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SCREENING FOR DRUG DRIVERS BRIEF

SUMMARY

The Home Office Scientific Development Branch (HOSDB) and the Technology Strategy Board are launching a SBRI competition to fund development work on an oral fluid screening device to aid the detection of drug drivers by the police.

Evidence suggests that drug driving is an increasing problem on UK roads. Current enforcement methods rely upon the officers' observation and assessment of the driver's impairment. Use of an oral fluid screening device would significantly assist officers and act as a strong deterrent to potential drug drivers. The aim of this competition is to identify drug detection technologies capable of detecting very low concentrations (ng/ml) of drugs and their active metabolites in oral fluid that can meet the challenging sensitivity, specificity and reproducibility requirements as part of a polydrug detection device.

The competition comprises several phases:

Initial application

Applicants outline their proposal, detailing how their proposed approach will meet the specified criteria and describe the technical work that will lead to a practical end user device. Applicants must show that their proposed device will have polydrug detection capabilities and should highlight the advantages their device demonstrates over current commercial devices. Applicants should include their plan for phase 1, to demonstrate proof of concept, and an outline of their plan for phase 2, to develop a prototype device. Due to the current economic conditions, applicants should note that funding for phase 2 may be subject to review.

Phase 1: proof of concept

Successful applicants will be offered a contract with 100% funding to show proof of concept of their research proposal. Each contract will be for a maximum of six months with funding

up to £100k. The expectation is that the initial six months funding will be completed by 16th March 2011.

Phase 2: development

Subject to funding constraints; companies that successfully complete phase 1 may compete and be offered a phase 2 contract with 100% funding to develop their prototype device. As part of the selection process for phase 2, applicants may have to attend an interview and present their proposal.

The competition is open to all companies, including those not currently engaged in the drug detection market. Individual companies or consortia may apply, and there is no limit on the size or type of company. We particularly welcome applications that enable small companies to participate within the supply chain.

Universities may apply, however they must demonstrate a route to market, and have a plan to commercialise the results of this work.

The detection targets for this research are controlled substances; it is expected that successful parties will hold the appropriate licences. Information on licensing requirements and the application process can be found at <http://drugs.homeoffice.gov.uk/drugs-laws/licensing/>.

BACKGROUND AND CHALLENGE

The Home Office Scientific Development Branch (HOSDB) provides advice and operational support for the Home Office and its partners on any issue relating to science and technology, creating new solutions where none exist. HOSDB helps the Home Office meet its strategic objectives in areas such as policing, crime reduction, counter terrorism and border security. The Road Policing Technology Programme forms part of HOSDB, focussing on the application of science and technology to address police operational requirements for policing the roads.

In 2008, the Department for Transport (DfT) published casualty data that suggested there were 56 fatal accidents in which impairment by a drug was judged to be a contributory factor (Reported Road Casualties Great Britain 2008, DfT). More than a fifth of adults admitted to using illegal drugs in 2008/9 (British Crime Survey, Hoare, 2009) and anecdotal evidence combined with the limited data available suggest that drug driving is becoming an increasing problem on UK roads.

Enforcement of drug driving currently relies upon evidence of impairment gathered through the officer's observations of the suspect driver. If appropriate the officer can require the suspect driver to take part in a Field Impairment Test (FIT). The FIT comprises a series of divided attention tasks and allows the officer to further assess whether or not the suspect driver may be impaired.

In addition to the FIT, the legislation sanctions the use of preliminary drug screening devices out of doors (e.g. at the roadside) or in a police station, using a sample of saliva or sweat. It is generally

accepted that saliva (a major component of oral fluid) is a preferable testing matrix to sweat, as it is less open to environmental contamination and the relationship between blood drug concentration and oral fluid drug concentration is better understood. It is hoped that introduction of such a screening test would significantly aid the police in the detection of drug drivers.

This competition is designed to address the need for a polydrug oral fluid screening device to be utilised by the police to detect drug drivers. There are challenging sensitivity, specificity and reproducibility requirements, as defined within the scope.

These devices will be operated by non-technical end-users and as such complex sample preparation or multiple sample transfer stages would be inappropriate. The end devices should be straightforward to use, with the minimum number of steps.

Applicants should note that drug screening devices to be utilised in the enforcement of drug driving must be Type-Approved by the Secretary of State for the Home Department. The Type-Approval specification, to be published, outlines the technical requirements to be met and contains details concerning device construction, operation and methods for testing prior to submission for consideration for Type-Approval. There are challenging environmental requirements that have to be met for use of such devices out of doors. The immediate imperative is therefore to make Type-Approved devices available in the less challenging environment of police stations. The scope below draws upon the Type-Approval specification, which is currently in draft format.

SCOPE

Current Commercial-Off-The-Shelf (COTS) devices generally suffer from either limited sensitivity or insufficient specificity. Additionally, these COTS devices are commonly only capable of detecting two or three drugs / drug classes at any one time, with the maximum currently set at detection of six drugs / drug classes simultaneously. We are looking for technologies that address these concerns and are true polydrug detection techniques, that fulfil the technical specifications below;

Technical specifications;

1. Ability to detect parent drugs and their active metabolites in the region of ng/ml or less, as per table 1 below;
 - The current drug driving legislation is based on impairment so there is a need to detect both active parent drug and metabolites. It is essential that all actively impairing substances are detected. Non-impairing metabolites should not be detected.

Table 1. Target Drugs and Analytical Cut-off Levels

Drug class	Compounds to be detected	Cut-off (nanogram/ml)
Cannabinoids	Delta-9-tetrahydrocannabinol	10
Benzodiazepines	Nordiazepam	10
	Oxazepam	10
Cocaine	Cocaine	30 (as a composite)
	Benzoylcochine	
Amphetamine	D-amphetamine equivalents	40
Methylamphetamine	Methylamphetamine	40
	MDA	40
	MDMA	40
Methadone	Methadone	50
Opiates	Morphine	40

NOTE

1. These cut-offs are not to be construed as a legal threshold or as an “impairment threshold”.
2. Reproducible
 - Any method employed must provide consistent, reproducible results to ensure for example, that an oral fluid sample with a drug concentration 40% greater than the cut-off is correctly detected 90% of the time. The percentage of false positive test results shall not exceed 5%.
3. Time to result from sample loading, not more than eight minutes.
 - The screening device is aimed at improving enforcement of the drug driving legislation. The requirement is for a quick ‘time to result’ test that completes the investigatory process pre-arrest.
4. Physically robust device, able to withstand normal operational use
 - For police station use; operational temperature range; 15 °C to 35 °C and storage temperature range; 0 °C to 35 °C. The device operator will be non-skilled, so minimal handling steps are required. It should not be possible to easily disrupt the drug detection technology preventing use.
5. Chemically robust detection technique
 - Interfering substances should not disrupt the drug detection technology for example, tobacco smoke should not be able to cause a false negative or false positive result or block the test from working correctly.

Of the drugs detailed in Table 1 above, cocaine and cannabis are thought to be the most prolifically encountered drugs on the road. As such, they should be the primary detection targets of the initial

phase 1 study. Demonstration of proof of concept for detection of cannabis and / or cocaine in the region of ng/ml levels and a clear path to show how these detection techniques can be extended to cover many more drugs, are the two essential components of phase 1. Applicants should be clear that the final device must utilise a polydrug detection technique capable of detecting multiple drugs simultaneously. Applicants should highlight the advantages their proposal demonstrates over current COTS devices.

Applicants are also asked to consider the challenge presented by so called “legal highs” and the newly controlled psychoactive substances such as GBL and mephedrone. A device that could rapidly respond to the ever changing environment of drug abuse would be advantageous.

Successful applications will be monitored by the Home Office Scientific Development Branch for the duration of the contract and contractors will be expected to provide regular up-dates on the progress of their work.

APPLICATION PROCESS

The competition is being run through the Technology Strategy Board’s SBRI initiative. This is a mechanism for government departments to find novel solutions to specific problems by engaging innovative companies they could not otherwise reach. This open and transparent competition will result in direct contracts between successful companies and the Technology Strategy Board.

Key Dates

Phase 1

Competition Opens	3rd June 2010
Deadline for Phase 1 applications	Noon, 15th July 2010
Notification of decision	26th August 2010
Feasibility Contracts awarded by	31st August 2010
Feasibility work begins	13th September 2010
Feasibility (Phase 1) stage ends	16th March 2011

Subject to available funding successful Phase 1 applicants may be invited to compete for a Phase 2 contract to work toward development of a prototype device.

Phase 2

Competition Opens	April 2011
Further dates to be confirmed.	

Directions on how to enter this competition and key dates and timelines can be found in the Invitation to Tender (SBRI_HO_040_001) and the Guidance Notes (SBRI_HO_040_003 Guidance).

More information on this and other competitions may be obtained at www.innovateuk.org.uk