Large-scale Cell and Gene Therapy Catapult manufacturing facility for current and future multi-product processes
The Catapults

- Part of a **world-leading network** of technology and innovation centres
- **Bridge the gap** between businesses, academia, research and government
- Access technical facilities and expertise to help adopt, develop and exploit innovations
- Established by **Innovate UK**

- The Cell and Gene Therapy Catapult mission:

  "Growing the UK cell and gene therapy industry, delivering health and wealth."
Cell and Gene Therapy Catapult

**Therapy industrialisation**
- Process development
- Analytical development
- GMP process proving
- Supply chain
- Commercial-facing manufacturing

**Business**
- Business development
- Business models
- Health economics

**Clinical trial and regulatory**
- Regulatory
- Clinical trial sponsor
- Clinical operations
- Pre-clinical safety

- ES and iPS cells
- HSC’s
- MSC’s

- T cells
- T Regs
- Dendritic cells

- Somatic cells
  - Islet cells
  - Fibroblasts

- Tissue / Scaffold
  Tech development
<table>
<thead>
<tr>
<th><strong>£125m</strong></th>
<th><strong>£21.3m</strong></th>
<th><strong>£13m</strong></th>
<th><strong>£55m</strong></th>
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<tbody>
<tr>
<td>£125 million <strong>funding</strong> into the Catapult over 5 years</td>
<td><strong>Invested</strong> £21.3 million in projects over the last three years</td>
<td>Invested more than £13 million in a state-of-the-art development facility</td>
<td>Investing £55 million in <strong>large-scale manufacturing</strong> centre in Stevenage</td>
</tr>
<tr>
<td><strong>£27.3m</strong></td>
<td><strong>Three</strong></td>
<td><strong>30+</strong></td>
<td><strong>120+</strong></td>
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<tr>
<td>Leveraged £27.3 million of <strong>third party funding</strong> into businesses and projects in the last three years</td>
<td>Formation of <strong>three</strong> spin out companies</td>
<td>Over 30 <strong>live projects</strong> across our capabilities</td>
<td>Over 120 <strong>cell and gene therapy experts</strong> from health economists and regulatory experts to leading edge translational scientists</td>
</tr>
</tbody>
</table>
Removing capital investment risk
Investing in infrastructure
Cell and Gene Therapy Catapult

**£70m Development Facility**

- **1,200m²** Custom designed cell and gene therapy development facility
- **Prime location** in the heart of the London clinical research cluster
- **120** permanent staff

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**£55m large scale manufacture center**

- **7,200m²** manufacturing centre designed specifically for cell and gene therapies
- **Located** in the Stevenage biocatalyst
- **Opening** 2017
State of the art laboratories in central London

- Replication of any process using configurable pod system
- Range of technologies to support upstream, bioreactor and downstream processing, fill and finish at commercial scale
- Technology transfer to full scale GMP
- Viral vector laboratory
CGT manufacturing centre
Why are we building a manufacturing centre?

- Market research – Feedback from SME’s and Large pharma
- Removing the capital investment risk for cell and gene therapy companies who need large-scale GMP manufacturing facilities.
- Collaborators will have control over their process within the facility.

Large-scale GMP manufacturing facility

- Multi-collaborator facility
- 7,200m² footprint
- 12 x 100m² Grade B to C cleanrooms
- Centralised QC, warehouse, facilities management & waste disposal
- Enables companies to scale up manufacture
- Flexible - allogeneic, autologous or viral vector processes
Segregation at heart of design and operation

- **Physical**
  - Architecturally segregated modules
  - Technical corridors separate modules
  - Walk on ceilings for plant access
  - Single pass HVAC dedicated to each module
  - Negative pressure sinks on all module entry and exit routes.

- **Information**
  - Segregated data within BMS and EMS
  - Hardwired & WiFi dedicated, secure Virtual Local Area Network.
People & material flow

Unidirectional people flows

Segregated product, material and waste flows
Flexible manufacturing

Allogeneic and viral vector

Autologous
Licensed facility

MHRA Licensed Facility

Collaborator 1
- Catapult “in module” QMS
- Product Specific MAA
- Manufacture, Quality Control & Batch Release
  - Portable

Catapult Quality Envelope
- Q Dir
- QP
- Tailored Quality Agreement

Collaborator 2
- Own in module QMS
- Product Specific MAA
- Manufacture, Quality Control & Batch Release
  - Independent

CEO

COO

Portable Tailored Quality Agreement
UK Golden Triangle

• Strongest biosciences cluster in Europe.
• Close proximity to strong academic base and a world-leading financial centre.
• The region is often seen as the gateway to Europe by large businesses.
• Consistent, secure, reliable, globally connected transport system.
The Cell & Gene Therapy Manufacturing Centre Progress

Investing in infrastructure
Facility design complete
Planning permission granted
Construction starts
Facility envelope watertight
Commissioning starts
Facility validation starts
Handover of building to CGT
Collaborator process validation begins
Collaborator process begins
First collaborators move in
Manufacturing centre licensed
CGT manufacturing centre
CGT manufacturing centre (Sep 16)
CGT manufacturing centre: Ground floor (Sep 16)
CGT manufacturing centre; Cleanroom ceilings (Sep 16)
CGT manufacturing centre; CNC corridor (Sep 16)
CGT manufacturing centre; HVAC ductwork (Sep 16)
CGT manufacturing centre; Warehouse (Sep 16)
CGT manufacturing centre; Plant room (Sep 16)
CGT manufacturing centre; Office block (Sep 16)
In Conclusion
Investing in infrastructure
World class expertise

The Cell and Gene Therapy Catapult manufacturing centre is supported by a team of world-class experts, with end-to-end knowledge to help collaborators commercialise their therapy.

- Health economics
- Regulatory support
- Clinical trial support
- Industrialisation
  - Process development
  - Assay development
  - Tech transfer
  - Manufacturing
For more information

To find out more about collaborating with us in the manufacturing centre, please contact us:

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ct.catapult.org.uk

- To view a video of the manufacturing centre, visit our Youtube channel.

- To watch the development of the site in real time, visit our website.