

i4i Challenge (Real World Implementation) Webinar Q&A

1. I am expecting to obtain CE marking in 6 months. Will I be eligible for the Challenge Award?

The Challenge Award is open to innovations that are market ready or near market, enabling real world implementation studies to be successfully conducted. We will therefore consider applications on pending CE marked products, evidenced by technical file submission to a Notified body for assessment.

2. Please clarify the i4i position on Tier 3 technologies from the NICE Evidence Framework

Tier 3 digital health technologies as defined by the NICE Evidence Framework, that have a potential application in the NHS, are eligible for this funding stream. Tier 3 comprises two sub-tiers: Tier 3a which constitutes self-management technologies that facilitate behavioural change; and Tier 3b which are categorically medical software and thus fall under the medical device regulation.

3. Which organisations can I go to for help with stakeholder and clinical engagement?

We encourage applicants to engage with relevant organisations that can help identify and establish clinical collaborations, including (but not limited to) the NIHR Medtech and In vitro diagnostics Co-operatives (MICs) and Collaborations for Leadership in Applied Health Research and Care (CLAHRCs), and to work closely with the Academic Health Science Networks (AHSNs). Please note that collaborations should be established prior to submitting a Challenge RWI application.

4. The Award requires that there is a collaboration with at least two types of organisations, of which one must be a healthcare service provider. Due to the impact of COVID-19 on NHS organisations, can you please advise?

Collaborations should have been established prior to considering submission of a Challenge RWI application. However, we understand that in the current COVID-19 climate, it may be difficult to secure clinical collaborations. We will accept applications where there's evidence to demonstrate favourable clinical/ stakeholder engagement but where collaboration agreements may not have yet been drafted.

5. I have developed a COVID-19 related technology and seeking funding for further development. Can I apply for an i4i funding competition?

If the proposed COVID-related technology will deliver public health benefit in 12 months, please apply to the NIHR/UKRI-MRC COVID-19 Rapid Response Rolling call, link [here](#). Alternatively, if the proposed COVID-related technology will deliver public health benefit beyond 12 months, it will be out of scope for the COVID-19 Rapid Response call, but can be submitted to one of our open i4i competitions provided that it meets our eligibility criteria.

6. Can the CEO of an SME be the lead applicant on a proposal, or does this have to be the scientific lead?

We expect the lead applicant to be the most relevant and appropriate person within the lead organisation, who can direct and coordinate the research project and demonstrate due commitment to the delivery of the project. As such, this could be the CEO or scientific lead alike, and will depend on the structure of the organisation.

7. The lead applicant has to be based in England. Is this also the case for the collaborators, or for example could the project involve hospitals in Scotland?

We only require the lead applicant to be based in England. If the NHS service provider is a collaborator, it can be based anywhere in the UK. Other types of collaborators (e.g. academic or commercial) may also be based overseas but a convincing justification must be made as to why equivalent collaborators could not be sought within the UK. Please note that the i4i Programme will not fund contributions from overseas collaborators.

8. Can the project focus on a technology owned by a foreign company?

Yes, provided that the lead organisation is based in England and has licensed/assigned IP rights to the technology. All prospective lead applicants entering contracts with the NIHR will be required to have full access to the technology's intellectual property by the start of the project.