

## Digital Innovation Hubs Call - Question and Answers

Date: 16/05/19

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"> <li>•Digital Innovation Hubs will have at least one physical location, which may be based anywhere in the UK.</li> <li>•The datasets and associated services of a Digital Innovation Hub should be available to users from all areas of the UK.</li> <li>•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</li> <li>•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</li> <li>•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</li> </ul>	<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"> <li>•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.</li> <li>•The list of disease areas is non-exclusive, and we welcome applications in all disease areas.</li> <li>•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"</li> </ul>	<p>10/05/2019</p>

3	<p>We are LMIC based research institued 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"> <li>•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.</li> </ul>	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"> <li>•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.</li> <li>•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.</li> </ul>	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"> <li>•Questions and Answers will be published during the call period in a generic format and will be available here <a href="https://www.hdruk.ac.uk/digital-innovation-hubs/">https://www.hdruk.ac.uk/digital-innovation-hubs/</a></li> <li>•The link for the Networking Event is: <a href="https://www.hdruk.ac.uk/events/digital-innovation-hub-networking-meeting/">https://www.hdruk.ac.uk/events/digital-innovation-hub-networking-meeting/</a></li> <li>•The link to register for the webinar is <a href="https://www.hdruk.ac.uk/events/register-for-our-upcoming-digital-innovation-hub-webinars/">https://www.hdruk.ac.uk/events/register-for-our-upcoming-digital-innovation-hub-webinars/</a></li> </ul>	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"> <li>•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.</li> <li>•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</li> <li>•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.</li> </ul>	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"> <li>•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.</li> <li>•Examples of datasets which are currently discoverable for research include Clinical Practice Research Datalink GOLD dataset and the NHS Digital Hospital Episode Statistics dataset</li> </ul>	16/05/2019

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"> <li>•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:</li> <li>•Disease-Focused Hubs which will create globally leading datasets and provide strong domain expertise</li> <li>•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</li> <li>•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</li> </ul>	16/05/2019
---	--	---	------------

<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> <p>9</p>	<ul style="list-style-type: none"><li>•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</li><li>•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</li></ul>	<p>16/05/2019</p>
--	--	-------------------

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"> <li>•Digital Innovation Hubs will have at least one physical location, which may be based anywhere in the UK.</li> <li>•The datasets and associated services of a Digital Innovation Hub should be available to users from all areas of the UK.</li> <li>•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</li> <li>•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</li> <li>•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</li> </ul>	16/05/2019
11	<p>For the Digital Innovation Hubs, do the funds come from iscf. Was there a requirement to raise matched industry funds before or during the bids to the call</p>	<ul style="list-style-type: none"> <li>•The Digital Innovation Hub Programme is funded by the Industrial Strategy Challenge Fund Programme - Data to Early Diagnosis and Precision Medicine Challenge.</li> <li>•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</li> <li>•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</li> </ul>	16/05/2019

12	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?	"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."	16/05/2019
----	--	---	------------