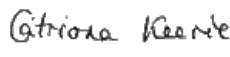
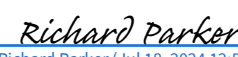




ECTU Central Office SOP ECTU_SOP_ST_01: Sample Size Calculation

Version No:	5.0
Issue Date:	22 Jul 2024
Effective Date:	08 Aug 2024

Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
Catriona Keerie, Senior Statistician	Author	18-Jul-2024	
Richard Parker, Senior Statistician	Reviewer	18-Jul-2024	 <small>Richard Parker (Jul 18, 2024 12:51 GMT+1)</small>
Steff Lewis, Statistic Team Lead	Approver	22-Jul-2024	
Tanya Tharakan, QA Manager	QA Authorisation	22-Jul-2024	 <small>Tanya Tharakan (Jul 22, 2024 08:50 GMT+1)</small>

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	6 th Aug 2012	Initial creation/New document
2.0	5 th March 2015	Clarification that validation should involve two people in section 3.3
3.0	13 th March 2017	Section 3.4 and 3.5 added after Sponsor audit recommendation
4.0	20 th February 2019	Updated at scheduled review. Document moved to new SOP template. Minor wording alterations to section 1, 3 and 4.
5.0	08 Aug 2024	Clarification around storing calculations and subsequent versions of calculations

The user of this document is responsible for ensuring it is the current version.

1.0 PURPOSE

This Standard Operating Procedure (SOP) outlines the procedures for performing, checking and documenting the sample size calculations.

2.0 SCOPE

This SOP applies to all randomised trials with full statistical support provided through ECTU.

3.0 RESPONSIBILITIES

It is the responsibility of the trial statistician (or designee) to ensure the sample size, as detailed in the protocol, has an accompanying calculation and/or justification.

4.0 PROCEDURE

Most prospective studies will have a sample size calculation prior to commencing the study. This is in order to maximise the chance that the study is large enough to estimate the true primary outcome effect, with sufficient precision, but is not too large, such that far more participants than necessary are exposed to trial interventions.

- 4.1 Detail the sample size, precision or power calculation, including dropout rates, relevant assumptions, justifications and methods in enough detail that the calculation can be repeated by someone else.
- 4.2 This information should go in the trial protocol, and a Sample Size Estimate Form should also be completed, and stored in the Statistics Master File, TMF Section 9 (see Section 5 for reference).
- 4.3 For a clinical trial of an investigational medicinal product (CTIMP), the sample size derivation should be done independently by two statisticians and this should be documented with the main details captured in form ST001 – Sample Size Estimate Form. One statistician should do the calculation, and the other should independently validate it.
- 4.4 Any programming, output, or written calculations, relating to the formal sample size calculation and its validation, should be stored, and the location clearly documented in the Statistics Master File,
- 4.5 If a study does not need a formal size sample calculation (e.g., a feasibility study), there should still be some justification for the sample size chosen. It is not necessary to validate such justifications but they should be documented on the Sample Size Estimate Form.
- 4.6 If a formal alteration of the sample size calculation is required, these should be clearly detailed, validated as required, and stored in the same manner as the original calculation, ensuring the new version is clearly labelled. A new version of the Sample Size Estimate Form should be completed, and clearly labelled.

The user of this document is responsible for ensuring it is the current version.

- 4.7 If exploratory additional sample size calculations are performed (e.g., when communicating with funders) but these do not form part of the protocol, then they should be clearly labelled as exploratory, such as by clearly labelling the electronic folders in which they are stored as exploratory in the Statistics Master File. No validation is necessary.
- 4.8 The most recent version of the Sample Size Estimate Form template should always be used, when writing or updating a sample size calculation.

5.0 RELEVANT DOCUMENTS AND REFERENCES

[ECTU Shared Drive](#)

- ST001 - Sample Size Estimate Form Template

The user of this document is responsible for ensuring it is the current version.











ECTU_SOP_ST_01 Sample Size Calculation v5.0 and ST001 Template

Final Audit Report

2024-07-22


Created:	2024-07-18 (British Summer Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAVm4nMFR8dixKWg2lyc_ABtIA7nvYyWfh

"ECTU_SOP_ST_01 Sample Size Calculation v5.0 and ST001 Template" History

-  Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2024-07-18 - 11:55:08 GMT+1- IP address: 192.41.114.230
-  Document emailed to Catriona Keerie (Catriona.Keerie@ed.ac.uk) for signature
2024-07-18 - 11:58:42 GMT+1
-  Document emailed to Richard Parker (Richard.Parker@ed.ac.uk) for signature
2024-07-18 - 11:58:42 GMT+1
-  Document emailed to Steff Lewis (Steff.Lewis@ed.ac.uk) for signature
2024-07-18 - 11:58:42 GMT+1
-  Document emailed to Tanya Tharakan (tanya.tharakan@ed.ac.uk) for signature
2024-07-18 - 11:58:42 GMT+1
-  Email viewed by Steff Lewis (Steff.Lewis@ed.ac.uk)
2024-07-18 - 12:50:09 GMT+1- IP address: 192.41.114.225
-  Email viewed by Richard Parker (Richard.Parker@ed.ac.uk)
2024-07-18 - 12:50:38 GMT+1- IP address: 104.47.11.62
-  Document e-signed by Richard Parker (Richard.Parker@ed.ac.uk)
Signature Date: 2024-07-18 - 12:51:31 GMT+1 - Time Source: server- IP address: 82.132.239.221
-  Email viewed by Catriona Keerie (Catriona.Keerie@ed.ac.uk)
2024-07-18 - 13:46:45 GMT+1- IP address: 104.47.11.254
-  Document e-signed by Catriona Keerie (Catriona.Keerie@ed.ac.uk)
Signature Date: 2024-07-18 - 13:47:13 GMT+1 - Time Source: server- IP address: 94.174.55.238

 Document e-signed by Steff Lewis (Steff.Lewis@ed.ac.uk)

Signature Date: 2024-07-22 - 08:46:50 GMT+1 - Time Source: server- IP address: 86.140.147.112

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

Signature Date: 2024-07-22 - 08:50:50 GMT+1 - Time Source: server- IP address: 192.41.114.230

 Agreement completed.

2024-07-22 - 08:50:50 GMT+1