CATAPULT
Cell and Gene Therapy

Annual Review 2020

Enhancing growth and productivity

in the cell and gene therapy industry

ct.catapult.org.uk/annualreviews

The Cell and Gene Therapy Catapult (CGT Catapult) is a private sector research organisation with a mission to grow the UK cell and gene therapy industry, delivering both industrial growth and health benefits. We are part of a network of Catapult centres supporting the implementation of the UK Government's Industrial Strategy, bridging the gap between scientific research and full-scale commercialisation.

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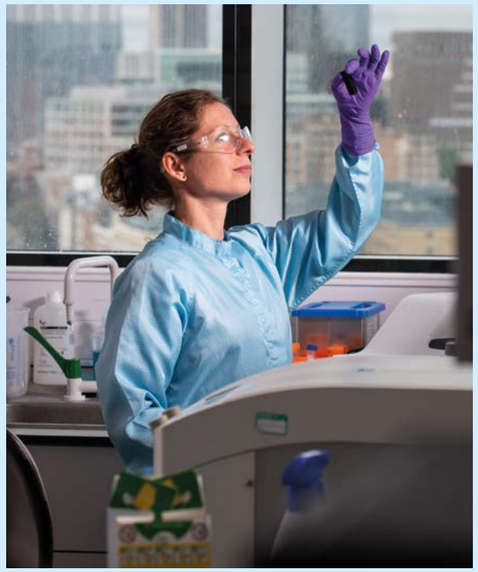


Our vision

Our vision is for the UK to be a global leader in the development, delivery and commercialisation of cell and gene therapies, and a place where businesses can start, grow and confidently develop advanced therapies, delivering them to patients rapidly, economically and effectively.

2019/20 in numbers

108
projects

32%
UK SME cell and gene therapy developers engaged with us

£6.7m
invested into cell and gene therapy projects

26
partnerships on CR&D projects totalling £3.8m

69%
companies manufacturing ATMPs in the UK have collaborated with us

10
spin-out companies and SMEs provided with tailored commercialisation support

UK industry growth

	2018	Growth	2020
Employment	1,500	100%	3,000+
Industry turnover	£100m	200%	£300m
Manufacturing space	12,500m^2	60%	20,000m^2
Phase III clinical trials	14	100%	28
Reimbursed therapies reaching patients	2	250%	7

Together, we have built a world-leading cell and gene therapy industry in the UK

Dr John Brown CBE, FRSE, Chairman

The UK cell and gene therapy industry is continuing to go from strength to strength. There are over 3,000 people employed in the sector as companies are expanding nationwide, and life-changing medicines are being delivered in the NHS across the UK for a range of therapeutic indications. We have seen a surge in clinical progress, with the UK now accounting for a disproportionately high 12% of global ATMP trials.

CGT Catapult is proud to be playing a pivotal role in this industry growth, with collaborators delivering therapies and bringing in unprecedented local investment. Our initiatives range from enabling clinical adoption to upskilling the industry, and our advice clinics are supporting early stage innovators to accelerate towards commercialisation.

This has all been possible because of the Government's continued support and commitment. On behalf of the Board, I would like to thank our partners in Government, industry and academia, and congratulate the whole CGT Catapult team, for the vital work they have done in shaping this truly unique UK cell and gene therapy industry.

The industry has also come together in a way that we have not seen before, in response to the COVID-19 pandemic. It is fantastic to see the life sciences sector combining its efforts, resources and expertise to limit the impact of the virus and amplify the response.

Finally, the Board would like to express our deepest thanks to Keith Thompson, our former CEO and Founding Member of the CGT Catapult, for his tireless work in helping to make the Company what it is today. The Board and the whole CGT Catapult team wish Keith the very best in his future endeavours.

Through collaboration, we are delivering therapies to patients internationally

Matthew Durdy, Chief Executive Officer

It has been another year of significant progress for CGT Catapult and for our many collaborators and partners in industry and academia. We have undertaken groundbreaking projects together to overcome barriers and further the development and commercialisation of transformative therapies.

The unique operating model of the CGT Catapult manufacturing centre means that collaborating companies are producing cell therapies, gene therapies and viral vectors at scale and products are being exported nationally and internationally while innovation continues.

We also completed the expansion phase of construction at the Manufacturing Centre in 2019, backed by £3.36m from the European Regional Development Fund and £12m from the Industrial Strategy Challenge Fund, and this is already benefiting new collaborators.

CGT Catapult is proud to be supporting the response to the COVID-19 pandemic, including as part of the UK BioIndustry Association taskforce for the development of vaccine candidates. We remain committed to assisting however we can and, crucially, we are ready to support innovating companies to catch up from these challenging times.

We are excited that this year ahead will provide more opportunities for collaboration and innovation, to accelerate the development, commercialisation and delivery of cell and gene therapies to patients worldwide.

230+

cell and gene therapy experts in:

- manufacturing
- industrialisation
- regulatory affairs
- clinical operations
- non-clinical safety
- health economics and market access

Making the UK

globally attractive

for advanced therapies commercialisation

Through a strategy of creating access to capability, technology and innovation, CGT Catapult has facilitated the growth of a complete ecosystem to support the research and commercialisation of advanced therapies.

Since the beginning of operations for CGT Catapult in 2012, the number of ATMP developers in the UK has tripled, the number of MHRA licensed manufacturing facilities has increased from 11 to 26, there are over 2,500 more people employed in the industry, and there are currently nine ATMPs approved in the EU.

> The UK is a world leader in developing innovative therapies. With the Cell and Gene Therapy Catapult playing a key role in advancing the development of these therapies, this will not only bring concrete benefits to patients but will also allow the UK sector to compete globally.
>
> **Dr Ian Campbell**
> Executive Chair, Innovate UK

Current state of the UK ATMP industry

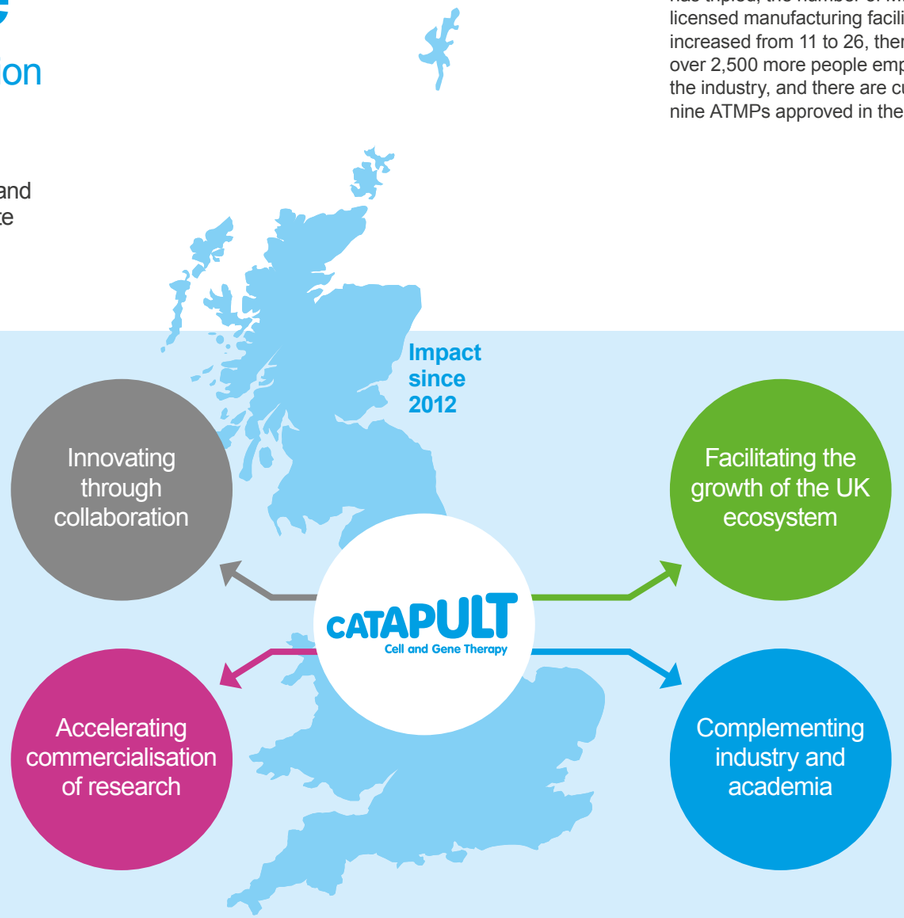
27%
ATMP companies in Europe operating in the UK

£2.5bn
investment received by UK companies since 2012

10
global pharmaceutical companies

90+
advanced therapy developers

9
licensed ATMPs approved



- Bringing together organisations to shape the environment and frameworks for ATMP development
- 147 collaborative projects to support cell and gene therapy development, bringing investment and productivity

- Commercial readiness advice clinics provided to 10 early stage companies
- Collaborated with over 100 different companies and over 25 UK universities

- £630m total investment into the CGT Catapult manufacturing centre and companies collaborating at the facility
- 6% of global ATMP clinical trials are run through Advanced Therapy Treatment Centres (ATTCs)
- 72 Advanced Therapies Apprenticeship Community (ATAC) apprentices employed by 27 UK companies

- 86 core research projects provided novel technologies to researchers and industry
- State-of-the-art technical facilities and expertise available for industry research and collaboration

Current state of the UK ATMP industry

12%
global ATMP clinical trials in the UK

£1.7bn
total financing for UK ATMP companies 2018-2020

3,000+
jobs in the sector

26
GMP manufacturing facilities

Largest
cell and gene therapy cluster outside of the US

Accelerating the large-scale

manufacture and supply

of cell and gene therapies

Clinical material being produced by our collaborators at the CGT Catapult manufacturing centre is now **reaching patients nationally and in the US**, progressing companies towards commercialisation of their innovative therapies.

Through the unique operating model at the 7,700m² CGT Catapult manufacturing centre, collaborators benefit from infrastructure, expertise and innovation that accelerates the development of their commercial and clinical manufacturing.

CGT Catapult capabilities in **logistics, quality control (QC) and integrated systems**, established in collaboration with our therapy developer and supply chain partners, are supporting companies to deliver therapies to patients:

- Cell therapy, gene therapy and viral vector manufacturing systems being developed within segregated manufacturing suites
- Rigorous onboarding process ensuring GMP compliance
- MHRA licence for clinical and commercial manufacturing

Cell therapy, gene therapy and viral vector manufacturing systems being developed

>50 batches of product produced*

* includes clinical and non-clinical batches

Products reaching patients nationally and in the US

Our Manufacturing Centre collaborators

ACHILLES THERAPEUTICS · Adaptimmune · Autolus · FREELINE · TCR² THERAPEUTICS · ThermoFisher SCIENTIFIC

Case study

Establishing scalable supply chain

Our collaborators have been enabled to operate at scale, and with greater autonomy, through our work in optimising supply chain provision at the Manufacturing Centre. We have introduced offsite solutions with expert third-party logistics providers, so collaborators can coordinate with them directly and providing the option of a 'just-in-time' operating model.

Case study

MHRA licensed ThermoFisher CryoHub

The ThermoFisher Scientific CryoHub received its MHRA licence to store and distribute drug products in October 2019. The CryoHub offers capabilities for the cryogenic storage of materials and global logistics solutions, making it a key part of the supply chain available onsite for collaborators.

Case study

Supporting rapid growth of collaborating companies

Since its initial public offering, Autolus has raised approximately £140m in public offerings and increased their number of employees by approximately 80%, to support promising data from their clinical trial programmes.

The unique operating model of the Manufacturing Centre has accommodated the considerable growth of Autolus throughout the past 18 months, enabling them to begin new collaborations with separate viral vector and cell manufacturing processing innovation. The model, infrastructure and systems in place have also ensured **uninterrupted production of clinical batches throughout the COVID-19 pandemic**.

European Union
European Regional Development Fund
INDUSTRIAL STRATEGY
UK Research and Innovation

Expanding
infrastructure and expertise
for companies to innovate and grow

We expanded capacity at the CGT Catapult manufacturing centre, now with 12 segregated GMP modules, enabling further collaborations, providing more companies with large-scale manufacturing support and **anchoring global cell and gene therapy manufacturing in the UK**.

> We are excited that this collaboration with CGT Catapult will enable us to increase our GMP manufacturing capacity as we progress our ongoing clinical trials. The opportunity to occupy a dedicated module with access to key support services and expertise will enable Achilles to establish a manufacturing platform to drive our growing pipeline.

Dr Edward Samuel
SVP Manufacturing, Achilles Therapeutics

European Union
European Regional Development Fund

Hertfordshire Local Enterprise Partnership

INDUSTRIAL STRATEGY

UK Research and Innovation

The Manufacturing Centre expansion phase was backed by £3.36m from the European Regional Development Fund and £12m from the UKRI Industrial Strategy Challenge Fund. The QC expansion is backed by £2.9m funding from the Hertfordshire Local Enterprise Partnership (LEP).

Case study

Achilles Therapeutics onboarding

The new modules at the CGT Catapult manufacturing centre are already supporting Achilles Therapeutics, now onboarding to set up operations for the large-scale manufacture of their novel T-cell therapy products. This will provide Achilles with the GMP facilities, supply chain and expertise to establish additional in-house manufacturing capability to supply clinical studies of their pipeline products for solid tumour indications.

Case study

Employing innovative technology in construction

Merit, a leading UK company in process engineering, constructed the new Manufacturing Centre modules, employing their offsite pre-assembly technology to speed up the process and reduce disruption. This significant project allowed the UK company to expand into a new market, and Merit will also construct the new QC laboratories at the centre.

Driving

productivity and investment

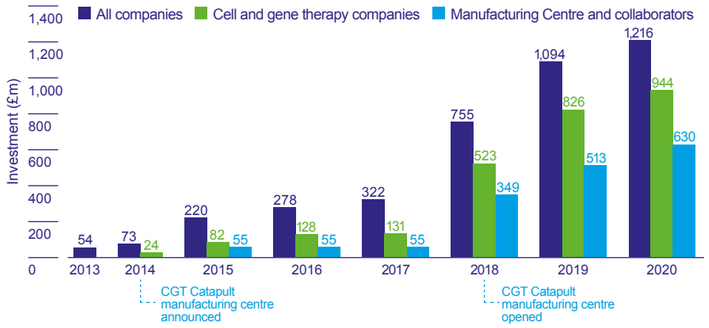
in the largest cell and gene therapy cluster outside of the US

The CGT Catapult manufacturing centre and collaborating companies have driven over half of the investment into the Stevenage Advanced Therapies Campus since 2013. This is at the centre of the **largest cluster of cell and gene therapy companies outside of the US**, a pivotal part of the UK ATMP ecosystem.

The CGT Catapult manufacturing centre is located at the Stevenage Advanced Therapies Campus, where companies are developing cutting-edge therapeutics, technologies and supply chain solutions.

These companies have experienced unprecedented growth, bringing in over **£1.2bn investment** since 2013, and over 77% of this has been driven by cell and gene therapy companies.

Total investment into the Stevenage Advanced Therapies Campus*



Data from Stevenage Bioscience Catalyst, 2020

*Data includes capital, equity and grant funding

Nadhim Zahawi MP, then Minister for Business and Industry at the Department for Business, Energy and Industrial Strategy, announced the LSOZ award at the Hertfordshire LEP Annual Congress in October 2019.

47
companies on campus

30%
campus tenants are cell and gene therapy companies

£944m
investment into cell and gene therapy companies

£630m
total invested into the Manufacturing Centre and companies collaborating at the facility

8
cell and gene therapy developers on campus

5
cell and gene therapy developers located at the CGT Catapult manufacturing centre

Government recognised Life Sciences Opportunity Zone

The Stevenage Advanced Therapies Campus and associated institutions (below) have been awarded Life Science Opportunity Zone (LSOZ) status, one of six locations across the UK. The LSOZ status recognises the area as a key driver of growth for the cell and gene therapy cluster, promoting the life sciences sector to investors internationally to deliver the Government's Life Sciences Industrial Strategy.

- Stevenage Bioscience Catalyst
- GlaxoSmithKline
- Hertfordshire LEP
- Kadans Science Partner
- CGT Catapult manufacturing centre
- LifeArc
- University of Hertfordshire
- Royal Veterinary College

Case study

Growing the largest cell and gene therapy cluster outside of the US

The CGT Catapult manufacturing centre has been influential in growing the cell and gene therapy cluster centred around Stevenage, which is a pivotal part of the UK cell and gene therapy ecosystem and the Government's Life Sciences Industrial Strategy. It provides infrastructure, expertise, supply chain and academic excellence to **drive investment, productivity and innovation nationwide.**

AstraZeneca furthers their research commitment on cell therapies

The global biopharmaceutical company has established a new cell therapy department, with ambitions to maximise the potential of their existing platforms including stem cell technologies. The news represents another major UK stakeholder that is investing in cell therapy development for the future.

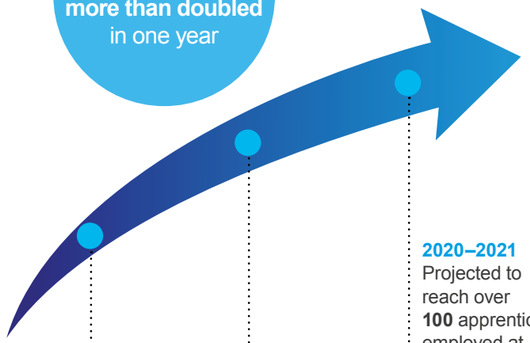
Addressing the specialist skills gap through novel programmes

To enable the rapidly growing industry, initiatives deployed by CGT Catapult are **upskilling and introducing new talent into companies across the UK**, helping to provide specialist skills for the manufacture of cell and gene therapies.

Advanced Therapies Apprenticeship Community (ATAC)
In response to recommendations by the Medicines Manufacturing Industry Partnership, ATAC was established in April 2018 to launch the first apprenticeship programmes specifically for the manufacture and delivery of advanced therapies at scale.

ATAC apprenticeship programmes	Level
Laboratory technician for ATMPs	3
Science manufacturing technician for ATMPs	3
Team leader/supervisor across advanced therapies	3
Laboratory technician apprenticeship (Wales)	3
Modern apprenticeship in life sciences (Scotland)	SCQF 7
ATMP technician scientist higher apprenticeship	5
ATMP bio/chemical engineer degree apprenticeship	6
Regulatory affairs specialist for advanced therapies	7
Research scientist degree apprenticeship	7
Senior leader in advanced therapies	7

The number of ATAC apprentices **more than doubled** in one year



2018–2019
29 apprentices employed by **11** companies **2** programmes launched

2019–2020
72 apprentices employed by **27** companies **10** programmes launched

2020–2021
Projected to reach over **100** apprentices employed at **35+** companies

INDUSTRIAL STRATEGY
UK Research and Innovation

ATAC is funded by the Industrial Strategy Challenge Fund, part of the UK Government's modern industrial strategy. The fund is delivered by UK Research and Innovation.

Case study

Reaching more companies nationally

UK ATMP companies and key stakeholders attended workshops from the ATAC team in Manchester, Stevenage and Oxford during National Apprenticeship Week 2020, to hear how advanced therapies apprenticeships can infuse new skills into their teams. The roadshow prompted fantastic engagement and provided many outcomes to take away to ensure the momentum of ATAC continues over the coming year.

Watch this video to find out more about the impact of ATAC so far:
https://ct.catapult.org.uk/ATAC-2020-roadshow

Case study

University of Hertfordshire UH

Upskilling new and existing staff for large-scale GMP manufacturing of ATMPs

A unique three-day programme is now available, designed by the University of Hertfordshire and CGT Catapult, to provide theoretical and practical training in aseptic technical skills for GMP manufacturing of ATMPs, as well as experience in grade C cleanrooms. The first training course was held in January 2020 at the university's College Lane campus and further courses will be run quarterly.

"This is only the beginning of what is needed to address the demand for skilled personnel as more cell and gene therapies reach the clinic and commercial-scale production. We are exploring further bespoke programmes and cross-sector training for the rapidly growing industry.

Dr Stephen Ward
Chief Manufacturing Officer, CGT Catapult

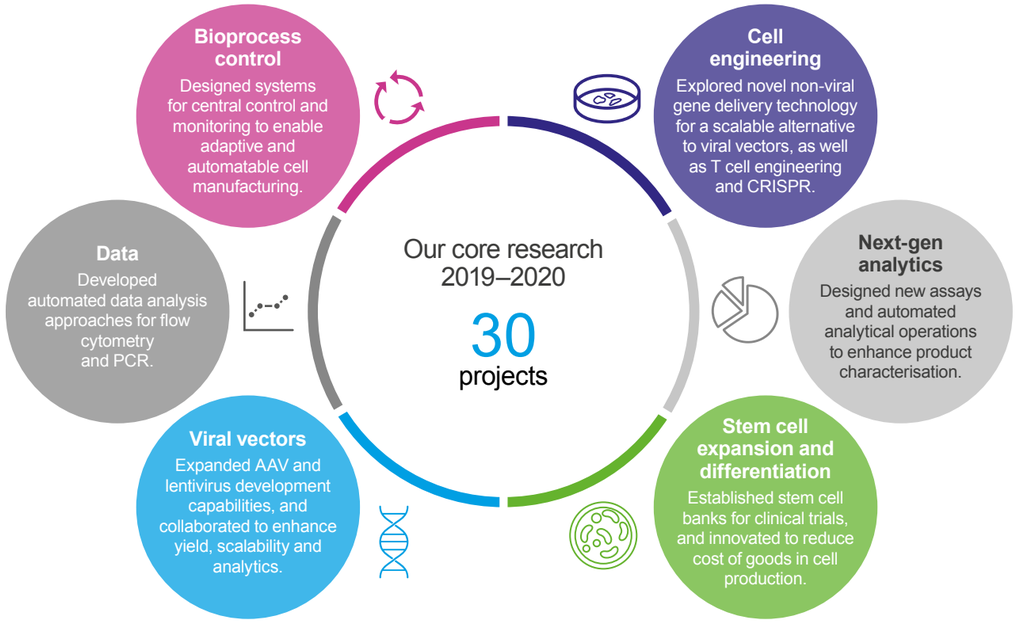
Stimulating innovation

in process and analytical development

CGT Catapult undertook a wide range of core and collaborative projects last year, to provide innovators worldwide with **pivotal solutions for cutting-edge research** into the industrialisation of cell and gene therapies.

19
projects in gene delivery

33
projects industrialising ATMP manufacturing



Our team of enthusiastic experts create a vibrant atmosphere through which we engage with industry and academia to research key challenges facing ATMP manufacture.

Dr Jonathan Appleby
Chief Scientific Officer, CGT Catapult

Case study

International stem cell collaboration

CGT Catapult and CiRA Foundation have launched a collaborative project focused on characterising induced pluripotent stem cells (iPSCs), the first time CiRA's world-renowned iPSC cell lines will be utilised outside of Japan.

This project aims to establish reliable tests to predict iPSC differentiation potential, a capability which could advance the use of these cells for advanced therapies.

We are very pleased to start our first collaborative research project since the launch of CiRA Foundation with Cell and Gene Therapy Catapult, an institution whose world-class expertise in the cell therapy field is dedicated to the stimulation of partnership between academia and industry.

Professor Shinya Yamanaka
Representative Director, CiRA Foundation

Case study

Extending shelf-life of cell therapies

We are working with Atelerix, a growing company based in Newcastle, to extend the shelf-life of cell therapies at room temperature from the current 2-day standard to 5-7 days. Shelf-life is a critical consideration in clinical adoption because of the time required to store, test, transport and administer cell and gene therapies.

Championing large-scale viral vector manufacturing globally

To provide a capability for producing high yield and purity viral vector batches to UK researchers and industry, CGT Catapult have developed a **world-leading viral vector manufacturing platform**. Pioneering research into viral vector manufacturing is essential to prevent bottlenecks in supply for cell and gene therapies.

CGT Catapult has developed a strong viral vector manufacturing capability through over 20 projects within our dedicated laboratory and team of experts.

Our research into adeno-associated viral (AAV) and lentiviral vector manufacturing at scale is providing solutions to prevent supply bottlenecks in the industry.

End to end solution for viral vector production

Upstream process **Downstream process**

Cell seeding and expansion	Virus production and cell lysis	Remove cells and debris	Purification and filtration	Formulation

- High virus production and recovery
- Platform tested with multiple AAV serotypes
- Compatible with real-time monitoring technology

A workflow for high throughput production of AAV vectors, proven with multiple serotypes. The platform utilises suspension-based cell culture and is compatible with real-time monitoring using process analytical technology.

Case study

Commercial-scale AAV vector manufacturing

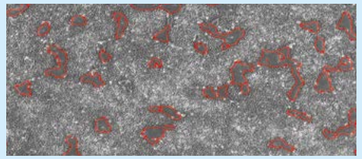
In a collaboration with the Rayne Cell Therapy Suite at King's College London, we are delivering an automated and optimised process for manufacturing AAV vectors, reducing cost and increasing throughput within the same GMP footprint. We have also developed and qualified qPCR, ddPCR, ELISA and transducing unit assays to enhance product characterisation, capabilities which will confer advantages to the pioneering research institution and the wider industry.

Case study

Reducing time and variability in cell culture

CGT Catapult released an online tool to provide fast, accurate and reproducible measurements of cell confluency, a key parameter in cell culture operations. Confluency refers to the percentage of an area covered by adherent cells, and our research shows that visual estimates of confluency can lead to inter-operator variability of up to 35%.

This resource automates confluency measurements from an uploaded cell culture image. The tool can be accessed at: https://ct.catapult.org.uk/cellconfluency



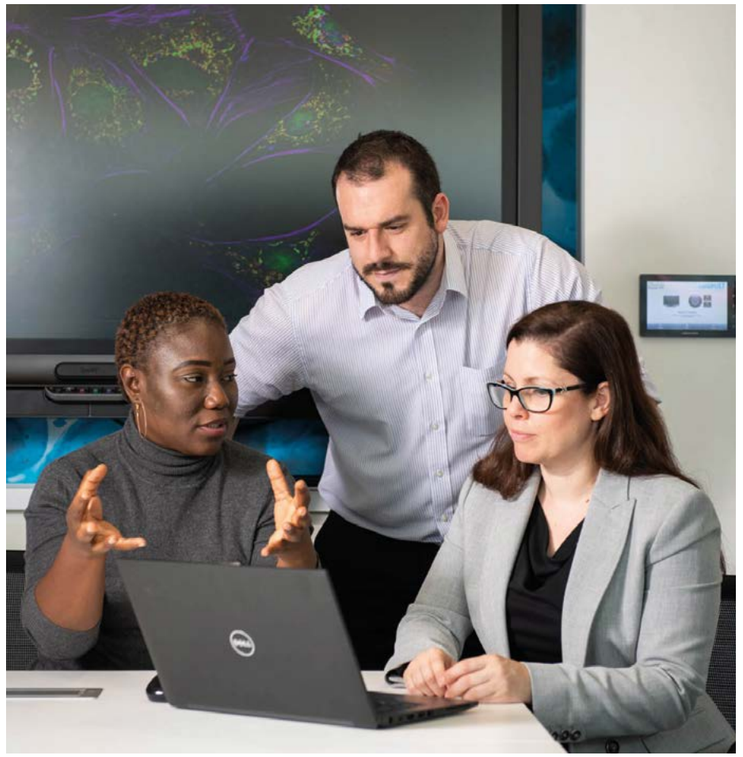
An example of a cell culture image with a confluency of 86.93%. Multiple images may be uploaded simultaneously, and processed images may be downloaded.

Supporting the commercialisation of groundbreaking research

We collaborated on 11 projects focused on the commercialisation of research over the last year, and supported 10 companies with tailored advice clinics, to **support researchers nationwide** to realise the potential of their innovation.

The UK has a strong research base for cell and gene therapies through leading academic institutions, and each year they uncover new and exciting approaches for life-changing medicines.

It is at the heart of our mission to support researchers in realising the potential of their innovation, and enabling them to take advantage of the unique UK ecosystem as they strive for commercialisation of their research.



European Union
European Regional Development Fund

The commercial readiness advice clinic programme is co-funded by the European Regional Development Fund, as part of a £3.5m grant awarded to CGT Catapult.

Case study

Supporting commercialisation of stem cell therapies

We worked with South Wales-based ReNeuron to review and optimise the manufacturing process for their pipeline of stem cell therapy candidates. We identified scalable and GMP compliant systems, streamlined process operations and designed assays that will help future commercial success and inform ReNeuron's manufacturing facility design.

Case study

Innovating in tissue bioengineering

For UK SME Bilitech's novel bioengineered bile duct technology, CGT Catapult provided process diagnostics, health economics assessment and manufacturing strategy support. Bilitech aims to advance the technology, shown to be successful in pre-clinical evaluation, to be a clinically viable therapy for replacing damaged bile ducts in humans.

Commercial readiness advice clinic programme

Spin-out companies and small and medium-sized enterprises (SMEs) can now receive tailored advice and support for the commercialisation of their research. The advice clinic programme gives innovators access to our experts in manufacturing, industrialisation and clinical adoption, providing early stage UK companies with a key platform for growth.

10
spin-out companies and SMEs supported

263
hours of support provided

15
companies signed up for future clinics

1. Company registers and initial discussion
2. Eligibility confirmed and information provided
3. Commercial readiness analysis by CGT Catapult
4. Output discussion and outcomes

Enabling national adoption

of cell and gene therapies into the NHS

The Advanced Therapy Treatment Centre (ATTC) network is bringing together the NHS, industry and academia to establish **systems and solutions for the clinical adoption** of advanced therapies.

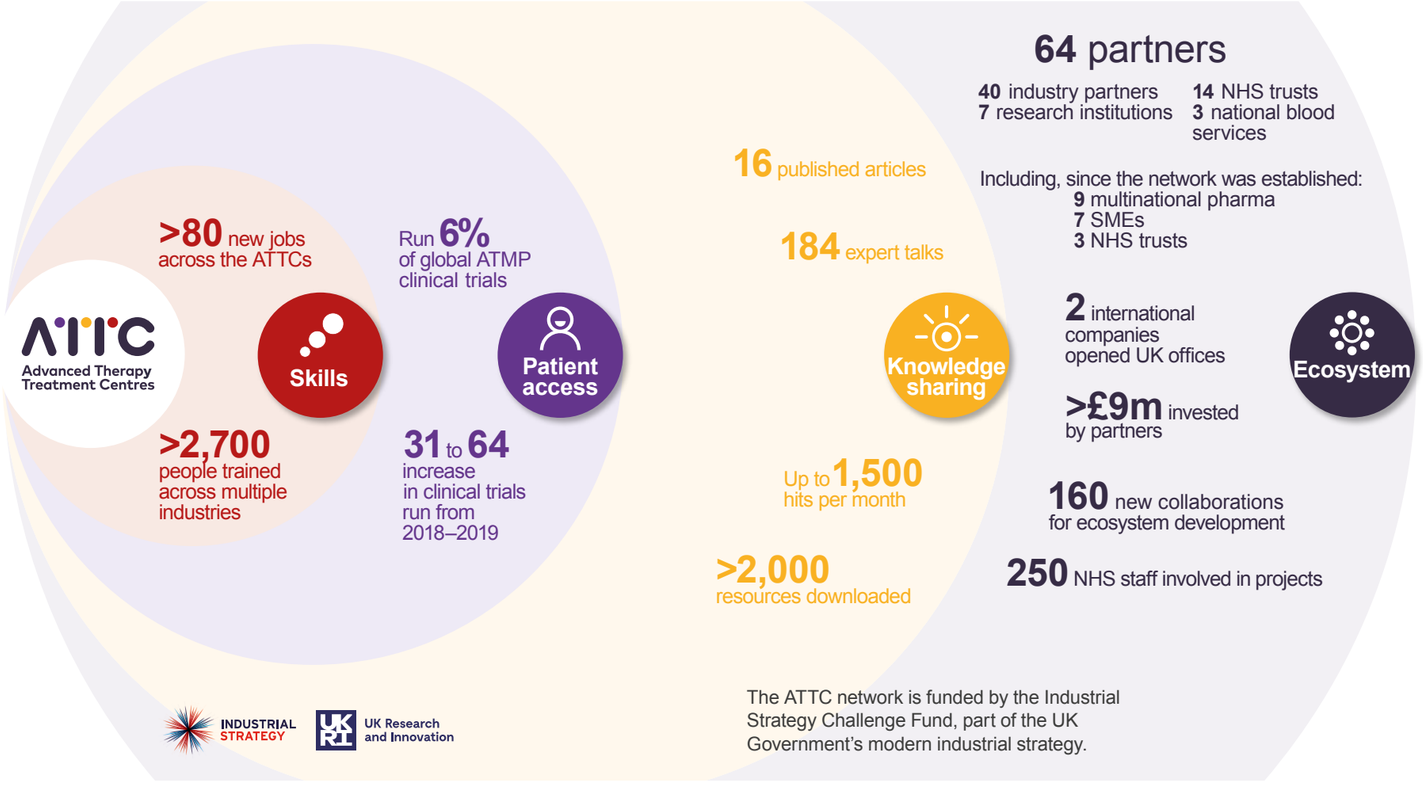
The ATTC network, set up in 2018 and coordinated by CGT Catapult, is developing systems, optimising processes and infrastructure, and scaling up clinical operations for the widespread delivery of advanced therapies.

The network comprises three regional UK centres:

- Innovate Manchester Advanced Therapy Centre Hub (iMATCH)
- Midlands and Wales Advanced Therapy Treatment Centre (MW-ATTC)
- Northern Alliance Advanced Therapies Treatment Centre (NA-ATTC)

> The coordination that the ATTC initiative allows is priceless for sharing best practice, exploring where standardisation across industry makes sense and helping to instigate the changes that need to happen.

Nicola Redfern
UK General Manager, bluebird bio



INDUSTRIAL STRATEGY
UK Research and Innovation

The ATTC network is funded by the Industrial Strategy Challenge Fund, part of the UK Government's modern industrial strategy.

> Asymptote Ltd has found the access to the NHS and ATMP developers through the ATTC network invaluable. Being part of this collaborative network has dramatically accelerated the development of Asymptote's technologies.

John Morris
Chief Executive Officer, Asymptote, Cytiva

Case study

Upskilling the UK NHS workforce

A highly skilled workforce is key to the widespread adoption of advanced therapies. The ATTC network has partnered with Health Education England e-Learning for Healthcare, the organisation that provides e-learning for the health and care workforce, to develop a series of modules on ATMPs. Resources will prepare staff for treating patients with ATMPs, and this training will be made freely available to healthcare professionals across the country.

Case study

Standardising practice across the UK

ATTC network experts are developing best practice across the entire UK supply chain. They aim to standardise material procurement, trial activities, data handling and pharmacy working for ATMP delivery.

The SAMPLE programme is one such initiative, standardising processes for collecting cells and tissues for ATMP development. This programme is also working with industry partners, such as Cytiva, to test novel devices for the collection and cryopreservation of surgical material.

Facilitating widespread
patient access
to advanced therapies

Exploring novel opportunities in clinical adoption and reimbursement, and collaborating across organisations, to bring **more life-changing therapies to patients worldwide.**

Over the last year, CGT Catapult experts in clinical adoption supported companies and engaged with regulators and healthcare providers worldwide, and explored novel reimbursement opportunities, to accelerate patient access to advanced therapies.

Case study

Enabling outcomes-based reimbursement (OBR)

The CGT Catapult health economics and market access (HEMA) team explored the suitability of existing UK data collection infrastructure for operating OBR in therapy areas relevant for upcoming ATMP launches. Through gap analysis of the SACT dataset and EBMT registries, they identified the magnitude of investment required for the infrastructure to enable OBR in oncology in England. Such insights aim to inform the creation of an infrastructure that supports the widespread adoption of cell and gene therapies.

8
regulatory and scientific meetings with MHRA, PEI and FDA

25
regulatory submissions supported

14
non-clinical development strategies generated

8
European and US companies provided health economics and market access support

2
HEMA publications in high impact journals
- J Mark Access Health Policy. 2019 Feb 4;7(1):1573164
- J Mark Access Health Policy. 2019 Jun 27;7(1):1635842

Collaborating with the NHS Accelerated Access Collaborative (AAC)

The NHS AAC brings together industry, Government, regulators, patients and the NHS to accelerate access to new treatments, such as cell and gene therapies.

In October 2019, a new programme of work was approved by the AAC Board focused on ATMP adoption. CGT Catapult and the ATTC network are pleased to be a part of this new initiative, covering topics such as optimising patient engagement, horizon scanning, standardisation and digital solutions. The project aims to disseminate best practice across the NHS to accelerate the scale-up and scale-out of ATMP adoption, and to identify strategies for addressing challenges with current assessment frameworks and commissioning mechanisms.

The clinical adoption function of CGT Catapult is proud to support companies to expand and progress towards commercialisation at a global level. Through this work and our coordination of the ATTC network, we are preparing for widespread adoption and accelerating patient access to transformative therapies.

Dr Jacqueline Barry
Chief Clinical Officer, CGT Catapult

Case study

Optimising the UK ecosystem for large-scale ATMP adoption

Claire Foreman, Head of Acute Programmes at NHS England, was seconded to CGT Catapult to undertake a project to understand UK preparedness for ATMP adoption. The project team engaged with patient groups, healthcare providers, payers, regulators, manufacturers and the NHS AAC, and set out areas for exploration to optimise the UK ecosystem for the large-scale adoption of ATMPs.

The report can be downloaded at: https://cutt.ly/preparedness

MHRA: Medicines and Healthcare products Regulatory Agency, UK PEI: Paul-Ehrlich-Institut, Germany FDA: Food and Drug Administration, United States

Measuring national progress

and preparedness for manufacturing and adoption

CGT Catapult's annual clinical trials, manufacturing and skills reports aim to **inform Government, industry and academic strategies** to continue the progress of the rapidly growing UK cell and gene therapy industry.

- 86% increase in phase II-IV ATMP clinical trials in the UK, as more companies progress to manufacturing at scale
- Increasing GMP manufacturing space, and over 2,000m^2 additional cleanroom footprint for ATMPs expected this year
- Employment in the ATMP industry projected to double by 2024

There is an urgent demand for skills to support this accelerating industry growth over the next five years and beyond.

UK clinical trials database 2019

https://ct.catapult.org.uk/clinical-trials-database

12%
global ATMP clinical trials in the UK

127
ATMP clinical trials (up 50% vs. 2018)

56
phase II-IV ATMP clinical trials (up 86% vs. 2018)

77%
ATMP clinical trials sponsored by commercial organisations (up from 24% in 2013)

UK GMP manufacturing report 2019

https://ct.catapult.org.uk/manufacturing-surveys

26
MHRA licensed facilities
(up 1)

~7,819m^2
cleanroom footprint
(up <5%)

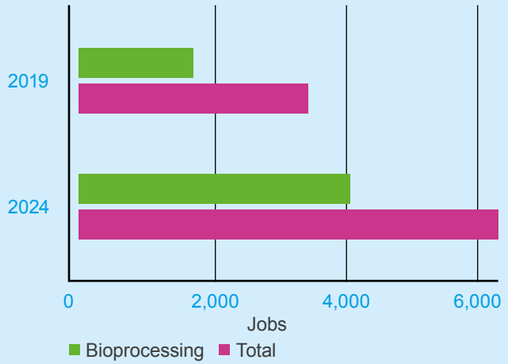
~8,354m^2
in-house QC footprint
(new data)

9
commercial developers
(up 2)

UK skills demand report 2019

https://ct.catapult.org.uk/manufacturing-surveys

ATMP industry employment (2019 and 2024 projected)



112%
projected increase in total industry jobs

126%
projected increase in bioprocessing roles

Looking forward

CGT Catapult strives to continue the significant progress being made by cell and gene therapy companies across the world, by collaborating on more innovative projects, overcoming barriers to growth, and **supporting companies to recover** after the COVID-19 pandemic.

COVID-19

The UK life sciences sector shifted focus in 2020 to respond to the emergent coronavirus, SARS-CoV-2, which has caused devastating loss across the world. The unprecedented collaborative response between Government, industry and academia has limited the impact of the virus and paved the way for recovery.

Moving forward, CGT Catapult is prepared to help UK companies to recover and resume innovating, with strong Government support, to ensure more transformative medicines can be delivered to patients across the world.

Collaboration laboratory

The new laboratories will provide a unique and confidential space for collaboration. Companies will be able to occupy this space in the coming year, accessing CGT Catapult's expertise while developing systems for deployment at the Manufacturing Centre and beyond.

Integration laboratory

CGT Catapult will join other companies in establishing new laboratory facilities near the CGT Catapult manufacturing centre. The new laboratories will support the scale-up of manufacturing, upskilling of staff, and new technology evaluation for our collaborating companies before they begin GMP manufacturing.

Furthering clinical adoption nationally

Building on the significant impact of the initiative so far, the ATTC network will initiate additional innovative projects over the coming year, such as expanding the network with additional clinical sites and delivering national education to patients and healthcare professionals.

Launching skills initiatives

We will develop further national initiatives to upskill new and existing industry staff for the manufacture of advanced therapies and vaccines, helping to drive the continuous and rapid growth of the UK cell and gene therapy industry following the COVID-19 pandemic.

Financial highlights

The financial information in this review represents the year end position for the Cell Therapy Catapult Limited group for the year ended 31 March 2020.*

Turnover

For the year ended 31 March 2020	2020 £'000's	2019 £'000's	2018 £'000's
Innovate UK revenue grant funding	**12,756**	15,276	12,580
Innovate UK capital grant funding	**3,000**	11,521	5,851
Third Party Revenue grant contributions	**3,816**	4,518	4,825
Third Party Capital grant contributions	**4,270**	–	–
Collaborator Contributions	**12,448**	4,539	–
Contract Research and Licence income	**2,519**	2,489	3,660
Total	**38,809**	38,343	26,916

Balance sheet

For the year ended 31 March 2020	2020 £'000's	2019 £'000's	2018 £'000's
Fixed assets	**56,337**	53,157	44,341
Net current assets	**12,519**	9,758	2,704
Creditors	**(7,022)**	(7,017)	(337)
Provisions for liabilities	**(10,295)**	(8,689)	(7,316)
Net assets	**51,539**	47,209	39,392
Capital and reserves	**51,539**	47,209	39,392

* 2018 and 2019 figures represent audited data. 2020 data is unaudited as of 14 July 2020.

Cell and Gene Therapy Catapult is a trading name of Cell Therapy Catapult Limited (limited by guarantee), 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.

Corporate governance

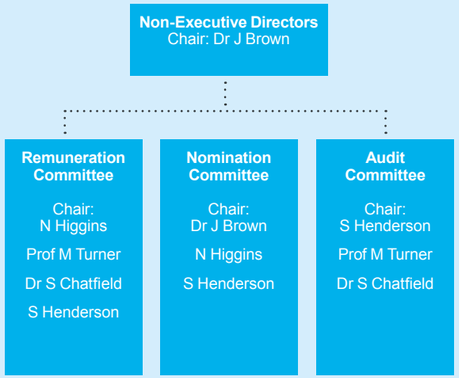
The Cell Therapy Catapult Limited is an independent private company limited by guarantee incorporated as a not-for-profit research organisation. CGT Catapult receives substantial grants from Innovate UK and works in coordination with them while remaining independent and is self-governing.

Operating subsidiary

- Cell Therapy Catapult Services Limited

Our committees as of April 2020

- We have established three committees that meet independently and make recommendations to the Board



Non-Executive Directors

Dr John Brown CBE, FRSE
Chairman

Dr Steven Chatfield
Director

Professor Uta Griesenbach
Director

Stuart Henderson
Director

Nick Higgins
Director

Sir Bruce Keogh
Director

Hilary Newiss
Director

Professor Marc Turner
Director

Executive team

Matthew Durdy
Chief Executive Officer

Dr Jacqueline Barry
Chief Clinical Officer

Dr Stephen Ward
Chief Manufacturing Officer

Dr Jonathan Appleby
Chief Scientific Officer

Brian Collins
Chief Financial Officer

Advisory panel

Professor Paul Fairchild University of Oxford

Professor Stuart Forbes University of Edinburgh

Professor Johan Hyllner AstraZeneca

Michael Hunt ReNeuron

Dr Edward Hodgkin Syncona Partners

Professor Graham Lord University of Manchester

Professor Chris Mason AVROBIO

Professor Petra Reinke Charité – Universitätsmedizin Berlin

Professor Bill Skarnes The Jackson Laboratory

Professor Michael Whitaker Newcastle University

Dr Steven Howe GlaxoSmithKline

CATAPULT
Cell and Gene Therapy

Thank you to the people we have worked with over the year, including:

Funders and investors

National and international organisations

National and international companies

National Health Services

Regulators

Researchers

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