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The Antidote

Understanding more on Genomics and Biohacking

Welcome to the fourth edition of The Antidote

Transforming Life Sciences through innovative technologies in 2015

The Life Sciences industry has been in the limelight recently. Speaking at the BIA Gala Dinner in London, George Freeman MP (Minister for Life Sciences) said that the industry was seeing a significant upturn in activity. 2014 saw the highest level of fundraising in many years with £1.25bn raised in Life Sciences IPOs and secondary offerings, as well as £1.5bn in innovation capital. The signs are good that this will continue - not only with big pharma companies, but also fresh activity from smaller and mid-cap sized companies, with potential for some exciting new entrants.

At the Scottish Enterprise Life Sciences Annual Dinner the emphasis was on "connected health". Both Dr Lena Wilson, CEO of Scottish Enterprise and Shona Robison MSP, Minster for Health, Wellbeing and Sport, highlighted the potential of digital technology to solve old and persistent problems in the healthcare system. eHealth initiatives promise increased efficiency, reduced costs and improved access. In light of the seemingly constant stream of headlines warning of an NHS "in crisis", eHealth could this year prove its worth.

Continuing with the technology focus, the potential of big data to revolutionise medical research will continue to be debated, whilst "biohacking" (see our article below) is likely to be one of 2015's buzzwords. Businesses looking for a slice of the action will have to navigate a complex and multi-faceted regulatory regime. With proper planning (and expected review of the applicable regulatory regimes both at the EU and UK level) the undoubted potential of new technology platforms might start to be more fully realised during this year.

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Genomics

The importance of genomics

At the end of 2014 the National Information Board set out its Framework of Action, containing commitments for the NHS to investigate how it can best use genomic datasets. Genomics is the study of all the genetic information in an individual. It plays an increasingly important role in ascertaining why certain people get some diseases, what drugs work best for them and identifying new therapeutic targets. Improved technologies mean that an entire human genome can now be sequenced for $1,000, as opposed to $95 million in 2001.

The preventative and personalised role genomics can play cannot be underestimated, both for patients and for the Life Sciences industry as a whole (CMS' recent webinar available at http://vimeo.com/cmslegal/review/110591765/e89544a456 considers personalised medicine in more detail).

Genomics England (a wholly-owned subsidiary of the Department of Health) aims to sequence 100,000 genomes from NHS patients with cancer, rare inherited disorders and infectious diseases. This new initiative is bringing together funders, academics, NHS clinicians and commercial partners with the aim of delivering healthcare benefits to patients. The challenge is legally and ethically managing a 'big data' project, which encapsulates arguably the most sensitive personal data each individual has. Equally, competing intellectual property interests must be carefully managed.

Data protection

The Data Protection Working Party has advised that under current European Data Protection legislation genetic data should be treated as 'sensitive personal data' and

the new draft European Data Protection Regulation makes this explicitly clear. The current exemption for processing when necessary for medical purposes is unlikely to apply to all uses of genomic data, and questions have been raised as to whether an individual's whole genome can be truly anonymised. This places huge importance on obtaining explicit consent and ensuring that it covers all potential uses of the genetic material, some of which may not be known at the time of consent. Data-access agreements will need to be robust to ensure public confidence and compliance with legislation.

Intellectual property

Ensuring public confidence that commercialisation will bring benefits to the NHS is one reason behind Genomics England's centralised ownership model, in which it will own not only genome sequence data but also any new intellectual property generated from the data. It will be interesting to see how the competing intellectual property interests of the various parties are reconciled, especially once commercial partners enter the arena. Genomics England has stated it will license this intellectual property back to third parties on 'favourable terms', but just how favourable those terms are, and more importantly who they are favourable towards, remains to be seen. Given the size of the public investment in gathering this generic data, it is to be hoped that the intellectual property terms will not prove to be a barrier to encouraging patient benefit.

Conclusion

Alongside data protection and intellectual property, complex issues include secure data storage for the anticipated 30,000 petabytes of data generated, competing interests regarding publication of results, concerns over use of genomic information by insurance companies and employers, and compliance with regulatory and ethical requirements. However, the potential benefits to all parties from genomic medicine mean that overcoming any possible legal hurdles should be well worth it.

The biohacking revolution

What is biohacking?

Biohacking is not a clearly defined concept but as the name suggests it can be generally defined as applying the hacker ethic to biology. Opinions differ, but anything from experimentation with synthetic (artificial) DNA through to worryingly named 'DIY' body enhancements, may be considered biohacking. This emerging and growing practice is normally associated with independent biologists and scientists ranging from professionals to curious amateurs: these are the biohackers.

Already the biohacking movement is giving rise to a wide spectrum of legal issues, and its rapid move online may throw up more yet. How the law develops and whether it can keep up will be interesting to see, particularly as the practice of online biohacking gains potency.

Biohacking in the technology age

Through online technologies such as cloud computing, biology itself is being transformed. Tech giants such as Google are creating cloud genomics platforms to facilitate genomic research. Start-ups are also taking a slice of the pie by creating web-based virtual labs, electronic lab books, cloud storage and open-source DNA design tools. These online platforms allow biohackers around the globe to experiment, collaborate and share research and resources to 'hack', sequence, reproduce, modify and/or create anything from living organisms or tissues, to medicines and foods.

Synbiota is an example of a biodevelopment platform which can also be used for biohacking. Mason Edwards, CTO of start-up Synbiota Inc, comments:

'Accessible biohacking tools combined with the cost reductions of synthetic biology are spearheading the way for a new and dynamic industry. The rate of innovation is increasing and we're on the cusp of a revolution that will dwarf the information age.'

The regulation of biohacking

Whilst online biohacking activity is still an emerging trend, it is a fast-growing one. Despite this, online science platforms and biohacking communities remain largely unregulated, at least expressly.

It is conceivable that some biohacking projects may fall within existing biosafety, biosecurity or dangerous substances regulatory regimes which in part govern innovative technologies such as genetic engineering and nanotechnology. But like these technologies, biohacking may develop and evolve at such a rate that its governing legislation struggles to keep pace. Looking at genetically modified organisms (GMOs) for example, whilst Europe has some of the strictest rules concerning GMOs in the world, developments in technologies such as synthetic biology have meant that certain projects fall outside their regulatory remit, requiring legislative changes which still may not be watertight.

Other considerations may arise through, for instance, the online sharing and modification of an individual's genetic data, which may warrant further advances in, for example, data protection laws (see further our article on Genomics above).

IP issues also arise: the virtual connectivity and the instantaneous sharing of data enable scientists to 'hack' protected products and processes, for example, to produce genetically identical synthetic versions more quickly and efficiently and often at a significantly cheaper price. With so many scientists coming together to work on projects over virtual platforms, it may be difficult to track developments and identify infringers. Similarly, in the absence of defined rules or agreements, issues also arise for the biohackers themselves such as to how IP rights in newly developed products will be shared among online contributors.

The world has seen how social media has transformed social communication. We will now see how virtual labs, connectivity and clouds will transform the progression of science.

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