

# Why Ireland for Cell and Gene Therapy Development and Manufacturing



Q3, 2020



## Well Established Biopharma Track Record Growing Cell and Gene Therapy Investment

- + **85+** Biopharmaceutical sites in Ireland.
- + **9 of the top 10** global pharmaceutical companies have substantial operations in Ireland.



**Takeda** have chosen Ireland to invest in a state-of-the-art facility for commercial scale cell therapy production dedicated to manufacturing a novel stem cell therapy.



In 2019 **Allergan** announced a gene therapy research collaboration with NIBRT that will address key challenges in the manufacture and characterisation of Adeno-Associated Virus (AAV)-based gene therapies.



**Avectas** is a cell engineering business focused on improving the cost, manufacturing and patient outcomes for the next generation of cellular therapies. Avectas is developing a unique delivery technology platform, Solupore®, to enable the ex-vivo manufacture of gene modified cell therapy products, with partners.



## Excellence in Advanced Manufacturing

Manufacturing in Ireland accounts for

**32%** of GDP  
(c €140.6bn in exports)

**261,400** direct employees (11.2% of workforce)

**35%** gross value added (EU average 16%)

Source: CSO, 2019

Recognised leaders in



**Design for Manufacturing**



**Operational and Innovation Excellence**



**Global Launch Sites**



**New Product Introductions**

- + Strength in implementation of next generation manufacturing technologies (robotics, automation, systems integration).
- + Ireland has the most Shingo prizes globally per capita.
- + DePuy Synthes - recognised global Digital Lighthouse (World Economic Forum).



## R&D and Training

Over **€12m** of research funding awarded in Ireland in areas of gene therapy and cell therapy in the last ten years by Science Foundation Ireland (SFI).

4 collaborative cell and gene therapy projects awarded **€25.5m** under first two Calls of Disruptive Technologies Innovation Fund (DTIF).

IDA Supports: **25%** R&D tax credit  
IDA Ireland offers a variety of grants available for qualifying R&D & Training.



**National Institute for Bioprocessing Research and Training (NIBRT)**

- + Trains over 4,500 people annually
- + NIBRT offer practical based training for industry in cell and gene therapy development and manufacture
- + 2 new courses 2020:
  - Fundamentals of Stem Cell Therapy Manufacture (in collaboration with CCMi)
  - Advanced Cell Therapy Technology Course (in partnership with GE Healthcare)
- + Industry Partners: Allergan, Pfizer, GE Healthcare



**Regenerative Medicine Institute (REMEDI)**

- + Multidisciplinary research in fundamental and applied cellular biotechnology
- + Clinical collaborations in corneal stem cell transplant and pancreatic islet transplant for treatment of type 1 diabetes.
- + Industrial & Ecosystem partners: Harvard Medical School, Royal College of Surgeons in Ireland, St. Vincent's University Hospital

# Clinical Trials in Ireland



Ireland has an evolving clinical trial ecosystem. **291** trial sites now open across the Irish network.

Multiple cell & gene clinical trials ongoing in collaboration with Galway University Hospital and St. James's Hospital.



There are **seven** clinical research facilities and centres across Ireland within an integrated clinical research network known as HRB Clinical Research Coordination Ireland (HRB-CRCI).

Source: HRB 2018

## Regulatory & Compliance

Ireland has Exemplary compliance record with regulatory agencies, the Irish Health Products Regulatory Authority (HPRA), European Medicines Agency (EMA) and the Food and Drug Administration (FDA).



Regulatory Science Ireland - a multidisciplinary stakeholder network informing industry and regulators on emergent regulatory requirements.

## Ireland's CMO/CRO Support Sector

- + **APC Ltd:** CMO in cell and gene process development.
- + **Centre for Cell Manufacturing Ireland (CCMI):** dedicated GMP cell therapy manufacturing facility with capacity in adenoviral vectors and adult mesenchymal stem cells.
- + **PPD® Laboratories:** Contract analytical capabilities to support development and manufacturing.
- + **Almac Group:** Partnering to advance human health.
- + **Eurofins BPT Ireland:** part of the World's largest network of trusted contract GMP analytical labs supporting life changing therapeutics.



## Facility Design, Build & Consultancy

Ireland is home to a number of excellent providers delivering bespoke building solutions in cell and gene development and manufacturing locally/globally.

Significant expertise in guiding companies on optimal build configurations (green field, brown field conversion, modular).

## Transport & Cold Chain Logistics

Multiple global and speciality providers in cell and gene therapy logistics operating in Ireland include:



**Airports:** 6 airports across Ireland, serving nearly 35 million passengers in 43 countries across 200+ scheduled routes.

- 10 Freight Forwarders & Courier Servicers
- 2 Freight Forwarders
- 2 Courier Servicers
- 1 Fullfilment Company



## Global Business Services

Ireland is a global location for centralised data management and advanced analytics

### Technology

- + The world's top 5 Software companies along with 7 of the world's top 10 Technology companies have operations in Ireland.
- + Ireland's technology sectors spans hardware, software, cloud, analytics, health IT.
- + Vibrant digital health cluster.

### Cyber Security

- + The world's top 5 cyber security companies have operations in Ireland.
- + Ireland has developed a leading cluster - Cyber Ireland.
- + Capability in threat research, security operations, platform development, risk.

### AI & Data

- + Open, vibrant cross sectoral capability in AI Trial and test bed facilities.
- + World class researchers, highest per capita number of EurAI Fellows.

### Internet of Things

- + Perfect collaboration environment - hardware, software, connectivity, microelectronics & sensors, Data and analytics.
- + Open, engaged partnerships to Collect data, Connect devices/systems and Transform data in actionable insights.

### Data Management

- + Manufacturing Data
- + Patient Data
- + Logistics Data
- + Clinical Trial Data
- + Regulatory Data
- + Supply Chain Data

