





Summary findings from:
"ATTCs, clinical infrastructure
requirements and adoption of
ATMPs" workshop
19 September 2018

## Introduction



On 19 September 2018 members of the organisations listed here met to address in an open and unattributed way what needs to be done to facilitate the adoption of Advanced Therapy Medicinal Products (ATMPs) in the UK NHS system. This document summarises the outputs of both the morning and afternoon sessions.



#### **Organisations represented**

**ABPI** 

Anthony Nolan

Atelerix

Bayer

Bellicum

Pharmaceuticals

BIA

BioMarin

Pharmaceutical

bluebird bio

Celgene

Cell Medica

Covance

Deltohn Ltd

Dignio

Exmoor Pharma

**Gilead Sciences** 

**Health Innovation** 

Network

Horizon Discovery

Health Research

Authority

iMATCH - Manchester

Advanced Therapy
Treatment Centre

Innovate UK / UKRI

Janssen-Cilag Ltd

Knowledge Transfer

Network

London Advanced

Therapy Network

MHRA

Midland & Wales

Advanced Therapy

**Treatment Centre** 

Muscular Dystrophy UK

NHS England

NHS Scotland

**NHS** Wales

**NICE** 

Northern Alliance

**Advanced Therapies** 

**Treatment Centre** 

**Novartis** 

Orchard

Therapeutics

Pfizer

Sanofi

Scottish Medicines

Consortium

TrakCel

Valid Insight

Videregen

Welsh Health

**Specialised Services** 

World Courier

Services



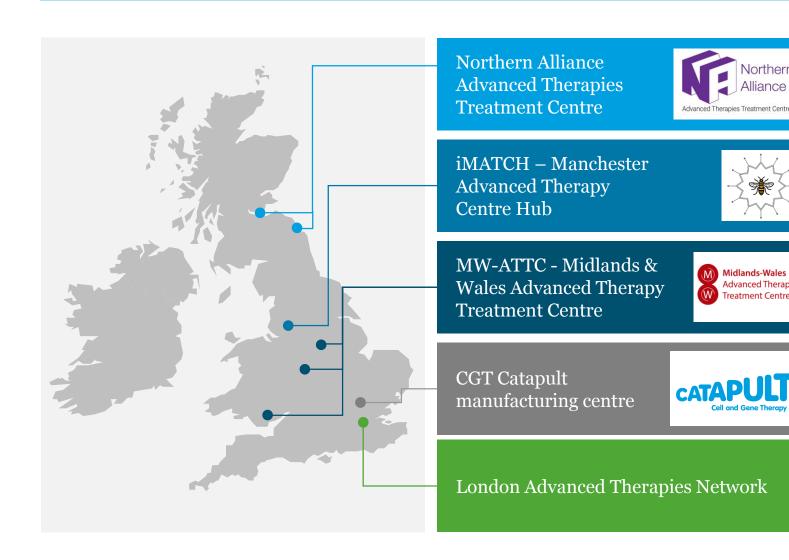
Morning Session:

Advanced Therapy Treatment Centres and NHS clinical infrastructure



## **Advanced Therapy Treatment Centre network**





The network of Advanced Therapy Treatment Centres will develop and deliver systems for the delivery of cutting edge cell and gene therapies.

- The network will increase the ability of the NHS to deliver disruptive medicines
- The centres will develop systems and processes within the trusts and hospitals capable of delivering advanced therapies at scale to patients across the NHS
- The learnings and systems from the initial centres will be rolled out to other centres in the UK

## **ATTC and ATN areas of focus**



#### Northern Alliance Advanced Therapies Northern Alliance **Treatment Centre**



- Supply chain, starting material procurement, secondary manufacturing, handling by clinicians and long term follow up, informatics infrastructure
- Stress test the system using four exemplars with different challenges particularly on the supply chain
- Evaluate the modality of distributed manufacturing

#### iMATCH – Manchester **Advanced Therapy** Centre Hub



- Developing a coordinated strategy to scale up advanced therapies for patients
- Maximising access to patients
- Delivering electronic sample traceability and tracking systems
- Maximising efficiency, data capture
- Clinical scaling-up activity
- Safe delivery of ATMPs with end to end training and education

#### MW-ATTC - Midlands Midlands-Wales Advanced Therapy Treatment Centre & Wales Advanced Therapy Treatment Centre

- Developing a patient and public engagement strategy
- Electronic capture of patient recorded reported outcome data such as quality of life, adverse events, feedback to the clinical team
- Development of a trial acceleration programme for cellular therapies (TAP-CT)
- Focus on health economics and clinical pathway mapping

#### London Advanced Therapies Network (ATN)

- Connecting capabilities in advanced therapies in London – Knowledge exchange
- Rapid resolution of IP problems within London – uniform protocols to allow third parties to interact with London in a single transaction in 14 days max
- Training: development of short courses that can meet these skills gaps

Cell and Gene Therapy Catapult coordination

# What is required to accelerate adoption





## Establish clear pathways to gather industry feedback:

Establishing streamlined information flow (e.g. through industry partner group) to ensure requirements of industry are taken into account.



#### Define common framework: Help companies navigate with harmonised procedures and practices:

e.g.: apheresis, treatment regimens, patient selection.

Work with companies and their specific protocols to produce common frameworks and systems.

IUK ATTCs,

London ATC and

other centres





#### **Speed of access:**

Streamline both procurement of starting material and delivery to product into health care system. Define courier best practice.



**Contract standardisation:** 

To ensure timely implementation

and adoption, contracts need to be

standardised.

Understanding what is required at organisational level e.g. number of apheresis units, ICU beds.





## Patient data collection and sharing

Bring data together, capture number of interventions post treatment, capture data in real time, agree where data should be held, connect with Digital Innovation hubs, development of Registries to meet both regulatory and reimbursement requirements.



Engaging the patients, patient groups and charitable associations further.



#### **Patient monitoring:**

Development of companion diagnostics, validated analytical methods and patient monitoring, staff training for safe patient management will need to take place.

#### Access to expert knowledge by industry:

Need for experts, education and physicians to help trial design, formulating a database of knowledge network.





## What next?



The ATTC network will work together with its partners to address the identified priorities to ensure they provide easily-run and ready to use systems and solutions that can then be rolled out to other NHS centres, leading to enhanced patient access to ATMPs.



Afternoon session:

Affordability, payment and reimbursement of cell and gene therapies



### **Recurrent themes**



There were many points raised, but a group of issues which came up repeatedly:



The high degree of novelty and the early stage creates an even greater need and opportunity for **patient involvement**.



There are many areas where there is a need to invest in new ways of **gathering**, **handling**, and **interpreting data**.



There is an opportunity to adopt new ways of following **patient progress**, including taking advantage of new technology.



There is an increased need to plan ahead for the investment in the **infrastructure** to accommodate novel ways of operating.



The scale of expected growth and change is not well understood; there is a need for information and forecasts for **planning** purposes.



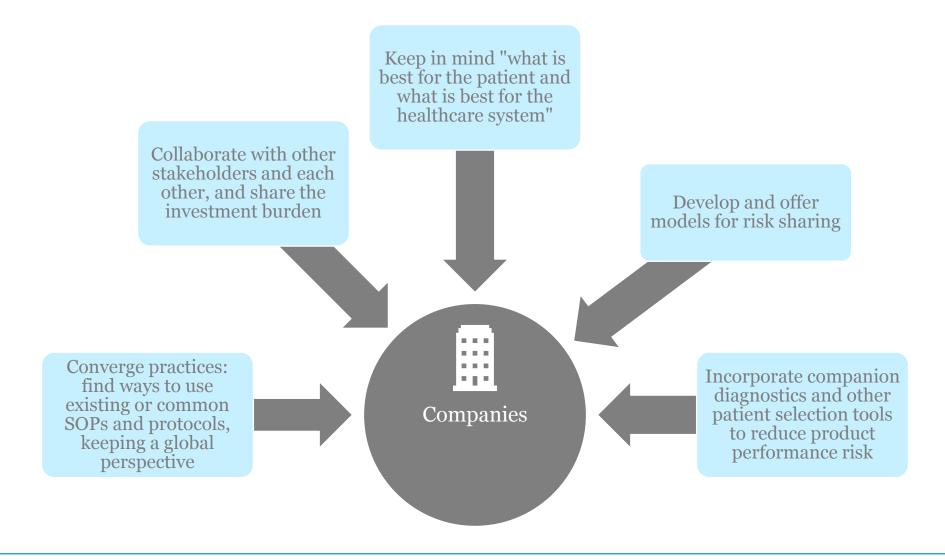
There is a need for development of novel, workable and mutually beneficial payment process, such as **outcomes-based payments**.



There is need to ensure **political support** through understanding of the potential of ATMPs to be transformative, at all levels.

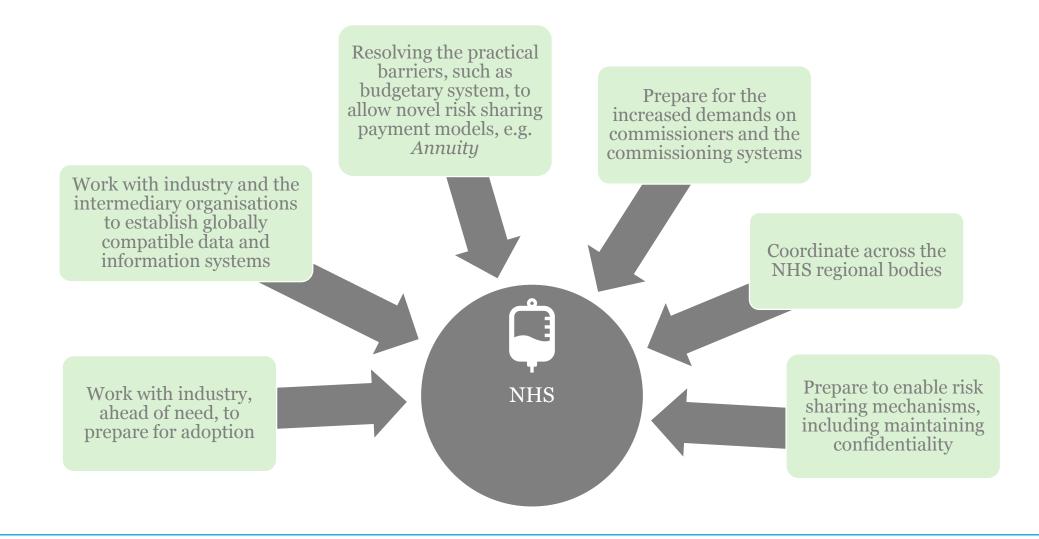
# Where individual companies can lead:





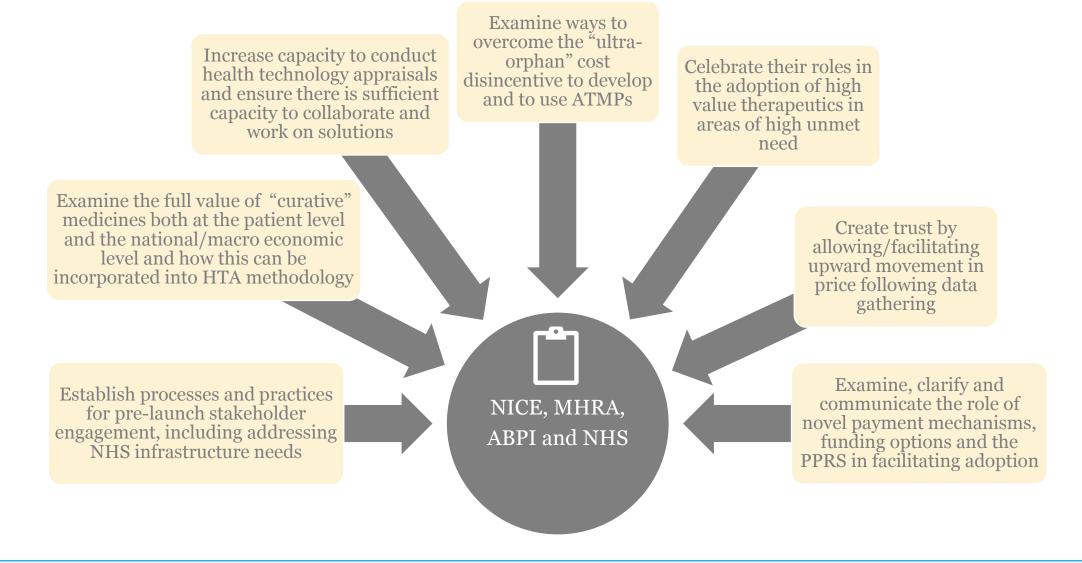
## Where National Health Services (NHS) can lead:





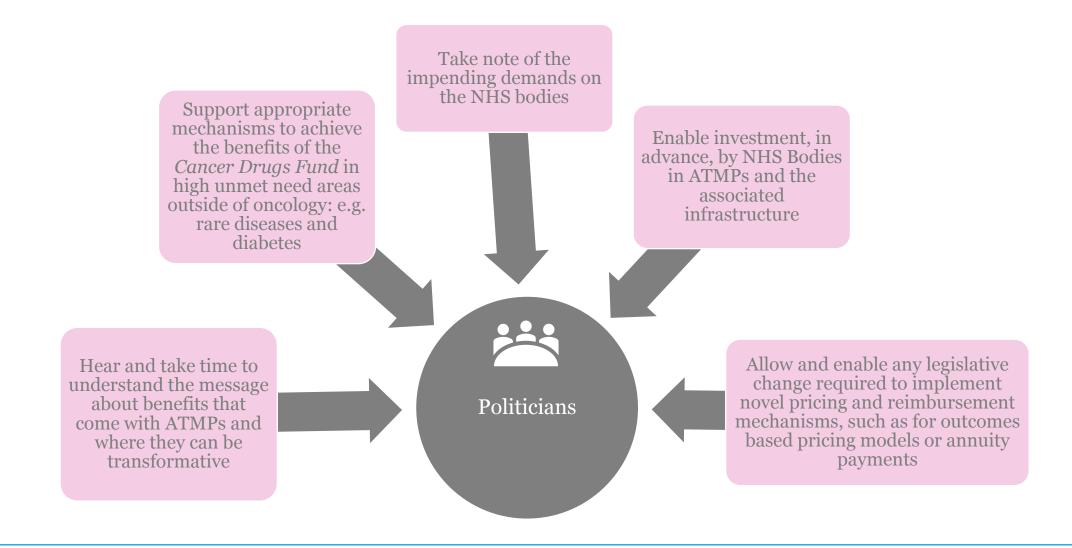
# Where "Regulators and Market Access stakeholders" can lead:





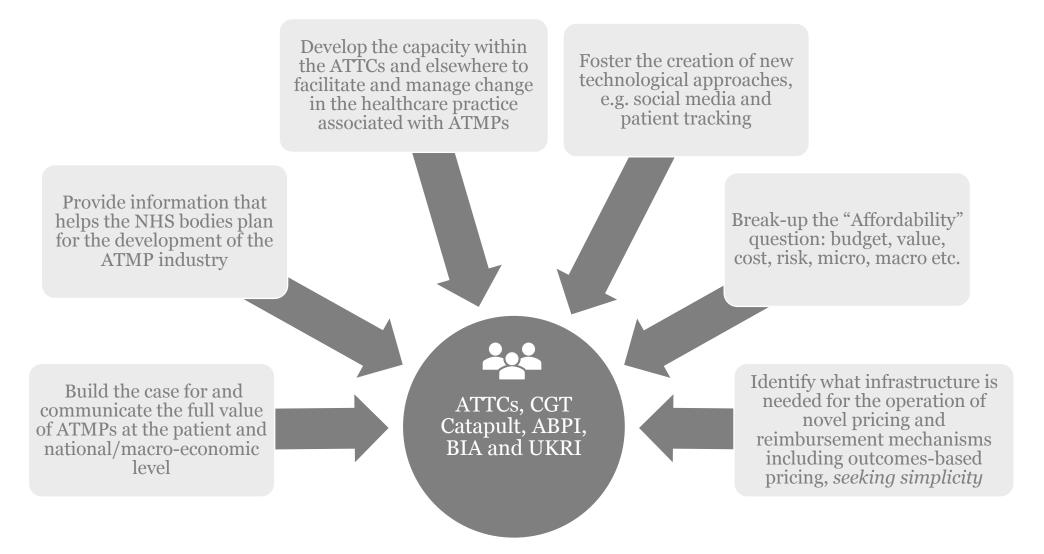
## Where political decision makers can lead:





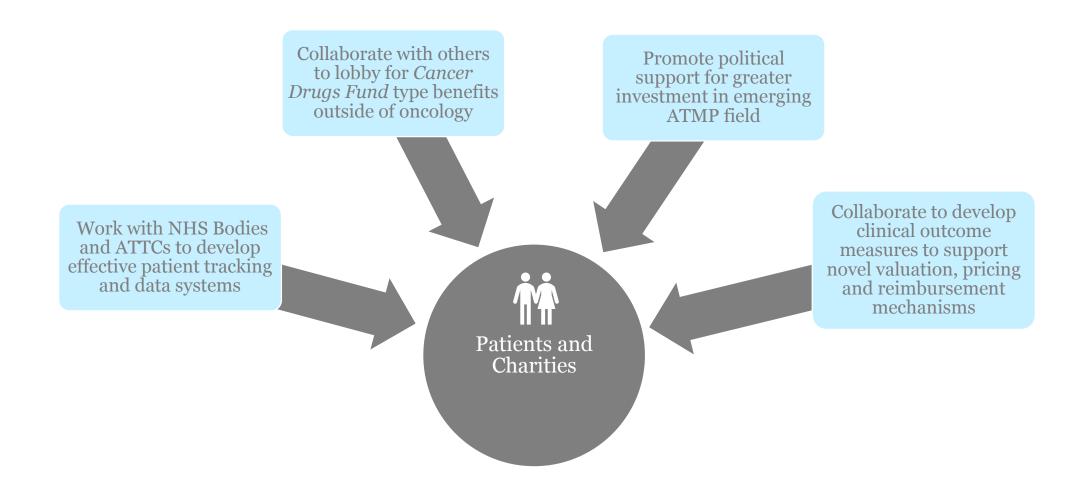
# Where "intermediary" organisations can lead:





# Where patients and patient organisations can lead:





## What next?



Individual organisations can and will create their own agendas going forward. Nonetheless, it is necessary for all the different stakeholders to come together to tackle these issues, as it is too big task for any one group to drive, and it is in everyone's interest to resolve.

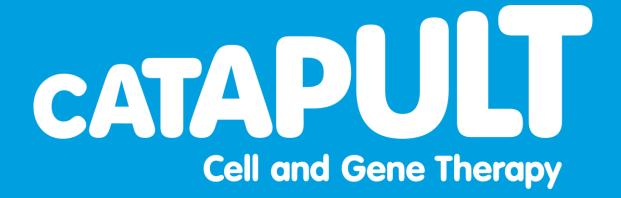
Any organisation seeking help or input in coordinating a further action or collaboration in this area should feel free to contact the Cell and Gene Therapy Catapult.

The Cell and Gene Therapy Catapult, through its coordinating role in the ATTC network and its "Proof of Adoption" strategic priority, will monitor progress over the coming months.

Regular consultation is anticipated to measure progression and impact.

This is just a starting point for a series of actions. It is hoped that, through this workshop, its outputs and the subsequent discussions, no critical area will be neglected or forgotten in the complementary activities that follow.

For more information contact us at **comms@ct.catapult.org.uk** 



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