****

**Advanced Therapy Education**

**Training Needs Package**

** **

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# Introduction:

The Northern Alliance Advanced Therapy Treatment Centre (NA-ATTC), formally established in March 2018, is a consortium of industry, NHS and academic organisations. The purpose of the centre is to develop the systems and infrastructure required to support the delivery of cell and gene therapies with the ultimate aim of increasing patient access to advanced therapy medicinal products (ATMPs) on a national level. ATMPs can be life changing, and in some cases curative but they are complex treatments, requiring safe innovative ways of working, new knowledge and skills. ATMP therapies present unique learning needs for the wider nursing community and for individuals responsible for clinical nurse education and training.

As part of the NA-ATTC training needs review, a training needs gap analysis questionnaire was distributed across the NATTC network with the aim of identifying current gaps in knowledge and experience relevant to advanced therapies. Fifty individuals replied and these were mainly representative of, but not exclusive to, nursing with varied levels of experience. The results strengthened previous acknowledgements that training needs are not adequately provided for and more guidance is needed, especially to those new to this specialist field. Over 62% of responders expressed that they would like to receive further training and educational resources.

This training needs package and competency guide has been developed for all healthcare and academic professionals involved in the delivery and direct care of patients receiving advanced therapy treatment; it provides information and signposting to external resources for independent training, learning and further reading on a number of key areas relevant to advanced therapies. The learning resources can be utilised and tailored to suit individual needs and those relevant to specific clinical/academic areas.

The aim of this training package is to facilitate advanced learning by providing structure to required theoretical knowledge and guide individual practice development. Evidence of training may consist of formal accredited training, attendance at local and national study days, clinical observation, peer feedback reflection, reading and e-learning. Please note that it is imperative that this training package does not replace any trial-specific teaching materials and training requirements. Additionally, a number of advanced therapy standard operating procedures (SOPs) are accessible. SOPS are crucial references for information for many of the topics covered in this workbook, please refer to those locally. *(Please insert local SOP signposting/Q-PULSE link).*

# Key contacts:

Your local advanced therapy research team is a multidisciplinary team with extensive knowledge and skills. The contacts listed below can support you throughout your learning journey:

*Please populate your local contacts before dissemination. We have included suggested key individuals/roles: research nurses, ATMP clinician leads, pharmacists, R&I key staff, CRF leads, clinical educators, quality assurance leads, CRN, etc)*

|  |  |  |
| --- | --- | --- |
| **Name**  | **Role** | **Contact email**  |
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# Competency template:

Please review the competencies and training requirements detailed below and identify your training needs. Learning objectives and progress can be recorded in each table.

|  |  |
| --- | --- |
| **Identified objectives & skills**  | **Current training resources available**  |
| Demonstrate a knowledge and understanding of what advanced therapy treatments are and the different classifications, including:* Gene Therapy medicinal products
* Somatic cell therapy medicinal products
* Tissue engineered products
 | Introduction to Advanced Therapy Medicinal Products- E-learning online module:<https://www.e-lfh.org.uk/programmes/advanced-therapy-medicinal-products/>A guide to gene therapy webinar:<https://event.on24.com/wcc/r/2649158/880804D0ADCCDC60D874FFCF46159077>Introduction to cell therapy webinar:<https://event.on24.com/wcc/r/2704544/0658090BB0C28BD9FF0C2D5E9C167E77>ATMP Overview:<https://www.ema.europa.eu/en/human-regulatory/overview/advanced-therapy-medicinal-products-overview> Advanced Therapies 2021 - Introducing Cell and Gene Therapies:<https://www.youtube.com/watch?v=xMNTSLVvBkw>  |
| **Individual training record*****Please utilise the space below to record evidence of learning and reflections*** |
|  |

##  1. Introduction to ATMPs

## 2. Clinical Indications

|  |  |
| --- | --- |
| **Identified objectives & skills**  | **Current training resources available**  |
| Recognise the clinical indications that ATMP therapies can be used forGain an understanding of how CAR T-cell therapy worksReview case studies for different disease groupsPatient and Public perspectives on ATMPS | The following video shows how CD 19 CAR-T cells work: <https://youtu.be/mXADrg_ckhI> The CAR T-Cell Therapy Clinical Journey Guide:[Autolus\_UK-Guide\_Digital.pdf (kxcdn.com)](https://attc-143fd.kxcdn.com/wp-content/uploads/2021/08/Autolus_UK-Guide_Digital.pdf)Advanced Therapy education webinar: Solid tumour treatment<https://event.on24.com/wcc/r/3104889/D577901301F6C0AA4A381965A123C37C> Advanced Therapies 2021 training video - Ask the Experts: Liver Disease and Rheumatoid Arthritis:<https://www.youtube.com/watch?v=dB5JBO60x4Q>Advanced therapy education webinar: Advanced therapies for diabetes:<https://event.on24.com/wcc/r/3105567/0C0D0F6CFBB651DDA6A063C44CA698EA>Patient and Public Perspectives on Cell and Gene Therapies:<https://www.youtube.com/watch?v=Hm5R4qnsXmM>  |
| **Individual training record*****Please utilise the space below to record evidence of learning and reflections*** |
|  |

## 3. Set up and Costings of ATMP Trials

|  |  |
| --- | --- |
| **Identified objectives & skills**  | **Current training resources available**  |
| Familiarise yourself with NIHR costing considerations specific to ATMPs and the resources available to guide you through the approval and set up processes. | NA-ATTC toolbox:[March-2022-updated-NAAATC\_toolbox\_EXTERNAL.pdf (theattcnetwork.co.uk)](https://www.theattcnetwork.co.uk/wp-content/uploads/2022/03/March-2022-updated-NAAATC_toolbox_EXTERNAL.pdf) Micro-costing toolkit for advanced therapy medicinal products:<https://www.theattcnetwork.co.uk/wp-content/uploads/2022/02/MWATTC-Micro-costing-Analysis-Toolkit.zip> <https://www.youtube.com/watch?v=2MkE1PAvSl8>Expertise sharing to accelerate trial set up: <https://www.theattcnetwork.co.uk/case_studies/expertise-sharing-to-accelerate-trial-set-up>  |
| **Individual training record*****Please utilise the space below to record evidence of learning and reflections*** |
|  |

## 4. Governance and Assurance

|  |  |
| --- | --- |
| **Identified objectives & skills**  | **Current training resources available**  |
| Establish an understanding of the governance and regulatory controls both locally and nationally.Familiarise yourself with local pathways and governance SOPS in relation to ATMPs. Does your local trust have an ATMP quality assurance committee and if so what is their role? | Institutional readiness:<https://www.theattcnetwork.co.uk/wp-content/uploads/2021/04/NA-ATTC-Institutional-Readiness-validated-questionnaire.docx> Advanced Therapy education webinar: Advanced therapies and NHS readiness:<https://event.on24.com/wcc/r/3098330/B6F1C5BF97D49528BEB4277CC6A4ED7C> GCP for ATMPS:[Good Clinical Practice - Health Research Authority (hra.nhs.uk)](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/good-clinical-practice/) Medicines and Healthcare products Regulatory Agency (MHRA):[Advanced therapy medicinal products: regulation and licensing - GOV.UK (www.gov.uk)](https://www.gov.uk/guidance/advanced-therapy-medicinal-products-regulation-and-licensing) JACIE readiness for immune effector cells:<https://attc-143fd.kxcdn.com/wp-content/uploads/2021/04/JACIE-readiness-for-immune-effector-cells.pdf> Pan UK Pharmacy Working Group Advice Document Regulatory Requirements for Export of ATMPStarting Materials:<https://www.sps.nhs.uk/wp-content/uploads/2019/09/Regulatory-Requirements-for-Export-of-ATMPs-starting-materials-FINAL.pdf>  |
| **Individual training record*****Please utilise the space below to record evidence of learning and reflections*** |
|  |

## 5. Manufacturing & Transportation Logistics

|  |  |
| --- | --- |
| **Identified objectives & skills**  | **Current training resources available**  |
| Establish an understanding of the manufacturing process of ATMP’s and unique challenges it presentsSuggested areas to focus on:Logistical considerations Chain of Custody/Chain of IdentitySupply chain issues Shipment/transportation StoragePackaging and labelling  | Advanced Therapy Webinar series: Introduction to ATMP manufacturing:<https://event.on24.com/wcc/r/2704700/8A6BFBFF235E2E311893171785503172>Just in Time delivery of ATMPs - Late-stage customisation of packaging and labelling:<https://attc-143fd.kxcdn.com/wp-content/uploads/2021/12/DL130-Thermo-Fisher-Scientific-ATTC-Late-Stage-Customisation-final_9Nov21.pdf> Tracking and storage considerations to maintain parameters during shipping & storage for different products:<https://attc-143fd.kxcdn.com/wp-content/uploads/2021/11/DL175_Tracking-and-storage-considerations-to-maintain-parameters-during-shipping-and-storage-for-different-products.pdf>Transporting advanced therapies animation:<https://attc-143fd.kxcdn.com/wp-content/uploads/2020/01/Transporting-Advanced-Therapies.mp4>Safe use of low temperature transport vessels e-learning module<https://portal.e-lfh.org.uk/Catalogue/Index?HierarchyId=0_45016_45921_51006&programmeId=45016>  Cellular ATMP Fresh Autologous: Example Receipt Checklist:<https://attc-143fd.kxcdn.com/wp-content/uploads/2021/10/MWATTC-Checklist-for-receipt-and-storage-of-allogeneic-fresh-cellular-ATMPs.pdf>  |
| **Individual training record*****Please utilise the space below to record evidence of learning and reflections*** |
|  |

## 6. Handling & Thawing of Cellular Therapies

|  |  |
| --- | --- |
| **Identified objectives & skills**  | **Current training resources available**  |
| ATMP trial specific protocols and investigator brochures will specify exact requirements for individual products but it is useful to gain an understanding of the fundamental principles around handling ATMPs and thawing of cellular materialsBiohazard and spills - identify local SOPControl of Substances Hazardous to Health (COSHH)Disposal of ATMP product- trial specific policy and local SOP | Example SOP: Handling and Administration of In vivo GMO Gene Therapies:<https://attc-143fd.kxcdn.com/wp-content/uploads/2021/10/MWATTC-SOP-Handling-and-Administration-of-in-vivo-GMO-gene-therapies-1.pdf> Considerations around thawing and visual inspection of cell therapy medicinal products- power point training tool:<https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.e-lfh.org.uk%2Fwp-content%2Fuploads%2F2021%2F03%2FFINAL-cell-therapy-visual-inspection.3.pptx&wdOrigin=BROWSELINK>EXAMPLE CHECKLIST FOR THE THAWING AND ADMINISTERING OF FROZEN CELLS:<https://attc-143fd.kxcdn.com/wp-content/uploads/2021/04/Thawing-Checklist.pdf> The Association of the British Pharmaceutical Industry: ATMPS Roadmap:<https://www.abpi.org.uk/media/o1npmwck/atmp-roadmap-tool_final_03122021-fullscreen.pdf>Example SOP: Management of GMO Spillage or Accidental Exposure in a Clinical Area:<https://attc-143fd.kxcdn.com/wp-content/uploads/2021/08/GMO-Spillage-exemplar-SOP-final-template.pdf>  |
| **Individual training record*****Please utilise the space below to record evidence of learning and reflections*** |
|  |

## 7. Administration and Supportive Care

|  |  |
| --- | --- |
| **Identified objectives & skills**  | **Current training resources available**  |
| As with traditional medicinal products, it is vital that patients are closely monitored for short term and long term side effects from treatment. Consider the following patient needs:Analgesia & concomitant medications Anti-fungal prophylaxis NutritionBlood product supportShared carePsycho-social support Long term follow up  | The CAR T-Cell Therapy Clinical Journey Guide:<https://attc-143fd.kxcdn.com/wp-content/uploads/2021/08/Autolus_UK-Guide_Digital.pdf> Advanced therapy education webinar series: Care of CAR-T patients; The nursing perspective:<https://event.on24.com/wcc/r/3105567/0C0D0F6CFBB651DDA6A063C44CA698EA>Example Adult CAR T Cell Shared Care Guidelines:<https://attc-143fd.kxcdn.com/wp-content/uploads/2021/10/MWATTC-Example-Adult-CAR-T-Cell-Shared-Care-Guidelines.pdf> Medication Restrictions for Patients Having CAR-T Cell Therapy Pan UK Pharmacy Working Group for ATMPs:<https://www.sps.nhs.uk/wp-content/uploads/2021/07/Medication-Restrictions-for-Patients-having-CAR-T-Therapy-V3-July-21.pdf>  |
| **Individual training record*****Please utilise the space below to record evidence of learning and reflections*** |
|  |

##  8. Toxicities

|  |  |
| --- | --- |
| **Identified objectives & skills**  | **Current training resources available**  |
| In addition to protocol specific toxicity guidelines, it is imperative that staff have an awareness of the common toxicities associated with ATMP treatments and the presentation, diagnosis and clinical management. This includes but are not limited to:Cytokine release syndromeImmune Effector Cell Neurotoxicity SyndromeHaemophagocytic Lymphohistiocytosis | Short clinical scenario training video on ‘Management of Cytokine Release Syndrome in patients receiving CAR T cell therapy’:<https://vimeo.com/600940785/b652e6dd2e> MHRA Yellow card recording system:<https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949130/Guidance_on_adverse_drug_reactions.pdf>Early warning systems to flag evolving toxicities through rapid turn-around monitoring capabilities and integration into digital algorithms:<https://www.theattcnetwork.co.uk/case_studies/early-warning-systems-to-flag-evolving-toxicities-through-rapid-turn-around-monitoring-capabilities-and-integration-into-digital-algorithms> Diagnosis and Medical Management of Acute CAR-T Cell Toxicities in Adults The first stop for professionalmedicines advice:<https://www.sps.nhs.uk/wp-content/uploads/2020/12/Diagnosis-and-medical-management-of-acute-CAR-T-cell-toxicities-in-Adults-V1.pdf>  |
| **Individual training record*****Please utilise the space below to record evidence of learning and reflections*** |
|  |

## Appendix 1:

### ATMP Data Sheet for Clinical Observation

*Use this template to record details of observed clinical practice in relation to the ATMP pathway and delivery. Think about the classification of the ATMP, the journey it has made prior to reaching the clinical environment and how clinical delivery differs from traditional CTIMP trial delivery. (Photocopy more sheets as required).*

|  |
| --- |
| Date:ATMP name: |
| ATMP classification *If it is a gene therapy is it in-vivo or ex-vivo?* *For cellular therapies where did the cells originate from (autologous or allogeneic)?* |  |
| Clinical indications/condition used for  |  |
| Manufacturing journey pre-clinical*For cell therapies find out how they have been manipulated/modified and where has this happened* |  |
| Pre administration investigations and patient safety checks |  |
| Method of administration  |  |
| Immediate side effects |  |
| Supportive care  |  |
| Follow up required  |  |

## Appendix 2

### Observed Practice Reflection Sheet

*You may wish to use this space to reflect on your clinical observation (as above). How has this clinical experience supported your learning and how does it relate to the theoretical knowledge you have gained working through these competency guideline. Please do not record any information that might identify an individual or patient. Photocopy more sheets as required.*

**Date:**

**Reflection of observed practice:**

References and Links to further resources**:**

ATTC network:[**https://www.theattcnetwork.co.uk/**](https://www.theattcnetwork.co.uk/)

Competency Framework for Clinical Research Nurses October 2011: [Microsoft Word - Competency Framework Version 2.docx (nihr.ac.uk)](https://cambridge.crf.nihr.ac.uk/wp-content/uploads/2015/04/Research_Nurse_Competency_Framework_-_Version_2_-_Full_-_Oct_20111.pdf)

E-learning for Health ATMP modules: <https://www.e-lfh.org.uk/programmes/advanced-therapy-medicinal-products/>

European Medicines Agency (EMA) Advanced therapy medicinal products: <https://www.ema.europa.eu/en/human-regulatory/overview/advanced-therapy-medicinal-products-overview>

London Advanced therapies: http://london-advanced-therapies.org/

NA-ATTC Website: [Northern Alliance Advanced Therapies Treatment Centre • ATTC Network - Advanced Therapy Treatment Centre (theattcnetwork.co.uk)](https://www.theattcnetwork.co.uk/centres/northern-alliance)

National Institute for Health Research NIHR learn: [Learning and support | NIHR](https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/)

Patient and Public Perspectives on Cell and Gene Therapies - Dr Lee Aiyegbusi: https://www.youtube.com/watch?v=Hm5R4qnsXmM

Ramello, M, C. et al. (2018) CAR-T cells and combination therapies: What's next in the immunotherapy revolution? Pharmacological research; 12, p. 194-203: [CAR-T cells and combination therapies: What’s next in the immunotherapy revolution? - ScienceDirect](https://www.sciencedirect.com/science/article/abs/pii/S104366181730600X)

The Association of the British Pharmaceutical Industry: ATMPS Roadmap:

<https://www.abpi.org.uk/media/o1npmwck/atmp-roadmap-tool_final_03122021-fullscreen.pdf>