Statistical Analysis Planning (SAP)

The George Institute for Global Health

2018 NHMRC Symposium on Research Translation

28 November 2018

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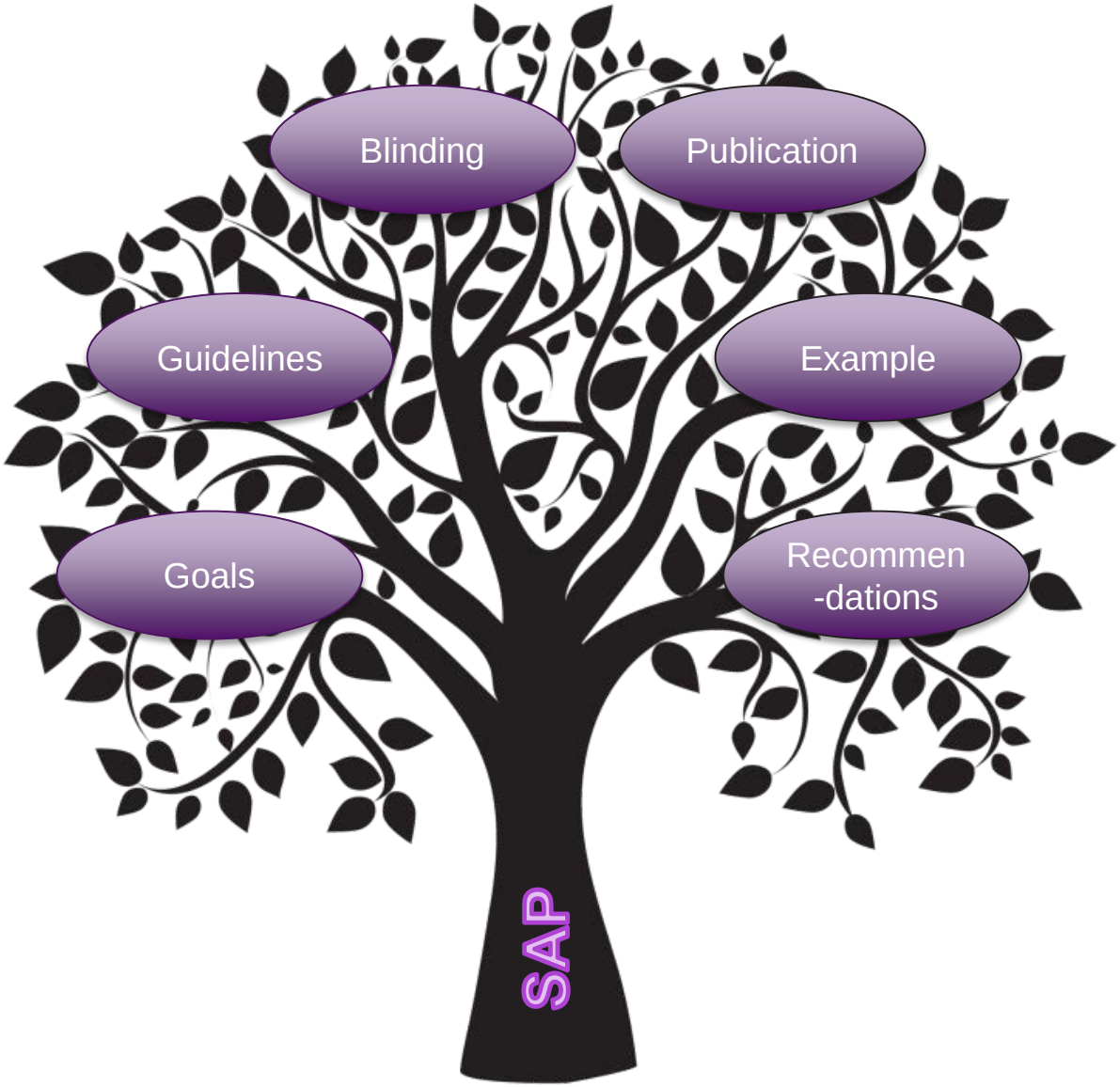
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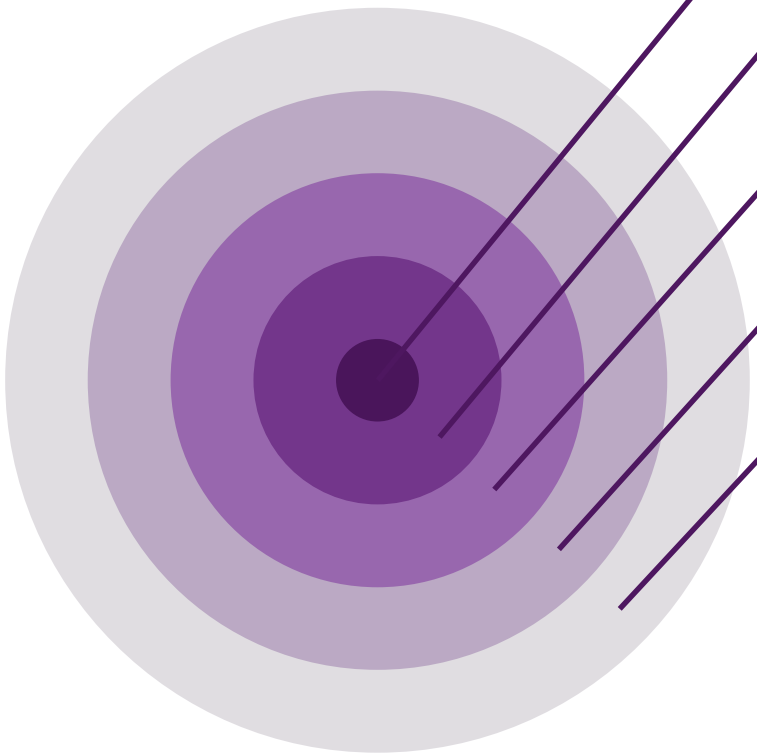
Goals of a SAP



Alignment

- Address question

Transparency

- Pre-specify

Reproducibility

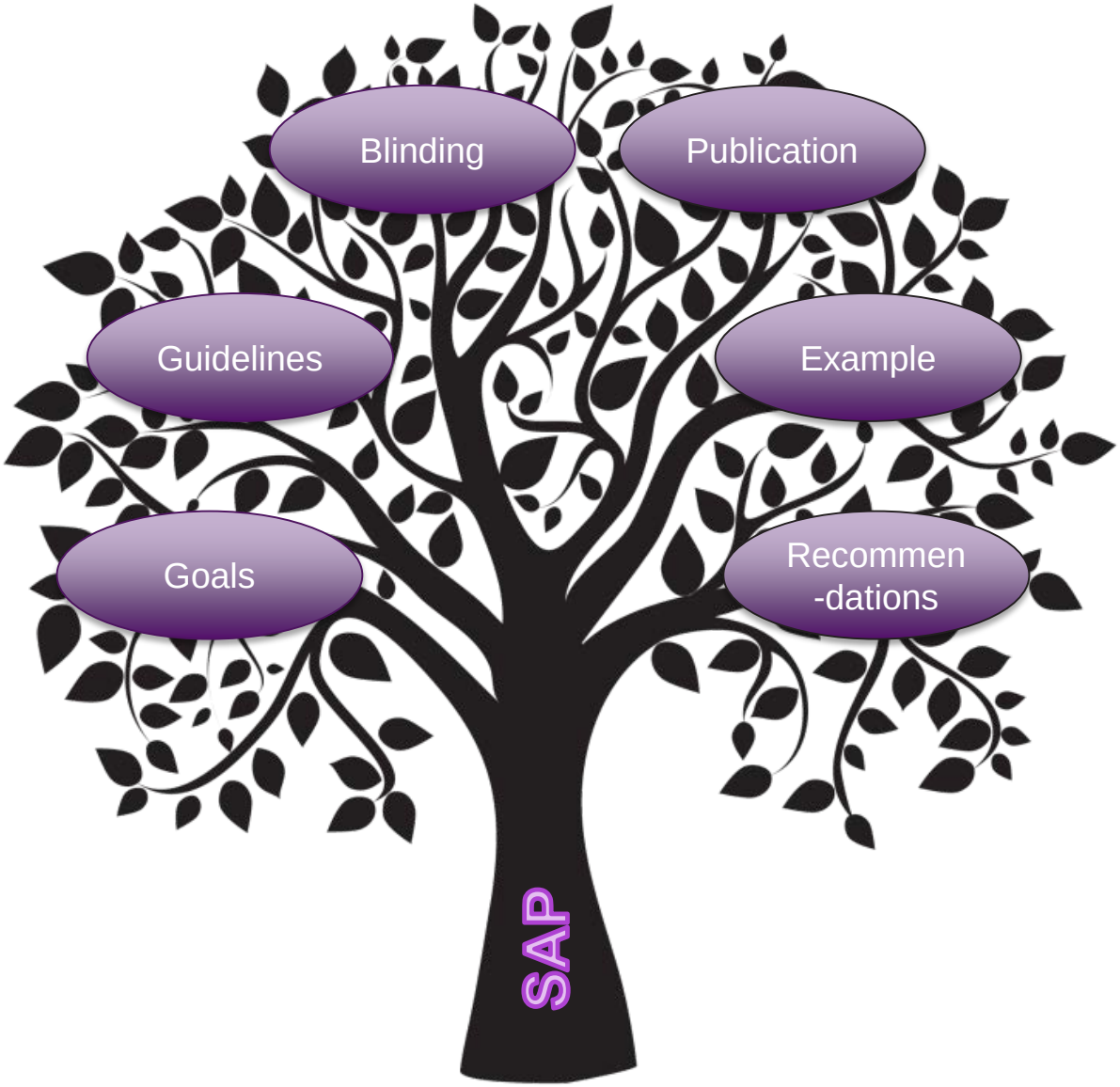
- Share details

Efficiency

- Save time and money

Impact

- Publish in major journal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JAMA guideline

- Administrative information
- Introduction
- Study methods
- Statistical principles
- Trial population
- Analysis

adjustment for covariates

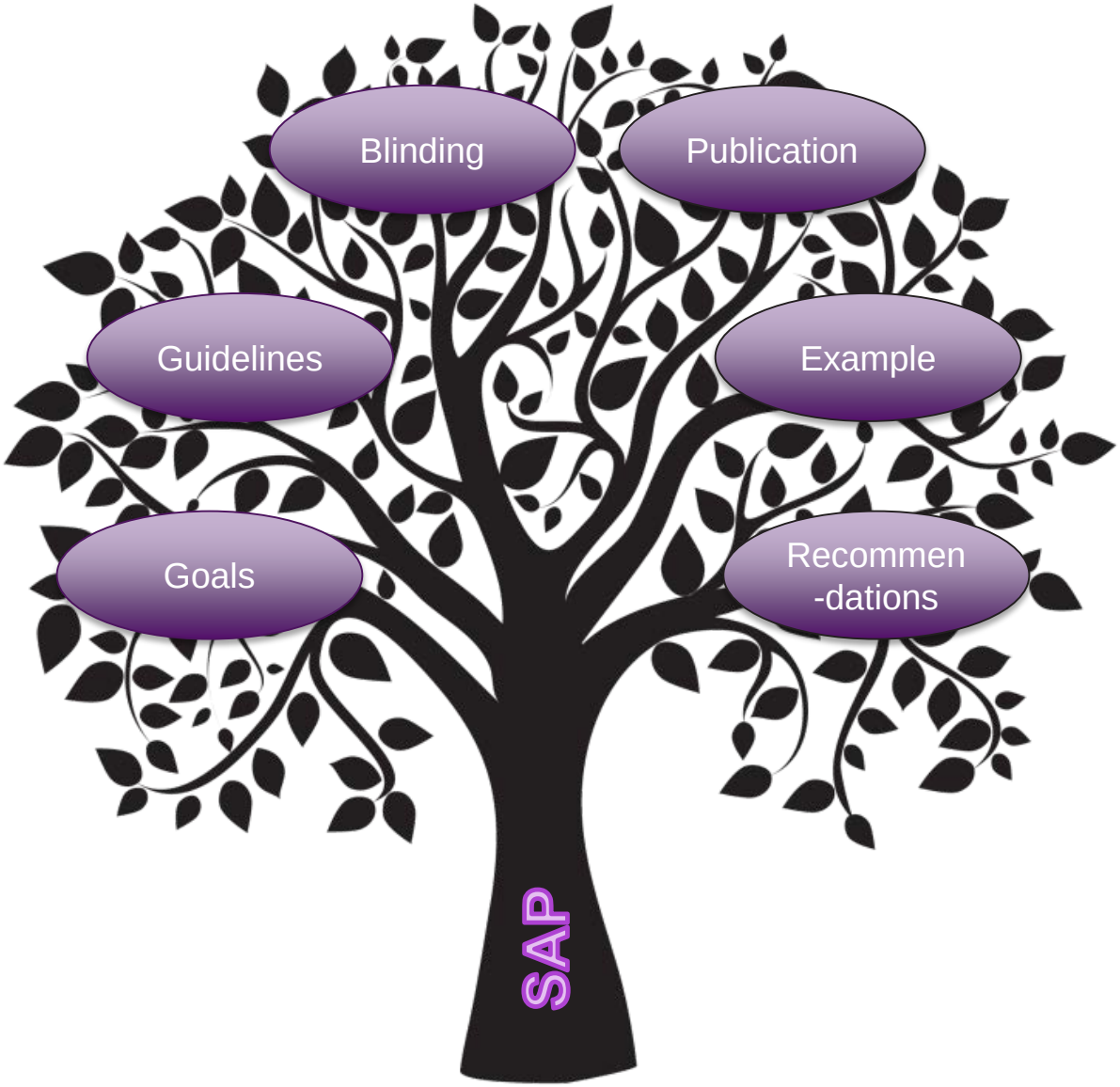
alternative methods

planned sensitivity analyses

planned subgroup analyses

methods to handle missing data

Source: https://jamanetwork.com/journals/jama/fullarticle/2666509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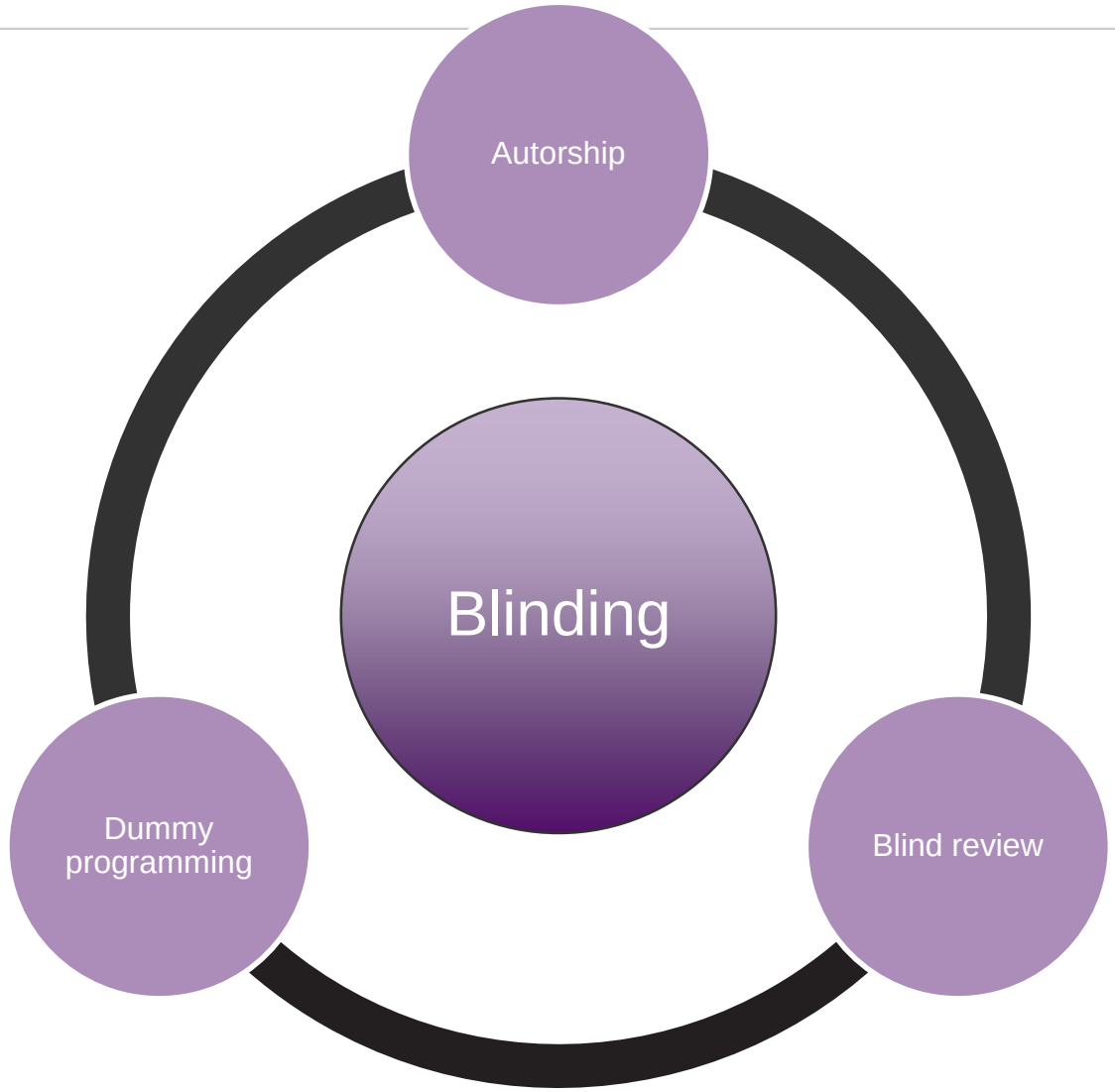
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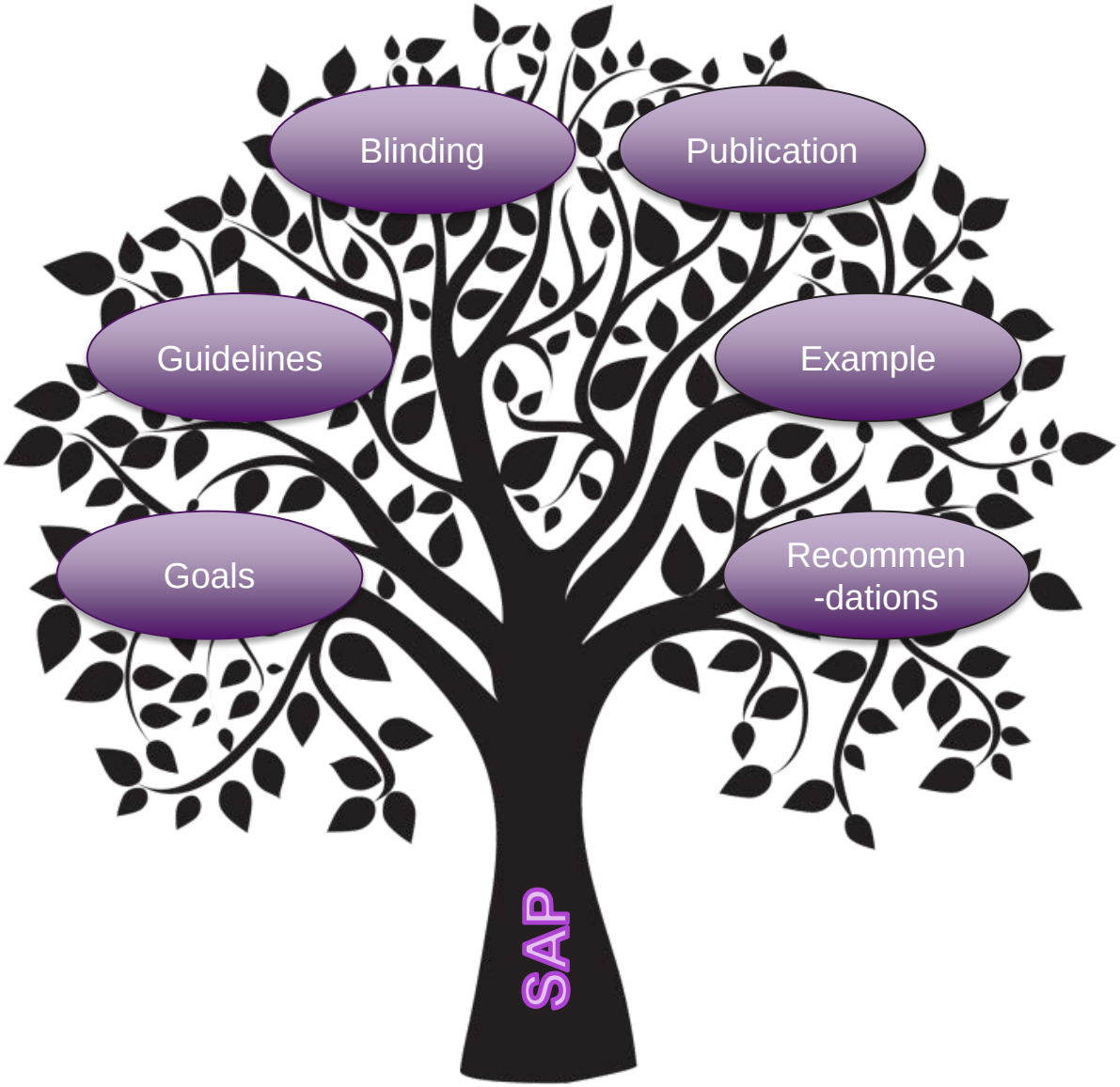
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Publication

STATISTICAL ANALYSIS PLAN APPROVAL SHEET

Study: UMPIRE

Title:

UMPIRE Use of a Multidrug Pill In Reducing cardiovascular Events

A randomised controlled trial of fixed-dose combination medication and usual care in those at high risk of cardiovascular disease.

Principal Author of Analysis Plan: Laurent Billot

Version: **2.1 (final – post blind review)**

Version date: **23 August 2012**

The undersigned have reviewed this plan and find it to be consistent with the requirements of the protocol as it applies to their respective areas. The principal author also finds this plan to be in compliance with ICH-E9 as well as The George Institute's SOP ST-SOP-04.

Laurent Billot
Study Statistician

24 August 2012
Date

Simon Thom
Project Coordinator / Principal Investigator

23. Aug 2012
Date

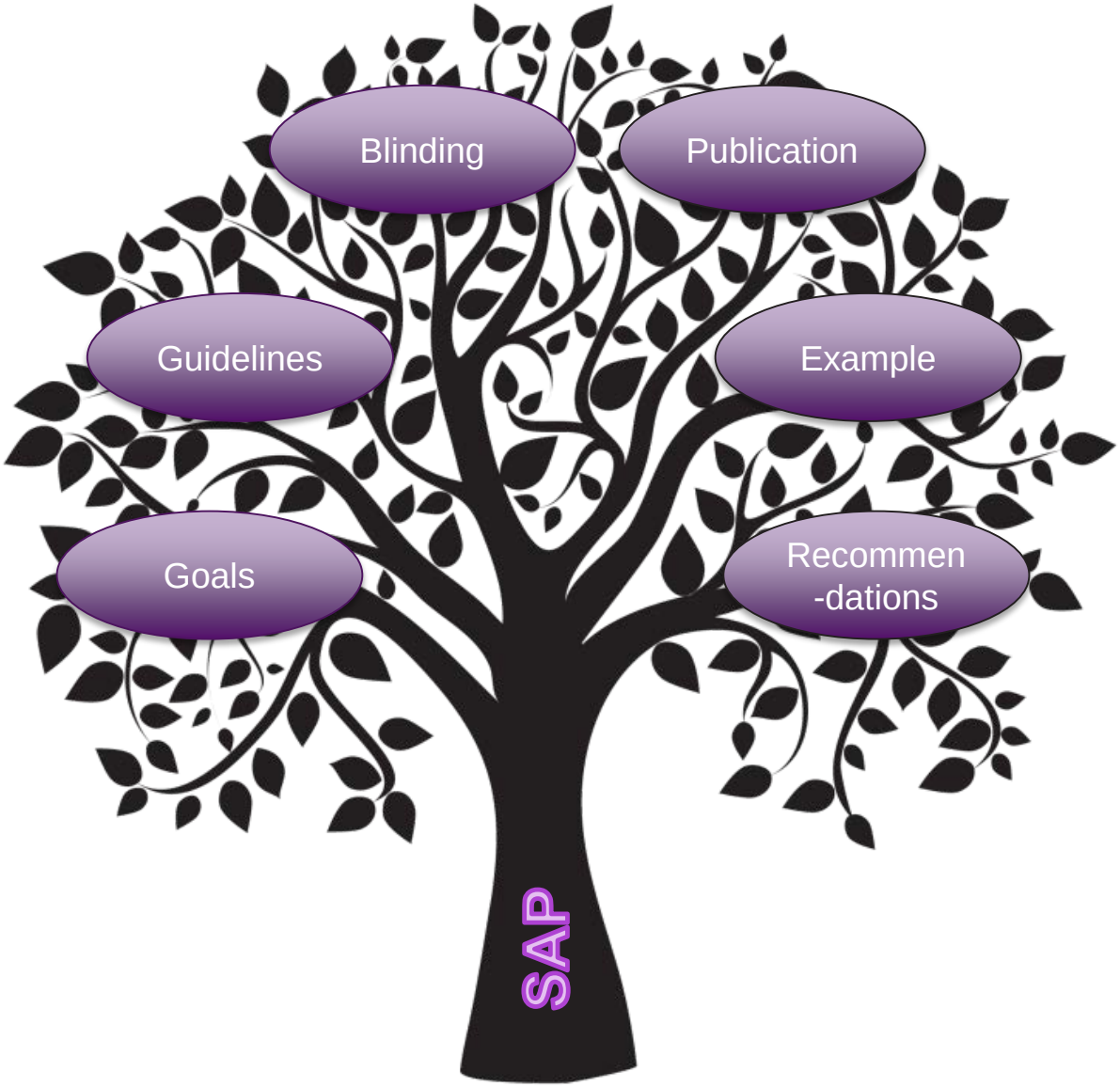
UPDATE Open Access

CrossMark

PRECISE — pregabalin in addition to usual care: statistical analysis plan

Stephanie Mathieson[1*], Laurent Billot[1], Christopher G. Maher[1], Andrew J. McLachlan[2], Jane Latimer[1], Bart W. Koes[3], Mark J. Hancock[4], Ian Harris[5], Richard O. Day[6], Justin Pik[7], Stephen Jan[1] and Chung-Wei Christine Lin[1]

The George Institute for Global Health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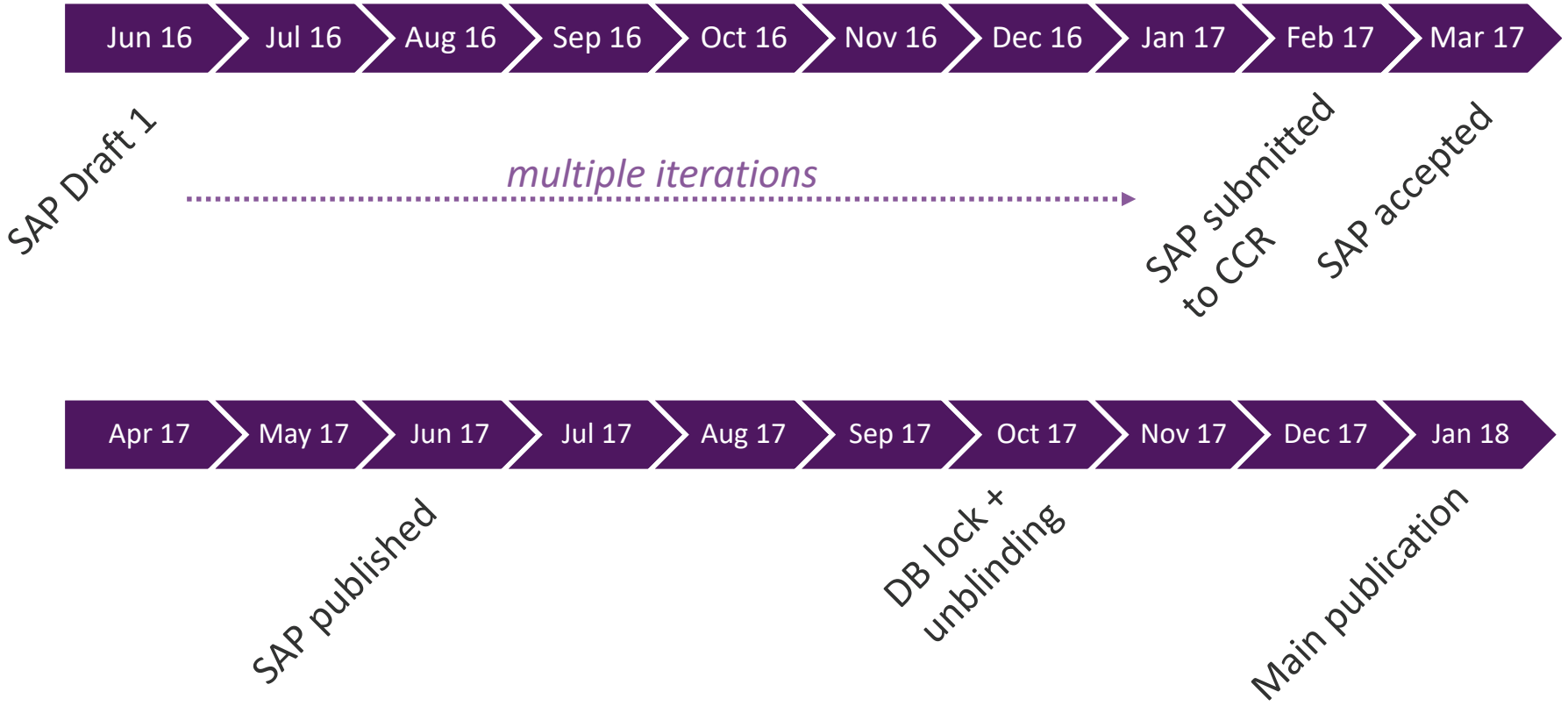
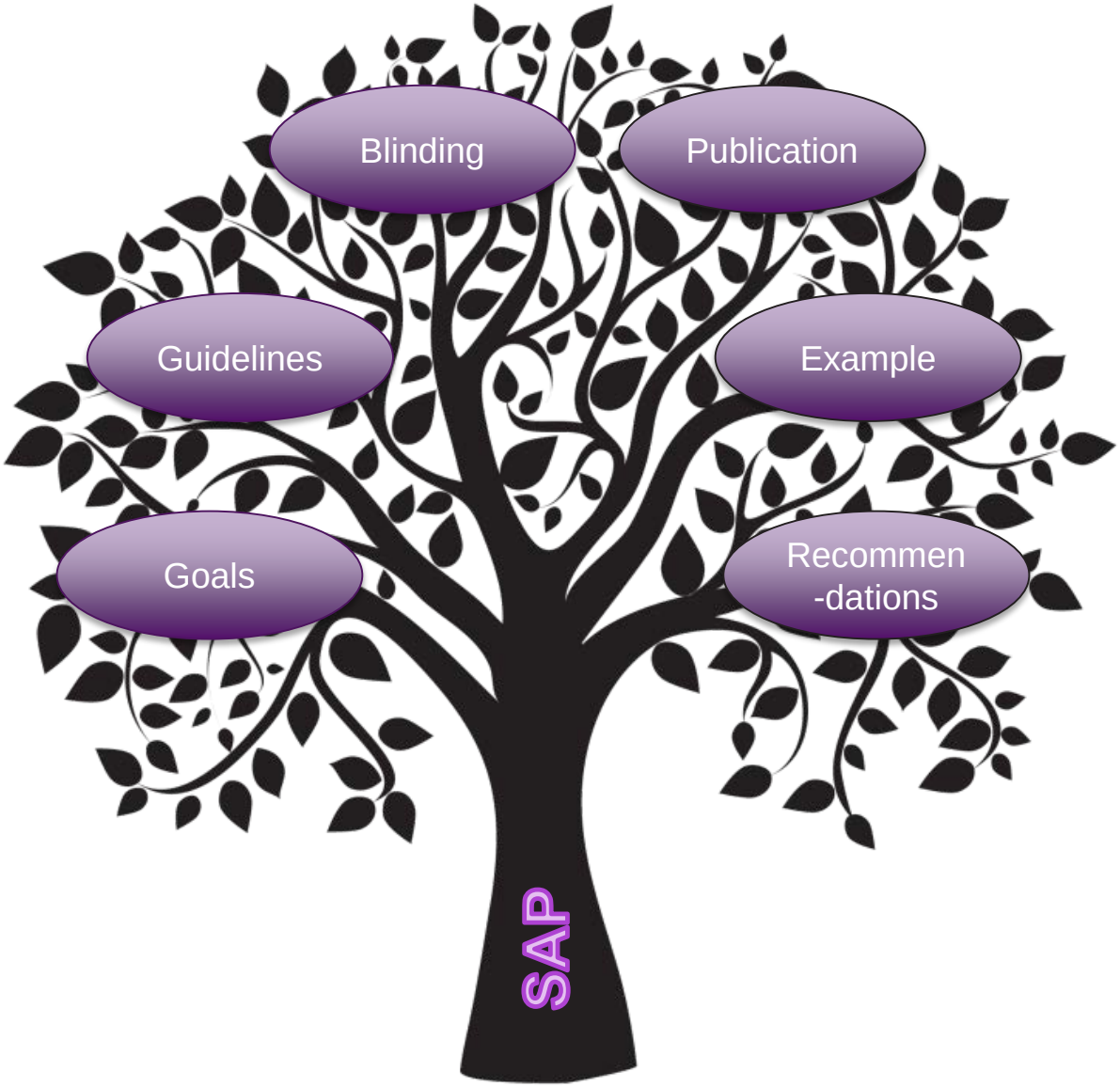
Case study: ADRENAL trial

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Recommendations

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- SAP critical for transparency and reproducibility of research
- Every NHMRC funded trial should have a pre-specified SAP made publicly available
- NHMRC/ACTA to develop template(s) and/or libraries of statistical analysis plans

Thank you

The George Institute for Global Health Australia

UNSW SYDNEY