

Digital Innovation Hubs Call - Question and Answers

Date: 10/06/19

Question	Answer	Date Response Posted
<p>1</p> <p>I would like to check if 'nationwide' refers to the UK's 66m population, and, if so, regional bids, such as from Wales, would be out of scope?</p>	<ul style="list-style-type: none"> •Digital Innovation Hubs will have at least one physical location, which may be based anywhere in the UK. •The datasets and associated services of a Digital Innovation Hub should be available to users from all areas of the UK. •The DIH Programme aims to increase the speed and scale at which research and innovation can take place, which will be supported by the datasets brought by hub applicants •These datasets should fit into one or both categories of disease-focused or clinical trials and/or real world evidence, and applicants will be required to demonstrate why these are particularly valuable for near term research and development work in industry and / or not-for-profit research •Applicants are required to describe the modes of data and the size and quality of the dataset(s) they will be contributing as a Digital Innovation Hub as part of their application, and this will be evaluated through the selection process. A compelling bid will set out how the data resources you are bringing (immediately and over the course of the award) address needs for access to aligned data at scale 	<p>10/05/2019</p>
<p>2</p> <p>How was the list of highlighted disease areas generated, and why is mental health not on it, given MRC and HMG's stated commitment to mental health?</p>	<ul style="list-style-type: none"> •The disease areas provided in the Guidance Notes for Applicants are based on engagement that took place over the Design and Dialogue phase of the programme, in which over 2,700 people were consulted. •The list of disease areas is non-exclusive, and we welcome applications in all disease areas. •As outlined in the Guidance Notes for Applicants document, Section 6, 2.1: Applicants are expected to make datasets available which are "valuable for near term research and development work in industry and / or not-for-profit research" 	<p>10/05/2019</p>

3	<p>We are LMIC based research institution located [outside of the UK]. Are we eligible to participate in this call as partner organization or lead. Please confirm.</p>	<ul style="list-style-type: none"> •The competition is hosted within the context of UKRI's over-arching eligibility criteria i.e. Higher Education Institutions and Research Organisations must also be based in the UK to be supported, whether as leads or as partners. As such, your organisation is not eligible to apply for funding from this call. 	10/05/2019
4	<p>There is a clear requirement for the Hubs to be disease focused (and I note the list of areas of interest stated in the programme prospectus) however we wondered if the each Hub would need to specialise in a single disease or could hold expertise across a number of key disease areas?</p>	<ul style="list-style-type: none"> •As outlined in the Guidance Notes for Applicants document, Section 6, applicants will be required to demonstrate the value of the datasets and services they will provide. •These datasets and services may be specific to a single area of expertise, or may be focused on several areas which provide a combined and compelling value to users. 	10/05/2019
5	<p>I notice in your guidance it says that an FAQ document will be released regularly, however I couldn't find one. Has this been released yet? How do we sign up for a webinar or the info event on 21 May?</p>	<ul style="list-style-type: none"> •Questions and Answers will be published during the call period in a generic format and will be available here https://www.hdruc.ac.uk/digital-innovation-hubs/ •The link for the Networking Event is: https://www.hdruc.ac.uk/events/digital-innovation-hub-networking-meeting/ •The link to register for the webinar is https://www.hdruc.ac.uk/events/register-for-our-upcoming-digital-innovation-hub-webinars/ 	10/05/2019
6	<p>Do we envisage that now that now that the Infrastructure has evolved into the Gateway, that industry and other external partners would potentially be able to approach either the DIHs or the Gateway directly - and that both layers will have a 'client-facing' service approach but with the main differentiator being the specialist data/services available. ie if I am a company and I wanted a dataset on something super-rare that is not covered by a DIH then I go direct to the Gateway and probably use my existing key opinion leaders in that area BUT if I wanted a dataset/expertise in eg asthma then i would go to a respiratory DIH</p>	<ul style="list-style-type: none"> •The Innovation Gateway would be open directly to industry users from all sectors, as well as researchers and innovators across the NHS and academia, and it is envisioned will become a common access point for UK health data. •Disease-focused Digital Innovation Hubs will provide high value data and expert services to support research within their domain and across the network of Hubs. These data and services should be available to users across the UK •Data held by current and future members of the UK Health Data Research Alliance, including that relating to areas not specifically covered by a Digital Innovation Hub, would be expected to be available through the Innovation Gateway in due course. 	16/05/2019

7	<p>Would you be able to help clarify a phrase in the guidance document for the Digital Innovation Hubs bid process? What the phrase “not currently discoverable for research” means on page 1 of the Guidance Document? Does this mean just registry and cohort datasets or does it describe all of the possible datasets listed? What for example is a dataset that is currently discoverable for research? Where does audit data fit?</p>	<ul style="list-style-type: none">• Datasets which are not currently available for research means any health data which would be valuable for research but is not openly available to researchers and innovators from industry, academia and the NHS. This may include audit data for example.• Examples of datasets which are currently discoverable for research include Clinical Practice Research Datalink GOLD dataset and the NHS Digital Hospital Episode Statistics dataset	16/05/2019
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8	<p>Can we submit a bid that addresses both themes – i.e. focussing on an important clinical domain (e.g. key aspects of healthy ageing and frailty) and also on the development and application of novel approaches to clinical trials? Our respective institutions have leading programs in both ageing and . In addition, we lead complementary data science programs focusing in particular on extending access to data from health, care, administrative and research sources (including from local government and civics) and on new approaches to data management and analysis, particularly federated analysis. Our approaches entail the use of robust metadata, analytic efficiency, sound but streamlined information governance and comprehensive quality management with use of rigorous technical/inferential standards. Would such a program of important clinical research underpinned by strong data science be viewed as appropriate for DIH if it focused down on a tightly specified set of clinical/scientific/technical questions? Or would it in practice be viewed as too broad regardless of the focus of its scientific because of the breadth of its underpinning foundations?</p>	<ul style="list-style-type: none"> •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: •Disease-Focused Hubs which will create globally leading datasets and provide strong domain expertise •Clinical Trials and/or Real World Evidence (RWE) Hubs will enable clinical trials using large scale data, and/or focus on using large scale data to enable evaluation through better use of real world evidence •Please note that the Digital Innovation Hubs competition will not fund “a programme of important clinical research”, as the purpose of the hubs is not to perform original research 	16/05/2019
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<p>A key element of such a program would be the identification, management and use of many different types of “Real World Evidence” which could be abstracted from health systems, local government, national administrative data, research-generated resources and repositories as well as from citizens via a variety of media and devices. Our clinical and data science programs address a range of novel approaches to the management and exploitation of such RWE and this would be critical, for example, if we are to address “frailty” where the causative determinants and quantitative metrics are numerous, poorly understood and often require a weak signal to be extracted from a lot of noise. However, in the launch webinar the concept of RWE was specifically exemplified by the use of safety information (possibly international) to place and interpret a clinical trial in a more informative context. I just want to check: is there an expectation that any use of “Real World Evidence” should simply be to strengthen and inform the use of novel approaches to clinical trials (these are the two components of theme 2) or does “Real World Evidence” refer to the sound use of real world data and information in any setting that can underpin a strong program of health, care or biomedical research?</p>	<ul style="list-style-type: none">•Real World Evidence as it applies to the DIH programme involves 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•Please note that the Digital Innovation Hubs competition will not fund a programme of research –the Hubs would provide data and services to support research, rather than directly undertaking research	<p>16/05/2019</p>
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10	<p>Relating to the two stated HUB themes: Disease focus and Clinical Trials/RWE focus: Could a HUB still be based around a geographical population and meet specific themes of interest for a population of ~10m (in the first instance) by joining a set of LHCR footprints? This approach would better support regional financial challenges, align better with regional LHCR requirements and potentially simplify governance arrangements. Once the DIH programme becomes more mature, there could still be data sharing in the future between the HUBs to increase the thematic population coverage."</p>	<ul style="list-style-type: none"> •Digital Innovation Hubs will have at least one physical location, which may be based anywhere in the UK. •The datasets and associated services of a Digital Innovation Hub should be available to users from all areas of the UK. •The DIH Programme aims to increase the speed and scale at which research and innovation can take place, which will be supported by the datasets brought by hub applicants •These datasets should fit into one or both categories of disease-focused or clinical trials and/or real world evidence, and applicants will be required to demonstrate why these are particularly valuable for near term research and development work in industry and / or not-for-profit research •Applicants are required to describe the modes of data and the size and quality of the dataset(s) they will be contributing as a Digital Innovation Hub as part of their application, and this will be evaluated through the selection process. A compelling bid will set out how the data resources you are bringing (immediately and over the course of the award) address needs for access to aligned data at scale 	16/05/2019
11	<p>Does the criteria for the Digital Innovation Hubs include a requirement for patient and public involvement and engagement and will the selection process involve people from the patients group?</p>	<p>"Yes, patient and public involvement and engagement (PPIE) is a key element of the criteria for organisations applying to become Hubs. As part of their application, organisations applying to establish a Hub will be expected to outline their track record in PPIE. They will also be expected to demonstrate their plans for engaging patients and members of the public and how they will be involved in decision-making and governance processes in the Hub at various milestones. Details of the selection panel for the Hubs are yet to be finalised, however it is expected that this will include representation from the patients/the public."</p>	16/05/2019

12	<p>Why should applicants develop a cardiovascular disease-focused hub if the British Heart Foundation and Health Data Research UK are proposing to develop the UK Cardiovascular Data Science Knowledge Hub separately?</p>	<ul style="list-style-type: none"> • The proposed British Heart Foundation UK Cardiovascular Data Science Centre is being developed by Health Data Research UK in partnership with the BHF, following an extensive dialogue with the UK cardiovascular research community, national data custodians and other stakeholders across the UK. • It is an ambitious UK wide collaborative initiative. Its purpose is to leverage the UK's unique cardiovascular 'big data' distributed across national registries, linked electronic health records and other relevant multi-dimensional datasets to enable a diverse range of high impact cardiovascular research at scale. • Disease-focused Digital Innovation Hubs developed through the DIH programme will focus on deep curation of specific datasets, data engineering and expert research services to meet specific industry and researcher user needs. They are required to describe the proposed DIH's distinct value and the unmet demand for the services that will be provided. Hubs would be required to make accessible specific datasets, which are not currently available for research. • Digital Innovation Hubs will be expected to work collaboratively with each other and with other components of the national health data research infrastructure. • Accordingly, any cardiovascular disease focused DIH must complement the BHF Initiative. The DIH will be expected to align, add-value and not duplicate the activities of the BHF Centre, as outlined in the Guidance Notes for Applicants: Selection Criterion 2.6. • DIH applicants who are interested in developing a DIH application focused on cardiovascular disease should contact Health Data Research UK and the British Heart Foundation in advance of submission, who can provide the detailed plans for the Cardiovascular Data Science Centre and provide further clarification as needed, to enable alignment. • Following submission of any cardiovascular disease focused DIH application, the MRC will share relevant applications with the BHF as part of the review process to check complementarity to the BHF Centre investment. 	28/05/2019
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13	For the Digital Innovation Hubs, do the funds come from ISCF. Is there a requirement to raise matched industry funds before or during the bids to the call?	<ul style="list-style-type: none"> •The Digital Innovation Hub Programme is funded by the Industrial Strategy Challenge Fund Programme - Data to Early Diagnosis and Precision Medicine Challenge. •Applicants will be required to demonstrate supporting contributions, or funding in kind, to at least 50% of the funding requested over the lifetime of the award and how this would enhance the initial investment •Each organisation's required contribution to bridge from the UKRI permitted percentage of Full Economic Cost (under the eligibility and funding rules) to the 100% Full Economic Cost of participation will be considered a contribution towards meeting this requirement 	28/05/2019
14	If organisations were to express an interest in a particular disease and other organisations were also express an interest in the same particular disease would you encourage them to combine bids or would they compete without necessarily knowing there was another consortia on the same disease?	<ul style="list-style-type: none"> •Health Data Research UK have encouraged collaboration throughout the Design and Dialogue phase of the programme, which has taken place through the period September – April and has allowed many organisations to develop joint applications. This collaboration has been further encouraged through the networking event held on 21st May. •This programme is an open call and there is no scoping review stage built into this programme. 	28/05/2019
15	Does the DIH money have to be awarded via a HDR UK Substantive site?	<ul style="list-style-type: none"> •The Digital Innovation Hub Programme is funded by UK Research and Innovation Industry Strategy Challenge Fund, delivered in partnership with Health Data Research UK. This call is administered by the Medical Research Council on behalf of UKRI ISCF and HDR UK and is separate from core funding provided to HDR UK and HDR UK's substantive sites. •Applications from or involving organisations that are part of HDR UK substantive sites will not receive any preferential treatment in the selection process. 	28/05/2019

16	<p>The Hubs need to be commercially sustainable for the long term. What does that mean?</p>	<ul style="list-style-type: none"> • Whilst Digital Innovation Hubs will be funded initially through the ISCF investment to kick-start the approach, it is expected that the funded Hubs will become self-sustaining following the initial grant period. This could be achieved through the development of a sustainable model, based on the commercial principles laid out in the consortium Head of Terms Agreement (see Section 7). Any approach will need to be consistent with wider Government policy on access to health data for research. • Applicants will be expected to explain how their business model will be commercially sustainable by the end of the initial investment period, while continuing to adhere to the Principles for Participation and a commitment to open access of methodologies, code and findings. 	28/05/2019
17	<p>What is the wordcount limit for the short title? The prospectus says that CVs should cover 2 pages - is that 2 pages per CV or 2 pages in total? Is it intended that the Gateway will absorb other services such as the Health Data Finder over time? And is it intended that application process for different data sets will be brought together into the Gateway, or will the Gateway signpost to the application processes run by other organisations? What is the composition of the panel that will assess the applications?</p>	<ul style="list-style-type: none"> • An error has been identified in the guidance for the short form title. This should be no more than 30 characters in length, including spaces. • CVs should be no more than 2 pages each. However, only CVs for the proposed Hub Director, leadership team and key personnel should be submitted. An exhaustive collection of CVs for all proposed staff is not required. • The Innovation Gateway is currently in development and updates will be available in due course. • Full details of the panel membership will be released in due course and prior to the assessment stage of the competition 	31/05/2019

18	<p>There are existing data sets where there is a significant delay of 18-24 months in release of the data. Does this count as “currently available” as faster access to these data would have value for both NHS and commercial purposes? We are aware that Innovate UK has a review process during similar calls to rule whether a potential bid is in scope or not. Is something similar available for this process?</p>	<ul style="list-style-type: none"> •The Digital Innovation Hub programme aims to increase the access to, and use of, health data for research. Applicants will be required to demonstrate access to distinct health data that will be made discoverable through the programme. This may represent data which is available but difficult to access – applicants will be required to demonstrate why this dataset(s) is particularly valuable for near-term research and development. •Hubs will be required to meet specific delivery milestones to receive continued funding. Within three months of funding commencing, the Hub will be required to make the dataset available and discoverable through the Innovation Gateway. Within 18 months, the Hub will be required to demonstrate improvements in the quality of the data, which requires that in the intervening period the data must be used for research and innovation •If the applicants can demonstrate value for researchers and innovators through increased ability to access, in a safe and ethical manner, data which is currently available, this would provide additional support to the application 	04/06/2019
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20	<p>DIH - balance of approach - particular disease focus vs. broader applications. Is the aspiration to ultimately have these capabilities across all diseases? If so, to what degree do we need to demonstrate a route-map (scalability and replicability) to that long-term vision?</p>	<ul style="list-style-type: none"> •Disease-focused Digital Innovation Hubs will provide high value data and expert services to support research within their domain and across the network of Hubs. These data and services should be available to users across the UK •As outlined in the Guidance Notes for Applicants document, Section 6, applicants will be required to demonstrate the value of the datasets and services they will provide. These datasets and services may be specific to a single area of expertise, or may be focused on several areas which provide a combined and compelling value to users. •Applicants will be required to demonstrate how the Hub will work in partnership with other Hubs to deliver a national offer, but this does not extend to demonstrating a route-map for coverage across all disease areas. •Whilst it is the ambition to provide a UK federated network offering broad coverage across all disease domains and capabilities needed for research and innovation, it is not expected that hubs will need to be able to cover all diseases or all capabilities in and of themselves. The portfolio of hubs funded through the programme will cover several diseases, as well as clinical trials and real world evidence services, and will aim to achieve a geographical spread of Hub locations across the UK. 	04/06/2019
21	<p>Is there is any limitation on a business being part of more than one bid for the DIH programme.</p>	<ul style="list-style-type: none"> •There is no limitation on the number of bids or consortia UK business can be involved in. Consideration should be given to capacity and the availability of resources should more than one bid be successful. Due consideration will also need to be given to the implications of such an approach to compliance with relevant State Aid regulations. 	04/06/2019

22	<p>Is this call intended to take the Sprint Projects forward - or would an application from a 'new' organisation be considered?</p>	<ul style="list-style-type: none"> •The Sprint Exemplar Projects are part of the overall Digital innovation Hub Programme and are funded as standalone short timescale delivery projects. The Sprint Exemplar Projects have influenced the design and dialogue phase of the Digital Innovation Hub Programme. •The purpose of the Digital Innovation Hub call is to select digital innovation hubs in the areas as specified in the Guidance for Applicants document. This is an open call and we welcome applications from new organisations which fit within the organisational criteria as specified in the Guidance for Applicants document. •Whilst existing sprint exemplar projects could be utilised and integrated as part of a consortium submission, this will not, of itself, confer a competitive advantage. 	11/06/2019
23	<p>On page 6 of the prospectus, the final paragraph states that public sector organisations can bid for 100% of grant funding for their eligible costs if “they are undertaking research (this may be experimental, theoretical or critical investigation work to gain knowledge, skills or understanding vital to the project”. Then on page 7, the last sentence states “funding from this call will not support specific research projects.” these appear to be contradictory. Would it be possible to clarify please?</p>	<ul style="list-style-type: none"> •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. •To achieve these objectives will require R&D activity. Whilst R&D activity will therefore be needed to develop the Hub offering as described above, the proposal may not include requests to support subsequent research projects that then go on to use the data and services being provided by the Hub e.g. to answer biomedical or social research questions, trials etc. 	11/06/2019
24	<p>As stated within a future DIH, all data custodians are required to sign up to the UKHDR Alliance. No details are available on the HDR UK website regarding the process of joining the Alliance and the expectations/benefits that come with being a member. Do you have any information that you are able to share regarding this?</p>	<ul style="list-style-type: none"> •Organisations taking part in the DIH Programme will be required to adhere to the Principles for Participation which form the underpinning values of the UK Health Data Research Alliance. •Beyond the broad principles set out in the guidance and on the Alliance webpages (https://www.hdruk.ac.uk/digital-innovation-hubs/uk-health-data-research-alliance/), it should be noted the Alliance is being developed in parallel with the Digital Innovation Hub call. •Further details relating to the Alliance will be available in due course as the members work together to bring these high-level principles into practice. 	11/06/2019

25	The hub scope discusses a 'data custodian'. Does this term mean the same as a 'data controller'?	<ul style="list-style-type: none"> •Yes, in this context they are one and the same. 	11/06/2019
26	Assessed Section – the instructions for this section asks respondents to 'take a new page for each point'. Is this sub section, e.g. 2.1, 2.2 etc or per bullet point underneath?	<ul style="list-style-type: none"> •'Take a new page' referrers to each subsection i.e. 2.5 Public Trust and the bullet points contained within that subsection. Please take note of the word count limits for each sub section which can be found section 8 of the Guidance for Applicants document; for example, 2.5 Public Trust should be no more than 800 words / 7000 characters including spaces. 	11/06/2019
27	UK based business of any size' and 'UK based Charity' – please clarify if 'base' relates to the location of the Head Office of the organisation or to the presence of a location in the UK	<ul style="list-style-type: none"> •UK based Businesses means those businesses which are registered with Companies House in the UK and possess a UK Clearing Bank Account. They must undertake relevant commercial activities within the UK in order to be eligible to apply for funding. UK-based Charities means those charities which are registered with one or more of the Charities Commission for England and Wales, The Scottish Charity Register (OSCR) and/or The Charity Commission for Northern Ireland. Please note, the programme of work funded by the DIH call must be carried out in the UK 	11/06/2019
28	Instructions in this section state 'Applicants will be required to submit finalised and signed consortium Heads of Terms as part of their application with the view that this is developed into the Consortium Agreement if funded' and 'This document should be no longer than 6 pages and be signed by someone with authority within each organisation to ratify the legal and financial commitment ' is each partner required to sign the Heads of Terms submitted within the application. If so, does the 6 pages include signature pages (which may be an individual signature page per organisation)	<ul style="list-style-type: none"> •The main body of content of the consortium Head of Terms document should be no more than 6 pages in length. Additional signature pages can be added to this but must contain signature related details only and be kept to a minimum. All participants (but not subcontractors) are required to sign the Heads of Terms, irrespective of whether or not they would be in receipt of funding from an award. 	11/06/2019