



Our strategy for regional growth and national change in health, life sciences and medicines manufacturing.

January 2021



Foreword

This strategy has been finalised at a time when the world is grappling with the social and economic consequences of COVID-19. The pandemic has challenged policy makers, health professionals and manufacturers to deliver immediate responses to the health challenges faced and to build a more resilient health environment for the future.

The North East has made an active contribution to the immediate response, both regionally and nationally through our manufacturing and innovation strengths, our public health and care services, and in the development of testing. This has utilised the best of our diverse life sciences, health innovation and medicines manufacturing capabilities - capabilities that are established and identified as an area of strategic importance in our Strategic Economic Plan (SEP).

We have opportunities to strengthen regional growth in the pharmaceuticals industry, which is valued at over \$1.25 trillion per annum globally, and to improve the performance of our healthcare system, which accounts for 10% of GDP, through new technologies and treatments that will have a positive impact on business growth and the quality of people's lives. Both areas are recognised by government as national strengths and a focus for investment, innovation and growth through the UK Life Sciences strategy. This regional strategy demonstrates how the North East can be positioned as a central contributor to this part of our country's economic future.

The health and life sciences industry generally is experiencing significant change. For our manufacturers, digitalisation is resulting in new methods of production and packaging. New methods of formulating drugs and new therapies are leading to novel treatments being trialled, developed and introduced. For health services, technologies like data and genetics are creating new opportunities to diagnose and target treatments. Digital communications are creating new possibilities to communicate between patients and practitioners. Each of these trends has been accelerated by the COVID-19 pandemic.

Looking forward, in a world increasingly characterised by population ageing, the countries and businesses that can add quality of life to these extra years will generate high levels of personal wellbeing, higher workforce productivity and new opportunities for economic value from these developments. The focus has therefore to be on integrating care and the development and production of more targeted and personalised medicines.

For these reasons our vision for this strategy is:

“To position the North East as a leader in the development, testing, manufacturing and adoption of people-centred treatments, therapeutics and medicines at a time of demographic change.”

It sets out the ambitious but realistic aims of doubling both the number of jobs and the number of businesses active in this area of our economy over the next decade and identifies priority interventions that will enable the trial and introduction of new and improved approaches which can improve global health from the North East.

The strategy has been developed by the North East Life Sciences Steering group which brings together leaders from all parts of our health, life sciences and medicines manufacturing eco-system to work together to drive forward the interventions.

I would like to thank the members of the Steering Group and pay tribute to the Chair, Professor Michael Whitaker for his personal commitment and excellent leadership. It provides a platform for collaboration with partners in government and other parts of the country, which I look forward to and I am delighted to see it come to fruition.



Lucy Winskell OBE
Chair, North East Local Enterprise Partnership

The North East has a diverse and vibrant clustering of life sciences, manufacturing and health services. I believe that the work that is being done in the North East can support more growth in the region and make a strong contribution to our wider UK initiative to promote research collaboration, partnership and investment globally as part of government's strategic national approach to life sciences.



Sir John Bell Regius Professor of Medicine, University of Oxford.
Champion and sponsor of the UK Life Sciences Industrial Strategy

The North East is home to international academic research expertise in health and life sciences which not only provides competitive advantage but creates significant regional benefits. Our growing reputation as a testbed and living lab is enabling us to accelerate innovation as well as attract investment and skills.

This Health and Life Sciences Strategy will enable us to further strengthen the excellent partnerships in place between industry, the public sector and our universities to grow the economy and improve health outcomes.



Professor Chris Day

Vice Chancellor, Newcastle University and Chair of the Office for Strategic Co-ordination of Health Research

One of the North East's great strengths is its ability to collaborate to deliver strategic goals and nowhere is this more evident than in the health and life sciences industry. Partnership between the public and private sector is more crucial than ever to ensure we form a core part of the UK's Industrial Strategy and to allow our capabilities to be recognised on a global stage.

We have a fantastic innovation ecosystem supported by an incredible translational environment where healthcare technologies and medicines are being constantly developed. Forward thinking leadership here in the North East is helping to drive forward global health services and markets – something of which we should all be very proud.



Professor Michael Whitaker FRSA FRSB FMBA FMedSci
Chair, Health and Life Sciences Group

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1. Executive summary

Our strategy for regional growth and national change in health, life sciences and medicines manufacturing.

1. Executive summary

Health and Life Sciences: An area of strategic opportunity for the North East

Health and Life Sciences was identified in the North East Strategic Economic Plan as one of four areas of strategic importance to the delivery of our ambitions to drive More and Better Jobs in the future.

By bringing together a range of established, high value and high productivity assets in the region, our aim is to strengthen our role in some of the most diverse, dominant and fast-changing economic sectors in the UK and globally with huge potential for growth in the future through science and research, innovation, manufacturing and export. Ranked 3rd in the world for this \$1.25 trillion sector after the US and China, the UK hosts assets ranging from the development and manufacture of drugs and treatments, the development of gene and cell therapies, and intelligent drug discovery and development to artificial intelligence, diagnostics, wearables, telemedicine and much more.

The identification of Health and Life Sciences as an area of strategic importance in the SEP reflects its profile in the region which includes:

- A large GVA and employment footprint.
- Major manufacturing capabilities – across active pharmaceutical products (API), finished products, niche products, diagnostics, and innovation.
- Science, research and development, and innovation expertise – located in local universities, catapults and private companies.
- 'Golden assets' - centres of healthcare and life science excellence including national innovation centres - these drive research and innovation.
- Excellent healthcare delivered by an innovation focused healthcare system with a strong capability in trials and demonstration and the active support of a UK leading innovation pathway.
- Significant growth potential across the sector, and an opportunity for strong collaboration.

It also reflects our understanding of the changes ahead across this eco-system as production processes, treatments and services transform in the future as a result of new medical and digital technologies. Together these create opportunities to target and personalise diagnostics and treatment, and for an effective response to the increasingly complex demands on health systems as a result of demographic ageing.

Key components of the health and life sciences sector in the North East include:

- **Med-Tech** – Companies developing clinical diagnostics, medical devices and equipment and digital health applications to diagnose and deliver care.
 - **Examples:** Biosignatures, Helena Biosciences, Rocket Medical, QuantuMDx, Femeda, Northgene, Intogral, MDNA Life Sciences .
- **Pharmaceuticals and biotechnology manufacturers** – Companies who create and manufacture medicines.
 - **Examples:** GSK, MSD, Recipharm, FuiFilm Diosynth Biotechnologies, Accord Healthcare, Sterling, Clinigen (Quantum Pharma) and Piramal Healthcare.
- **Support services and value chain** – Companies who either work across the supply chain or specialise in specific functions. These include specialists in the engineering and equipment supply chain and construction of facilities.
 - **Examples:** High Force Research, Datatrial, Arcinova, Alcyomics and Magnitude Biosciences, WH Partnership, Parker, Thermofisher.
- **Biotech** – A growing cluster of biotech businesses driven by corporate and university spinouts.
 - **Examples:** NewCells Biotech, Iksuda Therapeutics, Atelerix, AMLo Biosciences, 3D Bio-Tissues and Shield Therapeutics.
- **A broad eco-system** – A broad spectrum of institutions, innovation centres and networks that support the functioning, growth and development of the sector.
 - **Examples:** Academic Health Sciences Network (AHSN), CPI (which is part of the UK Catapult Network), cluster and sector bodies such as Bionow and NEPIC, universities and their programmes, research institutes like NIHR Med Tech NE, Diagnostics NE.
- **Academic science and research** – Nationally recognised assets in North East universities which develop new science, work in partnership with industry and the NHS to introduce new products and services and spin out new businesses.
 - **Examples:** One of eight Academic Health Science Centre partnerships in England, Ranked 4th in the UK for Research Intensity in Clinical Medicine, Europe's largest concentration of ageing-related interdisciplinary researchers and national centres of excellence in ageing, the *Northern Accelerator* partnership between our five universities.

- **The NHS** – The four hospital trusts and the wider commissioning and public health systems are key partners in the development and delivery of this economic strategy. The NHS performs three distinctive and important roles in the Health and Life Sciences strategy:
 - As an enabler of the ecosystem to support SMEs and spinouts to commercialise their products and services through validating ‘unmet needs’, real world evaluation, conducting clinical research and trials for product development, acting a testbed of technology innovation and accelerating the commercialisation of products.
 - As an innovator of products, services and processes internally.
 - As a significant health market in which to adopt these products and services. Healthcare spending in the UK totals about £200 billion annually, 10% of GDP.

Example: Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH) is consistently one of the highest performing and ranking trusts for clinical research and clinical trials, with over 500 clinical trials per annum facilitated through Newcastle Joint Research Office. As an example of the scale of NHS operations in the region, Newcastle upon Tyne Hospitals NHS Foundation Trust activity levels include 1.72m patient contacts per year, 14,725 staff employed and £1.087bn healthcare spend. Collectively they are rated CQC Outstanding and with the Great North Care Record recognised as a Global Digital Exemplar.

In addition, the region hosts a wider portfolio of knowledge and industrial assets in other sectors which can be mobilised to drive development in health and life sciences given some of the key directions of development in the sector. Leading examples include the research and knowledge strengths on ageing, bringing globally recognised insight into the causes and implications of global demographic change, expertise in diagnostics, which have shaped the North East’s excellence in translational research and in improving patient care with Diagnostics North East (NE) unrivalled in the UK, and the capabilities of the region’s vibrant digital sector as the healthcare and medicines manufacturing industries become increasingly digitally enabled.

Strategy and priorities for action

Our strategy aims to take advantage of our strengths and opportunities in business, science and our healthcare system to drive more and better jobs in the region and make a strengthened contribution to one of the UK’s priority industrial opportunities.

We aim to take opportunities to enhance our share of the global pharmaceuticals industry which is valued at over \$1.25 trillion per annum, and to continually improve the performance and offer of our healthcare system through new technologies and treatments to have a

positive impact on the quality of people's lives. This will in turn improve access to healthcare markets for North East businesses and innovators which currently represent 10% of UK GDP.

To achieve we will take advantage of a number of regional science, research and translational assets in business, universities and our NHS bodies which are well positioned at the leading edge of some of the major changes which are impacting on drugs, treatments and healthcare services. We will focus on:

- Strengths in production and digital delivery – supporting manufacturers to drive new methods of delivery and packaging and healthcare organisation to improve services, patient care and monitoring.
- New methods of formulating drugs, treatments, services and therapies, creating hubs to support development of these ideas and pathways to trial and introduce them into the health system.
- Diagnosis, taking advantage of new opportunities to diagnose and target treatments.
- The opportunities and impacts of demographic change – with a focus on using our globally acknowledged research to shape health, life sciences and drugs and treatments of the future.

We will use these assets to create new and better jobs by growing our science and research base, supporting growth in our small and medium businesses and securing higher levels of investment and engagement from manufacturers and investors into the assets in the region.

Underpinning this work will be continual strengthening of leadership, co-ordination and communication in the region and strengthening of national and international networks and connectivity to ensure that the North East is recognised for its assets and opportunities and is an accessible location for people to work and businesses to innovate and grow.

Together these areas of intervention will deliver a highly connected regional environment, which is recognised for its capacity to leverage its wide range of assets to identify, accelerate and translate drugs and treatments into key markets in health services and pharmaceuticals supply chains.

Our Vision

To position the North East as a leader in the development, testing, manufacturing and adoption of people-centred treatments, therapeutics and medicines at a time of demographic change

Strategic Aims

- To strengthen the distinctiveness and scale of the pharmaceuticals cluster with world-leading companies selecting the North East for the development and location of production.
- To provide a comprehensive support system which can enable high growth life sciences businesses and sub-sectors to be founded and grow in the North East.
- To unlock the commercial and health potential of North East universities' world-class research and assets, translating them into business and health innovations.
- To support business and NHS infrastructure to translate discovery through development to adoption by providing a comprehensive support system for key high growth businesses and sub-sectors and clinical trials.
- To be the leading region for NHS adoption of innovation through the development of the North East NE Health Evaluation System.
- To attract big players in the healthcare and life science investment community to the region to engage with its research, business and translation environment.

Strategic priorities

The Health and Life Science Steering Group has identified three strategic themes to support the delivery of these aims and outcomes in the North East (see figure 1).

1. Modernisation and growth of pharmaceutical manufacturing, in response to the rapid global growth in demand for medicines, health technologies and personalised treatments.
2. Support for a diverse community of health and life sciences SMEs to form and grow in the region ranging across university spinouts, new business formation, and the encouragement of health and life science companies to cluster in the North East. SMEs will be attracted by the availability of an excellent business growth eco-system, access to capital, access to excellent science, research, development and innovation capabilities and for clear and navigable pathways to key health and medicines markets.
3. Ongoing improvement of the co-ordination of the translational environment from discovery to implementation into the NHS and wider health and pharmaceuticals markets, ensuring that the region is recognised as a leading hub for innovation, testing and trials, in turn attracting investment into this environment with a progressively growing eco-system of hubs, networks and centre of excellence.

These themes will be supported and elaborated through the Health and Life Sciences Steering Group which will provide strong collaborative leadership for the strategy and be supported by key enabling actions, an excellent communications programme and a strong relationship with key government departments and agencies.



Figure 1: Strategic Framework for North East Health and Life Sciences Growth Strategy

Key measures and outcomes

Through a focus on these aims and themes, the Steering Group has identified key targets aligned with the key performance indicators set out in UK and regional strategies and plans.

By 2030, the Steering Group has set two overarching targets for the Health and Life Sciences strategy:

- To have doubled the number of businesses active in the health and life sciences community in the region.
- Noting that the industries in focus within this area of strategic importance tend to deliver high productivity technical and professional roles, to have doubled the number of jobs in the health, life sciences pharmaceuticals businesses and the research and

development community in the region, contributing in particular to the stock of 'Better' jobs.

Supporting these overarching targets, a number of sub-targets include:

- To be recognised as a key area for the co-design and delivery of early phase studies with SMEs and the life sciences sector and in clinical trials with Top 3 ranking NHS Trusts on a year-on-year basis.
- To be recognised as a leading area for the implementation of innovation into the NHS with a strong and navigable innovation pathway.
- To have quadrupled the number of university spin outs in this area of the economy.
- To be systematically recognised in UK government documents as a leading cluster location for health and life sciences.
- To secure one major and a number of smaller additional pharmaceuticals investments into the North East.
- To have secured strengthened physical connectivity along the pharmaceuticals supply chain including direct freight logistics links to the United States from the North East.

Key Data

There is a range of data which illustrates the current profile of health, life sciences and medicines manufacturing in the North East.

Economic value: In 2019, Health and Life Sciences in the North East region had a turnover of £1.7bn¹ (£1.5bn in 2018), with the combination of existing high productivity businesses and their capacity for growth and higher value employment making this broad area of the economy well placed to contribute to the key performance indicators set out in the SEP².

Employment: Figures from the Office for Life Sciences³ illustrate the size and contribution of the health and life sciences sector. In 2019, total North East regional employment in the health and life sciences sector was 7,680 (3.0% of UK total). This comprised of 2,060 (3.2% of the national total) in Biopharma core, 2,180 (3.6%) in Biopharma service and supply, 2,150 (2.1%) in Med-Tech core and 1,290 (4.5%) in Med-Tech service and supply. Between 2010 and 2019 overall employment in the sector increased by 1,400, which represents an equivalent increase of 22% compared to 9% nationally.

¹ Bioscience and health technology sector statistics 2019, <https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2019>

² Note that the definition used in this strategy focuses on the business, science and innovation assets in these sectors and excludes the wider health and social care services sector. This is a narrower definition than adopted in other similar strategies elsewhere and aims to reflect the economic growth focus of this report. As is noted, however, health and social care services make a significant and valued wider contribution to the regional economy including high levels of investment and employment and represent a further significant opportunity for the region.

³ *ibid.*

This trend is likely to continue with growth in manufacturing, SME growth and in the research and science base. For example, in its first three years, 48% of spinouts from the Northern Accelerator Programme came from life sciences businesses. In the response to the COVID-19 pandemic, businesses reported employment growth of over 300 jobs in the pharmaceuticals sector, at a time when other sectors were furloughing staff and concerned about future job losses. The new COVID Lighthouse Laboratory project in Gateshead and Newcastle is expected to deliver 1000 new jobs in research and testing.

Inward investment: The North East attracted 4.2% of all life sciences projects into the UK between 2013 to 2017, and there is more potential for growth with opportunity areas in pharmaceuticals, advanced therapies and ageing sciences and a target to achieve a ranking as a top 10 UK life science Foreign Direct Investment.

Pharmaceuticals and advanced manufacturing: The North East hosts a significant cluster of the global pharmaceutical industry generating £868 million for the regional economy in 2017. There are 73 pharmaceuticals and biotechnology supply chain companies in the region, employing 4,100 people with an annual turnover of £601 million. Its wider impact is estimated at £1.5 billion supporting between 18,800 and 23,500 jobs. This cluster sits within a wider advanced manufacturing footprint which accounts for 15.3% of the North East LEP area's GVA and 11.3% of employment and also includes chemicals and the major automotive manufacturing cluster focused on the Nissan car plant and a wider group of automotive OEMs based around Sunderland.

Large global pharmaceutical manufacturers are located in the region including Glaxo Smith Kline, MSD, Accord Healthcare, Recipharm, Arcinova, Sterling Pharma Solutions, Fujifilm Diosynth and Piramal. The North East also has a thriving SME base working closely with industrial partners and academic institutions' innovation assets in formulation, novel therapies and biologics.

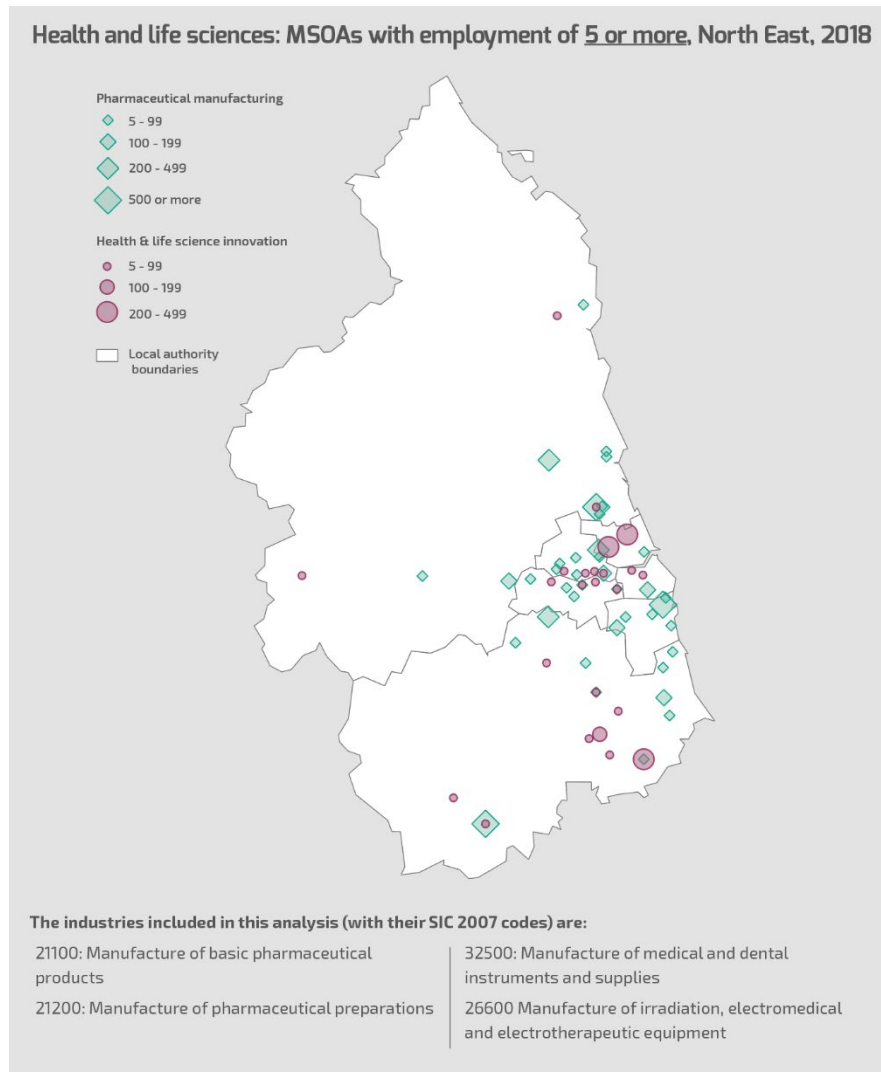


Figure 2: North East life sciences and pharmaceuticals industries by employment

Trade and exports: The North East has a strong export-led regional economy. The region exported £13.3 billion of goods in 2019, including £2.8 billion of chemicals and pharmaceuticals⁴. 86% of North East pharmaceutical production is exported, with 64% of finished products going to the United States.⁵

Development of the Strategy

Health and life sciences was first identified as an area of opportunity in the Strategic Economic Plan in 2017 following engagement through the Health & Life Sciences Steering Group and consultation with a wider range of stakeholders. Over 100 organisations have been consulted in total in the development of this strategy.

⁴ HMRC Regional Trade Statistics, <https://www.uktradeinfo.com/Statistics/RTS/Pages/default.aspx>

⁵ First for Pharma, CPI, North East LEP (2017), Profile and Importance of the North East Pharmaceutical Manufacturing Sector

The programme has already been the focus for a number of actions in the North East as follows:

- Convening and ongoing development of the Health and Life Sciences Steering group, with the aim of building a shared strategic ambition and approach and to foster collaboration in pursuit of growth in this area of the economy.
- Supporting the development of leadership in sector organisations and cluster bodies.
- Delivery of investment into infrastructure assets in the region including new national Innovation Centres at NETPark in County Durham, the Biosphere at the Helix site in Newcastle and support for key sites through the Enterprise Zone programme.
- Supporting partner-led action in a range of areas which have enabled support to the business base and enhanced the structure and navigability of eco-system.
- Significant development of the evidence base about the sector in the region.
- Sponsorship of events and publications which have provided opportunities for enhancing the region's profile and business networking.
- The building of relationships and partnership working with government departments and other parts of the UK in pursuit of shared aims.

Partners in the Steering Group have led the way in developing a wide range of other activities and interventions which are captured in the full strategy document and which provide the underpinning platform for this strategy.

Appointment of a Programme Lead in 2019, co-financed by the North East LEP, CPI and AHSN NENC, has enabled this work to be accelerated, building further collaboration and enabling the identification of a number of specific opportunities to strengthen the approach in the region.

The Steering Group commenced a formal strategy process in March 2020 and this document draws this work together with key input from both the Steering Group and the North East LEP team.

Opportunities and challenges

The strategy has identified several specific opportunities and challenges:

Opportunity area	Summary
Growth and modernisation of manufacturing and the supply chain	<ul style="list-style-type: none"> • Onshoring production facilities and securing new investment • Modernising manufacturing through digitalisation and automation of production and packaging • Growing contract manufacturing • Formulating and manufacturing new treatments and therapies
Development of new services and treatments	<ul style="list-style-type: none"> • Design and delivery of phase II translational clinical research studies • Growth and delivery of cell and gene therapies • Exploiting business and science strengths in diagnostics, digital health, ageing and medical technologies

	<ul style="list-style-type: none"> • Leverage of regional innovation assets in photonics and biologics
Collaboration with the NHS to adopt and commercialise drugs and treatments	<ul style="list-style-type: none"> • Active collaboration with an innovation-oriented health system to promote adoption of new treatments and processes • Utilisation and further development of a UK leading innovation pathway and trusted research environment • Growth in trials and demonstrators • Deployment of digital health services
Inward investment	<ul style="list-style-type: none"> • A strong record in securing manufacturing projects • Inward engagement with science, innovation and healthcare eco-system • Healthy ageing high potential opportunity (HPO) • Work with DIT to present further HPO processes including CGT
Growth and investment in life sciences SMEs	<ul style="list-style-type: none"> • Strengthening the business environment to support regional SMEs • A strong and growing programme of university and health service spinouts and collaborations
Strengthening our cluster	<ul style="list-style-type: none"> • Building leadership structures and institutions, and fostering collaboration between them • Building out the key locations in the region as hubs for collaboration and investment

Challenge area	Narrative and mitigation
Overall size of the economy	<ul style="list-style-type: none"> • Overall scale of the economy is a constraint <i>Position region at the hub of wider networks and collaborations including with national clusters, the Northern Powerhouse, collaboration with Scotland</i>
Brand and awareness	<ul style="list-style-type: none"> • UK industry is concentrated on golden triangle <i>Establish the region as a go-to in strength areas through communications and partnership working</i>
Connectivity	<ul style="list-style-type: none"> • Not currently directly connected to key markets and trade risks from political developments like EU Exit <i>Strengthen connectivity to targeted markets and collaboration with DIT to focus on opportunities</i>
Business environment	<ul style="list-style-type: none"> • Need to strengthen finance offer in key parts of this sector • Need to ensure that there are the right facilities to host business growth in SMEs and manufacturing • Need to maintain a strong skills supply • <i>Strengthen the property and facilities available for growth and inward investment</i> • <i>Deliver skills development initiatives across this eco-system</i>

Key interventions:

Theme 1: Growth and modernisation of pharmaceutical manufacturing

The following interventions have been identified as priority actions in this area of the strategy:

Strengthening regional pharmaceutical leadership: Development of a new leadership group, Pharma North East, to champion the role of the sector in the region. Lead: Pharma North East.

North shoring investment: Creation of a new facility providing new capacity to re-shore generics and medicines manufacturing, build resilience in the UK's supply chain in critical areas of NHS demand, and support pharmaceuticals innovation. Lead: Pharma North East.

Pharmaceuticals supply chain development plan: Supply chain development project to enable the North East to strengthen its supply chains and build as a primary location to manufacture generic drugs and medicines. Lead: NEPIC.

Support for export and inward investment activity: Strengthened support for trade and investment activity, with immediate focus on building the relationship with DIT and developing a strategic inward investment proposition. Specialism focus on healthy ageing HPO, with discussion envisaged about other opportunities. Lead: INEE, North East LEP, NECC, DIT.

Industrial digitalisation: North East Made Smarter programme; Collaborative programme to support and accelerate industrial digitalisation in North East manufacturing. Lead: North East LEP, TVCA.

Smart packaging and delivery of medicines: Development of 'testbed' models to demonstrate innovative models across the healthcare and the drug development supply chain including medicines packaging, drug delivery and devices and wearable devices. Lead: CPI.

Point-of-need diagnostics: Collaboration to position the North East as the go-to place for development, scale-up and demonstration of the next generation of point-of-need diagnostics. Lead: CPI and AHSN NENC, NHS with business.

Enhanced connectivity to markets: Market feasibility study will assess the potential for enhancing air connectivity between Newcastle and key growth markets for freight logistics. Lead: Newcastle International Airport, North East LEP.

Cluster development support: Funding to support our key cluster organisations with core and project funding. Cluster bodies in this area of strategic importance will be in scope for this fund. Lead: North East LEP.

Theme 2: Supporting health and life sciences SMEs to grow

The following interventions have been identified as priority actions in this area of the strategy:

Strengthening access to finance: Addressing gaps in the current finance offer with respect to life sciences SMEs as part of the review of North East access to finance provision. Lead: North East LEP.

Strengthening links to external investors: Building on initiatives such as the Innovation Supernetwork Finance Camp and the good practice of a number of successful regional businesses. Feasibility study about specific North East Investor Conference for Life Sciences. Lead: North East Innovation SuperNetwork and Steering Group.

Health and Life Sciences IP Protection Fund: Short term support for those businesses which have seen opportunities to deploy their intellectual property constrained by COVID-19. Lead: North East LEP.

Driving university spinouts through Northern Accelerator: Phase 2 programme to build on phase 1 success aiming to support growth of spin-out SME businesses through i) the Executives into Business programme and ii) its Venture North Fund. Lead: Northern Accelerator programme, led by Durham University with other universities.

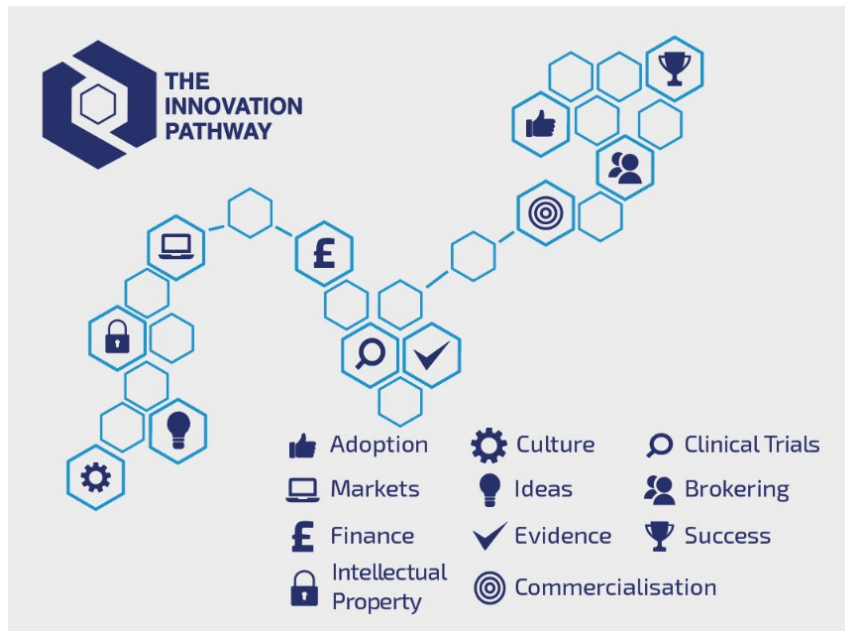
Purposeful Health Accelerator: Accelerator programme for SMEs focused on health, wellness and social care delivery sectors offering practical support, advice and capital investment. Lead: Northumbria University.

Building facilities and places to grow: Property study following on from development of new facilities at Helix and NetPark and use of existing manufacturing sites, to understand the needs of the sector and generate a development response. Lead: North East LEP and Local Authorities.

Theme 3: Supporting and enhancing our eco-system to support innovation and translation from discovery to implementation

Key interventions include:

Innovation Pathway: Further development of the innovation pathway to provide an organised and staged route to market into the National Health Service. Lead: AHSN NENC.



The following new interventions will build the strength of the pathway:

Great North Care Record: Enabling professionals, carers and patients to have legitimate access to patient access at the point of need through a region-wide, interlinked electronic health and care record platform, capable of transforming clinical care and supporting research.

Further extension will aim to facilitate trial design to deliver large patient cohorts for observation studies, real-world evaluation of products, and the evaluation of existing and new patient pathways, as well as a trusted Research Environment to improve access to data and analytics and enable population health planning and development and deployment of more innovative treatments and clinical trials.

North East Health Evaluation Ecosystem: A test bed to develop and evaluate the strengthening of the co-ordination of expertise and assets across the region in a systematic, transparent and accelerated way to speed the route of new products and services to market.

Digital Heath: Development of a strategy to identify where the digital sector could practically contribute to and support local health and life sciences development and articulate and agree how best to progress the sector's health tech agenda in the North East. Lead: AHSN NENC.

MedTech, internet of medical things and wearables: Building on the successful model of the National Healthcare Photonics Centre at CPI, NETPark County Durham, phase 2 of the project will extend the focus to include other key enabling technologies including flexible hybrid electronics, advanced materials, micro and nanotechnologies and biotech. It will extend CPI capabilities to provide deep R&D and innovation support to companies large and small in the broad area of MedTech, with a focus on point of need diagnostics, wearables, internet of medical things and internet of wellness things. This facility will enable academic partners, SMEs, investors, large companies, and the wider healthcare ecosystem to extensively collaborate. Lead: CPI.

Northern Alliance Advanced Therapy Treatment Centre: The NAATTC is a consortium of twenty industry, NHS and academic organisations led by Newcastle Hospitals and the Scottish National Blood Transfusion Service (SNBTS).

The purpose of the centre is to develop the systems and infrastructure required to support the delivery of cell and gene therapies, and to increase patient access to advanced therapy medicinal products (ATMPs) on a national level.

Early Diagnostics Institute: Innovation to detect multiple age-related conditions from one blood sample taken during a GP health check appointment to create an industrial approach to support applied clinical research, leading to development of an active central diagnostic testing and clinical trials centre. Lead: Turbinia working with NIHR MIC and the NIHR Newcastle Clinical Trials Unit, NCTU.

Innovation Delivery Partnerships: Our reach to global businesses seeking solutions to challenges in treatments will be enabled by the development of Innovation Delivery Partnerships, new models for collaborative innovation supported by the North East Innovation Board which seek to accelerate our assets' entry into markets of the future.

Theme 4: Cross-cutting and enabling actions

Supporting businesses

Business support and access to finance: Connection of the range of existing start up, scale up and finance services available to the sector through the Growth Hub. Lead: North East LEP.

Developing skills to support health and life sciences growth: Through the Skills Advisory Panel (SAP), facilitated by the North East LEP, a response will be developed which aims to respond to ongoing and futures skills needs. Lead: North East LEP.

Leadership and Co-ordination

Health and Life Sciences Steering Group

The Health and Life Sciences Steering Group provides strategic advice, support and coordination of partners to the LEP and oversight of the development of a Health and Life Sciences Growth Strategy and work programme. The Steering Group acts as a critical friend to the North East LEP by steering, advising and advocating the work of the Health and Life Sciences Steering Group and the LEP Executive team.

It brings together broad representation of the Health and Life Sciences community in the North East from the private, public, health and education sectors and draws together a unique set of skills, knowledge and perspectives. It reports into the North East LEP Board on development of the strategy and links directly to other boards and structures within the LEP through officers and membership.

Communications

The North East LEP and partners will work together to communicate effectively about the health and life sciences community and capabilities, and the priorities set out in this strategy, facilitated by the North East LEP.

Key audiences include:

- Businesses working in health and life sciences – to build confidence, provide support and encourage engagement and investment.
- Regional audiences – helping to ensure visibility and make collaborative links between partners.
- Policy and strategy - building the presence of the North East in government and amongst other key stakeholders.
- Investors and other economic actors – working directly and through partner and government channels to secure investment to support the objectives set out in the strategy.
- Students, graduates and workers – seeking to build the labour market capacity in the region and attract skills.

2. Introduction

Our strategy for regional growth and national change in health, life sciences and medicines manufacturing

2. Introduction

The North East LEP leads on driving economic growth across the North East LEP area, which includes Northumberland, Tyne and Wear and County Durham. Our overarching aim is to deliver 100 000 more and better jobs in the region.

Our approach is set out in the North East Strategic Economic Plan (SEP). The SEP identifies four areas of strategic importance for the regional economy; Health and Life Sciences; Energy, Digital, and Advanced Manufacturing. Each of these areas has a strong regional concentration of leading assets, expertise and capabilities in businesses and the wider economy, and are part of growing highly productive parts of the global and national economy. This combination of regional assets and global market opportunity together provide a strong opportunity to deliver our economic ambitions. The SEP sets out our programme to drive delivery towards these objectives through investment in business growth, innovation, skills, infrastructure and connectivity.

Working with and through the North East Health and Life Sciences Steering Group, the North East LEP has co-ordinated the development of this Health and Life Sciences Growth Strategy. It sets out how the region can deliver a strong contribution to the aims of the Strategic Economic Plan through a focus on its established pharmaceutical manufacturing cluster, its range of health and life sciences capabilities in business and research, and its excellent public health services and supporting ecosystem. Together, these assets provide a compelling opportunity and competitive advantage for the region, with the potential to transform the productivity and structure of employment in the region, in turn inducing a wider set of economic benefits.

These sectors and capabilities are recognised nationally as a key focus for the UK's industrial strategy given their global significance and the UK's national strengths. The world's top 25 Biopharma companies and 30 Med-Tech companies have operations in the UK. The life science sector directly employs over 220,000 people, with over 160,000 within core operations and a further 60,000 within service and supply. It generates a turnover of approximately £73.8bn a year. The UK is the third most popular destination of foreign direct investment in life sciences, after the USA and China.

With this focus, by working together partners in the region have the opportunity to position the North East to make a strong and visible contribution to UK growth at a time of challenge and change.

At the time of preparing this strategy, the UK has been progressively experiencing the COVID-19 pandemic, impacting directly on the health of individuals in the UK and internationally and changing the global economy in multiple ways, with many of the changes likely to be permanent. Our focus on health and life sciences here in the North East is therefore not only an urgent economic priority for the region, but also strongly aligned with the national priority to overcome the economic and health crisis which COVID-19 is creating, and to build a healthier and more resilient national economy and society over the longer-term.

In this strategy we build on the outline set out in the SEP to:

- Explore and explain our assets in the area of health, life sciences and pharmaceuticals.
- Set out how we can mobilise them through strong and co-ordinated regional partnerships and specific interventions to drive economic growth and more and better jobs.
- Secure these benefits through a combination of inward investment, strengthened innovation performance and business start-up and growth, supported by wider interventions into the region's physical infrastructure and skills, in an area of opportunity which is genuinely global and characterised by high value investment and strong productivity performance.

Development of the strategy

Since 2017 when health and life sciences was first identified as an area of opportunity in the SEP by the Health and Life Sciences Steering Group, the North East LEP has consulted with a wide range of stakeholders in the development of this strategy. Over 100 organisations have been consulted.

The initial aims of this work were set down in the Terms of Reference for the strategy:

With deep industry engagement, to develop an industry strategy and action plan which will foster growth of the health and life sciences sector in the North East to generate economic returns from more and better jobs.

To position the North East in key areas to attract more companies to locate and employ skilled people in the region.

To leverage relevant academic and clinical expertise to grow the sector and develop consequent economic benefits.

To leverage economic returns from key research institutes and catapults.

A number of key opportunities were initially identified in pursuit of these aims:

- To provide a comprehensive support system for key high growth businesses and sub-sectors.
- To develop a cluster economy opportunity around world-leading companies selecting the North East for production plants by supplementing the pharmaceuticals supply chain.
- To unlock the commercial potential of North East university world class research.
- To support business, and the NHS infrastructure to translate discovery through development to adoption.
- To be a leading region for NHS adoption of innovation.

These priorities have been the focus for a number of actions supported by the North East LEP including:

- Convening and ongoing development of the Health and Life Sciences Steering Group, with the aim of building a shared strategic ambition and approach and to foster collaboration in pursuit of growth in this area of the economy.
- Supporting the development of leadership in sector organisations and cluster bodies.
- Delivery of investment into infrastructure assets in the region including new national Innovation Centres at NETPark in County Durham, the Biosphere at the Helix site in Newcastle and support for key sites through the Enterprise Zone programme.
- Supporting partner-led action in a range of areas which have enabled support to the business base and enhanced the structure and navigability of eco-system.
- Significant development of the evidence base about the sector in the region.
- Sponsorship of events and publications which have provided opportunities for enhancing the region's profile and business networking.
- The building of relationships and partnership working with government departments and other parts of the UK in pursuit of shared aims.

Appointment of a Programme Lead in 2019, co-financed by CPI and AHSN NENC, key partners within the Steering Group, has enabled this work to be accelerated, building further our collaboration and enabling the identification of a number of specific opportunities to strengthen the approach in the region. The Steering Group commenced a formal strategy process in March 2020 and this document draws together this work with key input from both the Steering Group and the North East LEP team.

3. Economic and policy context

3. Economic and Policy Context

Economic, health and demographic context

Global trends in health, life science and pharmaceuticals

In identifying health and sciences as an area of strategic importance for the North East, the SEP acknowledges both an extensive and developing asset base in an area of significant global opportunity and rapid social and technological change presenting both opportunities and challenges. In the context of the region's key asset base, the following trends and trajectories are the focus for this strategy:

Growth and change in medicines and therapies

Development and production of new pharmaceuticals, therapies and treatments, and change in production methods means this is a rapidly developing area of the economy. With total annual overall value of \$1.25 trillion globally, continuing acceleration of demand, and transformation of treatments as technology, demography and markets interact, it is a market representing significant opportunity. Change is occurring in the types of treatment available, with the introduction of novel therapies to more traditional drugs including cell and genetic therapies, biologics, changes in diagnostics, and transformation of production and service models through automation and digitalisation of both creation and delivery processes. Key trends include:

- **Demand for Advanced Therapeutics:** There is strong interest in, and an urgent need for, more cell and gene therapy (CGT) production facilities, to meet accelerating demand. The global CGT market is predicted to grow by over \$8.95bn by 2025, reaching a value of \$11.96bn. In the UK, the number of patients treated using this therapy is expected to grow to 5,000 by 2023 and 10,000 by 2028. This will require significantly more highly specialist manufacturing facilities, a gap the government is looking to address.
- As more Biopharmaceutical companies develop CGTs, significant change will be required in **manufacturing processes**, as the drug manufacturing process can rely on the receipt of the patient's own or donor cells. Between 2016 and 2019, UK CGT manufacturing has increased by 80%. (Frost & Sullivan).
- **Continuous Manufacturing:** This streamlining of manufacturing processes, with products being created without the need to stop until the product is completed – is seeing a move away from the manufacturing, filling and packaging process. The region's centres of excellence are well placed to support businesses in this area. For example, GSK and AstraZeneca have partnered with CPI to build a continuous manufacturing capability at NETPark, in County Durham. It is estimated that this

investment could attract up to £88m worth of investment by 2028. (UK Life Science Sector Deal 2017).

- **Contract Manufacturing:** The biopharma and supply chain branch of life sciences, which includes outsourced, or contract manufacturing is also a major opportunity for the region which has grown 15% over the past five years. Med-Tech has also experienced similar levels of increased demand with growth of 9%. This demand for outsourced manufacturing has been rising. It is expected to continue, as companies (big and small) that lack in-house manufacturing capabilities begin to look to third-parties to reduce costs and form long-term relationships with suppliers as manufacturing becomes more complex.
- **Automation, digitalisation and advanced drug delivery technologies:** The emergence of new technologies is both enhancing and disrupting manufacturing operations, distribution and service provision in health services. These include opportunities to link production and delivery to strengthen the focus on individual needs. Emerging technologies include augmentation and virtual reality, robotics, big data and analytics. Nanoparticle-based drug delivery technologies are also now becoming a reality, enabling the successful adoption of a number of complex medicines and advanced therapies such as nucleic acid therapies.
- **Precision Medicine:** The rise of Precision Medicine (also known as Personalised Medicine) will give rise to the need for pharmaceutical manufacturers to produce a larger number of smaller batches of precision medicines, requiring new approaches to what has traditionally been a large batch scale production industry.
- **On Demand technologies:** 3D printing of medications and medical devices is fast becoming a reality. This could mean that drugs and devices are printed near the patient within very short timeframes.
- **Sustainability:** The need for sustainable manufacturing facilities and practices will become more pressing as eco-concerns continue to rise. Greater emphasis will be placed on the need to minimise waste, consumption of resources and the use of environmentally friendly materials.

Directions in health and care policy and services

Globally, health care policy and approaches are changing and developing in response to changing demographics which are driving different demands across the life-course and the possibilities of new drugs, treatments and interventions. Improved public health and the development of new interventions have both contributed to extended life expectancy and there is an increasing focus on quality of life so that extra years are healthy and productive.

There is an increasing focus in policy on the integration of health and care approaches to achieve this combination of goals, and also in holistic approaches which reflect the interaction of physical and mental health. The rapid development of the range of interventions available across public health, drugs and novel therapies is leading to key

questions about how to integrate interventions to provide more personal, individually tailored services, and to drive change in health and care delivery. Digital delivery and the use of artificial intelligence underpinned by detailed patient data mapping is becoming a reality across the health and care system, from consultation through to drug tracing and delivery.

This provides a complex environment for intervention with a range of issues around ethical and trust concerns about the use of personal data and the relationship between patients and professionals, but with multiple opportunities for research and science, testing, collaboration and innovation in delivery. In the UK, the government has highlighted the area of digital health as a priority theme for development within the NHS Plan, both as a driver for service improvement and commercial opportunity.

Social and demographic changes: Population ageing and diversity

Across the world, as these innovations in approaches to drugs, treatment and public health practice are changing the structure of health and care systems and improving lives for many people, they are also contributing to and responding to a wider demographic shift as the population ages and becomes more diverse.

The global population is projected to make a fundamental age shift to an older population by 2050, where it is expected there will be 2.1 billion people over the age of 60 globally, an increase of 218% compared with 2017. Population ageing is the world's dominant demographic trend. Most people in most countries can expect to live longer and healthier lives than previous generations, and the balance of our population is being transformed as extended life expectancy combines with declining birth rates.

Across the 33 member states of the OECD, for example, as the post-war baby boom works through the population, this combination of population trends is shifting the age-balance of our population steadily and permanently (see figure 1). By 2050, a 'new normal' age structure is projected to see about 1/3 of OECD population to be aged over 65, adding 245 million people to this age group compared with 2011.

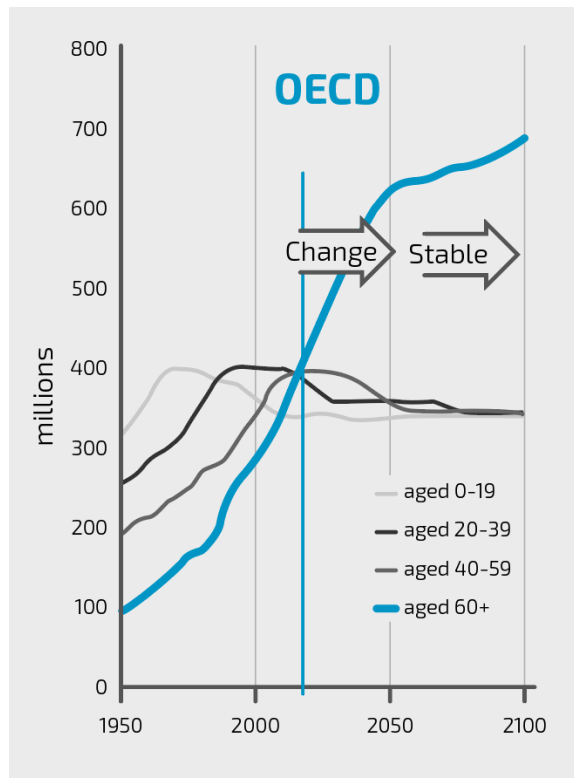


Figure 3: Changing numbers of people in different age groups across OECD member states. Source: OECD, adapted from the UN Population database

In the UK, the most recent projections⁶ show that the population is projected to increase by 9.6 million over the next 25 years from an estimated 63.7 million in mid-2012 to 73.3 million in mid-2037. It is forecast to reach 70 million in 2027.

These figures include an anticipated natural increase, with more births than deaths, as birth rates rise, and more people live longer lives. The population is also expected to continue ageing with the average age rising from 39.7 years in 2012 to 40.6 years in mid-2022 and 42.8 by mid-2037. The number of people aged 80 and over in the UK is projected to more than double to 6 million by mid-2037 (See figure 3).

⁶ ONS National Population Projections, 2012-based statistical bulletin, 6 November 2013

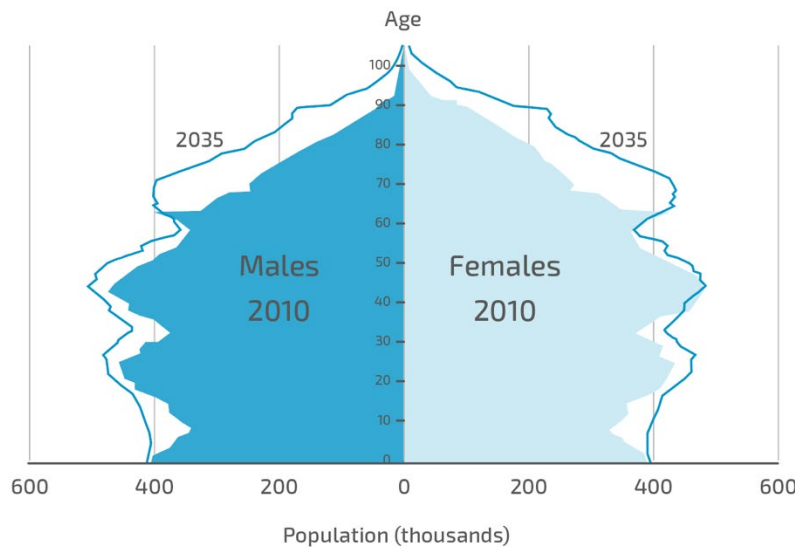


Figure 4: Projected age structure of the population in 2010 and 2035

Within these figures net migration plays an important role, with migrant populations tending to be concentrated amongst younger age groups. This will have two effects - adding about 4 million people to the overall population by 2035 and holding down the average age. As well as being younger in itself, this group tends to exhibit higher levels of fertility than the settled population, having an important effect on the rate of ageing overall (see table 1).

	2012	2017	2022	2027	millions 2032
	-2017	-2022	-2027	-2032	-2037
Population at start	63.7	65.8	68.0	70.0	71.7
Births	4.0	4.1	4.0	4.0	4.0
Deaths	2.8	2.8	2.9	3.1	3.3
Natural change	1.3	1.3	1.2	0.9	0.7
Net migration	0.8	0.8	0.8	0.8	0.8
Total change	2.1	2.1	2.0	1.8	1.6
Population at end	65.8	68.0	70.0	71.7	73.3

Note: Figures may not sum due to rounding

Table 1: Projected components of change, United Kingdom, mid-2012 to mid-2037

In common with the patterns in other OECD countries, by the end of this cycle, the rate of natural change in the UK is anticipated to slow to some extent as the accelerator effect of the 1945-1955 baby boom settles down, but the fundamental shift in the age structure and the overall diversity of the UK and wider population will have been established.

North East demographics

In the North East there is a subtle difference to national trends. Whilst the region exhibits the same ageing trends as the national population, it is growing more slowly, partially driven by lower levels of in-migration and partially by lower life expectancies. In fact, the home population net of migrants falls in more years than it grows, and it also remains less diverse. Whilst this presents some longer-term challenges for the productive capacity of the economy, it does provide a strong rationale for action in the region, and also means that the population is relatively stable and homogenous, creating a good location for trials and experimentation.

Overall, these trends create opportunities and challenges for ensuring that older age is healthy and productive, with success in that respect likely to be driven by a combination of social and medical interventions. This therefore provides a key context for health and life sciences sectors in the region.

The region is well placed to respond to these challenges, as Newcastle is one of two globally recognised hubs for science and research on ageing populations specialising in the development of medical science and social research in response. It leads the UK in translational ageing research, combining expertise in biology and epidemiology of ageing, experimental medicine and trials for older people. In addition to tackling “ageing syndromes” (sarcopenia, frailty and multimorbidity), it is increasing capacity through additional Newcastle Health Innovation Partnership strengths and by taking a life course approach to ageing. There is an opportunity to translate this into new treatments and services through the work of the National Innovation Centre of Ageing (NICA), with its role to build a UK and regional economic response to aspects of the ageing population.

Policy context

Key policy frameworks across a number of aspects of government and Regional policy present strong reference points for the Health and Life Sciences strategy. These include:

Policy context

Key policy frameworks across a number of aspects of government and Regional policy present strong reference points for the Health and Life Sciences strategy. These include:

Policy framework	Narrative
UK Industrial Strategy	The Industrial Strategy prioritises sector growth and improved economic productivity. It includes a sector deal for life sciences and ‘mission based’ Grand challenges on artificial intelligence and data, and healthy ageing.
Life Sciences Sector Deals	Two ‘sector deals’ have been produced which prioritise: <ul style="list-style-type: none"> • Strengthened environment for clinical trials and health research. <ul style="list-style-type: none"> ○ Data to early diagnostics and precision medicine

	<ul style="list-style-type: none"> ○ Genomics with whole genome sequencing of the UK Biobank ○ Digital diagnostics and artificial intelligence <ul style="list-style-type: none"> • New industry-led research centres in key parts of the UK for key healthcare challenges including diabetes, bioscience and creating 1000s of new jobs. • Sector-wide collaboration with government on advanced health research projects in areas including cancer, digital pathology and radiology. • Creation of new national facilities including: <ul style="list-style-type: none"> • A Medicines Manufacturing Innovation Centre • A Vaccines Development and Manufacturing Centre • Expansion of Cell and Gene Therapy Catapult Manufacturing Centre and creation of three Advanced Therapies Treatment Centres • Investment to grow advanced therapies manufacturing capacity in viral vectors • Improved access to new technologies in the NHS for SMEs by: <ul style="list-style-type: none"> • Establishment of an Accelerated Access Collaborative to develop a streamlined pathway and commit government funding to support innovators and the NHS locally • A digital health catalyst to support SME partnering with the NHS • Improvement of NHS England's commercial capacity and capability <p>Support the UK's health data infrastructure through NHS England, NHS Digital and Health Data Research:</p> <ul style="list-style-type: none"> • Develop regional, interoperable Digital Innovation Hubs which support the use of data for research purposes within the legal framework • Set clear standards and approaches for data and interoperability and streamline approvals for data access for researchers via NHS Digital • Create a sandbox for secure, remote data access for anonymised data in a safe environment
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	A regional approach to the life sciences sector deal working with clusters and administrations to develop local and regional investment programmes.
Life Sciences Skills Strategy	To produce a skills action plan to join up business growth and skills priorities and extend UK leadership in life sciences and pharmaceuticals.
NHS Long Term Plan	<p>The NHS long term plan sets out a framework to meet the need of a changing population and address the increased pressures and demands placed on the NHS by:</p> <ol style="list-style-type: none"> 1. Developing a new, service model for the 21st century 2. A proactive approach to prevention and health inequalities 3. Promoting digitally enabled care into the mainstream across the NHS <p>It calls for a ‘fundamental shift’ towards a more integrated way of working alongside patients and individuals with a focus on personalisation to support the growing complexity of needs and demands in the population and to take advantage of the growing range of treatments, drugs and therapies. It recognises the opportunities for digitalisation and deployment of technologies across the service.</p>
UK Research and Development Road map	The Road map sets out a programme of work to strengthen the UK’s R&D performance, in particular amongst businesses. Two priorities include mobilising R&D in the response to Covid 19 and focusing on R&D in places as part of the wider ‘levelling up’ agenda
Exit from the European Union	Two key issues have been identified by partners as the UK completes its exit from the EU single market and customs union: regulatory alignment for medicines and the sustainability of supply chains. The outcome of the trade deal and the consideration of alternative options will influence long term investment into the UK. A third issue which has been resolved is the continuing engagement in EU research programmes.
The UK Covid Recovery Road Map	The Road Map provides a framework for ensuring that the sector makes a swift recovery from the pandemic and identifies opportunities to build on the role it has played in supporting the response. Key opportunities identified include building on NHS transformation in digitalisation and testing; improvement of UK manufacturing including productivity and homeshoring; transforming clinical research; regulatory innovation
Regional strategies	Both the Strategic Economic Plan and the draft Local Industrial strategy highlight health, life sciences and medicines manufacturing as strategic

	opportunities for the region at a time of demographic change, with the regions research assets in ageing representing a significant opportunity
North East Covid 19 Recovery Plan	The regional Covid-19 recovery plan highlighted specific opportunities in this area of the North East economy related to accelerating growth in medicines manufacturing, homeshoring generics, testing of drugs and treatments and co-ordination of treatments and vaccination.

Annex 4 reviews these key policy frameworks in more detail and highlights their relevance for this strategy.



4. Health and Life Sciences in the North East

The North East Region

The North East is the most northerly Local Enterprise Partnership (LEP) area in England, located between Scotland, Cumbria, Tees Valley, North Yorkshire and the North Sea. At just over 3,000 square miles, we are the sixth largest LEP area in England by geographic size. The North East hosts a mix of urban, suburban and rural areas that span our seven local authority areas of County Durham, Gateshead, Newcastle, North Tyneside, Northumberland, South Tyneside and Sunderland. This variety of places and setting provides an excellent living and working environment with high quality of life and includes:

Three cities:

- Newcastle that has science, education, culture, digital and service sectors and acts as our transport gateway.
 - Durham that is a leading university, science and tourism centre at the hub of a largely rural county.
 - Sunderland, which is home of Nissan's UK-leading automotive manufacturing and has education, culture and a well-established digital software sector.
- Four universities: Durham, Newcastle, Northumbria and Sunderland. Two of these (Newcastle and Durham) are amongst the UK's 24 leading research intensive (Russell Group) universities.
 - Key industrial sites, business parks and innovation hubs, including Cobalt Business Park, Infinity Park, NETPark, Newcastle Helix, Integra 61, Quorum Business Park, the International Advanced Manufacturing Park and 21 Enterprise Zone sites.

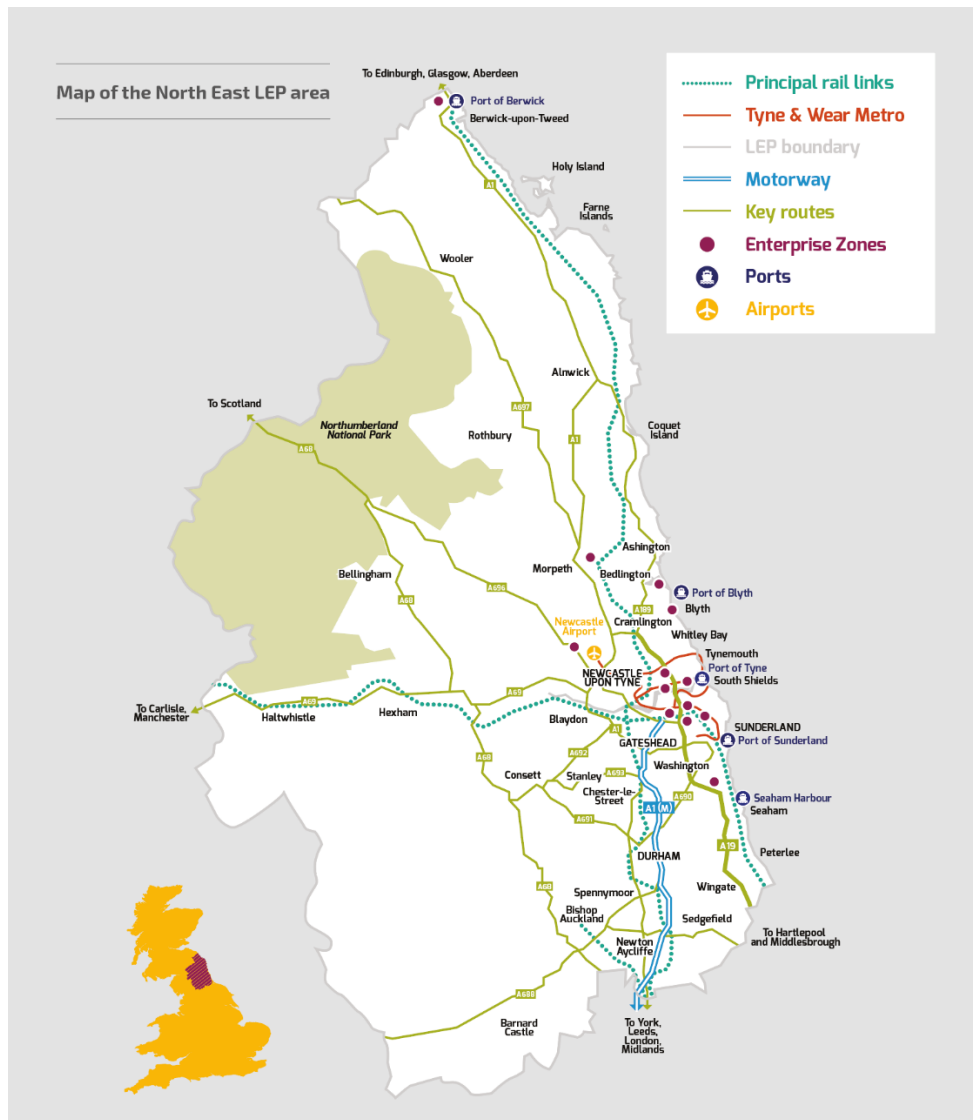


Figure 5: Map of the North East LEP area

The North East's communities and economic activities are heavily concentrated around the coast, the region's rivers and major transport routes. Reflecting this, the North East's five ports (Port of Berwick, Port of Blyth, Port of Sunderland, Port of Tyne and Seaham Harbour) are key assets, alongside Newcastle International Airport. Within the region, we have strong connectivity through public transport, roads, infrastructure and a UK leading digital infrastructure.

The region has a population of two million people, the ninth largest LEP area by population; 1.2 million are aged 16 to 65, with 32% of this age group having a degree or equivalent qualification. Our people are friendly, welcoming, collaborative and proud of their history. They have a strong and distinctive sense of place, a capacity for resilience, ingenuity, and a deep and shared passion for our landscapes, cities and culture.

North East regional businesses are strongly integrated into global markets. The business base includes significant international investments from the EU, US, Japan and India and exports £7.6 billion to the EU and £5.3 billion to the rest of the world.

With national and international connections through rail, air, sea, and digital infrastructure, the North East has strong links with the rest of the UK and the rest of the world.

While North East partners are well connected within a region of significant scale, it also works closely with partners from other parts of the UK. Its institutions are part of wider Northern partnerships, including the NP11 that brings together the 11 northern LEPs to promote northern growth, and Transport for the North, a new statutory authority, promoting northern connectivity. Its universities and sector bodies work across the UK and internationally and there are a number of key geographical partnerships which are relevant for different parts of the regional economy.

For example, North East pharmaceuticals are strongly connected to global value chains securing raw materials and ingredients in places including the Far East and exporting to US markets. In life sciences, there are strong university and health collaborations with other areas in the North of England through the Northern Health Science Alliance and business membership organisations, and connections to Scotland in pharmaceuticals and research activity and through the leadership role of CPI in medicines manufacturing innovation projects.

Overall, one of the features of the North East is its diversity and that it includes a relatively stable population structure and spatial composition which is a microcosm of the UK as a whole. This makes the region a useful focus for trials and demonstrator activities which require scale, but also seek to reproduce national conditions.

The North East Health and Life Sciences Landscape

The health and life sciences sector represents one of the most diverse and dominant economic sectors in the UK, including assets ranging from the development and manufacture of drugs and treatments, the development of gene and cell therapies, and intelligent drug discovery and development to artificial intelligence, diagnostics, wearables, telemedicine and much more.

The government refers to 'health and life sciences' as *"the application of biology and technology to health improvement, including biopharmaceuticals, medical technology, genomics, diagnostics and digital health."*

The identification of health and life sciences as an area of strategic importance in the SEP responds to this global and national economic and policy context, and reflects its profile in the region which includes:

- A large GVA and employment footprint.
- Major manufacturing capabilities – Active Pharmaceutical Product (API), finished products, niche products, diagnostics, and innovations.
- Local science, research and development and innovation expertise-driven through our universities, catapults and private companies.
- 'Golden assets' - centres of healthcare and life science excellence including an Academic Health Science Centre and national innovation centres - these drive research and innovation.
- An excellent healthcare and innovation system.
- Significant growth potential in the sector.

Key components of the health and life sciences sector in the North East include:

- **Med-Tech:** Companies developing clinical and point of need diagnostics, medical devices and equipment and digital health applications to diagnose and deliver care.
 - **Examples:** Biosignatures, Helena Biosciences, Rocket Medical, QuantuMDx, Femeda, Northgene, Integral, MDNA Life Sciences.
- **Pharmaceuticals and biotechnology manufacturers:** Companies which create and manufacture medicines.
 - **Examples:** GSK, MSD, Recipharm, FuiFilm Diosynth Biotechnologies, Accord Healthcare, Sterling, Clinigen (Quantum Pharma) and Piramal Healthcare.
- **Support Services and Value Chain:** Companies which either work across the supply chain or specialise in specific functions. These include specialists in the engineering and equipment supply chain and construction of facilities.
 - **Examples:** CPI, High Force Research, Datatrial, Arcinova, Alcyomics and Magnitude Biosciences, WH Partnership, Parker, Thermofisher
- **Biotech:** A growing cluster of biotech businesses driven by corporate and university spinouts plus the outputs of the Northern Accelerator is developing with companies such as NewCells Biotech, Iksuda Therapeutics, Atelerix, AMLo Biosciences, 3D Bio-Tissues and Shield Therapeutics.
- **Broader Ecosystem** – A broad spectrum of institutions, innovation centres and networks that support the functioning growth and development of the sector.
 - **Examples:** Academic Health Sciences Network (AHSN), Centre for Process Innovation (CPI), which is part of the UK Catapult Network, cluster and sector bodies such as Bionow and NEPIC, universities and their programmes, research institutes like NIHR Med Tech NE, Diagnostics NE.

- **Academic science and research:** Nationally recognised assets in North East universities which develop new science, work in partnership with industry and the NHS to introduce new products and services and spin out new businesses.
 - **Examples:** One of eight Academic Health Science Centre partnerships in England, ranked 4th in the UK for Research Intensity in Clinical Medicine, Europe's largest concentration of ageing-related interdisciplinary researchers and national centres of excellence in ageing, Northern Accelerator partnership between five universities.
- **The NHS:** The NHS performs three distinctive and important roles in the Health and Life Sciences eco-system:
 - As an enabler of the ecosystem to support SMEs and spinouts to commercialise their products and services through validating 'unmet needs', real world evaluation, conducting clinical research and trials for product development, acting a testbed of technology innovation and accelerating the commercialisation of products.
 - As an innovator of products, services and processes internally.
 - As a significant health market in which to adopt these products and services. Health care spending in the UK totals about £200 billion annually, 10% of GDP.

In the North East, the four hospital trusts (Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH), Northumbria Healthcare NHS Foundation Trust, South Tyneside and Sunderland NHS Foundation Trust, County Durham and Darlington NHS Foundation Trust) and the wider commissioning and public health systems are key partners in the development and delivery of this economic growth strategy.

Example: Newcastle upon Tyne Hospitals NHS Foundation Trust is consistently one of the highest performing and ranking trusts for clinical research and clinical trials with over 500 clinical trials per annum facilitated through Newcastle Joint Research Office. As an example of the scale of NHS operations in the region, Newcastle upon Tyne Hospitals Trust activity levels include 1.72m patient contacts per year, 14,725 staff employed and £1.087bn healthcare spend. Collectively they are rated CQC Outstanding and with the Great North Care Record recognised as a Global Digital Exemplar.

Key Data

Health and Life Sciences Economic Value

In 2019, Health and Life Sciences in the North East region had a turnover of £1.7bn⁷ (£1.5bn in 2018), with the combination of existing high productivity businesses and their capacity for growth making this broad area of the economy well placed to contribute to the key performance indicators set out in the SEP.

Growth in the sector will contribute to the target that 70% of the 100,000 more jobs aimed for by 2024 are 'better jobs', defined as being professional, technical and managerial. Employment growth in the sector is likely to have a higher concentration of these types of jobs than in most other sectors.

As a higher productivity area of the economy, the businesses and other organisations operating in this area of strategic importance are also more likely than others to strengthen the region's performance on productivity, measured by GVA per capita.

In employment terms, the overall growth trajectory of the sector in the North East was 22% compared to an 9% national growth between 2010 and 2019. This trend is likely to continue with growth in manufacturing, SME growth and in the research and science base. For example, in its first three years, 48% of spinouts from the Northern Accelerator Programme came from life sciences businesses. In the response to the COVID-19 pandemic, it reported employment growth of over 300 jobs in the pharmaceuticals sector, at a time when other sectors were furloughing staff and concerned about future job losses. The new COVID Lighthouse project in Gateshead and Newcastle is expected to deliver 1000 new jobs in research and testing.

In terms of employment, figures from the Office for Life Sciences⁸ clearly illustrate the size and contribution of the health and life sciences sector.

In 2019, total North East regional employment in the health and life sciences sector was 7,680 (3.0% of UK total). This comprised of 2,060 (3.2% of the national total) in Biopharma core, 2,180 (3.6%) in Biopharma service and supply, 2,150 (2.1%) in Med-Tech core and 1,290 (4.5%) in Med-Tech service and supply. Between 2010 and 2019 overall employment in the sector increased by 1,400, which represents an equivalent increase of 22% compared to 9% nationally.

The North East attracted 4.2% of all life sciences projects into the UK between 2013 to 2017. Despite this achievement there is more potential for growth and a target to achieve a ranking as a top 10 UK life science Foreign Direct Investment.

⁷ Bioscience and health technology sector statistics 2019, <https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2019>

⁸ *ibid.*

Pharmaceuticals and advanced manufacturing

The North East is a major location for the global pharmaceutical industry which makes a sizeable contribution in this area, generating £868 million for the regional economy in 2017. There are 73 pharmaceuticals and biotechnology supply chain companies in the region, employing 4,100 people with an annual turnover of £601 million. Its wider impact is an estimated contribution of £1.5 billion and it supports between 18,800 and 23,500 jobs.

This is part of a wider advanced manufacturing footprint which accounts for 15.3% of the North East LEP area's GVA and 11.3% of employment. Alongside pharmaceuticals and chemicals, the other key advanced manufacturing specialism is automotive manufacturing focused on the Nissan car plant and a wider group of automotive OEMs based around Sunderland, with a footprint across the wider region.

Large global pharmaceutical manufacturers are located in the region including Glaxo Smith Kline, MSD, Accord Healthcare, Recipharm, Arcinova, Sterling Pharma Solutions, Fujifilm Diosynth and Piramal. The North East also has a thriving SME base working closely with industrial partners and academic institutions' innovation assets in formulation, novel therapies and biologics.

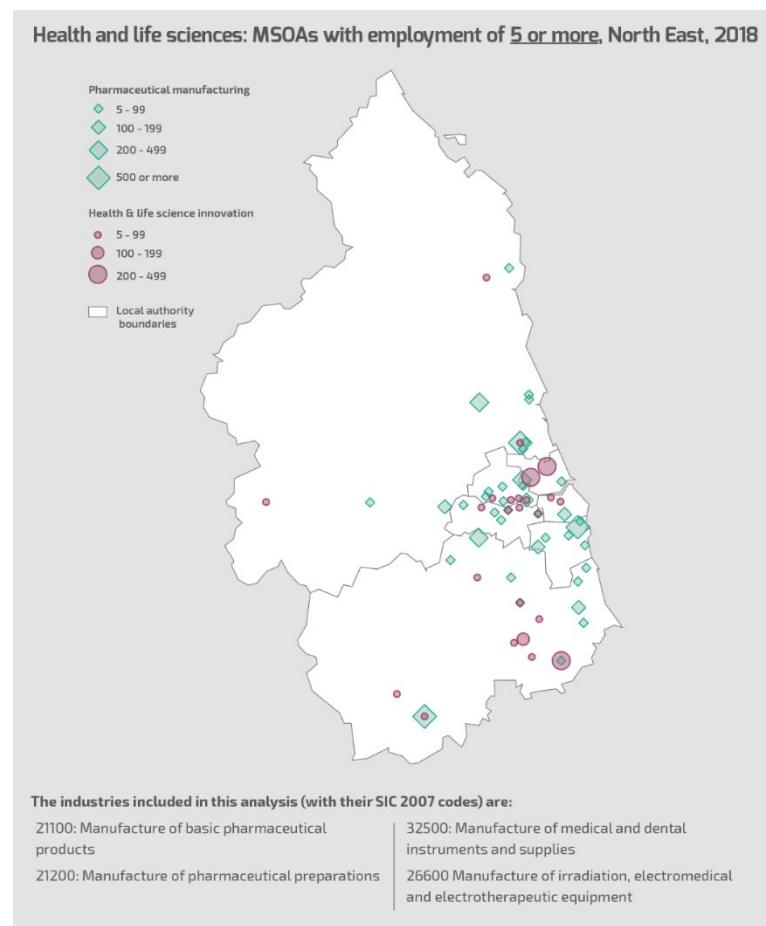


Figure 6 North East life sciences and pharmaceuticals industries by employment

Trade, exports and internationalisation

The North East has an export-led regional economy. The region exported £13.3 billion of goods in 2019; this included £7.3 billion of machinery and transport and £2.8 billion of chemicals (including pharmaceuticals)⁹.

The pharmaceutical manufacturing sector is a key driver of the region's export-based success. The figures show that 86% of North East pharmaceutical production is exported, with 64% of finished products going to the United States.¹⁰

This includes contract development and contract manufacturing concerning key supply chain companies and large multinational drug developers. Five pharmaceutical manufacturing sites in the North East are internationally owned. It is a highly efficient sector, which achieves its competitiveness through lean working practices, upskilling, reducing or mitigating costs, increasing quality and supply agility. The raw materials, chemicals and reagents involved are sourced from Asian markets such as China, higher-value processing equipment and specialised raw materials from North America, as well as other parts of the UK, Ireland and mainland Europe.

The North East is home to two of the UK's largest specials manufactures – Quantum Pharma (Clinigen) and The Specials Laboratory.

The North East Regional Asset Base

Support services and eco-system

These sectors sit within a wider eco-system of cluster bodies, support services, and key hubs and networks in the region which provide key support to the sector's growth potential. A number of these are specialist networks focused on the health and life sciences sector, whilst others provide the wider business support, skills and innovation infrastructure established in the North East.

There is also a wider network of assets around the North East, in adjacent LEP geographies, the wider North of England and in Scotland which has an existing relationship with partners in the region which can be leveraged for North East growth.

Unlocking the growth potential of the health and life sciences SME sector will require strategic collaboration between businesses and this network of key assets, institutions and networks.

The key assets within this eco-system are described below.

⁹ HMRC Regional Trade Statistics, <https://www.uktradeinfo.com/Statistics/RTS/Pages/default.aspx>

¹⁰ First for Pharma, CPI, North East LEP (2017), Profile and Importance of the North East Pharmaceutical Manufacturing Sector

Cluster and sector bodies

The North East life sciences community is supported by a number of cluster and sector bodies, each of which are active members of the Health and Life Sciences Steering Group and play distinctive roles in the economy.

The North East LEP recognises and supports the crucial role of these bodies in providing a framework for business leadership, collaboration and engagement with other partners and networks. These include:

Pharma North East

Recently founded to act as a strong voice for North East-based pharmaceuticals companies, the vision of the Pharma North East is to support North East pharmaceutical sector businesses and manufacturing sites to grow their employment, skills, investment, exports and supply chains through business-led collaboration.

Pharma North East grew from First for Pharma, a network of senior pharmaceutical sector leaders which existed to share knowledge and enhance the visibility of the sector nationally and internationally.

Pharma North East aims to support the development of a strategy for growth in the sector in the region taking advantage of the trend towards reshoring of pharmaceutical manufacturing. It acts to develop and communicate information about North East pharmaceuticals, ensure the long-term supply of skills, develop and secure the supply chain, foster improvement in the logistics and connectivity and support trade and exports.

North East Process Industries Cluster (NEPIC)

Formed in 2004, following a merger of the Pharmaceutical & Specialty Cluster with the Teesside Chemical Cluster, NEPIC represents the second largest process sector in Europe.

It brings together manufacturers, suppliers, universities and research and technology organisations (RTOs). It is an award-winning cluster body, the only such UK organisation to earn the prestigious European Secretariat for Cluster Analysis, Gold Label. It exists to help the manufacturers, supply chain companies, universities and RTOs in membership exploit the synergies that naturally exist between them, including trade, collaboration and sharing best practice across issues including safety, process productivity, quality, asset management, digitalisation, skills and other areas.

NEPIC's forward plan aims to strengthen support to the region's pharmaceutical companies and innovative SMEs. Its particular focus is on strengthening the innovation ecosystem within the North East to accelerate the short-term translation / adoption of knowledge and technology from academia and SMEs into industry and building the regional supply chain across chemical and pharmaceuticals. Strengthening these local relationships will improve the resilience of the region and encourage inward investment.

Bionow

Bionow is an award-winning not-for-profit membership organisation supporting the biomedical, pharmaceuticals and life sciences sectors. It does this by bringing people together at conferences and events across the North, being an advocate for the North, and providing comprehensive procurement member benefits that strengthen the competitiveness of the North's innovative life science sector. Activities are focused on life science companies located in the North and Bionow has a team and membership based in the North East.

Bionow provides the tools and support for member organisations to become among the most competitive in the industry through a range of specialist products and services and connects the life science sector with a range of sector specific conferences. These include annual conferences focused on Precision Medicine, Oncology and Pharma Manufacturing, all of which draw on expertise from the region and wider North with the aim of showcasing the assets, business and academic excellence. This is further highlighted at the annual BioFocus Conference which brings the North East life science community together.

North East Hubs, Networks and Centres for Excellence

The North East hosts several centres of excellence which have a national and international reputation, playing a vibrant role in the life sciences community.

Each of these centres for excellence are core assets providing a unique service to the region and a draw for potential investors.

Catapults

Centre for Process Innovation (CPI)

The CPI acts as a catalyst bringing together academia, businesses, government and investors to translate smart ideas and research into the marketplace. It is leading independent technology innovation centre and a founding member of the UK government's High-Value Manufacturing Catapult.

The teams based at CPI work together, applying their many years of experience to ensure that every great invention gets the best opportunity to become a successfully marketed product or process. CPI works with partners across diverse markets in the UK and around the world, driving their innovations forward and helping them to reduce the risk and cost associated with product development.

CPI currently hosts a number of national innovation facilities in the North East and adjacent areas, including a number focused on pharmaceuticals, MedTech, internet of medical things (IoMT) and in vitro diagnostics (IVD). It has £170 million of innovation assets and more than 490 staff (scientists, engineers drawn from industry and academia) housed within its facilities, including:

- National Formulation Centre (NETPark, Sedgefield).
- National Healthcare Photonics Centre (NETPark, Sedgefield).
- Medicines Manufacturing Innovation Centre (Glasgow).
- National Biologics Manufacturing Centre (Darlington).

Its expertise in pharmaceuticals and med-tech includes:

- Medicines manufacturing innovation covering multiple modalities (small molecules, biologics, complex medicines).
- Digitally enabled manufacturing of medicines.
- Development, scale-up and innovation in MedTech and diagnostics, undertaken under ISO 13485.
- Novel drug delivery systems to deliver advanced therapies and complex medicines (eg nanotherapeutic delivery systems – such as lipid and polymeric nanoparticles).
- Smart and intelligent packaging of medicines and smart connected medical devices.

North East and North Cumbria Academic Health Science Network (AHSN NENC)

The AHSN NENC has, since its inception, focused on economic growth by mobilising the assets within the region's trusts, clinical commissioning groups (CCGs) and universities to attract and grow business.

In recognising that economic growth can be driven by ideas and products that arise from within the NHS which have commercial potential, and through the development of products and services by companies through access to NHS expertise and markets, the AHSN NENC has developed and successfully implemented The Innovation Pathway. Now nationally adopted, the 'Innovation Pathway' sets out the stages and process of development to support the commercialisation of products and services in healthcare. There is significant activity in the North East to support business to easily and seamlessly access the support to navigate and support them through this complex landscape of commercialisation.

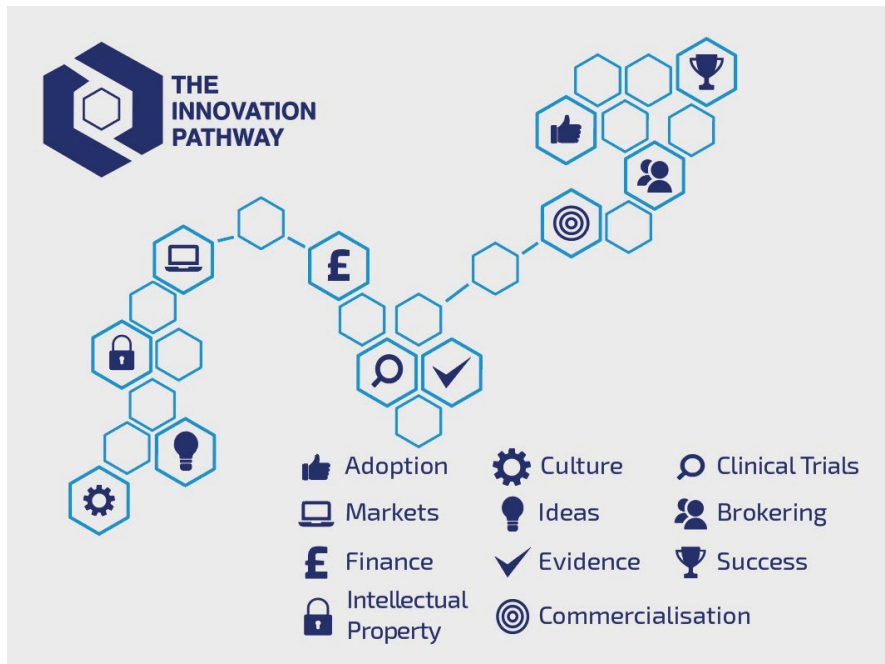
A key component of this is the Great North Care Record. This is the UK's leading initiative to share medical information across the North East and North Cumbria between authorised health and social care practitioners. It will ensure that health care activities such as diagnosis, medications, hospital admissions and treatments can be improved for both patients and the health system.

The work of the AHSN NENC focuses on four main areas:

- Supporting economic growth.
- Transforming patient safety and quality improvement.
- Digital transformation.
- Improving population health.

Across all these activities, the AHSN NENC acts as the trusted broker of cross-organisational work.

AHSN, CPI and the North East LEP have signed a joint memorandum of understanding which sets out how they will work together to facilitate the North East Health and Life Sciences programme.



University-led centres and programmes

Research on ageing

In Newcastle, the North East hosts Europe's largest concentration of ageing-related interdisciplinary researchers (more than 600 staff) and this capability has enabled the development of national leadership on this issue, including a number of pieces of research and delivery infrastructure. These include lead national centres of excellence in ageing research (NIHR Biomedical Research Centre, Alzheimer's Society Dementia Care, NIHR School Public Health Research), co-leads of a National Policy Research Unit for Older People and hosting of national innovation centres in Ageing and Data.

Campus for Ageing and Vitality (CAV)

Working in partnership, Newcastle University, Newcastle Hospitals (NUTH & CNTW) and the City Council have created a vision for the UK's very first Campus for Ageing and Vitality.

The 30-acre Campus for Ageing and Vitality (CAV) site for innovation and evaluation will include a translational ageing research hub to develop new treatments and technologies, feeding into a "Spectrum of Independence" model. This will comprise: (i) Intergenerational and independent living for older people; (ii) Intermediate care and (iii) A care home and dementia care village.

The associated National Innovation Centre for Ageing (see below) will generate a pipeline of external industry partners to utilise CAV as a collaborative research site and "living laboratory," integrated with strong academic and consumer partnerships.

National Innovation Centre for Ageing (NICA)

Set up in 2014, the UK's National Innovation Centre for Ageing is a world-leading organisation, created with a £40m investment from UK government and Newcastle University.

Leveraging the experience and expertise of older adults while harnessing big data, the UK National Innovation Centre for Ageing is uniquely positioned to help pharmaceutical, medical technologies and diagnostics, consumer brands and services optimise the opportunities provided by the demographic revolution and longevity economy.

Applying Ageing Intelligence™ to data enables organisations to generate new commercial insights and behavioural patterns to learn continuously from existing and real-time data into the ageing population and their wider social circle (stakeholders).

National Innovation Centre for Data (NICD)

The £30m centre is co-located with NICA and funded with £15 million from UK government and £15m from Newcastle University to:

- Address the availability shortage of data skills in the UK.
- Transfer practical data skills into the workforces of private and public sector organisations.
- Empower organisations to gain insights from their data to:
 - Optimise existing operations and create efficiencies.
 - Launch new products and services.
- Open access to a vibrant data ecosystem.

Research intensity in clinical research

Newcastle University was ranked fourth in the UK for Research Intensity in Clinical Medicine in the 2014 Research Evaluation Framework and is the only area outside the “Golden Triangle” to have hosted an NIHR Biomedical Research Centre since 2007. It has top 10-ranking in the MRC Translational Research report for “directed translational award funding” (2008-2018), with particular strengths in MRC Stratified Medicine Consortia. The Newcastle upon Tyne Hospital Trust hosted three of 24 European Reference Networks in Rare Disease (liver disease, immune disorders, neuromuscular disease), the only NHS Trust to host more than one.

National Institute for Health Research Innovation Observatory

Based at Newcastle University, the National Institute for Health Research will shape the future of health advances to provide better and more efficient healthcare for patients and the wider public. It applies state-of-the-art data analytics to explore trends in health innovation across drugs, medical technologies, diagnostic tools and healthcare services and offers academia and industry unique insights into areas to develop that can provide better healthcare and allow an opportunity for new innovations to be used in practice more rapidly.

Its major stakeholders include the National Institute for Health and Care Excellence (NICE), NHS England, healthcare providers, research funders and industrial partners.

Northern Accelerator

Northern Accelerator brings together academics and business leaders to form sustainable businesses that create more and better jobs. Enabled by £4.9m from Research England's Connecting Capabilities Fund, Northern Accelerator builds upon two European Regional Development Fund programmes to embed entrepreneurial business leaders into university spinouts at the earliest stage.

Successfully accelerating the spin outs from the four North East universities during the first phase of its work, the long-term vision is to deliver sustainable impact, developing an ongoing venture capital fund for university spinouts and a vibrant community of businesses created through the programme.

Arrow

The Arrow programme is an ERDF funded initiative that matches Newcastle University research, knowledge and innovation projects with the regional needs of SMEs. It targets SMEs looking into new products, processes or services and offers fully funded research and innovation support from university academics to accelerate progress. If Arrow can't find appropriate support within the university, it can provide up to 50% match funding, up to a value of £10k, to buy support from another provider.

Intensive Industrial Innovation Programme (IIIP)

The Intensive Industrial Innovation Programme (IIIP) is an ERDF funded programme led by Durham University. It is a collaboration between Durham, Newcastle and Northumbria universities whereby each university works directly with SMEs in the North East region to develop new services and products for the market.

Eligible SMEs are supported by a dedicated PhD research student for three years, as well as having access to senior academic researchers and university research facilities. The project is targeted at supporting businesses in the priority sectors identified in the strategic economic plan of the North East LEP. The ultimate aim of the IIIP is to encourage a culture of innovation that benefits business, leading to greater export opportunities and increased graduate employment, particularly in science and engineering.

For regional SMEs, this provides the opportunity to access regional academic expertise and support as well as a full-time research student to work on their proprietary research project. This is done at minimal cost to the SME which contributes approximately £5k annually towards costs. For post-graduate students, the IIIP programme offers individuals the opportunity to carry out research towards a PhD while gaining valuable industry experience and an insight into how academic research can help businesses grow and develop.

Newcastle Joint Research Office

Established in 2006, the Newcastle Joint Research Office (NJRO) is a partnership between The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) and Newcastle University supporting researchers in the development, implementation and delivery of world-class experimental, translational and clinical research. Through the partnership, NuTH acts as sponsor for all university research requiring access to its patients.

NJRO comprises both NuTH and university staff who work together to support clinical researchers through what can be a complex research process. Working with colleagues across NuTH and university, NJRO specialises in the development of funding applications (commercial and non-commercial), governance and regulatory compliance (from low-risk observational studies to high-risk international clinical trials), application submission, post-award contracting and intellectual property (IP) and post-award project management.

NJRO also works closely with other universities, NHS organisations, government departments and industry, and is involved in national working groups to share best practice, collaborate with the partnership and ensure that the clinical research delivered at Newcastle is safe, value for money and of the highest quality.

International Centre for Life (Life)

Life opened in May 2000 with the purpose of inspiring everyone in North East England to explore and enjoy science and to discover its relevance to their own lives. The Centre for Life has welcomed an average of 300,000 people a year to its science centre: families, adults and school groups. As well as hosting public exhibitions, ground-breaking research also takes place on-site. Newcastle University's Institute of Genetic Medicine is located within the Life Centre, as is the NHS's Newcastle Fertility Centre, recognising the benefits of running clinics outside of a hospital environment. More recently, a second NHS clinic is also situated on-site, the NHS Northern Genetics Service, which is part of the Institute of Genetic Medicine.

University and NHS-led bodies

Newcastle Health Innovation Partners / Academic Health Science Centre (AHSC)

The Newcastle Health Innovation Partners (AHSC) is one of only eight Academic Health Science Centres established in the UK. The National Institute for Health Research (NIHR), NHS England and NHS Improvement have joined forces to deliver a step-change improvement in the health, wealth and wellbeing of a population of 3.2 million people in the North East of England and North Cumbria.

The partnership comprises: Newcastle University, Newcastle upon Tyne NHS Foundation Trust, Newcastle City Council, the Academic Health Science Network for the North East and Cumbria and Northumberland, and Cumbria, Northumberland, Tyne and Wear Mental Health NHS Trust. AHSC seeks to create world-leading improvements in health and social care, through collaboration in translational health research, clinical care and education.

By improving population health, the AHSC sets out four goals:

1. Scientific advancement: We will discover new disease mechanisms, diagnostic tools and treatments in ageing, long-term and rare conditions where we have a track-record of excellence.
2. Translation into healthcare: We will “pull” new diagnostic and therapeutic advances from this discovery science into routine care, making a real difference to the NHS.
3. Careers and skills training: We will develop capacity and capability in the healthcare workforce through cutting-edge, research-led education, equipping the workforce of today for the health challenges of tomorrow.
4. Economic impact: We will contribute to economic growth by supporting industry to access the NHS whilst improving population health and thereby closing the productivity gap across the UK.

The NIHR has also funded other initiatives in Newcastle like the MedTech and in vitro diagnostics cooperative (MIC), Newcastle Innovation Observatory, and Patient Recruitment Centre. The latter is also developing innovative means of recruitment to low intensity phase III/IV studies utilising electronic patient records.

Diagnostics North East (DNE)

Diagnostics have shaped the North East’s excellence in translational research and in improving patient care. **Diagnostics North East (DNE)** is unrivalled in the UK. The region hosts cellular and molecular platforms that enable high quality translation, including unique biobanks and evolving strengths in digital/computational pathology. Newcastle is the only UK centre to host an MRC/EPSRC Pathology Node and NIHR *in vitro* Diagnostic Co-operative (MIC), one of four NICE External Assessment Centres, and the only NIHR Innovation Observatory.

DNE is a collaboration between Newcastle upon Tyne Foundation Trust, Newcastle University and the AHSN NENC working across the region providing a unique infrastructure with expertise spanning all elements of diagnostic pathway.

Northern Alliance Advanced Therapies Treatment Centre (NA-ATTC)

The Northern Alliance Advanced Therapy Treatment Centre, formally established in March 2018, is a consortium of twenty industry, NHS and academic organisations in the North East, Yorkshire and Scotland led by Newcastle Hospitals and the Scottish National Blood Transfusion Service (SNBTS). The purpose of the centre is to develop the systems and infrastructure required to support the delivery of cell and gene therapies with the ultimate aim

of increasing patient access to advanced therapy medicinal products (ATMPs) on a national level.

The centre is focused on all elements of the clinical delivery pathway from procurement of starting materials, near patient Good Manufacturing Practice (GMP), and distribution and administration, through to delivery of clinical trials and adoption and reimbursement across a range of advanced therapies and indications involving the participation and collaboration of nurses, medical clinicians, hospital pharmacists, NHS managers, clinical commissioners and companies.

A new phase of work is currently being scoped which will see the Centre working with partners in Northern Ireland to extend the reach and capability of the work.

North East Universities and Research Excellence

In the North East LEP area, the four universities - Newcastle, Durham, Northumbria and Sunderland - each provide a research base and level of specialist expertise in different disciplines that are crucial to growing the health and life sciences sector in the region. Key components include:

- **World-leading research** - 50% of biological sciences research at Newcastle University was rated four stars in the Research Excellence Framework 2014, meaning it is world-leading. This was also the case for 51% of research in psychology, psychiatry and neuroscience and 38% in clinical medicine
- **In the top 20 for research publications** - The Witty Review rated North East universities in the top 20 for 11 subjects including life sciences and regenerative medicine
- **Research funding secured by North East institutions** – Between 2008 - 2018 £92m was secured from the Biotechnology and Biological Sciences Research Council and £122m from the Medical Research Council
- **Leaders in clinical research** - North East Health Trusts are leading the UK for their involvement in clinical research, with Newcastle Hospitals NHS Trust being one of the highest ranking over the last seven years, with more specialist services than any other group of hospitals outside of London.

Research specialisms

Ageing and health

Ageing is a particular North East specialism, with an established focus on ageing and health. With over 600 academic staff involved in different aspects of ageing research, Newcastle is an acknowledged leader in the scientific response to global demographic change. Key areas of research and learning include:

- Underpinning biological mechanisms of ageing (eg mitochondrial dysfunction, fibrosis etc).
- Translational research into ageing syndromes and multimorbidity.

- Societal responses to the global phenomenon of ageing in areas including finance, culture and social relations.

Newcastle University has created University Centres of Research Excellence (NUCoREs) in Unequal Ageing, Rare Diseases and a nascent centre in Biomedical Engineering to enable it to strengthen its offer. Acting as a virtual hub, it will draw together staff from across the university to focus on wide-ranging inter-disciplinary programmes focused on research and innovation, engagement and knowledge transfer, and learning and teaching.

Newcastle University and Newcastle upon Tyne Hospitals NHS Foundation Trust are the only partnership outside the “Golden Triangle” to have hosted an NIHR Biomedical Research Centre since 2007.

Precision medicine

Newcastle has a well-developed programme focused on precision medicines. It leads two stratified medicine consortia funded by the Medical Research Council and is a key partner in three others. It co-chairs the Rare Diseases Translational Research Collaboration funded by the NIHR with the leadership of work focused on diseases of the liver.

It hosts:

- The Wellcome Trust Centre for Mitochondrial Disease.
- The Medical Research Council Single-Cell Functional Genomics Unit.

Newcastle University's Institute of Genetics, based at the International Centre for Life, is acknowledged for its world-leading research into rare diseases and cancer. This is an area of research with increasing worldwide recognition of the need for a specialised focus. The Newcastle facility combines research with practical diagnosis, treatment and care.

As a Cancer Research UK programme recipient for translational research and drug discovery, Newcastle University remains at the forefront of international development of cancer therapies. The university has been instrumental, with longstanding industry partnerships, in the discovery and delivery of two ground-breaking cancer drugs both now licensed and on the market. Most recently, in 2019, a platinum-based chemotherapy (rucaparib, sold as Rubraca®) that was discovered and developed in Newcastle was launched for women with relapsed ovarian, fallopian tube or peritoneal cancer.

5. North East Life Sciences; analysis of opportunities and challenges

5. North East Life Sciences; Analysis of opportunities and challenges

Given this external context, and the assets base reviewed above, there is much potential for the future economic development of health and life sciences in the North East. The Steering Group has identified a series of opportunities and challenges, many of which have been magnified or accelerated during the COVID-19 pandemic and the economic response.

Opportunities:

Growing and modernising pharmaceuticals manufacturing and its supply chain

Within both the Industrial Strategy and the UK COVID Recovery roadmap, several opportunities are envisaged to grow UK pharmaceuticals. Specific opportunities include:

- The vision of a comprehensive strategy to improve UK manufacturing capability and supply chain resilience in medicines, medical devices and diagnostics. The plan envisages that this will be delivered through a new group that is equipped to focus on supply resilience across the life sciences industry or through expanded sub-groups of the Life Sciences Council groups, including the Health Technology Partnership (HTP) and Medicines Manufacturing Innovation Partnership (MMIP).
- A focus on exporting and capital grants to support the building of manufacturing facilities in the UK, and on innovation funding to support collaborative R&D for manufacturing and skill support. A specific Life Sciences Council workstream to support growth in the Small and Medium Enterprise (SME) base would also ensure that UK manufacturing capability is broadened.
- An ambition to attract ten large and ten smaller manufacturing facilities to the UK, in line with the Life Sciences Strategy.

Specific North East opportunities include:

- **“On-shoring”** of pharmaceutical manufacturing by expanding aseptic secondary manufacturing and positioning of fill-finish facilities that could be co-located with other manufacturing assets to reduce costs and ensure regular usage, which could be converted for emergency provisions. “On-shoring” is not envisaged to secure complete UK self-sufficiency for the management of future health emergencies, as supply chains will remain global, but the aim is to take a targeted approach to strengthen supply chains focused on critical medicines and active pharmaceutical ingredients, or where there is a current weakness in supply chain resilience, procurement and /or strategic reserve-holding.

- **Smarter advanced manufacturing:** The demand for smarter and advanced manufacturing facilities as the sector transforms will require modernisation in the region to meet growing demand and new manufacturing models. Digitisation in manufacturing and product delivery processes are both opportunities and CPI is working on a project on smart delivery of medicines with a range of partners in the region which is exploring a range of changes in the delivery of medicines from formulation to digitalisation of packaging and delivery. 3D printing of medications and medical devices is fast becoming a reality. This could mean that drugs and devices are printed near the patient within very short timeframes.
- **Continuous and digitally enabled manufacturing:** Streamlining of the manufacturing process, with products being created without the need to stop until the product is completed – moving away from the manufacturing, filling, packaging process. The region's centres of excellence are well-placed to support businesses in this area. For example, GSK and AstraZeneca have partnered with CPI to build a continuous manufacturing facility enabled by capabilities at NETPark in Durham. It is estimated that this investment could attract up to £88m worth of investment by 2028. (UK Life Science Sector Deal 2017).
- **Contract Manufacturing:** The biopharma and supply chain branch of life sciences, which includes outsourced, or contract manufacturing is also a major opportunity for the region which has grown 15% over the past five years. Med-Tech has also experienced similar levels of increased demand with growth of 9%. This demand for outsourced manufacturing has been rising. It is expected to continue, as companies (big and small) that lack in-house manufacturing capabilities begin to look to third-parties to reduce costs and form long-term relationships with suppliers as manufacturing becomes more complex.
- **Advanced drug delivery technologies** (nanotherapeutic delivery systems) – Such as lipid nanoparticles, polymeric nanoparticles, exosomes etc to deliver the next generation of complex medicines (nucleic acid therapies, CRSPR therapies etc).

Development of new treatments

The future of healthcare will include a much more diverse mix of treatments and interventions, including cell and gene therapies and biologics.

The North East can respond to the urgent need for more cell and gene therapy (CGT) development and manufacturing facilities to meet the accelerating demand with the global CGT market. This will require significantly more highly specialist manufacturing facilities. As more biopharmaceutical companies develop CGTs, significant change will be required in manufacturing processes, as the drug manufacturing process relies on the receipt of the patient's own or donor cells. Between 2016 and 2019, UK CGT manufacturing has increased by 80%. (Frost & Sullivan).

The presence of the leadership of the Northern Alliance Advanced Therapy Treatment Centre (NAATTC) in Newcastle, working with partners in Leeds and Edinburgh, as one of three collaborations supported by the Cell and Gene Therapy Catapult to accelerate the technologies, represents an opportunity to play a key role in this growing area working with current and future business sponsors. NAATTC is accelerating patient access to, and building systems for, the manufacture and delivery of innovative cell and gene therapies, building on the success of stratified medicine programmes, and links to life science companies.

Similarly, the National Biologics Centre in Darlington represents an opportunity to build a broader-based community focused on development of the full range of novel therapies in the wider North East.

Collaboration with the NHS:

There is significant further scope for the North East health and life sciences ecosystem to work collaboratively with the NHS in order to achieve the ambitions set out in the NHS Long Term Plan and deliver economic benefits that will result from achieving these goals: better care, reduced health inequalities and a healthier workforce, maximising the economic impact of addressing the challenges set out in the Plan.

There are a number of specific opportunity areas with digital technology underpinning some of the plan's most ambitious targets. The North East is well placed to support in achieving the ambitions in:

- Supporting care at home through remote monitoring via wearable devices.
- Digital technology to facilitate service transformation, including the redesign of outpatient services and reorganisations of pathology and diagnostic imaging services.
- Digitisation of electronic records. The 'Global Digital Exemplars' programme will admit new organisations and create models for technology adoption and a shared record through Local Health and Care Record Exemplars. The region's Great North Care Record is being developed proactively to support this.
- Applying digital technologies to new models of care.
- The NHS app will act as a gateway for people to access services and information; people will be able to use it to access their care plan and communications from health professionals.

COVID-19 has been particularly catalytic for driving the adoption of a few digital health technologies with good results, and there is scope to use this as an opportunity to accelerate the uptake of a myriad of digital health and AI initiatives across the region from preventative and community health, through to digital pathology and artificial intelligence. The Northern Health Service Alliance has highlighted this opportunity in submissions to government.

The North East also has research and sciences' strengths which could be applied successfully in this context as follows:

- Cancer Diagnostics - Speeding up diagnosis of cancers at stages I or II.
- Cardiovascular Disease - Improving detection and care for people with cardiovascular disease (CVD) and respiratory disease, preventing diabetes and improving stroke services in order to prevent cases of heart attack, stroke and dementia.
- Primary care networks will be expected to take a proactive approach to managing population health and from 2020/21 will require them to assess the needs of their local population to identify people who would benefit from targeted, proactive support.

Supporting inward investment

Foreign direct investment has made a significant contribution to the North East health, life sciences and pharmaceuticals community, including global investment from different parts of the world. Technopolis¹¹ demonstrated how a range of 'golden' manufacturing assets can be added too, and the wider eco-system leveraged with the potential to act as a catalyst for change and a lightning rod for future inward investment, creating jobs and generating skilled employment. There are a number of potential opportunities to secure new and repeat investments into the region which should be the focus of work with the Department for International Trade (DIT), the business community and researchers. One mechanism for collaboration over and above existing collaboration is to exploit the High Potential Opportunities mechanism recently launched by DIT.

Healthy ageing HPO

High Potential Opportunities (HPO's) are a process to work jointly with the Department for International Trade on new potential specialisms to promote strengths for inward innovation engagement, investment and trade through the DIT Global network.

The North East has been selected to host four HPO projects with DIT on immersive technology, heat networks, plan-based products and ageing.

The Ageing HPO will be directly contributed through the health and life sciences strategy, providing an opportunity to profile our capability in response to demographic change and healthy ageing.

Looking forward, the forthcoming Export strategy and further HPO opportunities, for example on Advanced Therapies, could be a focus for joint work between DIT and the region.

Attracting investment in life sciences SMEs

In addition to fostering the region's homegrown talent through university spinouts, SME growth and the vibrant research base attached to our universities, there will also be a need

¹¹ Technopolis (2019), Review of Sectors, Competencies and Assets to inform development of the North East Local Industrial Strategy: Evidence report to the North East LEP

to attract inward investment into the North East life science SME sector to deliver growth and job creation.

With a world-class centre of healthcare excellence, a workforce underpinned by university graduate talent and pharmaceutical manufacturing prowess, the North East of England has a lot to offer life science investors.

However, it will be important to continue working at building the investment ecosystem here in the North East as investors outside the region are unlikely to act as lead investors in regional companies; investors outside the region are more likely to invest if they are able to 'follow' a 'local' lead investor who will perform most of the heavy lifting (due diligence, etc). It is also important to try and build more visible regional business angel networks that can play a role particularly in the earlier stages of start-up funding.

Supporting SMEs and advancing science

The North East has a thriving SME sector in the field of health and life sciences. Recent research by Knight Frank has listed Newcastle as one of the top ten cities for digital health investment having secured funding of £6.5m between 2014-2019.

SME health and life sciences companies can play a crucial role in delivering the SEP's goals of creating 'more and better' jobs. An important aspect of this is SME growth facilitated via university spinout businesses that are symbiotic with the research base of the four universities in the North East LEP area.

University spinouts

North East university partnership Northern Accelerator is a driving force behind university spinout activity in the North East. The partnership consists of Durham, Newcastle, Northumbria and Sunderland universities. It exists to translate world-class research into thriving spinout businesses boosting the region's economy.

- In 2019 48% of spinouts from the Northern Accelerator Programme were life sciences businesses.
- Based on the most recent data, the growth in spinout company creation has put the Northern Accelerator universities on a par with some of the UK's leading universities.
- The latest figures show that during the academic year 2018/2019 Northern Accelerator delivered 12 new spinouts, had 59 active spinouts, generated IP and licensing income of over £26m and a research grant income of above £170m.
- It has seen the most rapid growth in spinouts across the sector. The number of spinout businesses from partner universities has more than doubled over the past year and increased fivefold since the partnership began in 2016.

- In 2019, partner universities experienced the third-highest number of university spinouts created, bringing the region in line with Cambridge. They also raised the third-highest rate of IP related income and second-highest rate of licensing revenue.

The region's universities have a strong track record of producing innovative spinout businesses that have grown into thriving global companies. Recent success stories of spinouts that have flourished as a result of Northern Accelerator's help include Atelerix and Magnitude Biosciences. They secured significant funding to expand their businesses and are now operating in international markets. The North East LEP aims to build on and consolidate this legacy in the context of this strategy document.

Place based cluster development for SMEs

The North East hosts a number of key locations where the health and life sciences is clustering. There is a strong opportunity to complete the development of these locations, and to strengthen the linkages between them to ensure a vibrant regional eco-system.

Helix

Newcastle Helix is a unique ecosystem, purpose-built to enable the commercialisation of a company's new ideas, accelerating the concept-to-market timeline through access to its unique combination of co-located corporates. These include SMEs, research centres, National Innovation Centres and Newcastle University.

Supporting the delivery of the incubator facilities at Helix will ensure sufficient provision to meet the demand linked to the strategy. This will include an incubator/specialist space-provider support programme, enabling companies to engage with one another and share best practice, and a similar programme for sharing pharma specific best practice / collaboration.

The creation of the National Innovation Centre for Ageing (NICA), and the National Innovation Centre for Data (NICD), and their co-location at the Catalyst, on Newcastle's Helix development, represents a major opportunity to exploit the connection between the digital and the healthcare sectors.

The Biosphere

A crucial component of the Helix is the Biosphere Newcastle, which is a specialist facility tailored to the commercialisation of life sciences and innovation, research and development in the North East of England's regional and economic capital.

The Biosphere is a focal point for the cluster in Newcastle and offers high-quality biology and chemistry laboratories, Grade A offices and conference spaces. These infrastructure facilities are crucial growth enabling assets for the North East health and life sciences sector.

North East Technology Park (NETPark)

Located in Sedgefield, the NETPark Science Park hosts an established and growing science and innovation community encouraging collaborative multidisciplinary links in order to drive innovation, enterprise and economic prosperity.

It aims to provide a range of science, technology and engineering companies with a wide choice of world-class laboratory, clean room and office space from the incubation needed in the embryonic stage of growth to the larger spaces needed by companies who are ready to prototype and scale up to manufacture on site.

Through its wide network of business and practitioner relationships, and strategic partnerships with Durham University and CPI it provides companies with access to a focused and international community. Durham University's Research Institute and two CPI-led national innovation centres, the National Formulation centre and the National Centre for Health Care Photonics are located on the site.

NETPark hosts two UK Catapult Centres – through CPI's link into the High Value Manufacturing Catapult and the hosting of the North East Centre for the Satellite Applications Catapult.

6. Challenges

6. Challenges

The North East faces several key challenges in driving forward the health and life science sector:

- The size of the North East economy:** The North East has a smaller economy compared to other regions. In 2017, the GVA per head of the North East LEP area was £20,338. This is below the GVA per head of England excluding London (£24,181) and England as a whole (£28,096). This scale creates a number of risks including visibility of the region in global and UK markets; a lack of a career structure for skilled staff; and investment levels
- Collaborative working into other geographical areas:** Given this scale, while there is significant opportunity for growth in the region, there is a need for the North East LEP and the region's health and life science business community to work in partnership with organisations across the north such as The Northern Powerhouse Partnership and Core Cities to increase its voice and influence on a pan-northern basis, and to build partnerships with other parts of the UK where assets are complementary. There are good examples of this work being undertaken such as the Northern Alliance Accelerated Therapies Treatment Centre collaboration with Leeds and Edinburgh and engagement through the Northern Health Service Alliance, as well as global links through businesses and universities and civic lead relationships such as with Pittsburgh, but these need focused and co-ordinated engagement. Being outward looking and actively working with partners is crucial to our future success.
- Establishing the region as a go-to destination:** The conversation about the health and life science landscape in England has been dominated by traditional big players like Oxford, Cambridge, London and the South East. Cambridge, London, Oxford, and the South East of England are recognised as the UK's powerhouse for life sciences. All the world's top 20 pharmaceutical companies have invested in this region, which boasts three of the world's top 10 universities (Oxford, Cambridge and Imperial College). The North East has been successful in attracting high calibre applicants to its universities and is successful in creating a viable career ladder in this sector, but there is more to do to secure graduate retention from the skills generated in the region.
- Greater access to international markets:** 64% of the region's exported pharmaceutical and MedTech products are exported to the United States. Still, the region currently lacks a direct flight to the USA which imposes logistical limits on the export potential in this area, due to the lack of appropriate transport infrastructure. There is a need for the North East LEP to work in collaboration with Newcastle International Airport and business partners to make the economic case for re-establishing the direct flight links to America.

- **Existing EU and bilateral trade agreements:** The outcome of the negotiations with the European Union about our future trading relationship will have important implications for the North East pharmaceutical manufacturing sector. A crucial aspect of this will be the future regulatory alignment between the UK and the EU in this area. Following the UK exits the EU, the regulatory requirements for the pharmaceutical sector are now facilitated on a domestic level by Medicines and Healthcare products Regulatory Agency. The region needs to continue to promote a converged regulatory environment to ensure smooth access to the European market for North East businesses and take advantage of policy opportunities to promote frictionless trade.
- **Increasing levels of Foreign Direct Investment (FDI):** The North East has two of the world's top pharmaceutical companies operating and investing in the region (GSK & MSD) and attracted 4.2% of all life sciences projects into the UK between 2013 to 2017. Whilst there is a strong and established offer, the North East does not yet feature in the top 10 UK life science FDI destinations and missing out on potential opportunities from Japanese pharmaceutical companies which between 2005 and 2014 were the second-largest contributor to foreign direct investment for life sciences. For investments into the UK, the top local determinants for life sciences foreign direct investment (FDI) include:
 - Skilled workforce availability (15.7%).
 - Proximity to markets/customers (13.5%).
 - IPA / Government support (11.3%).
 - Domestic market growth potential (10%).
 - Infrastructure and logistics (9.1%).

The North East has strengths in a number of these areas, in particular in skills and domestic market potential but has more to do on connectivity to markets and logistics, and to secure government recognition and support.

- **Finance and facilities for SME growth:** There is evidence that the region needs to continue to build a supportive business environment to support SME growth. The opening of the Biosphere on the Helix site and specialist centres at NetPark have added new facilities close to science and research assets but have filled quickly. There is evidence of further demand which a wider property review needs to consider. There is also evidence from businesses in the region that there is a gap in the finance available to complement the offer from the Northern Accelerator programme for university spin outs. The short-term support which was made available to defend patents during the COVID response programme was quickly utilised, which, along with evidence from business owners, suggests that there is a wider gap to be assessed.
- **Awareness and representation:** A significant challenge to the North East is that its health and life sciences sector is not represented nor understood as a cluster, like that of the “golden triangle”, at a government level or in international trade discussions. The Steering Group has acknowledged the need to strengthen the brand of the region in this area of strategic opportunity.

There is a need for the sector to come together and speak as one voice, co-ordinating the regional health and life sciences sector which relies heavily on the companies based here to represent them, but which can have conflicting priorities. There are options to be explored about how to address this issue, looking to other sectors which work through a sector-led trade body such as Dynamo, the North East Automotive Alliance and NOF Energy, or from a health and life sciences figurehead with the gravitas to bring everyone together and represent the sector in Westminster and to government departments and agencies, drawing on the powerful existing assets and future potential set out in this report.

Our strategy and priorities for action

7. Our strategy and priorities for action

Our strategy aims to take advantage of our strengths and opportunities in business, science and our healthcare system to drive more and better jobs in the region and make a strengthened contribution to one of the UK's priority industrial opportunities.

We aim to take opportunities to enhance our share of the global pharmaceuticals industry, which is valued at over \$1.25 trillion per annum, and to continually improve the performance and offer of our healthcare system through new technologies and treatments to have a positive impact on the quality of people's lives. This will in turn improve access to health care markets for North East businesses and innovators which currently represent 10% of UK GDP.

To achieve this, we will take advantage of a number of regional science, research and translational assets in business, universities and our NHS bodies which are well positioned at the leading edge of some of the major changes which are impacting on drugs, treatments and healthcare services. We will focus on:

- Strengths in production and digital delivery: Supporting manufacturers to drive new methods of delivery and packaging and health care organisations to improve services, patient care and monitoring.
- New methods of formulating drugs, treatments, services and therapies, creating hubs to support development of these ideas and pathways to trial and introduce them into the health system.
- Diagnosis, taking advantage of new opportunities to diagnose and target treatments.
- The opportunities and impacts of demographic change, with a focus on using our globally acknowledged research to shape health, life sciences and drugs and treatments of the future.

We will use these assets to create new and better jobs by growing our science and research base, supporting growth in our small and medium businesses and securing higher levels of investment and engagement from manufacturers and investors into the assets in the region.

Underpinning this work will be continual strengthening of leadership, co-ordination and communication in the region and strengthening of national and international networks and connectivity to ensure that the North East is recognised for its assets and opportunities and is an accessible location for people to work and business to innovate and grow.

Together these areas of intervention will deliver a highly connected regional environment, which is recognised for its capacity to leverage its wide range of assets to identify, accelerate and translate drugs and treatments into key markets in health services and pharmaceuticals supply chains.

Our Vision

To position the North East as a leader in the development, testing, manufacturing and adoption of people-centred treatments, therapeutics and medicines at a time of demographic change

Strategic aims

- To strengthen the distinctiveness and scale of the pharmaceuticals cluster with world-leading companies selecting the North East for the development and location of production.
- To provide a comprehensive support system which can enable high growth life sciences businesses and sub-sectors to be founded and grow in the North East.
- To unlock the commercial and health potential of North East universities' world-class research and assets, translating them into business and health innovations.
- To support business and NHS infrastructure to translate discovery through development to adoption by providing a comprehensive support system for key high growth businesses and sub-sectors and clinical trials.
- To be the leading region for NHS adoption of innovation through the development of the North East NE Health Evaluation System.
- To attract big players in the healthcare and life science investment community to the region to engage with its research, business and translation environment.

Strategic Themes

The Health and Life Science Steering Group has identified three strategic themes to support the delivery of these aims and outcomes in the North East. (See figure x).

1. Modernisation and growth of pharmaceutical manufacturing, in response to the rapid global growth in demand for medicines, health technologies and personalised treatments.
2. Supporting a diverse community of health and life sciences SMEs to form and grow in the region ranging across university spinouts, new business formation, and the encouragement of health and life science companies to cluster in the North East. These will be attracted by the availability of an excellent business growth eco-system, access to excellent science and research and by clear and navigable pathways to key health and medicines' markets.
3. Improving the co-ordination of the translation environment from discovery to delivery into the NHS and wider health and pharmaceuticals markets, ensuring that the region is recognised as a leading hub for innovation, testing and trials, in turn attracting investment into this environment with a progressively growing eco-system of hubs, networks and centre of excellence.

These themes will be supported and elaborated on by the Health and Life Sciences Steering Group which will provide strong collaborative leadership for the strategy, supported by key enabling actions, an excellent communications programme and a strong relationship with key government departments and agencies.



Figure 7: Strategic Framework for North East Health and Life Sciences Growth Strategy

Key measures and outcomes

Through a focus on these aims and themes, the Steering Group has identified key targets aligned with the key performance indicators set out in UK and regional strategies and plans.

By 2030, the Steering Group has set two overarching targets for the Health and Life Sciences strategy:

- To have doubled the number of businesses active in the health and life sciences community in the region.
- Noting that the industries in focus within this area of strategic importance tend to deliver high productivity technical and professional roles, to have doubled the number of jobs in the health, life sciences pharmaceuticals businesses and the research and

development community in the region, contributing in particular to the stock of 'Better' jobs.

Supporting these overarching targets, a number of sub-targets include:

- To be recognised as a key area for the delivery of clinical trials with top 3 ranking NHS trusts on a year-on-year basis and a leading area for the translation of innovation into the NHS.
- To have quadrupled the number of university spin outs in this area of the economy.
- To be systematically recognised in UK government documents as a leading cluster location for health and life sciences.
- To secure one major and a number of smaller additional pharmaceuticals investments into the North East.
- To have secured strengthened physical connectivity along the pharmaceuticals supply chain including direct freight logistics links to the United States from the North East.

Taking action: key interventions

8. Taking action: Key interventions

In support of these aims and objectives, the Steering Group has been developing a programme of interventions under each of these strategic themes. It is envisaged that leadership be taken forward by a range of partners, supported by other members of the community and promoted through the strategic framework set out in this document.

The North East LEP has secured resources from the Local Growth Fund to support project sponsors to develop the detail of a number of these proposals, creating business cases to ensure they are investment ready. Delivery, and further development of this pipeline of intervention, will be key to the next phase of work.

Pillar 1: Growth and modernisation of pharmaceutical manufacturing

The following interventions have been identified as priority actions in this area of the strategy:

Strengthening regional pharmaceutical leadership: Leaders in North East pharmaceuticals business have agreed to come together to develop a new leadership group, Pharma North East, which will champion the role of the sector in the region and provide a collaborative, business-led structure focused on strengthened employment and skills, investment, exports and supply chains. It will work closely with a range of partners across the sector and seek to enhance engagement of the cluster of businesses into the health and life sciences community.

North shoring investment: Enabled by Pharma North East, a proposal is being developed to create a new manufacturing and innovation facility with the aim of providing new capacity to re-shore generics and medicines manufacturing and build resilience in the UK's supply chain in critical areas of NHS demand, and support pharmaceuticals innovation.

Pharmaceuticals supply chain development plan: Led by NEPIC, and aligned with the North shoring project, analysis of North East supply chain development needs from raw materials to production will be undertaken which will enable the North East to strengthen the resilience of its supply chains and build its position as a primary location to manufacture generic drugs and medicines.

Support for export and inward investment activity: Through Invest North East England and the North East Chamber of Commerce, strengthened support for trade and investment activity will be facilitated to support growth in the sector. An immediate focus will be building the collaborative relationship with DIT and developing an inward investment proposition linked to our communication programme. The healthy ageing HPO will provide a specialist focus, with discussion envisaged about other opportunities.

Industrial digitalisation: North East Made Smarter programme: Led by the North East LEP and Tees Valley Combined Authority, a collaborative bid with partners has been submitted to the UK government to support and accelerate industrial digitalisation across North East manufacturing as part of the Made Smarter Adoption programme. If successful, this will include a focus on pharmaceuticals and supply chain businesses in the region.

Smart packaging and delivery of medicines: CPI will lead this project to develop ‘testbed’ models for trials to demonstrate the value of innovative models across the healthcare and drug development supply chain with a number of key areas of manufacturing focus including medicines’ packaging, drug delivery and devices and wearable devices.

Point-of-need diagnostics: Collaboration between CPI, AHSN, private sector, academia and the NHS will seek to position the North East as the go-to place for development, scale-up and demonstration of the next generation of point-of-need diagnostics.

Enhanced connectivity to markets: Led by Newcastle International Airport and the North East LEP, this market feasibility study will assess the potential for enhancing the air connectivity between Newcastle and our growth markets (especially North America) built around freight logistics. It will have a particular focus on pharmaceuticals but will also explore potential in other areas of the economy.

Cluster development support: The North East has created a fund to support our key cluster organisations with core and project funding. Cluster bodies in this area of strategic importance will be in scope for this fund.

Pillar 2: Supporting health and life sciences SMEs to grow

The following interventions have been identified as priority actions in this area of the strategy:

Strengthening Access to Finance: Whilst the region has developed a strong finance offer, some gaps with respect to life sciences SMEs have been identified and will be in scope for a forthcoming review of North East access to finance provision led by the North East Business Growth Board. There are also opportunities to strengthen links to external investors, building on initiatives such as the Innovation SuperNetwork Finance Camp and the good practice of a number of successful regional businesses.

The interdependence of these two areas of activity are increasingly understood and the importance of continuing to work on the investment ecosystem here in the North East is clear to encourage investors from outside the region to join with regional and established investors able to undertake key roles such as opportunity identification and due diligence. In

addition, work will be done to build more visibility of regional business angel networks that can play a role particularly in the earlier stages of start-up funding.

With this in mind, we will explore the opportunities for extending the focus on the region amongst investors through communications activity and investor events including the potential of an annual investor conference, building on current activities and networks.

Health and Life Sciences IP Protection Fund: In the short term, support for those businesses which have seen opportunities to deploy their intellectual property constrained by the COVID-19 crisis will be able to access a unique £300k fund to help protect the intellectual property of high-value health and life sciences businesses in the North East. The COVID-19 Patent Protection Scheme will offer up to £25k to support high-value proposition (pre-commercial) health and life sciences businesses negatively impacted by the coronavirus crisis until 31 March 2021. This will mitigate the risk of losing their patents and intellectual property due to lack of funds.

Driving university spin-outs through Northern Accelerator: Building on its successful first phase since 2016, which has placed 20 CEOs in spinouts, created 21 businesses and allocated £1.7m worth of pre-incorporation funding to help 44 research projects move closer to commercialisation, the four North East universities plus new partner at Teesside University will deliver this phase 2 programme to support two new and crucial areas of its work that support access to finance for SME businesses in the health and life sciences sector. These are i) the Executives into Business programme and ii) its Seed Investment Fund.

- **Executives into Business:** This is Northern Accelerator's flagship support offer – recruiting talented business executives to lead strong and viable spinout businesses, turning world-class research into successful commercial opportunities.
- **Seed Investment Fund:** In August 2020, Northern Accelerator launched a £1.7m Seed Investment Fund, to make substantial investments in businesses with high growth potential in the healthcare, clean technology and data sector over 12 months. The fund will provide early-stage investment for the high-potential businesses created through Northern Accelerator's commercialisation processes and responds to strong investment demand generated by the programme. This will be followed by plans for a larger venture capital based Northern Universities Fund, which is in the early stages of development.

Purposeful Health Accelerator: Led by Northumbria University, this new accelerator programme for SMEs will support them to grow or expand into the health, wellness and social care delivery sectors. It will help them build on the product, process and service innovations many regional firms have come up with in response to the coronavirus pandemic, as well as look at the wider commercial opportunities available with these sectors. It offers practical support, advice and capital investment worth more than £1m.

Building facilities and places to grow: Following on from the successful development of new facilities at Helix and NetPark including the Biosphere and the growth of the manufacturing sector which has taken up existing sites, there is an ongoing need to understand the needs of the sector and generate a development response. Key perceived gaps include:

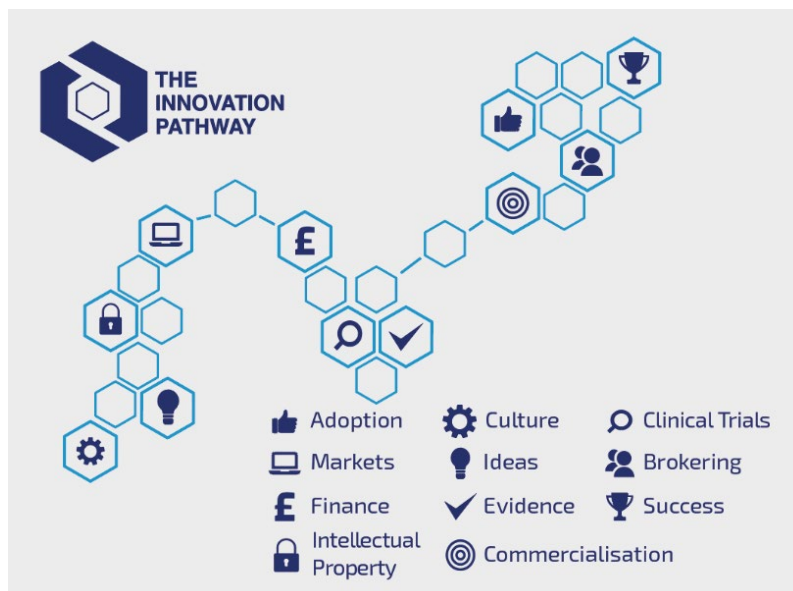
- Manufacturing sites and facilities.
- Grow on space for existing businesses incubated in these regional hubs.
- Laboratories and workshops that could be let on a flexible rented basis for companies that are young, IP rich but cash poor generated in the region or looking to locate here that need to start on research, and therefore not yet ready to move into the Biosphere or NetPark.

A property study will be undertaken by the North East LEP and local authorities looking at existing work and exploring the potential for use of sites around the region including Enterprise Zones and existing hubs, and exploring models from elsewhere including ITAC at SciTech Daresbury, with the aim of developing a ten-year property plan.

Pillar 3: Supporting and enhancing our eco-system to support innovation and translation from discovery to delivery

Pillar 3 aims to co-ordinate, extend and invest into the region's eco-system to deliver a progressively navigable network of services to enable an effective translation environment, working from the identification of ideas and discovery of treatments, to their development into business and the securing of market access into the NHS and pharmaceutical supply chains.

Key interventions include:



Innovation Pathway: Led by the Academic Health Sciences Network (AHSN), the Innovation Pathway provides an organised and staged route to market into the NHS. A number of new interventions will build the strength of the pathway:

Great North Care Record: The Great North Care Record will enable professionals and carers to have legitimate access to the right information at the point of need, ensuring our population get better, safer care regardless of setting or organisation. This will be a region-wide, interlinked electronic health and care record platform, capable of transforming clinical care and supporting research. 100% of primary care data is now supported, with continued expansion including community, secondary and social care and the provision of a research and population health data repository.

It will also improve access to information, allowing individuals to understand better and manage their wellbeing and care.

This, combined with a patient-facing digital infrastructure capable of supporting real-time patient feedback and easy adaptation for specific trial requirements, will enable pragmatic trial design to deliver large patient cohorts for observation studies, real-world evaluation of products, and the evaluation of existing and new patient pathways.

Importantly it will create a Trusted Research Environment to improve access to data and analytics, allowing better population health planning based on demand, and enabling the development and deployment of more innovative treatments and clinical trials.

North East Health Evaluation Ecosystem: This project will significantly strengthen the coordination of required expertise and assets across the region in a systematic, transparent and accelerated way to speed the route of new products and services to market. The proposition is to develop a ‘test bed’ approach which would allow for the accelerated evaluation of products, technology, diagnostics and digital services for early adoption into the NHS, within the wider ‘Innovation Pathway’.

The ecosystem will aim to provide hands-on support to innovators to understand product placement, impact, health economics and added value. Alongside the traditional health economics that is already offered across the North East, it is proposed that this system will bring together a wider wrap-around service to include: procurement support and advice (ie who is the customer and how they buy it) and a clear understanding of the funding flows in the NHS.

Digital health: Recognising the opportunities for transformational change across the health sector in the North East through digital health applications, the Digital Health and Care Tech Steering Group (Digital HCT Group) was formed in 2020 to enable large organisations and SMEs from health and digital sectors to connect, scope and collaborate to tackle a series of health and social care problems which could be addressed through digital applications and to enhance the digital sector.

Facilitated by the AHSN, NENC, the Digital HCT Group will develop a strategy to outline where the digital sector could practically contribute to and support local health and life sciences development and articulate and agree how best to progress the sector’s health tech agenda in the North East.

New innovation hubs and facilities

MedTech, internet of medical things and wearables: Building on the successful model of the National Healthcare Photonics Centre at CPI, NETPark County Durham, phase 2 of the project will extend the focus to include other key enabling technologies including flexible hybrid electronics, advanced materials, micro and nanotechnologies and biotech. It will extend CPI capabilities to provide deep R&D and innovation support to companies large and small in the broad area of MedTech, with a focus on point of need diagnostics, wearables, internet of medical things and internet of wellness things. This facility will enable academic partners, SMEs, investors, large companies, and the wider healthcare ecosystem to extensively collaborate. Lead: CPI.

Northern Alliance Advanced Therapy Treatment Centre, phase 2: The NAATTC is a consortium of twenty industry, NHS and academic organisations led by Newcastle Hospitals and the Scottish National Blood Transfusion Service (SNBTS).

The purpose of the centre is to develop the systems and infrastructure required to support the delivery of cell and gene therapies, and to increase patient access to advanced therapy medicinal products (ATMPs) on a national level. Lead; Newcastle upon Tyne Hospitals Trust

Early Diagnostics Institute: Innovation to detect multiple age-related conditions from one blood sample taken during a GP health check appointment to create an industrial approach to support applied clinical research, leading to development of an active central diagnostic testing and clinical trials centre. Lead: Turbinia working with NIHR MIC and the NIHR Newcastle Clinical Trials Unit, NCTU.

Innovation Delivery Partnerships: Our reach to global businesses seeking solutions to challenges in treatments will be enabled by the development of Innovation Delivery Partnerships, new models for collaborative innovation supported by the North East Innovation Board, which seek to accelerate our assets entry into markets of the future.

Cross-cutting: Enabling actions

In addition to these specific interventions, through the North East LEP work will be undertaken to ensure that there is a focus on the objectives of this strategy among the mainstream business support programmes within the region. Interventions will include strengthened communications to promote the availability of support or tailored engagement facilitated through the Steering Group. These include:

Business support and access to finance: The range of existing start up and scale up services available to the sector through the Growth Hub. Through the review of business support services being led by the North East LEP Business Growth Team, longer-term support needs will be identified. Current support includes:

North East Growth Hub: The North East LEP also manages the North East Growth Hub, which contains a comprehensive directory of business support and access to finance opportunities available within the region. Key services accessible through the hub include:

Scaleup North East: Support for SME businesses with high growth potential. This unique programme is targeted at ambitious and growing SMEs to increase productivity, invest in transformational activity and facilitate peer-led learning with business executives. Supported by a dedicated team of experienced business leaders it offers the following bespoke package of support to grow and develop business:

- Developing a business action plan.
- Providing one-to-one consultations.
- Access to masterclasses and workshops.
- Networking with a community of scale-up businesses.
- Monthly progress meetings to keep on track.
- Brokering strategic partnerships.
- Providing advice and access to funding opportunities.

Innovation SuperNetwork: North East Innovation SuperNetwork has a strategic alignment to the North East LEP. It exists to increase connectivity and collaboration between the region's business community to enhance innovation and share best practice.

The North East Innovation SuperNetwork has developed an Access to Finance programme that allows businesses to explore the different finance options available, providing them with the tools and knowledge to help them to raise finance for their business.

The programme is managed in partnership with NorthStar Ventures and includes one-to-one support and advice on grant funding and a dedicated programme designed to help to secure equity investment.

North East Access to Finance: This provides businesses with support in key areas:

- **An online funding toolkit:** This toolkit includes dedicated funding expertise, legal advice and tips on telling your business story. There is an online library readily available, which is regularly updated with new content to prepare businesses for funding.
- **Accessing angel investment:** This involves working with eligible innovative businesses to introduce them to a network of local and national investors. There is also the opportunity to secure extra investment through the Angel Investment Accelerator, which is supported by Innovate UK funding.
- **Innovation grants:** Businesses can receive advice and support about the range of grant funding available to regional companies. Key examples of innovation grants include:
 - **Supply Chain North East Grant:** SMEs can access up to 60% in grants towards pipeline projects stalled due to COVID-19 or activities aimed at developing the

supply chain. Grants of up to 80% are available for organisations that can potentially support supply chain needs relating to the health and social care sectors, for example in the provision of PPE, respirators and other products.

- **Scaleup North East Grant:** Up to 40% grant funding is available to help businesses grow and develop. Extra support and guidance from Scale Up business advisers are also available to help grow and support businesses.
- **NBSL Grant:** Small or medium-sized business based in Tyne and Wear can apply for a business grant of up to 35% for projects costing between £3,000 and £8,000 (a maximum grant of £2800).
- **North East BIC's Innovation Programme Grant:** The SME Innovation Programme is designed to help SMEs realise their innovative potential. There's up to 40% project funding as well as independent advice and guidance and access to industry experts and suppliers.

Developing skills to support health and life sciences growth: Through the Skills Advisory Panel (SAP), facilitated by the North East LEP, a response will be developed which aims to respond to ongoing skills needs. Initial discussion has identified the need for an ongoing and growing supply of skills to fill the current skills gaps and potential future needs as a result of the growth identified in this strategy, with some skills able to be secured locally through universities and movement within the sector, but also a reliance on national and international markets to fill senior level and technical opportunities.

The SAP has commenced a piece of work linked to the Life Science Skills Investment programme to look further into these needs. A starting point is a list of several key trends in the development of expertise and education within the region which require support as follows:

- Senior-level leadership and strategic-level employees are often sought outside the North East region from other regions within the UK and abroad. While companies have generally been able to recruit successfully into these roles, more needs to be done to develop the future supply of skills in the region to fulfil more of these roles as part of the SEP 'more and better' goal.
- Within research areas, high quality scientific analysts and formulation scientists are more difficult to recruit, whereas technicians and manufacturing operator positions have typically shorter recruitment cycles, largely sourced within the region.
- Graduate-level employees are attracted to the region or can be recruited locally, assisted by our four universities in Newcastle, Durham, Northumbria and Sunderland. These provide a research base and level of specialist expertise that is crucial to growing the health and life sciences sector in the region. Over one quarter of students at our universities study life sciences subjects, the highest number of life sciences students in England relative to the size of the workforce.

Immediate term initiatives underway in the region which have the potential to support these needs include the new Newcastle Futures UTC, specific initiatives in North East universities

and the new government funded Institute for Technology, a North East collaborative model across further education.

In addition, more needs to be done to encourage businesses to utilise Apprenticeship Levy funds. This is a major benefit for businesses to retrain, upskill, and retain staff.

Digital Skills Hub: The North East LEP is develop a Digital Skills Hub to enable development, training and adoption in robotic and digital surgery, mental health and rehabilitation. The hub will provide virtual learning and training environments for surgical skills and other clinical disciplines; a collaborative space between NHS, academia and industry to co-develop and co-produce virtual technologies for health improvement; and a collaborative space for research and evaluation of new virtual technologies into real-world settings.

Leadership and co-ordination

Health and Life Sciences Steering Group

The Health and Life Sciences Steering Group has been established to provide strategic advice, support and coordination of partners to the LEP and for oversight of the development of a Health and Life Sciences Growth Strategy and the work programme. The Steering Group acts as a critical friend to the North East LEP by steering, advising and advocating the work of the Health and Life Sciences Steering Group and the LEP Executive team.

It brings together broad representation of the health and life sciences community in the North East from the private, public, health and education sectors and draws together a unique set of skills, knowledge and perspectives. It reports into the North East LEP Board on development of the strategy and links directly to other boards and structures within the LEP through officers and membership.

Communications

The North East LEP and partners will work together to communicate effectively about the health and life sciences community and capabilities, and the priorities set out in this strategy, facilitated by the North East LEP.

Key audiences include:

- Businesses working in health and life sciences – to build confidence, provide support and encourage engagement and investment.
- Regional audiences – helping to ensure visibility and make collaborative links between partners.
- Policy and strategy - building the presence of the North East in government and amongst other key stakeholders.

- Investors and other economic actors – working directly and through partner and government channels to secure investment to support the objectives set out in the strategy.
- Students, graduates and workers – seeking to build the labour market capacity in the region and attract skills.

Annex 1: Summary of project pipeline interventions

Annex 1: Summary of project pipeline interventions

HLS Strategic Theme	Policy Fit						Name of Project / Activity	Summary of Purpose	Lead Body
	NHS Long Term Plan	Industrial Strategy	HLS Industrial Strategy	Local Industrial Strategy	NE COVID Recovery Plan	R & D Roadmap			
Building our eco-system for translation and innovation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	Early Diagnostics Institute	To develop a unique 'Early Diagnostics Institute' (EDI) in the North East, which will set out to discover five novel blood tests aimed at the earlier diagnosis (and therefore improved treatment) of high burden diseases, working in collaboration with regional partners. The EDI will provide a unique R&D facility which will further build on and enhance the existing expertise, capabilities and reputation of the region in its diagnostics capabilities, creating circa 300 highly skilled jobs.	Turbinia
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Digital Clinical Skills hub (robotics, immersive tech, AI)	To develop a UK leading Digital Skills Hub to enable the development, training and adoption in robotic and digital surgery, mental health, and rehabilitation, building on expertise across immersive tech, robotics and AI.	AHSN NENC
	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	NE Health Evaluation Ecosystem	This evaluation ecosystem model seeks to address a recognised gap in the UK for translational innovation, integration, scale up and pre-commercialisation activities in life sciences through the creation of a systematic, transparent and coordinated approach to enable innovators in the health and life sciences sector access to a unique evaluation system, providing a single point of access to support for businesses to accelerate the commercialisation of product development and adoption into the NHS / social care.	AHSN NENC
	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Great North Care Record	A digital platform enabling health professionals and carers to have legitimate access to the right information at the point of need, ensuring our population of circa 2 million get better, safer care regardless of setting or organisation. It will offer improved access to information, allowing individuals to better understand and manage their own wellbeing and care. Development of a 'Trusted Research Environment' - creating improved data access and analytics, allowing better population health planning based on demand, and enabling the development and deployment of more innovative treatments. Ambition to create a nationally recognised TRE of choice for industry collaborations.	AHSN NENC (with university and health trust partners)
	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	CPI – MedTech,	Innovation facility which focuses on the MedTech market to enhance our capabilities related to digital imaging and in-vitro and point-of-need diagnostics eg:	CPI

							internet of medical things and wearables	<ul style="list-style-type: none"> •Digital imaging: Machine vision, multimodal imaging, AI, flow cytometry •In vitro diagnostics: Laser-based manufacturing of IVDs, pilot line for manufacture of micro-arrays, automated preparation of histology slides •SONNET: Programme supports SMEs in the development of new digital technologies and in the application of digital technologies for solving real world problems including healthcare. <ul style="list-style-type: none"> • Internet of medical things, wearables. 	
	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	Northern Alliance Advanced Therapeutics Treatment Centre	A consortium of twenty industry, NHS and academic organisations led by Newcastle Hospitals and the Scottish National Blood Transfusion Service (SNBTS). The purpose of the centre is to develop the systems and infrastructure required to support the delivery of cell and gene therapies with the ultimate aim of increasing patient access to advanced therapy medicinal products (ATMPs) on a national level.	Newcastle University
		<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	Centre for Public health data	Building on data analytics expertise and capabilities, to support the development of the GNCr's Trusted Research Environment. To improve data access and analytics, allowing better population health planning based on demand, and enabling the development and deployment of more innovative treatments. Currently supporting the regional Trusts in planning and responding to COVID-19	Durham University
Growing Pharmaceutical manufacturing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	North Shoring (re-shoring manufacture of generic drugs/ medicines)	Develop a pharmaceutical innovation facility to enable and build resilience in the UK's supply chain and manufacture of NHS critical drugs and molecules, focusing on positioning the North East as a key location for manufacturing.	NE Pharma
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	CPI- Smart Meds (Health for All)	Developing 'testbed' models for trials to demonstrate the value of these innovations in real world settings to accelerate development and scaling of new technologies in the North East - driven by needs right across healthcare supply chains from pharma through to patient. Priority focus areas 1. Medicines packaging; 2. Drug delivery (medical) devices; 3. Wearable devices.	CPI
	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	North Shoring - supply chain development	Analysis of supply chain development needs (raw materials to production) to enable the North East to be a primary location to manufacture generic drugs and medicines.	NEPIC
Supporting Business to Grow				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Freight / logistics – market	Feasibility study to assess the potential for enhancing the air connectivity between Newcastle and our growth markets (especially North America) built around freight logistics (driven by pharmaceuticals in the North East but covering other sectors).	Newcastle

							feasibility study and access to air freight markets		International Airport
		<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Northern Accelerator	North East university partnership Northern Accelerator is a driving force behind university spinout activity in the North East. Its aim is to deliver a step change in commercialising research to deliver economic impact in support of the North East priority technology / industrial sectors. The Northern Accelerator will enhance the network of entrepreneurs embedded in early-stage spin-out formation, enhance academic commercialisation aspirations through an ideas impact hub, deliver proof of concept support and establish a seed capital investment fund.	Durham University – lead
		<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Purposeful Health Accelerator	Accelerator programme for SMEs to grow or expand into the health, wellness and social care delivery sectors, to build on the product, process and service innovations many regional firms have come up with in response to the coronavirus pandemic, as well as looking at wider commercial opportunities available with these sectors. Offers practical support, advice and capital investment worth more than £1m.	Northumbria University

Annex 2: Case studies

Case study: Arcinova, Alnwick

Dr Nathalie Huther, Senior Director of Business Development, Europe

Arcinova, Alnwick ¹²

What is your company's main business?

Arcinova is a contract development and manufacturing organisation that helps pharmaceutical and biotechnology companies across the globe develop life-changing medicines.

We employ a multidisciplinary approach to drug development by combining chemistry, biology and bioinformatics. All our services are delivered from our 15,000m² facility in Alnwick.

We leverage our decades of experience as a key research and development centre to deliver high quality end-to-end solutions. Our mission is to deliver best-in-class technology services in the fields of contract research, development and small-scale manufacturing to overcome project challenges and increase efficiency.

How long have you been established?

Arcinova was launched in February 2016, following the acquisition of the Covance site in Alnwick, Northumberland, by our Executive Chairman Ian Shott.

Ian is a big supporter of the North East. He knew there was a great opportunity for growth at the Alnwick site and was passionate about the expertise of the people working there.

Since then, we have experienced a massive growth in client acquisition. We now work with 220 global clients, up from 50 in 2016, and have recorded record sales this year. We employ over 180 people and are looking to recruit more.

We have a real global reach, exporting more than 80% of our sales outside of the UK. The majority are in Europe and the USA, we also export to clients in Japan, Australia, South Korea.

What are the benefits of being based in the North East?

The North East is known for life science. Being part of that group gives us credibility and room for our talent to grow.

So much investment and effort has been put into attracting companies to establish themselves in the North East life science sector. It has been great to experience how dynamic the LEP is in supporting us – it has created a very healthy environment for business.

The life sciences sector is like a big family in the North East. As well as this, the infrastructure in the region is fantastic. We have Newcastle Airport, and we are close to both major cities and the countryside.

¹² Note: On February 9 2021, Quotient Sciences announced its acquisition of Arcinova. See: <https://www.quotientsciences.com/news/quotient-sciences-acquires-arcinova-uk-based-contract-development-and-manufacturing-organization/>

The quality of life and the cost of living is second-to-none. We are in such a beautiful location in Northumberland that we can have clients over to visit our facility and then take them to Alnwick Castle.

What have you learned from the journey to get your business to where it is today?

We initially thought it could be a challenge to recruit the right people in Northumberland however we soon learned the North East has a remarkable talent pipeline.

The huge benefit of being based in the North East is that there is so much talent in the local universities and there is such a big pharmaceutical eco-system harnessing expertise in the region.

Being based somewhere where we can access the right talent has helped us to grow to where we are today.

Case study:
Iksuda Therapeutics,
Newcastle

Dr David Simpson, Chief Executive Officer,

Iksuda Therapeutics, Newcastle

What is your company's main business?

Iksuda is a drug development company specialising in an enhanced, new generation of Antibody Drug Conjugates (ADCs) targeting difficult to treat solid tumours. From our bases in Newcastle, UK, and Boston, MA, Iksuda is focused on improving the lives of patients living with cancer through building and refining approaches to ADC development and successfully responding to the industry-wide challenge of being able to treat all patients with cancer.

Iksuda is committed to building a pipeline of next-generation ADCs with improved therapeutic index, harnessing our deep understanding in the field and accepting the challenge of targeting areas of high unmet clinical need.

How long have you been established?

The company was established in 2007 through our investors and Bath University. Since then, we've built from being what was a technology company called Glythera into a drug development company with 12 full-time employees in Newcastle and 25 consultants in Boston and we're looking to grow further.

Have you always been based in the North East?

In 2012, we raised £2million through the North East Fund and relocated to our UK headquarters in The Biosphere, on Newcastle Helix.

Why did you choose the North East?

The reason we are based in the North East is because it is an ideal place for our business. The North East has multiple universities with science focus so in terms of talent recruitment, this region is a key place to be for us. The skills set here is a perfect fit for our industry. While our industry is global in terms of partners we work with, we are manufacturing our second drug in the North East.

The region is very well-placed in our drug class. We could actually take one of our drugs to Phase Two and not need to go any further south than Leeds. It's a pretty powerful story for the North East – as a region, we are incredibly capable of innovation.

What have you learned from the journey to get your business to where it is today?

This year has proved the importance of keeping going even though the journey is never straight. If you've got ambition and you've got a plan, it's about executing that plan. If there is a will, there is a way and we have proved that this year. Don't be narrow-minded about where your business opportunities are – we've recently done a big deal with a Korean company and that has been fantastic for us as a business. *The world is a rapidly-advancing place and there are lots of companies that want to work with us in the North East. We have a good product and a good skill-set and we have taken that and looked for opportunity wider in the world.*

Case study: **LightOx, Newcastle**

Dr Sam Whitehouse, Chief Executive Officer

LightOx, Newcastle

What is your company's main business?

LightOx's work is based around the development of new molecules that can penetrate and 'light up' damaged cells with a fluorescent drug in a multitude of cell types.

LightOx is now aiming to apply this technology in the treatment of oral cancers and looks to enter clinical trials in late 2021 following the rapid development of lead drug candidates in the last few years. LightOx closely works with the research teams of our academic directors to bring through new innovations, recruit new staff members and collaboration partners from around the world.

The drug development program will allow clinicians to treat early-stage lesions, with a topical application, and then activate the drug using a light source similar to that dentitions would use in their surgeries.

How long have you been established?

We started out in 2016, although really got going in the beginning of 2018 with some seed investment from a local business that knew of the work and the development we were planning.

Have you always been based in the North East?

Yes, originally the research was carried out in Durham University with a collaborative effort from LightOx CSO Professor Carrie Ambler and CTO Professor Andy Whiting. Now we have labs in Durham and an office in Newcastle and we plan to move into the Biosphere on the Helix site in 2021.

Why did you choose the North East?

Previously having worked for the N8 Research Partnership, *I think the North East has a lot to offer over and above other Northern cities - good access to the airport, reasonable living costs, a talent pool that extends North and South, a lively city centre; and two of the best hospitals in the country.*

The North of England presents some great opportunities to develop new drug entities. Commercialising and driving a drug to market involves the skill sets of a large number of companies to support, test, analyse and manufacture and protect your drug products.

Companies such as High Force Research who can develop new synthetic routes and provide GMP manufacture, Sygnature Discovery who can provide in-vitro and in-vivo testing models, Histologics who provide histology services, formulation work from CPI in Darlington, or Quay Pharma in Alderley Edge, Aptus Clinical on trial design and of course the many NHS trusts that can provide clinical trial sites.

And of course, protecting the intellectual property is key to making it to market and Definition IP in Newcastle are experts in the field, the list goes on and on.

The North of England has many companies that can make up part of the supply chain needed to bring a new drug to the market and provide world-class expertise to the industry.

What have you learned from the journey to get your business to where it is today?

Perseverance!

Also, I have learnt over the years that often when you take technologies forward, you have to spend a lot of time to find exactly where they might be best applied, what the best market might be and where the need for the product will lie.

The ability to build a strong team and also to give opportunities to those with the ambition to push a company forward is key. It is also good to have an open mind to new possibilities and collaborations and not limit yourself in terms of how much you can expand beyond the UK.

“To position the North East as a leader in the development, testing, manufacturing and adoption of people centred treatments, therapeutics and medicines at a time of demographic change”

Case study:

**Quality Hospital Solutions
and SamplePod Limited**

Andrew Turner, Inventor and Managing Director

Quality Hospital Solutions and SamplePod Limited, NETPark Science Park, Sedgefield

What is your company's main business?

Quality Hospital Solutions (QHS) is our parent company, which is purely focussed on NHS innovation. We have launched products such as beverage trolleys to be used within the NHS.

The idea for SamplePod, a revolutionary tracking and transport system for pathology samples, came about in 2017 as an innovation to help NHS pathology departments that receive thousands of specimens per day in many different types and sizes of tubes, using a huge amount of non-recyclable packaging.

SamplePod holds every possible sample size in an optimum upright position within one pod and can be used time and time again. By eliminating the use of plastic bags and paper request forms it removes more than five tonnes of waste from the process. It is set to revolutionise the way pathology samples are taken, transported and traced worldwide. SamplePod was developed over the last three years in partnership with investors Bill Scott, chief executive at Teesside-based Wilton Engineering, and David Frame, CEO of Sunderland technology company Asset55, and South Tyneside and Sunderland NHS. SamplePod has been successfully trialled at GP surgeries across the region and is expected to be rolled out worldwide early next year.

What are the benefits of being based in North East?

The North East innovation network that we have been able to tap into has been hugely beneficial. It has allowed us to accelerate our product quickly and keep much of our supply chain in the region.

The digitisation of the SamplePod tracking was facilitated by NETPark manager Janet Todd who introduced us to PragmatlC, the company that produced the flexible integrated circuit technology that is used on our smart labels. They are one of the only companies in the world that could offer this, and they also happened to be here in the North East.

This allows ultra-low-cost RFID to be added to every sample tube, giving each one a unique digital identity that can be read wirelessly. The individual sample IDs are locked to the master RFID chip within the SamplePod itself meaning each sample can be fully traced in real-time all the way through to the lab. The tracking technology allows time-sensitive samples to be prioritised automatically.

The access to innovation in the North East is superb. We also benefitted from support from our local investors and from the Academic Health and Science Network, as well as the Queen Elizabeth Hospital and Gateshead Pathology.

What have you learned from the journey to get your business to where it is today?

You have to manage your intellectual property and contracts properly. The partnerships that I have with the NHS and local investors greatly helped with this.

Having been through the process of bringing a product to market a number of times now, we've learned where to go to for advice and to engage. *The North East has a great network of world-class partners and we were able to successfully make use of that.*

Annex 3: Governance

Annex 3: Governance

Membership – Health and Life Sciences Steering Group

Michael Whitaker (Chair)	Pharma North East and Innovation Board member
Tim Hammond	Durham University
Geraint Lewis	Newcastle University
Mike Capaldi	Newcastle University
Tony Alabaster	University of Sunderland
Carolyn Horrocks	Northumbria University
Richard Baker	North East LEP
Alan Welby	North East LEP
Geoff Davison	Bionow
Nicola Wesley	AHSN
Philip Aldridge	NEPIC
Arun Harish	CPI
Rachel Burdis	Invest North East England
Sarah Pavlou	RTC North
Dale Athey	NPL
Kevin Cook	Sterling Pharmaceuticals
Will Dracup	Biosignatures
Roger Kilburn	Arcinova
Andrew Tasker	Femeda
Ben Cantwell	Kromek
Andrea Burroughs	Newcastle Upon Tyne Hospitals Trust
Peter Rippingale	North East Combined Authority
Vicky Cuthbertson	North of Tyne Combined Authority

Annex 4: Health and Life Sciences Steering Group Terms of Reference

Annex 4: Health and Life Sciences Steering Group Terms of Reference

Context

The North East Strategic Economic Plan is the plan for growing and developing a more productive, inclusive and sustainable regional economy. Its key objectives are to:

- Increase the number of jobs in the North East economy by 100,000 by 2024
- Ensure that 70% of the jobs growth is in **better** jobs

The delivery of Strategic Economic Plan is split into three distinctive parts:

Four areas of strategic importance: Where evidence tells us our assets and capabilities provide a strong opportunity for growth - Digital, Advanced Manufacturing, **Health and Life Sciences**, and Energy – these areas are where we can build a stronger North East economy; one that reinforces our position as a contributor to regional, national and global economic growth.

Four service sectors: Education, Financial, Professional and Business Services, Transport and logistics and Construction – these sectors support the wider economy and offer significant opportunity for more and better jobs in the North East.

Five programmes of delivery: Business growth, Innovation, Skills, employment, inclusion and progression, Transport connectivity and Investment and infrastructure – these programmes set out initiatives and projects that will deliver the ambitions of this Plan.

The role of the North East Local Enterprise Partnership (LEP) in delivering the Plan:

The North East Local Enterprise Partnership is a private, public and education sector partnership, supported by a small executive team that provides strong, collaborative leadership to support the growth and development of the North East economy.

Towards a Health and Life Sciences Growth Strategy:

In 2016, a small working group on life sciences, under the auspices of North East Local Enterprise Partnership Innovation Board, consulted with over 100 organisations and set out a series of recommendations to the LEP to enhance the sector.

As an evidenced and recognised area of strategic importance, the health and life sciences sector presents an opportunity for us to address the economic challenges through our excellence in clinical research, clinical delivery, innovation in pharmaceuticals, and responding to an ageing population; all of which enable us to respond to the changing global health services and markets.

The key aims identified by the working group in 2016 are still valid and continue to drive the focus of project and development and delivery. They are to:

- Provide a comprehensive support system for key high growth businesses and sub-sectors.
- Develop a cluster economy opportunity around world-leading companies selecting the North East for production plants by supplementing the pharmaceuticals supply chain.
- Unlock the commercial potential of North East university world class research.
- Support business and NHS infrastructure to translate discovery through development to adoption.
- Be the leading region for NHS adoption of innovation.

One of the key priority actions to enable the achievement of these aims was to appoint a Health and Life Sciences Programme Lead to provide dedicated resource to drive this work forward to support the ongoing growth of the sector. This appointment has been made.

Annex 5: Summary of key policy frameworks for the Health and Life Sciences Strategy

National Economic Policy

Industrial Strategy

In 2017 the Government published the *Industrial Strategy: Building a Britain fit for the future*.¹³ The Industrial Strategy aims to boost productivity by backing businesses to create jobs through investment in skills, industries and infrastructure. The strategy is structured around five foundations of productivity:

- Ideas – The world's most innovative economy.
- People – Good jobs and greater earning power for all.
- Infrastructure – A major upgrade to the UK's infrastructure.
- Business environment – The best place to start and grow a business.
- Place – Prosperous communities across the UK.

It provides the overarching policy framework for Sector Deals between government and key industries within the UK economy. To date, several Sector Deals have been developed and published, setting out priorities for growth and productivity in these sectors, with other Sector Deals forthcoming. A number of these are focussed on key North East sectors including:

- Automotive.
- Life sciences.
- Off-shore renewables.

Further, the Industrial Strategy identifies four Grand Challenges, 'mission based' programmes which aim to provide strategic focus for investment into research and development and innovation in key future areas of the economy. Two of these have specific application to life sciences in their focus on artificial intelligence and data, and healthy ageing.

The Industrial Strategy has a particular focus on driving productivity improvement and is underpinned by the National Productivity Investment Fund, which is being allocated to support these strategies and programmes.

Life Sciences Sector Deals

Following the publication of its Industrial Strategy, the government announced a series of sector deals for the UK life sciences industry. These are structured as agreements to work together and co-invest in interventions aiming to drive UK-based sector growth.

¹³ Available at: <https://www.gov.uk/government/publications/industrial-strategy-building-a-britain-fit-for-the-future>

The key features of the UK Life Sciences Industrial Strategy and the Sector Deal 1 and Sector Deal 2 are aligned to the UK Industrial Strategy and focus on:

Research and Development

Government investment to:

- Raise the intensity of research and development (R&D) in the UK to achieve 2.4% of GDP by 2027.
- Strengthen the environment for clinical trials by investing through the National Institute for Health Research in the research infrastructure in the NHS and the Health Research Authority speeding up approvals for clinical trials.
- Establish the Health Advanced Research Programme (HARP) as a co-ordinated programme across industry, charitable foundations and the NHS with focus on:
 - Data to early diagnostics and precision medicine.
 - Genomics with whole genome sequencing of the UK Biobank.
 - Digital diagnostics and artificial intelligence.

Life sciences sectors to invest in the UK with:

- New industry-led research centres in key parts of the UK on key health care challenges including diabetes, bioscience, creating 1000s of new jobs.
- New collaborations between companies and academia, developing innovative clinical trials in areas including cholesterol-lowering and mental health.
- Sector-wide collaboration with government on advanced health research projects in areas including cancer, digital pathology and radiology.

Support the growth of medicines manufacturing

- Working with the Medicines Manufacturing Industry Partnership¹⁴, creation of new national facilities including:
 - A Medicines Manufacturing Innovation Centre.
 - A Vaccines Development and Manufacturing Centre.
 - Expansion of Cell & Gene Therapy Catapult Manufacturing Centre and creation of three Advanced Therapies Treatment Centres.
 - Investment to grow advanced therapies manufacturing capacity in viral vectors.

Improve the UK environment for businesses with the potential to scale up

- Realise over £20 billion of patient capital investment over 10 years through a number of actions through:
 - The British Business Bank

¹⁴ For more information see: <https://www.abpi.org.uk/medicine-discovery/new-medicines-data/medicines-manufacturing-industry-partnership-mmip/#14bff55d>

- Building confidence in pension funds to invest in innovative firms by enhanced regulation.
- Expanding support for the Enterprise Investment Scheme (EIS) and Venture Capital Trusts (VCTs).

Improve access to new technologies in the NHS for small and medium-sized businesses:

- Establishment of an Accelerated Access Collaborative to develop a streamlined pathway and commit government funding to support innovators and the NHS locally.
- A digital health catalyst to support SME partnering with the NHS.
- Improvement of NHS England's commercial capacity and capability.

Support the UK's health data infrastructure through NHS England, NHS Digital and Health Data Research:

- Develop regional, interoperable Digital Innovation Hubs which support the use of data for research purposes within the legal framework.
- Set clear standards and approaches for data and interoperability and streamline approvals for data access for researchers via NHS Digital.
- Create a sandbox for secure, remote data access for anonymised data in a safe environment.

Implement a regional approach to the life sciences sector deal:

Work closely with key clusters and the devolved administrations to:

1. Develop local and regional investment programmes.
2. Facilitate clustering around key local science and research assets.
3. Invest in the wider regional infrastructure to connect science hotspots including Cambridge-Milton Keynes-Oxford corridor.

People and skills:

- Attract and retain globally mobile talent – including a system that facilitates recruitment and retention of highly skilled workers from the EU and beyond and does not impede intra-company transfers.
- Increase the take-up of science, technology, engineering and maths (STEM) subjects.
- Understand, anticipate and respond to skills gaps across occupations.
- Support mobility between sectors, for example, transfers between academic, clinical and commercial sectors to share knowledge and develop skills.
- Support training for migration of academic scientists into industry.
- Develop apprenticeships and facilitate take-up, particularly by SMEs; improving digital skills in the workforce.
- Accelerate convergence at the interface between life sciences, computer science, mathematics, statistics, engineering and chemistry in the fields of diagnostics, personalised medicine and data science.

The strategy sets an ambition to attract ten large and ten smaller manufacturing facilities to the UK, through the onshoring of manufacturing.

The Life Science Skills Strategy 2030

The government's Life Sciences 2030 Skills Strategy plays an important function in delivering the recommendations of the Life Sciences Industrial Strategy and the subsequent Life Sciences Sector Deals. This is based on the sector's potential for future growth and job creation.

The report sets out the following objectives:

- **The production and implementation of a Life Sciences Skills Action Plan** to oversee and coordinate the delivery of this strategy's recommendations through a partnership approach. This will ensure delivery of the UK's Life Sciences Industrial Strategy through the sector's commitment to skills.
- **A sector-based skills policy that joins up skills and business agendas and meets the ambitions of the Life Sciences Industrial Strategy.** This will ensure multi-disciplinary, industry-relevant learning and skills are embedded in the education system in schools and apprenticeship through to re-skilling.
- **Promote and incentivise the take-up of apprenticeships in all parts of the sector in line with formal academic routes.** Levy recovery is very low in life sciences, and much greater flexibility is needed to support the development of a skilled workforce.
- **Maintain the UK's world-leading position in the life sciences sector,** by supporting the facilitation of the transfer and exchange of a global workforce, and ensuring the UK is an attractive place to invest and work.
- **To meet the demand requirement for up to 133,000 jobs across the sector,** develop and roll out an attraction strategy to promote working in the life sciences sector to inspire, inform and build a diverse, entrepreneurial and resilient future workforce.

NHS Long Term Plan

The NHS Long term Plan (2019) responds to some of the trends identified above and sets out key ambitions for the service over the next 10 years. The plan builds on the policy platform laid out in the NHS five year forward view (Forward View) which articulated the need to integrate care to meet the needs of a changing population and address the increased pressures and demands placed on the NHS by:

1. Developing a new service model for the 21st century.
2. A proactive approach to prevention and health inequalities.
3. Promoting digitally enabled care into the mainstream across the NHS.

The long-term plan calls for a 'fundamental shift' in the way that the NHS works alongside patients and individuals. As part of this shift, the plan focuses on personalisation to support a range of people, from those with long-term illness and complex needs through to people managing mental health issues or struggling with social issues which affect their health and wellbeing. It helps them make decisions about managing their health so they can live the life they want to live based on what matters to them, working alongside clinical information from the professionals who support them.

There is a commitment to rolling out a comprehensive model of personalised care, which brings together six programmes aimed at supporting a whole population, person-centred approach.

Digital technology underpins the Plan's most ambitious targets and will also facilitate service transformation, including the redesign of outpatient services and reorganisations of pathology and diagnostic imaging services.

The plan recognises that the NHS does not operate in isolation and sets out critical interdependencies which exist between the NHS and local government, wider public services and communities.

In the North East, local NHS trust five-year strategies build on the NHS Long Term Plan and each identifies the need to expand the focus on partnerships across the region in a number of development and delivery areas; world class, cutting-edge diagnostics; treatment and care; research; education; innovation and management. These themes have been demonstrated during the early phases of the COVID-19 pandemic with respect to social care and health service interactions.

UK Research and Development Roadmap

The Department for Business, Energy and Industrial Strategy (BEIS) published its Research and Development Roadmap in 2020. It sets out the government's commitment to building on the UK's internationally recognised reputation for leadership in research and science, and to develop a more innovative economy to recover from the economic disruption of coronavirus.

The strategy document sets out the following key commitments:

- **Increase investment in research:** To unlock discoveries and to apply analysis to solving our most pressing problems in government, industry and across society.
- **For the UK to become world-class at securing the economic and social benefits from research:** This includes the establishment of an Innovation Expert Group to review and improve the UK's innovation system. This will involve strengthening the interactions between discovery research, applied research, innovation, commercialisation and deployment.
- **Supporting entrepreneurs and start-ups to increase the flow of capital into firms carrying out R&D enabling them to scale up:** The Government aims to exploit competitive and comparative advantage where the UK can lead the world in key industries, technologies and ideas.
- **Attracting, retaining and developing the talented, diverse people and teams:** This will be achieved through a new R&D People and Culture Strategy. An Office for Talent will be set up to attract and retain the most promising global science, research and innovation talent to the UK.
- **A greater role of place-based outcomes in how R&D decisions are made in the UK so that R&D contributes to our levelling up agenda:** This includes a commitment to publishing a new UK R&D Place Strategy to unlock local growth and societal benefit from R&D across the UK.

- **Providing long-term, flexible investment into infrastructure and institutions:** This will build on the UK's system of universities, public sector research establishments and other publicly funded laboratories, developing our large-scale infrastructure, facilities, resources and services to make them world leading.
- **Partnerships with other world-leading research and innovation nations, as well as strengthening R&D partnerships with emerging and developing countries:** This will involve maintaining a close relationship with European partners, seeking to agree a fair and balanced deal for participation in EU R&D schemes.

One of the key areas of focus in the government's R&D roadmap is using R&D as part of the levelling up agenda to rebalance growth across the different regions of the UK. The North East has been identified as a potential area of focus. The strategy makes the following key commitments to:

- Build on existing and emerging strengths in UK regions, irrespective of scale, to maximise the benefit from public investment.
- Support areas with untapped potential for future growth.
- Tailored support for less R&D-intensive regions to develop new capability and absorb new technology and innovations.
- Support increased collaboration between local, regional and devolved institutions on science, research and innovation, and ensure a strong role for local civic and business leaders in defining and delivering on local opportunities.
- Ensure that R&D interventions are in alignment with wider improvements made in support of levelling up areas across the UK.

The UK's exit from the European Union

The UK officially left the European Union (EU) on 31 January 2020. At the time of writing this document the transition period is set to expire on 31 December 2020, and a trade deal has still to be negotiated by the Government.

This presents two key issues for the North East life sciences industry future: 1) Regulatory alignment with the EU and 2) Continuity of existing supply chains post Brexit.

The nature of the life science sector is that its operations are interconnected with global supply chains and distribution. Potential disruption caused by exiting the EU could increase operational complexity, lead times and costs, putting the sector at a competitive disadvantage. This could also impact on the recruitment and investment decisions of business owners and operators. The industry has argued that a clear roadmap is required to ensure continuity of the existing arrangement as far as possible and minimise economic disruption.

Another crucial issue is the future regulatory alignment between the UK and the EU. The existing regulatory function provided by the European Medicines Agency will be provided by the Medicines and Healthcare Products Regulatory Agency on a domestic level post Brexit.

With respect of the future trading relationship between the UK and the EU, there remain a series of options available:

- WTO's 'Zero-for-Zero Pharmaceutical Initiative'. This includes the EU, the United States, Japan, Canada, Switzerland, Norway and Macao. It involves mutual recognition rules on product inspection and batch certification. Certification of manufacturers is laid down in Chapter 15 of the EU-Switzerland Mutual Recognition Agreement (MRA) of 2002.
- If the UK joins the European Economic Areas (EEA) it would automatically be subject to the provisions of the EU-CH MRA. However, should it choose to leave the EEA, nothing is preventing the conclusion of a separate EU-UK MRA, though this would be subject to negotiation.
- There is also the possibility of an EU Swiss-style agreement, which would maintain close alignment with the EU single market. This would be managed through a series of bilateral agreements, although this would involve acceptance of the four freedoms, including freedom of movement.

The continuing importance of the regulatory environment and the need to maintain access to international supply chains and markets will be a key forward priority for this strategy.

The National Life Sciences COVID Recovery Roadmap

The Life Sciences COVID-19 Response Group, which includes key industry bodies: Association of British HealthTech Industries (ABHI); the Association of the British Pharmaceutical Industry (ABPI); the Association of Medical Research Charities (AMRC); the British Generic Manufacturers Association (BGMA); the BioIndustry Association (BIA); the British In Vitro Diagnostic Association (BIVDA) and the Proprietary Association of Great Britain (PAGB) have published a Life Sciences Recovery Roadmap.

The document provides a strategic plan of how the sector can recover from the coronavirus disruption and drive the UK economic recovery. The report makes the following recommendations:

- **Partnering with the NHS to support the delivery of the NHS Long Term Plan:** Building on and learning from the COVID-19 response, government and NHS leadership should develop strategic processes to involve industry and charities in work to support NHS transformation and healthcare provision.
- **Developing a comprehensive strategy to improve UK manufacturing capability and supply chain resilience in medicines, medical devices and diagnostics.** While supply chains have responded well in the crisis, additional resilience could be provided through improved demand forecasts and transparency along the supply chain, support for supply diversification, international inventory management and development of a strategic reserve of essential medicines.
- **Powering up the benefits of spending on medical research and delivering bold policies to incentivise research investment:** The Government has already doubled

the R&D investment announced in the Budget. This should be matched with an aspiration to grow further the UK's lead in Foreign Direct Investment in Europe.

- **Transforming the UK's clinical research processes:** This will allow for rapid approval, set-up, recruitment and delivery of research across the NHS, powered by new technologies, data and approaches. This in turn will ensure that UK patients are amongst the first in the world to benefit from breakthrough treatments and technologies, with the added benefit of cost savings and investments for the NHS.
- **Taking an innovative approach to regulation:** The Medicines and Medical Devices Bill is to be reviewed to reflect innovative regulatory policies introduced by the Medicines and Healthcare Products Regulatory Agency (MHRA). Mutual Recognition Agreements should be leveraged to extend the UK's global reputation and influence through international networks and partnerships and biosimilar medicines.
- **Accelerating deployment of new and existing treatments and technologies where there are system and patient benefits:** The COVID-19 response has shown that rapid scale-up of existing therapies and devices, coupled with new medicines, medical technology and diagnostics, can significantly improve patient outcomes while making more effective use of NHS resources.

Regional Economic Strategy

North East Strategic Economic Plan

The North East LEP's Strategic Economic Plan (SEP) is focused on the growth and development of our region's economy. The SEP provides an evidence-based analysis of the long-term economic challenges and opportunities facing the North East and proposes a series of targeted interventions in response.

It was first published in 2014, covering a ten-year period and demonstrated how we propose to develop a more agile, modern, diverse and entrepreneurial economy in the face of change to deliver economic benefits to residents and businesses across the region. The original plan has subsequently been refreshed and updated, as our economy and operating environment has changed and developed.

The SEP, which provides the framework for delivery, identifies four areas of strategic importance where North East assets, expertise and capabilities provide a strong opportunity for growth of the regional economy. These are:

- Health and Life Sciences.
- Energy.
- Digital.
- Advance Manufacturing.

The SEP's overarching objectives are to deliver more and better jobs, have a more entrepreneurial economy and to ensure the benefits of growth are spread to our region's people and community. To measure progress against these ambitions, we have set six targets.

These include:

1. To increase the number of jobs in the North East economy by 100,000 between 2014 and 2024.
2. For at least 70% of the new jobs to be better jobs. A better job is defined as being in managerial, professional and technical roles.
3. To reduce the gap in private sector employment density by 50% by 2024.
4. To close the gap in the employment rate for people aged 16-64 by 50% by 2024.
5. To reduce the gap in economic activity for people aged 16 – 64 by 100% by 2024.
6. To reduce the gap in productivity by 50% by 2024.

North East Local Industrial Strategy

The development of Local Industrial Strategies (LIS) was identified as a key priority in the UK Industrial Strategy. These aim to identify local and regional assets across the UK which can be aligned to national Industrial Strategy themes to ensure that every part of the UK makes its contribution to UK industrial growth and is able to benefit from the investment made into the UK's industrial development.

Co-created with government, they are intended to represent place-based statements of industrial and economic priorities led by Local Enterprise Partnerships and Mayoral Combined Authorities to increase regional productivity and to focus investment. In the prospectus published by Government, their stated objective is to “*build on local strengths and deliver on economic opportunities*”.

In the North East, it was agreed that the LIS would be a document developed jointly by regional leaders and government to closely align the goals, objectives and assets set out in the North East Strategic Economic Plan (SEP) with the national Industrial Strategy and to shape investment priorities for national programmes resourced through the National Productivity Investment Fund and the UK Shared Prosperity Fund.

The draft LIS approved by the North East LEP Board in October 2019 with the support of government highlights four areas in which the North East has distinctive strengths and represents areas where the North East can make a significant contribution to UK productivity performance.

- **A clean growth future through energy and environmental assets:** With our objective being that the North East brings together its natural, research, science, testing and business assets to make a significant contribution to accelerating the decarbonisation of the global economy.
- **Transforming manufacturing: smarter, greener, global:** With our objective being to ensure that North East advanced manufacturing sectors are adapting and evolving to remain globally competitive by:
 - Developing smarter ways of working, utilising capabilities and technologies to drive new products and processes.
 - Developing more sustainable products and processes.

- Sustaining and growing our position in global markets.
- ***Innovating in health at a time of demographic change:*** With our objective being the North East strengthens its UK leading translation environment to facilitate continuous improvement in healthcare delivery and advanced manufacturing both within the region and beyond. It will have applied its science and research strengths to position the North East as the leading hub for responding to global ageing.
- ***Driving digital and knowledge-based services:*** With our objective being to further accelerate our fast growing and dynamic digital economy and utilising our digital expertise to develop niche business services, such as fintech and BIM, and transform our growing financial, professional and business service sector.

The LIS also sets out the region's planned approach to addressing the issues that underpin the North East's underperformance on productivity. These are structured under the UK Industrial Strategy's Five Foundations. The overall objectives for this part of the LIS are:

- To become a high productivity, high employment economy with:
 - A culture of innovation, where businesses, universities and others are engaging in and collaborating on innovation activities that will improve productivity.
 - A highly skilled population, with the focus on ensuring the region has the skills needed by employers to be productive and to enable greater entrepreneurship, business ambition and innovation.
 - An effective and inclusive labour market, where individuals are able to build careers and where they can access the support they need to move into and progress within employment.
 - Transport, digital and environmental infrastructure in place that supports productivity across all sectors, connects communities within the region and connects the region nationally and internationally.
 - A culture of entrepreneurship and business ambition, characterised by the region having more businesses, higher levels of business start-up, more businesses growing and more businesses trading internationally.
 - All communities contributing to and benefiting from the improvements in productivity including through improved connections between different communities across the North East.

North East - COVID-19 Economic Response

COVID-19 has significantly impacted the North East region. At the time of producing this document, as with the UK as a whole, the region was experiencing a fragile recovery as it emerged out of the summer of 2020. There were significant risks and challenges as it entered the Autumn with rising cases of COVID-19 and growing risks to employment levels as the support to the economy which had been introduced in March 2020 was slowly withdrawn and new controls introduced.

In March, the North East LEP Board formed the North East COVID-19 Economic Response Group to lead a joint response across all sectors to the pandemic, starting with an immediate response to support business and employment, and to co-ordinate action in the region to support national challenges.

Ongoing reviews of evidence provided to the LEP Board provide an insight in real time to some of the key national and regional data impacting on the North East economy. At its meeting on October 1 2020, the Board considered the latest data, with headlines including:¹⁵

- UK GDP had showed the third consecutive month of growth in July following the severe drop in GDP in April. Output growth has, however, only recovered 50% of the drop since the baseline figure in March 2020.
- 98% of businesses registered in the region continued to trade, however 58% said that they were at some risk of insolvency with 8% saying they were at moderate or severe risk.
- The unemployment rate in July 2020 was at 5.2%, the highest regional figure in the UK.
- Whilst employment between May and July had formally risen by 6000, this includes the figure for workers supported by the job retention scheme.
- A total of 267,000 employments (32%) had been furloughed at some point during the existence of the scheme, with 13% of workers furloughed at the end of July 2020.
- In August 2020, almost 91,000 people in the North East LEP area claimed benefits principally for the reason of being unemployed, an increase of over 36,400 since March.
- National commentators expected an increase in unemployment to 10-12% in the region by the end of the year.

The report also considered intelligence from 21 sectors of the North East economy. This demonstrated varied experience and performance with many sectors, particularly those services involving human contact, as having effectively stalled during the pandemic with poor future prospects.

Whilst these challenges affect much of the region, there is clear evidence that the life sciences and pharmaceuticals sector has performed well during the pandemic with growth in the pharmaceuticals manufacturing sector and strong performance from support organisations involved in the sector in the region in organising supply of essential products and medicines to support the UK response. There is anecdotal evidence of growth of about 500 jobs in the manufacturing sector in the region.

The region has also been successful in rapidly creating new healthcare facilities such as the Nightingale hospital in Sunderland and attracting one of the network of COVID-19 Lighthouse Centres to the North East, with three core components:

1. The Integrated COVID Hub: Hosted by Newcastle Upon Tyne Hospitals, the first NHS organisation to host one and it will be the biggest Hub nationally. This is based in Gateshead (next to Gateshead Stadium) and will have capacity to deliver 80,000

¹⁵ See Covid 19 Intelligence Report, North East LEP Board, October 1 2020

tests per day. It will employ over 1,100 staff in the NHS jobs and be additional to current testing capacity.

2. An Innovation Hub: Based at the Biosphere at Newcastle Helix. This unique offering will provide an ongoing focus for real world evaluation and testing working closely with industry, with the potential to create many jobs and generate inward investment.
3. Co-ordination and response centre. Based at the Lumen at Newcastle Helix. This will look at rapid testing and integrate testing, tracing and containment to enable rapid place-based response.

There are other specific opportunities and challenges of relevance to this strategy. There is a potential opportunity to respond to the emerging direction for home-shoring drug supply chains to ensure future resilience. However, there have also been downside risks for the sector, with the focus on the NHS on the immediate healthcare response. For small businesses in the region seeking to accelerate innovation, this has meant that some of the work to deploy intellectual property which was being targeted for translation into the health system being stalled.

In September 2020 North East leaders adopted a COVID-19 Recovery Plan which has been proposed to government in anticipation of the Comprehensive Spending Review. Within the plan, a number of priority actions set out in this Health and Life Sciences Growth Strategy sector are identified as stimulus and growth priorities for the Recovery Plan with the aim of building the regional cluster and reinforcing national resilience.

These are positioned as part of a significant Future Economy programme, which is one of five themes in the Recovery Plan. These include:

- Priorities to build further on key sites in the region including the Helix, NetPark and Enterprise Zones to build clusters located there.
- Continuing investment into the Northern Accelerator programme to stimulate spin outs from the four universities.
- Public-private investment into manufacturing and innovation facilities to home-shore generics, with associated supply chain activity.
- Investment into the North East Health Evaluation Innovation Ecosystem to coordinate a single point of entry for businesses to commercialise into the NHS.
- Next stage of the Northern Alliance Advanced Therapy Treatment Centre on Cell and Gene Therapy.
- Further development and investment into programmes to accelerate innovation in ageing.