
Executive Summary Of Collaborative Working Agreement

Project Name:	ATTC Bridging – CAR-T Patient Referrals Pathway Gap Analysis
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Document Control

Document History

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Reviewers & Approvers

This document will be reviewed and approved by the following people prior to issue for sign-off.

Name	Title	Version No	Release (draft/final)	Reviewed (Y/N)	Issue Date
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Distribution

The final signed-off version of this document is to be distributed to the following people for information purposes only.

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Asimina Pantazi - CGTC	Business Development Manager - UK North	0.1	Draft	9 th NOV 2022
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1.0 Organisations Involved

- Autolus Limited
- Cell and Gene Therapy Catapult
- Gilead Sciences Limited
- Janssen Cilag Limited
- NHS Blood and Transplant
- The Christie NHS Foundation Trust

2.0 Project Overview

Currently, demand for CAR-T referrals is relatively low within the NHS and relies on national structures such as the National CAR-T Clinical Panel (NCCP) or regional clinical trial networks to identify patients appropriate for CAR-T treatments. As the spread and scale of CAR-T widens, and with the potential loss of the NCCP, effective processes for referring patients are needed to maintain patient access to standard of care CAR-T as well as investigational CAR-Ts.

A group of institutions including, the Cell and Gene Therapy (CGT) Catapult, Advanced Therapy Treatment Centre (ATTC) Network Autolus Limited (Autolus), Gilead Sciences Ltd (Gilead),

Janssen-Cilag Limited (Janssen), NHS Blood Transplant (NHSBT) and The Christie NHS Foundation Trust (The Christie) (“the Parties”) have agreed to participate in a Collaborative Working Agreement in line with the ABPI Code of Practice to identify and analyse CAR-T patient referral pathways in the UK to recommend future best practice.

The project will be delivered by The Christie and NHSBT for the CGT Catapult in collaboration with the Parties. The project will capture the consolidated view of surveys, interviews and mappings at CAR-T treatment centres and convey the critical analysis of pathways with service improvement suggestions and the outline business case for change at the two sites of focus (The Christie and NHSBT).

This project involves a balance of contributions from all parties with the pooling of skills, experience and resources.

3.0 Project Plan

- Survey a broad range of adult CAR-T treatment centres, secondary referrals centres, patient advocacy groups and governing structures.
- Interview key opinion leaders from survey responses to further explore their opinions.
- Map the patient referrals processes from secondary referrals centres into CAR-T treatment centres, critically analyse referral practices, highlighting best practice and evaluating root causes for ineffective practices.
- Define patient and healthcare professional requirements for a high-quality referrals process.
- Explore how equity of access is affected by referral practices and how current processes can account for anticipated changes in CAR-T environment.

4.0 Expected Project Outcomes

The project outputs will be a white paper with a set of justified recommendations for improved, standardised future CAR-T patient referral practice and an outline business case for The Christie and NHSBT.

It is expected that this project will enable:

- The creation of powerful collaborations which overcome the challenges in CAR-T patient referrals pathways / processes and transform these barriers into industrial advantages that develop new perspectives on CAR-T patient referrals
- Support of clinical adoption and delivery of CAR-T therapies in the UK
- Better understanding of the challenges faced by NHS organisations providing CAR-T
- Informing of a best practice referral and care coordination process from referring centres to CAR-T centres which is patient-centric and fully supported by documentation.
- Creation of greater synergy between CAR-T treatment centres and referring centres.

5.0 Expected Project Benefits

To patients:

- More effective patient referrals and thus improved access to care.
- Equity of access to CAR-T around the country.

To the NHS:

- Better understanding of the challenges faced by NHS organisations providing CAR-T.
- Information on requirements to deliver better service for patients.
- Shared learning across the NHS through the white paper.

To the Cell and Gene Therapy Catapult:

- Better understanding of the challenges faced by NHS organisations providing CAR-T.
- Creation of powerful collaborations which overcome the challenges in CAR-T patient referrals and transform these barriers into industrial advantages that develop new perspectives on CAR-T patient referrals.

To the Pharmaceutical Company Partners:

- Better understanding of the challenges faced by NHS organisations providing CAR-T.
- Improved NHS processes to ensure increased access to CAR-T products for all eligible patients.

6.0 Duration of Project

10 months (Dec 2022 – Oct 2023)

7.0 Contacts

- Fiona Thistlethwaite, ATTC Project Lead / Director iMATCH
- James Griffin, NHSBT Lead / Medical Director Cell, Apheresis & Gene Therapies
- Justin Hayde-West, Janssen Cell Therapy Coordination Manager
- Luis Calleja Calatrava, Janssen Cell Therapy Account Lead
- Anita Ralli, Gilead UK Associate Director Government Affairs
- Sarah Waluda, Autolus Senior Director Clinical Programme Lead