



# SBRI Healthcare: NHS England and NHS Improvement competition for development contracts

Competition 18 - Stroke and Technology

#### FREQUENTLY ASKED QUESTIONS

#### 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 is a simple structured process. Typically competitions are structured in two phases.

Phase 1 proposals concentrate on that research and development which will significantly contribute to proving the scientific, technical and commercial feasibility of the proposed project. The results of Phase 1 determine whether the solution should go further to Phase 2, however not all projects will progress to Phase 2. The principal research and development effort takes place in Phase 2, which aims to produce a well-defined prototype. At the end of Phase 2 it is intended that what has been developed will be manufactured and marketed as a way of fulfilling requirements.

#### 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.

#### I am a pre-startup company, may I apply?

Yes, but contracts must be awarded to legal entities.

#### I am based at a university, may I apply?

Universities may apply, however they must demonstrate a route to market, i.e. the application must include a plan to commercialise the results. It is unlikely that a university will be able to demonstrate the appropriate level of commercialisation to be successful beyond Phase 1, therefore the application should explain how the product will be developed by a commercial organisation.

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

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

#### My company is a registered charity, can I apply?

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

### Do I need to have a clinical partner and do they need to be identified prior to Phase 1 submission?

It is strongly advised that you do. 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 NHS member of staff with whom you have had at least initial discussions about the feasibility of your project.

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

It is not an eligibility criteria 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.

### What is the minimum entry point for a Phase 1 award and what activities are fundable under a Phase 1 award?

Projects must have already demonstrated proof of concept as a minimum (TRL 3). Applicants are expected to have generated experimental data to support the case for further development and illustrate technical feasibility. Early stage research or discovery science is not fundable.

Phase 1 proposals should concentrate on research and development activities that will contribute to proving the scientific, technical and commercial feasibility of the proposed project. We fund a broad range of activities under Phase 1, these include but are not limited to:

- Feasibility studies
- Safety and effectiveness studies, including first-in-man and pivotal clinical studies
- Clinical utility studies, looking at the technology's usability, tolerability and user acceptance.
- CE/UKCA marking and other regulatory requirements
- Activities in relation to intellectual property protection, freedom to operate and market analysis or business case development, including plans for commercialisation and NHS adoption
- Health economic analyses and modelling
- Activities associated with the dissemination of outputs
- Identification of relevant stakeholders and/or partners to support the next stages in the development

#### 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 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.

# Our technology is agnostic and can be applied to different clinical questions other than stroke, do we need to show experimental data specific to this disease area to be eligible to apply?

Technologies that have been repurposed from use in other clinical areas are eligible to apply if there is sufficient evidence to demonstrate its applicability to stroke. This is dependent on the evidence generated for your innovation and the proof-of-concept data available.

If you would like to discuss your project in more detail, please contact us at sbri@lgcgroup.com.

#### How do I submit my application?

All bids should be made using the SBRI Healthcare portal which can be accessed via the competition pages of the SBRI Healthcare website www.sbrihealthcare.co.uk.

You must create a login using your email address and a password, via the 'Apply Now' link on the competition page.

Please note: SBRI Healthcare now uses the Programme Management Office Research Management System (RMS).

Please note that all project partners should be invited to the application through the system via email to participate as co-applicants after which they must both confirm and approve their participation; the application cannot be submitted without doing so.

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.

A Briefing event for businesses interested in finding out more about the competition was held on 17 June 2021. Please check <a href="https://www.sbrihealthcare.co.uk">www.sbrihealthcare.co.uk</a> for further information on the competition page.

### If my application fits more than one sub-category theme, can I apply to more than one?

Applications may fit multiple sub-category themes however, you may only select 1 category on the application portal so please select the most appropriate. The funding envelope is for the entire competition rather than specifically split between challenges or themes, so there is no advantage or disadvantage to selecting a specific sub-category theme.

#### What is the deadline for applications?

13:00, 24 August 2021.

#### How will the successful applications be chosen?

Proposals will be selected by an expert group of selected assessors and a final assessment panel. Phase 1 applications are reviewed by a pool of experts covering clinical, technical and commercial expertise. Up to 25 applications are shortlisted in the first round of assessments. Following shortlisting, applicants are invited to submit a video pitch to support their application which is reviewed by a Panel of experts and patient/public representatives. Applications are then selected to receive Phase 1 funding.

For more information on the application and assessment process, please refer to the <u>Invitation to Tender</u> and launch <u>webinar presentation slides</u>.

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

All applicants will be informed shortly after the assessments have been concluded. Applicants are expected to be notified on whether their proposals have been shortlisted in September 2021 and final outcome letters are expected to be released early November 2021.

### What are the requirements for the supporting video pitch to be submitted for the Panel meeting?

If your application has been shortlisted, you will be required to submit a video pitch to support your application assessment at the Panel meeting. The video should be <u>no longer than 3 minutes</u> and in MP4 format. Please upload the video on the file sharing platform of your choice and send the video link to SBRI@lgcgroup.com.

The deadline for the submission of the video pitch is 14 October 2021.

## Will stroke patients be expected to be consulted before applications are submitted and will they be part of the assessment Panel?

We expect applicants to have had an appropriate level of engagement with patients and the public prior to applying to the Programme in the development of their technology/intervention and to have collected sufficient evidence that demonstrates user acceptability, usability and validity.

We also highly encourage applicants to involve patients and members of the public in the development of their application and also to have an appropriate patient and public involvement and engagement (PPIE) plan going forward to ensure that the proposed approach is suitable and acceptable for patients.

There will be patient and public representatives in the assessment Panel.

# Where can we engage with stroke survivors and do you offer any support with patient and public involvement and engagement activities?

This competition call is being supported by Stroke Association and they can provide support with getting access to stroke survivors and can provide advice on conducting patient and public involvement activities.

For more information on involving stroke survivors in your research and how Stroke Association can support you please read this document.

### Do I need to have a Phase 1 award to be eligible for Phase 2 or can I apply directly to Phase 2?

Companies must first apply and be successful in securing Phase 1 funding in order to have access to Phase 2. Applicants cannot apply to Phase 2 directly. The aim is to de-risk projects and allow organisations to deliver feasibility work to make a stronger bid for Phase 2. The current open call is to apply for Phase 1 funding and an opportunity to apply for Phase 2 will follow after 6 months for those that were successful in securing Phase 1 funding.

#### 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.

#### Can I work in collaboration with other companies?

Contracts will only be awarded to individual organisations. However, applicants may identify components of the work which they wish to subcontract and may also employ specialist consultants or advisers if they believe this will increase the chances of the project being successful.

## What is the best way to find project partners (commercial partners or clinical partners)?

We strongly advise that you get in touch with your AHSN to develop partnership and get advice. You can also contact your local University. Alternatively the <u>signposting service</u> can help you find the right partners.

#### Should project costs include VAT?

Yes. The SBRI is a pre-commercial procurement process and the resulting development contract is subject to VAT. Therefore the maximum allowable budget also includes VAT. VAT is the responsibility of the invoicing business, and it is required that applications will list total costs inclusive of VAT. Should you consider you are VAT exempt then you may quote without VAT but you will not at a later date be able to increase invoice values to cover VAT.

#### 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.

#### I am based outside of England, can I apply?

We accept applications from any country in the European Union, including associated countries for EU Research and Innovation. However, please be aware that projects must show a clear health benefit to the UK.

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

In principle this is possible, as long as the applicants demonstrate how this will benefit UK healthcare and the economy.

## I am part of a large company (i.e. not an SME). Is there a disadvantage applying as a big company or would we require an SME partner?

There is no disadvantage in applying as a big company. The key issue is to demonstrate that the right expertise is available for the support of the project (e.g. if a trial is included the involvement of a healthcare provider would be expected.)

#### Can we apply to Phase 1 funding for longer than 6 months duration?

No, the maximum project duration is not negotiable and cannot be extended for funded projects.

#### Who should I contact if I have any further questions?

Questions on the specifics of this competition should be sent to <a href="mailto:sbri@lgcgroup.com">sbri@lgcgroup.com</a>.

Questions on the overall SBRI programme should be addressed to <a href="mailto:support@innovateuk.gov.uk">support@innovateuk.gov.uk</a>.