An opportunity for Data Partners to join a Real-World Evidence Network: Call for Funding (CFF)

Demonstrate the use of the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) in impactful cross-nation research studies.

11th July 2024

Overview

Funder:	Health Data Research UK
Amount:	Up to £300,000 distributed between up to seven Data Partners.
Duration:	9 Months
Start date:	September 2024

Funding Call Summary

Following a funding call earlier this year, Health Data Research UK (HDR UK) has established a Real-World Evidence Network co-ordination centre that will be led by Daniel Prieto-Alhambra and his team at the University of Oxford working in partnership with HDR UK.

The aim of this pilot Network is to demonstrate the potential of the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) as an enabler of efficient cross-nation federated research studies, utilising data from multiple NHS sources. The centre is currently funded for 12 months (June 2024-June 2025) and will serve as a proof of concept for a sustainable UK real-world evidence network. Studies should be completed by the end of the project. It is hoped that the network will demonstrate its potential and secure further funding to enable it to operate beyond the initial year.

The next stage is to recruit up to seven health care Data Partners from different parts of the UK through this Data Partner funding call.

The Data Partners will:

- Have access to UK-based existing Real-World Data in the OMOP-CDM versions 5.3 or 5.4 that they can analyse to use in studies which will generate Real World Evidence through federated analytics (i.e., the data remain in situ).

- Be able and willing to characterise their data sets by running study code and return de-identified, aggregated results to the network coordinators.

- Be able and willing to include metadata and aggregated data based on the data sets they have access to in a catalogue of data sources via the Health Data Research Innovation Gateway.

- Be able and willing to execute federated data analyses to address specific research questions (use cases) by participating in high-quality studies coordinated by the Network. This would include having or obtaining governance or ethics approvals, running analytical code provided by the network team, returning aggregated results, and supporting the publication and dissemination of research outputs including peer-reviewed papers.

The coordinating centre will support the Data Partners in these activities, for example by providing executable code, leading the selection and coordination of the proposed use cases, and addressing technical challenges that may arise during the project.

HDR UK will fund each Data Partner by issuing grant awards and making payments of actual costs incurred for delivery of milestones reflecting onboarding and data characterisation, and participation in research studies.

Background and rationale

HDR UK's mission is to accelerate trustworthy data use to enable discoveries that improve people's lives. To achieve this goal, we are committed to improving every step of the researcher journey, from data discovery to data analysis and generation of insights (Fig. 1).

Adoption of standards and common data models (CDM) is a necessary step to improve data usability and interoperability for real world evidence generation across multiple data sources that ultimately leads to patient benefit. The Observational Medical Outcome Partnership (OMOP) CDM is an established model currently used internationally to enable standardisation of observational data. It is maintained by the

Observational Health Data Science and Informatics international (OHDSI) community. The standard consists of data tables and vocabularies that encompass many types of data that are generated in medical practice. Mapping data to the OMOP CDM facilitates use of data from multiple sources, enabling federated or aggregated analyses.

The importance of using standardised structures, content and analytics has been demonstrated through various scientific use cases, for example in the areas of medical product safety surveillance, comparative effectiveness research, personalised risk prediction, and drug effectiveness[1]. In the UK, the need for generating and providing "real-world" high quality scientific evidence to clinicians and policy makers and the need to perform federated analyses using data from multiple sources have been highlighted[2]. However, the use of standardised formats and common data models is not consistent across the four nations.

HDR UK, through the UK Health Data Research Alliance and in collaboration with NHS England, recently surveyed data custodians and data users to better understand the current status and level of OMOP adoption in the UK (doi:10.5281/zenodo.8309536), highlighting the need for incentivising and driving use cases to demonstrate the impact of OMOP mapping (doi:10.5281/zenodo.10150185).

To understand and demonstrate the impact of research and innovation derived from use of high-quality data mapped to the OMOP common data model, we are supporting a pilot real-world evidence network. With this funding call, we aim to recruit Data Partners to the network who will provide access to research-ready datasets which can be used to answer priority research questions, and thus inform public health.

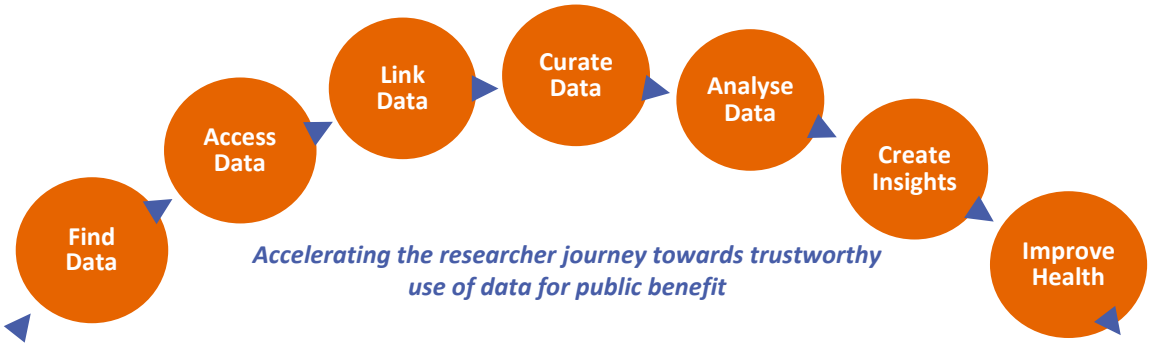

Figure 1. Visual representation of the researcher journey showing all the steps underpinning the data life cycle.

About the Real Word Evidence Network

Health Data Research UK (HDR UK) is establishing a pilot real-world evidence network that will utilise data gathered from multiple UK sources. The aim of the Network is to demonstrate the potential of the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) as an enabler of efficient cross-nation research studies.

Following a competitive funding call earlier this year, the Network Co-ordination Centre will be led by Daniel Prieto-Alhambra and his team at the University of Oxford, working in partnership with HDR UK.

[1] Voss *et al.*, (2024) *Journal of the American Medical Informatics Association*, 31(1):209–219
[2] Papez, et al., (2023) Journal of the American Medical Informatics Association, 30(1):103–111

The network coordinators will convene three work groups which will manage the three main workstreams of the project:

WG 1. **Data Network** – characterisation of Data Partners. Led by Martí Catala Sabate.
WG 2. **Pilot Studies** – study co-design. Led by Ed Burn.
WG 3. **Sustainability** – future sustainability of the network. Led by Dani Prieto Alhambra.

The Network will be guided by a review panel comprising representatives from stakeholders, HDR UK, the coordinating centre, and the public. The panel will assess applications from potential Data Partners and co-design the use cases for OMOP data which will inform the selection of network studies.

General requirements for Data Partners

Data partners must be UK Data Custodians with existing UK Real World Data sets in the OMOP-CDM that they want to use in studies which will generate Real World Evidence through network studies.

In addition, the following requirements will apply to Data Partners for the network:

1) **Research readiness**: the following will be considered when evaluating readiness:
   a. Experience participating in previous OMOP-based federated analyses led by OHDSI, EHDEN, DARWIN EU® or other similar initiatives.
   b. Clear governance and a previous track record of obtaining data access approvals, with a specific focus on federated analyses.
   c. Technical infrastructure capable to conduct large-scale federated analyses using OMOP analytical pipelines developed by OHDSI, EHDEN, or DARWIN EU®. This criterion will be assessed using benchmarking code.
2) **Data size**: both number of patients/records and number of domains/variables will be taken into account when evaluating data size
3) **Coverage**: special attention will be given to:
   a. **Geography**: we will aim for full UK-wide coverage
   b. **Healthcare settings** included: we will aim to include primary care as well as hospital data
   c. **Additional domains**: additional variables or OMOP tables like the Oncology extension, information on medical devices, or genetic information

The Data Partners must also:

- Be willing and technically able to characterise their data sets by running code provided by the network and returning the results to the network coordinators.
- Be willing to include their data sets' metadata in a catalogue of data sources available via the Health Data Research Innovation Gateway.
- Be willing and able to enter into any necessary agreements with the co-ordination centre (University of Oxford), including but not limited to any required data sharing agreements.
- Be willing to participate in publicity and dissemination activities promoting the network and its outputs

Application Requirements

Applicant organisations are required to complete an application form, split into the following sections:

1. Lead applicant details
2. Lay summary
3. Your Data Set(s)
4. Research Readiness
5. Team and resources
6. Delivery Plan
7. Finances
8. Supporting Documentation

In addition, Applicants should, if possible, run the feasibility code specified by the Network coordinators and submit the results along with their application form.

Eligibility criteria

The lead applicant should be based at an eligible organisation based in the United Kingdom. These include:

- Higher education institutions
- Approved independent research organisations or NHS bodies
- Government-funded organisations
- Institutes and units funded by research councils

See https://www.ukri.org/apply-for-funding/how-to-apply/check-if-you-are-eligible-for-research-and-innovation-funding/eligibility-as-an-organisation/#contents-list to check if your organisation is eligible.

You may subcontract part of your work to other organisations if necessary (you must justify this in your application). You may also partner with a commercial organisation, but they will not be eligible to receive grant funding. The Data Partner will remain responsible for the acts and omissions of their subcontractor(s) and must ensure that they comply with the terms and conditions of funding.

Selection criteria

Applicants must be able to produce evidence that:

- They have access to individual-level health relevant data collected in UK-based routine health and/or social care settings, mapped to the OMOP CDM format and of adequate quality for research use.
- Their Data is relevant to a wide range of likely use cases
- They have the capacity (resource) and technical skill to run R code on their data set for feasibility, characterisation and study data analytics.
- They have a mature governance framework that enables them to participate in RWE studies with their data assets without unacceptable delays to project delivery

Applicants will be scored against the following criteria:

- Quality and relevance of the written proposal, including the lay summary, and fit to the call requirements
- Expertise, track record, and capability of the team
- Credibility of delivery plan

- Relevance and quality of data assets
- Maturity of governance framework for RWE studies

Selection of use cases

The network coordinators will design pilot studies with three main aims. First, we will use these to fully understand the richness, size, and readiness of the data and infrastructure available to the selected Data Partners. Second, we will aim to produce actionable information that can inform decision making for national stakeholders, and relevant to patients and citizens. Third, we will conduct studies that will help us explore potential pathways for the sustainability of the proposed network in the future, and after this pilot phase.

With this in mind, the principles underpinning the design of use case studies will be:

1) **Co-creation**: research questions will be chosen in collaboration with key national stakeholders, including HDR UK, UK HDR Alliance, the NHS, NICE, MHRA, and UKHSA, and relevant patients/citizens
2) **Impact**: the proposed use cases will be chosen based on existing research questions and on their potential impact to inform decision making and hence to improve patient care
3) **Inclusivity**: we will prioritise studies that take into account geography, gender disparities, and the inclusion of ethnic minorities
4) **Alignment with HDR UK Research Driver Programmes**: we will align with HDR UK to maximise the alignment of our use cases with the ongoing programmes
5) **Collaboration**: our studies will be designed to involve and be relevant to as many of our Data Partners and stakeholders as possible
6) **Novelty and feasibility**: we will design studies that are feasible with existing tools and serve as a test of the network and tooling, and others that are novel in their design, coverage, or the proposed research question/s

Proposed Schedule

11th July 2024	Data Partner call opens
11th July-30th August	Applicants run feasibility code against their data sets, and include the resulting metrics in their application forms. Submission of completed application forms.
10th September 2024 - 12:00	Call closes
Mid-September	Panel reviews and scores applications
Mid-September	First Panel meeting; Data Partners selected
Mid/late September	Data Partners notified of outcome; Panel discusses potential use cases
26th September	Second Panel meeting; use cases selected
30th September – 18th October	Study designs agreed, award letters issued and signed
October-November 2024:	Data partner onboarding – Milestone 1 completed
November 2024 through April 2025:	Study delivery, including any study-a-thon(s)
May/June 2025:	Data Analysis and Reporting – Milestones 2…*n* Completed
10th June 2025	Network pilot phase concludes

Funding available

Up to £300,000 will be available split across up to 7 Data Partners which join the network. Whilst the Network Co-ordinating Centre will support the selection and recruitment, HDR UK will make awards directly to Data Partners. The co-ordinating centre will enter into any agreements with Data Partners that may be necessary for onboarding and support of Data Partners.

- Eligible costs
    - Salary costs for staff working directly on the project (e.g. scientific lead, data scientists, project management staff)
    - Travel and subsistence
    - Other direct costs to the study (these should be detailed in the budget template)
    - subcontractor costs
- Ineligible costs
    - Indirect and estate costs
    - PhD studentship costs

All successful data partners will be issued an award letter for Milestone 1 funding.

Milestone 1: Data set characterisation: **up to £10,000 actual costs incurred**
October/November 2024

This milestone establishes the quality of the data and its suitability for use in the studies selected by the centre, as well as the technical capability and capacity of the Data Partner's technical team. The milestone is completed when:

- Partners have successfully run the data set characterisation code supplied by the network
- Partners have returned the results of the analysis to the coordinators
- The coordinators have accepted that the results demonstrate that the data set is of sufficiently high quality and is suitable for network studies.
- Partners have provided evidence of previous successful applications for data access
- If data set is of sufficient quality and suitable for network studies, Data Partners will be invited to participate in one or more studies and supplemental award letters will be issued.

Milestones 2 through *n*: Study Participation: **up to £20,000 of actual costs incurred** *per study*
Time line: to be agreed on a study-by-study basis. There will be a minimum of 1, and a maximum of 3 studies by June 10th, 2025. There will be one milestone payment per study delivered. Should there be multiple studies they are likely to have staggered start/finish dates.

These milestone(s) will require the participation of the Data Partner in one or more studies, including successfully running study code and returning the results to the coordinators. Data Partners are also expected to participate in writing and dissemination of reports and manuscripts reflecting study results and participate in dissemination.

- Data Partners may participate in more than one study, should the Network choose to run more than one (maximum three in the first year). Each study participated in would qualify for funding up to the amount specified for actual costs incurred (up to £20,000).
- While the Network will strive to align Data Partners' data assets and the studies to be conducted, the Network does not guarantee that Data Partners will be able to participate in any or all studies.

- Where a study is particularly complex and requires more time and/or resource to deliver, the Network may elect to increase the amount of the Milestone 2 payment (up to a maximum of £50,000).

Application Process

If possible, applicants should run feasibility code against their data sets. The resulting CSV file should be submitted along with their application form. See Section 3 of the application form for details.

Please complete the provided application form and submit by 12.00 BST on 10th September 2024 to UKAlliance@hdruk.ac.uk and copy to procurement@hdruk.ac.uk:

- Completed proposal form
- Milestone 1 Costing spreadsheet (using excel template provided)
- CVs for Lead applicant and any key team members (max one page per applicant)
- Any supplementary documents (see application form for details)

Please submit all enquiries, clarifications, and completed applications to UKAlliance@hdruk.ac.uk and procurement@hdruk.ac.uk. The final date for queries will be 16th August 2024.

Terms and Conditions

Awards issued under this Call for Funding shall be subject to the Terms and Conditions of Funding as set out in Appendix A and the HDR UK Additional Requirements as set out in Appendix B.

About Health Data Research UK

Health Data Research UK (HDR UK) is an independent charity working to accelerate trustworthy data use to enable discoveries that improve people's lives. HDR UK's vision is for large-scale data to benefit every interaction with patients, every clinical trial and every biomedical discovery, and to transform public health. HDR UK works in partnership with the NHS, industry, charities and universities to realise the potential of the UK's wealth of health data in life-changing research. Patients and the public are actively involved in shaping HDR UK's work and ensuring it delivers public benefit.

HDR UK is pursuing three 5-year objectives.

1. **Accelerate trustworthy data use by sorting the data**
   - Make it easier and quicker for researchers to find, access and use high-quality, large-scale data
   - Fix the technical challenges needed for swift, safe and secure data use, by assembling innovative infrastructure solutions
   - Increase health research efficiency and productivity by accelerating adoption of the FAIR (Findable, Accessible, Interoperable and Reuseable) data principles.
2. **Improve people's lives by unlocking the power of data**
   - Deliver cutting-edge research that harnesses large-scale data to change health policy and practice
   - Exemplify trustworthy data use to deliver research that was previously impossible
   - Test and improve the infrastructure so it serves all researchers
3. **Shape the future of health data research**
   - Connect data, people and organisations to bring about cultural change and realise the UK's potential to be at the forefront of health data innovation
   - Develop people and teams with diverse perspectives and skills needed to deliver health data research

- Embed good practice in patient and public engagement and involvement to build confidence in health data research for public benefit by increasing transparency and trustworthiness.

About the UK Health Data Research Alliance

The Alliance's mission is to accelerate improvements in biomedicine, health and care by encouraging widespread and responsible use of health relevant data in a trustworthy and ethical way for the purposes of research and innovation. It has been established as a member-led collaboration to build communities that develop and adopt a portfolio of standards, tools, processes, capabilities and information governance approaches that will help organisations to unlock data-driven research and innovation.

The Alliance is managed by HDR UK and many of its activities are funded as part of HDR UK's 2023-2028 core work to accelerate the trustworthy use of health data for research. It was previously supported by UK Research and Innovation's (UKRI) Industrial Strategy Challenge Fund (through the 'Data to early diagnosis and precision medicine challenge') as part of the Digital Innovation Hub (DIH) Programme.

HDR UK's values

HDR UK's values guide how we work together within HDR UK and with our partners and other stakeholders:

1. **Transparency**: we will share information, insights and innovations so that we learn faster together.
2. **Optimism**: we believe that we can make things better, that we can do things differently and that we can overcome challenges to create a new and thriving health data ecosystem that benefits patients and the public, the NHS, scientific discovery and industry.
3. **Respect**: we deliver better results when we work in a truly interdisciplinary way. We listen, share and respect a diversity of thought and opinion, perspective and experience. We are inclusive - leveraging and fairly attributing the expertise and capabilities of others.
4. **Courage**: we are leading the way and will be prepared to try new things, take risks, embrace ambiguity and challenge the status quo. We will contribute opinions to shape the future of health data research.
5. **Humility**: we have a lot to learn from others; and aim to be free from pride and arrogance

Appendix A: Health Data Research UK Terms and Conditions of Funding

Health Data Research UK Terms and Conditions of Funding

These Terms and Conditions of funding (the "Terms and Conditions") relate specifically to funding (the "Grant Award") from Health Data Research UK (company registration number 10887014 and charity number 1194431) ("HDR UK").

HDR UK Ltd is funded by the Medical Research Council (being part of United Kingdom Research and Innovation) (MRC), National Institute for Health Research (NIHR), the British Heart Foundation (BHF), Cancer Research UK (CRUK), Economic and Social Research Council (being part of United Kingdom Research and Innovation) (ESRC), Engineering and Physical Sciences Research Council (being part of United Kingdom Research and Innovation) (EPSRC), Health and Social Care Research and Development Division (Welsh Government) (HCRW), Scottish Ministers Acting Through Their Chief Scientist Office of the Scottish Government Health and Social Care Directorates (CSO Scotland), Health and Social Care Research and Development Division, Public Health Agency (Northern Ireland) (HSC PHA NI) (together the "Funders"). These Terms and Conditions reflect the Funders' requirements.

Acceptance of a Grant Award constitutes acceptance of both these Terms and Conditions and any additional Terms and Conditions in the Grant Award agreement. These conditions also apply to activities subcontracted to third parties, collaborators or sub-awardees. These Terms and Conditions cannot be waived or varied without the consent of HDR UK. Compliance with these Terms and Conditions is a condition of funding.

Compliance with these Terms and Conditions is a condition of funding. Any obligations and responsibilities expressed in these Terms and Conditions to be obligations or responsibilities of one of more parties/persons shall be assumed by each such party/person on a several basis.

Data Protection

Provided in accordance with applicable data protection laws (including the Data Protection Act 2018, the Privacy and Electronic and Communications (EC Directive) Regulations 2003 and the retained EU law version of the *General Data Protection Regulation ((EU) 2016/679)* as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by Schedule 1 to the *Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 (SI 2019/419)* ("UK GDPR"), in each case as amended or replaced from time to time and together the "Data Protection Legislation"):

- HDR UK will use information provided by the Lead Organisation for processing funding proposals, the award of any consequential funding, and for the payment, maintenance and review of the funding and may share the information with Funders. This may include but is not limited to:
    - Registration of proposals
    - Operation of processing, funding and management information systems
    - Preparation of material for use by peer reviewers and peer review panels
    - Administration, investigation and review of funding proposals
    - Sharing proposal information on a strictly confidential basis with other funding organisations to seek contributions to the funding of proposals
    - Statistical analysis in relation to the evaluation of research and the study of trends
    - Policy and strategy studies

- To meet HDR UK's accountability obligations to the Funders and to disseminate information on research and training programmes, details of budget/awards, and research and training will be made publicly available e.g. on one or more of the HDR UK's or any of the Funders' websites, and/or other publicly available databases, including the Gateway to Research, in reports and documents (e.g. annual reports, council/board papers, portfolio's etc), and through responses by the relevant Funders to parliamentary business (e.g. parliamentary questions, inquiries, debates etc). Disclosable information would include:
    - general overview information on budget and research/training programmes/projects;
    - the names of investigators;
    - the dates associated with the Grant Award(s);
    - a description of research/training programmes/projects (e.g. project summary/abstract, and impact summary information).

During and after completion of the Grant Award, HDR UK or its Funders, may contact named Principal Investigators concerning funding opportunities or events, or for the purposes of evaluation.

Freedom of Information Act and Environmental Information Regulations

Attention is drawn to the provisions of the Freedom of Information Act 2000 ("FOIA") and the Environmental Information Regulations 2004 ("EIRs"), and their equivalents in Scotland where applicable, which apply to a number of HDR UK's Funders including the MRC, EPSRC, ESRC, NIHR, HCRW, CSO (Scotland), and PHA (but not BHF and CRUK). The relevant Funders have an obligation to respond to valid requests for information relating to these Terms and Conditions and may be required to disclose information in relation to HDR UK funding. In some cases, such Funders may consult with the Lead Organisation before disclosure, but they are under no obligation to do so. Where such Funders do consult, they will do so as soon as is reasonably practicable and shall take account of any representations made in respect of that information by the Lead Organisation as part of reaching their own, unfettered, independent decision on disclosure of the requested information.

In some cases, a Lead Organisation may be directly responsible for complying with requests made under the FOIA and the EIR; in such cases HDR UK accepts no responsibility for any failure by the Lead Organisation to comply with its own obligations in this regard. To the extent that any request for information under the FOIA or the EIRs is received by a Lead Organisation which includes information relating to HDR UK, any of the Funders or these Terms and Conditions, the Lead Organisation receiving the request shall promptly notify HDR UK as soon as reasonably practicable and in any event within 5 Business Days and shall take account of any representations made in respect of that information by HDR UK or any of the Funders as part of reaching its own, unfettered, independent decision on disclosure of the requested information

The following conditions of funding are the responsibilities of the Lead Organisation RO Principal Investigator; where any of the following conditions are expressed to be responsibilities of the Principal Investigator, the Lead Organisation will procure that the Principal Investigator is made aware of and complies with his/her responsibilities hereunder:

Governance

It is the responsibility of the Lead Organisation and Lead Organisation Principal Investigator (or other person where responsibility has been delegated) to ensure that the research at the Lead Organisation is

organised and undertaken within a framework of best practice that recognises the various factors that may influence or impact on a research project. Particular requirements are to ensure that all necessary permissions are obtained before the research begins, and that there is clarity of role and responsibility among the research team and with any collaborators. HDR UK expects the research it funds to be conducted in accordance with the highest standards of research integrity and research methodology.

- The Lead Organisation and Lead Organisation Principal Investigator are responsible for meeting HDR UK's expectations for good research practice at the Lead Organisation as set out in the MRC's 'Good research practice: Principles and guidelines (2012) and any subsequent amendments (see https://www.ukri.org/publications/principles-and-guidelines-for-good-research-practice/); and any other policy set by HDR UK from time to time and notified to the Lead Organisation.
- The Lead Organisation Principal Investigator must be aware of which activities come primarily under the responsibility of the Lead Organisation and which come primarily under the responsibility of HDR UK, and ensure that the Lead Organisation Principal Investigators are also aware.
- The Lead Organisation and the Lead Organisation Principal Investigator are responsible for ensuring that HDR UK expectations for management, finance, accountability, branding and translation are met in relation to the Lead Organisation. There must be regular communication with HDR UK
- The Lead Organisation and Lead Organisation Principal Investigator must ensure that the research at the Lead Organisation supported by the funding complies with all relevant legislation and Government regulation, including that introduced while work is in progress. This requirement includes approval or licence from any regulatory body that may be required before the research can commence.
- The Lead Organisation and the Lead Organisation Principal Investigator are expected to adopt the principles of the 2016 Concordat on Open Research Data (see **UKRI-020920-ConcordatonOpenResearchData.pdf**).
- The Lead Organisation must comply with the HDR UK Attribution policy (**https://www.hdruk.org/about-us/policies/hdr-uk-attribution-policy/**), the Open Access Policy (**https://www.hdruk.org/about-us/policies/open-access-statement/**) and the HDR UK Development Principles (**https://www.hdruk.org/about-us/policies/development-principles/**).

Research Ethics

The Lead Organisation is responsible for ensuring that ethical issues relating to the funded work are identified and brought to the attention of the relevant approval or regulatory body. Approval to undertake the research must be granted before any work requiring approval begins. Ethical issues should be interpreted broadly and may encompass, among other things, relevant codes of practice, the involvement of human participants, tissue or data in research, the use of animals, research that may result in damage to the environment and the use of sensitive economic, social or personal data and managing the risks of research misuse (e.g. bioterrorism). Policies and guidance relating to good research practice and research integrity can be found at **https://www.ukri.org/who-we-are/mrc/our-policies-and-standards/** and **https://www.ukri.org/councils/mrc/guidance-for-applicants/policies-and-guidance-for-researchers/**)

Medical and Health Research

The Lead Organisation is responsible for managing and monitoring the conduct of medical and health research of the Lead Organisation in a manner consistent with the Department of Health's Research Governance Framework for Health and Social Care (or equivalent). There must be effective and verifiable systems in place for managing research quality, progress and the safety and well-being of patients and other research participants. These systems must promote and maintain the relevant codes of practice and all relevant statutory review, authorisation and reporting requirements.

Research of the Lead Organisation involving human participants (including healthy volunteers and staff) or data within the social sciences that falls outside the Department of Health's Research Governance Framework must meet the provisions and guidelines of the ESRC's Research Ethics Framework. While this research may involve patients, NHS staff or organisations, it is defined as research that poses no clinical risk or harm to those who are the subjects of research. Any research involving NHS patients is automatically covered by the Research Governance Framework. The Lead Organisation and appointed Chief Investigator (with the Lead Organisation Principal Investigator taking procedural responsibility to ensure processes are followed) must ensure that appropriate arrangements are in place for independent ethics review of such research that meets research ethics committee standards.

Significant developments must be assessed as the research proceeds, especially those that affect safety and well-being of research participants, which should be reported to the appropriate authorities and to HDR UK The Lead Organisation and Lead Organisation Principal Investigator must take appropriate and timely action when significant problems are identified. This may include temporarily suspending or terminating the research.

The Lead Organisation is responsible for managing and monitoring statutory requirements, for example, in relation to legislation on clinical trials, use of human organs, tissues and data.

Guidance from the MRC on the conduct of medical research, and by ESRC on the conduct of social science research, provided on behalf of the Funders, must be observed.

The Lead Organisation and Lead Organisation Principal Investigator must ensure that the requirements of the Employing Organisation under the UK Policy Framework for Health and Social Care Research (see https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/) are met for research of the Lead Organisation involving NHS patients, their organs, tissues or data, and that the necessary arrangements are in place with partner organisations. Where the Lead Organisation accepts the responsibilities of a Sponsor (as defined in the Governance Framework), the I Lead Organisation must also ensure that the requirements for Sponsors are met by it.

When research involves clinical trials, award holders must act in accordance with MRC policy on UK clinical trials regulations (see **www.mrc.ac.uk/research/policies-and-guidance-for-researchers/clinical-research-governance/clinical-trials-regulations/**) in relation to ethical, sponsorship, reporting, monitoring and publication requirements.

The Lead Organisation must abide by UK Code of Practice for the use of Human Stem Cell lines and must deposit a sample of any newly derived primary human embryonic stem cell lines in the UK Stem Cell Bank.

Use of Animals in Research

The Lead Organisation is expected to:

- Adopt the principles of the 3Rs (Replacement, Reduction and Refinement, see **www.nc3rs.org.uk/the-3rs**).
- Abide by the core principles set out in the cross-funder guidance 'Responsibility in the use of animals in bioscience research: Expectations of the major research councils and charitable funding bodies' (see **Responsibility in the use of animals in bioscience research – UKRI**).
- Abide by the core principles set out in the Concordat on openness on animal research (UAR; see **Concordat on Openness on Animal Research in the UK | Openness in animal research (concordatopenness.org.uk)**

Wherever possible, Lead Organisation researchers must adopt procedures and techniques that avoid the use of animals. Where this is not possible, the research should be designed so that:

- The least sentient species with the appropriate physiology is used.
- The number of animals used is the minimum sufficient to provide adequate statistical power to answer the question posed.
- The severity of procedures performed on animals is kept to a minimum. Experiments should be kept as short as possible. Appropriate anaesthesia, analgesia and humane end points should be used to minimise any pain and suffering.

The provisions of the Animals (Scientific Procedures) Act 1986 must be observed. The entirety of the Grant Award is awarded on the absolute condition that no work which is controlled by the Act will begin until the necessary licenses have been obtained from the Home Office. Any recommendations arising from peer review processes with regards to animal use must be followed.

When animals are purchased from commercial suppliers, UK suppliers should be used wherever possible to minimise the risk of suffering during transport.

All research involving non-human primates must comply with the NC3Rs Guidelines 'Primate accommodation, care and use' (see **www.nc3rs.org.uk/non-human-primate-accommodation-care-and-use**).

Researchers should ensure that they report animal-based studies in accordance with the ARRIVE guidelines (www.nc3rs.org.uk/ARRIVE) as far as possible, taking into account the specific editorial policies of the journal concerned.

The Lead Organisation is expected to contact FESA to highlight mouse strains engineered, or characterised using the Grant Award, and are encouraged to deposit these strains with the archive.

Any new procedure likely to replace the use of animals in research or testing, reduce the numbers used or refine animal use must be reported to HDR UK and disseminated through the usual channels to all those who might make use of it.

Data assets

The Lead Organisation must comply with the Data Protection Legislation in relation to the use and sharing of data assets.

The Lead Organisation must comply with the MRC policy on research data sharing (**https://www.ukri.org/publications/mrc-data-sharing-policy/**) and the MRC policy on sharing of research data from population and patient studies (**https://www.ukri.org/publications/mrc-guidance-on-sharing-research-data-from-population-and-patient-studies/**).

Health and Safety

The Lead Organisation is responsible for ensuring that a safe working environment is provided for all individuals associated with a Lead Organisation co-ordinated by it. Its approach and policy on health and safety matters must meet all regulatory and legislative requirements and be consistent with best practice recommended by the Health & Safety Executive.

Appropriate care must be taken where Site staff are working off-site. The Lead Organisation must satisfy itself that all reasonable health and safety factors are addressed.

HDR UK reserves the right to require the Lead Organisation to undertake a safety risk assessment in individual cases where health and safety is an issue, and to monitor and audit the actual arrangements made.

Misconduct and Conflicts of Interest

The Lead Organisation must assume full responsibility for staff funded from the Grant Award and, in consequence, accept all duties owed to and responsibilities for these staff, including, without limitation, their Terms and Conditions of employment and their training and supervision, arising from the employer/employee relationship.

The Lead Organisation is required to have in place procedures for governing good research practice, and for investigating and reporting unacceptable research conduct, that meet the requirements set out in the Concordat to Support Research Integrity (2012) **www.universitiesuk.ac.uk/highereducation/Pages/Theconcordattosupportresearchintegrity.aspx** and the Research Councils' Code of Conduct and Policy on the Governance of Good Research Conduct (2013) **https://www.ukri.org/councils/esrc/guidance-for-applicants/research-ethics-guidance/our-policy-and-guidelines-for-good-research-conduct/uct – UKRI** and any subsequent amendments.

The Lead Organisation must inform HDR UK immediately of any issues or circumstances that arise that might result in a reputational risk to HDR UK and its Funders (including, without limitation, investigations of alleged scientific misconduct, breach of conditions of research ethics approval, breaches of data security

or data protection legislation, infringements of licences relating to the use of animals in research, or infringements of Health and Safety regulations, fraudulent activity or acts of bribery).

The Lead Organisation must ensure that potential conflicts of interest in research are declared by all research staff funded by the Grant Award and subsequently managed in a timely manner in accordance with the Lead Organisation's policy on managing conflicts of interest. Guidance on providing declarations of interest can be found at **https://www.ukri.org/councils/stfc/guidance-for-applicants/what-to-include-in-your-proposal/applicant-declarations-of-interest/– UKRI**

The Lead Organisation and Principal Investigator are expected to adopt the principles, standards and good practice for the management of research staff in the Lead Organisation, as set out in the 2008 Concordat to Support the Career Development of Researchers (see Home - The Concordat to Support the Career Development of Researchers (researcherdevelopmentconcordat.ac.uk)), and subsequent amendments. The Lead Organisation, together with the Principal Investigator, must provide an environment in which research staff are selected and treated on the basis of their merits, abilities and potential. The Lead Organisation must ensure that reliable systems and processes are in place so that the principles of the Concordat are embedded into practice within the Lead Organisation. The Lead Organisation must ensure compliance with all relevant legislation and Government regulation, including any subsequent amendments introduced while work is in progress and in particular compliance with the terms of the Equality Act 2010.

It is not permissible for the Principal Investigator to be changed without approval from HDR UK

The Lead Organisation will ensure that Lead Organisation employees and other persons engaged in research funded by the Grant Award of the Lead Organisation will operate to the highest standards of conduct.

Finance

Use of Funds

Subject to the following conditions, funds may be used, without reference to HDR UK, in such a manner as to best carry out the funded work. Funds cannot be used to meet the costs of an activity that will fall beyond the actual end date of the Grant Award, e.g. when travel falls after the end of the Grant Award, the costs cannot be charged to the Grant Award even if the tickets, etc. can be purchased in advance. Funds should be deployed with due consideration to value for money across all activities. All travel claims should evidence value for money as the primary consideration. Consequently, these should only include travel by standard class by train and economy class by air for flights.

The Lead Organisation and Principal Investigator must ensure proper financial management of HDR UK funding and accountability for the use of public and charitable funds. The Lead Organisation should have a dedicated cost centre within the Lead Organisation for the Grant Award. These obligations apply whether the research activities are carried out within the Lead Organisation or other research organisations eg by a collaborator, subcontractor or other third party. The Lead Organisation must maintain auditable accounts relating to the Grant Award in order to demonstrate how resources made available from all sources have been used, mapping them onto research and training activities, and type of spend.

HDR UK and its Funders reserve the right to inspect the records and financial procedures of the Lead Organisation, or to appoint any other body or individual for the purpose of such inspection, at any time upon giving reasonable notice. The Lead Organisation must, if required by HDR UK, provide a statement of account for the Grant Award, that is independently examined by an auditor who is a member of a recognised professional body, certifying that the expenditure has been incurred in accordance with these Terms and Conditions.

The value of the Grant Award may be varied by HDR UK during the lifetime of the Grant Award to take into account any decision of the Funders affecting the funding available to HDR UK. Funds are provided for the specific piece of work, under no circumstances may funds be used to meet costs on any other project or activity.

Starting Procedures and Payments

The funding for the Grant Award will be set out in the Grant Award agreement and will be profiled over the funding period and an expected payment schedule will be provided. The start of the work must not be earlier than the date of the Grant Award agreement itself.

Until further notice, Payment of the Grant Award will be made quarterly in arrears subject to an invoice accompanied by an expenditure and contributions statement and quoting the award reference. A template expenditure statement will be provided. Failure to submit them in a timely manner may result in delayed payments or subsequent payments not being met.

The final payment will be held by HDR UK and will be released as part of the end of the Grant Award reconciliation.

Any significant underspend against the expected profile will be discussed with the Lead Organisation. If there is no good justification for the underspend, together with plans for how the money will be spent, then HDR UK has the right to reduce the award total value and amend the expected payment profile.

Extensions and Supplements

No extensions or supplements will be made to the awards. Costs of Parental Leave and Sickness Absence during the original period of the Grant Award can be claimed from the award, in proportion to the percentage of that person's time allocated to the funded work. The Lead Organisation is responsible for any liability for costs of Parental Leave and Sick Leave pay for staff supported by the Grant Award outside the original period of the Grant Award.

Procurement, Estates & Assets

The procurement of equipment, consumables and services, including maintenance, must comply with all relevant national and EU legislation and the Lead Organisations' own financial policy and procedures. For all equipment and services where the contract value is more than £25,000, excluding VAT, professionally qualified procurement staff must be consulted before the procurement process begins, and, where appropriate, at the market research stage, and must approve the order/contract before it is placed with a supplier.

Equipment purchased from the Grant Award is primarily for use on the work for which the Grant Award was awarded and belongs to the Lead Organisation.

Where there is spare capacity in the use of the equipment, HDR UK expects this to be made available to other users. Priority should be given to research supported by HDR UK, HDR UK-funded students, any of the Funders, UKRI, and to UKRI-funded students. To facilitate this, equipment should be registered on the equipment.data.ac.uk database.

Sanctions

HDR UK reserves the right to impose financial and other sanctions (including withholding of payments) where they identify areas of non-compliance with the Terms and Conditions of the, these Terms and Conditions, or the Grant Award agreement.

Transfer of a Grant

It is not possible for the Grant Award to be transferred to another organisation without prior written permission of HDR UK. The Lead Organisation must consult with HDR UK if it is proposed to change the Grant Holder, for example, following retirement or resignation. In such cases HDR UK may consider termination of the award.

End of Grant Reconciliation

The Lead Organisation is accountable for funds dispersed and must complete and return an End of Grant Award Reconciliation form, documenting spend on the project, within one month of the end date of a Grant Award. The final quarterly payment will be withheld until the Grant Award reconciliation has been completed and agreed. Any balance will be released/clawed back. The reconciliation will be final.

Monitoring, Reporting and Evaluation

HDR UK requires the Lead Organisation research to be well-defined and to be fully costed and represented this way consistently, in returns to HDR UK and Researchfish.

HDR UK will provide the Lead Organisation with reporting templates. HDR UK reserves the right to make adjustments to its reporting templates should there be a business or regulatory need to do so. Any such change would be accompanied by explanatory information.

HDR UK captures data related to the outputs, outcomes and impacts of the research it funds via Researchfish. It is the responsibility of the Principal Investigator to ensure that all requests for submission of this data are met in a timely manner – research organisations must support their staff in the submission of this data. Data will be required annually throughout the duration of the funding, and for several years after the award has finished.

HDR UK may also require a separate final report on the conduct and outcome of the project. If so, it must be submitted by the Lead Organisation within one month of the end of the Grant Award, on the form provided.

While it is the responsibility of the Principal Investigator to manage the research at the Lead Organisation, HDR UK reserves the right to call for periodic information on progress and/or to visit the Lead Organisation. HDR UK may request Lead Organisation staff attend meetings to exchange information and ideas with others undertaking research in the same or similar fields; the I Lead Organisation must allow compliance with these requests.

HDR UK must be consulted in the event of any significant change in the proposed research funded by the Grant Award, including failure to gain access to research facilities and services, or to gain ethical committee approval for the research, particularly those which make it unlikely that the objectives of the research can be achieved. The Principal Investigator is responsible for notifying HDR UK of changes to the research funded by the Grant Award (***N.B. this notification must be provided in the quarter the programme has changed (i.e. started, updated or terminated).***

Exploitation and Impact

It is the responsibility of the Lead Organisation and the Principal Investigator to make every reasonable effort to ensure that the intellectual assets arising in the course of the research funded by the Grant Award, whether protected by intellectual property rights or not, are used effectively to the benefit of society and the economy, and to promote health data science research. Research outcomes must be disseminated to both research and more widespread audiences in a timely manner - for example to inform potential users and beneficiaries of the research.

Disclosure and Inspection

HDR UK reserves the right to have reasonable access to inspect the records and financial procedures associated with the Grant Award or to appoint any other body or individual for the purpose of such inspection. This includes expenditure by third parties. HDR UK shall be entitled to request and/or have access to any financial records and reports that are deemed appropriate to demonstrate the regularity and propriety of expenditure, including but not limited to:

- Annual report & accounts
- External audit management letter
- ISA260 – Communication with those charged with governance
- Related internal audit reports
- That required licenses, approvals, permissions and consent are in place, or were in place when the activity occurred.

The Lead Organisation must report to HDR UK:

- Any investigations (and their outcomes) into research misconduct associated with the Grant Award at the stage that it is decided to undertake an informal inquiry; and on request provide information on:
- Its management of research integrity and ethics as described at **https://www.ukri.org/what-we-offer/supporting-healthy-research-and-innovation-culture/research-integrity/**
- Details of any retractions or withdrawal of submissions/publications
- Any allegations, proven or not, of any cases of fraud.

The Lead Organisation must, if required by HDR UK, provide a statement of account for the Grant Award, independently examined by an auditor who is a member of a recognised professional body, certifying that the expenditure has been incurred in accordance with these Terms and Conditions.

Communications, Branding and Public Engagement

The public announcement of the Grant Award will be managed by HDR UK and is under embargo until notified by HDR UK. The Lead Organisation is expected to co-ordinate local announcements in line with the national communications and will contribute content (in the form of quotes and material for a case study) to support this.

In any online or printed materials (including procurement, press releases, poster, exhibition materials, PowerPoint presentations, digital and social media) related to activities funded by the Grant Award the Organisations must make reference to the HDR UK funding. Logos and other materials will be provided to the Lead Organisation to ensure appropriate representation of the HDR UK brand. Agreement on appropriate attribution should be agreed in advance by contacting **enquiries@hdruk.ac.uk**.

All outcomes and achievements should be communicated to HDR UK's Communications Team (**enquiries@hdruk.ac.uk**) before publication.

All publications resulting from this award are subject to the HDR UK Attribution Policy.
https://www.hdruk.ac.uk/about-us/policies/hdr-uk-attribution-policy/
Award holders must inform HDR UK as soon as a paper presenting outcomes funded by the Grant Award is accepted for publication. HDR UK must be notified at least five working days in advance of any publicity arising from work funded by the Grant Award, and any press releases referencing HDR UK must be approved by HDR UK before it is released to the media.
Funded organisations may be required by HDR UK to participate in communications activities e.g. blog posts and case studies.

It is the responsibility of the Lead Organisation and the Principal Investigator to communicate the research to the public at both local and national level, and to raise awareness of the role of science and research in any related issues of public interest.

Public Engagement, Publication and Acknowledgement of Support

HDR UK expects all publications to be deposited at the earliest opportunity, and certainly within six months of publication, in Europe PubMed Central (europepmc.org/). This applies both during and after the period of funding.

The Lead Organisation and the Principal Investigator are expected to adopt the principles, standards and good practice for public engagement with research set out in the 2010 Concordat for Engaging the Public with Research (see **Concordat for engaging the public with research – UKRI**). The Lead Organisation must ensure that the Lead Organisation provides an environment in which public engagement is valued, recognised and supported. It must ensure that reliable systems and processes are in place so that the principles of the Concordat are embedded into practice within the Lead Organisation.

The results of Lead Organisation research arising from the Grant Award are expected to be published in accordance with normal academic practice and in compliance with the UKRI Open Access Policy (https://www.ukri.org/publications/ukri-open-access-policy/). The Principal Investigator is expected to comply with requirements to encourage and support Lead Organisation staff in this. All researchers will acknowledge the support of HDR UK and its Funders in all communications, including

manuscripts submitted for publication, posters at conferences and other presentations. The form of words to use in publications is as follows:

"This work was supported by Health Data Research UK (insert award reference where relevant), which is funded by the Medical Research Council (UKRI), the National Institute for Health Research, the British Heart Foundation, Cancer Research UK, the Economic and Social Research Council (UKRI), the Engineering and Physical Sciences Research Council (UKRI), Health and Care Research Wales, Chief Scientist Office of the Scottish Government Health and Social Care Directorates, and Health and Social Care Research and Development Division (Public Health Agency, Northern Ireland)."

HDR UK brand identity (e.g. name, logo, etc.) must be preserved in all communications and publicity relating to the Project. The Funders' brand identities as Funders will be utilised alongside "Health Data Research UK" (e.g. name, logo, etc.), in accordance with the HDR UK Brand and Communication Policy (**https://www.hdruk.ac.uk/wp-content/uploads/2019/10/HDRUK-Brand-Guidelines.pdf**) and the HDR UK Attribution Policy (https://www.hdruk.ac.uk/about-us/policies/hdr-uk-attribution-policy/). All promotional work relating to the Grant Award (e.g. press releases, exhibitions, events, etc.) will be drafted in consultation with HDR UK, supported by the Lead Organisation.

Publications and other forms of media communication, including media appearances, press releases and conferences, must acknowledge the support received from HDR UK and its Funders.

The Lead Organisation is expected to adopt the principles of the Concordat on Open Research data (or equivalent). Award holders must comply with the MRC policy on research data sharing (www.mrc.ac.uk/documents/pdf/mrc-data-sharing-policy/) along with the MRC policy on sharing of research data from population and patient studies (www.mrc.ac.uk/publications/browse/mrc-policy-and-guidance-on-sharing-of-research-data-from-population-and-patient-studies/).
If the product of research is code then it should be published in accordance with HDR UK's Attribution Policy **https://www.hdruk.ac.uk/about-us/policies/hdr-uk-attribution-policy/**).

Disclaimer

HDR UK accepts no liability, financial or otherwise, for expenditure or liability arising from the funded work, except as set out in these Terms and Conditions, or otherwise agreed in writing.
Where studies are carried out in an NHS Trust, the Trust has a duty of care to its patients. HDR UK does not accept liability for any failure in the Trust's duty of care, or any negligence on the part of its employees.

HDR UK reserves the right to terminate the Grant Award at any time, subject to reasonable notice and to any payment that may be necessary to cover outstanding and unavoidable commitments. HDR UK reserve the right to amend the payment profile at their discretion. The Lead Organisation will be advised, in advance, of any such a change. Changes to payment profiles may affect the overall value of the Grant Award.

If a Grant Award is terminated or reduced in value, no liability for payment or redundancy or any other compensatory payment for the dismissal of staff funded by the Grant Award will be accepted.

Nothing in this section seeks to limit or exclude the liability of HDR UK where such limitation or exclusion is prohibited by law.

Status

These Terms and Conditions will be governed by the laws of England and Wales; all matters relating to the Terms and Conditions will be subject to the exclusive jurisdiction of the courts of England and Wales.

If any provision of these Terms and Conditions is found by a court or other legitimate body to be illegal, invalid or unreasonable, it will not affect the remaining Terms and Conditions which will continue in force.

These Terms and Conditions, together with any additional conditions set out in the Grant Award Agreement; contain the whole agreement between HDR UK and the Lead Organisation in relation to the stated research Grant Award. HDR UK and the Lead Organisation do not intend that any of these Terms and Conditions should be enforceable by any third party.

Version Control

HDR UK reserves the right to amend these Terms and Conditions. The most recent version of the Terms and Conditions will apply.

Appendix B: Additional HDR UK Requirements

1. Principles of Participation

The Data Partners shall abide by the UK Health Data Research Alliance Principles for Participation: https://ukhealthdata.org/wp-content/uploads/2023/03/Alliance-principles-for-participation_Mar2023-1.pdf