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**Institutional Readiness Levels:**

**Site assessment questionnaire**

Produced by Northern Alliance ATTC.

The Institutional Readiness questionnaire created by NA-ATTC is for use by NHS Clinical Sites to self-assess their own Institutional Readiness for adoption of ATMPs, both through clinical trials and licensed medicines. The toolkit contains the following documents:

 (A) Introduction and Background

 (B) Work Instructions for Site IR Self - Assessment

 (C) Institutional Readiness for ATMP Questionnaire

April 2021

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**(A) Introduction and Background**

It is recognised that successful adoption of ATMPs requires NHS Trusts / Boards to be able to adapt their skills, processes and practices at an institutional level. Institutional Readiness (IR) has been suggested as a means of assessing the capacity of an institution to adopt new technologies. Within the context of healthcare, IR can be defined as; *"Whether, and if so, how far, an organisation needs to adapt to embrace a new technology".* Gardner, Webster and Barry (2018) discuss the concept of IR in depth and examine the challenges of implementing regenerative medicine (RM) therapies within hospitals and clinics. They also highlight dynamics within existing healthcare systems that will present both hindrances and affordances for the implementation of new RM technologies within hospitals and clinics [1].

An IR Working Group consisting of stakeholders from each of the NA-ATTC clinical sites was established to develop a tool to assess IR based on previous work in the technology industry [1]. Using the table of criteria for assessing the IR of clinical delivery sites for RM therapies within the paper as a basis [1], and following a workshop with support from Prof Andrew Webster [1], NA-ATTC developed a questionnaire for its clinical delivery sites to self-assess their own IR for Advanced Therapies. The group agreed criteria against which IR was assessed which illustrated the breadth of IR that is necessary for successful adoption of ATMPs. IR was self-assessed by clinical sites for four exemplar products that were chosen to illustrate IR across the different classifications of ATMP.

This user-validated tool has been developed for use by clinical sites with aspirations to deliver ATMPs.  This work was led by Ewan Morrison, Director of Pharmacy (NHS National Services Scotland) and Ruaridh Buchan, Senior Clinical Trials Pharmacist (NHS Lothian) on behalf of the Northern Alliance Advanced Therapies Treatment Centre programme, in collaboration with Newcastle upon Tyne Hospitals NHS Foundation Trust, NHS Greater Glasgow and Clyde, Leeds Teaching Hospitals NHS Trust and NHS Lothian.

***Reference:*** [1] Gardner J, Webster A, Barry J. Anticipating the clinical adoption of regenerative medicine: building institutional readiness in the UK. Regenerative medicine. 2018 Jan;13(1):29-39.

**(B) Work Instructions for Site IR Self - Assessment Exercise**

1. Identify coordinator(s) within the NHS institution who will be responsible for identifying and convening the assessment panel, collating and interpreting the completed questionnaire and summarising key actions following assessment.
2. Identify key stakeholders within NHS institution with expertise in clinical delivery or professional interest in each class of ATMP to form an assessment panel. Suggested stakeholders include, but are not limited to:

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| --- | --- |
| * Stem cell laboratories
 | * Pharmacy
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| * Appropriate clinical delivery team
 | * Support departments (e.g. ITU, Neurology, Apheresis)
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| * Directorate/Trust/Board management
 | * Research & Development departments
 |
| * Ward managers
 | * HTA Licence Holder Designated Individual
 |
| * Quality management teams
 | * Financial management teams
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1. Supporting documentation should be highlighted including selected Summary of Product Characteristics from the relevant class of products. The four classes of ATMPs are Virus based gene therapy, Cell based gene therapy, Somatic cell therapy and Tissue engineered products. These documents should be circulated to the assessment panel ahead of meeting in order for members to familiarise themselves with the assessment process and classes of ATMP.
2. Convene panel to assess Institutional Readiness according to the criteria listed in the questionnaire against the four ATMP classes or ATMP class(es) of interest. Each criterion should be rated as follows:
* Red – not started at site
* Amber – in process of being developed
* Green – developed and evidenced.
1. It is important to document, with supporting comments, the rationale for assigning criteria a colour as this facilitates interpretation of the completed questionnaire.
2. The coordinator should analyse the completed questionnaire taking into account supporting comments in order to identify areas of good practice, areas where work is being undertaken and areas where further work is required.
3. It is recommended that the questionnaire is completed at regular intervals to assess progress within the NHS institution.

Other suggested resources include;

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| Advanced Therapies NHS Readiness Toolkit | https://www.theattcnetwork.co.uk/advanced-therapies-nhs-readiness-toolkit |
| Pharmacy oversight and supervision requirement for preparation of licensed ATMPs | <https://www.sps.nhs.uk/articles/pharmacy-oversight-and-supervision-requirements-for-preparation-of-licensed-atmps/> |
| Requirements for Governance and Preparation of Gene Therapy | <https://www.sps.nhs.uk/articles/requirements-for-governance-preparation-of-gene-therapy-pan-uk-pharmacy-working-group-for-atmps/> |
| Regulatory Requirement for export of ATMP starting materials | <https://www.sps.nhs.uk/articles/regulatory-requirements-for-export-of-atmp-starting-materials-pan-uk-pharmacy-working-group-on-atmps/> |
| Pharmacy institutional readiness for Marketed CAR-T Therapy | <https://www.sps.nhs.uk/articles/pharmacy-institutional-readiness-for-marketed-car-t-therapy-guidance-for-chief-pharmacists/> |
| Generic Autologous ATMP Clinical Flow Chart | <https://www.theattcnetwork.co.uk/wp-content/uploads/2020/01/Generic-Autologous-Patient-Pathway-V1.3-19.12.19-1.pdf> |
| Generic Allogenic ATMP Clinical Flow Chart | <https://www.theattcnetwork.co.uk/wp-content/uploads/2020/01/Generic-Allogeneic-V1.4-09.05.19.pdf> |

**(C) Institutional Readiness for ATMP Questionnaire**

**Tissue Engineered/Cell Based Gene/Somatic Cell/Virus Based Gene**

By product class in an NHS Trust/Board

|  |  |  |
| --- | --- | --- |
| **NHS Trust or Board:** | **Date:** | **Completed by:** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria relating to the ATMP technology or technique** | **Criteria relating to the potential site of clinical delivery** | **Red****Amber****Green** | **Comments in support of assessment** |
| **Target indication for the ATMP** | Existing expertise in delivering ATMP within class? |  |  |
| Operational capacity to treat expected patient cohort? |  |  |
| Opportunities for patient / public involvement & collaboration? |  |  |
| **Complexity of intervention** | Logistical clinical coordination - planning, procurement, production and distribution (within shelf life) for each individual patient? |  |  |
| Appropriate clinical infrastructure for administering treatments and supportive treatments?  |  |  |
| Reactive and flexible structures are in place to allow staff training as required? |  |  |
| **Governance** | Clear governance structures exist and can be evidenced for clinical trial and/or licensed medicines usage |  |  |
| **Perceptions of ATMP technology** | Goal alignment of front-line clinicians, administrators, managers and other stakeholders? e.g. CAR-T – growth of product would require more ITU beds. |  |  |
| Does the ATMP have high profile across the institution/geography? |  |  |
| **Place and mode of harvesting and packaging of starting materials and preparation of ATMP** | Access to relevant Pharmacy expertise? i.e. has Pharmacy readiness assessment been completed?  |  |  |
| Are facilities, staff and systems in place for procurement of starting materials? |  |  |
| Are facilities and processes in place to receive and store products as required? |  |  |
| Are processes in place as required for product preparation? |  |  |
| **Quality** | Are appropriate Quality Assurance staff in place? e.g. governance structure in place for supporting the use of specialist clinical trial products out of specification? |  |  |
| Are appropriate Quality Management Systems in place? |  |  |
| **Can costs and clinical outcomes be reliably monitored?** **Resource and expertise is available for data-collection infrastructure?** | Clinical Trials |  |  |
| Licensed products including early access to medicines |  |  |
| **Funding** **Resource and expertise available to secure appropriate funding and cost pathways [capital and revenue]?** | Clinical trials |  |  |
| Licensed products including early access to medicines |  |  |
| **Others** | Is there a mechanism to complete and approve local business case(s) through Trust/Board governance channels?  |  |  |

**Assessment Measures for each section**

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| --- | --- |
| **Red – Not started**  | In comments section describe whether it is intended to prepare for any or all of the ATMP class and any timescales that are currently being discussed. |
| **Amber – In process of being developed** | In comments section indicate what stage preparations are at in relation to each ATMP class, what plans are in place for attaining readiness and projected timescales. |
| **Green – In place and evidenced** | In comments section indicate which ATMP classes are ready to be delivered and share any learning which may benefit the other Hospitals. |