

## ECTU Central Office SOP\_TM\_12: Preparing for a Data Monitoring Committee

Version No:	7.0
Issue Date:	19 Dec 2024
Effective Date:	27 Jan 2025

Authorship and Approval			
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Tanya Tharakan, QA Manager	QA Authorisation	19-Dec-2024	 Tanya Tharakan (Dec 19, 2024 10:37 GMT)

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	01 Oct 2012	Initial creation
2.0	30 May 2016	Document extensively rewritten as part of regular review process. Working checklist removed and sections 3.1-3.8 added. Alteration to name. Document references added to section 4
3.0	25 July 2018	Updated at scheduled review. Document moved to new SOP template. Minor revisions to section 1 and 2. Formatting changes throughout (subsections added and renumbering throughout). Section 3.6.3 now included in section 3.4. Reference to QC Checks added to section 3.4.
4.0	20 Aug 2020	Updated at scheduled review. SOP author and reviewer changed. Section 3.6 (arrangements for members who

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		cannot attend in person) removed. Minor revisions throughout.
5.0	10 Dec 2020	Minor revisions to section 3.2.3 to clarify the role of the Trial Statistician.
6.0	25 Nov 2022	SOP has been transferred onto the new SOP template. Section 3 has been included which has had a knock on effect to the numbering of subsequent sections. Sections 4.8.2 and 5.0 were updated to remove reference to an obsolete ECTU SOP. Minor changes throughout to clarify where documents will be retained.
7.0	27 Jan 2025	Extensive updates as part of regular review process. Sections 4.2 and 4.3 summarised as content covered in ACCORD SOP and Charter. Changes made throughout to be more specific on Trial Management tasks.

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## **1.0 PURPOSE**

The remit of a Data Monitoring Committee (DMC) is to ensure the safety of trial subjects and to keep the Trial Steering Committee (TSC) informed of their findings. The use of DMC and TSC form part of the oversight and management of a trial.

This Standard Operating Procedure (SOP) provides instruction on preparing for and arranging Data Monitoring Committee (DMC) Meetings.

## **2.0 SCOPE**

This SOP applies to all ECTU staff who are responsible for organising DMC Meetings if required throughout the study.

## **3.0 RESPONSIBILITIES**

For CTIMPS the responsibilities of the delegated Trial Management team will be outlined in GS003 T04 Trial Support Responsibilities. For all other studies, the responsibilities will be agreed in advance.

## **4.0 PROCEDURE**

Requirement for a DMC, or other formal data monitoring arrangement, will be detailed in the trial protocol. The DMC may also be known as Data and Safety Monitoring Committee (DSMC), Data Monitoring and Ethics Committee (DMEC), Independent Data Monitoring Committee (IDMC), Data and Safety Monitoring Board (DSMB), etc.

### **4.1 DMC Members**

- 4.1.1 Refer to the DMC Charter for a detailed description of the constitution of membership, and ACCORD SOP CR015 Data Monitoring Committee and Trial Steering Committee Charters.
- 4.1.2 All potential DMC members should have sight of the protocol/outline before agreeing to join the committee. Additional information (e.g. trial Gantt) can be provided if requested.
- 4.1.3 If there are changes made to the DMC i.e. a member withdraws during the course of the trial, the Trial Manager can facilitate by informing the statistician, other members of the DMC and any other relevant parties as required.
- 4.1. For commercial studies it may be necessary for DMC members to sign a contract making clear the need for confidentiality and the liability status of the DMC members. Signed contracts will be filed in section 10.1 of the Trial Master File (TMF).
- 4.1.5 Conflicts of Interest should be included on the agenda as a standing item to prompt any changes to be recorded.

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- 4.1.6 If the DMC has any overseas members (including Rep. of Ireland), funder guidance should be checked for any specific requirements regarding these members.

## **4.2 DMC Roles and Responsibilities**

The roles and responsibilities of DMC committee members are outlined within the DMC Charter.

## **4.3 DMC Charter**

- 4.3.1 For UoE/NHSL sponsored studies, the DMC SOP and DMC Charter template available from ACCORD will be used (see section 5). Studies with a different Sponsor may provide their own guidance and template.
- 4.3.2 Alternatively, if no specific Sponsor template is available, the ECTU DMC Charter template can be used (see section 5).
- 4.3.3 The finalised DMC Charter will be filed in section 10.1 of the TMF.

## **4.4 General Meeting Guidance**

- 4.4.1 Prior to scheduling a DMC meeting the Trial Manager or designee should confirm with the Trial Statistician (or the Unblinded Statistician) and the data management team when to take the data snapshot.
- 4.4.2 When organising a meeting, the Trial Manager or designee should ensure that the date, time and suitable venue for the meeting has been finalised and that all committee members, the Chief Investigator (CI), the trial statistician and unblinded statistician (if applicable) are aware and have confirmed their availability.
- 4.4.3 It should be ensured before a meeting is conducted that there are enough independent vs non-independent members attending to achieve a quorate for decision making (as defined in the Charter). If there is not, the meeting should be rescheduled.
- 4.4.4 DMC meetings to review unblinded data will be closed meetings at which the Sponsor, CI and trial team will not be present.
- 4.4.5 The CI will be asked and should be available to attend open meetings of the DMC to discuss its conclusions and recommendations.
- 4.4.6 A Data Quality Check Plan should be in place for the study, and the proposed schedule for the checks may be aligned to the expected dates for the DMC (and/or TSC) Meetings (ECTU\_WPD\_DM\_W1 Preparing for and Completing Data Quality Control (QC) Checks), however the Trial Manager or designee should ensure that the Quality Control Checker is made aware of the finalised date so that adjustments can be made if necessary.
- 4.4.7 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

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must discuss this with the trial statistician and unblinded statistician to see how it can be achieved. Communication regarding these timelines should be via email and filed in section 10.1 of the TMF with the corresponding meeting paperwork.

- 4.4.8 The Trial Statistician or Unblinded Statistician will prepare the report(s) (blinded/unblinded where applicable) for the DMC. The trial management team can provide input if required to the blinded sections of the DMC report(s). Care must be taken to ensure that unblinded data is not made available to blinded members of the study team.
- 4.4.9 The Trial Manager or designee will prepare an agenda and any related documents for the meeting as directed by the Chair. These should be circulated to the Chair in the first instance for comment. The Trial Manager or designee and the DMC Chair will ensure that the DMC report, agenda and any other required reports/minutes have been circulated prior to the meeting.
- 4.4.10 The frequency of the meetings can vary, and is determined by the DMC, and in some cases by the Funder. The date of the DMC is recorded on the trial project plan (e.g. Gantt chart), if available.
- 4.4.11 The minutes for the open session will usually be taken by the Trial Manager or designee however alternative arrangements will need to be made for the closed session (e.g. unblinded statistician). Minutes should be reviewed by the chair of the DMC before circulation. Minutes from the open session will be circulated to all DMC members and filed in section 10.1 of the TMF. Minutes from the closed session will only be sent to those who attended the closed session and only sent to the trial manager and archived at the time of study closure.

#### **4.5 Preparations for the first meeting**

- 4.5.1 It is recommended that, if possible, the DMC meets before the trial starts or early in the course of the trial, to discuss the protocol, any analysis plan, future meetings, and to have the opportunity to clarify any aspects with the CI and trial statistician. It is important to define the data they will review at these meetings to give the trial team time to prepare the information prior to future meetings.
- 4.5.3 The DMC Charter template should be circulated to the DMC members in advance of the meeting by the Trial Manager, so that the specifics can be discussed during the meeting.

#### **4.6 After the meeting**

- 4.6.1 If instructed by the CI, the Trial Manager or designee will follow up on points to be actioned from the meeting. Any recommendations made by the DMC will be reported in writing by the DMC chair and if possible, should be sent in time for consideration at the next TSC meeting.
- 4.6.2 The Trial Manager or designee will ensure the DMC recommendations are distributed to the TSC or Sponsor's representative and the trial statistician.

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4.6.3 The CI, or Trial Manager, should notify the Research Ethics Committee (REC) of any recommendations made by the DMC if necessary and provide summary reports of interim analyses where appropriate. It is not considered necessary for the REC to see the minutes of all DMC meetings.

4.6.4 If the trial is to continue largely unchanged it is useful for the report from the DMC to include a summary paragraph suitable for trial promotion purposes i.e. to be circulated to trial sites.

#### **4.7 Expenses**

4.7.1 Members will be reimbursed for any reasonable travel and subsistence costs. These can be charged against the grant for the trial (if costed for in the budget).

4.7.2 Where practical, the travel arrangements should be made by the relevant team member at ECTU. Otherwise, DMC members will be asked by the Trial Manager or designee to retain their receipts for expenses claims and provide a University of Edinburgh Claim for Expenses form to complete. Expenses claims should abide by the University and/or funder policy (e.g. no first class travel, etc.).

#### **4.8 Publications**

4.8.1 DMC members will be named (unless they specifically ask not to be) in the primary published report. A brief summary of the timings and conclusions of DMC meetings could be included in the body of this paper.

4.8.2 Often the DMC will be given the opportunity to read and comment on any publications before submission. This should be documented in the Charter if applicable.

### **5.0 RELEVANT DOCUMENTS AND REFERENCES**

#### **ECTU Website**

- ECTU\_WPD\_DM\_W1 Preparing for and Completing Data Quality Control (QC) Checks

#### **ACCORD Website**

- ACCORD SOP CR015 Data Monitoring Committee and Trial Steering Committee Charters
- ACCORD DMC Charter CR015-T01 Template

#### **ECTU Shared Drive**

- ECTU DMC Charter Template

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Final Audit Report

2024-12-19

Created:	2024-12-18 (Greenwich Mean Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAMganbinuiIUW2jMNTGlebNZEFWLHpRmE

## "ECTU\_SOP\_TM\_12 Preparing for Data Monitoring Committee (DMC) Meetings v7.0" History

-  Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)  
2024-12-18 - 14:58:26 GMT- IP address: 192.41.114.230
-  Document emailed to Lauren Craig (Lauren.Craig@ed.ac.uk) for signature  
2024-12-18 - 15:02:32 GMT
-  Document emailed to Bea Selby (bea.selby@ed.ac.uk) for signature  
2024-12-18 - 15:02:33 GMT
-  Document emailed to Gina Cranswick (gina.cranswick@ed.ac.uk) for signature  
2024-12-18 - 15:02:33 GMT
-  Document emailed to Tanya Tharakan (tanya.tharakan@ed.ac.uk) for signature  
2024-12-18 - 15:02:33 GMT
-  Email viewed by Bea Selby (bea.selby@ed.ac.uk)  
2024-12-18 - 15:03:47 GMT- IP address: 104.47.11.254
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Signature Date: 2024-12-18 - 15:04:07 GMT - Time Source: server- IP address: 213.31.186.111
-  Email viewed by Lauren Craig (Lauren.Craig@ed.ac.uk)  
2024-12-18 - 15:10:56 GMT- IP address: 104.47.11.62
-  Document e-signed by Lauren Craig (Lauren.Craig@ed.ac.uk)  
Signature Date: 2024-12-18 - 15:12:45 GMT - Time Source: server- IP address: 192.41.114.225
-  Email viewed by Gina Cranswick (gina.cranswick@ed.ac.uk)  
2024-12-19 - 10:27:40 GMT- IP address: 104.47.11.126



Document e-signed by Gina Cranswick (gina.cranswick@ed.ac.uk)

Signature Date: 2024-12-19 - 10:27:54 GMT - Time Source: server- IP address: 151.224.224.52



Document e-signed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)

Signature Date: 2024-12-19 - 10:37:41 GMT - Time Source: server- IP address: 192.41.114.230



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2024-12-19 - 10:37:41 GMT



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