

## NA-ATTC Advisory Document

### NHS Business Case for Advanced Therapy Medicinal Product Service Provision

The Northern Alliance Advanced Therapies Treatment Centre (NA-ATTC) is an Innovate UK funded project with a consortium of twenty industry, NHS and academic organisations led by The Newcastle upon Tyne Hospitals NHS Foundation Trust and the Scottish National Blood Transfusion Service. The purpose of the centre is to develop the systems and infrastructure to support the delivery of cell and gene therapies, with the aim of increasing patient access to Advanced Therapy Medicinal Products (ATMPs) on a national level.

Work Package 4 of NA-ATTC, “Infrastructure, Reimbursement and Outcomes”, led by Tom Chubb, Rare Diseases Manager and Julie De-Almeida, Head of Market Access, Chiesi Ltd, and Ewan Morrison, Director of Pharmacy, NHS National Services Scotland, seeks to provide guidance to ATMP developers on regulatory and commissioning processes and pathways and support clinical delivery sites in identifying and addressing gaps in their “Institutional Readiness” to deliver ATMPs to patients at scale.

This advisory document, an output of Work Package 4, provides guidance and key points that should be considered for inclusion in NHS Trusts / Boards internal business cases where organisations are seeking to deliver ATMP treatments. In the table below the key areas are detailed, with examples provided by NA-ATTC clinical centres with previous experience of preparing business cases for ATMP provision.

#### Table of Considerations

Key Area	Example points for consideration
<b>1. Service description</b>	<ul style="list-style-type: none"> <li>• Description/ background to disease</li> <li>• Description of the proposed service</li> <li>• Assessment of benefits and risks of developing the service</li> <li>• Consideration of where the product currently is in the Development and/or licensing process</li> </ul>
<b>2. Directorate/ department strategy</b>	<ul style="list-style-type: none"> <li>• Describe how the proposal fit with overall strategy of department/directorate (e.g. integration, growth, consolidation)</li> </ul>
<b>3. Reason for request</b>	<ul style="list-style-type: none"> <li>• Targeted growth within the clinical area of NHS Trust/ Board</li> <li>• Enhancing capacity and/or promoting efficiency</li> <li>• Improving Research and Innovation</li> <li>• Investment to save scheme</li> <li>• New medicine(s) being approved for use (what are the other treatment options available?)</li> </ul>
<b>4. Summary of the technology/innovation</b>	<ul style="list-style-type: none"> <li>• Description of the technology</li> <li>• Expected patient numbers (e.g. disease prevalence, NICE resource impact template)</li> <li>• Description of the operational/clinical pathway</li> <li>• Referral criteria</li> <li>• Any complicating factors to treatment</li> </ul>

	<ul style="list-style-type: none"> <li>• Medical intervention required pre, post and follow up treatment</li> </ul>
<b>5. Financial</b>	<ul style="list-style-type: none"> <li>• Type of investment: e.g. revenue or capital &amp; revenue</li> <li>• If capital: New or replacement?</li> <li>• Estate requirements: Existing, reconfigured or new</li> <li>• Is the Finance department aware of the proposal?</li> <li>• Current national funding model</li> <li>• Cost of pre/post treatment medicines</li> <li>• Cost of post treatment review and follow-up</li> </ul>
<b>6. Impact on commissioners</b>	<ul style="list-style-type: none"> <li>• Consider: Capacity, activity, coding, tariff, costs</li> <li>• Have other internal options been considered or tried prior to submission?</li> </ul>
<b>7. Impact on IT services and estate department</b>	<ul style="list-style-type: none"> <li>• Does the proposal impact IT (e.g. long term follow up, database management for patients receiving ATMPs)?</li> <li>• Access to required patient registry</li> <li>• Is the IT department aware of the proposal?</li> <li>• Any issues from an estates perspective (e.g. Genetically modified waste management processes)?</li> <li>• Is the estate department aware of the proposal?</li> </ul>
<b>8. Support of NHS Trust sustainability</b>	<ul style="list-style-type: none"> <li>• Does it reduce energy use, water use, travel miles (patient or staff)</li> <li>• Deliver care closer to home (decreasing pressure on acute site resources)</li> </ul>
<b>9. Baseline activity</b>	<ul style="list-style-type: none"> <li>• Current UK NHS landscape</li> <li>• What other centres are treating this condition</li> <li>• Should be a local treatment or referral to other centre</li> </ul>
<b>10. Anticipated benefit/outcome</b>	<ul style="list-style-type: none"> <li>• How will this be measured?</li> <li>• Articulation of value for patients &amp; Board/Trust</li> <li>• Metrics and timescales</li> </ul>
<b>11. Impact on support services</b>	<p>Consider the following:</p> <ul style="list-style-type: none"> <li>• Radiology</li> <li>• Surgical departments – theatres/wards</li> <li>• Intensive care units</li> <li>• Medical records</li> <li>• Laboratories</li> <li>• Estates</li> <li>• Outpatients</li> <li>• Allied Health Professionals</li> <li>• Apheresis unit</li> <li>• Theatres</li> <li>• Palliative care</li> <li>• Pharmacy (including aseptic services)</li> </ul>
<b>12. Workforce and potential investment</b>	<ul style="list-style-type: none"> <li>• Outline additional workforce required to support delivery</li> <li>• Consideration of staff training and education</li> <li>• Referral pathways</li> </ul>

	<ul style="list-style-type: none"> <li>• New operational capacity? (e.g. Qualified Person)</li> <li>• Additional monitoring required? (i.e. reporting suspected adverse reactions, adverse events)</li> </ul>
<b>13. Risks arising from non-implementation</b>	<ul style="list-style-type: none"> <li>• Clinical</li> <li>• Financial, service delivery</li> <li>• Quality</li> <li>• Reputational</li> </ul>
<b>14. Spend to save initiatives</b>	<ul style="list-style-type: none"> <li>• Service efficiencies e.g. spend to save, waiting list initiatives</li> </ul>
<b>15. Project management</b>	<ul style="list-style-type: none"> <li>• Project plan</li> <li>• Key milestones</li> <li>• Timelines</li> </ul>
<b>16. Risk management</b>	<ul style="list-style-type: none"> <li>• Define how risk will be monitored during the project</li> </ul>
<b>17. Dissemination / communication</b>	<ul style="list-style-type: none"> <li>• Strategies to be employed to make others aware of the development (communications, marketing)</li> </ul>