

# BioIndustry Association response to the Science and Technology Committee's inquiry on commercial genomics

## May 2019



### Introduction

1. The BioIndustry Association (BIA) is the trade association for innovative life sciences in the UK. Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives.
2. Our members include:
  - Start-ups, biotechnology and innovative life science companies
  - Pharmaceutical and technological companies
  - Universities, research centres, tech transfer offices, incubators and accelerators
  - A wide range of life science service providers: investors, lawyers, IP consultants, and communications agencies
3. The BIA's members are responsible for over 90% of biotechnology-derived medicines currently in clinical development in the UK and are at the forefront of innovative scientific developments targeting areas of unmet medical need. This innovation leads to better outcomes for patients, to the development of the knowledge-based economy and to economic growth. Many of our members are small, pre-revenue companies operating at the translation interface between academia and commercialisation.
4. The BIA welcomes the opportunity to submit a response into the Committee's timely inquiry. The BIA represents a large proportion of the UK's thriving genomics SME community through our Genomics Advisory Committee.<sup>1</sup> The Committee works to ensure that the UK starts, scales and builds world leading genomic businesses. The Committee acts as a leadership platform for sharing and discussing issues of common concern between genomic businesses and provides expert advice to the BIA to collectively input to relevant policy discussions, especially with the UK Government.

### Summary

5. The strength of the UK's genomics sector is the result of the successful implementation of continuous industrial strategy.
6. Genomics England has a vital role in supporting the UK genomics sector and the completion of the 100,000 Genomes Project in December 2018 was an outstanding achievement.
7. The Government is right to continue to build on the UK's global competitive in genomics through the two Life Sciences Sector Deals and investment through the Industrial Strategy Challenge Fund. Innovate UK is an important funder of innovation in genomics in the UK.
8. The UK genomics sector is composed of SMEs, which are driving research and innovation and benefit from support from Innovate UK grants and fiscal R&D incentives, such as R&D tax credits. These provide

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<sup>1</sup> <https://www.bioindustry.org/bia-membership/advisory-committees/genomics-advisory-committee.html>

valuable financial support, particularly for start-ups, but more needs to be done to increase private investment in genomics to support scaling businesses.

9. Genomic data is incredibly valuable for understanding human biology and disease. Innovative companies need access to large data sets to generate accurate insights and develop new treatments.

## Recommendations

10. SMEs should be represented both throughout the development and in the outcome of the new National Genomic Healthcare Strategy.
11. The Government should appoint an SME representative to the National Genomics Board, or, if the Board is replaced by a new governance structure through the National Genomic Healthcare Strategy, appoint an SME representative to this new governance structure.
12. For Genomics England to fully succeed with its aim to kick-start and build a UK genomics industry, it is vital that Genomics England continues to work transparently and constructively with SMEs, including by adopting a flexible intellectual property (IP) model and enabling SMEs to provide input into its policies.
13. The Government and financial regulators are making positive changes to rules that govern pensions investments and offering encouragement to the pensions industry to increase private investment in innovative companies. This is welcome but will require a long-term, cross-government concerted effort to deliver meaningful change in investment behaviour.
14. The Government should increase Innovate UK's budget in the forthcoming Spending Review and commit to the continuation of the Biomedical Catalyst beyond 2020-21.
15. The Government should benchmark the R&D tax credits system to ensure it remains internationally competitive to attract investment, and its coverage of eligible costs remains relevant to R&D in the 21st century.

## The UK genomics sector and industrial strategy

### The strength of the sector

16. The UK is a global leader in genomics. The sector largely consists of innovative SMEs, which are underpinned by a world-leading science base with an unrivalled mix of world-leading research and medical institutions supported by charitable and government funding. The genomics sector is a key part of the wider UK biotech industry, which raised a record £2.2 billion of private investment in 2018, almost double the amount raised in the previous year.<sup>2</sup>
17. The strength of the UK's genomics sector is the result of the successful implementation of continuous industrial strategy, stretching from the establishment of the UK Biobank in 2006, through the formation of Genomics England, to the recent completion of the 100,000 Genomes Project. The current Government's modern Industrial Strategy is rightly continuing to build on these world-leading initiatives to boost the development of the UK genomics industry.

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<sup>2</sup> BIA and Informa (2019), "Confident capital: backing UK biotech": <https://www.bioindustry.org/resource-listing/confident-capital-backing-uk-biotech.html>

18. Genomics England has a vital role in supporting the UK genomics sector. Genomics England was established in 2012 to deliver the 100,000 Genomes Project. The completion of the project in December 2018 was an outstanding achievement. The project has been integral to ensuring that the NHS has the infrastructure and systems in place to deliver genomic medicine, with many thousands of diagnoses made which previously would not have been possible. Genomics England is facilitating new medical discoveries and innovation by giving researchers, NHS clinicians and trainees access to the data it has collected via its disease specific Genomics England Clinical Interpretation Partnerships (GeCIPs). Alongside this, Genomics England has made progress towards its aim of kick-starting and building a UK genomics industry by allowing industry to access the data that it holds, identifying opportunities for collaboration and creating demand for analysis and interpretation services. However, to fully succeed with this aim, it is vital that Genomics England continues to work transparently and constructively with SMEs, including by adopting a flexible intellectual property (IP) model and enabling SMEs to provide input into its policies.

### **The sector and the modern Industrial Strategy**

19. In the first Life Sciences Sector Deal, published in December 2017, the Government committed to investing £210 million through the Industrial Strategy Challenge Fund (ISCF) in data technologies that will support earlier diagnosis and the development of precision medicine.<sup>3</sup> Some of this investment was allocated to whole genome sequencing at the UK Biobank and to create a network of Digital Innovation Hubs. The Hubs will support the use of data for research and innovation and the implementation of the Hubs are led by Health Data Research UK (HDR UK).
20. In the second Life Sciences Sector Deal, published in December 2018, the Government continued to build on its previous investments by announcing the ‘Accelerating detection of disease’ challenge, which backed by up to £79 million from the ISCF.<sup>4</sup> The Government also committed to sequencing at least one million whole genomes within five years, including 500,000 whole genomes through the NHS. This is part of a wider Government ambition to sequence five million genomes within five years to help predict, diagnose and treat diseases.<sup>5</sup>
21. We welcome the Government’s support for the genomics sector through the Industrial Strategy and the Sector Deals. The Government’s support instils confidence in the sector and sends strong international signals that the UK continues to be the best location in the world to conduct genomics research and start and grow genomics companies.
22. We also welcome recent announcement of the forthcoming National Genomic Healthcare Strategy, which will ‘set out how the genomics community can work together to make the UK the global leader in genomic healthcare’.<sup>6</sup> As the UK has a vibrant SME genomics community and it is these SMEs that will drive the UK’s global competitiveness in the field, it is critical that the voice of these SMEs is heard both throughout the development and in the outcome of the Strategy.
23. The UK genomics landscape is currently overseen by the National Genomics Board, which brings together key civil servants, delivery partners, patient advocates and representatives from research

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<sup>3</sup> <https://www.gov.uk/government/publications/life-sciences-sector-deal/life-sciences-sector-deal>

<sup>4</sup> <https://www.gov.uk/government/publications/life-sciences-sector-deal/life-sciences-sector-deal-2-2018>

<sup>5</sup> DHSC (2018), “Matt Hancock announces ambition to map 5 million genomes”:

<https://www.gov.uk/government/news/matt-hancock-announces-ambition-to-map-5-million-genomes>

<sup>6</sup> DHSC (2019), “Health minister: NHS must lead the world in genomic healthcare”:

<https://www.gov.uk/government/news/health-minister-nhs-must-lead-the-world-in-genomic-healthcare>

organisations and industry.<sup>7</sup> However, the Board does not have an SME representative. This does not reflect the current UK genomics landscape, the majority of which consists of SMEs. The Government should therefore recognise the key role of SMEs in the genomics landscape by appointing an SME representative to the Board, or, if the Board is replaced by a new governance structure through the National Genomic Healthcare Strategy, appoint an SME representative to this new governance structure.

### **Government policy levers to support the sector**

24. Many of the SMEs in the UK genomics sector have ten or fewer employees and are at pre-revenue or spin-out stage. Genomics companies therefore struggle with many of the challenges common to start-ups and scale-ups across the biotech sector, most notably access to long-term finance. If the UK does not address this finance challenge, it will struggle to capture the full economic, health and commercial benefits of genomics. The story of Solexa illustrates this very well. Its revolutionary DNA sequencing technology was developed in Cambridge. However, the company did not have sufficient access to capital in the UK and was bought by the larger US company Illumina for \$600m in 2006. Solexa's technology fundamentally reduced the cost of DNA sequencing and underpinned the commercial success of Illumina, which today is valued at \$47 billion, up from \$1 billion in 2006.
25. The Patient Capital Review, which was carried out by the HM Treasury throughout 2017, sought to enable innovative firms' access to the finance that they need to scale up.<sup>8</sup> The Government made welcome commitments in the outcome of the Patient Capital Review, including an additional £6 billion to the British Business Bank to catalyse venture capital investment over the next ten years and a pledge to work with the pension fund industry to address the concerns of businesses that pension funds do not invest in UK early-stage companies. With £2.2 trillion under management,<sup>9</sup> UK pension funds are well placed to be significant patient investors in UK innovation. The BIA is currently engaging directly with pension fund managers and other institutional investors to promote the opportunity presented by the life sciences sector, including genomics companies. The Government and financial regulators are making positive changes to rules that govern pensions investments and offering encouragement to the pensions industry to increase investment in innovative companies. This is welcome but will require a long-term, cross-government concerted effort to deliver meaningful change in investment behaviour.
26. Innovate UK grant funding is a main finance source for genomics SMEs to grow, develop their technologies and attract new investors. In particular, the Biomedical Catalyst has been a successful funding stream. Grants to companies through the Biomedical Catalyst totalling £130m leveraged over £100m of private capital and enabled those companies to go on to raise over £1bn in further private finance.<sup>10</sup> As the Government and UK Research & Innovation (UKRI) work towards reaching 2.4% of GDP investment in R&D by 2027, it is important that Innovate UK's budget is increased in the forthcoming Spending Review and the Biomedical Catalyst is continued beyond 2020-21.
27. The success of the Industrial Strategy in enabling genomics SMEs to grow and leverage private investment also relies on fiscal R&D incentives. Fiscal R&D incentives utilise the tax system to promote

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<sup>7</sup> <https://www.gov.uk/government/groups/national-genomics-board>

<sup>8</sup> HM Treasury (2017), "Patient Capital Review": <https://www.gov.uk/government/publications/patient-capital-review>

<sup>9</sup> OECD (2018), "Pension funds in figures": <http://www.oecd.org/daf/fin/private-pensions/Pension-Funds-in-Figures2018.pdf>

<sup>10</sup> BIA (2015), "The Biomedical Catalyst: making the case to continue": <https://www.bioindustry.org/uploads/assets/uploaded/11a19dc6-ed68-422d-ac3a3a2dce128718.pdf>

R&D investment and commercialisation to benefit the UK socially and economically. They not only provide critical support to genomics SMEs throughout their life-spans, but also help to attract globally-mobile investment from overseas investors and international biopharmaceutical companies that would otherwise locate elsewhere.

28. Small and large R&D Tax Credit schemes are incredibly valuable to life sciences SMEs. Tax credits provide a minimal-bureaucracy system that rewards and amplifies companies' own investment in R&D, thus stimulating further investment. A 2015 government review of the regime estimated that for every pound spent on R&D tax credits, between £1.53 and £2.35 is additionally spent on R&D by UK companies.<sup>11</sup> The results are in line with previous international studies, which have found tax credits stimulate from around 0.3 to around 3 times their value in R&D investment.<sup>12</sup> As the precise research project that will lead to innovation can be difficult to predict, R&D tax credits complement public funding streams, such as the Biomedical Catalyst, by providing flexible funds for R&D that are not tied to a specific project. The Government should benchmark the R&D tax credits system to ensure it remains internationally competitive to attract investment, and its coverage of eligible costs remains relevant to R&D in the 21st century. Costs that are integral to genomics companies such as the purchase, storage and processing of datasets are not covered by the scheme currently.
29. Other fiscal R&D incentives that are beneficial to genomics companies include Entrepreneur's Relief and the Enterprise Management Incentive, venture capital schemes, and the Patent Box.

### The value of genomic data

30. Genomic data is incredibly valuable for understanding human biology and disease. For example, genomic data has enabled the development of more personalised therapies that can more effectively treat specific patients, potentially with fewer side-effects than their less-targeted counterparts. However, a single genome is only meaningful when compared to other genomes. Therefore, researchers and innovative companies need access to large data sets to generate accurate insights and develop new treatments.
31. Collecting, analysing and making sense of those large data-sets is a multi-disciplinary challenge. It requires data scientists, bioinformatics experts and engineers alongside biologists, chemists and clinicians. These experts are collaborating to enable, for instance, efficient, precise, cheaper and more convenient DNA sampling, sequencing, analysis, interpretation and application. They are building systems that combine genetic, epigenetic and other kinds of molecular data with clinical, behavioural and other kinds of information to help paint a more complete picture of human health and disease, and to help identify new drugs and diagnostics.

### A snapshot of UK companies driving excellence in genomics

32. In 2018, BIA published *Genomics Explained: A guide to genomics and UK excellence in the field*, which highlights the UK excellence in genomics along with several SME case studies.<sup>13</sup> The explainer is accompanied with a video which further explains the technologies that some UK genomics SMEs are

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<sup>11</sup> HMRC (2015), "Evaluation of Research and Development Tax Credit":

<https://www.gov.uk/government/publications/evaluation-of-research-and-development-tax-credit>

<sup>12</sup> Ibid.

<sup>13</sup> <https://www.bioindustry.org/uploads/assets/uploaded/367e0ae6-6fa4-47b1-aa80c77118ca0c83.pdf>

developing.<sup>14</sup> We have included some of the case studies below, which demonstrate the breadth and depth of the UK's innovative genomics SME community.

33. **Congenica.** Congenica's genome-analysis software filters raw genomic data and extensive clinical information to generate insights to help clinicians diagnose and treat patients with inherited diseases. Congenica's Sapiaientia platform is designed to provide genome sequencing, annotation, interpretation and customisable clinical reports, with the added flexibility of allowing genetic and relevant clinical data to be uploaded in a variety of formats. Using sophisticated data analysis tools Sapiaientia interprets the genetic and clinical "phenotype" information of the patient and also interrogates previous diagnosis or disease relationships seen at the population level to rapidly deduce the most accurate diagnosis for the individual patient. Validated as part of the UK 100,000 Genomes Project, Sapiaientia is being used by the NHS today to make important diagnosis and improve the lives of patients. The company is also partnering with clinical and research organisations across the world. In China, it is supporting whole-genome sequencing as part of the country's 100k Wellness Pioneer project, seeking to improve health through understanding the genomes and other molecular and clinical information gathered from 100,000 Chinese citizens.
34. **Eagle Genomics.** Eagle Genomics' smart data management platform is designed to help researchers turn genomics data into insights that can inform the development of new solutions across a range of industries. Eagle's platform curates, annotates and organises human genome data, as well as microbiomic data – from the genomes of micro-organisms in our gut or on our skin, for instance – highlighting connections and inter-dependencies within these data sources. The approach is accelerating research and R&D efficiency across areas including healthcare, cosmetics, food safety, biofuels and agriculture.
35. **Genomics plc.** Genomics plc uses the most powerful genomic engine in the world to find new drug targets for serious diseases, and to deliver precision health. The company's algorithms overcome the limitations of other methods, and are capable of working at an unprecedented scale of data to generate powerful insights about how any one of millions of genetic variants affects thousands of molecular, cellular, physiological and disease traits. In precision health, Genomics plc uses its engine to combine evidence of thousands of genetic variants relating to common diseases to identify individuals most at risk of serious diseases based on the DNA they have inherited. The company works with leading biotech and pharma companies, using its engine to turbo-charge their drug discovery processes. Genomics plc has offices in Oxford and Cambridge, UK.
36. **Global Gene Corp.** Global Gene Corp is building longitudinal genomic data sets from under-explored populations in India and South Asia. The genomics data company is working with over 50 partners worldwide to help democratise precision medicine, by ensuring that data is collected from less-studied patient populations such as those in South Asia. At the moment, 60% of the world's population accounts for only a tiny portion – less than 5% – of available genomics data. Yet certain diseases, such as cancer, may manifest differently in Indian and South-east Asian patients versus those in the US or Europe. Understanding those differences may ultimately lead to better treatments for patients everywhere. Global Gene Corp has R&D facilities at the Wellcome Genome Campus in Cambridge, UK and offices in Boston and Singapore.

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<sup>14</sup> <https://www.youtube.com/watch?v=MNmDn0W4yC4>

37. **Oxford Nanopore.** Oxford Nanopore’s range of real-time, low-cost DNA sequencing devices, from benchtop to pocket-sized, are opening up biological analyses to scientists across multiple disciplines, in multiple locations. Its tiniest sequencer, which weighs less than 100g and plugs into a laptop, has been used to answer biological questions in clinical research, on farms and in food production factories, and even on the International Space Station. The technology involves passing currents through biological nanopores – small holes made by special proteins – and measuring changes as molecules, like DNA or RNA, pass through or close to the nanopore. Oxford Nanopore’s technology is not only about size and convenience; it can also help make research more rapid and efficient. As a sample is analysed, data is streamed in real-time, meaning researchers can stop as soon as they have enough data to answer their question. Such rapid results mean that, for example in infectious diseases, pathogens and their drug resistance properties could be identified from their DNA in minutes or hours, rather than days or weeks.
38. **NewGene.** NewGene, in Newcastle, provides molecular diagnostic services to NHS hospitals and other healthcare providers, using high throughput genome sequencing and genetic profile analysis. These diagnostics help clinicians identify the most appropriate treatment for specific patients. The group, set up as a partnership between the Newcastle-upon-Tyne Hospitals NHS Foundation Trust and Newcastle University, also works with pharmaceutical companies and the NHS to validate novel biomarkers and to develop new diagnostic tests that can further guide treatment choices.
39. **Cambridge Cancer Genomics.** Cambridge Cancer Genomics is using artificial intelligence and smart genomics to develop new, smarter blood tests that can rapidly signal whether, and how well, a patient’s cancer treatment is working. Liquid biopsies test the blood for cancer cells or cancer cell DNA that may be circulating in the blood. Besides being relatively quick and simple, liquid biopsies could help pick up cancer at an earlier stage than other kinds of tests. They may one day be able to better predict the most appropriate therapy for patients before treatment has even started.
40. **Cambridge Epigenetix.** Cambridge Epigenetix is building diagnostics and therapies based on their understanding of the multiple epigenetic influences on disease. The epigenome is the set of chemicals and processes that make up our genetic “control panel”, regulating which genes are turned on or off, when, and for how long. Multiple external factors – our environment, lifestyle, diet, age, stress levels and more – can affect the structure of our epigenome, and with that, our risk of disease. Indeed, mutations within epigenetic regulators are among the most prevalent across all cancers. Cambridge Epigenetix’s range of technologies enable the identification of sensitive, disease-specific epigenetic markers from samples of blood and tissue. Such epigenetic markers may enable earlier detection of certain complex diseases like cancer. The company is developing diagnostics – including minimally-invasive liquid biopsies – for various important diseases and offers a biomarker discovery service.

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