SBRI Healthcare: Accelerated Access Collaborative for development contracts

Competition 21

FREQUENCTLY ASKED QUESTIONS

Eligibility

How does an SBRI competition work?

SBRI enables government departments to connect with technology organisations, finding innovative solutions to specific public sector challenges and needs. It aims to use the power of government procurement to accelerate technology development, supporting projects through the stages of feasibility and prototyping which are typically hard to fund. SBRI offers an excellent opportunity for businesses, especially early-stage companies, to develop and demonstrate technology, supported by an intelligent lead customer.

SBRI Healthcare Phase 3 focuses on the implementation of mature innovations to facilitate adoption by the relevant health or social care providers.

Do I need to have obtained SBRI Healthcare Phase 1 and 2 awards to be eligible for Phase 3?

Phase 3 is a standalone, independent competition and applicants do not require previous SBRI Healthcare awards to be eligible.

How is the SBRI initiative aligned with NHS Digital/NHSx initiatives?

While there are some overlaps, the SBRI Healthcare Phase 3 competition is broader than the NHS initiatives and welcomes application in pathway redesign, in-vitro diagnostics, behaviour intervention, in addition to AI and digital innovations.

Is my company/organisation eligible to submit an application to this competition?

The competition is open to single companies or organisations from the private, public, and third sectors, including charities, based in UK and/or Europe.

Please note, the programme has a strong commercial focus; therefore, it is expected that a clear route to commercialisation, further implementation, and adoption is clearly described irrespective of the type of company/organisation that leads the application.

Is my business eligible to submit an application to an SBRI competition?

Any organisation can submit an application, although it is expected that opportunities presented by SBRI will be particularly attractive for SMEs. SBRI is aimed at organisations working on the development of an innovative process, material, device, product or service. Successful applications will be those whose technology best addresses the specific needs identified, with the potential to make a measurable improvement to currently available products, processes materials, devices or services. Development contracts will be awarded only to individual organisations. However, organisations may also wish to demonstrate that successful collaboration will enhance their overall development. Work may be subcontracted but this is the responsibility of the main contractor.

Can an SME be the primary applicant for the application or does it have to be an NHS trust/organisation? Will the funds be directly allocated to the SME or to the NHS body?

SMEs can be the lead applicant on the application, and collaborate with an NHS provider for the delivery of the implementation study. Funds will be paid to the lead organisation who will be responsible for paying collaborators and subcontractors where applicable.

My organisation is a registered charity, can I apply?

Yes, registered charities are eligible to enter SBRI competitions via their trading company limited by guarantee. All organisations must demonstrate a route to market.

Are organisations registered outside of the UK and European Union eligible to apply?

Legal entities from EU Associated Countries can participate in the SBRI Healthcare Programme.

Legal entities from all other countries may be project partners, but can not be the lead organisation.

What innovations are considered eligible for SBRI Healthcare?

The competition is open to any innovation, including medical device, in vitro diagnostic, digital health solutions and AI solutions, behavioural interventions, and service improvements. All innovations must meet the entry criteria and challenges described in the Challenge Brief.

What is the minimum entry criteria to enter a Phase 3 competition?

The call is open to innovations that are in the advanced stage of development and that should demonstrate they have the following evidence:

- UKCA marked or CE-marked with a clear timeline to achieve UKCA by 01 January 2023. If UKCA, CE-mark or equivalent regulatory approval is not yet obtained, there must be evidence to demonstrate that the innovation is close to obtaining approval and/or a product/solution in use in at least 1 Trust.
- A clear partnership established with the relevant service(s)/site(s) and clinical team(s).
- Clinical efficacy and safety demonstrated through clinical trial(s).
- For digital solutions, evidence that the technology has passed or close to passing the necessary information governance and cyber security requirements where relevant. Evidence that the NHSX Digital Technology Assessment Criteria (DTAC) has been considered should be demonstrated in your proposal.

In addition to fulfilling the entry criteria, it is expected the innovation addresses the challenges described in the briefs.

Can I apply for a SBRI Healthcare award if I have other sources of funding?

Applicants with other sources of funding are eligible to apply to SBRI Healthcare, provided the project that would be funded by SBRI Healthcare is not already supported by another funding stream. Applicants must articulate how the SBRI Healthcare award would be distinct from the existing study and what additional evidence would be collected to support implementation and adoption of the proposed innovation.

Can I apply if regulatory approval (e.g. CE mark, UKCA) for my innovation is pending?

For medical devices/IVDs, a CE/UKCA mark is a pre-requisite for this call on Implementation. However, given the recent challenges of getting a CE/UKCA mark, we will also welcome applications with a 'near' CE/UKCA mark, where the technical file has been submitted to an Approved Body for conformity assessment and a decision is pending at the time of the SBRI application with a clear milestone for approval.

Can I apply with innovations that address more than one challenge sub-category?

Innovations that address more than one challenge sub-category are eligible. Please select the most appropriate sub-category in the application form. There is no advantage for selecting one sub-category over another. Please note, given that SBRI Healthcare Phase 3 has a focus on implementation, applicants are encouraged to considered what evidence could be feasibly collected within 12 months, the maximum duration of the award.

Project partners

Do I need to have a clinical partner for the application?

While it is not essential to have a clinical partner, it is strongly advised that you do, particularly for SBRI Healthcare Phase 3. The most successful applicants demonstrate an existing relationship with a named clinician or similar expert at the time of application. Ideally this will be a named member of staff with whom you have had at least initial discussions about the feasibility of your project.

What resources are available to help me find a clinical partner?

You may reach out to the AHSN to help facilitate conversations with the relevant clinical experts. The NIHR Office for Clinical Research Infrastructure (NOCRI) can also help connect you to experts in the NIHR research facilities and facilitate collaboration between your company and clinicians.

Do I need to partner with an AHSN to be eligible to apply?

It is not an eligibility criterion to partner with an AHSN; however, it is strongly encouraged that you do. The AHSNs are uniquely positioned to support the development of health innovation and, by partnering with them, you can tap into their knowledge, expertise and networks to support the spread and adoption of your technology. Any organisation based in the UK (including Scotland, Northern Ireland and Wales) can access the AHSN. To find out more information on the AHSNs and their contact details, you can visit their website here.

Evidence

Would clinical evidence gathered in other parts of the world be considered appropriate for this application?

The clinical evidence can be derived from anywhere in the world and would be considered as appropriate, provided there is clear evidence that this is applicable to the chosen NHS care pathway in the UK. Irrespective of where the evidence was derived, applicants should ensure the innovations are suitable for or could be adapted for the NHS or the relevant care provider in the UK.

Our technology can be applied to different clinical questions, do we need to show experimental data specific to the proposed condition or environment?

Innovations that can be repurposed from other clinical areas are eligible to apply, provided that it meets the entry criteria and there is sufficient evidence to demonstrate its applicability to the challenges.

My innovation was developed with the NHS clinical teams without public and patient involvement (PPI), am I eligible to apply to this competition?

While the programme appreciates that innovations may require different level of PPIE during development, it is expected that the organisation has involved patients/members of the public during the research and development phase.

There should be continued PPIE planned as part of the project, to ensure that patients and members of the public are involved and can provide feedback that will support the refinement of the innovation during the implementation stage, and this should be clearly described in the application.

Are innovations developed for social care and adopted by the local authority eligible for the competition?

Yes. We recognise the importance of innovations designed for the community, education, or home environment in addressing health challenges, and would welcome applications for these innovations provided they meet the entry criteria.

Do clinical trial studies need to take place in the UK?

Although this is not an eligibility criterion, it is strongly advised to carry out any clinical trial studies in the UK as the SBRI Healthcare programme acts a pre-procurement programme and the objective

of this competition challenge is to address NHS health needs. As such, it will be expected that any evidence generated can be translated to demonstrate the technology's applicability to be adopted into the NHS.

What is EDI and what is expected?

Equality, Diversity and Inclusion (EDI) is one of the assessment criteria. EDI can vary depending on the innovation and the proposal, however it is expected that any organisations consider an equal, diverse and inclusive approach to their activities and implementation studies.

In general, applicants are also expected to analyse the impact of their technologies on the wider population and people with protected characteristics, underserved and underrepresented population and to consider geographical reach.

Applicants can find more information on what could constitute health inequality on The King's Fund website.

What are the expected exit points of SBRI Healthcare Phase 3 projects?

The aim of the funding is to generate real-world evidence to support rapid local or regional roll out of the innovation. Awarded proposals are expected to demonstrate some of the following exit points upon project completion:

- Implementation effectiveness demonstrated
- Partnership developed for implementation in multiple sites
- Registration to HealthTech Connect / NHS Innovation Service
- Evidence of health and financial impact: health economics analysis (i.e., cost benefit analysis, budget impact model)
- NHS Business case
- Demonstrated impact (clinical/transformation/clinical pathway)
- Climate sustainability assessment
- Equality and Health Inequalities impact assessment
- Other relevant evidence to ensure local adoption following project completion, facilitating adoption further afield (e.g. scaling-up plan and strategic plan towards adoption and spread, marketing tools development)

Finance

What activities are funded under Phase 3?

Phase 3 projects should concentrate on implementation of the innovation in the relevant setting and collect the evidence that will facilitate subsequent adoption, procurement, or recommendations in official guidance. Activities that would be supported include, but are not limited to:

- Implementation studies
- Human factors
- Technology refinement
- Developing partnership with the relevant NHS, health or social care setting, or other providers.

- Health economics and cost benefit analyses
- Activities in relation to Intellectual Property, freedom to operate and market analysis
- Activities associated with the dissemination of outputs

SBRI Healthcare Phase 3 does not support proposals to procure products or services **without** the intention to generate evidence to support implementation and subsequent adoption.

What are the budgets available to each challenge?

The two challenges under Competition 21 will be assessed separately by the relevant subject experts and recommendations for funding will be based on the overall quality of the applications. There is not a ringfenced amount allocated to the specific challenges.

As a university, should I use Full Economic Cost (FEC)?

No. Costs should be calculated to reflect fair market value.

Can we apply for funding to support UKCA/CE mark in the application?

As CE/UKCA mark is a prerequisite for this call on Implementation, the funding would not cover regulatory marking costs. However, the funding can partially cover activities related to transitioning to UKCA.

Should project costs include VAT?

The maximum allowable budget of Phase 3 awards is £500,000 excluding VAT and applications must list project costs exclusive of VAT. Please note that SBRI is a pre-commercial procurement process, and the resulting development contract is subject to VAT. If VAT is applicable, this may be included in addition to the award when invoicing SBRI Healthcare. It is the responsibility of the invoicing organisation to determine whether VAT is applicable.

Can overheads be included in project costs?

An element of overheads may be included in project costs. However, such an element must be realistic. Assessors will consider financial costs in terms of 'value for money' at the assessment stage. Projects showing costs that are considered unreasonable will be rejected on these grounds.

Can I sub-contract work outside of England or the UK?

Sub-contractors may include contract research organisations, consultants, manufacturers (this is not an exhaustive list). In principle this is possible, as long as the applicants demonstrate how this will benefit UK healthcare and economy.

Administrations

How do I submit my application?

All bids must be submitted using the Programme Management Office Research Management System (RMS). You must create a login using your email address and a password. Details of the challenge and expected outcome of the projects can be found in the project documents. You are strongly advised to read all published competition documents before completing the application form.

Can each organisation submit more than one application?

Organisations are welcome to submit more than one application if they have multiple innovations that address the challenge brief and meet the entry criteria. However, there must be significant differences between the innovations submitted to this competition and consideration towards resources needed to deliver the projects.

How will successful applications be chosen?

Proposals will be firstly shortlisted after an assessment process performed by technical, clinical and commercial experts. The shortlisted applicants will be invited to an Interview Panel to present their proposals and the projects will be selected by an expert group of Panel Members against the criteria described in the invitation to tender document.

When will I find out if my application has been successful?

All applicants will be informed after assessments have concluded. We anticipate the outcome will be announced in November 2022.

Who owns the intellectual property generated by the project?

Intellectual property rights are retained by the applicant, although certain rights of usage may be applied by the funding authority including royalty-free, non-exclusive licence rights and the right to require licenses to third parties, at a fair market price.

When is the deadline for application?

13:00 (BST), 26 July 2022.