Clinical Trials Oversight Group
Terms of Reference

Purpose and scope

The Clinical Trials Oversight Group (CTOG) provides oversight of the pathway for investigator-led, locally Sponsored clinical trials at the University of Edinburgh (UoE). The overarching aim is to ensure the academic and financial success of the clinical trials pipeline.

Remit

In service of this purpose, CTOG will:

1. Celebrate the successes of locally sponsored clinical trials and encourage dissemination and implementation of their findings.
2. Monitor the implementation of the UoE's clinical trials strategy*:
    a. Review the implementation of the recommendations made by the 2020 external review of the clinical trials pathway**.
    b. Advise on barriers, facilitators, and capacity for locally Sponsored clinical trials.
    c. Consider the impact of locally Sponsored vs. hosted clinical trials on each other.
3. Review the size and composition of the portfolio of locally Sponsored clinical trials.
4. Advise on funding opportunities to develop locally Sponsored clinical trials.

Membership

CTOG membership consists of representatives of the main groupings within the UoE College of Medicine and Veterinary Medicine (CMVM) involved in planning, funding and delivering clinical trials, as well as the environment in which they take place. Members are supported by deputies, who inform CTOG activity and decisions through supplying up-to-date information ahead of meetings.

Members:

- UoE Edinburgh Clinical Trials Unit (ECTU) Director (s)
    - Deputy: UoE ECTU Chief Operating Officer
- UoE Edinburgh Research Office (ERO) Solicitor, Head of Research Contracts
    - Deputies: Clinical Research Funding Manager, Senior Contracts Manager
- UoE CMVM Research Office Head
    - Deputy: UoE CMVM Senior Strategic Research Coordinator
- Academic and Clinical Central Office for Research and Development (ACCORD)
    - NHS Lothian R&D Director

* https://www.ed.ac.uk/usher/edinburgh-clinical-trials/clinical-trials-strategy
** http://www.accord.scot/researcher-access-important-documents-researchers/guidance

- Deputy: Deputy R&D Director
- UoE Head of Research Governance

➢ NHS Lothian Director of Innovation

➢ Clinical Research Facility (CRF) Director
- Deputy: CRF Deputy Director

Stakeholders

The key CTOG stakeholders are University of Edinburgh Chief Investigators of clinical trials and their teams, as well as ECTU, ACCORD, CRF, ERO and CMVM Research Office.

Governance

The UoE ECTU Clinical Director chairs CTOG; there is no Deputy Chair. CTOG receives formal reports from ECTU, ACCORD, CRF, ERO and the CMVM Research Office. CTOG reports directly to the CMVM Dean of Research. CTOG minutes and outputs will also be shared with the UoE CMVM Head of College, CMVM Dean of Clinical Medicine, and the CMVM-NHS Lothian Joint Oversight Board.

Organisation of meetings

CTOG receives administrative and coordinating support from the UoE CMVM Research Office.

CTOG will meet at least twice per year. The meeting frequency will be determined by requirements, and the date of the next meeting will be discussed at the end of each meeting.

Meetings will be organised by the UoE CMVM Research Office based on the availability of Members. While there is no formal requirement for all Members to attend each meeting, representation from each key grouping is desirable; if a Member is unable to attend, they should be represented by their Deputy.

The organiser will circulate an agenda and papers by email at least five working days in advance, to Members as well as Deputies. Attendees are expected to familiarise themselves with meeting papers sufficiently far in advance so as not to delay meeting proceedings. Actions and minutes will be circulated by email within ten working days of the meeting, and approved at the next meeting

Meetings will take place virtually via Microsoft Teams, or in person when office-based staff are on campus. Any future in-person meetings will also include an option to join virtually.

Minimum term

No minimum term has been agreed.

Review of Terms of Reference

These Terms of Reference will be reviewed annually in April and updated as required. Each new iteration will be saved separately and labelled with the date of review.