Advanced Therapy Medicinal Products technical and regulatory assessment application

Organisation: iMATCH, University of Manchester NHS Foundation Trust

Document version number: 1

Date written: July 2020

Funded by UK Research and Innovation

Coordinated by CATAPULT Cell and Gene Therapy

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NHS
Manchester University
NHS Foundation Trust

ADVANCED THERAPY MEDICINAL PRODUCTS (ATMP)
TECHNICAL AND REGULATORY ASSESSMENT APPLICATION

Product details	
Product Name:	Click here to enter text.
Type of ATMP (click as many as apply)	☐ Cell Therapy ☐ Gene Therapy; Biosafety Level _1__ ☐ Genetically Engineered Tissue Therapy ☐ Medical devise
Mechanism of action	
Is it a licensed product in UK:	☐Yes Licensed Indication: Patient population (adult/children) : Disease state: see Licensed Indication ☐No
If not licensed in UK is it licensed in any other country:	☐ N/A ☐Yes Country licensed: Click here to enter text. Licensed Indication: Click here to enter text. Patient population (adult/children) Click here to enter text. Disease state: Click here to enter text. ☐No
Will it be used within the licensed indication?	X Yes ☐ No If not expand here:
Consultant Name and speciality:	
Site:	☐ Oxford Road Campus Location: ☐ Wythenshawe Hospital ☐ Withington Hospital ☐ Trafford General Hospital ☐ Altrincham Hospital
Documents provided in support of application	

-to include as a minimum: Summary of Product Characteristics (SmPC)	☐ SmPC ☐ Safety Data Sheet ☐ COSHH Form ☐ Other, please specify Click here to enter text.
Declaration by Consultant Applicant: The information in this form is accurate to the best of my knowledge and I take full responsibility for it. I understand that MMC/MOC will need to be notified of any changes to the information in this this form.	Consultant Signature: (Electronic accepted)

ATMP Assurance Committee USE ONLY **Document received by:** Click here to enter text. **MFT location:** Click here to enter text.	
Date received:	**Click here to enter text.**
Date of ATMP assurance meeting:	Click here to enter text.

This fully completed Risk Assessment is the basis for assessment of capacity and capability within Manchester University NHS Foundation Trust to deliver the ATMP.

1. Clinical Team

1.1 Consultant applicant	
1.1.1 Experience Using the Product (specify if licensed/unlicensed/ clinical trials, etc)	
Other relevant experience	
1.1.2 Role	
1.1.3 Training status	
Product training received?	☐ Yes / ☐ No Date of training: Click here to enter text. Training provider: Click here to enter text.
Advanced Life Support (ALS) training received in date?	☐ Yes (mandatory training) / ☐ No Date of training: Click here to enter text. Training provider: Click here to enter text.

1.2 Other Members of the Clinical Team		
Click here to enter text.		
Include name and roles for the clinical team leads, including HTA-DI, cell lab personnel when applicable, nurses, pharmacist etc. (This must include as a minimum: prescribing, dispensing and administering the medicinal product), each team lead is responsible to ensure any member of their team are adequately trained for the role they are performing in relation to the ATMP.		
Name	Role	Training (check box to confirm trained and valid)
1.		☐Product training date: Training provider:
2.		☐ Product training date: Click here to enter text. Training provider:
3.		☐ Product Training date: **Click here to enter text.** Training provider:
4		☐ Product training date: Click here to enter text. required Training provider: Click here to enter text.
5.		☐ Product training date: surgical training not required Training provider: Click here to enter text.

ATMP Assurance Committee USE ONLY	
Does the consultant/ clinical team require any further support?	☐ Yes / ☐ No / Recommendation: Click here to enter text.
Have training needs for the clinical team been identified appropriately? Other members of the clinical team will be further trained on practical issues, like handling the product and waste management on a dry run one week prior treating the first patient.	☐ Yes / ☐ No / Recommendation: Click here to enter text.

2. Patient Care Pathway

2.1 MFT Current Patient Care Pathway
Describe the current standard care pathway for the indication/indications this ATMP is proposed to be used in MFT (if this is in accordance to NICE Guidance, attach the document (s) to the application indicating the section of this form at the top)

2.2 Proposed Patient Care Pathway
Describe the proposed Patient Care Pathway in this section

See attached (if this is in accordance to NICE Guidance, just attach the document (s) to the application indicating the section of this form at the top)	
Does the care pathway involve other services (such as critical care, radiotherapy, etc) and has this been agreed? Please provide written evidence as an attachment to the application. Note operational implications of such therapy need to be agreed before approval. Click here to enter text.	
2.2.1 Decision to Treat	
How will patients be identified for treatment?	
How will participants be prioritised to obtain greatest benefits to the proposed therapy?	
What assessments will be required prior treatment?	
Is the timescale of the initial assessments crucial for the ATMP treatment? If so explain strategies to always comply with these as routine	☐ Yes / ☐ No
If any of these assessments fail will this patient be able to receive the therapy?	
Will local, regional or national MDTs always be involved in decision making	☐ Yes / ☐ No Specify which type of MDT and if not require please expand why.
2.2.2 Patient Admission	
Will the participant need admitting prior ATMP administration or after administration? Please specify reason for either answer (Yes/No), assessments, services impact (e.g. labs, theatres, equipment needed), location and duration of the admission	☐ Yes /☐ No
2.2.3 Product Preparation	
Does the product need Pharmacy Aseptic preparation? Attach to the application evidence (e.g. SmPC)	☐ Yes / ☐ No
Does the product need Cell lab handling/thawing? Attach to the application evidence (e.g. SmPC)	☐ Yes / ☐ No
What are the storage requirements for the IMPs including temperature?	
What is the shelf life of the product provided by the manufacturer? Once prepared for administration (including thawing), how much time is there to administer ATMP to the subject?	
Are there any issues with compatibility of the ATMP (does it need specific ancillaries, e.g. bag material, syringes, lines for administration, etc. to be used)	
2.2.4 Product Administration	
Where will this product be prescribed?	
Administration Guideline will be required, including Adverse Drug Reaction Guide. Included in this application	☐ Yes / ☐ No
Monitoring required during administration and after administration. Attach relevant guidance	
Is medical supervision required during administration and after administration, please provided details.	
Does the administration of the ATMP require stem cell lab supervision?	
State if a relevant specialist is required to be available	☐ Yes / ☐ No

to support emergencies and adverse event management. Please detail who is required and under what circumstances.	
Describe supportive drugs/concomitant medication required prior, during or after administration of ATMP	
Template Patient Alert Card provided by manufacturer. If yes, please attach to the application.	☐ Yes / ☐ No Click here to enter text.
2.2.5 Discharge and Follow up	
Please specify when patients will be discharged, follow up, assessments, services impact (e.g. labs, theatres, equipment needed), location and duration of the admission	Click here to enter text.

ATMP Assurance Committee USE ONLY Receipt of ATMPs will be by Pharmacy or Pharmacy approved location. The manufacturer will provide preparation instructions (e.g. as per SmPC). All staff involved in handling ATMPs will be trained in shipment receipt, handling (including thawing product when required), accountability, traceability and reporting product complaints. A flow chart and evidence of training will need to be in place and submitted to ATMP assurance committee prior to final ATMP approval for use in the Trust. Patient Alert Card will be required to be handed to the patients.	
Is the Patient Care Pathway proposed adequate and in line with National Guidelines? Including appropriate patient admission, prescription, product preparation and administration based on information provided	☐ Yes / ☐ No Recommendations: Click here to enter text.
Is there any risk perceived due to resource requirement (e.g. staffing, beds, support services, etc)?	☐ Yes / ☐ No Recommendations: Click here to enter text.
Comments and additional recommendations: Click here to enter text.	

3. Funding

Funding Arrangements – please attach letter or SSC from commissioner

Management of ATMP Product and Waste.

ATMP waste will be discarded as per MFT waste policy. In addition, GMM will be assessed as per information provided below as it constitutes a higher risk for the trust, staff, patient, environment and general public.

NOTE. If this product has been previously used in the trust as an investigational medicinal product and an application form has been submitted to the Early Phase Safety Committee for R&I governance arrangements and approval, do not complete the sections below, instead please attach the EPSC form to this application.

4	**Receipt and Storage of ATMP**
4.1	Where will the ATMP product be stored? Who is responsible its formal receipt on site and during storage? Do they need any specific training? Has this taken place?
4.2	How will the product be transported to the storage location?
4.3	Are there any particular requirements for storage eg. temperature control, room ventilation?
4.4	What is the contingency plan in the event of equipment failure? (include alarm alerts etc). .
4.5	What security measures are in place? Would you be able to easily and rapidly identify that a sample/stock was missing?
5	**Preparation of ATMP for Administration**
5.1	Is a safety cabinet required for preparation?
5.2	Are there specific requirements for the room ventilation?
5.3	Will centrifugation of the product be required? If so, will sealed rotors and buckets be used and where would these be open? Describe procedures if leaks and spillages occur in the centrifuge.
5.4	Disposal of excess ATMP
6	**Transport and containment of ATMP**
6.1	How will the product be transported from the storage area to administration area?
6.2	Describe who will transport it and the containment measures used.
7	**Administering the ATMP**
7.1	Where will the ATMP be administered to the patient?
7.2	Is the room to be shared with other patients? If yes, why is the patient not segregated?
7.3	Are there specific requirements for the room during administration? Eg. temperature, air pressure.
7.4	Is access to the room restricted?
7.5	How long will the patient stay in hospital after administration?
7.6	If, after administration, the patient is to be transferred, state the new location and answer questions 13.2 to 13.5 for this new location.
THE SECTIONS BELOW TO BE COMPLETED ONLY FOR GENE THERAPY PRODUCTS	
8	**For Gene Therapy Only: Sampling and monitoring of shedding (if required)**
8.1	How long will the GM organism persist following administration?
8.2	What is the route of shedding?
8.3	What level of shedding could occur?
8.4	How will shedding be monitored?
8.5	How will the shedding of the gene therapy product be contained?
8.6	What are the consequences for other body systems (non-target) from the systemic administration of the gene product?
8.7	What is the normal mode of transmission of the GMM?
8.8	What other routes of transmission are possible? Eg. needlestick injuries, how will these be minimised?

8.9	What are the possible consequences of an accidental exposure? (to the person administering the gene therapy product)
8.10	What samples are required to be taken from the patients following administration of the gene therapy product?
8.11	Who will take the samples?
8.12	What Personal Protective Equipment will they be required to use?
8.13	Where will these samples be taken to for analysis? Describe who will transport them and the containment measures to be used.
8.14	Who will analyse these samples? How and where will this waste be disposed of?
9	**Patient handling and emergency procedures**
9.1	Besides during sampling, what Personal Protective Equipment (PPE) is required whilst administering and subsequently caring for the patient?
9.2	What decontamination or disposal arrangements are in place for PPE?
9.3	Describe the procedures in place for dealing with spillages of the product.
9.4	Describe the procedures in place for an accidental exposure eg. eye splash, percutaneous inoculation. (immediate action, when and to whom to report the incident, medical intervention or prophylaxis)
9.5	Are there any specific arrangements required to evacuate a patient in the event of fire?
9.6	Are there specific actions to be taken in the event of death of the patient before the end of the treatment period?
9.7	Describe whether there are specific procedures to be followed in the event of the patient requiring resuscitation**.**
9.8	Describe the procedures to be followed if the patient suffers from post-operative infection. Would the patient require transfer to another location? Detail the potential for exposure to other personnel and the control measures in place to minimise this.
10	**Interactions with other patients and staff, visitors and family**
10.1	What risks are there for personnel, other than patients, potentially exposed to the gene therapy product at all stages of the trial; from preparation, transport, administration, on-going care, removal of samples, through to inactivation?
10.2	What training is being provided to all staff identified as being at risk of exposure? How will this be recorded?
10.3	Has local information been provided? Is it available to all those at risk of exposure?
10.4	Will visitors to patient be allowed? How will their risk of exposure be minimised? What information will they be provided with?
11	**Waste Pathway**
11.1	What are the stages at which contaminated waste is generated and what types/quantities of items will be produced?
11.2	How will GM waste be contained during transport and prior to disposal?
11.3	Will GM waste be inactivated and how?
11.4	How will inactivated waste be disposed of?
11.5	Will there be any waste still subject to GM legislation relating to transport and disposal?

ATMP ASSURANCE COMMITTEE USE ONLY: SUMMARY OF DECISION	
Has the ATMP been adequately risk assessed and is the patient care pathway proposed acceptable?	☐ Yes / ☐ No
Gene Therapy Product: What containment level is the product and is the product storage, handling and waste management appropriate and in accordance to the MFT waste management policy?	Level 1 ☐ / Level 2 ☐ / Above ☐ ☐ Yes / ☐ No
ATMP Assurance committee Approval **Comments:** Click here to enter text.	☐ Yes / ☐ No

Date of decision: Click here to enter text.

CSS Medical Director – ATMP assurance committee chair on behalf of the ATMP assurance committee group

Signature: Click here to enter text.

Name and Signature of Applicant: Click here to enter text.