

Clinical Adoption Day: Data collection requirements for Advanced Therapy Medicinal Product adoption into the NHS

Workshop report

7th November 2019



Introduction

On Thursday 7th November 2019, representatives from a wide range of health organisations came together to discuss how to optimise data collection infrastructure in the NHS to support the market authorisation and adoption of Advanced Therapy Medicinal Products (ATMPs).

This report summarises the key findings and conclusions from this year's workshop.

Organisations in attendance:

- Aptus Clinical
- Association of the British Pharmaceutical Industry
- Atara Biotherapeutics
- Autolus Therapeutics
- BioIndustry Association
- Cancer Research UK
- Catholic University of Rome Sacro Cuore
- Celgene
- Cell and Gene Therapy Catapult
- Dignio
- FarmaTrust
- Gilead Kite
- Immetacyte
- Innovate UK
- Innovate Manchester Advanced Therapy Centre Hub (iMATCH)
- JNJ Janssen
- Medicines and Healthcare Products Regulatory Agency
- Midlands and Wales Advanced Therapy Treatment Centre
- Newcastle University
- Newcastle Upon Tyne NHS Hospitals NHS Foundation Trust
- NHS Digital
- NHS Greater Glasgow
- NHS Lothian
- NHS Scotland
- NHS Wales Informatics Service
- North West E-Health Ltd
- Northern Alliance Advanced Therapies Treatment Centre
- Office for Life Sciences
- Oxford Academic Health Science Network
- Oxygen Strategy
- Pfizer
- Public Health England
- Sarepta Therapeutics
- Scottish Medicines Consortium
- Scottish National Blood Transfusion Service
- Swansea University
- The Christie NHS Foundation Trust
- University of Birmingham
- University College London
- UCL Biochemical Engineering
- University Hospitals Birmingham NHS Foundation Trust
- University of Warwick, Institute of Digital Healthcare
- Vitaccess
- Warwick Manufacturing Group
- Welsh Blood Service

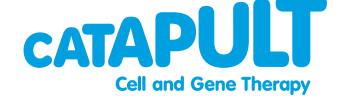


Advanced Therapy
Treatment Centres

Advanced Therapy Treatment Centres Network Update



Progress of the Advanced Therapy Treatment Centres



The Advanced Therapy Treatment Centres (ATTCs) Network was established 18 months ago. A world first, the network in brief :

- is composed of three centres operating within the NHS framework; NA-ATTC (Edinburgh, Glasgow, Newcastle & Leeds); iMATCH (Manchester) & MW-ATTC (Cardiff, Swansea, Birmingham & Nottingham)
- addresses the unique and complex challenges of bringing pioneering Advanced Therapy Medicinal Products (ATMPs) to patients
- is coordinated by the Cell and Gene Therapy Catapult

The UK ecosystem for ATMPs is robust. The ATTC network has, over the past 18 months, worked to help lay the foundations for routine clinical supply. The network to date has focussed on:

- ✓ Identifying key barriers to the authorisation and adoption of ATMPs in the NHS
 - ✓ Upskilling NHS staff
 - ✓ Building data and knowledge sharing platforms/fora
 - ✓ accelerating standardisation across system partners
 - ✓ trialling digital solutions for tracking and tracing
 - ✓ Improving local adoption systems
-

Advanced Therapy Treatment Centres

progress to date

200-250 people
with a network of
30 delivery
partners

Accelerated
research in ATMPs

iMATCH-
up to 5x increase
in number
of trials

Improved
standardisation

Best practice
sharing

Created 'plug and
play' supply chain
solutions for
ATMPs

Built a
knowledge-
sharing platform
(e.g. readiness
toolkit for
ATMPs)

Established
industry advisory
group with a range
of UK industry
leaders

Explored digital
solutions across
the treatment
pathway

Future priorities

- Preparing for **rapid scale-up** - embracing new treatment modalities and disruptive technologies
- Innovative **digital solutions** like data registry support – utilising integrated NHS data
- **Accelerating uptake** – supporting companies and the NHS to adopt therapies earlier
- Driving best practice – developing a **standards framework** for industry and the NHS
- Improving **public and patient engagement** – promoting public adoption and equitable access

Overarching considerations to improve NHS digital infrastructure

- Collaboration is key to facilitate co-design and co-delivery of systems and workflow processes.
- Use technology to work smarter, without losing the human component.
- Reduce bureaucracy and administrative processes to facilitate timely access to data.
- ATTCs should be working to break down barriers in the digital infrastructure identified by developers and manufacturers.

**Shift from
range of
systems to a
“single
comprehensive
system”**

- **Standardisation:**
 - co-developed by clinicians and industry experts
 - implemented prior to or in parallel with digitisation, not after.
- **Interoperability:**
 - void complete transformation
 - data and digital systems should be used seamlessly across the health system.
- Workflow across service boundaries must be improved to ensure we can capitalise on new standards and interoperability.

**Place
standardisation
and
interoperability
at heart**

**Shift from
reactive to
proactive
solutions**

- Collect data once and use often.
- Approach and use of data ensuring goal includes for example improvement of care, manufacturing or payment methods.
- Start with the data and develop the necessary algorithms.
- Data must flow through the system and always be fit for purpose for whoever wants to use it: from starter materials to patient-reported outcomes.
- Remember that digital systems do not "fix" a problem: the problem needs to be identified, issues assessed and resolved, and a digital system can then be introduced.

**Optimise
patient
engagement**

Bring patients and the public onboard: the role of the patient is only becoming more central to the care pathway and once informed, patients are usually keen to share data.

Data collection requirements for advanced therapy medicinal products adoption into the NHS

As increasing numbers of Advanced Therapy Medicinal Products (ATMPs) move through the development pathway, they face unique barriers to market authorisation and reimbursement in the UK.

In particular, there is a need to collect longer-term post-launch outcomes data to establish real-world performance of these therapies and ultimately to satisfy regulatory and reimbursement requirements. Note other innovative therapies and Medtech, besides ATMPs share that same need.

There is broad agreement amongst industry, regulators, payers and healthcare providers that current NHS digital infrastructure is suboptimal for this purpose. To rectify this, there are a number of key factors that should be considered.

Three models for NHS digital infrastructure to support ATMP adoption

There are a number of models that could be implemented to modernise NHS digital infrastructure to better meet the adoption needs of ATMPs and other innovative therapies. For example, stakeholders could:

- 1) **Improve the existing** digital infrastructure, including patient data registries and collection processes, by upgrading individual therapy area specific data registries and collecting more data in distinct therapy areas;
- 2) **Create a new** standalone infrastructure, designed specifically to facilitate data collection and processing to be used across all therapy areas to support any product;
- 3) **Create links between existing datasets** and improve data capture processes to collect patient data that is not currently being collected.

The above options were explored during the digital infrastructure workshop; the subsequent slides capture the findings, conclusions and recommendations from the discussions held

Model One: Improve existing digital infrastructure by upgrading individual therapy area specific data registries

Availability of data collection infrastructure varies across therapy areas

- Cancer represents about 40% of the mature ATMP pipeline; SACT dataset collects extensive data on all cancers in England and is mandatory for Trusts participating in the Cancer Drugs Fund.
- Outside cancer, about two-thirds of therapy areas (with anticipated ATMP launches in the near future) have data infrastructure.
- Bone marrow transplantations and haemoglobinopathies are relatively well served through the EBMT and NHR registries respectively.

Limitations with existing systems

- Raft of systems being developed and implemented resulting in duplication and inefficiencies; some are therapy rather than indication specific which further exacerbates duplication and lack of interoperability.
- Registries lack critical information needed by NICE and the NHS to inform commissioning decisions; not all relevant clinical, economic and humanistic outcomes are being collected.
- Variation in compliance with data entries results in evidence gaps.
- Periods of follow-up not always long enough to address the unique needs of ATMPs.

Improve existing digital infrastructure by upgrading individual therapy-area specific data registries

This is not the most efficient model overall.

- There is an overarching need to prioritise resources and avoid duplication; build around what already exists while avoiding an overly bureaucratic system.
- It is an option for therapy areas with relatively advanced infrastructure for data collection from routine clinical practice e.g. oncology, haemoglobinopathies.
- None of the current registries are without gaps or inefficiencies therefore investment will be needed to improve them; magnitude of investment will vary by therapy area: those with no infrastructure would require brand new systems.

Model two: Create new standalone infrastructure that accommodates any product or therapy area

- Purpose-built design can provide tailored solutions to key problems or system needs and flexibility for outcomes customisation at individual therapy level.
- High level of transparency.
- Relatively easy to measure performance.
- More easily controlled and maintained by the health system.
- Facilitate standardisation and interoperability.
- For high-cost drugs and interventions, there is a financial benefit to be had from developing a new rigorous digital system.
- Enable adoption of therapies with uncertain long-term performance.

- Uncertainty of sustainability and economic implications.
- Risk of system inefficiencies and duplication.
- Missed opportunity to capitalise on existing datasets and digital infrastructure.
- Challenge and complexity of ensuring comprehensive data collection.

**Create new
standalone
infrastructure that
accommodates any
product or therapy
area**

This is not the most efficient or effective model as it is additional to existing infrastructure.

- There is a need to draw on existing infrastructure rather than design an entirely new layer of bureaucracy and administration.
- The NHS should embrace routine data collection throughout the patient journey.
- The system must be able to support data collection becoming part of core, clinical care, which will require sustainable resources and workforce support.

Model Three: Create links between existing datasets and improve data capture processes to collect data not currently collected

- Leverage existing datasets and digital infrastructure more efficiently and effectively.
- Avoid duplication and unnecessary costs.
- Allows more targeted data collection to support ATMP adoption.
- Industry currently funds the development of data registries so they may fund the process to bring existing datasets together for specialised indications.

- Uncertainty regarding what data has previously been collected and where the gaps are.
- Different formats suggest standardisation and interoperability may be difficult to achieve.

Create links between existing datasets and improve data capture processes to collect data not currently collected

This model is perceived by workshop attendees as the best option.

- Facilitates capitalising on existing datasets and infrastructure.
- By embracing the shift away from product-based registries, it is possible to avoid the risk of data duplication.
- This model would facilitate collaboration between regulators, providers, industry and the NHS: stakeholders would focus on clear product needs and data gaps, with distinct responsibilities and defined and achievable aims.
- Given the purpose is capturing data generated through routine clinical practice, ownership of data solutions by the NHS will be key for its successful implementation across the entire NHS.

There is widespread agreement across health policy stakeholders that it would be inefficient and ineffective to try to improve the existing infrastructure by upgrading individual therapy-area specific data registries. These registries do not cater well to the needs of innovative therapies like ATMPs, for post-launch evidence generation, especially given that they do not perform well in long-term follow-up and do not collect information required for commissioning decisions.

Similarly, the creation of new standalone infrastructure to accommodate any product or therapy area does not solve key challenges, including system inefficiencies, and instead risks duplication of existing data and an increase in data entry efforts.

To best support the adoption of ATMPs and other innovative therapies, current digital infrastructure must be improved by creating linkages and interoperability between existing datasets and improving data capture processes to collect data not currently collected.

While each model poses unique benefits and risks for industry and the NHS, this final model holds the most potential to accelerate the adoption of ATMPs in the UK.

Recommendations on improving infrastructure for capturing data from routine clinical practice within the NHS

To facilitate the adoption of innovative therapies like ATMPs in the NHS, there are broad systemic changes required alongside the creation of linkages between existing datasets and improving data capture processes to collect data not currently collected.

There is a need to facilitate a more collaborative relationship across the health policy landscape to drive the successful co-design and co-delivery of data collection processes.

As such, industry, regulators, payers and the NHS have agreed a series of recommendations to address these critical issues and help create a more supportive environment for the authorisation and adoption of ATMPs.

Recommendations: Systemic changes needed to support real world evidence collection that addresses the adoption needs of innovative therapies

- 1. Improve understanding of the benefits of collecting data from routine clinical practice:** as a basis for practicing evidence-based medicine and supporting commissioning decisions
 - 2. Conduct a top-down review of current digital systems:** include a comparative analysis of system effectiveness across disease-areas to help drive resource allocation.
 - 3. Identify gaps in existing datasets:** improve awareness of what data already exists as well as where the gaps remain, with a focus on the needs of innovative therapies with limited evidence at launch.
 - 4. Build on current digital infrastructure and examine mechanisms for interoperability:** avoid excessive duplication and unnecessary cost by improving and cross-linking the systems that already exist.
-

Recommendations: Systemic changes needed to support real world evidence collection that addresses the adoption needs of innovative therapies

- 5. Collect data once and use often:** make use of the data that already exists, which will help make that data more useful and valuable.
 - 6. Introduce a single source of data management within the NHS:** facilitate the use of the significant data that exists in the UK.
 - 7. Develop a strong collaborative relationship between industry and the NHS:** NHS Digital needs to be central in the design of the digital solution and its implementation to allow sharing of data whilst protecting confidentiality.
 - 8. Ensure that healthcare providers lead this collaborative strategy:** bring stakeholders together to understand system needs and facilitate the development of standards and interoperability.
-

CATAPULT

Cell and Gene Therapy

Cell and Gene Therapy Catapult is committed to ensuring high standards of research integrity and research best practice in the activities we carry out. We subscribe to the principles described in the UK concordat to support research integrity.

Cell and Gene Therapy Catapult is a trading name of Cell Therapy Catapult Limited, registered in England and Wales under company number 07964711, with registered office at 12th Floor Tower Wing, Guy's Hospital, Great Maze Pond, London, SE1 9RT. VAT number 154 4214 33.

12th Floor Tower Wing
Guy's Hospital
Great Maze Pond
London SE1 9RT

info@ct.catapult.org.uk
ct.catapult.org.uk
Twitter: @CGTCatapult

