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UK Research
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HDRUK
Health Data Research UK



DIGITAL INNOVATION HUB PROSPECTUS

May 2019

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Purpose of document

This paper provides an overview of the Digital Innovation Hub Programme. It forms the Programme Prospectus in conjunction with three supporting documents: i) the Guidance Notes for Applicants ii) the UK Health Data Research Innovation Gateway Overview; and, iii) the Principles for Participation.

Industrial Strategy Challenge Fund

The Digital Innovation Hub Programme is funded by the Industrial Strategy Challenge Fund, part of the Government's modern Industrial Strategy. The fund is delivered by UK Research and Innovation. The Industrial Strategy Challenge Fund brings together the UK's world-leading research with business to meet the major industrial and societal challenges of our time. It provides funding and support to UK businesses and researchers, part of the government's £4.7 billion increase in research and development over the next 4 years.

UK Research and Innovation

UK Research and Innovation (UKRI) brings together the UK Research Councils, Innovate UK and Research England into a single organisation to create the best environment for research and innovation to flourish. The vision is to ensure the UK maintains its world-leading position in research and innovation. For more information visit www.ukri.org

Health Data Research UK

Health Data Research UK is the national institute for health data science. Its mission is to unite the UK's health data to make discoveries that improve people's lives. By working in partnership with the NHS, industry, academia and patients, and providing safe and secure access to rich health data, it aims to better understand diseases and discover new ways to prevent, treat and cure them. Health Data Research UK (HDR UK) is leading the development and delivery of the UK-wide Digital Innovation Hub Programme. For more information visit www.hdr.uk.ac.uk

1. Vision

Our vision is to make the UK home to data-driven research, scientific advances and innovation in healthcare to improve patient outcomes. To help realise this vision, the Government has committed £37.5m from the Industrial Strategy Challenge Fund (ISCF) to the Digital Innovation Hub (DIH) Programme that will be delivered by Health Data Research UK (HDR UK). Engagement with researchers and industry has shown that ease of access to high quality data, more efficient clinical trials, and better access to and use of real world data, are key to realising this vision. This must all be underpinned by public engagement and the highest standards of ethics and information governance.

The aim of the DIH Programme is to take a first-step in addressing these needs as part of our quest to create a robust UK-wide infrastructure for health data research and innovation. Through the Programme, we are supporting partnerships between patients, clinicians, industry, researchers and innovators to stimulate a new wave of innovation that will benefit the NHS, patients, the public, clinicians, researchers, and drive economic development across the UK.

In May 2019, we wish to select five initial Digital Innovation Hubs as part of the Programme. The purpose of the Hubs is to bring together data from “routine” NHS systems (e.g. NHS clinics, laboratories, diagnostics, primary care), and relevant registry or cohort data, and to curate these to provide new high value data resources for research and innovation. The Hubs will create new data assets; specifically, disease focused datasets, and data to enable clinical trial efficiency and/or real world evidence studies. Each Hub will improve secure access to data through membership of the UK Health Data Research Alliance (the ‘Alliance’) and use of the UK Health Data Research Innovation Gateway (the ‘Gateway’). This new Gateway will act as a common access point to UK health research data from across the Hubs and Alliance members for industry, researchers and innovators. The approach is outlined in figure 1. Note that the Gateway development does not form part of the Digital Innovation Hub Call, and more information on the Gateway development will be given at a future stage.

A key outcome of the DIH Programme is to deliver benefits to patients and members of the public. Increasing the speed and scale at which research and innovation can take place will allow for improved health outcomes and quality of life as a result of better treatments, interventions and health system management, bringing benefits across the NHS. Patients, the public and charities have provided early input into the design of the Programme. We are dedicated to increasing public involvement in the DIH Programme with a commitment to transparency about our work and how data is used; protecting confidentiality; and applying a robust governance framework to ensure that health data is used ethically, responsibly and where there is a demonstrable benefit to society.

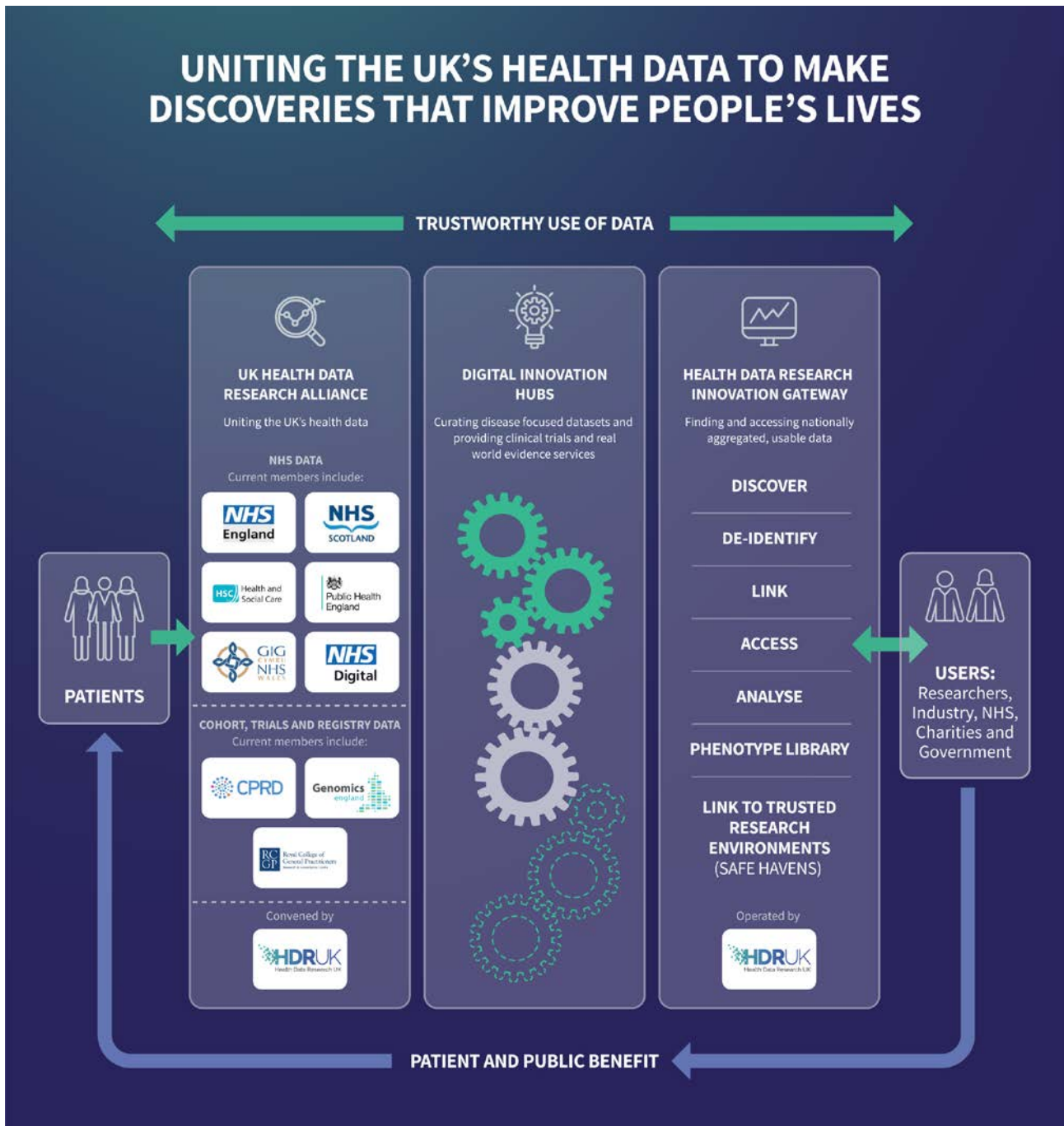


Figure 1: The layers of the Digital Innovation Hub Programme

2. Hub themes

The DIH Programme will fund the establishment of up to five Digital Innovation Hubs. Each will have a focus on one or both of the themes highlighted below:

2.1 Disease Focused Hubs

To act as a network to provide accessible resources for industry and academic researchers

The Hubs will create globally leading datasets and make these available to industry and researchers in areas of most value for research and innovation and where the UK is well-placed to lead the world. The Hubs will be partnerships of the UK's leading NHS, health research and innovation organisations. In any given disease area, they will define what health data needs curating, linking and storing. These datasets will be made available to industry, the NHS and academia to create real world insights, innovations and improvements in healthcare. The Hubs will work together as a national network, coordinating their efforts to make a significant impact on the UK's research and innovation capability.



The Hubs will focus on specific disease areas to curate specialised datasets of both breadth and depth. These may be in any disease area. However, specific projects in the following areas are of particular interest: cancer, cardiovascular, respiratory, neurodegenerative, dementia, diabetes and inflammation/immunity. We welcome focused bids which propose to curate data in disease sub-types (e.g. nationwide coverage of one type of cancer), which would be of benefit to researchers, industry and innovators. Each Hub will provide strong disease domain expertise and work with key stakeholders, such as the NHS (including regional healthcare systems) and industry, to establish the types of data that need to be curated, stored and made available to create this outstanding data resource, including data across a range of areas (e.g. molecular, imaging, prescribing data). This disease-focused approach will lead to improvements for patients and the NHS, enable the UK to consolidate its position of strength in these areas and put in place the foundation for a long-term effort that attracts global industry, innovators, investors and researchers.

The Hubs will provide expert health data research services relating to disease areas. In practice, this could mean matching holders and users of datasets with relevant clinical experts, data managers and/or technologists that understand the data and its limitations. It could also mean supporting researchers with study design and refining research questions in light of the available data.

For more information, read the Prospectus Appendix: Guidance Notes for Applicants on the [MRC website here](#).

2.2 Clinical Trials and Real World Evidence (RWE) Hubs

To bring clinical trials and evaluation into the 21st century

These Hubs will involve a novel approach to enabling clinical trials using large scale data. They will demonstrably improve the efficiency of clinical trials (e.g. reducing the time and cost of feasibility studies and/or contacting participants) in order to attract new clinical trials activity to the UK.

The Hubs will provide new capability for digital recruitment and implementation of digital randomised clinical trials (DRCTs). The clinical trials Hubs will support recruitment of participants nationally, with the aim of substantially reducing the costs of late stage studies.

These Hubs may also focus on using large scale data to enable evaluation through better use of real world evidence (RWE) to support industry studies of safety, effectiveness, and value. RWE projects should demonstrate a network linking primary, secondary and tertiary care data, as well as capabilities to provide data for pharmaceutical, MedTech/BioTech and AI innovations which would lead to improved treatments and interventions.

For more information, read the Prospectus Appendix: Guidance Notes for Applicants on the [MRC website here](#).

3. UK Health Data Research Alliance and Innovation Gateway

To make it easier, simpler and quicker for industry and academic researchers to securely access data

Secure speed of access to data is important in facilitating cutting-edge research and innovation. Clear, consistent, ethical governance processes and standards will be key to providing industry, researchers and innovators with streamlined access to data. This includes making the terms of access clear, such as expected timescales and costs, and being transparent about the type and quality of data available. Hubs will receive support in these areas from the other two components of the DIH Programme:

The UK Health Data Research Alliance was established in February 2019. The purpose of the Alliance is to bring together and facilitate partnership working across NHS organisations and other health data custodians, leading to an ethical, consistent approach to data provision and public engagement. The Alliance will coordinate identification and adoption of standardised tools, techniques, conventions and technologies for the use of healthcare data for research and innovation in a trustworthy way. The members will agree, with public participation, best practice and standards for governance and privacy. The Alliance is working closely with NHSX, NHS Digital and NHS bodies in the devolved nations to support alignment of best practice for health data research.

The Data controller organisations (e.g. NHS Trusts) that contribute to the Hubs will be required to become members of the Alliance, adhering to the Alliance principles. In this way, membership of the Alliance will grow, and the new data assets produced by the DIH Programme will be discoverable and accessible through the common UK Health Data Research Innovation Gateway.

The UK Health Data Research and Innovation Gateway is being established by HDR UK. Its purpose is to provide a common access point for industry, academia and NHS for discovering, accessing, linking and analysing data for research and innovation. This will include national data (from existing Alliance members) and the new curated data provided by the Hubs and other members of the Alliance. The Gateway will support interoperability, common standards and secure data provision across the DIH Programme. **The Gateway contains no personal identifiable information (PII). All PII is retained within the NHS to ensure General Data Protection Regulation compliance.**

The Gateway will be underpinned by a consistent governance framework and will link with Safe Havens (also known as Trusted Research Environments) which provide secure access to de-identified data for analysis of sensitive data within the NHS. It will provide opportunities for research and innovation, in a safe

and ethical manner, that protects privacy and creates a range of possibilities for linking this data with others to develop even greater insight.

The Gateway development will be delivered by HDR UK, in partnership with NHSX and other NHS partners across the UK. For more information, read the Prospectus Appendix: UK Health Data Research Innovation Gateway Overview on the [MRC website here](#). The Gateway does not form part of the Digital Innovation Hub Call, and more information will be given on this at a future stage.

Hubs will be required to host/use Safe Havens, to adhere to the Alliance principles and to make data discoverable through the Gateway.

4. Benefits to patients, industry and academic researchers

The DIH Programme will provide industry and researchers with improved secure access to high-quality data for innovation and more effective clinical trials. This will improve the way we are able to prevent, detect and diagnose diseases such as cancer, heart disease and other therapeutic areas and mean that patients and the NHS will benefit from scientific breakthroughs much more quickly. Industry and researchers will benefit from quicker access to data, providing more time to spend on discovery and innovation with the assurance that access is secure and easy to administer.



The Hubs will enable:

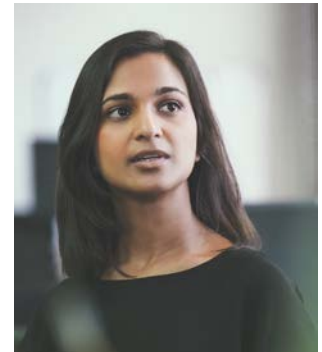
- faster, more accurate and less expensive research and development;
- the identification of new therapeutic targets or application of drugs; and
- industry, both large and small, to better develop, test and deploy new products, devices, tools and AI technologies in health and care earlier.

This will bring a wide range of benefits for patients, the NHS and clinicians with the potential for more accurate diagnosis and more personalised advice, care and treatment over time.

The ability to access data from all members of the Alliance through the Gateway will speed up the time to discover, request and access data in a secure environment. The DIH Programme provides industry, researchers and innovators with an opportunity to help shape the way in which the UK improves the quality of its data; to create a network of Hubs; and play a pivotal role in developing UK-wide research assets in healthcare.

Example use case

Aisha is a researcher working in a small company in Glasgow, which is developing new treatments for rare cancers. Following appropriate data governance processes, the UK Health Data Research Innovation Gateway has enabled her to discover and access a dataset of 1 million cancer patients across the UK, combining NHS and genomic data. By working directly with the Hub, Aisha has also accessed expert analytics services and world leading experts in cancer in the NHS and academia. The Hub services have ensured the data was usable, proportionate and directly applicable to her research. She is reassured that the data is accessed using trusted and secure networks and complies with the national governance standards, and this is clear to the data custodians.



5. Links to the wider data landscape and guidelines

The DIH Programme will complement existing clinical research infrastructure and contribute to a joined-up and UK-wide offer for industry and researchers in all sectors.

Hubs will be capable of integrating diverse health care data and existing services, such as data from Local Health and Care Records. The clinical trials and RWE service will enhance, link to and/or complement existing capabilities provided by NHS Digital (and equivalents in the devolved nations), Clinical Practice Research Datalink (CPRD), and the National Institute for Health Research (NIHR) clinical research infrastructure, including its Clinical Research Network (CRN) and equivalents in the devolved nations.

[10 Sprint Exemplar Innovation ISCF](#) projects were selected by HDR UK to develop and test different aspects of the DIH Programme. Lessons from these are being incorporated into the Programme. The projects are running from February 2019 to December 2019 and participants in these projects will be eligible to participate in the DIH Programme. However, Hubs do not need to be linked to a Sprint Exemplar Innovation project.

The Gateway will build upon existing infrastructure from data custodians and high quality services and tools that already exist, such as the metadata catalogue provided by the NIHR Health Data Finder tool. This will ensure that data is accessible and discoverable from all the data custodians who are members of the Alliance. The design of the Gateway will be informed through engagement with NHSX, national data custodians, (such as NHS Digital and the equivalent bodies in the Devolved Nations), existing large infrastructures in the NHS (such as Genomics England), research (such as UK Biobank, NIHR BioResource and CPRD) and industry.

The DIH Programme will also link with other ongoing digital health initiatives across the UK, such as the Digital Pathology, Imaging and AI centres of excellence, and the NIHR Health Informatics Collaborative, which is working in partnership with HDR UK¹.

¹ To note, this existing partnership would not preclude the NIHR HIC or other bodies who are working in partnership with HDR UK from bidding to become a DIH

HDR UK operates across [six substantive sites](#) that collectively comprise 21 university and research institutes across the UK.² These sites are engaged in nationwide research programmes using health data. These sites will be encouraged to use data through the DIH Programme and will also be eligible to apply for funding to create Hubs themselves. Applications from or involving organisations that are part of HDR UK substantive sites will not receive any preferential treatment in the selection process.

The DIH Programme will operate in line with all relevant frameworks in relation to confidentiality and data protection, including the National Data Guardian’s recommendations on patient data³. The recommendations aim to strengthen the safeguards for keeping health and care information secure and ensuring the public can make informed choices about how their data is used.

The DIH Programme will operate in line with the policy framework being developed to ensure the NHS receives fair benefit for the data it holds. Initial principles were proposed in the Life Sciences Sector Deal 2 (see section “Creating the right framework to realise benefits for patients and the NHS where data underpins innovation”⁴). Further updates will be published in due course.

The DIH Programme will operate in line with the Code of Conduct for Data-driven Health and Care Technology⁵.

6. Engagement and Next Steps

6.1 Public engagement, understanding and involvement

To date, patients and the public have been engaged through attendance at a frontiers event in January 2019, and through close working with public and third sector initiatives including UseMyData, Understanding Patient Data and the Association of Medical Research Charities (AMRC). Health Data Research UK’s Public Advisory Board has provided early input to the Digital Innovation Hub Programme, elements of the model and this Prospectus.



This process has helped shape the principles of responsible and ethical use of health data for research and innovation and the criteria required for public engagement by the Hubs as set out in the Guidance for Applicants. This approach aligns with Health Data Research UK’s commitment to engage and involve patients and the public at all stages of the research and innovation process. Specifically, Hubs will be expected to demonstrate plans for including patients and members of the public in decision-making and governance and how the Hub will ensure that research outcomes from its work are linked to patient benefits. This will be critical to the selection process for Hubs.

6.2 Industry, academic and community engagement

Extensive engagement with industry has been undertaken to understand how the DIH Programme can meet industry needs, while maintaining robust information governance processes. Specifically, this has targeted input on how health data science and digital innovation can support business needs, priority

² <https://www.hdruk.ac.uk/about/structure/>

³ <https://www.gov.uk/government/publications/review-of-data-security-consent-and-opt-outs>

⁴ <https://www.gov.uk/government/publications/life-sciences-sector-deal/life-sciences-sector-deal-2-2018>

⁵ <https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology>

datasets, how to do business with the DIH Programme (Hubs, Alliance and Gateway), as well as technology partner, commercial and investment opportunities.

Input from this engagement exercise has informed the design of the DIH Programme and highlights that the data that is required for research purposes should be disease-focussed, longitudinal, event-based and linked datasets, relating where possible to disease pathways or sub-groups. UK-wide data coverage is expected and valued by many in industry, with some sectors also valuing regional linked data. The need for high quality data to be provided in a timely manner, supported by clear expertise, was raised consistently as a key theme.

Industry engagement across a wide range of companies spanned October 2018 to April 2019. Continued engagement will take place during the competition phase (7 May to late summer 2019) that meets procurement guidelines.

Health Data Research UK has worked in partnership with the Office of Life Science, Medicines Discovery Catapult, the Association of the British Pharmaceutical Industry, the UK BioIndustry Association and the Pistoia Alliance in his phase. Methods deployed include face to face interviews, workshops, events, webinars and desk research.

6.3 Next Steps

The key timeline for the DIH Programme is shown below, with more detail included in the Prospectus Appendix: Guidance Notes for Applicants on the [MRC website here](#).

