Statistical Analysis Plan

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Author:	Dr Ranjit Lall, Principal Research Fellow (Statistician)
Reviewers:	Dr Jane Warwick, Associate Professor Dr Louise Hiller, Principal Research Fellow James Griffin, Research Associate
CTU approval:	Natalie Strickland, CTU Manager
Sponsor approval:	Debbie Ranger, Head of Governance & Quality, WMS

Revision Chronology:	Effective date:	Reason for change:
Version 1.6	11 July 2016	Biennial review: Clarification of who should review and sign off the SAP in section 3.3. Minor text changes to clarify link to SAP template.
Version 1.5	13 January 2014	Addition of template for Statistical Analysis Plan and process for its generation, review and approval.
Version 1.4	4 February 2013	Minor text changes to section 3.3.9
Version 1.3	8 October 2012	Minor text change to section 3.3.3
Version 1.2	30 March 2012	Format change to comply with SOP 1. Minor amends to text in section 3.3.10
Biennial review March 2010		No changes.
Version 1.1	31st January 2008	Bi-annual review: Format change.
Version 1.0	March 2006	

Statistical Analysis Plan

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to detail what is required in a Statistical Analysis Plan (SAP) for a Randomised Controlled Trial (RCT).

2. Background

The SAP will provide guidelines for the presentation and analysis of data at various stages of the trial. There may be several versions of the SAP during the course of a trial (e.g. those based on the analyses required for the Data Monitoring Committee (DMC) meetings, interim reporting and final reporting of the trial).

3. Procedure

3.1 Who?

This SOP has been written primarily for the statistician who is responsible for analysing the data and reporting the results of the trial.

3.2 When?

The SAP should be based on the trial protocol, but need not be written until after the trial protocol and Case Report Forms (CRFs) are finalised. It should be written prior to any formal analysis of the data and finalised prior to end of patient recruitment.

3.3 How?

Once the SAP has been drafted by the trial statistician, it will be reviewed by the Chief Investigator (CI) and other members of the Trial Management Group (TMG), the Trial Steering Committee (TSC) and the Data Monitoring Committee (DMC). Each version should be signed off by the CI, the author and the senior statistician using the key document review/approval form. In addition, the final draft should be blind reviewed and signed by a statistician independent of the study.

Each signed version should be filed in the Trial Master File (TMF).

The structure of the SAP should follow the SAP template, using the sections that are relevant for the trial.

3.3.1 Template for Statistical Analysis Plan

Refer to the template SAP document aligned to this SOP for additional details.

1. **Summary of trial protocol**
2. **Overall analysis strategy**
3. **Data**
4. **Recruitment**
5. **Descriptive analyses**
6. **Treatment**
7. **Outcomes**
8. **Safety and adverse event reporting**
9. **Analyses of subgroups and treatment effect modifiers**
10. **Sensitivity analyses**
11. **Additional analyses**
12. **Dummy tables**
13. **Amendments**

List of Abbreviations

CI	Chief Investigator
CRF	Case Report Form
DMC	Data Monitoring Committee
RCT	Randomised Controlled Trial
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

Template Documents

21-1	Template Statistical Analysis Plan
4-2	Key Document Review/Approval Form