Medicines Manufacturing Challenge Celebration Event

12th July 2022
Manchester, etc Venues

Wifi password: wifi4072
Social Media: #MedMan2022

UKRI Innovate UK KTN

Welcome and Introduction

Andy Jones
Sarah Goulding
Challenge Directors, Medicines Manufacturing
Innovate UK

UKRI Innovate UK KTN

Creating value & underpinning resilience

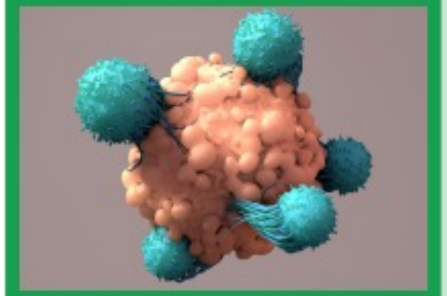
Making the UK one of the best places to manufacture medicines

UK Research and Innovation | Innovate UK | ktn

'Thanks to the groundwork laid by the Medicines Manufacturing Challenge, we are now offering lifechanging therapies to many more patients.'

Fiona Thistlethwaite, The Christie NIHR CRF Director and Medical Oncology Consultant, iMATCH Director

CASE STUDY



Autolus: From spin out to a potential billion dollar business

Autolus makes personalised cancer treatments known as CAR-T cell therapies. These are created by harvesting a patient's own immune cells, modifying them, before returning them to the patient where they locate and destroy tumours. Many cancer patients who receive the treatment go into remission.

Since founding in 2014 as a spin out from UCL, Autolus has received £7.4 million in funding from Innovate UK and has received investment of approximately £500 million. It became a publicly listed company on Nasdaq in 2018. The company has created over 300 jobs with further expansion currently ongoing at its Stevenage facility.

Medicines Manufacturing Challenge funding was important to Autolus' growth. Obtaining development and manufacturing space in Stevenage allowed the company to focus on developing innovative manufacturing approaches, alongside running proof-of-concept trials. And once Autolus had invested in upskilling their UK workforce, they were incentivised to keep their business in the country.

Without Medicines Manufacturing Challenge support, Autolus' growth would have been slower, and would likely have been placed outside of the UK. Instead, it has created jobs, investment and potential revenue of £1 billion per year once the Company's lead products are commercialised.

'Life sciences manufacturing is highly innovative, and offers opportunities to bolster health resilience but also deliver economic growth through high value jobs and exports.'

The Rt Hon Nadhim Zahawi MP, Minister for Business and Industry & Minister for COVID Vaccine Deployment [Aug 2021]

CASE STUDY

Oxford Biomedica: Rising to the COVID-19 vaccine challenge

Founded as a spin out from the University of Oxford in 1995, Oxford Biomedica was the first commercial manufacturer of viral vector-based vaccines and therapeutics in the UK. Today, the company is split across several locations in Oxfordshire and employs more than 670 people. Throughout its growth, Oxford Biomedica has benefited from capital funding through the Medicines Manufacturing Challenge to expand its manufacturing facilities. This has attracted further investment through the public markets, enabling the building of Oxbox, a manufacturing site in Oxford that was opened by the Prime Minister Boris Johnson in January 2021 and has become integral to the UK's COVID-19 response.

The established manufacturing capability at Oxford Biomedica meant that it was well positioned to take on production of the viral vector-based Oxford AstraZeneca vaccine. With a boost of support through a collaboration with VMIC towards manufacturing equipment for the expanded facilities, the company was able to secure a five-year deal with AstraZeneca to produce millions of litres of the vaccine. These vaccines have since been used to protect nearly a third of the UK population, helping to bring us back to normality.

CASE STUDY

SageTech: Recycling anaesthetics to reduce carbon emissions

SageTech was founded in 2015 with the goal of reducing the cost and environmental impact of inhaled anaesthetics.

Inhaled anaesthetics are essential in modern surgery, but patients in the operating theatre take up less than 5% of the anaesthetic they breathe in. The rest goes into the atmosphere, adding up to the equivalent of around 3 million tonnes of CO_2 every year - the equivalent of powering half a million homes for a year.

SageTech has developed patented technology that captures, extracts and purifies inhaled anaesthetics so they can be recycled and reused. The ultimate goal is to extract the captured waste volatile and purify it to meet MHRA standards, so producing a volatile drug that can be clinically reused to anaesthetise patients.

In 2018, SageTech, in collaboration with the University of Exeter Medical School, received funding through Innovate UK to help commercialise their technology, developing a waste anaesthetic collection programme across NHS hospitals and creating a commercial-scale purification plant. Their work is now attracting further investment, with a recent funding round raising £2.9 million in private investment that will help further scale-up and commercialisation.

CASE STUDY

Increasing access to experimental medicines through collaboration

The Innovate Manchester Advanced Therapy Centre Hub (iMATCH) is a consortium made up of The Christie and Manchester University NHS Foundation Trusts, the University of Manchester and nine commercial partners, focused on scaling up the development and delivery of advanced therapies.

The Christie has partnered with GSK to trial a new cell therapy for certain types of cancer, which involves genetically modifying patients' immune cells so that they can seek out and destroy tumours. Patients were recruited to the study through the Christie Hospital in May 2020 and by November the first patient received their modified cells. iMATCH supported the infrastructure required to make this cutting-edge clinical trial happen.

There are multiple benefits from this kind of collaboration. Industry partners have access to a location for trials and patients who want to take part, while NHS hospitals benefit from infrastructure development and staff training readying them to deliver advanced therapies as they become more widely available. Importantly, patients gain early access to experimental therapies and the infrastructure and skills being put in place mean that the wider population will be able to benefit from advanced therapies in the future.

Agenda

Morning Session		
10:30 – 10:40	Welcome	Andy Jones, Challenge Director, Medicines Manufacturing, Innovate UK
10:40 – 10:50	Keynote Address	Ian McCubbin, Chair of C&GTC
10:50 – 11:50	Panel Session: Innovation Centres for Impact: Featuring: • NeRRe Therapeutics • Cell and Gene Therapy Catapult • Advanced Therapies Treatment Centre • Medicines Manufacturing Innovation Centre • Vaccine Manufacturing Innovation Centre Q&A	Chaired by Sarah Goulding Challenge Director, Medicines Manufacturing Innovate UK Jo Craig, Senior Vice President for Chemistry, Manufacturing and Controls Stephen Ward, Chief Manufacturing Officer Jaqueline Barry, Chief Clinical Officer Katie Murray, Technology Director Andy Jones
11:50 - 12:00	Summary of morning session	Sarah Goulding
12:00 – 13:20	**Lunch and networking**	Automation/Robotics Exhibition Poster Exhibition

Innovate UK KTN

Agenda

Afternoon session		
Delivering economic growth for CR&D		
13:20 – 13:30	Highlights of the CR&D Portfolio	Nick Medcalf, Deputy Challenge Director, Medicines Manufacturing, Innovate UK
13:30 – 14:30	Case study presentations:	Autolus, Phico, Quotient, Oxford Biomedica, Pharmaron
14:30 – 15:00	*Coffee break*	
The future for medicines manufacturing innovation		Chaired by Andy Jones
15:00 – 15:10	EPSRC	Lydia Gardner, Head of "Manufacturing the Future'
15:10 – 15:25	MMIP innovation priorities	Brian Henry, MMIP Chair and Head of Drug Product Design at Pfizer
15:25 – 15:40	Manufacturing's Future Priorities	Juliette White, Vice President Global SHE and Sustainability, AstraZeneca
15:40 – 16:20	Panel discussion with Q&A	Andy chair, plus speakers (with Ian McCubbin)
16:20 - 16:30	Wrap up	Sarah Goulding

UKRI Innovate UK KTN

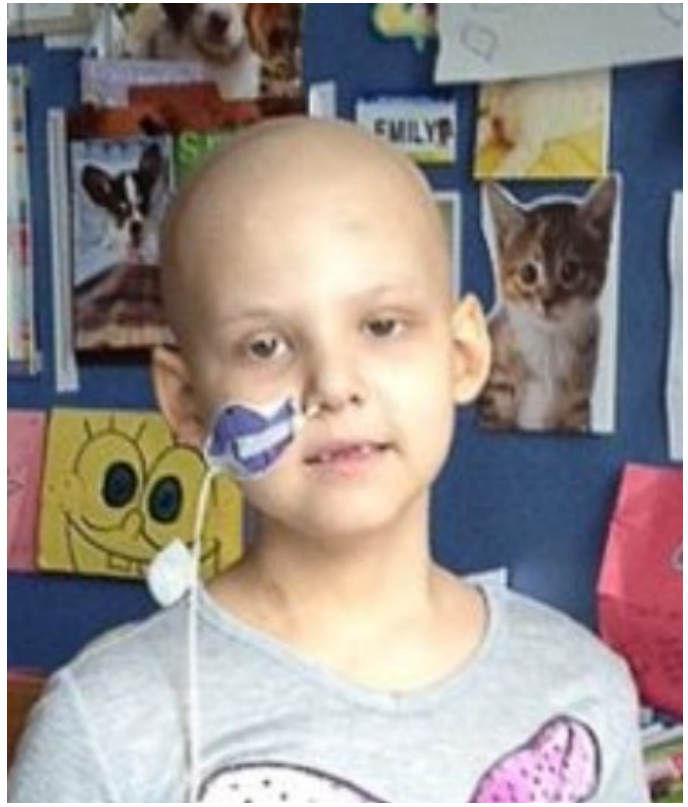
Supporting advanced therapy manufacturing

12 July 2022

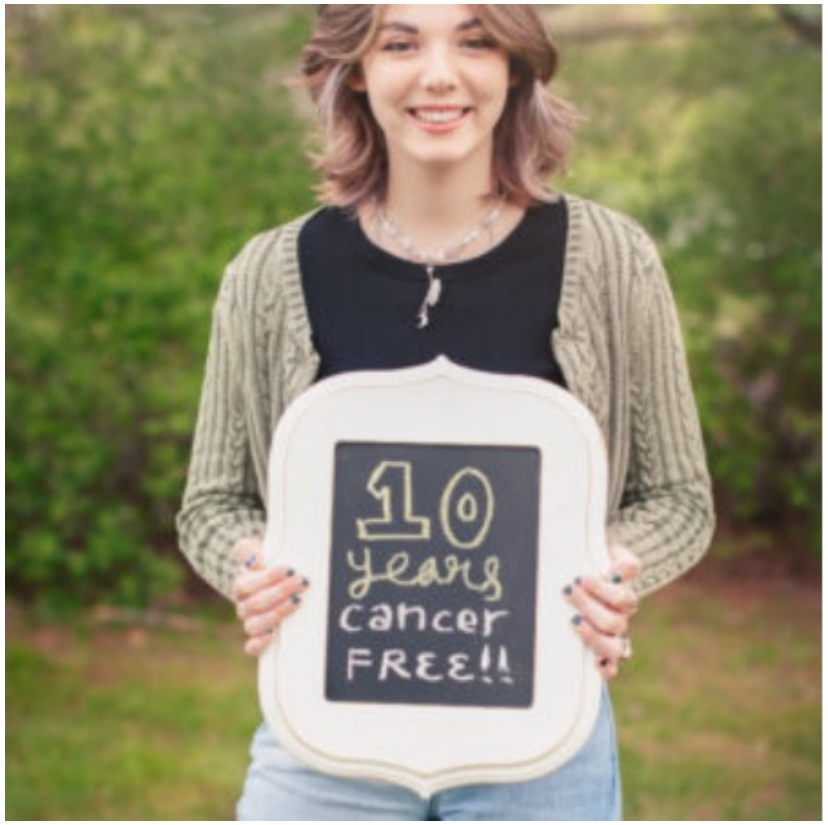
Stephen Ward, Ph.D

Chief Manufacturing Officer

a new approach to healthcare



Emily Whitehead



…..an intent to cure

Case study; demonstrable **impact** from evidence based intervention

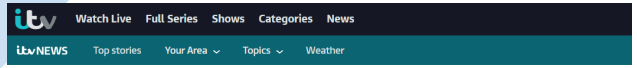
Evidence based intervention

World leading innovation

Aligned with industry needs and government strategies

Demonstrable impact in private investment; 11 x leverage of local and government investment

Demonstrable impact in retaining companies to manufacture in the UK and attracting inward investment



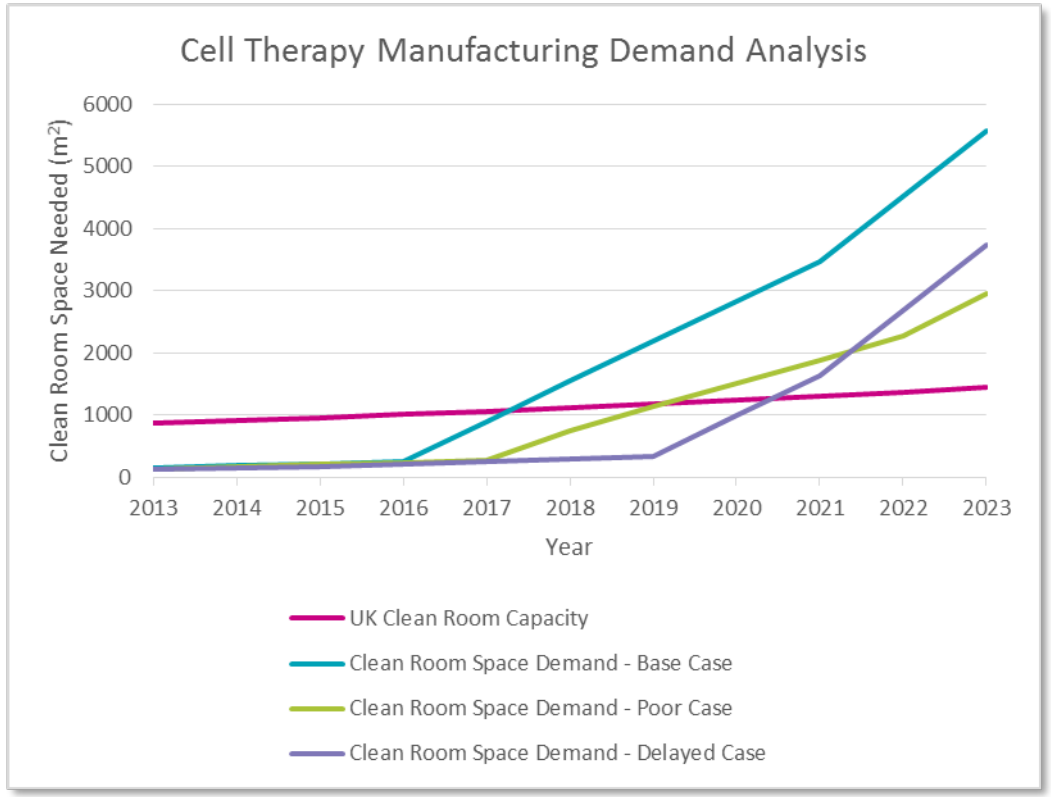
Biopharmaceutical company plans £65 million HQ in Stevenage

UK barrier to success

Manufacturing demand analysis performed in 2014 by Cell and Gene Therapy Catapult

Predicted that ATMP manufacturing space demand would outstrip supply within 3-6 years

Formed part of the business case for building the Manufacturing Innovation Centre in Stevenage



The intervention - staged investment into Stevenage Manufacturing Innovation Centre

2019
£3m CGTC investment
£2.9m Herts LEP to extend QC laboratories adding 6 more.

2017
£3.36m ERDF, £5m CGTC investment and £12m Medicines Manufacturing Industrial Strategy Challenge Fund to fit out 6 additional production Modules

2014/15
£55m initial investment to build and operationalise the MIC, including 6 flexible production Modules and 9 associated QC laboratories

Funded by
INDUSTRIAL STRATEGY
UK Research and Innovation
European Union
European Regional Development Fund
Hertfordshire Local Enterprise Partnership

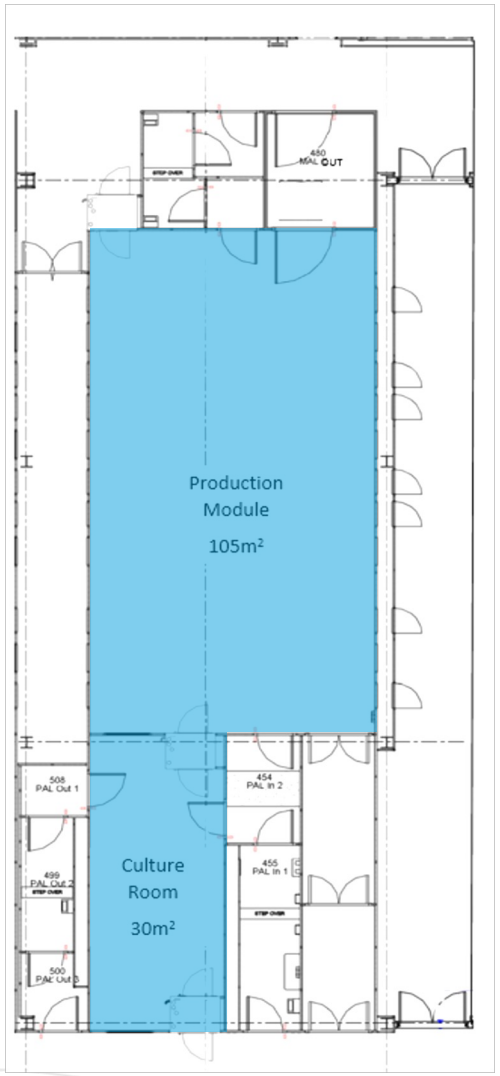
Expansion-phase modules

Additional capacity

- Six new enlarged modules
- Segregated Production Module and Culture Room
- Enhanced throughput and batch capacity
- Vapourised Hydrogen Peroxide decontamination chambers on exit

Leveraged from initial phase

- Fit out of existing shell and core
- Electronic and physical systems
- Operating and quality model



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Hertfordshire Local Enterprise Partnership

World leading, innovative collaboration model

CATAPULT Cell and Gene Therapy

Facility design and operation

- Collaborators occupy production modules to perform their own processes with their own people
- Fully segregated modular design for companies to build up and own their process IP and know how

GMP Quality

- CGT Catapult operates the building, GMP support services and obtains manufacturing licences (clinical and commercial)
- Collaborators apply for manufacturing licences for in-Module activities only

Collaborative finance

- Collaboration through a cost and risk sharing model

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Hertfordshire Local Enterprise Partnership

Outcome

- **Accelerated route to best practise GMP manufacturing**

- To date, nine companies have collaborated
- Over 400 people currently access the Stevenage MIC
- Range of processes developed– viral vector manufacturing, autologous and allogenic cell therapies
- Four companies (some with multiple Modules) have MHRA GMP approval, with more planned in 2022
- CGTC hold MHRA authorisation for commercial manufacturing
- FDA engagement and acceptance of model for future US commercial supply

CATAPULT
Cell and Gene Therapy

Outcome: establishing national supply chain solutions

Streamlining manufacturing processes and increasing batch throughput

- MHRA and HTA authorised **ThermoFisher** Cryohub co-located on site
- Demonstrated both cleanroom and non-cleanroom kitting solutions with two national third party logistics companies
  - **Central Pharma**
  - **ThermoFisher**

Impact: attracting significant private investment

Leveraging initial funding – growth of campus

Over £1.8bn investment attracted into the campus in Stevenage.

- **£1.3bn has been in companies with focus on cell and gene therapy technology** of which **£850m is directly from collaborators at the CGTC Stevenage Manufacturing Innovation Centre**.

This represents **11x** leverage from the CGTC facility and its collaborators from the original £72m investment

Growth of companies

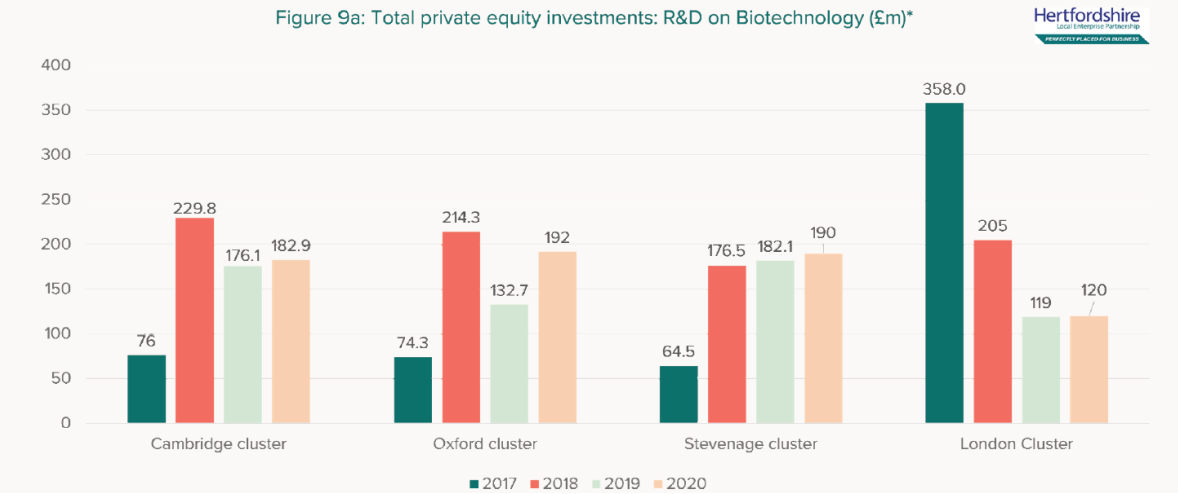
Autolus located £66m manufacturing investment in Stevenage

Reef developing 33 acres of GSK land to unlock up to £900m in new investment and create up to 5,000 highly-skilled jobs, over the next five to ten years

Attracting inward investment

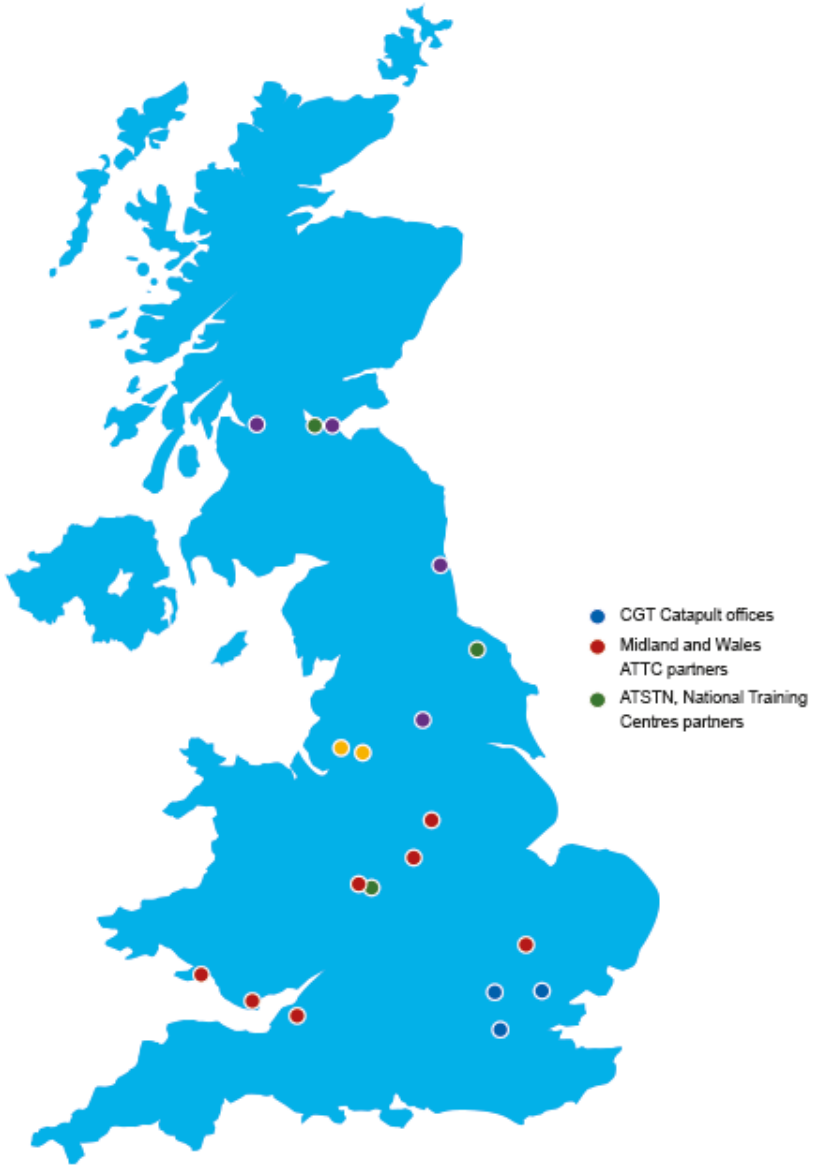
Attracts inward investment from international companies

- **German CDMO**, Rentschler Biopharma selected Stevenage MIC as location for ATMP Centre of Excellence



*Biotechnology as defined by SIC code 72110 Source: Beauhurst courtesy of Hertfordshire LEP
Graph reference: SBC Economic Impact Report https://www.stevenagecatalyst.com/impact/economic-impact-report/

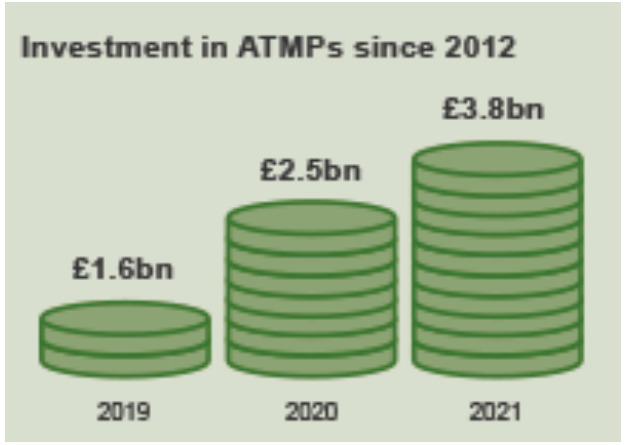
Impact: Building on investment to deliver a thriving industry across UK

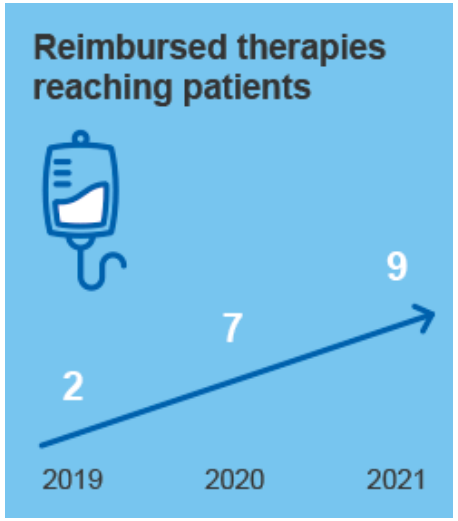


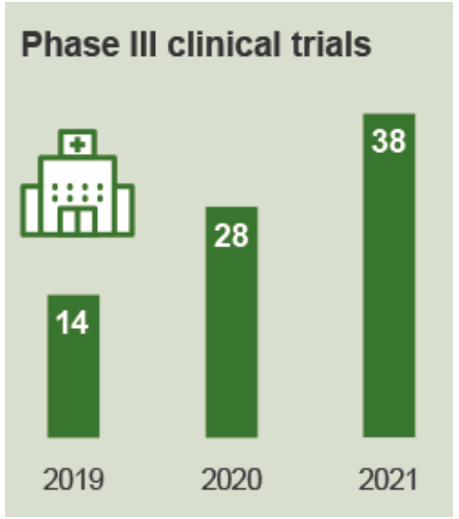
- Partnering with DIT to deliver inward investment through the High Potential Opportunity
- Building pipeline of facilities for emerging companies with MedCity
- Leveraging pharmaceutical quality system and operational model to support Sheffield GTIMC viral vector hub
- UK wide engagement with industry, NHS, academia and local government to deliver UK-based manufacturing and supply chain
- Engagement with Scottish Enterprise, Northern Health Science Alliance (NHSA) and DIT Northern Powerhouse to support growth of Northern advanced therapies cluster
- Engagement with SELEP to develop cluster around Braintree MIC
- Close working with Hertfordshire LEP and Stevenage Bioscience Catalyst to deliver Stevenage as a STEM town
    - Cell and Gene Therapy Cluster Action Plan

The UK cell and gene therapy landscape in 2021

- The UK: place of choice to set up ATMP activities
- Therapies are reaching patients
- Significant growth and investment despite the COVID-19 pandemic







29% European ATMP companies operating in the UK

99 advanced therapy developers

11 global pharmaceutical companies developing ATMPs with UK presence

26 GMP manufacturing facilities

12% of global ATMP clinical trials represented in the UK

20% increase in clinical trials in the UK compared to previous year

12 EMEA licensed ATMPs available

UK Largest cell and gene therapy cluster outside the US

Data to April 2021

ct.catapult.org.uk/annual-reviews

Sustained, Policy driven, favourable UK ecosystem

CATAPULT Cell and Gene Therapy

Questions?

CATAPULT
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UKRI Innovate UK

Advanced Therapy Treatment Centres

ATTC Network Coordination

Jacqueline Barry

Cell and Gene Therapy Catapult
July 2022

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UK Research and Innovation

Coordinated by

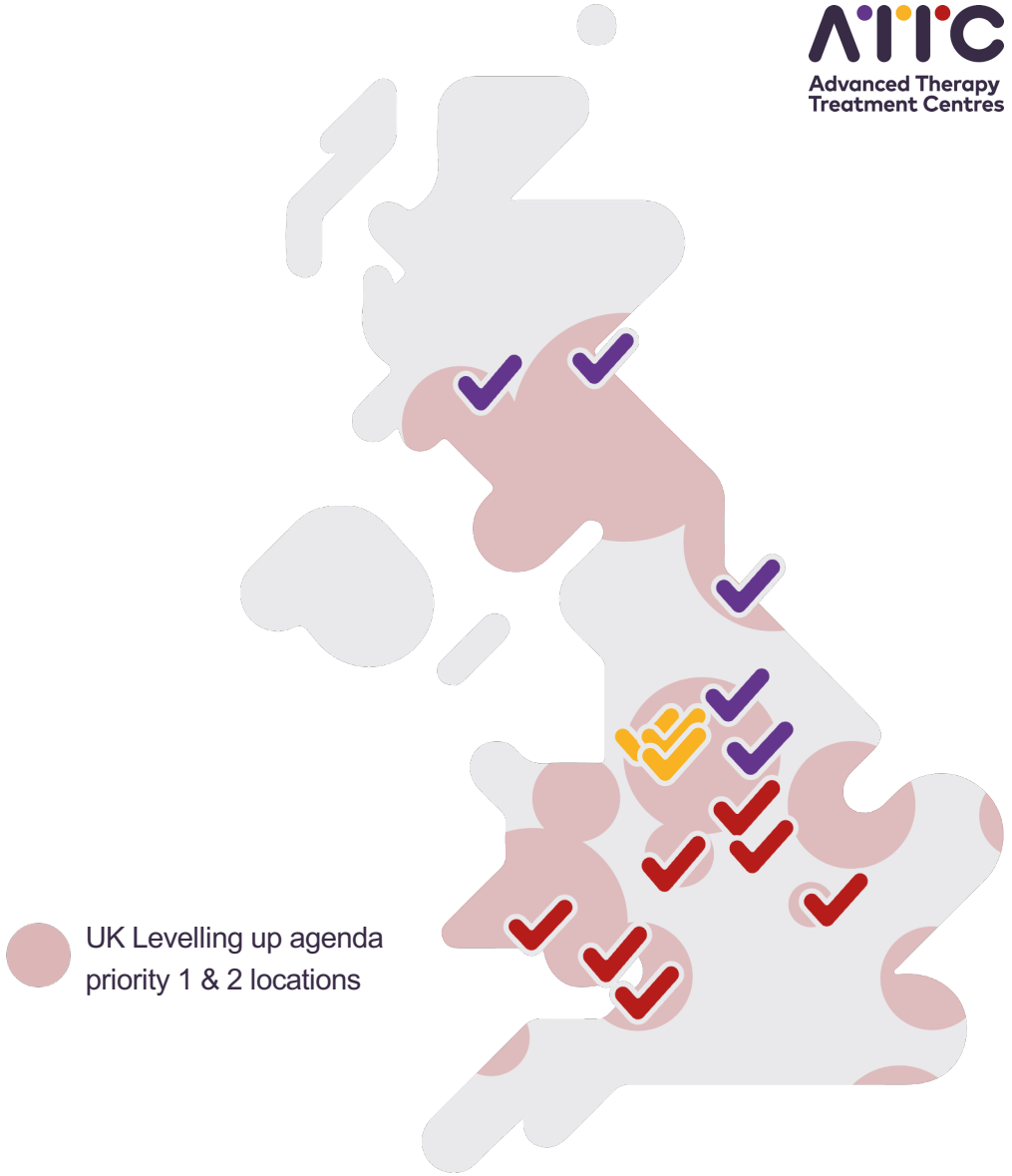
CATAPULT Cell and Gene Therapy

ATTC
Advanced Therapy Treatment Centres

The ATTC network, coordinated by Cell and Gene Therapy Catapult, was founded in 2018 to find innovative solutions to the unique and complex challenges associated with delivery of pioneering advanced therapy medicinal products (ATMPs)

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

The network involves over 800 people across industry, the NHS and public sector who work together to develop the necessary processes and infrastructure required to increase patient access to these potentially life-changing medicines.



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Northern Alliance Advanced Therapies Treatment Centre
Midlands-Wales Advanced Therapy Treatment Centre

Coordinated by
CATAPULT Cell and Gene Therapy

The ATTC network has demonstrated impact across six core areas through industry led innovative solutions

1

Commercial growth and attractiveness

The ATTC network has improved the UK's global reputation for ATMP supply and adoption, attracting greater inwards investment to grow the UK ATMP pipeline

2

Engagement and collaboration

The ATTC network, as the final segment in the supportive UK ecosystem for ATMP, has facilitated diverse collaboration across stakeholder groups

3

Leader in international standards and best practices

The network's focus on standardisation, covering the entire ATMP supply pathway, has cemented the UK's international reputation and promotion of global best practice

4

Clinical trials and patient access

Patient access to ATMPs has increased as a result of ATTC trial support, increasing the attractiveness of the UK for the conduct of clinical trials

5

Manufacturing, supply chain and logistics

ATTC network improvements to supply chain and logistics processes have increased patient access to ATMPs and made the UK more attractive to manufacturers

6

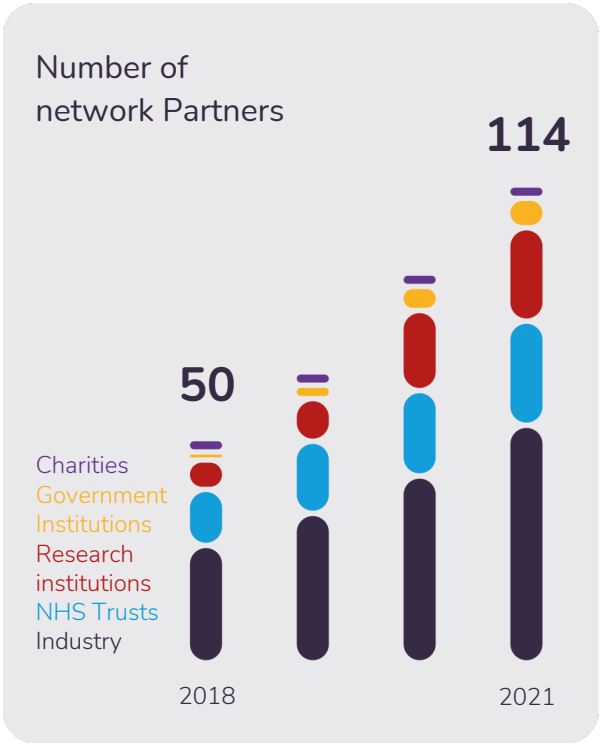
Education and workforce

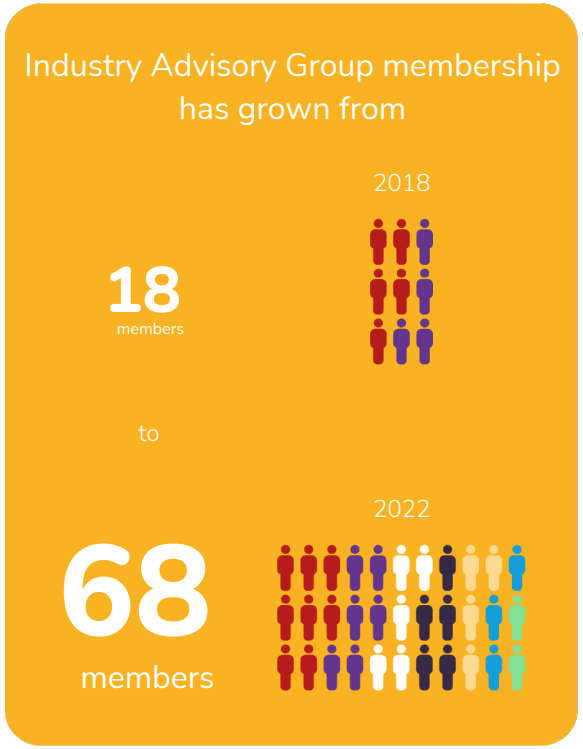
The ATTC network has played a huge role in upskilling the UK ATMP workforce and has created multiple educational resources to support UK institutions in ATMP delivery

Collaboration driving commercial growth and attractiveness

Advanced Therapy Treatment Centres

The value driven through multi-stakeholder collaboration within the ATTC network has improved UK's reputation globally in the ATMP arena





> **The ATTC network is an exemplar for how industry can collaborate with the NHS and service providers to support delivery of care to patients – Autolus**

> *The Industry Advisory Group is an essential* ***expert network to ensure companies are able to navigate challenges and barriers speedily*** *as we bring innovative, but at times complex, treatments to the UK market – Gilead*

Coordinated by CATAPULT Cell and Gene Therapy

The ABPI welcomes the work undertaken by the ATTC network to drive standardisation and alignment across the UK's ATMP ecosystem. These ongoing efforts are vital to maintain the UK's position as a leading destination for ATMP manufacturers – ABPI

If the UK is to retain its leading role in the development of innovative treatments like cell and gene therapies, it is essential that we are able to deliver these life-changing treatments to the patients who need them. The ATTC network will have an increasingly important role to play in ensuring the NHS has the capacity and capability to deliver these new treatments – UK BioIndustry Association (BIA)

ATTC Industry Advisory Group

Advanced Therapy Treatment Centres

Objectives	Membership
Support and inform the ATTC network's activities.	ATMP Manufacturers
Develop the ATMP industry.	Clinical Research Organisation
Identify, discuss issues affecting the ATMP ecosystem.	Logistics Providers
Collaboratively develop solutions	Digital Solution Developers
Develop standards for the future.	NHS Trusts
	Government Bodies (NHSE, MHRA, HTA, NICE)

Growth

	2018	2022
Companies	18	68
People	20	>180

Procurement & Labelling
Standardising procurement data capture

ATMP Adoption
Consultations: NICE Methods, NHSE IMF
Consensus Paper on NHS ATMP preparedness
National Cell and Gene Therapy Vision

Clinical Trials
New draft Model Clinical Trials Agreement
Standardisation of ATMP QTAs
Costing Guidance

GMOs Streamlining
Documentation covering handling GMO

IAG Membership in 2018: Autolus, Imetacyte, Novartis, Bluebird, Cell Medica, Aptus, World Courier, Trackcel, GE Healthcare, Terumo, Dignio, Gilead, Rexgenero, Chiesi, Agentus, Orbsen Theraputics, Roslin, ABPI

Coordinated by CATAPULT Cell and Gene Therapy

Collaboration driving increased patient access

ATTC network representation in global ATMP trials has more than doubled since the programme began

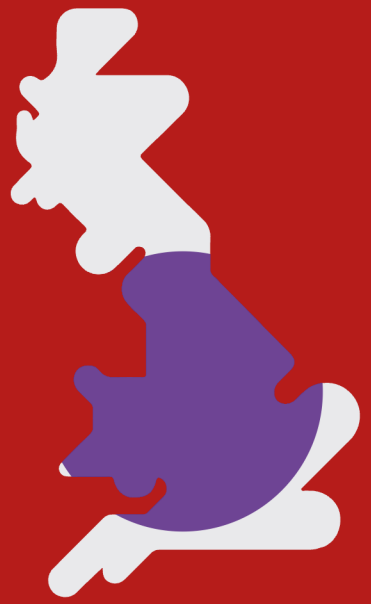
Advanced Therapy Treatment Centres

Number of ATTC network supported ATMP trials

2018

31 trials

36% of UK
2% representation of global



2021

92 trials

55% of UK
5% representation of global*

~£74m

NHS income received from commercially sponsored ATMP trials p.a. [1]

3 products commercialised through the ATTC network

14 ATMP enabling products adopted into clinical practice

> **ATTC network has helped boost the UK's reputation internationally for investments through the inclusive approach Cell and Gene Therapy Catapult has taken** – NHS England

Coordinated by CATAPULT Cell and Gene Therapy

* This has reduced from 7% in 2020 due to the addition of new data to Alliance of Regenerative Medicine Global data

Collaboration driving increased UK's reputation globally

Advanced Therapy Treatment Centres

The ATTC network has developed the NHS readiness toolkit to aid treatment centres in the delivery of ATMPs to patients

- Common platform for ATMP industry and healthcare stakeholders, from what was previously a highly fragmented landscape.
- Through pan-industry and NHS collaboration, materials and resources developed
- Increased the UK's reputation as a leader in ATMPs

17,787

Number of times the NHS Readiness Toolkit has been accessed across

43 countries

Coordinated by

CATAPULT Cell and Gene Therapy

* Data as of March 2022

Preparing for the future of advanced therapies

The need for a National Cell and Gene Therapy Vision for the UK

ATTC Advanced Therapy Treatment Centres

Document commissioned by the Cell and Gene Therapy Catapult and funded equally by Innovate UK (I-UK), Astellas Gene Therapies, Bristol-Myers Squibb, Gilead and Novartis

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INDUSTRIAL STRATEGY
UK Research and Innovation

Coordinated by
CATAPULT Cell and Gene Therapy

The Medicines Manufacturing Innovation Centre Journey

Katie Murray
Technical Director
Medicines Manufacturing Innovation Centre, CPI

Mission

Accelerate pace of manufacturing innovation through understanding the needs of:

- Patients (rapid translation of medical science to benefit)
- Industry (ensure access to medicines via agile, secure supply chains)
- Regulators (ensure patient safety)

Productivity

Compliance

Carbon footprint

Community and collaboration

Health excellence

Skills strategy

Part of UK Government Strategy to ensure Pharma manufacturing technology is fit for the future

University of Strathclyde Glasgow

cpi

www.uk-cpi.com/mmic

What Medicines Manufacturing Innovation Centre will deliver to the Life Sciences Sector

The centre provides innovative solutions to industry-wide technology challenges, maximises digital technology opportunities and reduces the environmental impact within the pharmaceutical supply chain (3 Year Strategy Document)

Skills and capabilities

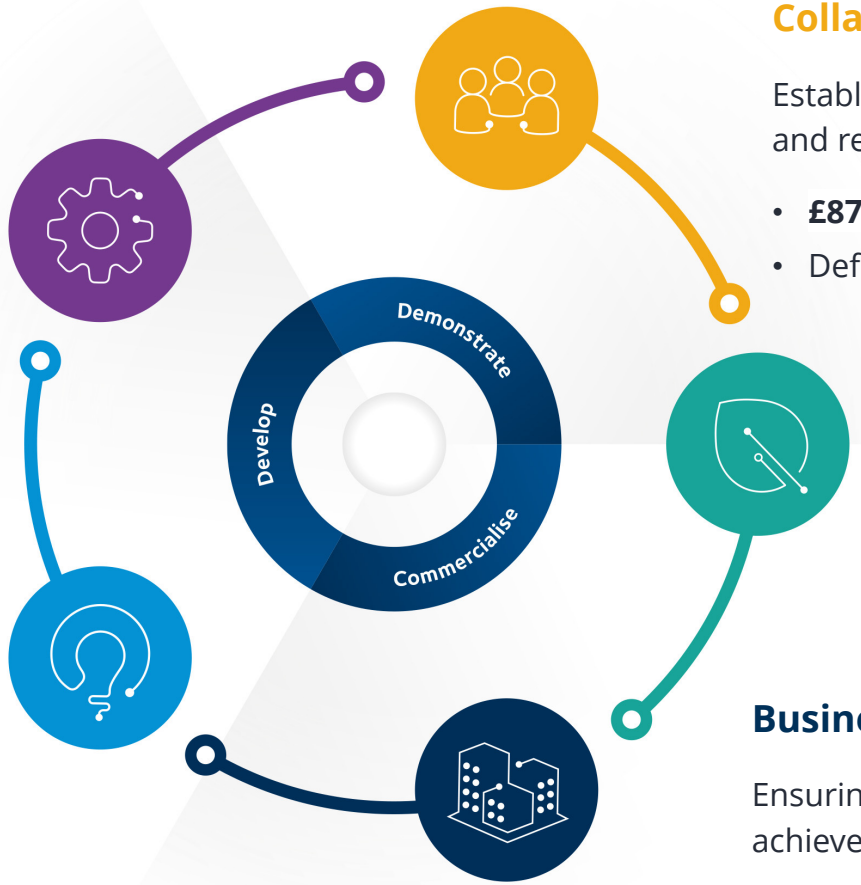
Enabling the development and sustained deployment of the technology into the wider ecosystem

- Deliver a coordinated, holistic skills and capability roadmap

Commercialisation of advanced technologies

Addressing industry's greatest manufacturing challenges through our technology innovation

- Evolve with intent into new technology areas
- Build out our digitally connected supply chain narratives



Collaboration and partnerships

Establishing and fostering relationships to accelerate and realise the full value of the technology

- **£87m secured from 22 Partner organisations**
- Define regulatory strategy and plan

Sustainable technology leadership

Promoting a sustainable future for the industry

- Drive net-zero through innovation leadership
- Articulate and benchmark the environmental impacts from the Grand Challenges

Business growth

Ensuring we have the resources and investment to achieve our bold ambitions

- Capitalise on our assets and capabilities
- Diversify our external sources of funding

University of Strathclyde Glasgow

cpi

www.uk-cpi.com/mmic

Medicines Manufacturing Innovation Centre partners

Founding partners

cpi

University of Strathclyde Glasgow

Scottish Enterprise

UK Research and Innovation

AstraZeneca

GSK

Technology partners

CMAC Future Manufacturing Research Hub

CME

PSE

EXACTMER

Applied Materials

Gerlcke

SIEMENS

Stream Native

DFE pharma

// WYOMING

NPL National Physical Laboratory

Pharmaceutical partners

Pfizer

NOVARTIS

Alnylam Pharmaceuticals

Quotient Sciences

Business partner

pwc

MMIC Facility: Design and Build in Glasgow

- **Key Stats**
  - Cost: £26m
  - Programme: 22 months (Sep '20 to Jun '22)
    - Ground-breaking event - Oct '20
    - Topping out event – Aug '21

- **Project Delivery**

Challenges	Mitigation
Covid: Major impact on cost (+40%); volatile supply chains; remote working	Further funding from IUK; delivery schedules carefully managed, design options; experienced team
First developer on AMIDS: Major impact on programme (+ 4months) and significant impact on cost (+£1.5m)	Working closely with Renfrewshire Council and utilities companies, use of temporary utilities; further funding from IUK and SE
Design for flexibility and future proofing while GCs 1&2 being defined and remainder of GCs unknown at the outset	Design input from GCs, founding partners, MHRA. Cleanroom area is column free, flexible services from above, built for expansion

MMIC Business Model: What is a Grand Challenge?

A £MMs, ambitious project which industrialises new technology to transform the manufacturing of medicines

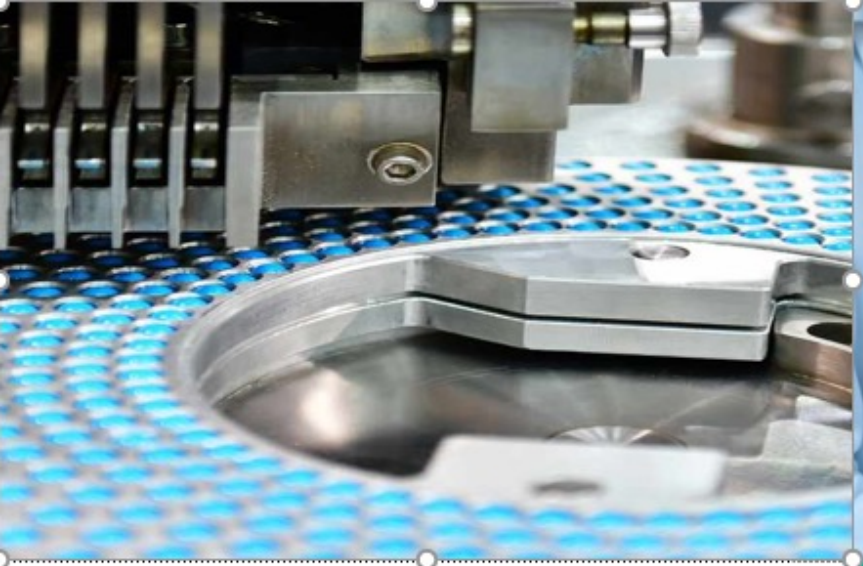
Collaboration between pharma companies, technology companies, academia and Government.

Challenge areas defined by partner input, cross-industry groups, ideation events, government strategy, academic proposals etc.

Strong skills development agenda, to deliver the workforce required for Pharma 4.0

Enabling new 'disruptive technologies' to be proven at scale in a GMP-representative environment:

- Modular designs for continuous manufacturing
- Digital product and process design & operation
- PAT- and digitally enabled real-time quality control
- Supply chain integration



GC1 – Continuous and Mini-Batch Direct Compression Digital Test-Bed

We believe stream-lined, agile formulation technologies and digital twins should be employed in drug product development and commercial manufacture, thereby reducing the development burden, cost to patients and carbon footprint of medicines production

GC2 – Automated Clinical Trial Packing & QP Release Platform

We believe patients deserve faster and cheaper supply of clinical trial medicines, with much less waste

GC3 – Cost Effective & Sustainable Oligonucleotide Manufacturing

We believe a paradigm shift is needed in the manufacturing of oligonucleotides to ensure this exciting class of new medicines will be available to treat patients at affordable prices and in a sustainable way

VMIC

VMIC:

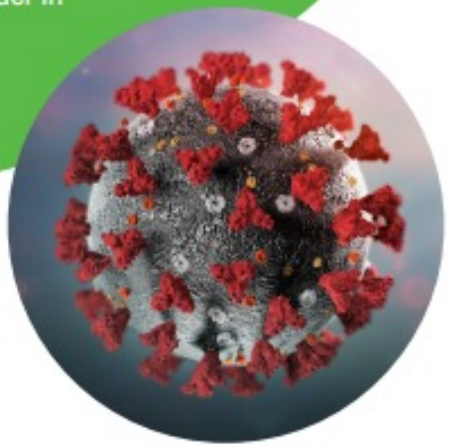
“the centre has accelerated Oxford’s vaccine programme by months and saved many lives”

Sandy Douglas

Oxford University

An agile response to COVID-19

The COVID-19 pandemic has had a major impact on health and the economy here in the UK and around the world. Vaccines are a major part of the route to recovery, and early investment in cutting-edge technologies and manufacturing has enabled the UK to become a global leader in the vaccine rollout.



Late in 2019, the world was hit by the worst pandemic in living memory. As day-to-day life began to lock down and international travel was all but halted, it became clear that the only way back to near-normality would be a mass global vaccine rollout.

By the middle of June 2020, three COVID-19 candidates were ahead of the pack: the Oxford AstraZeneca vaccine, developed in the UK, along with mRNA vaccines from Pfizer and Moderna.

A connected ecosystem acting at speed

Our integrated medicines manufacturing ecosystem enabled a nimble response to the challenge of manufacturing new vaccines at speed during the crisis. The Vaccines Manufacturing Innovation Centre (VMIC), although not yet physically completed, was able to support establishment of the clinical supply chain for the Oxford vaccine using their in-depth understanding of existing networks and infrastructure. This collaboration helped underpin the rapid clinical evaluation of the new vaccine.

Further to this a partnership between VMIC and the advanced therapy manufacturers Oxford Biomedica allowed them to quickly establish vaccine production in their existing regulatory-compliant manufacturing facilities. Oxford Biomedica subsequently signed a deal with AstraZeneca worth more than £100 million to manufacture the vaccine, securing vaccine supply for the UK population and beyond.

Early investment pays off

The seeds of this success were sown back in 2017, when the Medicines Manufacturing Challenge awarded £5.6 million to Oxford Biomedica and Cobra Biologics to advance the UK’s ability to produce viral vectors, as used in the Oxford AstraZeneca vaccine. This early investment undoubtedly helped underpin the fastest vaccine rollout in Europe.

We can draw a direct line from this early investment in the UK’s viral vector manufacturing capability to protecting our citizens and growing the economy.

Protection for the future

The UK’s rapid and successful vaccine response to COVID-19 has highlighted the value of previous investment into technologies and manufacturing that were used for vaccine production. We must now build on this foundation to ensure we are ready for the next outbreak.

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Ian McCubb
Manufacturi
Group Chai
Challenge

12:00 – 13:20 Lunch Break

Lunch (Panorama Lounge)

Networking

Automation and Robotics Exhibition (Scan room)
Posters (main auditorium)

Back at 13:20 for afternoon programme

Wifi password: wifi4072
Social Media: #MedMan2022

Innovate UK
KTN

13:20 **Welcome back!**
Session 2

Highlights of the CR&D Portfolio

Nick Medcalf
Deputy Challenge Director
nicholas.medcalf@iuk.ukri.org
12th July 2022

Multiple competitions

Two rounds of CR&D funding

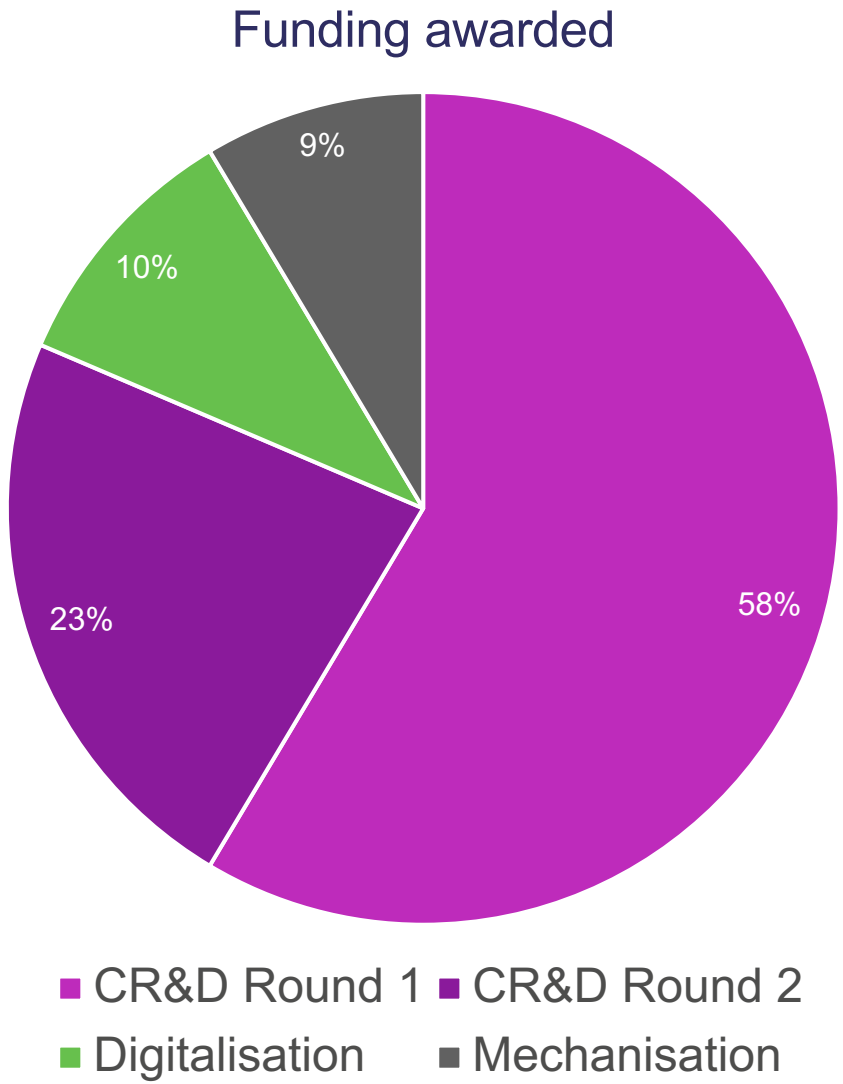
- Total of £25m allocated

Digitalisation of medicines manufacture

- Single or collaborative
- Projects in early 2019 (3-4 months)
- £8m in the fund

Mechanising and improving advanced therapy manufacture

- Collaborative only
- Projects 2020-21 (12-14 months)
- £3.7m in the fund



UKRI Innovate UK

Overview

Themes	Instances
Novel process/process improvement/increase yield	10
Integration/closed system/automation/continuous	9
Cell therapy/autologous/small batch	8
Novel formulation/3D printing/tablets	6
Manufacturability/cell free	5
Real time test/potency assay	3
Viral vectors	2
Highly potent	2
Bacterial spore/phage	2
mAbs	2
Microfluidics	1
Circular economy	1
Supply chain	1
Vaccines	1

UKRI Innovate UK

Accelerating QC (1) [105852]

Mechanising and improving advanced therapy manufacture

- **Lead Organisation:** Cytera Cellworks Ltd
- **Project Title:** Automated cell culture for batch release assays
- **Challenge:** Assays for efficacy of ATMPs are frequently cell-based, take weeks to perform and depend on human operators working in controlled environments.
- **Innovation:** Assays automated for three gene therapy candidate products one of which was already approved.
- **Impact:** **Reduce unnecessary batch failure and cost of QC.** Allow more rapid transfer to multiple sites.

UKRI Innovate UK

Cytera CellWorks

Orchard therapeutics

Accelerating QC (2) [105851]

Mechanising and improving advanced therapy manufacture

- **Lead Organisation:** Pharmaron (Allergan at time of award)
- **Project Title:** Assessing process analytical technologies (PAT) for process monitoring and modification of viral vector manufacture processing.
- **Challenge:** Increase scale and reproducibility of processes to manufacture AAV.
- **Innovation:** Emphasise reproducible instrument outputs and feedback to process control. Replace conventional time-consuming and labour-intensive wet-biochemical techniques.
- **Impact:** **Reduce waste and operating costs, increase scale-up speed**, strengthening corporate competitiveness.

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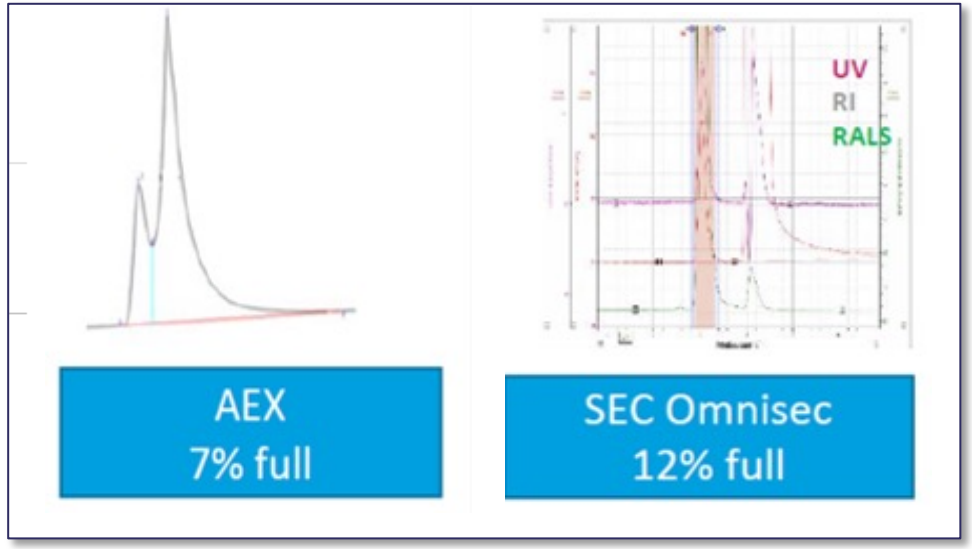
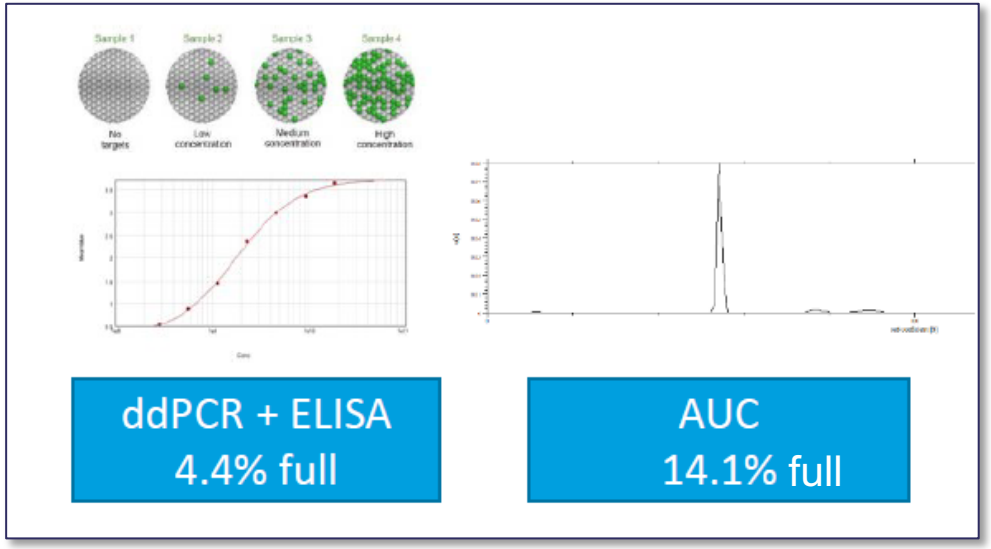
康龙化成 PHARMARON

CATAPULT Cell and Gene Therapy

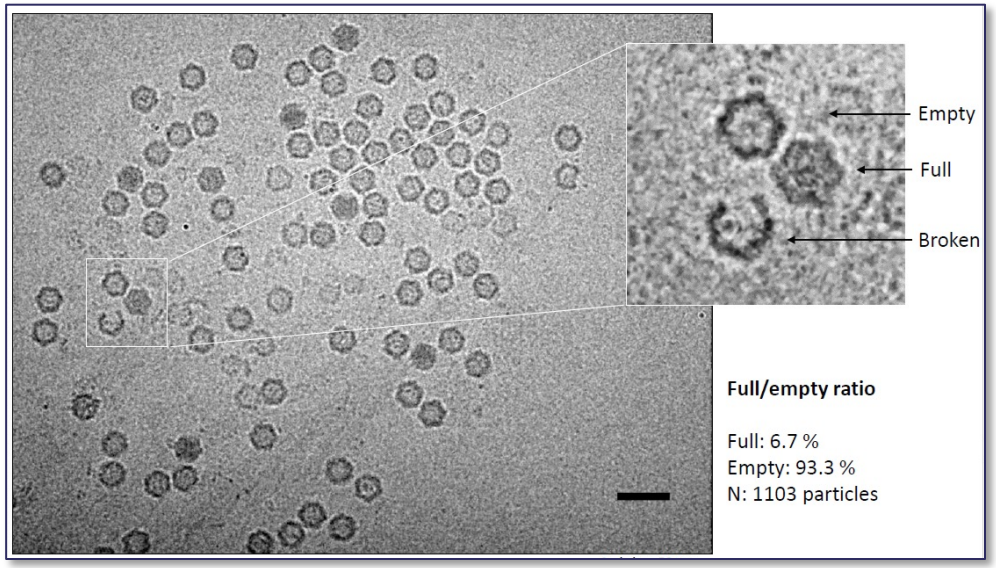
NPL National Physical Laboratory

Validation of in/at-line results: Viral full particle percentages at harvest





- Comparison of in-line SEC Omnisec and off-line anion exchange chromatography
- Pharmaron Off-line: ELISA-based approach (4.4 %) and Analytical ultra centrifugation (AUC) (14 %)
- NPL: Cryo-electron microscopy (6.7 %)



Accelerating QC (3) [104196]

Collaborative R&D Round 1

- **Lead Organisation:** Teraview
- **Project Title:** Terahertz real-time release testing for pharmaceutical products
- **Challenge:** Introduce a rapid, non-destructive alternative to current tablet tests.
- **Innovation:** Develop a new test instrument that predicts tablet efficacy and performance, based on measurements of tablet porosity using terahertz light.
- **Impact:** **Real-time, in-line test and feedback mechanism** as the industry moves towards Continuous Manufacturing.

UKRI Innovate UK TeraView gsk Huxley Bertram UNIVERSITY OF CAMBRIDGE

Improved processes (1) [104197]

Collaborative R&D Round 1

- **Lead Organisation:** Ixaka (formerly Rexgenero)
- **Project Title:** Cost-driven process redesign, automation and scale-out for commercial manufacture of REX-001 therapy
- **Challenge:** Supply was limited by ability to manufacture and deliver sufficient doses in a robust, cost-effective manner, transportation logistics and shelf life. **Innovation:** Automated needle-to-needle supply chain management and extended shelf life.
- **Impact:** **Increased availability** to the many patients who are likely to benefit and increased usability at the hospital.

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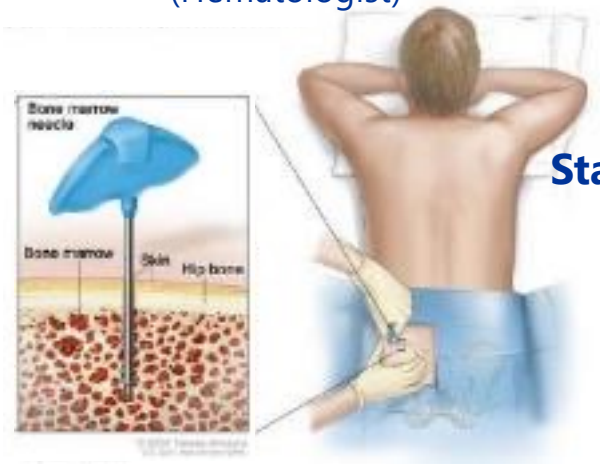
ixaka CATAPULT Cell and Gene Therapy ThermoFisher SCIENTIFIC TrakCel

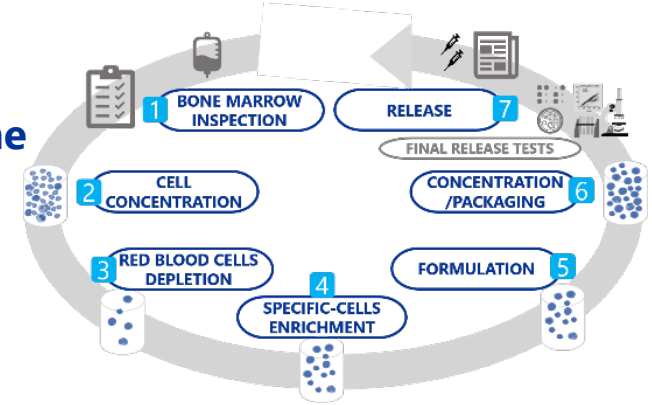
REX-001: autologous cell therapy for CLTI

Bone marrow extraction
(Hematologist)



Stabilized bone marrow

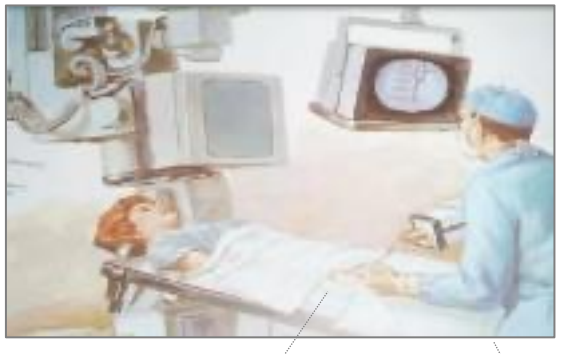
Ixaka proprietary manufacturing process

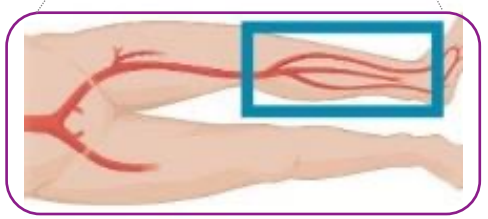


- **6-hour turnaround**
- **Patient treated within two days**

REX-001

Therapy infusion
(vascular surgeon)

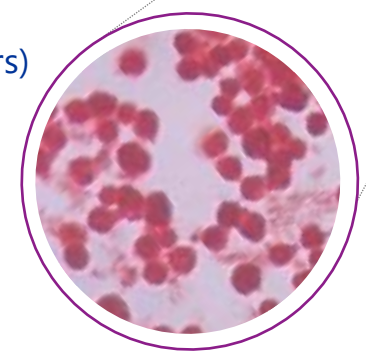




Intra-arterial administration

Synergistic combination of active cells

- CD34+/CD45+ cells (progenitors)
- CD34+/CD133+ cells (EPCs)
- Endothelial cells
- Monocytes
- Lymphocytes
- Regulatory T cells
- Granulocytes



UKRI Innovate UK

ixaka

Improved processes (2) [104523]

Collaborative R&D Round 1

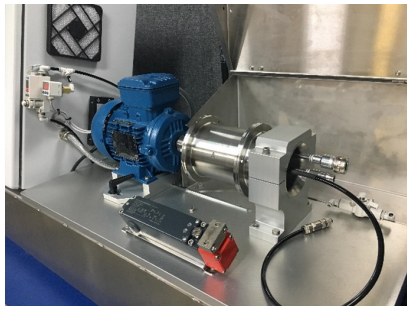
- **Lead Organisation:** Aston Particle Technologies (APT)
- **Project Title:** A Novel and Improved Commercially Viable, Cost -Effective Manufacturing Process for Fixed Dose Combination Dry Powder Inhaler Formulations
- **Challenge:** Few processes for particle surface modification do not adversely affect the properties of the core particles. State-of-the-art blending technologies are often unsuitable for processing sensitive APIs or lead to variable product.
- **Innovation:** A novel dry particle coating process (APT-Hale®), which could be a game-changer.
- **Impact:** This simple and relatively **easy to implement platform for scale up** could eventually lead to registration of a suite of generic FDC inhalers.

Innovate UK

Aston Particle Technologies Ltd (APT)

- APT spin out from Aston University Drug Delivery Group
  - Commercialising a disruptive, patented powder coating / blending technology
    - ***Isothermal Dry Particle Coating (iDPC)***
- Innovate UK Support
  - iCURe grant-facilitated incorporation 2016
  - Three further grants including
    - **Medicines Manufacturing 2017**

    Developing patient friendly 'Fixed Dose Combination' Dry Powder Inhalers
    - Multiple drugs in a single formulation for use in Controller Medication
      - Contract work with a large generic Pharma company
      - Fundamental work with two further Big Pharma companies
      - Multiple presentations to other major companies with inhalation portfolio
      - Interest in wider applications (e.g. with major CDMOs)



- APT have been able to raise ~£1million in April 2022 to further exploit iDPC

Isothermal Dry Particle Coating

Aston Particle Technologies Ltd

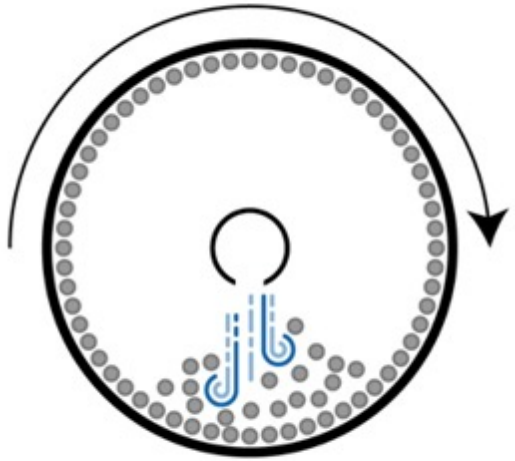
Key Features (already known)

Broad applicability to powder types:
- Hydrophobic / hydrophilic / crystalline / amorphous / biological
- Particle size from nano to 0.5mm
- Wide concentration range – 0.1 - 80% $^{w}/_{w}$

Simple manufacturing technology:
- 3 critical process parameters
- Environmentally friendly
- Cost effective

Direct manufacturing scalability:
- Benchtop R&D (1-20g) to
- Pilot (100g-2kg)

Simpler supply chains:
- Utilise off the shelf material
- Reduced cycle time
  - Easier handling (no quarantine) post manufacture



Aston Particle Technologies Ltd.
Aston University
Aston Triangle
Birmingham
B4 7ET

info@astonparticletechnologies.com
+121 204 4183

Support from Innovate UK has enabled case study generation

Medicines Manufacturing Data Packages:
- New standards in double drug combinations
- Simpler access to triple combinations

Broader Capability in Dry Powder Inhalers:
- Single drug e.g. high dose
- Multiple drug (Fixed Dose Combination)
  - formulation stability
  - simplified manufacture

Exploitation:
- Fixed Dose Combination project with large Generic Pharma
  - Stable performance in Innovator device
  - Follow on projects

Higher Scale manufacture (Innovate Loan):
- Pipeline– Semi-continuous (10kg/hr) –

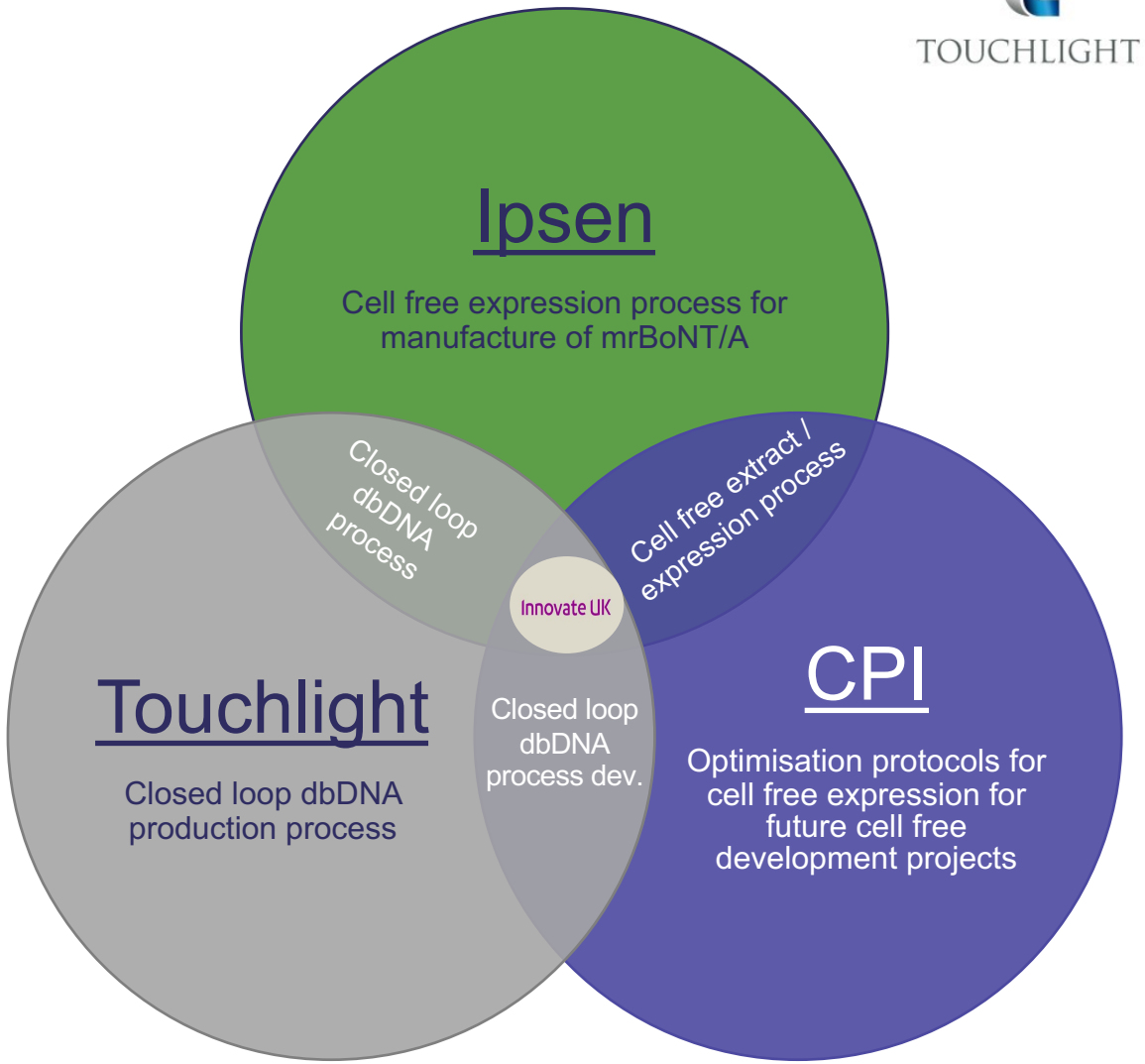
Process integration [104201]

Collaborative R&D Round 1

- **Lead Organisation:** Ipsen
- **Project Title:** Novel production process for a highly potent recombinant protein using doggybone DNA (dbDNA) vector and cell free expression technology
- **Challenge:** High potency products need minimal doses and material requirements are low. However, working with these toxic products can be problematic, and traditional manufacturing routes are often unsuitable.
- **Innovation:** Develop a closed system for producing dbDNA. Screen a range of conditions to optimise cell free expression for enclosed processing of toxins.
- **Impact:** Negate the health and safety risks and yield limitations with high potency biopharmaceutical production and reduce production costs.

Cardinal objectives of the project

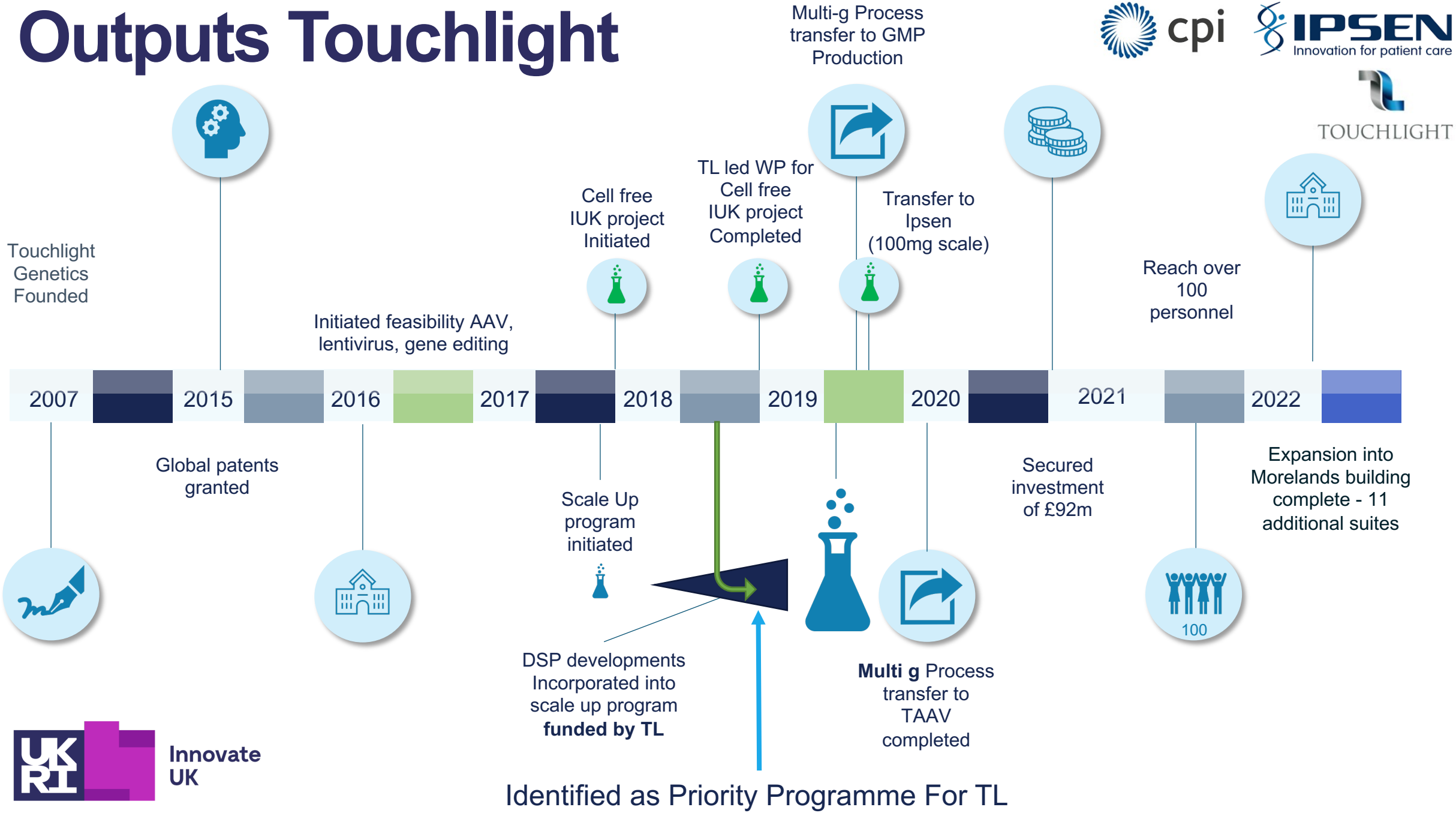
- **Main objective:**
  - Establish a production process for therapeutic proteins using a cell free expression system
- **Additional objectives for the project:**
  - Develop a scalable closed loop process to produce dbDNA
  - Develop high throughput cell free optimisation protocols



Outputs CPI

- Significant upskilling in synthetic expression and scale up enabling CPI to be at the forefront of mRNA development in UK
- Supported mRNA (vaccine and libraries) work as part of the Vaccines Taskforce
- CPI will leverage the experience and apply it to the manufacture of more complex proteins.
- CPI is interested in how Cell Free approaches could be used to revolutionise large molecule manufacture and support distributed manufacturing.

Outputs Touchlight



Innovate UK

Thank you

@InnovateUK

Innovate UK

Innovate UK

@weareinnovateuk

Autolus

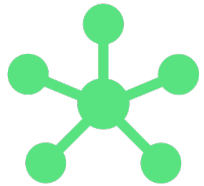
Developing Next Generation Programmed T Cell Therapies

Darren Blamire GM UK and Ireland

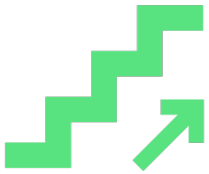
July 2022

Building a fully integrated CAR T company developing Next Generation therapies

Best-in-class lead asset



Pipeline



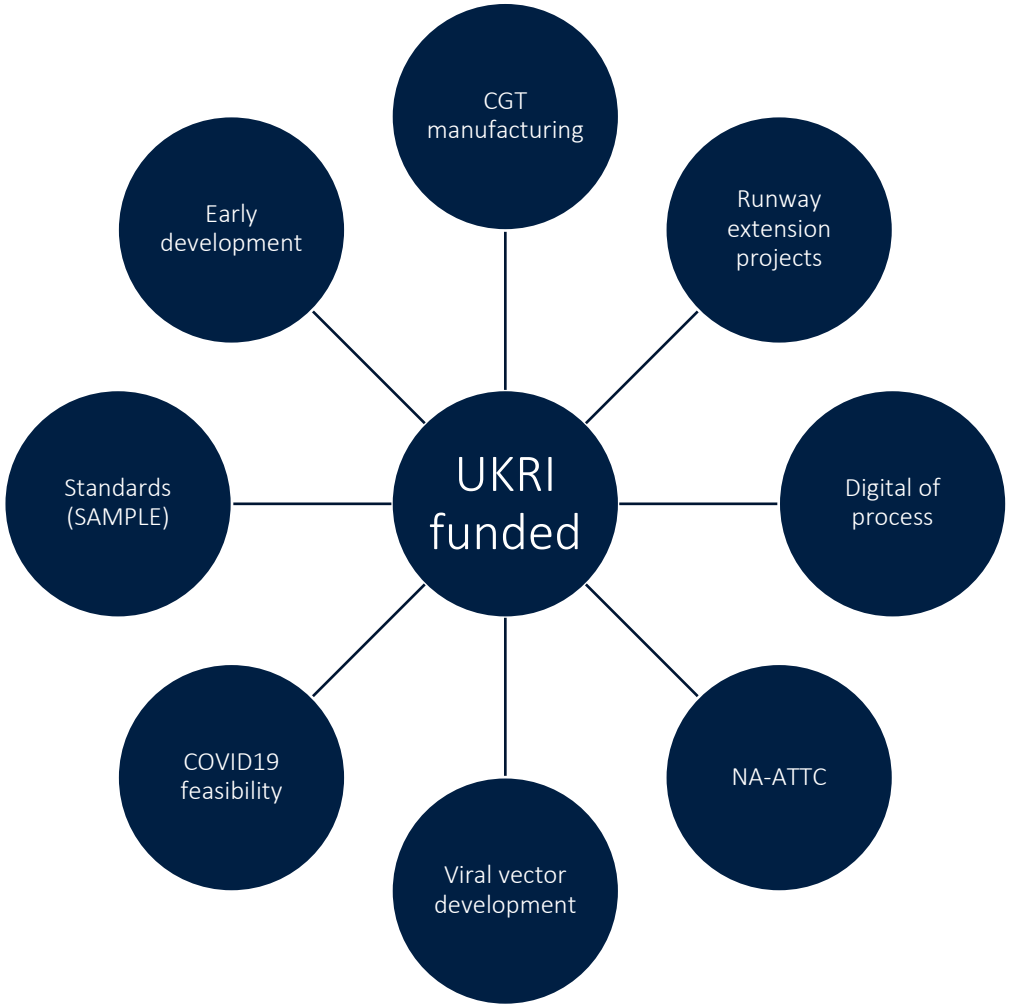
Scalable manufacturing

Collaboration

Autolus is a UK-based biopharmaceutical company developing an innovative portfolio of CAR T cell therapies. The UK is a world leader in the provision of advanced gene and cell therapies. How could a private and public partnership provide a sustainable solution for access to these therapies?

Autolus collaboration with UKRI enabled development of a world class CAR T portfolio

10 grants awarded



- Translating world-leading UK research into a highly innovative and clinically differentiated portfolio of CAR T therapies
- UKs first commercial ACGT manufacturing facility in Stevenage
- Inward investment into UK from Blackstone Life Sciences of up to $250 million to support launch of obe cel

First UK CAR T commercial facility expected to be ready for GMP operations in mid 2023

- Highly experienced team running manufacturing operations and supporting new facility build
- 70,000 ft^2 commercial facility under construction in Stevenage
  - Commercial Cell capacity of 2,000+ Batches per year
  - Vector capacity for clinical activities
  - In process and release QC – Drive down V2D time
- The Stevenage facility supports retention of key staff and build of critical mass for US and EU expansion

PHICO
THERAPEUTICS

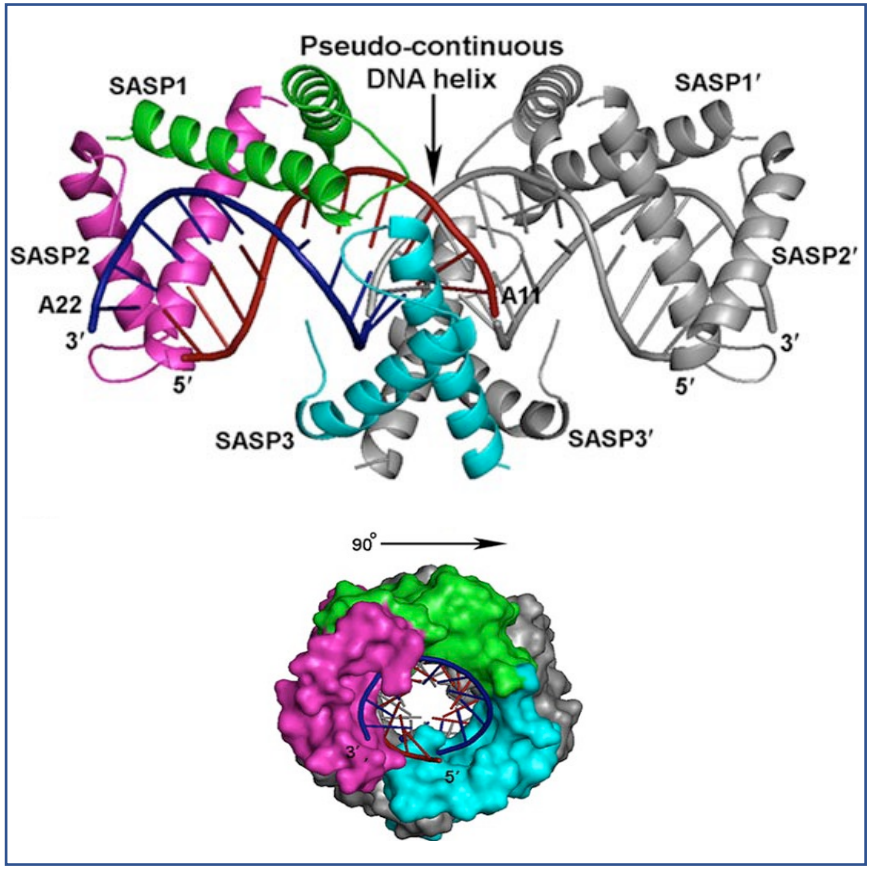
How could Phico’s technology save lives

Phico's SASPject® technology…..

- Phico is establishing proof of concept of its SASPject platform technology
  - Unique, first in class mode of action
  - Targetting high value, high clinical need markets
- Taken first intra-nasal product against MRSA through a Phase 1 clinical study
- With more than £15 M in recent funding taking first IV product against *Pseudomonas aeruginosa* (PT3) into the clinic in 2023
  - Critically enabled by Phico's IUK grant for £1.4 M to develop a manufacturing process for IV-suitable PT3 to treat vHAP/VAP

Anti-bacterial protein, SASP inactivates bacterial DNA independent of DNA sequence

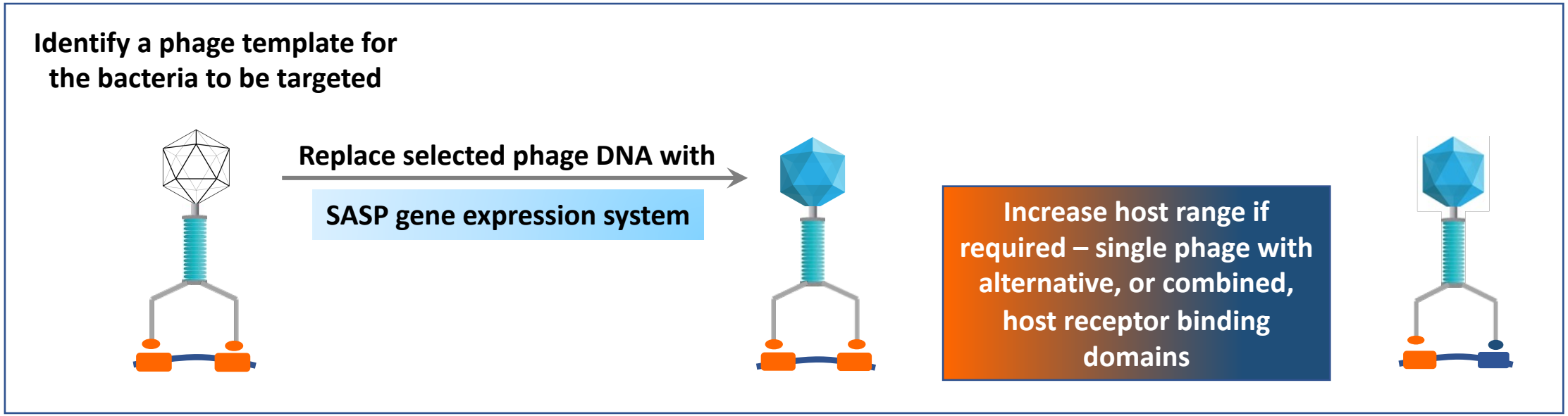
- Small acid-soluble spore proteins (SASPs) bind to and inactivate bacterial DNA
- SASPs bind to the DNA in a non-sequence specific manner
  - mutations in the DNA have no impact on SASP activity
  - halt DNA replication and, where bound, gene transcription
- Mode of action makes resistance unlikely
- SASPs do not enter mammalian or bacterial cells



SASPs shown bound to DNA

SASPject® technology delivers SASP by engineered phage delivery vehicles

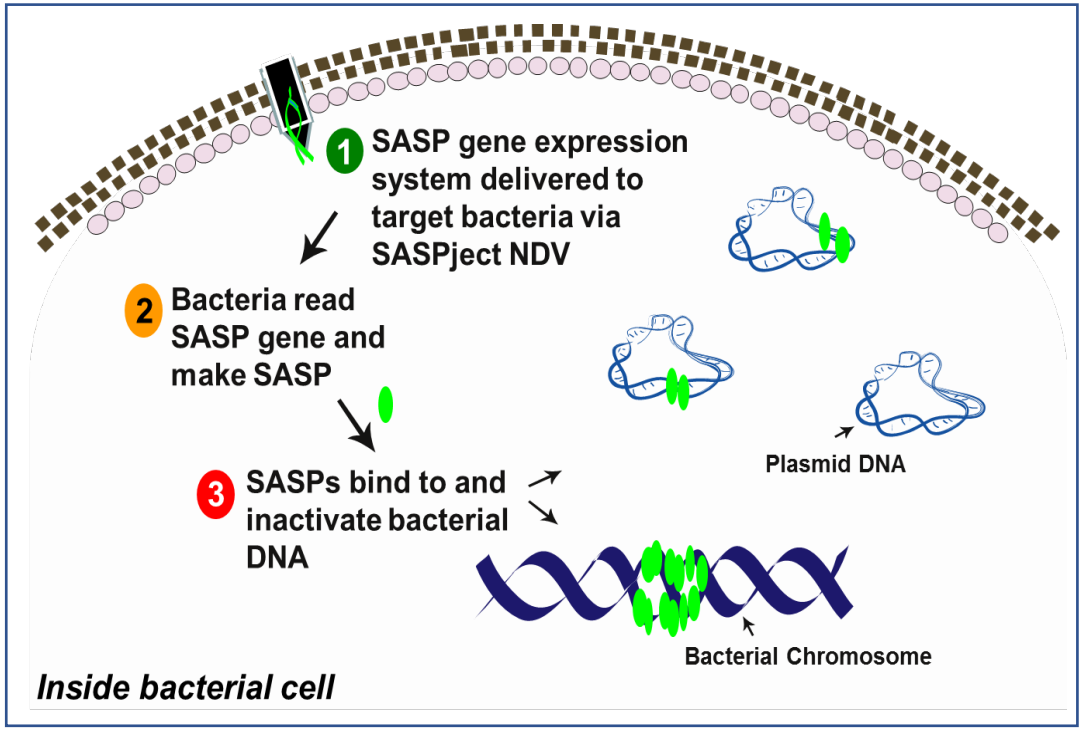
- SASPject® utilizes a single lead phage for each target pathogen and engineers it to improve its characteristics where necessary, for example optimizing its manufacturability, increasing its host range etc.



Development of engineered SASPject® phage delivery vehicles

SASPject Mode of action

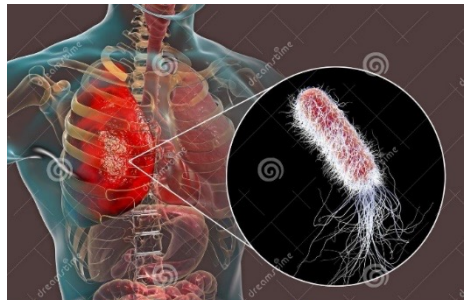
- Production of SASP uses the expression machinery of the target bacteria and commences immediately and continuously
- SASPs bind to the bacterial DNA and immediately inhibit DNA replication and gene transcription
- SASPs inactivate plasmid DNA helping to stop the spread of antibiotic resistance

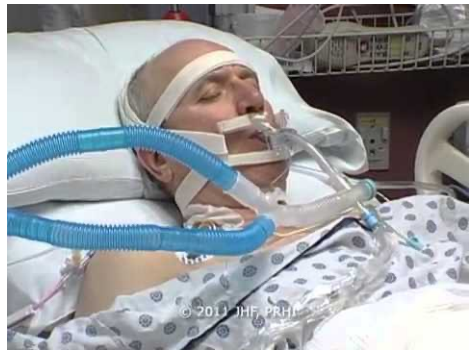


Engineered phage delivers SASP gene to target bacteria (1). Bacteria produce SASPs (2) which bind to and inactivate the bacterial DNA (3).

Our *Pseudomonas aeruginosa* program SASPject® PT3.9 - IV

SASPject® PT3.9 is focused on serious infections with few existing treatment options



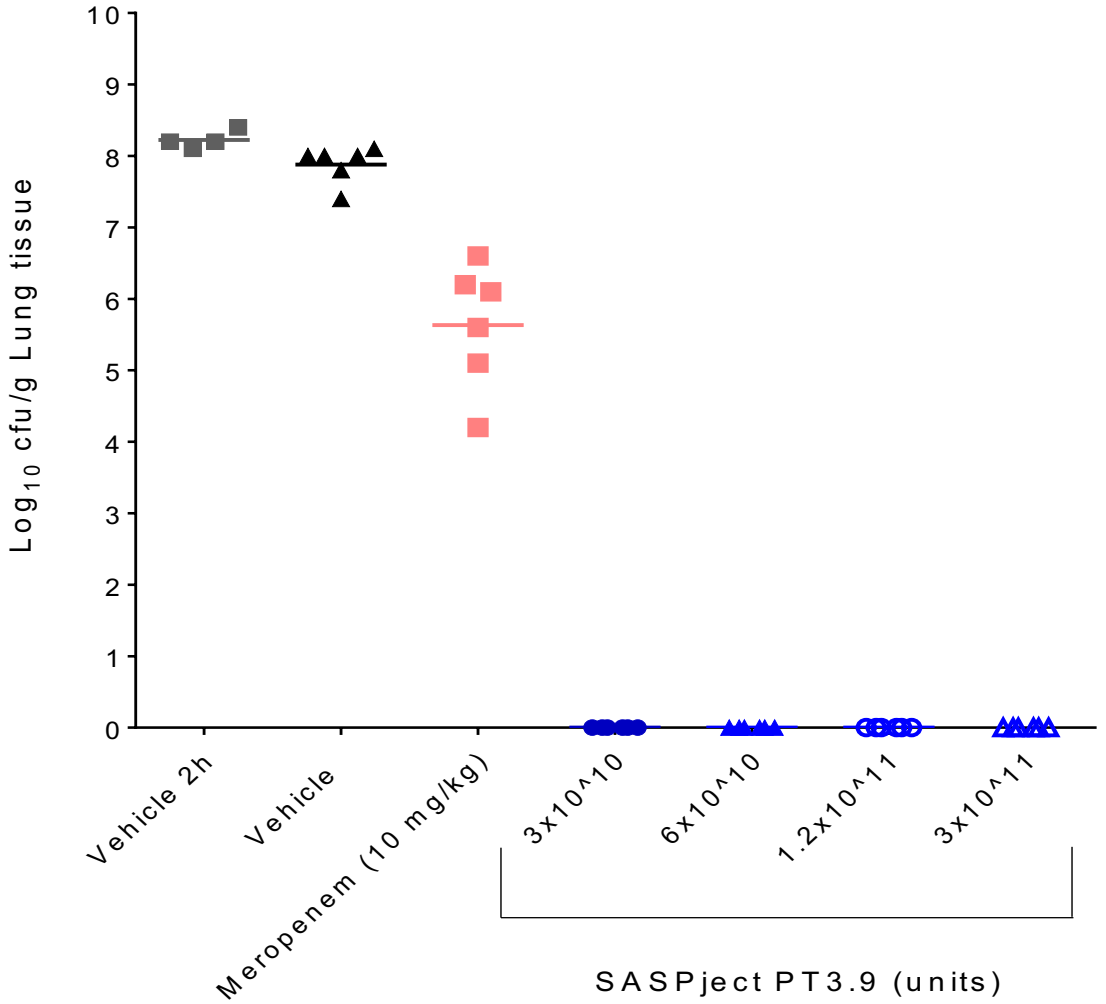


- *P. aeruginosa is* a leading cause of pneumonia in hospital patients, especially those on a ventilator
- One of the top three bacteria listed by WHO as “critical” priorities for the R&D of new antibiotics
- Causes severe and even deadly infections (around 50% mortality for *P. aeruginosa* infections)

UKRI Innovate UK

CARB-X Global Accelerator Network

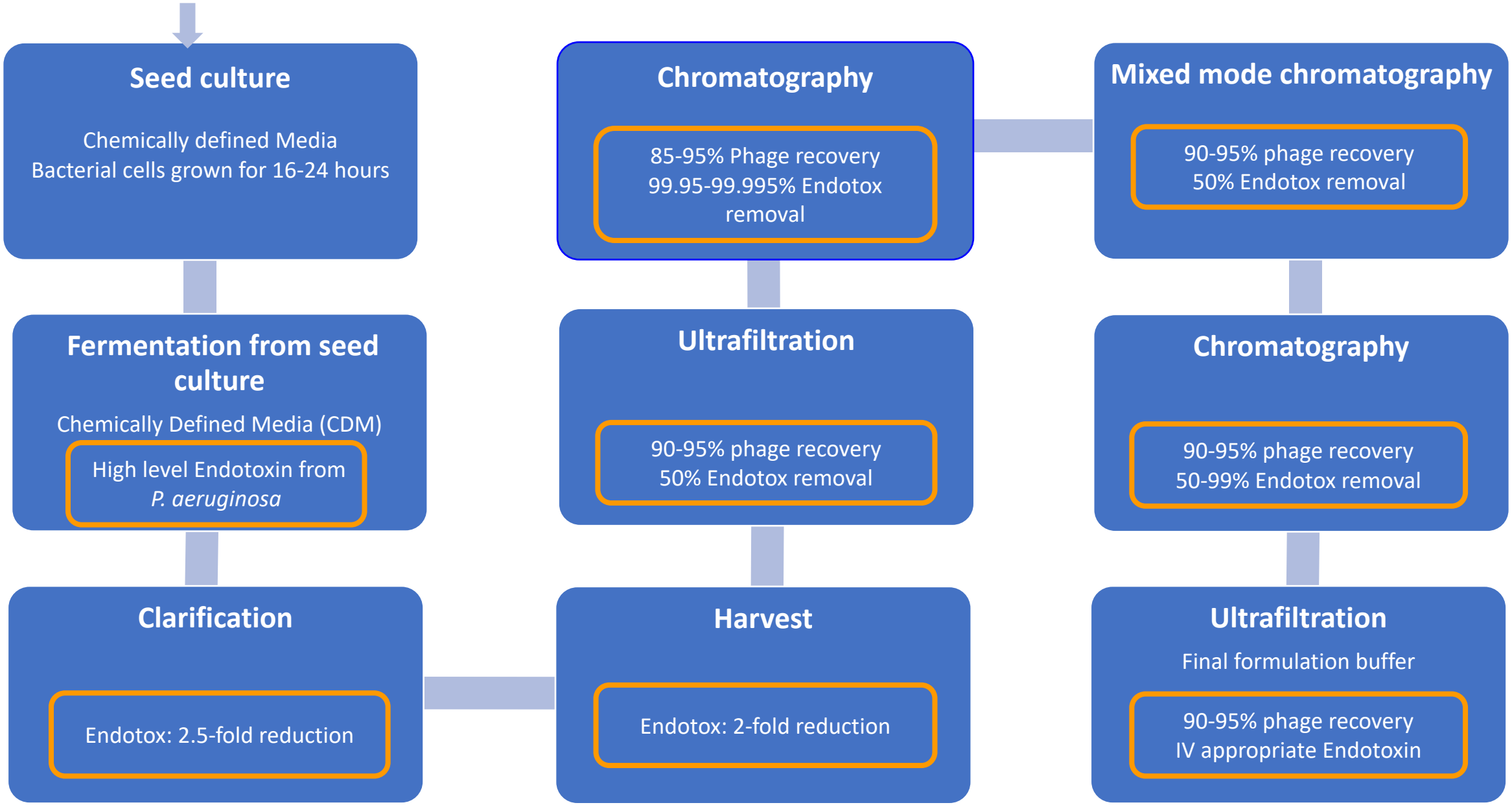
SASPject® PT3.9 (IV) activity in immuno-competent murine lung infection model



SASPject® advantages

- The unique mode of action of SASP proteins –inactivating all bacterial DNA irrespective of DNA sequence or which bacteria is being targeted
- The same SASP is used across all target bacteria ensuring the robust applicability of the platform
- Formal safety studies have been conducted with Phico's selected SASP protein
- Phico has extensive experience in engineering phages, both lytic and lysogenic
  - To carry the SASP gene and ensure SASP protein is produced immediately and continually
  - To broaden the breadth of bacterial strains that each SASPject® product targets (if necessary)
  - To remove the need for phage cocktails – each product is based around a single phage entity

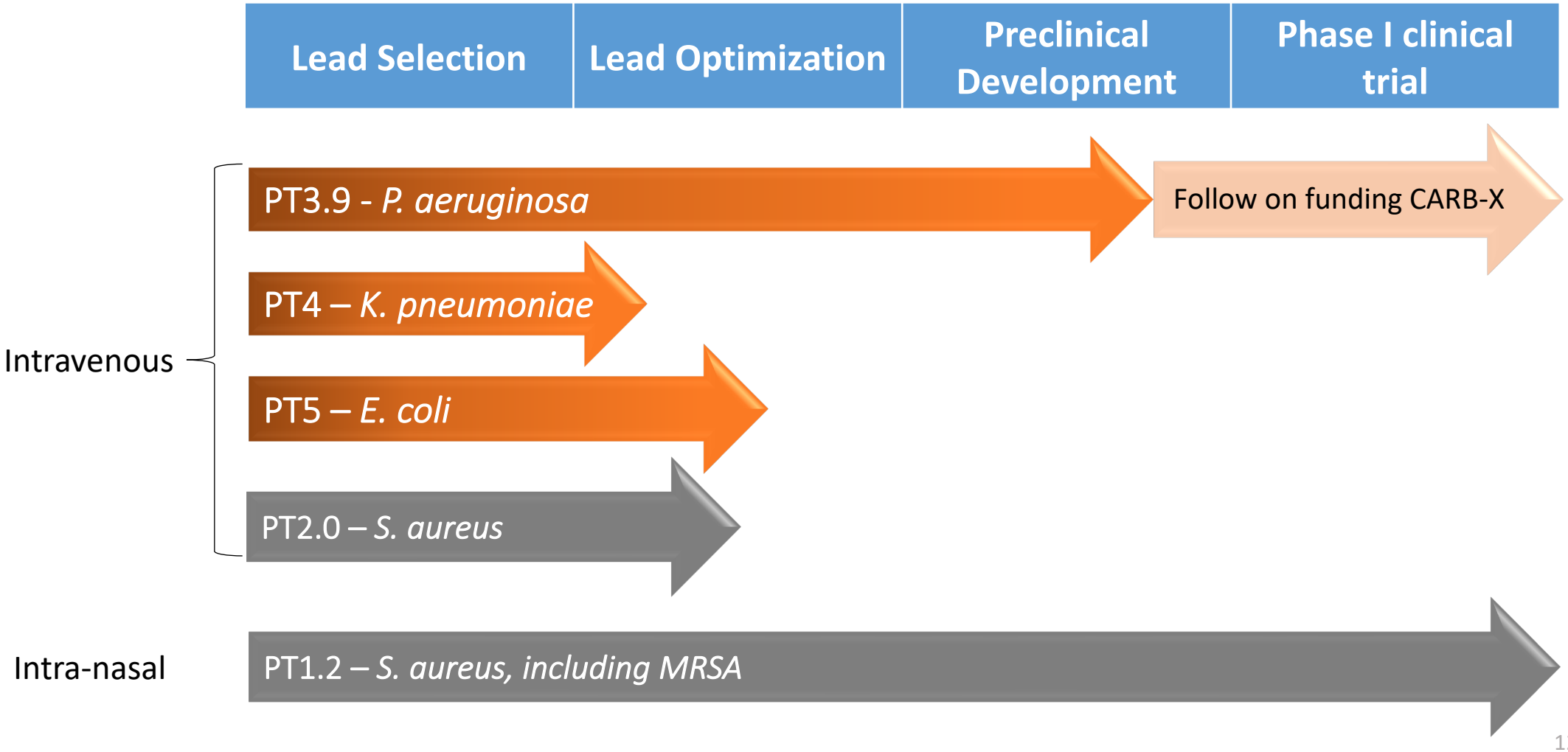
CMC process overview: Recoveries & impurity removal rates



How has funding from IUK improved our manufacturing process

- The development and use of Chemically Defined Media (CDM) in the upstream process reduces the risk of biological contaminants which are present in animal derived products
- A robust fermentation process
- Improved recovery of product at the harvest step with reduction in consumables wastage, improvement to the harvest duration along with minimal loss of product compare to the previous process
- A 50% improvement in the total amount of Endotoxin removed during the purification steps compared to the previous process
- An 85-99% improvement in phage recovery at purification steps
- 10 fold reduction in the amount of buffer used in purification steps compared to previous process

Building an Innovative Antibacterials Pipeline: Targetting World Health Organisation's global top threats



Phico's proprietary platform: Strong IP position

- SASPject® technology patent, and S. *aureus* SASPject® PT1.2 product patent
  - Granted EU/US/Australia/Japan/Canada
- 4 patent applications covering *P. aeruginosa* SASPject® PT3
- 2 applications covering techniques relating to SASPject® PT3.9
- 2 further filings April 2016
- IP position underpinned by extensive platform and manufacturing know-how

Phico has…….

- **A technology that is being exemplified for serious therapeutic applications but has wide ranging potential**
- **A team experienced in designing and developing engineered phage products and viral manufacturing processes**
- **A robust and reproducible manufacturing process applicable to all products**
- **GMP manufacturing experience at three sites**
- **A pipeline built on the de-risked manufacturing across the platform**

If you want to hear more about our ambitious plans and exciting next phase, contact us….. info@phicotx.co.uk

Quotient Sciences

Molecule to cure. Fast.™

Quotient Science MMCC Case Study Manchester 12th July 2022

About Me

Dr Paul Quigley

Principal Research Fellow – Drug Substance

Paul was head of Technology Transfer for Johnson Matthey Ltd. and was previously head of New Product Introduction and Head of Technical Services for Shasun. Paul has over 20 years experience in the Fine Chemical and Pharmaceutical industries in a variety of senior management roles, covering Technical Management of UK Sites, and Senior Project and Operational roles within a number of international organizations including ICI, Schering Plough, Clariant, Johnson Matthey and Rhodia. Paul graduated with a PhD in Natural Product Chemistry from University College Dublin in 1988 and with an MBA from Warwick Business School in 2000. He has co-authored a number of papers in the areas of Biocatalysis, Organic Synthesis, Polymer Chemistry and Natural Product Chemistry, and has generated several Patents in this area. Paul is a Member of the Royal Society of Chemistry and the Association of MBAs.

Who we are

Molecule to cure. Fast.™

Quotient Sciences is a **drug development** and **manufacturing accelerator** providing **integrated services** across the entire **development pathway**

30 years' experience

Customers

550+
active customers from around the world

The world's top
20
pharma companies have put their trust in us

Small biotech and emerging pharma make up
70%
of our business

Molecules

Experience of
3000+
molecules across all stages of development

Work on
150+
new molecules each year

200+
peer reviewed publications and scientific posters

How we work with our customers

Integrated Programs

Turnkey solutions for shortening development times

Candidate Selection

Selecting the right molecules for development

Early Development

Accelerating molecules through to proof-of-concept

Late Development

Accelerating products through to commercial manufacture

Tailored services

Individual services to meet customer needs

Formulation Development

Clinical Trial Manufacturing

Commercial Manufacturing

Drug Substance

Clinical Pharmacology

Bioanalysis

Data Sciences

Drug Development Consulting

Quotient Sciences

Molecule to cure. Fast.™

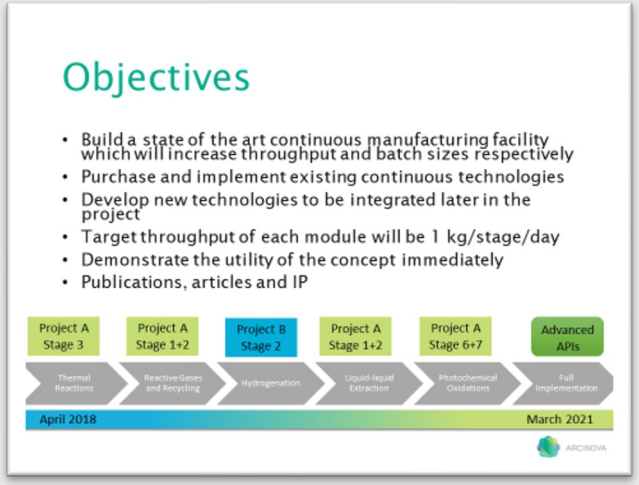
Project Flowinova

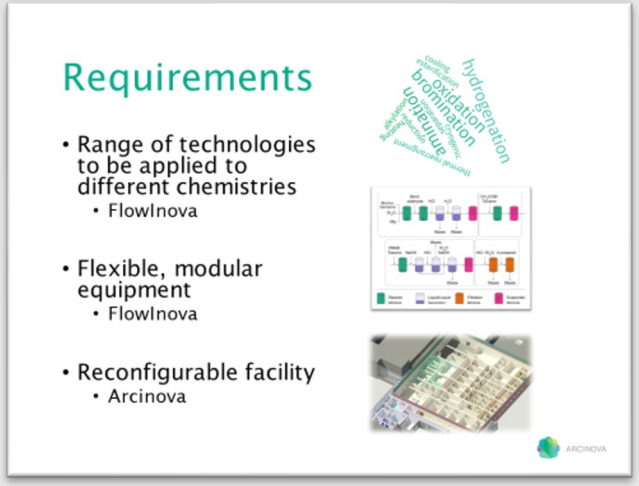
Problem Statement / Funding Need

- Small molecule drugs major % of NMEs being developed and approved each year
- More targeted through increased complexity with less manufacturing volume requirements
- Emerging requirement to make some very complex molecules at the kilo to 100s of kilos scale
- Process intensification technology, including continuous processing has been ‘miniaturised’ for use in flow chemistry for pharma applications over the last 10-15 years
- We wanted to adopt this technology to create a flexible, modular manufacturing facility within a laboratory based environment to enable the development of innovative continuous processes by first intent

What the funding enabled Quotient to do (what the impact is/will be)

- **Invested in people and technology to enable a smarter approach to PR&D**
  - We use automated chemistry platforms for our experiments and capture online data.
  - Build and then refine process models to enhance understanding of the chemistry
- **Client driven projects, different processing needs for different chemistries**
- **Some were already available off the shelf, but for some, we weren't happy with the existing technology and our collaboration partnership with the University of Nottingham has helped innovate new prototype equipment for particular classes of chemistry**
- **Flexible, modular approach so that we can plug and play different equipment choices to match the requirements of the project we're working on, all based around a throughput of a few kilos per day**



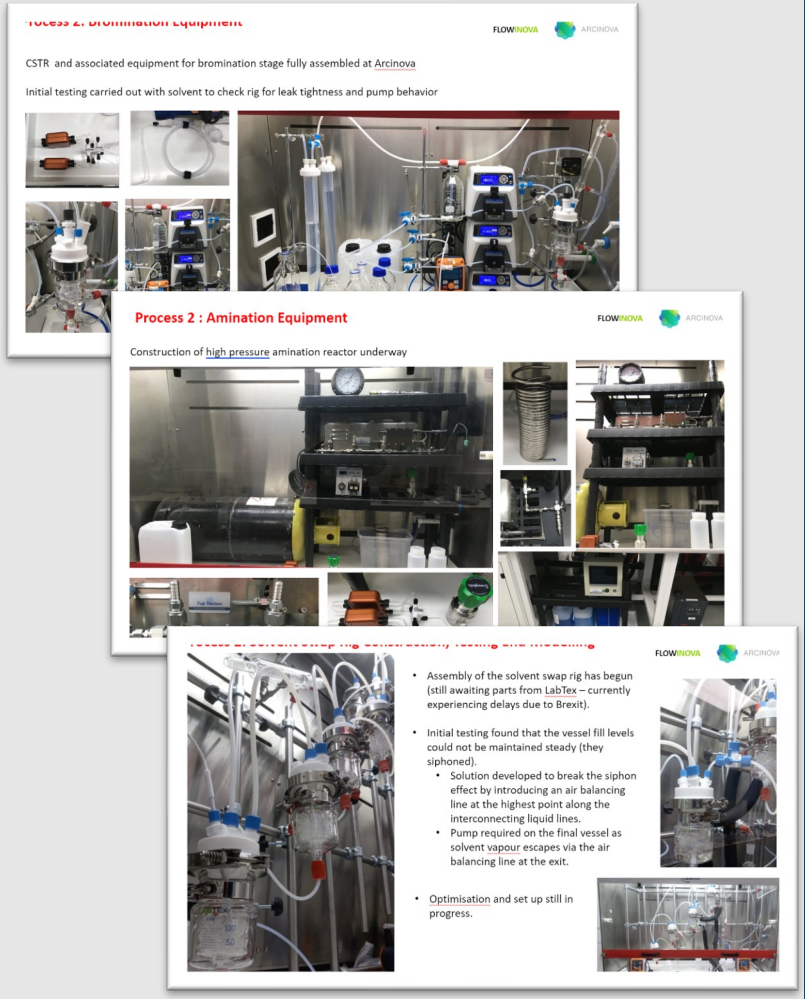


Additional Benefits

- Networking opportunities (e.g. Medicines Manufacturing community) with others in the same space
- Exploring other Collaborations / Funding Opportunities
- Promoting our success to inspire others to innovate as well

What's Next For Quotient?

- We have all of the building blocks we've been working on over the last 3 years and are now putting them all together
- We have shown that our approach will daisy chain together a number of stages of an API to produce multi kilo quantities is a small fumehood space
- This year will also see us start to build our mini-factory facility – this is a 5000m2 extension on our site which will house all our advanced medicines manufacturing
- The success of our FlowInova project and the growth of Arcinova has been recognised by Quotient Sciences who acquired the business at the start of 2021 – this is a very exciting continuation of the journey as both companies share the common belief that ideas need to become solutions, molecules need to become cures, fast.



Quotient Sciences

Molecule to cure. Fast.™

Alnwick Building 2 API Facility

Differentiating Technologies

Differentiating Technologies

Alnwick API Road Map

Molecule to cure. Fast.™

Hardware

- **2022:** API Facility that is “Industry 4.0” by design
- **2023:** Process Analytical Technology (PAT)
- **2023:** More instrumented mini jacketed vessels for PR&D
- **2024:** Modular Flow Reactors
- **2024:** Continuous Crystallisation
- **2025:** Continuous Carousel Filter Drier

Software

2022 — Pharma MV (Stage 1):

- Remote process control with tablets
- Batch context for process data
- Electronic balance recordings

2023 — Pharma MV (Stage 2):

- Integration of Process Analytical Technology (PAT) with Adaptive Process Control (APC)
- Roll out to PR&D to facilitate building “digital twin” mechanistic models that aid scale up
- Automated DoE

2024 — Pharma MV (Stage 3):

- Self optimising continuous processes (i.e. crystallisation to target PSD)
- Well developed “digital twin” data-base for all vessels

2025 — Reduced cycle time from beginning of PR&D through to multi-kg GMP synthesis due to:

- Data from PR&D gathered automatically to feed into modelling software
- Equipment selection (batch vs continuous) and scale-up performed *in silico*

Quotient Sciences

Molecule to cure. Fast.™

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Paul Quigley

Principal Research Fellow - Drug Substance

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Oxford Biomedica – Match Funding Case Study

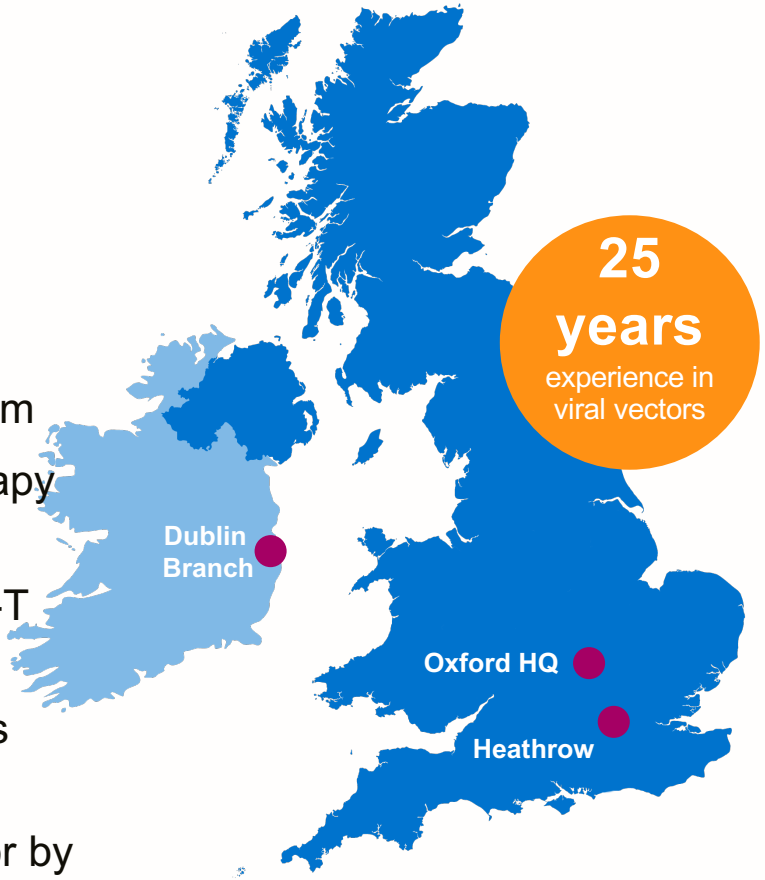
Medicines Manufacturing Challenge Celebration Event

Dr. Simon Simpkins, VP, Head of Operational Strategy

12th July 2022

Oxford Biomedica – An overview

- **Founded** in 1996, based in Oxford, UK, & Boston, USA
- **HQ:** Oxford UK, over 800 Employees
- **80%** share in OXB Solutions: Bedford MA, US (AAV capabilities March 2022)
- **Mission** – Delivering life-changing gene therapies to patients
- **Core LentiVector® technology platform** based on lentiviral vector *in vivo* and *ex vivo* gene delivery system
- **1st** world-wide to administer lentiviral vector gene therapy *in vivo* (both brain and eye)
- **1st** commercial supplier of lentiviral vectors, post CAR-T approval (Novartis, Kymriah®)
- Large scale commercial manufacture of AstraZeneca's COVID-19 vaccine – **Millions** treated
- **Thousands** of patients treated by Oxford Biomedica or by its partners using OXB LV
- **Strong Reputation** as a Leading Company in Cell and Gene Therapy



Medicines Manufacturing Challenge Community

Project: Investment in Process Development capability, and capacity expansion

Problem Statement: Rapid growth in the field of advanced therapies has resulted in a number of products with genuinely disease-transforming potential being commercialised. Further expansion of facilities and capabilities is necessary in order to supply the continuously increasing demands from existing and future partners.

The need:

i) provide a level of financial support - de-risking need to raise capital to make investment
ii) provide additional capacity to enable OXB to work with an increased number of partners and products
iii) help to catalyse the investment decision for OXB

Match Funding Award - 2017

£3m

Match Funding

Award Dec 2017, spend by 31st Mar 2018

A) Investment in critical equipment

Vector process development

Vector Manufacture

Research & Development

Increased throughput with acquisition of an Ambr®250 HT system

Increasing Vector production

Purchase of 50/200L bioreactor skids

B) Concept design - Oxbox Manufacturing Facility

7,800 m²
Manufacturing Capacity & Facility

State-of-the-art GMP facility

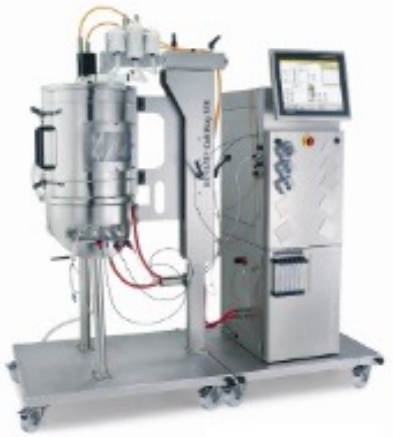
4 Vector Suites
2 Fill & Finish Suites
Warehousing

Process Development

15 mL

250 mL

5 L



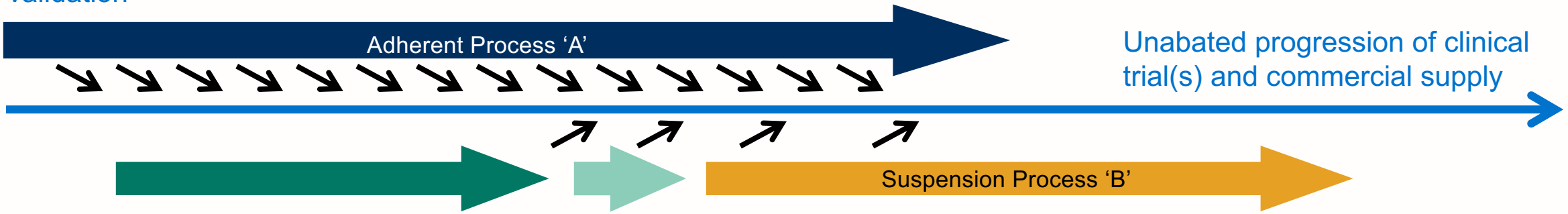
50-200 L

- Ambr®250HT micro reactor system - *enables faster development*
- The HT (High Throughput) unit enables 12 independent reaction conditions to be investigated simultaneous
- Considerably shortens wet-work by ~50% compared to previous projects
- Qualified Scale-Down Model system – *cuts material waste as we can work on a smaller scale*
- Dramatically improves process characterisation capability – *products get to commercial faster*
- Drives platform development - *significant scope for future process intensification work*

Increased Manufacturing Capabilities

2017 Strategy:

Existing process - ongoing supply, characterisation & validation



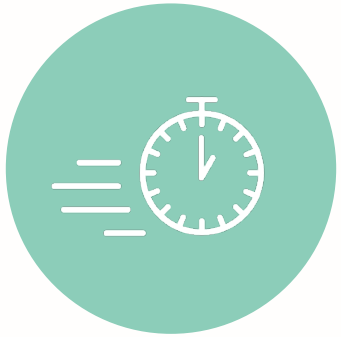
Parallel development of future process(es)

	Raw Materials	Batch Scale	Cost of Goods	Process intensification
Adherent Process 'A'	Serum Containing	36 x 1 L cell factories	£££££	Limited
Suspension Process 'B'	Serum-free	1 x 200 L Single-Use Bioreactors	£££	More control of parameters – higher yields

Innovate grant used to purchase equipment to convert Yarnton facility to our new Serum-free 200L suspension process
Purchase of additional Single-Use Bioreactors for the planned Oxbox facility

Capacity Expansion - Oxbox

IUK funding covered **concept design work** on Phase I of the Oxbox building (5815 m^2 of an available 7800 m^2).
A further >£20m of OXB funds contributed to complete the project



Purpose Build

Designed specifically for the manufacture of multiple viral vectors. Contamination controls built into the heart of the design

Bioreactor Suites

Four fully-independent 200L or 1000L bioreactor suites operating at CL2

Warehousing

Substantial warehousing and increased cryo-storage capabilities

Automated Filling

Two independent filling areas. Automated filling line installed in a bespoke Grade A isolator

Rapid Response

Unique facility within the UK – size and capability

Outcomes and Additional Benefits

Manufacturing Capability

- Funding supported the growth of OXB's manufacturing capability
- Key equipment for three suites supported from IUK funding
- Oxbox concept design progressed

Process Development

- OXB able to offer more services to customers
- Increased PR&D throughput – products get to patients faster

Room for Growth

- Springboard for further significant investment
- Decisions made in 2017/2018 led to the availability of Oxbox facility critical for Pandemic response in 2020
- Significant growth - *new jobs*

Pharmaron Gene Therapy

Medicines Manufacturing Challenge Celebration Event

12th July 2022


Laboratory Services


Chemistry, Manufacturing and Control


Radiolabelled Sciences


Clinical Development


Biologics & CGT

Rob Olliver & Mike Devey

Pharmaron Overview

PHARMARON is a leading fully integrated pharmaceutical R&D services platform with global operations and has a well-established team of over 16,000 employees working in 18 different sites located in China, the United States and the United Kingdom.

Mission

To support our partners' success in discovery, development and commercialization of innovative medicines

Vision

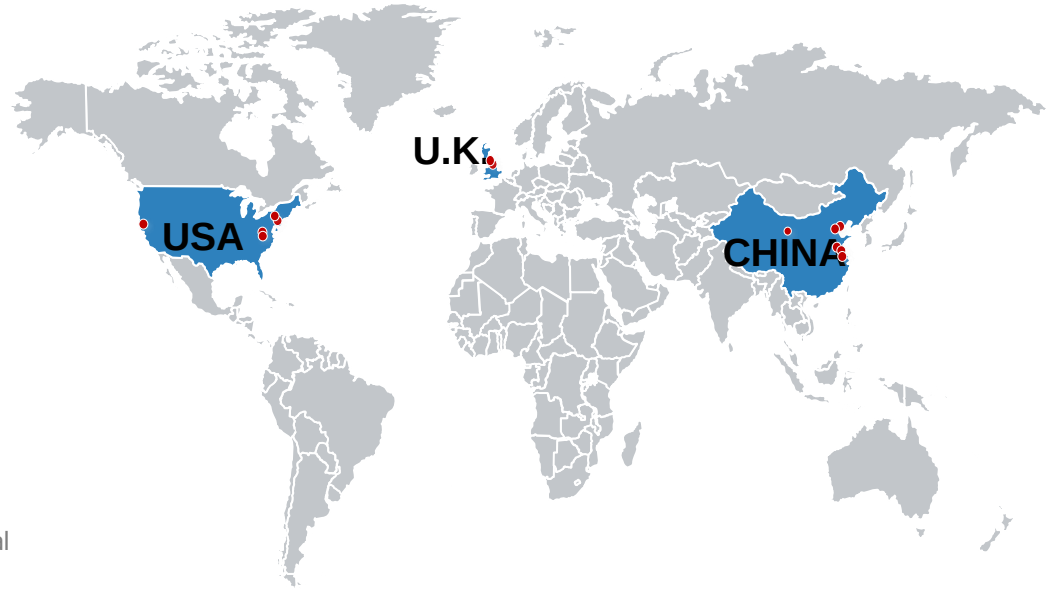
To become the world-leading life science R&D service company

Global Footprint

8 China Sites

5 UK Sites

5 US Sites



Gene Therapy Capability at Pharmaron, Liverpool, UK

World Class Centre for Gene Therapies

cGMP
cGMP multi-product bio-manufacturing facility with the latest automation

Viral Vector
Specific site focus of viral vector development and clinical manufacture

Gene Therapy
Key site focus since 2018

c.200 FTE
Highly talented employees focused on supporting the development of innovative gene therapies

Analytics
State of the art equipment and enhanced through collaborations with centres of excellence

MHRA MA (IMP)
Facility authorised to manufacture Human Investigational Medicinal Products for Clinical Trials

Pharmaron Gene Therapy

Employer's Perspective
Apprenticeships


Laboratory Services


Chemistry, Manufacturing and Control


Radiolabelled Sciences


Clinical Development


Biologics & CGT

Education Liaison is Important to Us

Our external Talent Pipeline is strong, and starts early…

Age:	7 – 11yrs	11 - 14yrs	14 - 16yrs	16 – 18yrs	18+yrs	25+yrs
	School KS2	School KS3	School KS4	6th Form / College	Higher Education	CPD

Careers Carousels

Work Experience

- Work closely with local schools to promote science
- Strong links to Universities (placements students & collaborations)
- Eleven Apprentices via Cogent and Two Up-skilling opportunities
- Multiple Industrial Placement Students (12 mo) via Cogent
- Pharmaron are proud to be part of NW 'Biohub' of industry & academia

Apprenticeships

Cogent Preferred Supplier

PhD Case Awards

Biotechnology University of Manchester

Industrial Placement Students

Target Universities
Liverpool, John Moores Manchester, Sheffield, Birmingham, UCL

MSc / PhD Placements

Target Universities
Liverpool, John Moores University of Kent

Sponsor further education studies in-house / training programmes

Pharmaron and T-level Students

ABOUT T LEVELS

T Levels are a new qualification for students aged 16 to 19 who've finished GCSEs. They are the biggest reform to vocational training in a generation, giving young people the skills, knowledge, and attitude to excel in their careers.

Pharmaron Welcomed Apprenticeship Cohort

Employer's Perspective

EMPLOYER BENEFITS

- Great Opportunity to Upskill existing employees, through apprenticeships
- Good opportunity for Senior Scientist to experience supervising junior members.
- Apprentices are eager to learn, enthusiastic, energetic and can bring drive to teams.
- Opportunity to recruit someone who knows the business, is established within teams.
- You can chose to utilise Cogent Skills experience for the management of apprentices – this is something we have chosen to do.
- Employer isn't required to make an offer of employment to apprentices at the end of the course.

康龙化成 PHARMARON

Pharmaron Gene Therapy

An Apprentice's Perspective


Laboratory Services


Chemistry, Manufacturing and Control


Radiolabelled Sciences


Clinical Development


Biologics & CGT

Apprentice's Perspective

Leon Jacob

Senior Reliability Site Engineer (Mechanical)

- I have completed a Level 6 Apprenticeship, in Manufacturing Engineering Systems.
- While studying, I was a Member of the Institute for Apprenticeships – part of the young members panel – who approve all apprenticeship standards across the UK.
- I joined the panel to expand knowledge, understanding and help shape crucial alternative learning for the next generation.
- I was awarded Regional Apprentice of the Year 2017 (Wales & North West).

Helene Trottin

Senior Leaders Masters Degree

- I'm currently employed by Pharmaron within Process Sciences team, as Senior Technical Specialist.
- I have completed 2 years of the Open University course, and aim to finish at end of 2022.
- I chose this course to widen my skills and knowledge, by supplementing my technical background with a strong business understanding.
- The MBA degree is internationally recognised and I was hoping this would also boost my career.

Mike Devey

Laboratory Scientist

- I'm currently studying Level 6 C&GT Apprenticeship.
- After completing my Level 5, I accepted a permanent role at Pharmaron, as an Associate Scientist and I'm now completing my Level 6 as an upskilling opportunity.
- I was lucky to be able to enrol on the first Cell and Gene Therapy degree cohort which started in 2018.
- I like to take every opportunity and have been heavily involved in promoting Apprenticeships through networking and conference panel discussions.

Michael Devey – Associate Scientist, Process Sciences

My Role

- Associate Scientist within the Downstream Process Science team
- Process Development and GMP Manufacture of Advanced Therapy Medicinal Products with focus on: Viral Vectors and Plasmid DNA (pDNA)

My Journey

2013

Joined Eden Biodesign as an apprentice production operator

Started my level 2 NVQ in Process Operations (Wirral Met)

2016

Continued onto my Level 4 HNC in Applied Bioscience (Wirral Met)

Moved from purely manufacturing to both GMP and PD

2018

Started my Level 5 FdSc in Applied Bioscience (Uni of Kent)

Became one of the first cohort of ATAC Apprentices

2021

Was made a permanent member of staff at Pharmaron Biologics

Started my Level 6 top up to gain my BSc in Applied Bioscience

Michael Devey – Associate Scientist, Process Sciences

Highlights

- Getting invited to events and other work sites through the ATAC.
- Gaining a head start on your career path.
- Working and growing around incredible people.

My Advice to Employers

- Utilise your Senior Apprentices/Scientists.
- Give your Apprentices room to grow.
- Think creatively about where to utilise apprentices.

Current Apprentices and Opportunities

Apprentice Level 4	Apprentice Level 6	Apprentice Level 7	Current Vacancy
Process Sciences • Lauren Beasley • Tom Conroy Analytical Sciences • Andy Campbell	Process Sciences • Mike Devey	Process Sciences • Hélène Trottin	1x Analytical Vacancy • Scientist Apprentice (Level 5)

Thank You

If you are interested in learning more about our advances in Gene Therapy Product Development, please register for our webinar series:

CGT Webinar Series

www.pharmaron.com/webinars

Laboratory Services

Chemistry, Manufacturing and Control

Radiolabelled Sciences

Clinical Development

Biologics & CGT

Website: Biologics & CGT | Pharmaron

Medicine Manufacturing Industrial Partnership

The future for medicines manufacturing innovation

Brian Henry, MMIP Chair

July 2022

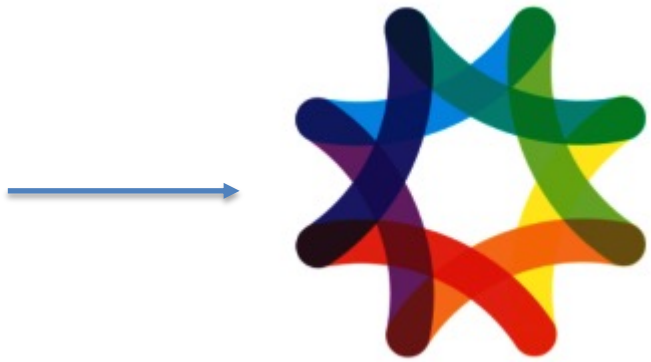
Medicine Manufacturing Industrial Partnership

MMIP

Vision

For the UK to be recognised as a world-class, advanced centre for medicines manufacturing

Strategic partnership of the medicines manufacturing industry working together with the government and its agencies, to drive a growth agenda for medicines manufacturing in the UK



Medicines & Healthcare products Regulatory Agency

Office for Life Sciences

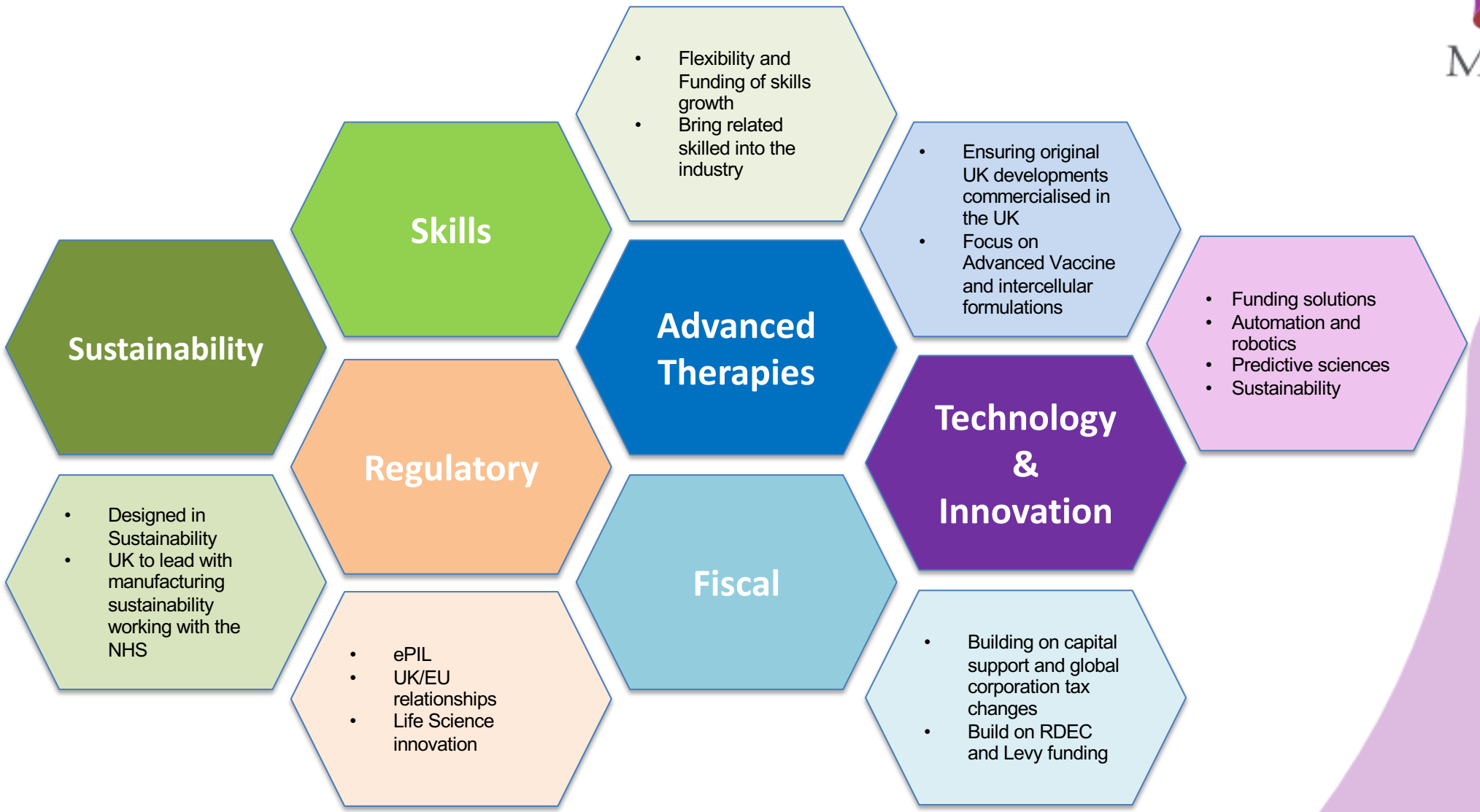
UKRI Innovate UK

Department for International Trade

abpi

BIA UK BioIndustry Association

MMIP Focuses implementation by workstream



MMIP Supported Facilities established with UK Government Funding support

CATAPULT Cell and Gene Therapy

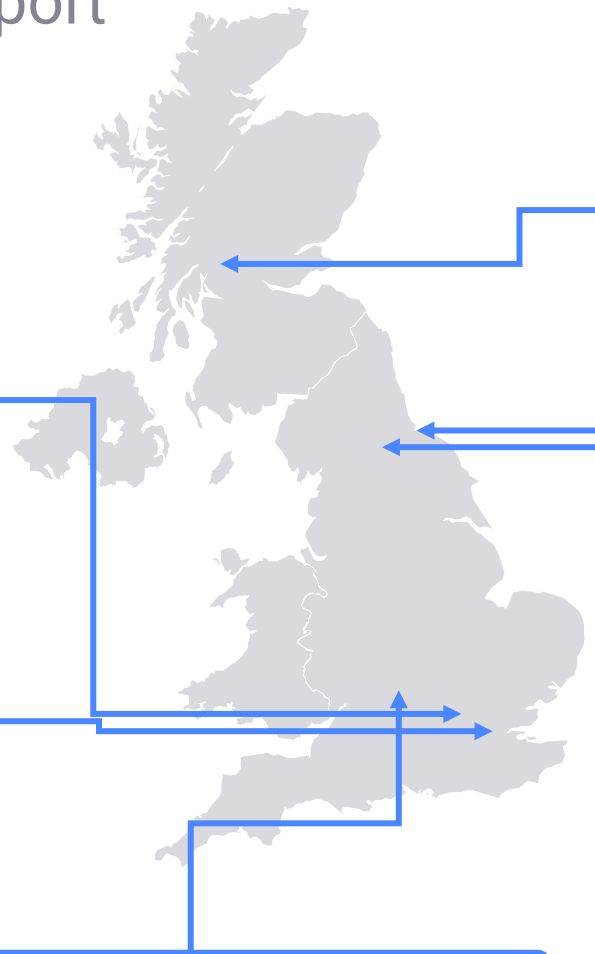
cpi

CGTC Stevenage Manufacturing Innovation Centre

£67m
ATMP GMP manufacturing innovation for clinical and commercial supply

CGTC Braintree Manufacturing Innovation Centre

£100m
ATMP GMP manufacturing innovation for clinical and commercial supply



VMIC

Vaccines Manufacturing Innovation Centre

£215m
Development and manufacture of vaccines

Medicines Manufacturing Innovation Centre

£15m
Developing next-generation pharmaceutical manufacturing processes

National Formulation Centre

£28m
Drug delivery systems, drug formulation and nanomedicines

National Biologics Manufacturing Centre

£38m
Accelerating the development and optimisation of biologics

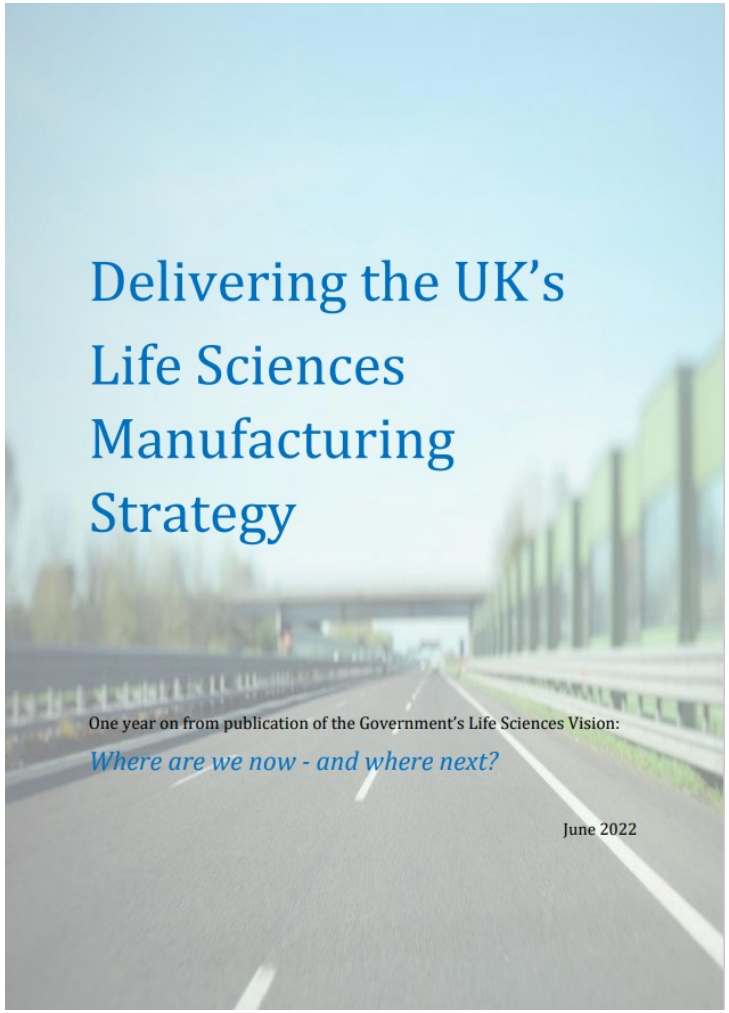
RNA Centre of Excellence and Training Centre

£26m
Development and scale-up of RNA based therapeutics

Life Science Vision published July 2021

- **Build on the UK's Pandemic Manufacturing Infrastructure and deliver the Medicines and Diagnostics Transformation Fund**
- **Continue to support the UK's manufacturing innovation ecosystem**
- **The UK's competitive tax environment**
- **Support the formation and expansion of Manufacturing Clusters**
- **Enhance the Manufacturing Skills Base**
- **Support the Transition to Net Zero**

MMIP perspective - One year on from the Life Science Vision



Where next for a UK Medicines Manufacturing Strategy?

Call to action from for today's focus?

Where do we want to be in 10 years?

- How does the UK secure the medicines it needs from vulnerable, complex and global supply chain?
- How many more jobs can we create?
- How to ensure the UK is the world leader in climate friendly medicines manufacture?
- How do we ensure a resilient flexible scalable base for manufacture of medicines for future pandemics?

Proposed to focus on six key areas

- A globally competitive fiscal environment for Life Sciences investment
  - Establish team and well connected to building a broader cross sector view
- A holistic approach to growing the manufacturing skills base
  - Tangible impact on the 1000's of new people needed
- Transformed medicines manufacturing through innovation
  - Focus on robotics, automation and predictive science
  - Advanced therapies
  - Sustainable medicines
  - Maintain the balance of current focussed investments (CGT, MMIC …) with new areas (i.e. mRNA)
- Global leadership in medicines manufacturing sustainability goals and metrics
  - New area and ripe for the UK to take a global lead
    - NHS, government and private sector together
- Growth across the end-to-end medicine supply chain and the broader medicines manufacturing ecosystem
  - Recognises that the medicine manufacturing based goes beyond just the larger companies
  - No-one voice that connects fine chemicals, suppliers and the contract manufacturing base
- A resilient and stable manufacturing base to supply UK and global needs
  - Focus on the global nature of medicines manufactures
  - Frictionless movement of all the materials need to make and supply medicines