

## Every (research) tree needs SAP: Why Statistical Analysis Plans are vital to robust research?

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### Background

Value in research relies on robust design, conduct and analysis. The objective of a statistical analysis plan (SAP) is to document how one plans to analyse his/her clinical trial data before gaining any knowledge of the results. It is necessary to ensure interpretability and integrity of final results. In fact, leading medical journals require a pre-specified analysis plan before publishing the results of clinical trials.

### Objectives

SAPs serve a range of purposes including making sure the planned analyses answer the key research questions, providing a detailed guide for the statistician(s) responsible for the analysis as well as enhancing transparency and credibility by clearly identifying pre-planned vs post-hoc analyses.

### Method

This non-technical presentation will discuss why a SAP is such a pivotal element of every clinical trial, what should be considered when preparing a SAP and how to structure an efficient SAP. It will summarise recent guidelines<sup>1</sup> and include examples of two recently completed NHMRC-funded trials<sup>2,3</sup>.

### Results

A robust SAP ultimately maximises the value of the research data. A pre-published SAP should be part of every NHMRC-funded clinical trial.

### References:

1. *Gamble C et al. Guidelines for the Content of Statistical Analysis Plans in Clinical Trials. JAMA. 2017 Dec 19;318(23):2337-2343.*
2. *Billot L et al. Statistical analysis plan for the Head Position in Stroke Trial (HeadPoST): An international cluster cross-over randomized trial. Int J Stroke. 2017 Aug;12(6):667-670.*
3. *Billot L et al. Statistical analysis plan for the Adjunctive Corticosteroid Treatment in Critically Ill Patients with Septic Shock (ADRENAL) trial. Crit Care Resusc. 2017 Jun;19(2):183-191.*