



## **SBRI Healthcare: Cancer Programme – Competition 1**

### **FREQUENTLY ASKED QUESTIONS**

#### **How does an SBRI competition work?**

SBRI enables government departments to connect with innovation organisations, finding innovative solutions to specific public sector challenges and needs. It aims to use the power of government procurement to accelerate innovation development, supporting projects through the stages of feasibility and prototyping which are typically hard to fund.

The Cancer Programme competition is delivered by NHS England and NHS Improvement in partnership with SBRI Healthcare. This competition will focus on the implementation of late stage 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. However, clinical sites must be based in England.

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.

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

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

#### **Is the collaboration with a Cancer Alliance mandatory for this competition?**

Involvement of Cancer Alliances is not mandatory, but strongly encouraged. Please note that every NHS Trust in England is associated with a Cancer Alliance. As each Cancer Alliance has their own focus, it is encouraged that the applicants investigate and determine the alliance that is best positioned to support the proposed innovation. Please use this [link](#) for a list of Cancer Alliance websites and contacts.

### **Do I need to have a clinical partner?**

It is strongly advised that you do. The most successful applicants often have an existing relationship with named clinician(s) or similar expert(s) at the time of application. The clinical partner(s) will likely help you develop the clinical aspect of the project, identify suitable NHS Trusts or Cancer Alliances, and build the relationship with the chosen clinical sites. Although clinical partners can be based anywhere in Europe, it is strongly recommended that the clinical partner is based in the UK to ensure the project is appropriately delivered in the NHS setting. Clinical partners outside of the UK will need to be fully justified. Clinical sites must be based in England.

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. Please note, the project team's skills is one of the assessment criteria, and sufficient detail should be provided to assure the Panel that the project team will have the appropriate expertise to plan and deliver the project.

### **Do I need to have identified all of the implementation sites within my application?**

No. If applicants have not identified all participating sites at the time of application, NHS England's Cancer Programme Team can facilitate interactions with the appropriate Cancer Alliances and hospital trusts to identify potential sites for the project if the application is awarded. Applicants are advised to provide realistic total cost estimates for sites that are not yet on board when submitting the application.

After the award, NHSE might also connect funded innovators with additional appropriate sites to supplement and/or complement those proposed in the application.

### **Are early detection innovations eligible to apply for this competition?**

Early detection innovations (medical device, in vitro diagnostic, digital health solutions, behavioural intervention, software, hardware, technology, new models of care) that are CE marked (or equivalent) and/or in use/have been used by at least 1 NHS Trust are eligible (This can be in a research setting).

### **What are the entry criteria of innovations for this competition?**

The call is open to innovations that have CE mark or equivalent regulatory approval obtained, and /or be in use in at least 1 Trust (use in a large-scale research study would qualify for this criterion). In addition, we expect the innovations to have already proven their clinical effectiveness and are ready to be rolled out locally or nationally for real world testing.

### **Will the Cancer Programme prioritise funding for certain types of innovations or innovations that target certain cancer types in this competition?**

The Programme is cancer agnostic and will consider all innovations that address the challenge brief. Eligible innovations for this competition include medical device, in vitro diagnostic, digital health solutions, behavioural intervention, software, hardware, technology, and new models of care. Awards will be made based on the assessment criteria detailed in the Invitation to Tender document.

**Are Artificial Intelligence innovations eligible to apply for this competition?**

AI software that address the challenge brief are eligible. However, the AI in Health and Care award was established to specifically support AI innovations and we would recommend applicants to consider this and other similar funding schemes in the first instance. For AI innovations to be eligible for this competition, the proposed innovation must be at the appropriate stage of development, have not secured funding from the AI in Health and Care Award, or has significantly changed since rejection.

The SBRI Healthcare PMO will conduct an overlap check on the applications.

**Are innovations that focus on interventions or support/improve outcomes of cancer patients eligible for the Cancer Programme competition?**

This competition focusses on improving early detection and diagnosis, and diagnostic service. Innovations that support intervention and improving outcomes in patients living with cancer are not within the scope of this call.

**Will early detection liquid biopsy innovations be considered given the ongoing GRAIL Galleri blood test pilot?**

Liquid biopsy innovations will be considered if they meet the criteria described in the challenge brief. It is strongly encouraged that applicants should provide sufficient detail to describe how their innovation would provide a competitive advantage over other solutions in the current care pathway or are under development.

**Is obtaining UKCA certification of an existing innovation in use in one NHS Trust an eligible component of applications?**

Considering the timelines for this first competition and project duration, projects might end before UKCA certification becomes a requirement. There is an understanding that UKCA registration will be needed at some point for technologies that have existing regulatory approvals, and this can be discussed if the problem arises. Therefore, the main focus of the proposals should be real world implementation studies, and not activities to gather evidence for regulatory approvals.

**Will support be provided for innovations seeking adoption in locations other than the pilot location, e.g. taking innovation from one Cancer Alliance and implementing in another?**

Support will be provided to applicants if the innovation was being piloted by the Cancer Alliance in order to accumulate data to support more wide-spread implementation. Support will be provided to scale up innovations, including across multiple Cancer Alliances. Applicants should consider what data would need to be collated to support more wide-spread implementation, for example addressing implementation barriers.

**Can confirmatory guidance on specific clinical pathways in advance of application submission be provided?**

Applicants can make a brief enquiry relating to specific clinical pathways before submitting their application.

**Will patient and primary care education aimed to improve diagnostic referral rate be supported through this competition?**

Innovations that support primary care education and behavioural interventions to improve diagnostic referral rates for early cancer diagnosis, are within the scope of this competition.

**How do I submit my application?**

All bids must be submitted using the Programme Management Office Research Management System (RMS), which can be accessed on the competition page. 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.

**When is the deadline for applications?**

13:00, 21 April 2021.

**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. There must be significant differences between the innovations submitted to this competition.

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

Proposals will be selected by an expert group of Panel Members based on peer review comments and an interview assessment 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 shortly after the assessments have been concluded. We anticipate that outcome will be announced in August 2021.

### **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.

### **Do SBRI contracts constitute state aid?**

No. Where public authorities buy R&D from organisations at a fair market price, not for their exclusive use and where the competition is advertised in an open market, there is no advantage and consequently no element of state aid.

### **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.

### **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. However, all clinical sites must be located in England.

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

Applications may fit multiple challenges and you may select both challenges on the application portal. 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-theme.

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

Questions on the specifics of this competition should be sent to [sbri@lgcgroup.com](mailto:sbri@lgcgroup.com). Questions on the overall SBRI programme should be addressed to [support@innovateuk.gov.uk](mailto:support@innovateuk.gov.uk).

**Can you give a bit more information on the level of evidence you think is needed to be successful? Is it tied to proving that stage shift would occur with implementation of the innovation?**

Applicants should provide sufficient evidence to demonstrate that the innovation can address one, or both, of the challenges, and can demonstrate advantages compared to current standard of care.

**Do I need to make separate applications for each Cancer Alliance I work with?**

Please submit one application per innovation, irrespective of the number of Cancer Alliances that are involved in the project. The lead organisation may involve as many clinical sites as necessary, subject to justification and that it is realistic, in the project proposal.

**Can a Cancer Alliance submit a bid?**

The lead organisation of an application must be a legal entity. Cancer Alliances are generally not legal entities and are hosted by NHS Trusts.

**Can Cancer Alliances help identify primary care partners/sites for projects?**

Applicants may contact Cancer Alliances to identify suitable primary care partners/sites. Please see a list of Cancer Alliances and their contacts using this [link](#).

**It is essential to include an AHSN as a partner in the application?**

The AHSNs have expertise to help with the commercialisation and deployment of innovations. However, it is recognised that similar expertise can be provided by other entities. Therefore, it is not essential to include an AHSN on the application and application assessment would be determined by the project team's composition and expertise.

**Can we apply for funding to test an existing innovation on a new patient cohort/disease area?**

Provided the innovation meets the specification detailed in the challenge brief and the entry criteria, you may submit an application. However, applicants must ensure that there is sufficient existing evidence to suggest the innovation is effective for the proposed patient cohort or disease area. Innovations without evidence in the proposed patient cohort or disease area are not eligible.

**Would clinical evidence gathered in other parts of the world be considered as 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 cancer patients in England. Irrespective of where the evidence was derived, applicants should ensure the innovations are suitable for or could be adapted for NHS use.

**Will the programme view projects with geographical spread in England for implementation more favourably than regional or limited centre implementation?**

The programme would consider both local and national implementation projects. Awards will be made based on the assessment criteria detailed in the Invitation to Tender document.

**Can I apply if the CE marking (or similar regulatory approval) for my innovation is pending?**

Regulatory approval is one of the eligibility criteria. If the innovation has not been in use by at least one NHS Trust (this can include in a research setting), or demonstrated its clinical effectiveness, then it must be CE marked (or equivalent). If the application for CE mark has been submitted by the application deadline, you may apply to the programme, but regulatory approval must be obtained and the SBRI Healthcare PMO notified by 25<sup>th</sup> May. Otherwise, the application will be rejected based on eligibility.

**If an innovation has received funding previously and is currently part of other formal research projects, would this exclude the innovation from this challenge?**

The Cancer Programme will not fund the same project that is supported by other funders. If the proposed project is sufficiently different to an existing project, and meets the challenge brief and eligibility criteria, you may submit an application. However, any funding overlap should be made clear in the application.