

Life sciences in Hertfordshire and the emergence of a global cell and gene therapy cluster

Evolution and prospects

Report to Hertfordshire LEP



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Cover image courtesy of Cell and Gene Therapy Catapult.

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Glossary of key terms

Term	What it means
Cells and genes	Cells are the basic building blocks of all living organisms, and genes are found deep within cells. Genes are small sections of DNA that carry genetic information and instructions for making proteins, which help build and maintain the body ¹ .
T cells	T cells are a type of white blood cell. They are part of the immune system and develop from stem cells in the bone marrow. They help protect the body from infection and may help fight cancer ² .
Genetic mutations and diseases	Genetic mutations arise when a critical piece of DNA is substituted, deleted or duplicated. ³ It is estimated that millions of people globally suffer from more than 10,000 rare diseases caused by mutations of single genes ⁴ . For these people, cell and gene therapies offer hope and potential cures for previously untreatable diseases.
Cell and gene therapy	<p>Cell therapy and gene therapy are overlapping fields of biomedical research and treatment. Both therapies aim to treat, prevent, or potentially cure diseases, and both approaches have the potential to alleviate the underlying cause of genetic diseases and acquired diseases.⁵</p> <ul style="list-style-type: none"> • Cell therapy aims to treat diseases by restoring or altering certain sets of cells or by using cells to carry a therapy through the body. With cell therapy, cells are cultivated or modified outside the body before being injected into the patient. The cells may originate from the patient (autologous cells) or a donor (allogeneic cells)⁶. • Gene therapy is the introduction, removal, or change in the content of a person's genetic code with the goal of treating or curing a disease⁷. Genes are transferred into cells using transporters known as vectors, which are often made from modified, inactivated viruses that do not cause disease⁸.
Regenerative medicine	Regenerative medicine seeks to replace tissue or organs that have been damaged by disease, trauma, or congenital issues. ⁹ While still in its infancy, regenerative medicine uses special techniques to try and stimulate the body's natural healing and regeneration processes.

¹ National Institutes of Health (NIH) U.S. National library of medicine. What is a gene?

² <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/t-cell>

³ National Institutes of Health (NIH) U.S. National library of medicine. What kinds of gene mutations are possible? Available at: <https://ghr.nlm.nih.gov/primer/mutationsanddisorders/possiblemutations>. Last accessed April 2019.

⁴ World Health Organization. Genes and human diseases.

⁵ American Society of Gene & Cell Therapy. Different approaches.

Available at: <https://www.asgct.org/education/different-approaches>. Last accessed April 2019.

⁶ American Society of Gene & Cell Therapy. Different approaches.

Available at: <https://www.asgct.org/education/different-approaches>. Last accessed April 2019.

⁷ <https://www.asgct.org/education/more-resources/gene-and-cell-therapy-faqs>

⁸ American Society of Gene & Cell Therapy. Different approaches.

Available at: <https://www.asgct.org/education/different-approaches>. Last accessed April 2019.

⁹ <https://mirm-pitt.net/about-us/what-is-regenerative-medicine/>

List of acronyms and abbreviations

Acronym / abbreviation	What it means
ATAC	Advanced Therapies Apprenticeship Community
ATMP	Advanced Therapy Medicinal Product
BRES	Business Register and Employment Survey
CDMO	Contract Development and Manufacturing Organisation
cGMP	current Good Manufacturing Practice
CGT	Cell and gene therapy
CGTC-MC	Cell and Gene Therapy Catapult Manufacturing Centre
CMO	Contract Manufacturing Organisation
EEDA	East of England Development Agency
GMP	Good Manufacturing Practice
GSK	GlaxoSmithKline plc
IPO	Initial Public Offering
LEP	Local Enterprise Partnership
MHRA	Medicines and Healthcare products Regulatory Agency
MRC	Medical Research Council
OLS	Office for Life Sciences
R&D	Research and Development
SBC	Stevenage Bioscience Catalyst
SIA	Science and Innovation Audit
SIC	Standard Industrial Classification
TSB	Technology Strategy Board
UCL	University College London
VC	Venture Capital

Executive Summary

Life sciences in Hertfordshire

1. Hertfordshire's life sciences sector has emerged over many decades. Today there are over 200 life sciences businesses in the county. Within this:
 - biopharmaceuticals businesses are concentrated in Stevenage, but with notable activity also in Hatfield and Welwyn Garden City, two other towns on the A1(M) Corridor
 - medical technology activity is much more widely distributed, with Hemel Hempstead, Stevenage and the north Hertfordshire towns of Hitchin/Letchworth/Baldock leading the way.
2. In explaining the evolution of the sector, the role of 'big pharma' has been critical. Through major companies like GSK (GlaxoSmithKline), MSD (Merck Sharp & Dohme) and Roche, Hertfordshire has seen periods of investment and growth in pharmaceuticals since the 1930s – partly because of its proximity to London and partly because, at key moments, pharmaceuticals businesses have been able to secure major sites. But there has also been 'churn' and phases of restructuring and retrenchment. This has all created both a legacy and an endowment, linked for example to workforce skills and supply chain possibilities.

The early growth of the cell and gene therapy cluster

3. It is within this context that the cell and gene therapy cluster has emerged over the last decade or so. In 2008/09 – against a backdrop of the then-pending 'patent cliff' and the more general credit crunch – GSK investigated the idea of developing a major campus at Stevenage, premised on principles of open innovation. Signalling a major departure from past models, the intention was that this should be developed in stages, creating an ecosystem in which companies could collaborate and share facilities and advice, allowing them to grow.
4. Through a £38m partnership with then-Department of Business, Innovation and Skills, Wellcome, then-Technology Strategy Board and then-East of England Development Agency, GSK provided land and investment to build and launch what is now Stevenage Bioscience Catalyst (SBC). This formally opened in 2012 and by spring 2017, Phase 1 was at capacity. In 2017, the Cell and Gene Therapy Catapult Manufacturing Centre opened. With £55m investment – and additional support from Hertfordshire LEP – this sought to address a critical part of the translation process – from laboratory scale activity to small scale batch production which is needed for Phase III clinical trials.

5. Currently, it is estimated that the cell and gene therapy campus in Stevenage – including both the Catalyst and Catapult – is delivering over 1,000 jobs and is home to over 45 companies, 13 of which are in the cell and gene therapy space¹⁰. Some of these have received equity funding from Syncona (the investment company set up by the Wellcome Trust) and many have links with UCL; the inference – borne out through consultations undertaken for this study – is a research-funding nexus with its origins in the Knowledge Quarter area of London (around the Francis Crick Institute, UCL, Wellcome Trust, King’s Cross/Euston) but extending to Stevenage, some 20-30 minutes away (by train), where early stage businesses can progress towards clinical trials. Many of the cell and gene therapy businesses also have strong international connections, and in this context, the Cell and Gene Therapy Catapult Manufacturing Centre is seen by many as a unique facility globally.
6. The government’s recently-published *Life Sciences Vision* observes that “*the UK has a very strong cluster of Advanced Therapy companies forming in Stevenage around the Cell and Gene Therapy Catapult*”¹¹. This has been recognised as the UK’s largest cell and gene therapy cluster, and the third largest globally¹². The companies within it have attracted private sector equity investment which sums to more than £739m. In 2020, private equity investment in R&D activities linked to biotechnology was higher in Stevenage than for the clusters in Cambridge and London, and very close to the figure for Oxford.

Growing the cluster

7. The challenge now is to harness the momentum that has been generated and to sustain and enable the cluster’s further growth. For cell and gene therapies, this means providing an environment in which businesses can scale up very complicated production processes. It will therefore be imperative locally to ensure:
 - that there is provision of sufficient and appropriate sites and buildings, both to accommodate scaled-up production *and* to facilitate the growth of the wider supply chain, including with regard to specialist logistics
 - that it is possible to staff those facilities with appropriately trained and qualified personnel (reflecting the comment from many businesses that there is real ‘competition for talent’)
 - that Stevenage is regenerated as a vibrant 21st Century New Town in which the cell and gene cluster can thrive.
8. Particularly with regard to sites and buildings, local partners have done much to engineer short term solutions – through, for example, the modular Spark Building. Kadans acquired Sycamore House which is being redeveloped and will open in 2021 to provide further

¹⁰ See <https://www.hertfordshirelep.com/news/2020/stevenage-named-high-potential-opportunity-zone-for-cell-and-gene-therapy/>

¹¹ *Life Sciences Vision*, HM Government (2021) – page 48

¹² GSK unveils plan for one of Europe’s largest life science campuses in Stevenage. GSK Press Release – 16th July 2021

capacity. In addition, over recent months, a planning application for a bio-pharmaceutical lab on Marshgate car park on St George's Way, Stevenage, has been submitted to Stevenage Borough Council. In the longer term, GSK's announcement linked to the redevelopment of 33 acres on its Research and Development site over 5-10 years could also prove to be very important¹³. All these ventures need to be pursued, and more generally, it will be imperative that appropriate provision is made on Gunnels Wood Road and, potentially, on relevant sites within Stevenage town centre.

9. Looking ahead, global assessments of the cell and gene therapy industry are invariably quick to emphasise the importance of software and data science in many different forms. Appropriate provision will be needed for the digital dimensions of the cluster's growth. Broadband infrastructure needs to be exemplary and capable of handling large amounts of data across cell and gene therapy businesses and the wider cluster. In addition, digital skills will need to be enhanced.
10. Finally, it will be essential that the global nature of cell and gene therapy is fully recognised. Hertfordshire must be prepared to compete with established and emerging clusters world-wide (such as Kendall Square, Boston, and Navy Yard, Philadelphia). Within this context, the designation of Stevenage as first (in 2018) a Life Sciences Opportunity Zone and then (in 2020) a High Potential Opportunity Zone has helped give the cluster profile.

Next steps

11. This report was commissioned by Hertfordshire LEP with the aim of providing the evidence base for a Cell and Gene Therapy Cluster Action Plan. The report concludes with a series of recommendations surrounding priority actions and the LEP will need to consider these. Where appropriate, it will need to develop the recommendations within the Cluster Action Plan. In so doing, it will need to work closely with Hertfordshire Growth Board and a range of other partners. These include the bioscience community both locally and nationally (including Stevenage Bioscience Catalyst, Cell and Gene Therapy Catapult Manufacturing Centre, GSK and other private sector partners); Stevenage Borough Council and Hertfordshire County Council; and central government and its key agencies.

¹³ GSK unveils plan for one of Europe's largest life science campuses in Stevenage. GSK Press Release – 16th July 2021

1. Introduction

Global life sciences – and the potential of cell and gene therapies...

- 1.1** Shortly before the pandemic started to unfold, Deloitte published its *2020 Global Life Sciences Outlook*¹⁴. Its opening comment was that “*the life sciences sector is at an inflection point*”. It went on to describe the transformative potential of cell and gene therapies in relation to diseases that were previously considered incurable; it made the connection to artificial intelligence and machine learning in relation to the pace (and cost) of innovation; and it described the rise of the patient-centric models and personalised healthcare.
- 1.2** The pandemic has raised the profile of life sciences even further – both in terms of the transformative power of the underlying science, and the commercial implications. It is important to recognise, however, that the process of commercialisation is long and complicated: it is highly regulated, and the risks (and stakes) associated with it are enormous at every stage. Reference is often made to the ‘discovery process’ in relation to the underlying science, but the term applies equally to the commercialisation journey. Indeed, the challenges surrounding this translational process are redefining the life sciences sector more generally. As Deloitte observed:

...large pharma companies will likely need to keep acquiring and making bets on cell and gene therapy companies, focused on oncology and rare diseases. However, significant work remains to be done in scaling the gene and cell therapy model, from development through commercialization, which in turn is putting pressure on legacy models.

In the future, smaller companies may ultimately take an increasing share of the market from big pharma by developing and commercializing products independently. With the recent influx of private equity and venture capital (VC) investment going into the biotech market, emerging companies have been able to pursue development into later stages. In the long run, this may make it more difficult for big pharma to buy innovation¹⁵.

- 1.3** The inference is that big pharma will need to continue to adapt, but also that the behaviour of private equity and venture capital investors – in response to the possibilities of commercialisation – is having a growing influence. As a consequence, smaller companies are likely to play an increasingly prominent role, particularly in those parts of the life sciences sector that are most innovative.

Anticipated through, and supported by, national policy...

- 1.4** These developments have largely been anticipated within UK science and industrial policy over recent years (see Table 1-1). While this report is not primarily a policy review, it is impossible to understand the recent evolution of the sector – or its future growth prospects – without some reference to the policy sphere. It must be recognised that governments around

¹⁴ *2020 Global Life Sciences Outlook: Creating new value, building blocks for the future*, Deloitte Insights

¹⁵ *2020 Global Life Sciences Outlook: Creating new value, building blocks for the future*, Deloitte Insights, page 10

the world – UK included – are playing a substantial role, both in defining the regulatory environment and in investing directly. As set out in the *Advanced Therapies Manufacturing Action Plan* (2016):

The UK took an early lead in capturing advanced therapy medical research and now has a recognised leading international position in the discovery and development of advanced therapies with world-class academics, innovation infrastructure including the Cell and Gene Therapy Catapult, investors, many SMEs, and now pharmaceutical companies, concentrating their research in the UK.

This emerging industry is at a critical stage in translating this research into manufactured products with the focus now on planning manufacturing scale-up in order to commercialise these therapies. In this context, the UK has the opportunity to secure its position as a global hub for researching, developing, manufacturing and adopting advanced therapies¹⁶.

Table 1-1: Major UK policy statements in respect of life sciences in general and cell and gene therapy in particular

Title	Key elements
<i>Taking stock of regenerative medicine in the UK</i> (BIS/DoH, July 2011)	Early report which identified “ <i>steep technological, regulatory and strategic barriers to realising regenerative medicine's significant potential</i> ”.
<i>Strategy for UK Life Sciences</i> (BIS/OLS, December 2011)	<p>Actions to protect the UK's status as a world-leader in life science innovation, focused around: building the UK life sciences ecosystem; attracting, developing and rewarding talent; and overcoming barriers and creating incentives for the promotion of healthcare innovation.</p> <p>This strategy paved the way for the formation of the Cell and Gene Therapy Catapult in May 2012.</p>
<i>Strategy for Regenerative Medicine</i> (March 2012) – published by Research Councils and (then) Technology Strategy Board	<p>This identified eight strategic objectives, including, <i>inter alia</i>:</p> <ul style="list-style-type: none"> • (3) product development: linking early stage regenerative medicine product development with the establishment of manufacturing, transportation and delivery solutions • (5) innovation and value systems: investigations addressing issues such as the evolution of new business models, product development mechanisms (including reimbursement and adoption), and open innovation • (8) promoting interdisciplinary collaboration: bringing together strong complementary skills, expertise and infrastructure across disciplines.
<i>Advanced Therapies Manufacturing Action Plan</i> (July 2016) – published by the Advanced Therapies Manufacturing Taskforce	Drawing on a substantial input from the life sciences industry, this document set out a six-point plan to retain and attract advanced therapies manufacturing in the UK. This included, <i>inter alia</i> , actions linked to talent management and investment in innovation.

¹⁶ *Advanced Therapies Manufacturing Action Plan: Retaining and attracting advanced therapies manufacture in the UK* – Report by the Medicine Manufacturing Industry Partnership (2016) – page 3

Title	Key elements
<i>Life Sciences Industrial Strategy</i> (August 2017) – Report to government from the life sciences sector	This set out recommendations to government on the future of the life sciences sector in general. The recommendations were very wide ranging but included “ <i>accepting in full the recommendations of the Advanced Therapies Manufacturing Action Plan</i> ”.
<i>Life Sciences Sector Deal 1</i> (December 2017) and <i>Deal 2</i> (December 2018) – HMG/BEIS	These documents set out a series of commitments to deliver the Life Sciences Industrial Strategy including (particularly in Deal 2) further commitments in respect of cell and gene therapy manufacturing.
<i>Budget 2020</i> (HMT, March 2020) – <i>Life Sciences Investment Programme</i>	This announced the introduction of the Life Sciences Investment Programme to provide the British Business Bank with additional resources to make up to £200 million in equity commitments to support the UK’s most innovative health and life sciences firms over five years. Invested alongside private sector capital, this was expected to enable £600 million of finance to create high-quality jobs and help UK patients benefit from more ground-breaking treatments and care.
<i>UK Research and Development Roadmap</i> (HMG/BEIS, July 2020)	This explained how the commitment to invest 2.4% of GDP in R&D by 2027 would be achieved. Its focus was much broader than life sciences, but it signalled on-going commitment to investment in the sector. Overall, the Roadmap focused on increasing investment in research; securing economic and social benefits; supporting entrepreneurs and start-ups; attracting, retaining and developing talent; taking greater account of place-based outcomes; securing international collaborations; and engaging more broadly in the possibilities of R&D.
<i>Life Sciences Vision</i> (HMG/BEIS, July 2021)	<p>This built on the 2017 Life Sciences Industrial Strategy and Life Sciences Sector Deals in the context of the UK’s departure from the European Union; the impact of the pandemic; and the organisational transformation of the NHS in England.</p> <p>It set out a vision of what is needed to create an environment in which industry can grow and succeed in the UK, and patients and the NHS can receive a real benefit. The vision focused on four themes:</p> <ul style="list-style-type: none"> • building on the new ways of working from Covid-19 to tackle future disease missions • building on the UK’s science and clinical research infrastructure and harnessing the UK’s unique genomic and health data • supporting the NHS to test, purchase and spread innovative technologies more effectively, so that cutting-edge science and innovations can be embedded widely across the NHS as early as possible, and rapidly adopted in the rest of the world • creating the right business environment in the UK in which companies can access the finance to grow, be regulated in an agile and efficient way, and manufacture and commercialise their products in the UK.

Title	Key elements
	It also committed to ‘missions’ that are disease or technology specific. One of the identified missions was “ <i>enabling early diagnosis and treatments, including immune therapies such as cancer vaccines</i> ”.

Realised within Hertfordshire...

- 1.5** In general terms, it is an uncomfortable moment when any narrative shifts from ‘the global and national’ to ‘the local’, especially when the reference point is an English shire county without a high-profile Russell Group University. But as this report will demonstrate, **these global processes and national policy priorities are being played out to the full in Hertfordshire. The extent to which Hertfordshire is able to respond to – and to some extent facilitate – the ongoing commercialisation journey will have a major bearing on what happens next.** Some of the solutions may need support from central government, but others will appear prosaic. That makes them no less important; indeed, it will be incumbent on Hertfordshire LEP and its partners from Hertfordshire Growth Board and the private sector to ensure that they are appropriately delivered.
- 1.6** The report that follows is divided into five further chapters:
- **Chapter 2** considers the scale of the life sciences sector in Hertfordshire relative to elsewhere in the UK
 - **Chapter 3** describes its evolution – focusing both on the role of big pharma and the emergence of a cell and gene therapy cluster
 - **Chapter 4** then investigates the nature of the cluster in more detail, including through a series of case studies
 - **Chapter 5** considers the prospects, opportunities and challenges in respect to its future growth
 - **Chapter 6** recommends a range of infrastructure and policy-related interventions which could be taken to address market failures and support the cluster’s continuing growth.

Acknowledgements

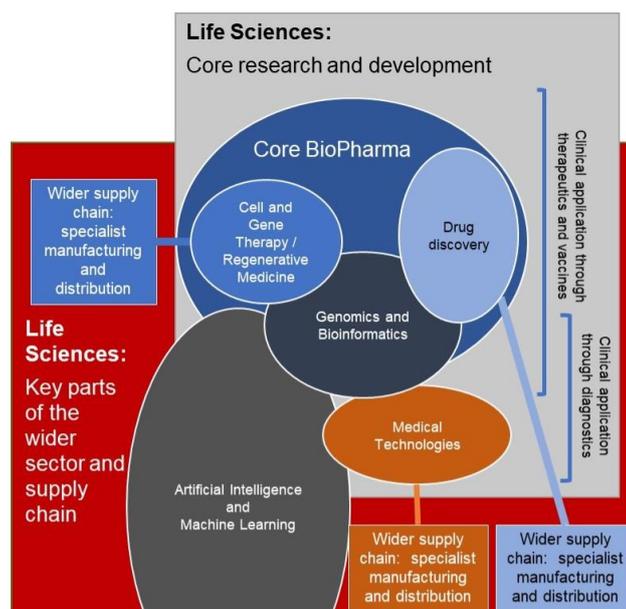
- 1.7** In preparing this report, we have benefitted from substantial inputs from others – notably colleagues at Hertfordshire LEP, Stevenage Bioscience Catalyst (SBC), Cell and Gene Therapy Catapult Manufacturing Centre, Stevenage Borough Council and from among cell and gene therapy businesses. We are very grateful for all of these different contributions.

2. Overall scale of life sciences within Hertfordshire

Defining life sciences

- 2.1 Life sciences** embraces a wide range of activities which are increasingly difficult to demarcate in very precise terms. The graphic below attempts to identify some of the principal elements – and to illustrate the major overlaps between them. **Drug discovery** has long been at the core of the pharmaceuticals sector, and it continues to be extremely important; it has driven the growth of ‘big pharma’ and it remains centre-stage for the likes of GSK, Pfizer and AstraZeneca. Separately, **medical technologies** have also played a major role, through companies such as GE Healthcare and Johnson & Johnson. For many decades, these two elements were easily distinguished from each other – one relied on pharmacology (and related disciplines), while the second had a much closer link to materials, engineering and physical sciences.

Figure 2-1: Key activities within the life sciences sector



Source: SQW

- 2.2** Over the last decade or thereabouts, there has been substantial disruption across life sciences as technologies have converged. **Cell and gene therapy** has created the possibility of **regenerative medicine**, and this has been part of a wider shift towards **precision (or personalised or stratified)** solutions which are driving change within the core biopharma sector as a whole. Much of this has in practice been underpinned by enormous advances with respect to **genomics and bioinformatics**, which in turn are increasingly facilitated by powerful digital sciences, linked particularly to **artificial intelligence and machine learning**. These are also important for the long-established specialisms in medical

technologies and drug discovery. At the core of life sciences research and development, there has then been a rapid convergence across underlying scientific disciplines, making boundaries increasingly difficult to define.

- 2.3** In addition, the wider supply chain has played a critical role, particularly as the science has moved through the process of translation towards clinical application. Sophisticated therapies are frequently very difficult to manufacture at scales beyond the test tube – and without scale, vaccines, therapeutics and diagnostics are very unlikely to be viable. The wider supply chain has therefore played a crucial role in an increasingly complicated commercialisation journey. While frequently dismissed in ‘Cinderella’ terms, elements of it (e.g. logistics) can be highly specialised in their own right.

The overall scale of life sciences activities

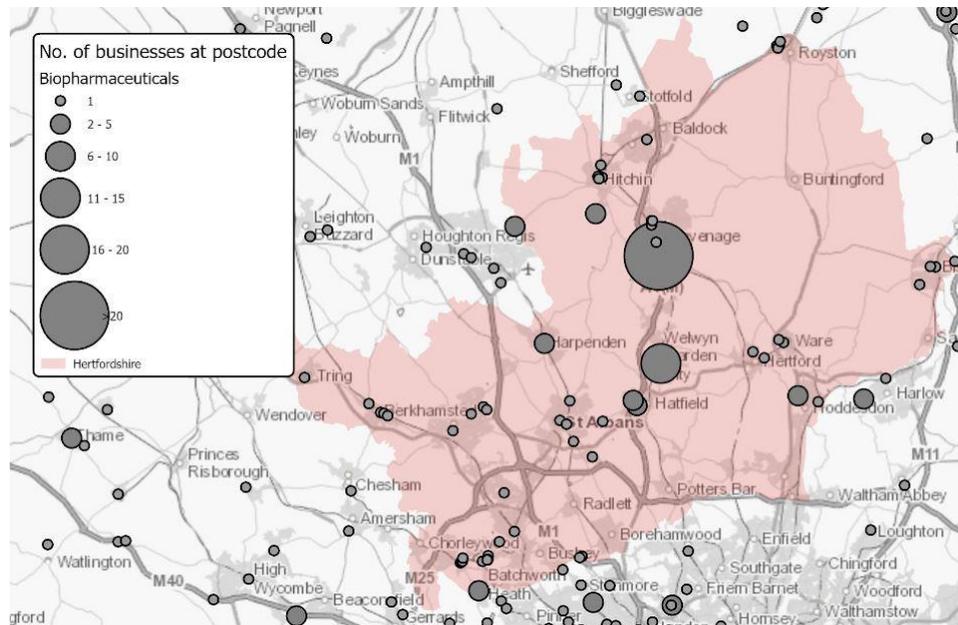
- 2.4** Given processes of this nature, it is very difficult to measure the scale of the sector. The Office for Life Sciences (OLS) estimates that **in 2019, the UK life sciences industry employed 256,100 people in 6,300 businesses and generated a turnover of some £80.7bn**. This actually pointed to a faltering national growth narrative: between 2010 and 2019, employment in the sector grew modestly (and more slowly than across other sectors) while turnover actually declined (in large part because of the restructuring of big pharma).
- 2.5** Nationally, OLS notes that the core biopharma sector is concentrated within the South East and East of England particularly in the area from Cambridge to Reading, including Stevenage and London. In terms of change over time, the authors note an increase in employment in core biopharma in the East of England (and a decline in the South East). The geography of core medtech is different, and here the focus is more on London and the North West¹⁷.
- 2.6** Digging beneath these headlines, OLS’s database **suggests there are over 200 life sciences businesses in Hertfordshire**¹⁸. Their distribution – by geography and broad life sciences sector – is shown in the maps below. Although the classifications are no doubt debatable, the maps suggest that:
- **biopharmaceuticals businesses** are concentrated in **Stevenage**, but with notable activity also in **Hatfield** and **Welwyn Garden City**, two other towns on the A1(M) Corridor
 - **medical technology** activity is much more widely distributed, with **Hemel Hempstead**, **Stevenage** and the north Hertfordshire towns of **Hitchin/Letchworth/Baldock** leading the way.

¹⁷ *Bioscience and health technology sector statistics 2019*. Report published by Office for Life Sciences, August 2020

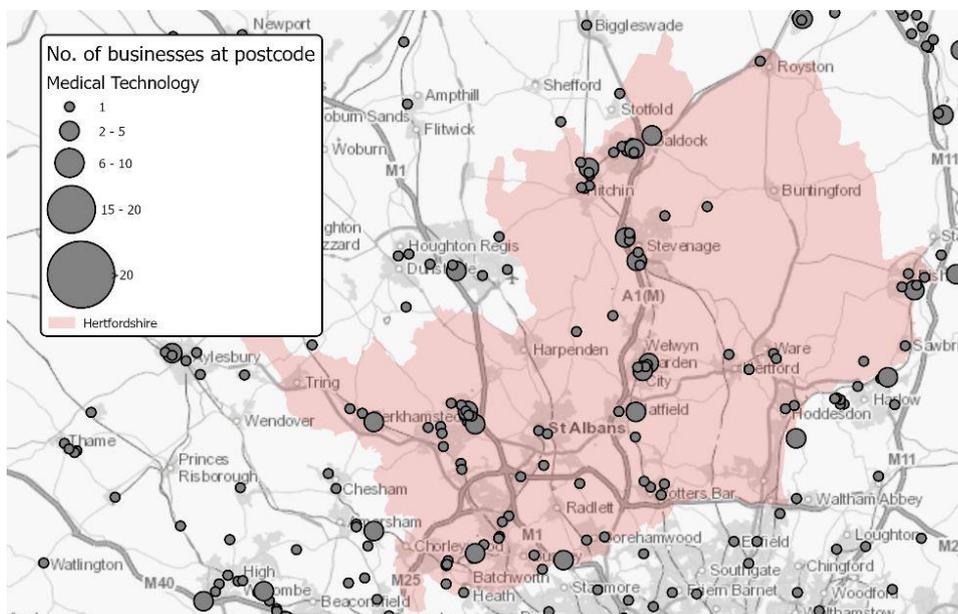
¹⁸ This estimate follows some re-coding from the information in the ‘raw’ database (to address some boundary issues)

Figure 2-2: Maps showing the distribution of life sciences businesses across Hertfordshire

Map A: Biopharmaceuticals businesses in Hertfordshire



Map B: Medical Technology businesses in Hertfordshire



Source: Map produced by SQW 2021 (Licence 100030994) using the database provided in August 2020 alongside "Bioscience and health technology sector statistics 2019", published by Office for Life Sciences

2.7 To put these data in a broader context:

- Hertfordshire ranks fourth in relation to the number of core biopharmaceuticals businesses by LEP area in England; and Hertfordshire plus its two neighbours (Cambridge sub-region (GCCP) and London) together account for just under half of the UK total.

- Looking at the same data at the town-level suggests that Stevenage (with a population of less than 100,000) ranks sixth across the UK – equal with Manchester and ahead of the likes of Nottingham and Glasgow – in relation to core biopharmaceuticals businesses.

2.8 From the OLS data, it is not possible to estimate **employment numbers** for life sciences in Hertfordshire. Estimates can however be made using data from the Business Register and Employment Survey (BRES). On this basis, the table below shows that total employment in Hertfordshire in core life sciences Standard Industrial Classification (SIC) codes (as identified by OLS) rose from 3,975 to 4,450 jobs between 2015 and 2019 (although it fluctuated year on year). The most consistent growth appears to have been in ‘*Research and experimental development on biotechnology*’.

Table 2-1: Estimates of the scale of employment in Hertfordshire in core ‘life science’ SIC categories

	Year	2015	2016	2017	2018	2019
Manufacture of basic pharmaceutical products		800	800	1,000	300	600
Manufacture of pharmaceutical preparations		2,000	1,500	1,500	1,500	1,750
Manufacture of irradiation, electromedical and electrotherapeutic equipment		225	175	350	350	300
Manufacture of medical and dental instruments and supplies		800	1,000	800	700	800
Research and experimental development on biotechnology		150	150	300	500	1,000
	Total	3,975	3,625	3,950	3,350	4,450

Source: BRES (Open Access)

2.9 However, it is important to note OLS’ comment that “*only 25% of businesses in the life sciences database fall into the standard SIC codes used to identify the life sciences industry. The remaining businesses fall into another 250 SIC codes*”¹⁹. It is also important to recognise that BRES may capture data relating to registered addresses, rather than the location at which activities take place; this is a particular issue for larger, multi-site, businesses. For both reasons, we suspect that BRES underestimates life sciences employment in Hertfordshire. From other sources, we know that GSK and Roche alone account for well over 4,000 jobs within the county, and many other smaller businesses also contribute to the overall total.

¹⁹ *Bioscience and health technology sector statistics 2019*, Office for Life Sciences (2020) – page 32

3. The development of the sector and the emergence of the cell and gene therapy cluster

- 3.1** The pharmaceuticals sector has long been a global industry. In part because of the need to navigate complex regulatory environments, it has also been a turbulent one: with escalating costs, and both highs and lows in the pipeline of drug discovery (all with commercial ramifications), it has seen countless mergers, acquisitions and divestments over many decades. **Some of this ‘churn’ has been played out in Hertfordshire – partly because of its proximity to London and partly because, at key moments, pharmaceuticals businesses have been able to secure major sites. The life sciences sector in Hertfordshire is now changing quickly and new investments are being made, but it continues to draw on the legacy and the endowment (linked for example to workforce skills and supply chain possibilities) of past investment.** The character of, and prospects for, life sciences in Hertfordshire – and its vulnerabilities and challenges – need to be understood in this context.

The formative role of ‘big pharma’

- 3.2** Big pharma has played a key role throughout. It continues to be very significant, accounting for the lion’s share of life sciences employment and output.
- 3.3** For example, the Swiss pharmaceuticals company, **Roche**, established a site in Welwyn Garden City in 1937, before moving to Shire Park in 2005. At this time, one of its vacated buildings was acquired by the University of Hertfordshire with funding from the then-East of England Development Agency (EEDA). In 2006, it opened as **BioPark** – a complex of labs and serviced offices for small life science businesses. However, BioPark closed in 2019 and the site was sold; it is likely now to be redeveloped, primarily for housing. At Shire Park, Roche continues to employ around 1,500 people, mainly in early development and clinical trials across a range of therapeutic areas. It is therefore a big local employer. Globally, Roche employs around 200,000 people in 100 countries.
- 3.4** Similarly, **MSD (Merck Sharp & Dohme)** is an American-owned global biopharmaceuticals business; it currently employs around 71,000 people in 140 countries²⁰. It has a network of UK sites and for some years, its UK headquarters were in Hoddesdon in south east Hertfordshire. It previously had sites in nearby Harlow and Enfield, but these were closed some time ago as part of a wider restructuring process. In 2020, it announced that it had selected a site in central London for its future Discovery Research Centre and UK headquarters; this is near the Francis Crick Institute and the London Bioscience Innovation Centre, and adjacent to King’s Cross and St Pancras stations. The consequence is that MSD will cease to have a physical presence in Hertfordshire. In 2016, it was announced that MSD’s

²⁰ See website: [MSD | Our history](#)

Hoddesdon site was being acquired by Pharmaron, a Chinese-owned CMO²¹; with MSD's departure, it will be important that the site is used well in relation to the future of life sciences across Hertfordshire.

- 3.5** For many years, **GSK (GlaxoSmithKline plc)** has also had big facilities in and around Hertfordshire. In 1958, then-Glaxo Laboratories absorbed Allen and Hanbury's, a pharmaceuticals manufacturer based in Ware. Over 60 years later, GSK continues to have a major **manufacturing facility (with some R&D)** on the same site. This has seen new investment in recent years; for example, in 2016, GSK opened a £56 million manufacturing facility, creating 150 new jobs. However, GSK's major Hertfordshire site is in Stevenage. This is now one of its two **global R&D hubs** (the second is in Pennsylvania, USA), with intensive research across four core therapy areas: respiratory, HIV and infectious diseases, oncology and immune-inflammation. The Stevenage site had previously been home to the Warren Spring Laboratory (the government's environmental research laboratory). It is now the main focus for life sciences in Hertfordshire and much investment has followed, but the initial catalyst was relatively simple: the availability of a large employment site at the right time in broadly the right location.
- 3.6** The overall narrative in relation to 'big pharma' in Hertfordshire is double edged. **The sweep of history suggests periods of investment and growth – but equally, phases of restructuring and retrenchment.** This pattern is continuing today; and it is intrinsic to a global sector in which both risks and rewards are high. For any local economy, the consequences are difficult to manage. **Despite the scale of investment, levels of embeddedness and 'spatial fixity' within big pharma are in practice modest. At the same time, however, the legacy and endowment are invaluable (not least in relation to the emergence of a specialist labour market). Although global location decisions are fickle, Hertfordshire has accumulated – and continues to accumulate – real assets.**

The emergence of the cell and gene therapy cluster

- 3.7** The emergence of the cell and gene therapy cluster has been both a response to the turbulence within big pharma – but also an underlying cause, particularly insofar as it has disrupted processes of innovation profoundly. It has also been a focus for policy intervention.

Beginnings... linked to the possibilities of open innovation and the formation of Stevenage Bioscience Catalyst

- 3.8** In 2008/09 – against a backdrop of the then-pending 'patent cliff' and the more general credit crunch – GSK investigated the idea of developing a major campus, premised on principles of open innovation. Signalling a major departure from past models, the intention was that this should be developed in stages, creating an ecosystem in which companies could collaborate and share facilities and advice, allowing them to grow. At the time, demand-side assessments

²¹ See <https://www.pharmaron.com/news/pharmaron-and-msd-agree-deal-to-acquire-msd-s-uk-hoddesdon-site>

noted a change in the nature of early stage life sciences spin-outs: there were fewer of them than previously; they were shifting to more translational research, often conducted with a partner that was active in the commercialisation process; and they were often combining some level of service provision with core research interests to sustain a revenue stream.

- 3.9** Through a £38m partnership with then-Department of Business, Innovation and Skills, Wellcome, then-Technology Strategy Board and then-East of England Development Agency, GSK provided land and investment to build and launch what is now **Stevenage Bioscience Catalyst (SBC)**. This formally opened in 2012 to provide incubator and accelerator spaces. By spring 2017, Phase 1 was at capacity and SBC had 49 tenants. These included blue chip companies (such as **GE Healthcare, Johnson & Johnson, Eli Lilly** and **Sanofi**), but also small start-ups and inward investors such as **Aglaris Limited**. Translational laboratories had also been established at SBC by both the **University of Cambridge** and **University College London (UCL)**; and **LifeArc** (formerly **MRC Technology**) had relocated all of its drug discovery operations (and 70 staff) from London to Stevenage. SBC was therefore functioning as an important hub within the wider GSK campus.
- 3.10** SBC developed plans for a Phase 2 with the intention of expanding, in particular, the bio-incubator. A full business plan was prepared. Wellcome, GSK and Hertfordshire LEP (through Local Growth Fund) all provided indicative funding commitments, but a substantial funding gap remained and the plan for Phase 2 did not move forward.

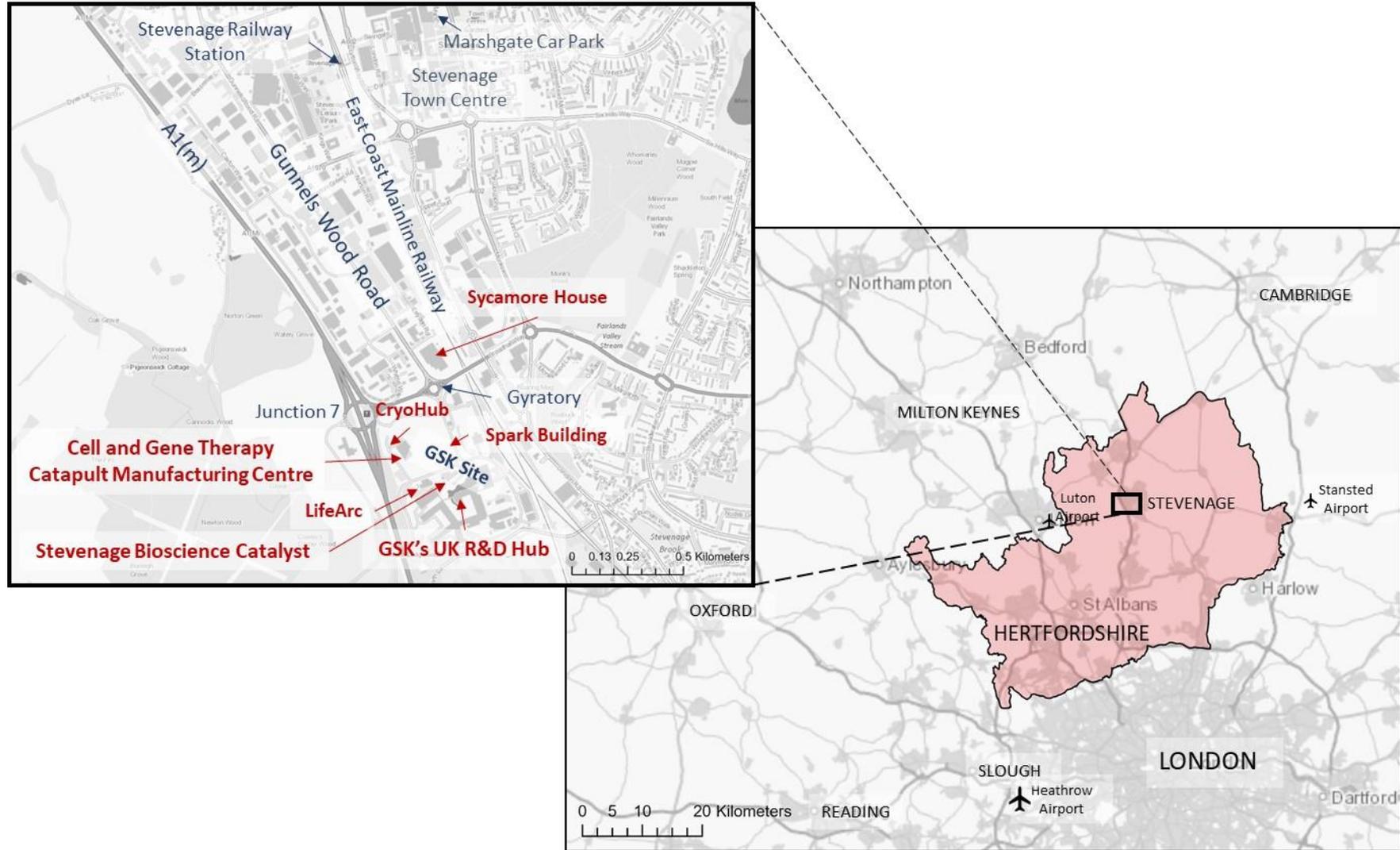
Cell and Gene Therapy Catapult Manufacturing Centre

- 3.11** At about the same time, plans for a **national Manufacturing Centre** linked to the **Cell and Gene Therapy Catapult** were set out in the 2014 Budget. The intention was that the manufacturing centre would “*complement the existing early phase network and will complete the translational landscape in the UK allowing therapies to move from basic research, into the clinic and finally to commercial products*”²².
- 3.12** In December that year, it was announced that the facility would be built on the GSK campus in Stevenage. The new facility sought to address a critical part of the translation process – from laboratory scale activity to small scale batch production which is needed for Phase III clinical trials. It constituted a significant investment – totalling some £55m – with additional support from Hertfordshire LEP. The Catapult reported at the time that Stevenage met all of the necessary criteria including, crucially:
- good access to major clinical centres across Europe (mainly via Heathrow Airport);
 - attraction and retention of key talent – reflecting in large part the life sciences labour market between London and Cambridge; and
 - physical capacity to accommodate a 5,000 sq. m. facility as part of a growing cluster²³.

²² *Cell therapy GMP manufacturing in the UK: Capability and capacity analysis*. Published by Cell Therapy Catapult (May 2014)

²³ *Why build a cell therapy manufacturing centre in Stevenage?* (catapult.org.uk). Published by Cell and Gene Manufacturing Catapult (October 2016)

Figure 3-1: Key locations in relation to the cell and gene therapy cluster



Source: Produced by SQW 2021. Licence 100030994

3.13 Hence the assumption of growth potential was designed in from the outset. Further investment was secured from Local Growth Fund to enhance quality control and environmental control systems (which had been identified as a bottleneck in the operations of the Manufacturing Centre). Subsequently, in July 2018, a further £3.36m was secured (from the European Regional Development Fund (ERDF)) to enable a second floor expansion; this was completed in September 2019.

'Crowding in' businesses, equity funding and funding for innovation

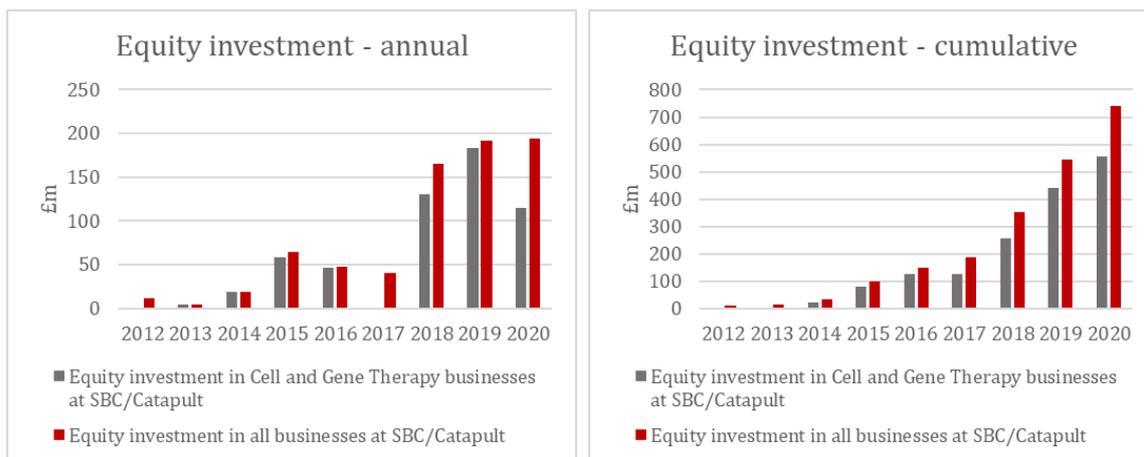
3.14 The first phase of the new facility was opened in 2017. **Thermo Fisher Scientific** announced a collaboration to provide developers with both the manufacturing capability and distribution, logistics, and storage capacity needed to create a seamless supply chain to accelerate cell and gene therapy development and commercialisation. This led to the creation of the **CryoHub** which serves as the central storage and distribution facility in support of CGT collaborators as well as other pharma/biopharma manufacturers²⁴.

3.15 **Autolus** and **Cell Medica** were the first companies to move into the Cell and Gene Therapy Catapult Manufacturing Centre. Early in 2018, both **Adaptimmune** and **Freeline Therapeutics** also announced that they would be collaborating with the Catapult, with a focus on viral vectors. **Achilles Therapeutics** announced in 2020 that it would be taking expansion space at the Catapult, consolidating its local presence (from offices at SBC). Hence the new facility quickly secured important collaborations. Many of these were linked to **Syncona**, the organisation set up in 2012 by the **Wellcome Trust** to invest in innovative, early stage, life sciences companies, especially those with a focus on cell and gene therapy.

3.16 Particularly once the Manufacturing Centre was on the horizon, there was also a genuine 'crowding in' of both investment and expertise to the GSK site. Information gathered by SBC suggests that **cell and gene therapy businesses which have been based at either the Catalyst or Catapult have secured over £550m of equity funding since 2012 (and over half of the total has been announced since 2018). Across the life sciences sector more broadly, the total linked to the Catalyst/Catapult in Stevenage (over the period 2012-2020) is £739m.**

²⁴ See website: [Stevenage, UK Site | Patheon](#)

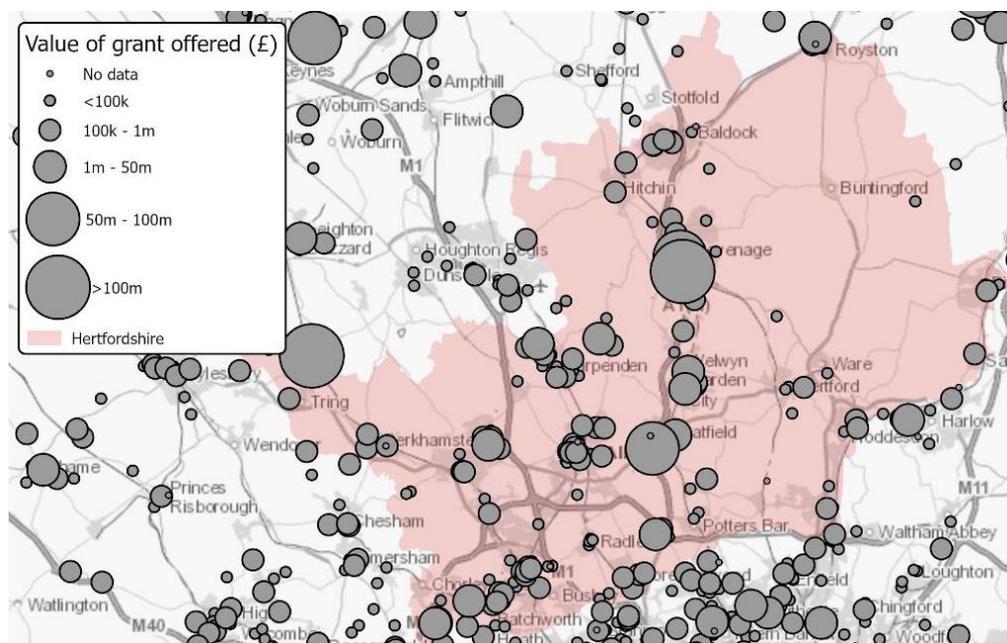
Figure 3-2: Equity investment in businesses at SBC and/or the Catapult on GSK’s site



Source: Data provided by Stevenage Bioscience Catalyst

3.17 Some of those businesses have also secured investment from Innovate UK. The map below shows investment in Hertfordshire across all sectors, but it demonstrates that investment in companies linked to SBC – based on the GSK site – have accounted for a significant proportion of the whole over the last decade. It also flags the importance of the A1(M) corridor in relation to innovation activity more broadly.

Figure 3-3: Total value of grant offered by Innovate UK between April 2011 and January 2021



Source: Map produced by SQW 2021 (Licence 100030994) based on data from Innovate UK

Fuelling growth...

- 3.18** One of the immediate consequences of this investment was early demand for additional floorspace²⁵. Full plans for Phase 2 of SBC (from 2014) were not progressed because of a major funding gap so proposals were developed for a modular build project, driven by SBC with the purpose of providing space for firms collaborating with the Catapult. In response, Hertfordshire LEP made a £1.2m capital contribution (from the Local Growth Fund) towards the development of the new **Spark Building**. This was intended to provide interim lab and office accommodation whilst more permanent accommodation was developed nearby. Netherlands-based Kadans Science Partner acquired **Sycamore House** from GSK. The plan is that Kadans will redevelop and extend Sycamore House into a multi-tenanted R&D facility with expected completion in 2021. The building will provide grow-on space for overflowing demand from the Catalyst and Catapult²⁶. In addition, over recent months, a planning application for a bio-pharmaceutical lab on **Marshgate car park** on St George's Way, Stevenage, has been submitted to Stevenage Borough Council. In the longer term, GSK's recent announcement linked to the redevelopment of 33 acres on its **Research and Development site** over 5-10 years could also prove to be very important (see Chapter 5) in ensuring that the potential of the cluster is realised²⁷.
- 3.19** **Although they have been separate ventures, the relationship between Stevenage Bioscience Catalyst and the Cell and Gene Therapy Catapult Manufacturing Centre has been synergistic: they have evolved together at the heart of the emerging cluster.** Currently, it is estimated that the cell and gene therapy campus in Stevenage – including both the Catalyst and Catapult – is delivering over 1,000 jobs and is home to over 45 companies, 13 of which are in the cell and gene therapy space²⁸. The growth potential linked to those companies is substantial.

Cell and gene therapy cluster in Hertfordshire – a comparative perspective

- 3.20** The public sector – through central government and its agencies and/or at a local level – has played a key role in the emergence of the new cluster. **Overall, it has invested some £120 million in the life sciences sector linked to the GSK site in Stevenage over the last decade. Around half of that total has been directed explicitly towards the possibilities of cell and gene therapy; the remainder has focused more on facilitating open innovation within life sciences more generally.** The main focus of the investment has been on the Catalyst and Catapult buildings, and linked to this, there has been some investment in further workspace as well as enabling infrastructures. **This in turn has led to substantial**

²⁵ <https://www.stevenagecatalyst.com/news/12m-investment-reinforce-stevenage-campus-world-cl/>

²⁶ <https://www.businessweekly.co.uk/news/biomedtech/dutch-company-buys-stevenage-facility-gsk>

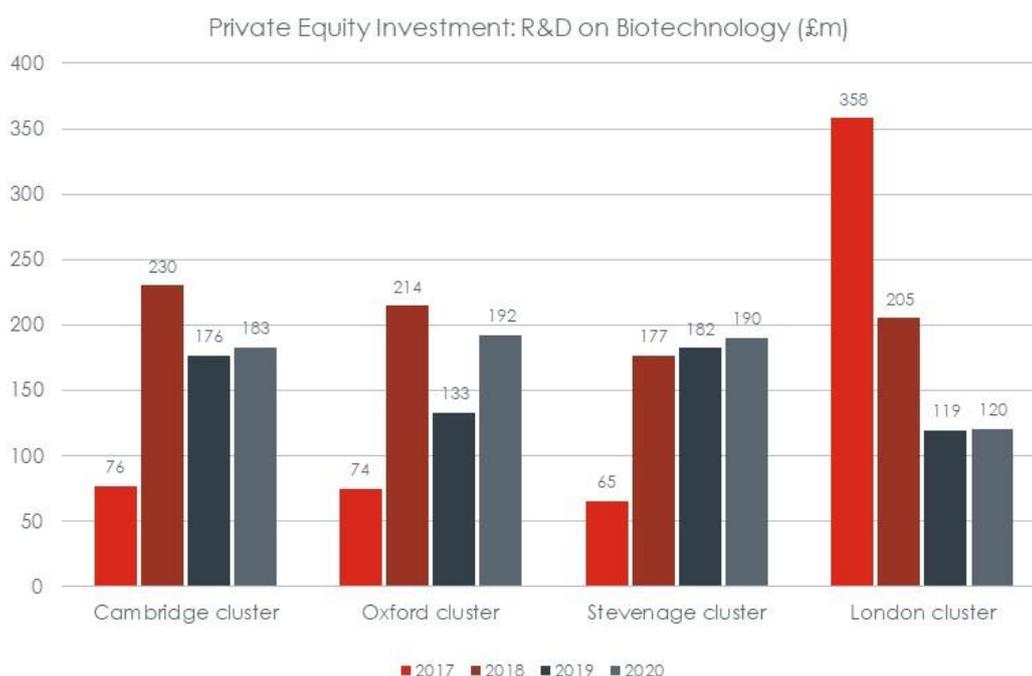
²⁷ GSK unveils plan for one of Europe's largest life science campuses in Stevenage. GSK Press Release – 16th July 2021

²⁸ <https://www.hertfordshirelep.com/news/2020/stevenage-named-high-potential-opportunity-zone-for-cell-and-gene-therapy/>

private sector equity investment which sums to more than £739m (over the period 2012-2020) according to data from SBC.

3.21 Data sourced from Beauhurst by Hertfordshire LEP have a different provenance, but they point to a similar picture and they allow a comparative vantage point. Private equity investment in R&D activities linked to biotechnology in Stevenage has risen progressively in recent years. In Figure 3-4 below, this is benchmarked against the ‘Cambridge cluster’²⁹ (which includes, *inter alia*, the Genome Campus at Hinxton, Babraham Science Park, Cambridge Science Park and Cambridge Biomedical Campus); the ‘Oxford cluster’³⁰ (including Oxford Science Park and Milton Park); and London. **Private equity investment in ‘R&D on Biotechnology’ has grown in Stevenage year on year and in 2020, it was higher than for the clusters in Cambridge and London, and very close to the figure for Oxford**³¹. Moreover, from the Beauhurst data, we know that the average deal size is bigger in Stevenage than elsewhere (Figure 3-5) suggesting, perhaps, a focus on businesses that are closer to market/clinical application and further advanced in the translation/commercialisation journey.

Figure 3-4: Scale of private equity investment in ‘R&D on Biotechnology’ in Stevenage and selected comparators, 2017-2020



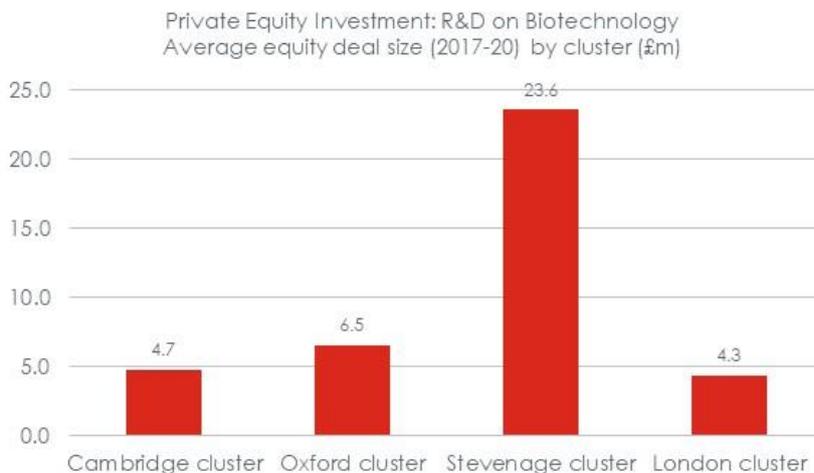
Source: Beauhurst, based on data sourced by Hertfordshire LEP, March 2021

²⁹ In spatial terms, this is defined here as Cambridge City and South Cambridgeshire districts

³⁰ This includes Oxford, South Oxfordshire and Vale of White Horse

³¹ Using different metrics and definitions, a recent report identified Stevenage as the sixth most important UK ‘city’ in terms of venture capital investment into life sciences companies in 2020. On this measure, it was behind London, Oxford, Cambridge, Manchester and Aberdeen, but ahead of Brighton, Newcastle and Reading. See *Life Sciences Innovation: Building the Fourth Industrial Revolution*, Report by Perkins and Will, Blackstock and Savills (May 2021)

Figure 3-5: Average equity deal size (2017-20) in 'R&D on Biotechnology' in Stevenage and selected comparators



Source: Beauhurst, based on data sourced by Hertfordshire LEP, March 2021

Conclusion

- 3.22 The scale of investment in cell and gene therapy in Stevenage has therefore been substantial, both absolutely and relatively.** The government's recently-published *Life Sciences Vision* observes simply that “the UK has a very strong cluster of Advanced Therapy companies forming in Stevenage around the Cell and Gene Therapy Catapult”³². Already, it is recognised as the UK's largest cell and gene therapy cluster, and the third largest globally³³.
- 3.23** Looking back over the last decade, much has been achieved, and many of the original objectives for Stevenage Open Innovation Bioscience Park (which became SBC, linked to the Cell and Gene Therapy Catapult Manufacturing Centre) have indeed been realised, albeit through a ‘journey’ that has been different from what was originally intended. The graphic overleaf summarises the original ‘key benefits’ identified through the Phase 1 Business Plan³⁴, and progress to date.

³² *Life Sciences Vision*, HM Government (2021) – page 48

³³ GSK unveils plan for one of Europe's largest life science campuses in Stevenage. GSK Press Release – 16th July 2021

³⁴ Stevenage Open Innovation Bioscience Park Business Case Submission, by GSK (August 2009)

Table 3-1: 'Key benefits' linked to the "first purpose-built Open Innovation campus for Drug Discovery and Development" in the UK – as set out in the Business Plan for Phase 1

Objectives from Phase 1 Business Plan in 2009	Progress by 2021
<i>Create a unique asset for the region and UK;</i>	Particularly with the Catapult on site, the innovation campus is a unique asset regionally and nationally.
<i>Maximise the economic impact of existing academic science and expertise;</i>	It is very difficult to claim that impacts are 'maximised' and we do not have the counterfactual, but there is evidence to suggest that the campus is making a major contribution to translation processes. Major economic impacts are likely to accompany the transition to production, which is still an on-going 'project'.
<i>Enable a more rapid impact from translational funding initiatives by other parties (Technology Strategy Board, Wellcome Trust and UK research councils);</i>	The synergies between the Catalyst and Catapult have been extremely important, and the Catalyst – alongside the LEP and other partners – has played a major role in trying to make provision for Catapult companies.
<i>Act as a catalyst to position the UK at the forefront of scientific innovation, helping to regain the ground the UK has lost in the last 10-15 years;</i>	Particularly with the Catapult on site, the open innovation campus is attracting interest from around the world (see case studies in Chapter 4). The cell and gene therapy cluster in Stevenage has recently been recognised as the largest in the UK and the third largest globally.
<i>Enable increased chances of success of development of new drugs;</i>	With the Catapult on board, the possibility of a new generation of advanced therapies is now being realised.
<i>Create 1,500 new jobs;</i>	It is estimated that there are around 1,000 jobs on site currently and prospectively far more off-site – although these require additional premises.
<i>Stimulate the creation of at least 5 new businesses;</i>	New early-stage businesses are being accommodated in the Catalyst and formed through collaborations with the Catapult.
<i>Foster a successful model that is attractive to all big pharmaceutical companies globally as the industry undergoes a forced operating model change;</i>	Global reviews of the cell and gene therapy market point to the challenges of the manufacturing process but also the importance of it in relation to big pharma and more generally.
<i>Attract additional investment to the UK.</i>	As the case studies in Chapter 4 demonstrate, many of the early collaborators at the Catapult have strong international credentials. They represent inward investment to the UK.

3.24 The fact that this investment was secured locally highlights the strength of Hertfordshire's asset base, as well as its wider locational advantages (especially given its proximity to both London and Cambridge), in the context of a sector which is growing globally and to which UK central government is strongly committed. But this flow of investment also now brings with it real responsibilities: the investment that has been made needs to unlock improved healthcare outcomes around the world, and it should generate economic impacts in the process. Against this backdrop, the continuing growth of the emerging cluster – and particularly its transition from clinical trials to the production of therapies for wider clinical use – must be facilitated at a local level to turn 'amber' assessments in the table above, into 'green'. It must also be recognised that a failure to address them could convert 'amber' assessments to 'red'.

4. Perspectives from within the cell and gene therapy cluster

4.1 Chapter 3 provided the headline narrative in relation to the formation and early growth of the cell and gene therapy cluster within the broader evolution of Hertfordshire’s life sciences sector. To understand better the dynamics of the cluster, the perspectives of individual businesses are important. During 2020 and 2021, SQW consulted in detail with seven cell and gene therapy businesses (and others in the wider cluster) to understand something of their individual histories and future business plans, and what they considered might prove to be the challenges. These discussions built on those conducted as part of two Science and Innovation Audits – one for London’s Knowledge Quarter (from 2018) and a second for the East of England (from 2017). Although the interviews were conducted at different times, they covered similar ground and are appropriately regarded as part of the same evidence base. In distilling it, this chapter presents three full case studies³⁵ and it also draws out key themes, looking across the full set of business consultations.

Understanding the cluster

4.2 Currently, most of the cell and gene therapy companies with a presence in Stevenage are early stage businesses. This reflects both the maturity of the sector, and the particular purpose of the Cell and Gene Therapy Catapult Manufacturing Centre (to expedite the translational journey from laboratory activity to later-stage clinical trials).

Linked to universities, hospitals and specialist investment

4.3 Within this context there continue to be strong on-going relationships between the companies and individual academics and/or research groups. Links to London-based universities and hospitals seem to be especially prominent and, within this, UCL features heavily (see the case studies below of both Freeline and Achilles). Many of the companies associated with the Catapult have received equity funding from Syncona (the investment company set up by the Wellcome Trust) and some talked of a “*Syncona family*” in which “*sister companies collaborate*”. The inference is **a research-funding nexus with its origins in the Knowledge Quarter area of London (around the Francis Crick Institute, UCL, Wellcome Trust, King’s Cross/Euston) but extending to Stevenage, some 20-30 minutes away (by train), where early stage businesses can find the facilities and an environment in which to progress towards clinical trials.**

³⁵ We are very grateful to Freeline, Achilles Therapeutics and Rentschler Biopharma for agreeing to be case studies for this report. The three case studies have been reviewed by the relevant companies.

International dimensions – and the global challenges linked to production

- 4.4** In terms of company origins, a second common thread was also striking: **most businesses have strong international credentials, either in ownership terms or in terms of key personnel.** Many links were described with Boston (and particularly Kendall Square, which many would regard as the epicentre of life sciences globally), Navy Yard (Philadelphia) and with European centres such as Munich.
- 4.5** **What brought these very early stage companies (and highly mobile individuals) to Stevenage was primarily the possibilities associated with the Cell and Gene Therapy Catapult Manufacturing Centre. This was seen by many as a unique facility globally.** It addresses a critical challenge in the commercialisation journey – namely the need to produce cell and gene therapies at a scale sufficient for clinical trials.
- 4.6** In considering the counterfactual, consultees generally described two alternative solutions in moving towards the batch production of cell and gene therapies. Some consultees identified that the main alternative, particularly in north America, was the use of Contract Manufacturing Organisations (CMOs). However, although these have a role to play, they also have limitations. Specifically, **there is almost as much knowledge, know-how and (potentially) competitive advantage bound up in the process of production as there is in the underlying science.** One company identified three limitations surrounding the CMO route: the lack of control and flexibility; the difficulty of building knowledge within the company; and issues of confidentiality as most CMOs work for competitors. For all three reasons, the CMO route was not preferred. **The inference is that early stage businesses need to be more ‘hands on’ and have greater control of the process – and the ability to learn from it.**
- 4.7** Going to the other extreme, a second possibility for cell and gene therapy businesses seeking to move to production for clinical trials was to invest in their own facilities. However, **none wanted to go down this route – for reasons of cost, risk, timescale and focus.** As one consultee explained:

For an early stage cell and gene therapy business, it is simply impossible inside a three year window to build manufacturing capability, validate a novel platform and find the money for it all.

- 4.8** The evidence therefore suggests that **the Catapult’s investment in the Manufacturing Centre has plugged a major market failure and one that is recognised globally.** For this reason, it seems likely that early stage cell and gene therapy businesses will continue to be attracted to Stevenage from key bioscience research centres around the world. Drawing on one interview with a small cell and gene therapy business:

It was a very smart move by the UK government to build this wonderful facility in Stevenage, providing small companies with the opportunity to develop manufacturing capabilities, and meet the needs of clinical trials whilst having the flexibility to bring along other partners and

some CMOs.... There is nothing like the Stevenage facility in the USA – probably because of the dominance of the venture capitalists and the very limited role played by government.

Specialist labour markets

- 4.9** The research intensive nature of the businesses and the strong international networks also framed a third key element of the emerging cluster. In any knowledge economy, access to a specialist labour market is critical and the cell and gene therapy businesses are no exception.
- 4.10** In general terms, businesses described a **spatially extensive labour market which certainly encompasses London and Cambridge, and in practice much of the greater south east including Oxford(shire). It also has strong international dimensions given the highly specialist nature of many of the surrounding skills.** Some of the companies with a presence at the Manufacturing Centre are growing very quickly (one, for example, has increased its headcount from about 30 to 200 in three years). In all cases, the labour market – on this broad spatial definition – was described in highly favourable terms, certainly as compared to Boston, USA (which for some was the obvious comparator). To quote one of our consultees:

With the scale of labour market constraints in and around Boston, going to Stevenage and tapping into the talent pool in the Oxford-Cambridge-London Triangle made a lot of sense.... We are very happy with the quality of the people we have found.

Specialist international logistics and distribution

- 4.11** The international narrative was also apparent in relation to businesses' growth models. In essence, most are seeking to run Phase III clinical trials. In practice, these take different forms within different national and international regulatory environments and healthcare regimes. For this reason, **businesses need to be able to distribute batches of therapeutic products internationally at speed and on a highly controlled basis.** For one of the companies we consulted, this meant manufacturing its viral vector at the Catapult facility in Stevenage, and then transferring the product to a facility in Philadelphia to be used in clinical trials. At present, the logistics infrastructure in and around Stevenage supports this business model. **The associated logistics operations are therefore sophisticated, and they must be seen as an integral element of the emerging cluster³⁶.** In this context, the co-location of Thermo Fisher Scientific (described in Chapter 3) was seen as very important, as was the proximity of Heathrow Airport.
- 4.12** Looking ahead, there will be issues to navigate. For example, cross-border logistics becomes particularly challenging when undertaking autologous cell therapy clinical trials. During this therapy, a patient's white blood cells are collected and sent to a manufacturing site to be transformed into the drug product. They are then sent back to the clinical site to be used on the patient. This whole process must happen quickly. In autologous cell therapy where rapid

³⁶ This is recognised in 'UK Innovation Strategy: Leading the future by creating it' (BEIS, July 2021) which observes that "manufacturing and logistics are critical elements of an R&D ecosystem" (page 20)

T cell manufacturing is required, having a manufacturing centre closer to the clinical site becomes more important. This may have implications for how the cluster evolves.

Cluster dynamics

- 4.13** Overall, the cell and gene therapy businesses which are operating from the Catapult and/or Catalyst are very positive about Stevenage. Principally because of the facility provided at the Catapult, one firm described it as *“the core of cell and gene therapy in the UK”*. Another company explained that the Cell and Gene Therapy Catapult Manufacturing Centre provides a supportive community for companies at a similar stage in their development. There is some collaboration between companies. This was explained to be:

...less in the fundamental science than in the sharing of experiences in the complicated process of supply chain, GMP manufacture and QC testing of cell therapies as operations are scaled up.

- 4.14** As a result, the point was made that because of the Catapult, *“the cell and gene therapy sector has started to congregate in Stevenage – more so than in Cambridge and Oxford”*. These early stage – and inevitably high risk – businesses are attracting substantial sums of equity investment on the back of world class science in a market that has transformative potential. They need an advanced production facility, and thus far – following the Catapult’s investment at the GSK site – Stevenage has proved itself to be highly effective in these terms; it has put itself on the global life sciences map.

- 4.15** Looking ahead, there are both opportunities and challenges. One consultee commented:

*There is a need for innovation in cell manufacturing processes and this in turn **needs a whole ecosystem to come together**. Potentially this could include advanced logistics providers as well as many different forms of microbial and other testing, and a group of CROs should also be part of the mix.*

- 4.16** A second business reflected:

*In order to remain attractive, Stevenage must ensure that cell and gene therapy business can **access larger scale commercial facilities** once they outgrow the Catapult. It will be equally important to ensure growing companies can **continue to recruit** by providing a steady stream of people with appropriate technical skills.*

- 4.17** The observation of Achilles (one of the case studies presented below) was insightful in this context. In addition to those with PhD-level research training, the need now is to attract and retain graduates with a broader interest in the field. In this context, Achilles saw itself as having to *“grow and develop a labour force”* – although it also considered that cell and gene therapy is ‘gaining traction’ and *“as soon as a few biotechs make it, the flow of skilled people will follow”*.

- 4.18** The question now is how the momentum linked to the cell and gene therapy cluster should be sustained.

Case Studies

- 4.19** Three detailed case studies – which describe the growth of individual cell and gene therapy businesses – are presented in the pages which follow. These add depth to many of the observations summarised above.

Case Study – Achilles Therapeutics

Company origins

Achilles Therapeutics is a biopharmaceutical company developing personalised cancer immunotherapies targeting clonal neoantigens³⁷. Achilles was founded by Professor Karl Peggs, Professor Mark Lowdell, Professor Charles Swanton and Professor Sergio Quezada – all of whom are professors at University College London (UCL). The company received seed funding from Syncona and was incorporated in 2016.

The company is developing a personalised tumour-derived precision T cell therapy to treat multiple types of solid tumours by targeting clonal neoantigens. Achilles refers to its product as Clonal Neoantigen T cell therapy, or cNeT. One of its founders, Professor Charles Swanton, is the chief investigator of the CRUK-funded cancer evolution study TRACERx³⁸. The scientific discoveries from this study have been central to establishing the concept of clonal neoantigens. Exclusive commercial access to the genomics data from over 600 cancer patients in the TRACERx study has enabled the company to develop and build PELEUS™, a commercially focused bioinformatics platform for identifying a patient's tumour clonal neoantigens.

Using the genomics information from a patient's cancer, Achilles is able to target clonal neoantigens on the tumour with the patient's own T cells in a truly personalised therapeutic approach. In 2019, Achilles received approval from the UK Medicines and Healthcare products Regulatory Agency (MHRA), for two open-label, proof-of-concept clinical trials.

- CHIRON is a Phase I/IIa clinical trial evaluating its Clonal Neoantigen T cell therapy (cNeT), for the treatment of advanced Non-Small Cell Lung Cancer (NSCLC); the first patient was treated with this therapy in June 2020.
- THETIS is a Phase I/IIa clinical trial evaluating its Clonal Neoantigen T cell therapy (cNeT), for the treatment of metastatic or recurrent melanoma; the first patient was treated with this therapy in May 2020.

Subsequently Achilles submitted an Investigative New Drug (IND) application for the CHIRON study to the US Food & Drug Administration (FDA) which was successfully approved.

Following approval from the UK MHRA, Achilles commenced manufacture of its T cell therapy products at the Centre for Cell, Gene and Tissue Therapeutics (CCGTT), based at The Royal Free London NHS Trust where another founder, Professor Mark Lowdell, is the Centre Director. At the stage of early process development and to successfully tech transfer into clinical production, access to state of the art GMP cleanrooms for manufacturing advanced therapy medicinal products (ATMPs) at the CCGTT was a critical component for delivering

³⁷ Neoantigens are the mutations on every single cancer cell that are not found in normal, healthy tissues.

³⁸ TRACERx: TRACking Cancer Evolution through therapy Rx

products for Phase I/II studies. Institutions and networks linked to UCL, Royal Free Hospital and the Francis Crick Institute were (and are) therefore very important.

What brought Achilles to Stevenage

In 2017, Achilles looked to the Stevenage Bioscience Catalyst (SBC) for additional R&D laboratory capacity. SBC was considered a good fit, partly because it was already home to a number of other Syncona funded companies.

Like many growing cell therapy companies, Achilles wanted to expand its manufacturing capabilities whilst maintaining full control of the process and without having to use a Contract Manufacturing Organisation (CMO). At the time, the Cell and Gene Therapy Catapult Manufacturing Centre in Stevenage was the only feasible option in the southeast UK with sufficient space to support Achilles' expansion plans. There was no other facility available that enabled companies at an early stage of clinical development in cell and gene therapy to continue to develop and scale their manufacturing processes in-house without having to invest in their own facility. At that stage, it would have been particularly challenging for Achilles to commit the scale of capital investment required to build a large-scale manufacturing facility.

The Cell and Gene Therapy Catapult Manufacturing Centre was also a sensible option because it was home to several other companies developing cell and gene therapies. As a result, it provided a supportive community for companies at a similar stage in their development. There is some collaboration between companies – less in the fundamental science than in the sharing of experiences in the complicated process of supply chain, GMP manufacture and QC testing of cell therapies as operations are scaled up.

Operating in Stevenage – and looking ahead

At present, Achilles employs 50-60 people in Stevenage, at three different locations: CGTC-MC, Stevenage Bioscience Catalyst and at the Spark Building. Once it is completed, some activities will be transferred to Sycamore House. It is envisaged that these different sites will continue to be important for the foreseeable future, and Stevenage will therefore be a key hub for clinical manufacturing and translational science.

In late 2020, Achilles opened new R&D labs and offices in Hammersmith, which now functions as its corporate headquarters. In total, Achilles currently employs about 180 people, mainly in the UK. It also has a small US presence.

Achilles' footprint will continue to grow as it develops its manufacturing capabilities and clinical trials expand. This in turn is likely to generate a number of new collaborations throughout the end to end supply chain and particularly with specialist digital companies.

To this end, Achilles conducted an extensive site selection process which covered a large area including Oxford and Cambridge and extending across Greater London and west as far as Reading. It was seeking a site which would be: suitable for a commercial manufacturing facility; large enough to accommodate 250 people (who also require good access to it, recognising that many will need to travel to the site given the specialist nature of skills requirements); equipped with a good power and utility infrastructure; and able to provide good access to transport links for global shipment of starting materials and drug products. The search was not easy; there were very few sites that met all the technical criteria and none within close proximity to its activities in Stevenage. Co-location with activities in

Stevenage would have been desirable but was not absolutely essential. The chosen site is in West London.

Looking ahead, Achilles recognises that recruiting appropriately skilled people will be important. It commented that in addition to those with PhD-level research training, the need now is to attract and retain graduates with a broader interest in the field. In this context, Achilles sees itself as having to “*grow and develop a labour force*” – although it considers that cell and gene therapy is ‘gaining traction’ and “*as soon as a few biotechs make it, the flow of skilled people will follow*”.

Case Study – Freeline

Company origins

Freeline is a clinical-stage biotechnology company developing transformative gene therapies for patients suffering from inherited systemic debilitating diseases. Seed-funded by Syncona, Freeline was founded in 2015 by a University College London (UCL) academic, Professor Amit Nathwani.

Freeline was initially based at the Royal Free Hospital in London. It moved its headquarters to Stevenage in 2017 where it has laboratories and growing manufacturing and testing operations, along with a number of non-laboratory-based functions. The company has also built up and retains an international footprint with operations in Munich, New York and Boston.

What brought Freeline to Stevenage

Freeline’s decision to move to Stevenage was driven in a large part by the collective intent of Stevenage Bioscience Catalyst (SBC), GSK and the Cell and Gene Therapy Catapult to develop a cluster that would support cell and gene therapy innovator companies by creating critical mass and developing an overall ecosystem spanning research through to manufacturing and the supply chain. The facilities provided by SBC, together with the Cell and Gene Therapy Catapult Manufacturing Centre, allowed it to quickly establish and grow its operations without needing to deploy significant capital. At the time of its move to Stevenage (in 2017), it had around 40 people; today Freeline employs some 160 people in Stevenage.

The benefits of Stevenage as the mid-point between London and Cambridge

Collaborations with world class academic groups and other technology companies remain critical for Freeline as it develops its pipeline of therapies and its technology platform. The Stevenage location, in the middle of the triangle between London, Oxford and Cambridge, is ideal. The logistics connections to Stevenage by road, rail and air are very strong – this is important due to the international nature of its operations.

Additionally, the cell and gene therapy sector is in its infancy. As a result, there are a limited number of people with suitable experience and skills. The Stevenage location allows Freeline to “*cast the net widely*.” In coming years, developing training capabilities in the area will be critical to ensuring a continued pipeline of skills at all levels to support growing research and manufacturing operations.

The challenges of growth

Despite the enormous importance of SBC and the Catapult, and the benefits of Stevenage in terms of accessing skilled labour, growing the company locally has had its challenges. Whilst the Catapult Manufacturing Centre is proving to be an effective start-up facility for its manufacturing technology, it cannot support Freeline's growing demands as its portfolio matures. Equally, the SBC has been unable to expand as quickly as needed to accommodate all of its tenants. As a result, Freeline has taken on additional sites and is investing capital to secure larger research facilities.

Looking forward, Freeline needs to expand its manufacturing capability. It is currently working with a UK based contractor to design its own facility and is in the process of identifying suitable locations. Ideally, the company would prefer to stay near Stevenage as this would enable it to build on its existing employees and the skills and experience developed whilst maintaining the closest possible integration between research and manufacturing operations.

Case Study – Rentschler Biopharma

Rentschler Biopharma is a well-established family-owned business that was formed in Laupheim (southern Germany) in 1927. It is a contract development and manufacturing organisation (CDMO) which operates from current Good Manufacturing Practice (cGMP) facilities. It works for over 150 biopharmaceuticals clients from around the world.

From this foundation – and reflecting the way in which the biopharmaceuticals sector is evolving globally – Rentschler Biopharma took the decision to establish a manufacturing capability in Advanced Therapy Medicinal Products (ATMPs), including Adeno-Associated Virus (AAV) Vectors for clinical trial supply. This is a major investment for the company.

To make this transition, Rentschler Biopharma wanted to work through an incubator setting with an initial focus 'inside the clean room'. This reflects the challenges linked to cell and gene therapy manufacturing and the scale of learning that is associated with it. Rentschler Biopharma considered different options around the world but there were only two or three possibilities, of which the Cell and Gene Therapy Catapult Manufacturing Centre in Stevenage was identified as the best. This assessment reflected:

- the high cGMP standards which have been created within the Manufacturing Centre
- the proximity of Stevenage to Rentschler Biopharma's HQ in Germany, and the relatively good access (via Heathrow)
- the fact that Stevenage is very well located in relation to 'the competition for talent' (noting that associated skills are in short supply globally, but that Rentschler Biopharma considers the UK to be well placed in these terms as a result of "*long sighted and clever investment*" through UK universities and by UK government).

Rentschler is currently in the process of establishing itself within the Catapult and has already hired an expert team. The company expects staff numbers to triple quickly and then to grow steadily over the next few years. This is Rentschler's first investment in the UK – and it has been made against the backdrop of the UK's departure from the EU, which has added some complication. However, Rentschler is learning from the Catapult and recognising the importance of the design of manufacturing space.

Rentschler has been able to recruit locally – and Stevenage’s location within the London-Cambridge-Oxford Golden Triangle is considered to be crucially important in these terms. It is also regarded as a vibrant academic area with cross-fertilisation between universities and biotech start-ups. In this context, UCL, University of Cambridge and University of Oxford are all regarded as important. Overall, Stevenage is described as a really good location – outside London and a bit less expensive, but with good access via Heathrow Airport.

In time, Rentschler will need more space and it has yet to decide how this will be resolved. The next step will be to develop a high quality cGMP facility, but this will take a long time to design and build. Hence although it has only just moved into the Catapult – and it plans to be there for around six years – it is already thinking about its longer term plans. Any new facility will be built in a modular way, but it could quickly scale in employment terms (perhaps to create 200 - 600 jobs). Where the investment takes place will depend on many factors, including the availability of talent and space; ideally – having invested in people – it would not want to move far from the Catapult and so Stevenage would be its preference.

In planning its own growth, Rentschler will want to work with collaborators and partners. This approach is already part of the company’s strategy to offer best-in-class solutions across the biopharmaceutical value chain. Here there may be opportunities. It will need partners to collaborate on analytical methods, and also to work on fill and finish. The quality will need to be outstanding, and the collaboration will need to provide a benefit to Rentschler’s clients, but in principle, there are opportunities to build a distributed, “localised” value chain.

Looking around the world, there are comparator schemes which are noteworthy. The King of Prussia in Philadelphia – which includes a major GSK facility – is being redeveloped to become a global focus. Within this, a new Center for Breakthrough Medicines was formed by a current good manufacturing practice (cGMP) manufacturing services provider (The Discovery Labs) and a healthcare investment management firm (Deerfield Management Company) in January 2020. The new facility could occupy 680,000 sq. ft. and would support the development of therapies from the pre-clinical stage through clinical and commercialisation within a single facility³⁹. It is much bigger than the Stevenage facility, but it signals something of the global potential linked to cell and gene therapy.

³⁹ See The Center for Breakthrough Medicines’ Cell and Gene Therapy Manufacturing Facility, King of Prussia (accessed April 2021 from www.pharmaceutical-technology.com)

5. Prospects, opportunities and challenges

- 5.1** Although the growth of the cell and gene therapy sector has been temporarily slowed by the pandemic, its importance has arguably increased; most commentators are still anticipating very rapid (double digit) growth over the years ahead. Given the emergence of the cell and gene therapy cluster over the last decade in Stevenage, this suggests that there could/should be major opportunities.
- 5.2** Based on a review of the wider literature and discussions with key industry stakeholders, this chapter outlines some key themes that could either accelerate or stifle the growth of the cluster locally. Chapter 6 (which follows) distils these into a recommended set of priority actions.

Recognise the need to enable the continued growth of the cell and gene therapy cluster locally

- 5.3** As noted throughout, the production of cell and gene therapies at a scale sufficient for clinical trials constitutes a major challenge. The Catapult's response – through the Manufacturing Centre located in Stevenage – has been highly effective. Yet if cell and gene therapies are to gain wider traction – which is what most commentators expect to see – then there will be a need for greater provision as individual therapies start to be approved by the relevant regulators. Autolus, for example, recently made the following statement:

Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announced its updated manufacturing facilities strategy for commercial supply of AUTO1. Autolus now plans to establish global commercial launch capacity in the UK, enabling the company to leverage the expertise and skill base of its UK employees. This will be provided by a combination of the existing clinical trial manufacturing facility at the Cell and Gene Therapy Catapult (CGTC) facility and a new Autolus facility⁴⁰.

- 5.4** Given the emerging cluster, Stevenage (and surrounding areas) could/should be the obvious choice for businesses seeking to move to the next stage. There will, in addition, need to be provision for specialist logistics⁴¹.

⁴⁰ "Autolus Therapeutics Announces Updated Manufacturing Facility Strategy Leveraging its UK Operations" – Press Release dated 29 March 2021

⁴¹ As noted earlier, the importance of specialist logistics in commercialising research is acknowledged in *UK Innovation Strategy: Leading the future by creating it* (published by BEIS in July 2021)

5.5 To realise the wider potential, it will be imperative locally to ensure:

- that there is provision of **sufficient and appropriate sites and buildings**, both to accommodate scaled-up production *and* to facilitate the growth of the wider supply chain, including with regard to specialist logistics
- that it is possible to staff those facilities with **appropriately trained and qualified personnel**
- that **Stevenage is regenerated as a vibrant 21st Century New Town** in which the cell and gene cluster can thrive.

5.6 These three themes are considered in the paragraphs that follow.

Land and property considerations in and around Stevenage

5.7 Gunnels Wood Road is a substantial industrial area to the west of Stevenage town centre and in the south, it abuts the extensive GSK site on which both the Catapult and Catalyst are located (see Figure 3-1). In principle at least, land and property therefore ought not to be a constraint on the growth and maturation of the cluster. However, in practice there are some complicated issues to address.

GSK Research and Development site

5.8 The **GSK site** is both large and the obvious focus for some elements of the growing cluster. Stevenage Borough Council's adopted Local Plan⁴² states that:

In relation to the Stevenage GSK and Bioscience Catalyst Campus, initial master planning undertaken by GSK suggests that this site may have capacity for a significantly greater level of B1(b) and B1(c) floorspace than has previously been consented on the site. Any floorspace beyond the previously consented floorspace would need to be the subject of a fresh planning application. Other uses will be allowed where they are ancillary to these uses and help to nurture the continued growth of this international facility.

5.9 Further development on the site will trigger a planning requirement for infrastructure investment linked to the gyratory at the site's entrance. Although Hertfordshire LEP has at various times indicated its willingness to make capital funding available, the costs associated with the gyratory continue to be a concern.

5.10 However, GSK has recently announced that it is formally starting the process of seeking a development partner. The intention is to transform land within its Research and Development site with the aim of creating "one of Europe's largest clusters for biotechnology and other early-stage life science companies". Some 33 acres of land is being sold in order to

⁴² Stevenage Borough Local Plan, 2011-31 (Adopted May 2019) – para 6.2

unlock £400m of new investment from a private sector developer to build the new campus over 5-10 years. This in turn could potentially create up to 5,000 jobs⁴³.

Gunnels Wood Road

- 5.11** Immediately to the north of the GSK site, the **Gunnels Wood Road** industrial area is large and incoherent. A major study completed in 2011 classified it as “*a mixed-use strategic employment site with reinvestment needs and future potential*”⁴⁴. In some respects, this description has barely changed a decade later: Gunnels Wood Road still hosts a miscellany of different uses ranging from high value, knowledge intensive businesses (such as Airbus and MBDA) to social care facilities, retail parks, car showrooms, local authority offices and distribution centres. In total, it is estimated that there are 300 businesses in the Gunnels Wood industrial area, accounting for 19,000 employees⁴⁵. It also has complicated land ownerships.
- 5.12** A study completed in 2020 suggested that “*densification and placemaking*”⁴⁶ were appropriate interventions for Gunnels Wood Road. In addition, “*Gunnels Wood Road Infrastructure Improvements*” form a key focus within the recently-agreed Stevenage Town Investment Plan⁴⁷, and these ought to be helpful. However, given the substantial opportunities linked to life sciences in general and cell and gene therapy in particular, it arguably merits more focused consideration. In this context, Policy SP3 from Stevenage Borough Council’s adopted Local Plan (2019) is important. It commits to:

Continue to remodel Gunnels Wood to meet modern requirements and provide a high quality and attractive business destination. This will include the continued development of the Stevenage GSK and Bioscience Catalyst Campus at the south of the employment area.

- 5.13** As noted already, the cluster needs a range of land and property types – including office, manufacturing and distribution space – and steps should be taken to find appropriate solutions within Gunnels Wood Road. **Sycamore House** (on Gunnels Wood Road) is being redeveloped and should provide 105,000 sq. ft. of laboratory, office and collaboration space by late 2021. However it is already fully let and additional space is needed. Early indications are that specific buildings/sites such as **Leyton House**, **Bladen House** and **the Roebuck site** – all on or close to Gunnels Wood Road – could be appropriate.

Stevenage town centre

- 5.14** Over the last year or so, the possibilities surrounding sites in Stevenage town centre have also been recognised in relation to the cluster’s growth potential. Within the Stevenage Town

⁴³ GSK unveils plan for one of Europe’s largest life science campuses in Stevenage. GSK Press Release – 16th July 2021

⁴⁴ Hertfordshire Strategic Employment Sites Study, Regeneris Consulting (April 2011) – for Hertfordshire County Council and EEDA

⁴⁵ Stevenage Borough Local Plan, 2011-31 (Adopted May 2019) – page 185

⁴⁶ Hertfordshire Key Employment Sites – Strategy and Action Plan (March 2020) – for Hertfordshire LEP, Hertfordshire County Council and Hertfordshire Infrastructure and Planning Partnership

⁴⁷ Stevenage Town Investment Plan, November 2020

Investment Plan (which led to a Stevenage Town Deal worth £37.5m), **Marshgate** was identified as one of seven key projects which will “*directly respond to the need for additional space (Office/ Tech Labs 76,437 sq. ft.) to meet continued growth of Stevenage’s specialist bioscience cluster, whilst at the same time also meeting the need for local key worker housing on the site (69 units)*”⁴⁸. As noted earlier, a planning application for a bio-pharmaceutical lab on Marshgate car park on St George's Way, Stevenage, has recently been submitted to Stevenage Borough Council.

Wider challenges linked to sites and premises

- 5.15** More generally, there is much evidence to suggest that Hertfordshire has haemorrhaged commercial employment land over recent years – particularly as sites have been diverted to residential uses through permitted development rights against a backdrop of very strong residential values⁴⁹. The inference is that provision for commercial uses may well be more limited than previously. It is notable also that technical work completed in the context of the Stevenage Local Plan pointed to a shortfall of employment land in the period to 2031 and a need, therefore, to co-operate with other local authorities. **Given both the boundaries of the Borough and the spatial footprint of biopharma (see Figure 2-2), Welwyn Hatfield and North Hertfordshire may be especially important in this context.**
- 5.16** **If Hertfordshire is to realise the full potential of its cell and gene therapy cluster, it must resolve issues relating to sites and premises – recognising a need for manufacturing/distribution and some office space, ideally within close proximity to the GSK site.** There are already examples of cell and gene therapy businesses going to extreme lengths to find premises within this area; one described how it was having to operate from four different sites around Stevenage. The scale of the opportunity is recognised by private sector developers. Some – notably Kadans Science Partner – have been active locally (focusing in that case on Sycamore House); and it has also been reported that around £2.4bn was invested in life sciences property in 2020 across the wider Golden Triangle⁵⁰. While developments at Marshgate and GSK’s recent announcement could prove to be very important, more needs to be done and with some urgency.
- 5.17** As discussed in Chapter 4, cell and gene therapy businesses have strong global connections and their commitment to the local area could prove short-lived if appropriate accommodation simply cannot be found. In this context, it is important also to note the scale of investment which is being made in competitor locations around the world; San Diego, for example, is seeing the creation of an ambitious life sciences hub, including a substantial ‘Research and

⁴⁸ *Stevenage Town Investment Plan, Stevenage Development Board, November 2020*

⁴⁹ See for example *Loss of Employment Space in Hertfordshire – Study into extent, implications and solutions* Lambert Smith Hampton, February 2019, Available at www.hertfordshirelep.com/media/rmphpd5mk/loss-of-employment-space-in-hertfordshire-february-2019.pdf

⁵⁰ The estimate of £2.4bn was made by Bidwells and reported in the *Financial Times* on 17th July 2021 within an article called ‘GSK to redevelop life sciences park in Stevenage and create up to 5,000 jobs’

Development District⁵¹ while global demand for lab space to accommodate life sciences businesses is reported as being very strong across many cities⁵².

Issues relating to skills and the labour market

- 5.18** In 2019, the Cell and Gene Therapy Catapult ran a (national) survey of businesses in the sector, focusing on skills needs. This updated an earlier survey (from 2017) and it found that the actual pace of growth had been faster than anticipated two years earlier. Within this, there were concerns in relation to the availability of key skills areas. Uppermost among these were those identified as ‘manufacturing’, followed by ‘process development’ and ‘total quality’. Conversely, ‘research and development/discovery’ appeared to be of less concern, even though demand was growing⁵³.
- 5.19** As set out in Chapter 4, cell and gene therapy businesses that are located in Stevenage have so far drawn on a very large labour market. It extends across much of the Golden Triangle and it also has strong international dimensions. As businesses move from research/discovery towards production, their workforce requirements will also change. There will, gradually, be more emphasis on technician-level skills and rather less, relatively, on skills linked to scientific research and discovery, and its early clinical application. Inevitably, this will mean that firms start to look towards a labour pool that is rather more local in focus.
- 5.20** Potentially, this presents a real opportunity for the people of Stevenage and the surrounding areas. The A1(M) corridor has a long history linked to engineering and advanced manufacturing as well as big pharma and there ought therefore to be real potential synergies. Moreover, some relevant initiatives have already been put in place. For example, early in 2020, the Cell and Gene Therapy Catapult and the University of Hertfordshire launched a new short course focusing on the skills gap in the manufacture of cell and gene therapies; this was designed to “*provide theoretical and practical training on the aseptic manufacturing of cell and gene therapies in line with European regulatory guidance for good manufacturing practice (GMP)*”⁵⁴. Building on initiatives of this type, **workforce skills will need updating, refreshing and to some extent ‘pivoting’ to reflect the particular opportunities associated with the cell and gene therapy businesses and its wider supply chain.**

Regenerating Stevenage as a vibrant 21st Century New Town

- 5.21** At the same time, however, **it will be essential that Stevenage is a place in which talented people – many of whom are potentially internationally mobile – choose to develop their own careers** (noting the huge “*competition for talent*” referenced in the case studies in Chapter 4). Wider commitments linked to the regeneration of Stevenage – through the

⁵¹ IQHQ | IQHQ Completes Acquisition, Breaks Ground on Iconic Development to Transform San Diego’s Waterfront into a Life Science Hub - IQHQ (iqhqreit.com), September 2020

⁵² See ‘Here comes the life sciences land rush’ *Life Sciences Labs Are Hot Covid-Era Real Estate - Bloomberg*, September 2020

⁵³ *UK Cell and Gene Therapy Skills Demand Report 2019*, published by the Cell and Gene Therapy Catapult

⁵⁴ Supporting progress of cell and gene therapy industrialisation with new aseptic manufacturing course (catapult.org.uk)

£37.5m Town Deal – are therefore very important. Stevenage’s Town Investment Plan set out a vision to *“build on our New Town values and unlock growth in some of the UK’s cutting-edge sectors, in a way which promotes and delivers opportunities for local people”*⁵⁵. It set out seven key projects, including major investment at Station Gateway to create a new thriving commercial and residential quarter for the town.

5.22 In highlighting the importance of providing appropriate sites and premises, and the criticality of attracting and generating workforce skills, **we are, fundamentally acknowledging the significance of place in relation to the growth of the cell and gene therapy cluster**. This concurs with the advice of the Place Advisory Group – reported in BEIS’ new Innovation Strategy – that *“R&D interventions seeking to make the most of places’ potential must be part of a wider strategy for that place, considering skills, infrastructure, business support and regeneration, tailored to each place’s needs”*⁵⁶. The link between the delivery of Stevenage’s Town Investment Plan (and the subsequent Town Deal) and the growth potential of the cell and gene therapy cluster is therefore critical.

Recognise the importance of data – genomics, bioinformatics, etc.

5.23 Global assessments of the cell and gene therapy industry are invariably quick to emphasise the importance of software and data science in its many different forms. In part this is evidenced through the volume of mergers and acquisitions between pharmaceuticals businesses and those with specialisms in software and data science. Within Stevenage itself, the ongoing collaboration between GSK and Google – through Verily – is a good illustration of the wider process of convergence. Looking ahead, the data component of cell and gene therapy is very likely to grow substantially⁵⁷.

5.24 Within this context, it will be important that appropriate provision is made for the digital dimensions of the cluster’s growth. This means, for example, that:

- broadband infrastructure needs to be exemplary and capable of handling large amounts of data across cell and gene therapy businesses and the wider cluster
- digital skills need to be enhanced – both among those who will work in manufacturing roles, and at other levels; indeed 63% of respondents to the Cell and Gene Therapy Catapult’s skills demand survey indicated that *“digital skills will be important for their future workforce, mainly due to automation and data management”*⁵⁸.

5.25 In addition, the opportunities for genomics and bioinformatics in Hertfordshire ought to be explored actively. These allied sectors are likely to be at the core of the personalised medicine that is made possible through cell and gene therapy and the links therefore should be strong ones. It may be that this is best achieved through links with other centres – and Cambridge and London both have much to offer. Equally though, in those parts of the county that have

⁵⁵ *Stevenage Town Investment Plan* – Stevenage Development Board, November 2020

⁵⁶ *UK Innovation Strategy: Leading the future by creating it* Published by BEIS, July 2021 – page 73

⁵⁷ 2020 Global Life Sciences Outlook: Creating new value, building blocks for the future, Deloitte Insights

⁵⁸ UK Cell and Gene Therapy Skills Demand Report 2019, published by the Cell and Gene Therapy Catapult

particularly strong data science credentials, there may be scope to nurture relevant businesses, and the University of Hertfordshire could also have an important role to play.

Recognise that this is a global sector and one which is highly networked – which means that Hertfordshire must compete with ‘the best’

- 5.26** The achievements of recent years have been considerable. However, the cell and gene therapy sector is extremely competitive globally and Hertfordshire will need to continue to compete with global locations if it is to sustain the progress it has made. The absence of both a major teaching hospital and a Russell Group university could have precluded the cluster’s growth, but Hertfordshire has succeeded because of its connectivity, its talent pool and its willingness thus far to accommodate growth proactively. It is really important that all three of these elements continue to evolve in a positive way.
- 5.27** Within this context, the designation of Stevenage as first (in 2018) a **Life Sciences Opportunity Zone** and then, in 2020, a **High Potential Opportunity Zone** has helped to give the cluster profile, and ought to ensure its prominence not least with central government. But it is crucially important that the significance of wider networks is also recognised and invested in. These networks frequently play a key role in, essentially, de-risking an inherently risky commercialisation journey and links to academics, investors and other entrepreneurs are likely to be critical. These softer connections frequently underpin cluster growth whilst fuelling innovation, and it will be essential that the cell and gene therapy cluster continues to be at the forefront of both.

6. Priorities in growing the cluster and the wider sector

- 6.1** The cell and gene therapy cluster is nested within a broader life sciences sector, and Hertfordshire has strong assets in relation to both. It has substantial opportunities looking ahead. However, actions need to be taken to ensure that these are realised. In many cases, these are really quite urgent. Informed by the preceding analysis, a set of recommended priority actions is presented in the tables below. These will need to be considered by Hertfordshire LEP and its partners. If the recommendations are accepted, they will need to be developed and driven forward through the forthcoming Cluster Action Plan.

Table 6-1: Recommended priority actions: cell and gene therapy cluster

Action 1:	<p>Develop a <u>comprehensive sites and premises strategy</u> for the cell and gene therapy cluster, focused on Stevenage but also including North Hertfordshire, Welwyn Hatfield and other areas as appropriate. This needs to support the developments planned at the GSK site, but it should also have regard to wider opportunities linked to Gunnels Wood Road and possibly some sites in Stevenage town centre (noting the proposed redevelopment at Marshgate car park). It should include:</p> <ul style="list-style-type: none"> • additional provision for very early stage businesses; • a 'property ladder' for core cell and gene therapy businesses as they move towards manufacturing (noting its particular requirements); and • a range of provision for wider supply chain partners, including those whose principal focus is distribution and logistics.
Rationale	<p>There are major constraints in relation to the growth of the cluster that are linked to land and property issues. These need to be addressed urgently. If they are not addressed, existing businesses will relocate, recognising that many are internationally mobile. Conversely, if these issues are addressed, further cell and gene therapy businesses could well be attracted into the area in order to take advantage of being part of a growing cluster. The requirement is especially for manufacturing space and some provision linked to specialist distribution. There is likely to be a particular opportunity over the next period associated with the GSK site. This needs to be advanced alongside a broader approach to development on Gunnels Wood Road and within central Stevenage.</p>
Action 2:	<p>Develop <u>appropriate intervention mechanisms</u> to deliver the sites and premises strategy, and ensure that these are adequately resourced</p>
Rationale	<p>Delivery of the sites and premises strategy may not be straightforward through normal channels and more interventionist approaches may well be necessary. Consideration could be given to a local delivery vehicle and/or public/private partnership/special purpose vehicle to ensure that land and property solutions are taken forward – including potentially with respect to land assembly, evergreen funding models, etc.</p>

Action 3:	Support the <u>further expansion of the Cell and Gene Therapy Catapult Manufacturing Centre in Stevenage</u>
Rationale	The first phase of the current facility was completed in 2017 and a further floor has been added subsequently. It is already at capacity and there is a strong case for an <i>in situ</i> expansion.
Action 4:	<p>Through the development of a <u>cell and gene therapy workforce development plan</u>, put in place measures to ensure that cell and gene therapy businesses are able to find advanced manufacturing skills (including GMP) locally. This will involve:</p> <ul style="list-style-type: none"> • the use of apprenticeships and vocational T Level qualifications; • working through national ventures such as the Advanced Therapies Apprenticeship Community (ATAC); and • the development of local initiatives led by the University of Hertfordshire and other partners. <p>It should also involve the Skills Advisory Panel, including potentially a task force focused on cell and gene therapy.</p>
Rationale	These skills sets are likely to be critically important as businesses move from clinical trials into larger scale production. They are specialist and will require some investment, but there ought to be a good match with the character of Hertfordshire's labour market.
Action 5:	Explore whether there is a case to <u>establish a major training facility</u> linked to cell and gene therapy manufacturing skills; this would need to be recognised as a national investment
Rationale	The scale of the opportunity is such that existing provision is unlikely to be sufficient and there may therefore be a case for a major project and the creation of a substantial training centre. This would need full industry support and it could potentially cover many elements of the GMP process in relation to cell and gene therapy. It would require substantial and careful feasibility work.
Action 6:	Take steps to <u>accelerate the delivery of the Stevenage Town Investment Plan</u>
Rationale	<p>Many elements of the Stevenage Town Investment Plan are concerned directly or indirectly with the cell and gene therapy cluster – most obviously proposals linked to Marshgate car park. These will need to be advanced.</p> <p>For the cell and gene therapy cluster to thrive, Stevenage will need itself to function as an international hub where internationally mobile people choose to work. Delivering the Station Gateway will have a bearing on perceptions of the place and this is likely to be very important.</p> <p>Equally, it will be important that young, internationally mobile, and highly qualified workers are able to secure housing that meets their aspirations. The importance of the housing dimensions of the cluster should not be overlooked. In this context, the</p>

	thinking around innovation districts (which are mixed use in character) is potentially important.
Action 7:	<u>Animate and develop the links between the cell and gene therapy cluster and wider networks</u> – such as One Nucleus, MedCity, Cambridge Network and appropriate investor networks – and support businesses in engaging with those networks
Rationale	<p>The cluster needs to be well networked in order to de-risk key elements of the growth process. Hertfordshire has historically been quite challenging in networking terms (in large part because it lacks a natural centre). But it must engage fully and actively with the key sector networks, including those focused largely on both Cambridge and London.</p> <p>Within this, the need for appropriate investor/business angel networks is perhaps especially important. Despite some recent progress, Hertfordshire still lacks 'brand visibility' in these terms.</p>
Action 8:	<u>Building on the High Performance Opportunity Zone designation, ensure that the cell and gene therapy cluster is appropriately marketed on an international stage</u>
Rationale	Cell and gene therapy is clearly global and it will need to continue to compete globally – for equity investment and for talent as well as for potential in-moving firms. The profile of the emerging cluster needs to be high and it must also be actively promoted.
Action 9:	<u>Build a stronger dialogue with the wider cell and gene therapy community, particularly in London and Cambridge, involving civic and business leaders in the process</u>
Rationale	In many respects, the growth of the cell and gene cluster cannot be understood apart from the science and investment community in London (and to a lesser extent Cambridge). There are administrative boundaries, but it is functionally one wider cluster. This has worked both ways for Hertfordshire. Growth in Stevenage is the upside – and it presents many more opportunities. The downside, arguably, is the loss of certain life sciences players to either London or Cambridge – most notably, MSD's decision to relocate from Hoddesdon to London's Knowledge Quarter. The wider cluster ought to function as one and these synergies ought to be recognised, nurtured and managed – in order to maximise the national impact overall.

Table 6-2: Recommended priority actions: wider life sciences sector

Action 1:	Take steps to <u>ensure that across Hertfordshire, appropriate sites and premises are made available to support the wider life sciences sector</u>
Rationale	Over many decades, the growth of the life sciences sector has often reflected the availability of appropriate sites: Hertfordshire was a 'good' location, but it was not the only possible location and the choice of Hertfordshire often reflected site availability. Hertfordshire's credentials and attributes have grown – particularly in cell and gene therapy, but also in other aspects of drug discovery and across med-tech and wider life sciences activities. Its links into the emerging innovation district around the Francis Crick Institute (with links via King's Cross and Euston) are a particular (and distinctive) source of wider competitive advantage. Hertfordshire needs to ensure that the supply of appropriate sites continues and – where opportunities arise – it needs to make sure that the possibilities surrounding the full breadth of life sciences are taken on board fully. This should include both incubator/innovation centre provision (including both wet and dry labs), but also move-on and manufacturing space, and appropriate provision for distribution activities. Particularly in relation to wet lab space for early stage businesses, there are known market failures and public sector intervention may well be needed, particularly given the loss of capacity at BioPark.
Action 2:	Take steps to <u>ensure that Hertfordshire's digital infrastructure is genuinely world class</u>
Rationale	Life sciences businesses (including those focused on cell and gene therapies) are likely increasingly to be heavy users of data. It will be important that the digital infrastructure is exemplary in this context.
Action 3:	Take steps to <u>improve the provision of digital skills across Hertfordshire and at different levels in the labour market (but including advanced data science)</u>
Rationale	Digital skills will grow in importance – both within the cell and gene cluster and more broadly across life sciences. It will be important that local people are appropriately equipped in this context.



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