The NIHR Invention for Innovation (i4i) programme

A review of progress and contributions to innovation in healthcare technologies

Extended summary

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Extended summary

Introduction: Evaluating the NIHR Invention for Innovation (i4i) programme

Evidence on the impact of various innovation, finance and governance models in the medical technology, diagnostics and devices space is scarce, particularly for public financing models and their contributions. The National Institute for Health Research (NIHR) Invention for Innovation (i4i) programme aims to support the development of innovative medical technologies for patient benefit. Since its inception, the programme has identified and assisted projects of critical clinical importance. It does so through funding for the development of innovative technologies and their translation into the clinical environment, as well as through business support and scientific advice to medical technology innovators. The i4i programme fills a crucial gap in the innovation finance system by providing funding at an earlier stage than alternatives such as venture capital. Projects involve collaboration between at least two partners from academia, the NHS and industry.

RAND Europe was asked to evaluate the programme, to identify outputs and impacts of i4i projects, and to examine the factors influencing performance and progress. This should help inform the future of the programme. The evaluation used a multi-method approach, including a review of background information from i4i, scoping interviews with key informants, a survey of programme participants, and case studies of projects demonstrating diverse technologies and health needs.

This is an Extended Summary based on the full report that is available online (www.rand.org/t/rr1101). The main report describes the full methodologies used by RAND Europe and more detailed findings (including an analysis of outputs and impacts, programme strengths, areas for future attention and methodological caveats.

Impacts from the i4i programme – the highlights from a stakeholder survey and interviews

The i4i programme is helping to bridge the 'valley of death' in early-stage innovation.
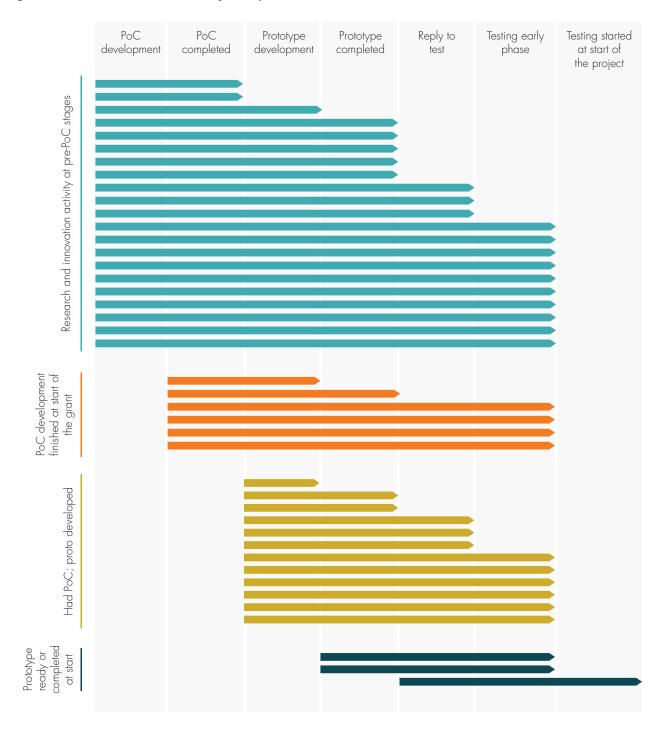
It is supporting projects with diverse starting points, ranging from pre-proof of concept to a completed prototype. The programme is helping innovators reach a point where they can attempt to attract funding for further downstream development and commercialisation.

The paths travelled by individual projects vary (See Figure 1).

For example, some of the projects examined in this evaluation moved from pre-Proof of Concept to a completed prototype, while others started at a proof of concept phase and reached readiness for clinical testing. A minority of projects entered the programme to develop prototypes and progressed to conduct early-phase clinical testing as part of the funded project. According to the survey results: (i) a proof of concept was completed in over half of the cases investigated (64%); (ii) the majority of projects (88%) completed a prototype during the life of the contract; (iii) over half of the projects (55%) started testing or a pivotal clinical trial; and (iv) the contracts also helped a minority of projects (14%) get to the stage where they were ready to start testing or a pivotal clinical trial soon after project completion.

The i4i programme has placed innovators in a position to pursue further downstream development after project completion, including further testing and pivotal clinical trials, commercialisation and – in a minority of cases – uptake in the NHS and product placement on the market.

Figure 1. Main milestones achieved by start position

Based on an online survey, our study found that most commercialisation activity related to the finalisation of intellectual property arrangements (23 Principal Investigators [PIs] reported this, 52%) and business plans (12 PIs reported this outcome, 27%). Six PIs (14%) also reported starting a company on the basis of i4i-funded work, and an additional seven PIs (16%) noted that another company continued downstream development. In four cases, PIs reported uptake in the NHS (9%) and two PIs (5%) reported placing a product on the market.

i4i is widely seen as rare funder of high-risk early innovation in the medical devices, diagnostics and medical technologies landscape in the United Kingdom.

According to interviewees, a number of factors make i4i unique. These include a willingness to support individuals outside of the 'usual suspects'; an openness to diverse themes and disease areas; and being an adaptable and responsive funding source with a less bureaucratic management approach than some other investors in this space. Some evaluation participants felt that the prestige associated with i4i funding facilitated interactions with other stakeholders that are needed for successful product development and uptake. As one case-study interviewee highlighted: '*When we seek advice from NHS-aligned stakeholders … they are more willing to help you actively if you have got an NIHR grant*'.

The i4i Secretariat, through its application and selection process for funding, has helped drive proposal improvements, primarily through feedback on the scientific content but also through business-related advice.

Evaluation participants appreciated i4i's enabling roles both at application and selection stages, and throughout project implementation. As illustrated by one interviewee: '*I was very impressed by the support i4i gave us; we had questions about what i4i wanted around the commercialisation plan and they got back to us on that.… They came to all board meetings and were very positive and gave good suggestions where it was required*'. Another interviewee highlighted that: '*The i4i Secretariat was instrumental in raising the visibility and the overall impact of the work*'.

Several enablers of project progress, as well as challenges to implementation and uptake, were highlighted by project participants.

Key reported enablers include the expertise and skills of the project team, the technical and scientific nature of a project, and access to clinicians as a useful source of insights on the usability of an innovation. On some occasions, scientific and technical issues also represented challenges. Other key challenges that i4i project participants highlighted include issues related to product design and usability and regulatory constraints. Inertia and resistance to change, procurement channels into the NHS and financial challenges to implementing pivotal clinical trials are expected to be key barriers going forward. Some of the project representatives we consulted also highlighted a need to clarify the relative weighting of different technical, social and commercial criteria in the application and selection guidance, so that applicants could be better informed about expectations associated with successful bids. Related to this, study participants identified additional areas for reflection to include: prospects for expanding the selection panel to cover broader technical expertise; opportunities for more sustained panel engagement throughout a project's life in an advisory role; and scope for further engagement between the i4i Secretariat and host institutions to coordinate IP management more effectively, and to ensure mutual understanding of the policy and structure of IP management within the programme and a project's host institution.

Insights from case-studies of i4i projects

As part of this research, RAND Europe also conducted four case studies of i4i projects, selected in consultation between the i4i Secretariat and RAND Europe, to reflect the diversity of innovations and stages in the innovation pathway that i4i supports. These included case studies of a saliva-based chronic obstructive pulmonary disease (COPD) sensor; a low-cost, non-invasive visual aid for severely sight-impaired individuals; next-generation mobile HIV diagnostics with wireless connectivity; and a cervical orthosis for people with motor neuron disease (MND). Highlights from the case studies are presented in the boxes below (Boxes 1-4).

Box 1. A saliva-based chronic obstructive pulmonary disease (COPD) sensor

Core project aim: to develop a prototype device to predict and manage chronic obstructive pulmonary disease (COPD) exacerbations at point of care, based on biomarkers in saliva.

Key outputs and achievements:

- Completion of a longitudinal study involving 60 patients to establish that three key saliva biomarkers could be used to predict COPD exacerbations.

- Advance of a saliva-based point-of-care COPD sensor from proof of concept initiation to prototype initiation.

- Development of an electronic patient wellbeing diary mobile application (app) which combines saliva biomarker results with patients' health scores. The app is available from the Apple store.

- Significant progress with securing IP protection needed for future commercialisation: (1) granted a US patent on saliva biomarkers and filed for a similar patent in Europe and Canada; (2) filed for an UK patent on the saliva sampler design; (3) secured Europe (EU) and US copyrights on the electronic wellbeing diary mobile app; (4) filed for US and EU patents on the saliva-based COPD sensor.

Key enablers:

- A well-defined clinical problem stemming from an earlier feasibility study fully funded by i4i.

- Access to proven sensor magnetic immune-affinity assay (MIA) technology to build on, for developing the COPD sensor.

- A multidisciplinary and fully engaged team ensuring the right breadth of expertise: clinicians, biochemists, engineers, software developers, data analysts, regulatory experts and health economists.

- Access to patients to conduct a longitudinal study, as well as consultation and engagement with patient groups: focus groups to test the electronic wellbeing diary and obtain users' insights on the COPD sensor design features.

- Substantial consultation with regulatory experts and healthcare professionals to (1) understand the regulatory framework and (2) obtain perceptions on clinical device costs, implementation routes and potential barriers for adoption. These consultations helped to focus the development of the technology.

- Perceived prestige of an i4i grant, which facilitated contacts with stakeholders.

- Support from the i4i Secretariat, and panel suggestions (e.g. advice to move from a paper-based to an electronic patient wellbeing diary).

Key challenges:

- Difficulty in engaging an industry collaborator to identity commercialisation strategies going forward at this early product development stage.

- Though not explicitly mentioned as a challenge, IP protection and commercialisation ambitions can present challenges to dissemination and the awareness-raising efforts of a project.

Next steps: Develop a close-to-market fully integrated prototype; define more detailed commercialisation plan.

Box 2. A low-cost, non-invasive visual aid for severely sight-impaired individuals

Core project aim: to develop a low-cost, non-invasive visual aid to help improve the quality of life for severely sight-impaired individuals, helping them regain a degree of independence, vision and mobility.

Key outputs and achievements:

- The i4i contract allowed the project team to develop a visual aid that could significantly improve the quality of life for sight-impaired people. The project moved from a very early prototype to a prototype that is nearly ready for market.

- After the i4i contract, the team won a Google Impact Challenge of £500,000 to collect further data from a take-home trial to support the final phase towards commercialisation.

Key enablers:

- Early consultation with patients to understand their needs and how they relate to product design and function, across different areas of application and patient segments.

- Flexibility within the i4i contract allowed the team to make modifications to the original research plan, which contributed to the rapid development of the device.

- According to the Principal Investigator, substantial media attention helped enable fundraising efforts.

- Co-location of the key team members facilitated team interactions and relationships

Key challenges:

- Staff resources; more specifically a lack of capacity at the start of the project hindered initial progress at the desired pace. With additional resources from i4i, this was resolved by hiring an additional team member to manage patient trials.

- Clinical time was not costed in the proposal, which limited clinical collaborators' ability to contribute to the extent they may have desired.

- Ensuring realistic patient expectations – though not reported as a formal challenge – was identified as a potential risk area needing careful management, so as not to create false expectations about product availability and health potential.

Next steps:

- On the basis of the data collected through the take-home trial, and with the support of investors, the team will aim to launch a spin-out company.

Other points to note:

- The project focused as much on the technological aspects of the overall product that was being developed as it did on the design and user-experience aspects. The team saw both to be important for overall product uptake. As a result, the process of innovation involved substantial consultation with potential users.

- Estimates of staffing levels and costing of clinical staff can be hard to provide upfront, and may be an area to which i4i can pay more explicit attention at the proposal stage.

- The NHS is not seen as the primary channel of distribution as the NHS at present has limited access to assistive technologies, and new healthcare developments with resource implications would need assessment by the National Institute for Clinical Excellence (NICE). i4i may wish to consider how it can support innovative health projects targeting different types of procurement and distribution channels.

Box 3. Next-generation mobile HIV diagnostics with wireless connectivity

Core project aim: to develop an innovative HIV diagnostic tool in order to address the need for more widely available, accurate and fast HIV testing outside a hospital setting. The project focused on developing a prototype for a wirelessly connected HIV diagnostic device.

Key achievements and outputs:

- Development of an initial proof of concept (during the proposal phase).

- Development of a pre-market prototype of a portable device.

- Associated microchips and the coatings for the detection of HIV antibodies.

- The project tested the device in a small-scale clinical pilot.

- The team also developed an exploitation plan and a roadmap for the next stages of the work.

- The team achieved the milestones and overall objectives of the i4i-funded project, which helped to attract further support from the Engineering and Physical Sciences Research Council (EPSRC) in the form of an £11 million collaborative grant to further investigate the engineering and physical science research challenges and wireless connectivity aspects of diagnostic devices. It is important to note that the EPSRC funding does not support product development.

Key enablers:

- Team members brought complementary skills and expertise from a wide range of backgrounds (e.g. clinical research, chemistry, technology management).

- Strong and committed leadership made successful cooperation possible within a large and diverse group.

- The industry partner's openness to sharing detailed information on the technology development process facilitated effective academic-industry cooperation by providing an extended evidence base to the development of chemical compounds used in the device.

- A series of site visits with stakeholders enabled the team to understand the needs of the prospective users of the diagnostic device and to integrate these into product development.

Key challenges:

- Developing the technology and the chemical compounds in parallel: design changes to either of these resulted in setbacks to the clinical validation phase.

- Potential future challenge to uptake: current regulation requires extensive counselling for patients diagnosed with HIV, which can limit the uptake of an HIV device of this nature.

Next steps: Finalising the development of the prototype and starting the regulatory approval process.

Other points to note:

- The project has conducted no formal health economics analysis to date, and did not incorporate regulatory, procurement or pricing considerations into the design. Affordability of the device is one of the explicit priorities of the project, so this may be an area for future attention.

- The partners were ready to proceed with the project in the absence of i4i funding, but the scope of the work would have been compromised. It may be interesting to reflect on the role of matched public-private financing arrangements in which i4i could participate in the future, where there is willingness from industry to invest in the same areas supported by i4i.

Box 4. A cervical orthosis for people with motor neuron disease (MND)

Core project aim: The project aimed to develop a supportive neck collar for patients with motor neuron disease (MND).

Key outputs and achievements: With i4i support, the project team established a prototype and performed an early clinical evaluation of a small set of devices, manufactured in-house.

Key enablers:

- The involvement of patient groups enabled recruitment of patients for testing, input into product design, feedback and adaptations in design. Related to this, a patient association was included as a co-applicant on the project.
- i4i was seen a flexible and approachable funder. Personal relationships and approachability made it possible for the project team to deal with unforeseen developments during the lifetime of the project. These included delays in finding a manufacturing partner and the consequent need to apply for CE marking in house (as opposed to relying on a partner for this).

Key challenges:

- An initial, conservative costing of the project – tailored partially around innovators' perceptions of 'funding ceilings' in the i4i programme – created challenges for project delivery. This resulted in the team contributing significant resources to the work beyond the funding.
- The project team originally underestimated the amount of evidence from prototype testing necessary to construct a business case that would be attractive to potential licensed manufacturing partners, which complicated efforts to find such a partner.

Next steps:

- The project has received an extension from i4i to support further testing and to assist with finding a manufacturing partner.

Other points to note:

- The need for a novel cervical orthosis was identified by end users – this was a demand-driven innovation project.
- The project team conducted a health economics assessment and developed initial design concepts during the application phase. This helped address reviewer concerns from an initially rejected bid.
- The team that worked on the project has continued to collaborate on other initiatives, such as preparing another NIHR grant application in a different area of work.
- According to the interviewees, the most effective outreach method towards the MND community was a YouTube video produced by the team, in which a patient with MND described her experience with the collar. This received 1,057 hits (at the time this evaluation was conducted).

Recommendations on further maximising prospects for impact

There are a number of areas for policy consideration that emerge from the evaluation evidence (including from interviews, surveys and case studies). They relate to programme design and to the role of the Secretariat in facilitating impact and knowledge management. For each area we have identified actions which could help maximise i4i programme impacts. Our intention is not to prescribe specific actions, but rather to raise issues which require careful consideration by i4i programme management. Core actions to consider include:

1. Does the Secretariat have the capacity to actively run a responsive review mechanism for projects so that decisions on the amount of funding i4i provides are phased and determined reactively, following an initial phase of work?

To ensure staffing continuity, time-lags between reassessment and work continuation would need to be kept as short as possible.

2. Can the Secretariat do more to encourage applicants to consider adoption, health economic analysis and product design issues at application and selection stages, possibly through the design of the funding application forms?

The i4i programme ultimately aims to achieve patient benefit and some of the challenges to adoption may be mitigated if they are identified and considered in a timely manner. The constitution and terms of engagement of the i4i selection panel should also be reflected on, to see whether there is scope for providing longer term and broader technical expertise to successful projects. There could be scope for more sustained panel engagement throughout a project's life, in an advisory role.

3. Is there opportunity for enhancing the scope and scale of business-related guidance and advisory support that the i4i Secretariat can provide?

There are three key areas of additional support which the programme participants we surveyed and interviewed thought would be useful for advancing their projects and maximising prospects for impact. These include:

a. Engagement in facilitating networks with industry, clinicians and other stakeholders, which could assist product development and uptake.

b. Awareness raising and information sharing about the i4i programme, for example through roadshows, showcase events and/or awards recognising leading innovators.

c. Providing training in business and entrepreneurship skills, supported through additional programme funds.

4. The i4i programme Secretariat should consider how best to track the long-term impacts of i4i projects, after the completion of i4i funding.

This could include follow-up on success rates with downstream fundraising, commercialisation and uptake of projects which the programme has supported. This work needs to also consider updates and some improvements in management information systems within the programme.

5. The Secretariat may wish to reflect on the mix of academically-, industry- and clinically-led projects in the portfolio and the roles and levels of engagement by different project partners, throughout the duration of projects.

This current mix may be appropriate, but academically-led projects in particular may benefit from active Secretariat or external support in identifying commercialisation and NHS uptake partners.