PoCoG
Psycho-oncology Co-operative Research Group

Statistical Analysis Plan

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SOP development and approval

SOP developed by	Date	Associated document(s)
Melanie Bell Biostatistican	**13/07/2012**	**SOP_6.4.1-SAP-120807-SAP_Template**
Melanie Bell Biostatistican	**13/07/2012**	**SOP_6.4.2-SAP-120807-SAP_Example**

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SOP Revisions

Approved by:	Date	Signature (only required for PoCoG hard copy)	Description of change(s)

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Foreword

The Psycho-Oncology Cooperative Research Group (PoGoG) has developed a program of quality assurance for Psycho-Oncology Research. PoCoG's Quality System requires documentation of both management and procedural activities. This guidance document provides a standard working tool to creating a statistical analysis plan.

Questions regarding this document should be directed to:
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Overview

This document contains guidance for developing a statistical analysis plan.

Purpose

The Statistical Analysis Plan (SAP) is the guiding document for all analyses which are performed during or at the end of the study. The SAP should carefully align with the research objectives and hypotheses, as stated in the study protocol.

Scope

This SOP applies to the preparation of a Statistical Analysis Plan for all PoCoG studies, and can be used by any member of PoCoG.

Guiding Principles

Statistical analyses should be performed that follow best practice, as assessed by experts in the field. Thus, this document has been guided by the following resources:

- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Statistical Principles for Clinical Trials (E9), http://www.ich.org/home.html
- ICH General Considerations for Clinical Trials (E8)
- CONSORT Statement (Consolidated Standards of Reporting Trials) http://www.consort-statement.org/
- STROBE Statement (Strengthening the Reporting of Observational Studies in Epidemiology) http://www.strobe-statement.org/
- TREND Statement (Transparent Reporting of Evaluations with Nonrandomized Designs) http://www.cdc.gov/trendstatement/

Qualifications and Responsibilities

It is strongly encouraged that a qualified biostatistician writes, and is responsible for, the statistical analysis plan. If this is not possible, a biostatistician should, at the very least, be consulted. The Principal Investigator (PI) of the study and the research manager have the responsibility of reviewing the SAP with the biostatistician or researcher who is performing analysis, to ensure that the aims, research questions, and statistical analyses align.

1 Procedure(s)

The SAP is a very detailed description of the planned analyses and is an expansion of the Statistical Considerations section in the grant proposal and protocol. It should be finalised before breaking the blind and database lock. For the types of studies which PoCoG is involved in, changes to the SAP will not, in general, need to be reviewed by ethics boards, nor incur a protocol amendment, although in the case of drug trials this may not be the case.

As a minimum, the grant proposal's statistical considerations should include the primary and secondary outcomes, the sample size, and the primary and secondary analyses.

Possible steps:

1. Read proposal, identify aims, objectives, and research questions.
2. Discuss proposal with the Principle Investigator, including the primary outcome and research question.
3. Formulate ideas about analyses that can address primary research question.
4. Perform sample size calculations based on step 3.
5. Write statistical analysis section for the grant proposal.
6. Expand for study protocol.
7. Expand further to give a detailed plan of analyses; this may include table shells and figures.
8. Review by Principal Investigator, senior biostatistician, research manager.

2 SAP documentation

The trial biostatistician should maintain the current version of the SAP both in the study documents directory and master file (likely to be on a shared network drive) as well as in their own files. Version control can be facilitated through the use of consistent nomenclature.

3 Statistical programs/ coding/ syntax

The statistical programs (e.g., the file which contains the coding/syntax in the statistical languages SAS, SPSS, Stata, R) are where the SAP is implemented.

In order to strive towards reproducible research, all results of analyses which are performed need to be traceable back to the program that created them. This means that point and click analyses (such as in SPSS) must use the paste option to create syntax. The final programs should be clear of extraneous manipulations and procedures, and should clearly indicate which analyses were used to populate the various tables in the formal study reports and papers which result from these analyses.

It is recommended that data cleaning, manipulations and analyses should be performed in separate programs. These might be named, for example, as

```
Projectname_cleaning.SAS
Projectname_data .SAS
Projectname_analysis.SAS
```

or similar, with appropriate and consistent suffixes or prefixes for version control.

It is the trial biostatistician and the data manager's responsibility to ensure that all statistical programs, both data manipulation and analyses, are tidy, clear and well documented with extensive commenting throughout. This includes, but is not limited to, the following information at the top of the file:

```
Author:
Date:
Project:
Project PI:
Notes:
```

The final programs should be included in the master file, and should allow for all results to be repeated.

Also see the SOP for data management, particularly the section on data cleaning.

4 Quality Assurance (QA) - templates, forms and checklists

QA should take the form of having the PI and research manager review the SAP with the biostatistician. If the chief biostatistician on the study has not written the SAP they also need to review it. If there is a junior biostatistician working on the study, the senior biostatistician must check the SAP, as well as all analysis programs. The biostatistician should also be working closely with the data manager.

Validation details of who checked each SAP and statistical program (if applicable), what was checked, any problems found, actions taken and date of approval should be documented.

The documentation of statistical programming as described in section 3 will also facilitate QA and QC.

4.1 Statistical Analysis Plan Template

The SAP template (SOP_6.4.1) is attached. Many of the sections in this template will not be relevant for all types of studies, and they can either be removed or stated that they are not applicable.

4.2 Statistical Analysis Plan Example

An example of a SAP is included (SOP_6.4.2).