ECTU Central Office SOP ECTU_ST_03: Data Monitoring Committee

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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

		2, word “principals” corrected, it should has been “principles”
6.0	06 Dec 2023	SOP has been transferred onto the new SOP template. Updated at scheduled review. Minor revisions in document.

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 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.

4.2 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

4.3 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. Paper copies should not be held in the Statistics Master File.

5.0 RELEVANT DOCUMENTS AND REFERENCES

- ECTU_SOP_TM_12 Preparing for Data Monitoring Committee (DMC) Meetings
- ECTU_WPD_ST_W3 DMC Reporting
- ECTU Central Office WPD ECTU_ST_W5 Statistical Analysis and Reporting (ECTU Shared Drive)
- 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)