Advanced Therapy Treatment Centres

Establishing the role of Advanced Clinical Practitioner in Advanced Immunotherapy and Cell Therapy Research

Background

The Advanced Clinical Practitioner (ACP) role is relatively new within the Research and Innovation division at The Christie NHS Foundation Trust. ACPs are experienced healthcare professionals who develop advanced skills and knowledge within clinical research which enables them to take on an expanded role. Those who take on the role come from a range of clinical backgrounds, including nursing. Key components of the role include:

- Applying advanced clinical skills to research participants
- Working within study protocols with investigators and research teams
- Ensuring Good Clinical Practice (GCP): safety, consent, documentation
- Understanding clinical trial basics: eligibility, procedures, AE reporting
- Supporting high-quality research delivery and service improvement

Gemma Butterworth is the first ACP at The Christie NHS Foundation Trust, working on Advanced Therapy Medicinal Product (ATMP) clinical trials in the Advanced Immunotherapy and Cell Therapy team. Since joining the organisation as a nurse in 2011, Gemma has spent most of her career working in research, and in recent years completed an MSc in Advanced Clinical Practice.

Gemma has provided her thoughts on her experience of the ACP role below:

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What led you to the ACP role?



I decided to become an ACP because I wanted to challenge myself professionally and develop a broader range of clinical skills, while still maintaining the patient contact that has always been the most rewarding part of my role. Throughout my career, I found myself wanting to take on greater responsibility in decision-making and contribute more directly to patient management. The ACP role offered the perfect opportunity to combine advanced clinical practice with leadership, service development and education. I was particularly attracted to the autonomy of the role and the chance to make a wider impact on patient care, while continuing to build strong relationships with patients and their families.

What are the key challenges for an ACP?

There are specific challenges for the role on both a local site level and in the wider clinical research field.

Thinking about the challenges at my Trust, I have found that there can be some reluctance in accepting the role amongst medical colleagues. There is also a general lack of awareness of the ACP role across the Research and Innovation division.

Thinking beyond my Trust, it has also been challenging to gain acceptance of the ACP role from trial sponsors. This has often come from their interpretation of the wording within GCP regulations.

How did you overcome these challenges?

To start to address these challenges I have taken steps to engage with stakeholders on both local and wider levels.

I have taken the opportunity to present on my role wherever possible, including at events led by clinical research networks. My aim is to hopefully help to not only increase general awareness of the ACP role, but to also encourage understanding of the benefits of ACPs and how they can fit in successfully within established clinical research teams.

I have also spent a lot of time engaging with trial sponsor organisations to obtain their approval for me to take on a delegated sub-investigator role as an ACP working in ATMP clinical trials. One of the key barriers in this process has been sponsor interpretation of the wording of GCP regulations. The changes to the regulations which came into force in 2026 have been really helpful

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in encouraging sponsor acceptance of ACPs as sub-investigators. The wording of the regulations now explicitly allows for non-physician healthcare professionals (HCPs) as the responsible clinician where permitted. As a result of these conversations, I have been able to successfully obtain approval for my role from multiple commercial sponsors.

These discussions have not only enabled approval for my own delegated sub-investigator role, but have also helped demonstrate that ACPs can safely and effectively undertake advanced clinical research responsibilities. This has provided greater flexibility within research delivery teams and contributed to building confidence in the role amongst sponsors and investigators.

What are the benefits of this role?

The ACP role bridges the gap between research delivery and clinical care, allowing patients to receive highly specialised research treatment while maintaining access to advanced clinical support.

The ACP role offers benefits across the entire research pathway, supporting both high-quality research delivery and patient care. In my role as an ACP at The Christie, these include:

- *Providing medical support for the Clinical Research Facility (CRF)*
- *Clerking and discharge of overnight patients when primary clinical team are unavailable*
- *Handover to on-call medical team for acutely unwell patients within the department*
- *Completing medical assessment / triage of unwell patients on the CRF*
- *Prescribing supportive medications / to take outs (TTOs)*
- *Training and education of CRF staff – leadership skills and support for staff*
- *Acting as lead for emergency scenario training*
- *Completion of work within the senior leadership team – development of SOPs, change management, projects and audits*

For patients participating in complex ATMP trials, having an ACP within the research team improves access to timely clinical assessment, decision-making and continuity of care, helping to ensure concerns are addressed promptly while reducing reliance on multiple clinical teams.

What does the future look like for ACPs?

As the first ACP within the Research and Innovation Division, the role has provided an opportunity to establish a new clinical career pathway within research while demonstrating how advanced clinical practice can complement traditional research delivery models.

There are changes happening on both the local and national levels that I'm hopeful suggest that there is a bright future for the ACP role.

As advanced therapies become increasingly complex, ACPs are well positioned to support the sustainable delivery of these studies through advanced assessment skills, prescribing, clinical decision-making and leadership. I believe the role has the potential to become an integral part of specialist research teams nationally.

Thinking about our Trust, here at The Christie my aim is to continue to demonstrate the effectiveness of the ACP role in clinical research to ultimately support recruitment of more ACPs across our Research and Innovation division.

Looking beyond the Trust, I am working to continue to promote the benefits of the ACP role to both trial sponsors and wider clinical research networks. There is also increasing support available to enable healthcare professionals working in clinical research to develop their learning and practical research to enable moving into the ACP role, for example the NIHR Principal Investigator Pipeline Programme.

"Gemma's role as an ACP in our Advanced Immunotherapy and Cell Therapy team has shown value of expanding roles within clinical research teams. By enabling Gemma's clinical skills to be applied as a sub-investigator, we have been able to demonstrate to trial sponsors and medical colleagues that pushing the boundaries of 'traditional' roles in research effectively supports high-quality research delivery."

Professor Fiona Thistlethwaite – iMATCH Director and Head of the Advanced Immunotherapy and Cell Therapy Team at The Christie

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