
Research and Innovation Trial Feasibility proforma (IEC trial protocol review)

Organisation: The Christie NHS Foundation Trust

Document version number: v12_10_18

Date written: 2018

End user rights:

This document is shared with permission for re-use to distribute, remix, adapt, and build upon the material in any medium or format for non-commercial purposes only, so long as the attributions listed below are given.

Attributions: The Christie NHS Foundation Trust

This document is made available under a Creative Commons Attribution-NonCommercial 4.0 International License as described here:

<https://creativecommons.org/licenses/by-nc/4.0/>

The information, materials and any opinions contained in this document are provided for general information and educational purposes only, are not intended to constitute legal, medical or other professional advice and should not be relied on or treated as a substitute for specific advice relevant to particular circumstances. Although we make all reasonable efforts to ensure the information is up to date, we make no representations, warranties or guarantees in that regard. In no event shall the creator(s) be liable for any direct, indirect, special, consequential or other claims, losses or damages that are related to the use or reliance whatsoever in the content of the document or any part thereof, except to the extent that such liability cannot be excluded by

Funded by

Coordinated by

law. We do not seek to exclude or limit in any way our liability to the user for personal injury or death caused as a result of our negligence or seek to exclude or limit our liability for fraud or fraudulent misrepresentation by us.

We reserve the right to make changes and improvements to any information contained within this document, at any time and without notice. Where this document contains hyperlinks to other websites operated by parties not connected to us, such hyperlinks are provided for your reference only. We do not control such websites and are not responsible for their contents. The inclusion of hyperlinks from this document or the website to such websites does not imply any endorsement of the material on such websites or any association with their operators. We accept no responsibility of any nature whatsoever for linked web sites or any information contained in them.

Funded by



UK Research
and Innovation

Coordinated by

CATAPULT
Cell and Gene Therapy

IEC (Immune effector Cell) Trial Protocol Review

To be presented by PI/CI or suitable delegate – 10min overview to the group to cover the following:

TITLE					
Proposed PI					
Disease group					
SCIENTIFIC MERIT					
Type of IEC (Immune effector cell) 1) Eg. CAR,TCR,TIL 2) Autologous or Allogenic					
Type of the Vector					
PROTOCOL DESIGN To include details of expected inpatient stay					
Conditioning and/or additional treatment requirements (eg IL2) include regime and doses					
Anticipated in Patient length of Stay					
Description of Clinical Risk (include factors described in appendix 1)					
Level of care (please circle)	1	2	3	4	5

	Outpatient care anticipated	Additional level of ward care anticipated eg overnight stay	Outreach input on ward is probable	CCU admission significant possibility	CCU admission expected and with risk of patient death
RECRUITMENT TARGET (number of patients)					
Anticipated PPFV					
Recruitment period					
Protocol differed variance from standard of care SOPs Eg. Required access to 24 hour ECG)					
Apheresis/procurement comments (eg capacity or barriers)					
Nursing comments (eg. capacity or barriers)					
Pathology/Stem Cell laboratory comments					
Other comments eg CCU					

OUTCOME Accept/ reject onto ATMP portfolio or defer until further clarification	
Proposed clinical area for delivery if accepted	

Appendix 1

1. Intensity of pre-conditioning chemotherapy regime
 - i. Level 1 = myeloablative
 - ii. Level 2 = 'full dose' non-myeloablative cyclophosphamide (2 days 60mg/kg 5 days) fludarabine (3 days 30mg/m²) or equivalent
 - iii. Level 3 = reduced dose cyclophosphamide + fludarabine or equivalent
 - iv. Level 4 = standard chemo or equivalent
 - v. Level 5 = none
2. Additional combination therapies eg IL2 (high dose or low dose)
3. First in human
4. Anticipated toxicities with explanation as to why (or why not) these are anticipated
 - a. CRS
 - b. Neurotoxicity
 - c. Other