Challenge Brief

What do you mean by 'impact on earlier diagnosis'?

The NHS Cancer Programme at NHS England and NHS Improvement (NHSEI) are looking for innovations or new approaches that will increase the proportion of cancers that are diagnosed at stage one or two. More information on the challenge areas can be found in the challenge brief.

What are the relevant healthcare settings for this call?

The NHS Cancer Programme welcomes applications from any setting, provided the innovations address the challenge brief and meet the entry eligibility criteria. There is no preference for primary, secondary, tertiary, or community care.

Will the NHS Cancer Programme prioritise funding for certain types of innovations or innovations that target certain cancer types in this call?

The call is cancer agnostic and will consider all innovations that address the challenge brief. Eligible innovations for this call include medical device, in vitro diagnostic, digital health solutions, behavioural intervention, software, artificial intelligence, and new models of care. Applications from multi-cancer innovations which could have a bigger impact on early diagnosis rates are particularly welcome. Awards will be made based on the assessment criteria detailed in the Invitation to Tender document.

Is this call looking for replacements for current standard of care or additive tests?

Innovations offered as an additional test or a replacement for current standard of care are both eligible. Applicants are strongly encouraged to consider how the innovation could be rolled out and implemented in the NHS, and the competitive advantages over current practice.

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.

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

Innovations that support primary care education and behavioural interventions to improve diagnostic referral rates for early cancer diagnosis, are within the scope of this call. Innovations that are targeting generic online educational tools for GP are not in scope.

Can I apply for this call to obtain regulatory approval (e.g. UKCA certification) of an existing innovation that is in use in one NHS Trust?

The main focus of the proposals is real world implementation studies to gather evidence for adoption in the NHS, and not activities to gather evidence for regulatory approvals. There must be appropriate regulatory approvals already in place to allow adoption. However, applicants can

consider including regulatory work packages to meet new or emerging regulatory requirements if these would strengthen their case for adoption and spread.

Eligibility

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

The call 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, commercialisation is one of the NHS Cancer Programme's scoring criteria; therefore, it is expected that a route to commercialisation, further implementation, and adoption is clearly described irrespective of the type of organisation leading the application.

Can a Cancer Alliance submit an application?

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

What are the entry criteria of innovations for this call?

The call is open to innovations that have CE mark or equivalent regulatory approval obtained, and /or are in use in standard routine care in at least 1 Trust. 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.

Can I apply if the CE marking (or similar regulatory approval) for my innovation is pending or marked for a different use?

Regulatory approval is one of the eligibility criteria. If the innovation has not been in use by at least one NHS Trust as a standard of care (non-research), then it must be CE marked (or equivalent) if applicable. 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 for the specific use intended and PMO notified by **24th June 2022**. If regulatory approval has not been obtained by the 24th June 2022, the application will be rejected based on eligibility.

Are diagnostic technologies that improve diagnostic efficiency and free up resources eligible for this call?

Innovations focusing only on increasing diagnostic efficiency and to free up resources are not eligible for this call. However, applicants are encouraged to consider the impact of their innovation on the current patient pathway. If an innovation to improve diagnostic efficiency tools is deployed alongside the innovation to improve early diagnosis, appropriate standards must be in place.

Are innovations providing educational or clinical decision support to healthcare professionals eligible?

In principle, any innovations that address the challenge brief and meet the entry criteria are eligible. However, applicants must provide evidence to demonstrate their proposed innovation can improve diagnosis of cancer at stage 1 or 2. If the educational or clinical decision support tools are intended

for primary care use, applicants must demonstrate that their innovation can improve conversion from GP referrals to diagnosis.

Are innovations that focus on prevention or support/improve outcomes of cancer patients eligible for the NHS Cancer Programme Innovation Open Call?

This call focusses on improving early detection and diagnosis of cancer. While cancer treatment and prevention of primary and secondary cancers are important areas for NHS England and NHS Improvement, these are not within the scope of this call.

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

The innovation must meet the specification detailed in the challenge brief and the entry criteria. Applicants must ensure that there is sufficient existing evidence to suggest the innovation is effective for the proposed patient cohort or disease area and that there is regulatory approval for the innovation to be deployed for the proposed new patient cohort.

Innovations without evidence in the proposed patient cohort or disease area are not eligible.

If I was unsuccessful in the first competition, can I apply to the second call?

Yes. Please ensure the feedback provided in the outcome letter is taken into consideration when you prepare the new proposal.

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 NHS Cancer Programme Innovation Open Call 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.

Clinical partners, Contractors, and Other Partners

Is it mandatory to work with the company that developed the innovation?

If the proposal is coming from the NHS, HEI, or other organisations, involvement of the company that developed the innovation is not mandatory, but strongly encouraged, as this could address some implementation barriers, which can be key contributors to the adoption and spread of the findings associated to innovations.

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?

While implementation of existing technology at additional locations are suitable for this call, procurement exercises are not appropriate for this open call. Projects looking at scaling up adoption to multiple locations must include considerations on how the innovation would be implemented, how to address existing implementation barriers, and what additional evidence is needed and can be collected to facilitate wider adoption of the innovation into routine care.

Do I need to have a clinical partner?

Given the nature of the projects expected for this call, 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 in this project 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 composition of the project team 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.

Is the collaboration with a Cancer Alliance mandatory for this call?

Involvement of Cancer Alliances is not mandatory, but strongly encouraged. The Cancer Alliances have cancer expertise and will be able to facilitate links to NHS Trusts and expert clinicians within their area. Please note that every NHS Trust in England is associated with a Cancer Alliance. As each Cancer Alliance has their own priorities, applicants are encouraged to investigate and determine the Cancer Alliance that is best positioned to support the proposed innovation. Please use this link for a list of Cancer Alliance websites and contacts.

Applications will be assessed on the project team's composition and expertise.

Is the collaboration with an AHSN mandatory for this call??

Involvement of AHSNs is not mandatory, but strongly encouraged. The AHSNs have expertise to help with the commercialization and deployment of innovation.

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.

Applications will be assessed on the project team's composition and expertise.

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. If you are working with more than one Cancer Alliance, please clearly state each of their roles in the application.

Is there a forum for local innovations that are currently supported by the Cancer Alliances to be shared and assessed for implementation in other parts of the country?

There is no formal forum for sharing local innovations between Cancer Alliances, however a matchmaking event is being hosted on the 24th March to initiate conversations with organisations and Cancer Alliances. Please register your interest to participate in the event here.

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.

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

Sub-contractors may include contract research organisations, consultants, and manufacturers (this is not an exhaustive list). The applicants must demonstrate how this will benefit UK healthcare and economy. All clinical sites must be located in England.

Assessment criteria

What are the requirements of the independent evaluation and what is considered independent?

All projects are required to complete an independent (service) evaluation as part of the project within the duration of the project. You must demonstrate your evaluation is robust and can undergo independent scrutiny. The evaluation should be delivered by an independent organisation from the study team. Further information on the requirements of the independent evaluation are provided in the applicant's guidance.

Can you provide more information on the level of evidence you think is needed to be successful?

Applicants should provide sufficient evidence to demonstrate that the innovation can address the challenge, provide clear clinical benefits, and can demonstrate advantages compared to current standard of care. Where applicable, clinical efficacy and effectiveness should be referenced and verifiable.

Is there a pre-defined metric for measuring impact on cancer diagnosis?
There are a number of domains that can be used to define impact in this context, and applicants should consult the applicant and portal guidance to provide the required information needed to assess their innovation's potential impact through:

- Cancer detection in asymptomatic population
- Improving screening uptake/adherence
- Proactively target/stratify patients
- Encourage patients to present earlier
- Increasing referrals
- Rule out/in for lower risk patients

Will the call priortise projects with a geographical spread in England?

Both local and national implementation projects will be considered. Awards will be made based on the assessment criteria detailed in the Invitation to Tender document.

Would clinical evidence gathered in non-English sites and outside the UK 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 meet the challenge brief, entry criteria, and are suitable for or could be adapted for NHS. The site(s) for the proposed project must be in England.

Finance

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

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

Should project costs include VAT?

The call is a pre-commercial procurement process and the resulting development contract is subject to VAT. While the applicants must submit the NET cost (excluding VAT), it is the invoicing business's responsibility to determine whether VAT should be applied in invoices.

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.

General Information

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 call 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 call documents before completing the application form.

When is the deadline for applications?
13:00 GMT, 24 May 2022.

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 call.

How will the successful applications be chosen?

Proposals will be selected by an expert group of Panel Members based on peer review comments, impact analysis by NHSEI, 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 after the assessments have been concluded. We anticipate the outcome will be announced in October 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.

Does the NHS Cancer Programme contract 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 call is advertised in an open market, there is no advantage and consequently no element of state aid.

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

Applicants can make an enquiry at sbri@lgcgroup.com relating to specific clinical pathways before submitting their application. Applicants are invited to attend the Q&A session on 05 April 2022, which will provide an opportunity to have an one to one session with the NHS Cancer Programme and PMO teams. You may register your interest to attend the Q&A session using the relevant link on the website.

Where can I find additional information about the NHS Cancer Programme Innovation Open Call?

Additional information will be published on the competition website as they become available. Applicants are encouraged to consult with all published materials when completing their application to ensure that the appropriate information is provided to assist with the assessment process.