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BIA
UK BioIndustry Association

UK Life Sciences Manifesto 2015-20

UK life science has benefited from the long-term vision of the last two governments. Building the infrastructure and developing an ecosystem where scientific innovation can flourish cannot be achieved over the life of a single parliament. Now is the time to build on this cross-party foundation.

"The UK life science sector is crucial for developing leading edge treatments for patients, and has a leading role in the UK economy. That is why the UK government has prioritised it through the development of the UK's 10 year Strategy for UK Life Sciences, launched by the Prime Minister in 2011 as part of our long term economic plan. The BIA plays an important role in representing the views of the sector, and I would encourage UK bioscience companies to work with it in order to ensure that government is aware of their views"

George Freeman MP, Minister for Life Sciences

"Labour is determined to see life sciences, as a vital sector to the UK economy, given the recognition, drive and priority it needs as part of a proper, co-ordinated industrial strategy. We established the Office for Life Sciences and put in place the Patent Box to attract and retain innovative research and manufacturing in this country. Britain has an economic advantage in Life Sciences, but other nations are steaming ahead. The recommendations in the BIA's manifesto chime with Labour's aim to build an economy for the long-term, with a highly-skilled workforce based upon bringing high value innovative research to market. Labour will work with industry to ensure that skills, access to finance, a supportive tax environment and a favourable innovative ecosystem are in place to make the UK an attractive place to undertake work in biotech"

Rt Hon Liam Byrne MP, Shadow Minister for Universities, Science and Skills, and Iain Wright MP, Shadow Minister for Industry

"The UK has a proud history as a world leader in the life sciences sector, but maintaining our prime position will require continued innovation, investment and strong government support. The BioIndustry Association has provided excellent advocacy for the bioscience industries across the country, and I look forward to it providing a powerful voice for the best in British science over the coming parliament"

Dr Julian Huppert MP, Parliamentary Office of Science and Technology (POST) Board member

The UK BioIndustry Association (BIA) together with United Life Sciences partners Bionow, BioPartner UK and One Nucleus, has engaged with bioscience companies large and small across the UK to voice their priorities. Member company contributions shape this document. Since joining United Life Sciences in March 2015, MediWales is also a key supporter of the aims of this manifesto.

Executive summary

The UK has a proven track record in life science, with one-eighth of the world's most popular prescription medicines being developed here. With this world leading science base, UK life science - referring in this document primarily to bioscience and biomedical technology - forms the basis of a bio-industry of great strategic importance to the future economy. UK life science companies continue to tackle long-term health challenges such as cancer and antimicrobial resistance, and in addition to this many companies are using bioscience to address a range of issues including environmental challenges and chemical production. This predominantly healthcare-focused manifesto also recognises the growing importance of these new applications.

Life science can transform health, create jobs and grow the economy. The sector is rightly a national priority for the UK, with the pharmaceutical, medical biotechnology and medical technology sectors together employing 165,000 people in around 4,500 companies and generating a turnover in 2012-13 of over £50 billion.

The purpose of this manifesto is to put the needs of UK life science, particularly bioscience, front and centre of political thinking between now and 2020. It is also a call to arms for the sector to continue its innovative work and communicate the success of UK bioscience to investors and the public.

Consistent focus and support must be maintained by successive governments in order to ensure the continued success of the sector:

- In 2013 the government named several **strategically important technologies** – including regenerative medicine and synthetic biology – with great potential to benefit the UK economy. The focus on these areas is welcome and must continue.
- A **supportive tax and finance environment** is essential for a successful life science sector. Current provisions including the Biomedical Catalyst, R&D Tax Credits and the Patent Box provide vital support to innovative companies and must be continued.
- The medical pipeline is increasingly comprised of biological medicines, which are expensive to develop and manufacture but can offer great benefits for patients. With limited healthcare budgets, ensuring patient access to the latest medical advances will require new **flexible routes for licensing, evaluation, uptake and reimbursement**. We will examine lessons to be learned from the European Medicines Agency's Adaptive Licencing pilot, and we maintain that for the Early Access to Medicines Scheme to fully benefit patients it must be centrally funded and reimbursed.

Introduction

The BIA is the trade association for innovative healthcare enterprises rooted in the UK's bioscience base. In our strategic partnership with other UK bioscience membership organisations - BioPartner UK, Bionow and One Nucleus - we look to represent and support the sector to deliver the best possible environment for growth and innovation. The sector continues to evolve, investing significantly in research and development activities, and excelling in translating research from the UK's world leading research base into commercial, innovative products.

There is great depth and breadth in UK biotechnology: from a strong and emerging regenerative medicine and cell therapy sector, to specialist biomanufacturing companies developing therapies for cancer treatment, to personalised treatments and new antimicrobials. Advances in technologies such as synthetic biology are impacting upon the development of new types of therapeutics and new production methods.

Bioscience describes any science that deals with the biological aspects of living organisms, and biotechnology is the technological application of such science to develop products or processes. UK bioscientists work with living organisms to drive the development and advanced manufacture of drug treatments and advanced therapies and diagnostic tests.

The terms bioscience and life science are often used interchangeably. The government's Strength and Opportunity 2013 report defines the UK life science industry as being comprised of the pharmaceutical, medical technology, medical biotechnology and industrial biotechnology sectors.

In this document we highlight key themes of importance to the bioscience sector:

Throughout the document we have highlighted '**policy recommendations**' (areas where policymakers can take action to improve the environment for UK life sciences; shown in purple boxes) and '**sector challenges**' (areas where we as a sector can take action on some key issues; shown in grey boxes). These recommendations and challenges have been developed by the BIA and partners in consultation with the sector.

UK LIFE SCIENCE

Medical biotech sector employs **26,900** people

4th largest biotech pipeline in the world and largest in Europe

Biotech products accounted for **71%** of revenue generated by the top 10 selling pharmaceutical products worldwide in 2012

Number of biologics in clinical trials grew 155% in 11 years to 907 in 2012

2001 +155% 2012

UK biotech leads **Europe** in the amount of total **capital raised** as well as the number of **financing rounds**

Worldwide biotech product sales grew **353%** between 2001 and 2012, reaching $163bn

The UK is home to **4** of the world's top 6 universities

and **6** of the top 50 universities for clinical, pre-clinical and health research

Medical research

charities invest over

£1 billion

into UK medical research per year

Case study: How effective policy making supports company growth and development of new medicines

Kymab, a biopharmaceutical company based in Cambridge, is discovering and developing fully human monoclonal antibody therapeutics and vaccines using a pioneering new technology. Founded in 2009, by mid-2014 Kymab has raised $70 million of investment equity from the Wellcome Trust Investment Division and The Bill and Melinda Gates Foundation. This investment enables the company to progress therapeutic development in areas of unmet medical need including immuno-oncology and auto-immune disorders. In addition to working on its own drug discovery programmes and with pharmaceutical companies, Kymab is also collaborating with the Gates Foundation on vaccine antigen discovery and development with an initial focus on malaria and HIV.

"Kymab has successfully grown since our founding to our position now where we are attracting substantial equity investment for the development of first-in-class therapeutics in areas of significant unmet medical need. And I'm delighted that's happened here in the UK. The strength of the bioscience sector here - with world leading universities, a wealth of pioneering life science companies and supportive government initiatives - makes the UK a great location for highly innovative R&D. To build on this foundation, joined-up and long-term policymaking is absolutely vital for patients and the economy alike"

Dr Christian Grøndahl, Chief Executive Officer, Kymab

Photo credit: Kymab

The UK medical biotechnology sector consists of over 1000 companies, one-third of which are discovering and developing new drugs, and generated £4.2 billion turnover in 2012-13.

The UK has the largest biotech pipeline in Europe, developing over 450 potential new products in 2012.

A supportive finance and tax environment

Finance and tax are fundamental to the success of the sector, determining not only whether a company can survive and conduct its research and development (R&D) activities but also whether companies can grow in the UK or must 'exit' via merger or acquisition. They also strongly influence whether the UK is an attractive destination for overseas companies to locate their activities.

Tax

The creation of a competitive fiscal and tax environment is key to enhancing the UK as a location for medical research and development. For many in the bioscience industry, the UK is in the top tier for fiscal incentives. There are already a number of supportive policies in place, the most important being R&D tax credits and the Patent Box. These policies have cross-party support and were created through the work of successive governments.

R&D tax credits continue to be the lifeblood of pre-revenue, research intensive bioscience companies. The R&D tax credit has been enhanced in successive Budgets for both large and small companies, and it is currently benefiting both.

CellCentric
unlocking epigenetics

"Quite simply, R&D tax credits meant we could do more R&D and keep that activity here in the UK. They helped support operations and attract foreign investment at a key stage in CellCentric's growth"

Dr Will West, Executive Chairman, CellCentric

vectura

"R&D tax credits are vital for pharmaceutical product development companies. They enable companies such as ours to re-invest in R&D and to progress projects further along the development pathway. Recent changes to the R&D tax credit scheme, such as the increase in the rate of R&D tax credit payable, have made the scheme even more valuable to companies such as Vectura"

Dr Chris Blackwell, Chief Executive Officer, Vectura

The **Patent Box** results in a lower rate of corporation tax (10%) for profits arising from UK-owned intellectual property, and is therefore influential in the strategic decisions of bioscience companies. The Patent Box was cited as one of the reasons why AstraZeneca announced in 2013 that they would relocate their global R&D centre and corporate headquarters to Cambridge, opting to remain in the UK instead of moving overseas.

Policy recommendation

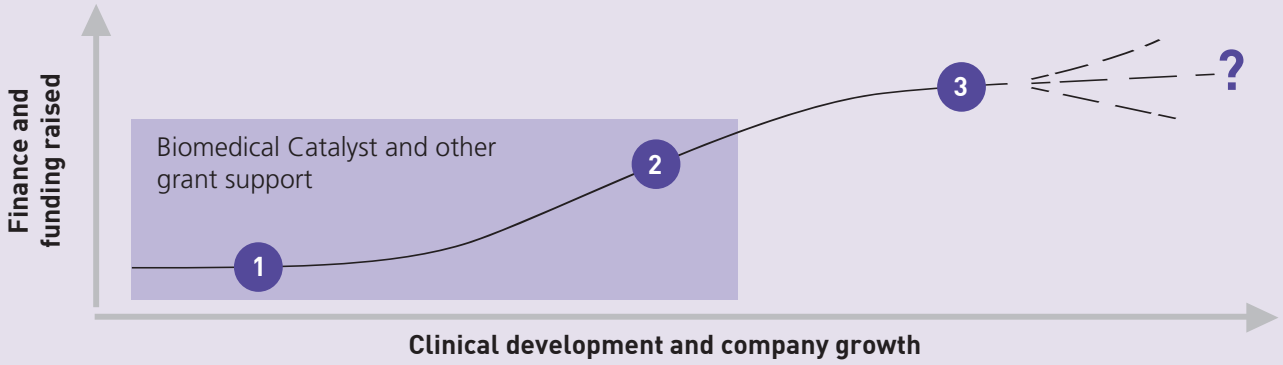
We call on all political parties to maintain and further enhance the fiscal and tax environment for research intensive companies. The R&D tax credits and Patent Box must be maintained and must remain globally competitive.

Finance

Difficulty accessing finance is a major hurdle for bioscience companies. The R&D of a successful new medicine takes on average 12 years at an average cost of £1.15 billion. Discovering and developing new treatments is difficult but the real challenges come when attempting to turn breakthroughs into safe, licensed products; companies must ensure they achieve regulatory compliance whilst also raising capital. Yet the majority of UK bioscience companies are pre-revenue small to medium-sized enterprises (SMEs). Access to finance and capital is essential for their success.

Policy should be aimed at attracting much-needed new investment into the sector. To ensure patients have access to the latest treatments, companies – particularly innovative SMEs – must have access to finance both at breakthrough and licensing stage. This section addresses the funding needs at the following key points along the bioscience funding ladder.

Key points on the funding ladder



1 Early funding landscape

Early stage funding for translation of academic research and university spin-outs is often found in the form of angel or venture capital investment, medical research charity investment and grant funding around the £100,000 to £1 million range.

This allows product development and validation. Government support through the tax framework is vital to incentivise and underpin private investment such as through the Enterprise Investment Scheme. The Biomedical Catalyst supports investment through feasibility grants.

2 Venture capital and growth finance

Following pre-clinical work a product will go into clinical trials. A company may continue to develop its product or platform technology, broaden its intellectual property (IP) base and start to engage in corporate partnering and other collaborations. Significant levels of funding are required here. Traditionally, venture capital investors would support this area, but this source of finance has been reduced since the financial crisis of 2008. Other forms of funding can be found, for example through early and late stage Biomedical Catalyst awards. However, more could be done.

3 The UK public markets

In order to grow independently, bioscience companies need access to larger amounts of capital that only the public markets can realistically provide. Since the financial crisis there has been a severely limited route to the public markets available, contrasted with the USA where 2013 proved to be a record year for bioscience listings. Part of the solution rests with the sector itself and increased dialogue and engagement with investors. However, all policymakers need to be aware of the funding bottleneck and it is important to ensure that the success of the Biomedical Catalyst in supporting early stage R&D is not undermined by an inability for companies to source later stage funding for those projects.

The early funding landscape

At the earliest funding stage, investment through **tax-advantaged investment schemes** such as the Enterprise Investment Scheme (EIS), Seed EIS (SEIS) and Venture Capital Trusts (VCTs) is vital. These funds should always be targeted towards encouraging innovation in the UK.

Policy recommendation

Government should maximise the potential of tax-advantaged investment schemes by ensuring they:

a) Are better aligned with areas of future growth and innovation - schemes such as the Enterprise Investment Scheme (EIS) and Venture Capital Trusts (VCTs) should be better targeted towards truly innovative research intensive companies, supporting higher risk activities

b) Bring increased investment and pass on the tax-advantage benefit to the general public: a tax-advantaged investment scheme supporting UK innovation should be accessible not only to 'sophisticated' high net worth investors but also to the general public via high-street retail.*

*For more information about the BIA's proposal for tax-advantaged **Citizens' Innovation Funds**, see http://bit.ly/biacifreport2

The Biomedical Catalyst

The government's Biomedical Catalyst scheme provides competitive funding that can support companies at early research stages and in bridging the so-called 'valley of death' for the translation of research. The scheme opened for applications on 30 April 2012 and by early 2014 had opened its seventh funding round, with more planned. It provides vital support for early stage companies, and its 'rolling' rounds ensure it always remains open for applications.

By June 2014 over 130 business-led projects around the UK had been supported with funding worth over £99 million, leveraging significant additional match-funding. A broad range of therapeutic areas had been funded including oncology, infection and neurology.

> *"... the Biomedical Catalyst has got a simple aim: getting the best ideas through proof of concept stage so we can get them into clinical development and get our entrepreneurs selling them around the world"*
>
> **David Cameron MP, UK Prime Minister, 2011**

Location of business-led Biomedical Catalyst awards (by number of awards)

For further information please read the BIA's Biomedical Catalyst report http://bit.ly/BIA_bmc

In a recent survey of BIA members over 90% stated that it is essential for the Biomedical Catalyst to continue.

"Our Biomedical Catalyst awards are making significant contributions to our research into antibacterial vaccines; this not only supports high risk product development by UK bioscience, but also promotes research in a field of significant public health need"

Dr Fiona Marston, Chief Executive Officer, Absynth Biologics

"Autifony Therapeutics was set up to focus on hearing disorders, but we believe that the ion channel mechanism we are targeting has important potential in other areas also. With our first (Early Stage) Biomedical Catalyst award, we were enabled to explore the mechanism's potential for use in schizophrenia, an area of great unmet need, in collaboration with the universities of Manchester and Newcastle, and to progress a different molecule through preclinical development.

We were then fortunate in securing a Late Stage award, which is allowing us to fund a Phase IIa clinical trial in the UK to test our lead molecule AUT00063 for treatment of tinnitus, an area where no satisfactory treatments exist. Our original investor funding would only have been sufficient for a Phase IIa trial in age related hearing loss, so the Biomedical Catalyst has played a vital role in progressing our products through development phases, and we urge the government to continue to fund it"

Dr Charles Large, Chief Executive Officer, Autifony Therapeutics

"The Biomedical Catalyst has had a positive impact on our business, and the UK bioscience sector as a whole. It has allowed us to continue our exciting research into treatments for Duchenne Muscular Dystrophy, and Summit looks forward to its continuation"

Glyn Edwards, MBE, Chief Executive Officer, Summit

summit plc

Policy recommendation

The Biomedical Catalyst must continue. Government should provide a commitment to year-on-year funding for the scheme that will provide certainty and predictability to UK businesses, supporting innovative companies and leveraging private finance into the UK. Government should also engage the bioscience industry in any evaluation or review of Innovate UK funding mechanisms.

Sector challenge

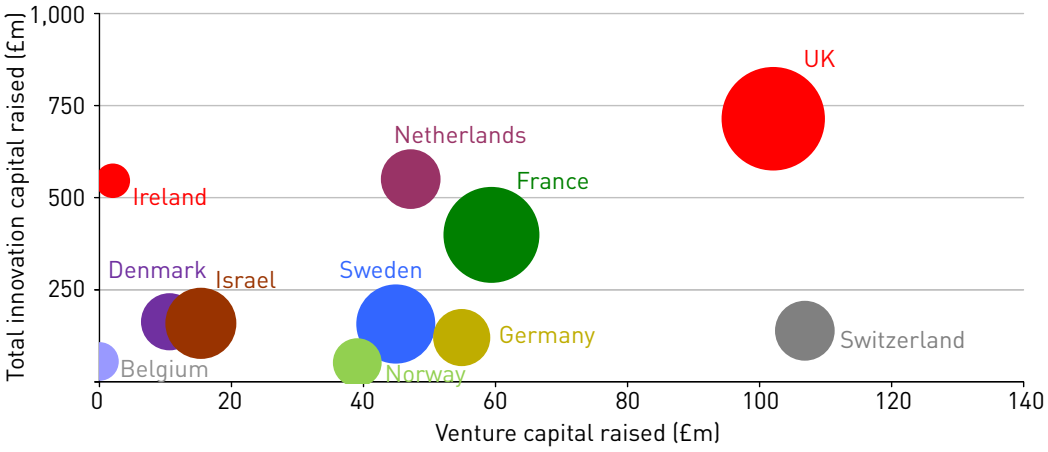
The Biomedical Catalyst is highly competitive. The sector should communicate to investors the value of succeeding to review stage, and should champion the value of the validation and expert scrutiny of the Biomedical Catalyst process.

Venture capital and growth finance

Beyond early stage research, companies require venture capital finance to continue to develop their technology – often up to and over £15 million for reaching phase II clinical trial results and growth capital for another £20 million to reach small phase III trial results. Schemes such as the Biomedical Catalyst can help companies to fund early stage research, but the funding required to take a promising product through phase II and phase III trials is far harder to access.

In the past, venture capital investors were fully able to support these stages of finance. However, since the economic downturn it is perceived this source of finance has remained flat or even dropped. To maintain a globally competitive bioscience ecosystem the UK should aspire to have as vibrant a funding community as the east or west coast of the USA.

Capital raised by leading European countries, January - June 2014



Source: Ernst & Young, Capital IQ, BioCentury and VentureSource
Notes: Size of bubbles shows number of financings per country.
Capital raised is illustrated by the centre of the bubble.
Innovation capital is the capital raised by companies with annual revenues of £365m.

The public markets

Case study: Financing company growth in the UK bioscience sector

Abzena's mission is to enable the development of better biopharmaceuticals, which includes therapeutic proteins, antibodies and antibody-drug conjugates for the treatment of a wide range of diseases including cancer, inflammatory and auto-immune disorders. Abzena was created as the group holding company and investor-focused brand for its two trading subsidiaries, Antitope and PolyTherics.

Having grown as a private company, with financing from institutional investors, venture capital funds, VCT and EIS investors, Abzena completed its Initial Public Offering (IPO) on the Alternative Investment Market (AIM) segment of the London Stock Exchange in July 2014, raising £20 million to enable the further growth of this leading business within the UK sector.

> *"At Abzena, we have built a business that provides a range of services and technologies for our partners that can enhance biopharmaceutical product profiles and reduce the risk of their candidates failing during development.*
>
> *We are proud of the UK heritage of our scientific roots and the close connections we have with UK academic institutions. The Abzena story highlights the value of a vibrant mutually supportive ecosystem of world-leading science, a dynamic investment environment for private investors and in the public markets, and the fiscal incentives to recognise and encourage the commercialisation of innovative solutions within the life sciences industry"*
>
> **Dr John Burt, Chief Executive Officer, Abzena**

Since the economic downturn there has been a limited route into the UK public markets, although the first half of 2014 has witnessed the definite reopening of the UK IPO market. However despite this uplift, the UK still lags when compared to the US which had a record year in 2013 for public market flotation in bioscience. The challenge for the sector remains in how to sell the value of their commercial innovation and the attractiveness of the UK market to investors. Without fully harnessing this potential, the value of earlier stage support such as funding through the Biomedical Catalyst risks being undermined.

Sector challenge

There is a role for UK companies to learn how best to communicate the value of their commercial innovation science and the UK market to investors, and to engage with various audiences.

Photo credit: Abzena

Supporting pre-clinical and clinical research

Clinical research is the point at which promising new medicines are tested in humans to establish safety, dosage and efficacy. Prior to that point, pre-clinical research includes proof-of-concept work and certain studies in animal models.

UK drug development is shaped by European and domestic regulation. These regulations are simultaneously a factor of the cost of UK drugs, and a guarantor of their global quality. Appropriate regulations for new therapy areas – and their evolution as the science develops – are key to the future of the sector.

The use of animals in research

Animal research is essential for the development of medicines. It is a legal obligation for researchers to ensure that promising new medicines are tested for safety and efficacy before they are tested in humans.

The BIA is a signatory of the **Concordat on Openness on the Use of Animals in Research**, an agreement supported by a range of organisations to commit to being open about the use of animals in research in the UK.

The UK has among the highest standards in the world for the welfare of animals used in research, including a commitment to the 3Rs - the reduction, replacement and refinement of animals used in research. Significant work is ongoing in this area. The BIA supports the aims of the Concordat, which will help the research community to communicate about the benefits, limitations and nature of animal research to ensure the public has the information they need to develop informed views on this topic.

Sector challenge

The BIA will make a continued pledge to be open about animal research and to improve awareness of the need for it in medical research. We will support our members to do the same, by signposting examples of good practice.

Policy recommendation

We call on government to vocally support the vital and legal role of animal research in medical development. Government must ensure the ongoing protection of staff, open and secure supply chains, and the intellectual property associated with animal research in the UK.

Clinical research infrastructure

The UK has an excellent and well-funded research infrastructure. It is vital that this is easily accessible to companies, particularly in the experimental medicine phase. This is where the UK has a real competitive advantage.

In 2012, government committed £800 million to the National Institute for Health Research over five years.

The National Institute for Health Research (NIHR) and its Office for Clinical Research Infrastructure (NOCRI) have an important role and have made progress over the last few years to open up infrastructure through initiatives such as the Translational Research Partnerships.

A long-term challenge has been the inability for companies to secure a single R&D approval to conduct clinical trials across multiple sites in England. This is particularly challenging for SMEs which lack the resources needed to complete the complex processes involved in obtaining multiple approvals.

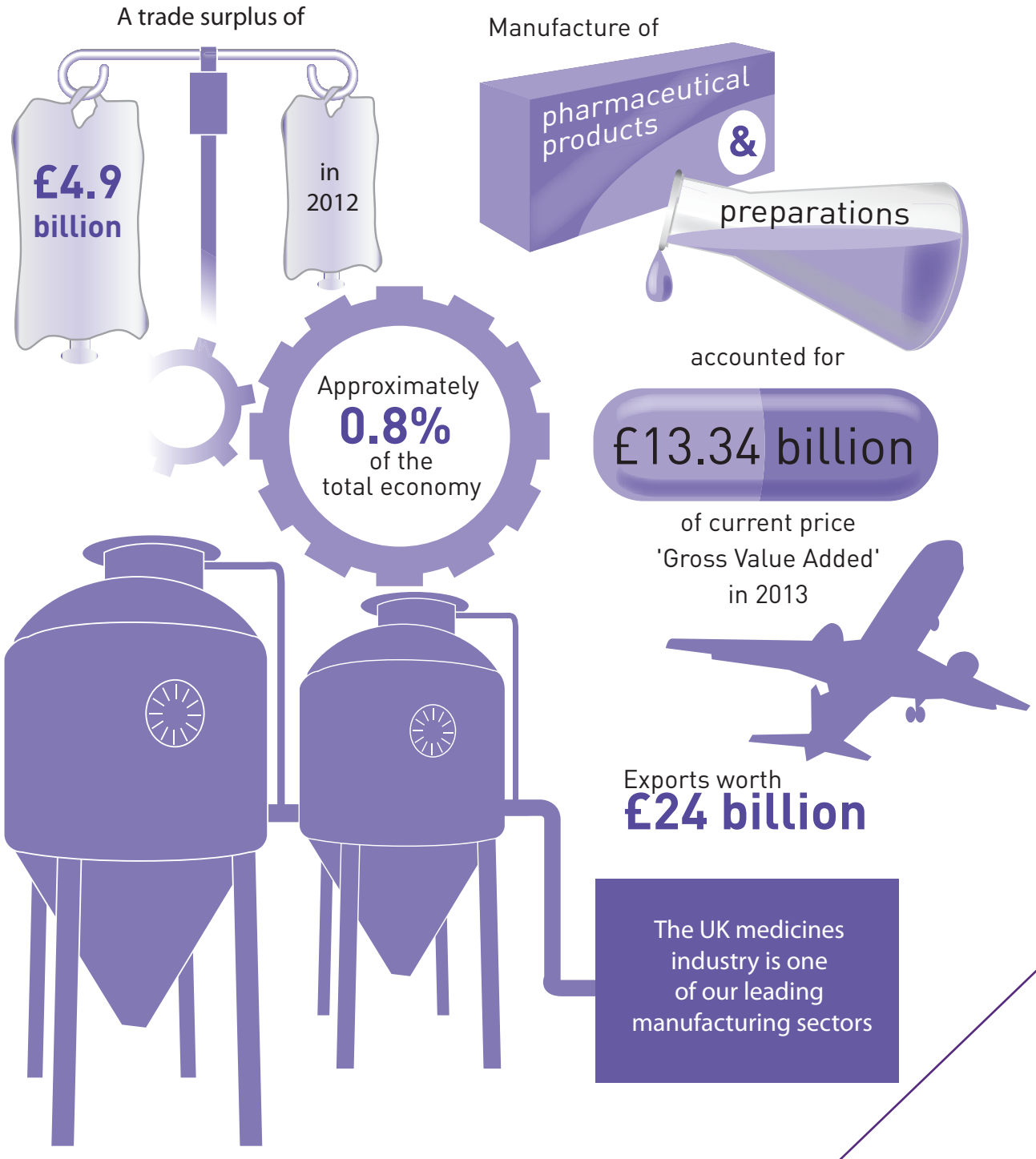
Policy recommendation

In March 2014, the Department of Health approved the Health Research Authority (HRA)'s plan to work with the Medicines and Healthcare products Regulatory Agency (MHRA) to deliver a single approval system for all health research studies in England. We welcome this move and urge the government to ensure its implementation.

Manufacturing

Medicines manufacturing is shifting away from the dominance of small molecule products to combinations of small molecule, biologic and cell and gene therapy treatments. Biologics already account for around 10 – 15% of the current pharmaceutical market and the sector is outperforming the market as a whole. Their manufacture requires hi-tech facilities, highly skilled staff, and resilient supply chains. Futhermore, the ability to affordably scale up production of a drug can be as important as the original discovery.

The UK medicines manufacturing industry



Case study: Manufacturing growth in the UK

In October 2013, **FUJIFILM Diosynth Biotechnologies** opened a new mammalian cell culture manufacturing facility in Billingham, Teeside. The multi-million pound facility, which includes industrial-scale bioreactors and is purpose-built to utilise mostly single-use manufacturing technologies, is the first of its kind in the UK and has the potential for rapid further expansion to meet customer demand.

Factors which influenced this advanced manufacturing investment in the UK included a good track record at the site, access and proximity to development expertise, and the UK's fiscal package.

Exciting scientific advances will allow industry to meet the challenges of evolving medicines manufacture, and the UK could be at the forefront of re-shoring this opportunity. It is vital that medicines manufacturing can continue to thrive in the UK – particularly advanced manufacturing, which is unlikely or more difficult to relocate once established.

Government support for UK medicines manufacturing

- ***£55 million funding for a Large Scale Cell Therapy Manufacturing Centre***
- ***£38 million for the National Biologics Manufacturing Centre in Darlington***
- ***Advanced Manufacturing Supply Chain Initiative (AMSCI): two successful AMSCI bids worth £30.7 million, led by Oxford BioMedica for a centre of excellence for gene-based therapies, and by GSK for facilities for continuous manufacturing***
- ***Announcement of a further round of AMSCI funding to the tune of £100 million***

We welcome key government announcements in the area. We are very encouraged by tangible progress made by the Ministerial Industry Strategy Group (MISG) and the **Medicines Manufacturing Industry Partnership (MMIP)**, now formalised in partnership with trade associations and the Knowledge Transfer Network. There is a role for the MHRA's Innovation Office to take the manufacture of drugs into account at an early stage in its dialogue with companies.

Policy recommendation

For the UK medicines manufacturing sector to remain competitive there must be a unified vision of the supporting infrastructure, skills and investment required. The government must ensure that UK regulators stay up to speed with developments in manufacturing technologies and regulate them appropriately.

Access to highly skilled employees such as biomanufacturing engineers is essential for the UK to retain advanced biological manufacturing - including for biologics, cell and gene therapies. This is particularly important if support is to be provided to companies with in-house manufacturing capabilities as well as the many specialist providers of manufacturing technology and services.

Companies generally find it difficult to source qualified persons (QPs) with the necessary skills to work in biological advanced manufacturing. Transitional QPs are helping to meet current demand, but once these QPs retire there will be significant need for succession planning from within. The requirement for trainee QPs to acquire a wide breadth of knowledge in areas they may come into little or no contact with throughout their career presents a further obstacle.

Policy recommendation

In order to meet the potential demand for advanced biologic medicines in the near future, the government should consider initiatives to incentivise the training of biological advanced manufacturing qualified persons (QPs).

Optimising access to medicines

While it is important that the UK has a supportive environment for bioscience companies, the ultimate aim is always for patients to have access to life-saving or life-enhancing new medicines.

Having a supportive home market (even if it represents only 3% of global sales) is important to UK SMEs. Uptake of new medicines is front of mind for global decision makers when considering where to invest. It is far harder for UK-based management to promote the UK in global boardrooms if access to new therapies is blocked in the UK.

For the UK to be an attractive location for research and development, companies need to know their medicinal products will reach UK patients.

There are a number of considerations around how a medicine reaches patients. The typical route to licensing involves conducting phased clinical trials and obtaining a marketing authorisation.
There are also routes exploring adaptive pathways.

Ultimately a major consideration is whether payors - especially the NHS in the UK - can afford to use the medicine. Biological medicines, especially advanced therapies like cell and gene therapies, have particularly high development and manufacture costs. But they may also provide healthcare benefits that ultimately save the NHS money down the line. There is a need for policymakers to consider short, versus long-term, trade-offs and to propose models for realistic reimbursement plans.

The Early Access to Medicines Scheme

We support the Early Access to Medicines Scheme (EAMS). It has the potential to bring promising medicines to patients faster. It can also help companies to demonstrate the potential of their products. It aims to give patients with life-threatening or seriously debilitating conditions access to new medicines prior to marketing authorisation.

The introduction of the Promising Innovative Medicines (PIM) designation, which the BIA recommended to government based on the breakthrough therapy designation in the USA, is particularly welcome. In order for this scheme to be a success, companies must participate.

At present the following financial considerations may deter companies from the EAMS proposal:

- The proposed £29,000 application fee at the scientific opinion stage
- There is no dedicated budget or money to pay for drugs commissioned through EAMS

Policy recommendation

For the Early Access to Medicines Scheme to benefit patients it needs to be centrally funded and reimbursed. The equivalent scheme in France since 1994, the Autorisations Temporaires d'Utilisation de cohorte (ATU de cohorte), is fully reimbursed and highly successful.

Sector challenge

The Early Access to Medicines Scheme is a great opportunity to demonstrate the need for a scheme which grants patients access to new promising medicines. It is up to the sector to utilise it and demonstrate its full value.

Case study: Alternative pathways to deliver medicines to patients

Cell Medica is a London-based cellular therapeutics company engaged in the development and manufacture of T cell immunotherapies for virus associated cancer and infections.

"Developing any medicine is a long and expensive process but developing advanced biologic medicines like cellular therapeutics involves additional challenges. In 2014 Cell Medica received Orphan Drug Designation in the EU for Cytovir ADV, a novel T cell immunotherapy for the treatment of adenovirus infections in patients following a bone marrow transplant. Alternative regulatory pathways like Orphan Drug Designation, the Early Access to Medicines Scheme and the Adaptive Licensing pilot help to support and accelerate approval of these new therapies to address medical needs for which no currently available drugs are effective"

Gregg Sando, Chief Executive Officer, Cell Medica

Adaptive Licensing

The UK faces a global challenge if it is to remain a launch country for innovative medicines and profit from the jobs and growth that go alongside this.

In March 2014, the European Medicines Agency (EMA) launched the Adaptive Licensing pilot project (now known as Adaptive Pathways) with the aim of providing patients in the EU, who have life-threatening or seriously debilitating conditions, timely access to new medicines which address unmet medical needs. The pilot project could potentially allow patients access to medicines that otherwise would only be accessible within a clinical trial. This pilot differs from the EAMS because it is an alternative route to licensing, as opposed to earlier patient access to unlicensed medicines.

This pilot project is a positive step towards more flexible licensing, and will lead to better patient access to innovative medicines in areas of unmet need. The BIA will continue to engage with members to assess the success of the pilot.

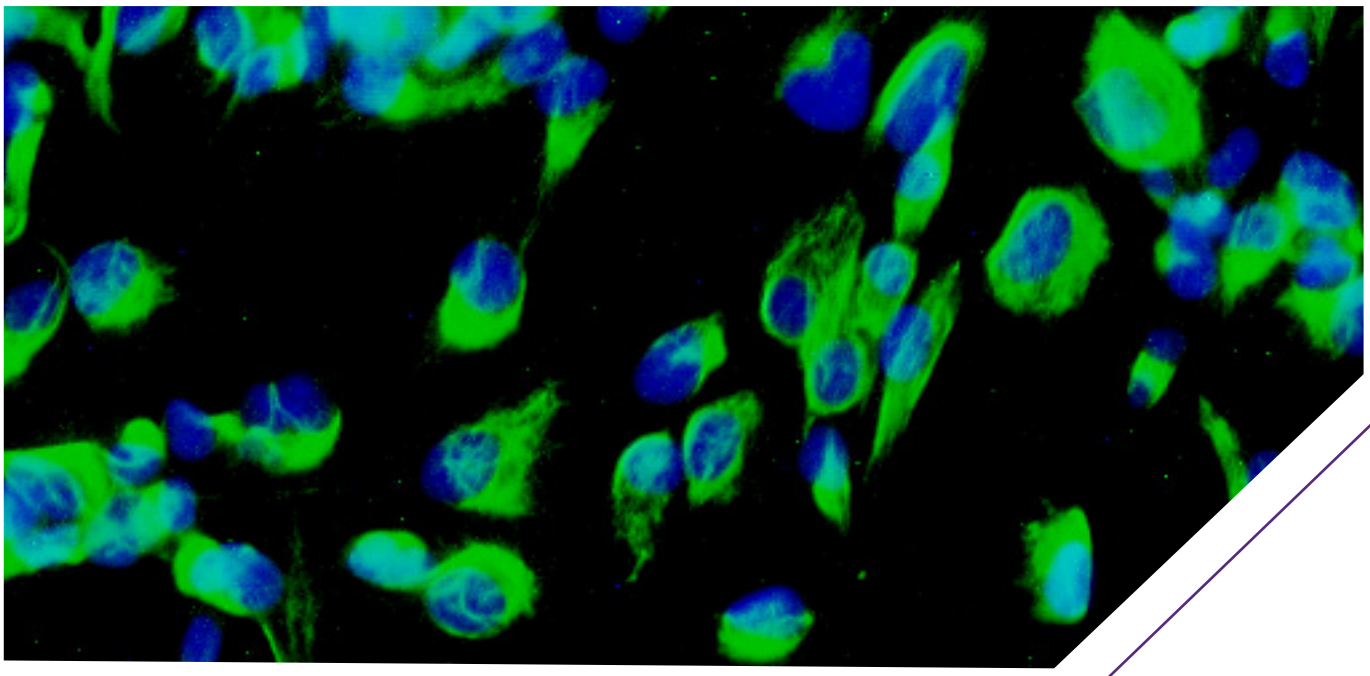


Photo credit: ReNeuron

Evaluation: pricing, reimbursement and market access

Challenges in the evaluation of medicines apply to overlapping themes: rare diseases, the advanced therapies which often provide the treatments for them, and the move towards stratified or personalised medicine.

Rare diseases

Being rare is increasingly common. The research and development of new highly specialised treatments for rare and very-rare diseases is vitally important for the patients who suffer from these conditions. It is also expensive, and at the same time the NHS budget is under increasing pressure. Budget holders are rightly concerned about being able to ensure patient access to these treatments.

The formation of the Advisory Group for National Specialised Services (AGNSS) in 2010 brought together clinical and financial decision-making for rare disease treatments into one group, designed to assess high-cost, low-volume drugs. The creation of NHS England saw assessment of rare disease drugs (orphan medicines) moved over to NICE's Highly Specialised Technology (HST) programme.

The nature of the evidence base for treatments for rare and very rare diseases is very different to that of drugs for common conditions; small patient pools for clinical trials can affect the quality of data generated. There is a need for a holistic approach to their evaluation. Orphan treatments for very rare diseases have relatively high prices because the costs of development have to be recouped from a smaller treatment population.

Policy recommendation

There are unique characteristics and challenges involved with evaluating medicines for very rare conditions. In line with the political support demonstrated via independent research in the BIA's 'Very rare diseases, complex issues' report (http://bia.me/VeryRareDiseases), government should establish a separate evaluation framework for orphan medicines for very rare diseases.

Personalised medicine

Personalised medicine (also called stratified, or precision medicine) is a medical approach which is tailored to the patient or a group of patients, and ensures they receive the most suitable treatment.

Personalised medicine is no longer a hope for the future, but a realistic medical innovation which can be used today. Yet there is still a lot to do to make sure patients fully benefit.

We look forward to gaining a better understanding of the plans for the Precision Medicine Catapult.

Case study: Challenges in evaluation

Kalydeco is a personalised medicine developed by **Vertex** for a very rare genetic subset of a more common disease, cystic fibrosis. In 2012 neither NICE nor the AGNSS considered appraising this new medicine.

In August 2012 the North of England Specialised Commissioning Group (the national commissioning lead for cystic fibrosis) commissioned a clinical and cost-effectiveness evaluation of Kalydeco on behalf of all Specialised Commissioning Groups in England.

In December 2012, NHS England's Clinical Priorities Advisory Group (CPAG) accepted Kalydeco's clinical-effectiveness and announced that Kalydeco would be provided to all clinically appropriate patients from January 2013.

NICE and NHS England should ensure that the process followed to appraise Kalydeco informs the Highly Specialised Technology programme and the Rare Diseases Advisory Group's work so future medicines for very rare diseases can be robustly appraised within a similar time frame.

Support for strategically important biotechnologies

In 2013 the government named 'eight great technologies' – strategically important technology areas with great potential to benefit the UK economy. The focus on these areas has been welcome and should be maintained. They include regenerative medicine and synthetic biology, both of which are considered here.

Regenerative medicine and cell therapy

Regenerative medicine and cell therapies have enormous potential to treat and cure diseases, offering particular hope for the future treatment of long-term conditions. Yet there are still challenges to address in the regulation, market access, pricing and reimbursement of these medicines.

The government has significantly supported the regenerative medicine sector in the UK. The Research Councils and Innovate UK have established a UK Regenerative Medicine Platform, and government has established and set up the Regenerative Medicine Expert Group to establish a pathway for delivery in the NHS. The Cell Therapy Catapult is highlighted internationally as a centre of excellence and a valuable component of the UK's regenerative medicine landscape, having already signed a number of collaborative agreements with universities and industry. In the 2014 Budget, government announced £55 million for a new Large Scale Cell Therapy Manufacturing Centre – a welcome signal that policymakers are considering a whole pipeline approach.

'Regenerative medicine' is focused on the regeneration of tissues and organs using all the different therapeutic platform technologies available including small molecule drugs, biologics, medical devices and cells.

'Cell therapy' uses living cells as treatments aimed at a wide range of medical indications including cancer and immune diseases as well as regeneration.

To build on these existing achievements, policymakers must sustain this focus on supporting the UK's regenerative medicine sector while the infrastructure and the product pipeline become established.

Case study: UK strength and support in regenerative medicine

Stem cell therapy company **ReNeuron** is developing cell-based therapies for the treatment of significant disease conditions including treatments for patients left disabled by stroke, for critical limb ischaemia and for blindness-causing diseases of the retina.

"The UK has a truly supportive environment for regenerative medicine. ReNeuron has received significant sums through the government's Biomedical Catalyst and dedicated Regenerative Medicine grant calls to support clinical development. We established the first commercial link with the Cell Therapy Catapult, and in July 2013 we completed a £33 million fundraising with support from the Welsh government to continue development and build a new manufacturing facility near Cardiff.

It's now vital that the UK maintains its competitive edge by ensuring that our framework for regulation and reimbursement of advanced therapies is fit for purpose"

Michael Hunt, Chief Financial Officer, ReNeuron

Policy recommendation

The UK government should examine examples of best practice in regulation of regenerative medicines and move quickly to ensure that UK regulation and reimbursement is streamlined and globally competitive.

Policy recommendation

The government should respond promptly to recommendations from the report by the Regenerative Medicine Expert Group addressing issues around the UK regenerative medicine landscape.

Policy recommendation

The government should recognise the unique challenges of developing and commercialising regenerative medicine and show support by continuing to fund schemes such as the dedicated Regenerative Medicine funding competition from Innovate UK.

These cutting edge treatments - which often target rare or very rare diseases - pose specific challenges for regulation and reimbursement that are also discussed in the previous section; it is challenging to set a fair price for treatments that are expensive to develop and produce but will lead to ongoing savings for the healthcare system.

Policy recommendation

Health technology assessment processes must be evaluated in order to ensure that patients can have full access to cutting edge treatments in regenerative medicine and cell therapy. The government should examine methods such as: post-launch data collation activities (e.g. registries); risk sharing agreements between the industry and the NHS; and mechanisms for SMEs to access NICE advice in a cost-effective manner.

Sector challenge

The sector must engage in raising public, patient and NHS workforce awareness of these regenerative medicines and their potential benefits for patients.

Photo credit: ReNeuron

Building on the successful work of sector-specific knowledge transfer communities, the not-for-profit company Knowledge Transfer Network Limited (KTN Ltd) was set up by Innovate UK to stimulate innovation and improve collaboration in areas including biopharmaceuticals, synthetic biology, regenerative medicine and manufacturing, amongst others.

Synthetic biology: New tools and approaches in biotechnology

The practical application of synthetic biology has only been possible in recent years, yet it could help to tackle major global challenges across many sectors. Synthetic biology's contribution to the bio-economy and the wider economy is predicted to grow increasingly in the short and long-term.

The UK was amongst the first to recognise and respond to the opportunities raised by synthetic biology, by leading the way with publicly funded studies which the sector is now being built upon.

> *"Synthetic biology is the design and engineering of biologically based parts, novel devices and systems as well as the redesign of existing, natural biological systems. It has the potential to deliver important new applications and improve existing industrial processes – resulting in economic growth and job creation"*
>
> **A Synthetic Biology Roadmap, Research Councils UK**

Multidisciplinary expertise is already enabling the UK to make significant contributions to international research programmes and respond to global developments. Synthetic biology is solving problems in areas including the following:

- Medicines and healthcare
- Fine and speciality chemicals
- Energy
- The environment
- Food and agriculture

Case study: New approaches to solving healthcare problems

Keele-based company **Prokarium** is using a synthetic biology platform, Vaxonella, to make vaccines more accessible to travellers and people living in rural and resource-poor areas.

Oxfordshire-based **Oxitec** uses advanced genetics to control insect pests in an environmentally sustainable way. In all field trials in urban environments Oxitec have demonstrated over 90% reduction in target mosquito populations.

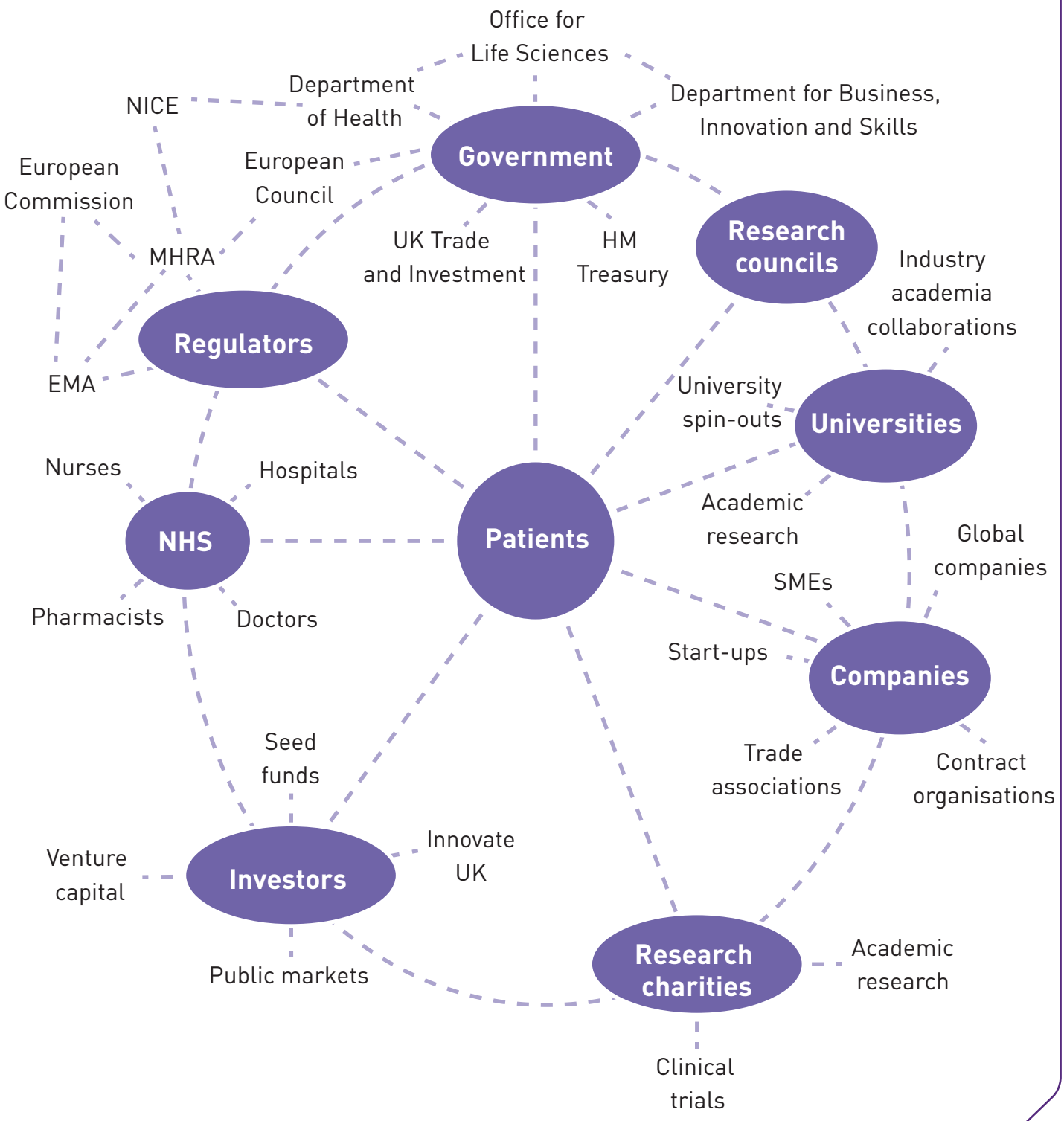
Building the bioscience ecosystem

The bioscience industry – which includes organisations ranging from spin-outs to multinational biopharmaceutical companies – forms part of a wider ecosystem which includes universities, hospitals, medical research charities, patient groups, learned societies, knowledge transfer networks, venture and corporate-venture capital providers, suppliers, consultants and service providers. These organisations interact with and benefit from one another.

A skilled workforce is crucial to the system, and IP is its life-blood; these important parts of the ecosystem flow through universities, SMEs and larger organisations to sustain a healthy sector.

Collaborations between industry and medical research charities are increasingly recognised as a beneficial relationship, bringing the patient perspective to companies and enabling patients to access clinical trials or to stay informed about R&D, and even allowing vital funds to be channelled into clinical research.

An evolving bioscience ecosystem - a snapshot



Policy recommendation

The UK bioscience ecosystem is built on a world-class academic science base. It is vital that government recognises the interconnected nature of the ecosystem and that the UK continues to fund our excellent academic community to maintain our global leadership.

Skills

The UK has an enviable science base with four of the world's top six universities and access to world-leading research. A highly skilled workforce is key to maintaining a world-class science base, so attracting and maintaining talent must remain a priority.

Policy recommendation

Tier 1 science visas should be available for industry as well as academic scientists. The BIA is keen to be the industrial partner of the Royal Society to administer this.

Through Cogent, the science skills sector council, industry partners are rolling out the **Science Industry Partnership (SIP)**, an employer-led raft of programmes for science skills training. The SIP is funded by over £65 million of public and private investment involving 100 employers. An important aspect of the SIP will be a workforce development stream, including a voucher scheme for SMEs which could cover up to 50% of their training costs.

Engagement with industry is essential for guaranteeing the validity of workforce schemes. The BIA is supportive of initiatives such as:

- Training through industrial placements
- Apprenticeships and trainee schemes
- Ongoing skills development opportunities for the existing bioscience workforce

Sector challenge

Companies must make use of the Science Industry Partnership to shape the future of skills training within the sector.

Technology transfer

The importance of a thriving academic science base to the continued strength and success of the UK life sciences industry cannot be underestimated. There are many examples of world leading medical products and technologies that have their origins in UK academic institutions. Ensuring that the technology transfer environment remains fit for purpose is important to ensure UK research can be effectively translated into commercial products in the UK.

There is a need for improvement in this area. Engagement with the BIA membership shows a desire from companies to see better alignment of incentives between SMEs and universities. For example, the technology transfer experience for SMEs can vary significantly between the academic institutions that they engage with.

Government initiatives such as Knowledge Transfer Partnerships and the Catapult Centres demonstrate a commitment to driving forward the translation and commercialisation of UK research.

Many BIA members have expressed a view that IP clearing houses (e.g. the sharing of university assets on an easily navigable online platform / directory) might offer a way forward. Some universities are already collaborating on such projects. This may make better use of finite resources and remove unnecessary competitive barriers.

Policy recommendation

The UK needs to improve the current 'tech transfer' operational model to ensure that intellectual property generated in academia is commercialised to its fullest potential.

Case study: Industry-academia collaboration

Critical Pharmaceuticals established a successful collaboration with the University of Nottingham and Nottingham University Hospitals NHS Trust to start the first phase I clinical trial in healthy post-menopausal women of a nanotechnology-enabled product for the treatment of osteoporosis. The project is using Critical Pharmaceuticals' CriticalSorb nasal drug delivery technology alongside the internationally-recognised medical imaging expertise of the University of Nottingham.

CRITICAL PHARMACEUTICALS

Intellectual property (IP)

Robust and enforceable IP rights are a fundamental pillar of the life science community. Research and development of a medicine is costly and often risky. Obtaining a patent, which provides market monopoly for a limited period, is necessary for justifying this level of risk to investors. This is especially true for pre-revenue SMEs. A predictable, robust and enforceable IP regime therefore supports companies' ability to attract finance.

The UK is well regarded for the quality, efficiency, and reputation of its IP framework. This is an important selling point when it comes to promoting the UK as a centre for life science.

Bolar provisions allow manufacturers and developers of pharmaceutical products to carry out clinical trials without risking infringement of third party patent rights. The government has made welcome changes to the research and Bolar provisions (EC Directives 2001/82/EC) in the UK, bringing us in line with best practice in the USA and Germany.

As we head into a new era of personalised medicines, to ensure a fair return whilst keeping products affordable, policymakers will also need to consider whether the current IP system will remain appropriate.

The introduction of a Unified Patent Court (UPC) represents one of the biggest changes to the European IP framework. There is a need to:

- Establish whether the system is fit for purpose
- Better educate the sector about the upcoming changes and how it will affect their patenting strategies
- Ensure the new system is affordable and accessible for companies.

The BIA is pleased to see the UPC's appeals division with responsibility for life science is to be based in London, recognising the UK as a global leader in this field.

Policy recommendation

Government should closely monitor implementation of the Unified Patent Court to ensure it delivers a cost effective, reliable and predictable regime for the enforcement of patents.

Medical research charities

Collaboration between medical research charities and the bioscience industry can deliver significant benefits for patients, wider society and the UK economy. We boast a world-leading cluster of expertise and companies for charities to partner with, and the UK is fortunate to have the most generous public in Europe when it comes to medical research donations.

To achieve the shared objectives of research charities and the bioscience sector, government support is needed to enable secure and stable funding for research to develop promising ideas, a flexible regulatory and licensing framework that promotes innovation, and a healthcare system that adopts proven innovations that benefit patients.

Sector challenge

The BIA will work with the Association of Medical Research Charities and with charities directly to encourage more effective collaboration between industry (particularly small-to medium-sized enterprises) and medical research charities.

Global, European and regional perspectives

The global picture for bioscience and medical research is evolving. Population demographics are changing – the UK's is ageing rapidly – and medical research must reflect this. When deciding where to invest and which markets upon which to focus, companies must consider the picture at global, European and local levels.

Global

Antimicrobial resistance

The importance of tackling antimicrobial resistance (AMR) has been well articulated by the Chief Medical Officer Professor Dame Sally C Davies, and the bioscience sector welcomed the Prime Minister's July 2014 announcement of an independent review by economist Jim O'Neill into the incentives in place to encourage the development of new antibiotics.

Modern medical practice relies on the widespread availability of effective antimicrobials to prevent and treat infections in humans and animals. The rapid development of resistance to antibiotics is of huge concern. Continued growth in the number of hard to treat infections will make it increasingly difficult to control infection in a range of routine medical care settings.

Increased resistance means that we must use antibiotics as infrequently as possible, which means the commercial incentive to invest in antibiotic development is small. The UK government is taking a leading role on tackling the threat of AMR. The next step should be to drive new incentives and funding models, which will be crucial for encouraging the development of these vital drugs.

Redx Pharma

"The threat posed by AMR is a complex one with issues around dry pipelines, a broken economic model, animal health use and a challenging regulatory environment to name a few. Whilst Redx is working hard to develop new therapeutics, the challenge of AMR can only truly be addressed through an integrated approach tackling all facets of the problem. The UK is uniquely placed to establish a centre of excellence to develop a comprehensive response to this critical threat"

Dr Neil Murray, Chief Executive Officer, Redx Pharma

Policy recommendation

The UK government must ensure that tackling antimicrobial resistance remains a global priority and should speedily adopt recommendations made in Jim O'Neill's review of the R&D incentivisation, economics and usage of antimicrobials.

Europe

The European Union (EU) legal framework for medicinal products is intended to promote the functioning of the internal market. To guarantee the highest possible level of public health protection and secure the availability of medicines to UK and EU patients, all medicinal products must be authorised by the competent authorities. In addition, the system is supported by a regulatory agency in charge of providing the EU institutions with scientific advice on medicinal products - the European Medicines Agency (EMA) based in London.

A lot has been achieved since the first European Pharmaceutical Directive in 1965, including the development of rigorous safety regulations and approval mechanisms, incentives for innovation and licensing flexibilities for faster approval of medicines.

Europe is the single biggest global market, and access to this market is a key reason for global biopharmaceutical companies deciding to establish their European HQ in the UK and invest in R&D activities. It is vital that the UK remains engaged in the EU and takes a leading role in shaping legislative and regulatory policy developments affecting the life sciences sector. We support the following changes at a European policy level, in order to ensure patients can access the medicines they need.

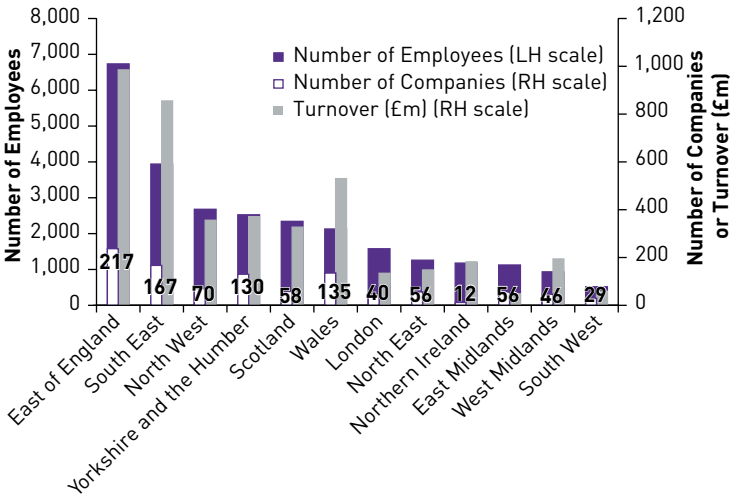
Policy recommendation

If there is an in/out referendum on UK membership of the European Union, the UK government should set out a plan of the expected disruption to UK life science businesses. In particular this should include how it would expect to handle the European Medicines Agency and Unified Patent Court leaving London, how medicines would be approved and regulated, and the likely impact on investment.

Policy recommendation

The EU clinical trials portal and database must be developed and fully functional by mid- 2016, through engagement with the European Medicines Agency.

UK regions



Geographical distribution of medical biotechnology companies.

Image sources: Strength and Opportunity report 2013

The UK is a thriving bioscience cluster in its own right. Although activity is concentrated in the South and East of England, there are significant concentrations in Scotland, Wales and the North West of England. It is therefore important that regional policy supports the local bioscience ecosystem which allows innovation to thrive.

When planning for a bio-economy, infrastructure, transport and housing must all be considered. We welcome the establishment of City Deals, which empower local authorities to promote local economic growth independently. In particular, our sector has worked successfully with Local Enterprise Partnerships (LEPs) to determine growth priorities and increase job creation across the country. Economic growth beyond the boundaries of LEPs should also be encouraged by government.

Policy recommendation

Local, regional and national planning should enable the bio-economy. All planning decisions should be carefully considered, so as to maximise the economic benefit of the UK bioscience industry.

Appendix

Engagement process

This manifesto reflects the views of the BIA, Bionow, BioPartner UK and One Nucleus memberships, following a lengthy consultation process.

Over a 12 month period there have been opportunities for member companies to share their views at numerous events across the country. During the drafting of the manifesto, detailed input was received from all eight of the BIA's expert advisory committees. The BIA also received emails, messages and phone calls from members keen to contribute, and significant engagement from the sector in response to policy questions posed via direct mailings and social media.

Locations of manifesto engagement processes

The BIA, Bionow, BioPartner UK and One Nucleus would like to thank all our members for sharing their views and experiences, which have enabled us to develop this UK Life Sciences Manifesto 2015-20 on behalf of the sector. Additionally we would like to thank the BIA's advisory committees and other sector stakeholders for their input and help with the reviewing process.

Glossary of abbreviations

AGNSS	Advisory Group for National Specialised Services
AIM	Alternative Investment Market
AMR	Antimicrobial resistance
AMSCI	Advanced Manufacturing Supply Chain Initiative
BMC	Biomedical Catalyst
CPAG	Clinical Priorities Advisory Group
EAMS	Early Access to Medicines Scheme
EIS	Enterprise Investment Scheme
EMA	European Medicines Agency
HRA	Health Research Authority
HST	Highly Specialised Technology
IPO	Initial Public Offering
LEPs	Local Enterprise Partnerships
MHRA	Medicines and Healthcare products Regulatory Agency
MISG	Ministerial Industry Strategy Group
MMIP	Medicines Manufacturing Industry Partnership
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NOCRI	NIHR Office for Clinical Research Infrastructure
PIM	Promising Innovative Medicine
POST	Parliamentary Office of Science and Technology
QPs	Qualified Persons
SEIS	Seed EIS
SIP	Science Industry Partnership
SMEs	Small to Medium-sized Enterprises
VCTs	Venture Capital Trusts

Referenced sources and useful links

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16. AMRC website, research expenditure data http://bit.ly/1CmTdCD
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18. Office of National Statistics, pharmaceutical industry information http://bit.ly/1oiPPAF

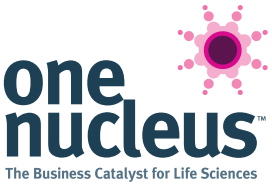
Summary of policy recommendations

A supportive finance and tax environment	We call on all political parties to maintain and further enhance the fiscal and tax environment for research intensive companies. The R&D tax credits and Patent Box must be maintained and must remain globally competitive.
	Government should maximise the potential of tax-advantaged investment schemes by ensuring they: a) Are better aligned with areas of future growth and innovation: schemes such as the Enterprise Investment Scheme (EIS) and Venture Capital Trusts (VCTs) should be better targeted towards truly innovative research intensive companies, supporting higher risk activities; b) Bring increased investment and pass on the tax-advantage benefit to the general public: a tax-advantaged investment scheme supporting UK innovation should be accessible not only to 'sophisticated' high net worth investors but also to the general public via high-street retail.
	The Biomedical Catalyst must continue. Government should provide a commitment to year-on-year funding for the scheme that will provide certainty and predictability to UK businesses, supporting innovative companies and leveraging private finance into the UK. Government should also engage the bioscience industry in any evaluation or review of Innovate UK funding mechanisms.
Pre-clinical and clinical research	We call on government to vocally support the vital and legal role of animal research in medical development. Government must ensure the ongoing protection of staff, open and secure supply chains, and the intellectual property associated with animal research in the UK.
	In March 2014, the Department of Health approved the Health Research Authority (HRA)'s plan to work with the Medicines and Healthcare products Regulatory Agency (MHRA) to deliver a single approval system for all health research studies in England. We welcome this move and urge the government to ensure its implementation.
Manufacturing	For the UK medicines manufacturing sector to remain competitive there must be a unified vision of the supporting infrastructure, skills and investment required. The government must ensure that UK regulators stay up to speed with developments in manufacturing technologies and regulate them appropriately.
	In order to meet the potential demand for advanced biologic medicines in the near future, the government should consider initiatives to incentivise the training of biological advanced manufacturing qualified persons (QPs).
Optimising access to medicines	For the Early Access to Medicines Scheme to benefit patients it needs to be centrally funded and reimbursed. The equivalent scheme in France since 1994, the Autorisations Temporaires d'Utilisation de cohorte (ATU de cohorte), is fully reimbursed and highly successful.
	There are unique characteristics and challenges involved with evaluating medicines for very rare conditions. In line with the political support demonstrated via independent research in the BIA's 'Very rare diseases, complex issues' report, government should establish a separate evaluation framework for orphan medicines for very rare diseases.
Strategically important bio-technologies	Health technology assessment processes must be evaluated in order to ensure that patients can have full access to cutting edge treatments in regenerative medicine and cell therapy. The government should examine methods such as: post-launch data collation activities (e.g. registries); risk sharing agreements between the industry and the NHS; and mechanisms for SMEs to access NICE advice in a cost-effective manner.
	The UK government should examine examples of best practice in regulation of regenerative medicines and move quickly to ensure that UK regulation and reimbursement is streamlined and globally competitive.
	The government should respond promptly to recommendations from the report by the Regenerative Medicine Expert Group addressing issues around the UK regenerative medicine landscape.
	The government should recognise the unique challenges of regenerative medicine and show support by continuing to fund schemes such as the dedicated Regenerative Medicine funding competition from Innovate UK.
Building the bioscience ecosystem	The UK bioscience ecosystem is built on a world-class academic science base. It is vital that government recognises the interconnected nature of the ecosystem and that the UK continues to fund our excellent academic community to maintain our global leadership.
	Tier 1 science visas should be available for industry as well as academic scientists. The BIA is keen to be the industrial partner of the Royal Society to administer this.
	The UK needs to improve the current 'tech transfer' operational model to ensure that intellectual property generated in academia is commercialised to its fullest potential.
	Government should closely monitor implementation of the Unified Patent Court to ensure it delivers a cost effective, reliable and predictable regime for the enforcement of patents.
Global, European and regional perspectives	The UK government must ensure that tackling antimicrobial resistance remains a global priority and should speedily adopt recommendations made in Jim O'Neill's review of the R&D incentivisation, economics and usage of antimicrobials.
	If there is an in/out referendum on UK membership of the European Union, the UK government should set out a plan of the expected disruption to UK life science businesses. In particular this should include how it would expect to handle the European Medicines Agency and Unified Patent Court leaving London, how medicines would be approved and regulated, and the likely impact on investment.
	The EU clinical trials portal and database must be developed and fully functional by mid- 2016, through engagement with the European Medicines Agency.
	Local, regional and national planning should enable the bio-economy. All planning decisions should be carefully considered, so as to maximise the economic benefit of the UK bioscience industry.

Founded over 25 years ago at the infancy of biotechnology, the BioIndustry Association (BIA) is the trade association for innovative enterprises involved in UK bioscience. Members include emerging and more established bioscience companies; pharmaceutical companies; academic, research and philanthropic organisations; and service providers to the bioscience sector. The BIA represents the interests of its members to a broad section of stakeholders, from government and regulators to patient groups and the media. 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.

Bionow is the life-sciences membership organisation for the North of England and supports business growth, competitiveness and innovation within the biomedical and life science sectors. Bionow's membership offering focuses upon the specific needs of firms at their different stages of development, including dedicated business support programmes, shared procurement schemes with significant cost savings, exclusive insurance benefits, recruitment and training services, local and national events and access to a vibrant network of businesses.

BioPartner UK is an independent, accredited trade organisation, promoting international partnering for trade, investment and collaborations with UK Life Science companies. BioPartner's UK Delegations promote the UK presence at major international biopharma conferences, and all UK-based companies can access government grants and heavily discounted entry fees. BioPartnership programme members benefit from partnerships with Government and Network alliances, industry expertise, and cost savings through bulk purchasing; as well as policy updates and lobbying efforts of the UK BioIndustry Association.



Established in May 2010, One Nucleus is the result of the merger of ERBI and London Biotechnology Network. One Nucleus is a not-for-profit membership organisation for international life science and healthcare companies and the largest of its kind in Europe. The company is based in Cambridge UK and London, at the heart of Europe's largest cluster. The 470 members include pharmaceutical, biotech, medical device and diagnostic companies and associated technical and commercial Service Providers.

The BIA, Bionow, BioPartner UK and One Nucleus are founding partners of United Life Sciences, a strategic partnership representing the life sciences sector. Since joining United Life Sciences in March 2015, MediWales is also a key supporter of the aims of this manifesto.

For further information on the bioscience sector or the content of the manifesto please contact the BioIndustry Association on info@bioindustry.org or 020 7630 2180

We are at the forefront of UK bioscience, connecting individuals and organisations, helping to shape the future of the UK sector

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