Artificial Intelligence in Health and Care Award 2020 - Guidance for Phase 1, 2 and 3

Phase 1, 2 and 3 of the Artificial Intelligence in Health and Care Award are managed by the NIHR Invention for Innovation and SBRI Healthcare Programme Management Office.

The Artificial Intelligence in Health and Care (AI) Award

In August 2019 the Health Secretary announced funding of £250m over three years for the formation of an NHS Artificial Intelligence (AI) Lab to develop and adopt the technologies that are most promising for health and social care.

Artificial Intelligence (AI) has the potential to make a significant difference to health and care. The AI Lab has been established to ensure the NHS is harnessing these benefits in a safe and ethical fashion that is supported by patients, the public and clinicians. As stated in the State of the Nation report, securing clinical understanding that AI will be used to supplement, and not replace, human clinical decision-making, is essential, as is realistic expectations of what AI technologies have to offer.

Given the ethical and safety concerns associated with the use of AI in health and care, the AI Lab will align to the principles of the NHS Constitution, addressing transparency, safety and privacy by building on the foundations already laid out, for example in the NHS’ Code of Conduct for Data-Driven Health and Care Technologies. The AI Lab will address barriers to adoption and development of AI, including an AI SWAT team, Skunkworks, Regulation Incubator, the Accelerating of Diseases programme, the Disease Clusters AI programme and an AI in Health and Care Award (AI Award). The Accelerated Access Collaborative (AAC) will lead delivery of the AI Award, working with NHSX, NIHR and relevant AAC partners.

The AI Award will deploy £140m over three years to accelerate the testing and evaluation of the most promising AI technologies that meet the strategic aims set out in the NHS Long Term Plan. The award will support technologies across the spectrum of development, from initial feasibility to evaluation within clinical pathways in the NHS and social care settings, to the point that they could be nationally commissioned.

The AI Award will be run at least twice yearly through an open competitive process. AI technologies responding to the call for applications may have a variety of applications in health and social care; key areas of focus for this call include screening, diagnosis, decision support and improving system efficiency:

<table>
<thead>
<tr>
<th>Health promotion &amp; prevention</th>
<th>Diagnosis &amp; treatment</th>
<th>System efficiency</th>
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</thead>
<tbody>
<tr>
<td>Digital epidemiology and disease surveillance</td>
<td>Symptoms checkers and decision support for differential diagnosis</td>
<td>Optimisation of care pathways</td>
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<td>National screening programmes</td>
<td>Risk stratification</td>
<td>Identification of resource requirements</td>
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<tr>
<td>Preventative advice</td>
<td>Prediction of deterioration</td>
<td>Electronic roster system</td>
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<tr>
<td>Self-management</td>
<td>Personalised treatments</td>
<td>Natural Language Processing for administrative tasks</td>
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</table>

Figure 1: Examples of AI solutions which have applications in health and social care

This initiative will run in parallel with other public sector investments in AI, including an upcoming NIHR Call specifically aimed at developing a better understanding of co-occurrence of multiple chronic conditions and multi-morbidity trajectories over the life course through innovative data science and AI tools. Applicants are encouraged to subscribe to the NIHR Twitter feed to be alerted of this additional opportunity when it launches. Further information will be available on the NIHR website in due course.

The AI Award supports innovators and technologies across the spectrum of development, from concept through to initial NHS adoption and testing of the AI technology within clinical pathways.
The application process for Phase 1-3 is run in two stages:

**Overview of the application process**

The application process for Phase 1-3 is run in two stages:

1. **Application and assessment process**
2. **Portal**

For further information, please download the relevant document from our website. All applications must be made through the online application portal.

### Feedback

**Phase 1 - Feasibility**

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<td>Development &amp; clinical evaluation</td>
<td>Real World Testing</td>
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**Phase 1**

- **Feasibility**
  - To show product and clinical feasibility of proposed innovations in health and social care
  - To develop prototypes and generate early clinical safety/efficacy data towards CE marking
  - 6-12 months and up to £150k per product
  - 12-36 months, uncapped funding award per product

**Phase 2**

- **Development and evaluate early clinical safety and efficacy data**
  - First real-world testing in health and social care settings to develop evidence of efficacy and preliminary proof of effectiveness, including evidence for routes to implementation to enable more rapid adoption
  - 12 months, uncapped funding award per technology

**Phase 3**

- **Support first real-world testing**
  - To facilitate initial systems adoption of the AI technologies with market authorisation into the NHS, evaluating the AI technology within clinical or operational pathways to determine efficacy or accuracy, and clinical and economic impact
  - 12 months to 3 years, uncapped funding award per technology

**Phase 4**

- **Facilitate initial systems adoption**
  - To address barriers to adoption into routine care for NICE-approved products with proven health system benefits, in order to facilitate rapid uptake nationally
  - Not eligible for research and development funding under this programme

**Figure 2: Product lifecycle phases and funding objectives**

<table>
<thead>
<tr>
<th>Product lifecycle phases</th>
<th>Funding objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Feasibility</strong></td>
<td>6-12 months, uncapped funding award per product</td>
</tr>
<tr>
<td><strong>Phase 1</strong></td>
<td>12-36 months, uncapped funding award per product</td>
</tr>
<tr>
<td><strong>Phase 2</strong></td>
<td>12-24 months, uncapped funding award per product</td>
</tr>
<tr>
<td><strong>Phase 3</strong></td>
<td>12 months to 3 years, uncapped funding award per technology</td>
</tr>
<tr>
<td><strong>Phase 4</strong></td>
<td>Not eligible for research and development funding under this programme</td>
</tr>
</tbody>
</table>

Phase 1-3 cover the translational development and clinical evaluation of innovative artificial intelligence products. We support product or technology development, first-in-man and clinical feasibility studies, pivotal clinical studies to evaluate the safety and effectiveness for the intended use and real world validations of transformational technologies. The ultimate aim is to get products or services to a position where they can enter and be used within the NHS or a social care setting.

Applications that do not meet the criteria for Phase 1-3 may be signposted to alternative support. Applications which are ready for national spread and adoption are not eligible for funding through the AI Award.

**Please note that in the following this guidance document describes the application and assessment process for Phase 1-3 only. For Phase 4 guidance, please download the relevant document from our website. All applications must be made through the online application portal.**
Stage 1 expressions of interest must meet all award specifications and funding prerequisites to be considered for review. Applications that do not meet these essential requirements may be rejected at this stage. Eligible applications will be reviewed against the AI Fund Phase 1-3 assessment criteria and a selection of applications will be shortlisted and invited to submit a full application. All applicants will be notified of the outcome. Due to the volume of applications we may not be able to provide feedback to unsuccessful applicants at this stage.

The Stage 2 (full application) process varies with the phases:

- For Phase 1, an application form and a 3 minute video pitch must be submitted and will be reviewed by expert and public panel members.
- For Phase 2 and 3, an application form must be submitted and will be subject to peer review. Applicants will have the opportunity to provide a response to reviewers’ comments (rebuttals) and will be invited to present their project at the panel meeting.

**Award specifications**

- Lead applicants for Phase 1-3 must be based in the UK (please note that this is different from Phase 4 which allows lead applicants to be based anywhere in the world).
- Lead applicants must be from an NHS Trust or service provider, Higher Education Institution, SME or charity.
- For Phase 2 and 3, a minimum of two different organisation types must collaborate, of which one must be an NHS organisation for Phase 3. For Phase 1 projects collaborations are not required but we encourage applicants to form partnerships as early as possible.
- Projects must not exceed the respective funding limit:
  - Phase 1: Up to £150,000
  - Phase 2: Uncapped but costs must be sufficiently justified and proposals must provide value for money
  - Phase 3: Uncapped but costs must be sufficiently justified and proposals must provide value for money
- Projects must not exceed the maximum duration:
  - Phase 1: 12 months
  - Phase 2: 36 months
  - Phase 3: 24 months

**Funding prerequisites**

The following funding prerequisites apply to all applications and will be considered by the funding panel:

- The AI technology utilises artificial intelligence to address a need or problem facing the NHS in a priority area, which may include those identified in the NHS Long-Term Plan
- The AI technology has the potential for routine use in health and social care as demonstrated by a clear route to market and ability to scale-up
- Sufficient evidence that the AI solution can meet at least one of the following criteria at a level appropriate to the stage of development:
  - Improvement in patient outcomes
  - Improvement in patient experience
  - Improvement in operational efficiency
- A commitment to involving members of the public and patients in the design and management of the research, evaluation or study.
- Commitment to relevant standards: Where appropriate, these will include the AI Code of Conduct for data-driven health and care technology (for artificial intelligence systems used by the NHS), the NICE Evidence Standards Framework for digital health technologies, the NHS Digital Standards for commissioning or developing Personal Health Records
- Ability to demonstrate interoperability with existing NHS systems or a commitment to work towards and fund any relevant product development required to achieve interoperability
- Relevant approvals in place or working towards relevant approvals:
  - Regulatory, intellectual property protection, ethical framework or any other relevant approvals
  - Conformité Européenne (CE) marking and/or market approvals
  - Completed or commitment to complete the Digital Assessment Questions/digital health technology standard (if the AI solution utilises digital technology or software)
  - Demonstrate Information Governance (IG) compliance in sites using the technology by having IG toolkits or a contract in place with applicable providers/commissioners
  - Not subject to any Medicines and Healthcare products Regulatory Agency (MHRA) safety alerts

**Phases, entry points and fundable activities**

**Phase 1 - Product and clinical feasibility**

The objective of Phase 1 projects is to show product and/or clinical feasibility of proposed innovations in health and social care and confirm the basis for further development over a 6-12 month period with a maximum budget of £150,000.

The entry point (or the minimum requirement on eligibility) for Phase 1 projects is experimental proof-of-concept (TRL3). However, where there is significant evidence in the literature or from previous studies by the applicants that there is a strong case for further development, a
formulated technology concept may be sufficient (TRL2). As an example, a project may be based on prototype-level machine learning not yet incorporated in the intended system (which could be a medical device, in vitro diagnostic or digital health technology) with significant relevance to the NHS. Projects may focus on standalone software or medical devices or in vitro diagnostic devices with embedded AI, which require further training using clinically meaningful datasets.

Fundable activities include, but are not limited to:

- Research and development to demonstrate feasibility and/or produce prototypes or minimum viable products
- Acquisition of big data through technology development or by acquiring existing clinical datasets for the purpose of training the technology
- Research and development activities relating to training of the algorithm, including cleaning and annotating new data
- Assessments to determine user requirements
- Feasibility studies to evaluate the technology's fit for the proposed problem
- Research to support regulatory approval strategy and to satisfy the requirements for pre-clinical evidence generation and its documentation
- Activities in relation to intellectual property protection, freedom to operate and market/competitor analysis or business case development, including plans for commercialisation and NHS adoption
- Research to support patient and public engagement or involvement
- Identification of relevant stakeholders and/or partners to support the next stages in the development

Please see What we do not fund for activities we do not fund.

Technology Readiness Levels as defined by the European Commission for public sector innovation

**Phase 2 - Development & clinical evaluation**

The objective of Phase 2 projects is to develop and evaluate prototypes and generate early clinical safety and efficacy data towards CE marking over a period of up to 36 months.

The entry point (or the minimum requirement on eligibility) for Phase 2 projects is usually a technology validated in a lab (TRL4). As an example, projects may focus on AI innovations that require a second wave of product development or have not been clinically tested before and now require clinical validation including a number of training and testing iterations in order to achieve the finished product.

Fundable activities include, but are not limited to:

- Research and development to enable clinical use
- Acquisition of big data through technology development or by acquiring existing clinical datasets for the purpose of training the technology
- Studies to provide data relating to the safety and efficacy of the technology including small-scale randomised controlled trials
- Interventional studies that may demonstrate non-inferiority/equivalence in comparison to a standard of care or an existing benchmark
- Large scale randomised controlled trials for marketing approval and to facilitate identification of any adverse effects due to population-based generalisations
- Usability trials to determine wider clinical acceptability and tolerance and where applicable patient-reported experiences
- CE marking and other regulatory requirements, including any associated preparation for a future clinical trial application
- 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 including cost-effectiveness or budget impact analyses to ascertain value for money in accordance with the NICE Evidence Framework (Section B)
- Health economic modelling to forecast the long-term health benefits as a result of technology use
- Activities associated with the dissemination of outputs
- Research to support patient and public engagement or involvement
- Identification of relevant stakeholders and/or partners to support the next stages in the development

Please see What we do not fund for activities we do not fund.

**Phase 3 - Real world testing**

The objective of Phase 3 is to carry out the first real world testing of an innovation in health or social care settings over a period of up to 24 months to develop evidence of effectiveness in practice, including evidence for routes to operational implementation to enable more rapid uptake.
The entry point (or the minimum requirement on eligibility) for Phase 3 is usually a technology that has been validated in a relevant environment (TRL5). As an example, this may be an AI product that has been tested in a clinical or social care setting, has generated a significant amount of safety and efficacy data and is close to CE marking or newly CE-marked and requires further evidence to demonstrate effective implementation of the technology in clinical practice.

Fundable activities include, but are not limited to:

- Activities associated with the design and delivery of evaluations of AI solutions in health and social care settings, including any trial methodology aimed at demonstrating the clinical utility of the product with respect to its real-life implementation and use:
  - Prospective studies that evaluate the ability to estimate outcomes where there is typically no suspected risk
  - Qualitative research on setting-specific aspects including readiness to cultural change, clinical adaptation (IT, information governance and data infrastructure) and long-term adherence to the technology
  - Technology pilots to determine the impact on service delivery and management and/or to support re-design of the clinical pathway
- Collection of efficacy data if this is part of a clinical utility study
- Small changes to the technology that might be needed for its optimisation during the lifetime of the project, e.g. any changes deemed required for end user acceptance as part of this evaluation but not requiring any further regulatory approvals
- Activities associated with the data analysis, management and governance of the real-world evaluations
- Development of rich and in-depth case studies conducted in single or multiple NHS sites that may serve as adoption exemplars and reference sites
- Costs associated with implementation research, including the design of the implementation strategy, clinical pathway analysis and sustainability evaluation
- Training associated with the implementation of new technology, including the development of training resources and materials
- Health economic analyses including cost-effectiveness, cost-utility or cost-benefit analyses to determine any cash savings or cash releases
- Activities in relation to business development, market analysis and development of a case for adoption
- Activities associated with the dissemination of outputs
- Research to support patient and public engagement or involvement

Please see What we do not fund for activities we do not fund.

**Phase 4 - Health system adoption**

The objective of Phase 4 is to demonstrate clinical and economic impact of promising products in the NHS setting to inform reimbursement and procurement decisions and facilitate systems adoption.

The entry point (or the minimum requirement on eligibility) for Phase 4 is CE-marked AI products with clearly identified NHS benefits derived from a robust health economic assessment or NICE appraisal (TRL6-7).

**Phase 4** is intended to identify medium stage AI technologies that have market authorisation but insufficient evidence to merit large-scale commissioning or deployment. Grants are uncapped, funding awards are per technology. The AAC Delivery team will work with NHS sites to support their adoption of these technologies, to stress test and evaluate the AI technology within routine clinical or operational pathways to determine efficacy or accuracy, and clinical and economic impact.

**What we do not fund**

The following activities will not be considered for funding under this competition:

- Basic science (TRL1 space)
- R&D around drug discovery and development

**Stages of assessment**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Screening for prerequisites</th>
<th>Assessment of expressions of interest</th>
<th>Peer review and panel assessment</th>
<th>Ratification</th>
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<tbody>
<tr>
<td>Stage 1</td>
<td></td>
<td>Expressions of interest will be screened against award specifications and prerequisites. Applications may be deferred to another Phase if deemed more appropriate.</td>
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<tr>
<td>Stage 2</td>
<td>Assessment of expressions of interest</td>
<td>Proposals that meet the award specifications and prerequisites will be assessed against the Phase 1-3 criteria by expert reviewers. A selection of applications will be shortlisted and applicants will be invited to submit a full application. All applicants will be notified of the outcome. Due to the volume of applications we may not be able to provide feedback to unsuccessful applicants at this stage.</td>
<td>Phase 1 applications, including a video pitch, will be assessed by the expert and public reviewer panel and scored against the assessment criteria. Phase 2 and 3 applications will be subject to independent peer review. Applicants will have the opportunity to provide a response to reviewers’ comments (rebuttals) and will be required to present their project at the panel meeting, followed by a Q&amp;A session. Applications will be scored against the assessment criteria.</td>
<td>Panel outcomes will be ratified by the Department of Health and Social Care Deputy Director of Research Programmes.</td>
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<tr>
<td>Stage 3</td>
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<td>Stage 4</td>
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**Assessment criteria**

### Expressions of interest

Expressions of interest will be assessed against the following criteria:

- **NHS unmet clinical need & market pain:** How well does the AI solution support health and social care priorities and align with wider government strategies?

- **Innovativeness:** How innovative is the proposed solution? How significant is the competitive advantage, which this technology affords, over existing or alternative technologies that can meet the market needs?

- **Benefit to patients, the NHS and the wider population:** What is the expected improvement in health outcomes, operational efficiency, patient experience and/or safety and quality of care? What is the evidence of reducing health inequalities?

- **Project plan (plus Gantt chart):** How appropriate is the proposed project plan? Are the risks (technical, clinical, commercial and environmental) to project success appropriately articulated and how effectively will these be managed?

- **Team:** To what extent does the project team appear to have the right skills and experience to deliver the intended benefits?

- **Value for money:** How appropriate is the proposal financially? Is the overall budget realistic and justified in the application portal of the aims and methods proposed?

### Full applications

In addition to the above criteria, full applications will also be assessed against the following criteria:

- **Roadmap to NHS uptake:** How appropriate is the proposed plan for adoption?

- **Intellectual property (IP) and roadmap to commercialisation:** Are IP arrangements clear and appropriate? To what extent does the proposed project have commercial potential? How appropriate is the commercialisation strategy?

- **End user engagement and patient & public involvement (PPI):** How well proposes the team to engage with end users of the technology and with patients?

### Key dates

The table below highlights the key application dates. Please note that we reserve the right to alter these dates if deemed required.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Date</th>
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<tbody>
<tr>
<td>Open for applications</td>
<td>28 January 2020</td>
</tr>
<tr>
<td>Suite of WebEx events open for applicants to address queries regarding</td>
<td>4 February 2020, 11 February 2020, 18 February 2020, 25 February 2020</td>
</tr>
<tr>
<td>the AI Award application process (please visit our website to join these events)</td>
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<tr>
<td>Applicant information event (London)</td>
<td>3 February 2020</td>
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<tr>
<td>Application deadline for expressions of interest</td>
<td>4 March 2020, 1:00pm</td>
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<tr>
<td>Invitations to submit a full application</td>
<td>15 April 2020</td>
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<tr>
<td>Stage 2 deadline for Phase 1</td>
<td>13 May 2020</td>
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<tr>
<td>Stage 2 deadline for Phase 2 and 3</td>
<td>20 May 2020</td>
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<tr>
<td>Panel meeting Phase 1</td>
<td>W/c 1 June 2020</td>
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<tr>
<td>Panel meetings Phase 2 and 3</td>
<td>W/c 22 June 2020</td>
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<tr>
<td>Outcomes communicated to applicants Phase 1</td>
<td>W/c 15 June earliest</td>
</tr>
<tr>
<td>Outcomes communicated to applicants Phase 2 and 3</td>
<td>W/c 6 July earliest</td>
</tr>
<tr>
<td>Projects start</td>
<td>From July 2020 earliest, subject to due diligence</td>
</tr>
<tr>
<td>Next AI Award competition</td>
<td>Launching autumn 2020</td>
</tr>
</tbody>
</table>
How to apply

Applications must be made through the online application portal. A template application form may be downloaded from the website, however, please note that this is for demonstration purposes only and may not be used to submit an application.

To submit an application, you must complete all the relevant sections of the online form available within the online application portal. This can be accessed through this link.

The ‘System Help’ document found on the application portal’s web pages provides extensive step by step instructions on how to make use of the portal.

Registration

Only registered users of the application portal can apply. Applicants new to using the application portal should register as a new user. Once logged into your account the application portal home page is the starting point to create applications, access co-applications and to update contact information and professional details.

Managing my details

Lead applicants and co-applicants can manage their basic contact information and curriculum vitae (CV) through the ‘Manage my Details’ link on their application portal home page. Lead and co-applicant contact information and CV details are integrated by the application portal into the relevant fields during the application process. Please note that only lead applicant CV details are mandatory at Stage 1 (expressions of interest) while basic contact information is required for co-applicants. If applicable, lead applicants should ensure entry of their ORCID iD number. At Stage 2 (full application), lead and co-applicant CV details are mandatory.

Creating an application

The lead applicant must initially create the new application. Clear instructions on how to start a new application can be found in the ‘System Help’. The research team can collaborate with the lead applicant to edit the content in the application by being invited to be a co-applicant through the co-applicant section of the application form.

The lead applicant can use the search tool to find co-applicants and then to invite them to join the application. The application portal will automatically dispatch an email inviting the co-applicant to confirm their participation in the application. Co-applicants can then decide whether to accept the invitation and consent to the application being submitted jointly in their name. They will need to log into the application portal and follow the links to ‘Confirm’ their involvement on the co-application summary page. Once confirmed, the co-applicant will be granted access to edit the online application form.

All co-applicants must not only ‘Confirm’ but also ‘Approve’ their invitation to participate in the application electronically on the co-application summary page in advance of the submission deadline.

Completing an application

From the application summary page, the application can be edited by clicking on the ‘Edit’ button. The different sections of the application form can then be accessed via the list of hyperlinked buttons on the left hand side of the application portal webpage. You can move from page to page either by using the ‘Previous’ and ‘Next’ buttons, or using the list on the left-hand side of the web page.

Most questions are associated with contextual help buttons and clicking on them will open up pop-up windows containing brief guidance notes that supplement the published guidance for applicants. It is strongly advised that applicants refer to the published guidance first and then use contextual help as they complete and review each question as contextual help is not designed to replace it. Mandatory questions are flagged with a red dot.

The system will prevent your co-applicants accessing your application at the same time as you. This stops applicants and co-applicants inadvertently making changes to the same part of the application at the same time and overwriting each other’s work.

For more details on the electronic approvals required from official representatives of the host organisations in advance of submitting your application, please refer to the published guidance for applicants.

Remember to save your work

You will be prompted to save your work if you leave the browser in application editing mode. We recommend you save your work regularly to minimise the risk posed by any local computer or internet problems. You can save and return to the application form as often as you like prior to submission.

Exiting and returning to work on your form

Should you wish to exit your form, you can return at any time; simply log in using your username and password and select ‘My Applications’ from the menu. You will then be presented with a list of all the applications you are currently involved with as well as providing details as to their stage in the submission process.

Validation and submission of the form

The lead applicant can review the progress of their application at any time by selecting the ‘View/Print’ option on the application summary page to generate the application as a PDF File.
When the application form has been completed, the lead applicant must use the 'Validate form' tool within the online application form. The validation step is a check run by the application portal to assess whether all the mandatory questions contain information. It will provide a list of links to any parts of the form where corrections or additional content are needed.

Once the application has been validated successfully and no further corrections are needed, the lead applicant can submit the application by clicking on the 'Submit' button on the lower right-hand side of the application summary page.

**Following submission**

A programme specific reference number will be assigned to the application once it has been submitted. After the relevant competition round closes, the application will automatically enter the process of being considered for funding.

If you have any questions regarding your application, please email enquiries@ai-award.info.

**Appendix 1 - Application Form Guidance for Stage 2**

**SECTION 1: Background Details**

**Lead organisation**

Provide details of the organisation who will be the contractor if the project is funded.

**Lead organisation details (UK Companies only)**

Please provide the following information about your company:

- Company size
- Company status
- Main Business activity
- Business sector
- Annual Turnover

Please also state if you have had previous private or public funding, and the amount.

**Lead applicant**

Please provide contact details for the lead applicant.

**Project title**

The project title should state clearly and concisely the proposed AI solution and what it does. Any abbreviations should be spelled out in full.

**AI solution category**

Please select the appropriate category that best describes your technology from the list below:

- Health promotion & prevention
- Diagnosis & treatment
- System efficiency
- Other

A description of these categories can be found in Figure 1 in Section 1.

**Project duration**

Ensure you include sufficient time to complete all aspects of the research including applications for regulatory/ethical approvals and in particular, patient recruitment, where required.

Phase 1 (product and clinical feasibility) projects can be a minimum of 6 months up to a maximum of 12 months in duration.

Phase 2 (product development and clinical evaluation) projects can be a minimum of 12 months up to a maximum of 36 months in duration.

Phase 3 (real world testing) projects can be a minimum of 12 months up to a maximum of 24 months in duration.
Proposed start date if funded

Please be realistic about your possible start date taking account of the necessary contract negotiations and staff recruitment prior to starting your project.

Total project costs requested

Please enter the total project costs, not including any NHS support and treatment costs.

Please note that the maximum funding for Phase 1 projects is £150,000.

There are no set budget limits for Phase 2 or 3 projects.

Please ensure you complete and upload an AI Award Finance Form with your application.

Support and Treatment costs.

Further details about LCRN contacts are available at: https://www.nihr.ac.uk/explore-nihr/support/clinical-research-network.htm

SECTION 2: Plain English Summary

A clear and concise scientific summary of the Detailed Project Plan.

The following is a list of potential elements / headings that might be included depending on the design of the proposed project. Applicants may find the guidance on the EQUATOR Network website (www.equator-network.org) useful.

1. Background
2. Aims and Objectives
3. Project plan and methods used
4. Timelines for delivery
5. Anticipated Impact and Dissemination

SECTION 4: Detailed Project Plan

Using all of the headings in the order presented below, please use this section to clearly explain your proposed project.

The Opportunity
NHS unmet clinical need & market pain

Provide a clear explanation of the health or social care problem to be addressed, the impact on patients as well as health and social care services, and how the proposed work would fill a demonstrable evidence gap. Please also provide a description of how your AI solution will support the NHS Long Term Plan, NHSX strategic priorities and/or wider government priorities including the Industrial Strategy grand challenges or resource efficiency. Please report market size, any related trend or forecast, patient population affected, NHS cost burden, and state of the art.

Benefit to patients, the NHS and the wider population

Provide a clear case of how the proposed device, technology or intervention will change clinical practice and provide benefit to patients (such as reduced mortality or morbidity, improved quality of life, reduced misdiagnosis, and improved patient outcomes and experiences). Potential cost savings for the NHS should also be provided.

Clearly articulate the expected benefit to patients, the NHS and/or social care settings and the wider community. Please note that your AI solution must have the potential to be cost effective and meet at least one of the following criteria:

- Improvement in patient outcomes
- Improvement in patient experience
- Improvement in operational efficiency

Describe the impact the project aims to achieve. Impact may include but is not restricted to:

- Patient & public wellbeing (improved quality of life, improved safety, improved satisfaction with care, improved independent living, improved health, slowed progression of ill health)
- Clinical benefits (improved accuracy of diagnosis, improved detection rates, reduced false positives/negatives, improved health data quality/availability; improved effectiveness of the therapy, improved availability of the therapy, improved ability to stabilise/manage the condition)
- Staff & service provision benefits (improved staff capacity, improved staff capabilities-knowledge and skills-, simplified/improved care pathway, more efficient care pathway, reduced number of procedures, reduced waiting times)
- Economic benefits & commercial ROI (reduced service delivery costs, improved organisation/service cost control, reduced treatment cost to patient, reduced staffing cost)
- Social and policy benefits (change in policy, change in professional guidance, improved awareness)

The Proposed Innovation

Provide a clear description of your AI solution covering comprehensive details of its functionality, structure and intended use. Explain the level of innovation of the proposed technology and the intellectual property position, accompanied by a review of the existing evidence surrounding similar products that may already be on the market, and of any relevant ongoing research in the area of focus. A consideration of the proposed barriers to clinical/social adoption must also be clearly articulated.

Detailed project plan

The project plan should include the following:

- Aims and objectives of the project
- The individual work packages within your project, including deliverables and milestones (a Gantt chart indicating the schedule for the completion of work must be attached). Work packages may focus on, for example, technical, clinical or commercial aspects of the project.
- A description of the main hurdles to be overcome technically, clinically and commercially.
- The key risks to your project (including technical, clinical, financial and IP risks) and the steps you will take to manage and mitigate these risks. Ensure that these risks are considered when defining milestones (the go/no go points for your project).

Patient & public involvement (end users involvement)

Evidence must be presented of early engagement with end users (e.g. NICE, clinical commissioning groups, etc.) and their provisional interest in the product.

Patients, carers, service users and the public can also be involved in every stage of the project, from developing a proposal through to dissemination and evaluation. Describe how Patient and Public Involvement (PPI) activities have been included throughout the project lifecycle.

You should describe who has been involved and why this is appropriate, what role(s) they have played and what influence or change has happened as result of their involvement.

Public co-applicants

We encourage the inclusion of public co-applicants, where appropriate. Please include a clear description of their role and the reasons why a public co-applicant is joining the team. For further information please access the 'Public Co-Applicants in Research' guidance: https://www.invo.org.uk/posttypepublication/public-co-applicants-in-research-guidance-on-roles-and-responsibilities/.
Resources for evaluating impact and reporting of PPI
You will also need to describe how you will record and evaluate the impact PPI has on the research. The level of evaluation should be proportionate to the level and complexity of the proposed PPI activities. The following resources may be useful as they provide different frameworks for assessing impact and reporting PPI:

- Public Involvement Impact Assessment Framework http://piiaf.org.uk/
- GRIPP2 for reporting PPI https://www.bmj.com/content/358/bmj.j345

The Team

Explain why the group is well qualified to run this project, describing the track record of the team in health research, technology development and commercialisation. Explain how the applicants work together (or propose to work together if they have not done so previously), and identify other major collaborations important for the research.

If a company leads the project or is a co-applicant, please provide a summary of the company’s activities, including, if applicable, other products in development, any synergies of the proposed project with an already existing portfolio, or any other relevant information.

Sub-contractors may provide external specialist services which cannot be provided by the organisation leading the project or its co-applicants or collaborators. Services include, for example, consultancy, design services, or the development and provision of specialist equipment. These costs can be requested for organisations providing these services in a territory that is outside the UK, but suitable justification is required.

Describe the existing research support (e.g. funding from other sources) available to the research team, which is relevant to this proposal. Clearly delineate the proposed project from other related research, funded from another source.

Finance analysis

Provide the details of the company’s cash flow forecast and funding strategy here.

The full details of the spending plan for the project should be included in the AI Award Finance template, to be uploaded with this application. Justification for the costs included in the Finance template should be provided here. For more information, please refer to Appendix 2 - Finance Guidance.

Patient data use and monitor of patient safety

Describe any known limitations of the data used and algorithms deployed by the AI solution. Include an ethical examination of how the data would be used, and how it would comply with the AI Code of Conduct. Explain how the product’s performance would be validated and how it would be integrated into health and care provision. Demonstrate that security of the data is integral to its design.

Please include details of how you will monitor and report patient safety or data issues, including any recovery plan.

Ethics and regulatory approvals

Outline any ethical issues associated with this research and the arrangements for handling them. If there are no plans to obtain ethical review, this must be clearly justified. Note that work outlined in your application must adhere to the UK Framework for Health and Social Care Research.

Intellectual Property (IP) and commercialisation strategy

All background and any potential foreground IP arising from the project must be described in the application. An initial freedom to operate opinion must be provided, referencing any third parties’ rights which may affect the implementation of your device or technology. A strategy should be proposed for how third party rights will be managed to allow for further development, implementation and commercial exploitation.

Provide details of any new types of IP that may arise during the project, including ownership arrangements and management of the IP.

IP arrangements between collaboration partners, and with consultancies and sub-contractors must be regulated by appropriate agreements. The Lambert Toolkit provides model agreements for collaborations between universities and companies.

Please include details of the intended market, barriers to entry, and competitor analysis as well as details of your sales strategy/channels and marketing plans. Include a pricing strategy. Provide any details of market traction, interested customers and their potential value for the company, and/or any income already being generated. Market opportunities, both domestic and global can be explored.

Dissemination and NHS adoption strategy

Please describe the planned outputs of the research and how they may lead to short and longer-term NHS and patient impacts. As far as possible, indicate anticipated timescales for these benefits and a quantitative estimate of their scale. Impacts may include, but are not restricted to - patient benefit; healthcare staff benefits; changes in NHS service (including efficiency savings); commercial return (which could contribute to economic growth); public wellbeing.

Describe how the outputs of the research will be communicated and to whom. Identify key stakeholders, and your plans for engaging them. To realise impact, it is unlikely that simply making outputs available will be sufficient. Please consider and outline the active approach you will take...
to engaging key parties to disseminate the work.

Present a specific strategy for adoption of the technology into the NHS. Describe the process by which the technology will enter the healthcare environment, including how your solution will be acknowledged, selected and introduced for use in the health and care service or wider society. Detail what current and future barriers to adoption are likely to be encountered, and a strategy for overcoming them. Where possible, consider how your solution will be adopted and implemented longer term, and what efforts and investment are likely to be needed beyond the project to achieve widespread NHS adoption.

**Video Pitch (Phase 1 only)**

The 3 minute video presentation should complement your application. We do not expect professionally produced videos (you can use a smartphone), however, please ensure the visual and audio is of good quality.

**Gantt chart**

It is mandatory to attach a Gantt chart indicating a schedule for the completion of work, including the timing of key milestones and deliverables.

**Finance form**

Please attach a copy of your completed AI Award finance form. For further information, please refer to Appendix 2 - Finance Guidance.

**SoECAT form**

When considered necessary by the LCRN AcoRD specialist, a completed Schedule of Events Cost Attribution Tool (SoECAT) is required to be uploaded and submitted as part of the application submission for all applications. When a completed SoECAT is not considered necessary by an AcoRD specialist, only the front page (study information tab) of the SoECAT needs to be uploaded and submitted as part of the application submission. The SoECAT must be authorised and signed off by an AcoRD Specialist even where there are no excess treatment costs.

The SoECAT and more information can be found here: [https://www.nihr.ac.uk/researchers/collaborations-services-and-support-for-your-research/run-your-study/excess-treatment-costs.htm](https://www.nihr.ac.uk/researchers/collaborations-services-and-support-for-your-research/run-your-study/excess-treatment-costs.htm)

Guidance for completing the Schedule of Events Cost Attribution Template (SoECAT): [https://www.nihr.ac.uk/documents/schedule-of-events-cost-attribution-template-soecat-guidance/23214#Completing_a_SoECAT](https://www.nihr.ac.uk/documents/schedule-of-events-cost-attribution-template-soecat-guidance/23214#Completing_a_SoECAT)

Please be advised that owing to current circumstances, if you are unable to obtain timely SoECAT sign off, we will accept an unsigned form for the time being. Should you be successful, we will require sign off before contracting.

**SECTION 5: The Team**

**Applicant and team details**

Specify the role of the lead applicant as well as all co-applicants, providing a summary of their expertise and how it will be leveraged in this project. State clearly the particular contribution that each of the applicants will make towards the project as well as any patient and public leads.

If, for any reason, salary costs of members of the team are not going to be sought via this application, it should be made clear how their contribution will be supported in the ‘Finance Analysis’ section of the Detailed Project Plan.

**Joint Lead Applicant**

Where appropriate, it is acceptable for the application to be led by Joint Lead Applicants. Justification should be given to demonstrate why more than one person would be required to lead this project and how the additional lead’s relevant expertise and track record adds value.

**Public (PPI) Co-applicants**

We recognise and value the varied perspectives that patients/service users and carers bring to a project as applicants. In this section, please provide a summary of any relevant knowledge, skills and experience that you will draw upon to contribute to this project.

**SECTION 6: Other supporting roles - Signatories (electronic)**

The following supporting roles from the host organisation must be added to the application:

- Director of Finance or equivalent

If the lead organisation, e.g. a UK Company, does not have these supporting roles, these fields should be completed with the details of the person fulfilling these functions.

**Electronic signatures**
On assigning these contacts an email will be sent to each by the system requesting they approve the application and confirm the content by checking the boxes below. Ticking this box constitutes an electronic signature of the supporting role for the full application.

We recognise that the lead applicant of the application may also be the Director of Finance. Within your RMS account you are able to switch between these accounts. This guidance outlines how you can switch between roles to fill out the relevant sections of the RMS application form. Please do not create two RMS accounts.

The Lead Applicant will also be required to tick a check box to indicate that they have read and understood the terms on which he/she has been nominated as Chief Investigator for this proposal along with the associated documentation and accept this role.

Once these contacts have approved the application you will be able to proceed to submit.

No wet ink signatures are required for this application.

**SECTION 7: Uploads**

Please note that all supporting documentation uploaded should be given concise and clear file name descriptions. These should be headed by a numbered ‘Appendix’ and a brief filename description that clearly describes the file (e.g. Appendix_References).

The following attachments are mandatory for all applicants:

- List of references cited in the application
- Gantt Chart
- AI Award Finance Form
- Completed Schedule of Events Cost Attribution Tool (SoECAT)

If claiming Clinical Trials Unit support, the following files are considered mandatory:

- CTU letter of support

The following file(s) are considered non-mandatory to submission; please number your files and attach:

- Any further supporting documentation (flow diagrams, pictures, logic models, trial protocols, any letters of support etc.)

No more than 8 separate files are permitted. The total file size should not exceed 6Mb. Total file sizes larger than this may not be considered as part of this submission. We strongly recommend that only .doc or .pdf files are uploaded as some file types are not supported by the system (such as .xls and .zip file types which will not render out into the final version of the application form). Should you wish to upload documents of other file types, we encourage you check that they appear in the PDF of the application form prior to submission as changes cannot be made after the deadline has passed.

**SECTION 8: Acknowledge, review and submit**

Please declare any conflicts or potential conflicts of interest that you or your co-applicants may have, including any facts that, should they come to light at a future date, could lead to a perception of bias. Include any relevant personal, non-personal & commercial interest that could be perceived as a conflict of interest. Examples include (this list is not all encompassing) secondary employment, consultancy, financial or commercial gain (pensions, shareholdings, directorships, voting rights), honoraria, etc. In a case of commercial sector involvement with the application, please state clearly the relationship to ownership of data, access to data, and membership of project oversight groups.

**SECTION 9: Validation Summary**

Please follow these steps as indicated to complete your application submission:

- Validate all mandatory/required fields listed below (that are required to be completed/amended before submitting)
- Check all co-applicants have completed their CV details as appropriate and review the PDF final version for any formatting issues
- Click ‘Save and Close’
- Click the ‘Submit’ option

You will receive an automated email containing the acknowledgment that we have received your application.

If there are no validation requirements above you may be ready to submit the application. To do so ‘Save and Close’ the application and then click ‘Submit’.

**Appendix 2 - Finance Guidance**

Please note that this information is intended to help applicants complete the detailed finance form required only for a full application (Stage 2). However, you may find this useful at the expression of interest stage to categorise your costs.

The information entered in the finance section should provide an analysis of the total funds requested to undertake the research proposed and should be based on current prices. These costs will be used to assess value for money.
It is in your best interest to undertake a thorough, realistic and accurate costing. Where an outline/stage 1 application has been produced and this is the full stage (2) application, the committee/panel will pay close attention to any material increase in costs. You must provide a clear and full justification for all costs including NHS costs. You must also ensure that you include all costs including those required to secure good research management.

- When justifying staff costs you should also provide the % amount of time input of each member of staff and link this to the specific area/work package of the proposed study where this input will be taking place.
- Costs must be provided at current prices. An adjustment for inflation may be made annually thereafter at rates set by the Department of Health and Social Care. Whilst allowances for incremental increases should be included on the form, nationally or locally agreed pay increases should be excluded.
- Years should be calculated starting from the anticipated start date of the proposed research. For example, if your research is expected to start on 1 June 2020 then its second year starts 1 June 2021.
- Further itemisation of costs and methods of calculation may be requested to support the application at a later date.
- Payments will be made to the contracted organisation only and the contracted organisation will be responsible for passing on any money due to their partner organisation(s).
- Appropriate sub-contracts must be put in place for any element of the research which is to be paid to another organisation.

- NHS support costs are funded via Clinical Research Networks. Researchers should contact their local NHS R&D department initially and if they are unable to help directly or if there is no local NHS R&D department, contact the Local Comprehensive Research Network (LCRN) senior manager for advice on NHS support costs. Further details about LCRN contacts are available at https://www.nihr.ac.uk/nihr-in-your-area/local-clinical-research-networks.htm.
- All applications are expected to have appropriate NHS, HEI, commercial and other partner organisation input into the finance section of the application form.

Please note that whilst the applicable percentages will be used to calculate the maximum award payable, the programme reserves the right to award less than this maximum where it is considered appropriate.

Direct costs
These are costs that are specific to the research, which will be charged as the amount actually spent and can be supported by an audit record. They should comprise:

**Details of posts and salaries (posts and salaries summary)**
This section presents an overview of salary and associated on-costs for the applicant(s) contributing to the research, including normal salary increments broken down individually.

- Please include all members of staff working on the research by clicking ‘Add Staff Details’ or editing a current one.
- If there are any applicant(s) whose costs are not being claimed you should still include their details within this section, but don’t include any actual costs.
- Where applicants are already in receipt of NIHR funding for any part of their salaries (e.g. NIHR Fellowships), these should not be additionally charged to the project.
- Where applicants are already receiving salaries funded by NIHR, these should be declared in the application.
- The Apprenticeship Levy can be included in the salary costs from 1 April 2017 where relevant.

**Salary costs (apply to years)**
This section specifies the annual costs of each applicant contributing to the research. You should now allocate the individual staff member costs to each year of the research, allowing for increments. Use current rates of pay, and build in any known annual increments (again at current rates). You will not be able to claim for pay awards retrospectively, once your research is underway.

- Please note the 'Total' and 'Overall' column figures need to be calculated using the current annual costs, %FTE and number of months. If the research lasts for several years and an individual’s involvement varies over the course, it may be necessary to explain fully in the justification of costs section the % FTE and months per year for an individual staff member.
- It is important to double check that the % FTE, total months and yearly costs information are consistent with the information presented in 'Details of Posts and Salaries' ('Details of Posts and Salaries' should show the full current staff costs independent of % FTE etc., whereas the yearly costs in 'Annual Costs of Posts' depend on % FTE etc.).
- Please ensure that you check the 'Type of Cost' box which describes the employing organisation for a member of staff as this impacts on the level of funding provided. Staff employed by a Higher Education Institution (HEI) are funded at 80% of cost and staff employed by NHS, commercial or other partner organisation at up to 100% of cost.

Please note that this section also includes ‘Shared Staff Costs’ which is located under directly allocated costs in some other funders’ applications. These are costs of an institution’s research resources which can be charged to the research on the basis of estimated use, rather than actual costs. These may include: IT technicians, laboratory staff, and costs of pooled staff efforts. HEI indirect costs cannot be claimed on these shared costs.

**Travel, subsistence and conference dissemination costs.**
This section includes journey costs, subsistence and conference fees. Where applicable, you will need to include the travel and subsistence costs of your project advisory group, steering committee and/or data monitoring & ethics committee. Travel and subsistence costs relating to dissemination should also be included here, as should costs relating to overseas travel.

**Journey costs**
Enter the total cost of transport for all journeys for destination/purpose. If travel is by car, apply your institution’s mileage rates (however this
should not exceed HMRC approved mileage allowance payments, which is 45p per mile for the first 10,000 miles and 25p thereafter. Travel by the most economic means possible is encouraged. NIHR programmes do not usually fund first class travel.

**Subsistence**
Subsistence covers accommodation (if necessary) and meals associated with the travel, excluding any alcoholic beverages.

**Conferences**
Where national or international conference costs are included, a statement naming the conference or purpose of travel and the benefit to the research must also be made; failure to adequately justify your attendance at a conference will mean the programme will not fund this cost.

For research of up to five years, the programme will usually fund up to a maximum of two international conference attendances. For research beyond five years, the programme will usually fund up to a maximum of two international conference attendances per five year or part of five year research period.

**Equipment**
Essential items of equipment plus maintenance and related costs not included as part of estates should be input in this section. These can be lease or purchase costs.

- The purchase cost of pieces of equipment, valued up to £5,000 excluding VAT, will be considered.
- Pieces of equipment costing more than £5,000 to purchase will usually need to be leased. Where applicants are leasing equipment with purchase price of more than £5,000, a comparison of leasing versus purchasing costs must be provided in the ‘Justification of Costs’ section.
- Items of equipment valued at £250 or more must be itemised separately; however grouping same type equipment is permitted.
- Costs of computers are normally restricted to a maximum of £650 each excluding VAT and a statement of justification must be included, in the relevant ‘Justification of Costs’ section for any purchase above this limit.
- Equipment must exclude VAT, but if your organisation is unable to reclaim/recover the VAT on a piece of equipment, you should check the box ‘VAT cannot be reclaimed’.
- You will need to seek expert advice from the organisation purchasing the equipment regarding its VAT status. If you check the ‘VAT cannot be reclaimed’ column, VAT at 20% will automatically be calculated into the overall cost of that item.

**Consumables**
This section includes non-reusable items specific to the research. Please itemise and describe the requirements fully (e.g. postage, stationery, photocopying). These items should be research specific, not just general office costs which should be covered by indirect costs.

**Other direct costs**
These are costs, not identified elsewhere, that are specifically attributed to the research. For example, open access costs, other dissemination costs, costs associated with the use of research facilities, external consultancy costs, computer licensing, recruitment and advertising costs. Please note that for organisations claiming indirect/overhead costs, costs such as recruitment of staff, and general training (e.g. in common IT packages) are costs that should be covered by the indirect costs element of the award being sought and should not appear in this section. If external consultancy costs are included in this section they must be fully justified in the ‘Justification of Costs’ section. Please specify the hourly rate and the number of hours and note that consultants must not be people who are already employed by the applicant’s institution. If they are, any costs should be entered as direct costs in the ‘Details of Posts and Salaries’ and ‘Annual Costs of Posts’ sections.

**Open access costs**
During the course of your project and throughout the review and publishing phase, you may choose to submit an article based on your research to an open access publication. Depending on the publication, you may be subject to an Article Processing Charge (APC). APC rates vary but are usually within the range of £300 and £3000. Open access publications usually list their APC rates on their websites. Where possible, you should include an estimate for any APC in your funding application, since NIHR expects that APCs will be covered by the funding award. [https://www.nihr.ac.uk/about-us/our-purpose/principles/nihr-open-access-policy.htm](https://www.nihr.ac.uk/about-us/our-purpose/principles/nihr-open-access-policy.htm)

**Other dissemination costs**
Any large costs should be further detailed with a breakdown of constituent parts or a timescale profile of the costs. Meetings to share best practice, training events and events to disseminate research findings must be run at the lowest possible cost with minimal catering. ‘Conferences’ which are described as such are not eligible for funding.

**Indirect costs/overheads**
Indirect costs will be charged in proportion to the amount of research staff effort requested on the award. They comprise:

- General office and basic laboratory consumables
- Premises costs
- Library services/learning resources
- Typing/secretarial
- Finance, personnel, public relations and departmental services
- Usage costs of major research facilities
- Central and distributed computing
- Charge out rates for shared equipment
- Cost of capital employed

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**NHS bodies or other providers of NHS services indirect costs**

NHS indirect costs cannot be claimed through NIHR/DH programme funding. NHS bodies or other providers of NHS services have been allocated NIHR Research Capability Funding (RCF) to contribute to the cost of hosting NIHR/DH-supported research. For more information please click on the link below:

https://www.nihr.ac.uk/research-and-impact/nhs-research-performance/research-capability-funding.htm

**HEI indirect costs**

Total HEI indirect costs must be fully justified. HEIs are permitted to claim estate and other indirect costs. These costs are calculated on the basis of TRAC methodology. Proposals from other types of institutions/organisations should leave this section blank.

- HEI indirect costs are based on the number of full-time equivalent research staff working on the research and the indirect/estates charges set by an institution.
- Where staff from more than one HEI are working on the research there may be different indirect/estates charges for each one. Please list each institution on a separate line.
- Please note HEI indirect costs cannot be claimed on shared staff costs. The applicant(s) should consult their HEI finance departments for the appropriate figures to include in the estate charges and other indirect cost section.

**Commercial/other partner organisation indirect costs**

Commercial/other partner organisations cannot claim indirect costs which are the costs of resources used by the research that are shared by other activities. Please seek advice from your finance department about the appropriate cost for this section.

Total Commercial/other partner organisation indirect costs must be fully justified.

**NHS support and treatment costs (incl. excess treatment costs/savings)**

The finance section includes a section that asks researchers to provide an estimate of the patient care costs associated with the research (if applicable). An explanation of why these costs are being incurred and the basis on which the estimations have been made should be fully detailed under the relevant ‘Justification of Costs’ section.

The committee/panel will take NHS support and treatment costs into account when considering the value of money of the research. It is important that you consider these costs and discuss them with the NHS bodies or providers of NHS services involved in order to avoid any delay in commencing the research.

Please be aware that the research award does NOT include NHS support and/or treatment costs. NHS support costs will be funded via the Comprehensive Research Networks. NHS treatment costs, including any excess treatment costs/savings, will be met by the NHS through normal patient care commissioning arrangements.

A representative of the NHS body or provider of NHS services - incurring any NHS support and treatment costs - must sign off the application.

The ‘Other supporting roles – signatories (electronic)’ page is intended to ensure that the aforementioned organisation is satisfied that all NHS support and treatment costs in the application are correct and is prepared to meet these costs.

**Upload a Schedule of Events Cost Attribution Template (SoECAT) form**

It is mandatory to attach a Schedule of Events Cost Attribution Template (SoECAT) form.

Please note that as part of the work to address the issues surrounding the way in which Excess Treatment Costs are funded, new arrangements are now being implemented as part of a pilot. To underpin the new arrangements, a cost attribution tool has been created by the Health Research Authority (HRA) in partnership with charity funders and research sponsors. This tool provides a standardised approach across England, ensuring that the attribution of study activities complies with the Department of Health and Social Care Guidance on Attributing the Costs of Health and Social Care Research and Development (AcoRD). As part of their funding applications, researchers are required to complete this new tool, known as a Schedule of Events Cost Attribution Tool (SoECAT) for clinical research, which has been developed from the current HRA Schedule of Events. This tool is designed to capture the different costs associated with clinical research and attribute them accordingly. The totals for excess treatment costs and NHS support costs are calculated by using the SoECAT. Therefore, you are not required to add costs to the online application form under the ‘NHS Support Costs’ or ‘NHS Treatment Costs’ sections. However please still complete the question over whether the costs have been discussed and agreed with the Lead Network.

Researchers and/or their study teams and Research Sponsor/ Lead NHS Provider (e.g. R&D office/ Clinical Trial Unit) are supported by AcoRD Specialists in the Local CRN to verify the accuracy of the SoECAT. For more information please see the NIHR CRN Routemap available at https://www.nihr.ac.uk/funding-and-support/study-support-service/resources/supporting-research-in-the-nhs.htm

Under the new arrangements, sign off via the LCRN AcoRD Specialist is required to confirm the study attribution complies with the Department of Health and Social Care AcoRD guidance. This early attribution support will underpin the excess treatment cost management process by providing formal sign off, supporting the role of the research sponsor and lead R&D office or Clinical Trial Unit. Completion of the Schedule of Events Cost Attribution Template will be required for studies eligible for the NIHR portfolio and the support this provides, which will include access to excess treatment cost payments under the new arrangements. This ETC value, alongside recruitment activity in the NIHR Central Portfolio Management System, will then be utilised to inform the payments to NHS providers.

SoECATs will need to be updated and re-submitted for studies that are dependent on the outcomes of work completed in the first part of the programme.

A completed Schedule of Events Cost Attribution Template (SoECAT) is now required to be uploaded and submitted as part of the application submission for all applications. The SoECAT must be signed off by an AcoRD Specialist even where there are no Excess Treatment Costs.

The SoECAT Form and more information can be found here

Guidance for completing the Schedule of Events Cost Attribution Template (SoECAT)

**NHS support costs**

These are the additional patient care costs associated with the research, which would end once the R&D activity in question has stopped, even if the patient care service involved continues to be provided. These might cover items such as extra patient tests, extra in-patient days and extra nursing attention. Researchers should contact their local NHS R&D department initially and, if they are unable to help directly or if there is no local NHS R&D department, contact the Local Comprehensive Research Network (LCRN) senior manager for advice on NHS support costs. Further details about LCRN contacts are available at https://www.nihr.ac.uk/nihr-in-your-area/local-clinical-research-networks.htm
*Please note: you are not required to add NHS Support Costs on the online form as these are now part of the new SoECAT form. However, please still complete the question over whether the costs have been discussed and agreed with the Lead Network*”

**NHS treatment costs**
Please read the following guidance on the funding of excess treatment costs prior to completing your application
https://www.england.nhs.uk/ourwork/research/etc/. These are the patient care costs that would continue to be incurred if the patient care service in question continued to be provided after the R&D activity has stopped. In determining NHS treatment costs you must assume that the patient care service being assessed will continue even though there may be no plans for it to do so. Where patient care is being provided which differs from the normal, standard, treatment for that condition (either an experimental treatment or a service in a different location from where it would normally be given), the difference between the total treatment costs and the costs of the “usual standard care” (if any) constitutes excess treatment cost/saving, but is nonetheless part of the treatment cost, not an NHS support or research cost. These costs should be determined in conjunction with your NHS body or provider of NHS services and their commissioners.

Please note if the patient care intervention under investigation is in addition to usual care there is no need to complete the ‘Usual Treatment Costs’ section however this will need to be justified in the relevant ‘Justification of Costs’ section. If the patient care intervention under investigation either wholly or partially replaces usual care, the ‘Usual Treatment Costs’ section must be completed.

*Please note: you are not required to add NHS Treatment Costs on the online form as these are now part of the new SoECAT form. However, please still complete the question over whether the costs have been discussed and agreed with the Lead Network*”

For further information, please see:
Attributing the costs of health and social care research and development (AcoRD).
HSG(97)32: Responsibilities for meeting patient care costs associated with research and development in the NHS