Technology Strategy Board
Driving Innovation

Stratified medicine: Determining patient response

SBRI Competition for development contracts
March 2012

SBRI Government challenges. Ideas from business. Innovative solutions.

DH Department of Health

Summary >

The Technology Strategy Board and Department of Health are to invest up to £7.5m in the development of novel and innovative diagnostic tests and assessments to determine an individual patient's response to therapeutic intervention. The projects will be selected primarily on their potential value to the health service and on the improved outcomes delivered for patients.

The competition will run in two phases. Applicants successful in phase 1 will be funded to produce a development plan, including a detailed assessment of the economic value of the product. The products combining the best value and greatest technical feasibility will be selected for development in phase 2. The competition has been developed in collaboration with the partners of the Technology Strategy Board's Stratified Medicine Innovation Platform to address the key issue identified in the Stratified Medicine Technology Roadmap to incentivise uptake of new stratified medicine approaches within the UK healthcare system.

This competition is open to single companies or organisations from the private, public and third sectors, including charities. We have allocated up to £1m for phase 1 of this competition. Projects can last up to six months and successful applications will attract a 100%-funded development contract. We expect development contracts in phase 1 to be up to a maximum of £100,000.

This competition opens on **26 March 2012**. The deadline for registration is noon on **6 June 2012** and the deadline for applications is at noon on **13 June 2012**. A briefing event will be held on **4 April 2012**.

Background and Challenge >

The current system for gaining acceptance of new therapies involves large-scale trials designed to look for improved average health outcomes. Data from current therapies confirms that different patients have a variable response to a treatment in terms of both benefit and side effects, and that grouping (or stratifying) patients according to their likely responses could have marked therapeutic benefits, reduce risks, lead to greater uptake and bigger cost savings, and allow early switching to other more effective therapies.

Each year in the UK, adverse reactions to drugs are estimated to result in £1bn in additional hospital bed days alone. It is also estimated that for 90% of prescribed drugs, only 30-50% of patients will respond to treatment. The ability to switch early to other therapies can improve patient care and optimise use of the NHS drug bill, currently more than £10bn a year. There is potentially a huge global market for stratification tests. It is estimated that the treatment of adverse reactions costs $5bn in the US alone. Non-response rates for major drugs are similar across the world.

Healthcare providers could both achieve significant savings in the clinical care pathway by using more targeted products and at the same time dramatically improve the outcomes for patients with a range of different clinical conditions. However, calculation and forecasting of the real market value and potential cost savings for specific products are complex and hinder production and uptake.

In the recently published technology roadmap for stratified medicine in the UK, one key issue identified as critical to the development of stratified products was encouraging adoption of products by health service providers, specifically the NHS in the UK. Defining the value of the product to the healthcare provider in the broadest sense across the whole clinical pathway was thought to have the greatest importance in providing the incentive for the provider to adopt stratification tests. Pressure on NHS resources means products that can demonstrably improve healthcare efficiency and effectiveness and improve patient care will be attractive.

This competition aims to allow the healthcare industries to bring together the different players necessary to evaluate and implement such diagnostic tests, to establish the clinical value chain and to determine the potential for commercialisation and uptake.

The key challenge for industry lies in accurately identifying, and providing suitable evidence of, the cost/benefit balance for healthcare providers of testing. This may be particularly true for small and medium-sized enterprise (SMEs) which may have limited access to marketing forecasts and health-economic modelling.

The aim of this competition is to establish if stratified medicine can be used to improve the current clinical care pathway in the UK by addressing the risks of adverse reactions to drugs and/or by identifying those unlikely to respond. While the total opportunity is significant, it is not clear whether this is the sum of a large number of highly fragmented markets or of a few high-value target areas.

Phase 1 of this competition will fund feasibility studies to provide both an assessment of economic viability of the approach and some preliminary assessment of the suitability of

the biomarkers and their ability to distinguish between different cohorts. Phase 1 will clarify the development path for the product, identify what data is required and define any clinical trials. It is our intention to run a second phase that will fund the development of products with the most convincing value for the health service.

Scope >

We wish to demonstrate the value of stratified medicine to the healthcare system in as short a time as possible, so projects must be able to demonstrate preliminary evidence of the technology performance and anticipated application.

Proposals for funding should be industrially focussed and business-driven, and must clearly present the economic benefits to be gained through exploitation of the product.

We will support projects seeking to develop biomarker-based stratified medicine approaches such as diagnostic tests, analytical algorithms, clinical patient-related indices or other approaches capable of predicting either the response to a specific therapy and/or an adverse response. Point-of-care and laboratory–based tests/algorithms are equally eligible as are more novel holistic diagnostic approaches to identifying response and assessing risk. As the aim is to identify ways to incentivise uptake of the tests, projects must address a therapy currently licensed for use in the UK. Developing tests for use of therapies in clinical development will not be in scope for this competition.

The definition of biomarker is wide – for example, but not limited to, genetic variation, changes in protein markers, metabolic changes, analysis of images, and other pathophysiological measures or markers. While validation of the technology is not required in phase 1, the feasibility of using the selected technology and relevant biomarker should be shown and the validation pathway required for future development identified.

The output expected from the project will be a business/development plan for a product that addresses the challenge posed by a particular therapy. The plan will be shared with the Technology Strategy Board in the form of a final report. Where appropriate, the document should describe the adverse events and their severity, the costs of alternative treatments and the potential benefit to the patient.

For the current market calculation there should be quantification of:

- number of patients currently treated with the therapy in the UK and worldwide and their response profile
- the predicted cost of testing these patients
- number or proportion of adverse events/non-responders noted
- cost of remedial treatment for these patients
- if significant, the drug costs saved by not treating
- the cost of alternative treatment of patients identified as adverse or non-responders
- overall cost benefit to the health system of testing
- overall patient outcomes.

The document should describe:

- market opportunity as assessed by the details above
- how, by whom and where the proposed product will be used within the patient pathway, for example primary care, secondary care, point of care
- any regulatory requirements and clinical evidence required for specific market claims
- the estimated sales price and sales projections
- the expected return on investment
- the expected technical performance of the product (in brief outline)
- early biomarker data as evidence of feasibility.

For phase 1, a detailed technical description of the product is not required, applicants should simply be able to provide an outline specification of how/where and by whom the product/test would be used along with some credible evidence that the markers are appropriate, the development of the test is feasible, and the platform is fit for purpose. The phase 1 report will form the basis for an application to phase 2.

Applicants have the opportunity to request free access to a design mentor during the application phase of this competition. The aim is to help businesses to think more about design at the start of a project. Details of the process will be available once you have registered. Applicants interested in taking up the design option must register this by noon **12 April 2012**. The deadline for submitting a design option request is noon **18 April 2012**.

SBRI and funding allocation >

SBRI enables public sector bodies to connect with innovative ideas and technology businesses to provide innovative solutions to specific public sector challenges and needs.

The public sector is able to find innovative solutions by reaching out to organisations from different sectors, including small and emerging businesses. New technical solutions are created through accelerated technology development, whilst risk is reduced through a phased development programme. SBRI also provides applicants with a transparent, competitive and reliable source of early-stage funding.

SBRI competitions are open to all organisations that can demonstrate a route to market for their solution. The SBRI scheme is particularly suited to small and medium-sized businesses, 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 an open competition and retain the intellectual property generated from the project, with certain rights of use retained by the contracting authority. This is an excellent opportunity to establish an early customer for a new technology and to fund its development.

The Technology Strategy Board and Department of Health have together committed £1m for phase 1 and £6.5m for phase 2. In phase 1, the maximum allocation to any individual project will be £100k and projects should last a maximum of six months. Companies may make multiple applications for different projects. The best projects will go forward to stage 2 where we expect grants to be in the range of £1m-2m. This competition is open to single companies or organisations from the private, public and third sectors, including charities.

Application process >

This is a two-phase competition which opens on **26 March 2012**. The deadline for registration for phase 1 is noon on **6 June 2012** and the deadline for applications is noon on **13 June 2012**.

A briefing event will be held on **4 April 2012** to highlight the main features of the competition and explain the application process.

Key dates >

Competition launch	26 March 2012
Briefing event	4 April 2012
Registration deadline	6 June 2012 noon
Deadline for applications	13 June 2012 noon
Applicants notified of decision	13 Jul 2012
Contracts awarded	31 Aug 2012
Contract return date	10 Aug 2012

Further information >

To apply for this competition you must first register with us. You can do this by going to the web page for this competition at **www.innovateuk.org** under Competitions. When you register you will get access to all the supporting information you need to read before you apply, including the *Guidance for Applicants* and the application form.

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

Competition Helpline:
0300 321 4357

Email:
competitions@innovateuk.org

Publicity >

As part of the application process all applicants are asked to submit a public description of the project. This should adequately describe the project but not disclose any information that may impact on intellectual property, is confidential or commercially sensitive. The titles of successful projects, names of organisations, amounts awarded and the public description will be published once the award is confirmed as final. Information about unsuccessful project applications will remain confidential and will not be made public. E-mail pressoffice@tsb.gov.uk with any queries.

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The SBRI scheme is one of the tools 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.