



Fighting infection through detection

**COMPETITION FOR FUNDING: FEASIBILITY STUDIES,
FAST-TRACK AND LARGER R&D PROJECTS**

JANUARY 2010

Together with the Department of Health, in January we are launching an £11 million competition to fund projects that aim to develop diagnostic devices and improve their uptake in the human and animal healthcare sectors – to fight infection through detection.

This competition is split into three different project types: feasibility studies, fast-track projects and larger collaborative R&D projects.

Through this funding we aim to reduce the social and economic impact of infectious agents in animals and humans.

Fighting infection through detection

JANUARY 2010 COMPETITION FOR FUNDING

Summary

We are launching a competition with up to £11m available to fund feasibility studies, fast-track projects and larger R&D projects. The Technology Strategy Board will invest up to £10m, and the Department of Health (DoH) will invest up to £1m. The aim of the competition is to support the development and uptake of diagnostic devices that will reduce the social and economic impact of infectious agents in animals and humans, and create opportunity and wealth for UK industry.

The competition will fund three project areas:

Feasibility studies – up to £2.5m funding

- to advance diagnostic capabilities for the detection of infectious agents in humans and animals, either by modifying and/or improving existing systems or by exploring the ability of novel technologies to deliver components of a diagnostic system. Any measurements must focus on areas identified by the DoH and the Department for Environment, Food and Rural Affairs (Defra) (see p4); up to £0.5m is available to fund projects exclusively for animal infectious agents
- projects should last for a maximum of one year and cost no more than £160,000 in total; up to 75% funding is available
- industry-led consortia and single small to medium-sized enterprises (SMEs) may apply.

Fast-track projects – up to £1m funding

- pilot schemes to test rapid/point-of-care (POC) devices in the environment for which they have been developed, focusing on areas identified by the DoH and Defra (see p4); up to £0.2m is available to fund projects for animal infectious agents
- projects should last no longer than 18 months and have a maximum total cost of £200,000; we will fund up to 50% of costs
- industry-led consortia and single SMEs may apply; they must be able to demonstrate a credible route to market.

Larger R&D projects – up to £7.5m funding

- to develop rapid/POC tests from development to use in a clinical setting in the areas of sexually transmitted infections (chlamydia and gonorrhoea) and hospital-acquired infections (meticillin-resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile*, and extended spectrum beta lactamase (ESBL)-producing bacteria)
- projects may last up to five years
- we will mainly fund applied research and development (50% public funding); we will also consider experimental development (25% public funding) and industry-orientated basic research (75% public funding)
- industry-led consortia may apply; they must be able to demonstrate a credible route to market.

Background and challenges

Infectious diseases are a constant threat to the health and wealth of the nation. In the UK approximately 10% of all deaths and 4% of all hospital admissions are attributed to infectious diseases, and 35% of GP consultations (50% in children) are due to an infection. Hospital-acquired infections cost the NHS around £1bn each year. Taking into account loss of national productivity and payment of sickness benefit the cost is considerably higher; around £3-11bn for MRSA alone.

Animal diseases can be equally costly and serious. The 2001 outbreak of foot and mouth disease cost the UK about £7bn; and bovine tuberculosis, the largest endemic animal health issue in Great Britain, cost the taxpayer around £80m in 2007/08 for surveillance, research, testing and compensation.

To address these challenges we have created an innovation platform for the detection and identification of infectious agents (DIIA) in humans and animals; the Secretary of State announced the new platform in October 2008. To implement the DIIA programme we will invest up to £50m in activities over five years, and the DoH will invest up to £5m more.

The purpose of this competition is to reduce the impact of infectious agents by supporting the development and uptake of diagnostic devices that are clinically useful and commercially viable. The competition will focus on the development of high-quality POC devices and rapid tests that encompass, for example, tests in mobile units, bench-top systems close to wards, and handheld devices. The critical factor is the time from sampling to decision-making and action, enabling faster intervention and leading to less spread of disease and better patient outcomes.

DoH priority areas for human health

- tuberculosis
- sepsis
- antimicrobial resistance:
 - hospital-acquired infections:
 - MRSA
 - *Clostridium difficile*
 - ESBL-producing bacteria
 - community-acquired pneumonia
 - antibiotic prescribing in primary care (diagnostic tools to reduce the inappropriate prescribing of antibiotics)
- sexually transmitted infections:
 - chlamydia
 - gonorrhoea.

Defra priority areas for animal health for this competition

Defra's priority is to develop rapid/POC devices to detect the following infectious agents in animals:

- foot and mouth disease virus
- swine vesicular disease virus
- *Mycobacterium bovis* (in live cattle only)
- bluetongue virus
- classical swine fever virus
- African swine fever virus
- avian influenza virus (H5 and H7).

Differential diagnosis between foot and mouth disease and swine vesicular disease virus, and between classical swine fever and African swine fever virus on the same diagnostic device would be beneficial.



Scope

We have launched this competition in response to priority areas for human health identified by the DoH, and priority areas for animal health identified by Defra.

This competition will invest around £11m in joint funding (up to £10m from the Technology Strategy Board and up to £1m from the DoH) to support three separate project areas:

- feasibility studies: designed to explore novel solutions to DIIA and to lead to the development of rapid/POC devices
- fast-track projects: to test devices in the environment for which they have been developed to encourage the adoption and uptake of rapid/POC devices into clinical practice
- larger R&D projects: to span from development through to pilot schemes to test devices in the environment for which they have been developed.

The feasibility studies and fast-track projects will support all of the areas prioritised by DoH and Defra; a maximum of 20% of the overall investment in these two projects will be for animal infectious agents. The larger R&D projects will address a subset of DoH priorities: chlamydia, gonorrhoea, MRSA, *C. difficile* and ESBL-producing bacteria. Further details of the scope of each project area are provided as follows.

All proposals should explain how the project team intends to exploit the deliverables. For the fast-track projects and the larger R&D projects, consortia must be able to demonstrate a credible route to market for their products.

This competition supports the development of rapid/POC diagnostic tests to be used by healthcare professionals, veterinarians or other suitably qualified personnel only.

Funding allocation and project details

Feasibility studies

We welcome proposals for feasibility studies to explore novel solutions to DIIA and lead to the development of rapid/POC devices to identify infectious agents in humans and animals. While applicants may modify and/or improve existing systems, projects in this category do not have to consider a complete system, they can address a combination of elements of a device including sample preparation, antigen detection, miniaturisation, waste disposal, systems integration, and safe and secure data capture. However, applicants must clarify how the technology will advance the development of a diagnostic capability or system and must define the steps needed to deliver a complete solution.

Up to £2.5m has been allocated to fund feasibility studies with a maximum length of one year, for projects of up to £160,000 in value. Up to 75% funding may be available, although the exact amount will depend on the size of the company (or companies) and the nature of the project (for more information, please refer to the Guidance for Applicants at www.innovateuk.org under Competitions). A maximum of 20% of the overall investment will fund projects on animal infectious agents.

Industry-led consortia can apply for feasibility funding, and companies of any size and turnover can participate. A single company can apply for feasibility funding provided it is an SME (for a definition of SME, see the Guidance for Applicants).

Fast-track projects

This project area will support pilot schemes to test the performance of rapid/POC devices in the environment for which they have been developed. This will necessitate working with, for example, clinicians and hospital managers or veterinarians and others to test the technologies in healthcare settings.

In working with clinicians and veterinarians it is envisaged that applicants will need to consider the device characteristics and test considerations outlined in Table 1.

For the identification of infectious agents in animals, Defra has stipulated that rapid/POC devices should have the following characteristics:

- be physically robust and self-powered, and able to be operated in a field environment, submersed in water and disinfected
- sample processing should be integrated into the system and waste must be self-contained
- testing time should be less than 90 minutes
- ideal costs should be less than £15,000 per instrument and less than £50 per test
- maximum instrument weight should be 15kg (ideally less than 10kg)

- the system should be capable of sending results over a mobile network to a central data server
- sensitivity and specificity must match or exceed those of current tests recognised and used by Government.

Up to £1m has been allocated to fund fast-track projects lasting no longer than 18 months and with a maximum total project cost of £200,000. We will fund up to 50% of project costs (to an amount no greater than £100,000). A maximum of 20% of the overall investment will fund projects on animal infectious agents.

Industry-led consortia can apply for funding and companies of any size and turnover can participate. A single company can apply for funding provided it is an SME. We will only consider applications that are in the areas prioritised by the DoH and Defra.

Larger R&D projects

We have allocated up to £7.5m to fund collaborative R&D projects that will support the development of rapid/POC tests from development through to clinical adoption in the following areas:

- hospital-acquired infections:
 - MRSA
 - *C. difficile*
 - ESBL-producing bacteria

- sexually transmitted infections:
 - chlamydia
 - gonorrhoea.

We welcome applications from industry-led consortia and will support projects lasting up to a maximum of five years. We will allocate most of the funding to proposals in the categories of applied R&D (attracting 50% public funding) or possibly experimental development (attracting 25% public funding). We will also consider projects involving industry-orientated basic research (75% public funding) but applicants must make a robust case to support the level of funding they are requesting. (Definitions of the above research categories can be found in the Guidance for Applicants.)

Consortia should consider the factors outlined in Table 1 in their product design.

The competition is not limited to diagnostic companies, and industries with any relevant capability may join consortia; this will include companies with an interest in biomarkers, biosensors, microfluidics, mechanical and electronic miniaturised systems, data capture and analysis, and connectivity. The end point of projects should be products that are ready for clinical adoption, 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.

Table 1: Factors to consider when developing a rapid/POC device

Device/system-related capabilities and characteristics	Test considerations
<ul style="list-style-type: none"> ■ ease of use ■ time to result ■ maximum achievable sensitivity and specificity ■ maximum achievable positive and negative predictive value in test cohort ■ quality control ■ waste disposal ■ maintenance and decontamination ■ data capture and security ■ cost per test and of instrumentation 	<ul style="list-style-type: none"> ■ test cohort ■ who will perform the test, where and when ■ level of training required ■ impact on disease management processes ■ impact on patient experience ■ regulatory requirements

Table 2: Product specifications for rapid/POC devices

Infectious agent/challenge	Preferred time to result (minutes)*	Sample	Guideline maximum cost per test (£)	Additional comments
MRSA	<20	Easily obtainable, e.g. nasal, rectal or wound swabs	15	
<i>C. difficile</i>	<20	Easily obtainable	20	Ideal tests should distinguish between <i>C. difficile</i> carriage and disease
ESBL-producing bacteria	<30	Easily obtainable	20	Ideal tests should be a one-step process (from the operator's perspective) and cover predominant enzyme types
Chlamydia	<15	Urine preferred, swabs acceptable	15	Single or combination tests for chlamydia and gonorrhoea are acceptable
Gonorrhoea	<15	Urine preferred, swabs acceptable	15	

* A time to result of 5-10 minutes is the ultimate goal, but it is more important to achieve the sensitivity and specificity targets than to reduce the time. A maximum time of around 45 minutes can be tolerated, but the shorter the time to result the greater the possibility of directing the therapeutic intervention during consultation.

The product specifications for the rapid/POC devices are shown in Table 2.

A time to result of 5-10 minutes is the ultimate goal for all of the tests listed in Table 2, but it is more important to achieve the sensitivity and specificity targets given below than to reduce the time. A maximum time of around 45 minutes can be tolerated but applicants should note that the shorter the time to result the greater the possibility of directing the therapeutic intervention during consultation.

Sensitivities and specificities must be fit for purpose and, as outlined in Table 1, take into account the test cohort. The

target sensitivities and specificities for hospital-acquired infections are around 95/95%, and for sexually transmitted diseases around 98/98%.

We recognise that the strategy of some companies may be to deliver multi-test panels (for example, a comprehensive panel for sexually transmitted infections) and to determine strains and antibiotic sensitivity as well as identifying infective agents. These tests may be more costly and we will consider such projects on the merit and clinical utility of the additional diagnostic information provided by the test panel.

Examples of clinically useful devices that could be developed include:

- a rapid/POC screening test for MRSA using an easily obtainable sample that could be performed by a healthcare worker as part of a hospital admissions programme
- a rapid/POC test for *C. difficile* able to distinguish between carriage and disease that could be carried out on wards using a rectal swab
- a rapid/POC test for ESBL-producing *Escherichia coli* in urine that could be used throughout the healthcare system
- a highly specific and sensitive rapid/POC test for chlamydia and gonorrhoea that could be used in a genitourinary medicine clinic.

Application process

Feasibility studies and fast-track projects

These are single-stage competitions that will open on **18 January 2010** and close on **25 February 2010**.

Larger R&D projects

This is a two-stage competition; it will open on **18 January 2010** and expressions of interest (EOI) must be submitted by **25 February 2010**.

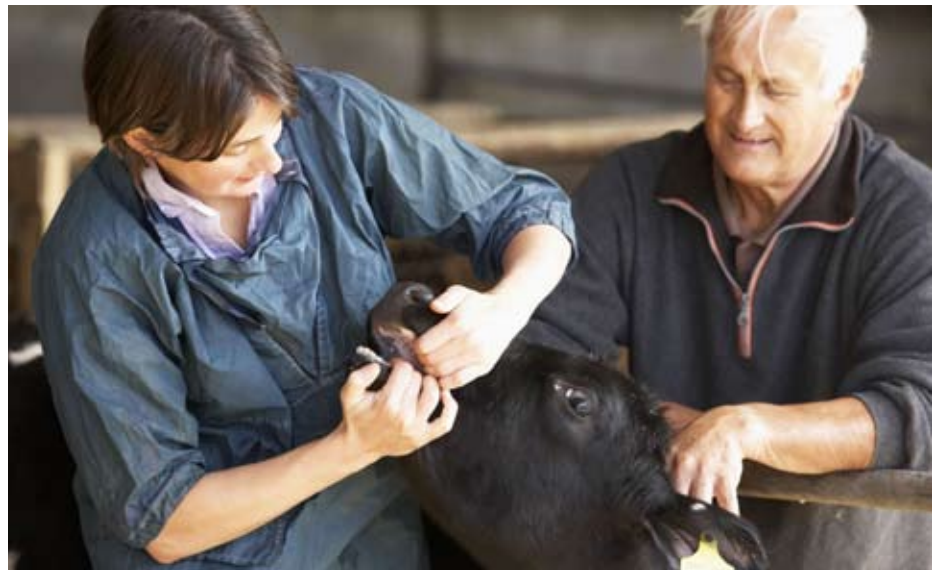
The process gives applicants the opportunity to make an initial optional EOI before submitting their compulsory EOI application. We will look at the optional EOI and aim to provide feedback to applicants within three working days. Applicants may take advantage of this up to one week before the deadline for the submission of the compulsory EOI. The second stage for invited applications will open on **22 March 2010** and close on **29 April 2010**.

The key dates for all applications are provided opposite. The Guidance for Applicants explains the application process in detail (see www.innovateuk.org under Competitions).

You can download the application form from the Technology Strategy Board website at **www.innovateuk.org**.

If you have any queries about the technical scope of the competition or the application process, please contact the competitions helpline on 01355 272155 or email **competitions@tsb.gov.uk**

We will require all projects to provide a non-commercially confidential summary at the start and the conclusion of the project for dissemination.



Key dates

Feasibility study and fast-track project applications

Competition opens	18 January 2010
Briefing day (optional)	27 January 2010
Deadline for receipt of applications	25 February 2010
Decision to applicants	19 March 2010

Larger R&D project applications

Competition opens	18 January 2010
Briefing day (optional)	27 January 2010
Optional expressions of interest submission period	18 January 2010 to 18 February 2010
Expressions of interest deadline	25 February 2010
Feedback on expressions of interest provided by	19 March 2010
Stage 2 opens (for invited applications)	22 March 2010
Applicants briefing (compulsory)	31 March 2010
Registration of intent to submit (compulsory)	22 April 2010
Deadline for receipt of full applications	29 April 2010
Decision and feedback to applicants	4 June 2010

More information

For more information about this and other competitions, and details of how to register and apply, please see Competitions at **www.innovateuk.org**. The Guidance for Applicants is also available online at **www.innovateuk.org** under Competitions.

Competition helpline:
01355 272155

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.



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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