The Christie NHS Foundation Trust Cellular Therapy and Transplant Programme

The cellular therapy and transplant programme at the Christie was first JACIE accredited in 2009 and has since been re-accredited in 2013 and 2015. In 2018 the Christie led a Manchester health consortium known as iMATCH to gain funding from Innovate UK to scale up advanced therapies and make them as routine to deliver as non advanced therapies. In October 2018 the cellular therapy and transplant programme was accredited to version 6.01 of the JACIE standards and was selected as a first wave UK centre for CAR-T therapies.

As part of the iMATCH project and the scale up of advanced therapy activities at the Christie hospital the cellular therapy and transplant programme are to include the NIHR Manchester Clinical Research Facility at the Christie (CRF) as a clinical facility for the next JACIE accreditation inspection due in 2020. Specifically this will only be for advanced therapies conducted at the CRF.

Throughout 2018 and 2019 the preparation for the JACIE re-accreditation was undertaken and through the iMATCH funding new roles were appointed to help the process of including the CRF. The roles included:

- Clinical Research Nurses - to increase the CRF's staffing establishment to help cover the increase in inpatient stays due to advanced therapies.
- Clinical Practice Facilitator - to create and deliver a comprehensive educational programme in line with the JACIE standards for the delivery of advanced therapies.
- Quality Manager - to assess and facilitate compliance of the CRF against the JACIE clinical standards.

The process included a rigorous gap analysis of the JACIE clinical standards and working practice in the CRF. This involved creating processes and work streams to integrate advanced therapies conducted on the CRF into the cellular therapy and transplant programme to comply with the JACIE standards.

The cellular therapy and transplant programme modified existing and created a number of documents in order to deliver advanced therapies and comply with JACIE's immune effector cell standards (edition 6.01). The list of new/modified documents is below:

Collection facility

- Assessment and eligibility of patients undergoing HPC collection
- CAR-T Washout Letter
- CAR-T work up checklist
- Clinical apheresis unit structure and referrals
- Coordinating a Chimeric Antigen Receptor T-Cell (CAR-T) therapy (including TCR)
- Labelling of cellular apheresis and bone marrow products
- Medical assessment form for patients
- Optia MNC Procedure for HPC and T-Cell Collection

Clinical facility

- Business Continuity Plan Outpatients
- Business Continuity Plan Ward
- Cardiovascular Disease Following Stem Cell Transplantation and Cellular Therapy
- CAR-T discharge checklist
- Chimeric Antigen Receptor T-cell Therapy discharge and follow up
- CCU Admissions and Discharge Policy
- Data management and completion of med A/B forms
- Guidelines for the Management of Cytokine Release Syndrome Associated with Cancer Immunotherapies

- Guidelines for the Management of Sepsis
- Hepatic Veno-Occlusive Disease (Sinusoidal Obstruction Syndrome) and Liver Dysfunction
- HLH and Macrophage Activation Syndrome
- Infusion of Cellular Products
- Inpatient Management of Patients Receiving Immune Effector Cells (Including CAR-T Cells)
- Management of Anaphylaxis
- Neurological Disease in Stem Cell Transplantation and Cellular Therapy
- Nurse and AHP Training
- Nursing observations for all haematology and cellular therapy patients
- Pathway for Patients with Suspected Sepsis – To Achieve One Hour to Antibiotics Administration
- Renal Disease Following Stem Cell Transplantation and Cellular Therapy Including Thrombotic Microangiopathy (TMA)
- Respiratory Disease Following Stem Cell Transplantation and Cellular Therapy
- SOP for the Transfer of Critically Ill Adults
- Stem Cell Infusion Checklist for Nurses
- Thrombocytopenia, Bleeding and DIC
- Training Pack for the Infusion of Cellular products
- Trust PGD Directions (including antibiotic & saline)

Pharmacy

- Pharmacy/Pathology Management of Cellular Therapy Products (CTPs) as Advanced Therapy Medicinal Products (ATMPs)
- Haematology Summary of Prophylaxis
- Medicines Practice Operational Policy
- Training for Pharmacists Involved in Haematopoietic Cellular Therapies
- Tumour Lysis

Processing facility

- Checklist for the thawing and administration of frozen cells
- Checklist for the Transport, Storage and Administering of Fresh Cells
- Cleaning and disinfection policy and procedure
- Issuing Frozen Cells to the ward
- Labelling Policy
- Management of Non-conforming (inc. contaminated) Cellular Product
- Order Notification Form for Processing
- Policy for the Receipt and Release of Products
- Policy for the storage of fresh product and consumables
- Receipt of harvests
- Request for issue of IMP or ATMP
- Stem Cell (HPC) and T Cell (T-CT) Processing Request Form
- Storage Policy for Cryopreserved Cells
- Traceability and tracking policy
- Transport Policy (Lab and Collection Facility)