Sepsis I: Multi-pathogen detection and/or simple discrimination

COMPETITION FOR COLLABORATIVE R&D FUNDING
AUGUST 2011
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Summary

The Technology Strategy Board, in partnership with the Department of Health (DH), is to invest up to £5m in collaborative research and development projects to develop point-of-care (POC) diagnostic tools to assist clinicians and health workers in the management of sepsis. The scope of the competition includes the development of devices capable of detecting multiple pathogens and devices for distinguishing between bacterial, viral and fungal infections. The Ministry of Defence and the Home Office have also expressed an interest in funding this competition; decisions will be made on a project-by-project basis.

Proposals should be collaborative and business-led. Applicants must establish relationships with clinical experts and microbiologists to ensure their proposed product is fit for purpose – these experts can be consortia partners, sub-contractors or upfront advisors.

The competition opens on 30 August. It is anticipated that most applications will focus on applied research attracting up to 50% of the total project costs. We expect most projects will have a total project cost of less than £3m but projects above this will be considered; the Technology Strategy Board’s assessors will comment on value for money. Projects may last up to four years.

Our HealthTech and Medicines Knowledge Transfer Network will be organising events and providing further information on this competition, and offering networking and consortia-building opportunities. See https://ktn.innovateuk.org/web/healthktn

The registration deadline for this competition is 9 November. Those applicants interested in taking up the Design Option in the competition must register this by noon 12 September and submit the subsequent Design Option request by noon 15 September.

Background and Challenges

The Detection and Identification of Infectious Agents (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.

One of the priorities identified by DH for the programme is sepsis, a life-threatening illness caused by the body overreacting to an infection. The body’s immune system goes into overdrive, setting off a series of reactions that can lead to widespread inflammation and blood clots in vital organs. It can be triggered by bacterial, viral or fungal infection.

This competition has two strands and both call for the development of POC diagnostic tools related to pathogen detection rather than assessment of the host response and a diagnosis of sepsis. It is envisaged, however, that these tools will be used in combination with clinical expertise and parameters such as body temperature, heart rate, respiratory rate and blood pressure, to aid clinicians and other health workers in diagnosis and decision-making. Early pathogen detection allows timely appropriate treatment, decreasing the likelihood of patients going into septic shock. Conversely, the ability to exclude pathogens would reduce unnecessary antibiotic use and reduce the selection of antemicrobial resistance.

The need to address infection in primary care and develop new and improved diagnostic tools to assist clinicians in diagnosis and treatment has been a strong recommendation of the innovation platform’s steering group and advisors.

The documented incidence of sepsis worldwide is 1.8 million cases per year, but low diagnostic rates and difficulties in tracking it in many countries mean that the true figure is likely to be significantly higher. Estimates of 18 million cases have been made. In the UK, sepsis costs the NHS about £2.3bn a year and causes 36,000-64,000 deaths. The mortality rate from severe sepsis is 28-50%. Patients with severe sepsis use 46% of all intensive care unit bed days and the risk of death increases by 6-10% every hour from onset of septic shock to the start of effective treatment.

There is universal agreement that in the area of sepsis the diagnostic tools available to clinicians are inadequate and/or would benefit from further development. We are challenging consortia to develop high-quality POC devices and rapid tests including, for example, tests in primary care settings, accident and emergency departments, GP surgeries and clinics, and systems close to wards and intensive care units. Taking into account factors such as when and where the proposed tests are to be used, the devices themselves can be hand-held or small bench-top systems. The critical factor is the time from sampling to decision-making and action, enabling faster intervention and better patient outcomes.

Addressing sepsis effectively may also reduce the inappropriate use of antibiotics,
The scope of this competition is an appropriate and timely manner. will deliver information of value to clinicians in upfront advisors. This competition is about be consortium members, sub-contractors or product is fit for purpose – these experts can microbiologists to ensure their proposed relationships with clinical experts and Proposals should be collaborative and

**Scope**

Proposals should be collaborative and business-led. Applicants must establish relationships with clinical experts and microbiologists to ensure their proposed product is fit for purpose – these experts can be consortium members, sub-contractors or upfront advisors. This competition is about developing robust, cost-effective devices that will deliver information of value to clinicians in an appropriate and timely manner.

The scope of this competition is outlined below:

- multi-pathogen detection at the point-of-care which, with clinical justification, may include:  
  - assessing the antimicrobial resistance/sensitivity of pathogens and/or  
  - devices that can detect pathogens and the host response to infection  
  - simple devices for use in primary care settings. NB where there is a clinical need the use of such devices in secondary care will also be in scope.

Examples could include:

- tests with a high negative predictive value of clinical significance, to rule out infection  
- tests/devices to distinguish between bacterial, viral and fungal infections  
- tests capable of distinguishing between Gram positive and Gram negative bacteria (this could be taken further to include, for example, the determination of antimicrobial resistance in pathogens).

The important thing is to keep things simple and develop devices that are affordable and not overly complex for the clinical setting or the information required. The use of any appropriate clinical sample is in scope for both strands.

Consortia should be clear about the clinical significance of measuring a group of pathogens in combination in a particular setting or settings. The combination selected must be scientifically and clinically relevant with input from microbiologists and paediatric and/or adult infectious disease clinicians as appropriate.

Consortia should consider the factors outlined in Table 1 in their product design. The competition is not limited to diagnostic companies. Industries with any relevant capability may join consortia, including companies with an interest in biosensors, microfluidics, mechanical and electronic miniaturised systems, data capture and analysis, and connectivity.

The preferred, and acceptable, time to result will depend upon many factors including the severity of the patient’s illness and the clinical care pathway into which the test is to be introduced. Applicants need to consider how their proposed products will fit into existing or realistic patient-care pathways and design their product specifications accordingly.

**Out of scope**

- development of central laboratory-based tests and systems. NB devices suitable for near-patient testing in areas adjoining intensive care units, for example, will be in scope. However, devices must be easy to use and not require extensive training  
- devices targeted at the consumer market  
- devices covered by the larger R&D project strand of the DIIA Innovation Platform’s ‘Fighting infection through detection’ competition. For example, a test to detect Meticillin-resistant Staphylococcus aureus (MRSA) alone would be out of scope. However, with clinical and scientific justification, the detection of MRSA could form part of a panel  
- devices for identifying pathogens on surfaces, medical equipment and in the environment.

### Table 1 – Factors to be considered in the development of a rapid/POC device

<table>
<thead>
<tr>
<th>Device/system related capabilities and characteristics</th>
<th>Test considerations</th>
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<tbody>
<tr>
<td>Ease of use</td>
<td>Test cohort</td>
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<tr>
<td>Time to result</td>
<td>Who will perform the test, where and when</td>
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<tr>
<td>Maximum achievable sensitivity</td>
<td>Level of training required</td>
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<tr>
<td>and specificity</td>
<td>Impact on disease management processes</td>
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<tr>
<td>Maximum achievable positive and negative predictive value in test cohort</td>
<td>Impact on patient experience</td>
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<tr>
<td>Quality control</td>
<td>Regulatory requirements</td>
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<tr>
<td>Waste disposal and safety</td>
<td>How quality assurance will be delivered</td>
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<tr>
<td>Maintenance and decontamination</td>
<td>Data capture and security</td>
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<tr>
<td>Data capture and security</td>
<td>Cost per test and of instrumentation</td>
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</table>
Funding allocation and project details

We have allocated up to £5m 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 partner in a consortium.

Projects can range from industry-orientated basic research through applied research to experimental development (attracting up to 75%, 50% and 25% of total project costs respectively). For this competition we anticipate that most applications will focus on applied research. We are looking to support six to eight projects of different sizes but this is flexible and will depend on the proposals submitted and any additional investment from other funding bodies. Definitions of the above categories of research can be found in the Guidance for Applicants.

Further information is available in the Guidance for Applicants (see the competitions section of our website, www.innovateuk.org) and at a briefing that will be held in London on 5 October.

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 30 August, applicants must register by 1 November and compulsory expressions of interest (EOIs) must be submitted by 9 November. Those applicants interested in taking up the Design Option must register this by noon 12 September and submit their Design Option request by noon 15 September.

The process gives applicants the opportunity to make an initial optional EOI before submitting their compulsory EOI application. We will look at the optional EOI and provide feedback to applicants. Applicants may take advantage of this up to 10 working days before the deadline for the submission of the compulsory EOI.

Applicants submit a compulsory EOI which is assessed by an independent panel of experts. All project applications are assessed on their merits irrespective of whether they have taken up the Design Option. Selected applicants are invited to submit a full application. The second stage for invited applications will open on 5 December and closes on 25 January 2012.

Note that ALL deadlines are at noon.

Key dates

<table>
<thead>
<tr>
<th>Event</th>
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<tr>
<td>Competition opens</td>
<td>30 August 2011</td>
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<tr>
<td>Registration deadline for Design Option</td>
<td>12 September 2011</td>
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<td>Deadline to submit Design Option request</td>
<td>15 September 2011</td>
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<td>Applicant briefing day</td>
<td>5 October 2011</td>
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<td>Optional expressions of interest deadline</td>
<td>27 October 2011</td>
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<tr>
<td>Registration deadline for expressions of interest</td>
<td>1 November 2011</td>
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<td>Expressions of interest deadline</td>
<td>9 November 2011</td>
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<td>Stage 2 opens (for invited applications)</td>
<td>5 December 2011</td>
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<td>Full stage applicants’ briefing (for invited applicants)</td>
<td>14 December 2011</td>
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<tr>
<td>Deadline for receipt of full applications</td>
<td>25 January 2012</td>
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<td>Full stage applicants informed</td>
<td>24 February 2012</td>
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Further information

You must register for this competition to access all of the supporting documents, including the Guidance for Applicants, and the application form. For more information about this, Sepsis II and other competitions, and details of how to register and apply, please see the competitions section of our website at www.innovateuk.org.

Email: competitions@innovateuk.org

Competition helpline: 0300 321 4357

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.

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.

Collaborative research and development is part of the Government’s Solutions for Business portfolio.

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