The research commercialisation office of the University of Oxford, previously called **Isis Innovation**, has been renamed **Oxford University Innovation**

All documents and other materials will be updated accordingly. In the meantime the remaining content of this Isis Innovation document is still valid.

URLs beginning www.isis-innovation.com/... are automatically redirected to our new domain, www.innovation.ox.ac.uk/...

Phone numbers and email addresses for individual members of staff are unchanged

Email : enquiries@innovation.ox.ac.uk

Bench to bedside

Andrew Goff, Head of Oxford University Consulting, discusses the growing take up of diagnostics in primary care and how OUC consultancies in the sector will benefit patients

Diagnostic tests have an increasingly important role to play in 21st century health care – ruling in or ruling out particular conditions, monitoring people with established diseases, or screening asymptomatic people for disease. Nearly three quarters of all the clinical decisions made are done so on the basis of the results from standardised diagnostic tests (e.g. blood results or imaging results). The UK is the fifth largest market for in-vitro diagnostics in Europe and the UK medical technology industry consists of over 3,000 companies with a combined turnover of £15bn.

It is perhaps surprising therefore that, in contrast to pharmaceutical products, there is currently no single European institution that evaluates diagnostic tests. This has hampered a standardised approach to generating evidence and its subsequent evaluation not only for regulatory approval but also for impact analysis. While in the USA FDA approval is required before the introduction of a new test, for introduction in Europe the majority of diagnostic tests need only CE marking (EU conformity compliance), requiring no formal evidence to demonstrate clinical utility, impact on health outcomes or cost effectiveness. This 'void' between industry, clinicians and researchers risks stifling innovations that could both improve health care and strengthen the UK's life sciences industry, particularly in the rapidly growing international market for point of care testing.

So it is exciting that a team of Oxford academics – OUC consultants – has now been nationally recognised as the UK's leading experts in the assessment of in-vitro diagnostics (IVDs), particularly in primary care. By 'assessment' we mean the generation of robust evidence for clinical validity, clinical utility and cost effectiveness, as well as care pathway benefits. Directed by Dr Matthew J Thompson and Professor Carl Heneghan, the team, many of whom are also active GPs working for the Oxford Health NHS Foundation Trust, has recently been designated a Diagnostic Evidence Co-operative (DEC) by the National Institute for Health Research (NIHR).

"The focus of the DEC is to improve the bench-to-bedside processes needed to implement new IVDs in primary care," says Dr Thompson. "The ultimate aim is to improve the quality and effectiveness of diagnostic tools available within the NHS. We will develop collaborations between frontline clinicians, diagnostic test researchers, the diagnostics industry, NICE diagnostics programme, and other relevant NHS groups to bring into primary care the newest medical technology across a range of common diseases."

"The consultancies will lead to improvements in healthcare services"

The team works across five multidisciplinary research themes which aim to:

- Develop methods to identify and prioritise new and emerging diagnostic technologies, through meeting with the diagnostics industry and scanning both journal and industry resources.
- Evaluate which IVDs are needed in primary care settings in the UK and other western countries, to help prioritise R&D efforts.
- Find better ways of integrating point of care tests with laboratory services and clinical information systems.
- Understand the impact of diagnostic tests on patients and front line clinicians in order to facilitate wider implementation of IVDs by utilising the team's considerable experience of point of care testing in hospital settings, primary care settings and in patient homes/nursing homes.
- Improve the efficiency of research designs for diagnostics, including better ways of translating research findings from one type of clinical setting to another.

Through these activities, the team is developing a "diagnostic evidence toolkit" which will propose a common approach to understanding the evidence needs at each step from test development to adoption, including what evidence is needed, what study designs are appropriate, which research designs are most efficient, and which translate between countries and different settings. In parallel, the team is undertaking consultancy through OUC to advise IVD companies on the evidence base required to support the adoption of their new IVDs while simultaneously promoting better informed clinical decision-making and improved NHS commissioning. This will lead to improvements in healthcare services as patients will access the most appropriate treatments more quickly and help the NHS make the best uses of its resources.

For more information, please contact

Andrew Goff
Head of Oxford University Consulting,
T +44(0)1865 280866
E andrew.goff@isis.ox.ac.uk