# **Biopharmaceuticals Sector** Proposition

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Department for International Trade

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### **DIT Contacts**

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### **General Enquiries**

If you would like to talk to our specialist team about the opportunities for your business in the UK and how we can help, contact <u>lifescience@trade.gov.uk</u>.

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# Reasons to invest in the UK

Why Invest in the UK?

The UK's biopharmaceuticals industry is collaborative, mature and dynamic and has facilitated the worldwide growth of the industry. It has been at the forefront of the global effort against COVID-19, an effort which has benefited from the UK's world-class science infrastructure, discovery and innovation capability, large and streamlined clinical trials capacity and high-quality manufacturing facilities for commercialisation. Discovery Talent, data, biosamples, platforms and partners for discovery research.

Manufacturing High-quality, low-cost locations to manufacture and access to expert national manufacturing innovation infrastructure. Development Expert experimental medicine and clinical research infrastructure and services to accelerate your pipeline.

Commercialisation Excellent location for international or European headquarters, with a supportive competitive business environment and access to global markets.

- Research & Innovation Excellence
- Streamlined Clinical Trials Operations
- World-Class Science Infrastructure
- Government Leadership
- Supportive Business Environment
- > Opportunities Across All Regions

### Advanced Therapy Medicinal Products (ATMPs)

Medicinal products which is either a gene therapy medicinal product, a somatic cell therapy medicinal product or a tissue engineered product

### Antibodies

Proteins produced by our immune system to fight off invading pathogens. Antibodies are a very important class of drug therapies, and are also used as research tools. Many targeted cancer drugs, including immuno-therapies, are antibodies.

### Biologic

Protein-based therapy produced from microbes or cell cultures, typically taken as an injection. Also referred to as "large molecule" drugs. They include antibodies, therapeutic proteins, advanced therapy medicinal products (ATMPS), vaccines and **Biopharma:** used to refer to therapeutic-focused biotech companies, often but not always the more developed companies of the sector. In this proposition:

- Core Biopharma includes all businesses involved in developing and/or producing their own pharmaceutical products – from small, R&D focused biotechs to multinational Big Pharma. Subsegments include Small Molecules, ATMPs, Therapeutic Proteins, Antibodies, Vaccines and Blood & Tissue Products.
- Biopharma Service & Supply comprises businesses that offer goods and services to Core Biopharma companies including, for example, Contract Research and Manufacturing Organisations (CRMOs) and suppliers of consumables and reagents for R&D facilities.

### Biotechnology

Biology-driven technology that uses biological processes to develop products, systems and tools that can help improve our health.

### Cell & Gene Therapy

Treatment that involves extracting certain cells from a donor or patient, engineering them outside the body and re-injecting them; and treatment that involves replacing a faulty or missing gene with a working copy.

### Genomics

An interdisciplinary field focusing on the study of the human genome and the application of resulting knowledge to human health. Genomics is sometimes considered the entry point for other lines of study (other 'omics'), including proteomics, transcriptomics and metabolomics.

### Life Sciences

Ranging from basic and applied bioscience and biomedical research to the development of pharmaceuticals, biotechnologies, and medical and health technologies.

### **Precision Medicine**

The use of genetic or biological markers to determine whether or not a patient will respond positively to the medicine.

### **Small Molecules**

Chemical medicines below a certain size threshold that can be synthesized in the laboratory and are usually taken in pill form.

Sources: BIA, 'Opportunity on your Doorstep,' Sept 2020; OLS, 'UK Bioscience and Health technology Sector Statistics 2019,' 2020; Vailati-Riboni, Mario et al, 'What Are Omics Sciences,' Aug 2017; UK Gov, 'ATMPs: regulation and licensing,' 2015.

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# Acronyms Guide



AAC	Accelerated Access Collaborative
<u>ABPI</u>	Association of the British Pharmaceutical Industry
AHSN	Academic Health Sciences Network
AMRC	Association of Medical Research Charities
BBB	British Business Bank
BBSRC	Biotechnology and Biological Sciences Research Council
<u>BIA</u>	BioIndustry Association
BIVDA	British In-vitro Diagnostics Association
<u>BSI</u>	British Standards Institute
<u>CGTC</u>	Cell and Gene Therapy Catapult
<u>CRN</u>	Clinical Research Network
DHSC	Department of Health and Social Care
DIT	Department for International Trade
IDR UK	Health Data Research UK
<u>HTA</u>	Health Technology Assessments
<u>ILAP</u>	Innovative Licensing and Access Pathway
IRAS	Integrated Research Application System
MDC	Medicines Discovery Catapult
MHRA	Medicines and Healthcare Products Regulatory Agency
MMIC	Medicines Manufacturing Innovation Centre
MMIP	Medicines Manufacturing Industry Partnership

<u>MRC</u>	Medical Research Council
<u>NHS</u>	National Health Services
<u>NICE</u>	National Institute for Health and Care Excellence
<u>NIHR</u>	National Institute for Health Research
<u>OLS</u>	Office for Life Sciences
<u>STEM</u>	Science, Technology, Engineering & Mathematics
<u>UKRI</u>	UK Research and Innovation
<u>VMIC</u>	Vaccines Manufacturing Innovation Centre

# A Rapidly Growing Global Market

### Biopharma – The Future of Medicine

The global drugs market is growing dramatically, with some biopharma market reports projecting 7.3% CAGR through 2026. Global medicine spending is also projected to increase 2-5% annually, exceeding \$1.1 trillion in 2024. COVID-19 has further highlighted the opportunities in this sector with recordbreaking investment in 2020; the more than \$17.2bn in Q2 equity funding was the largest ever witnessed in a quarter.

Biotech now accounts for a large, and growing, share of the global clinical development pipeline at 80% of the total in 2018. More medicines are also being approved than ten years ago, and two-thirds of launches will be specialty products for chronic, complex or rare diseases.

### Major Trends Impacting the Global Industry

### Ageing Society

By 2050, one in six people in the world will be over age 65 (16%), up from one in 11

#### in 2019

#### **Technological Advancements**

Innovation in cell and gene therapies, artificial intelligence and new digital technologies is driving

### growth.

#### Future Epidemic Preparation

Recent pandemics, such as Ebola, H1N1 and COVID-19 especially, are driving greater demand for health services.

### **Rise in Multiple Chronic Conditions**

The WHO has warned against rising chronic conditions, noting an 11% increase in global disease burden since 2001.

### Growing Demand in Emerging Markets

Demand for health services is growing in emerging economies, particularly BRIC and others in the Asia Pacific. \$496bn global market value in 2026

> **7.3%** CAGR, 2021-26

\$17.2bn in Q2 equity funding, 2020

**\$1.1tr** global medicine spending by 2024

Sources: IBISWorld, 'Biotechnology in the UK,' Sept 2020; World Economic Forum, 'This is the biggest challenge to our health,' Dec 2017; PwC, 'Chronic diseases and conditions are on the rise', 2017; United Nations, 'World Population Prospects', 2019; Mordor Intelligence, 'Biopharmaceuticals Market - Growth, Trends, COVID-19 Impact, And Forecasts (2021-2026),' 2020; Panda International, 'Life Sciences Investment in 2020 - Why Biotech is Flourishing,' Nov 2020; BIA, 'Opportunity On Your Doorstep,' Sept 2020.

# Opportunities to Invest

The UK has strengths across the biopharma sector, providing the expertise, skilled workforce and established infrastructure needed to take advantage of the growing opportunities.



## **Opportunities Overview**

Biopharma



7.3% CAGR globally through 2021-2026



Biologics

Small

**Molecules** 

Precision

Medicine

<sub>Nearly a</sub> third of global drugs sales

globally through 2026

by 2025, from \$37bn in

\$57bn

2019

global market

8% CAGR

\$134bn

by 2025

global market



**400% increase** in investments in the UK since 2012

£31.7bn UK annual turnover

£55.1bn

£544m

in R&D funding

**UK** annual turnover

**UK Leadership** through Genome UK, Genomics England and UK Biobank

Sources: Mordor Intelligence, 'Biopharmaceuticals Market - Growth, Trends, COVID-19 Impact, And Forecasts (2021-2026),' 2020; IBISWorld, 'Biotechnology in the UK,' Sept 2020; OLS, 'UK Bioscience and Health technology Sector Statistics 2019,' 2020; Imarc, 'Vaccine Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2020-2025,' 2020; BIA, 'Opportunity On Your Doorstep,' Sept 2020; Mordor Intelligence, 'Small Molecule Drug Discovery Market - Growth, Trends, COVID-19 Impact, and Forecasts (2021-2026),' 2020; Frost and Sullivan, ' Global Precision Medicine Growth Opportunities, Forecast to 2025', 2017.

The UK has a vibrant and international industry benefiting from long-term vision, partnership between government and the sector, and supported by a worldclass talent base.

# Home to a Dynamic Biopharma Sector

### The UK's Leading Biopharma Position

The UK's biopharma industry is collaborative, mature and dynamic and has moreover facilitated the growth of the global industry. In 2001, the UK helped kickstart a key breakthrough in biotechnology when scientists, many based at the UK's Wellcome Sanger Institute, sequenced the entire human genome. We have continued to innovate, developing a core biopharma industry with £36.7bn in annual turnover and a service and supply chain industry worth another £18.4bn in 2019.

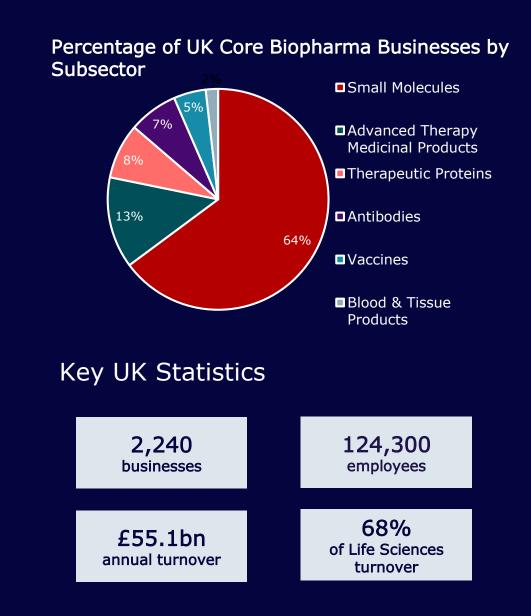
The UK is the **biggest life sciences cluster in Europe** # 1 with total turnover at £80.7bn, over 250,000 employees and 6,300 businesses.

In Europe, the UK has **the highest number of** #1 pharma and biotech companies in the leading 1000 companies, more than double its biggest competitor - France.

### A Global Life Sciences Cluster

**Ranked #1** for the number of life sciences FDI projects among European comparator projects and 2<sup>nd</sup> globally, behind the US. The value of the overall **inward FDI** reached £1.1bn in capital expenditure that year - a **37% increase** from 2017 levels and the highest in the provinue 8 years

Sources: OLS, 'UK Bioscience and Health technology Sector Statistics 2019,' 2020; Statista, 'Number of pharmaceutical and biotechnological companies in the leading 1000 companies in the EU from 2017 to 2019, by country, 2019; IBISWorld, 'Biotechnology in the UK,' Sept 2020; GTAI, 'Biotechnology Clusters in Germany,' 2020; ; OLS, 'Life Science Competitiveness Indicators', 2019.



# Vaccine Leadership Through COVID-19



### Supporting a Vital Sector

Vaccines are among the most important inventions in human history, preventing various life-threatening diseases, including measles, polio, meningitis, influenza and now coronavirus. Recent advancements in biotechnology have created new opportunities for vaccine manufacturing, improving existing vaccines, developing new ones and increasing the amount of vaccine that can be produced.

The <u>Vaccines Manufacturing Innovation Centre</u> (VMIC), located at the <u>Harwell Science and Innovation Campus</u> in Oxfordshire, will house the country's first bespoke strategic vaccine development and manufacturing capability. It will fast-track development of new and innovative vaccines through collaborations with industry, research and academia. VMIC received £65m in 2018 and a further injection of £131m as the pandemic accelerated.

*Sources: Imarc, 'Vaccine Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2020-2025,' 2020; OLS, 'UK Bioscience and Health technology Sector Statistics 2019,' 2020; IBISWorld, 'Biotechnology in the UK,' Sept 2020; NIHR, 'Case study: UK leads rapid delivery of Novavax Phase 3 COVID-19 vaccine trial,' Mar 2021.* 

### Oxford-AstraZeneca COVID-19 Vaccine

The <u>Oxford-AstraZeneca vaccine</u> is a weakened version of a common cold virus, known as an adenovirus, that has been genetically changed so that it cannot cause infections in humans. Funded by UKRI, Oxford University and AstraZeneca were among the first in the world to develop a vaccine for COVID-19, a speed that was enabled by the years of prior vaccine research on Ebola and MERS and supported by the government. It has been authorised for emergency use by the World Health Organisation, and AstraZeneca aims to supply three billion doses to people in 145 countries by the end of 2021.

### Novavax COVID-19 Vaccine

<u>Novavax's vaccine</u> combines an engineered protein from the virus that causes COVID-19 with a plant-based ingredient to help generate a stronger immune response. Based on its phase III trial data from over 15,000 participants recruited through the National Institute of Health Research vaccine registry, the vaccine has shown 89.3% efficacy. Thanks to its advanced research infrastructure, integrated within the NHS, the UK was able to quickly and efficiently deliver its phase III trial ahead of parallel trials in other countries.

> The Liverpool School of Tropical Medicine and the University of Liverpool constitute the UK's largest concentration of expertise in translational-focused R&D and innovation in infectious diseases. Major manufacturers in the area include AstraZeneca, Seqirus, Bristol Myers Squibb and more.



The UK government has pledged £544m towards vaccine research and development

# Vaccine Opportunities Beyond COVID-19

### Transformative Vaccine Technologies

The vaccine development process can take up to 30 years, but new vaccine technologies are opening up opportunities to more quickly and cost-effectively develop novel vaccines against a range of diseases, potentially curbing the high use of antibiotics.

- mRNA technology is a transformative and pathogen agnostic vaccine platform which uses the genetic code of part of a virus to produce a molecule that will trigger the body's natural immune system. It provides the opportunity to make therapeutic as well as preventative vaccines for conditions and illnesses beyond just infectious disease, including cancer, dengue fever, HIV, Zika, herpes, hepatitis and malaria. Large quantities of this vaccine can also be made by a relatively simple chemical process, cutting time and costs for future vaccines.
- Viral vectors are tools designed to deliver genetic material into cells and are used by the Oxford/AstraZeneca vaccine to protect against COVID-19. The UK helped fund the set-up of a rapid deployment facility at Oxford Biomedica in Oxfordshire, which was a major milestone in increasing UK manufacturing capability of viral vector vaccines.
- Other advanced technologies include bioconjugation and adjuvants. GSK's new vaccine for shingles contains an adjuvant to help strengthen the immune response, creating a therapeutic vaccine delivered after the initial infection of a virus.

Sources: UK Gov, 'Extra £47.6 million for Vaccines Manufacturing and Innovation Centre,' Mar 2021; Labiotech, 'How the Vaccine Industry and Biotechs Can Accelerate Pandemic Responses,' Jan 2021; Wired, 'The mRNA vaccine revolution is just beginning,' Jun 2021

### INFLUENZA

Seqirus has developed <u>the first adjuvanted quadrivalent influenza vaccine</u> (aQIV) to become available across Europe. The vaccine will be manufactured end-to-end in Liverpool at a **new high-speed fill-and-finish facility**; it is the largest vaccine manufacturing facility in the UK, producing over 50m doses of seasonal influenza vaccine each year, with the ability to increase production to 200m doses.

### OLA

The European Commission has approved Janssen's new Ebola vaccine, developed in partnership with Oxford University; it is designed to induce long-term immunity against the Ebola virus in adults and children. The <u>Oxford Vaccine Group</u> was able to enrol thousands of participants in sub-Saharan Africa and helped accelerate the vaccine through **multiple clinical trials across three continents**.

#### MALARIA

Researchers from the University of Oxford and their partners have become **the first to meet the World Health Organization's Malaria Vaccine Technology Roadmap goal** of a vaccine with at least 75% efficacy. They completed a Phase IIb trial of a candidate malaria vaccine, <u>R21/Matrix-M</u>, which demonstrated high-level efficacy of 77% over 12-months of followup.

*Sources: Seqirus, 'Seqirus strengthens U.K. influenza vaccine response as high-speed fill and finish facility begins rolling 30 million doses in Liverpool,' Jun 2021; University of Oxford, 'Ebola vaccine approved for use by the European Commission,' 2020; The Telegraph, 'Three revolutionary technologies that could cut vaccine development times by half,' 2019.* 

# Leaping Forward with Biologics

### Invest in Next-Generation Therapeutics

Biologics, also called large molecule therapeutics, have a large, complex molecular structure and are consequently more difficult and expensive to produce than small molecule drugs. Despite the cost, biologics are receiving skyrocketing interest given the promise they show in providing treatments to a wide variety of illnesses and the ability to correct or replace faults in the body; they now comprise seven of the top ten bestselling drugs worldwide and generate nearly a third of global drug sales



The UK biologics segments together make up 18% (11,700) and 10% (£3.8bn) of biopharma employment and turnover respectively.



Advanced Therapy

**Medicinal Products** 

(ATMPs)

In Phase II data, Southampton-based <u>Synairgen</u> has shown its therapy can drastically reduce instances of severe symptoms in COVID-19 patients with **odds of improvement more than two-fold** greater than the placebo group.

Antibodies

es Therapeutic Proteins

eins Blood & Tissue Products

Sources: BIA, 'Opportunity On Your Doorstep,' Sept 2020; OLS, 'UK Biopharmaceutical Sector Statistics,' 2020; Pharmaceutical Technology, 'The top selling prescription drugs by revenue,' 2019; Statista, 'Medical Biotechnology – Statistics & Facts,' Sept 2020; MHRA, 'The Medicines and Healthcare products Regulatory Agency annual report and accounts 2019/20.' 2020.

### UK's Track Record of Discovery

The UK has a history of revolutionary research and discovery in molecular biology. The <u>MRC Laboratory of Molecular Biology</u> (LMB) is one of the birthplaces of modern molecular biology. Many techniques have been pioneered at the laboratory, including DNA sequencing, methods for determining the three-dimensional structure of proteins and the development of <u>monoclonal antibodies</u>. Over the years, the work of LMB scientists has attracted 12 <u>Nobel prizes</u>, dozens of <u>Royal</u> <u>Society awards</u> and numerous other scientific honours.

The UK has also discovered a number of the top selling biologics medicines and developed platforms for antibody discovery. And now, through the <u>UK Regenerative Medicine</u> <u>Platform</u>, <u>Cell and Gene Therapy (CGT) Catapult</u> and <u>National</u> <u>Biologics Manufacturing Centre</u>, the UK continues to pave the way in large public health issues. With five consecutive years of raising over £1bn in biotech and a 400% increase in investments since 2012, the sector is in a very strong position heading into a new decade.

### Setting the World Standard

The <u>National Institute for Biological Standards and Control</u> (NIBSC) is responsible for developing and producing over 90% of the international standards in use around the world to assure the quality of biological medicines. Biological medicines include vaccines, antibodies, cells and hormones, which influence the systems of the body to improve resistance to and

# Advancing Healthcare with Cell & Gene Therapies

### Advanced Therapy Treatment Centres Network

The ATTC network programme is a world-first, UK system of Advanced Therapy Treatment Centres operating within the NHS framework and coordinated by the CGT Catapult to address the unique and complex challenges of bringing pioneering ATMPs to patients. The centres include:

- Innovate Manchester Advanced Therapy Centre Hub
- Midlands-Wales Advanced Therapy Treatment Centre
- <u>Northern Alliance Advanced Therapies Treatment Centre</u>

The network is initially supported by the <u>Industrial Challenge Strategy</u> <u>Fund</u> and delivered by <u>UK Research and Innovation</u>, aiming to develop first-of-a-kind technologies for the manufacture of innovative medicines across areas including blindness, cancer, heart failure, liver disease, neurological conditions and rare paediatric diseases.



### Strong Growth Trajectory in the

The humber of ATMP clinical trials in the UK continues to increase year-on-year, with 154 trials reported as ongoing in 2020, indicating more than a 20% increase from 2019. This is representative of approx. 12% of all ATMP trials in progress globally.



The UK is the **largest cluster of advanced therapies companies outside the US** and has the **largest biotech pipeline in Europe**.

### **Opportunities in Advanced Therapies**

Advanced Therapy Medicinal Products are a type of biologic that is either a gene therapy, a somatic cell therapy or a tissue engineered medicinal product. These products are different from existing treatments because they are designed to restore normal function, sometimes offering cures where an unmet medical need exists.

The UK is aiming to develop robust systems for the routine delivery of ATMPs as a standard of care throughout the NHS. To this end, the UK has set up the <u>CGT Catapult</u>, which is home to two large-scale manufacturing assets, and the <u>Advanced Therapy Treatment Centres (ATTC)</u> <u>Network</u>.

Initial work with CGT Catapult has led to <u>Purespring Therapeutics</u>, a University of Bristol spin-out company, commercialising its groundbreaking gene therapy technology for chronic kidney diseases. The company has been awarded £45m from Syncona, one of the largest single investments made to a new UK university biotech company.

*Sources: BIA, 'Opportunity On Your Doorstep,' Sept 2020; OLS, 'UK Biopharmaceutical Sector Statistics,' 2020; Pharmaceutical Technology, 'The top selling prescription drugs by revenue,' 2019; Statista, 'Medical Biotechnology – Statistics & Facts,' Sept 2020; Cell and Gene Therapy Catapult ATMP clinical trials report 2020.* 



# Big Opportunities in Small Molecules

### Rising Applications of Small Molecule Drugs

Small molecule drugs have been the mainstay of the pharmaceutical industry for nearly a century. Any organic compound with low molecular weight and complexity, small molecule drugs have some distinct advantages as therapeutics: most can be administered orally and pass through cell membranes to reach intracellular targets. They can also be designed to engage biological targets and their distribution can further be tailored, for example, to allow for systemic exposure with or without brain penetration.

The rising applications of small molecule drugs alongside the accelerating technological advancements in the field are boosting the industry, with drug discovery growth projected to be just over 8% CAGR globally through 2026. Small molecules are expected to provide effective treatment against chronic disease, with oncology and rare diseases as the largest therapeutic segments.

Sources: Astrazeneca, 'A big future for small molecules: targeting the undruggable,' accessed Mar 2021; Mordor Intelligence, 'Small Molecule Drug Discovery Market - Growth, Trends, COVID-19 Impact, and Forecasts (2021-2026),' 2020; OLS, 'UK Biopharmaceutical Sector Statistics,' 2020.

### Transformative Solutions in the UK

With annual turnover reaching £31.7bn in 2019, the UK is already showing its strength in this sector. The sector is further supported by the <u>Medicines Manufacturing Innovation Centre</u> (MMIC), a unique, state-of-the-art facility offering transformative solutions in small molecule and fine chemical manufacturing. The MMIC's two key goals are:

- to develop an innovative continuous direct compression (CDC) platform enabling oral solid dosage medicines to be formulated more robustly and efficiently; and
- to use digital technology and automation to improve just-in-time medicine supply; this will reduce waste and improve flexibility during clinical trials

The UK also set up the <u>RECOVERY trial</u> the world's largest clinical trial into treatments for COVID-19. It found one of the world's first COVID-19 treatments, dexamethasone. Cheap and readily available, the steroid was shown to reduce deaths of patients in hospital with COVID-19 by one third.

# **Pioneering in Precision Medicine**

### Invest in the Future

Precision Medicine, personalising medicine based on individual gene variation, has the potential to revolutionise the medical landscape. Technological breakthroughs in genomics are accelerating cost reductions and expanding methods of application. The technology, especially when combined with data and informatics, offers a tremendous opportunity for companies looking to invest in a variety of rapidly growing start-ups; in fact, personalised medicines are three times more likely to succeed than conventional drugs.

### Leading the Way on Precision Medicine

The UK's leadership in precision medicine has been facilitated by ground-breaking research programmes. Their outputs have been used extensively worldwide and placed the UK in the premier league for genomics.

<u>Genome UK</u>	An ambitious programme to sequence 5 million genomes by 2023/24.
<u>Genomics</u> England	Building on the <u>100,000 Genomes</u> project, to sequence 5 million genomes by 2023/24.
<u>UK Biobank</u>	A large-scale biomedical database with medical and genetic data from 500,000 participants.

Sources: UK Gov, 'Human genome: UK to become world number 1 in DNA testing', 2014; NHS, 'Personalised medicine', 2020; BIA, 'Opportunity On Your Doorstep,' Sept 2020; Frost and Sullivan, ' Global Precision Medicine Growth Opportunities, Forecast to 2025', 2017; KTN, 'IUK Precision Medicine: Connecting Industries to UK



The global precision medicine market is expected to reach **\$134bn by 2025**, growing at a **CAGR of 13.3%** from 2015 to 2025.



<u>Cancer Research UK</u> has **funded one of the** world's largest precision medicine clinical trials to explore how cancer patients respond. The oncology application is expected to hold the largest market share over 2020-2025.



The Industrial Strategy Challenge Fund invested £210m into the sector via the Data to Early Diagnosis and Precision Medicine Challenge theme.



Key national assets, such as <u>Precision</u> <u>Medicine Scotland Innovation Centre</u> and <u>Living Laboratory for Precision Medicine</u> in Scotland and <u>Precision Medicine Centre</u> in Northern Ireland, will translate innovation into clinical practice.

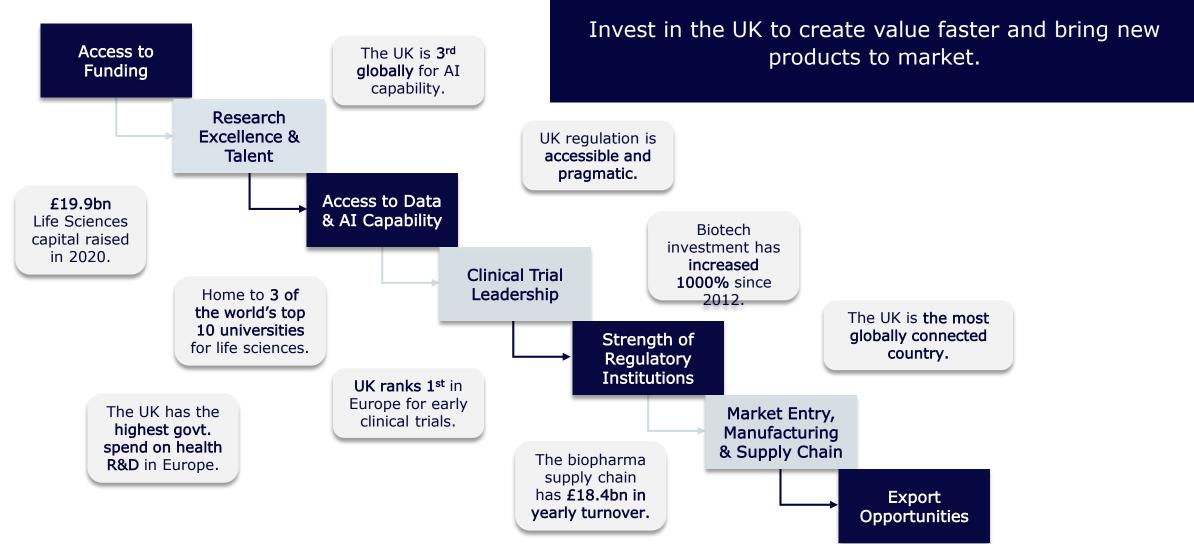
The UK's track record of discovery in genomics is world renowned. It includes **discovering the structure of DNA**, building the **Solexa** (now Illumina Sequencing) **sequencing platform**, role in the **Human Genome Project**, and undertaking the **100,000 Genomes Project**.

# Why Invest in the UK?

The UK meets investors' needs from the R&D stage through to manufacturing, distribution and trade with global markets.



# Capability & Excellence Along the Value Chain



Sources: Savills, 'Spotlight: Life Sciences – Trends & Outlook 2021,' Jan 2021; Oxford Insights, 'Government Artificial Intelligence Readiness Index 2019'; OLS, 'Life Sciences Competitiveness Indicators 2020,' 2021; BIA, 'The Science of Success: UK Biotech Financing in 2020,' Feb 2021; APBI, 'Clinical Trials Report,' 2019; OLS, 'UK Bioscience and Health technology Sector Statistics 2019,' 2020; NYU, 'DHL Global Connectedness Index 2020,' 2020.

# Access Funding throughout the R&D Process

### A Mature and International Capital Market

With a mature and highly sophisticated capital market, the UK is both a leading destination and source of capital investment for companies across the scale spectrum. The UK is the second biggest global hub for private equity and venture capital after the US. Alongside generous government support and tax relief, biopharmaceutical companies will be able to access private finance from the business setup and R&D stage with seed funding, through clinical trials and to regulatory approval with series funding.

### Generous Support

- > Government-backed venture capital schemes and tax reliefs can facilitate swift and smooth scale-up for businesses at varying development stages. They include generous tax reliefs of between 30%-50% to investors.
- > The British Business Bank (BBB) is prioritising finance for small, innovative businesses, unlocking over £20bn of investment over 10 years, including enabling up to £600m of funding for the UK's life sciences sector.
- > Companies in the UK seeking investment are supported by the Department for International Trade's Capital Investment team. Contact the team to learn more here.

UK HO'd life £19.9b sciences firms raised 23% more capital in Life Sciences capital raised in 2020 1000

2020 than in 2019 Life Sciences VC

funding grew by 44% in 2019

The UK has four of 15 top markets for life sciences VC volumes.

Over 80% of investment comes from outside the UK.

### Investment

%

Biotech

investment

growth since

£12.8

Record biotech

investment in

£20h

2020

through BBB Sources: Department for International Trade, 'UK FinTech: State of the Nation,' 2019; Savills, 'Life Sciences: Trends & Outlook,' Mar 2020; Savills, 'Spotlight: Life Sciences - Trends & Outlook 2021,' Jan 2021; BIA, 'The Science of Success: UK Biotech Einancing in 2020 / Eab 2021

# Research Excellence and Skilled Talent

### A Proven Record of Talent

Life sciences in the UK is well known as a forward-thinking industry with a track record of scientific breakthroughs and over 80 Nobel Prizes relating to the field to prove it.

37 UK universities are ranked among the world's top for life sciences medicine, and Oxford, Cambridge and University College London all rank in the top ten.

UK's share of the top 1% of life sciences academic citations is 18%.

Some 42% of UK biotech companies have spun-out from academic institutions, and pharma is the top sector for university spin-outs in the UK.

UK is home to five of the top ten universities in the world by value of capital raised via their spin-out start-ups.

### Dedicated Research & Skills Infrastructure

A dedicated research and skills infrastructure is part of the UK's unique life sciences landscape.

- > <u>Medical Research</u> <u>Council</u>
- <u>Cell & Gene</u> <u>Therapy Catapult</u>
- Francis Crick Institute
- > <u>Wellcome Sanger</u> <u>Institute</u>

- <u>Medicines</u>
   <u>Discovery Catapult</u>
- Rosalind Franklin Institute
- <u>Biotechnology and</u> <u>Biological Sciences</u> Research Council
- Advanced <u>Therapies Skills</u> <u>Training Network</u>

In 2019, STEM graduates in the UK numbered over 220,000.

The UK is home to three of the top ten universities in the world for life sciences.

It's half as expensive to hire R&D talent in Oxford than Boston or San Francisco.

UK research accounts for 12% of all life sciences academic citations globally.

### Funding Research & The OK flast highest Government spend on health R&D in Europe. By 2027, UK will spend

**2.4% of GDP on R&D**, with a longer-term aspiration of 3.0%.

£25bn

Industry

spend on

health R&D

£3bn Government spend on health R&D £1.9bn Charity spend on health R&D

Sources: OLS, 'Life Sciences Competitiveness Indicators 2020,' 2021; DIT, 'Life Sciences GSP,' 2020; QS World University Rankings 2021; Pharmaphorum, 'COVID-19 is causing a renaissance in the UK biotech sector, we must ensure it lasts,' Aug 2020; EY, 'Realising the value of health care data: A framework for the future,' 2019; HESA Student Record 2018/19; RAENG, 'Spotlight on Spinouts,' Jan 2021.

# Access to Data Sets & World-Leading AI Capability

### Artificial Intelligence: An Economic Priority

Artificial intelligence are technologies with the ability to perform tasks that would otherwise require human intelligence, such as visual perception, speech recognition, and language translation. Government, world-leading UK universities and industry have been working together to improve the supply of skills to attract and retain the best AI talent, launching new AI training programmes, agreeing to a <u>£1bn AI</u> <u>Sector Deal</u>, funding <u>research centres</u>, including the renowned <u>Alan Turing Institute</u>.

### **Countless AI Healthcare Applications**

AI solutions are already being applied across sectors, potentially generating savings up to 25% and boosting productivity by 30%. Given the <u>access to healthcare data in the UK</u>, applications in the sector and specifically biotechnology are many: accelerating drug discovery, enabling the growth of personalised medicine, identifying and tracking potential

*Sources: Oxford Insights, Government Artificial Intelligence Readiness Index* 2019'; Tech Nation Report 2020; Tech Nation Dealroom.co, 'UK Extends Leadership in Artificial Intelligence', Feb 2019; AI in UK. Artificial Intelligence Industry Landscape Overview Q3/2018. , a London-based AI firm which specialises in machine learning, advanced algorithms and systems neuroscience, was acquired by Google

, based in Oxford Science Park, apply AI to precision engineer medicines and has delivered the first three AI-designed drugs to enter clinical trials. The UK is one of the global leaders in the development of world-class AI technologies and is now #3 in the global AI race, behind only the US and China.

- The UK has a world-leading AI ecosystem and is home to a third of Europe's total AI companies - twice as many as any other European country.
- The UK government is leading the way on AI investment in Europe and has become the 3<sup>rd</sup> biggest spender on AI in the world.
- The UK is a global top performer for VC investment into AI with £2.42bn raised in 2019.
- In Oxford Insights Government AI Readiness Index 2019, the UK ranked 2<sup>nd</sup> for preparedness to capitalise on AI technologies in public services (topped only by Singapore).
- > The UK counts at least five AI-tech unicorns vs. two in the rest of Europe (<u>BenevolentAI</u>,

# Innovation Friendly Clinical Trials Leadership

### Competitive and Collaborative

With a competitive and collaborative research base, healthcare data assets and significant capabilities in clinical research and NHS translation, the UK's pre-clinical and clinical trials network is world-leading, allowing companies to quickly scale up.

<u>The National Institute for Health Research (NIHR)</u> invests over £1bn each year in research centres and facilities in leading universities and hospitals, focused on translational research and delivery of early-phase studies. The <u>NIHR</u> <u>Clinical Research Network</u> (CRN) is the research delivery arm of the NHS, and in 2019/20, more than 732,000 participants were recruited by the NIHR CRN into health and social care studies.

Over 1000 early phase industry contract and collaborative studies are delivered annually in the UK's translational research infrastructure, and over 1 million participants were recruited to clinical studies in 2019.

The UK's experimental medicine and clinical research infrastructure offers expertise across a wide range of therapeutic areas and clinical applications and offers the flexibility to design and run both established protocols and highly innovative studies.

A streamlined and forward-thinking regulatory system provides confidence and accelerates approval.

### Access Data to Support Innovation

The UK is a global leader in real world data and UK datasets have an excellent reputation and provide a wealth of data for epidemiology across all care settings. In fact, the NHS open data is valued at £9.6bp per year

UK BioBank	CancerData	
<u>National Joint</u> Registry (NJR)	Patient data registries	
<u>Medicines</u> <u>Discovery</u> <u>Catapult</u>	<u>SAIL Data Bank</u>	
<u>Clinical Practice</u> <u>Research</u> Datalink (CPRD)	<u>HDR UK Data</u> <u>Hubs</u>	
<b>UK FANKS L<sup>SC</sup></b> in Europe for early clinical trials		

£2.7bn per year worth of clinical trials

28%

of EU applications are from UK



The <u>UK Therapeutics Taskforce</u> is overseeing a world-leading programme of clinical trials to identify safe and effective treatments and get them to patients rapidly, reducing the impact of COVID-19. They have been established to test promising COVID-19 treatments across all phases of human trials and in a range of

# An Accessible and Pragmatic Regulatory Authority

### **Globally Respected Regulation**

The <u>Medicines and Healthcare Regulatory Agency</u> (MHRA) regulates medicines and medical devices for the UK to protect public health. It prioritises simplified product entry and early engagement, coordinates with other healthcare institutions, including <u>NIHR</u>, <u>NICE</u> and <u>AAC</u>, and works alongside industry to streamline the regulatory process.

The MHRA has a strong global reputation for innovation and leadership in the field of regulation, having been instrumental in shaping the European regulatory systems, and is seen by global industry as a "jewel in the crown" of the UK life sciences ecosystem.

MHRA received 955 requests for clinical trial authorisations (CTA) in 2018, with an average of **977 CTA applications per year** since 2016.

### **Regulatory Independence**

The UK agreed to a <u>Trade and Cooperation Agreement</u> with the EU effective 1st January 2021. MHRA is now the UK's standalone medicines and medical devices regulator, empowered by the Medicines and Medical Devices Bill. The UK will have full independence on regulatory decisions, able to provide a clear, straightforward path.

### Working with industry

In 2017, Achilles Therapeutics approached the MHRA to discuss quality, nonclinical, clinical and regulatory aspects of ATL001, a potential advanced therapy medicinal product. The MHRA also gave advice on the manufacturing of the product and clinical advice on the protocol design. Through close collaboration with the MHRA, Achilles Therapeutics has managed to take its investigational clonal neoantigen-based therapy from a concept into the clinic in less than three years.

### Key Support Organisations & Programmes

- MHRA Innovation Office: Provides free and confidential expert regulatory information, advice and guidance to organisations of all backgrounds and sizes based nationally or internationally
- Innovative Licensing and Access Pathway (ILAP): Aims to accelerate the time to market, facilitating patient access to medicines
- Integrated Research Application System (IRAS): A single system for applying for the permissions and approvals for health, social and community care research and development in the UK
- Health Technology Assessments (HTAs): funds research about the clinicaland cost-effectiveness and broader impact of healthcare treatments and tests
- British Standards Institute (BSI Group): The UK national standards body that helps companies comply with regulations and standards, avoiding product failures and recells

product failures and recalls Sources: UK Gov, 'Clinical trials for medicines: authorisation assessment performance,' April 2020; DIT, 'Invest in UK Clinical Research SP,' 2020

# Support throughout Product Assessment and Market Entry

### National Institute for Health and Care Excellence As an Assessment Partner

The National Institute for Health and Care Excellence's (NICE) role is to improve outcomes for people using the NHS and other public health and social care services. They do this by:

- > Producing evidence-based guidance and advice for health, public health and social care practitioners.
- Developing quality standards and performance metrics for those providing and commissioning health, public health and social care services.
- > Providing a range of information services for commissioners, practitioners and managers across health and social care.

### As a Market Access partner

NICE provides opportunities for industry to engage at all stages of health technology development, helping them deliver better and measurable outcomes. It helps companies to:

- > Navigate the healthcare system
- > Understand evidence requirements
- > Demonstrate the value of your health technology
- Get new and innovative health technologies adopted as quickly as possible

<u>NICE Office for Market Access (OMA)</u> provides expert advice and helps companies navigate the differing approaches to market access, considering the implications for the technology

### Selling to the NHS

Companies have multiple pathways available to them in order to sell to the National Health Service:

- Companies can identify and get in touch with the right contact (generally clinicians, the procurement team and the finance team) within the selected NHS organisation.
- Companies can also look to the <u>NHS Commercial Medicines Unit</u> which is responsible for buying and securing the supply of medicines prescribed in NHS hospitals in England.
- National Frameworks through the Crown Commercial Services, the biggest public procurement organisation in the UK, offer a further pathway to selling to the NHS.
- > Find further guidance on partnering with the NHS here.

### Innovative Medicine Fund

Thanks to a new <u>Innovative Medicines Fund</u>, which is building on the success of the <u>reformed Cancer Drugs Fund (CDF</u>), and £680 million of ringfenced funding, NHS patients with any condition, including those with rare and genetic diseases, are set to benefit from early access to potentially life-saving new medicines, such as cutting-edge gene therapies.

### DHSC spending in England was £212.1bn in 2020/21; in 2019/20, the NHS spent £20.9bn on medicines procurement.

Sources: The King's Fund, 'The NHS budget and how it has changed,' Mar 2021; NHS Digital, 'Prescribing Costs in Hospitals and the Community 2019-2020,' Nov 2020.

# A Thriving Supply Chain & Services Ecosystem

### High Quality End-To-End Support

The UK's network of 1,500 biopharma service & supply firms provide an integrated supply chain that offers a range of services to support product delivery from start to finish. The UK also follows good manufacturing practice (GMP) and good distribution practice (GDP), ensuring products are consistently high quality, appropriate to their intended use and meet the requirements of the market authorisation or product specification.

The UK biopharmaceuticals sector also has a strong <u>trade</u> <u>bodies ecosystem</u> ready to support industry. Read more <u>here</u>.

### NHS Supply Chain

<u>NHS Supply Chain</u> manages the sourcing, delivery and supply of healthcare products, services and food for NHS trusts and healthcare organisations across England and Wales. NHS Supply Chain systems consolidate orders from over 800 suppliers, saving trusts time and money and removing duplication of overlapping contracts.

Suppliers can benefit from lower sales and marketing costs, having a single route into the national market, a joined-up approach across the NHS and a clear route for innovative products.

*Sources: OLS, 'UK Bioscience and Health technology Sector Statistics 2019,' 2020; DIT, 'Invest in UK Advanced Therapies GSP,' 2020; UK Gov, 'Good manufacturing practice and good distribution practice,' Dec 2020.* 

### Industry Facts & Figures

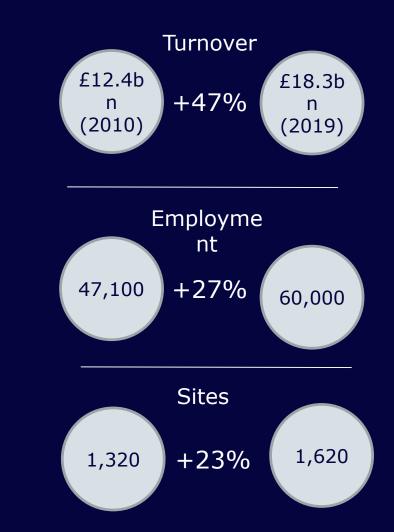
Two-thirds of the biopharma supply & service sector employees are outside London and the South East.

The largest segments by employment are contract manufacturing & research, reagent & equipment suppliers, and clinical research organisations.

These three largest segments together employ 41,100 people and account for 81% (£14.9bn) of the sector turnover.

The UK has **26 manufacturing facilities for ATMPs** with more growth planned.

### A Growing Sector



### Contract Research & Manufacturing Partners

The global CDMO market is expected to reach **US\$279bn by 2026**, up from US\$130bn in 2018 and growing at 10% CAGR over the time period.

The UK is home to more than 130 Clinical Research Organisations and over 350 Contract Manufacturing/ Research Organisations

# A Large and Growing Manufacturing Sector

The UK is one of the best places in the world to develop, manufacture and commercialise clinical products and pharmaceuticals. We offer leadingedge research and talent, established platforms for innovation and clinical trials, access to supply chain and service partners, and support for scaleup and commercial manufacturing, as well as world-renowned regulatory expertise and standards.

The sector is benefitting from both new and existing growth drivers: governments are pushing for resilient supply chains; increased demand for generics and biologics; SMEs without commercial scale manufacturing capacity; high demand for agile production capabilities; and more.

### Government-Supported Manufacturing Innovation Infrastructure

The government is prioritising the life sciences manufacturing sector, supporting the industry with specialist contract development manufacturing facilities and centres of excellence. They include:

- Cell & Gene Therapy Catapult
- <u>Cell & Gene Therapy Manufacturing Innovation Centre</u> (open Dec 2021)
- Medicines Discovery Catapult
- National Biologics Manufacturing Centre
- Medicines Manufacturing and Innovation Centre (Open 2022)
- <u>Vaccines Manufacturing and Innovation Centre</u> (Open early 2022)
- <u>Centre for Process Innovation</u>

### **Key Players**

The following are examples of the UK's thriving contract biopharmaceutical manufacturing sector, supported by the sector trade body, the <u>Clinical & Contract Research Association</u> (CCRA). Whilst this list is not exhaustive, it provides perspective on the #DB h and breadth of the sector. Cobra Biologics

<u>Porton Biopharma</u>

Lonza Oxford BioMedica Custom Pharma Services Roslin CT Surepharm

*Sources: Fortune Business Insights, 'Contract Development and Manufacturing Organization (CDMO) Outsourcing Market,' 2020; OLS, 'UK Bioscience and Health technology Sector Statistics 2019,' 2020; UK Gov, 'New £20 million fund to grow UK life sciences manufacturing opens for applications,' Apr 2021.* 

### Springboard for Global Opportunities

### An International Powerhouse

The UK is one of the biggest recipients of international investment in the world, receiving \$59bn in foreign direct investments in 2019 – above both Germany and France by some \$20bn. Given the economy's centrality to the world economy, the UK has strong links to international markets to which biopharma investors can export. In fact, the value of UK exports reached almost \$571bn in 2019; the value of medicinal and pharmaceutical products exports reached \$21bn, 6.8% of total goods exports.



The **UK's top five trading partners** are the United States, Germany, China, the Netherlands and France, accounting for 46% of UK total trade in goods across sectors in the first half of 2020.



In 2019, the **UK ranked 1<sup>st</sup>** for the number of life sciences FDI projects (72 projects) among European comparator projects and 2<sup>nd</sup> globally, behind the USA.

The UK is the number one most globally connected country in the world, given its international trade, capital, information and people flows.



### Supporting Exports

In order to fully take advantage of the international markets available, companies can make use of three key policy mechanisms that support UK exports: <u>Export</u> <u>Development Guarantee (EDG)</u>, <u>UK Export Finance (UKEF)</u> and <u>DIT Support</u>.

The UK has an ambitious programme of Free Trade Agreement (FTA) negotiations. We have agreed trade deals with 68 countries including Switzerland and Turkey plus the EU, that account for  $\pounds$ 744bn of UK bilateral trade in 2020.

Building on agreements signed so far, we will put the UK at the centre of a network of modern deals spanning the Americas and Pacific.

Sources: fDi Markets, accessed Nov 2020; OLS, 'Life Sciences Competitiveness Indicators 2020,' 2021; DIT, 'Trade and Investment Core Statistics Book,' Feb 2021; NYU, 'DHL Global Connectedness Index 2020,' 2020.

# Government Leadership & Support

The UK provides access to a supportive business ecosystem with opportunities to network and grow.

### Government Leadership & Support

The links below go to Government strategy documents & departments relating to the Life Sciences sector. More details on the following pages.

Government Leadership			
Life Sciences Vision		Clinical Reso	earch Vision
Life Sciences Industrial Strategy		<u>R&amp;D Roadmap</u>	
NHS Long-	<u>Term Plan</u>	<u>UK Innovati</u>	on Strategy
Life Sciences Investment Programme		UAE-UK Sovereign Investment Partnership	
Supportive Public Institutions			
Office for Life S	<u>ciences</u> (OLS)	National Health	
National Institute for Health Research (NIHR)		<u>Academic Health</u> <u>Sciences Networks</u> (AHSNs)	Accelerated Access Collaborative (AAC)
<u>UK Research a</u>	& Innovation	Non-Depa	artmental
<u>Innovate UK</u>	Research Councils	<u>National Institute for</u> <u>Health and Care</u> <u>Excellence</u> (NICE)	<u>Health Data Research</u> <u>UK</u> (HDR UK)

# Largest and fastest ever expansion of support for research and innovation

### 2.4% of GDP on R&D by 2027, with a longerterm aspiration of 3.0%

- Additional £4bn invested in R&D since 2017
- 2<sup>nd</sup> globally for government spend on health R&D

# **Government Strategy and Programmes**

### **UK Life Sciences Vision**

<u>UK Life Sciences Vision</u> sets a 10-year strategy for the sector to build on the successes of our COVID-19 response and accelerate delivery of innovations to patients. The sector and the NHS will work together to make the UK a globally leading location for life science investment and innovation.

The Vision outlines <u>seven critical Healthcare Missions</u> that government, industry, the NHS, academia and medical research charities will work together on at speed to solve – from cancer treatment to tackling dementia.

### **Clinical Research Vision**

The <u>Clinical Research Vision</u> (CRV) outlines the UK's ambition to remain a globally-leading destination for cutting-edge clinical research with seven key commitments making the UK a more patient-centred, pro-innovation and digitally-enabled clinical research environment, where research is easier and faster to deliver across all research phases. It will be delivered through the UK Recovery, Resilience and Growth Programme (RRG).

### Life Sciences Industrial Strategy & Sector Deals

The Life Sciences Industrial Strategy and Sector Deals leading up to the new Life Sciences Vision have helped the UK to boost productivity and capitalise on the UK's existing competitive advantages, by setting and taking action with the industry to make the UK the home of clinical research and medical innovation, support higher risk science, and build on the UK's world-class

### R&D Roadmap

In the Government's <u>R&D Roadmap</u>, its long-term objectives for research and development (R&D) are clear: to be a science superpower and invest in the science and research that will deliver economic growth and societal benefits across the UK for decades to come, and to build the foundations for the new industries of tomorrow. This was supported by the unprecedented commitment at to increase public investment in R&D to £22bn by 2024-2025.

This plan represents the largest and fastest ever expansion of support for basic research and innovation, taking direct support for R&D to 0.8% of GDP and placing the UK ahead of the USA, Japan, France and China.

This high level of government investment provides the confidence required for investors to follow:

MSD will locate their new <u>Discovery Research</u> <u>Centre</u> and UK Headquarters in Central London. The <u>\$1.32bn complex</u> will accommodate 800 employees.

Brookfield is <u>investing hundreds of millions of</u> <u>pounds</u> into the growth of the <u>Harwell Science</u> and Innovation Campus.

BioMed Realty are <u>investing £850m into</u> <u>Cambridge</u> to double their current life sciences real estate footprint and offer more high Increasing public investment in R&D to £22 billion by 2024-2025.

Sources: UK Gov, 'UK Research and Development Roadmap,' Jan 2021; UK Gov, 'Bold new life sciences vision sets path for UK to build on pandemic response and deliver life-changing innovations to patients,' Jul 2021.

## Government Strategy and Programmes

### NHS Long-Term Plan

Launched in January 2019, the NHS Long Term Plan is a new plan to accelerate the redesign of patient care to future-proof the NHS for the decade ahead. It aims to improve the quality of patient care and health outcomes and sets out how the £20.5bn budget settlement for the NHS, announced by then Prime Minister Theresa May in summer 2018, will be spent over the following 5 years.

With thirteen areas of work, the 10-year plan will make sure the NHS is fit for the future. This bold vision will be implemented in cancer, cardiovascular disease, ageing well, digital transformation, prevention, stroke, respiratory disease and others. It includes measures to prevent 150,000 heart attacks, strokes and dementia cases and accelerating access to treatments, including therapeutics, genetic testing and more.

### UK Innovation Strategy

The UK's Innovation Strategy sets out the government's vision to make the UK a global hub for innovation by 2035 and is centred around four key pillars: Unleashing Business; People; Institutions & Places; and Missions &

- Technologies. Advanced Materials and Manufacturing
- Bioinformatics and Genomics
- AI, Digital and Advanced Computing
- Engineering Biology

### Life Sciences Investment Programme

The government has announced a new dedicated investment programme of around £600m to unlock the potential of the UK's best health and life science innovations, allowing companies to grow and ensure the UK remains a world-leader in life sciences innovation.

The funding will comprise a £200m investment through the government-owned British Business Bank alongside private sector investment which is expected to contribute a further £400m, creating high quality jobs and helping UK patients benefit from more ground-breaking treatments and care.

### UAE-UK Sovereign Investment Partnership (SIP)

DIT's Office for Invesment (OfI) and Abu Dhabi's Mubadala Investment Company, one of the world's leading sovereign investors, have signed a long-term investment agreement, the Sovereign Investment Partnership.

SIP includes an initial £800m commitment from Mubadala to invest in UK life sciences over five years as the first focus. The sum will be deployed alongside the UK's £200m Life Sciences Investment Programme, a vital pool of patient capital for the sector that will enable more UK life sciences businesses to scale and grow. The OfI and Mubadala will work together to identify commercially viable opportunities for investment into the sector.

# Navigating the Innovation Pathway

The organisations included below are the key public institutions involved at each step of the innovation and commercialisation pathway; further details are available on the following pages.

## Innovation

### **Evaluation**

# Adoption

### 1. Product Creation

Identification of market value of concept, impact on outcomes and market access barriers.

### 2. Product Development (Prototype)

Development and refinement of product ready for regulatory assessment and clinical



### 3. Product Development (Trials)

Clinical evaluation of product to demonstrate that it is safe and performs as intended.

### 4. Regulation

Assessment of product to ensure it conforms to the requirements for the relevant legislation in each jurisdiction in which the product is to be marketed.

### 5. Evaluation

Evaluation and endorsement of the health and economic case, clarification of reimbursement

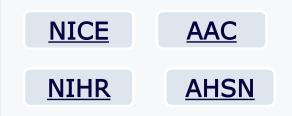


### 6. Adoption

Preparation for and entry to market, development of business case of patient & economic benefit and healthcare system impact.

### 7. Monitoring

Product is continually monitored whilst on the market to ensure continued safety and efficacy compliance.



# Public Institutions Supporting Innovation

### Office for Life Sciences (OLS)

The <u>Office for Life Sciences</u> champions research, innovation and the use of technology to transform health and care service. It is responsible for the sector's policy and the implementation of the newly launched <u>Life Sciences Vision</u>.

### UK Research and Innovation (UKRI)

With a budget over £7bn, <u>UKRI</u> is a public body which supports multidisciplinary research, bringing together <u>seven research councils</u>. It is funnelling £300m of investment towards developing world-class scientific and research infrastructure. It has also invested over £554m in a diverse range of over 3,600 new COVID-19 research and innovation initiatives in the UK and globally.

The research councils working to advance biotechnology include the <u>Biotechnology and Biological Sciences Research Council</u> (BBSRC) and the <u>Medical Research Council</u> (MRC).

#### Innovate UK

<u>Innovate UK</u> is the national innovation agency, working with industry players to drive science and technology innovations. It established the Catapult centres, a network of specialised world-leading technology centres, including <u>Medicines Discovery</u> (MCD) and <u>Cell and Gene Therapy</u> (CGT).

Innovate UK runs <u>grant funding competitions</u> and also offers other forms of funding, including <u>Smart Grants</u> and the <u>Small Business Research</u> <u>Sourcestor Live</u>, Stiffle AD007 Representation of the State of Source of Reverses Mar 2027: Investor Live, UKRI welcomes £300m investment in research infrastructure across UK, 'Jul 2020. businesses to innovate.

### National Institute for Health Research (NIHR)

The <u>NIHR</u> is the nation's largest funder of health and care research and provides the people, facilities and technology that enable research to thrive. It works in partnership with industry to successfully translate innovative ideas into the clinical setting.

The <u>Clinical Research Network</u> (CRN) is funded by the government and acts as the research delivery arm of the UK's National Health Service. It aims to provide a range of free services to help life science companies deliver clinical research in England.

You can access the interactive NIHR Industry Route Map of the CRN Study Support Service <u>here</u>.



In 2019/20, more than **732,000 participants** were recruited by the **NIHR Clinical Research Network** into health and social care studies.



NIHR supported 4,304 commercial contract studies in the same year and had 1,286 industry collaborative research projects.



NIHR awarded **over £250m of funding** to 310 new projects.

# Public Institutions as Data and Research Hubs

### Health Data Research UK (HDR UK)

HDR UK is the <u>national institute for health data science</u>. As an independent, nonprofit organisation, it works to unite the UK's health data to enable discoveries that improve people's lives through access to large scale data and advanced analytics.

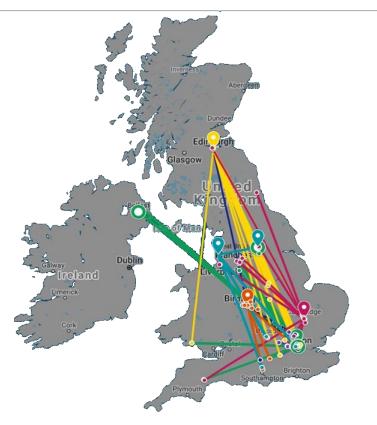
<u>HDR Innovation Hubs</u> are formal collaborations between the NHS, academic organisations, patients, charities and industry – in all totalling over 100 organisations across the UK. They are set up to demonstrate and drive the utility of expert health data science, based on an area of expertise, and provide and curate the data and offer services for research and innovation. To gain access to health data via the HDR Innovation Gateway, click <u>here</u>.

### HDR UK Health Data Research Hubs

<u>Health Data Research Hubs</u> are centres of excellence that focus on curated, disease-focused datasets, clinical trials and real world evidence. A network of expertise, tools, knowledge and ways of working, they involve patients and the public in shaping research activities and improve secure and responsible access to

<u>BREATHE</u> – Respiratory Health	<u>DATA-CAN</u> – Cancer
<u>Discover-NOW</u> – Real World Evidence	<u>Gut Reaction</u> – Inflammatory Bowel Disease
<u>INSIGHT</u> – Eye Health	<u>NHS DigiTrial</u> – Clinical Trials
PIONEER – Acute Care	<u>Alleviate</u> – Pain Research
DATAMIND – Mental Health Data	<u>BHF Data Science Centre</u> – Safe Data Usage

HDR UK established the <u>International COVID-19 Data</u> <u>Alliance</u> as a highly-secure <u>data platform</u> for scientists across the globe to collaborate more effectively on treatments to combat COVID-19.



Map of the HDR Hubs across the UK. Click on the image to access the interactive online map to learn more.

# Public Institutions Supporting Route to Market

### National Health Service (NHS)

The NHS is the world's largest integrated health service, providing a research, implementation and evidence generation platform with globally-unique data capabilities and deep clinical insights.

The NHS has been rated the top health system in the world and serves a genetically diverse population of over 66 million people; in fiscal year 2020/21, the NHS spent £212bn on healthcare and medicines procurement. Moreover, 100% of its hospital trusts were involved in non-commercial research in 2019/20.

To read more about selling to the NHS, click here.

### National Institute for Health and Care Excellence

<u>NICE</u> provides national guidance and advice on how to improve health and social care in order to make healthcare treatment more consistent across the UK. It works with medical colleges and expert organisations to provide the necessary guidelines.

- <u>NICE Scientific Advice (SA)</u> offers a fee-based consultancy service to biopharma medicine developers.
- <u>NICE International</u> advises international health organisations, ministries and government agencies seeking to use evidence-based decision making to improve their health and social care systems.

NICE's <u>RAPID C-19 initiative</u> has already given NHS patients rapid access to

### Academic Health Sciences Networks (AHSNs)

<u>AHSNs</u> facilitate access into the NHS to identify and spread health innovation at pace and scale. The 15 AHSNs, spread across England, work across their own distinct geographies and provide access to multiple avenues of <u>innovation support</u>, including the <u>Innovation Exchange</u> and the <u>NHS Innovation Accelerator</u> (NIA). The NIA has so far successfully supported 49 Fellows representing 52 innovations.

### Accelerated Access Collaborative (AAC)

<u>NHS Accelerated Access Collaborative (AAC)</u> brings together industry, government, regulators, patients and the NHS to remove barriers and accelerate the introduction of ground-breaking new treatments and diagnostics. The AAC has supported the spread of 26 late-stage innovations, and from April to December 2019, provided access to these products for over 400,000 patients.

The AAC has added two monoclonal antibodies, PCSK9 inhibitors from Sanofi and Amgen, to its list of <u>Rapid Uptake Products</u> (RUP) to help treat high cholesterol as part of a novel, NICE-approved clinical pathway for <u>lipid management</u> – read more <u>here</u>.

*Sources: NICE, 'Research to access pathway for investigational drugs for COVID-19 (RAPID-C19),' accessed Mar 2021; BBC, 'NHS ranked 'number one' health system,' 2017; NIHR, 'NIHR Annual Report 2019/20,' 2021.* 

# The Biopharma Landscape

The UK provides access to a supportive business ecosystem with opportunities to network and grow.



# The Biopharma Landscape



### **Centres of Excellence**

Benefit from world-leading centres of excellence across the country to develop innovative new medicines.



### Third Sector

Take advantage of the research funding, connections and clinical data offered by established charities and patient organisations.



### Trade Associations & Networks

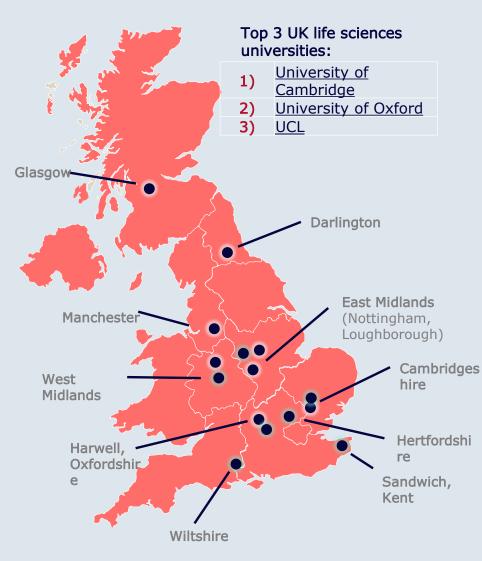
Connect with trade associations and networks to link with suppliers, buyers and institutions and be represented both nationally and internationally.



### Companies

Join other companies who have established themselves in the UK and benefited from the multitude of institutions, research networks and funding options available. The UK biopharma sector enjoys collaboration across industry, academia, government, the NHS, and other health funders.

### **Biopharmaceuticals Centres of Excellence**



Examples of life sciences centres of excellence – list not exhaustive

Centre of Excellence	City
MRC Laboratory of Molecular Biology	Cambridge
Wellcome Sanger Institute	Cambridge
National Horizons Centre	Darlington
National Biologics Manufacturing Centre	Darlington
Medicines Manufacturing and Innovation Centre	Glasgow
Precision Medicine Scotland Innovation Centre	Glasgow
Rosalind Franklin Institute	Harwell
Nucleic Acid Therapy Accelerator	Harwell
Francis Crick Institute	London
Centre of Excellence in Biopharmaceuticals	Manchester
Cancer Research UK Manchester Institute	Manchester
Manchester Centre for Genomic Medicine	Manchester
EPSRC Centre for Innovative Manufacturing in Regenerative Medicine	Nottingham, Loughborough
Nottingham University Therapeutic Antibody Centre	Nottingham
Vaccines Manufacturing and Innovation Centre	Oxford
Life Science Opportunity Zone*	Region
Stevenage Advanced Therapies Campus	Hertfordshire
Birmingham Health Innovation Campus	West Midlands
Harwell Science and Innovation Campus	Oxfordshire
Cambridge Biomedical Campus	Cambridgeshire
Porton Science Park	Wiltshire
Discovery Park	Kent
Charnwood Campus	East Midlands

\*Life Science Opportunity Zones are areas selected to highlight opportunities with available lab space, land to develop new facilities and links to universities.

Source: The World University Rankings 2021

# Biopharmaceutical Centres of Excellence

#### Harwell Science & Innovation Campus

The Harwell Science & Innovation Campus is a cutting-edge science campus based in Oxfordshire and covering over 700 acres. Named one of seven Life Science Opportunity Zones in the country, it hosts 1,000 people across 40 HealthTec / Life Sciences organisations, many utilising the capabilities of the large "open access" facilities such as the Diamond Light Source Synchrotron or the Central Laser Facility's "Octopus" for drug discovery and the development of biocompatible materials. Harwell is also home to the new <u>Rosalind Franklin Institute</u>, which is working to speed up drug design and development, the <u>Vaccines Manufacturing</u> and <u>Innovation Centre</u> and the <u>Nucleic Acid Therapy Accelerator</u>.

#### Medicines Manufacturing Innovation Centre

The <u>Medicines Manufacturing and Innovation Centre</u> (MMIC) in Glasgow is a unique, state-of-the-art facility offering transformative solutions in small molecule and fine chemical manufacturing. It is a collaboration between CPI, University of Strathclyde, UKRI, Scottish Enterprise and industry partners, AstraZeneca, Pfizer and GSK.

The centre will ensure the UK is a technology and innovation leader in pharmaceutical manufacturing, and the initial focus will be on technology translation for small molecule drug manufacture. It aims to address two challenges: the first is to develop an innovative continuous direct compression (CDC) platform enabling oral solid dosage medicines to be formulated more robustly and efficiently; the second is around using digital technology and automation to improve just-in-time medicine supply.

#### Francis Crick Institute

<u>Francis Crick Institute</u> is an independent organisation, established to as a flagship UK institute for discovery research in biomedicine. Its <u>founding partners</u> are the Medical Research Council (MRC), Cancer Research UK, Wellcome, University College London, Imperial College London and King's College London. The Crick was formed in 2015 and in 2017 became fully operational in a <u>state-of-the-art building</u> in central London, making it the biggest biomedical research facility under a single roof in Europe. 1,900 researchers and support staff bring together their wide-ranging knowledge and expertise to work across disciplines and explore biology at all levels, from molecules through cells to entire organisms.

#### National Biologics Manufacturing Centre

The <u>National Biologics Manufacturing Centre</u> aims to significantly increase the UK's manufacturing capability in biologics. The centre provides the facilities and extensive expertise to bridge the gap between academia and business, helping to turn great ideas into commercial reality. The £38m centre promotes industry collaboration across the supply chain, from research through to manufacture and commercialisation.

The Centre is part of the <u>Centre for Process Innovation</u> (CPI), a leading independent technology innovation centre and a founding member of the UK Government's High Value Manufacturing Catapult. CPI collaborates with universities, SMEs and large companies to help overcome innovation barriers and develop next generation bioproducts and bioprocesses.

Sources: Harwell Life Sciences Brochure, 'HealthTec at Harwell'; NEPIC, 'CPI Partners With Pfizer To Transform The Production Of Oral Solid Dosage Medicines, ' Feb 2021.

## Charity and Patient Organisations

The UK has a large, mature and powerful charity sector that supports industry research and development. In 2019/20, these organisations **contributed £1.9bn to UK health research**.

Association of Medical Research Charities (AMRC) brings together and supports health and medical charities to produce high-quality research. The AMRC's success is a result of influencing policy and research, and highlighting the sector's contribution to patient and public health.

<u>Wellcome Trust</u> has been a major driver of the UK's competitive international position, being pivotal in enabling world-leading centres such as the Sanger Institute, the Wellcome Genome campus and the Wellcome Trust Centre for Human Genetics. As the largest UK charity, it funds research across numerous health categories: in 2018, its research expenditure was £521m.

British Heart Foundation funds research into all heart and circulatory diseases and their causes. In 2018, it spent £86m on cardiovascular research.

<u>Stroke Association</u> provides specialist support, funds critical research and campaigns to make sure people affected by stroke get the very best care and support to rebuild their lives.

<u>Alzheimer's Society</u> is the UK's leading dementia charity. It supports those who are living with dementia, campaigns for change and funds research to find a cure. *Sources: UK Clinical Research Collaboration, 'UK Health Research Analysis 2018'; OLS, 'Life Sciences Competitiveness Indicators 2020,' 2021.*  <u>Cancer Research UK</u> funds research into pioneering work on the prevention, diagnosis and treatment of cancer in order to help save millions of lives. With great progress made over the last decades, the charity continues its work, which included  $\pounds$ 234m funnelled into cancer research in 2018.

<u>Asthma UK</u> supports world-leading research and scientists working to stop asthma attacks and, ultimately, cure asthma. In 2020, it merged with the British Lung Foundation, creating <u>a partnership</u> that will bring lasting benefits to everyone in the UK affected by asthma and other lung diseases.

<u>Diabetes UK</u> is a leading diabetes charity focused on providing healthcare and research to help those living with Diabetes. In the last decade, it has invested over  $\pounds 66m$  into critical research.

<u>Cystic Fibrosis Trust</u> is the only UK-wide charity dedicated to fighting for a life unlimited for everyone affected by cystic fibrosis. It works towards a brighter future for everyone with cystic fibrosis (CF) by funding cutting-edge research, driving up standards of care and supporting people with the condition and their loved ones every step of the way. It also has one of the <u>world's leading databases of patient</u> information, holding the data of 99% of people with CF in the UK.

## Trade Associations & Regional Networks

#### Medicines Manufacturing Industry Partnership (MMIP)

<u>MMIP</u>, supported by ABPI, BIA and the Knowledge Transfer Network, represents the voice of medicines manufacturers in the UK. It was established jointly by the Government and the biopharmaceutical industry in 2014 to ensure that the UK is recognised by the global medicines industry as a world-class advanced centre for medicines manufacturing.

#### Association of the British Pharmaceutical Industry (ABPI)

The <u>ABPI</u> is the UK's leading industry association for health technology (HealthTech). Members, including both multinationals and SMEs, supply products from syringes and wound dressings to surgical robots and digitally enhanced technologies. They represent the industry to stakeholders, such as the government, NHS and regulators.

#### **BioIndustry Association (BIA)**

<u>BioIndustry Association</u> is the trade association for innovative life sciences in the UK, and it aims to secure the UK's position as a global hub and as the best location for innovative research and commercialisation. It works to further the interests of members and the industry both nationally and internationally. Members include start-ups, emerging and more established bioscience companies; pharmaceutical companies; academic, research and philanthronic organisations; and service providers to the

#### British Generics Manufacturers Association (BGMA)

The <u>BGMA</u> represents the interests of UK-based manufacturers and suppliers of generic medicines and promotes the development of the generic medicines industry in the United Kingdom. Its members account for approximately 85% of the total UK generic market by volume.

#### Knowledge Transfer Network (KTN)

Established by Innovate UK, the <u>Knowledge Transfer Network (KTN)</u> is the UK's innovation network. It brings together business, entrepreneurs, academics and funders to develop new products, processes and services across sectors, including <u>Biotechnology</u> and <u>Health</u> with further specialist areas.

**Regional Trade Associations** include <u>One Nucleus</u> (Greater London-Cambridge), <u>OBN</u> (UK-wide), <u>BioNow</u> (North of England), <u>SEHTA</u> (South East England), <u>Scottish Life</u> <u>Sciences Association</u> (Scotland), <u>HIRANI</u> (Northern Ireland), and <u>MediWales</u> (Wales).

**Click** for a comprehensive list of the UK life sciences trade organisations, membership associations, clusters, and research and innovation networks support.



82%

82% of the businesses in the industry are SMEs; these employ 24% of the industry total and generate 10% of the turnover.

31%

The Core Biopharma sector has a higher percentage of non-SME businesses at 31% compared to 18-19% for all other sectors.



The Top 25 Global Pharmaceutical companies with activity in the UK (and are non-SMEs) employ 55% of the Core Biopharma sector.

Sources: OLS, 'UK Bioscience and Health technology Sector Statistics 2019,' 2020;

### Location and relative level of employment for the Core **Biopharma and Service & Supply**



\*SME status is based on the European definition of Small and Medium-Sized Enterprises (SMEs) and refers to businesses with fewer than 250 employees

#### Autolus

<u>Autolus</u>, spun out of University College London, is a clinical-stage company developing next-generation programmed T cell therapies for cancer treatment. It established its HQ and research operations in the UK, creating over 300 jobs and raised more than \$500m when it was listed on NASDAQ in 2018.

Autolus benefited from the favourable environment in the UK, including manufacturing support from the CGT Catapult in Stevenage, academic collaborations with several UK universities and 7 Innovate UK grants totalling more than £10m. It is also an active partner in the <u>Advanced</u> <u>Therapy Treatment Centres</u> (ATTC) project.

#### Cell and Gene Therapy Catapult

The Cell and Gene Therapy Catapult manufacturing centre is home to manufacturing bases for Freeline Therapeutics, Autolus, Achilles Therapeuticsa and Adaptimmune. The CGT Catapult has helped to more than triple the size of the advanced therapies industry in the UK since 2012. Benefit from the innovation Catapults and generous grant funding.

Manufacture novel medicines at dedicated world-class facilities

*Sources: DIT, 'Invest in UK Life Sciences GSP,' 2020; DIT, 'Invest in UK Medicines Manufacturing GSP,' 2020; DIT, 'Invest in UK Advanced Therapies GSP,' 2020.* 

## Novartis and Oxford Biomedica

Oxford Biomedica has the first commercially approved lentiviralbased gene delivery system and helped Novartis deliver the first FDA and EMA approved CAR-T cell therapy, Kymriah. Novartis used Oxford Biomedica's LentiVector platform to develop their CAR-T therapy for acute lymphoblastic leukaemia. Kymriah was approved by the European Commission in August 2018.

A commercial deal with NHS England was approved less than 10 days later, representing one of the fastest funding approvals in the 70-year history of the NHS. Several hundreds of patients globally have now received treatment with therapies that use Oxford Biomedica's lentiviral vectors.

#### **Cynata Therapeutics**

In 2017, <u>Cynata Therapeutics</u>, a small Australian company, brought its clinical research to the UK to investigate the safety and efficacy of a new stem cell treatment. Cynata picked the UK after speaking to regulatory authorities in the UK, Europe and other regions, finding that the MHRA was particularly helpful and pragmatic in terms of what was required from the company to be able approve the clinical trial in the UK.

The UK clinical research sites exceeded Cynata's recruitment target for the rare disease under study, successfully recruiting 16 patients by May 2018. Smarter working between NHS and industry means faster access for patients

Benefit from pragmatic regulation and fast recruitment for clinical research

#### ADDoPt

<u>ADDoPT</u> is a four-year, £20.4m project addressing the pharmaceutical industry's desire to deliver medicines more effectively to patients. It is supported by MMIP, industry partners such as Pfizer, GSK and AstraZeneca UK, and the University of Leeds and Cambridge.

This collaboration has enabled partners from across the pharma value chain to define a system for top-down, knowledge-driven digital design and digital operation for drug products and their manufacturing processes.

#### Novo Nordisk

<u>Novo Nordisk UK</u> is investing £100m in a landmark strategic alliance with the University of Oxford, the Novo Nordisk Research Centre Oxford (NNRCO) that will employ more than 100 scientists. With close proximity to academic centres of excellence in Oxford, London and Cambridge, NNRCO is focused on target discovery and translational research for type 2 diabetes and cardiovascular disease.

NNRCO is embracing collaboration, making use of academic-industry collaborations, human genetics and big data from sources such as UK Biobank. Work across the industry to find solutions and enable digital transformation

Make use of high-quality research and data sources like UK Biobank

*Sources: DIT, 'Invest in UK Life Sciences GSP,' 2020; DIT, 'Invest in UK Medicines Manufacturing GSP,' 2020; DIT, 'Invest in UK Advanced Therapies GSP,' 2020.* 

#### NHS and Novartis

In 2021, <u>Novartis</u> agreed a deal with NHS for use of the new type of cholesterol-lowering drug Inclisiran. This first NHS 'population health agreement' will enable 300,000 patients with high cholesterol and a history of cardiovascular disease to benefit from the lifesaving drug over the next three years, a figure that could rise to nearly half a million people beyond that initial period. It has been estimated that Inclisiran could prevent 55,000 heart attacks and strokes, with the potential to save 30,000 lives within the next 10 years.

Leading up to this rollout, the UK supported Novartis (and before Novartis, The Medicines Company) on clinical trials for this innovative medicine and on innovation in manufacturing.

This type of population medicine deal is a win-win for industry and for the NHS and patients, delivering new and improved treatment and prevention options faster by working in partnership. Innovative partnership working between NHS and industry on population health solutions

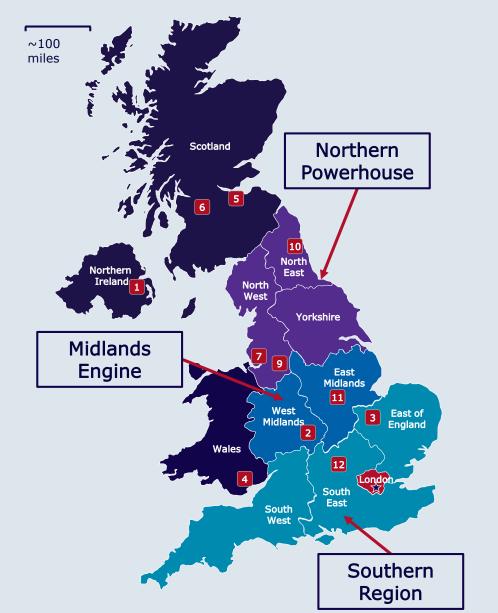
*Sources: DIT, 'Invest in UK Life Sciences GSP,' 2020; DIT, 'Invest in UK Medicines Manufacturing GSP,' 2020; DIT, 'Invest in UK Advanced Therapies GSP,' 2020.* 

## Local Strengths and Capabilities

The UK demonstrates local strengths and capabilities in a number of regions.



## Opportunities and Expertise Across the UK



#### **Regional Summary**

The UK's biopharmaceuticals opportunities span the country. Each region's economy is supported by a large, talented workforce, 66% of which lies outside the South East and London; world-class life sciences infrastructure including lab space, science parks and manufacturing facilities, as well as incubators and accelerators in which to start up and scale up; established clinical trials networks for streamlined trial operations; and access to public and private funding.

Specialised clusters offer opportunities in high growth subsectors such as precision medicine, cell and gene therapies, vaccine manufacturing, data science and more. The UK has highlighted these High Potential Opportunities (HPOs) to increase inward investment into the UK. Information on HPOs is available on the Great Asset Library. Finally, Northern Ireland, Scotland, Wales and much of the North of England and Midlands benefit from lower costs, taking into consideration salaries and Grade A office space.

The UK's high-growth and high-potential biopharma cities include: 1) Belfast 7) Liverpool

2) Birmingham

8) London

- 3) Cambridge
- 4) Cardiff
- 5) Edinburgh
- Glasgow 6)

- 9) Manchester
- 10) Newcastle
- 11) Nottingham
- 12) Oxford

Learn more about each region's biopharmaceutical offer by reaching out to local investment agencies. More information for England here; Scotland; Wales; and Northern Ireland.

## Scotland

#### **Overview & Specialisms**

Scotland benefits from an integrated healthcare infrastructure which has received significant recent investment to advance R&D for stem cell-based treatments, invitro applications and <u>precision medicine</u> (Scotland won a High Potential Opportunity bid for its Precision Medicine sector). Its ATMP sector is growing rapidly, and the region has one of the largest (stem) cell research cohorts across Europe with the <u>Scottish National Blood Transfusion Service</u> acting as a leading authority in developing cell-based therapies; specific expertise exists in cystic fibrosis, cardiovascular disease and neurodegeneration.

With <u>a vibrant industry cluster</u> and supply chain, growing GMP manufacturing capabilities – including the <u>MMIC</u> in Glasgow – and ongoing public/private investment, Scotland provides a fantastic opportunity for companies. This is particularly true of the gene therapy activity in Scotland as exemplified by the recent acquisition of <u>Synpromics</u> by US company AskBio (now part of Bayer).

#### Research Excellence & Health Assets

Centre for Tissue Repair	Jack Copland Centre
NHS Research Scotland	Northern Alliance ATTC
Scottish Biologics Facility	<u>UK Advanced Therapies Skills and</u> <u>Training Network (ATSTN)</u>
Scottish Centre for Regenerative Medicine	Medicines Manufacturing and Innovation Centre

#### Skills & Talent

With over 21,000 STEM graduates in 2018/19, Scotland is home to a thriving pipeline of talent for the biopharma sector. Future biopharma skills are a crucial component of Scotland's ATMP & Vaccines Growth Strategy and are already being delivered through a Scottish consortium as part of the Cell & Gene Therapy Catapult-funded <u>ATSTN</u>. <u>University of</u> <u>Edinburgh</u> is also home to cell and gene therapy-based research with a reputation for excellence, and a variety of <u>apprenticeships</u> help employers develop their workforce through training and upskilling.

#### Business & Scale-Up Ecosystem

A growing biopharma hub is based in Edinburgh made up of spin-outs through to established global companies – specifically in the corridor extending between <u>Edinburgh</u> <u>BioQuarter</u>, <u>Bush Estate BioCampus</u> and the <u>Riccarton</u> <u>Campus</u>. Both the BioQuarter and Riccarton sites have GMP manufacturing facilities with additional biomanufacturing capacity in the pipeline. Scotland is also home to a supportive and internationally acclaimed clinical trial infrastructure.

The country's biopharma companies include TC Biopharm, Valneva, <u>Roslin Cell Therapies</u> and Syneos; world-leading service providers such as <u>Charles River Laboratories</u>, <u>Merck</u> <u>BioReliance</u>, <u>Thermo Fisher</u>, <u>Catalent</u> and <u>IQVIA</u>; and specialised 'home-grown' companies like <u>Scotia Biologics</u> and <u>Symbiosis</u>.

Support and funding are available through <u>Scottish</u> <u>Bruce of Striken and Contained (SDP)</u>, <u>Scottish</u>

## Northern Ireland

#### **Overview & Specialisms**

Northern Ireland offers a strong connected and collaborative setting where global pharma companies work with academia, health organisations and government to maximise opportunities from research, manufacturing and sales. The region's large cluster of companies have capabilities spanning the whole drug development value chain with specialism in drug development and strengths in biomarker discovery and validation. NI's pharma sector has also achieved strides in biomedical research for cancer, cardiovascular disease and cystic fibrosis.

The Belfast Region City Deal, a bespoke investment of £850m, has a major focus on skills development to support the life sciences sector, including in healthcare data and technology-related areas, and three life sciences focused projects: <u>CDHT</u>, <u>iREACH</u> and <u>GII</u>. This deal aligns with the <u>NI Life & Health Sciences Foresight</u> <u>Report</u>.

#### Business & Scale-Up Ecosystem

The pharma sector in Northern Ireland supports 7,800 FTE jobs and generates  $\pm$ 310m in GVA. Northern Ireland offers an extremely cost competitive business environment to inward investors; office rents are among the lowest in Western Europe, and salary levels are extremely competitive. Teva NI, Millicent Pharma, Terumo BCT, Norbrook Laboratories, Millicent Pharma are some of the major companies who have chosen to locate in Northern Ireland.

<u>Invest Northern Ireland</u> supports inward investors at every stage of their journey, and support packages can include grants, R&D schemes, non-financial incentives and support and more.

#### **Dual Market Access**

The Northern Ireland Protocol has created dual market access to the EU and UK markets for businesses. It is now the only place where businesses can operate free from customs declarations, rules of origin certificates and non-tariff barriers on the sale of goods to both GB and the EU. It is also the only part of the UK where batch release is recognised by the EU, making it an ideal location for biopharma

#### Skills & Talent

NI is home to almost 4,000 students across STEM subjects, and Queen's University and Ulster University offer a wide range of courses aligned to the life sciences sector. Northern Ireland also provides Higher-Level Apprenticeships (HLA) foundation degrees in Life and Health Sciences such as Applied Industrial Sciences in the Higher Education Colleges and the <u>Assured Skills</u> <u>Programme</u>.

Research Excellence & Precision Medicine Centre	Northern Ireland Centre for
of Excellence (PMC)	Stratified Medicine
Wellcome-Wolfson Institute for Experimental Medicine	<u>Health Innovation</u> <u>Research Alliance Northern</u> <u>Ireland (HIRANI)</u>
<u>Northern Ireland Clinical</u>	Medicines Optimisation
<u>Research Network (NICRN)</u>	Innovation Centre (MOIC)
Patrick G Johnston Centre for Cancer Research	

Sources: Invest Northern Ireland, Apr 2021; ABPI, Contribution of the pharmaceutical sector to Northern Ireland's economy', Oct 2020; HESA 2018/19.

## Wales

#### **Overview & Specialisms**

Wales has leading global clinical and research expertise in wound healing, neurosciences, oncology and regenerative medicine. Wales is particularly strong in precision medicine as home to <u>Genomics Partnership Wales</u>. Cardiff University and its partners have a wide portfolio of multidisciplinary research in precision medicine, including in imaging, AI, clinical diagnostics, diagnostic biomarker technologies, genomics, advanced therapies and data science, alongside strong links with clinical and business partners.

Wales is at the forefront of eHealth research and maximizes the use of routine data for research. NHS Wales allows access to anonymised healthcare data for the whole population in one database – <u>SAIL</u> – and enables clinical trials to access three million people with a single co-ordinated permissions process. It's easy to collaborate with NHS clinicians and universities to move research projects towards market readiness.

#### Business & Scale-Up Ecosystem

The Welsh Government has a dedicated team that looks after investors in the country and offers companies a range of business support, including relocation incentives and the <u>Development Bank of Wales</u>. Research and incubation space is available at <u>Clinical Innovation Accelerator</u>, <u>AberInnovation</u>, <u>North Wales Clinical Research Centre</u> and <u>Cardiff Medicentre</u>.

Biopharma companies in Wales include Ipsen, Trakcel, Neem Biotech, Wockhart, Cellpath, Cytiva, ADC Biotech and PCI Pharma

#### Skills & Talent

Wales had around 11,500 STEM graduates in 2018/19 and has also become the first country in the world to launch specialised <u>Intensive Learning Academies</u> that will deliver transformational training and support across preventative health, Value-Based Health and Care, and innovations in health and social care.

Wales has competitive strengths in enabling technologies such as Cyber security, big data analytics and AI which underpin digital innovation in healthcare; 45,000 people are employed in the digital economy. It is also developing as a hub of advanced manufacturing, attracting companies such as ReNeuron which has one of the most advanced commercial cell therapy manufacturing facilities in the UK in Pencoed, South Wales

MRC Centre for	<u>Cardiff University Brain</u>
Neuropsychiatric Genetics	<u>Research Imaging Centre</u>
and Genomics	<u>(CUBRIC)</u>
European Cancer Stem Cell <u>Research Unit</u>	Life Sciences Hub Wales
<u>Welsh Wound Innovation</u>	<u>Institute of Life Science</u>
<u>Centre</u>	(Swansea)
<u>IBERS</u>	<u>Health &amp; Care Research</u>
(Aberystwyth)	<u>Wales</u>
Cardiff Institute of Tissue Engineering & Repair (CITER)	

## London

#### **Overview & Specialisms**

London sits at the heart of the UK's "Golden Triangle" for Life Sciences. The region (consisting of Greater London, Cambridge and Oxford) forms a world-leading cluster rivalled by few in terms of sheer size, diversity and depth of commercial and academic life. There are over 1,300 life sciences companies in London alone, and together, the wider region is home to 3,700+ companies, 193,000+ employees and 19 of the top 20 global pharmaceutical companies. The Golden Triangle life sciences sector attracted £3.3bn of capital in 2020.

London has specialisms in advanced therapies/cell & gene therapy and the application of data and AI in biopharma. Nine MHRA-licenced cell and gene therapy manufacturing sites are based in London, with a total of 836m<sup>2</sup> of cleanrooms, and the <u>Advanced Therapies Network</u> (ATN) connects businesses, investors and researchers. Companies like Benevolent AI are using AI to speed up drug discovery, and global biotech Synthace uses AI to automate lab experimentation. Data assets are available through inter alia East London Genes & Health, the 100,000 Genomes Project and the cancer-focused <u>canSAR database</u>.

Biopharma companies also have access to a diverse NHS patient population to run clinical trials. Between 2015 and 2020, over 5,000 commercial clinical trials took place in London Mandy nearby ty Anap, Opr popple a Ware if estimited. Trends & Outlook, ' Jan 2021; London & Partners, Apr 2021; HESA 2018/19.

#### Business & Scale-Up Ecosystem

London offers a 3-month <u>Business Growth Programme</u> to help start-ups grow across the capital as well as a 12-month Mayor's <u>International Business Programme</u> to helps scale-ups grow internationally. To date, these programmes have supported more than 2,000 London-based companies, creating more than 15,000 jobs. Further life sciences incubators and accelerators include <u>London BioScience Innovation Centre (LBIC)</u>, <u>QMB</u> <u>Innovation Centre</u>, <u>KQ Labs</u>, <u>P4 Precision Medicine Accelerator</u> and <u>Imperial White</u> <u>City Incubator</u>.

Some of the key companies operating in London include Cell Medica, Novartis, Ori Biotech, Merck, Orchard Therapeutics, MeiraGtx, Pfizer, GSK, Autolus, AbbVie and Capella Bioscience.

#### Skills & Talent

With almost 40,000 graduates across STEM subjects in 2018/19 as well as worldrenowned universities such as UCL, Imperial College London, Kings College London, Queen Mary and London School of Hvaiene & Tropical Medicine. London is a thriving hub of new Wellcome Trust Erancis Crick Institute

new	<u>Wellcome Trust</u>	Francis Crick Institute
	Alan Turing Institute	Barts Health NHS Trust
	<u>Cell &amp; Gene Therapy</u> <u>Catapult</u>	Institute for Cancer <u>Research</u>
	South London Genomic Medicine Centre	Guy's and St Thomas' NHS Foundation Trust

## Northern Powerhouse

#### **Overview & Specialisms**

The Northern Powerhouse competes globally, outperforming other key cities and regions with lower costs and a consistently high-quality labour force and world-class facilities. It offers opportunity to ambitious biopharma companies in the main clusters around Manchester, Liverpool and Newcastle, and the region has local expertise in genomics and biomarker discovery, cell & gene therapies, ATMPs, antibody sequencing, immunology and digital health. After London, Manchester is the UK's leading digital city.

The region also has a large and robust clinical trial ecosystem with leading NHS Trusts such as the Christie Foundation Trust, Manchester Royal Infirmary, Newcastle Upon Tyne Hospitals and St James Hospital in Leeds. Both the Christie and Newcastle Upon Tyne trusts run around 500 trials annually.

<u>Alderley Park</u>, a world-renowned science park located outside Manchester, is the UK's largest single site life science campus. It provides a space for international collaboration whilst benefiting from Enterprise Zone status, has an Oncology Development Programme and is partnered with the Medicines Discovery Catapult and <u>Cancer Research</u> <u>UK</u> (CRUK). One of CRUK's five major research centres is also located in Manchester.

Other parks include <u>Liverpool Science Park</u>, <u>York Biotech</u> <u>Campus</u>, <u>Netparks</u>, <u>The Biosphere</u> <u>Jocated</u>, <u>in</u>, <u>the Helix</u>, in <u>Newcastles</u> <u>LiverprovAcceverator</u>, <u>shealth Innovation Campus</u> in Lancaster. South Tees Bio-incubator and Manchester

#### Business & Scale-Up Ecosystem

Local agencies across the region offer a range of support service, soft landing packages and access to funding, including the <u>Greater Manchester and East Cheshire</u> <u>Life Science Fund</u>, <u>Access 2Finance</u>, <u>Deepbridge Life Sciences EIS</u> and the <u>Northern</u> <u>Powerhouse Investment Fund</u>. Life sciences businesses are connected <u>Bionow</u> and the <u>Northern Health Science Alliance</u> (NHSA), and through the <u>NW HealthTec Cluster</u> in the North West.

#### Skills & Talent

Over 55,000 STEM students graduated in 2018/19 from the North's Universities of Manchester, Durham, Sheffield, Leeds, Liverpool, Newcastle and more. The region is focusing on further developing the necessary skills through programmes such as Manchester's <u>Skills and training</u>, Lancashire's <u>Skills Hub</u> and Tees Valley's <u>National</u> Horizons Cé

<u>ns C</u>	North West e-Health	NIHR Leeds Biomedical Research Centre
	Manchester Institute of Biotechnology	Healthcare Innovation Centre
	<u>Christabel Pankhurst Institute</u> <u>for Health Technologies</u>	Centre for Health Informatics, Computing, and Statistics
	Biomedical and Life Sciences Centre	UCLan Research Centre for SMART Materials
	National Biologics Manufacturing Centre	North East Process Industry Cluster (NEPIC)

## Midlands Engine

#### **Overview & Specialisms**

The Midlands is home to one of the most concentrated clinical trials clusters in Europe and carry out the largest number of cancer trials in the UK, underpinned by novel design and delivery and supported by the <u>NIHR Clinical Research</u> <u>Network West Midlands</u> and the <u>Nottingham Biomedical</u> <u>Research Catalyst</u>. The West Midlands is also home to one of the UK's three Advanced Therapy Treatment Centres (<u>Midlands and Wales Advanced Therapy Treatment Centre</u>), established to address the unique and complex challenges of bringing pioneering advanced therapy medicinal and products to patients, with a particular focus on proving supply chain capabilities.

There are two Life Science Opportunity Zones in the Midlands: <u>Birmingham Health Innovation Campus</u> and <u>Charnwood Campus</u>. Charnwood Campus houses the Almac Group's drug development services, research and GMP manufacturing facility, 3M Health Care's national centre, Kindeva Drug Delivery's manufacturing and R&D, and one of the diagnostic megalabs called <u>Lighthouse Labs</u>.'

#### Skills & Talent

The Midlands is home to several large hospital trusts and world-leading research institutions. In 2018/19, the region's universities – Universities of Aston, Coventry, Birmingham, Warwick, Wolverhampton and others – produced over 36,000 STEM graduates, delivering on the future skills and talent Sources: HESA 2018/19: Greater Manchester LEP; Lancashire LEP; North East NEP, Tees Valley LEP, York & North Yorkshire LEP.

#### Business & Scale-Up Ecosystem

The region has a vibrant accelerator and incubation ecosystem which includes <u>BioHub</u> <u>Birmingham</u>, <u>Warwick Science Park</u>, <u>Spark Business Incubation Centre</u>, <u>Leicester Life</u> <u>Sciences Accelerator</u> and <u>C3 Innovation Centre</u>. <u>BioCity Nottingham</u>, part of the We are Pioneer Group, is one of the UK's largest bioscience incubators with over 60 companies and has a dedicated <u>Business Accelerator Programme</u>. Businesses in Leicestershire can also take advantage of <u>SoLSTICE</u>, a project which provides support, advice and grants for life science businesses.

Over 90% of the UK market can be reached within 4 hours travel time which is ideal for companies looking for a sales and distribution base. Some of the key companies in the region include Abbot Health, Clinigen, AAH Pharmaceuticals, Catalent, Sygnature Discovery, Albumedix.

#### Research Excellence & Health Assets

Birmingham Health Innovation Campus	Birmingham Precision Medicine Centre
Charnwood Campus	Precision Medicine Institute
Institute of Translational Medicine (ITM)	Nottingham School of Medicine Division of Cancer and Stem Cells
<u>Manufacturing Technology</u> <u>Centre</u>	<u>Warwick Centre for</u> Industrial Biotechnology and Biorefining

## Southern Region

#### **Overview & Specialisms**

The life sciences ecosystem in England's southern region is highly diverse, with exceptional skills and talent in genomics, small molecules, oncology, advanced therapeutics, digital healthcare, infectious diseases, vaccines and personalised healthcare. It is also home to the 'Golden Triangle', one of the strongest life science and healthcare clusters in the world (after the Boston/ Massachusetts and San Francisco/Bay Area clusters). The region benefits from strong connections between an innovative private sector, local hospital trusts and world-class academia, which allows for the sourcing, delivery and supply of healthcare products and services and results in high growth; the Cambridge Cluster has been growing employment by an average of 10% a year for the last six years and turnover by 18% a year over the same period.

Moreover, five of the seven <u>Life Science Opportunity Zones</u> are located across the South and have acted as engines for growth. The Advanced Therapy Campus at Stevenage has been instrumental in growing the largest cell and gene therapy cluster outside of the US.

The University of Oxford's <u>Old Road Campus</u> is also home to much of the institution's world-leading clinical medical research and is close to Oxford's hospitals, including <u>Oxford</u> <u>University Hospitals NHS Foundation Trust</u>; Addenbrookes Hospital in Cambridge, Salisbury NHS Trust, Berkshire NHS Trust and others also support critical medical research. The <u>Norwich Research Park Office</u> offers a gateway to the <u>partner</u> <u>Institutions</u> and their <u>facilities</u>. And the UK's Medical Research Council, Innovate UK and the Biotechnology and Biological Sciences Research Council are beadquartered in Swindon.

#### Business & Scale-Up Ecosystem

Businesses and investors in the South benefit from a range of leading accelerators and incubators, support, funding and a high quality of life. They can access the <u>Joint</u> <u>Research Office</u>, <u>Bioinnovation Hub</u> and <u>Didcot Growth Accelerator (EZ)</u> in Oxford; <u>Babraham Research Campus</u>, <u>Start Codon</u> and <u>EpiCentre</u> in Cambridge; Dorset's <u>One</u> <u>Health Accelerator</u>; the <u>Thames Valley Science Park</u> in Reading as well as <u>Norwich</u> <u>Research Park</u> and <u>Hethel Engineering Centre</u>. Key companies in the region include Illumina, Bespak, Horizon Discovery, AstraZeneca, Sanofi, Lab 21 Healthcare, Baxter Healthcare, WyChem, Sigma Aldrich, Achilles Therapeutics, Catalent and more.

#### Skills & Talent

The South encompasses some of the world's best universities, including the Universities of Cambridge and Oxford (Oxford was ranked the best in the world for four consecutive years), and in 2018/19, just over 60,000 graduates completed degrees across STEM subjects, forming a strong pipeline of talent for the key skills

Cambridge BioMedical Campus	Surrey Research Park
Target Discovery Institute	Rosalind Franklin Institute
Wellcome Centre for Human Genetics (Oxford)	National Institute for Biological Standards and Control
Wellcome Sanger Institute/Genome Campus (Cambridge)	National Institute for Cardiovascular Outcomes Research (NICOR)
Vaccines Manufacturing Innovation Centre (VMIC)	Bristol Synthetic Biology Research Centre
<u>John Innes Centre;</u> <u>Earlham Institute;</u> <u>Biomedical Research Centre</u>	

*Sources: Invest Bristol & Bath/WECA, May 2021; HESA 2018/19; Cambridgeshire & Peterborough LEP; Coast to Capital LEP; Dorset LEP; Hertfordshire LEP; Oxfordshire LEP; Swindon & Wiltshire LEP; Thames Valley Berkshire LEP, New Anglia LEP.* 

Additional Propositions of Interest

There are a number of other propositions which may be of interest.



## Have you seen these Repeace Stherphopositions which complement this Medical Technologies proposition and may be of interest.











#### Upcoming High Potential Opportunities

- Cell and Gene Therapy Hertfordshire
- Molecular Diagnostics & Early Detection – Greater Manchester and Cheshire
- Precision Medicine Scotland
- Precision Medicine –Northern Ireland
- Data Driven Healthcare and Technologies – Greater Birmingham and Solihull
- MedTech Health Wales

Department for International Trade Offer

The Department for International Trade (DIT) can provide support and assistance for your business.



## DIT support for Investors

The Department for International Trade (DIT) provides endto-end support for inward investors in the UK.

We support your investment journey whether you are a brand new inward investor or already have an established business in the UK.

If you would like to talk to our specialist team about the opportunities for your business in the UK and how we can help, contact <u>lifescience@trade.gov.uk</u> or your local DIT contact.

You will be introduced to an experienced account manager in the UK or in your home market.

#### Where will we go from there?

- We will scope your requirements and where you are now along your investment journey
- We will agree with you a set of next steps
- We will assemble a team to support you
- We can help you benchmark the UK against other locations
- We can arrange and host visits to the UK to meet with potential partners or to see locations and sites
- We can coordinate your UK site search
- We can connect you to subject matter experts in a range of areas
- We can advise on tax incentives and access to finance
- We can connect you into the industry community and other sector networks, to facilitate networking and peer-

Services we provide to overseas companies (inward investors) include:

- Accessing market opportunities: helping international companies assess market opportunities in the UK
- Access and introductions to the right people: working with every UK government department to support access to a vast network of industry experts
- Setting up in the UK: we provide a range of support from applying for visas and entry to the UK to set up procedures, to the UK tax system and site selection
- Bespoke market research: compiling in-depth factual reports including market entry support, research and development collaborations and cost analysis
- On-going government support: continued support after your business is established in the UK, providing assistance on expansion and representing your interests in government
- Entrepreneurial assistance through a network of mentors to help make a commercial success of early stage companies



#### Department for International Trade

The UK's Department for International Trade (DIT) has overall responsibility for promoting UK trade across the world and attracting foreign investment to our economy. We are a specialised government body with responsibility for negotiating international trade policy, supporting business, as well as delivering an outwardlooking trade diplomacy strategy.

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