Developing an NIHR CRF for safe delivery of Oncology ATMP trials

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Developing an NIHR CRF for the safe delivery of Oncology ATMP Trials

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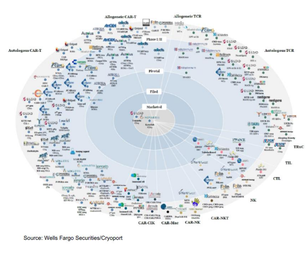
Introduction

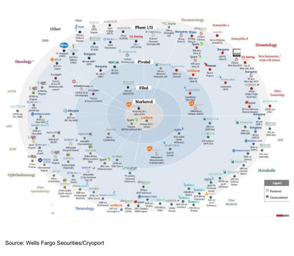
- An advanced therapy medicinal product (ATMP) is a medicinal product which is either:[1]
  - a gene therapy medicinal product
  - a somatic cell therapy medicinal product
  - a tissue engineered product
- ATMP clinical trials in oncology are predicted to grow exponentially. This is due in part to the success of the recently licensed CD19 Chimeric Antigen Receptor T cell (CAR-T) products which offer unprecedented promise for long term remission for some pre-treated and refractory B cell malignancies.[2]

Immune-oncology Landscape



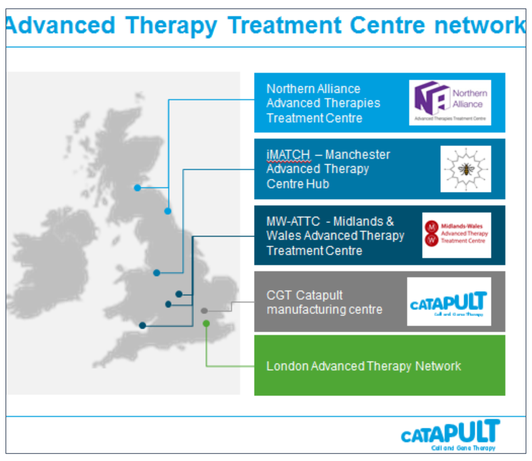
Source: Wells Fargo Securities/Cryoport

Gene Therapy Landscape



Source: Wells Fargo Securities/Cryoport

iMATCH



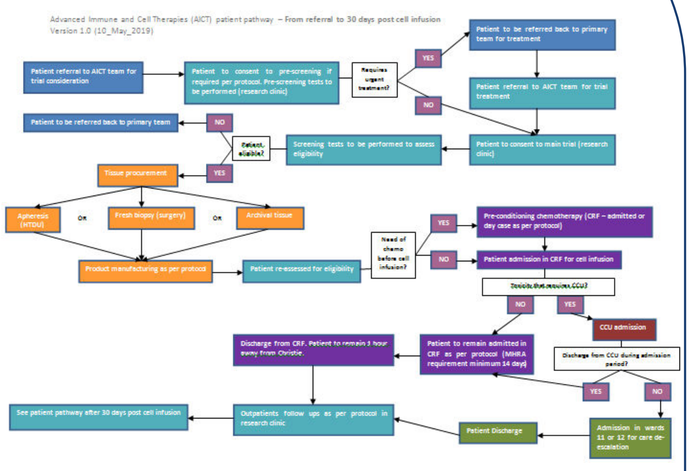
- iMATCH (Innovate Manchester Advanced Therapy Centre Hub) is one of three Advanced Therapy Treatment Centres (ATTCs) awarded funding from Innovate UK. The national network of ATTCs will develop and deliver systems for the delivery of cutting edge cell and gene therapies
- The Christie is the lead organisation in the iMATCH consortium. The CRF plays a central role in delivering iMATCH milestones while benefiting from funding for key new posts central to ensuring the CRF has operational capability for ATMP trial delivery

CRF Development

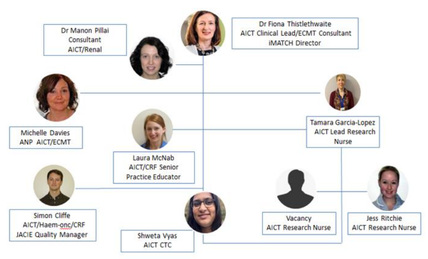
- Oncology ATMP trials are logistically difficult, can be associated with potentially severe and sometimes life threatening toxicities and often require patients to undergo prolonged inpatient stays[3]. Therefore these trials are often delivered on haematopoietic stem cell transplant (HSCT) units with JACIE accreditation. JACIE is an internationally recognised quality system which promotes quality across all aspects of cell therapy.
- To enhance capacity for growing numbers of ATMP trials, the Christie is taking a novel approach by utilising the NIHR CRF to deliver Oncology solid tumour ATMP trials. Due to the potentially high risk nature of these trials, the CRF has undergone an intensive period or re-organisation and training to ensure patient safety is paramount.

Methodology

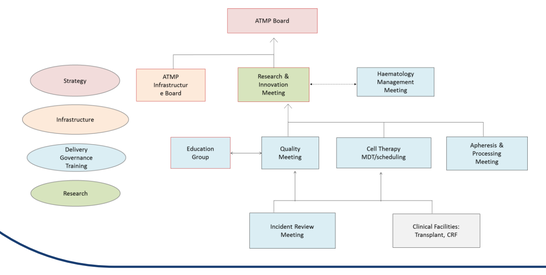
- Process mapping of the patient pathway alongside a gap analysis using JACIE standards, provided a framework to underpin the development of the CRF with a focus on:

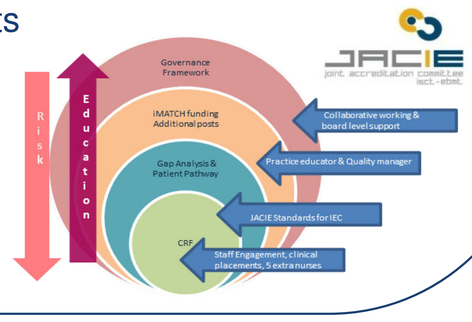


The Advanced Immune and Cell Therapy (AICT) Research Team



- Developing a specialist team
- Embedding an ATMP education programme
- Recruitment of additional staff
  - Quality Manager
  - Practice Educator
  - Consultant
  - CRF nurses
- Governance Structure and Arrangements





Results

- Recruitment of ATMP specialist staff is complete, the ATMP education programme is well established and key relationships with essential specialties such as critical care, neurology and haematology/transplant in place.
- Work is ongoing to ensure the CRF meets appropriate JACIE standards with a JACIE inspection planned for 2020.
- There is an expanding portfolio of solid tumour ATMP trials with two studies currently open to recruitment, three opening imminently and several more approaching set up following feasibility assessment.

diease	Study Status	Predicted Recruitment	Recruitment Start	Recruitment End	Estimated Frequency of Recruitment	Sponsor	Recruitment data
Solid tumour	Open to recruitment	2	May-18	Dec-19	1 every 7.5 months	Adaptimmune	20 patient pre-screen
Solid tumour	Open to recruitment	10	Feb-19	Aug-19	1 every 0.6 months	Immunocore	1 patient pre-screen
Solid tumour	In set up	5	May-19	Sep-21	1 every 5.6 months	Achilles	
Solid tumour	In set up	4	May-19	Mar-20	1 every 2.5 months	Adpatimmne	
Solid tumour	Feasibility	10	Jul-19	Jul-21	1 every 2.4 months	Immetacyte	
Solid tumour	Feasibility	6	Jul-19	Jun-20	1 every 2 months	Achilles	
Solid tumour	Feasibility	2	Aug-19	TBC	TBC	adaptimmune	
Solid tumour	Feasibility	4	Jun-19	May-20	1 every 4 month	GSK	
Solid tumour	Feasibility	TBC	TBC	TBC	TBC	GSK	

Conclusion

- iMATCH has provided essential funding for ATMP specific staff which has supported the development of the CRF to undertake complex ATMP trials.
- The ATTC network has facilitated information sharing and other CRFs have already benefited from the Christie CRF ATMP operational plans.

References

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BE PART OF RESEARCH

The NIHR Manchester Clinical Research Facility comprises four dedicated experimental medicine research units at The Christie NHS Foundation Trust, Manchester Royal Infirmary, Royal Manchester Children's Hospital and Wythenshawe Hospital.