UK. • The DIH Hubs have benefited from wider support and programme management from HDR UK. This type of approach could potentially have been used with the DigiPath Centres of Excellence. Although they were set up using a traditional competition, they are somewhat different from Innovate UK's usual CR&D projects in the terms of the imperatives to ensure linkages and interoperability across the Centres. As a result, the Centres would have benefited (and would benefit going forward) from more hands-on programme management from UKRI.

Source: SQW

Recommended improvements

21. Based on the evidence from the progress and process evaluation the following recommendations are provided for the remained of the D2EDPM Challenge:

- **Improve the external communications to ensure successful outcomes and benefits are widely communicated nationally and internationally** - this would both demonstrate the returns on investment and promote the existence of valuable research assets to potential future investors, researchers and businesses, thereby contributing to longer-term outcomes.

- **Improve the communications to other parts of UKRI and other organisations supporting the growth of precision medicine in the UK**. The work of the Challenge needs to be better integrated with other healthcare and technology-related programmes being delivered by UKRI and other agencies. Other relevant organisations would include Academic Health Science Networks, KTN, the Catapults, health charities and industry bodies such as ABPI, BIA and BIVDA. In addition to better leveraging of the Advisory Group, the evaluators recommend the Challenge team investigate with the KTN the potential to establish Challenge Community, similar to what has been set up for the Medicines Manufacturing Challenge.

- **Leverage the expertise that exists in the Advisory Group more effectively** to promote the Challenge achievements, make the links with other complementary programmes and provide advice to key issues such as interoperability, technology adoption in the NHS and how to secure more commercial investment into the UK's data driven healthcare sector.
- **Support more internal collaboration between different strands and partners involved in the Challenge** – events to share progress, successes and future directions, with time for discussion of cross-strand opportunities for future collaboration and/or suggestions and ideas for future Challenges could help foster new linkages and ideas. Brokered meetings could also facilitate these types of opportunities, especially for smaller businesses that have less capacity to source such openings.
- **Provide more support on monitoring and reporting** – particularly in terms of resolving any outstanding issues on providing financial data and ensuring timely payment of project claims.
- **Provide more support on sustainability and greater clarity on what happens after D2EDPM ends**. As projects come towards the end and there is no clarity on long term funding then staff may leave to look for more stable/certain employment elsewhere. If greater clarity can be provided or sustainability achieved earlier, then the capacity and capability built up could help initiatives into their next phase.
- **Develop a long-term plan to build on and engage with the Challenge achievements well beyond the end of the funding period** - many opportunities will only emerge after this point and realising the maximum benefits from the Challenge investment will require further action.

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) Industrial Strategy Challenge, and the complementary investment by the Office for Life Sciences in the Centres of Excellence.

1.2 The consortium comprises PHG Foundation, Impact Data Metrics, ADL and IFF Research as well as SQW. The evaluation aims to assess both the impact of the D2EDPM Challenge and the process through which it is delivered.

1.3 There are 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. This report presents the findings of the third stage of the study, and is an interim progress and process evaluation. The final stage, the impact evaluation, will report in spring/summer 2023.

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

Progress and process evaluation approach

1.5 The research for this phase of the evaluation was undertaken between August and December 2021 and included three stakeholder workshops which were held in early December 2021 to discuss emerging findings. There was some variation in the timescale for the monitoring data provided by project managers but most data related to the period up to June/July 2021. Although stakeholder consultations took place in October and November 2021, the feedback focused mainly on the performance of the Challenge up to late summer 2021. The evidence reported, analysis undertaken and conclusions reflect this period for which data and feedback were collected.

1.6 The approach to the progress and process evaluation was agreed in the evaluation framework and involved two main research tasks:

- **Stakeholder, beneficiary, partner and non-beneficiary consultations** – discussions with 69 representatives involved in various roles associated with the D2EDPM Challenge were held. This included UKRI Innovation Leads, Challenge Advisory Group members, the directors and managers of projects funded by the Challenge, and wider partners of the investments, including from academia, the NHS and the private sector. The consultations also included two unsuccessful applicants.
  - The consultations focused on main achievements, key lessons, progress in terms of delivered outputs and early outcomes from Challenge funded projects, governance and management, Challenge promotion, and Equality, Diversity and Inclusion (EDI).

- **Analysis of project monitoring data** – templates were sent out to all live projects to provide a consistent approach to monitoring project performance in terms of spend, activities and outputs.

Report structure

1.7 The Progress and Process evaluation report is structured as follows:

- Section 2 provides an overview of the Challenge delivery to date based on the data provided in the monitoring templates
- Section 3 highlights the main lessons from project delivery, including what has worked well and not so well
- Section 4 summarises the evidence on how the different strands of the Challenge, and the projects within them, are progressing towards their intended outcomes, including case examples of early key achievements
- Section 5 provides an assessment of the effectiveness of the governance and management of the Challenge
- Section 6 sets out the main conclusions from the progress and process evaluation.

1.8 The following Annexes are also attached:

- Annex A provides a list of all the stakeholders that participated in the research
- Annex B provides project level summaries

2. Challenge delivery to date

2.1 In this section we provide analysis of the Challenge delivery to date based on monitoring data for spend, activities and outputs submitted to the evaluation team. It should be noted that the data provided has been taken as correct; we have not undertaken any verification on the data aside from sense checking what was submitted.

2.2 It is important to highlight that the reporting periods across strands and projects varies considerably. All projects were asked to report the latest available data and return monitoring templates to the evaluation team by mid-August 2021 (with some submitted in September 2021). The timing of the template returns (August/September 2021) then informed the subsequent consultations that took place in autumn 2021, providing a consolidated interim assessment of progress and processes. In some cases, there have been issues with the financial claims systems and where claims have still to be signed off early data had to be included in the templates.

2.3 In common with other sections in this report, we have broken down reporting by the three strands of the Challenge:

- **Genomics:** £100m UKRI investment in whole genome sequencing and linked informatics, which together with a further £150m from industry and the Wellcome Trust, has enabled whole genome sequencing and informatics on all 500,000 UK Biobank participants. This strand also includes funding for Genomics England to support WGS in cancer trials, and six collaborative R&D (CR&D) projects.
- **Centres for digital pathology, radiology, AI and machine learning and enabling integrated diagnostics (DigiPath strand):** an initial allocation of £50m in UKRI funding has been used to create a network of Centres of Excellence in digital pathology and radiology, focusing on the use of artificial intelligence and digital solutions. There is also £16m for integrated diagnostics CR&D projects.[1]
- **Digital Innovation Hub (DIH) Programme:** £37.5m UKRI investment in the Digital Innovation Hub Programme. This has created five Health Data Research Hubs, managed by HDR UK, a Health Data Alliance and an Innovation Gateway to facilitate access to new data-sets for researchers and industry. The investment is linking routine NHS and R&D data, and providing analytic tools and informatics support for businesses alongside access to integrated UK-wide data.

2.4 More detailed project summaries with monitoring data can be found in Annex B.

[1] A further £9m has been provided in costed extensions for the Centres of Excellence and an extra £2m for the Integrated Diagnostic CR&D projects

Summary of Challenge delivery to date

- The largest single investment of the Challenge, the £100m funding for the UK Biobank Whole Genome Sequencing project, was fully spent by the time of the monitoring in summer 2021. This also attracted £100m in match funding from industry along with £50m from the Wellcome Trust.
- The UK Biobank WGS investment is making good progress in the sequencing of 500,000 Biobank participants. The public release of data for the first 200,000 in September 2021 was a significant milestone.
- Across other elements of the Challenge, the level of expenditure to the point of the evaluation was lower than expected due to issues around set-up of projects and disruptions caused by the COVID-19 pandemic. For instance, the spending of Challenge funding on the Centres of Excellence in digital pathology and radiology was around 70% of what was planned by summer 2021, and on genomics CR&D projects the spend was around 50% of what was planned.
- In line with the delays to set-up, there had been some knock-on effects on the delivery of activities and outputs reported. That said, a range of indicators of progress were noted in the data:
  a) The genomics CR&D projects reported various early activities to recruit patients and create datasets.
  b) The five Centres of Excellence reported progress in setting up the infrastructure and facilities, delivering the exemplar projects and starting to develop the AI tools and diagnostic technologies for use in the NHS.
  c) The Health Data Alliance had grown its membership to over 60 members and the Innovation Gateway signposts to 699 datasets, some of which are visible exclusively via the Gateway - the target is to include 2,000 datasets by 2023.
  d) The five UKRI-funded Research Hubs had brought together range of partners, had curated just under 500 national datasets for major diseases, and had delivered 122 CR&D projects to date.

Genomics

Spend

2.5 Table 2-1 provides a summary of UKRI investment and match funding for projects in the genomics strand of the Challenge. The largest investment in the genomics strand relates to the £100m funding for the UK Biobank Whole Genome Sequencing project. This contribution was provided to the industry consortium in 2018 which is also providing £100m in match funding, along with £50m from the Wellcome Trust.

2.6 Nearly £7.9m of UKRI funding has been approved for Genomics England's (GEL) WGS in cancer trials project and around £1.1m had been spent to May/June 2021 which was around half of what was planned by this stage. Six smaller CR&D projects have been funded with

grants totalling around £3.2m, of which £0.8m had been spent (again around half planned spend by that point). In all cases, the level of spend has been lower than expected due to issues around project set-up and disruptions caused by the COVID-19 pandemic.

2.7 In addition to the £150m in match funding leveraged through the UK Biobank WGS project, the other genomics projects are also securing significant match funding. Across the GEL and CR&D projects, there was nearly £1m in match funding from industry spent by summer 2021 which will increase to £3.7m by the end of the projects.

Table 2-1: Genomics strand investment (actuals until May/June 2021)

	Project totals (£m)	Planned spend (£m) to May/ June 2021	Actual spend (£m) to May/ June 2021	Actual spend as % of planned	Actual spend as % of total
UK Biobank WGS project – UKRI funding	100.00	100.00	100.00	100%	100%
UK Biobank WGS project – match funding	**150.00**	**150.00**	**150.00**	**100%**	**100%**
GEL WGS in cancer trials – UKRI funding	7.88	2.17	1.06	49%	13%
GEL WGS in cancer trials – match funding	**2.30**	**1.48**	**0.63**	**42%**	**27%**
Genomics CR&D projects – UKRI funding	3.16	1.51	0.78	52%	25%
Genomics CR&D projects – match funding	**1.44**	**0.59**	**0.29**	**50%**	**20%**

Source: SQW analysis of D2EDPM Challenge monitoring templates completed by project managers

Activities and outputs

2.8 The main activities and outputs from the Genomics projects are summarised in Annex B. This information is based on the monitoring returns provided in August/September 2021.

2.9 The UK Biobank WGS project brings together nine major industry partners (UK Biobank, GSK, AstraZeneca, Janssen/J&J, Amgen, Wellcome Sanger Institute, deCODE genetics, DNAnexus and Amazon Web Services) and, as will be discussed in later sections, is making good progress in the sequencing of 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.

2.10 In terms of the GEL project, four of the eight studies had so far submitted their first batches of samples by summer 2021, and a further two were ready to submit imminently. However, the pandemic has had a major adverse effect on clinical trial recruitment. Many of the other projects have progressed well against reprofiled plans, e.g. in terms of partner engagement,

creating new datasets and analysing data. One of the projects (CUP-COMP) had been affected in terms of patient recruitment and site activation.

DigiPath

Spend

2.11 As shown in Table 2-2, a total of £59m in UKRI funding has been allocated to the five Centres of Excellence for digital pathology and radiology. Based on the monitoring returns, £25.2m had been spent by summer 2021, which represents two-thirds of planned expenditure by this stage. In addition, the Integrated Diagnostics CR&D projects had spent £3.9m which was 69% of planned spend.

2.12 The level of expenditure has been lower than expected due to projects having to be paused during the pandemic and a number of projects were subsequently provided with costed extensions.

2.13 In addition to the UKRI investment, there has been £14.5m spent in match funding for the Centres of Excellence (versus a total commitment of £43.3m). and a further £4.2m in match funding for the CR&D projects to date (out of a total commitment of £14.2m).

Table 2-2: Centre of Excellence investment (actuals until spring/summer 2021)[2]

	Project totals (£m)	Planned spend (£m) to spring/ summer 2021	Actual spend (£m) to spring/ summer 2021	Actual spend as % of planned	Actual spend as % of total
Centres of Excellence – UKRI funding	59.02	35.72	25.24	71%	43%
Centres of Excellence – match funding	**43.29**	**12.81**	**14.47**	**113%**	**33%**
Int. Diag. CR&D projects – UKRI funding	17.97	5.67	3.93	69%	22%
Int. Diag. CR&D projects – match funding	**14.17**	**3.40**	**4.18**	**123%**	**29%**

Source: SQW analysis of D2EDPM Challenge monitoring templates completed by project managers

[2] The latest spend data varied across the five centres from January 21 to June 21

Activities and outputs

2.14 A summary of the main activities and outputs relating to the five digital pathology and radiology Centres of Excellence is provided below. Due to COVID-related delays, the Centres of Excellence workplans were reprofiled with costed extensions. **Based on the revised work plans** and monitoring data provided by the project managers, the projects are largely on track. The five centres have made good progress in setting up the infrastructure and facilities, delivering the exemplar projects and starting to develop the AI tools and diagnostic technologies for use in the NHS. Across the Centres, there are 37 exemplar projects being delivered, four AI tools have already developed and a further 28 AI tools are currently in development. However, in light of the slower levels of spend to date it is clear that the progress in delivering the exemplar projects and AI tools is behind what was originally envisaged at the start of the projects in 2019.

Table 2-3: ICAIRD CoE metrics reported to date (to Apr 21)

Indicator	Project target	Target to date	Achieved to date
No. of project partners (total)	14	14	14
No. of commercial partners	**8**	**8**	**8**
No. of new data storage facilities	3	3	3
No. of exemplar projects	**14**	**6**	**5**
No. of AI tools in development	5	5	5
No. of AI tools developed	**5**	**0**	**0**
No. of AI tools validated	5	0	0
No. of NHS sites with enhanced diagnostic equipment	**3**	**3**	**3**
No. of AI evaluation platforms deployed	4	4	4
No. of AI training platforms deployed	**4**	**4**	**2**
No. of clinicians/ researchers trained	38	21	21
No. of PPIE events	**3**	**3**	**12**
No. of PPIE participants	N/A	N/A	201

Source: SQW analysis of D2EDPM Challenge monitoring templates completed by project manager

Table 2-4: LMIAI CoE metrics reported to date (to Jul 21)

	Project target	Target to date	Achieved to date
No. of project partners (total)	21	21	22
No. of commercial partners	**13**	**13**	**14**
No. of new data storage facilities	4	4	4
No. of NHS sites using the facilities	**3**	**3**	**3**
No. of new data sharing platforms	1	1	1
No. of exemplar projects	**16**	**16**	**17**

	Project target	Target to date	Achieved to date
No. of AI tools in development	12	12	14
No. of AI tools developed	**12**	**0**	**0**
No. of AI tools validated	5	0	0
No. of PPIE events	**N/A**	**N/A**	**11**
No. of PPIE participants	N/A	N/A	3*
No. of publications by CoE partners	**N/A**	**N/A**	**44**

*Source: SQW analysis of D2EDPM Challenge monitoring templates completed by project manager * PPIE participants refer to patient reps on data allocation committee rather than individuals attending events*

Table 2-5: PathLAKE CoE metrics reported to date (to Jun 21)

	Project target	Target to date	Achieved to date
No. of project partners (total)	14	14	14
No. of commercial partners	**6**	**6**	**6**
No. of new data storage facilities	1	1	1
No. of new data sharing platforms	**1**	**1**	**1**
No. of exemplar projects	4	4	4
No. of AI tools in development	**7**	**7**	**7**
No. of AI tools developed	7	0	0
No. of AI tools validated	**7**	**0**	**0**
No. of clinicians/ researchers trained	N/A	N/A	60
No. of NHS sites with enhanced diagnostic equipment	**5**	**5**	**5**
No. of fully digitalised labs	5	5	3
No. of PPIE events	**5**	**5**	**4**
No. of PPIE participants	N/A	N/A	9
No. of publications by CoE partners	**N/A**	**N/A**	**35**
No. of CoE enquiries from new potential business partners	N/A	N/A	29

Source: SQW analysis of D2EDPM Challenge monitoring templates completed by project manager

Table 2-6: NPIC CoE metrics reported to date (to Jul 21)

	Project target	Target to date	Achieved to date
No. of project partners (total)	23	23	23
No. of commercial partners	**10**	**10**	**10**
No. of new data storage facilities procured	1	1	1
No. of NHS sites using the facilities	**6**	**1**	**1**
No. of NHS sites with enhanced diagnostic equipment	6	1	1
No. of fully digitalised NHS labs	**6**	**1**	**1**

	Project target	Target to date	Achieved to date
Digitised slides as a % of all slides collected by NHS labs receiving investment	100	36	36
No. of PPIE events	**10**	**5**	**5**
No. of PPIE participants	89	39	39
No. of publications by CoE partners	**19**	**13**	**13**
No. of UK events to promote exemplar projects	18	16	16
No. of overseas events to promote exemplar projects	**10**	**9**	**9**
No. of CoE enquiries from new potential business partners	N/A	N/A	3
No. of new jobs created	**29**	**25**	**25**
Tests on monitors completed using Point of Use QA tool developed by NPIC	N/A	N/A	1044

Source: SQW analysis of D2EDPM Challenge monitoring templates completed by project manager

Table 2-7: NCIMI CoE metrics reported to date (to Jun 21)

	Project target	Target to date	Achieved to date
No. of project partners (total)	39	31	34
No. of commercial partners	**20**	**12**	**13**
No. of new data storage facilities	15	13	8
No. of NHS sites using the facilities	**18**	**12**	**7**
No. of data sharing platforms	1	1	1
No. of NHS sites using the platforms	**15**	**15**	**14**
No. of exemplar projects	26	17	11
No. of AI tools in development	**14**	**5**	**2**
No. of AI tools developed	14	3	4
No. of AI tools validated	**8**	**2**	**2**
No. of NHS sites with enhanced diagnostic equipment	14	14	54
No. of clinicians/ researchers trained	**55**	**35**	**321**
No. of PPIE events	9	5	5
No. of PPIE participants	**185**	**80**	**125**
No. of publications by CoE partners	24	9	13
No. of UK events to promote exemplar projects	**53**	**48**	**76**
No. of overseas events to promote exemplar projects	17	12	17

	Project target	Target to date	Achieved to date
Regulatory approvals for developed AI algorithms	**7**	**3**	**5**
No. of CoE enquiries from new potential business partners	N/A	N/A	8

Source: SQW analysis of D2EDPM Challenge monitoring templates completed by project manager

2.15 The Integrated Diagnostics CR&D projects are generally at an earlier stage of delivery than the Centres of Excellence (with most starting in early 2021) and this is reflected in the activity and output data provided by the project managers. In the early phases of project delivery covered by the monitoring templates (up to summer 2021), projects have been collecting and preparing the range of diagnostics and patient data, recruiting patients and setting up the infrastructure which will then allow the development of new diagnostic tools and clinical pathways. The monitoring data provided by project managers appear to show that projects are largely on track. The extent to which the projects are delivering against the objectives of the Challenge can be evaluated once the diagnostic tools have been developed.

DIH Programme

Spend

2.16 A total of £37.5m in UKRI funding has been allocated the Digital Innovation Hub (DIH) Programme. Around £13m has been allocated to HDR UK to deliver the core programme including the Alliance and Gateway, £22m provided in direct funding to the DIH Research Hubs and £2.6m provided to deliver 10 Sprint Exemplar projects which completed in 2018/19.

2.17 Up to December 2021, 85% of UKRI funding for DIH Programme management and 70% of the funding for the Alliance and Innovation Gateway had been spent (no planned spend up to this point was available) – this amounted to £9.7m (Table 2-8). Three quarters of the UKRI funding for five DIH Hubs had been spent, which totalled £16.3m (in line with planned spend to this stage). These Hubs have also leveraged £21.3m in match funding from the host universities.

2.18 A further £2m has been invested by HDR-UK in two other Research Hubs which are also part of the DIH Programme, and these Hubs have also leveraged £6.3m in match funding to date.

Table 2-8: DIH Programme investment (actuals to Dec 2021)

	Project totals (£m)	Planned spend (£m) to Dec 2021	Actual spend (£m) to Dec 2021	Actual spend as % of planned	Actual spend as % of total
DIH Management – UKRI funding	3.75	N/A	3.19	N/A	85%
DIH Alliance and Gateway – UKRI funding	**9.29**	**N/A**	**6.49**	**N/A**	**70%**

	Project totals (£m)	Planned spend (£m) to Dec 2021	Actual spend (£m) to Dec 2021	Actual spend as % of planned	Actual spend as % of total
DIH Hubs - UKRI funding	21.81	16.69	16.30	98%	75%
DIH Hubs – match funding (UKRI Hubs only)	36.15	27.23	21.26	78%	59%
DIH Hubs - HDR UK funding (for Digitrials and Pioneer)	2.08	2.08	2.08	100%	100%
DIH Hubs – Match funding (for Digitrials and Pioneer)	6.81	6.81	6.29	92%	92%

Source: SQW analysis of DIH Monitoring workbook submitted by HDR UK

Activities and outputs

2.19 HDR UK has provided data for a range of metrics that demonstrate progress of the different parts of the DIH Programme. Some of the key indicators from these metrics are shown in Table 2-9. HDR UK has delivered a range of events to promote the Programme which have involved over 4,400 attendees to date. The Health Data Alliance continues to grow its membership and now has over 60 members. The 10 Sprint Exemplars in 2018/19 involved 49 different partners. There were no targets set for the metrics provided below.

2.20 The five UKRI-funded Research Hubs also bring together 49 partners. These Hubs have curated just under 500 national datasets for major diseases and have delivered 122 CR&D projects to date.

Table 2-9: DIH programme activities and outputs – actuals to date (Nov 21)

	2018	2019	2020	Jan-Nov 2021	Total to date
No. of attendees at workshops to promote DIH programme	390	1429	651	1,973	4,443
No. of new Alliance members		25	18	18	61
No. of Sprint Exemplars		10			10
No. of partners involved in Sprint Exemplars		49			49
No. of commercial partners involved in Sprint Exemplars		15			15
No. of partners involved in Research Hubs		49			49
No. of commercial partners involved in Research Hubs		20			20
No. of national datasets for major disease areas curated by Research Hubs		43		455	498

	2018	2019	2020	Jan-Nov 2021	Total to date
No. of CR&D projects delivered by Research Hubs		14	29	79	122
No. of data applications submitted to Research Hubs				**259**	**259**
No. of individuals attending training events			1,080	4,603	5,683
No. of individuals involved in PPIE events		**272**	**13,711**	**25,404**	**39,387**
No. of research publications by DIH partners			27	6	33

Source: SQW analysis of DIH Monitoring workbook submitted by HDR UK

3. Key lessons from project delivery

3.1 This section highlights feedback from the consultations on the main delivery lessons in terms of what has worked well and not so well at the programme level and across the three strands. The section includes discussion on the main barriers and enablers, and specific consideration of how the COVID-19 pandemic has affected the progress of the Challenge.

3.2 In the following sections we also consider the additionality of the project activities funded through the Challenge, i.e. the extent to which the Challenge has supported activities that would not have happened otherwise or would not have been delivered in the way that they have.

Key lessons from delivery

Genomics

- The process of setting up the UK Biobank WGS project and the industry-led consortium was extremely complex and therefore time-consuming. Successful conclusion of the set-up itself was a major achievement for the Challenge, and considered by participants to have been an important factor in subsequent success of the project, putting in place structures and relationships that enabled negotiation of initial and subsequent challenges such as contractual, financial and technical issues.
- The project has created new relationships between major industry players that are competitors, and will provide a foundation for further collaboration.
- There have been technical challenges in developing the informatics platform and this has 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.
- For the CR&D projects, the overall project support and delivery structures were felt to have worked well, and project managers also highlighted that the UKRI monitoring officers have been helpful.

DigiPath

- A key lesson highlighted by the Centres of Excellence has been the need for scale and critical mass to bring together NHS Trusts/ academics and industry – however, projects still need to be manageable.
- Both the Centres of Excellence and the Integrated Diagnostics CR&D projects highlighted the success of collaborative working and close working relationships between partners.
- A lot of time has been spent putting in place local management teams and structures - quarterly monitoring meetings and input from Innovate UK monitoring officers were highlighted as having worked well.

- However there have been some project delays due to the complexity and delays caused by University/ NHS Trust governance structures and processes, and formalising relationships with industry partners.
- There have been a number of admin and claim related frustrations from projects in terms of change requests and accessing the claims system.

DIH

- The collaborative approach to shaping and developing the DIH programme has been effective with a range of academic, clinical and commercial partners now involved in the Hubs and Health Data Alliance.
- The programme has increased awareness of clinical work and data among commercial partners and the involvement of independent experts in project oversight was considered to have enhanced credibility of the projects and provided useful support and continuity.
- The milestone approach to managing the Hubs caused additional administrative burden for some, especially those judged to require intervention and additional monitoring to meet milestones, but was generally acknowledged as a robust and effective mechanism for tracking progress.
- Although progress has been made in growing the list of data controllers that have joined the Alliance, there could be more information sharing across the Challenge on data standards.

COVID effects

- There has been disruption across the Challenge caused by the COVID-19 pandemic in terms of staff availability, project teams reallocated to pandemic response, access to labs and supplies, and patient recruitment. UKRI was felt to have been understanding and flexible about the need for some parts of the Challenge to pivot to pandemic responses, and provided the necessary extensions for projects.
- There have been some positive wider effects in terms of: increased capacity and profile for whole genome sequencing; the data, analysis and new tools developed by some of the DIH Hubs to support the pandemic response; and the importance of what Centres of Excellence are seeking to deliver in terms of more virtual and flexible diagnostic services.

Genomics

What has worked well

3.3 Overall, stakeholders were very satisfied with how well both the UK Biobank Whole Genome Sequencing (WGS) project and the genomics CR&D projects had progressed so far. For the Biobank WGS project, it was highlighted that the negotiations between industry partners and planning needed to create an initial strategy and action plan was complex. A lot of time and effort was required to agree the best approach and responsibilities.

3.4 A key success factor in the UK Biobank WGS project was the partnership development and collaborative approach, the foundations of which were established in set up stage. The Biobank WGS project was seen as complex and ambitious across multiple partners. Therefore, there were challenges in set up and the negotiations between industry partners took a lot of time and resource. The fact that these partners persisted and produced an agreed plan was viewed as a very positive outcome. This enabled, and indeed required, partners from across the sector to work together, resulting in a robust approach on which there was strong consensus. Partners also noted that having regular and ongoing meetings together was very useful; both for strategic decision-making, and more frequently to discuss how to approach technical challenges. Stakeholders felt that these meetings enabled the project to adapt to issues as they arose and where necessary alter course, enabling all partners to meet their objectives.

3.5 Another perceived success from the Biobank WGS project was the decision to have two sequencing providers involved in the project. This decision proved to be highly valuable when the COVID-19 pandemic necessitated one sequencing provider to divert their efforts to viral sequencing as an urgent public health service. The project partners were able to reallocate capacity towards the second provider of sequencing, allowing the project to progress without undue delay.

3.6 For the CR&D projects, the overall project support and delivery structures were felt to have worked well, and project managers also highlighted that the monitoring officers have been helpful (these projects used traditional UKRI project structures and monitoring systems). Some stakeholders found the Innovate UK reporting requirements onerous, but most recognised why such reporting was necessary. One project consultee thought that the small size of their organisation had been helpful in enabling greater flexibility (than say larger organisations and initiatives), notably to adapt to issues posed by the pandemic.

What has not worked so well

3.7 The key concern that was raised in relation to the Biobank WGS project was getting the informatics in place. At the point of interviewing for this evaluation, the final informatics platform (developed and run by Wellcome) was operational, but had not been fully tested through wider public research access to the genomic data. Industry partners expressed some reservations in using the platform in its current form and that it would have been better to have had a co-development process to enable optimisation of the platform. To overcome this issue, industry partners have developed their own independent data access systems, with support from UK Biobank.

3.8 The main problems with the Biobank platform from an industry perspective were functionality and cost. Analytical tools and capacity were said to be inadequate for large-scale data analysis; there was a lack of access to important supplementary datasets (e.g. clinical variant classification); and solutions to these and other technical issues offered by providers such as AWS and DNAnexus were considered costly and inefficient.

3.9 For the 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 Genomics England; 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 one had to establish additional infrastructure to address this barrier. Consultees also identified delays arising from the need to provide additional support and guidance for partners who were less experienced with contractual requirements – for example, academics or smaller start-up companies that were less accustomed to confidentiality agreements. For one project there were also issues with financial allocations to academic and industry partners, and it was felt in this situation Innovate UK might have acted faster.

Barriers and enablers

3.10 For the UK Biobank WGS project, there was a strong consensus that the creation of a collaborative space where partners from different sectors could work together was the key enabler of the project. It was reported that building trust between partners - including among those who were direct competitors - and sharing best practice, knowledge and expertise, went beyond expectations and was a highly positive and supportive factor.

3.11 One delay encountered was in relation to negotiations over financial risk. Sequencing consumables were paid for in US dollars ($) for sequencing taking place in either Iceland or the UK, where the two providers were based. Potential fluctuation in currency exchange rates was considered to create a significant financial risk, given the scale of the project, and negotiations over who should shoulder this risk was said to have been a major point of contention that caused delays. Several stakeholders commented that UKRI should have assumed this risk.

3.12 For the smaller CR&D projects, academic partners suggested that an enabler for future projects would be for more direct support on administration and in facilitating industry collaborations. Effective collaborations between academia and industry can make a difference to progress. For instance, one project was able to make rapid progress thanks to previous work on sample sequencing and data storage capacity and systems by the academic partner. The industry partner was then able to make use of these infrastructure elements (including Amazon Web Services), thereby giving them a head start and useful knowledge of infrastructure and system requirements for this type of work.

How COVID has impacted on delivery

3.13 The COVID-19 pandemic, unsurprisingly, affected all the genomics projects to some extent. The main challenges were delays in access to sequencing materials (such as pipette tips and plates), samples and essential infrastructure and personnel (e.g. laboratory staff, facilities and equipment); mitigation steps were required to address many of these issues. Some felt that shortages of materials were potentially further exacerbated by Brexit-linked border delays;

sample shipping was delayed by restrictions placed on laboratory staff, and there were wider delays arising from the reallocation of human and technical capacity towards specific pandemic responses. The most notable of these was viral genome sequencing and analysis for public health surveillance, but also in some cases diversion of medically qualified staff towards clinical care. Recruitment of participants to research trials was also paused, with an inevitable negative impact on those projects dependent on enrolling patients and securing samples.

3.14 Whilst the pandemic had few direct benefits, many stakeholders spoke of the wider positive impacts, most notably in terms of the increased genomic sequencing capacity driven by the need for viral sequencing, and in demonstrating the value of whole genome sequencing. The scientific benefits were also thought to be highly significant, in particular the rich research resource offered by having genomic and linked clinical data to enable understanding of COVID-19 disease progression and the differences in risk of severe disease between individuals (host genomics). The combination of genomics and NHS patient records was suggested to be unique and powerful, and had further demonstrated the value of access to detailed whole genome sequence information in the context of understanding COVID-19 patient responses.

"...we have been able to identify individuals in the cohort who have been sequenced who have suffered with COVID - those hospitalised or sufficiently ill that it was reported in their NHS records. So we have data potentially relating to genetic understanding of disease progression for COVID patients from this cohort. There are very few other mechanisms to capture something like that in the world; most healthcare systems are not like the NHS"

[UK Biobank project partner]

3.15 It was also felt that there have been some more general benefits from the pandemic, in terms of public understanding and appreciation of the value of rapid clinical research, and of the use of primary care data for research. As an illustration of this, some consultees felt that the concerns around data linkage had decreased. Some projects had also relaxed their clinical trial enrolment requirements as a result of the pandemic - for example, to permit non-simultaneous as well as simultaneous whole genome sequencing of liquid and solid tumour biopsies. These changes were driven by practical challenges arising from pandemic restrictions, but projects cited the increased accessibility as a benefit; more patients became eligible for enrolment. There was also mention of more rapid ethics approval processes.

"In some respects COVID was a great test case for big population datasets being linked to primary care data – there was a clear demonstration of the value of being able to do that".

[UK Biobank project partner]

"There has also been an improved relationship with ethics committees, who are now achieving much faster turnaround on research applications (even for non-COVID) and there is also a lot more scope now for remote consent processes for participants, which is a really positive impact"

[CR&D genomics project partner]

3.16 In addition, the scientific and technical capacity and expertise developed as a result of the pandemic were suggested to have probable future benefits; one example given was the realisation that bioinformaticians (as opposed to wet-lab personnel) were able to work from home effectively, which was thought to potentially improve future recruitment and flexibility of skilled labour, perhaps enabling access to remote workers from other countries.

Additionality of activities

3.17 Stakeholders reported a clear and consistent view that without Challenge funding, the UK Biobank WGS project would not have proceeded on anything like the scale achieved. Whilst some elements of the project might have progressed, it was felt that these would have been in a more piecemeal fashion, at a smaller scale and at a much slower pace. Consultees stated that the full sequencing effort would have been too ambitious for any single organisation to lead, and creating a consortium of pharma and sequencing partners without the catalyst of UKRI funding would have been too difficult. The funding was seen as demonstrating a clear UK government commitment to ongoing support of the UK Biobank cohort as a national research resource, which directly enhanced the confidence of industry partners and enabled them to make the financial case for support.

3.18 Similarly, those involved with the CR&D genomics projects largely felt that they would not have proceeded without the Challenge funding. These projects would have not been able to secure the R&D investment to explore the opportunities around WGS and to develop highly innovative genetic tests and technologies. Consultees indicated that the area of whole genome sequencing is still seen as quite early-stage and therefore high risk for other potential funders. Notably, most of these projects did not receive additional funding or advice other than through the Challenge; some start-up companies may have had access to other sources of support at some level, but not the same scale of funding offered by the Challenge. It was noted that at least some SMEs had enabled the delivery of patient diagnoses and in at least one case had grown global business opportunities as a result.

DigiPath

What has worked well

3.19 A key lesson highlighted by the Centres of Excellence has been the need for scale and critical mass to bring together NHS Trusts/ academics and industry. The scale and scope of funding has encouraged bringing together new partnerships, and the scale has been welcome in

attracting partners. But, at the same time, there is a need for keeping investments realistic in terms of the size of partnerships and focus. Whilst it is difficult to be specific on the optimal size of partnerships (which will be affected by the nature of activities and roles of different partners), particular care is needed when initiatives of this nature are reaching 20+ partners. Securing the engagement and creating new networks has taken a significant amount of time and effort (particularly for NHS partner organisations not used to Innovate UK funding and reporting requirements), but consultees highlighted the opportunities to build on these foundations for future projects.

3.20 Both the Centres of Excellence and the Integrated Diagnostics CR&D projects highlighted the success of collaborative working and close working relationships between partners which have been facilitated by regular meetings and good channels of communication.

3.21 Related to collaboration, consultees noted that **having strong management and delivery teams** has helped to drive projects forward. In particular, having an engaged and competent management team in place was essential:

"Having a good project manager in place has been really important, particularly in setting up virtual meetings and maintaining communication during the pandemic. The PM has kept on top of the detail of all of the workstreams and which has been crucial to enabling progress"

[Centre of Excellence project partner]

3.22 The **quarterly monitoring meetings and input from Innovate UK monitoring officers** were also highlighted as having worked well. The meetings provided impetus for projects, helping them to ensure they stayed on track, and support from the monitoring officers was regarded as "*useful*" and "*appropriate*". Most projects stated that monitoring officers have been helpful in answering questions, been easy to get in touch with, and have made valuable introductions.

3.23 Other aspects of project delivery that have worked well include:

- the **ability to be agile and adapt to evolving situations**; as one consultee recognised, this is particularly important when conducting novel research
- **having previous relationships** with partners, which helped to ensure effective collaborative working
- **establishing clear goals that were ambitious, whilst also achievable and sufficiently focused**
- being able to draw on **an appropriate level of finance** in a timely manner

What has not worked so well

3.24 Stakeholders highlighted the complexity of agreeing governance structures and processes with university, NHS Trusts and industry partners when setting up the Centres of Excellence. In some cases, activity was held up by six to 12 months due to issues around data ethics and access and also IP issues with industry partners. These types of issues are perhaps not surprising given the number of project partners, the involvement of NHS Trusts and their relative lack of experience in these types of R&D projects, and the increased focus on industry engagement.

3.25 Some consultees suggested that the Centres perhaps underestimated the challenges in formalising their consortia and setting up projects. There was also the suggestion that having too many project partners and exemplar projects can adversely affect delivery. Conversely, the Centres highlighted what they viewed as unrealistic expectations put on them by Innovate UK to deliver such complex projects over a three-year period.

3.26 Other issues highlighted by the Centres and CR&D projects were the poor state of IT infrastructure and lack of digital capacity in the NHS Trusts which have caused delays.

3.27 As highlighted in the Baseline report, some of the Centres suggested that there was not enough clarity on the issue of interoperability and this has only come to the fore over the last year or so. Discussion on the progress that has been made in terms of interoperability is included in Section 4. Following the initial Challenge competition in 2018, the English centres were subsequently asked to bid competitively for OLS scale up funding in 2019. This caused more tension between centres and has made collaboration more difficult, including on interoperability where some earlier joint thinking might have been helpful. Nevertheless, there have been some examples of bilateral links, and also a coming together across Centres on the interoperability issue.

3.28 The feedback from the Centres and CR&D projects highlighted some operational issues in relation to Innovate UK processes:

- Project **funding change requests have been processed very slowly**, inhibiting progress for some projects. For some of the Centres of Excellence, it took 12 months to finalise the costed extensions. Consultees described the process of re-allocating budgets as "*a massive hindrance", "restrictive", "slow",* and "*not conducive to a fast-running and dynamic programme".*

- Technical **problems relating to accessing and using the portal for financial claims and monitoring** have also caused delays. Some aspects of the portal were considered ineffective even when functioning properly, such as the need for zero-funded partners to submit claims to the portal.

- The **level of admin** associated with the projects was considered to be unreasonably high by some consultees, whilst others noted that certain elements simply took longer than expected, notably setting up the contracts.

Barriers and enablers

3.29 **COVID-19 was the most cited factor which delayed the start of CR&D projects.** This was primarily due to: lack of access to patients to collect data; university/hospital policy to pause all non-essential research; and the reprioritisation of academic and clinician time to the pandemic response. The effects of COVID-19 on project delivery are covered in more detail below. Other factors which delayed the start of projects included staff turnover, delays in securing ethics approval and contractual issues stemming from the complexity of projects.

3.30 **Agreeing contracts was a more significant issue for the Centres of Excellence.** This was, in part, due to the size of projects both in terms of the number of partners and the value of funding:

"The project started slower than expected due to the length of time it took to agree contracts with other members of the consortium. There were lots of meetings with the main industry partner about how they wanted to use the data, and this took three to four months. It was quite a painful all-consuming process at the time but in retrospect the project managers did this quite well"

[Centre of Excellence project partner]

3.31 In addition to contractual issues, some Centres of Excellence started later than planned due to **delays in the award of grant funding** whilst others were held back by resourcing issues (e.g. some consultees reported that recruitment of key individuals took longer, or was more costly, than expected). Following the delays at the outset, most CoE consultees reported that project activities remained slightly behind schedule. This was primarily due to the knock-on effect of the initial delays but was worsened in some cases due to the complexity of data sharing arrangements and the impact of COVID-19.

How COVID has impacted on delivery

3.32 The consultation feedback indicated a range of both positive and negative effects from COVID-19. Undoubtedly, COVID-19 has been problematic in terms of meeting the original project plans and adversely affecting progress. However, there have been some benefits to delivery, and a wide range of enabling factors associated with the pandemic.

3.33 First, in terms of the negatives, most consultees reported ways in which **COVID-19 had adversely affected project progress.** Specific examples included the following:

- **Reduced academic and clinician availability** affected most projects. Staff resources were often redirected to focus on the pandemic and in some cases, projects were directly affected by sick leave as a result of the virus.
- **Data collection** was hindered for some projects due to difficulties associated with patient recruitment and a reduction in the number of regular scans and tests that were taking place. Furthermore, one consultee noted that the physical process of collecting samples

was more difficult due to the increased cleaning and safety precautions necessary during patient recruitment.

- **Home- and remote working** affected delivery in different ways. For some Centres, the technical capacity of the system struggled to cope with the sudden surge in remote users. In one case, it was reported that remote working had made staff recruitment more difficult.
- **Lockdown limited access to sites.** For example, in some projects, scanners were based in university buildings and could not be accessed during lockdown.
- **Reduced laboratory capacity** was caused by social distancing requirements and this reduced project efficiency.

3.34 In contrast to the above points, several consultees felt that remote working had been of benefit to projects, by reducing travel times and increasing partner engagement (including internationally).

"Activity has been helped by COVID-19 in that all of the meetings have been held online. This means that meetings can be set up and attended quickly and efficiently, and that travel budgets have been significantly reduced"

[Centre of Excellence project partner]

3.35 In addition to the increased efficiency enabled by homeworking, it was highlighted that the pandemic has acted as an enabler for projects in other ways:

- **DELTA** reported that its technology (the Cytosponge) was introduced to a clinical setting faster than it otherwise would have been as it is able to replace endoscopy (endoscopy procedures were halted during lockdowns).
- **ID-LIVER** reported that the pandemic brought about increased willingness to adopt a community diagnostics model, which boosts the potential uptake of technologies developed through ID-LIVER.
- **ICAIRD** reflected that the programme extension that was implemented due to COVID-19 provided sufficient time for ICAIRD to get AI projects on board and begin to deliver, which would not have been possible in a shorter timescale.
- **NPIC** reported that the pandemic has "*made the case*" for digital pathology because it allows for remote working.
- **PathLAKE** made a similar point to the above – the pandemic brought digital pathology to the fore and reinforced the need to digitise.
- **LMIAI** noted that ethics approval was accelerated due to COVID-19 as the pandemic brought a "*drive to help people access data*".

- **IDX-LUNG**, which uses nasal brushing to collect samples, reported that widespread use of lateral flow tests during the pandemic had improved patient recruitment, as the public is more used to the procedure.

3.36 Interestingly, several projects noted new opportunities which had arisen from the pandemic. LMIAI pivoted its activities to focus on projects linked to COVID-19, and was able to do so as a result of the systems and infrastructure put in place through the Challenge:

"COVID-19 was a success story for us because we already had the staff in place and the infrastructure set up. We were able to quickly collect COVID-19 patient data and share it. Without the funding to get these processes set up we wouldn't have been able to contribute data in the way we did"

[LMIAI Centre of Excellence project partner]

3.37 Similarly, ICAIRD's AI for lung x-ray project was able to pivot to look at x-rays for COVID-19 patients:

"ICAIRD wanted to find a way to contribute to the fight against COVID-19. Our AI for lung x-ray project was able to pivot in order to look at x-rays for COVID-19 patients which meant that the R&D did not have to shut down and the project could continue to build out its infrastructure"

[ICAIRD Centre of Excellence project partner]

3.38 Generally it was felt that UKRI has been understanding and flexible in how it has managed the Centres and CR&D projects through the disruption caused by the pandemic. All partners accepted that some activity had to be put on hold but also that there was a need and opportunity for some projects to pivot to supporting the COVID-19 response. The costed extensions were welcomed but again there were some frustrations about the time it took to finalise the extensions.

Additionality of activities

3.39 The additionality of activities in the DigiPath strand was reported as being very high. None of the interviewees suggested that the activities would have been undertaken to the same scale, speed, quality and level of collaboration as they would have done without the Challenge funding. In fact, many consultees considered the project activities to be fully additional (i.e. they would not have happened at all), primarily because the funding was essential to: (i) create collaborations which were instrumental in undertaking the project activity (for example some of the pre-revenue partners would not have been able to contribute without the funding); and (ii) recruiting staff and purchasing vital equipment would not have been possible for projects without the Challenge funding.

3.40 Many consultees also reported scale additionality. In these instances, projects may have proceeded using smaller funding packages administered over shorter timescales. With less funding, some elements of the projects may not have been undertaken as projects would have been forced to prioritise certain elements.

DIH Programme

What has worked well

3.41 Stakeholders reported that the focus on advance planning (laying the groundwork in advance of project initiation), and doing so in a collaborative fashion, was particularly successful; building on earlier sprint exemplar projects also provided useful learning. In some cases, taking the time to identify the main challenges to project delivery, gather information and discuss and refine plans required effort, but paid off, as did collaborative working between partners and the creation of active networks of cross-sector collaborators.

3.42 Academic, clinical and commercial partners across the DIH programme were perceived to have complementary expertise. The collaborative approach to working together to gather and share knowledge, plan activity and solve problems was considered valuable in helping to develop useful datasets that benefit all stakeholders. It was further felt that the collaboration had increased awareness of clinical work and data among commercial partners. The involvement of independent experts in project oversight was considered to have enhanced credibility of the projects and provided useful support and continuity.

3.43 Although the milestones structure (checkpoints for HDR UK to ensure progress) for the Hubs met some initial resistance from partners, the process was largely accepted by the time of the consultations for this evaluation. There were differing opinions expressed as to whether the reporting, governance and management requirements and processes were necessary and proportionate. The creation of four distinct assessment categories for milestone 2, which included the possibility of Hubs passing with minor or moderate concerns, thereby initiating an improvement phase of increased scrutiny and support, was considered beneficial by some. However, some hubs felt that the increased reporting requirements imposed by this oversight was actually counterproductive, causing further delays to progress.

3.44 Partners agreed that the Health Data Research Innovation Gateway was an ambitious initiative, requiring significantly more work beyond the initial minimal viable product version to ensure it meets the needs for both groups making data available, and groups wanting to access data for research. There were mixed views about how effective the Gateway is likely to be; some consultees noted that using the Gateway was currently too cumbersome, and if this were not improved then the interest in using it (and the perceived value of datasets it signposted) was likely to go down. Others felt that it would successfully boost access to these datasets. Plans to further improve both data visibility and user accessibility via the Gateway were acknowledged, along with the inevitable complexities of needing to involve a wide range of stakeholders and perspectives.

What has not worked so well

3.45 Whilst cross-sector collaboration was generally viewed as a positive aspect of this strand, it was not without challenges. Conflicts arose from the need to balance the different needs and requirements of academic, clinical and commercial partners with respect to datasets and their use. Technical challenges around data extraction and curation and the need to create unifying processes for these across different organisations and sectors created further difficulties.

3.46 The disruptions arising from the pandemic imposed some particular obstacles to progress, notably around managing conflicting priorities for different partners (some of whom had greater focus on direct pandemic responses or actions than others) and in maintaining or re-establishing momentum for projects that were delayed or paused. Staff turnover was reported to exacerbate this problem; over and above the problems of retention and recruitment, it was noted that teams require time together to 'gel' and work most effectively.

3.47 The other widely expressed concern was that of limited opportunities to celebrate and communicate success stories more widely, and that, as a result, potential further interest and benefits were being missed out on. This strand of the project was felt by partners to have a limited network that, combined with generally poor perceptions of health data innovation and access in the UK, suggested that more active promotion of the Hubs as part of the wider Challenge by UKRI (in addition to the promotion of the Hubs more specifically by HDR UK) would offer important benefits, with UKRI perceived to have a wider audience and reach. In particular, partners – many of whom had successes to report – noted that raising wider awareness of the various projects could only enhance further commercial interest and potential further investment and returns on the original investments.

Barriers and enablers

3.48 One of the main barriers to progress reported by the digital hubs was obtaining data access from NHS Trusts. Always a lengthy process, this was said to be further complicated by a lack of consistency between different NHS Trusts as to both the requirements for data sharing, and the individuals that need to be involved in obtaining permission for access. These existing challenges were further exacerbated by the pandemic, which naturally resulted in NHS trusts and their personnel having to focus primarily on pandemic responses, producing less engagement and lengthier delays in securing access to the required data. Lack of consistency between NHS Trusts went further in also applying to the nature of the data obtained. It was noted that there was no standardisation between different organisations and the data proved highly variable in format, typically necessitating a high level of curation before deposition in the hubs.

3.49 Another delaying factor reported was the length of time required for internal sign-off processes within different organisations. The NHS was said to have a reputation for being slow, but several interviewees also reported longer delays after the NHS / academic side of the contractual arrangements had been completed and handed over to the pharma or tech

companies. This is probably due to the internal sign-off processes in the commercial sector (especially larger companies) where multiple departments need oversight of contracts.

3.50 In some cases, reported cultural resistance to commercial collaboration from non-commercial organisations required additional effort from project leaders to navigate.

3.51 There were said to be challenges around achieving agreement on data standards between the Hubs and HDR UK, and in some cases misunderstandings between HDR UK and individual hubs around expectations for the project milestones. It was suggested that there should be more information sharing on data standards, not just across the DIH programme but also involving the other strands of the Challenge.

3.52 There are potentially useful lessons from the UK Biobank's approach to using cloud-based systems and partial encryption that could be applied elsewhere in Challenge funded projects.

3.53 Finally, some stakeholders highlighted the continuing challenges around public understanding and trust around the use of health data. Although all of the Hubs that are part of the programme all have public advisory bodies and lay representation, there remains significant work to do in terms of other data controllers and how they unlock their data for research and innovation purposes. Some consultees highlighted that there had been some erosion of public trust around data sharing following media coverage of NHS Digital's plans to collect patient data from primary care in summer 2021 (General Practice Data for Planning and Research); this was considered to have had a negative impact on progress.

How COVID has impacted on delivery

3.54 The impact of the COVID-19 pandemic varied considerably between different hubs, partly depending on the relevance of their clinical focus.. Some hubs were able to pivot to directly support the pandemic research response, which was generally viewed positively – but it also reduced the time available for them to progress their originally agreed projects. Some frustration was expressed by hub partners that in their view, reactive COVID-19 efforts were not fully acknowledged or taken into consideration in terms of assessing whether their milestones had been met or not.

3.55 Case studies of how Hubs had supported the response to COVID-19 are set out below.

Case study: BREATHE

The BREATHE health data research hub has a focus on enabling UK-wide access to high quality respiratory data. As a unit of expertise in respiratory disease, the hub shifted focus in response to the pandemic, for example by hosting the data from the ZOE COVID tracker app securely in the SAIL databank and facilitating research on these data, including examining ethnic differences in responses to COVID-19 infections.

The BREATHE EAVE II project has been using patient data to track the COVID-19 pandemic and vaccine effectiveness across Scotland, providing information to support the Scottish Government's policy response to the pandemic. Other opportunities arising from the pandemic have included engagement with industry with data contributing to vaccine programmes, and collaborations exploring other respiratory viruses.

Case study: DATA-CAN

A DATA-CAN report 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, and in attendance of cancer patients for chemotherapy. The researchers' modelling based on these data indicated that the initial six weeks of national lockdown would be expected to result in an additional 40-50k deaths due to missed or late cancer diagnoses, with increases expected the longer lockdown was extended. These findings were highlighted in a BBC Panorama documentary, resulting in a policy shift around cancer patient care. They also illustrate the importance of wider health sector research using high quality data.

Case study: Gut Reaction

Although the Gut Reaction hub was not one of those with immediate clinical links to the pandemic research, it nevertheless acted to protect inflammatory bowel disease (IBD) patients, a high proportion of whom are immunocompromised, with a potentially elevated risk of poor outcomes from the disease. The IBD Registry rapidly produced a patient-friendly COVID-19 risk self-assessment tool for IBD patients, based on national data and produced through a team of clinical, scientific, patient, and communications experts. The tool was used by over 34,000 patients by the end of the shielding period for clinically vulnerable people, recognised by the Agility and Flexibility Award in the 2021 Healthcare Communications Communiqué Awards.

3.56 Besides those hubs that pivoted to support COVID-19 work, most hubs experienced delays due to the redeployment of clinical and scientific staff to support the NHS and other pandemic

efforts; the availability of clinical colleagues was sharply reduced, and Challenge projects were considered very low priority due to NHS demands. Further delaying factors included the need to switch staff to working from home where possible during lockdowns. Overall, all hubs managed to maintain progress, but the delays arising from the pandemic were considered to have resulted in industry partnerships in particular being less well advanced than originally planned for this stage of the projects (i.e. at milestone 2).

3.57 However, the pandemic also produced some positive outcomes for the hubs. These included new collaborative research opportunities and enhanced network building for hubs in clinically relevant areas, and in some cases additional external funding for COVID-19 projects, which could in turn be leveraged for the core work programme, and publications arising from the additional research directions.

"In sustainability terms, these efforts [to support the pandemic] had a two-fold beneficial effect of both raising awareness of these hubs and their work, as well as building partnerships for future projects beyond the pandemic"

[HDR UK partner]

3.58 Even for those hubs not directly engaged in pandemic research, there were fringe benefits. The Control of Patient Information (COPI) notices issued to NHS Digital to enhance pandemic responses by enabling easier sharing of confidential patient information with selected organisations accelerated access to some data for hubs. Stakeholders also reported a general increase in awareness of the value of health data, increased levels of cross-border research, and new opportunities for patient engagement.

Additionality of activities

3.59 A key aspect of additionality from the Challenge funding was around not just the scale of projects, but also their scope. This was particularly associated with the collaborations that the funding encouraged, which resulted in different types of activities being taken forward; the Challenge encouraged people to work outside the 'bubble' of academia. It was felt that the Challenge funding was a specific attraction for commercial partners, and successful commercial-healthcare data research partnerships have resulted (for example, INSIGHT and AstraZeneca). Respondents felt that the Challenge had also supported industry engagement more generally, encouraging ongoing and future commercial collaborations, as opposed to just further academic/clinical collaborations.

4. Evidence on progress

4.1 This section summarises the evidence on progress in terms of outputs and early evidence of outcomes created by the Challenge investments. This also considers the evidence on the additionality of the key outputs and outcomes achieved to date.

Summary of evidence on progress

Genomics

- The WGS UK Biobank project has progressed significantly, with some real accomplishments in the provision of genomics data. It means that in 2022, 500,000 whole genome sequences will be available to UK Biobank users, with an informatics platform for the storage, curation and analysis of the data.
- Stakeholders reported wider benefits, in particular increased investment in genomics and other omics research, skills and capability development, improved industry-academic collaboration, and maintaining if not enhancing the UK's global reputation.
- The GEL project has created a cohort sequencing pipeline that enables integration of data and samples from any research cohort.
- New cross-sector collaborations (between academia, the NHS, charities and industry) have already arisen from the CR&D projects, with more expected in the future. Several projects have created new technologies or generated evidence to validate or enhance existing tools or technologies.

DigiPath

- Although there was disruption caused by the pandemic and other factors delaying planned activities, the five Centres have made good progress in setting up the infrastructure and facilities and delivering the exemplar projects. They are now starting to develop the AI tools and diagnostic technologies for use in the NHS.
- There is some early evidence of increased profile for the Centres of Excellence in a UK and international context, increased commercial R&D investment, improved digital skills amongst clinicians and indirect business benefits. However, most of the outcomes will be achieved in the future.
- Although the requirements around interoperability were not well understood at the start, consultees reported that some progress had now been made through the eight workstreams led by the Centres with support from UKRI.
- Despite initial delays caused by the pandemic, most Integrated Diagnostics CR&D projects have progressed well so far in their early stages. Consultees were confident that the projects will deliver clinical benefits over the next two to three years.

DIH

- The Health Data Research Alliance has grown from eight founding members to a total of 61 data controllers and data custodians. The target is to grow to 200 members by 2025.
- The Health Data Research Innovation Gateway was launched in June 2020 and now signposts 699 datasets, some of which are visible exclusively via the Gateway (e.g. ZOE tracker information). The Hubs have made 100 datasets discoverable through the Gateway, and the aim is to increase this to 2,000 datasets by 2023.
- The Research Hubs have all passed Milestone 2 which confirms that they have demonstrated data improvement and improved accessibility. Consultees reported that the Hubs are making good progress in terms of creating TREs, improving access to health data, and increasing collaboration and engagement with industry, NHS trusts and academia.
- There have been some strong early examples of impacts by the Hubs, such as in generating commercial interest and investment, and through outputs such as academic papers. HDR UK indicated that all Hubs are on track to be self-sustaining and this will be formally assessed in Milestone 3 scheduled for March 2022.

Genomics

4.2 The main outputs and emerging outcomes that have been achieved to date are described in the sections below. This is followed by an overall assessment against the logic model for this strand of the Challenge.

WGS UK Biobank project

4.3 **The WGS UK Biobank project has progressed significantly, making some real accomplishments in the provision of genomics data.** It means that in 2022, 500,000 whole genome sequences will be available to UK Biobank users, with an informatics platform for the storage, curation and analysis of the data. Stakeholders reported wider benefits, in particular increased investment in genomics and other omics research, skills and capability development, improved industry-academic collaboration, and maintaining if not enhancing the UK's global reputation.

4.4 At the time the evaluation was undertaken, the project had achieved the first milestone of sequencing 150,000 whole genomes. These data (along with that of the 50,000 genome sequences from the vanguard study phase) had been made available to the industry partners, ahead of wider availability for public research in the following months. Sequencing of the full 450,000 whole genomes was also nearly complete, with release to industry partners and later public access to follow as planned. At this point, all whole genome sequence datasets will be accessible to registered UK Biobank users.

4.5 The Wellcome Trust had created and implemented an informatics platform for the secure storage, curation and analysis of data, including a portal for managed access controlled by UK

Biobank; industry partners have developed their own informatics platforms for the same purpose. Creation of the infrastructure and analytical pathways to handle large-scale genomic information was considered by stakeholders to be a real accomplishment.

4.6 The industry partners have undertaken some degree of genomic data analysis, including the use of artificial intelligence (AI) and data mining techniques, but research into genetic drivers of disease is just beginning and is expected to expand rapidly over the coming years. Another achievement of note is the creation of new collaborative partnerships between industrial and academic partners.

Genomics CR&D projects

4.7 Genomics England has created a cohort sequencing pipeline that enables integration of data and samples from any research cohort; at the time of evaluation, they had obtained samples and data from four of the eight cancer patient cohorts and generated genome sequences, with the other cohorts expected to follow once samples were received. Of the genome sequences completed, around 1,200 were reported to have been made available for research, with the others still in the bioinformatics (analytical) pipeline.

4.8 It was expected that sequenced datasets would be achieved for all projects, and an informatics platform for secure data storage, curation and access was in place. Most projects had finalised the fundamental analytical pathways for assessing large-scale genomic data, and were undertaking or preparing to undertake whole genome sequencing data analysis via AI and data mining, in some cases with support from Genomics England. A number had created novel software platforms and pipelines, some with commercial or collaborative potential.

4.9 New cross-sector collaborations have already arisen from the CR&D projects, with more expected in the future. In addition to software platforms, these are based on relationships between Genomics England and the various individual research cohorts, and on applications of technology within the NHS. Several projects have created new technologies or generated evidence to validate or enhance existing tools or technologies; one has improved IP protection in this way, creating a more robust evidence base for a patent. Several projects are producing or expect to produce academic papers, and one has delivered a single-centre clinical trial.

UK Biobank whole genome sequencing project

Main achievements to date

- **1st milestone of sequencing 150,000 whole genomes has been met**; data will be released publicly in coming months (following industry-only preferential access period) along with that of the 50,000 genome sequences from the vanguard study phase.
- **Portal for data storage and analytics has been developed and implemented.**
- **Sequencing of all 450,000 whole genomes is almost complete** and release should take place by the end of 2021 (for industry partners, with wider public access to follow in early 2023).

Wider benefits reported by stakeholders

Increased investment in genomics

- New, entirely industry-funded collaborations and projects have been spun off from the initial project, including in data analysis, imputation and proteomics. Further collaborations/activities/ideas are expected as these data are made available to researchers around the world.
- The UK Biobank was felt to be seen as a flagship project globally, and the whole genome sequencing work was expected to enhance that, being already seen as gold standard for population genetics research.
- An enhanced global reputation for clinical trials may follow based on biomarkers identified from genome data.

Skills and performance

- Improved skills capacity and capability for genomic technologies has been achieved within industry, but is expected to evolve further as researchers from other sectors begin to use the new data.
- Improved business performance in industry partners is happening and expected to happen further as a dataset of this magnitude has never been available before.
- Academic partners felt they had benefited from more commercial engagement.
- One interviewee commented these types of projects help to celebrate and retain skilled technical staff, not just academics.

Anticipated research benefits

- Scientific insights and advances will be generated from research on sequenced data.
- Overall, it was considered that it was too early to see all outcomes from this project, which are expected to become clearer in 12-18 months; some outcomes will be much longer term, e.g. drug discovery based on datasets.
- Having the infrastructure and expertise and ability to large handle volumes of genomic data was considered broadly beneficial for science.
- Improved data access for patient stratification and new methods for identifying therapeutic targets are expected over the next 10 years.

Genomics CR&D projects

Main achievements to date

- Projects have largely progressed in line with their revised plans – so they are not as far progressed as original expectations, but are now delivering towards their intended outcomes.
- All projects have sequenced cancer datasets; in most cases, analysis of these has been completed or is underway.
- Genomics England has created a cohort sequencing pipeline that enables integration of data and samples from any research cohort; samples and data have been obtained from four of the eight cohorts so far, and around 1,200 whole genome equivalents have been made available for research.
- Most projects have delivered software platforms and pipelines, several of which can be commercialised or used as the basis for further collaborations.
- Several projects have built new technologies and tools or have generated evidence to validate or enhance existing technologies.
- Academic papers, clinical trials and improved intellectual property protection have been produced by different projects.

Wider benefits reported by stakeholders

Increased investment in genomics

- The knowledge gained from the project is allowing companies to approach collaborations with a new and different value proposition.
- Further investment has already occurred in some companies, receiving additional money to do further genomics analyses.
- Some interviewees reported that new companies have engaged with the UK as a result of this project, but largely by paying to access the data remotely rather than establishing a physical location in the UK.
- There were mixed views on an enhanced global reputation for genomic technologies and use of WGS in clinical trials. Some thought it was too early to say, others thought the reputation for genomic technologies had already been achieved. It was generally felt for clinical trials that it was too early to comment, though one project reported that the data generated should enable larger scale clinical trials.
- Of relevance to cancer sequencing projects, companies currently use the Foundation One panel instead of WGS, which makes it harder to leverage money for WGS of cancer (as the benefits have not yet been demonstrated). The forms of genomic cancer analysis offered by the NHS Genomic Medicine Service may not yet align with the way in which projects use WGS. This could delay direct clinical implementation of new knowledge, because there is not an immediate opportunity for translation into clinical practice.

Skills and performance

- Improved skills capability for genomic technologies was widely reported, and it was also reported that collaborating companies have now learned these skills from academia, which is just as valuable as IP.

- Some companies are in a stronger position to attract new investment, others expect this to happen in future.

Anticipated research benefits

- Many future outcomes are expected, notably patient stratification and new methods for identifying therapeutic targets.

Additionality of outputs and outcomes

4.10 As set out in section 3, the Challenge funding (and the inferred government commitment to the UK Biobank as a national research resource) was key to the additionality of the activities, i.e. making the genomic sequencing work and infrastructure development possible, and generating essential match funding from industry. This in turn has been key to the additionality of outputs and outcomes so far.

4.11 Bringing together industry partners for this project has generated further commercial collaborations and projects entirely funded by industry. In particular, it was said that the Illumina industry collaboration would never have happened without the initial Challenge funding. The Illumina project is a wholly industry-funded collaboration trialling the use of DRAGEN (Dynamic Read Analysis for GENomics), a new ultra-rapid approach to secondary analysis of whole genome sequence data, which would otherwise not have been undertaken.

"UK Biobank is a flagship project globally for this type of research and WGS further enhances that."
[UK Biobank project partner]

"UK Biobank is the gold standard for population genetics in the world. This WGS of the UK Biobank is only going to add further weight to that"
[UK Biobank project partner]

4.12 Strong and trustworthy relationships, not least with the scientific and operational leadership of UK Biobank, were reported to have been another important driver of success, including by enabling knowledge sharing. These relationships may well not have been developed without the Challenge-funded activities.

"We have created an amazing collaborative space where everyone trusts and learns from each other, even amongst competitors. Sharing best practice and insider knowledge has occurred beyond what we expected".
[UK Biobank whole genome sequencing partner]

4.13 With respect to the CR&D projects, it was felt that without UKRI support, some elements of the projects might have proceeded and produced limited outputs, such as a paper or even a patent, but the Challenge created better quality, larger scale and more rapid outputs than would otherwise have resulted. For some CR&D projects, Challenge funding was felt to have

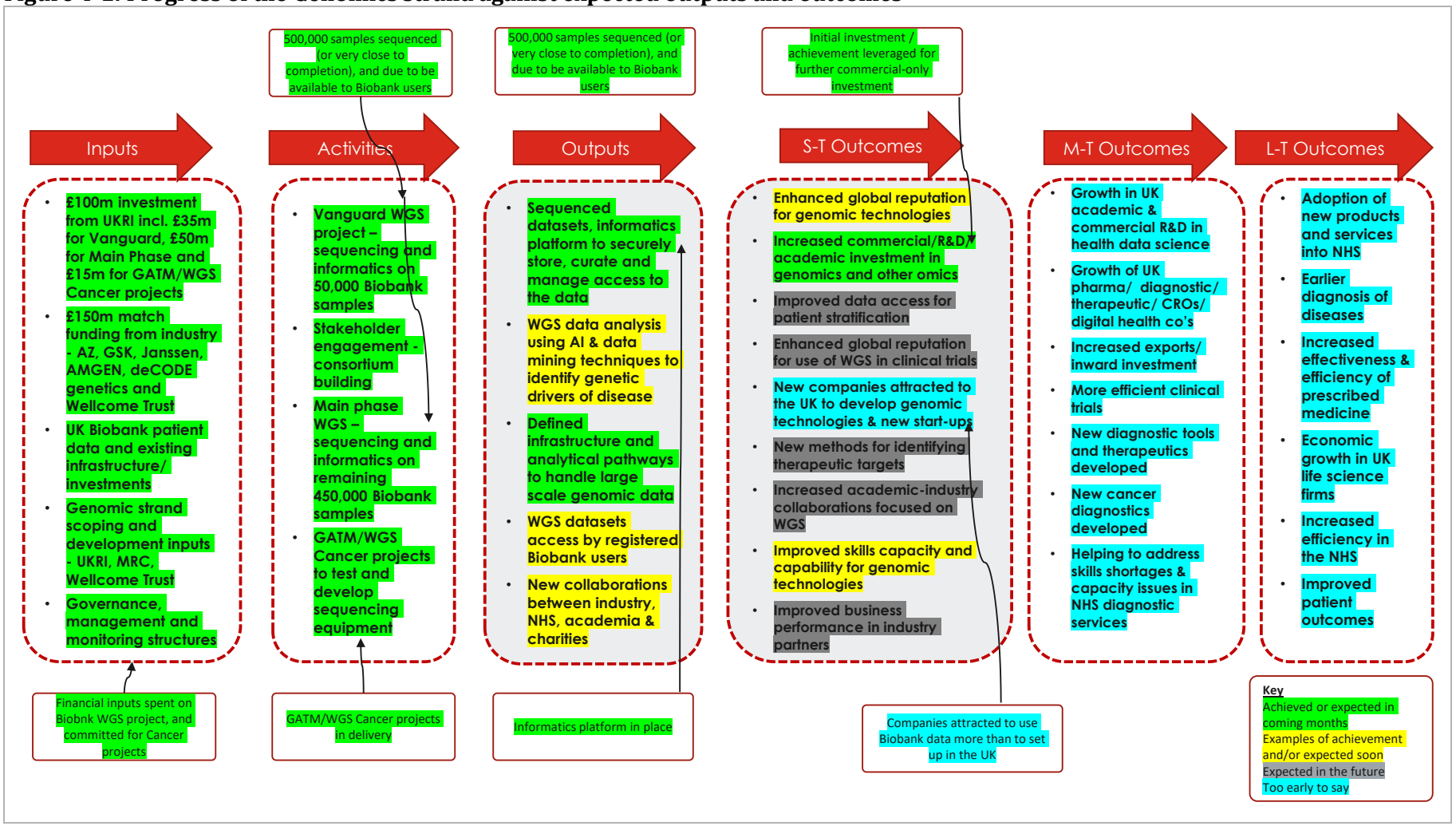
made it possible for companies to expand into new areas (such as different cancer indications) and make new relationships and networks with clinicians and other stakeholders.

4.14 Our assessment of progress made to date in the Genomics strand of the Challenge is highlighted below mapped onto the logic model included in the M&E framework. This depiction is based on the qualitative consultation evidence as well as the monitoring data summarised in Section 2.

4.15 This shows the progress through to the intended outputs of the strand, notably in terms of sequencing and infrastructure, as well as key examples of collaborations, and access and analysis of data. There is also good evidence of achievements to date in terms of investment in research, one of the key short-term outcomes. It is reasonably expected in the near future that, off the back of progress to date, other short-term outcomes such as global reputation, new methods and business performance effects will be achieved. At this interim stage, therefore, noting that it is too early to explicitly assess the extent to which medium- and long-term outcomes may be achieved (as these will depend on the success of investment, collaborations, access to data etc.), this strand of the Challenge is achieving in line with the expected logic of the intervention.

4.16 One area of uncertainty is the extent to which new companies will be attracted to the UK, reflecting that access to the data can be made globally without a presence required in the UK. This is not necessarily a reflection on the performance of the strand, rather a point about the nature of research and innovation in this field. Attracting international investment requires other levers alongside the delivery of globally-renowned research assets.

Figure 4-1: Progress of the Genomics strand against expected outputs and outcomes



Source: SQW team, based on evaluation evidence

DigiPath

4.17 The main outputs and emerging outcomes that have been achieved to date are described in the sections below. This is followed by an overall assessment against the logic model for this strand of the Challenge.

Centres of Excellence

4.18 The progress of the digital pathology and radiology Centres of Excellence has undoubtedly been delayed, partly due to the disruption caused by the pandemic but there have been other factors which resulted in a slower start than planned, as outlined in detail in section 3. These ambitious projects have proved complex in terms of formalising relationships and contracts with partners from universities, NHS Trusts and industry. The delays resulted in requests for extensions which then took some time for UKRI to sign off. A further £9m of funding for costed extensions was provided to the Centres and this was viewed as sufficient to ensure the projects can deliver against their original objectives.

4.19 Overall, the stakeholder consultations indicated that the five Centres have made good progress in setting up the infrastructure and facilities, and delivering the exemplar projects. They are now starting to develop the AI tools and diagnostic technologies for use in the NHS. Inevitably some Centres have progressed faster than others and the evidence from consultations indicated differences in focus, number of partners and project management resources have played roles in varying levels of progress. It was also highlighted that the level of engagement with industry differed across the Centres and this may have impacted on the pace of delivery. In some cases, strong industry engagement has helped drive progress; in others problems with commercial partners pulling out of certain activities have caused additional challenges for project managers.

Centres of Excellence

Main achievements to date

- Three Centres (ICAIRD, NCIMI and PathLAKE) reported that they have successfully established new data storage facilities and platforms.
- Consultees also stated that a lot of time and effort had gone into establishing new processes, guidance and contractual arrangements for data processing and sharing across the consortia, including ethics frameworks.
- LMIA has successfully delivered and deployed two major software platforms. These are the Federate Learning and Interoperability Platform (for R&D) and the AI Deployment Engine (a platform for delivery of models into clinical care).
- NPIC's data sharing platform had been procured and will be operational over the coming months.
- Delivery of exemplar projects is ongoing, and these projects are expected to support the development/validation of new AI diagnostic tools. There are already some AI tools in development, and one industry partner stated they will have a product on the market during 2022.
- Some formal and informal links exist across the Centres of Excellence and this has increased recently through the interoperability workstream in the DigiPath strand of the Challenge.

Wider benefits reported by stakeholders

Enhanced reputation and increased profile

- The Centres have increased their profile through research papers on the Challenge funded activity, delivering national and international events, and advice. Over 100 publications have already been produced by partners involved at the Centres. It was considered by one Centre lead that the Challenge investment has helped put the UK ahead of the US in relation to digital pathology R&D.
- Examples illustrating the profile gained include: PathLAKE held a conference in September 2021 with c. 170 attendees; NPIC has held two public engagement events, one was a citizen's jury and the other an exhibition on AI in healthcare; and ICAIRD has a role advising the Scottish Government.

Improved digital skills

- ICAIRD and PathLAKE reported improved skills amongst clinicians trained using the new digital diagnostics. NPIC expect that once the scanners are installed and in use, this will help improve digital skills clinician understanding and trust in digital diagnostic technologies.

Increased commercial investment in R&D

- Consultees stated that there has been significant in-kind funding contribution made by industry partners across the five Centres. This has totalled £14.5m out of planned investment of £43.3m by the end of the projects.
- Once the data sharing platform is in place for NPIC, the Centre will increase academic/industry collaborations and commercial R&D investment.

Other anticipated benefits

- The Centres highlighted the expected benefits through increasing digital skills once new facilities and equipment are fully operational. Although there are some early examples of industry partners reporting business benefits from being part of the Centres of Excellence, most benefits will come in the coming years from successful commercialisation of technologies.

4.20 As highlighted above most of the business benefits from the Centres of Excellence will come through in the next few years as the outputs of the exemplar projects are commercialised.

"The Challenge helped us to secure new R&D investment into the UK from the global group"

[Centre of Excellence industry partner]

"Being part of the Centre has helped the company grow as we have gone on to secure large contracts with big pharma"

[Centre of Excellence industry partner]

Interoperability

4.21 Consultee feedback highlighted that interoperability requirements were not well understood by project teams at the outset. Some consultees reported that, whilst it was clear the solutions developed needed to have to potential to be interoperable, it was not clear that they would need to collaborate with other Centres to create these. As highlighted by the Innovation Leads, the requirement for interoperability was set out in the competition documents but consultees suggested there was a lack of clarity between *intraoperability* within regional networks and *interoperability* across the country. Whilst a different approach may not have helped given the lack of understanding at the outset, a drawback of the bidding process was that the Centres were not allowed to talk to each other, nor could they plan for collaboration at an early stage. More engagement and support for the network of Centres would have been beneficial but this was difficult when the four English Centres were being asked to compete to secure OLS scale up funding. An interoperability workshop planned for April 2020 was also postponed because of the pandemic.

4.22 Although the requirements around interoperability were not well understood at the start, consultees reported that some progress was now being made. There was a cross-Centre interoperability workshop held in summer of 2021, and since then the project managers from the Centres have had weekly meetings to share knowledge and identify areas for potential collaboration. A follow-up workshop was held in November 2021. Eight workstreams have been established and are being led by different Centres; these focus on evaluation, deidentification, federation, data transfer standards, TREs, image standards for clinical use, image format, and quality assurance. However, some consultees raised concerns that this takes time away from delivering primary activities (even though this should have been built

into the original project budgets) and that there are risks in trying to achieve single or streamlined solutions:

"Now we not only have to manage the complexity of our own project but also the complexity of all other projects"

[Centre of Excellence project partner]

"There is a risk of putting all of your eggs in one basket when there is still so much to learn. I am worried about committing to one approach when we still don't know exactly what does and doesn't work."

[Centre of Excellence project partner]

4.23 In response to these comments UKRI highlighted that 72 separate non-collaborative interoperability projects across the centres have been reduced to eight workstreams with each Centre leading only one or two workstreams. In addition, it was clarified that there are two image standards workstreams which demonstrates the solution will not always involve just one approach.

Integrated Diagnostics CR&D projects

4.24 Despite initial delays caused by the pandemic, most CR&D projects have progressed well so far and consultees were confident that the projects will deliver clinical benefits. The main outputs and emerging outputs from the CR&D projects are summarised below.

Integrated Diagnostic CR&D projects

Main achievements to date

- Consultees from three out of the five CR&D projects reported that new data storage facilities have been developed.
- Four projects stated that they have created new integrated data sharing platforms, and this is expected by a fifth project. This tended to be the focus of industry partners (except in the case of IDX-LUNG).
- One project had developed/validated a new AI diagnostics tool but most expected this only by the end of the programme.
- One project had developed new clinical pathways whilst four others expect to achieve this. However, for two projects this is not within the scope of their activity.
- Some examples of linkages across CR&D projects and with the Centres of Excellence (e.g. between the DART and IDX-LUNG project and between DART and the NCIMI Centre)

Wider benefits reported by stakeholders

Improved digital skills

- IDX-LUNG noted that digital skills are being improved through the use of new digital technologies deployed by the programme in NHS labs and amongst clinicians.
- DELTA reported that, although this was not an intended outcome of the programme, the implementation of the Cyted platform is having this effect.
- ID-LIVER has improved digital skills through the implementation of a new MRI scanner which produced digital images.
- Improving digital skills has helped to improve clinician understanding and trust in new digital diagnostics technologies. However, some consultees reflected that this is a long-term transition which cannot be achieved within the timescales of the programme.

Increased commercial investment in R&D

- Project match funding to date has totalled £4.2m out of a total commitment of £14.2m by the end of the projects.
- DART reported an increase in R&D investment from industry partners.
- ID-LIVER's project partner Jiva had an oversubscribed seed funding round in May 2021 – being involved in D2EDPM enhanced Jiva's credibility.
- DELTA's project partner Cyted also reported they had commercially invested as the project has progressed more quickly than expected.
- Two projects reported improved business performance in industry partners and this outcome was expected by others.

Additionality of outputs and outcomes

4.25 As with activities, the additionality of achieved outputs and outcomes for the Centres and CR&D projects was reported to be high for a variety of reasons.

- **Collaboration and partner engagement**: Without the Challenge funding, the partners would not have come together with a coherent proposal. Any progress on individual elements would therefore have been siloed and would not have produced the same benefits
- **Staff recruitment:** Some projects relied on the funding to recruit the relevant staff, without whom the project could not have progressed.
- **Equipment purchase:** Similarly, the funding was used, in some cases, to buy essential equipment which could not have been purchased otherwise.
- **Framework and governance:** The Challenge brought a necessary framework, governance and reporting requirements which were considered important in achieving outputs and outcomes.

4.26 Other consultees reported that outputs and outcomes were achieved faster, on a larger scale, or to a higher quality than they would have been without the Challenge funding. The funding

was seen as the catalyst for investing in new equipment, recruiting additional staff and securing the buy-in from industry partners.

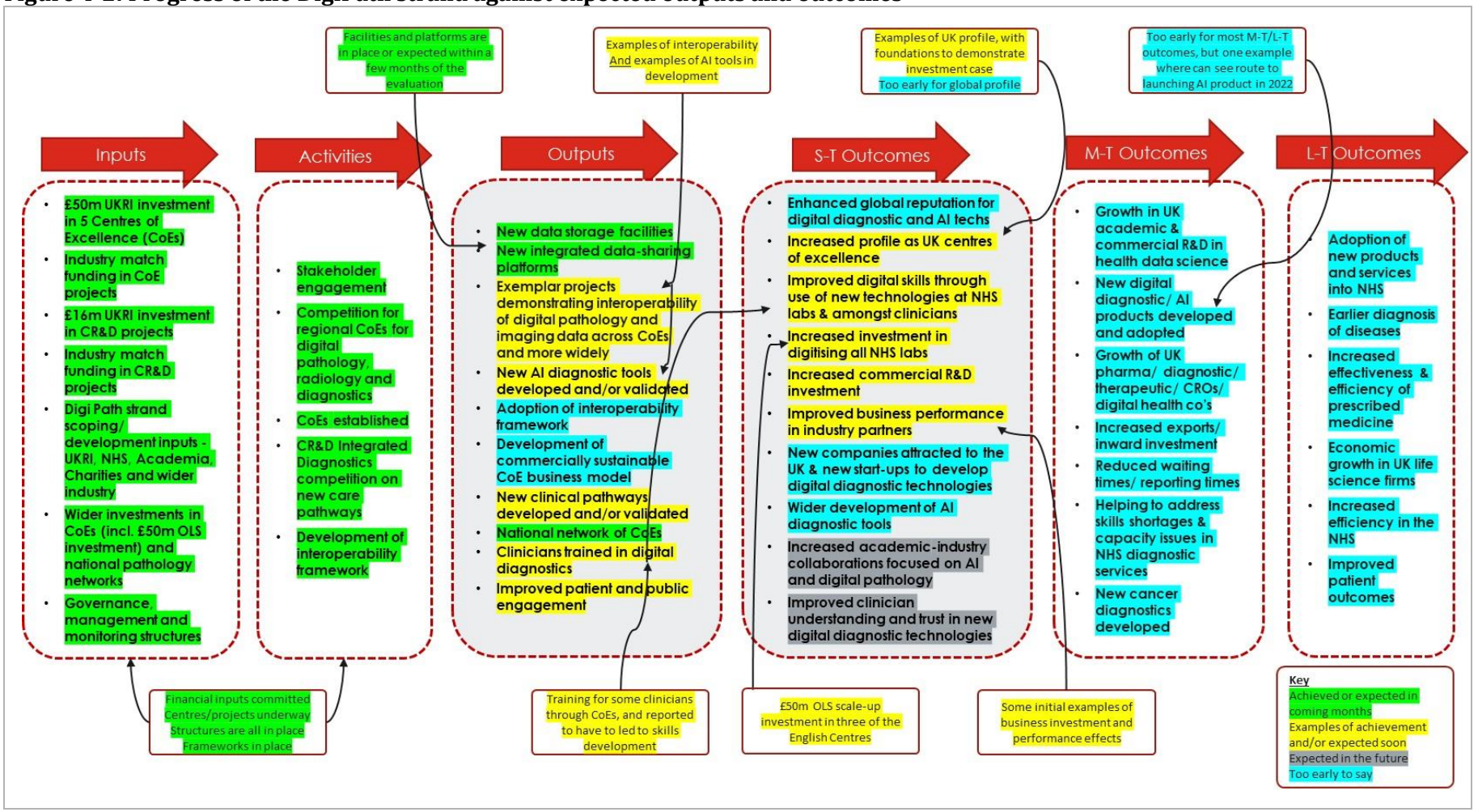
4.27 The high levels of self-reported additionality is reinforced by a consultation with an unsuccessful applicant who was looking to become a Centre of Excellence. Their project aimed at encouraging collaboration with industry around three disease areas. Although some bilateral discussions have continued with some partners, the consortium did not progress. However, the consultee was subsequently successful with an Integrated Diagnostics CR&D project which had a narrower focus on one disease area.

4.28 Our assessment of progress made to date in the DigiPath strand of the Challenge is highlighted below mapped onto the logic model included in the M&E framework. This depiction is based on the qualitative consultation evidence as well as the monitoring data summarised in Section 2.

4.29 This shows key progress in terms of the provision of facilities and platforms across this strand of the Challenge. For other outputs and short-term outcomes there are examples of achievement by the point of the evaluation (or very close to being achieved) rather than these being in evidence across this strand. This includes examples of AI tool development, interoperability, and the training and development in digital skills for clinicians. Encouragingly, there have also been examples of commercial effects, both R&D and performance (such as attracting finance), which are key short-term outcomes.

4.30 At this interim stage, the evidence indicates that progress is being made in terms of the underlying logic of this strand of the Challenge. We would anticipate that this would become more pervasive across the strand over the next 18 months (and beyond) if the work of the Centres and projects continues to progress as it has done in recent months. There are some areas that will need careful attention going forward, notably in terms of progressing with the interoperability actions (which we know is underway) and in developing models for sustainability

Figure 4-2: Progress of the DigiPath strand against expected outputs and outcomes



Source: SQW team, based on evaluation evidence

DIH Programme

4.31 The main outputs and emerging outcomes that have been achieved to date are described in the sections below. This is followed by an overall assessment against the logic model for this strand of the Challenge.

Alliance and Innovation Gateway

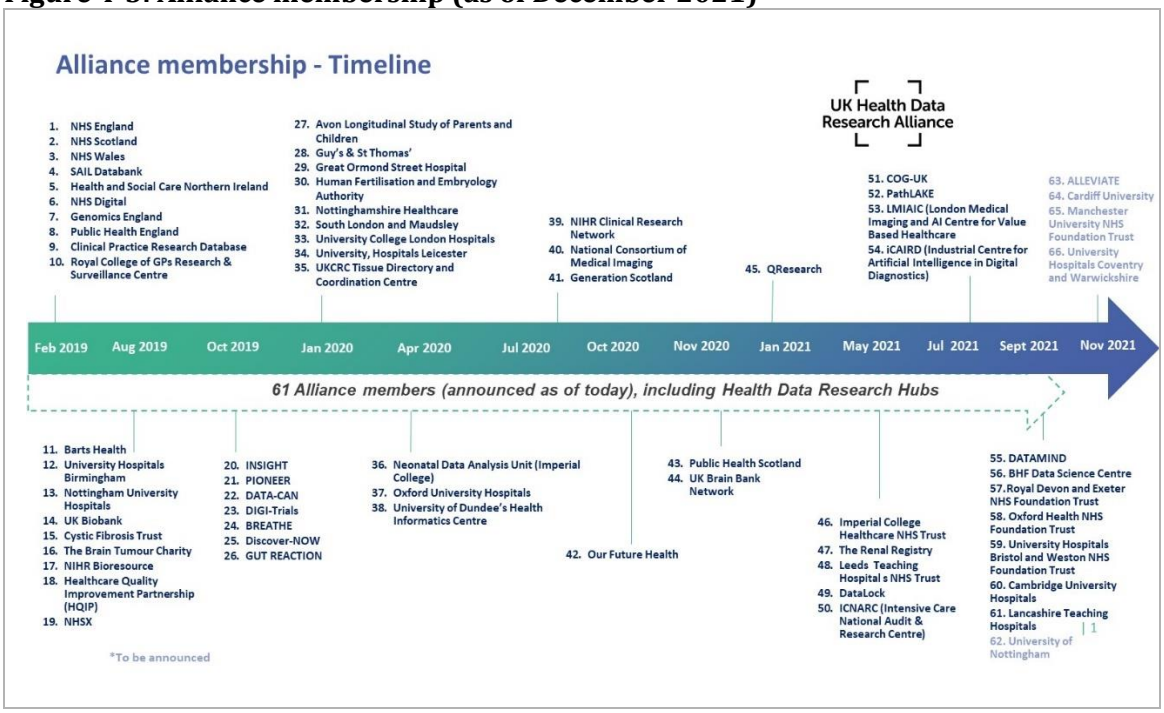
4.32 The Health Data Research Alliance has grown from eight founding members to a total of 61 members at the time of evaluation (Figure 4-3). This forum brings together key health data controllers, a range of Government bodies, NHS organisations, NHS X, public sector, charities, and industry partners. The expectation is to achieve around 200 members of the Alliance by 2025, increasing from the current focus on data custodians to a wider membership with links to data policy and governance. HDR UK aim to create a varied membership able to bring skills and insights to solving problems around data discovery, standards, and governance, as well as making datasets identified as valuable for currently unmet user needs accessible via the Gateway.

4.33 These members have all signed up to a set of principles and are committed to addressing problems around data access, governance, and data sharing. Stakeholders recognised the role of the HDR Alliance in supporting efforts to bring together hubs and partners, organising and supporting work on Trusted Research Environments (TREs), acting as a central voice on data governance issues and facilitating timely access to health data.

4.34 Alliance members are represented on various sub-groups providing guidance, producing Green Papers and advising on the ongoing development of the Innovation Gateway. For example, in 2021 the Alliance produced the following publications: Data utility framework Green Paper; Data Standards Green Paper; Data Use Registers Green Paper; and Principles and Best Practices in TRE ecosystems. This type of structure did not exist prior to the Challenge and is therefore seen as a key platform for addressing the issues and opportunities around health data research and innovation.

4.35 HDRUK working together with Alliance members have developed a health data framework to objectively evaluate improvements in quality of datasets and establish guidance on what information on the dataset should be available to inform access requests. This framework is now publicly available and has been adopted by governments, charities and companies. Version 3 of the metadata specification for the framework is expected to launch in summer 2022; this update is expected to make the data more streamlined such that access for researchers is made easier, without becoming more onerous for data custodians.

Figure 4-3: Alliance membership (as of December 2021)

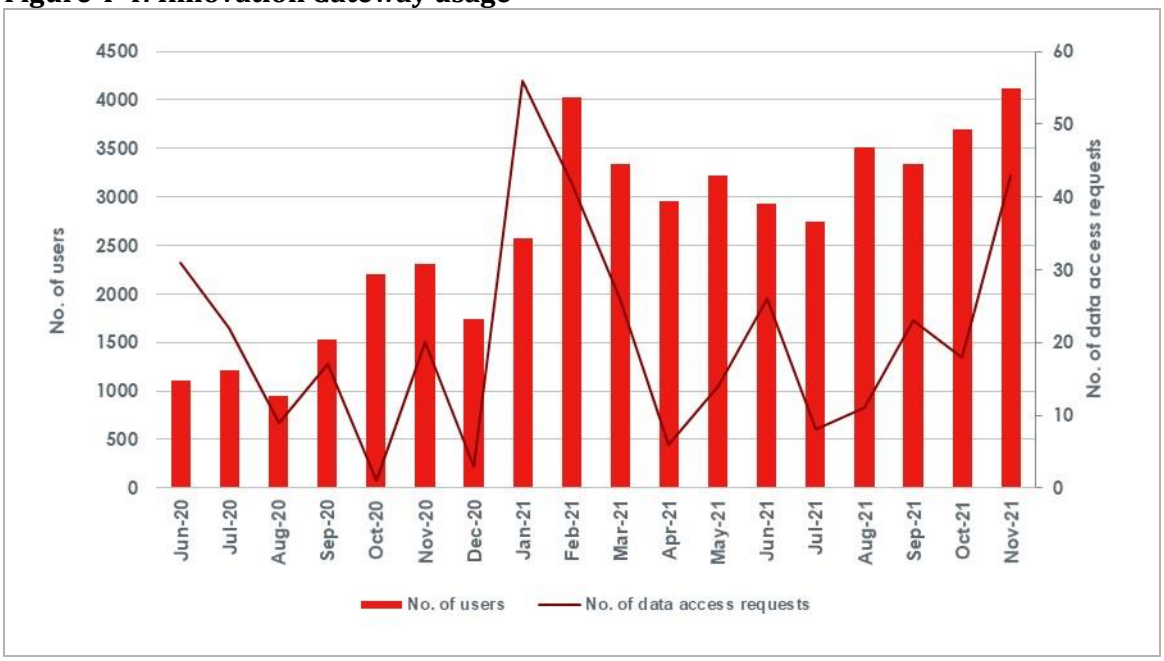


Source: HDR UK

4.36 At the time of evaluation, the Health Data Research Innovation Gateway was launched in June 2020 and now signposts 699 datasets, some of which are visible exclusively via the Gateway (e.g. ZOE tracker information). Around 10% of data assets discoverable through the portal are reportedly being widely used. Stakeholders highlighted that the precursor to the Gateway, Health Data Finder UK, had 32 datasets and so this illustrates the progress that has been made over the last 2-3 years with support from the Challenge. The expectation is that the Gateway will signpost around 2,000 datasets by the end of the Challenge period, which HDR UK believes is around one fifth of estimated UK data assets.

4.37 The Hubs have made 100 datasets discoverable. Stakeholders commented that the quality of data was improving and that HDR UK are continually looking to make enhancements based on user feedback.. Monthly usage of the Innovation Gateway has increased steadily from an around 1,000 unique users in July 2020 to over 4,000 unique users in November 2021 (Figure 4-4).

Figure 4-4: Innovation Gateway usage



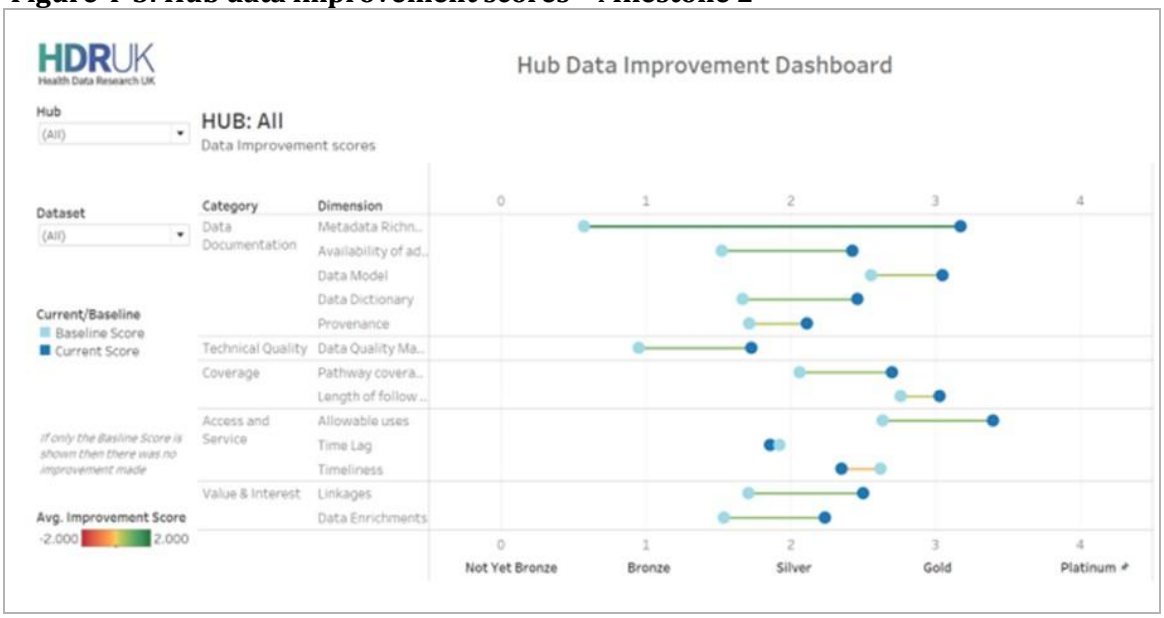
Source: SQW analysis of HDR UK website

Health Data Research Hubs

4.38 Five Research Hubs were created in 2019 using UKRI funding: BREATHE, led by the University of Edinburgh; DATA-CAN led by UCL Partners; Discover-NOW led by Imperial College Health Partners; INSIGHT led by University Hospitals Birmingham NHS Foundation Trust; and IBD Digital Innovation Hub/ Gut Reaction led by Cambridge University Hospitals NHS Foundation Trust. Two other Hubs were funded directly by HDR UK: NHS DigiTrials and PIONEER.

4.39 HDR UK put in place a milestone performance management structure with three milestones: by Milestone 1 in December 2019 the Hubs had to submit datasets on to the Innovation Gateway (MVP at this stage); by Milestone 2 in March 2021 the Hubs had to demonstrate data improvement and improved accessibility. There was also a requirement to provide updates on PPIE activity and Hub sustainability plans. All Hubs have passed Milestone 2, although three of the five were required to carry out some remedial activity to satisfy the programme requirements and expert panel (and ultimately passed in October 2021). Figure 4-5 shows the aggregate change in data improvement across the five Hubs from baseline to Milestone 2.

Figure 4-5: Hub data improvement scores – Milestone 2



Source: HDR UK (2021), Improving UK Health Data

4.40 In addition to passing Milestones 1 and 2, the Health Data Research Hubs (digital innovation hubs) reported the following additional benefits and achievements:

Health Data Research Hubs

Main achievements to date

- The creation of Trusted Research Environments (TREs) – secure systems to enable data access and analysis.
- Increased availability and accessibility of high-quality curated datasets for a wide range of stakeholders.
- Increased collaboration and engagement with industry, NHS trusts and academia, including growing interest from international pharma and other companies; four global pharma/tech companies are now investing in the Hubs (seven-figure contracts in progress), having realised that UK assets offer answers to their research questions, and US-based SMEs are working on synthetic datasets and imaging data.
- £16.3m of UKRI funding had been spent on the five DIH Hubs and these had also leveraged £21.3m in match funding.
- All Hubs are on track to be self-sustaining for 2-5 years beyond the end of the Challenge.
- Increased external contracts / finance secured with industry and other partners; all hubs have made new connections and collaborations, and have been awarded contracts from industry/SMEs/academia/health sector. This amounted to a reported 150 commercial and 170 academic contracts in place across the programme.
- Creation of a range of expert services and functions to support individual hub areas of expertise, including risk assessment and AI tools.

- Publication of a range of academic peer-reviewed papers, including some arising directly from the pandemic.
- Building on the attraction and securing of funding, all hubs expect to meet the aim of becoming self-sustaining beyond the end of the Challenge funding (at least in terms of core funding). Some expect this to be in part through academic income as well as commercial income (as was envisaged by HDR UK).

Case study: INSIGHT

The INSIGHT health data research hub has created a national resource of eye health related data from large populations in Birmingham and London NHS Trusts, and made them available for discovery research and applied health research. One of the hub's aims, in addition to a focus on traditional eye health, is to use images from eye health checks to develop diagnostic markers for systemic health issues, for example hypotension or early dementia. The hub is also focused on the use of imaging data and the applications of AI to support image analysis.

INSIGHT provided clinical evidence of the impact of pausing treatments during the pandemic, and the urgency of re-opening services on the basis of the numbers of patients whose sight would be saved by doing so.

All of the INSIGHT datasets meet the 'platinum' criteria which indicates the highest quality of data according to standards established by HDR UK. It is the highest fidelity imaging database in the world; a smaller, lower-quality dataset produced by a US company was produced using much higher levels of seed funding, demonstrating just how impressive these new data assets are. There has been increased commercial interest in INSIGHT's work, particularly for AI tools, evidenced by investment from Roche and Google.

4.41 There were high levels of optimism from programme interviewees around the ability of the Hubs to meet Milestone 3 (i.e. become financially sustainable), and that wider outcomes and impacts from the programme (including bespoke and specific data curation, federation, access and analysis services) would gradually become more apparent, though it was too early to predict exactly what the long-term outcomes would be. Some Hub partners observed that greater recognition was needed (in general, and in terms of evaluation) that data investments take time to realise. It was further noted that the benefits of Challenge funding were likely to

be demonstrated by how the Challenge has enabled other projects and encouraged further investment.

"The project has been able to get consent and ethics in place for the database, which will have a legacy output - the re-consent process enabling data linkage will expand access to this patient data as a research tool"

[Hub partner]

4.42 The value of the Hubs is demonstrated by the fact they have started to generate additional income through research contracts; over 500 contracts have been secured to date from a range of sources. Data provided by HDR UK indicates that 39% of Hub contract income to December 2021 has come from academia, 34% from industry, 21% from the NHS and the remaining 6% from overseas. Although HDR UK cannot currently release the actual value of the contracts as these are covered by NDA between the Hubs and their clients, some aggregate income data will become available after Milestone 3 (scheduled for March 2022).

4.43 Of note, HDR UK funded two additional Hubs that technically sit outside the Challenge funding. HDR UK was able to fund these as a result of the provision of Challenge funding for the other five hubs, and so the establishment of these is considered to be an indirect outcome of the Challenge. DigiTrials is a hub for clinical trial data; Pioneer is a hub for acute care data. Due to investment arising from the pandemic they are now becoming established fixtures in the health data landscape; for example, DigiTrials is now an arm of NHS Digital. These additional hubs closely mirror those within the Challenge, having the same management, milestones and forming part of the same hub network within HDR UK; only their funding source and stipulations vary.

Additionality of outputs and outcomes

4.44 Stakeholders highlighted high levels of additionality in terms of what has been achieved by Challenge funding for the DIH programme to date. Consultees indicated that the Challenge support has accelerated the process and improved the quality and scale of new structures and systems for improved data integration and access. The Challenge is felt to have enabled the involvement of a wider range of stakeholders than would otherwise have been likely, and encouraged people to work outside the 'bubble' of academia.

4.45 It was stated that Challenge funding has been enabler for fundamental infrastructure investment to improve data linkage and visibility/ discoverability, as well as being the impetus to encourage further investment to develop these projects. The Challenge has supported industry engagement more generally and has encouraged ongoing commercial collaborations as opposed to just further academic/clinical collaborations. One good example is the new research partnership created between INSIGHT and AstraZeneca. There was a consistent view that the Hub projects would not have been possible, or certainly not at the same scale, without Challenge funding.

"The ISCF funding has made it possible to accelerate this data integration project, and enabled more interaction with industry / commercial sector than would have been possible otherwise"

[Hub partner]

"The achievement across the hubs has been phenomenal. The hubs are very different and have been set up in different ways so it has been fantastic to bring this work together in this way"

[Hub partner]

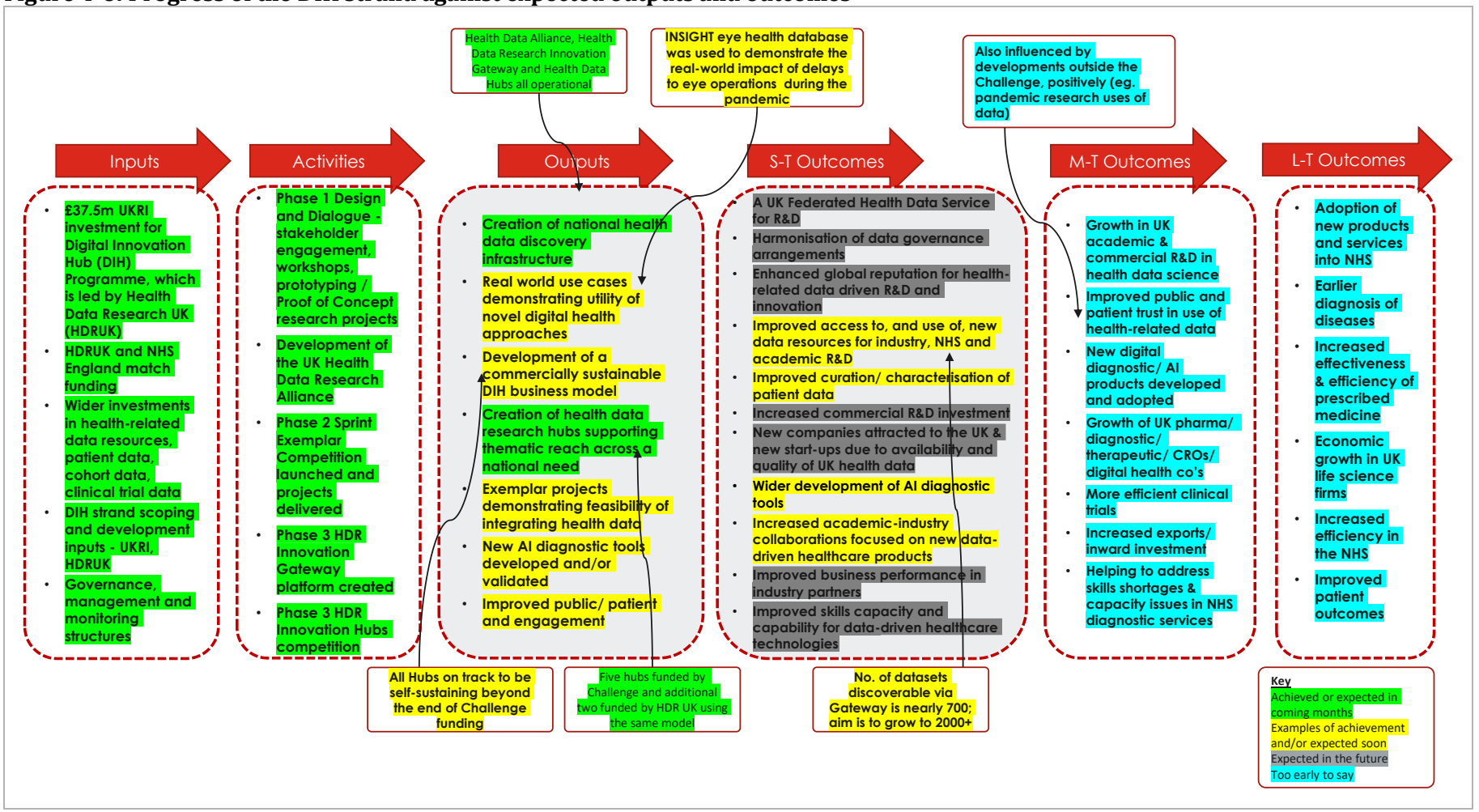
4.46 Once again the feedback on additionality was reinforced by a consultation with an unsuccessful Hub applicant. Their bid was to provide access to curated data for addressing challenges in respiratory medicine. Following the decision from UKRI, the project concept has was not progressed, but the process helped the organisation develop new relationships with regional partners and secure some research funding from other sources.

4.47 Our assessment of progress made to date in the DIH strand of the Challenge is highlighted below mapped onto the logic model included in the M&E framework. This depiction is based on the qualitative consultation evidence as well as the monitoring data summarised in Section 2.

4.48 The progress shows that the fundamental infrastructure and hubs supporting research have been put in place. From this there are a range of examples of achieved outputs and short-term outcomes in line with the underlying logic, e.g. novel approaches, demonstrating the feasibility of integrating health data, AI tools, curation of data and new collaborations.

4.49 At this interim stage, therefore, this strand is demonstrating that the intended short-term effects can be achieved. It is expected that more of these, and other, short-term outcomes will be achieved going forward. These also include the intended commercial effects, and harmonisation of data governance. Whilst it is too early to comment on medium- and long-term outcomes, it is conceivable to envisage achievements in areas such as the growth in R&D in health data science, adoption of new tools and the growth of digital health companies.

Figure 4-6: Progress of the DIH strand against expected outputs and outcomes



Source: SQW team, based on evaluation evidence

5. Governance and management

5.1 A key area for the process evaluation is to assess the effectiveness of the governance and management of the D2EDPM Challenge. For some stakeholders, discussions focused on how the Challenge as a whole is being managed and the findings here build on some of the feedback contained in the baseline research. In this phase of the research we also sought to assess how individual projects have been managed and to identify key lessons for the remainder of the Challenge and for other similar programmes in the future.

Governance and management

Programme level

- The Programme Board was seen to be working well in terms of providing oversight on progress, and consultees believed that the structures and systems compare well with other similar Government programmes.
- In July 2021, the Challenge Director left and a replacement was recruited by November 2021. This transition period was viewed as well-managed by the UKRI team and other stakeholders.
- Stakeholders highlighted that there was good representation on the Challenge Advisory Group from relevant organisations and that there have been useful conversations in the first two meetings of the Group.
- However, Advisory Group members found it difficult to talk in detail on the performance of the Challenge to date, and were keen for greater clarity on the role of the Group over the remaining 12-18 months of the Challenge.
- Across all strands of the Challenge, consultees suggested that there has been limited promotion of the other areas of activity and felt that this should be managed and coordinated more effectively by UKRI.
- Although there were cases of individual projects promoting their activity, consultees indicated that there is little or no external promotion of the Challenge, and this was limiting some of the potential effects of the Challenge.
- Stakeholders advised that UKRI undertake more Challenge promotion through more detailed information on its website, and cross Challenge events and webinars.

Genomics

- The UK Biobank WGS project is managed by the industry consortium with UK Biobank providing update reports to the Joint Operating Committee which are then summarised to the Programme Board. This approach was seen as effective and UKRI was seen as a key partner helping to advise the industry consortium.
- Promotional activity has included publications, presentation at conferences, mainstream media coverage (interviews) and updates to networks such as the Early Cancer Medicine Centres.

- For the CR&D genomics projects, management structures were also seen as effective, with companies managing projects with their own staff, who were drawing on support from monitoring officers from Innovate UK.

DigiPath

- Many consultees involved in the Centres of Excellence highlighted the complexity of setting up local governance arrangements for groups of universities, NHS Trusts and industry partners.
- Stakeholders were generally positive about the quarterly reviews and the support provided by the UKRI monitoring officers.
- However, there were some elements of management by Innovate UK that have not worked well. First, in some cases, claims and reporting processes were considered to be prohibitively slow. Second, the claims portal was deemed ineffective by some consultees.
- A new interoperability workstream has been established by UKRI to encourage more joint thinking and collaboration on issues such as deidentification, data transfer standards and TREs. The Centres have welcomed more UKRI support in this complex area of interoperability.

DIH

- Stakeholders had varying perspectives on reporting requirements and management of the DIH programme. Although most consultees complemented the robust and transparent management structures and processes built into the DIH programme, some of the Hub interviewees said that reporting to HDR UK and UKRI felt quite onerous.

Programme level overview

5.2 There are two main governance and management structures that oversee the delivery of the D2EDPM Challenge – the Programme Board, which meets every six weeks and brings together the Challenge Director and UKRI innovation leads responsible for the three strands of the Challenge, and the Challenge Advisory Group which brings together external experts from the health data and precision medicine landscape.

5.3 In line with the feedback provided for the Baseline report, stakeholders viewed the Programme Board as working well in terms of providing oversight on progress. Consultees stated that robust systems and structures have been put in place to ensure effective information flow from individual projects and monitoring officers to innovation leads and the Programme Board. Overall, it was felt that the programme management structures compare well to other similar Government programmes.

5.4 The Baseline report highlighted the progress that was made after the Challenge Director was recruited in terms of encouraging more collaboration across the Challenge and driving activity around the issue of interoperability. However, there has subsequently been some disruption in the Programme team over the summer 2021 when the first Challenge Director

left her role. One of the innovation leads took on the role as Interim Director and the recruitment of a new Challenge Director was completed by November 2021. This transitional period was viewed by stakeholders as having been well-managed under the Interim Director.

5.5 The Challenge Advisory Group met for the first time in May 2021 and had met for a second time by the time of the evaluation consultations in autumn 2021. This group brings together experts from academia, NHS, the Royal Colleges of Pathologists and Radiologists, and industry (LifeArc and ABPI) to provide challenge and scrutiny to drive success of the programme. Stakeholders highlighted that there is good representation from relevant organisations and that there have been interesting conversations in the first two meetings of the Advisory Group.

5.6 However, members of the Advisory Group indicated a lack of clarity on its purpose and remit. If it is there to provide an external perspective on delivery and progress then it needs to see more detail on what has actually been delivered through the Challenge to date. Alternatively, if the Group's remit is to provide advice on particular data-related issues or to make linkages with other parts of the health data and precision medicine landscape then it needs to be given some clear 'asks'. Advisory Group need to have sufficient clarity on the progress being made to promote the Challenge through other networks and to encourage new collaborations through the Challenge structures.

5.7 Some consultees thought that the Advisory Group needs to be tasked with providing UKRI with more advice around strategic direction and how to ensure the sustainability of Challenge funded infrastructure and projects. In addition to better leveraging of the Advisory Group, the evaluators recommend the Challenge team investigate with the KTN the potential to establish Challenge Community, similar to what has been set up for the Medicines Manufacturing Challenge.

Genomics

Strand level governance and management

5.8 For the UK Biobank WGS project, governance and management structures (relating to technical/operational oversight, and more strategic oversight including risk and financial management) were considered by stakeholders to have been effective. Industry partners tended to express the view that they had largely led governance and organisation (for example, creating governance structures and organising meetings), albeit openly, with UKRI approval and involvement, and in line with the shared values of all partners.

5.9 The value of a collaborative approach to project planning and management was widely agreed on, especially in enabling partners to act together to manage the challenges and uncertainties imposed by the pandemic. The commitment and flexibility of the sequencing partners in particular were said to have been of particular value in this respect. The importance of UKRI involvement and public reporting of progress was also referred to, along with input from the

UK Biobank expert panel. In general, reporting requirements were felt to have been very reasonable and not created undue burdens on funding recipients.

5.10 In terms of setting up the collaborations (especially the UK Biobank sequencing), delays arose from negotiation of contractual arrangements between partners. It was suggested by some that a UKRI-led organisational construct similar to that eventually created for this project could be used as a platform for future partnerships and projects of this kind, and could accelerate progress.

5.11 For the smaller CR&D genomics projects, management structures were also seen as effective, with most companies managing projects with a combination of their own staff alongside the monitoring officers from Innovate UK. Risk registers were in place and reports produced for UKRI every three months. Several stakeholders commented that UKRI staff provided appropriate and useful support, including outside the regularly scheduled meetings. However, some had experienced difficulties with the reporting requirements, in particular the nature of information sought and timing of reporting. In addition, the monitoring reports were not always tailored to the recipients, making it harder to fill them in.

Promotion and links at Challenge level

5.12 Across the genomics strand, stakeholders reported strong feelings of isolation from other parts of the Challenge. Views varied on the clarity of internal communications about the nature and wider purpose of the Challenge, beyond the specific genomics strand projects. Most did not know of any links between the different strands, and had little or no awareness of what was happening outside their own strand, or what other work was funded under the Challenge. Several said it would be useful to see the UKRI reports summarising investments across the Challenge; others suggested that the actual 'Challenge' designation was unhelpful, since whilst it describes the aim and ambition, it carries no obvious indication of funding.

5.13 There was said to be an absence of systems to enable potentially useful synergies or connections between different strands of the Challenge. Whilst consultees said they would like greater knowledge about the wider Challenge, there was no consensus on whether the absence of this connectivity was problematic or not. A few of the CR&D projects did have some links to other parts of the Challenge such as through making data available through the HDR UK innovation gateway, or through links to the UK Biobank, but these connections tended to predate the Challenge.

5.14 Many stakeholders recommended that UKRI should consider investing in capacity and structures to enhance internal communication and potential collaboration. For example, an individual could be tasked with actively convening cross-strand and wider community meetings that could foster useful synergies and connections. It was felt that this would improve both general awareness and knowledge sharing, and help lay the groundwork for potentially valuable future collaborations. This could be of particular help to smaller commercial entities, which lack the capacity to make connections and discuss early stage or

abstract collaborative ideas. Small amounts of additional funding specifically for post-Challenge collaborations could also prove valuable in terms of additional outcomes.

5.15 In terms of external communications, there was consensus that there had been very limited promotion or awareness of the Data to Early Diagnosis and Precision Medicine Challenge, with much of the wider precision medicine community remaining unaware of it, despite being familiar with Innovate UK and UKRI. Some projects did enjoy greater visibility with certain stakeholders (such as specific cancer projects and corresponding communities), and Genomics England was said to boost this through their own communications. It was also acknowledged by some that the pandemic had potentially further reduced general visibility of the Challenge, and by others that communication of impact was inevitably limited until evidence appeared (for example, scientific publications) and would improve over time. On this issue, the need to ensure that outcomes are monitored for years to come (i.e. well beyond the conclusion of the Challenge itself) was emphasised by some. Researchfish was suggested as a potential model for a tool to help UKRI deliver such long-term monitoring.

5.16 However, most felt that greater promotion of the Challenge activities and outcomes by UKRI both within and beyond the genomics strand would be valuable, and in general it was felt it would be good for UKRI to make more 'noise' about the funded projects.

EDI and PPIE

5.17 In general, EDI was not a significant consideration for the genomics strand projects, since they largely drew on pre-existing patient cohorts with limited scope to enhance EDI; partners acknowledged the limited diversity of datasets, especially UK Biobank itself. EDI was also not seen has being fundamentally embedded within the Challenge, although most corporate partners have their own EDI values and priorities.

5.18 PPIE was also limited for genomics. Many projects were highly technical and so less accessible or interesting to the wider public; others were early stage projects that would go on to incorporate more formal PPIE if they led to larger future projects. Partners such as UK Biobank and Genomics England have their own well-developed PPIE programmes in place, which were useful, and other projects used focused, small-scale PPIE where appropriate.

5.19 Patient / participant input has been especially useful to sense-check information and materials; the Genomics England participant panel has helped improve the wording on consent agreements to enable consent to future projects, which should maximise utility of the genome sequencing of their research cohorts. Consultees highlighted that EDI will be more proactively built into future work that develops from projects, such as larger scale prospective studies.

DigiPath

Strand level governance and management

5.20 As indicated earlier, many consultees involved in the Centres of Excellence highlighted the complexity of setting up local governance arrangements for groups of universities, NHS Trusts and industry partners. Project managers from the Centres highlighted the time and resource required to pull together information from a large group of partners for monitoring and reporting purposes. The evaluation feedback indicated that project managers have invested significant time into ensuring robust governance and monitoring systems.

5.21 However, the evaluators feel 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. Given the level of funding and complexity of working with NHS data and systems it would have made sense to limit the number of partners to around 20 and the number of projects to say 10 per Centre.

5.22 Similar to the Genomics CR&D projects, UKRI organises quarterly monitoring meetings for all the Centres of Excellence and Integrated Diagnostics CR&D projects. These meetings discuss progress in terms of spend and how projects are progressing in terms of their original objectives. Many consultees reflected positively on the quarterly reviews and input from monitoring officers, noting that:

- it is an effective way of keeping partners focused on the project
- the meetings provide an opportunity for partners to learn from one another
- the monitoring officers are pragmatic and knowledgeable
- Innovate UK has been easy to contact with a good level of communication.

5.23 Overall, the management and monitoring by Innovate UK was considered to be useful and appropriate. However, as noted in Section 3, there were some elements of management by Innovate UK that have not worked well. First, in some cases, claims and reporting processes were considered to be prohibitively slow. Second, the claims portal introduced in August 2020 was deemed ineffective by some consultees. Specific issues identified included the lack of support function available on the portal when it failed to work properly, the lack of flexibility to use other reporting mechanisms if the portal was not working, and the delay that both of these factors caused in uploading monitoring data. Some consultees from the Centres were disappointed and frustrated when these operational issues were highlighted but then took a long time to resolve.

5.24 The Baseline report indicated a desire from the Centres to have more support from UKRI on interoperability and knowledge exchange between the five Centres. From mid-2021, UKRI's innovation lead has organised a programme of activity involving partners from the five

Centres. Eight interoperability workstreams have been established and are being led by different Centres. These focus on evaluation, deidentification, federation, data transfer standards, TREs, image standards for clinical use, image format, and quality assurance. At the time of interviewing, these workstreams were still being established and so it was too early for the consultees to comment on the benefits of this work, but there was an appreciation of further support on the complex issue of interoperability.

5.25 Given the scale of ambition and funding being provided to the Centres of Excellence, the evaluators recommend that more resource is allocated to the programme management of the five Centres. There is around 12-18 months left for the projects to complete their exemplar projects, develop the new AI tools and prove they can be used to improve diagnostic services in the NHS. This is a critical period to ensure the success of one of the flagship investments by the Challenge and, as discussed above, there is a need for continued coordination on interoperability and ensuring the sustainability of new data storage facilities. It is interesting to contrast the central UKRI support to the Centres with the larger scale of support provided by HDR UK to the DIH Hubs (which are smaller in terms of funding).

Promotion and links at Challenge level

5.26 As highlighted in the Baseline report, although individual Centres do their own promotion, consultees once again stated that UKRI should be doing more to promote the network and facilitate links with other parts of the Challenge and with other new initiatives. Most consultees felt that the Challenge was not being promoted effectively and several consultees did not know that their project was part of a Challenge initiative.

5.27 There was a general feeling that UKRI could do more to "*shout about*" what was being achieved by the Challenge, through more detailed information on its website, and cross Challenge events and webinars. This was regarded as a missed opportunity by some consultees who think improved publicity would engage more of the precision medicine community and maximise potential spillovers. Some consultees suggested ways that UKRI could improve its external communications:

"UKRI could do much more to publicise the outcomes generated. Part of that is about equipping the centre administrators with the knowledge of how to make an impact through press and media. UKRI has a role in this – they should be giving instructions to the centres, drawing on the internal expertise that they have"

[Centre of Excellence project partner]

5.28 Consultees also reflected that more could be done to facilitate links within the Challenge. Some formal and informal links exist across the Centres of Excellence and this has increased recently through the interoperability workstream in the DigiPath strand of the Challenge. Consultees also highlighted other examples of links across the Centres:

- **PathLAKE and ICAIRD** both have the same equipment supplier and so have been in regular contact since the start of the project. When the industry partner pulled out of the AI development it affected both projects, so PathLAKE and ICAIRD worked together to find a new more flexible solution that will enable third parties to link their AI into the system.
- **NPIC, NCIMI and PathLAKE** have ethics leads which had pre-existing relationships before the programme. These pre-existing relationships allowed them to set up a formal cross-centre ethics initiative.
- Partners from **NPIC and PathLAKE** collaborate on exemplar projects and the two Centre directors meet frequently through their involvement on the National Pathology Network.

5.29 A small number of consultees involved in the Integrated Diagnostics CR&D projects reported some ties with other projects participating in the Challenge. For example, IDX-LUNG is in contact with DART as both projects are working in a similar area. They are discussing areas of commonality and potential cross learning. This link was facilitated partly through existing relationships between team members and also through the monitoring officer, who supports both projects. The DART project has also been working closely with the NCIMI Centre of Excellence. However, most consultees from the CR&D projects reported that no links had been established with other projects, and it was often not regarded as a priority:

"This [forming links] hasn't been the focus so far as we have been too busy managing the progress of our project. With the project more established now, there may be more time for building wider links with other parts of the challenge"

[Integrated Diagnostics CR&D project manager]

"I'm aware of other projects but there haven't been any formal links, partly because COVID hit when individual projects were just getting up and running"

[Integrated Diagnostics CR&D project manager]

EDI and PPIE

5.30 In terms of formal engagement with the public and patients, each of the Centres have formed PPIE groups and it was highlighted how the pandemic has actually made it easier for people to attend these meetings rather than having to physically travel. Some of the Centres have surveyed patient groups to see how they feel about use of data and use of AI in diagnostics in relation to the exemplar projects. A PPIE and ethics webinar series is being delivered by NPIC and PathLAKE Centre of Excellence.

5.31 PPIE staff across the five Centres have delivered a range of outreach activity including schools events and visits to youth group to promote the use of AI in healthcare and to encourage careers in pathology and radiology. As an example PathLAKE delivered two events each with

c. 100 children taking part. These involved 'Beat the Pathologist' competitions where children had to annotate images.

DIH Programme

Strand level governance and management

5.32 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.

5.33 Partners reported varying perspectives on reporting requirements and management of the DIH programme. Although most consultees complimented the robust and transparent management structures and processes built into the DIH programme, some of the Hub interviewees said that reporting to HDR UK and UKRI felt quite onerous.

5.34 Many expressed the feeling that reporting requirements could have been better coordinated between HDR UK and UKRI; some referred to too many 'layers of bureaucracy' at HDR UK, or reported frustrations in overlapping but not identical requirements and timescales / periodicity for HDR UK and UKRI reporting. Some said that the changing templates for reporting made it more challenging to comply with, though there was sympathy with the difficulty of harmonisation of reporting requirements across Hubs with very different goals (indeed some of the changes were actually requested by the Hubs). A suggested improvement was for clear, consistent reporting requirements for the same types of data at consistent times.

5.35 Some concerns were raised around Milestone 2, due to COVID-19 negative impacts of COVID-19 on progress. Hubs that did not passed the milestone smoothly reported that mitigation of the concerns required a lot of work and, while successful, some felt it could have been handled in a more flexible way.

5.36 Overall, there were good levels of satisfaction with project-level management. Many hubs have established boards and steering groups to support projects - these also integrated PPIE – and the model for the programme board structure at the Hubs was viewed positively, enabling useful regular stakeholder interactions.

5.37 There was positive feedback on the Health Data Research Alliance, which was seen as a useful resource and offering a recognised opportunity to develop data standards and Trusted Research Environments. Some 'teething issues' were mentioned, but these were said to have been resolved. Similarly, stakeholders were positive on the ambitions of the Health Data Innovation Gateway, but noted that work was still needed to demonstrate full utility of this resource; some were more doubtful than others how useful it would be, and expressed concerns that the data access process can be difficult. Having a forum that brings together the

main data controllers and custodians to address these long-standing issues is a key benefit of the Alliance.

Promotion and links at Challenge level

5.38 Communications between the Hubs and from HDR UK were felt to be quite good by stakeholders. Some felt that initially UKRI did not communicate well with the Hubs, but this was noted to have improved. One area for improvement was for greater clarity around the longer term goals for the DIH strand beyond the specific Hub funding and purposes.

5.39 Feedback about wider Challenge level communications were more varied; there was generally low awareness of other parts of the Challenge among respondents, and reportedly no active coordination between DIH and other strands of the Challenge. Some Hubs had established collaborations due to mutual interest or geographical proximity, but such partnerships had not been indicated as a component of the wider work programme. Some DigiPath centres were said to be joining the DIH network, but requests for improved interoperability between strands were not considered feasible.

5.40 In terms of external communications, there was a consistent view from stakeholders that there was a serious lack of UKRI-led communications about the Challenge. It was noted that DIH strand information and progress is not shown anywhere on the UKRI website in great detail, so more communication was felt to be badly needed. In particular, it was said that profiling success stories with the greater reach UKRI could achieve was important to boost the UK's image as a leader in health data innovation, and to attract wider interest and investment.

EDI and PPIE

5.41 As for some of the genomics strand projects, EDI efforts were said to quite constrained by the Hubs working with pre-existing datasets, which do not always have the desirable levels of diversity. Partners from these Hubs emphasised the need to focus on increasing the diversity of future datasets, and one Hub noted that their recruitment of new datasets had an active focus on obtaining more demographically diverse data for this reason. PPIE elements were said to have been established for all projects as part of Milestone 1, and the value of steady, ongoing engagement was noted by some.

5.42 Most respondents referred to the HDR UK Health Data Science Black Internship Programme as a positive EDI initiative; some Hubs were directly involved in this. Many Hubs also reported utilising existing hospital or academic PPIE resources to make the most of their expertise. Patient advisory groups were considered particularly useful to advise on materials (e.g. lay summaries of research), as well as to review project updates and data requests.

Overall Challenge design

5.43 It is worth reflecting on the feedback on Challenge governance and management to consider the main lessons for this type of programme in the future. These lessons need to be seen in the context of a complex programme with lots of different types of projects. These projects are seeking, through different routes, to leverage the use and benefits of health data for better diagnosis, accelerate the adoption of Precision Medicine, and ultimately stimulate economic growth through the creation of new business opportunities in the UK.

5.44 In terms of how the Challenge has been delivered there has been a mix of traditional Innovate UK CR&D competitions, co-development and funding of the UK Biobank WGS project and sub-contracting of the DIH Programme to HDR UK. The UK Biobank project could not really have been delivered any other way and, although it took significant effort to set up, the pharma consortium approach to deliver it has been seen as the most appropriate mechanism.

5.45 The evaluators assess that the sub-contracting of the DIH Programme was also the correct decision given HDR UK's central role in the health data landscape. From the start of the Challenge in 2018, HDR UK has undertaken significant consultation and engagement to help shape the DIH Programme. Although there is clearly more work to be done there is some early progress in terms of the number of organisations joining the Alliance to address the continuing issues around data governance and standards. HDR UK has also put in place a robust management process to support the development of the Hubs.

5.46 This type of approach could potentially have been used with the DigiPath Centres of Excellence. Although they were set up using a traditional competition, they are somewhat different from Innovate UK's usual CR&D projects in the terms of the imperatives to ensure linkages and interoperability across the Centres. As a result, the Centres would have benefited (and would benefit going forward) from more hands-on programme management from UKRI.

5.47 Based on the evaluation evidence to date, the Challenge has focused on the correct areas in terms of building on the UK's genomic sequencing strengths, accelerating digital diagnostics and trying to ensure a more integrated health data landscape. Across the Challenge there is also a strong focus on oncology and this again makes sense to address the significant market opportunities forecast in personalised cancer treatments globally.

6. Conclusions

6.1 In this section we draw together the main conclusions from the Progress and Process Evaluation of the D2EDPM Challenge, and make recommendations for improvements for the remainder of the Challenge.

Progress evaluation

6.2 This Challenge is a complex and ambitious programme of investment that is seeking to accelerate the use of data and new technologies in the diagnosis of disease and adoption of precision medicine. This is a fast-changing landscape and the context has clearly been impacted significantly by the COVID-19 pandemic.

6.3 Measuring progress of this £210m investment is not straightforward given the number and variety of projects that have been supported under the three strands of the Challenge (Genomics, DigiPath and the DIH Programme). As highlighted in the M&E framework there are different routes and timescales to impact, and the investments made by the Challenge have started at different points over the last three years.

Overall progress towards Challenge objectives

6.4 The objectives of the D2EDPM Challenge are to: encourage greater adoption of precision medicines including through earlier diagnosis; increase the UK share of global diagnostic market; 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; and increase efficiency in the NHS. As identified in the M&E framework these objectives will take at least five to 10 years to come through. However, there are shorter term outcomes that can be assessed to demonstrate progress towards these longer-term objectives and these are set out in Table 6-1.

6.5 Based on the evidence in the progress evaluation, the evaluators expect that the Challenge will meet its target budget and outputs by the time of the final phase of the evaluation in 2023. The research also indicates that progress is starting to be made against the shorter-term outcomes, and examples are provided in the Table below – albeit that there is more to do. Taking into account the inevitable time-lag for many of the Challenge outcomes and the fact that some projects have been delayed, the evaluators believe that the progress made to date is largely where it should be at this stage of implementation. This is particularly true for the Genomics and DIH strands. The DigiPath strand needs to progress more quickly going forward in order to make up on some of the delays encountered.

6.6 Significant delays have affected the delivery of various aspects of the Challenge, and this has especially been so for the DigiPath strand. Most of the delays have been in some way related to the pandemic, but the Centres of Excellence have also been delayed by issues specifically

related to the Challenge – primarily through applicants and UKRI underestimating the complexity of delivering the Centres together with project administration issues.

Table 6-1: Summary of emerging outcomes

	Key evidence on progress to date
Enhanced global reputation for: genomics, WGS trials, health data driven R&D and innovation (incl. diagnostics and AI)	• Due to its scale, ambition and level of collaboration between key industry partners, the UK Biobank Whole Genome Sequencing project was viewed as a flagship project globally and regarded as the gold standard for population genetics research. The profile generated by the investment has started to escalate following the first public release of sequenced data. • The digital pathology and radiology Centres of Excellence have increased their national profile through research papers on the Challenge funded activity and delivered national events. Over 100 publications have already been produced by partners involved at the Centres. There have also been international events, though there is work to do to translate this into global profile.
Increased commercial and academic R&D investment, including in related areas (e.g. other omics)	• The Challenge has successfully attracted funding from partners, as demonstrated by the figures below. In addition, there are already examples of the Challenge leading to subsequent/related research investments. • £150m in match funding leveraged through the UK Biobank WGS project, the other genomics projects are also securing significant match funding. Across the GEL and CR&D projects, there was nearly £1m in match funding for the Genomics CR&D projects which will increase to £3.7m by the end of the projects. • £14.5m in match funding for the Centres of Excellence to date (which will rise to £43.3m) and £4.2m for the Integrated Diagnostics CR&D projects (increasing to £14.2m). £21.3m in match funding to date for the Health Data Research Hubs in the DIH Programme which will increase to £36.2m.
Improved access to, and use of, data resources for industry, NHS and academic R&D	• The data resources are being made available, though more evidence is required, at the final stage, to demonstrate widespread use across different stakeholder groups. • For example, Health Data Research Innovation Gateway was launched in June 2020 and now signposts to 699 datasets, some of which are visible exclusively via the Gateway - the target is to include 2,000 datasets by 2023
Improved curation/ characterisation of patient data	• The Health Data Research Hubs have so far made 100 datasets discoverable and, in meeting Milestone 2, they have demonstrated data improvement and improved accessibility.

	Key evidence on progress to date
New companies attracted to the UK & new start-ups due to availability and quality of UK health data, genomics capabilities and AI/digi diagnostics capabilities	• Limited evidence of this happening to date. • Whilst there is confidence this will start to happen as new technologies funded by the Challenge start to be adopted by the NHS, it is noted that presence in the UK is not necessarily a requirement to take advantage of the data resources on offer (e.g. through the UK Biobank).
New AI diagnostic tools developed and/or validated	• Across the Centres, there are 37 exemplar projects being delivered, four AI tools have already been developed and a further 28 AI tools are currently in development. By this point of the evaluation, this is encouraging, and we expect much more progress by the time of the final evaluation.
Increased academic-industry-NHS collaborations focused on new data-driven healthcare products/ AI and digital pathology/ WGS	• This is a key area of achievement by the Challenge with new collaborations evident across all strands of the Challenge. For example, by the end of 2021, the Health Data Research Hubs had secured over 500 contracts with a range of academic, industry and NHS clients.
Improved business performance in industry partners	• It is perhaps too early for substantial evidence of this outcome. There are nevertheless some early individual examples of industry partners reporting business benefits from being part of the Centres of Excellence. However, most benefits will come in the coming years from successful commercialisation of technologies.
Improved skills capacity and capability for genomic and data-driven healthcare technologies	• Improved skills and capability for genomic technologies reported by pharma partners involved in the UK Biobank WGS projects, and this is expected to evolve further as researchers from other sectors begin to use the new data. • There are also examples from the digital pathology and radiology Centres of Excellence. ICAIRD and PathLAKE reported improved skills amongst clinicians trained using the new digital diagnostics. NPIC expect that once the scanners are installed and in use, this will help improve digital skills clinician understanding and trust in digital diagnostic technologies.

Source: SQW

Genomics

6.7 Most progress in terms of investment has been in the Genomics strand where over £100m of UKRI's investment has already been made and this has leveraged a further £150m in match funding from the four pharma partners and Wellcome Trust. The WGS UK Biobank project has progressed significantly, making some real accomplishments in the provision of genomics data. It means that in 2022, 500,000 whole genome sequences will be available to UK Biobank users, with an informatics platform for the storage, curation and analysis of the data.

6.8 Although the utility of the sequenced data will be tested by the pharma partners and wider research community over the coming 12 months, the evaluation found that the project has already increased the UK's profile and reputation for whole genome sequencing and is expected to help deliver better and more targeted medicines over the next 10 years. The project has been challenging but is already starting to generate benefits through increased investment in genomics and other omics research, skills and capability development, and improved industry-academic collaboration.

6.9 There are also emerging benefits under this strand from the GEL and Genomics CR&D projects which are developing new WGS related technologies. Around £2m in UKRI funding had been spent on these projects by summer 2021 out of an allocation of £11m. There was nearly £1m in match funding from industry spent by summer 2021 which will increase to £3.7m by the end of the projects. Early benefits from these projects include new cross-sector collaborations (between academia, the NHS, charities and industry) new products or new evidence to validate or enhance existing tools or technologies.

6.10 At this stage, the strand is on track to deliver the types of outcomes expected, including investment in research, cross-sector collaboration, and capability and capacity development for innovation and research. If research and investment prove successful, then business and health benefits would be expected to follow. The early indications suggest that the investment has aided the UK's reputation internationally, though it is not clear at this point whether this will lead to inward investment and attraction of companies – reflecting the nature of the asset, which can be accessed from anywhere in the world.

6.11 The Challenge funding, and the inferred government commitment to the UK Biobank as a national research resource, was key to the additionality of the activities, i.e. making the genomic sequencing work and infrastructure development possible, and generating essential match funding from industry.

DigiPath

6.12 The progress of the digital pathology and radiology Centres of Excellence has undoubtedly been delayed, partly due to the disruption caused by the pandemic but there have been other factors which resulted in a slower start than planned. Around £25.2m of UKRI funding had been spent by summer 2021 (out of an allocation of £59m) with £14.5m in match funding spent to date (versus a total commitment of £43.3m).As a result, the evidence at this stage is focused on the delivery of key outputs, with the five Centres having made good progress in setting up the infrastructure and facilities and delivering the exemplar projects. Some are also starting to develop the AI tools and diagnostic technologies for use in the NHS. Across the Centres, there are 37 exemplar projects being delivered, four AI already developed and a further 28 AI tools currently in development.

6.13 The evaluation found some early evidence of increased profile for the Centres of Excellence in a UK and international context, increased commercial R&D investment, improved digital skills amongst clinicians and indirect business benefits (e.g. examples of early stage

companies being able to more readily attract investment, partly aided by involvement in the Challenge). If these early individual cases of outcomes continue and spread, then this strand is well-placed to achieve its intended effects; though we caution that at this point of the evaluation, most of the outcomes will be achieved in the future. Although the requirements around interoperability were not well understood at the start, consultees reported that some progress is now being made through the eight workstreams led by the Centres with support from UKRI.

6.14 Despite initial delays caused by the pandemic, most Integrated Diagnostics CR&D projects are now making progress. Around £4m of UKRI investment had been spent by summer 2021, out of an allocation of £16m. Around £4.2m in match funding has been spent out of a total commitment of £14.2m.

6.15 The evaluation found high levels of additionality in terms of what has been funded and what has been achieved to date in terms of outputs and emerging outcomes. The funding was seen as the catalyst for investing in new equipment, recruiting additional staff and securing the buy-in from industry partners.

DIH

6.16 By December 2021 around £26m had been spent in UKRI funding on the Digital Innovation Hub programme out of a total of £37.5m. As part of the investment to date, £16.3m of UKRI funding had been spent on the five DIH Hubs and these had also leveraged £21.3m in match funding.

6.17 The DIH programme which was delegated to HDR UK has three main areas of activity. The Health Data Research Alliance has grown from eight founding members to a total of 61 data controllers and data custodians. The Health Data Research Innovation Gateway was launched in June 2020 and now signposts 699 datasets, some of which are visible exclusively via the Gateway. - the target is to include 2000 datasets by 2023. The Hubs have made 100 datasets discoverable through the Gateway.

6.18 The Research Hubs have all passed Milestone 2 which confirms that they have demonstrate data improvement and improved accessibility. Consultees reported that the Hubs are making good progress in terms of creating TREs, improving access to health data and increasing collaboration and engagement with industry, NHS trusts and academia. There have been some strong early examples of impacts by the Hubs, such as in generating commercial interest and investment, and through outputs such as academic papers. Again, these need to continue to and spread for the strand to achieve its intended effects.

6.19 Once again the evaluation found high levels of additionality in terms of what has been achieved by Challenge funding for the DIH programme to date. Consultees indicated that the Challenge support has accelerated the process and improved the quality and scale of new structures and systems for improved data integration and access. The Challenge is felt to have

enabled the involvement of a wider range of stakeholders than would otherwise have been likely, and encouraged people to work outside the 'bubble' of academia.

Process evaluation

6.20 The M&E framework set out the key research questions for the process evaluation. This section summarises the key findings in relation to each of these questions.

Did the programme meet its target budget and outputs efficiently and effectively?

6.21 The largest investment in the genomics strand relates to the £100m funding for the UK Biobank Whole Genome Sequencing project. This contribution was provided to the industry consortium in 2018 which is also providing £100m in match funding, along with £50m from the Wellcome Trust. Nearly £7.9m of UKRI funding has been approved for Genomics England's (GEL) WGS in cancer trials project and around £1.1m had been spent to May/June 2021 which was around half of what was planned by this stage. Six smaller CR&D projects have been funded with grants totalling around £3.2m, of which £0.8m had been spent (again around half planned spend by that point). In all cases, the level of spend has been lower than expected due to issues around project set-up and disruptions caused by the COVID-19 pandemic.

6.22 A total of £59m in UKRI funding has been allocated to the five Centres of Excellence for digital pathology and radiology. Based on the monitoring returns, £25.2m had been spent by summer 2021, which represents two-thirds of planned expenditure by this stage. In addition, the Integrated Diagnostics CR&D projects had spent £3.9m which was 69% of planned spend. The level of expenditure has been lower than expected due to projects having to be paused during the pandemic.

6.23 A total of £37.5m in UKRI funding has been allocated to HDR UK to deliver the Digital Innovation Hub (DIH) Programme. This includes £2.6m to deliver 10 Sprint Exemplar projects which completed in 2018/19. Up to December 2021, 85% of UKRI funding for DIH Programme management and 70% of the funding for the Alliance and Innovation Gateway had been spent (no planned spend up to this point was available) – this amounted to £9.7m. Three quarters of the UKRI funding for five DIH Hubs had been spent, which totalled £16.3m (in line with planned spend to this stage). These Hubs have also leveraged £21.3m in match funding from the host universities.

6.24 Overall, therefore, the Challenge is slightly behind schedule on expenditure mainly in relation to the DigiPath strand but there have been costed extensions approved for the Centres of Excellence which will mean those projects finish in late 2022/early 2023. Although there has been some slippage, the evaluators expect that the Challenge will meet its target budget and outputs by the time of the final phase of the evaluation in 2023. This should be regarded positively given the context in which the Challenge has been delivered, and the complex nature of many of the activities.

To what extent did the governance, monitoring, management, and communications (internal and to external participants) enable programme delivery?

6.25 The D2EDPM Programme Board has generally been effective in terms of providing oversight on progress, and consultees believed that the structures and systems compare well with other similar Government programmes. One area highlighted in the baseline research was the time taken to recruit a Challenge director at the outset of the Challenge, which should have been addressed earlier. In July 2021, the first Challenge Director left and a replacement was recruited by November 2021. The transition period between July and November was viewed as well-managed by the UKRI team and other stakeholders, with one of the Innovation Leads taking on the role as Interim Director effectively, enabling good continuity at a key time.

6.26 There is good cross sector representation on the Challenge Advisory Group from relevant organisations and there have been useful conversations in the first two meetings of the Group. However, Group members found it difficult to talk in detail on the performance of the Challenge to date, and were keen for greater clarity on the role of the Group over the remaining 12-18 months of the Challenge. It is clear to the evaluators that this external expertise needs to be leveraged more effectively by UKRI to maximise the impact of the Challenge investments. Advisory Group need to have sufficient clarity on the progress being made to promote the Challenge through other networks and to encourage new collaborations through the Challenge structures.

6.27 Across all strands of the Challenge, there would appear to be robust management structures in place to ensure effective delivery of projects for the remainder of the Challenge. However, finalising project-level governance arrangements took longer than expected, particularly in relation to the Centres of Excellence and this caused delays to delivery which were then compounded by the disruption caused by the COVID-19 pandemic.

6.28 Project extensions were provided but the evaluators believe that additional support and guidance on sustainability should be provided to the Centres. A new set of interoperability workstreams have been established by UKRI to encourage more joint thinking and collaboration across the Centres on issues such as deidentification, data transfer standards and TREs. This additional support has been broadly welcomed.

6.29 The evidence from this and the Baseline phase of the evaluation indicated that there has been limited communication and coordination across the strands of the Challenge. The evaluators believe that this should be managed and coordinated more effectively by UKRI.

6.30 Although there were cases of individual projects promoting their activity, the evidence indicates that there has been little or no external promotion of the Challenge, and this will limit the potential effects of the Challenge if not addressed. Once again, the evaluation feedback indicated the need for more promotion of the Challenge and its achievements to ensure the R&D projects across the three strands can influence wider policy and leverage

further investment in the UK's data driven healthcare and precision medicine sector. This is also one area in which the Advisory Group's networks may be of benefit to the Challenge.

How effective were risk management strategies in anticipating and mitigating risks?

6.31 Risk management strategies have been built into the different levels of governance and management structures from the Programme Board down to local project management teams. The UKRI monitoring officers meet quarterly with the Genomics CR&D projects, Centres of Excellence and the Integrated Diagnostics CR&D projects to track progress, assess key risks to project delivery and to identify mitigation of these risks. These processes were seen to be working effectively, and the project leads consulted with valued the input from the monitoring officers in helping to keep projects on track. The fact that none of the Challenge projects have failed reflects well on the UKRI application process – i.e. funding new R&D but at the same time ensuring the projects are deliverable.

6.32 In the DIH programme, HDR UK has put in place a milestone performance management structure to track progress of the Hubs. All Hubs have now passed Milestone 2 (although three of the five required to undertake remedial activity) where they had to demonstrate data improvement and improved accessibility. There was also a requirement to provide updates on PPIE activity and Hub sustainability plans. Whilst there was feedback that the additional requirements placed on Hubs following milestone reviews were excessive, it should nevertheless be seen as a strong approach to risk management for what are complicated investments.

6.33 For the UK Biobank WGS project the collaborative approach and project level governance has been effective in responding to issues and risks. As part of this, the regular and ongoing meetings have enabled partners to address technical challenges adapting to issues as they have arisen. Two key issues have arisen in terms of risk. The first was in relation to sequencing, with the decision to have two sequencing partners proving to be critical when one was diverted to the response to the pandemic. The second one was on financial risk associated with the potential fluctuation in currency exchange rates (with sequencing paid for in dollars, though taking place in the UK and Iceland), requiring extensive negotiation to resolve. Industry partners believed that UKRI should have automatically taken on this risk.

Was monitoring effective in keeping the programme on track?

6.34 The monitoring and reporting produced for the Programme Board is generally fit for purpose with appropriate summaries provided by UK Biobank and the sequencing partners on the UK Biobank WGS project, and HDR UK in reporting progress on the DIH programme. This monitoring is appropriate for the Programme Board which is closer to the detail of the different strands of activity. The Advisory Group recommended that it should receive clearer programme monitoring feedback at an appropriate level of detail on progress on the

Challenge – currently, members of the Advisory Group did not feel that they were receiving appropriate updates on progress that could enable them to feed in their advice.

6.35 For the Genomics CR&D projects, Centres of Excellence and Integrated Diagnostics CR&D projects UKRI employ monitoring officers to meet project managers on a quarterly basis to review progress against spend and project milestones. The feedback from projects highlighted that these meetings are helpful to review progress.

6.36 However, there were some elements of management by Innovate UK that have not worked well. First, in some cases, claims processes were considered to be prohibitively slow. Second, the claims portal was deemed ineffective by some project consultees. The evaluators understand that improvements have been made to the new claims system. Any outstanding issues should be discussed with projects and resolved as soon as possible.

Were there barriers or enablers for the programme?

6.37 The main barrier to delivery to date has been the COVID-19 pandemic which has caused disruption and delay across the three strands of the Challenge due to problems with staff availability, project teams reallocated to pandemic response, restricted access to labs and supplies, and patient recruitment.

6.38 However. the pandemic has generated some positive wider effects in terms of: increased capacity and profile for whole genome sequencing; the data, helping to accelerate analysis and new tools developed by some of the DIH Hubs to support the pandemic response; and the increased awareness of what Centres of Excellence are seeking to deliver.

6.39 The complexity of partnership working was another key barrier. The evaluation has highlighted various examples where the process of setting up projects and finalising governance and contractual arrangements has taken longer than expected and has required significant project management resource. The UK Biobank WGS project is one example, but there were similar issues in many of the Centres of Excellence. The findings from the evaluation indicated that there is a fine balance to strike in developing suitably ambitious projects with the relevant partners, yet also having sufficient focus and manageability.. Given the level of funding and complexity of working with NHS data and systems it would have made sense to limit the number of partners to around 20 and the number of projects to say 10 per Centre.

6.40 Collaboration itself, which was in direct response to the Challenge's ambitions, is also proving to be an enabler. The evaluation has highlighted early evidence of strengthened relationships between academia, NHS Trusts and industry which are starting to deliver new products and technologies, and are also providing the platforms for collaboration on other projects.

To what extent has the D2EDPM Challenge ensured that equality, diversity and inclusion is achieved by broadening sector engagement and embracing differences?

6.41 There was a good awareness of the EDI objectives across the Challenge, and a recognition that UKRI has been promoting this more as the Challenge has progressed. All the main partners highlighted their individual organisations' commitments to EDI, and the Centres of Excellence and DIH Hubs confirmed that they have PPIE activities built into their Challenge projects. The evaluation found examples of patient groups being consulted, lay representation on project committees and some outreach activity to promote better understanding of how patient data is being used.

6.42 EDI was seen to be more challenging for the genomics strand where projects largely drew on pre-existing patient cohorts with limited scope to enhance EDI. PPIE was also limited for genomics since many projects were highly technical and so less accessible or interesting to the wider public; others were early stage projects that would go on to incorporate more formal PPIE if they led to larger future projects. Partners such as UK Biobank and Genomics England have their own PPIE programmes in place, which were useful, and other projects used focused, small-scale PPIE where appropriate.

To what extent has the programme's design and delivery enabled it to meet its objectives?

6.43 As reported in the Baseline report, the design and set-up stage was viewed as effective, notably in relation to securing industry investment and engagement, and in designing in additionality. In addition to the traditional approach to CR&D competitions, UKRI co-developed and directly funded the UK Biobank WGS project and sub-contracted delivery of the DIH Programme to HDR UK. This mix of approaches has been appropriate given the unique roles of the pharma partners, UK Biobank and HDR UK.

6.44 Across all parts of the Challenge, there have been high levels of additionality – the Challenge funding was reported to have accelerated projects, strengthened partnerships, and helped to bring in new industry partners. Some activities are unlikely to have happened at all. Feedback from two unsuccessful project applicants also confirmed that they were unable to progress their original project ideas in the absence of Challenge funding.

6.45 The process evaluation found that there is still limited engagement and interaction across the three Challenge strands, although the Centres of Excellence have recently joined the DIH Health Data Alliance which should facilitate more opportunities for collaboration around issues such as data interoperability.

6.46 The complexity of individual projects and the disruption and delay caused by the COVID-19 pandemic has resulted in project managers focusing primarily on their own projects. This is understandable but UKRI should provide additional support to bring together the three strands of the Challenge in the remaining year of the programme.

6.47 The DIH Hubs have benefited from wider support and programme management from HDR UK. This type of approach could potentially have been used with the DigiPath Centres of Excellence. Although they were set up using a traditional competition, they are somewhat different from Innovate UK's usual CR&D projects in the terms of the imperatives to ensure linkages and interoperability across the Centres. As a result, the Centres would have benefited (and would benefit going forward) from more hands-on programme management from UKRI.

What lessons are there for the remainder of the Challenge and for future programmes?

6.48 The main improvements identified in the research for the remaining year of the D2EDPM Challenge are set out below, and relate primarily to governance, management and promotion:

- **Improve the external communications to ensure successful outcomes and benefits are widely communicated nationally and internationally** - this would both demonstrate the returns on investment and promote the existence of valuable research assets to potential future investors, researchers and businesses, thereby contributing to longer-term outcomes.
- **Improve the communications to other parts of UKRI and other organisations supporting the growth of precision medicine in the UK**. The work of the Challenge needs to be better integrated with other healthcare and technology-related programmes being delivered by UKRI and other agencies. Other relevant organisations would include Academic Health Science Networks, KTN, the Catapults, health charities and industry bodies such as ABPI, BIA and BIVDA. In addition to better leveraging of the Advisory Group, the evaluators recommend the Challenge team investigate with the KTN the potential to establish Challenge Community, similar to what has been set up for the Medicines Manufacturing Challenge.
- **Leverage the expertise that exists in the Advisory Group more effectively** to promote the Challenge achievements, make the links with other complementary programmes and provide advice to key issues such as interoperability, technology adoption in the NHS and how to secure more commercial investment into the UK's data driven healthcare sector.
- **Support more internal collaboration between different strands and partners involved in the Challenge** – events to share progress, successes and future directions, with time for discussion of cross-strand opportunities for future collaboration and/or suggestions and ideas for future Challenges could help foster new linkages and ideas. Brokered meetings could also facilitate these types of opportunities, especially for smaller businesses that have less capacity to source such openings.
- **Provide more support on monitoring and reporting** – particularly in terms of resolving any outstanding issues on providing financial data and ensuring timely payment of project claims.

- **Provide more support on sustainability and greater clarity on what happens after D2EDPM ends**. As projects come towards the end and there is no clarity on long term funding then staff may leave to look for more stable/certain employment elsewhere. If greater clarity can be provided or sustainability achieved earlier, then the capacity and capability built up could help initiatives into their next phase.
- **Develop a long-term plan to build on and engage with the Challenge achievements well beyond the end of the funding period** - many opportunities will only emerge after this point and realising the maximum benefits from the Challenge investment will require further action.

Annex A: Consultee list

Table A-1: Consultee list

Name	Organisation
Abi Kerridge	University of Cambridge
Alastair Denniston	University Hospitals Birmingham NHS Foundation Trust
Alexander Weir	Canon Medical
Amied Shaadman	GEHC
Andrew Thompson	Jiva AI
Anna Schuh	University of Oxford
Anne Powell	University of Oxford
Awais Rashid	University of Bristol
Ben Gordon	HDR UK
Casey Capparelli	Amgen
Charles Gibbons	HDR UK
Chris Orton	Swansea University
Clara Fennessy	HDR UK
Colette Goldrick	ABPI
Daljeet Bansal	NPIC
Darren Treanor	NPIC
David Snead	University Hospitals Coventry and Warwickshire NHS Trust
Deborah Griggs	University Hospitals Coventry & Warwickshire NHS Trust
Derek Hill	University College London
Dominique French	Queen's University of Belfast
Fergus Gleeson	Oxford University Hospitals NHS Foundation Trust
Gareth Bryson	NHS Greater Glasgow and Clyde
Heather Fitzke	University College London
Ian McKay	UKRI - Innovate UK
Jackie James	Queen's University of Belfast
James Blackwood	NHS Greater Glasgow and Clyde
Jane Rex	GEHC
Jason Swedlow	Glencoe Software Limited
Jason Yip	Tailor Bio
Jenny Nelder	Cyted
Jenny Quint	Imperial College London
Jo Martin	Royal College Pathology
John Bradley	Addenbrookes Hospital
John Connell	Perspectum

Name	Organisation
John Stageman	LifeArc/ Bionow
John Whittaker	GSK
John Zurowski	NHS Greater Glasgow and Clyde
Jorge Cardoso	King's College London
Julia Wilson	Wellcome Sanger Institute
Karen Lightning-Jones	Roche
Kay Snowley	HDR UK
Kim Gasuad	Roche
Laura Towart	My Personal Therapeutics
Letizia Goretti	J&J Janssen
Louise Knowles	National Institute for Health Research
Lucy O'Neil	LMIAI Centre
Manuel-Salto-Tellez	Queen's University of Belfast
Mariella Chapman	Roche Diagnostics
Mark Avery	Eastern Academic Health Science Network
Mark Caulfield	Genomics England
Mark Beggs	NCIMI
Michael Boniface	University of Southampton
Nasir Rajpoot	University of Warwick
Neil Hanley	University of Manchester
Nina Hallowell	Ethox
Oliver Street	University of Manchester
Paul Colville-Nash	UKRI - MRC
Paul Smith	BC Platforms
Peter Sasieni	King's College London
Ravi Chana	Roche
Rebecca Fitzgerald	University of Cambridge
Sarah Dance	Roche
Sebastian Schneeweiss	Harvard Medical School
Shahla Salehi	Genomics England
Shan Raza	University of Warwick
Stuart Taylor	University College London
Tim Padgett	UKRI - Innovate UK
Trevor Howe	J&J Janssen
Victoria Goss	University of Southampton

Source: SQW

Annex B: Project level summaries

Genomic strand

Genomics England Project

Table B-1: Whole genome sequencing of liquid biopsies to predict doxorubicin response in ovarian cancer

	Monitoring data summary
Full project name	Whole Genome Sequencing in cancer trials".
Lead organisation	Genomics England
Project summary (as stated in application)	The project plans to support the following trials: • TRACERx Renal CR-UK and AstraZeneca (RAMPART Trial) • CR-UK Personalised Breast Cancer Programme CR-UK and AstraZeneca (PARTNER Trial) • CR-UK PATHOS and NICO Trials in Oropharyngeal cancer • Tessa Jowell Brain Matrix Trial Brain Tumour Charity • OxPloreD Johnson and Johnson • Metastatic Melanoma RMH Cancer Charity • ESCALATE Oesophageal Cancer Study The aim is to sequence 2,980 cancer patients and 3,820 tumour samples
Key outputs	• 2 NHS partners (as planned) • 3 academic partners (as planned) • 1 commercial partners (as planned) • 1 other partner (as planned) • 4 clinical trials supported (5 planned to date, with a further 3 trials planned to be supported by early 2022) • 1547 patients sequenced (850 planned to date, with a further 2030 planned by early 2022) • 1548 tumour samples sequenced (1910 planned to date, with a further 3450 planned by early 2022
Key outcomes	None reported
Progress commentary	Three of the current 7/8 studies have so far submitted their first batches of samples, we have a further two studies ready to submit imminently, however, the impact on trial recruitment has delayed others. We are working with all cohorts to ensure that we can mobilise samples and data as soon as it is available.

Source: SQW Based on project monitoring data

Genomics CR&D Projects

Table B-2: Whole genome sequencing of liquid biopsies to predict doxorubicin response in ovarian cancer

	Monitoring data summary
Full project name	Whole genome sequencing of liquid biopsies to predict doxorubicin response in ovarian cancer
Lead organisation	Tailor Bio Ltd (formerly known as Pinpoint Oncology)
Project summary (as stated in application)	The project involves the development of new genetic tests on DNA from tumours to improve the cancer treatment choice. The firm's previous tests used shallow whole genome sequencing of patient tissues biopsies. This project focuses on adapting the technology to liquid biopsies (such as blood tests) that contain cell free tumour DNA. If successful, the new test will be cheaper, less invasive for the patient, safer and more convenient. At the time of application, the firm was developing its first product for commercialisation, the project aimed to "assist in establishing its market position".
Key outputs	• 2 project partners (3 planned) • 1 new dataset created (as planned) • 1 clinician clinicians/ bio-medical scientists trained in sequencing technologies (as planned) • 96 patient samples sequenced (against target of 100)
Key outcomes	• 1 academic /industry collaboration related to the project activity is underway • 1 new cancer diagnostic tool has been developed • 1 publication is planned
Progress commentary	This period saw the generation of additional datasets to be analysed for the project. An existing patent was supported via the addition of data generated in the innovate UK project.

Source: SQW Based on project monitoring data

Table B-3: Personalised therapies based on simultaneous targeting of complex oncogenic networks identified by WGS

	Monitoring data summary
Full project name	Personalised therapies based on simultaneous targeting of complex oncogenic networks identified by WGS.
Lead organisation	My Personal Therapeutics Ltd (MPT)
Project summary (as stated in application)	This project involves a collaboration between MPT and London NIHR IVD Co-operative to develop treatments for gastrointestinal cancer (GIC) patients. MPT uses Personal Discovery Process (PDP) technology (which enables simultaneous modelling and subsequent targeting of multiple mutations which drive tumorigenesis) to generate personalised therapeutic recommendations. PDP has already demonstrated improved therapeutic outcomes for GIC patients, however the process of using it can take months and is costly. This project will employ machine learning to create a PDP-based Big Data product (BD-PDP) that is able to match an

	Monitoring data summary
	incoming patient's tumour profile with a database of previous patient genome and drug screening data. This can be used to predict a patient's response to a particular drug. Overall, the project aims to transform PDP into a faster, lower-cost, data-driven and commercially feasible process. It will deliver fully personalised treatment recommendations to improve GIC outcomes based on patient's tumour WGS
Key outputs	• 2 project partners (as planned) • 6000 tumour profiles analysed (4000 planned) • 40 genetic signatures created (as planned) • 11 patients recruited (8 planned to date, with a further 12 planned by early 2022) • 1 new database created (as planned) • 9 GIC (gastro-intestinal cancer) avatars created (as planned, with a further 31 planned by early 2022) • 1 new method for identifying therapeutic targets developed and validated (as planned, with 1 more planned by early 2022) • 40 new therapies (drug combinations) expected to be identified by early 2022 • 1 UK and 2 overseas patents planned by mid-20 22
Outcomes	• 1 academic industry collaboration linked to project activity • 40 new therapies (drug combinations) expected to be identified by early 2022 • 1 UK and 2 overseas patents planned by mid-20 22
Progress commentary	The cancer variant selection tool software/application that was developed during the first 2 quarters has been adapted for whole genome sequencing data analysis. The variant identification tool has also been modified to be able to incorporate data from different DNA sequencing providers. This represented an issue as different providers utilize diverse tools and software to analyse mutations, structural variations and copy number variations. Pre-selection of GIC profiles: MPT worked with Genomics England (GEL) cancer databases (with a focus on colorectal cancer -CRC-) to generate a method to perform cluster analysis involving cancer gene mutations , incorporating also copy number variations (CNV) to the analysis. Mutational data (variants) and CNV are separated entities within Genomics England database (and public databases too) and therefore it was challenging to create signatures including both. To tackle this, they developed a number of technical approaches to create comprehensive signatures (detailed in the progress report). The project finished the design, synthesis, cloning and microinjections of 11 avatars from the signatures identified. They keep synthesis, cloning and microinjections of additional 9 avatars. Developments of in-house facilities have also taken place 11 patients have been recruited from the London NIHR IVD Co-operative (IVD). Surgery was performed on them and samples are under current WGS sequencing.

Source: SQW Based on project monitoring data

Table B-4: A novel method for single-step, ultra-sensitive, combined DNA methylation and mutation detection of cancer from liquid biopsies using WGS

	Monitoring data summary
Full project name	Base Genomics: A novel method for single-step, ultra-sensitive, combined DNA methylation and mutation detection of cancer from liquid biopsies using WGS
Lead organisation	Base Genomics Limited
Project summary (as stated in application)	At the time of application, Base Genomics had developed an innovative sequencing method, known as TET-assisted pyridine borane sequencing (TAPS). This process has been demonstrated to simultaneously detect DNA mutations and DNA methylation (both types of DNA changes which cause many diseases including cancer), which, unlike previous methods, does not destroy the DNA in the process. It therefore allows sensitive detection of DNA changes in a single sequencing experiment, using a small amount of DNA. Compared to existing methods, TAPS will provide more precise results at a lower cost. This project makes use of samples and WGS data from the Genomics England Cancer Pilot. In the first set of experiments, it compares TAPS to existing methods using liquid biopsies from patients with early stage cancer to test whether TAPS is superior in detecting both DNA mutations and DNA methylation changes from liquid biopsies that are specific to cancer tissue. If this is the case, the project will go on to test in a larger cohort, whether TAPS can correctly identify patients with cancer from liquid biopsies.
Outputs	• 6 project partners (as planned) • 24 new datasets created (26 planned to date, with a further 291 planned by early 2022) • 2 new methods for identifying therapeutic targets developed (1 planned to date, with a further 2 planned by early 2022) • 2 clinicians/ bio-medical scientists trained in sequencing technologies (as planned) • 2 new analysis methods generated (1 planned to date, with a further 2 planned by early 2022) •
Outcomes	• 1 UK and 1 overseas publication (as planned) • 1 UK and 1 overseas patent planned by early 2022 • 1 new cancer diagnostic tool expected by early 2022
Progress commentary	According to the latest monitoring data, the focus for the quarter was on developing analysis pipelines that can be used for all work packages and development and tech transfer of a stable protocol with which to complete work package one.

Source: SQW Based on application form and project monitoring data

Table B-5: Carcinoma of Unknown Primary Site (CUP) a comparison across tissue and liquid biomarkers (CUP-COMP)

	Monitoring data summary
Full project name	Carcinoma of Unknown Primary Site (CUP) a comparison across tissue and liquid biomarkers (CUP-COMP)

	Monitoring data summary
Lead organisation	Roche Products Limited
Project summary (as stated in application)	Patients with Carcinoma of Unknown Primary (CUP) have widespread cancer at diagnosis however the specific site of origin cannot be found making it difficult to treat. CUP demands that integration of everything known about the patient's cancer: patient's symptoms, blood test results, radiological imaging and pathology results are all currently used as standard diagnostics to make clinical decisions for CUP patients. To date there have been limited studies investigating molecular genomics in CUP patients, as a result there is limited evidence to evaluate whether genomic profiling has added value over and above the standard diagnostics provided in the NHS. As a result, this project will carry out; • Assessment of genomic sequencing (both in tissue and blood) for the diagnosis and treatment stratification in patients with CUP including a comparison of the effectiveness of tissue and blood-based biomarkers • Collection of evidence to further develop technology that predicts an individual's response to a treatment • Development of innovative systems of clinical data capture in patients with CUP • Investigation into novel biomarkers to determine the primary tumour location The aim is to improve the prognosis and access to treatments in CUP.
Outputs	• 4 project partners (11 planned to date) • 1 PPIE participant (as planned) • 4 patients recruited (65 planned to date, with a further 55 planned by end 2022) • 4 sites activated (16 planned to date, with a further 16 planned by end 2022) • 1 secure computation environment completed (as planned) • 1 data transfer completed (as planned, with a further 2 planned by end 2022) • 3 UK publications planned by end 2022 • 12 academic industry collaborations planned by end 2022
Outcomes	• 3 UK publications planned by end 2022 • 12 academic industry collaborations planned by end 2022
Progress commentary	The work that has taken place in the period 1st July 2020 to 31st March 2021 was predominantly focussed on project setup. There were some delays to progress. Financial review checks delayed the signature of the collaboration agreement. COVID has meant that some of the study sites are only now getting back on their feet and ready to start study site set up

Source: SQW Based on application form and project monitoring data

Table B-6: Integrated whole genome sequencing into care for patients with liver tumours

	Monitoring data summary
Full project name	Integrated whole genome sequencing into care for patients with liver tumours

	Monitoring data summary
Lead organisation	Perspectum Ltd
Project summary (as stated in application)	This project proposes to develop a product which integrates MRI image analysis, digital pathology, and whole genome sequencing (WGS) to improve detection and treatment of patients with suspected liver tumour, including hepatocellular carcinoma (primary liver cancer). This has the potential to improve clinical outcomes for the patient and reduce costs for the healthcare system. The project will first establish the analytical validity and clinical validity of either whole tissue or single cell whole genome sequencing (WGS). It will then undertake a prospective study, in which patients can be included as part of their standard package of care. Perspectum will then provide a detailed consolidated and actionable report containing quantitative MRI imaging, digital pathology and WGS. This report will then be provided to the physician to assess the value of these additional metrics and whether they would have influenced the physician in determining the most appropriate treatment pathway for the patient.
Outputs	• 3 project partners (as planned) • 31 datasets created (55 planned to date, with a further 45 planned by early 2022) • 4 clinicians/ bio-medical scientists trained in sequencing technologies (as planned) • Hepatica paper accepted for publication August 2021 • 1 UK patent for cancer diagnostic tool • 1 US patent expected by early 2022
Outcomes	• Hepatica paper accepted for publication August 2021 • 1 UK patent for cancer diagnostic tool • 1 US patent expected by early 2022
Progress commentary	The clinical utility information collected within the trial is considered to be extremely useful. A case report is to be drafted on a participant from this trial. The US Market access activities are ramping up for this product. There is a follow-on study Precision 2 in planning phase with NHS Lothian and NHS Greater Glasgow Clyde. The Q4 spend under review and will be discussed in detail with Monitoring Officer in Q4 meeting.

Source: SQW Based on application form and project monitoring data

Digi-Path Strand

Digital Pathology and Radiology Centres of Excellence

Table B-7: I-CAIRD

	Monitoring data summary
Full project name	I-CAIRD: Industrial Centre for AI Research in Digital Diagnostics.
Lead organisation	University of Glasgow

	Monitoring data summary
Project summary (as stated in application)	The project is led by the University of Glasgow and brings together 17 partners from NHS, academia and industry. ICAIRD focuses on application of AI to digital diagnostics at the Queen Elizabeth University Hospital in the academic-industry zone established by University of Glasgow and NHS Greater Glasgow & Clyde. The key objectives of I-CAIRD are as follows: develop infrastructure to apply AI in digital diagnostics, fast tracking Scottish NHS pathology data to create the largest fully digital laboratory in Europe; create a network of regional centres for AI development; establish national pathology image archive; ensure SME-led exemplars use the platform to apply and validate AI in a number of medical areas; create a national network allowing exemplars to train through standardisation of application programming interfaces; and establish an SME accelerator programme.
Outputs	• 14 project partners engaged: 2 NHS; 4 academic; 8 commercial • 3 new data storage facilities. There are 2 types of data storage that I-CAIRD is dealing with: 1) radiology work streams storage has been allocated to support the SHAIP platform in order to store data for training, validation and evaluation purposes - this has been deployed at NHS in Glasgow & in Grampian 2) Regarding pathology, storage has been deployed at the Queen Elizbeth University Hospital Pathology department to store scanned WSIs and also in Edinburgh at the EPCC to create a data lake of de-identified WSIs to be used for R&D purposes • 5 exemplar projects started • 5 AI diagnostic tools in development -WP6 Chest X-ray / WP9 endometrial / WP9 cervical / WP11 COVID triage / WP4 stroke • 11 joint CoE events held • 21 clinicians/bio-medical scientists trained in digital diagnostics • 3 NHS sites provided with new or enhanced digital diagnostic equipment/infrastructure - NHS GGC Pathology Lab has been supplied with Digital Pathology equipment from Philips; NHS GGC Safe Haven has been supplied with machine learning infrastructure from Nvidia + partners; DaSH (Grampian safe haven) has been supplied with machine learning infrastructure from Nvidia + partners • 424,692 digital pathology images collected • 4 AI evaluation platforms deployed - 2 instances of AI evaluation cockpit deployed per I-CAIRD hub site (1 for AI review during training the other for AI evaluation in near clinical practice). Note: platform development is iterative therefore they are deployed early and a system of continuous integration (with regular feedback loops) employed to improve the quality of the platforms during the course of the programme • 12 PPIE events held, with 201 participants in total
Outcomes	• 2 new academic industry collaborations linked to CoE activity - UoG/ NHSGGC (clinical academics) working with Canon on the development of stroke exemplar and also collaborating on work in adversarial testing. St Andrews cooperated with Philips but will be changing to new commercial partner. Canon and UoE have a long-

	Monitoring data summary
	standing collaboration on healthcare projects and are working on adversarial testing as well • 1 new NHS CoE partner (NHS Lothian) • 2 new commercial CoE partners (Blackford Analysis & Dell) • 19 UK events held to promote exemplar projects and 2 held overseas
Progress commentary	Key variation in spend caused by pandemic that affected a lot of activity and also Philips pulling back from AI development. ICAIRD have mitigated both situations in the first instance by deploying effort into a COVID response project which allowed the project to continue to build out infrastructure and secondly considerable effort has been expended in attracting commercial 3rd parties to build or evaluate Pathology AIs using the facilities built with Innovate's investment. Although the project was delayed, it is now back on track to deliver on the plan during the extension period being offered by Innovate UK.

Source: SQW Based on application form and project monitoring data

Table B-8: LMIAIC

	Monitoring data summary
Full project name	London Medical Imaging & Artificial Intelligence Centre for Value-Based Healthcare
Lead organisation	King's College London
Project summary (as stated in application)	Led by King's College London, the centre applies AI approaches to medical imaging and related clinical data. Brings together industry, SMEs, academics, clinicians, and experts in data science/governance. In collaboration with universities (Kings, Imperial and QMUL), NHS Trusts (Guy's & St Thomas', King's College Hospital, South London & the Maudsley and Barts Health), multinational industry (Siemens, NVIDIA, IBM, GSK), 10 UK-based SMEs and the Health Innovation Network, with a physical hub at St Thomas' Hospital and underpinned by the Wellcome/EPSRC Centre for Medical Engineering, a flagship investment in medical imaging. The project aimed to have 12 exemplar projects covering early life (foetal diagnosis) to old age (dementia), organ systems including cardiac, brain and lungs, and diseases such as heart failure, headache, congenital conditions and cancer.
Outputs	• 22 project partners: 4 NHS; 3 academic; 14 commercial and one other • 4 new data storage facilities: 1 in 2019 and 3 in 2020-Jan 2021. In 2020-Jan 2021, 3 NHS sites were using the facilities. • 1 data sharing platform became operational in 2019 , with 2 NHS sites using the platform in Jan 2021. • 17 exemplar projects started: 5 exemplar projects started between 2020-Jan 2021; 7 started between Feb-April 2021; and 5 started between May-July 2021. • 14 AI diagnostics tools in development: 2 AI diagnostic tools began development between 2020-Jan'21; 7 in Feb-April'21; and 5 in May-July'21. • 11 joint CoE events carried out

	Monitoring data summary
Outcomes	• There were 9 international publications authored by CoE partners in 2019, 16 in 2020-Jan'21, and 19 in Feb-April 2021 (44 total) • 6 new CoE partners, 1 new academic CoE partner, and 2 new commercial CoE partners joined in 2020-Jan'21 (in addition to the original consortium)
Progress commentary	The target number of projects started in 2020 was reduced from 12 to 6, due to COVID-19. This was due to no non-COVID projects being approved to access data during this time.

Source: SQW Based on application form and project monitoring data

Table B-9: PathLAKE

	Monitoring data summary
Full project name	Pathology image data Lake for Education, Analytics and Discovery.
Lead organisation	University Hospitals Coventry & Warwickshire NHS Trust
Project summary (as stated in application)	PathLAKE will create a national centre of excellence for digital pathology and AI in pathology, creating an ecosystem for AI development in comprising of digital and computational innovators from NHS, academia and industry. PathLAKE will establish data centre resourced in annotations and meta-data, support growth of the sector and jobs, generate knowledge focused on tissue and cellular pathology, ensure mechanisms to transfer tech to industry partners, and create a pathway for AI tool adoption in NHS. Will focus on 2 exemplar projects to develop algorithms and a centre will be developed to provide training and support to pathology and computer scientists.
Outputs	• 14 project partners: 4 NHS; 4 academic; 6 commercial • 1 new data storage facility operational in 2020, used by 4 NHS sites – a new NHS partner joined in March 2020 not yet using the facilities. • 1 new data sharing platform established in 2020, which 3 NHS sites used. • 4 exemplar projects started in 2019 • 7 AI diagnostic tools in development in 2020 • 7 training programmes developed: 1 in 2019, 4 in 2020, and 2 in April-June 2021. • 60 clinicians/biomedical scientists trained in digital diagnostics in April-July 2021 – though data have not been collected to date but will do so going forward • 4 NHS sites were provided with new or enhanced digital diagnostics equipment/infrastructure in 2019 and 1 in 2020 • 1 fully digitalised NHS lab in 2020, and 2 in Jan-March 2021 • 22,686 digital pathology images collected: 7,100 collected in 2020, 5.900 in Jan-March 2021 and 9.686 in April-July 2021 • 13 joint CoE events • 4 PPIE events held with 9 participants
Outcomes	• 35 international publications: 5 international publications in 2019, 15 in 2020, 4 Jun-March'21, 11 April-June'21 (35 total). Note: "Overseas" replaced with international. All publications are effectively international - so UK publications not relevant.

	Monitoring data summary
	• There have been 25 CoE enquiries from new potential business partners in 2020, 1 in Jan-March'21 and 3 in April-June'21. Note: the figure for 2020 is the number of SMEs/industry who had approached PathLAKE to end 2020. Figures for 2021 need further confirmation to eliminate duplication.
Progress commentary	Digitisation of NHS Labs: Oxford University Hospital achieved 100% digitisation in Sept 2020. Belfast is also fully digitised and all breast cases at Nottingham University Hospitals Trust are now being reported digitally. University Hospitals Coventry & Warwickshire NHS Trust is in progress towards 100% digital. Frimley Park has scanner installed but awaiting server installation before progressing to user acceptance testing. Data Lake and analytics engine: Data is flowing in from the four main NHS sites into the central Data Lake. A front-end for the portal for viewing and annotating images has been developed and is in the last stages of alpha testing. Work to integrate the Data Lake with the Analytics Engine is progressing; the IBM ESS has been commissioned and its integration with the DGX-2 -completed. as has the final commissioning of IBM Discover data lake management system and the corresponding server machine. The PathLAKE Access Committee has approved its first application for data from an overseas SME, two further applications are under consideration. Exemplar projects: Good progress is being made on algorithm development in the exemplar projects and preliminary results are promising. One AI tool is undergoing validation. Training and education: The Digital Pathology Tutor training platform continues to grow and by end of Q10 had 219 registered users (an increase of 57% during Q10). Additional material (such as videos from the recent Digital Validation Workshop) has also been added to the Tutor platform. A CPD accredited "AI for Pathologists" Masterclass was held virtually in May 2021, open to all and free of charge. Over 240 attendees from across the world attended. Videos from the masterclasses have been made freely available on YouTube. Recent and upcoming events are detailed in our Summer 2021 newsletter (https://www.pathlake.org/out-now-pathlake-summer-2021-newsletter/). PPIE: Several of the project's PPI advisers who sit the steering and data access committees agreed to be interviewed for a 2-page article in the Summer 2021 newsletter (see link above). One lay advisor has also agreed to be PPI co-applicant on an upcoming grant application to the NIHR AI awards competition 3. Other: PathLAKE has joined the UK Health Data Research Alliance.

Source: SQW Based on application form and project monitoring data

Table B-10: NPIC

	Monitoring data summary
Full project name	NPIC: The Northern Pathology Imaging Collaborative.
Lead organisation	University of Leeds

	Monitoring data summary
Project summary (as stated in application)	NPIC is led by the University of Leeds and a dual qualified pathologist and computer scientist Dr Darren Treanor. It includes two major industry partners (Leica, Roche), covers all the major sectors in digital pathology (hardware, software, services) and includes several UK companies (FFEI, Heterogenius) who have matched industry funding of £7m. NPIC is a co-operative with a shared goal, led by doctors, this project will ensure that AI systems are safe, and that doctors and the NHS are in control of how they are used. Innovation within the project will be on clinical adoption of primary digital pathology, development of a data library, development of standards and systems for interoperability, and new products and business opportunities. NPIC will also facilitate the creation of 3 exemplar AI tools. NPIC will also put scanners in 12 Northern NHS hospitals to gather digital pathology images training.
Outputs	• 23 project partners: 6 NHS; 6 academic; 10 commercial; 1 other • 1 NHS site using the facilities in 2020-Jan'21 • 1 NHS site using platforms in 2019 • 1 NHS site provided with new or enhanced digital diagnostic equipment/infrastructure in 2020-Jan'21. • 1 fully digitalised NHS lab in 2020-Jan'21 • 300,000 digital pathology images collected in 2020-Jan'21, with 36% of the slides collected coming from NHS labs receiving investment • 5 PPIE events held with 39 participants
Outcomes	• 4 UK patents for AI tools developed by CoE partners • 13 UK publications: 1 UK publication authored by CoE partners in 2019 (1), 10 in 2020-Jan'21 and 2 in May-July'21. • 16 UK events to promote exemplar projects and 9 overseas • 3 CoE enquiries from new potential business partners in 2020-Jan'21 • 15 new jobs created in 2019, 5 in February-April'21; and 5 in May-July'21. • 11 grants applied for in 2019, of which 5 were awarded.
Progress commentary	Deployment in West Yorkshire - Several trusts now have predicted 'go live' dates in 2022 (these were unclear last Q): Bradford, Airedale, Calderdale, Mid-Yorks and Harrogate in Nov/Jan 2022, with a combined population of 20,00,000. Project mandate and project plan completed, or near completion for all. Local business cases all progressing with Trusts. As per last prediction in last submission deployment completed in Leeds Teaching Hospitals, anticipating a 6 - 12-month timeframe for pathologist to be fully validated for primary diagnosis. Public Engagement - Planned patient and public advisory group (PPAG) went ahead, further events have been planned for next quarter, including an exhibition at the Oxford Festival of Ideas, an event at Leeds University with alumni association, as well as a further two PPAGs. Events to Promote NPIC - 12 key events in this quarter inc. Global Engage Asia, The Pathological Society Undergraduate Day at the

	Monitoring data summary
	University of Manchester, and NPIC hosted one of the 'AI Centres of Excellence Ethics in Imaging' webinars, as well as attending the PathLAKE led session. Tango Study - Quality control staining study paper written after study concluded, and patent filed. Initial paper title: " The Use of a Tissue Mimicking Biopolymer for Stain Assessment and Quality Control in Pathology". Quality Control Centre - Established a digital histopathology quality control co-ordination centre. This will allow centralisation of QA results and shared experience. Centre will be run under ISO 9001:2015 principles. New starters – NPIC recruited further posts during last quarter (Q10). Deployment Senior Project Manager x2 Business Benefits Analyst and a System Administrator. x2 Research Innovation Managers, NPIC Business Manager.

Source: SQW Based on application form and project monitoring data

Table B-11: NCIMI

	Monitoring data summary
Full project name	National Consortium of Intelligent Medical Imaging (NCIMI)
Lead organisation	University of Oxford
Project summary	Led by the University of Oxford, the consortium has a permanent physical base at the Oxford BDI but is conceived of as a national Cloud-connected network. Clinicians, academics, companies, and charities have jointly defined the projects where they have expertise and ability to deliver AI solutions by 2021 and will progress 11 exemplars along the pipeline. Oxford has numerous advantages, including strength in AI, proximity to GE in Amersham, significant investment in the Big Data Institute, experience in governance and management of patient data in large trials (UK Biobank, National Caldicott Guardian) and success in spinning out and financing innovative companies. They aim to work with academics and NHS hospitals across the UK, with the programme includes predominantly UK based companies ranging in size from a few employees to hundreds. Programme of work will include the analysis and testing of algorithms on data for which there is already patient consent and collecting new patient data after gaining consent.
Outputs	• 8 new data storage facilities: 2 in 2019, 4 in 2020, 1 in Jan-March'21 and 1 in April-July. • 7 NHS sites using the facility • 1 data sharing platform in 2019 with 14 NHS sites using it • 11 exemplar projects started: 2 in 2019, 8 in 2020 and 1 in April-June'21. Note: defined by first access of clinical data at NHS site. • 1 AI diagnostic tool in development in 2019 and 1 in 2020; 1 AI diagnostic tool developed in 2019, 2 in 2020, and 1 in Jan-March'21; 1 AI diagnostic tool validated in 2020 and 1 in Jan-March'21; 1 AI diagnostic tool evaluated in 2020 and 1 in Jan-March'21.

	Monitoring data summary
	• 1 training programme developed by the CoE • 321 clinicians/biomedical scientists trained in digital diagnostics: 35 in 2020, 38 in January-Match'21 and 248 in April-June'21 • 54 NHS sites provided with new or enhanced digital diagnostic equipment/infrastructure: 14 in 2020 and 40 in April-June'21.
Outcomes	• 3 UK publications authored by CoE partners: 2 in 2020 and 1 in April-June'21 • 10 overseas publications authored by CoE partners: 3 in 2020, 2 in January-March'21 and 4 in April-June'21 • 6 academic industry collaborations linked to CoE activity: 5 in 2020 and 1 in April-June 2021 • 8 CoE enquiries from new potential business partners: 3 in 2019 and 5 in 2020 • 3 new commercial CoE partners in 2020 • 3 other new CoE partners in 2020 • 5 regulatory approval for developed AI algorithm: 1 in 2020, 2 in January-March'21, 2 in April-June'21
Progress commentary	Activities and Outputs table has had an additional pair of columns added to match the Outcomes table. This covers deliverables/reportables past Jan 2022. NCIMI funding now runs to March 30 2023 with many activities therefore completing past Jan 2022. All Financials are reported on a project quarter basis as this is the level of granularity reported to us and by us. Amendment now made to incorporate additional funded extension financials now PCR is approved. Financial actuals for Q10 are provisional and subject to Quarter end book closure/amendment Apr-June '21: Significant progress with clinician training by RAIQC (inc NGT tube placement) Apr-June '21: Rollout of Bainomix e-stroke suite now at 39 hospital sites (of which 33 live) – 5,229 patients with scans processed this quarter Apr-June '21: Significant events/publications on UK/global basis by NHS, Industry and NCIMI - includes Gleeson Radiology publication July' 21: Gleeson group OUH awarded £1.8m from NIHR to evaluate Xe-MRI as tool for long COVID DX

Source: SQW Based on application form and project monitoring data

Integrated Diagnostics CR&D Projects

Table B-12: DART

	Monitoring data summary
Full project name	(DART): Integration and Analysis of Data using Artificial Intelligence to Improve Patient Outcomes with Thoracic Diseases

	Monitoring data summary
Lead organisation	University of Oxford
Project summary	Led by the University of Oxford and in partnership with Royal Brompton & Harefield NHS Foundation Trust, GE Healthcare Ltd., Roche Diagnostics Ltd., Optellum Ltd., Nottingham University Hospitals NHS Trust, Royal Marsden NHS Foundation Trust, and Roy Castle Lung Cancer Foundation. DART aims to develop integrated diagnostics that will enable the earlier diagnosis of lung cancer. Using their Imaging AI centre and the National Consortium of Intelligent Medical Imaging's (NCIMI) data infrastructure, DART will collect and transfer clinical and imaging data; generate novel digital pathology images and blood-derived data from patients, and transfer these to our secure data 'lake' based at the University of Oxford. DART will define a new set of standards for lung cancer diagnosis that will generate large cost and time savings to the NHS and the novel diagnostics will also be translatable to non-screening settings and be applicable outside the UK.
Outputs	• 11 project partners (as planned, with a further 12 partners planned to joining late 2022/ early 2023) • 11 AI diagnostic tools planned for the project – 4 by end 2021 and a further 2 in 2022 and 5 in 2023 • 6 AI diagnostic tools will be validated - planned by end 2023 • 4 new clinical pathways will be developed - planned by 2023
Outcomes	None to date
Progress commentary	While no outputs or outcomes were planned for April to June 2021, much has been achieved towards these in future quarters. • Optellum Emphysema quantification: ability to accurately quantify emphysema has been internally validated • Optellum LCP for screening: solution optimised ready to be used on data • Histopathology pilot slides have been contoured and annotated • GE Healthcare has coronary calcification technology which DART could use with non-gated screening scans • The primary care team has extracted data from the QResearch database and cleaned datasets to understand the pathways to lung cancer • Population health team have reviewed the original decision-analytic model developed by Exeter to assess the cost-effectiveness of low dose CT screening for lung cancer • The blood biomarkers work package has agreed statistical considerations and drafted the statistics analysis plan • Outcome prediction data requirements and analysis plan has been discussed with DART clinicians and academics team • Quality assurance leads have started designing the QA training software • Optellum's algorithm, LCP, has received some coverage in the press due the company along with several DART collaborators – Nottingham, Royal Marsden and Oxford – being awarded the NHSX AI award (phase 3). AI in Health and Care Award - funded projects 2021 (nihr.ac.uk)

	Monitoring data summary
	• Rohan Chakraborty (WP4) submitted a methodology paper using a public lung histology dataset to MIUA workshop of MICCAI conference (currently under review)

Source: SQW Based on application form and project monitoring data

Table B-13: ID-LIVER

	Monitoring data summary
Full project name	Integrated Diagnostics for Early Diagnosis of Liver Disease [ID-LIVER]
Lead organisation	University of Manchester
Project summary	Led by the University of Manchester, ID-LIVER works with academics, businesses, public sector organisations, and charities to address shortfalls in early detection of liver dysfunction. It will do this by the co-creation of data science solutions to integrate a wide range of multimodal diagnostics and patient data. They will grow SMEs, such as Jiva.ai and Perspectum, by co-creation in partnership with academic researchers in Manchester and Nottingham under the umbrella of the NAVIFY platform being co-developed by Roche Diagnostics and GE Healthcare. The three precise areas of innovation will be the early diagnosis and prognostication of liver disease in the community; integration of minimally invasive diagnostics and data to elevate MRI beyond the current utility of highly invasive liver biopsy; and early diagnosis and stratification of patients with liver disease who are at significant risk of developing hepatocellular carcinoma and where late diagnosis equates to a terminal outcome. In addition to clinical and academic experts, they have created an innovative 'wrap around' of dedicated NHS IP expertise, nationally leading PPI/E, Venture Capital mentorship, health economics, a route to NHS adoption and a cross-sector advisory board of leading international and national experts. Primary success will be SME growth from co-created products that draws on the global leverage of the major international partners to disrupt the currently inadequate clinical care pathway.
Outputs	• 14 project partners (as planned) • 1 new clinical pathway developed and/or validated (as planned, 2nd pathway was planned for late 2021) • 1 2 Liver Assessment Clinics set up (as planned, 3 more clinics planned by May 2022) • 1 new AI diagnostic tool planned for early 2022
Outcomes	None to date.
Progress commentary	The ID LIVER project is on track to achieve its original objectives and significant progress was made in Q3; particularly work towards recruiting patients in a community setting in Year 2 of the project and the co-development of a clinical decision platform to diagnose and manage patients with liver disease earlier. Both of these of these are major milestones for the project and as a consortium the efforts in Q3 towards delivering these outputs have been substantial. Patient recruitment commenced at a second Liver Assessment Clinic (LAC) during this period and is located at the central hospital site.

	Monitoring data summary
	Recruitment will be supplemented by case finding in the community through NorthWest EHealth's (NWEH) Feasibility and Recruitment System for Improving Trial Efficiency (FARSITE) tool. This tool has allowed ID LIVER to identify 2,005 patients in Manchester with 3 or more risk factors for liver disease that have never been assessed in hepatology clinics. We found a further 55,286 patients and 13,278 patients who had more than 1 or more than 2 risk factors respectively who had not been seen in a secondary care hepatology clinic. In Q3, the team met with three GP practices to introduce ID LIVER and discuss the opportunity to set-up a LAC at their practice. Managing abnormal liver tests in the community has been identified by GPs as an area of need and each site was very supportive of our proposal and the prospect of recruiting patients at their practice. Co-development of the NAVIFY clinical decision platform is ongoing and the design of the 'Clinician View' interface was a particular focus in Q3, along with mapping the integration between the relevant parties [Roche, University of Manchester, University of Nottingham, Perspectum, Jiva.ai]. We anticipate the platform being ready to receive prospective and retrospective data in Q4. The pandemic has impacted on staff recruitment and therefore spend across the project. The UK Government has allocated covid-19 funding to existing UKRI grants. For lead organisation, The University of Manchester, this means that some of the DI staff posts that were due to commence on the project start date are now anticipated to start in Year 2. We propose 'doubling-up' staff posts where appropriate and subsequently account for any anticipated underspend. Where possible, some work elements have been brought forward to capitalise on home/ remote working and advance downstream aspects of the technical development. For example, data sharing agreements between data controllers (Manchester and Nottingham) and Jiva.ai have accelerated the analysis and development of the statistical and machine learning models. The operational team continue to meet on a monthly basis to capture progress across work packages and discuss opportunities as they arise. We have had exciting discussions around the wider potential for far-reaching impact through ID LIVER, beyond our baseline milestones. The opportunity to gain further insight into the needs of the Greater Manchester population, as well as sub-populations within it, provides the necessary information to carry out important future interventions. Impact has already been achieved for Jiva.ai - one of the SMEs - who in Q3 were successful for raising £1.3M seed financing from VC, state-aid backed entity and angel investors to expand their prostate diagnostics and AI platform. It was noted that investors were particularly interested in Jiva's partnership with ID LIVER and what the project is aiming to achieve.

Source: SQW Based on application form and project monitoring data

Table B-14: iDx-LUNG

	Monitoring data summary
Full project name	iDx-LUNG - Integrating non-invasive diagnostics into NHSE Lung Health Checks in Wessex and Yorkshire
Lead organisation	University of Southampton
Project summary	Led by the University of Southampton and in partnership with the University of Leeds, Oncimmune Ltd., Inivata Ltd., Roche Diagnostics Ltd., BC Platforms, and the Leeds Teaching Hospitals NHS Trust, iDx-LUNG integrates established and emergent technologies in early cancer detection with NHS England Lung Health Check (LHC) pilots in Wessex and Yorkshire. LHC will evaluate computed tomographic (CT) scanning to diagnose lung cancer at an early stage, piloted at 10 sites in expectation that this will progress into standard practice. iDx-LUNG will test the approach of detecting several biomarkers that will improve the efficiency of screening CT scans. They will recruit 15,000 people to donate samples of blood for autoantibody, protein and nucleic acid biomarkers, and nasal epithelium for transcriptomic analysis, and collate the results in an integrated data platform linked to clinical systems. The NIHR Leeds InVitro Diagnostic Co-Operative will facilitate analysis of the added value of these markers, to indicate how they should be most effectively applied in the NHS. Technologies brought together in the programme include: • Oncimmune EarlyCDT Lung: detects endogenous auto-antibody responses generated as much as 5 years before cancers become clinically detectable. Data from a randomised study has shown that this test in high risk smokers resulted in 36% less cancers being diagnosed at an advanced stage. • Roche 6TM biomarker panel. Six protein targets comprise a combination test which has shown good predictive values for early lung cancer detection at the time of diagnosis, and negative predictive value of 71.8% patients with nodules less than 3 cm on CT. • Inivata Invision First Lung panel: Detects mutations present in circulating DNA released from tumours (ctDNA). This is licenced for characterisation of advanced cancers in place of tissue biopsies. We will investigate its use to provide information in people whose screening CT yields indeterminate findings. By demonstrating the presence of ctDNA it may be possible to circumvent the need for repeat interval imaging and proceed to direct investigation for cancer. • Janssen transcriptome analysis from nasal epithelium, which replicates the gene expression changes in bronchial epithelium in smokers. Knowledge of the prevalence and prognostic impact of such changes will aid construction of better risk models for CT screening and the investigation of indeterminate findings.
Outputs	• 9 project partners (as planned)

	Monitoring data summary
	• 630 patients were recruited (586 planned to date, with a further 26,924 planned) • 5 academic industry collaborations linked to project activity (5 planned)
Outcomes	• In November 2020 – January 2021, there were 5 academic industry collaborations linked to project activity.
Progress commentary	In terms of publications, the project has had an abstract accepted for the NCRI conference (Nov 21) which has been selected as a pre-recorded presentation. There are no outcomes to report yet- the iDx-Lung study has a projected recruitment period of approximately 18 months beginning in May 2021 (once it has real-life data being returned on recruitment rate it will be able to accurately project length of recruitment and if any mitigation plans are needed to achieve this). Following recruitment of the last patient the project will then have a one year wait to collect the outcome data at which point partners will be able to begin statistical analysis to correlate the laboratory analysis with clinical diagnosis. Planned recruitment figures have been entered- there is currently a shortfall against the target which the project is looking to mitigate by opening at a third site, and so these figures are subject to change.

Source: SQW Based on application form and project monitoring data

Table B-15: INCISE

	Monitoring data summary
Full project name	Integrated Technologies for Improved Polyp Surveillance (INCISE)
Lead organisation	University of Glasgow and NHS Greater Glasgow and Clyde
Project summary	Led by the University of Glasgow with NHS Greater Glasgow and Clyde (NHSGGC) and in partnership with pivotal industrial collaborators (Canon Medical, Oracle Bio, Bio Clavis), INCISE will utilise the latest developments in digital pathology, machine learning and next generation sequencing techniques to develop a comprehensive real-time risk stratification tool to accurately assess the need for follow-up colonoscopy after polypectomy. This tool will benefit from direct access to patient data and clinical samples through established, underpinning infrastructure including NHSGGC SafeHaven and Public Health data records and be developed and evaluated in a live clinical setting in partnership with industrial-Centre for AI Research in Digital Diagnostics (iCAIRD). The tool will be validated in other NHS Boards through iCAIRD partnerships and the existing SBoPS network and, in parallel will be subject to a rigorous health economics assessment, before rollout across Scotland and the UK.
Outputs	• 5 project partners (as planned) • 1 conference presentation - CRUK's Early Detection of Cancer Conference in October 2020

	Monitoring data summary
	• 1 new AI diagnostic tool (score for predicting future polyp risk) planned by April 2023
Outcomes	• 2 UK publications authored by project partners (as planned, 1 more planned for early 2022) • 1 academic industry collaboration linked to project activity (as planned) •
Progress commentary	No. of NHS partners:_NHS Greater Glasgow & Clyde are a collaborator on the INCISE project and will be involved throughout the lifetime of the project. No. of Academic partners:_The University of Glasgow is the lead partner on the INCISE project and will be involved throughout the lifetime of the project. No. of commercial partners:_Canon Medical Europe, BioClavis Ltd. and OracleBio Ltd. are all collaborators on the INCISE project and will be involved throughout the lifetime of the project. No. of AI diagnostic tools developed:_The goal of the INCISE project is to develop a comprehensive real-time risk stratification tool (RST) to accurately assess the need for follow-up colonoscopy after polypectomy. The prototype RST is not expected to be developed until the end of the project. Validation and evaluation of risk score will be the focus of future grant proposals. Academic conferences:_The INCISE partnership presented a poster at CRUK's Early Detection of Cancer Conference in October 2020 and it is anticipated that we will present progress at future conferences. No. of UK patents for AI tools developed by project partners:_It is anticipated that any IP generated by the INCISE project through developing the RST will be patented to facilitate commercialisation. No. academic industry collaborations linked to project activity: Leveraging both the physical and intellectual resources of the INCISE collaboration, the University of Glasgow and BioClavis have secured over £120,000 in funding from Medical Research Scotland is support a 4-year PhD studentship. The PhD project will examine the role of the gut microbiome in influencing the risk of future colorectal polyps. The PhD will begin 1st October 2021.

Source: SQW Based on application form and project monitoring data

Table B-16: ACTIONED

	Monitoring data summary
Full project name	The ACTIONED Consortium: integrAted moleCular soluTIons fOr diagNostics and Early Detection
Lead organisation	Queen's University of Belfast
Project summary	Led by the Queen's University of Belfast, ACTIONED is a consortium of three main partners: Precision Medicine Centre of Excellence at Queen's University Belfast or PMC); Roche Diagnostics; and Sonrai Analytics.

	Monitoring data summary
	Their key objectives are a) To integrate tissue-based and genomic-based analysis of cancer samples in a single laboratory operation; b) to create the interconnectivity via AI algorithms that would allow these two parallel pathways to work in a fully integrated fashion; c) to prove the clinical superiority of this integrated analytical approach addressing two clinical needs unmet to date. ACTIONED aim to present the clinical relevance of this approach focusing on 2 key clinical problems in colorectal cancer: • Early detection of recurrence risk in stage II/III CRC. Both Roche and PMC have demonstrated independently the value of digital pathology and genomics in this space. ACTIONED findings from tissue testing and NGS testing will demonstrate the overall value of integration of the various diagnostic methods along with exploration into interpretive algorithm development (WP3). • Application of these tools to earlier stage disease detection (Tis/TI), and other solid tumour types. An investigational cohort of such samples will be explored as part of the proposal ACTIONED is fully innovative in: • Its conception: full integration of 2 existing pathways have not been tried/achieved before • Its partners: only Roche has whole laboratory pathways and only PMC has a genuine "integrated laboratory approach" • Its future: once established, the ACTIONED lab will be able to continue championing laboratory integration in many other initiatives
Outputs	• 3 project partners (4 planned) • 1 AI diagnostic tool developed (as planned, 2nd tool planned for early 2022) • 2 AI diagnostic tools will be validated – planned by end 2022 • 1 new clinical pathway will be validated - planned by early 2023 • 5 publications planned for early 2023
Outcomes	• 1 academic industry collaboration linked to project activity (as planned, 2nd collaboration planned for early 2023) •
Progress commentary	There are two main reasons for the underspend in the first year of the project: • the COVID-19 pandemic presented some delays • the agreement of the MDTA between the 3 partners (QUB, Roche Diagnostics & Sonrai Analytics) and the agreement with regard to the Terms & Conditions of the equipment from Roche Diagnostics took longer than had originally been anticipated. Therefore, this has delayed the installation of the equipment from Roche into the QUB laboratory and therefore the consumable expenditure on the project has been significantly reduced.

Source: SQW Based on application form and project monitoring data

Table B-17: DELTA

	Monitoring data summary
Full project name	Project DELTA - integrateD diagnostic solution for EarLy deTection of oesophageal cAncer
Lead organisation	University of Cambridge
Project summary	Led by the University of Cambridge, the project aims to tackle oesophageal cancer. The main risk factor is chronic reflux disease and due to the high prevalence and non-specific nature of these symptoms most patients are managed with acid-reflux medication (PPI) without referral for endoscopy. The Cytosponge-TFF3 test is a disruptive technology developed by this team (MRC funded) that could revolutionise the clinical care pathway for reflux disease. This device has been shown to be safe and acceptable to patients in studies involving \>4,000 individuals across 3 continents and a randomised trial of over 13,000 eligible individuals has just been successfully completed (CRUK funded). This innovation could focus procedures on those are greatest risk of cancer - especially relevant since Project DELTA have effective, NICE approved endoscopic interventions for early oesophageal cancer. improved diagnosis we can also reduce the over-use of proton pump inhibitor (PPI) medication which is expensive with long-term side-effects. The device has been licensed to Medtronic by the MRC. A new Early Detection company called CYTED has been spun out from the University of Cambridge and is providing quality assured processing of Cytosponge with AI solutions for economic high throughput (Company Number: 11478299).
Outputs	• 6 project partners (as planned) • 1 new patent registered • 1 AI diagnostic tool is planned by early 2023 • 1 new clinical pathway (pre-screening model for Cytopsonge pathology) is planned to be developed and validated by early 2023
Outcomes	• 1 UK publication authored by project partners
Progress commentary	As reported by Monitoring Officer: • Progress has been reported in all active work packages. • The first Cytosponge mobile unit clinic was launched in Cambridge. • 193 patients accepted invitations to screening at the mobile unit. 40 self-referrals were eligible for screening and were booked. • Out of 120 tests completed, 7 patients have been referred for endoscopy. • The mobile unit will go to Chelmsford in Q7 and then to Eye in Q9. • AI assessment of Cytosponge test requests has high sensitivity and specificity. • A new cytosponge testing antibody is being tested with Pathognomics, to replace the Roche antibody used currently. • Progress was reported on studies of methods to identifying people at risk of developing oesophageal cancer. • The main cost components of cytosponge and endoscopy in secondary care have been identified.

	Monitoring data summary
	• All grant receiving partners have either submitted or prepared their Q6 grant claims.

Source: SQW Based on application form and project monitoring data

Table B-18: Quantitative Reporting in Crohn's Disease

	Monitoring data summary
Full project name	Quantitative Reporting in Crohn's Disease: Maximising available MRI data to better direct patient treatment, speed up treatment decisions and improve healthcare outcomes
Lead organisation	Motilent Ltd.
Project summary	New approaches to identify earlier which Crohn's Disease patients will/will not respond to biologic treatment are urgently required: non-responders could be switched to alternative treatments and the total time to remission reduced. Magnetic Resonance Imaging (MRI) is now widely used by the NHS to assess disease response (2 scans per patient per year) but interpretation is subjective. MRI based manual, semi-quantitative, scoring systems to determine CD treatment response have been developed and are used routinely in research and clinical trials. However, they're cumbersome, difficult to generate and are not used in the clinic. IF these scores could be generated quickly they would be used. A patient could have an MRI at 3-months rather than 6-months and that crucial medication switch would be brought forward. The technology to deliver this advance is called GISeg and the project focuses on the following; 1. Automating and standardising the current time-consuming elements of providing the CD Activity Score from MRI data 2. Demonstrating non-inferiority of GISeg with existing, validated manual scores of CD activity; 3. Demonstrating the value and impact of the technology in better directing diagnosis and treatment by integrating its use into the latest research projects from three leading NHS institutions.
Outputs	4 project partners
Outcomes	No project monitoring form received
Progress commentary	Latest monitoring officer report available states that the project is on track to complete all of its original objectives on time.

Source: SQW Based on application form and project monitoring data

SQW

Contact

For more information:

Jonathan Cook
Director, SQW
T: +44 (0)20 7391 4105
E: jcook@sqw.co.uk

2nd Floor
14-15 Mandela Street,
London
NW1 0DU

www.sqw.co.uk

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