
Advanced therapies and NHS readiness

Professor Phil Newsome

Director, Midlands & Wales Advanced Therapy Treatment Centre

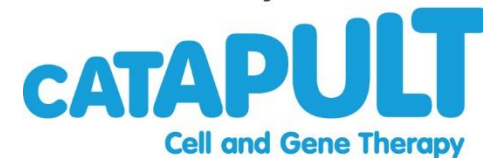
Ewan Morrison

Director, Pharmacy, NHS National Services Scotland

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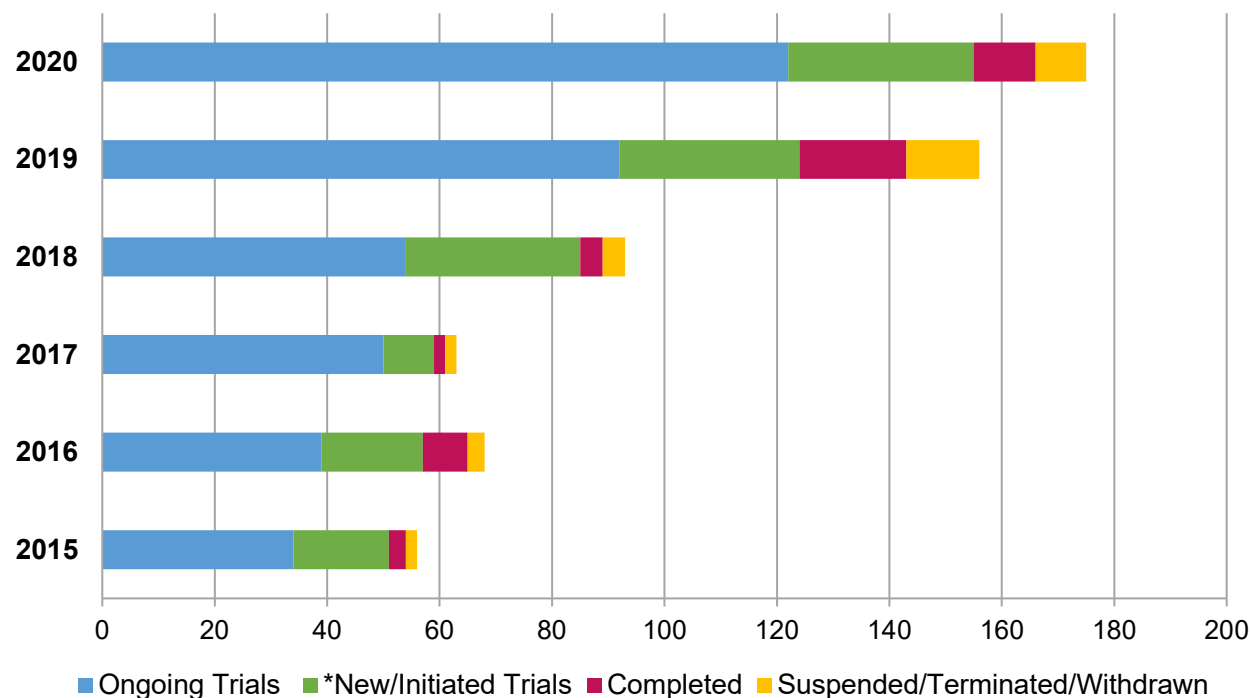


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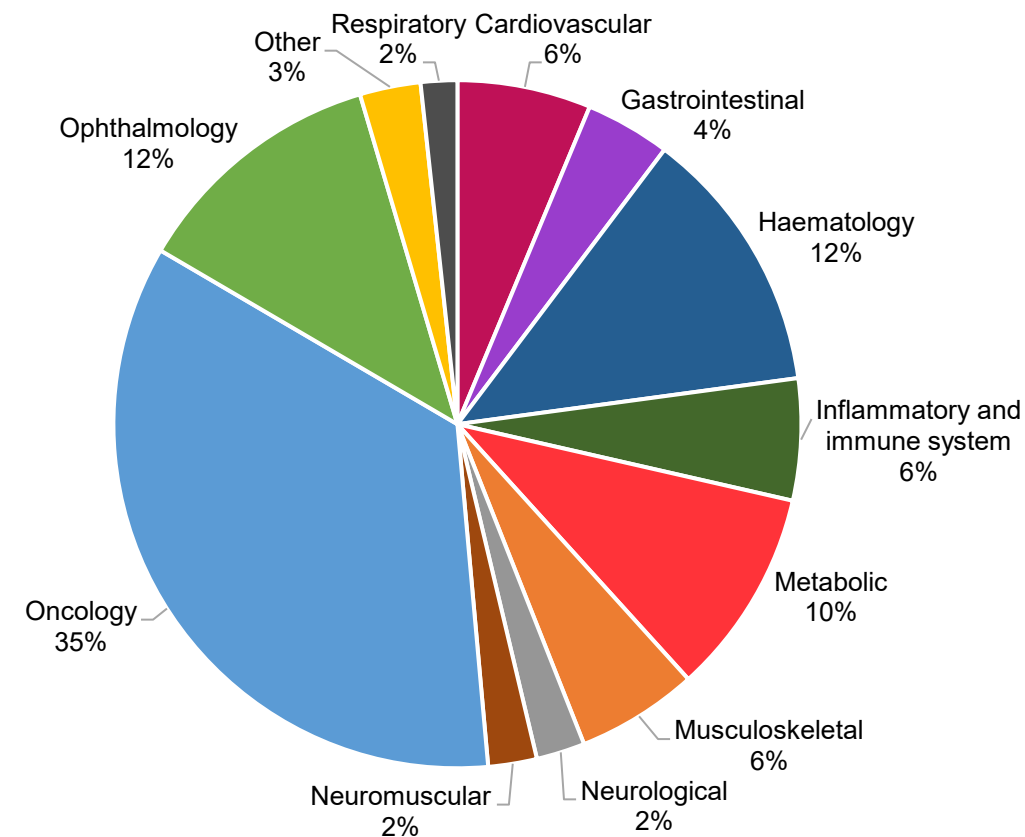


Potential of cell and gene therapies – Patients

Number of ongoing, initiated, completed, and closed trials 2015-2020



Distribution of UK ATMP clinical trials by therapeutic area in 2020



Data from CGT Catapult Clinical Trials Database, Feb 2021

Increasing availability of products

NICE National Institute for Health and Care Excellence

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NHS patients to benefit from first full access deal in Europe for new CAR-T therapy recommended by NICE

NICE has agreed a managed access agreement, via the Cancer Drugs Fund with manufacturer Kite, so more data can be collected while patients can access the treatment.

19 January 2021

NICE National Institute for Health and Care Excellence

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NICE approves life-changing gene therapy for treating spinal muscular atrophy

A new and potentially curative one-off gene therapy for babies with the rare genetic disorder spinal muscular atrophy (SMA) is set to become the most expensive treatment ever approved by NICE.

08 March 2021

NICE expect to review up to 30
ATMPs 2020-2023

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Multiple barriers to adoption

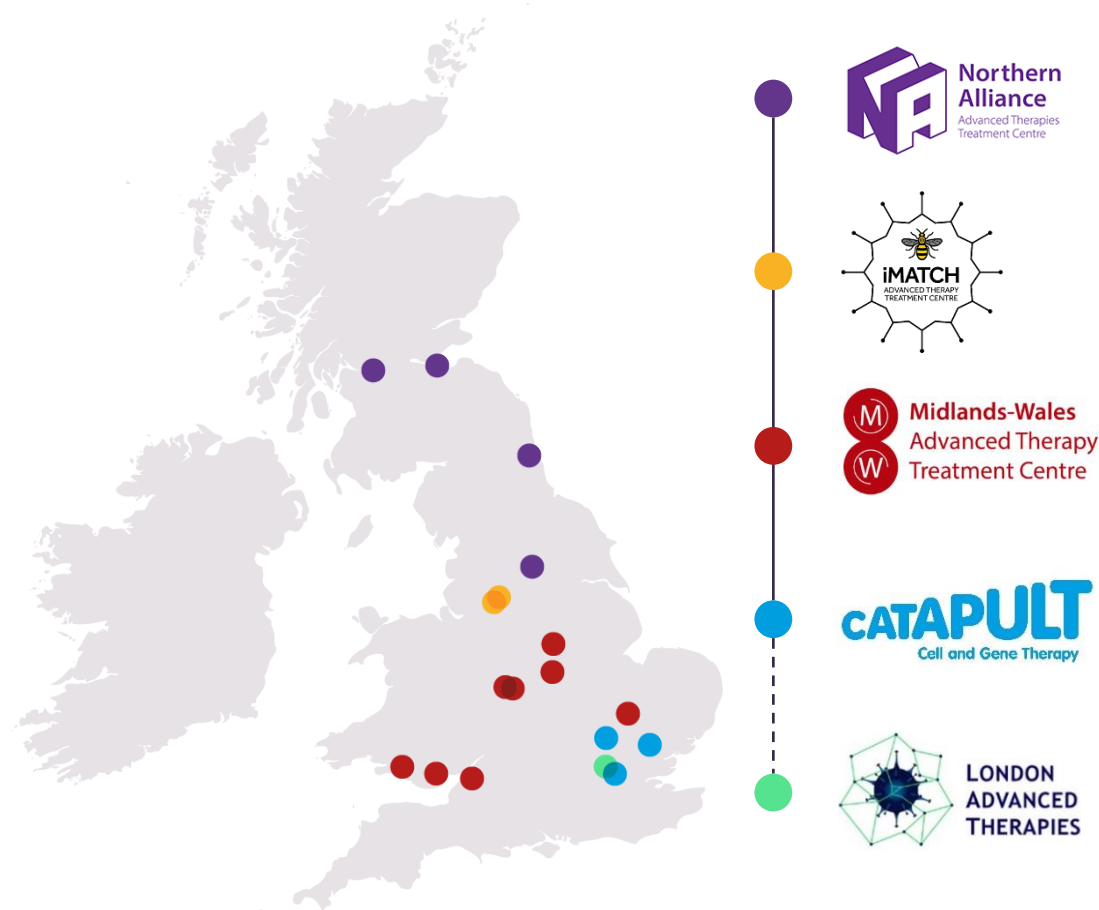
- Disruptive process requiring unprecedented levels of collaboration within hospitals and industry
- Lack of standard processes
- Requires new infrastructure
- Complex pathway from start to finish
- Experience located in a few specialist hospitals



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Cell and Gene Therapy

Our network

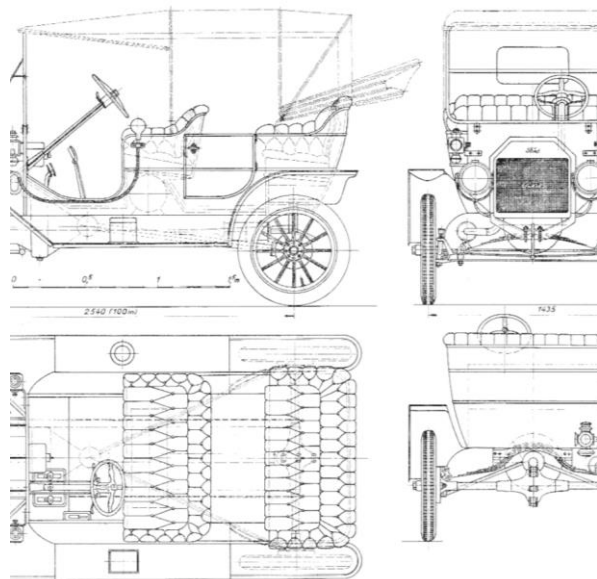


- Develop and deliver systems for the routine delivery of these disruptive therapies.
- Disseminating the learnings and systems from the ATTC clinical centres to enable more widespread adoption of these innovative therapies across the NHS.
- **64 partners** – true collaboration between NHS, industry and academia.
- **200 – 250 people** working on the programme.
- Working in collaboration with London Advanced Therapies.

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What is Institutional Readiness?



IR: *'Whether, and if so, how far, an organisation needs to adapt to embrace a new technology'*

TRL → SRL → IRL



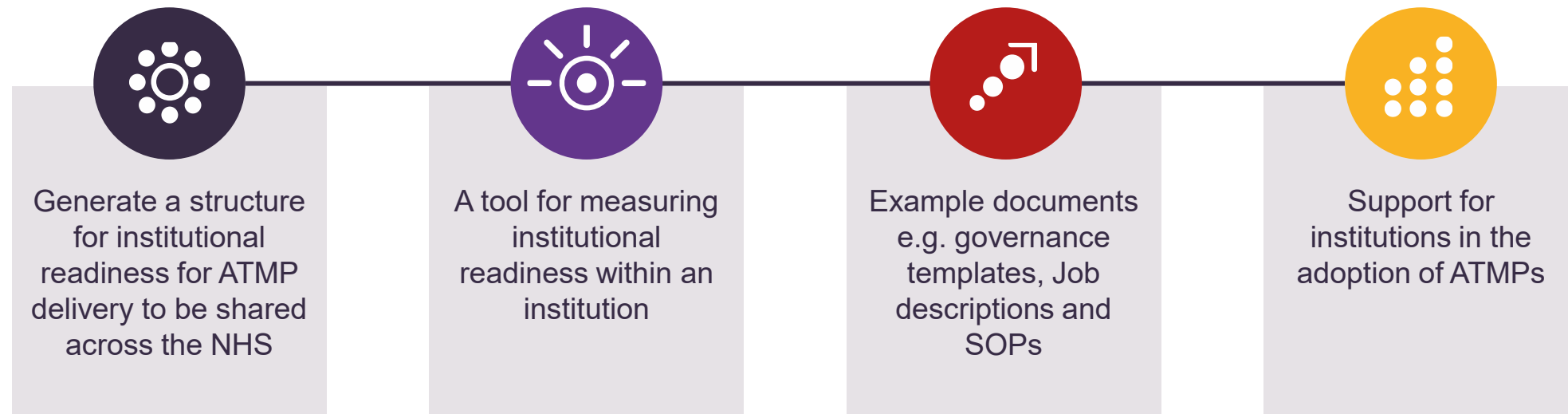
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Advanced Therapies NHS Readiness Toolkit

Free online resource to accelerate and enable clinical adoption of ATMPs in hospitals across the UK

- Reduce duplication of effort across the UK
- Shared best practice from centres of excellence
- Strengthens the UK health service's leading position globally



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Advanced Therapies NHS Readiness Toolkit

The Advanced Therapies NHS Readiness Toolkit provides resources for healthcare organisations that are working towards the delivery of advanced therapies for patients.

The toolkit is intended for senior hospital management, operational managers, clinicians, pharmacists, nurses and others involved in the delivery of advanced therapies.

A searchable repository of best practice guidance and templates from across the ATTC network:



Governance



Clinical practice



Business and financial planning



Education and training resources



Quality assurance and risk management



Long term follow up



Operational delivery



Outcomes and impacts (coming soon!)

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Example documents – operational delivery

Search this section

Document Type ▼

Treatment ▼

Date (Newest) ▼

Keywords

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Handling dry ice and vapour phase nitrogen shippers – advice for hospital pharmacies

16/10/2020 · EXTERNAL LINK

Some medicines, including many ATMPs, achieve greatest stability at ultra-low temperatures. Therefore the use of -80°C and below is commonplace to achieve optimal product shelf-life. As the usage of ATMPs is increasing, Pharmacy departments are becoming required to receive shipments and to store products at ultra-low temperatures

IMP or ATMP product issue checklist

03/08/2020 · DOCX >

Ex Vivo (cell based) gene therapy medicinal products – pharmacy institutional readiness guidance

21/07/2020 · EXTERNAL LINK >

In Vivo (virus based) gene therapy medicinal products – pharmacy institutional readiness guidance

01/07/2020 · EXTERNAL LINK >

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Hospital Business Manager

Need to understand how ATMPs will affect my unit



Governance

This section is intended to assist NHS organisations to create or modify governance structures to permit the introduction of advanced therapies, encompassing all levels of governance responsibilities and reporting within hospitals. Also see: Business and financial planning, Operational delivery

Find out more >



Business and financial planning

The introduction of advanced therapies into hospital treatment pathways requires a significant financial investment in resources and facilities. Information available here will help organisations to develop the appropriate business and financial plans as they prepare to deliver advanced therapies.

Find out more >



Quality assurance and risk management

This section provides examples of and guidance on the implementation of quality systems and risk assessments for safe delivery of advanced therapies towards preparing for regulatory inspections.

Find out more >



Operational delivery

The documents in this section will assist in the implementation of new advanced therapy services in a clinical setting, supporting the reduction of guidance to practice. Documents include process and patient flow charts to map the treatment pathway and information on the in-hospital logistics requirements.

Find out more >

Hospital Business Manager

Resources currently available to support greater understanding of how hospitals will be affected

ATMPs on the horizon – webinar

22/03/2021 · EXTERNAL LINK

Focussing on four upcoming ATMPs in 2021, how they work, how patients might benefit, how they are given and other practical issues staff need to aware of.

Business case for ATMP service provision

01/02/2019 · PDF

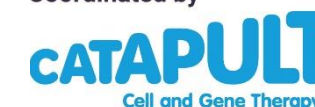
Key factors to consider to make the business cases for implementation of a new ATMP service

Lead research nurse job description

24/07/2018 · PDF

An example job description for a clinical trial lead research nurse providing leadership and management of the cell therapy clinical research team

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Oncology clinician

Would like to see how others are delivering CAR T therapy to patients



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Find out more >



Clinical practice

Information is available here to support the clinical practice of the delivery of advanced therapies to patients, including patient assessment, handling advanced therapies, product administration, infusion, treatment and monitoring and recording treatment and side-effects.

Find out more >




Education and training resources

To safely deliver advanced therapies to patients, staff need to be trained in this new modality of therapeutic intervention. This section includes resources that enable staff to learn more about ATMPs including e-learning, facilitating face to face training and competency assessments, and materials to support patient education.

Find out more >

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Oncology clinician

Resources available to support CAR T therapy delivery

Consent for CAR-T therapy treatment for ALL

21/06/2020 · PDF

Example of a patient consent form for CAR-T therapy to treat Relapsed/ Refractory Acute Lymphoblastic Leukemia

Apheresis process flow

01/06/2020 · PDF

A document summarising the challenges and solutions the the collection of starting materials for ATMP manufacture though apheresis

Infusion of CAR T cells

01/06/2020 · PDF

A standard operating procedure for the infusion of CAR T cells

Management of cytokine release syndrome neurotoxicity and CAR-T-cell related encephalopathy

01/06/2020 · PDF

This standard operating procedure for the assessment, grading and management of neurological and immunological adverse events following CAR T treatment

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Hospital pharmacist

Looking to begin using an *in vivo* gene therapy in a clinical trial



Governance

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Hospital pharmacist

Looking to begin using an *in vivo* gene therapy in a clinical trial

In Vivo (virus based) gene therapy medicinal products – pharmacy institutional readiness guidance

01/07/2020 · EXTERNAL LINK

The purpose of this document is to outline the key areas where chief pharmacists should focus pharmaceutical expertise prior to an organisation implementing any in vivo (virus based) Gene Therapy Medicinal Product (GTMP) e.g. IMP for Clinical Trials or Marketed ATMPs.

Gene therapy medicinal products governance and preparation requirements

· EXTERNAL LINK

Pharmacy is often the first port of call when an organisation wishes to use a gene therapy and needs to provide pragmatic guidance to facilitate the introduction of these innovative products. This document is designed to give practical advice to centres wishing to undertake gene therapy trials and need to understand the requirements and recommendations for governance and, in particular to have in place a Genetic Modification Safety Committee. The document also gives practical advice for centres to help them understand operational requirements including deciding the optimal location for preparation.

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The Advanced Therapies Readiness Toolkit

Now available! <https://www.theattcnetwork.co.uk/advanced-therapies-nhs-readiness-toolkit>

- Driving and sharing best practice across the UK
- Easing the burden of adopting advanced therapies within the NHS
- Targeted at NHS clinical, technical and managerial roles from across the UK
- An ever growing repository of information

Coming soon...

- *Hospital overarching ATMP governance examples*
- *National apheresis guidelines*
- *Patient pathways for different treatment types*

Please send any feedback to attc@ct.catapult.org.uk

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Special thanks

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