

Manufacturing for Advanced Therapy Medicinal Products

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European Union
European Regional
Development Fund



**INDUSTRIAL
STRATEGY**



**UK Research
and Innovation**

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

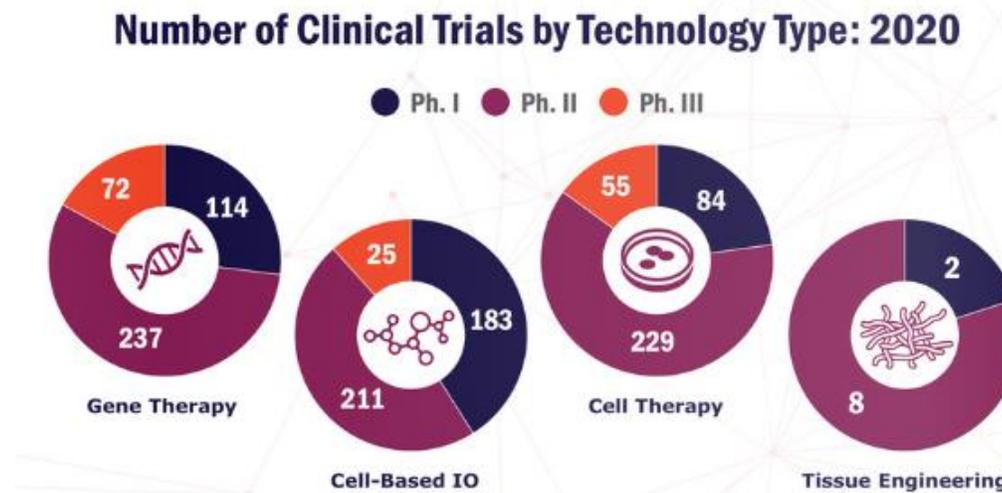
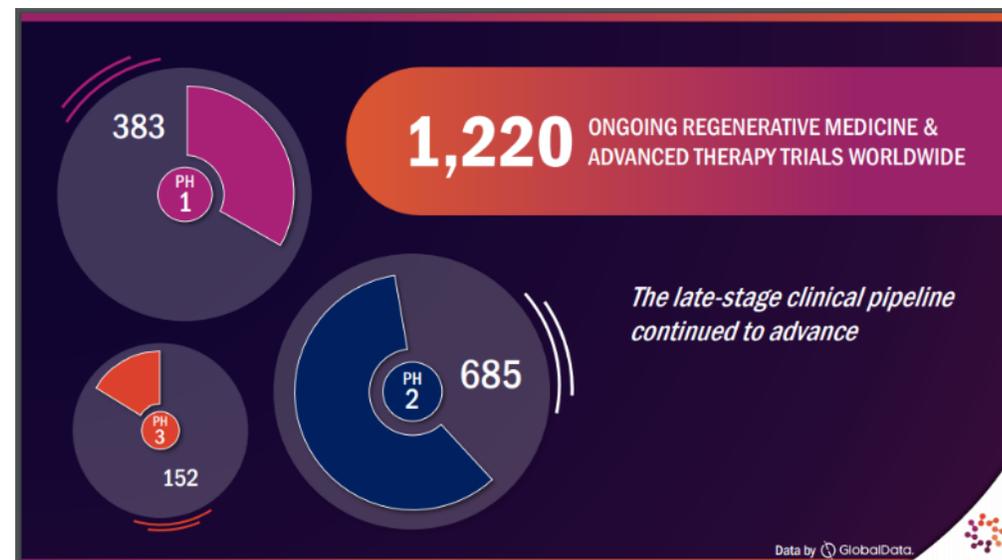
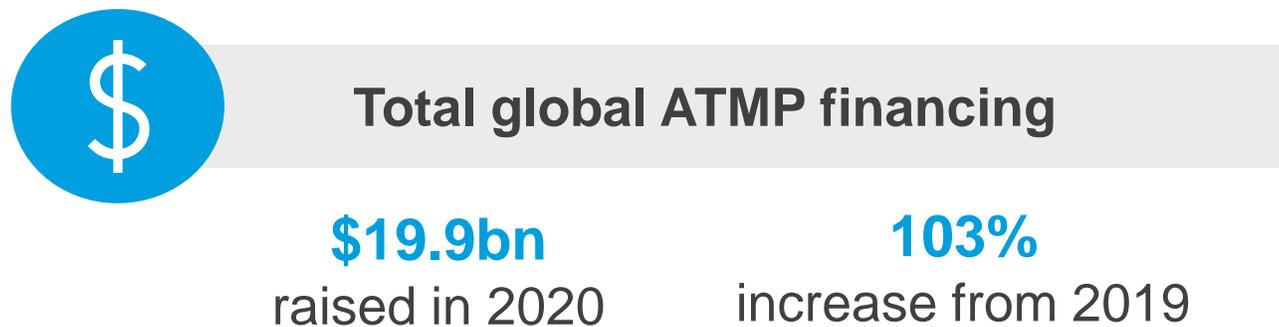


Established by Innovate UK as a **not-for-profit**, independent centre

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** these transformative therapies, delivering them to patients rapidly and effectively.

Global ATMP landscape



The UK's leading position in the global industry



10
Licensed ATMPs approved



33%
Share of global ATMP companies in Europe



10
Global pharmaceutical companies



Largest
cell and gene therapy cluster outside of the US



26
Manufacturing facilities



3,000+
Jobs in the sector



12%
Global ATMP trials in the UK



90+
Therapy developers



£2.5bn
Investment received by UK companies since 2012



£1.7bn
Total financing for UK ATMP companies in 2018-2020



3
Advanced Therapy Treatment Centres



Global **1st** CGT specific apprenticeship programme and industry driven training network



2025 vision

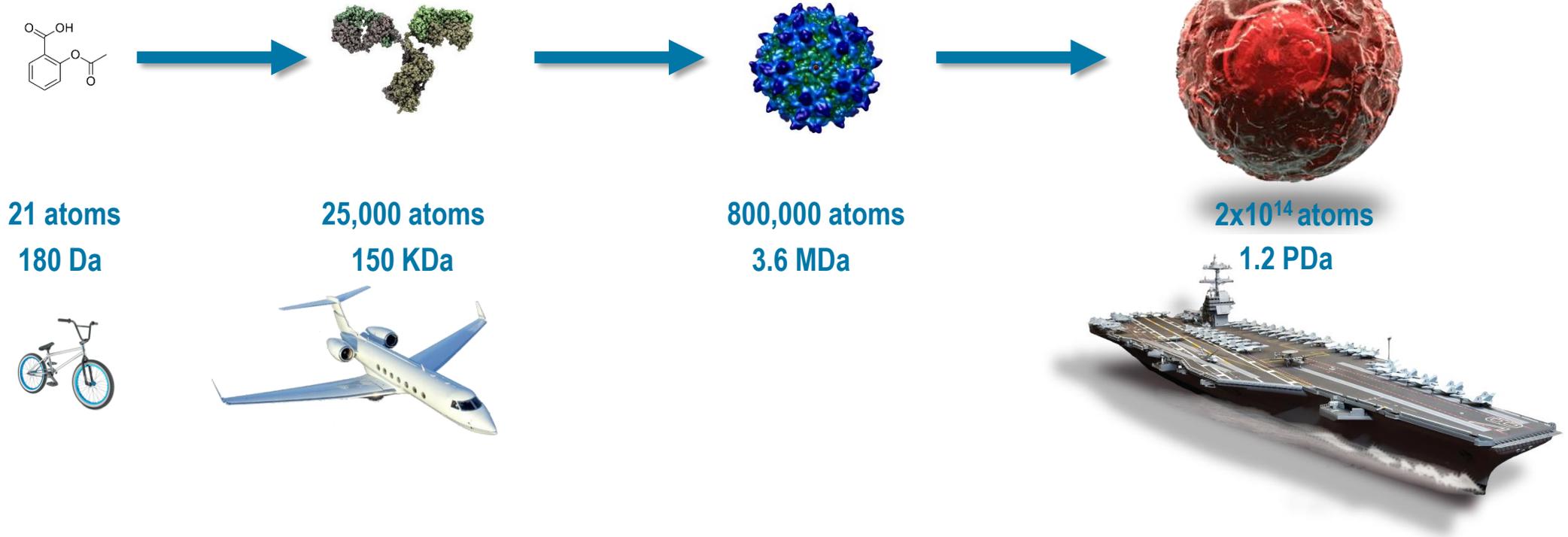
- 4,000+ jobs
- £2bn in revenue

2035 vision

- 18,000+ jobs
- £10bn in revenue

Cell and Gene therapies Industry Challenges

Cell and Gene therapies are the most complex drugs ever developed



Rapidly growing industry – huge demand for facilities, people and materials

Autologous

- **Variable starting material**
 - **Genetics / epigenetics**
 - **Clinical treatment history**
 - **Collection and shipment**
- **Labour intensive manufacture**
 - **Open processing**
 - **Batch segregation**
- **Fast turn around times**
 - **IPC & Release**

Gene Therapy

- **Supply chain**
 - **Plasmids**
 - **Fill and Finish**
- **Highly variable analytics**
 - **Drive large Batch size**
- **Scale up costs (Plasmids)**
 - **Batch size limitations**

Addressing the challenges- our facilities



London

- 1,200m² purpose built centre on the 12th floor of Guy's Hospital
- Analytical characterisation
- Process development
- Viral vector
- Stem cell differentiation
- 10th floor collaboration laboratory



Stevenage

- 7,700m² facility designed specifically for cell and gene therapy manufacturing at scale
- 12 segregated cleanroom modules
- Secure collaborative model
- At the centre of the third largest cell and gene therapy cluster globally
- Expanded QC capacity and capability



Braintree

- 4,627m² facility to support national COVID-19 vaccine manufacturing
- Fully operational by Dec 2021 to meet immediate vaccines demand
- To become innovation centre for cell and gene therapies and develop technology transfer innovation

Stevenage Advanced Therapies Campus



£1.66bn

total investment into the campus since 2013

£1.13bn

investment into CGT companies

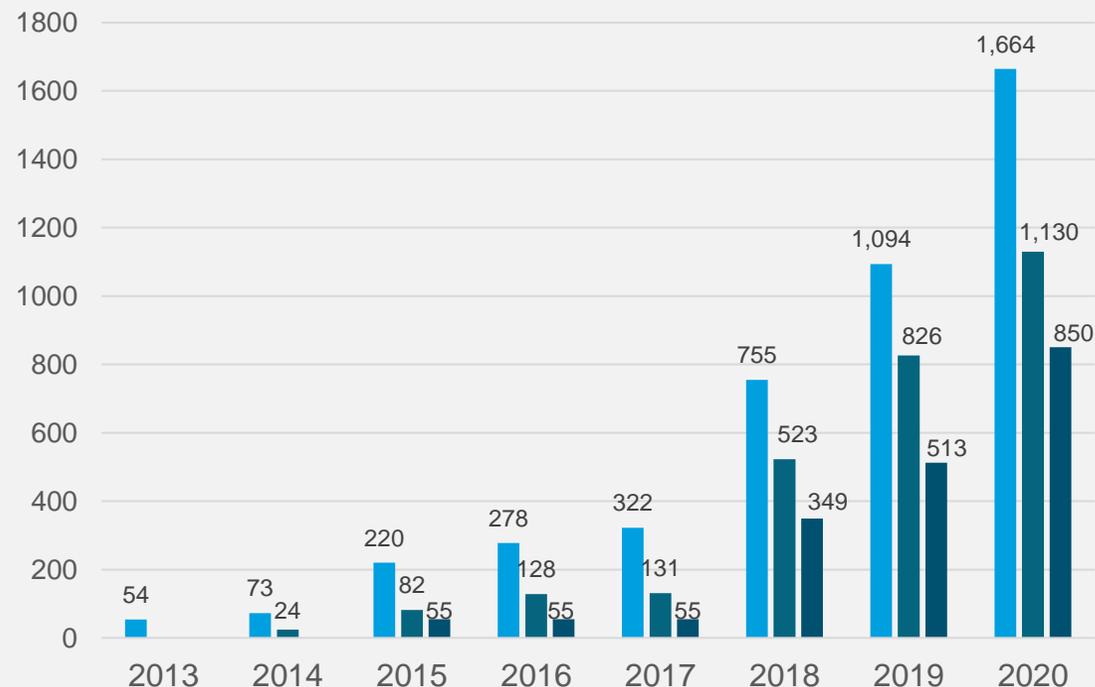
31%

campus tenants are CGT companies (14/45)

7

CGT developers located at the CGT Catapult facility (out of 14 on campus)

Total investment into the Stevenage Advanced Therapies Campus
Cumulative investment - £m



- All companies
- Cell and gene therapy companies
- CGTC Stevenage facility and collaborators

CGT Catapult Stevenage opened

Stevenage facility operating model

- CGT Catapult operates the building, GMP support services and obtains manufacturing licences (clinical and commercial)
- Collaborators occupy production modules to perform their own processes with their own people
- Collaborators embedded in the UK supply chain and work with CGT Catapult to strengthen it
- Modular design and operations to facilitate future expansion of collaborators



Funded by:



12 modules, 7 collaborating companies operating

Autolus

Manufacturing viral vectors and cells
for **programmed T cell therapies**

Rentschler Biotechnologie

Manufacturing **ATMP products**
for clinical trials



Manufacturing **neoantigen-targeting T cell therapies**



GMP cell processing for
clinical trials



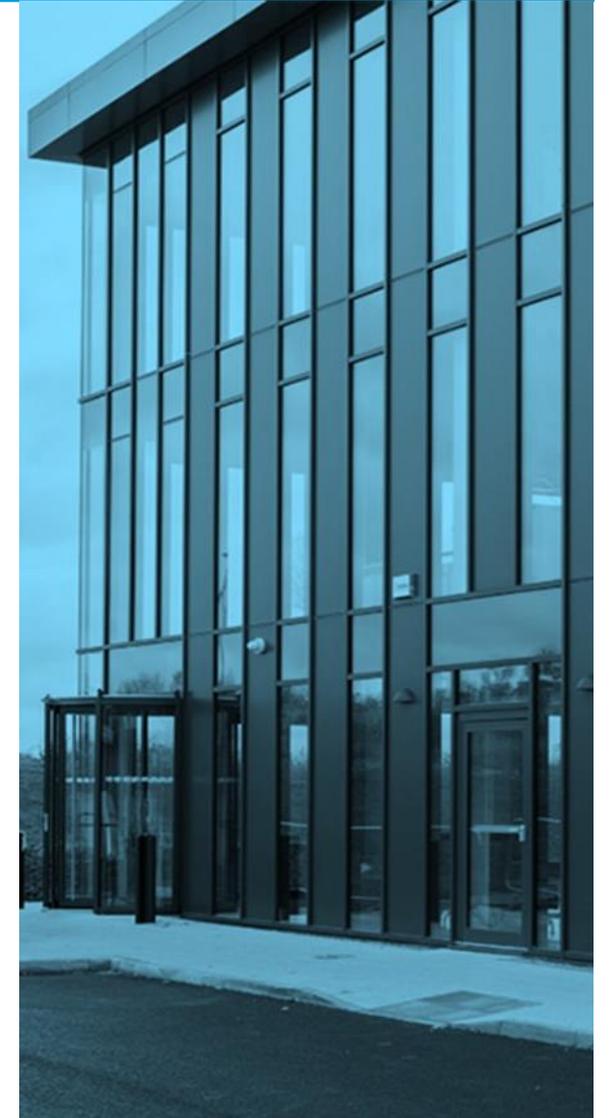
Manufacturing **T cell receptor therapies**



Manufacturing viral vectors for **T cell therapies**

FREELINE

Manufacturing viral vectors for
gene therapies



Support systems available

The centre provides access to the expertise, skills, facilities and equipment as the stepping stone needed for organisations to develop new technologies and systems for large-scale manufacturing.



Quality control



Qualified persons



Operating policies



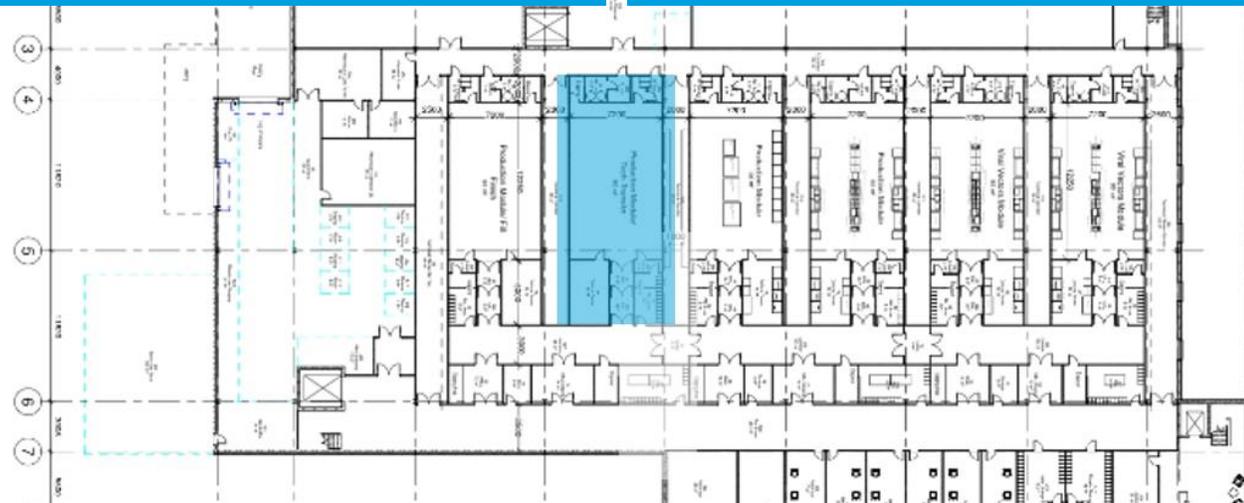
Warehouse management



Development assistance

Predicted ATMP output:
528 batches per year per module
5,280 batches per year for facility

Predicted QC sample output:
>8,000 samples per year per module
>105,000 samples per year for facility



Engineering maintenance:
>3,000 key equipment pieces for
building function

Warehouse:
>1.0M material picks per year for
facility

Adaptable to your own process, whether it is allogeneic, viral vector or autologous.

As you grow, take on more modules or replicate your module design in your own facility.

Autologous



Allogeneic and viral vector



MHRA licensed facility

The CGT Catapult Stevenage facility is MHRA licensed for the manufacture of ATMPs to support clinical trials and commercial supply



Access established supply chain

Link into UK supply chain and NHS



Raw materials



Fill and finish



Product release



Cryostorage



Clinical sites



Transport and logistics including international airports

ThermoFisher
SCIENTIFIC

ThermoFisher Scientific's European CryoHub adjacent to the CGTC Stevenage facility

- GMP controlled temperature storage
- Ultra-cold chain logistics

 **TrakCel**

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

- Enhanced visibility of the entire cell therapy process

***symbiosis**
Pharmaceutical Services

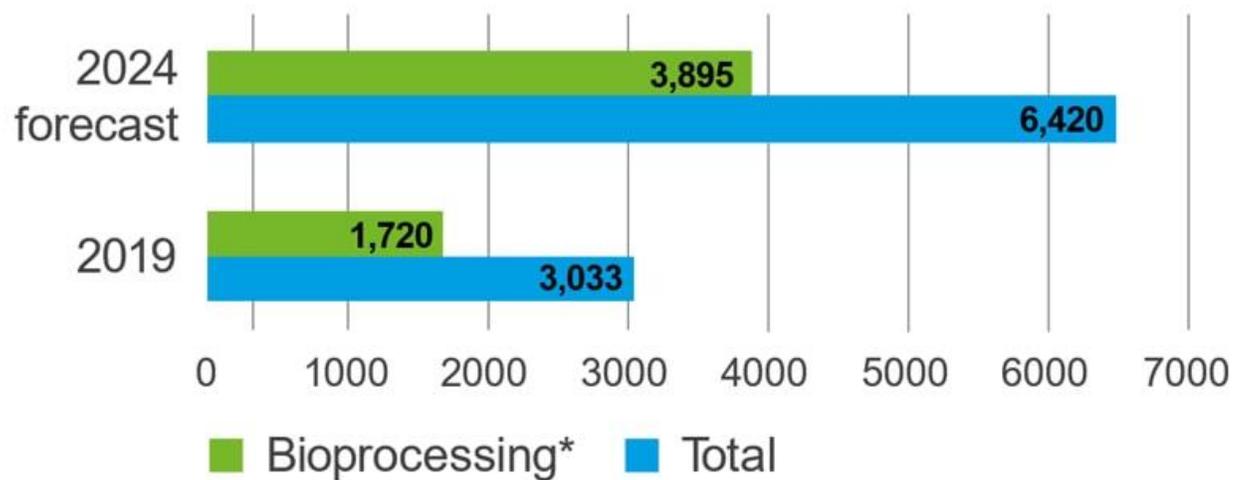
Specialist viral vector drug product manufacturer

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

Futureproofing the growth of the industry



Industry employment to double 2019-2024

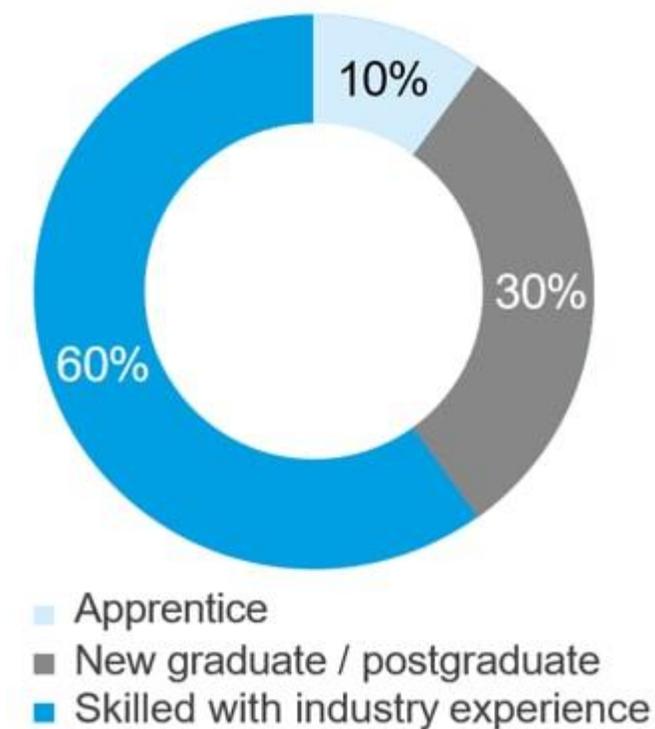


Total number of jobs: **+3387** **↑112%**

Number of
bioprocessing roles:* **+2175** **↑126%**

*Includes manufacturing, supply chain and logistics, process development and total quality.

Forecasted source of skills



Data from CGT Catapult skills demand report 2019

Securing the advanced therapies talent pipeline

ATAC Advanced Therapies Apprenticeship Community

- Established by CGT Catapult and MMIP
- £1.5M award from ISCF
- First advanced therapies apprentice programme
- Aims to provide the skills required to fuel industry growth

137
apprentices
have now been
employed

36
companies have
hired ATAC
apprentices

10
programmes
have been
developed

ATSTN Advanced Therapies Skills Training Network

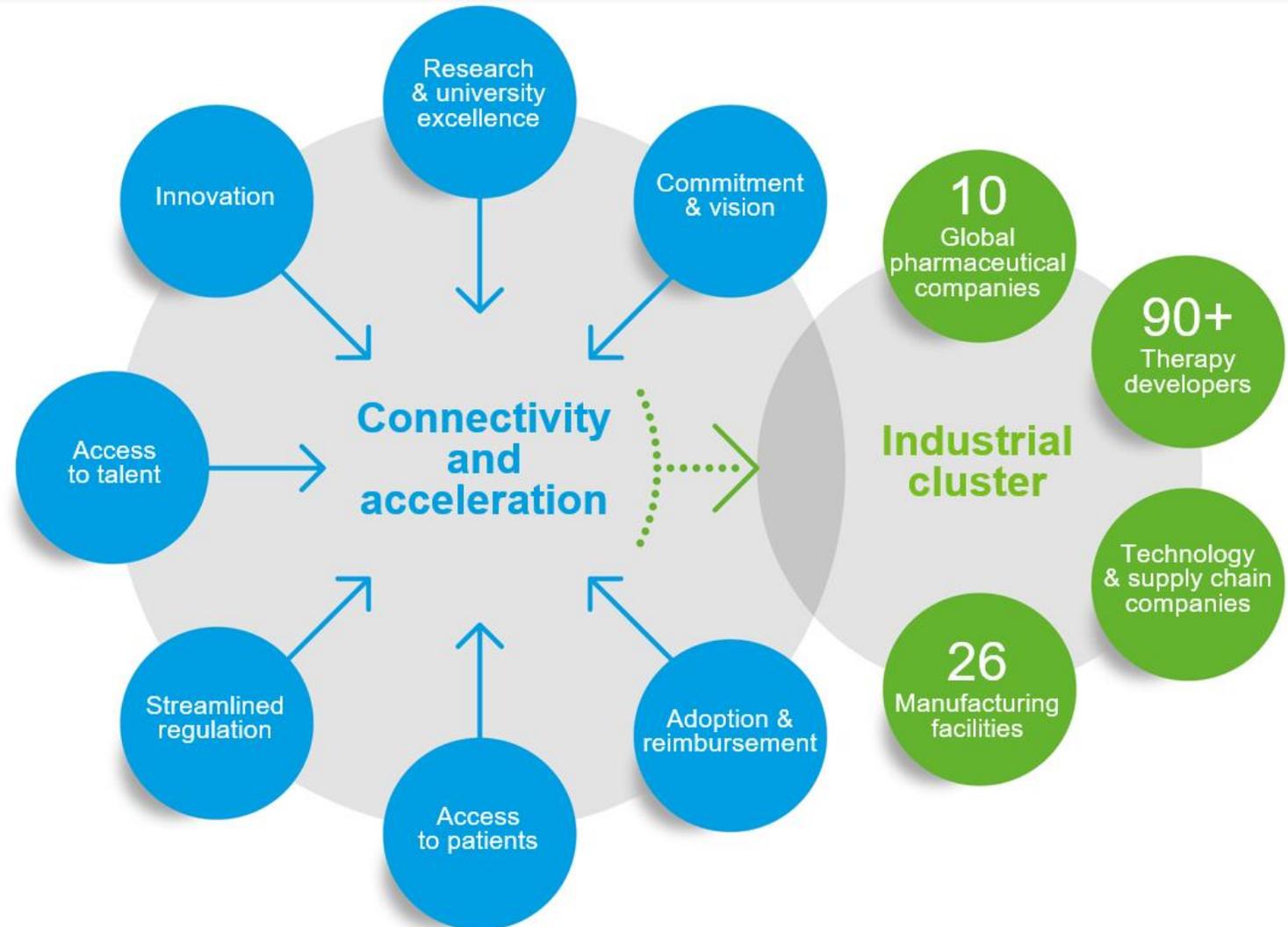
- £4.7m funding from BEIS to establish an online training platform and national training centres
- Career Converter tool to attract talent from outside the industry
- Training for industry skills in advanced therapy and vaccine manufacturing
- Will develop skills and experience in aseptic techniques for GMP to the rapidly growing industry



The UK cell and gene therapy ecosystem

The UK has become the go-to place for cell and gene therapy development and boasts a complete cell and gene therapy ecosystem.

CGT Catapult is facilitating the growth of the UK ecosystem by working with industry, the research base, Government, the NHS, industry associations and international organisations.



CATAPULT

Cell and Gene Therapy

Cell and Gene Therapy Catapult is committed to ensuring high standards of research integrity and research best practice in the activities we carry out. We subscribe to the principles described in the UK concordat to support research integrity.

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Innovate UK