ECTU Central Office WPD_ST_W3:
Data Monitoring Committee Reporting

Version No:	6.0
Issue Date:	12 Dec 2025
Effective Date:	12 Jan 2026

Authorship and Approval			
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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	13 Mar 2017	Initial Creation
2.0	12 Mar 2018	Addition of instructions regarding centre split in section 2.3.4 and 2.3.5
3.0	27 April 2020	Updated at scheduled review. Document moved to new WPD template. N/A has been amended to Version 1.0 in the Document Revision History – N/A was included in error. Minor revisions throughout document.
4.0	16 June 2022	WPD has been transferred onto the new WPD template. Updated at scheduled review. Minor revisions throughout document.

5.0	06 Dec 2023	Updated at review of corresponding ECTU_SOP_ST_03 Data Monitoring Committee SOP. Minor revisions throughout document.
6.0	12 Jan 2026	Updated at scheduled review. Clarification to check that randomisation allocation is working correctly.

1. INTRODUCTION

This Working Practice Document provides guidance on preparing statistical analysis reports for Data Monitoring Committees (DMC) as referred to in ECTU Central Office SOP ECTU_SOP_ST_03 Data Monitoring Committee.

2. INSTRUCTIONS and GUIDANCE

2.1 Planning and executing analyses for DMC

2.1.1 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 can be explored using a cross-tabulation of treatment allocation with any stratification/minimisation factors used in the randomised allocation. This is suggested to be after a sufficient number of participants have been randomised to identify any issues e.g 16 participants when a maximum block size of 8 has been used and the treatment imbalance within a strata should not be greater than 4. This process should then be repeated regularly throughout the trial.

2.1.2 Obtain the most up to date version of the protocol and charter (if available), in particular if the trial master file (TMF) is not held in ECTU (partial service).

2.1.3 There should be documentation of the analyses that the DMC require to see at their first meeting where data are available. There is no strict rule on the format or location of this documentation. It might be detailed in the DMC Charter, a DMC statistical analysis plan (SAP), or as a dummy report without data for example.

2.1.4 Unless the DMC specifically ask for a lot of data to be presented, keep the report reasonably brief and to the point (Pogue and Sackett, 2014).

2.1.5 Obtain lists of protocol deviations and violations, serious adverse events and pregnancy information from the sponsor (for example ACCORD), if not recorded on the trial database, and if not already requested by another member of the trial team (e.g. the trial manager). For ACCORD studies, the appropriate contact details are:

SAEs: safety@accord.scot

Deviations/Violations: qa@accord.scot

2.1.6 It should be stated clearly throughout the report exactly how many participants should have data in each table and how many have missing values.

2.1.7 ECTU Central Office WPD ECTU_ST_W5 Statistical Analysis and Reporting should be referred to for general guidance on analysis processes.

2.1.8 Run the DMC reports, usually an open (blinded) version (for those who are to remain blind to results split by treatment allocation) and a closed (unblinded) version.

2.1.9 Send the reports to DMC members a suitable length of time before the date of the DMC (for example 2 weeks, but the DMC Charter must be checked for details).

2.1.10 Clearly label the file names to distinguish between the open (blinded) and closed (unblinded) reports. First send the open (blinded) report to the Trial Statistician to confirm that it is the blinded report. It can then be sent to others to prevent unblinded data and/or the unblinded report being circulated by mistake. The closed (unblinded) report should NOT be copied to the Chief Investigator, Trial Manager or anyone else who should remain blind to results split by treatment allocation.

2.1.11 Ensure that the closed (unblinded) report is sent via a secure method, such as the University of Edinburgh DataSync Service. Instructions on how to do this are available on the site). A non-password protected version of the report must be available in the unblinded folder of the Statistics directory for the trial.

2.1.12 For recipients of the closed (unblinded) report, it is also useful for them to receive the open (blinded) report as reference during the open part of the meeting.

2.1.13 Record the date, version number and file location of each DMC report in the ST006A ECTU Statistical Master File Essential Document checklist. The reports should be kept as an electronic copy only in the Unblinded folder of the Statistics directory for the trial.

2.1.14 Record details of DMC meeting dates in the ECTU Statistics Team Projects document (see Section 3 for details). In particular, it can be useful to note if there has been a meeting with no data, the date of the most recent meeting, and the date of the next planned meeting.

2.2 Recommended Content for DMC Reports

The following are recommendations only for the contents of DMC reports (also see ST003 Example DMC report). The reports should reflect the agreed contents specified in Section 2.1.3. An additional check against the current protocol is worthwhile in case of protocol updates which may impact on DMC reporting. Review previous DMC meeting minutes and update reports if necessary.

2.2.1 Title Page

- Name of trial and logo (if available)
- Name and number of report and version no. The report name should be clear and unambiguous and it should also be clearly specified whether the version is a final or draft version
- Date that report was produced and who produced the report
- Current protocol version

- Date of trial database analysis

2.2.2 Introduction

- Trial summary - this may be useful as a reminder to the DMC members without having to refer to the protocol. The trial summary may include information on: trial design, interventions, participants, eligibility criteria, primary research question, primary outcome measure, secondary outcome measures, trial start and end date, target sample size, interim analyses and stopping rules. The content of this section should be carefully reviewed for each report as certain aspects (for example eligibility criteria, trial end date etc.) may change throughout the trial.
- Trial Flow Chart - a simple overall summary of patient status in the study by treatment group, including the number of withdrawals from treatment and/or follow-up (including reasons for withdrawal).

2.3 Suggested Analyses for unblinded (closed) report

2.3.1 Dates of randomised patients

Include the dates of the first and last randomised patient included in the current report

2.3.2 Recruitment – generally not split by randomised treatment

A summary of recruitment and whether it is on target. Depending on how responsibilities are divided between the TSC and the DMC, this could include numbers screened and screening failure reasons in addition to numbers randomised and could include recruitment by centre.

2.3.3 Baseline Balance – split by randomised treatment

A summary of key baseline variables to show balance with a clear indication of what minimisation/stratification variables there are. This should be used as a check that the randomisation allocation is working correctly.

2.3.4 Data Completeness – split by treatment

A more complex summary of expected number of participants at each visit and number of patients with data at each visit (to show which data/forms are missing) along with details of how many are long overdue or are missed completely.

2.3.5 Adherence – split by randomised treatment

Whether any ineligible participants are in the trial or whether any have become ineligible (violate inclusion/exclusion criteria); number not receiving any study treatment or crossing over to a different treatment arm (including reasons for this), whether treatment has been received as planned (dose, number of tablets, number of therapy sessions etc.); whether treatment given at the right time and/or assessments made at the right time; whether blinding has been broken for any participants (in the

case of blinded trials); if there is adjudication of outcomes, whether this is happening in a timely manner.

If the data allows, adherence should be split by centre, particularly to assess whether there are too many crossovers/non-adherers at any centre i.e. people getting the opposite treatment to that allocated.

2.3.6 Primary Outcome – split by randomised treatment

A suitable summary of the primary outcome.
If formal analyses are planned in a group sequential design then could include a chart showing the analyses over time.

For trials without pre-specified analyses, no formal tests of hypotheses will be performed for the DMC unless they specifically request it. An appropriate method needs to be used to avoid inflation of the type I error rate and should be stated in the DMC charter, for example at least 3 standard errors between groups in an interim analysis of the primary outcome is needed to justify halting, or modifying, a study before the planned completed recruitment. This criterion has the practical advantage that the exact number of interim analyses would be of little importance, and so no fixed schedule is proposed.

If there is sufficient data and the DMC request it, some subgroup analyses could be provided. Similarly, primary outcomes could be split by centre to look for centre-outliers for example, too few or too many primary outcome events.

2.3.7 Secondary Outcome – split by randomised treatment

To be provided where relevant. If there is sufficient data, centres could be presented individually to check for too few or too many secondary outcome events.

2.3.8 Safety – generally split by treatment received

A summary of any safety areas the DMC needs to consider – including pregnancies if relevant but more generally adverse events. If there are any serious unexpected suspected adverse reactions (SUSARs), these need to be listed. All adverse events could be listed if that is requested by the DMC.

2.3.9 Any other relevant information

For example, similar trials that have been recently published, updated systematic reviews (if requested by the DMC).

2.4 Suggested Analyses for blinded (open) report

2.4.1 Similar analyses will be performed as for the closed report but analyses will NOT be split by randomised treatment. Careful consideration should be given as to the inclusion of data that has the potential to unblind for example, patient visit schedules

that reflect their treatment allocation and should not be included in the blinded (open) report.

3. RELEVANT DOCUMENTS AND REFERENCES

ECTU Website

- ECTU_SOP_ST_03 Data Monitoring Committee
- ECTU_WPD_ST_W5 Statistical Analysis and Reporting (ECTU Shared Drive)
- Templates (shared drive location: \ECT Unit\SOPs\Finalised SOP and WPD\ST\Supporting Document and Templates\Current)
  - ST003 - Example DMC Report
  - ST006A Statistical Master File Essential Document Checklist
  - ST007 - Statistical Review Checklist

Others

- POGUE, J. & SACKETT, D. L. 2014. Clinician-trialist rounds: 23. When an RCT's Data Center Report drowns vital information in seas of data: where's Waldo? *Clin Trials,* 11, 601-4.
- University of Edinburgh DataSync Service
- ECTU Statistics Team Projects Document (ECTU Statistics Microsoft TEAMS site)

ECTU_SOP_ST_03, W3 Data Monitoring Committee and associated documents

Final Audit Report 2025-12-12

Created:	2025-12-11 (Greenwich Mean Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAjj_JBNbI2OdF_6bPYuO8dZp8MSOYmL70

"ECTU_SOP_ST_03, W3 Data Monitoring Committee and associated documents" History

Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2025-12-11 - 16:34:48 GMT- IP address: 192.41.114.230

Document emailed to Jacqueline Stephen (Jacqueline.Stephen@ed.ac.uk) for signature
2025-12-11 - 16:39:39 GMT

Document emailed to Catriona Keerie (Catriona.Keerie@ed.ac.uk) for signature
2025-12-11 - 16:39:40 GMT

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2025-12-11 - 16:39:40 GMT

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2025-12-11 - 16:39:40 GMT

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2025-12-11 - 16:43:12 GMT- IP address: 86.161.124.127

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2025-12-11 - 16:43:19 GMT- IP address: 104.47.11.254

Document e-signed by Christopher Weir (Christopher.Weir@ed.ac.uk)
Signature Date: 2025-12-11 - 16:43:34 GMT - Time Source: server- IP address: 86.161.124.127

Document e-signed by Catriona Keerie (Catriona.Keerie@ed.ac.uk)
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2025-12-11 - 17:57:28 GMT- IP address: 80.189.251.114

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2025-12-12 - 15:43:17 GMT- IP address: 104.47.11.254

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Signature Date: 2025-12-12 - 15:43:53 GMT - Time Source: server- IP address: 176.27.132.230

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Signature Date: 2025-12-12 - 15:47:37 GMT - Time Source: server- IP address: 192.41.114.230

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2025-12-12 - 15:47:37 GMT