Monitor
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Office for
Life Sciences

Genomics in the UK

An industry study for the Office of Life Sciences

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Contents

Foreword

Welcome to the Monitor Deloitte report on Genomics.

This is one of a series of reports reflecting work commissioned by Office of Life Sciences in March 2015 on key healthcare and life science industry segments in the UK.

Genomics is the study of the complete set of DNA within an individual. Knowledge of individuals' genetic make-up can help understand their predisposition toward certain genetic diseases, inform the best course of treatment and contribute to precision medicine. These advanced applications of genomics have only recently become a possibility due to the exponential decline in the cost of genome sequencing, large scale public sector and pharmaceutical investment and promise to change the way healthcare is delivered and patient lives and life expectancy improved.

This report analyses trends in human genomics and the UK market position based, discussions with industry and public sector stakeholders literature review and our work in the sector. It focusses on the United Kingdom but in the context of the global market and draws on examples from other countries.

The report considers the challenges to growth, barriers to adoption, shifting dynamics and how the emergent industry is developing. The intention is to provoke discussion and offer readers an overview of the industry challenges and dynamics in the UK.

We welcome your feedback and comments.

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Executive summary

This report is a study of the human genomics industry in the UK. It provides context around market history, as well as UK market size and growth of the global market. The global market drivers and constraints are discussed and the UK industry composition is described in terms of company size and location. The value chain, the activities by stage that are involved in genomics, is examined. Finally, it reviews the UK's international competitiveness.

Genomics is a discipline which analyses the function and structure of genomes (the complete set of DNA within a single cell of an organism). It uses DNA sequencing techniques and bioinformatics to decode, assemble, and analyse genomes. Genomics enables the study of the complete set of DNA within an individual. Knowledge of individuals' genetic make-up can help understand their predisposition toward certain genetic diseases, inform the best course of treatment and contribute to precision medicine. These advanced developments have only recently become a possibility due to an exponential decline in sequencing costs, more clinically relevant sequencing timescales and large scale public and pharmaceutical industry investment.

The genomics value chain describes the process by which genomic samples are transformed into useable information to guide and develop treatments or improve patient care. We have chosen to split the value chain into five stages as follows:

- **Sampling:** extracting, cleansing and transporting DNA samples (e.g. blood or saliva samples).
- **Sequencing:** decoding the sequence of nucleotides within a genome.
- **Analysis:** understanding whether the sequence of nucleotides reveals any variation when compared to other genomes.
- **Interpretation:** translating any observed variations into clinical actions and treatment options.
- **Application:** consumer-facing treatments, pathways and information provided to individuals based on their genome.

The global genomics market is valued at over £8 billion[1], though estimates vary. It is forecast to grow rapidly, driven by a number of factors. These include the falling cost of sequencing, growing investment from pharmaceutical companies and national and international projects. Such projects include the Human Genome Project, the Saudi Human Genome Project and the UK's 100,000 Genomes Project[2]; the latter is explored in this report. As the scale of genomes data grows, services further down the value chain such as data analysis and clinical interpretation will be in high demand. It is expected that this high demand will drive investment in areas such as analytics, data management and ethics training. However, the genomics industry is still at a very early stage of development. Using genomics to predict, cure disease and improve disease management is not just dependent on following the stages listed in our value chain but also involves understanding interactions between multiple genes and the impacts of environmental factors and requires significant clinical investment. This complication will act as a constraint to industry growth and, in particular, to the growth of the genomic applications market.

The UK genomics industry contributes 10% to the global market, a total value of £0.8 billion. It is expected to outpace the global market, growing at a 20% CAGR partly as a result of the 100,000 Genomes Project and investments into genomics. The UK genomics industry is characterised by smaller companies, many of which have 1-10 employees and are at a pre-revenue or spin-out stage. These tend to be concentrated around Cambridge and London, reflecting the strong academic base for genomics in the UK. The large genomics companies in the UK are foreign-owned, a theme we return to for the UK competitive position section.

The UK genomics market can also be viewed in terms of the revenues attributed to different stages of the value chain. Currently, over 60% of UK genomics revenues are generated by companies focused on the sequencing stage, with only small proportions assigned to sampling, analysis, interpretation and analysis[3]. However, the sequencing stage is relatively mature and expected to be the slowest-growing of the value chain stages. Going forward, we can expect significantly more commercial revenues from genomic analysis and interpretation.

The UK is in a strong position internationally in the field of genomics. It has played a role in the history and development of genomics and is seen as having strong academic talent and expertise in the field. UK universities are also improving their abilities to turn academic insights into commercial solutions through technology transfer offices. This can be seen in the growing number of medical spin-outs in the UK and also in the industry composition of UK companies. The challenge for the UK is to scale and effectively commercialise more ideas so that its academic advantage is reflected in industrial success at scale.

Conclusions

Genomics is a fast-growing and highly dynamic global industry. Government investment in this industry has had a multiplier effect with regard to associated industrial jobs. Current genomics industry revenue in the UK is concentrated in sequencing, however over time the analytics, interpretation and applications components will significantly increase in value and increase growth still further.

In writing this report, we acknowledge the important actions that have been taken so far to build and grow the UK genomics industry. However, overcoming the key challenges identified by our research will be important in securing the UK's competitive advantage going forward.

These key challenges include:

1. Skills shortage in bioinformatics and genomics. These are key skills required to grow genomics commercially and improve the application of genomics in the NHS; their shortage restricts potential growth.

2. Commercialisation and scale up remain a key constraint for UK industry. It will be valuable to learn from the challenges seen in the growth of the UK biotech industry to help the emergence of scale genomics businesses.

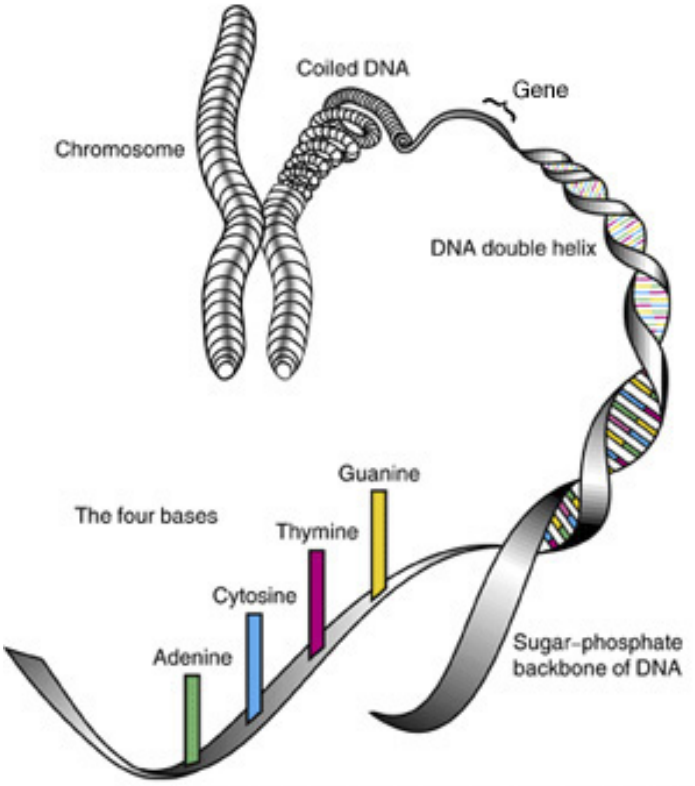
3. Accelerating application and reducing barriers to NHS adoption. Continuing to build the relationship between academic research and clinical application in the NHS will be critical; including improving reimbursement pathways and reviewing any commissioning opportunities.

The global genomics market is valued at over £8 billion[1], though estimates vary. It is forecast to grow rapidly, driven by a number of factors. These include the falling cost of sequencing, growing investment from national and international government sponsored projects and pharmaceutical companies.

Part 1. Developments in genomics

Genetics is the study of heredity and impact of individual genes, as opposed to the study of the full genome (Figure 1). Advances in both genomics and genetics improve our understanding of individuals' susceptibility toward particular diseases. For example, genetic testing refers to the examination of specific parts of DNA that have a known function, usually in a protein-coding gene. This is conducted based on some prior understanding of the underlying biological contribution to a trait or disease.

Figure 1. What is genome?



Source: DOW Joint Genome Institute website www.jgi.doe.gov

History of genomics in the UK

The UK has played a key role in the development of genomics since the double helix structure of DNA was first discovered by Crick and Watson in Cambridge in 1953. The first genome was sequenced by Fred Sanger in the 1970s and a number of scientific and technological breakthroughs have taken place since, leading to the current state of modern genomics (Figure 2). These include the development of significantly faster and much cheaper methods of sequencing, making the field of genomics more accessible to a greater number of scientists, as well a number of national and international genomics research projects to boost our understanding of the human genome.

Figure 2. History of genomics

1980	DNA Sequencing methods are pioneered
1985	DNA profiling methods developed
1990	Launch of Human Genome Project
1992	Wellcome Trust and the UK medical research council agree to fund new research centre
1996	Two yeast, a nematode and 1/6 of the human genome sequenced
1997	36 million bases of human DNA sequenced
1998	Mycobacterium tuberculosis is the first bacterium to be sequenced
2000	Shotgun sequencing used to create the draft of the human genome released
2003	In early 2000's DTI suggested main UK strength predominantly in agrifood applications. Following Bell report, emphasis shifted towards health & medicine
2003	The finished version of the human genome released
2007	Introduction of Next Generation Sequencing (NGS) increases output 70x
2006-14	Wellcome Trust, Sanger Institute and EBI both focus on open source and open access public domain principles
2013	Genomics England set up to deliver the 100,000 genomes project
2014	Ability to sequence a genome for less than $1,000 announced

Source: Deloitte analysis

Genomics applications

Research looking at the connection between genetic differences and their clinical expression has helped identify genes involved in a number of rare genetic disorders. Some disorders are a result of the expression of one specific gene; others derive from complex interactions between various genetic factors and non-genetic factors over which people have control, such as diet, exercise, and smoking. It is important to note that the industry is still nascent, and tackling the complex interactions between multiple genes and non-genetic factors is still predicted to be a long way off.

Drug treatments can also now be targeted towards specific genetic profiles. Two examples already in the market are imatinib and trastuzumab. Imatinib is used in the treatment of chronic myelogenous leukemia, targeting the BCR/ABL complex, a specific protein expressed in this disease that when blocked lends patients up to several years of remission from the cancer. Similarly, trastuzumab targets and binds to the HER2 receptor which is present in about 15-25% of breast cancers. The emergence of precision medicine and oncogenomics will further increase the importance of the genomics industry.

Analysis of the genomics industry

Given the broad and nascent nature of the genomics industry, analysis of the genomics market can be undertaken in different ways. These perspectives include:

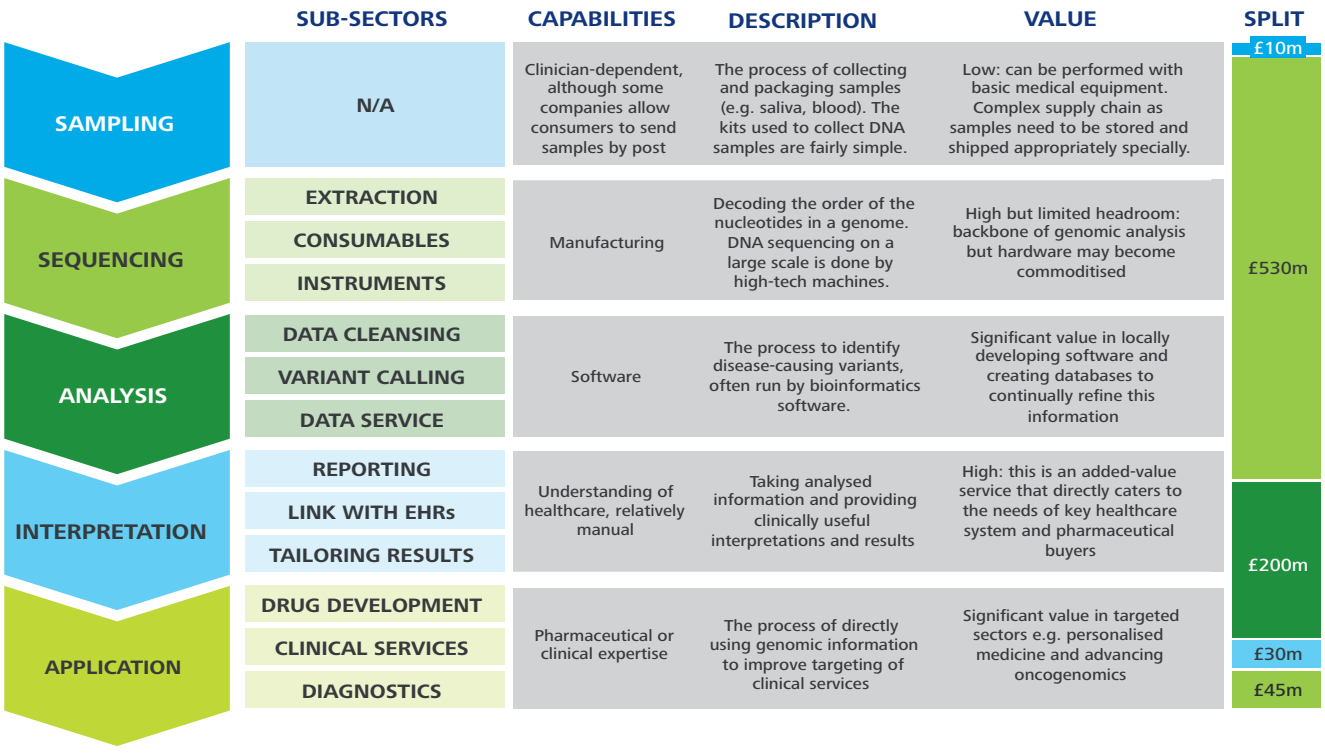
- products versus services;
- supply-side versus demand side;
- clinical versus pharmaceutical;
- commercial versus non-commercial; and
- value chain.

This report will consider the value chain perspective (Figure 3) as it has informed our understanding of the market.

The genomics value chain

The genomics value chain is composed of five elements: sampling; sequencing; analysis; interpretation and application.

Figure 3. Genomics value chain



Source: Company reports and accounts, Deloitte analysis

In order to reach the above value chain split, we reviewed the revenues of genomics companies in the UK their revenues where available:

Sampling

Sampling refers to the process of taking a human DNA sample (blood, saliva etc.) and transporting it safely to a laboratory where it can be analysed. Overall, sampling has historically been considered a low-value area, as shown by the fact it does not necessarily require clinicians to complete it. Going forward however, the ability to reach consenting volunteers and collect these samples will be of high value.

Sequencing

Sequencing is the process of decoding the order of the nucleotides in a genome. Large-scale machinery is an integral part of the sequencing process: sequencing on a large scale is usually carried out by high-tech equipment. There are a number of different types of sequencing processes and machines. In addition to the process, there are a number of consumables required: perishable items used during the sequencing process. In total, sequencing is currently the largest part of the value chain, generating revenues in the UK of c.£500 million and companies are clustered in Cambridge and Oxford. The UK is strong in terms of generating and using new methods of DNA sequencing, but weaker in terms of scaling up these methods to grow and gain economies of scale.

Analysis

Once DNA has been sequenced it can hold a variety of data forms. By performing analysis using software and other methods, this information can be standardised, compared, and areas for investigation can be identified. It can also be compared against phenotypic information in order to draw meaningful conclusions at interpretation stage. It is a highly important area in which the UK could build some advantage in the future. Across analysis companies in the UK, there are revenues of c.£206 million from over 40 companies. Similar to sequencing, there are a number of US-headquartered players who dominate revenues in genomic analysis. These larger companies are likely to offer analysis as an add-on to sequencing services. The UK is strengthening its offer through Genomics England's annotation partners, as explained in Section 3.

Interpretation

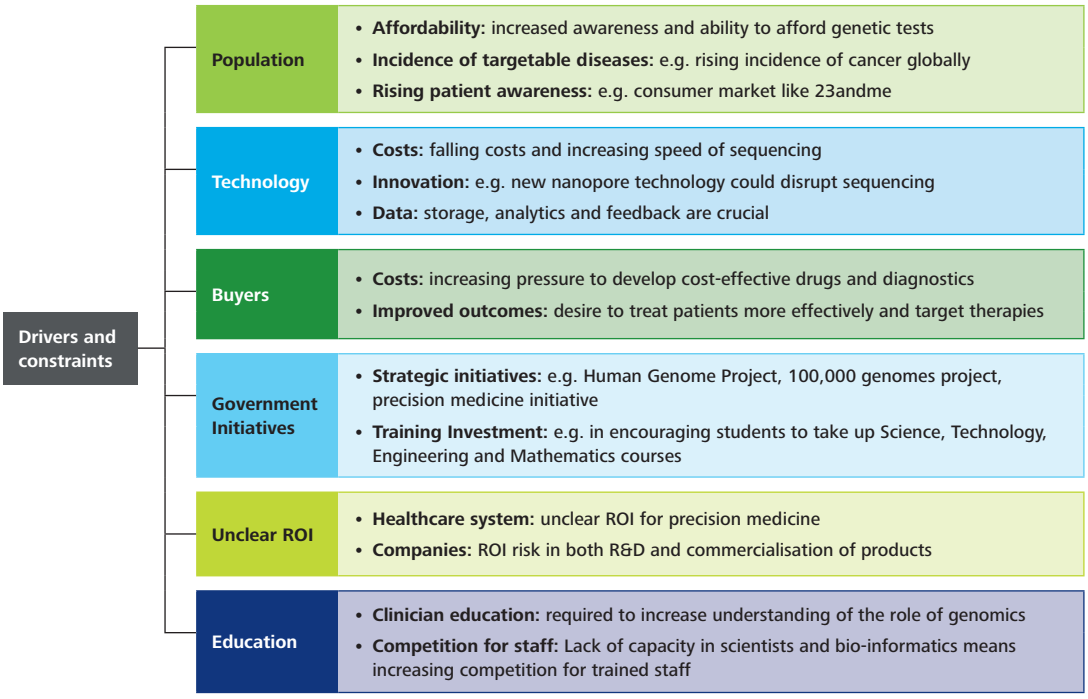
Interpretation is currently the smallest of the sub-segments, valued at c.£32m. Interpretation is the process of translating analysed genomic information into insights for clinicians and pharmaceutical companies. Clinicians should be able to make treatment decisions based on this interpretation. It is currently a relatively immature commercial market and key to unlocking the translation of genomic information. It should be reiterated that our sizing of the value chain is based on commercial revenues and that as a result, the interpretation sector is likely to be larger than this as it includes a lot of activity taking place in a non-commercial setting. We predict that the commercial sector will grow rapidly as the 100,000 Genomes Project generates demand for formalised interpretation companies.

Application

Application is the final stage of the genomics value chain, in which the genomic information is used to provide diagnostic treatments, targeted therapies or inform drug development. The main users of applied genomics are pharmaceutical companies and, in the long-term, healthcare systems and clinicians. Genomic applications are one of the smaller sub-sectors, valued at c.£45 million. This is reflective of the immature nature of genomics as a whole: sequencing and analysis are far more developed whilst interpretation and application will take time, significant data volumes and sufficient skilled workers to develop to the attainable level.

Part 2. The trends driving growth

Figure 4. Key genomics drivers and constraints



The genomics market faces a number of key market drivers and constraints (Figure 4), from broad demographic requirements for more genetic testing or incidence of targetable diseases, to falling sequencing costs and government initiatives and investments in the sector.

Based on our analysis of all the drivers, we can see the following four themes in the genomics market:

1. Lower sequencing costs, industrial policy and pharmaceutical investments are driving scientific activity.
2. High levels of complexity and uncertainty remain and these may limit the growth and advancement of genomics, particularly its application.
3. The economics for investing in genomics is highly important: precision medicine requires precision economics.
4. Data analysis and interpretation are increasingly important parts of the value chain; this drives investment in the supporting infrastructure around the technologies and analytics that will deliver value.

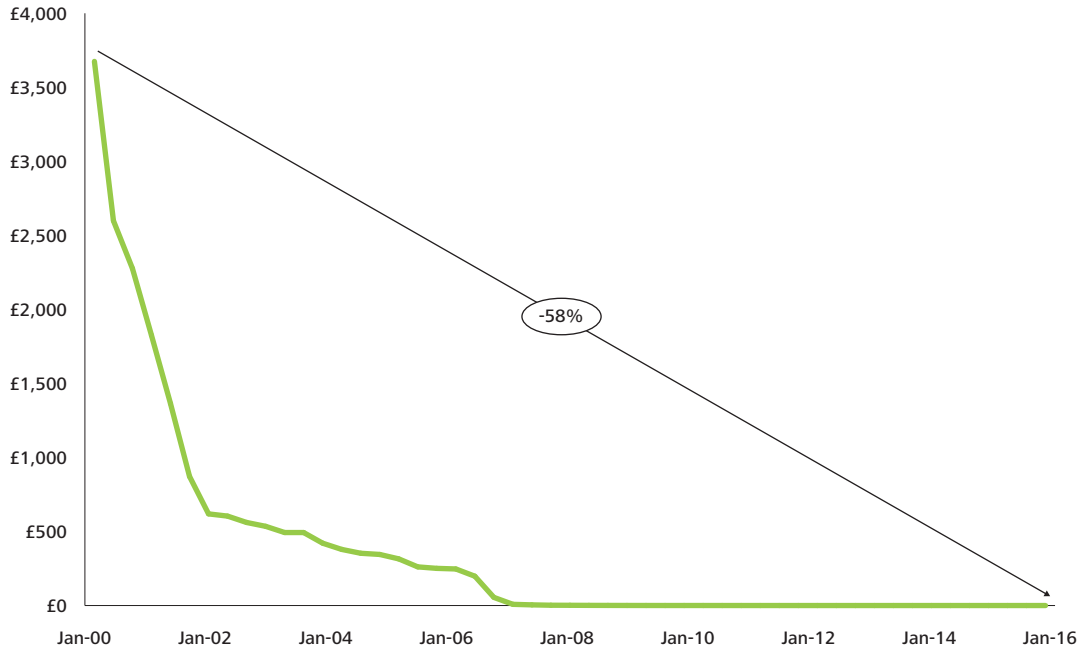
The economics for investing in genomics is highly important: precision medicine requires precision economics.

Growth drivers and barriers

Theme one: Lower sequencing costs, industrial policy and pharmaceutical investments are driving scientific activity

The cost of whole genome sequencing has dropped rapidly over the last decade as a result of the evolution of next generation sequencing. The rapid evolution of DNA sequencing technologies in recent years has meant that the cost of sequencing one mega-base of DNA has decreased by almost 60% CAGR over the past decade, from over £3,600 down to £0.03 per mega-base of DNA in April 2015 (Figure 5).

Figure 5. Cost of sequencing one mega-base of DNA (£)



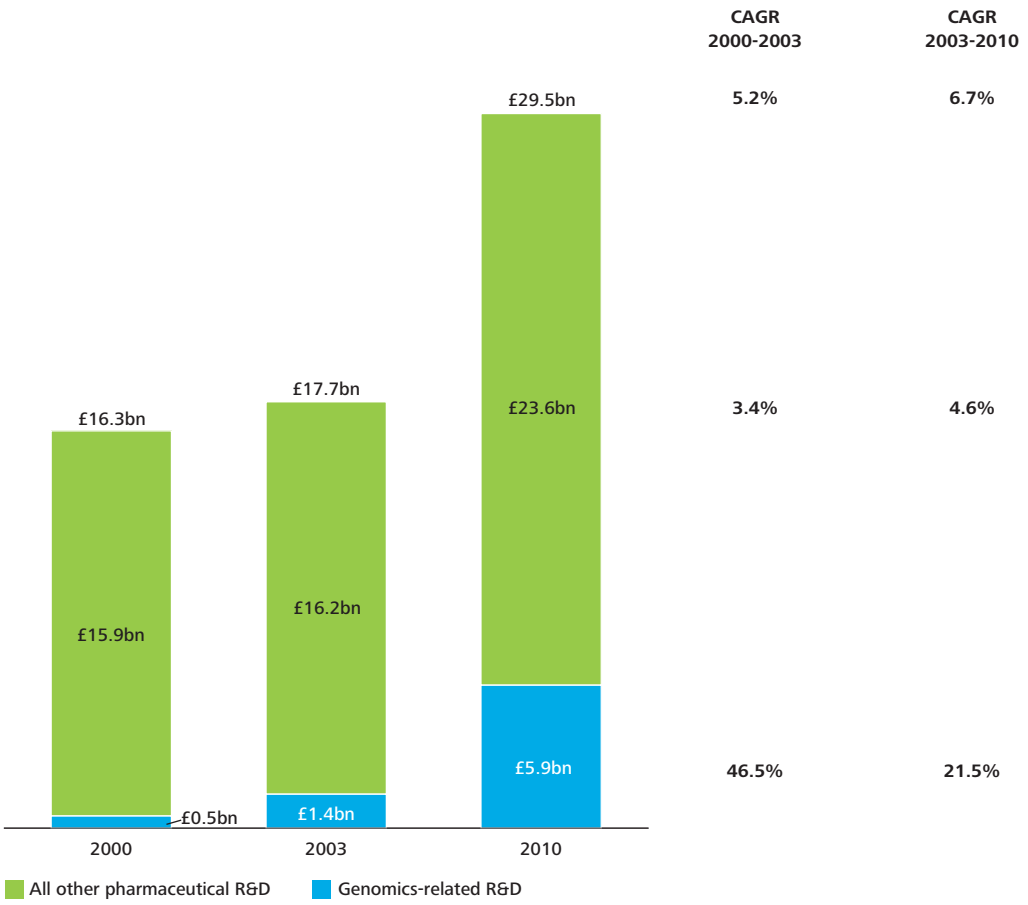
Source: National Human Genome Research Institute

Illumina estimates that the number of genomes sequenced will double every year, up to 1.6 million genomes by 2017.[4] For Illumina's prediction to be true, we would expect sequencing costs to continue to fall. However, this rate of reduction is slowing, suggesting that falling sequencing costs will not be as big of a market driver going forward unless there is another significant market disruption. Fixed costs such as clinician time currently limit the floor of sequencing costs. Some of these fixed costs can be reduced through greater automation; however other costs, such as reagents, are unlikely to fall in at the same rate.

Over the last decade, the Food and Drug Administration (FDA) has started to encourage the integration of biomarkers in drug development as a way of fostering innovation in the development of new medical products[5]. Biomarker-targeted drugs are those that identify and treat specific genetic mutations present in a subgroup of people with a particular disease. Actions taken to boost the development of biomarker-targeted therapies include a voluntary submission process (to enable open scientific discussions without the judgement of a regulatory outcome) and online education tools on the topic. This increased interest has provided an incentive for pharmaceutical companies to invest in such treatments. After four decades of limited growth, the number of new biomarker-targeted drugs approved by the FDA increased by 350% between 1989 and 2009.[6]

This increased interest in biomarkers is driving interest in genomics-related pharmaceutical R&D, which has grown significantly since 2000 as seen in Figure 6 below.

Figure 6. US spend on genomics-related pharmaceutical R&D



Source: 'Note that CAGR values refer to original dollar amounts to remove exchange rate fluctuation'

Furthermore, industrial policy and national and international projects have been a key driver of scientific activity in the genomics field. The international Human Genome Project in the 1990s and early 2000s provided the first sequenced human genome and launched the genomics industry on a global scale. Companies such as Illumina were early entrants in this industry and continue to grow the genomics industry in the US and internationally.

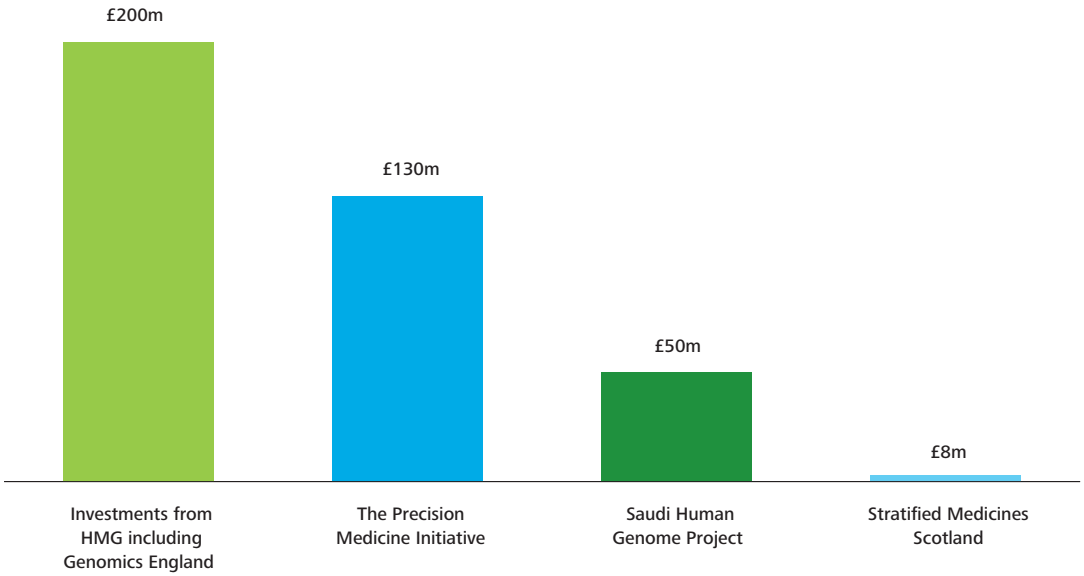
Illumina growth story[7]

Illumina was founded in 1998, borne from the discovery of BeadArray technology at Tufts University. The company quickly raised initial funding of £5.4 million and used this to develop core technology and an intellectual property portfolio. Illumina negotiated an exclusive license for its BeadArray technology and completed its initial public offering just two years later in 2000. In 2001, the company began offering genotyping services and consistently developed new services and benchtop systems. It conducted some strategic acquisitions and focused on commercialising an expanding product portfolio. However, until the acquisition of Solexa, a UK-based genomic-scale sequencing technology, Illumina did not have the complete tool set for genomic analysis. The acquisition in 2006 saw revenues double.

A number of countries have recently invested in genomics either through collecting genomic information for databases or by generating research (Figure 7). One of the largest financial investment, the UK's 100,000 Genomes Project, launched in 2012, will contribute significantly to the growing number of genomes sequenced and should drive industry growth.

Historically national investments have proven effective at growing the genomics industry. The US investment in the international Human Genome Project saw a very high return on investment of $141 to every $1 invested, with an immediate return of 310,000 jobs and over £500 billion in income[8].

Figure 7. National investments and projects in genomics



Source: Deloitte research and analysis

Recent government initiatives in genomics

- The 100,000 Genomes Project[9] was launched by the UK government in 2012 with the aim of sequencing 100,000 human genomes, setting up a genomic medicine service for the NHS, enabling new scientific discovery and kick-starting the development of the UK genomics industry. It will initially focus on rare diseases and cancer and has received over £200 million in investment.
- The US Precision Medicine Initiative[10] was announced by President Obama in his 2015 State of the Union Address, with the aim of investing £130 million to test at least one million volunteers to see how their genomic data and other health information will help understand how genes interact with environmental factors. This research will be used to advance pharmacogenomics, identify new targets for treatment and prevention, test the role of mobile devices in encouraging health behaviours and lay the scientific foundation for precision medicine.
- The Saudi Human Genome project[11] was launched in late 2013 and funded by the Saudi Arabian National Science Agency. It aims to create a DNA database to develop precision medicine and up to 100,000 people in Saudi Arabia are expected to have their genetic codes mapped. Research will take place at 10 genome centres across Saudi Arabia with another five expected to be created.
- The Stratified Medicine Scotland (SMS) Innovation Centre[12] was launched in 2014. It aims to create capacity to serve the health needs of the Scottish population, improving both diagnosis and treatment of diseases. The SMS Innovation Centre will have the capability to link phenotype and genotype data together to better predict patient response to individual therapy. Projects include identification of additional genetic mutations to improve treatments for cancers. There is also a funded programme for an MSc in Stratified Medicine and Pharmacological Innovation, a joint degree offered by the Universities of Aberdeen, Glasgow and Strathclyde.

Complexity remains

Theme two: there remain high levels of complexity and uncertainty which may limit the growth and advancement of genomics, particularly its application

Together, the falling cost in sequencing, growing potential for pharmacogenomics and government policies have helped drive scientific activity. There are a significant number of whole sequenced genomes and public/locally available databases of both genotypes and phenotypes. However, over the last decade, the boost in scientific activity has not been matched with a corresponding boost in genomic application. There are a number of potential reasons for this.

The first reason is the inherently uncertain nature of genomics. Genetic and genomic data is largely probabilistic and few certainties exist, especially if it is to be interpreted in a medical setting. As whole genomes are sequenced, a large number of variants will be identified in an individual, and yet their significance will be largely unknown. A 2012 test of the utility of whole-genome sequencing found that comprehensive clinical interpretation and reporting of clinically significant findings were seldom performed. Furthermore, "human resource needs for full clinical interpretation… remain considerable, and much uncertainty remains"[13]. Research on schizophrenia in 2014 revealed that over 100 gene variants could be linked to the disease. Previously successful pilots, such as gene therapy for blindness, have recently found that the positive effects of treatments to restore vision have started to fade after a few years.

The second reason is the growing realisation that our knowledge of genomics is equally at an early stage. For example, understanding the phenome, the physical expression of the genomes, is crucial to applying genomics in a clinical setting but Professor Steve Brenner, of the University of California, stated that "we don't understand much about the genome yet, despite all the years we've been studying it."[14]

NHS organisations such as Great Ormond Street Hospital and the Bristol blood group are making important contributions to developing new knowledge. They build new capabilities in non-invasive prenatal or genetic based diagnostics.

The UK could also move forward by looking more broadly at activities and solutions beyond whole genome sequencing, such as exome sequencing. The exome consists of all the exons of a genome – the coding portions of genes. It is a subset (1-2%) of the genome and is usually cheaper to sequence, allowing for larger population numbers. Additionally, ribonucleic acid (RNA) is the messenger molecule that converts the information in DNA into a form that can be used to produce proteins. Studies of RNA have revealed that RNA-based mechanisms are responsible for a large proportion of the fine-tuning of gene expression and regulation.

It is important to have knowledge of these different areas of analysis, and the purpose they are best suited to. For example, RNA can be used for dementia diagnostics. It is also continuous data, and there is significant growth in RNA diagnostics in the US. Therefore investors and entrepreneurs should remain flexible in their positioning and consider options alongside DNA whole genome sequencing.

The economics of precision medicine

Theme three: The economics for investing in genomics remains important: precision medicine requires precision economics

Understanding genomic data is a key element of the move towards precision medicine. There are a number of proposed benefits to precision medicine, including more effective treatment and potentially lower population costs.

However, in order for the genomics industry to successfully move toward precision medicine it will require significant buy-in and investment from healthcare systems and the pharmaceutical sectors. A review of the health economics reveals that there may be barriers in the future for both the precision medicine and genomics industries.

Beginning with healthcare systems, the investment in translatable genomics and precision medicines is cost-effective if the targeted nature of treatment improves patient outcomes whilst reducing overall costs compared to the current model of care (for a given level of health improvement), a measurement known as QALY. For example a drug that was traditionally provided to all repatients might only receive a response from some patients whilst others suffer adverse events. In a successful personalised medicine model, where only patients with a relevant biomarker are treated, more patients will respond to treatment and there will be fewer or no adverse events. For this model to be a reality there are a number of conditions that must be met:

- biomarker information for all patients (or a relevant diagnostic) must be available;
- the relevant treatment must be available and tested; and
- this entire process should still be cost-effective for this smaller patient group.

Within the pharmaceutical industry more generally, it is important to consider the potential return on investment from genomics, given the squeezed environment in which they are currently operating. Until 2014 the return on R&D had been falling making an increasingly targeted investment programme important. Deloitte's analysis of the returns on the top 12 pharma companies showed that ROI fell from 10.1% in 2010 to 5.1% in 2013 before improving slightly in 2014[15].

Precision medicine requires precision economics because the costs of treatment will be high, driven by significant R&D investment for relatively small populations. The challenge is that precision medicine could transform lives and determining the precise value of these intentions is difficult. In addition, the savings from not-treating some patients who would not benefit should not be counted in the economic case. As a result, there is uncertainty about when precision medicine tests provide economic value and there are gaps in the evidence base. A recent US paper noted that cost per QALYs gained by personalised medicine tests are only cost-saving in 20% of cases and less than $50,000 in 43% of cases, making the other 36% outside of the UK's NICE cost effectiveness threshold[16].

This investment has not been spread evenly among pharma companies, with some companies making larger investments than other. Pharma companies are taking a variety of strategic approaches to building genomics capabilities:

- M&A – most of the top pharma companies have acquired genomics-related companies in recent years. For example, Roche has made strategic acquisitions to renew its focus on genomics. Recent acquisitions include: acquiring or investing in 6 companieis since June 2014.
- Partnerships – organisations typically have multiple partnerships; for example Regeneron has a five year collaboration with Geisinger Health System using genomic analysis to study 100,000 patients[22].
- Organic growth – some pharma companies have taken to focused and steady investments in growing their precision medicine business. For example Sanofi has defined translational medicine as one of its two pillars in R&D[23].

These investments and strategic actions suggest that many pharmaceutical companies see genomics and precision medicine as a key strategic priority, despite uncertainties in the health economic reimbursement model.

Challenges in analysis and intepretation

Theme four: Data analysis and interpretation are becoming increasingly important parts of the value chain; this drives investment in the supporting infrastructure

As more data is generated from ever-cheaper sequencing methods, data analysis and interpretation is key in order to translate the insights from sequencing into healthcare interventions and treatments. This was recognised by our interviewees (Figure 9) as well as by Genomics England, which has set up the Clinical Interpretation Partnership to analyse and interpret the 100,000 genomes data set.

The full value created through analysis and interpretation is not necessarily reflected in current UK companies' revenues. This is because analysis and interpretation occurs in a number of settings, including non-commercial settings such as within hospitals, research laboratories or charities. It is expected that this activity will move toward the commercial sector over the next five years as more interpretation and analytics start-ups are created and private sector salaries for qualified analytics and interpretation professionals rise in line with demand for their expertise.

Figure 8. Responses to the question "What are the biggest challenges and opportunities in genomics currently?"

Source: Deloitte interviews

During the UK's 100,000 Genomes Project, phenotypic information will be used together with genomic information for analysis and interpretation purposes; a similar principle is also being followed by the US Precision Medicine Initiative. Genomics companies which collect or collate real world data are likely to see an increase in demand. In addition, there will need to be a standardised method of collecting and recording real world evidence and phenotype information. Similar to the initial sequencing efforts many decades ago, we are likely to see increasing standardisation in the analysis and interpretation sectors.

Analysis and interpretation will require specialists, including bioinformaticians, statisticians, geneticists and technicians (though the number of technicians may fall as analysis is increasingly automated). This will include academic training, ethics management and the collection of phenotypic data and real world evidence.

Health Education England (HEE), a part of the NHS, has established a £20 million, three year genomics education programme that supports and enhances Genomics England and the 100,000 Genomes Project to provide education and training in genomics for all NHS staff. Nine higher education institutions across England will deliver the Master's in Genomic medicine and HEE will fund over 500 places for NHS staff. Forty extra healthcare science training places are being commissioned in genomics and bioinformatics in 2014/15[24].

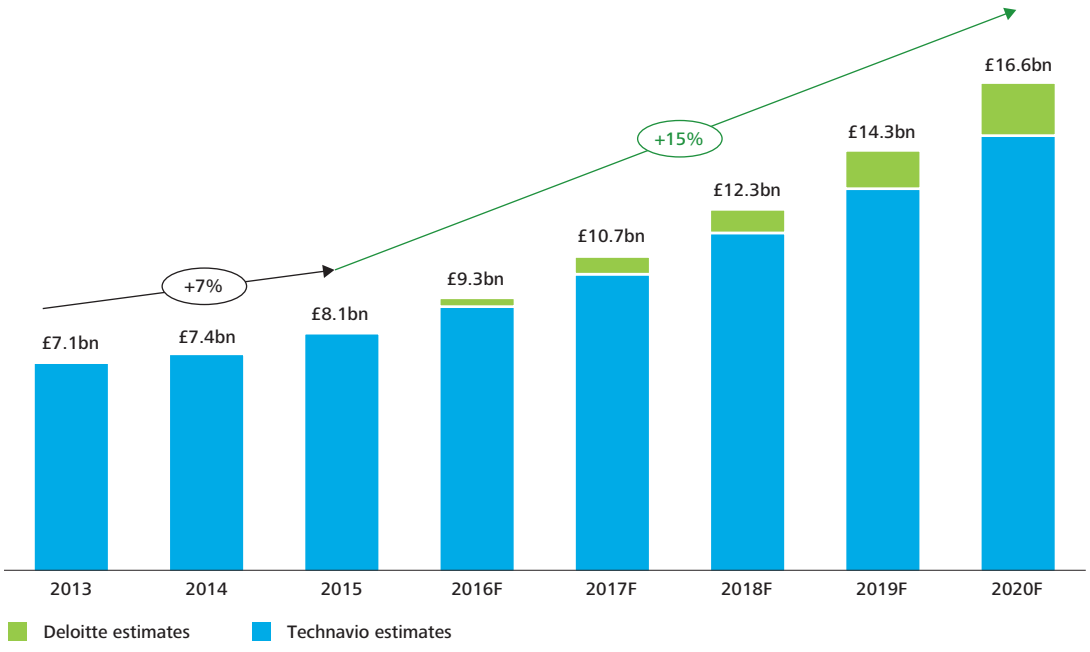
Other countries are following suit: there are a number of degree courses in genomics, genetics and bioinformatics in the United States. Coursera, a Massive Open Online Course website, lists at least thirty free online courses from universities such as Johns Hopkins and the University of California.

These courses also include a significant element of ethics, a crucial part of the conversation around genomics. The Genomics Education Programme offers a course on "Preparing for the consent conversation" around the 100,000 Genomes Project. The University of California offers a course on "Ethical and Social Challenges of Genomic and Precision Medicine". As genomic initiatives ramp up awareness and volunteer numbers, it will be crucial for those involved to have a clear view of the risks and ethics involved. Additionally, clinicians will increasingly be providing advice and counselling to the growing numbers of patients taking genetic tests, and the necessary infrastructure will need to be in place for this.

Market size and growth

Technavio analysis suggests that the global genomics market (excluding pure plant and animal genomics players) is currently valued at c. £8 billion, and expected to grow at a CAGR of 12%[i], in line with other market reports. However, interviews with market experts suggest that this rate may be conservative when compared to the rapid growth experienced by market-leading firms. For example Illumina- the global market leader in genomic sequencing- is forecast to grow at a CAGR of 21% over the next five years[ii]. For this reason we have amended the growth rate upwards, in line with other high-growth industries, to 15%.

Figure 9. Global genomics market (2013 – 2020) (£bn)



Source: Technavio (2014) Global Genomics Market 2014-2018, 2014, Deloitte research and analysis
Note: Technavio analysis has been extrapolated to 2019/2020

The Americas currently account for just under half of the global genomics market (44.7%) whilst EMEA accounts for just over one third (36.2%); APAC is the smallest region at 19.2%[27]. The high share from the Americas is largely due to the strength of US-based firms contributing to global genomics revenues. Many of these US-based firms, such as Illumina, are also leading players in the UK.

However, genomics in the APAC region has grown significantly in the last few years, a trend that is expected to continue. Many global players have recently expanded operations to Asia to reflect growth in local demand.

The growing middle class has contributed to the rise of genomics in Asia. The OECD predicts that Asia, which accounted for 28% of the global middle-class population in 2009, will count for 66% of the global population by 2030, and 59% of global middle-class consumption[28]. In addition, there have been favourable genomics-related government policies and investments in Asia (e.g. in the 2003 Indian Genome Variation Initiative and the emphasis on biotechnology in China's 2011-2015 Five Year Plan).

Rising consumer incomes are combined with a growing awareness and appreciation of health. For example, in China the historic impact of the one-child policy has meant that middle class parents are increasingly interested in the health of their children. This could include the use of prenatal genetic testing to identify genetic diseases. BGI, a Chinese genomics leader, provides the Nifty test, a non-invasive prenatal test, to Chinese citizens as well as exporting to the UK and other countries. There are also a handful of personal genomics companies in India, such as MapMyGenome and Meragenome, which cater to the increasingly health-conscious upper class; a similar market position to 23andme in the US and UK.

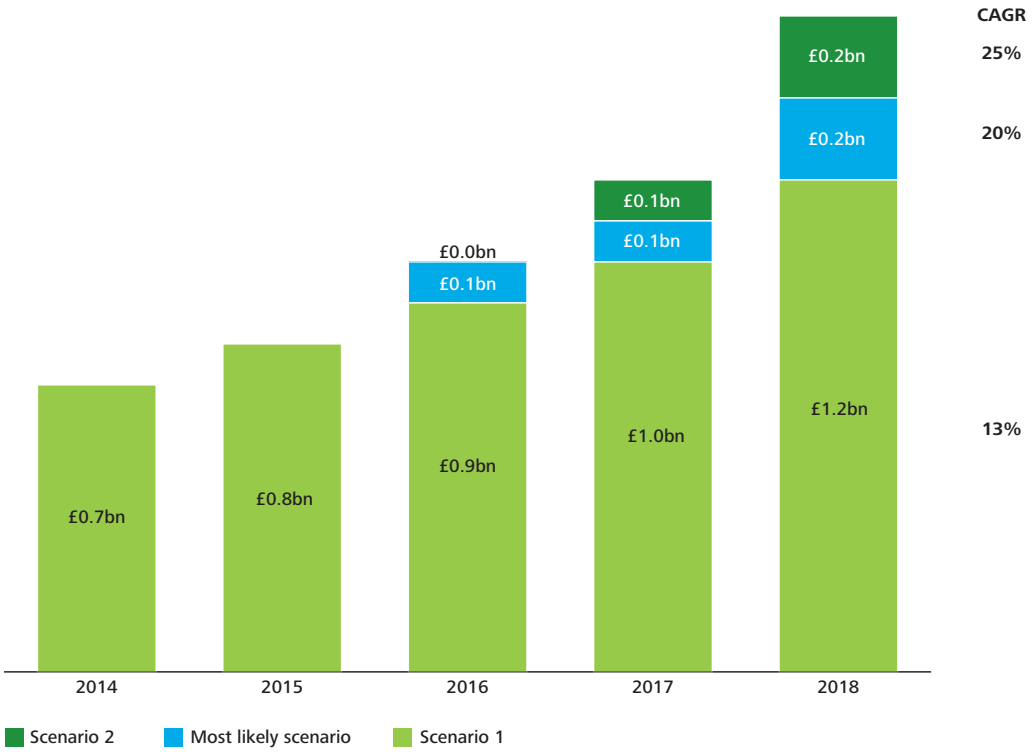
Moving operations to local markets is important in order to understand local dynamics and educate key policy-makers. For example, the Chinese government banned all medical applications of gene sequencing technologies in February 2014, only to reverse the decision a few months later. Local processing centres can also be important for the speed of tests. As a result, UK organisations looking to export genomics and genetics-related products to markets in Asia should carefully consider their export model based on the urgency/local sensitivity of their products and services.

UK market size and growth

In order to size the market we focused on UK commercial revenues related to genomics, which total around £0.8 billion (excluding pure plant and animal genomics players).

The rate of overall industry growth forecast is dependent on a number of assumptions specific to UK performance and range between 13% and 25% (Figure 10).

Figure 10. Three potential growth rates for UK-based commercial genomics revenues (excluding pure plant and animal players)



Source: Deloitte research and analysis

Many of our interviewees considered that the most optimistic growth rate of 25% could be too high due to the time taken and skills required to translate whole sequenced genomes this into commercial applications. They believed that the programme's benefits were certain, but the timeline less so. In 2014, a lead scientist from Genomics England was quoted as saying "the process of translating research into clinical practice is usually slow. You might raise some grant funds, you would do your study, analyse the results and you would try and publish it. That could take some time. In fact, we know that medical findings can take as long as 17 years to propagate into clinical practice[30]."

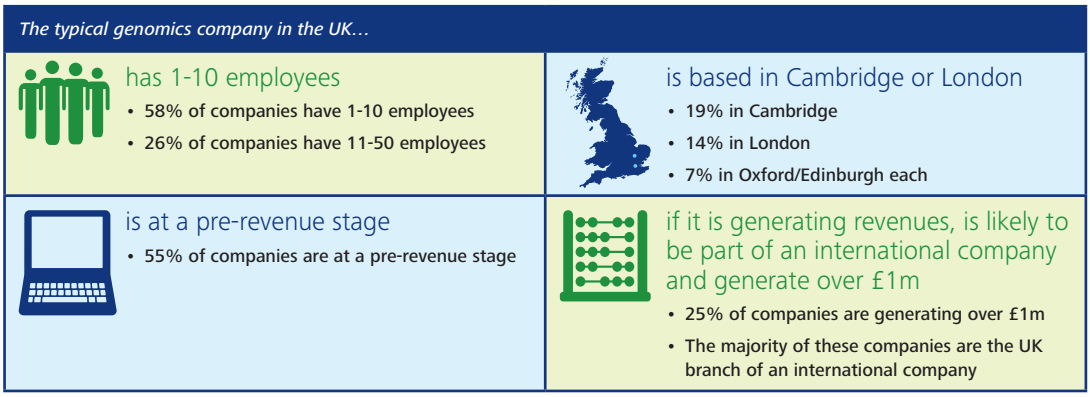
On a more positive note, one of our interviewees noted that, of the many national programmes to boost genomics, only Genomics England and Stratified Medicines Scotland had a strong focus on the translational and application elements of genomics. It is reasonable that analysis and interpretation will the parts of the value chain that grow most quickly as these are very young industries and the 100,000 Genomes Project should provide a core customer for annotation and interpretation partners. Our most likely growth scenario for the UK genomics industry is 20% until 2018.

Part 3. UK competitive position

UK industry composition

The UK genomics industry employs over 10,000 employees and consists of 164 genomics and genomics-related companies. The industry is relatively fragmented but an analysis of the typical UK company (Figure 11) provides some insight into the challenges for developing the UK market:

Figure 11. The typical UK genomics company

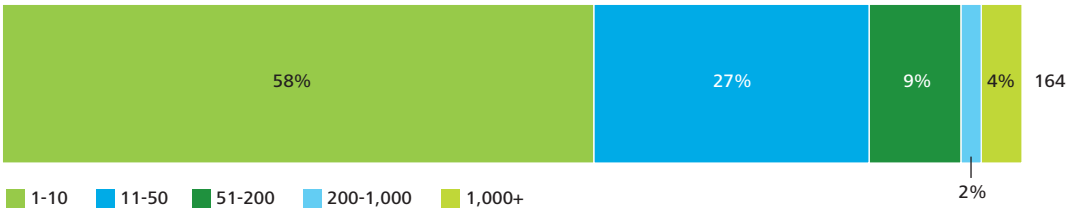


Source: Deloitte analysis

A 2004 ESRC paper found 30 genomics companies in the UK, the majority of whom were university spin-outs; the rest split between product-focused companies and larger, less focused companies such as Celltech and Pharmagene. In comparison to their US counterparts, UK companies are smaller, started later and operate on smaller budgets – a result of the US's first mover advantage and investors' higher risk appetites.

In total there are over 10,000 people in the UK working for genomics or genomics-related companies. However, this figure is inflated by the presence of large companies which do not focus purely on genomics. In terms of employment from pure genomics companies, this is estimated to be c.1,500 people. This number has been triangulated against publicly-available information but it is important to note that many smaller companies do not update such information so it may be a slight underestimate. Where reasonable we have applied assumptions to cover this possibility (Figure 12).

Figure 12. UK genomics companies by employee numbers



Source: Deloitte analysis

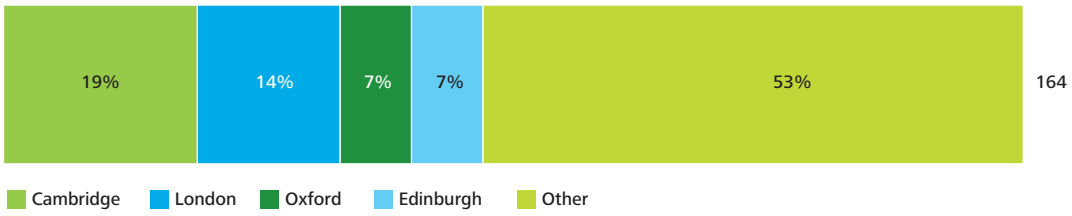
58% of UK genomics companies have only 1-10 employees; only 2% have 200-1000 employees. Companies with more than 500 employees in total are headquartered outside of the UK. Larger companies are more likely to export and hire sales and marketing employees – for example Illumina Cambridge have a roughly equal split of sales and R&D staff and are export-focused.

47% of companies located in the UK are located in Cambridge, London, Oxford or Edinburgh, showing evidence of clustering (Figure 14). This is in line with interviews, which suggest that the UK's core strengths in genomics are in research and spinning out companies from academic institutions. An example of clustering can be seen with The Wellcome Genome Campus in the Cambridge area. The Campus is home to both the Wellcome Trust Sanger Institute and the EMBL-European Bioinformatics Institute, representing a significant aggregation of genomics and bioinformatics skills within a single campus.

Vision for the Wellcome Genome Campus

Recognising the increasing opportunity for genomics to impact healthcare, a 25 year vision is being developed to establish the Wellcome Genome Campus in the Cambridge area as the European hub. The vision aims not just for scientific excellence, but also to make the campus into a destination for innovative genomic and biodata businesses and an environment to foster discussion of the scientific, medical and wider implications of genomes. The new Biodata Innovation Centre will open on the Campus to its first tenants from July 2016. The 25 year vision plans significant further growth in the space and accommodation available for genomic pharma and biotech activities.

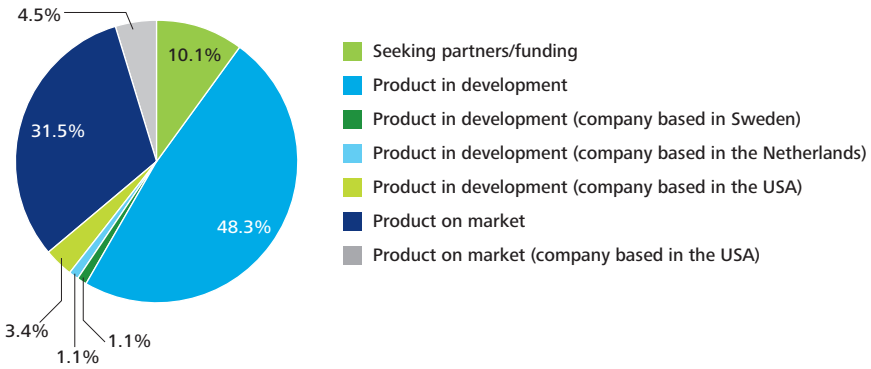
Figure 13. UK genomics and genomics-related companies by location



Source: Deloitte analysis

Academic spin-outs have varying levels of success and are at different stages of development; the majority will develop their products in the UK (Figure 14).

Figure 14. UK genomics-related spin-out companies by development stage, 2014



Source: Medical Research Council

UK's competitive position

In this section we evaluate the UK position within the international genomics industry, and areas for further development. Our analysis suggests that overall the UK holds a strong position and there is significant potential to grow this into a leading position if the development areas can be addressed effectively.

We tested the following three hypotheses over the course of our study:

- the 100,000 Genomes Project is a key opportunity for the UK to build its genomics industry;
- the UK has world-class academic research, supported by strong incentives and collaboration clusters; and
- UK genomics companies struggle to scale for a number of systemic and cultural reasons.

The role of 100,000 genomes

The 100,000 Genomes Project is a key opportunity for the UK to build its genomics industry

The UK launched the 100,000 Genomes Project in 2012, with the goal of sequencing 100,000 whole genomes from NHS patients by 2017. The programme aims to:

- create an ethical and transparent genomics programme based on consent;
- bring benefit to patients and set up a genomic medicine service for the NHS;
- enable new scientific discovery and medical insights; and
- kick-start the development of a UK genomics industry.

The project is expected to create opportunities for the genomics industry by providing funding, by creating opportunities for combining existing assets (academia, spin-outs, NHS data and phenotype data), engaging industry in a collaborative manner and encouraging connection across the value chain. The majority of the £200 million government investment was initially focused on sequencing. This was demonstrated by the central role of Illumina as the first partner, with a contract worth £78 million[32].

More recently, the Small Business Research Initiative assessment of Enabling Technologies for Genomics Sequence Data Analysis and Interpretation seeks development of technological innovations that will enhance genomics sequence data analysis capabilities. Many of the successful companies were small and often rapidly scaling UK businesses: Congenica, Genomics Plc, Oximon UK Ltd and Oxford Gene Technology. Although the total amount that will be available for product development (£8 million[33]) is lower than the amount paid to Illumina it is likely to have a significant impact on these companies as many have emerging revenues of <£1m.

In terms of fostering collaboration, the Genomics England Clinical Interpretation Partnership (GeCIP) is the way that funders, researchers, trainees and clinicians will collaborate. It aims to:

- optimise clinical data and sample collection, clinical reporting and data interpretation for return to clinicians and patients;
- perform research to further improve our understanding of the implications of the findings for genomic medicine in the clinical setting; and
- provide a rich training environment for trainees both within the Genomics Education programmes and with Health Education England.

The Genomics Expert Network for Enterprises (GENE) Consortium is a selection of industry partners who are allowed access to Genomics England's data during an industry trial throughout 2015. Membership fees for the consortium are either £25,000 or £250,000, depending on organisational size. The lower pricing is available for companies with a market capitalisation below £625 million. Members are from the pharmaceutical, biotech and diagnostics sectors and are expected to pool knowledge and share the results of their analysis.

Being a member of the GENE consortium also presents a number of conditions. The companies do not own the data they use (although they can use it to improve their genomic products and services). They are obliged to publish all findings and research from the industry trial at the point at which intellectual property for any product is protected.

Whist industry members generally agreed that the 100,000 Genomes Project will have a positive impact on industry, determining the *scale* and *timeline* of these impacts is difficult:

- "The 100,000 Genomes Project will significantly move things forward, but [a mature genomics market] is still a long way off" Financier, UK.
- "It will definitely have a positive impact, but we're yet to understand how much of the data will be translatable" Sales Director, Top 5 sequencing company.

As an example, the international Human Genome Project was responsible for kick-starting the United States industry. The US was a primary investor in the Human Genome Project, but the UK also benefited as one third of the genome was sequenced in the UK and this led to the growth of a genomics cluster in the UK. The industrial growth promoted by the Human Genome Project is aspiration that is shared by the 100,000 Genomes Project.

A question remains as to what can be done by the UK government to replicate the success of the Human Genome Project through the 100,000 Genomes Project. There are a number of commercial models that the UK could use to maximise the impact of a national genomics programme.

World-class research

The UK has world-class academic research, supported by strong incentives and collaboration clusters

When asking interviewees about the competitive strengths of the UK, there was a clear consensus in responses (Figure 15).

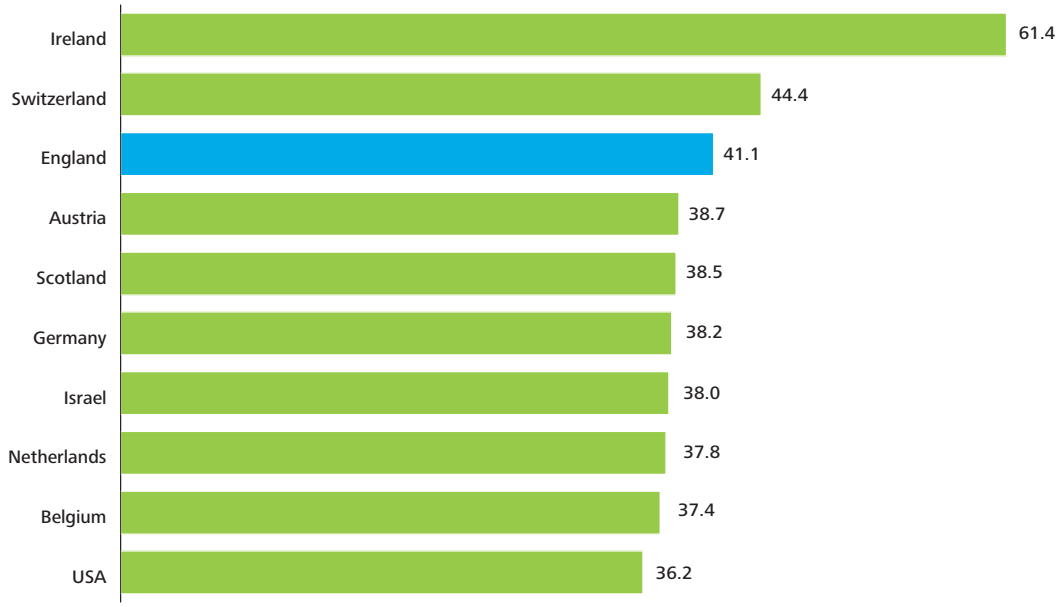
Figure 15. Responses to the question "What is the UK's competitive strength in the genomics industry?"

Source: Deloitte interviews

The UK's strong academic base comes from a legacy of providing the right incentives and funding for genomics research, in order to generate some of the most impactful original DNA research. As early as 2006, the UK played a prominent role on a global stage in terms of contributing funds to genomic research at an early stage. It is estimated that 12% of funding for genomics research came from the UK, with only the US providing more funding at 35%. Over time the UK's prominence has grown: as we have seen, the 100,000 Genomes Project is a larger investment than the US precision medicine initiative.

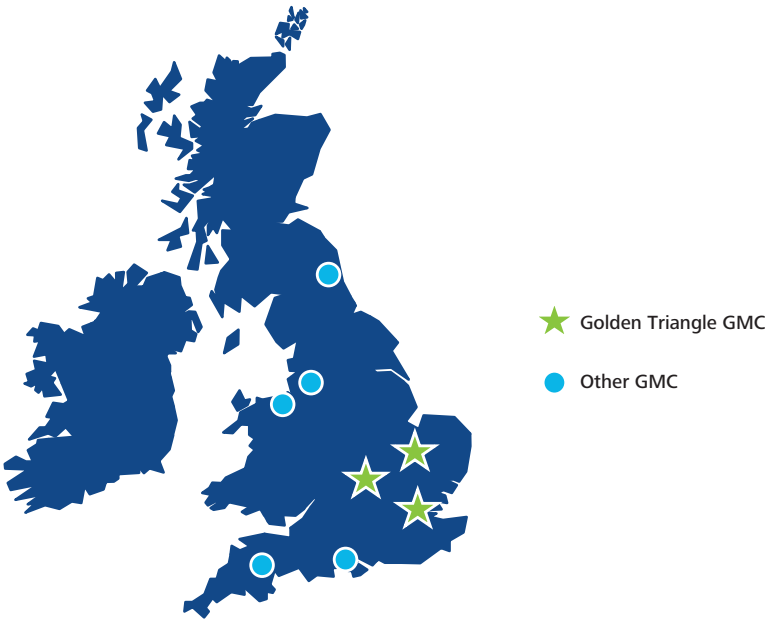
Using the number of citations per articles as a measure of the quality of research produced, the Life Sciences journal Lab Times sees Ireland as the global leader in molecular genetics and genomics, followed by Switzerland and England. The US is ranked 9th in comparison, using an index which measures the number of citations per article (Figure 16).

Figure 16. Number of citations per genomics/genetics article by country of researcher, 1997-2008



Source: Lab Times. 2010

Figure 17. Genomics England Genomic Medicine Centres (GMC)



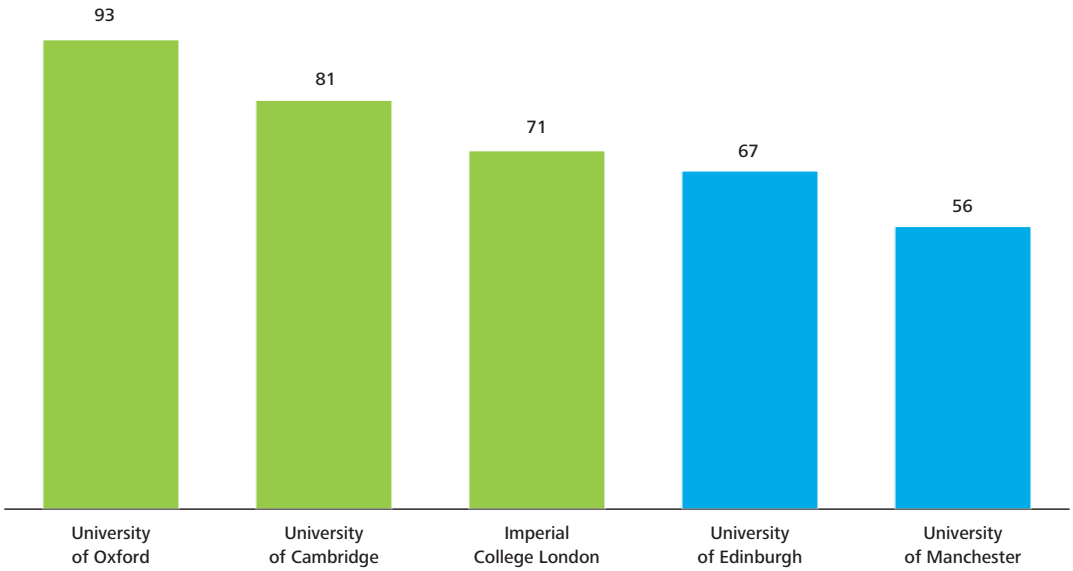
Source: Genomics England, 2015

A significant volume of genomics research comes from the UK's 'golden triangle' of London, Oxford and Cambridge. This can be seen in both translational research grant funding and industry-sponsored clinical trials where London, Oxford and Cambridge hold an important role. These clusters are important not only for research but also commercialisation, as the UK has greatly improved its abilities to spin companies out from academic institutions (Figure 18). Across all types of industries, there are currently over 1,300 university spin-outs since 2000 (c. 50 are genomics-related)[36], and over a quarter of these come from just five universities (Figure 19):

Figure 18. Number of medically-related spin-out companies from academic institutions, 1994-2012 (three year moving average shown)

Source: Medical Research Council

Figure 19. Top five universities based on number of spin-outs (all industries), cumulative figures 2000-2014



Source: Spinouts UK

Following the Bayh-Dole Act (1980) in the US, TTOs have emerged as a dominant model of technology transfer, a model that has extended to the UK. The model has been successful for a few institutions; for example the Office of Technology Licensing at Stanford University received more than $108.6 million in gross royalty revenue from 655 technologies [37].However, in the UK most TTOs run at a loss: in 2012, only 2-4% of the £3 billion external income leveraged by British higher education establishments comes from licensing and sales of shares in spin-outs. For example, the technology transfer group of Isis Innovation in Oxford raised £6.4 million revenue in 2012 for over £500 million university research income[38]. This highlights that there is a greater opportunity to successfully commercialise research in the UK than currently occurs.

A number of UK universities have formed partnerships with firms which specialise in advancing the commercialisation of intellectual property. Many are in the form of technology transfer offices (TTO), which are dedicated to identifying research which has potential commercial interest and strategies for how to exploit it. In the case of UK universities these can be specialised and local contacts (e.g. ISIS Innovations at the University of Oxford) or large commercialisation partners such as IP Group, Braveheart, Fusion IP and Frontier IP.

Growing the UK genomics market

UK genomics companies struggle to scale for a number of systemic and cultural reasons

Figure 20. Responses to questions about why UK companies remain small

Source: Deloitte interviews

Currently genomics companies in the UK sit between two extremes: small pre-revenue spin-outs and large companies owned by an international parent. It is important to understand why relatively few British companies are growing to the scale and international dominance of companies like Illumina or BGI.

Based on data provided by the Medical Research Council, just under half of all university spinouts since 2000 are at product development stage. Less than 10% have been acquired or merged and this has happened on average six years after incorporation.

We found that there are a number of reasons companies do not reach full scale, including:

1. Cultural and systemic preferences for acquisition (for example, by venture capital investors).

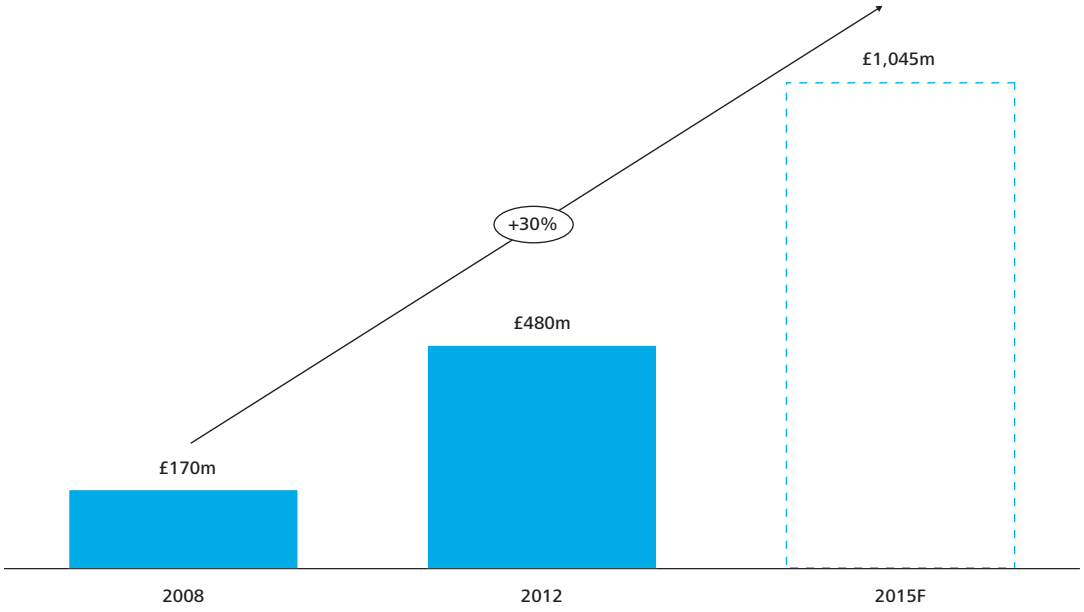
2. Lack of a natural/scalable local customer (e.g. the NHS or pharmaceutical companies).

3. Commercial skills gap in the UK.

1. The challenge of scale-up

The first of these reasons, the challenge of scaling up and a cultural and systemic preference for acquisition was brought up by a number of interviewees. This is true of genomics internationally: the key difference was quoted to be that UK investors are more risk-averse than their American counterparts. Interviewees and workshop attendees suggested a number of reasons for this, ranging from the overall culture difference between the two countries with regards to building a company (the US being more accepting of failure in previous business ventures), to the risk-averse background of many UK venture capitalists e.g. "our experience is that UK investors are more pharma-driven and very conservative".

Figure 21. US Capital invested in genomics-related companies (£m)



Source: Fairview Capital update on Healthcare Venture Capital
Note: 2012 rate used; assuming the same compound annual growth rate of 2008-2012, we have forecasted a 2015 figure

This low appetite for risk, combined with 5-10 year funding cycles, has resulted in a focus on companies being able to exit to provide a return to their investors: most often via acquisition.

This situation carries a long-term risk. If companies continually operate in the UK at the start-up 'valley of death' stage (i.e. investing in R&D, pre-revenue) and sell before they can make the most of the commercial opportunities, the UK economy will not necessarily benefit from the long-term annuity revenues available from scaling the company independently. This is a particular issue in the UK, given the strength of the UK research abilities, many UK companies focus on IP and technological/scientific innovation. These aspects are more 'portable' than manufacturing, meaning that when a UK company is acquired, there is less of a requirement to maintain activity in the UK.

2. The role of the NHS

A second reason why UK companies struggle to scale could be due to financial and system constraints in the natural local customer, the NHS. The NHS serves more than 60 million people and is the largest united healthcare system in the world. Some interviewees and workshop attendees noted that, for its size, the NHS could be commissioning more genetics and genomics related services.

There are a number of reasons why the NHS is not yet a scalable customer for genomics companies, from a lack of available spending to organisational and structural constraints.

In general, NHS budget constraints are likely to limit the uptake of whole genome sequencing unless clear cost effectiveness over existing methods can be demonstrated. The clinical benefits of genomic technology in many clinical areas are still being established and evaluated.

A geneticist from a leading specialist hospital has stated that it can be hard to recruit clinicians with a strong understanding of genetics both in theory and in practice; these and other cultural barriers within the NHS limit the uptake and understanding of new technologies.

Finally, there are also organisational constraints that limit the role of the NHS as a large and easy-to-access customer. General challenges for innovation include:

- Commissioning timelines which generally require new technologies to save money within first year.
- Budget siloes and a difficulty in realising savings (e.g. block contracts for regional genetic testing means there is little incentive for trusts to adopt better techniques not specified in the block contract, this can be seen in the slow adoption of non-invasive rather than invasive pre-natal testing).

More specifically, until the recent 100,000 Genomes Project high-quality phenotypic data has been difficult to access when it has been available. Patient data security and anonymity is another key challenge.

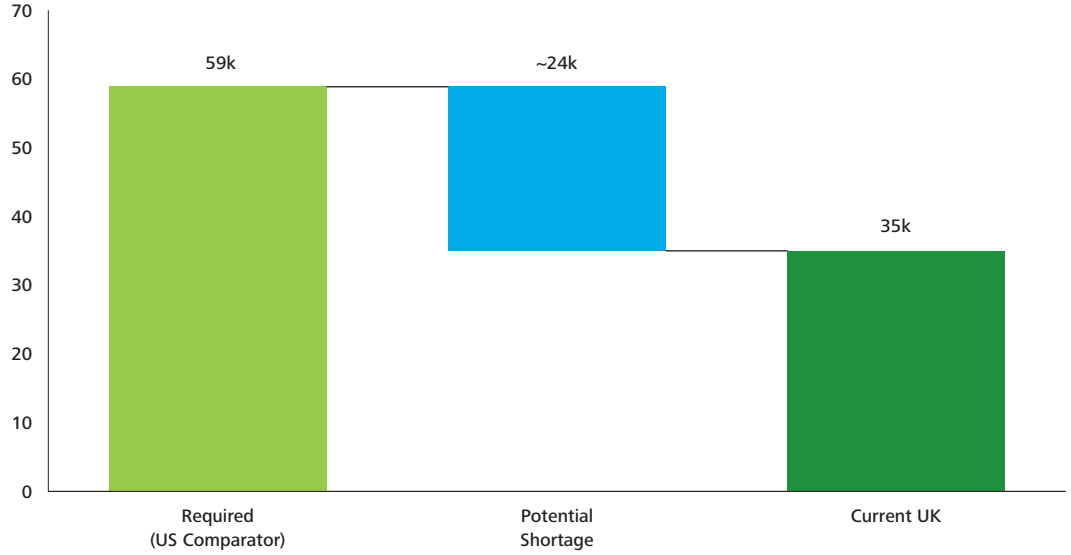
A private market for genomics in the UK would be focused on pharmaceuticals, private healthcare and potentially consumer-led genetic tests such as those provided by 23andme. This is certainly an area where UK companies could provide services, and these are likely to be centred on analysis and interpretation of the genomic data. However overall volumes would not be very significant in the next few years.

The NHS serves more than 60 million people and is the largest united healthcare system in the world. Some interviewees and workshop attendees noted that, for its size, the NHS could be commissioning more genetics and genomics related services.

3. Skills gap

Additionally, the UK appears to face a skills gap when compared to a best-in-case example of the US. As an example, if we scaled current US healthcare informatics professionals to match the UK market, to make a fair comparison with a 'best practice' system, we would expect to see 59,000 professionals. The UK currently has c. 35,000 health informatics professionals, leaving a gap of close to 24,000 professionals.

Figure 22. Estimated NHS informatics supply gap vs. best-in-class comparator health system



Source: Monitor Deloitte analysis

Interviewees suggest that the NHS has a lower clinical capacity for widespread use of genomic medicine than the US: before 2010 there were at least 40 clinical scientist geneticists in training per annum. In 2010, the UK Government launched an initiative called 'Modernising Scientific Careers' to address the training and education needs of the NHS workforce. However, post-2010 we are seeing even lower levels of clinical geneticists in training according to interviewees. Additionally there is the emergence of genomics as a new specialism. Interviewees noted that the focus of the Scientist Training Programme (STP) has recently shifted away from trainees supporting on service delivery at an early stage to pure training, which places a squeeze on resources at a laboratory.

There is additional training pressure for clinical scientists. In addition to informatics skills, the UK also requires trained clinical scientists to interpret genomic analysis. In order to meet demand, some laboratories have to recruit pre-registration scientists outside the STP, who require three years' training to be eligible for registration.

Glossary of terms

- **Aneuploidy** is a condition in which the number of chromosomes in the nucleus of a cell is not an exact multiple of the monoploid number of a particular species.
- An **assay** is an investigative (analytic) procedure for qualitatively assessing or quantitatively measuring the presence or amount or the functional activity of a target entity.
- **Bioinformatics** is an interdisciplinary field that develops methods and software tools for understanding biological data. Can be an umbrella tool for the body of biological studies that use computer programming as part of their methodology as well as specific analysis pipelines repeatedly used, particularly in the fields of genetics and genomics.
- **Bioinformatics pipelines** enable life scientists to effectively analyse biological data through automated multi-step processes constructed by individual programs and databases.
- **Biomarkers** is a word derived from "biological marker," which indicates a substance or physical event that can be measured and correlated with health, disease or drug treatment. One practical example of a macroscopic biomarker for cardiovascular disease is the measurement of blood pressure. At the molecular level, the expression of certain genes is used as biomarker to determine the appropriate therapy for cancer patients. Biomarkers are thus a key component of Personalized Healthcare approaches. Appropriate biomarkers are also essential to design clinical studies and to define their intended or expected outcome. Diagnostic methods aim at identifying and quantifying disease-relevant biomarkers.
- **ChIP-sequencing**, also known as ChIP-Seq or ChIP-seq, is a method used to analyse protein interactions with DNA.
- **Dideoxynucleotides** are chain-elongating inhibitors of DNA polymerase, used in the Sanger method for DNA sequencing.
- **DNA**, or deoxyribonucleic acid, a self-replicating material which is present in nearly all living organisms as the main constituent of chromosomes. It is the carrier of genetic information.
- A **DNA microarray** (also commonly known as DNA chip or biochip) is a collection of microscopic DNA spots attached to a solid surface, used to measure the expression levels of large numbers of genes simultaneously or to genotype multiple regions of a genome.
- **DNA polymerases** are enzymes that create DNA molecules by assembling nucleotides, the building blocks of DNA
- **DNA sequencing** is the process of determining the precise order of nucleotides within a DNA molecule. It includes any method or technology that is used to determine the order of the four bases – adenine, guanine, cytosine, and thymine – in a strand of DNA.
- **Epigenetics** is the study of heritable changes in gene regulation occurring without a change in the DNA sequence, including the study of DNA methylation arrays/sequencing, small RNA-mediated regulations and DNA/protein interactions.
- An **epigenome** consists of a record of the chemical changes to the DNA and histone proteins of an organism; these changes can be passed down to an organism's offspring.
- **FFPE:** formalin-fixed parrafin-embedded samples for genetic analyses.
- **Genomics** is a discipline in genetics that applies recombinant DNA. DNA sequencing methods and bioinformatics to sequence, assemble and analyse the function and structure of genomes (the complete set of DNA within a single cell of an organism).
- **Gene therapy** is the therapeutic delivery of nucleic acid polymers into a patient's cells as a drug to treat disease. The polymers are either expressed as proteins, interfere with protein expression, or possibly correct genetic mutations.

- A **genome browser** is a graphical interface for display of information from a biological database for genomic data. Genome browsers enable researchers to visualize and browse entire genomes (most have many complete genomes) with annotated data including gene prediction and structure, proteins, expression, regulation, variation, comparative analysis, etc..

- **Genotyping** is the process of determining differences in the genetic make-up of an individual by examining the individual's DNA sequence using biological assays and comparing to another individual's sequence – revealing the alleles an individual has inherited from their parents.

- **Karyotyping:** a test to examine chromosomes in a sample of cells, which can help identify genetic problems as the cause of a disorder or disease, through a visual map of the chromosones.

- **Metastasis,** or metastatic disease, is the spread of a cancer or disease from one organ or part to another not directly connected with it.

- **Next generation sequencing** applies to genome sequencing, genome resequencing, transcriptome profiling (RNA-Seq), DNA-protein interactions (ChIP-sequencing), and epigenome characterization.

- **Nucleotides** are organic molecules that serve as the monomers, or subunits, of nucleic acids like DNA and RNA.

- A **phenome** is the set of all phenotypes expressed by a cell, tissue, organ, organism or species.

- **Phenotype** is the physical appearance resulting from the inherited information. e.g. someone with blue eyes has the phenotype blue eyes.

- **QF-PCR:** a laboratory technique used to copy small sections of DNA in order to precisely quantify the amount of DNA present.

- **RNA,** or ribonucleic acid, helps carry out this blueprint's guidelines. Of the two, RNA is more versatile than DNA, capable of performing numerous, diverse tasks in an organism, but DNA is more stable and holds more complex information for longer periods of time.

- **Sanger sequencing** is a method of DNA sequencing based on the selective incorporation of chain-terminating dideoxynucleotides by DNA polymerase during in vitro DNA replication.

- The **transcriptome** is the set of all RNA molecules, including mRNA, rRNA, tRNA, and other non-coding RNA transcribed in one cell or a population of cells.

- **Transcriptome analysis** may involve characterization of all transcriptional activity (coding and non-coding), or a select subset of RNA transcripts within a given sample.

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Footnotes

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