

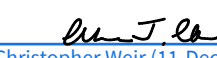
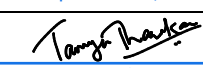


ECTU Central Office SOP ECTU_ST_03: Data Monitoring Committee

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Authorship and Approval			
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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	6th Aug 2012	Initial creation
2.0	15 Sep 2014	Insertion of new section and deletion of previous section 3.11 (validation procedure)
3.0	26 Jun 2017	Changes made at scheduled two-year review on recommendation of Sponsor Audit due to duplication with corresponding TM SOP. Alterations to Sections 1-4 and subsections in Section 3.
4.0	26 Aug 2019	Updated at scheduled review. Document moved to new SOP template.
5.0	20 Oct 2021	The SOP has been reviewed and it still represents current practices therefore there were not changes implemented to procedure. Spelling mistake on section

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		2, word “principals” corrected, it should have been “principles”
6.0	06 Dec 2023	SOP has been transferred onto the new SOP template. Updated at scheduled review. Minor revisions in document.
7.0	12 Jan 2026	Updated at scheduled review. Alterations to include reference to the Trial Statistician requiring oversight of the DMC charter. Included specific guidance in relation to studies where analyses are performed in a safe haven/trusted research environment. Included reference to performing checks of randomisation allocation.

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1.0 PURPOSE

To define the procedures for the creation of statistical reports for the Data Monitoring Committee (DMC).

2.0 SCOPE

This SOP applies to all randomised trials run through ECTU that require a DMC.

The definition and function of a DMC is in accordance with the protocol, the principles of Good Clinical Practice (GCP) and the applicable statutory and regulatory requirements.

3.0 RESPONSIBILITIES

It applies to the statistician(s) involved in the creation of statistical reports for DMCs.

The organisation of the committee and preparation for the meetings is a task covered by the Trial Manager and guidance on this is provided in [ECTU SOP TM_12 Preparing for Data Monitoring Committee \(DMC\) Meetings](#). For partial studies, ECTU's expectation is that the external TM would perform these duties and inform the Trial Statistician

4.0 PROCEDURE

Whether a DMC is required will be determined through early discussions in the planning stages between the Trial Sponsor, the Chief Investigator (CI) and the Trial Steering Committee (if applicable), and typically mentioned in the protocol. A DMC may not be required for all trials.

4.1 Planning for DMC reporting

- 4.1.1. The Trial Statistician or designee should have oversight of the DMC Charter when in draft and for any subsequent versions to ensure the wording appropriately reflects the trial design and monitoring requirements. This will be documented in the Statistical Review Checklist (ST007). It is recommended to include a clause in the charter that allows observers to attend DMC meetings (including the closed session) for training purposes.
- 4.1.2 As specified in ECTU_SOP_TM_12 Preparing for a Data Monitoring Committee the unblinded statistician should be given at least six weeks' notice for a required report and they must confirm that they are able to meet the planned timing. In urgent and exceptional circumstances, if a shorter timescale is essential, the trial manager must discuss this with the trial statistician and unblinded statistician to see how it can be achieved. Where analyses are to be performed in a safe haven/trusted research environment additional time should be allowed due to any potential technical issues accessing the environment and the additional step required of requesting release of reports and disclosure checking. This should be conveyed to the Trial Manager.

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- 4.1.3 Perform an early check that the randomisation allocation is working correctly as the first DMC with data could be up to 1 year after recruitment has begun depending on what is agreed in the charter. This process should then be repeated regularly throughout the trial. More details are provided in ECTU Central Office WPD ECTU_ST_W3 DMC Reporting.

4.2 DMC Reporting

The below considerations are determined by the DMC based upon the trial and specified in the DMC Charter. Detailed guidance can be found in [ECTU SOP TM 12 Preparing for Data Monitoring Committee \(DMC\) Meetings](#)

The DMC will receive reports at intervals throughout the trial which will usually be prepared by an unblinded trial statistician. These reports are often, but not always, unblinded to trial treatment, and they will often contain (but not limited to) the following sections:

- recruitment summary
- retention and data completeness
- compliance and protocol violations
- primary outcome data
- secondary outcomes
- adverse events

Detailed guidance on preparing statistical analysis reports for DMC meetings can be found in ECTU Central Office WPD ECTU_ST_W3 DMC Reporting and ECTU Central Office WPD ECTU_ST_W5 Statistical Analysis and Reporting.

4.3 Unblinded DMC Reports

Unblinded DMC reports should not be circulated beyond the DMC and the staff who have prepared the report, unless there is a specific request to do so by the DMC Chair. Appropriate measures should be taken to achieve this level of confidentiality. Detailed guidance is located in ECTU Central Office WPD ECTU_ST_W3 DMC Reporting and [ECTU SOP TM 12 Preparing for Data Monitoring Committee \(DMC\) Meetings](#)

4.4 Retention of Analysis Data

The data used for analyses for DMC meetings, reports presented at DMC meetings and all minutes of DMC meetings should be stored electronically in blinded or unblinded folders of the Statistics Master File as appropriate. Where analyses are performed in a safe haven/trusted research environment, data used for the analyses should be stored in appropriately named folders within the environment. Care should be taken to ensure the data is not over written when running subsequent DMC reports or interim/final analyses. Paper copies of DMC reports and minutes should not be held in the Statistics Master File.

5.0 RELEVANT DOCUMENTS AND REFERENCES

ECTU Website

- ECTU_SOP_TM_12 Preparing for Data Monitoring Committee (DMC) Meetings
- ECTU_WPD_ST_W3 DMC Reporting
- ECTU_WPD_ST_W5 Statistical Analysis and Reporting
- Statistical Review Checklist Template – ST007 (Shared drive location: \ECT Unit\SOPs\Finalised SOP and WPD\ST\Supporting Document and Templates\Current)

Others

- [Grant AM, Sydes M, McLeer S, Clemens F, Altman DG, Babiker A, Campbell MK, Darbyshire J, Elbourne D, Parmar M, Pocock S, Spiegelhalter D, Walker A, Wallace S. Issues in data monitoring and interim analysis of trials \(the DAMOCLES study\). Health Technol Assess. 2008, 9 \(7\)](#)

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ECTU_SOP_ST_03, W3 Data Monitoring Committee and associated documents

Final Audit Report

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