Logo of the innovation company

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**NHS Cancer Programme Innovation Open Call**

Scoping Plan

MM/YYYY

## Current context and scope of project

The NHS Cancer Programme Innovation Open Call is an investment funded by the NHS Cancer Programme at NHS England and NHS Improvement. The NHS Cancer Programme Innovation Open Call runs a competitive process to identify global market-ready solutions and support implementation with a financial commitment to the supplier.

The aims of the programme, as part of the wider NHS Cancer Innovation Programme are:

* + Identify and prioritise innovations that will have an impact on the Long Term Plan ambitions for cancer.
	+ Fund real world implementation pilots of prioritised innovations to speed up the pathway to implementation and support large scale roll-out.
	+ Create an evidence base to enable faster adoption and scale-up of innovations.
	+ Enable and support industry to work with the NHS.

The programme supports real world implementation studies at local, regional, and national levels; and will generate evidence as part of a robust evaluation to support further roll-out.

The primary purpose of the evaluations is to help determine whether the innovation should be adopted across the health and social care system in England, and if so, build the evidence base required to support a national roll-out.

This scoping plan sets the foundation of the initial engagement between [evaluation partner name] and [company name], dated and signed when the scope is agreed. Note that the suggestions in this document are non-exhaustive, further ones might be uncovered.

## [Innovation name]

[Short description of the company and problem the innovation addresses. Description of the innovation itself and any innovative elements]

[Adherence to standards/regulatory approvals to demonstrate the stage the innovation is at, if relevant]

[Define the clinical problem]

### Population

As the purpose of the evaluation is to assess the innovation suitability for national roll-out or widescale deployment, understanding its applicability across the England population will be crucial.

[Patient population intended for the innovation

This sub section should describe:

* the population subgroups, health inequality considerations (access to care, outcomes)
* the variability in patient population across the UK
* the population profile in the sites of deployment
* how representative is the sites’ population compared to the national patient population. If not representative, what could be the impact on the evaluation findings and what steps will be undertaken to mitigate this]

### Intervention

[Description of the intervention to be evaluated

* Main features
* Fit in the clinical pathway and setting (description of the changes needed in the current clinical pathway and current setting to implement the innovation)
* Integration: hardware/software, need for training]

### Comparator

[Description of the comparator for the innovation in the NHS

This sub section should describe:

* Established current practices and current clinical pathways.
* Limitations/gaps in the current practice when compared to the clinical guidelines
* Variability in practices and clinical pathways: process, IT systems, clinical team, metrics used for reporting
* Practices and clinical pathways in the deployment sites
* An assessment of the differences between current practices and the intervention at deployment sites.
* Anticipated differences in patient outcomes between current practices and pathways and sites receiving the deployed intervention.

### Theory of Change (Logic Model)

Developing a robust evaluation is dependent on having a thorough understanding of what it is the programme or policy is trying to achieve and how. This may be referred to as the **logic** or **theory** behind the programme of work, which sets out the problem being addressed (**rationale**), what the programme sets out to achieve, and how it is going to achieve (**inputs**) the desired **impacts** through a series of **activities** and expected **outputs** and **outcomes**.

[Include a theory of change model]

*Please create a diagrammatic representation of the relationship between the innovation resources, activities and intended outcomes. This logic model should provide a clear description of the intervention and its causal assumptions. Information on how to develop a logic model can be found* [*here*](https://www.gov.uk/government/publications/evaluation-in-health-and-well-being-overview/introduction-to-logic-models)*. A template logic model has been provided.*

*Please use the logic model template to list the:*

* *Rationale*
* *Inputs*
* *Activities*
* *Outputs*
* *Outcomes*
* *Impacts*
* *Assumptions*

*The evaluation questions should correspond with the listed outputs/outcomes/impacts within this logic model.*

### Outcomes

[What are the anticipated clinical and economic benefits of the innovation?]

### Regulatory Information

The NHS requires all medical devices to be compliant with the legal requirements before a device can be commissioned.

[Description of regulatory information / compliance in England, e.g. CE marked and classification or N/A if this does not apply to your innovation]

## Selected sites

[Description of the selected sites. For each include the name of the clinical lead, communication strategy, activities to date/planned

For each site, where possible, the evaluation should indicate:

* the expert professional(s)/ clinician(s), whose role is to provide insight into the use of the innovation in the site and to potentially critique the evidence
* the patient representatives/groups, whose role is to provide insight from the user perspective
* the relevance of the site to this evaluation activities and evaluation questions (i.e. why were these sites selected?)]

## Suggested evaluation approach and timeline

### Purpose and Approach

There are eight principles of the evaluation to be considered. This evaluation will respond to four key evaluation principles: Effectiveness, Implementation, Value and Safety. You may consider responding to the additional four principles in the evaluation: Accuracy, Fit with site, Scale up, Sustainability.

Table 1: Evaluation principles

|  |  |  |
| --- | --- | --- |
| Principles | Considerations  | Evaluation type |
| Effectiveness | Outcomes for clinical, operational etc (acceptability by clinicians/users, user experience and satisfaction) | Impact |
| Implementation | Integration/training/associated costs/barriers and enablers | Process |
| Value | Health Economics  | Economic |
| Safety | Key risks, assurance management in place | Process |
| Accuracy | In the real-world environment and key elements such as sensitivity and specificity  | Impact |
| Fit with site | Risk assurance management in place; acceptability  | Process |
| Scale up | Feasibility/timeline/strategy/adaptability assurance | Process / Economic |
| Sustainability | Continuity of organisation fit/continuous evidence generation/evaluation | Economic |

[Outline the purpose of the evaluation, and why the specific approach has been suggested. Include who the evaluation is intended for and why it is important.]

[Describe the process of determining what the evaluation should be: such as including clinical expert collaboration or using the theory of change for example]

### Identified evidence to-date and evaluation gaps

[Where applicable, provide a description of the gaps as identified in the NICE META tool review and core evidence/evaluation exercises to date

Indicate which documents are publicly available, which have been peer-reviewed or published. Where possible, the evaluation will encourage the publication of data to enable further review.

Provide appropriate links to online published material or external documentation]

### Evaluation questions

[Describe the evaluation questions and the rationale (NICE META review for instance), provide a prioritisation of these evaluation questions]

Examples of Questions in response to the four main principles are:

* + Effectiveness – does the innovation have an impact on earlier diagnosis and/or diagnostic efficiency (and resource use / demand of services; clinical capacity; patient compliance; patient experience; patient quality of life; patient outcomes; faster diagnosis)
	+ Implementation – what are the barriers and enablers to the implementation of the innovation?
	+ Value – what is the health economic and budgetary impact of the innovation?
	+ Safety – what are the key risks and what assurance/management is in place?

Table 2: Rationale for inclusion and prioritisation for each evaluation question

|  |  |  |
| --- | --- | --- |
| Evaluation question | Rationale for inclusion and prioritisation | Evaluation type |
| [Evaluation question #1] | TBD | [Impact / Process / Economic] |
| [Evaluation question #2] | TBD | [Impact / Process / Economic] |
| [Evaluation question #3] | TBD | [Impact / Process / Economic] |
| [Evaluation question #4] | TBD | [Impact / Process / Economic] |
| [Evaluation question #5] | TBD | [Impact / Process / Economic] |

### Methodology, metrics, and outcomes

**Types of methodologies**

*GUIDANCE (this text should be deleted): This is typically determined by the evaluation partner and should be specified as a required activity in the evaluation contract.*

*Your company or organisation may have some initial ideas on the types of methodologies for this evaluation and these ideas should be outlined here.*

[The methods could include but are not limited to:

* + Qualitative method: case studies, Delphi studies, ethnographic study, focus groups, interviews, performance monitoring, surveys, documentary analysis
	+ Experimental and quasi-experimental methods: pre and post, interrupted time series analysis, instrumental variables or natural experiments, observational studies, propensity score matching, regression discontinuity analysis, stepped-wedge trials, synthetic control methods, timing of events.
	+ Economic analysis methods: budget impact analysis, cost-benefit analysis, cost consequence analysis, cost-effectiveness analysis, cost-efficiency (cost minimisation) analysis, cost-utility analysis, social return on investment analysis.]

**Determining data collection methods and outcomes**

[Please note that this section is dependent on the type of innovation and evaluation gaps identified.]

[A few pointers to support the writing of this section include:

* The evaluator should note that in addition to descriptive studies it is useful to gather comparative data. This section should specify how the evaluators propose to collect the comparative data. A clear explanation of the baselining exercise and site data collection approach should be provided. This section should provide appropriate and suitable methods (potentially mixed) using qualitative/quantitative methods/case studies/responsive QI to findings. Preferably this is shown illustratively, using the design matrix below to link to each evaluation question to the data collection methods used. This section should also describe secondary data sets to collect additional data.
* Description of sampling approaches and statistical methods used
* Description of health economic studies
* Description of health inequalities methods.]

Table 3: Methods and metrics selected for each evaluation question

|  |  |  |
| --- | --- | --- |
| Evaluation question | Methods used to answer the evaluation question | Metrics and outcomes used to answer the evaluation question |
| [Evaluation question #1] | TBD | TBD |
| [Evaluation question #2] | TBD | TBD |
| [Evaluation question #3] | TBD | TBD |
| [Evaluation question #4] | TBD | TBD |
| [Evaluation question #5] | TBD | TBD |

All initial data used to build the economic models and to answer the evaluation questions will be based on:

* + Any data and information provided by [innovation name] with respect to existing studies or related to data generated by [innovation name] during the deployment
	+ Any data provided by the deployment sites (pseudonymise/aggregated patient data, site-level data, costing data, etc.)
	+ Scientific research papers, relevant data sets and guidance documents, when applicable
	+ Survey
	+ Structured interviews
	+ Etc.

Note that information on how data will be shared is outlined in the DPIA/DSA.

### Additional considerations and risks for adoption and impact

[e.g. discussion around supply chain, interoperability, process service, redesign, change in funding approaches

Consider what contracts are already in place, there may be a requirement for decommissioning services to be replaced, or for contract amendments to account for variations in service.

This scope should also describe the potential impact of Covid-19 on the deployment (uptake, resources, collection of recent baseline) and the actions they could take to mitigate the impact on the evaluation, as well as any existing NHS programmes that may have a potential impact on deployment.

Initial considerations around monitoring for adverse events]

### Activities

To design this approach, the following documents were considered i.e. [insert relevant documents such as NICE meta analysis]

* [Document 1]
* …

[Please ensure you specify and distinguish evaluation components, the ones evidencing the technology’s clinical effectiveness but also its economic evaluation and relevant cost data collection.]

Table 5: Evaluation components and associated timeline

| Evaluation component  | Details | Timeline |
| --- | --- | --- |
| E.g. NICE meta analysis | E.g. Economic evidence | MM/YYYY- MM/YYYY |
| E.g. study / academic paper |  E.g. results | MM/YYYY- MM/YYYY |
|  |  | MM/YYYY-MM/YYYY |
|  |  | MM/YYYY- MM/YYYY |

[Ensure that the evaluation component includes evaluation plan / study design, execution and final report]

## Results and deliverables

### Evaluation service offer

[Description of the expected deliverables, e.g., how will evidence surrounding clinical/patient outcomes, economic benefits and unintended consequences generated from this evaluation be disseminated to address the decision problem.

This should include:

* Interim reports (frequency)
* Early economic modelling presentation (timeline)
* Final report with:
	+ Evidence to support the evaluation questions
	+ Economic model (timeline)]
	+ Considerations and recommendations for scale up and QI opportunities
* Consider additional deliverables that would benefit the conduct or utility of the evaluation.]

### Cost of services

The cost of the services offered for a predicted period of X months represent £XX,XXX+ VAT.

[Include a budgeting section with resources, equipment and total costs]