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# The Development of an Advanced Therapy Clinical Trials Toolbox

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## The Challenge

The ability for sponsors to bring innovative Advanced Therapies (AT) to patients fast and effectively is a significant challenge. It requires a new foundation to be built, allowing these novel therapies to help manage, and in some instances cure, diseases which were until recently considered untreatable. AT trials are intensely complex and come with requirements and considerations above and beyond those needed for clinical trials of traditional medicines, such as small molecules and biopharmaceuticals.

## The solution

The Northern Alliance Advanced Therapies Treatment Centre's (NA-ATTC) Advanced Therapies Clinical Trial Toolbox addresses this challenge by encompassing information and guidelines which will assist NHS Trusts and Boards, clinical leads and industry and academic partners to better understand the diverse and specialised processes involved in the set-up and delivery of AT trials and to streamline trial set-up within the NA-ATTC. The development of the toolbox has been enabled via NA-ATTC's Clinical Advisory Group and Trial Co-ordination Unit; these groups have established a wide reach within and beyond NA-ATTC's geography, resulting in a tool that has utility and applicability across the UK.

## The results

Through consultation with relevant stakeholders, a digital brochure has been created which includes:

- Organograms – to enable easy identification of key contacts within each NA-ATTC site.
- Costing guidelines – to support NHS sites to accurately cost AT trials and reduce the length of time taken to agree budgets.
- Site level requirements – to provide information on individual NA-ATTC NHS site requirements for set-up and delivery of AT trials.

Through the NA-ATTC Clinical Advisory Group, significant reach across the region and wider to support the uptake of AT clinical trials has been achieved, as shown in Figure 1

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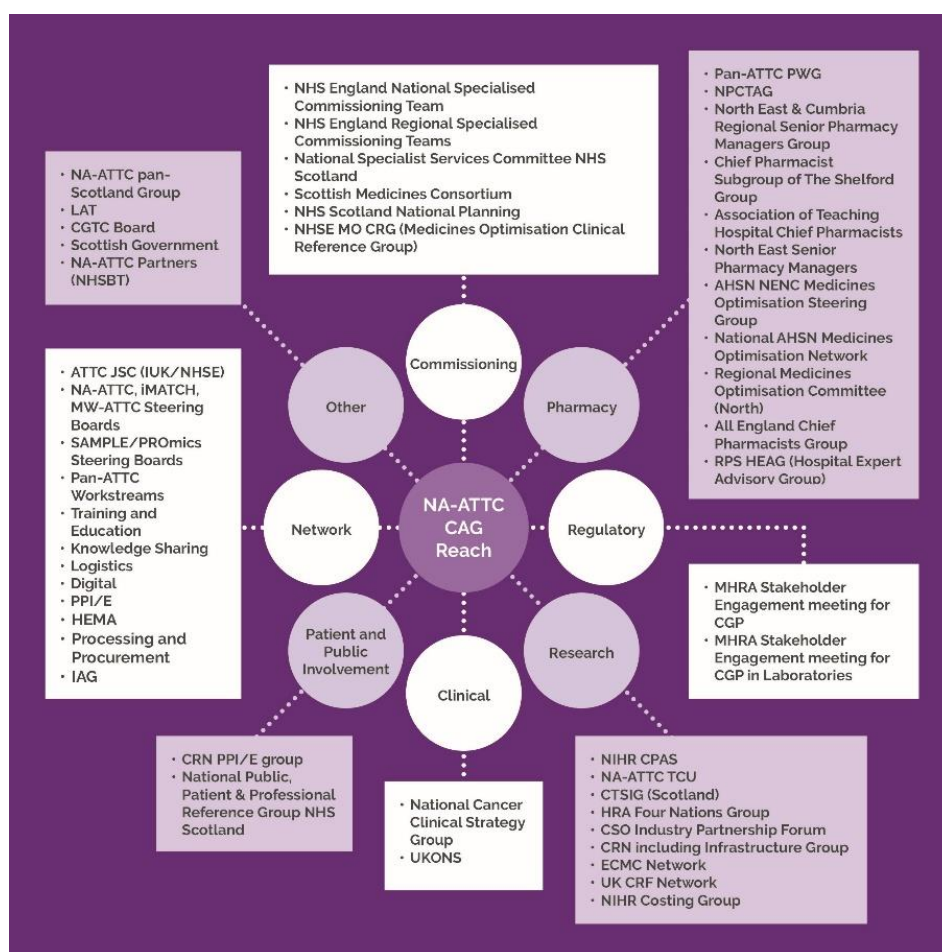


Figure 1. A visual display of the reach achieved by the NA-ATTC Clinical Advisory Group

The Toolbox can be accessed here: <https://www.theattcnetwork.co.uk/wp-content/uploads/2020/02/NAATTC-WP3-external-toolbox.pdf>

## Making further impact

The NA-ATTC is a key part of the ATTC programme to make the UK a preferred place to conduct clinical research and ensure equitable patient access to Advanced Therapies. The Clinical Trials Toolbox will aid this by contributing to the upskilling of NHS staff, reducing trial set-up time and helping industry partners to fully understand the site level requirements, thereby leading to increased synergy and efficiencies between the NHS and commercial partners and to growth in Advanced Therapy trials activity.

With thanks to contributing NA-ATTC partners, this work was led Newcastle University and The University of Edinburgh in collaboration with Leeds Teaching Hospitals NHS Trust, NHS Greater Glasgow & Clyde, NHS Lothian and The Newcastle upon Tyne Hospitals NHS Foundation Trust.

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