

Clinical Trial Pathway: Responses to the Stakeholder Survey 2025

Introduction

In early 2025, a confidential survey was conducted to capture views about the clinical trials pathway in Edinburgh. The survey solicited honest opinions and both positive and negative comments. The responses were collated and reviewed by the Clinical Trials Oversight Group (CTOG).

Below are the responses from the CTOG stakeholders to the feedback provided in the survey.

ACCORD:

We have refreshed the ACCORD website to enhance accessibility to information and contact details. We are committed to the ongoing development of training resources and opportunities and are improving financial guidance and training for stakeholders. Additionally, we are refining our Sponsor processes and resources, which include updating templates and guidance. We aim to clarify risk assessment requirements by providing FAQs and offering text examples for the completion of forms to further clarify Sponsorship roles within ACCORD. Efforts are also being made to reduce duplication in technical assurances for research, such as information governance. Our Quality Assurance (QA) team is actively updating our QA management system to align with the new clinical trials regulations, and appropriate training will be provided.

College of Medicine and Veterinary Medicine Research Office:

We are pleased to hear positive comments about the support provided by our staff and the ongoing modernisation efforts within the college.

We acknowledge the need to clarify the roles and responsibilities of the different stakeholders involved in the clinical trial pathway at the university. These clarifications will be made available on a new website and through additional outreach as needed.

Edinburgh Clinical Trials Unit:

ECTU are very pleased to hear the positive comments about professionalism, organised approaches, responsiveness and collaborative spirit. The other comments are not surprising to us, but we will take them seriously.

Like others, we feel that researchers do not fully understand the role, remit and responsibilities of the various stakeholders, and so resolving this as a CTOG-wide team would be very beneficial. We think the idea of a roadmap of stakeholders is a good one. Within ECTU, we have already done a lot of work to alleviate the issues raised. We have had extensive recruitment into the data management and programming teams, and all posts within the teams are currently filled. We are in the process of recruiting a new Data

Management & Programming Team Lead who will line manage the programmers and data managers and provide necessary senior technical oversight. The appointment of the ECTU Director has concluded and we are delighted to welcome Professor Amanda Farrin to ECTU. We are continuing to explore our operational costs, although in the current university financial climate, these are not simple to reduce, and pressures continually push them upwards. Professor Farrin is in discussions with College regarding the strategic and long-term plans for ECTU, and more widely to explore alternative funding options for ECTU infrastructure support.

Edinburgh Clinical Research Facility:

The Edinburgh Clinical Research Facility (CRF) welcomes the findings of the 2025 Stakeholder Survey and appreciates the opportunity to respond.

The CRF supports a wide range of clinical specialties and study types, providing facilities, research nursing expertise, sample processing services, and training to enable high-quality research. We are disease- and specialty-agnostic, offering equitable support across the research community. We very rarely decline studies and often assist investigators with limited resources, ensuring research can proceed safely and effectively. All NHS-based CRF staff and facilities comply with NHS Lothian operating procedures and policies, including Health & Safety and Infection Prevention and Control, and deliver research in accordance with GCP and clinical trial regulations. These standards ensure a safe and high-quality environment for participants and staff. The CRF approval process, used consistently across all cores and aligned with Edinburgh Imaging, runs in parallel with sponsor and R&D approvals to minimise delay.

We acknowledge feedback about the need to increase awareness of CRF capabilities. Early engagement - ideally during grant development or pre-site selection - helps manage expectations, define timelines, and plan resourcing effectively.

Space and capacity remain key challenges as demand for clinical research grows. We continuously review utilisation to ensure fair access but are constrained in our ability to accommodate large equipment or long-term storage.

The CRF remains committed to collaborative working with investigators, ECTU, ACCORD, and NHS Lothian. We are always happy to meet to discuss requirements and identify solutions. The CRF provides a safe, compliant, and supportive environment for research delivery and is dedicated to improving communication, visibility, and efficiency across the clinical trials pathway.

Edinburgh Research Office

ERO Context

The volume of research we are applying for is increasing, at November 2025 our application value is 21% higher than our three-year average and our award value is 35% higher than the three-year average.

During the latter part of 2024 and throughout 2025, we have been carrying vacancies for sustained periods of time across all operational teams. Due to the University's financial

position, there is no additional budget available to increase the capacity in any of the operational teams and therefore, the only option open to improve our service levels is to change our processes and ways of working.

Our response to the survey results is centred on the changes to the ways of working that have taken place over 2025 and projects which are ongoing. We will be undertaking our planning for the next academic year in early 2026.

ERO works closely with the Research Support Operations Executive who represent the Colleges and Schools to improve understanding and reporting of service levels along with joint working on how this can be supported from within each area.

Research Operations Directorate

In January 2025, Edinburgh Research Office moved to a Directorate structure which included bringing the Research Funding Team, Research Contracts Team, Research Grants Team and Research Project Management Team into the Research Operations Directorate.

The focus for the Directorate in 2025 has been to implement the Directorate leadership group where we can proactively manage cross team relationships, ways of working and to allow issues to be identified and resolved jointly. Next, we will be implementing a review of new large and complex awards to identify where there may be opportunities to trial new approaches.

We can see from the comments that it is not always clear which services are provided by each team. We have been working on improving our communication methods and will be implementing a new approach to pushing communications out to the research community in the new year.

Across all teams within the Research Operations Directorate, there have been a significant number of vacancies which we were unable to fill for a sustained period over 2025. We are in the process of recruiting to all teams to the baseline level of resource, which will have a direct impact on service levels over the coming months.

Research Funding Team

The team have implemented a new approach to work allocation in response to increased demand for our services as research applications and awards have increased. This is continually under review as team members change and we aim to ensure appropriate alignment between our team and Schools.

We have an ongoing project to develop trackers using Worktribe data, which will give team members a clearer and more transparent view of upcoming deadlines. Once fully tested, School Research Offices will have access, allowing a consistent view of deadlines.

Research Contracts Team

As we progress with recruitment and onboard our new team members, our triage process shows that unallocated contract requests were increasing but have now levelled off and are starting to gradually decrease. We expect to see escalations continue for a period of time, we will be working with Colleges in the new year to prioritise unallocated contracts and the focus for the team will be to address the outstanding contract requests.

We have two team members who have recently undertaken additional training on contracting for clinical trials to increase the breadth of knowledge across the team.

Research Grants Team

In January 2025 the Research Grants Team restructured, moving from a one person, one School support model to a funder-based team structure. All communications were moved into UniDesk and a redesign of the team tasks allocated in Worktribe has been completed.

This has given us increased transparency of the volume of outstanding tasks, particularly on award setup and invoicing deadlines, and the ability to allocate these based on priority and capacity. We have seen marked improvements in the volume of tasks completed. However, resource constraints remain while posts continue to be vacant, award volumes are increasing and funder reporting requirements become more challenging.

In May 2025, the Research Salary Management project went live which has improved the timeliness of recording research salaries into research projects making project finances more accurate and reducing the manual intervention required by Schools and ERO.

The next set of improvements in ways of working will be prioritised in early 2026.