

Technology Strategy Board

Driving Innovation



Assessing the impact of near-patient testing

SBRI Competition for development contracts

September 2011

Summary >

The Technology Strategy Board, in partnership with the Department of Health (DH), is to invest up to £1m in projects to produce new and improved tools, products or capabilities in the field of health economics to assist companies in the design and evaluation of diagnostic clinical trials. It is envisaged that the new tools will lead to better adoption of new diagnostic products, where appropriate, by providing assessors and decision-makers with high-quality data on their impact.

This competition has been developed in discussion with the National Institute for Health and Clinical Excellence (NICE) and the British In Vitro Diagnostics Association (BIVDA). The competition aims to generate health economics capabilities and models that will assist companies in predicting the impact of the introduction of point-of-care (POC) diagnostics. Applicants may directly evaluate the impact of the introduction of CE marked products to collect data to inform their models. The CE marked products and models must be for a disease or condition prioritised by DH for the Detection and Identification of Infectious Agents (DIIA) programme (see scope).

This competition will open on **26 September 2011** and close at noon on **16 November 2011**. It is open to single companies or organisations from the private, public and third sectors, including charities. Projects can last up to 24 months and successful applications will attract a 100%-funded development contract. We expect that contracts will be in the region of £100,000 to £350,000. The

Technology Strategy Board's assessors will consider value for money.

Successful applicants must make the resulting models, tools and capabilities accessible through, for example, licensing or an alternative approach proposed by the applicant. This will not infringe the ability to patent novel ideas and products.

Background and Challenge >

The DIIA Innovation Platform aims to reduce the economic burden, death and illness due to infectious agents in humans and animals by encouraging the development and clinical adoption of commercially viable diagnostic devices that will create business opportunity and wealth in the UK.

The Wanless reports, published in 2001 and 2004, identified the NHS as a slow adopter of new technologies. This is especially true for disruptive technologies, which can have a significant impact on the status quo. POC diagnostic technologies fall into this category. Their uptake may require or evoke a change in the patient care pathway and result in, for example, the need for new procedures, roles and responsibilities for healthcare workers and others.

Whilst there are many challenges to the adoption of POC diagnostic solutions, the lack of evidence presented to assessors and decision-makers about the benefits of a new product can be a significant barrier.

Although NICE and other organisations commission studies to model the economic and healthcare consequences likely to be associated with new tests, incomplete data and a lack of modelling tools can make this a difficult task and result in estimates with considerable degrees of error and uncertainty.

The design of clinical trials for the evaluation of POC devices is often geared towards collecting data required for regulatory approval and may not generate the data required for assessment by NICE and others. Ideally, diagnostic clinical trials should

be designed so that the impact on public health, patient outcome and overall cost to healthcare systems can be ascertained.

Introducing POC devices and changing the patient care pathway may result in a requirement for education and training and extended or new roles for central laboratory personnel, who may need to establish and oversee quality assurance schemes for POC devices and ensure that results are captured and linked into patient records.

Those recommending and commissioning POC tests need to take these factors into account as well as the savings made by a reduction in the number of clinic visits and the consequences of early detection combined with appropriate treatment. The social and behavioural aspects of engaging patients in their diagnosis and treatment selection may lead to greater treatment compliance and a more positive patient experience.

The challenge of estimating the impact of the introduction of novel POC diagnostics is a complex one, exacerbated by patient co-morbidity and multiple patient care pathways for a single disease or condition. Furthermore, different healthcare systems can make it inappropriate to extrapolate health econometrics data from, for example, one country to another.

There are three competitions in this, DIIA's second series of competitions, and applicants may wish to consider applying for the collaborative R&D competitions; 'Sepsis I: Multi-pathogen detection and/or simple discrimination', or 'Sepsis II: Advancing biomarker use in sepsis management', details of which can be found at www.innovateuk.org under Competitions.

For more details of events related to this competition and to others in the DIIA series go to <https://ktn.innovateuk.org/web/DIIA>

Scope >

This competition aims to generate new and improved health economics tools, products and capabilities to model and assess the impact of near-patient tests and to provide tools that will help companies and organisations design and/or evaluate diagnostic clinical trials. The term near-patient testing includes POC tests used in a variety of healthcare settings including primary care, accident and emergency departments, outpatient clinics, and systems close to wards and intensive care units. Modelling the impact of the introduction of laboratory-based tests is out of scope but applicants may consider near-patient testing in areas adjoining, for example, intensive care units.

We are challenging applicants to consider the evidence required for the assessment of POC technologies and to develop new and improved health-economics modelling tools that will help companies and organisations design and/or evaluate diagnostic clinical trials. Applicants may evaluate the impact of the introduction into the UK of CE marked products to collect data to design, refine and test their models. This, however, is not mandatory and the development of modelling tools and scenario generators are equally in scope. The CE marked products and models must be for POC diagnostics and must be for one or more of the DH priorities for the DIIA innovation platform.

The DH priorities are:

- tuberculosis
- sepsis
- antimicrobial resistance
 - hospital-acquired infections (meticillin-resistant *Staphylococcus aureus*; *Clostridium difficile*; extended-spectrum beta-lactamase producing bacteria)
 - community-acquired pneumonia
 - antibiotic prescribing in primary care (ie, diagnostic tools to reduce the inappropriate prescribing of antibiotics)
- sexually transmitted infections
 - chlamydia
 - gonorrhoea.

Applicants may consider different product specifications (e.g. time-to-result, sensitivity and specificity) in their models. They may also consider how the models and tools they develop could be applied to healthcare systems outside the UK.

Applicants must not work in isolation and it is anticipated that they will liaise with and subcontract to a variety of experts and organisations to deliver the new tools and ensure their dissemination. The mix of experts required to address the challenge may include, but is not limited to, diagnostic companies, health economists, modellers, medical statisticians, clinicians and managers and decision-makers within the NHS. It is important to understand in detail the limitations of the tools and models available today and to design and develop new and improved capabilities.

Out of scope

- development of POC devices
- generating data with POC devices that are not CE marked
- modelling disease areas not prioritised by DH for the programme. NB some understanding of the generic nature of the solutions is desirable
- modelling the impact of devices aimed at the self-testing market.

SBRI and funding allocation >

SBRI enables the public sector to find innovative solutions to the challenges it faces by reaching out to organisations from different sectors, including small and emerging businesses, and to contract them to develop the products and capabilities required.

In line with the SBRI programme, this competition is open to all organisations that can demonstrate a tangible route to exploiting their findings, tools, products and capabilities. Public, private and third sectors, including charities, may apply. The SBRI scheme is particularly suited to small and medium-sized business, as the contracts are of relatively small value and operate on short timescales. Developments are 100% funded and focus on specific identified needs, increasing the chance of exploitation. Suppliers for each project will be selected by open competition and retain the intellectual property generated from the project. This is an excellent opportunity to establish an early customer for a new technology and to fund its development.

A total of £1m is allocated to this competition and it is anticipated that development contracts will be in the region of £100,000 to £350,000. The Technology Strategy Board's assessors will consider value for money.





Further information >

For more information about this and other competitions, including Sepsis I and Sepsis II, and details of how to register and apply, please see the competitions section of our website at www.innovateuk.org

For more information about SBRI see www.innovateuk.org/sbri

Competition Helpline:

0300 321 4357

Email:

competitions@innovateuk.org

Application process >

To apply for funding through this competition and to get further details you will need to register your interest via the Competitions section of our website at www.innovateuk.org by noon **9 November 2011**.

This is a single phase competition which opens on 26 September 2011 and closes at noon on 16 November 2011; applicants will be notified of the decision on 16 December 2011.

The briefing day, on 5 October 2011, will describe all three competitions in this series and provide applicants with an opportunity to seek clarity on the application process and scope.

If you have any queries about the technical scope of the competition or the application process, please contact the Competitions helpline on 0300 321 4357 or email competitions@innovateuk.org

Key dates >

Competition launch	26 September 2011
Briefing day	5 October 2011
Deadline for registration	9 November 2011 noon
Deadline for applications	16 November 2011 noon
Applicants notified of decision	16 December 2011
Contracts awarded	27 January 2012
Feedback provided by	27 January 2012

Publicity >

The Technology Strategy Board frequently publicises the results of competitions and this includes engagement with the media. Applicants will be asked to provide an agreed form of words for use in publicity material. E-mail pressoffice@tsb.gov.uk with any queries.

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The SBRI scheme is one of the tools that the Technology Strategy Board uses to drive innovation. The Technology Strategy Board is a business-led executive non-departmental public body, established by the government. Its role is to promote and support research into, and development and exploitation of, technology and innovation for the benefit of UK business, in order to increase economic growth and improve quality of life.

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