

CATAPULT
Cell and Gene Therapy

Introduction to the Cell & Gene Therapy Catapult



About us



Part of a **world-leading network** of technology and innovation centres



Provide access to unique technical **facilities** and **expertise** to help adopt, develop and exploit innovations



Bridge the gap between businesses and academic research



Established by Innovate UK as a **not-for profit**, independent centre

It is our vision for the UK to be a **global leader** in the development, delivery and commercialisation of cell and gene therapies.

Where **businesses can start, grow and confidently develop** advanced therapies, delivering them to patients rapidly and effectively.

Summary:

Accelerate	Complement	Innovate	Facilitate
the commercialisation of innovations from research	industry and academia with unique technical facilities and expertise	in collaboration with academia and industry	operating in UK as a global centre; working with Government, the NHS and international regulators

Development laboratories

- 1200m² purpose built centre
- Analytical characterisation
- Process development
- Viral vector



Manufacturing centre

- 7000m² manufacturing centre designed specifically for cell and gene therapies
- 12 segregated large clean room modules
- Secure supported collaboration model
- Centre of a cell and gene therapy cluster



← **Cell and gene therapy specialists (>200)** →

Industrialisation

- Process development
- Analytical development
- Manufacturing systems
- Supply chain

Regulatory and clinical development

- Regulatory
- Non clinical safety
- Clinical delivery
- Programme management

Engagement

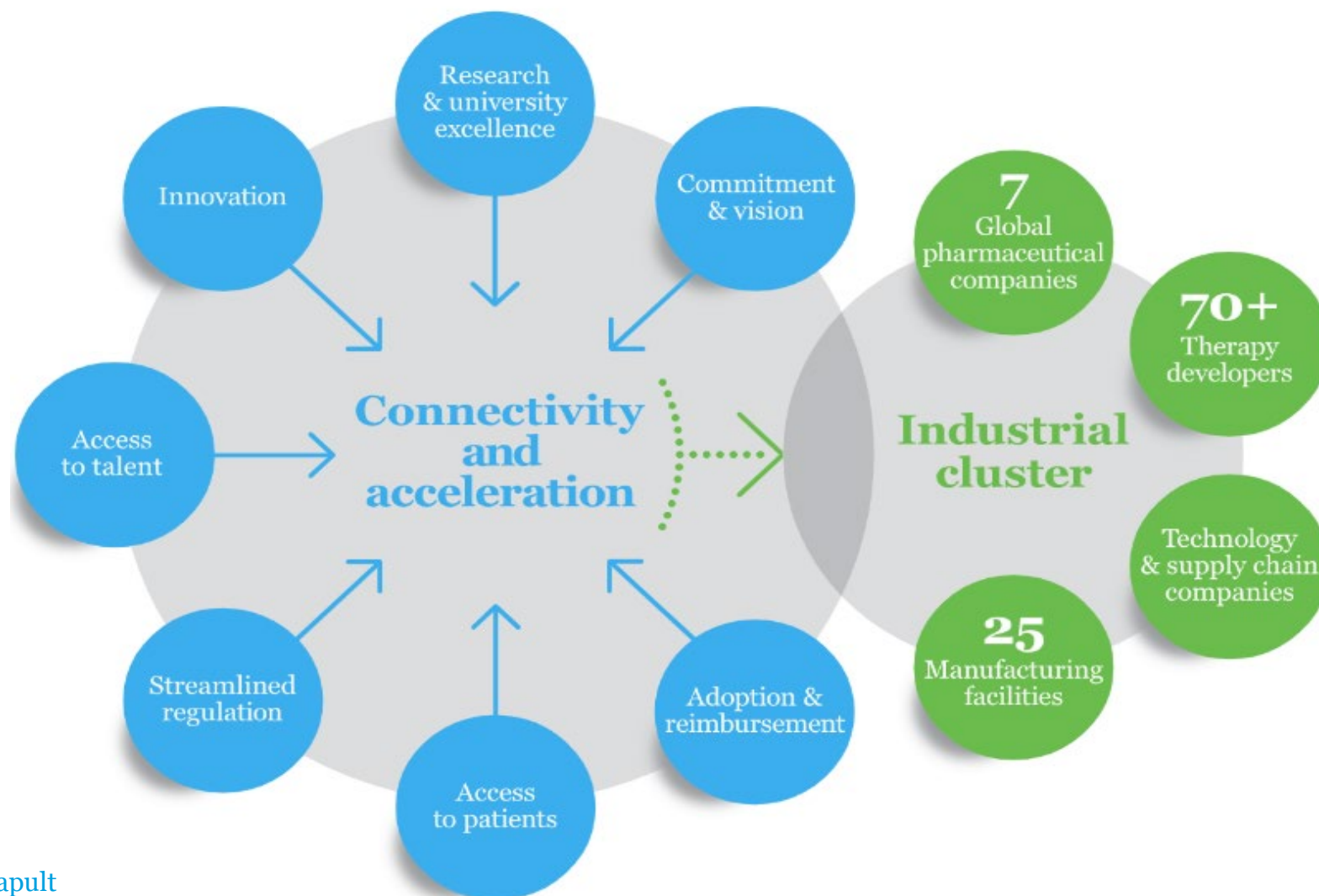
- Collaboration formation
- Intellectual property and patent
- Health economics
- Reimbursement

A Leader in Innovation: The UK's ATMP Ecosystem



A complete UK Ecosystem

“The UK’s advanced therapies ecosystem is flourishing, and the UK is the go-to place for cell and gene therapy development. This is evidenced the growth in the number of companies in the UK compared to the 64 companies reported in July 2018 and also the number of international companies who have chosen to expand or relocate to the UK.”

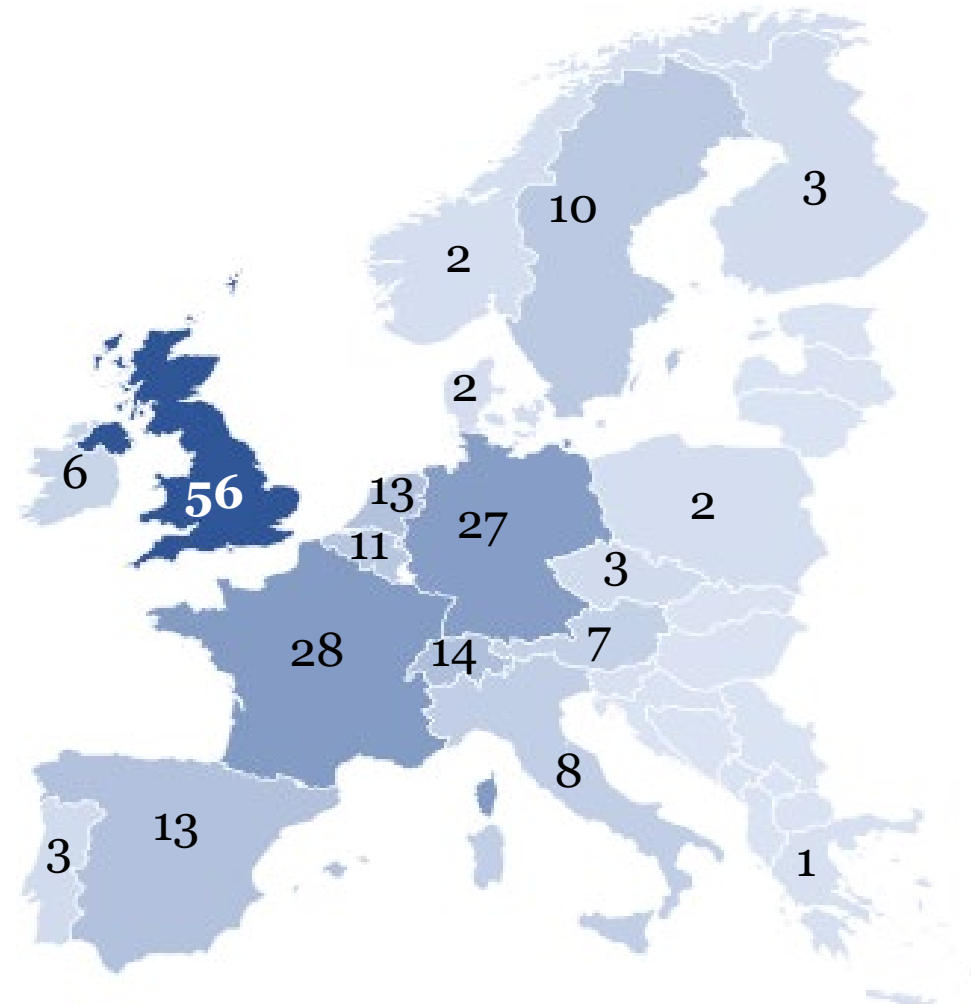


Keith Thompson
Chief Executive Officer, Cell & Gene Therapy Catapult

ATMP therapy developers based in Europe

The UK has the major share (24%) of the companies in Europe

There are 70+ ATMP therapy developers operating in the UK of which 56 are head quartered in the UK



Research hotspots throughout the UK

BY PHASE

93 ATMP focused clinical trials

27 Phase III

45 Phase II

21 Phase I

BY TECHNOLOGY TYPE

48 Gene therapies

25 Gene-modified cell therapies

16 Cell therapies

4 Tissue engineering



Cluster development: Stevenage is one of the largest cell and gene therapy clusters globally

60%

increase in manufacturing space in the UK

1,500m²

manufacturing cleanroom space coming online in 2019

30%

increase in employment in the UK manufacturing industry

12

companies developing their manufacturing strategies in the UK

Data from CGT Catapult GMP manufacturing report 2018

Research conducted by CGT Catapult showed major investment in the size and scale of the UK's manufacturing capability in 2018, supporting a significant growth in jobs and the production of cell and gene therapies. An increase in private and Government investment has led to a 60% increase in manufacturing space in the UK.

The CGT Catapult manufacturing centre has experienced exceptional demand for collaboration and as a result is doubling existing capacity with help from a £3.36m grant from the ERDF and a £12m ISCF award. Construction of a further six cleanroom modules is expected to be completed in 2019.



“

The go-ahead to make cell and gene therapies that could ultimately save lives is a great boost for the area, but also shines a light on the whole of the UK as an attractive place for this innovative industry to thrive. This project supports the ambition of our modern Industrial Strategy to maintain the UK's standing as a world leader in research and innovation.

Lord Henley
Life Sciences Minister

Case study



Collaborating companies

Autolus

“CGT Catapult’s unique operational model allows us to grow our manufacturing capacity, while accessing a range of services provided by the centre.” **Jim Faulkner, SVP and Head of Product Delivery**



“We are delighted to establish this collaboration for our next generation AAV gene therapy platform for chronic systemic disease.” **Jan Thirkettle, Chief Development Officer**



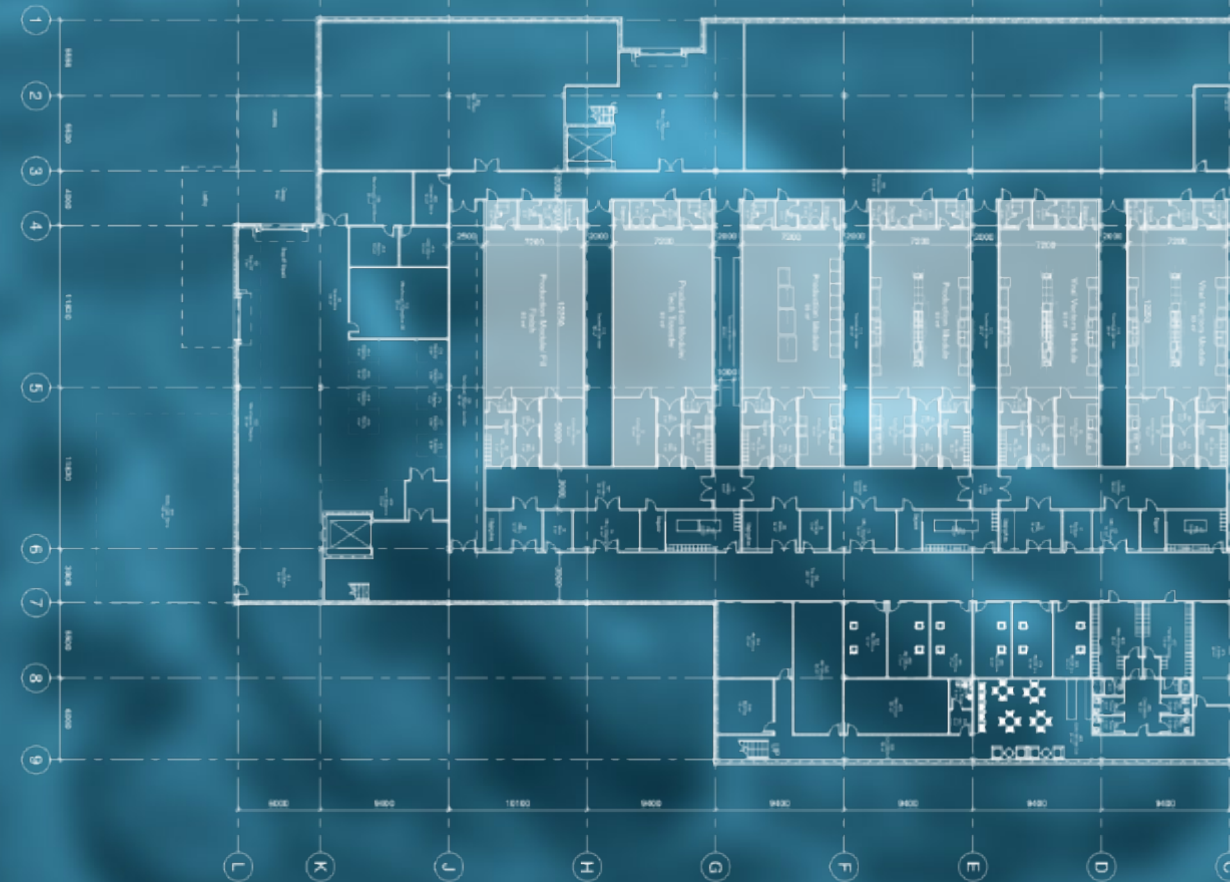
“We are looking forward to an important collaboration with CGT Catapult scaling-up GMP manufacturing strategies for commercial production.” **Gregg Sando, CEO**



“With our own vector manufacturing capability at the Catapult facility, we will extend vector supply capacity beyond 2020.” **James Noble, CEO**



“Having advanced manufacturing facilities already in place allows quick set up.” **Garry Menzel, CEO**



Access established supply chain and wider cluster

Link into UK supply chain and NHS



Raw materials



Fill and finish



Product release



Cryostorage



Clinical sites



Transport and logistics including international airports



A Thermo Fisher Scientific Brand

Fisher BioServices' European CryoHub located at CGT Catapult manufacturing centre

- GMP controlled temperature storage
- Ultra-cold chain logistics



Unique software solution to collate, track, and document process information

- Enhanced visibility of the entire cell therapy process

Growing Stevenage Cluster



Specialist viral vector drug product manufacturer

- Establishment of rapid release testing
- Facilitating manufacturing slot visibility and panning



Distribution of MHRA-licensed GMP facilities

25 MHRA licensed
GMP facilities

23 in 2017

22 in 2014

121 Clean rooms

100 in 2017

56 in 2014

81% Overall booked
capacity

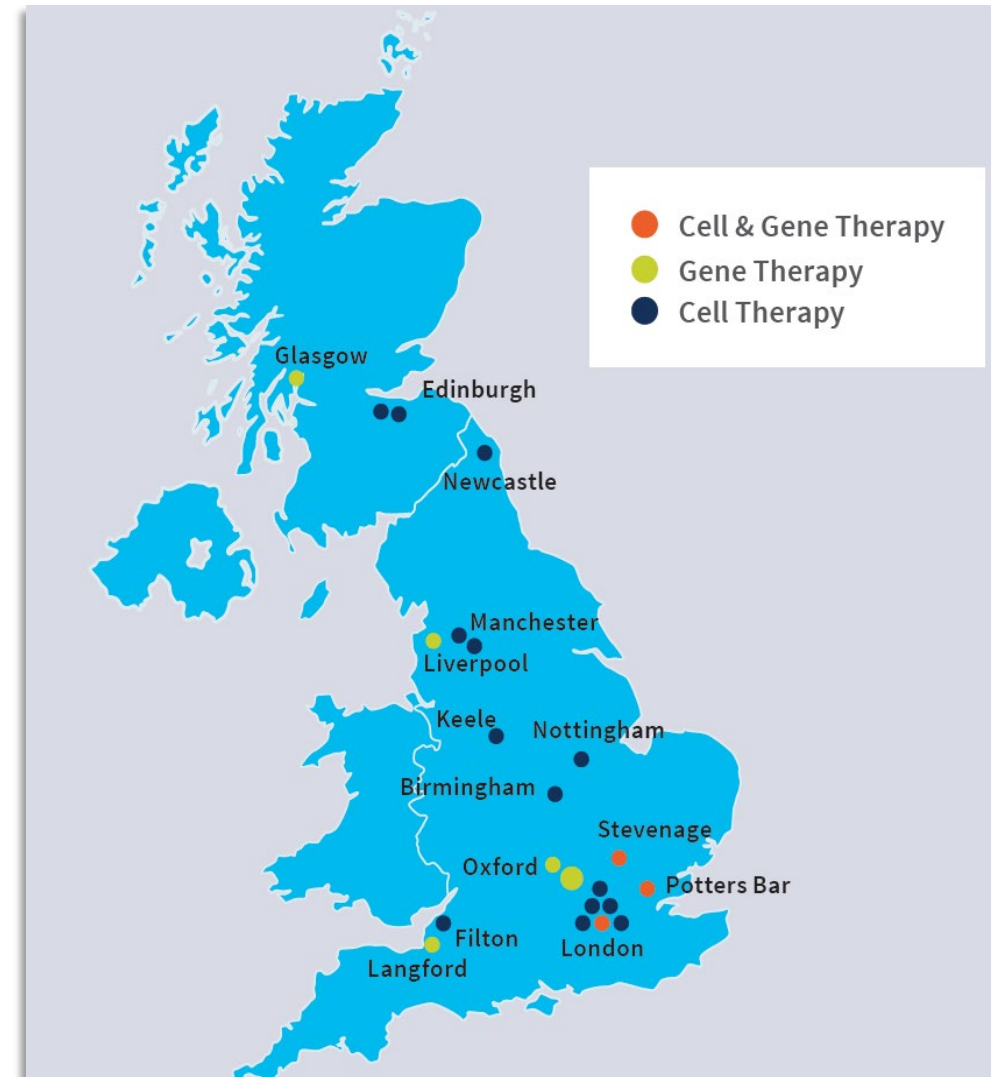
77% in 2017

55% in 2014

555 Full time
employees

390 in 2017

£104k GVA per employee





Medicine Manufacturing
Industry Partnership

abpi BIA Innovate UK
Knowledge Transfer Network

Advanced Therapies Manufacturing Action Plan

Retaining and attracting advanced
therapies manufacture in the UK

4. Set out an end-to-end talent management plan to secure the relevant skills for emerging manufacturing technologies⁵

- Industry to lead with support from multiple stakeholders including academia, Higher Education, Innovate UK and research bodies, the creation and implementation of an end-to-end talent plan for the sector. The plan will encompass integrated strategies to develop the talent pool at multiple entry-points. These range from manufacturing technicians through to post-doctoral and professional levels
- Efforts should be concentrated on leveraging existing initiatives, with the expectation that the majority of funding will come from industry, either through direct subscription or through Apprenticeship Levy funds
- Seed funding of £1.5 million from Government is recommended to enable successful set-up and coordination of the plan

Advanced Therapies Apprenticeship Community

- Established by CGT Catapult and MMIP
- £1.5M award from Industrial Strategy Challenge Fund
- First advanced therapies apprenticeship programme in England and Scotland
- Aims to provide the skills required to fuel industry growth
- First cohort recruited in September 2018

65 apprentices

have been employed

21 companies

have hired apprentices and formed the advanced therapies apprenticeship community

5 programmes

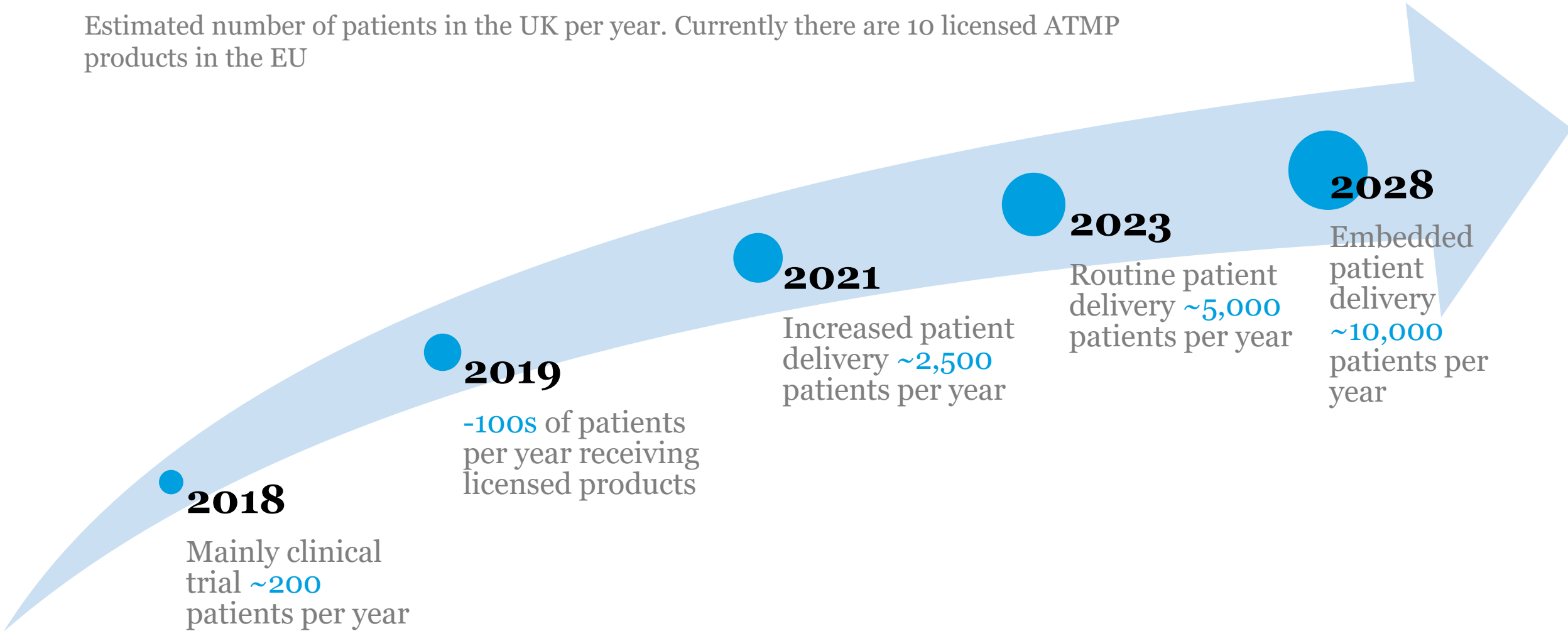
have been developed to provide the skills the industry needs

- Science Manufacturing Technician (Level 3)
- Advanced Therapies Scientist (Level 5)
- Senior Leaders (Level 7)
- Regulatory Specialist (Level 7)
- Modern Apprenticeship in Life Sciences (Scotland)

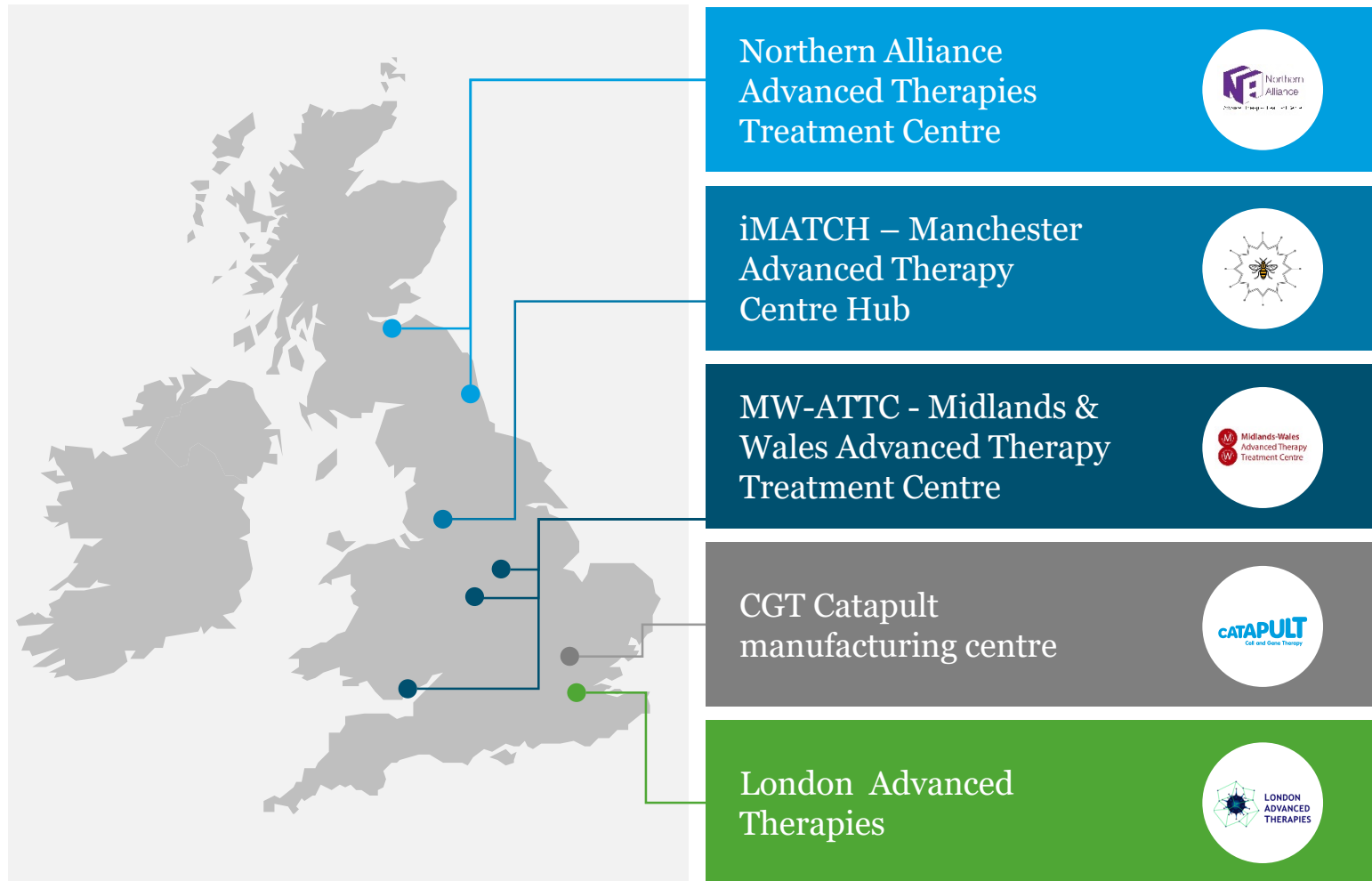


The clinical adoption challenge

Estimated number of patients in the UK per year. Currently there are 10 licensed ATMP products in the EU



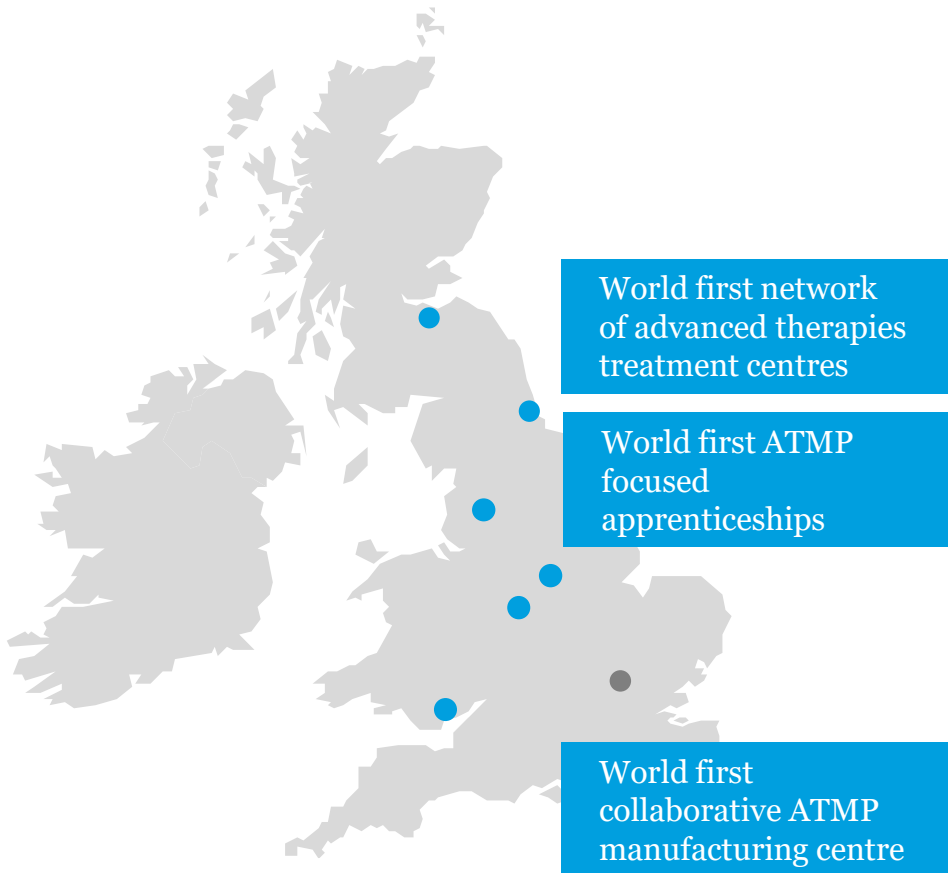
Advanced Therapy Treatment Centre network



The network of Advanced Therapy Treatment Centres will develop and deliver systems for the delivery of cutting edge cell and gene therapies.

- The network will increase the ability of the NHS to deliver disruptive medicines
- The centres will develop systems and processes within the trusts and hospitals capable of delivering advanced therapies at scale to patients across the NHS
- The learnings and systems from the initial centres will be rolled out to other centres in the UK

The growing UK cell and gene therapy industry



22
companies in 2012

70+
companies in 2019 and **rapidly** growing

£35m+
investment attracted by UK companies
2012

£3Bn+
investment received by UK companies
since 2013

21
clinical trials in 2012

93
clinical trials in 2019

11
manufacturing facilities in 2012 totalling
5,900m²

25
GMP facilities in 2019, with the **CGT
Catapult manufacturing centre**
providing an extra 7000²

540
jobs in 2012

+18,000
jobs by 2035

CATAPULT

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Cell and Gene Therapy Catapult is a trading name of Cell Therapy Catapult Limited, registered in England and Wales under company number 07964711, with registered office at 12th Floor Tower Wing, Guy's Hospital, Great Maze Pond, London, SE1 9RT. VAT number 154 4214 33.

We work with
Innovate UK

ATMP approved in the European Union

Product	Company	Product type	Indication
Zynteglo	bluebird bio	Gene therapy	Beta thalassaemia
Luxturna	Spark Therapeutics	Gene therapy	Hereditary retinal dystrophy
Yescarta	Kite/Gilead	Gene therapy	B-cell lymphoma
Kymriah	Novartis	Gene therapy	B-cell acute lymphoblastic leukaemia
Alofisel	Takeda Pharma A/S	Cell therapy	Complex perianal fistulas in adult patients with Crohn's disease
Spherox	CO.DON AG	Tissue engineered product	Cartilage repair of the knee cap
Zalmoxis	MolMed	Gene therapy	Haematological malignancies
Strimvelis	GSK	Gene therapy	Severe combined immunodeficiency due to adenosine deaminase deficiency (ADA-SCID)
Imlygic	Amgen Europe BV	Gene therapy	Melanoma
Holoclar	Chiesi Farmaceutici S.p.A.	Tissue engineered product	Corneal diseases

Adapted from Tracy T. et al 2018