Stratified medicines programme: Tumour profiling and data capture to improve cancer care

COMPETITION FOR COLLABORATIVE R&D FUNDING

JANUARY 2011
As part of an £11m programme in stratified medicines, the Technology Strategy Board is to invest up to £5.6m in collaborative research and development projects in the area of tumour profiling and data capture to improve cancer care by providing cancer specialists with information specific to the patient’s tumour which will enable more targeted treatment to be provided.
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Summary

One of the major challenges in this area is that currently available tests only analyse single mutations or genes. Cost and time constraints mean that multiple tests cannot readily be done in the NHS, where results are often needed in days. In addition, there is no integrated IT system where assay results and longitudinal clinical information can be securely stored and interrogated to inform research where consents are in place.

The aim of this competition is to help businesses overcome these barriers by:

- supporting the development and uptake of multiplex mutation testing of tumour DNA
- supporting the capture of relevant clinical and test data to inform treatment and guide future research and development in the area
- enabling commercial solutions to be adopted in the NHS, improve patient care and outcomes and potentially save the NHS money in the long term.

Proposals should be collaborative and led by a business, and must clearly present the benefits to business.

The competition opens on 10 January 2011 with successful projects generally focused on applied research attracting up to 50% of public funding.

Challenge

In the UK, 280,000 new cases of cancer are diagnosed every year, and 1 in 4 people die from cancer. The four major types (breast, lung, colorectal and prostate) account for over half of all new cases. Tumour growth is driven by genetic changes. An increasing number of causal gene mutations are being identified and the genes in which they occur are being used as targets for therapeutic intervention. However, in practice only a limited number of situations occur where tumours are tested to direct targeted therapy. The impact of this is that patients may not receive optimal treatments at the earliest opportunity, thus potentially reducing positive outcomes. Routine comprehensive molecular profiling of tumours upon diagnosis has the potential to open up more effective treatment options and, in conjunction with related clinical data, would dramatically increase our understanding of the power of targeted therapies, which could then be applied to drug development.

This competition aims to help businesses address these challenges by developing commercial products or services which can be readily adopted by NHS commissioners for the improvement of patient outcomes.

Background

Most medicines are developed and prescribed to a one-size-fits-all model. Perhaps then it is unsurprising that most medicines are only effective in 30-70% of patients. Because the technology to predict which medicines will work for which patient is at a very early stage, prescribing usually follows a trial and error approach. Recent advances in genetics and diagnostic technology mean that in some cases it may now be possible to subgroup patients (ie, to stratify them) to identify which treatment will be optimal for them.

Cancer treatment is at the forefront of this move towards stratification, with drugs such as Herceptin and Iressa already on the market. However, there is still uncertainty about how to integrate the paradigm of test-and-treat into a clinical setting, leading to inconsistencies in medical practice. It is widely held that a move towards comprehensive tumour profiling in the majority of cancers would inform cancer therapy, leading to better patient outcomes.

The UK has the potential to be a world leader in this area, due to the single healthcare system, the existence of cancer registries and a relatively small (about 800) consultant oncologist community which operates in regional networks.

Cancer Research UK (CRUK) is implementing its own Cancer Stratified Medicines (CSM) Programme which aims to demonstrate the benefit of routinely testing 6,000 tumour samples as a standardised, cost effective process, for consenting patients over the next two years, and collating genetic and clinical data to inform research. The commercial solutions funded by Technology Strategy Board via this competition will support the aims of the CSM programme.

Scope

There are two separate aspects of this competition: development of assays for DNA mutations and electronic data handling. We welcome industry-led proposals addressing either of these areas or both combined.

The projects should result in products or services that are ready for clinical adoption and implementation, and during the projects consortia will be expected to work with clinicians, hospital managers and others, as appropriate, to test their technologies in healthcare settings.

We are working closely with CRUK as it develops its CSM programme and will assist applicants to this competition to identify relevant NHS partners, resources and infrastructure within CRUK as needed.

Development of assays for DNA mutations

The aim of the competition is to develop and validate rapid, robust and sensitive technology solutions for the molecular profiling of tumours with a view to guiding therapy and producing research data in specified cancers (lung, breast, colorectal and prostate).
Successful projects will:
- profile DNA mutations (although we will also consider epimutation or cytogenetics approaches)
- have the capacity to grow in line with future demands for genotyping, taking into account the potential of next generation sequencing.
- aim to develop a service or product that is:
  - reliable to clinical standards (CE for products, ISO for laboratory services)
  - real-time (for clinical turnaround normally within days)
  - cost-effective at less than £300 per panel.

Applicants should also consider all of the factors outlined in Table 1 (opposite) when developing their solutions.

In developing their products or services, applicants will need to incorporate a minimum set of mutations. These are shown in Table 2 opposite. Winning consortia will have the opportunity to demonstrate the validity of their solutions on consented samples from the CRUK programme, demonstrating technologies that can be applied routinely in the NHS.

Electronic data handling
We are also providing funding for projects to design and develop new commercial IT solutions to provide storage, integration, retrieval and analysis options and capabilities for a wide variety of data. These solutions will enable outputs from clinical sources and molecular profiling to be used by cancer researchers in academia or industry to compare genetic variations with treatment effectiveness in the real world. The solutions must be able to link to existing data sources with clear explanation and demonstration of how they would be useful in cancer science and medicine.

Projects will need to address these areas:
- retrieval and integration of diverse NHS datasets concerning cancer patients (eg, minimum datasets, genetic data and patient records)
- maintenance of a secure database where the individual’s right to privacy is demonstrably protected
- allocation of controlled access to validated members of the research community
- scalability – any solution will need to be scalable to ultimately incorporate millions of patient records, including varied clinical data with the expected massive scale of stratification data (molecular or imaging) and formats (images, defined datasets, free text).

In addition, there are practical issues that will have an impact on the design of any processes and architecture, and will need to be considered in the project proposals, such as:

a. **Identification.** Much of the information required will be collected through electronic forms completed by staff across multiple geographical locations that may need to be processed and coded before communication to a central service. Identification mappings and governance will be key considerations.

b. **Interoperability.** Some of the information required will be stored on existing computer systems within the hospital: on systems for patient...
particularly welcomed but is not mandatory.

c. **Integration.** As the system will need to operate alongside existing systems, the value of participation will be measured against the additional workload – which will include records transcription. The system should not impose extra work on NHS staff.

d. **Integrity.** The complex, detailed nature of the information, and the intention to support meta analysis or integration at a national level, necessitates careful control of definitions: of data items and fields, of value sets and codes, and also of processes and workflows. These definitions need to be as carefully managed as the core patient data, as without associated, authoritative metadata the validity of any derived data, and thus any scientific inference, may be called into question.

Applicants should demonstrate knowledge of relevant IT standards in the biomedical and clinical domains and outline the expected frameworks that they would recommend for any proposed solution. We strongly encourage applicants to incorporate existing internationally recognised standards into their solutions and a model-driven approach for systems design and implementation would be particularly welcomed but is not mandatory.

Applications are expected in the area of applied research, which can attract up to 50% public sector funding of total eligible project costs. Projects are expected to take up to three years.

Further information is available in the Guidance for Applicants (see the Competitions section of our website, [www.innovateuk.org](http://www.innovateuk.org)) and at an optional briefing that will be held in London on 19 January 2011.

Any industries with relevant capability may join consortia; in addition to diagnostic companies and IT solution providers, this may include companies with an interest in biomarkers, biosensors, microfluidics, mechanical and electronic miniaturised systems, data capture and analysis, and connectivity.

The projects should result in products or services that are ready for clinical adoption and implementation, and during the projects consortia will be expected to work with clinicians, hospital managers and others, as appropriate, to test their technologies in healthcare settings.

**Application process**

This is a two-stage competition:

**Stage 1:** applicant submits an expression of interest

**Stage 2:** we invite selected applicants to submit a full application.

The competition will open on 10 January 2011 and compulsory expressions of interest (EOIs) must be submitted by 17 February 2011.

The process gives applicants the opportunity to make an initial optional EOI before submitting their compulsory EOI. We will look at the optional EOI and provide feedback to applicants. Applicants may take advantage of this up to one week before the deadline for the submission of the compulsory EOI.

The second stage for invited applications will open on 14 March 2011 and closes on 28 April 2011. The Guidance for Applicants explains the application process in detail and is published with this document on our website together with the application form (see [www.innovateuk.org](http://www.innovateuk.org) under Competitions).

The Technology Strategy Board is working closely with CRUK as it develops its CSM programme and will assist applicants to this competition to identify relevant NHS partners, resources and infrastructure as needed. We will help applicants in finding the right resource for their project within CRUK.

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@tsb.gov.uk. We strongly recommend applicants attend the optional briefing before making their application.

**Key dates**

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<thead>
<tr>
<th>Event</th>
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<tr>
<td>Competition opens</td>
<td>10 January 2011</td>
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<tr>
<td>Optional briefing day</td>
<td>19 January 2011</td>
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<tr>
<td>Optional expressions of interest submission period</td>
<td>10 January 2011 to 10 February 2011</td>
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<tr>
<td>Compulsory expressions of interest deadline</td>
<td>17 February 2011</td>
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<td>Stage 2 opens (for invited applications)</td>
<td>14 March 2011</td>
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<td>Compulsory applicants’ briefing</td>
<td>23 March 2011</td>
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<td>Registration of intent to submit</td>
<td>21 April 2011</td>
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<tr>
<td>Deadline for receipt of full applications</td>
<td>28 April 2011</td>
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**Funding allocation and project details**

We have allocated up to £5.6m to fund collaborative R&D projects that are within the scope of this competition.

Projects must be collaborative and can involve science-to-business or business-to-business interactions. Projects must be business-led, therefore academics can apply only as a collaboration partner in a consortium.

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Further information

For more information about this and other competitions, and details of how to register and apply, and the Guidance for Applicants please see Competitions at www.innovateuk.org.

Competition helpline:
0300 321 4357

Email:
competitions@tsb.gov.uk

Publicity

The Technology Strategy Board frequently publicises the results of competitions and this includes engagement with the media. All applicants will be given a chance during the competition process to opt out of any publicity. Willing 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.