







Clinical Trial Pathway: Survey of Stakeholders 2025

Executive summary

A survey of the communities that use Edinburgh's clinical trials pathway was conducted by the University of Edinburgh's Clinical Trials Oversight Group (CTOG) 20 January – 4 February 2025. There were 63 respondents. The proportion of respondents who rated stakeholders as excellent, very good, or good ranged from 29% to 95%. Respondents often indicated that they find the clinical trial pathway complex and would benefit from more orientation to how it works. The survey indicated varying opinions on the management and support of clinical trials between the University of Edinburgh and NHS Lothian. Positive aspects included responsive and skilled teams, and the operational effectiveness of some units. However, there are noted challenges with governance, financial processes, and administrative support. Respondents strongly advocate for more streamlined processes, better resource use, clearer role definitions, and improved staff welfare. The results of the survey have been considered by each CTOG stakeholder, who will be responsible for addressing the feedback specific to them.

Introduction

In 2020, stakeholders in Edinburgh's clinical trials pathway shared their views as part of an external review, culminating in a <u>local clinical trials strategy</u> later that year. The report of the external review is available here: https://www.accord.scot/researcher-access-important-documents-researchers/guidance.

Subsequently, the CMVM <u>Clinical Trials Oversight Group</u> (CTOG) was formed to provide oversight of the pathway for locally sponsored clinical trials at the University. The CTOG has monitored progress with the implementation of the recommendations of the external review over the last five years, during which time numerous changes have occurred.

In early 2025, a confidential survey was conducted to capture views about the clinical trials pathway in Edinburgh, seeking honest opinions and comments (positive and negative). The responses were to be considered and collated for consideration by the CTOG.

Methods

The survey was developed by Prof Rustam Al-Shahi Salman (Clinical Trials Oversight Group [CTOG] chair), Prof Julie Jacko (Interim Director, Usher Institute), Prof Sarah Walmsley (Dean of Medical Research, College of Medicine and Veterinary Medicine (CMVM)), Prof David Argyle (Head of CMVM), and Prof Alasdair Gray (NHS Lothian R&D Director) in cooperation with the CMVM Research Office (CMVM RO) and ran from 20 January to 4 February 2025.

The survey was distributed to mailing lists that covered all stakeholders in the clinical trial pathway: Academic and Clinical Central Office for Research and Development (ACCORD), Edinburgh Clinical Trials Unit (ECTU), Edinburgh Clinical Research Facility (CRF), Edinburgh Research Office (ERO), CMVM RO and through a number of local mailing lists within the College reaching, amongst others, chief investigators, Edinburgh Clinical Academic Track fellows, and non-ECTU clinical trial managers.

Respondents were invited to indicate how they have been involved in the clinical trials pathway, provide their main affiliation and rate each stakeholder's support for the pathway









(Excellent, Very good, Good, Fair, Poor), as well as providing free text comments about what works well and what could work better. All responses were anonymous.

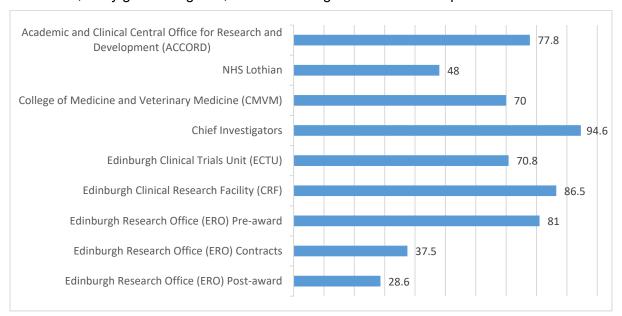
The quantitative and qualitative responses were gathered. Disregarding responses to questions where there was no comment, we grouped "excellent", "very good" or "good" ratings and expressed their frequency as a percentage. We used AI to summarise free text responses, which were reviewed and compared to the summary, and the summary was modified to be accurate, appropriate, and representative, if required.

CTOG reviewed drafts of this report at their meetings on 25 February 2025 and 24 April 2025.

Results

63 people responded, who were: leading as a chief investigator (23%), collaborating as a researcher (19%), delivering trials as a stakeholder (15%), providing support/oversight (15%), recruiting participants (12%), or fulfilling another role (12%).

The graph below shows the percentage of responses that rated each stakeholder group as "excellent", "very good" or "good", not considering "no comment" responses.



Qualitative summaries of stakeholders' free text responses are presented below.

ACCORD (Co-Sponsors):

Respondents expressed a high degree of satisfaction with the collaborative and supportive environment provided by ACCORD, emphasising effective communication, responsive and knowledgeable staff. Online resources such as websites, Standard Operating Procedures, and templates has been positively received, along with a streamlined approval process and the implementation of a single contact point for enquiries. Co-localisation with other teams such as ECTU and the CMVM RO in the Usher Building was praised for improved relations and facilitated interactions. Concerns were predominantly about certain inefficiencies and slow processes, especially in Information Governance and protocol approvals which are perceived as more cumbersome than those in other organisations. Slow response times and









bureaucratic delays that affect project timelines and productivity were also mentioned, as well as a tendency towards critical oversight rather than facilitative engagement.

NHS Lothian:

Respondents expressed appreciation for the electronic medical records and online IT system tools, along with the commitment and expertise of doctors, research nurses, and staff engaged in clinical trials. However, they also noted that IT provisions and security measures were overly restrictive and excessively cautious. Additional concerns included the slow progress of research and development (R&D) processes, challenges in integrating trials across departments, and issues in financial account management and support. Furthermore, difficulties were highlighted in the interactions between the UoE and NHS Lothian's R&D department, particularly regarding communication and financial matters.

College of Medicine and Veterinary Medicine Research Office:

Respondents mentioned the support provided by staff and highlighted the current college modernisation process. However, there was a widespread lack of awareness and clarity about the roles and contributions of CMVM. This suggests that many respondents either have limited interaction with the Research Office or are unsure of its function. Some of the discontent and criticisms were misattributed or misplaced, suggesting that stakeholders are not fully aware of who is responsible for various aspects of the clinical trial pathway.

Chief investigators:

Feedback from responses underscored the value of chief investigators (CIs) who possess deep expertise in their fields, strong collaborative skills and effective communication, leading to proactive engagement with teams and stakeholders Conversely, challenges arose with inconsistencies in CI engagement and variations in the quality of collaboration. Another significant concern was the limited understanding of clinical trial processes by some CIs.

Edinburgh Clinical Trials Unit:

Respondents praised the professionalism and commitment of the trial managers and the multi-disciplinary teams involved, the organised approach to trial setup and grant development, with noted improvements in these domains, overall communication, responsiveness and collaborative spirit. Concerns included efficiency and resource management issues, high operational costs, and occasional slow responses, especially during critical phases such as database setup and ongoing trial management, the variability in responsiveness and adaptability in data management, and discrepancies in the level of support provided across different studies.

Edinburgh Clinical Research Facility:

Respondents highlighted the management of clinical spaces and nursing support, robust educational and training infrastructure, and availability of dedicated clinical spaces, and suggested enhancing awareness of the facilities amongst CIs. Concerns included a somewhat bureaucratic nature, the facility's operational procedures which are perceived by some as prioritising certain types of studies, and the lack of capacity for more specialised tasks.









Edinburgh Research Office pre-award support:

The responsiveness, professionalism, and efficiency of the team were highlighted, as well as the effective communication with ACCORD and ECTU. Respondents were aware the team can be understaffed and overstretched. Suggestions included proactive support for novice researchers.

Edinburgh Research Office contracts:

Respondents highlighted the team's expertise, particularly in managing intellectual property and negotiating robust contracts. Improvements in the team's performance have also been noted, attributed to increased capacity and the implementation of new processes that effectively reduced backlogs and enhanced response times. In contrast, responsiveness was considered inconsistent by some, due to the high workload. Despite improvements, respondents said issues with prolonged delays remain, potentially impacting critical milestones, and also mentioned discrepancies in engagement and support, particularly during the initiation of contracts.

Edinburgh Research Office post award support:

Feedback suggested disparate experiences and issues impacting the efficiency of financial management in research projects. While some respondents commended the proactive engagement and expertise of certain staff members, others pointed to major delays and communication gaps that disrupted grant management processes. Criticisms focused on system limitations, capacity backlogs, understaffing, and delays in invoice processing and grant reconciliation.