

**Instructions for SAP Template use only – Remove this page from study specific versions**

This Statistical Analysis Plan (SAP) template is intended as a suggested layout for all SAPs authored by statisticians in ECTU.

The content and layout of this template can be altered depending on the nature of the trial.

All text in red is for guidance only and should be deleted from the final versions.

Blue text is suggested text for inclusion in a SAP, but this is optional.

Black text should be included in all SAPs.



<<Trial Logo (if available)>>

<<Trial Name and Acronym>>

**Statistical Analysis Plan**

**CONFIDENTIAL**

(This should be included if requested by the trial team)

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| **SAP Version No** |  |
| **Chief Investigator Name** |  |
| **Chief Investigator Email address** |  |

Further tables to include optional details such as Funder Name, current registry number etc. can be included here if required.

Authorship of the SAP should be described in detail in the table below. The number of rows required depends on the number of authors working on the SAP. Please include ALL authors that contributed to the SAP.

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| --- | --- | --- | --- | --- |
| SAP authors | | | | |
| **Number** | **Name** | **Date involvement started** | **Date involvement finished** | **Notes (optional)** |
| **1** |  |  |  |  |
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| SAP Approval Signatures | |
| **Trial Statistician:** | **Date Approved:** |
| **Chief Investigator:** | **Date Approved:** |

Further signatories should be added to the table above if required.

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| **SAP Document History** | | |
| **Version No** | **Date** | **Summary of Revisions** |
| 1.0 |  | Initial Creation |
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The Table of Contents is held in an automatic format within this document. Any additional sections added must be formatted correctly in order to be included in this table. To do this, ensure that the section headings to be included are formatted using Heading 2 in the References Menu, click on the Table of Contents below and select Update Table (Update entire table) to update the list.

The Section headings listed below should be included in all SAPs, however extra sections and sub-headings can be added as needed and where appropriate. The Table of Contents should be updated as detailed above with each addition.

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## **List of Abbreviations**

Compile a list of abbreviations that will be used throughout the document

|  |  |
| --- | --- |
| **Abbreviation** | **Full name** |
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The following individual section headings should be included in every SAP. Additional sections or sub-sections can be included if required (e.g. randomisation method, estimands).

Guidance regarding the recommended contents of each section is given below. Additional contents may be included as per study requirements.

## **1. Introduction**

A brief (1 paragraph) description of the trial design. This should include whether parallel-group, cluster, factorial etc., the patient group, intervention and control, whether single or multi-centre and the number of patients to be randomised (if applicable). Details of what the randomisation is stratified/minimised on and the version and date of the protocol that was used should also be included.

## **2. Statistical Methods section from the protocol**

Text from the Statistical Methods section in the protocol should be included in this section. This does not need to include the sample size calculation or a long list of outcomes. It is included here so that it is clear what was written in the protocol, and so that any necessary changes from planned methods can be presented.

It is suggested that the text from the protocol included in this section is all in italics to help distinguish it from the other sections of the SAP.

## **3. Overall Statistical Principles**

In this section you should define analysis populations (e.g. ITT, per protocol) in an unambiguous fashion, state overall level of significance (e.g. p=0.05) and state any other relevant information that will be used in the majority of analyses (e.g. treatment of missing data, adjustment for covariates, adjustment for multiplicity, adjustment for p-value(s) due to interim analyses).

## **4. List of Analyses**

List each analysis that will be done, in order.

## 4.1 Sub-section 1

## 4.2 Sub-section 2

## 4.3 Sub-section 3

* For each of the listed analyses describe precisely each outcome, any transformations on the data likely to be required before analysis, the analysis method to be used, any sensitivity analyses, any deviations from the methods listed in ‘Overall Statistical Principles’ and any subgroup analyses.
* It is only necessary to list the first choice analysis (e.g. no need to detail an alternative if it turns out you don’t have proportional hazards in survival analysis).
* Clearly describe calculation of derived variables if this is not given elsewhere.
* Dummy tables could be included here or in an additional separate section.

## **5. Validation and QC**

Detail what will be independently validated/QC’d and how this will be done.

This will usually include separate programming and checking of the primary analysis of the primary outcome. Validation of secondary analyses could also be considered.

Example text is as follows:

The following will be performed by a second statistician:

1. Separate programming and checking of the primary analysis for the primary outcome.

2. The end of trial statistical report will be read and sense-checked for accuracy and consistency.

The above text should be edited according to the specific study requirements.

## **6. Data sharing**

The following is example text only – it may not apply to all studies. It should be amended as appropriate to the specific study:

A file, or set of files, containing the final data will be prepared, along with a data dictionary. These will be made available to the Chief Investigator after the primary results paper based on the final statistical report has been published.

Note that if any participants have opted out of sharing anonymised data, then their data must not be included in any dataset for sharing.

## **7. References**

Include any references that back up the proposed methods (if applicable).

**This page is for template use only and should be removed from study specific versions**

**Document ID: ST004**

**Version no: 5.0**

**Effective date: 16 Oct 2023**

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| Template Revision History | | |
| Version No | Date | Summary of Revisions |
| 1.0 | 13th March 2017 | Initial creation |
| 2.0 | 12th March 2018 | New format throughout. Addition of Template Revision History |
| 3.0 | 20th February 2019 | Updated at scheduled review. Effective Date changed to Date Finalised |
| 4.0 | 25 March 2021 | Addition of data sharing section |
| 5.0 | 16 Oct 2023 | New authorship table on first page. Clarification that section headings are all essential but contents are not. Suggestion to include detail on estimands in additional subsection. Substantial edits including moving some material to the WPD to make the template easier to read/edit. Clarification regarding which text is description, which text is optional, and which text should be included in every SAP. |