

▶ Success Stories

Randox Laboratories develops Point of Care Testing for a range of disease applications

As the UK's largest privately owned Diagnostics Company Randox, based in Northern Ireland, has been at the forefront of Point of Care Testing since it developed its unique Biochip Array Technology (BAT), an innovative assay technology for multi-analyte screening of biological samples in a rapid, accurate and easy to use formats.

The technology has enabled Randox to develop multi-analyte Point of Care Testing for a wide range of disease applications from cardiac disease to cancer. The company has been very active in the Technology Strategy Board Detection and Identification of Infectious Agents platform winning grants for projects to develop rapid POC Tests for HCAI, Sepsis and TB against stiff competition.

The company will continue to develop new technologies and platforms to deliver rapid POC tests that are specific and sensitive in an increasing number.

DNA Electronics was spun out of Imperial College in 2001

The company was founded on Professor Chris Toumazou's invention of detecting protons released during DNA synthesis as a method for DNA sequencing using a standard silicon-chip based transistor. Based on this technology DNA Electronics is creating a suite of electronic microchip-based solutions to enable faster, simpler and more effective DNA analysis. The platform allows rapid sample-to-answer analysis that can be analysed by plugging into any consumer electronic device.

QuantuMDx Group leverages Technology Strategy Board funding to expand globally

Founded in 2008 by Jonathan O'Halloran with Elaine & Julian Warburton, QuantuMDx started from somewhat humble beginnings over ten years' ago in Jonathan's garage where he re-arranged chemicals, reagents and biological processes and sensed them using computer transistors which provided sufficient proof of principle for his novel nucleic acid sequencing technology. Elaine, using her healthcare background and extensive commercial experience harnessed Jonathan's technology to develop it into commercially viable and simple to use devices to meet many of today's health challenges.

QuantuMDx is now leveraging its global network and expertise across many fields and has developed a suite of diagnostic and sequencing bio-chips capable of being assembled into a wealth of low cost but highly accurate handheld devices for the next generation of doctors, health professionals, scientists, vets, military and police. The Group has now expanded to include subsidiaries in the USA & Asia as well as acquiring a commercial molecular laboratory, which it has subsequently ISO accredited. The company has recently won two Technology Strategy Board grants – one to develop a comprehensive PoC test for Multidrug-Resistant Tuberculosis (MDR-TB) and the other to develop a rapid tumour profiler. In addition QuantuMDx won the UKTI's Exporting for Growth award in 2013.



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▶ Market Opportunity

- The UK *in vitro diagnostics* (IVD) market was worth \$1.09bn in 2011. **Growth in the UK IVD market is forecast to average 7.1% from 2011-18¹.**
- Within the IVD market is Point of Care testing which comprises of the performance of a test in the immediate vicinity to a patient to provide a rapid result outside the conventional laboratory environment.
- Global healthcare markets are all facing the same challenges: ageing populations, increases in chronic diseases and the continuing rise of healthcare costs as a proportion of GDP.
- Point of Care testing provides a route to reduce many of the challenges placed on global healthcare systems allowing clinicians to make more efficient diagnosis and even monitor patients remotely.
- **The National Health Service (NHS) treats almost 1 million patients every day** and is the largest unified healthcare system in the world.
- Clinical Commissioning Groups will be seeking to improve prevention and diagnosis while improving the efficiency of the system and reducing the costs of unnecessary testing and referrals whilst accelerating the decision making processes.
- **70% of clinical decisions in the NHS are based on diagnostics tests².**
- The emergence of new organisations and programmes within the NHS to meet the changing healthcare delivery model provide a range of opportunities for your business to tap into e.g. NHS Screening Programme and NHS Genetic Testing Network.

Source:

1. Frost & Sullivan: Western European IVD Market (2012)
2. Report of the Review of NHS Pathology Services in England (2008)

▶ Ease of Doing Business

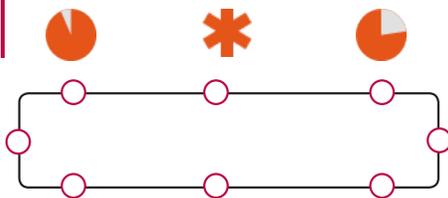
With the increasing cost, risk and complexity of research and development, it is ever more challenging for medical technology companies to commercialise innovations. To address this challenge, the UK Government has introduced a suite of fiscal measures, grants and funds including:

Funding initiatives and tax incentives to stimulate innovation and growth:

Patent Box
– 10% rate of corporation tax

R&D tax credits for SMEs worth up to 27p on every £1 (7p for large companies)

Low corporation tax rate currently standing at 23% decreasing further to 20% by April 2015



UK Research Partnership and UK Investment Fund aims to stimulate R&D partnerships between universities business & charities

Funding available to encourage research and innovation for your IVD company:

£180 million Biomedical Catalyst non-dilutive funding for translation and commercialisation

Technology Strategy Board Smart Scheme offers funding to small and medium-sized enterprises (SMEs) to engage in R&D projects

The NIHR Invention for Innovation (i4i) supports R&D collaborations that develop innovative healthcare technologies in vitro diagnostic devices



▶ Rich Diverse Ecosystem

Some of the UK Centres of Excellence who house state-of-the-art innovative facilities for research in Point of Care testing, include:

- **University of Cambridge Diagnostics Development Unit** – the goal of the unit is to develop innovative tests that are rapid, simple, cost-effective and more sensitive than currently available rapid tests.
- **Imperial College Molecular Diagnostic Unit** – specialises in providing fast, accurate diagnostic tests for the management of infectious and genetic diseases.
- **Oxford University (MADOX)** – Oxford Centre for Monitoring and Diagnosis in Primary Care (MaDOx) is a research programme funded by the National Institute for Health Research (NIHR) based in the Department of Primary Care Health Sciences at the University of Oxford (PHC).
- **Inverness Diagnostics Cluster** – The region is building a strong competency in preventative and personalised healthcare. Industry presence around Inverness has stimulated a cluster of expertise in clinical diagnostics leading to the creation of a Diabetes Research Institute.
- **Cranfield University** – has invested significantly in new, state-of-the-art facilities to house the health and applied science activities, and this has become a major centre for the healthcare activities within the university.

The UK has the visionary science, centres of academic and clinical excellence, key opinion leaders, experienced partners, and the tools to help your Point of Care business to:

- understand disease biology
- develop sensing and diagnostic technologies
- deliver engineering and informatics solutions
- product and application development.

The Medical Research Council funds disease-focused consortia of academic and industry partners.

The Wellcome Trust funds both basic biomedical research and translational projects.

HealthTech & Medicines Knowledge Transfer Network helps connect organisations to catalyse innovation through events and workshops in stratified medicine.

Cancer Research UK and **Cancer Research Technology** also provide core oncology research funding, and offer translational funding and expert capabilities.

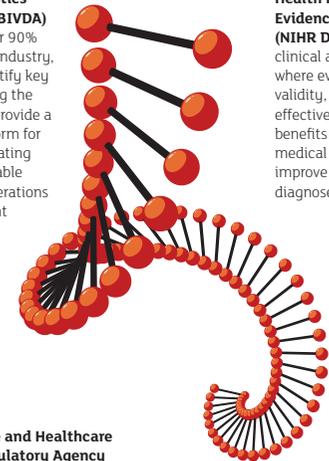
The Technology Strategy Board has created a new Innovation Platform for the Detection and Identification of Infectious Agents and invests nearly £50 million to support the development of new point of care technologies to enable rapid detection of diseases such as HCAI, STI, Sepsis and TB as well as endemic animal diseases.

The Royal College of Pathologists aim to advance the science and practice of pathology.

▶ The UK Offers

The UK offers a national infrastructure to support innovation and appraise new technologies in Point of Care.

The **British In Vitro Diagnostics Association (BIVDA)** represents over 90% of the UK IVD industry, it aims to identify key issues affecting the industry and provide a national platform for discussion creating a more favourable climate for operations and investment



The **National Institute for Health Research Diagnostic Evidence Co-operatives (NIHR DECs)** will focus on clinical areas or themes where evidence of the clinical validity, clinical utility, cost-effectiveness and care pathway benefits of in vitro diagnostic medical devices (IVDs) can improve the way diseases are diagnosed in England.

The **Medicine and Healthcare projects Regulatory Agency (MHRA)** recently established an Innovation Office to promote early dialogue between the MHRA and companies developing innovative products. The MHRA has also produced some general guidance feeding into the IVD Medical Devices Directive, 98/79/EC.

The **NICE Diagnostics Assessment Programme (DAP)** is suitable for evaluating diagnostic tests and technologies where such evaluation is complex, for example, where recommendations can only be made on the basis of clinical utility and cost-effectiveness analysis or where meaningful assessment requires the consideration of multiple technologies or indications.

Public Health England (PHE)

PHE will lead on the development of a 21st century health and well being service. The UK National Screening Committee and NHS Screening Programmes have become part of PHE in the restructuring of the NHS through the 2012 Health and Social Care Act.

The NHS Screening Programme

The NHS Screening Programme looks at a wide range of disease areas at different stages in the life of the population. Some tests are population wide but triggered by reaching certain age points while others can be focused on at risk populations. Many of these services rely significantly on pathology services opening new opportunities for developing improved technology or data management systems.

NHS Health Check

NHS Health Check focuses on prevention and early intervention and is a national risk assessment and prevention programme that systematically targets the top seven causes of preventable deaths: high blood pressure; smoking; high cholesterol; obesity; poor diet; physical inactivity and alcohol consumption.

The NHS Genetic Testing Network

The NHS Genetic Testing Network was established to ensure the same level and quality of genetic services across the UK and to check that new genetic tests put forward for acceptance into the UK GTN listing are effective to influence the way the NHS manages genetic services.