# Developing a framework for linking medical research charity registries with the national research volunteer registry

# SPECIFICATION OF REQUIREMENTS

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# Specification of Requirements

## Background to the requirements

### Context

#### Health research is the single most important way in which we make ground-breaking advances in patient care, helping us to transform the way we diagnose and treat health conditions, prevent illnesses, and achieve better outcomes for people.

#### The UK vision for research[[1]](#footnote-2) is to give people greater opportunities to get involved in research, increasing the speed of recruitment as well as the numbers of people recruited, resulting in improved outcomes for people and improved service delivery.

#### [The Long Term Plan](https://www.longtermplan.nhs.uk/online-version/chapter-3-further-progress-on-care-quality-and-outcomes/better-care-for-major-health-conditions/research-and-innovation-to-drive-future-outcomes-improvement/) (LTP)[[2]](#footnote-3) sets out NHS (National Health Service) England’s commitment to increase the number of people who register their interest to take part in research to one million by 2023/24. In doing so, a pool of people interested in taking part in research will be created, ready to be recruited into trials by researchers.

### Current arrangements

#### There are many research registries currently operating in the UK. Some have a local or regional focus, or they are established for specific purposes such as the [UK Biobank](https://www.ukbiobank.ac.uk/). Others are part of the infrastructure of disease specific charities which include volunteer, Patient Reported Outcome Measures (PROM) and Patient Reported Experience Measure (PREM) registries.

#### The National Institute for Health and Care Research (NIHR) recently launched [*Be Part of Research service*](https://volunteer.bepartofresearch.nihr.ac.uk/participants/introduction)*,* (BPoR) - England’s online national research registry, where people can sign-up their interest to volunteer for research and set their preferences such as specifying the conditions they are particularly interested in being contacted about. The registry uses the NHS login and is also linked from the NHS App.

#### Most of these research registries currently operate in silos, often competing with each other, resulting in inefficiencies in resources, and creating a disjointed experience for people interested in volunteering for research. *Be Part of Research* works in a collaborative way with links to many other parts of the health research system to ensure that the volunteers can find the research suitable for them and to simplify the process for the researcher.

## Scope of the Procurement

### Aims & Objectives

#### Key to simplifying participation in health research for the public and making it easier for researchers to recruit to clinical trials faster, is to connect and transform current research registries.

#### NHS England is seeking to assess the feasibility of providing connectivity between medical research charity health data assets and NIHR's *Be Part of Research* to:

#### create a networked and federated model of registries where the benefits and promotion of the networked registry are shared by individual registries.

#### drive better opportunities for volunteering for research by reducing the duplicative efforts of signing-up to multiple registries and providing better access to more research opportunities for patients, leading to faster discovery of therapeutic innovations that can benefit people accessing NHS services.

#### make it easier for researchers to recruit to studies from a wider, more diverse pool of volunteers.

#### The project will explore ways to reduce duplication, elevate the profile of all assets, create mutually beneficial partnerships between NHS England, NIHR and medical research charities and build public confidence.

#### For this purpose, the work will explore how to collect and link information available from various sources to best achieve these aims.

#### To achieve the general objective, the project will achieve the following:

1. Provide a mapping of all medical research charities - those currently with and without registries. For charities with registries outline the characteristics of the data assets held including:
	* the type and format of the data.
	* the volunteer identifiers used by each registry.
	* a gap analysis of information not readily available which may be deemed to be important for connectivity with NIHR's *Be Part of Research*.
	* type of consent currently applied for the use of the data.
2. For each registry, an assessment of whether and how interconnection of data assets with NIHR *Be Part of Research* would be feasible by identifying operational and IT challenges, as well as any other barriers to connectivity.
3. Analysis of the legal feasibility including the information governance considerations including consent and permissions for connectivity of data assets.
4. Develop detailed technical options outlining the possible design and scope of connecting medical research charity registries with *Be Part of Research* including common standards for future-proofing interoperability such as HL7 FIHR and, outlining a framework of the tasks, timelines, cost options, and roadmap. Include considerations for NHS Service Standard (Alpha assessment) and/or Digital Technology Assessment Criteria where applicable.
5. For charities without registries, outline the technical mechanisms to deploy a white-label offering to charities, including broad tasks and timelines to undertake to achieve, making use of components developed by NIHR to achieve this task where appropriate. Outline the risks and opportunities for wider research participation from encouraging charities to set up their own registry.
6. A framework to link other local registries including but not limited to those managed by NHS trusts.
7. Test technical solution options, using approaches such as a proof-of-concept demonstration in a sandpit environment and demonstrate an alpha build of a white-label solution.

#### The contract is proposed to run for four months.

### Constraints and Dependencies

#### The supplier will need to work with NIHR Clinical Research Network (CRN) and work with the current architecture of the *Be Part of Research* service, but must be mindful of being future proofed against potential changes in technology platforms used by medical research charity registries and NIHR.

#### Any proposed solutions will be required to work with the standards specified by NIHR *Be Part of Research*.

#### Medical research charities may not have the resources to undertake the work being requested. The supplier will need to work with a representative body of the medical research charities to help facilitate progress.

#### The deliverables, material and any other output developed by the Supplier as part of the Services in accordance with the Specification, shall be owned by NHS England. No data or information about or pertaining to the work may be shared without prior consent of NHS England.

## Requirements

### Mandatory Requirements

#### Five or more years experience prior experience with advising the public health sector and developing complex technical solutions involving collaborations between organisations.

#### Five or more years experience in designing and implementing similar database systems with data volumes and complex structure including strong knowledge of API development.

#### Five or more years experience in implementing information governance and security standards considerations when connecting data between organisations.

#### The supplier must be able to manage complex partnerships or collaborations to achieve an agreed set of aims with appropriate governance to manage this.

#### The detailed characteristics of the requirements are set out below:

|  |
| --- |
| **Task 1: Selecting charities [Objectives i and ii]** |
| The supplier will outline potential medical research charity collaborators to fulfil objective 1 and 2. i.e.: 1. Medical research charities with public research registries and
2. Medical research charities without public research registries but with an interest in a ‘white-label’ customisable registry aimed at encouraging their supporters to sign-up to *Be Part of Research*.

For the purpose of this task, the following non-exhaustive list of activities must be performed collaboratively with the charities involved. * Desk-research and analysis of existing data sources
* Interviews with medical research charity managers. The supplier must conduct interviews with at least 10 charities. Seven of those must have patient data assets.
* Interviews conducted under this task may be combined with interviews referred to in other tasks
 |
| **Task 2: Requirements gathering: mapping of existing registers [Objective i]** |
| The mapping must include:* Data sources that are needed for minimal connectivity.
	+ A description of the data stored including exact scope, definitions and format of the information recorded in the register, and data that could be utilised for connectivity with *Be Part of Research* to form a better consolidated registry including number of people in each registry.
* Schema of the data sources and standards, including common data items with *Be Part of Research* and gaps to address to allow connectivity and interoperability.

For the purpose of performing that task, the following non-exhaustive list of activities should be performed:* Analysis of documentation of existing registries when available or provided by the charities in charge of the registries.
* Questionnaire sent to charities identified in Task 1.
* Interviews with the key stakeholders in charities identified in Task 1.
 |
| **Task 3: Operational/IT feasibility assessment, cost/benefit analysis, and development of functional specification [Objectives i and ii]** |
| For the purpose of performing an operational and IT feasibility assessment, the project must precisely identify the requirements to reach the objectives of interconnection of medical research charity registry data assets and *Be Part of Research*, medical research charities without data assets, scope and level of harmonisation required including:* Use cases demonstrating how interoperability could operate and the functional requirements for each case [this may be bespoke for each medical research charity with a data asset].
* Underlying architecture required for connectivity [drawings, standards, programmes.
* Feasibility of using customised APIs for interconnectivity and adding value for charities.
* Feasibility of establishing a centralised ‘consent engine’ to hold levels of permissions against an individual subject to GDPR considerations, including where information may be stored, communicated and the feasibility of establishing dynamic consent when registries are linked.
* Subject to GDPR investigate how those permissions for data use are communicated, stored and how easy they are to revoke for the user
* Reliability of the information (quality control methods to for interconnectivity).
* Security of information exchanges.
* Consideration for obsolete technologies and suggestions to overcome these issues.
* Consideration for using the NHS Login as the golden thread for connectivity and assurance of identity.
* Consideration for scalability for larger databases.
* Level of maintenance required.

As part of the IT feasibility assessment, the cost benefit analysis must more precisely assess the IT standards, consent mechanisms and models used by the seven charities with the data assets (selected in task 1) and analyse their potential for interoperability. These estimates should take into account all aspects of the establishment of interconnectivity of *Be Part of Research* and charity registry data assets (logistical, technical, licencing technologies, human resources, etc). The analysis should include:* An analysis of the administrative costs that the creation of interoperable registries would entail.
* Barriers and challenges that must be overcome to make interconnectivity feasible.
* The benefits of interconnectivity including realistic projections of subsequent increase in number of people signed up *Be Part of Research* and medical charity registries.
* The cost per conversion of sign-up based on possible scenarios (e.g. 1% uptake, 5% uptake).

For the purpose of performing that task, the following non-exhaustive list of activities should be performed:* Workshops and Structured interviews with stakeholders involved in data assets teams in medical research charity registries and *Be Part of Research*, and with business development/IT teams in medical research charities without data assets.
* Elaboration of the difference scenario and cost assessments on the basis of achievement of task 3.
* To substantiate the findings of the operational and IT feasibility assessment, the supplier is expected to conduct case studies in each of the charities with data assets.
 |
| **Task 4: Legal, regulatory and governance considerations [Objective iii]** |
| The supplier will conduct a legal and regulatory assessment that includes the following dimensions:* Legal considerations relating to the General Data Protection Regulation and other appropriate data protection considerations.
* The supplier will set out the type and precise scope of information that can be exchanged between the legal entities of NIHR *Be Part of Research* and the medical research charities under consideration in this project, including providing guidance about which organisations would own the data and associated responsibilities.
* Establish junctures where differing levels of permissions would need to be sought from the individual in line with NHS Personal Demographics Service (PDS) service levels. i.e. ask for permission to elevate the registry entry to a national level.
* Considerations for governance arrangements and research ethnics that.

For the purpose of performing that task, the following non-exhaustive list of activities should be performed:* Legal analysis including advice from lawyers or academics where appropriate.
 |
| **Task 5: Technical options and roadmap for the design and functionality of interconnectivity between medical research charities and *Be Part of Research* [Objective iv and vi]** |
| On the basis of the feasibility and legal considerations in previous tasks, the supplier will provide a description of the technical issues and possible solutions (with an options appraisal) for the setting up, and maintenance of interoperable registries (for charities with and without registries). Solutions will have consideration for: * **The main parameters of the IT infrastructure** (conditions for access by the users, search functionality, governance structure, data controllership, and any mock up screens for the user access).
* **Technical specification**, including systems used, data security, routing components data exchange protocols and any other specifications such as NHS Login that is integral to understand and enable interconnectivity and future proofing.
* **Cost of establishment and maintenance** including any significant user training needs.
* **Projected benefits** of each option.
* **Barriers and challenges** including:
	+ Barriers to interconnectivity and interoperability of data assets.
	+ Mechanisms to make the partnerships mutually beneficial for both charities and *Be Part of Research* that would incentivise charities to take up the offer, including any technical enhancements required of *Be Part of Research* to make the partnership beneficial to charities and their supporters.
* **Policy steps** that would need to be undertaken to achieve the objectives.
* **A framework for connecting other registries** - based on the solutions for interconnectivity between medical research charities with data assets, provide a framework for connecting other research registries with *Be Part of Research*, including minimum standards for connectivity.
* **A testing and quality assurance plan** – for the proposed framework.

The supplier will also outline a roadmap, strategy and outline project plan that could be put in place for achieving interconnectivity in the short and medium-term future, detailing all the necessary steps to achieve this. The report should be written to allow seamless handover to an implementation team in the next phase of development.  |
| **Task 6: Framework for a white label offering [Objective v]** |
| For charities without existing registries, provide a framework for a white-label offering including: * the necessary technical designs.
* incentivisation proposals.
* data storage/ownership considerations.
* white-label registry set-up and maintenance considerations.
* cost-benefit analysis of for a medical research charity using a white-label approach versus creating their own volunteer registry.
* a programme plan to connect the registries, including any barriers to be mindful of and suggestions to mitigate.

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| **Task 7: Proof of concept demonstration [objective vii]** |
| For the technical design described in Tasks 5 and 6, provide a demonstration in a test environment to show proof of concept and how the solution may work in practice when implemented, including an alpha build of a while-label proposal.  |

### Desirable Requirements

#### Prior experience working with medical research charities, with a specific focus on management of data assets to navigate the complexity of complex and sensitive data built on a strong trusted relationship with patients.

#### Prior experience working with NHS organisations involved in research and understand governance processes for recruitment from research registries.

### Timescales & Implementation

#### To be delivered within the 16-week contract time frame from the agreed contract commencement date with the appointed.

#### The key milestones, deliverables, and performance measures in section 3.7, require all to be delivered within 12 weeks, allowing for a four-week flex period to be agreed in advance with NHS England.

### Location

#### The supplier is expected to work remotely where possible to minimise travel but should expect travel to relevant charity locations where the work necessitates.

### Roles and Responsibilities

#### NHS England will lead on contract management and arranging progress meetings on a bi-weekly basis. This will be via video-conference call or in person as agreed with NHSE project manager.

#### NHS England will have a project management team in place. The appointed supplier will work with the NHS England project management team for the duration of the contract.

#### NHS England will monitor progress against agreed milestones and help troubleshoot any arising issues.

#### The appointed supplier will be required to report on a regular basis on the following areas:

#### A breakdown of spend to date against projected spend (monthly)

#### Risks and issues (bi-weekly)

#### Progress against anticipated milestones and key deliverables (bi-weekly for the first month and monthly later)

* + - 1. Progress reports will need to be sent 2 days prior to the scheduled meetings.

#### The appointed supplier will be responsible for complying with all performance management requests from NHS England as outlined in sections 3.6 and 3.7.

#### The appointed supplier will be responsible for the overall project management. This will include the production of materials and set up of stakeholder meetings as necessary.

### Management Information & Governance

#### Strategic progress reports are expected on a weekly basis to the NHS England Research Team in a written form (either in Microsoft Word or PowerPoint formats). The final report is expected in a Microsoft Word format.

#### Operational progress reports will be expected on a weekly basis.

### Performance and Measurement

#### Key Performance Indicators

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **KPI Ref. Number** | **Services that KPI relates to** | **Description of KPI** | **Measurement** | **Delivery Time** |
| KP1 | Tasks 1, 2,  | A detailed description of asset registries covering all potential sources of information, existing medical research charity registries in new registries to be created and interconnected (tasks 1,and 2) within 4 weeks of kick off. | A report detailing the requirements of task 1 and 2 including a comprehensive conclusion of the findings from the mapping and scoping work (tasks 1, and 2). | 4 weeks |
| KP2 | Tasks 3, 4 | A **comprehensive interim** report 8 weeks after the start of the work (kick-off meeting). It will demonstrate the state of progress of the implementation of the action and will be accompanied by the first opinions on the legal and operational feasibility of setting up a connected research volunteer registry.  | Delivery of an interim report. NHSE will comment on the interim report within 10 working days after the date of its reception.  | 8 weeks |
| KP3  | Tasks 5, 7 | A **draft final report** 12 weeks after the start of the work (kick-off meeting) including all elements in Tasks 5 and 7  | Delivery of final draft report | 12 weeks |
| KP4 | Task 5, 6 | A final report addressing comments received from NHSE and colleagues [10 working days allowed for comments to be received] | Delivery of final report for sign off | 16 weeks |
| KP5 | Task 7 | Proof of concept demonstration and alpha build of a white label product | Delivery of a proof of concept and alpha build demonstration by virtual meeting | 14 weeks |

### Contract Term

* + 1. This is a fixed term 16 week assignment of work, which will start on an agreed contract commencement date between NHS England and the appointed supplier with the majority of the deliverables expected to be delivered by week 12 and all deliverables being complete by week 16.

### Budget

#### There is a capped budget of £650k (including VAT) to deliver this work. Bidders will be required to provide a breakdown of their proposed costs against this amount in Document 6 Commercial Schedule.

#### Bids exceeding £650k (including VAT) will not be evaluated by NHS England and will be deemed as ‘non-compliant’. Non-compliant tenderers will therefore be eliminated from the procurement exercise immediately.

### Social Value Requirements

#### This will include the number of people-hours spent supporting local community integration, such as volunteering and other community-led initiatives, under the contract.

#### Plans should include positive actions with community groups.

#### There should be a demonstration of collaboration with patients and the public in the co-design and delivery of the contract where appropriate, to support strong integrated communities.

#### There should also be an understanding of local demographics, needs and opportunities for the co-design for the framework for linking registries delivered under the contract.

#### Measures to involve patients and the public where appropriate in design (e.g., in the design of a white-label front-end, or engagement with users for their input on how their data might be used).

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### Sustainable Development Requirements

#### The NHS is committed to reaching [net zero](https://www.england.nhs.uk/greenernhs/get-involved/suppliers/) by 2040 for the emissions we control directly, and by 2045 for the emissions we influence, through the goods and services we buy from our partners and suppliers.

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#### In April 2022, the NHS adopted the government’s Procurement Policy Note [PPN 06/20](https://www.gov.uk/government/publications/procurement-policy-note-0620-taking-account-of-social-value-in-the-award-of-central-government-contracts) (taking account of social value in the award of central government contracts), making a 10% weighting for net zero and social value compulsory in all procurements, with Fighting Climate Change included in every tender.

#### Though not a requirement for this procurement process, the [Evergreen Sustainable Supplier Assessment](https://www.england.nhs.uk/nhs-commercial/central-commercial-function-ccf/evergreen/) is an online tool designed for suppliers to engage with the NHS on their sustainability journey and to understand how to align with the NHS net zero ambition. The tool will serve as a pathway for communications and data gathering between suppliers and NHS decision makers across NHS organisations and will provide a mechanism for suppliers to showcase their sustainability efforts. **The assessment has not been designed to be included as a scored or evaluated requirement in procurement**.

1. https://www.gov.uk/government/publications/the-future-of-uk-clinical-research-delivery [↑](#footnote-ref-2)
2. https://www.longtermplan.nhs.uk [↑](#footnote-ref-3)