Manchester CRF (Christie site) Research Application Form

Organisation: The Christie NHS Foundation Trust

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Funded by UK Research and Innovation

Coordinated by CATAPULT Cell and Gene Therapy

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Manchester CRF (Christie Site) Research Application Form

Please complete this form in Word. Please use the drop-down boxes where applicable.

It is essential for this form to be reviewed and validated for clinical accuracy by a Clinical Research Nurse before submission to the CRF

Please note if this application is incomplete, we will be unable to consider the application and the form will be returned.

General Study Information & Finance	
Full study title	
Short title/acronym	
DOG Number	
Funding Category	Choose an item.
Sponsor	
Funding Type? Guidance	
If trial is Non-Commercial, is funding available for CRF activities?	Choose an item.
Which organisation is the main funder for this study?	
Lead Centre (CI Based, See IRAS)	
NIHR-Required Study Categorisation	
A) Please choose a research type for your study	Choose an item.
B) If you selected "Other research" in A) please clarify further	
C) Please indicate the phase of trial	Choose an item.
D) If you selected "Other study" in C), please clarify further	
E) Is Ethical Approval required for this trial	Choose an item.
Please indicate the Primary intervention type?	Choose an item.
If other, please specify	
Does the study involve gene therapy/biological therapy? ***If you have answered yes, a review by the Trust's Biological Agents Safety Committee may be required. If approval already obtained, provide with submission.***	Choose an item.
Randomised trial?	Choose an item.
Experimental medicine? **i.e., Phase I to IIa**	Choose an item.
First in human?	Choose an item.

Contacts			
Principal Investigator (PI)			
Title	Choose an item.	Full name	
ORCID (Required if trial is PI's first CRF trial application)			
Clinical Research Nurse (CRN)			
Title	Choose an item.	Full name	
Telephone		Email	
Clinical Trials Coordinator (CTC)			
Title	Choose an item.	Full name	
Telephone		Email	
Preferred day to day contact:			

Clinical Requirements	
This section is intended to be completed by a Research Nurse	
Resources Required	
What CRF Facilities will be required? – please tick all service requirements which may occur at any point during the trial. Please tick as many that apply.	☐ Clinic ☐ Phlebotomy (Blood) ☐ Lab processing ☐ Lab storage ☐ Treatment Chair/bed ☐ Overnight bed ☐ Weekend visits ☐ Non-Treatment Chair/bed e.g., PK / Obs only ☐ Other
If you have selected 'Other', please specify.	
Any specific equipment required? E.g., IV giving sets, water bath, ECG machine	
Will any equipment be provided by sponsors? If Yes, please indicate equipment being provided ***If Yes, please see the Trust's Medical Devices policy for acceptance and maintenance of loaned equipment***	
Please indicate if any specialist training required i.e., Ward based preparation of CTIMP	

Are there any specific medical cover requirements	☐ Medic/Clinician present during infusion ☐ Escalation to CCU ☐ Trust handover for overnight stays ☐ Daily reviews ☐ Other
If there answered 'Other' to the previous question, please specify what other requirements will be required.	
Recruitment	
Estimated start of recruitment at the Christie CRF	Click here to enter a date.
How many participants do you plan to recruit at the Christie?	
Clinical speciality	Choose an item.
Age range e.g., 18yrs+	
Clinical Trial Delivery	
Sections A-D provide detailed information in relation to the delivery of a clinical trial on the CRF. Please complete as many sections as required for your study delivery.	
Section A – Clinics/Phlebotomy	
What clinic(s) will patients attend? E.g., Monday Gynae research AM	
Will patients be receiving any oral or subcutaneous trial treatments in clinic? If yes, then please complete Section D.	Choose an item.
What will be the frequency of the clinic visits?	
Will the patients require phlebotomy in the CRF blood room?	Choose an item.
What will be the frequency of the phlebotomy visits?	
Section B - Labs	
Does this study require any samples to be processed in the CRF Lab?	Choose an item.
Please outline the timepoints for sample processing?	
Do any of the samples require complex processing i.e., PBMCs?	Choose an item.
Do any of the samples require long term storage in the CRF lab? (longer than 4 weeks)	Choose an item.

Section C - Treatment Chairs or Beds	
What is the preferred day(s) of the week for treatment on the CRF?	☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday ☐ Saturday ☐ Sunday
Is there an option for patients to be treated on 2-day treatment?	Choose an item.
If answered yes to please specify the options available i.e., Review Monday and treat Tuesday.	
What is the frequency of treatment visits / cycles? e.g., 3 weekly	
What is the total number of treatment visits expected? e.g., 6 cycles, or until PD.	
Is there a requirement for overnight visits on the CRF?	Choose an item.
Please specify the frequency, duration and days when overnights are required.	

Section D - Treatment Regimens: IMP and other drug/s name and class

Please include all drugs to be delivered as part of the trial regimen, including any standard SACT drugs or pre meds/fluid for hydration. Please add more rows as required.

#	Drug name	Drug Class e.g., SACT, Monoclonal Antibody	Type i.e., Pre-med, IMP, SOC	Delivery method i.e., IV, Oral, SC	Location (CRF treatment chair or Clinic)	Administration time (Initial & Subsequent)
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Additional Clinical Information
Please include any immediate significant potential reactions / clinical concerns relating to study treatment (e.g., TLS, CRS, IRR)

Long Stay or Short Stay Visits	
Will the disease team Research nurses deliver any of the treatment visits instead of the CRF nurses?	Choose an item.

Please outline the expected CRF visits requiring treatment chairs or beds. Please add more rows as required.

Visit time point:	Total Time of visit (Please include PK and Observation time in the total)	Approx. visit time dedicated to treatment delivery	Approx. visit time dedicated to non-treatment activity (Obs, PK's etc)	Please indicate any treatments which will be delivered by the disease team Research nurses
E.g., Arm A C1D1	*E.g., 10 Hrs*	*E.g., 2 Hrs*	*E.g., 8 Hrs*	

Comments and Contact info
Please use this section to add any further details as required.

Guidance for completing the application form

Funder Type

Industry Contract

The CRF (via contracts with the CRF's host NHS Trust) provides services to industry fora fee; overall responsibility for the studies lies with the Company. These studies involve NHS patients and/or healthy volunteers and are carried out by the CRF at the behest of industry. The Company instigates trial development and has full control of study design and management. The Company also sponsors the study. Neither the CRF nor the contracting CRF host/NHS Trust has any responsibility for protocol development and they have no discretion in regard to changes to the protocol. Data is owned and analysed by the Company, though for research governance reasons, contracts must protect NHS organisations' and Investigators' rights to review all data and publish results of scientific interest.

Industry Collaborative

Industry Collaborative Clinical Research studies are under the joint responsibility of industry and the CRF (via contracts with the CRF's host NHS Trust). Sponsorship duties may be assumed by either the commercial or a non-commercial partner. Collaborative clinical studies may involve some or all of the following from the CRF:

- The provision of clinical expertise, resources and facilities
- Scientific planning;
- Ongoing research oversight

If industry contract/collaborative, please specify industry type

Pharma - a company which develops, produces, and/or markets drugs or pharmaceuticals licensed for use as medicinal products.

Biotech - a company which is primarily concerned with the development, production and/or marketing of biological products

Medtech/Device - a company that makes and/or sells medical devices or other healthcare technology products. The term medical devices covers products used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability excluding (for the purposes of this report) in vitro diagnostics (see below) and software as well as licensed medicinal products.

In vitro diagnostic - a company which develops, produces and markets *in vitro* diagnostics. *In Vitro* Diagnostics are defined as diagnostic tests which are used to analyse a sample taken from the body *e.g.* blood, urine, sputum.

CRO (Contract Research Organisation) - a commercial organisation contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

Non-life sciences company – a company that is not defined as pharma, biotech, medtech/device or diagnostic according to this guidance. Examples could include software companies, design companies etc.