

CLINICAL ADVISORY GROUP (CAG) TERMS OF REFERENCE

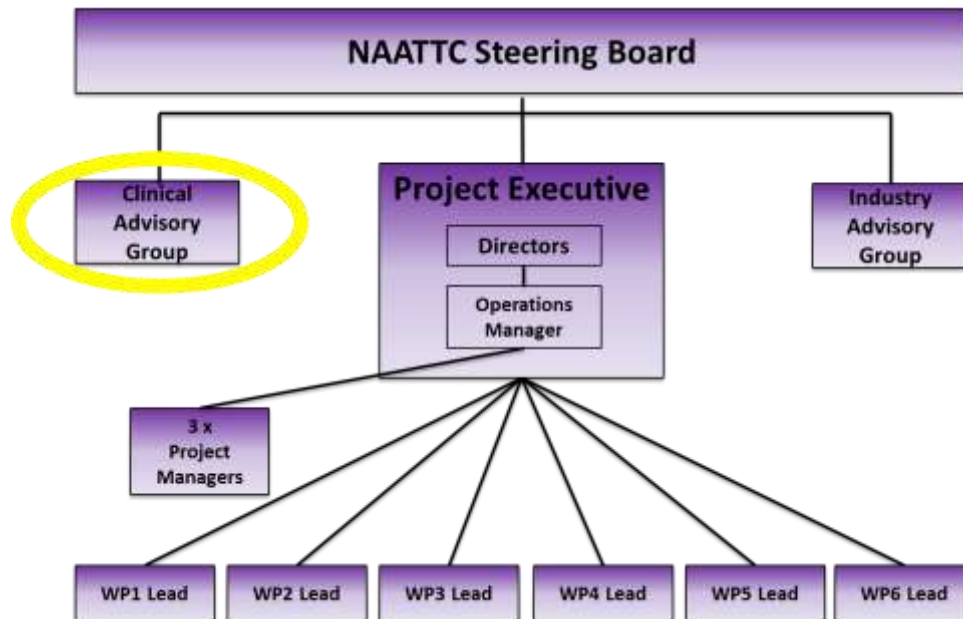
A. Terms of Reference

The Northern Alliance Advanced Therapies Treatment Centre (NAATTC) is a collaboration between industry, NHS and academic organisations, with a vision to increase patient access to advanced therapy medicinal products regionally and nationally by growing a cost-effective clinical delivery pathway which meets the needs of the providers of advanced therapy products.

The CAG will be responsible for:

- Establishing a forum to discuss and foster patient-centred AT development and provision in the UK including wide stakeholder representation
- Providing public / patient stakeholder representation within NAATTC
- Providing patient-informed feedback to the Executive Team on overall Northern Alliance progress and direction towards patient-centred, sustainable and equitable AT provision nationally
- Identifying barriers to optimal and equitable patient access to ATs
- Overseeing the Trials Coordination Unit in fostering pathways for effective late phase clinical trials
- Reviewing post-marketing NHS adoption of ATs and foster pathways for equitable patient-centred delivery
- Overseeing WP3 progress, Milestones and Deliverables
- Publishing a toolbox on patient-centred AT trial design and clinical delivery within the NHS
- Interacting with the Industry Advisory Group to understand industry barriers to patient-centred AT adoption
- Fostering partnerships between the other ATTCs and other stakeholder groups nationally / internationally
- Horizon-scanning to include institutional readiness for AT adoption in much larger patient numbers with common chronic diseases and scale up of gene therapy / editing clinical implementation

B. Governance



C. Membership

The CAG consists of a Chair, Scientific Advisor, NA Clinician Scientist Lead, Trials Coordination Unit lead, Patient / Public Representative, PPI/PPE Methodology Representative, Health Care Professional Representatives from Newcastle / Leeds / Edinburgh / Glasgow (4 members), Chair of NAATTC Industry Advisory Group, NHS Commissioning Representative (England and Wales / Scotland) (2 members), Regulatory Representative, Head of ATTC Network Coordination, Cell and Gene Therapy Catapult.

Potential additional representation (Health Economist and Senior NHS Trust Manager) will be discussed within CAG with putative start date of 1st January 2020.

If the normal representative is unable to attend, a deputy may be sent and the Chair should be informed.

Other specialists / stake-holders will be invited to attend meetings when appropriate to discuss, report or advise on specific issues.

D. Reporting

Chair of CAG will:

- Report to the Executive Team on a quarterly basis.



- Submit quarterly CAG summary reports to the Operations Manager (to be used in the Project Progress Report, part of Innovate UK's monitoring requirements)

E. Meetings

Ordinary meetings of the CAG will be called quarterly by the Chair; extraordinary meetings can be called at any time upon written request of any Member of the Group.

Agendas will be circulated to members 5 business days prior to any meeting.

Minutes will be made available to all CAG members and the Executive Team.

The Chair will report to the Executive Team on a quarterly basis.