

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 sustainability of research excellence and financial sustainability of the clinical trials pipeline.

Remit

In service of this purpose, CTOG will:

1. Develop and monitor a clinical trial strategy for the College of Medicine and Veterinary Medicine (CMVM) that aligns with the CMVM and wider University of Edinburgh Research and Innovation Strategy
2. Ensure that the infrastructure to support clinical trials and related research is fit for purpose in the CMVM
3. Develop and oversee a risk management strategy for all parts of the clinical trials pathway; actively identify and monitor current and emerging risks to successful clinical trial research through the research life-cycle and develop mitigation strategies
4. Ensure key information and developments in policy, governance, funding, and regulation at national and international level are collated and disseminated cross the CMVM, and wider University of Edinburgh as appropriate.
5. Celebrate the successes of locally sponsored clinical trials and encourage dissemination and implementation of their findings.
6. Review the size, composition, and focus of the portfolio of locally Sponsored clinical trials.

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.

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:

- CMVM Associate Dean for Clinical Research Delivery (Chair)
- Edinburgh Clinical Trials Unit (ECTU) Director and Deputy Director (Clinical)
 - Deputy: ECTU Chief Operating Officer
- Edinburgh Research Office (ERO):

- Head of Research Contracts
 - Deputies: Senior Contracts Manager
- Pre-award Clinical Research Funding Manager
- Post-award
- Head of CMVM Research & Innovation Operations
 - Deputy: CMVM Senior Strategic Research Coordinator
- Academic and Clinical Central Office for Research and Development (ACCORD)
 - NHS Lothian R&D Director
 - Deputy: Deputy R&D Director
 - UoE Head of Research Governance
- Clinical Research Facility (CRF) Director
 - Deputy: CRF Deputy Director

Governance

- The UoE CMVM Associate Dean for Clinical Research Delivery Chairs CTOG. There is no Deputy Chair.
- CTOG receives brief structured reports from ECTU, ACCORD, CRF, ERO and the CMVM Research Office prior to each meeting. These are intended to:
 - Provide brief information on key developments
 - Provide structured information on key areas of current risk to clinical trial pathway delivery
- 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, CMVM Dean of Innovation.
- CMVM Research Committee
- CMVM-NHS Lothian Joint Oversight Board.

Organisation of meetings

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

CTOG will meet every 3 months, and at least 3 times 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.

A structured report from each stakeholder including current key developments and risks will be provided prior to each meeting. 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.

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.