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/...

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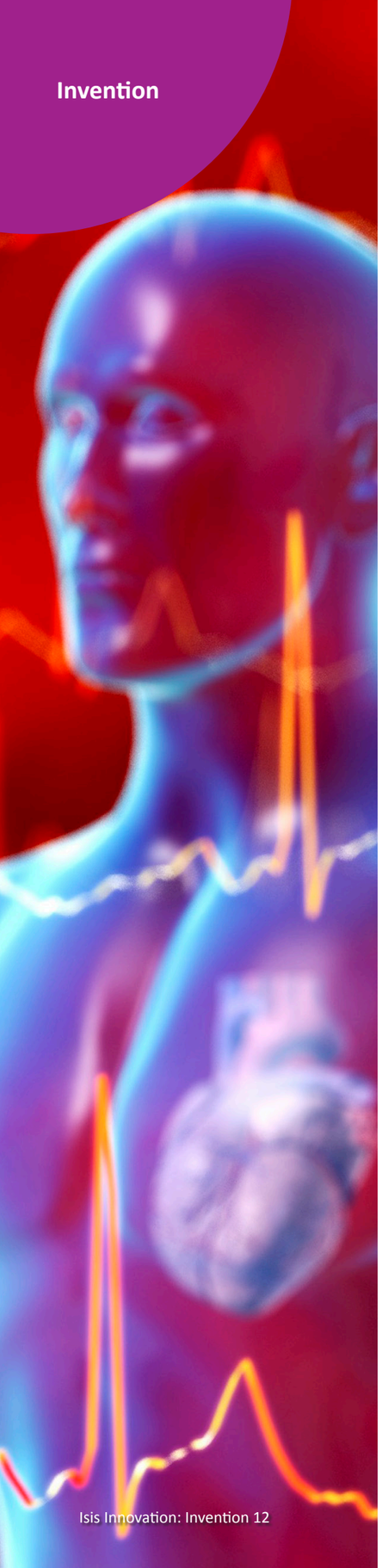

Virtual Assay – easy to use drug screening software becomes a reality

Safer and more effective drugs, and reduced dependence on animal testing, are amongst the benefits of drug screening software, described by Dr Fred Kemp

Earlier this year, the US Food and Drug Administration (FDA) proposed a new regulatory paradigm that could revolutionise the drug testing process. For the first time they are proposing to specifically require computer modelling of cardiac electrophysiology to be carried out, alongside existing in vitro methods for pre-clinical screening. The announcement has highlighted the importance of an Isis drug screening software technology, Virtual Assay.

Modelling the heart

The FDA proposal has generated great interest in "in silico" modelling from both the academic community and the pharmaceutical industry bringing both together to define these new methodologies. A recent successful "Computational Technologies in Biomedicine and Pharmacology" workshop, held at Oxford University included more than 10 global pharmaceutical and CRO companies, alongside leading researchers from more than a dozen international universities. The event was organised by Professor Blanca Rodriguez, Professor of Computational Medicine and lead inventor for Virtual Assay. Prof Rodriguez leads a team with a diverse and interdisciplinary background to create computer modelling methods that look at healthy and diseased states in the human heart.

"It is exciting to feel that you are exploring a genuine frontier," said DPhil. Student, Oliver Britton, in a recent interview in the Guardian.

"No two individuals respond to a drug in exactly the same way. Due to sometimes subtle variability at a physiological level, what works for one person may not work for another, even before taking into account any additional complicating factors. This is one of the most significant challenges faced by the pharmaceutical industry; clearly it is neither practical nor desirable to test a new drug on the entire population to ensure it is both safe and effective."

Matching models to empirical data

"So we came up with this idea of using a population of varied models," says Britton, one the 2014 UK ICT Pioneers finalists. "This was the key step, as we can achieve more accurate results by first generating lots of different models of a human heart cell, then simulating how they would behave in control conditions and then discarding those that don't fit the range of experimental data we have available."

An additional benefit is the potential reduction in animal testing. Animal testing dates back to the 4th century BCE, and it has been a regulatory requirement for approval of new drugs since the 1938 Federal Food, Drug, and Cosmetic Act was introduced in response to the Elixir Sulfanilamide incident, where over 100 people died. From a safety and efficacy perspective, animal testing remains an inconsistent measure of how humans might react to the drug. Similarly, in vitro testing on human cell lines doesn't take into account potential systemic effects.

Computer modelling of physiological responses, has promised to revolutionise drug testing since the first mathematical model for transmission of nerve signals was published in 1952, but until now the regulatory agencies have been reluctant to make them a required part of testing procedures.

Avoiding unanticipated effects

With over half of the 40 drugs withdrawn from the market in the last 20 years being withdrawn for unanticipated cardiac effects such as drug-induced arrhythmia, or long QT, the FDA has understandably focussed on cardiac cell modelling. Virtual Assay was first developed for that purpose.

Virtual Assay would be applicable to a number of other cell, types, tissues and disease pathologies such as nerve cells, kidneys, liver, chronic pain and diabetes, etc. An easy to use, extensible version, developed over the past nine months with Oxford Computer Consultants, has been well received, and attracting the attention of the FDA. With FDA approval, it could usher in an era of safer and more effective drugs.

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