

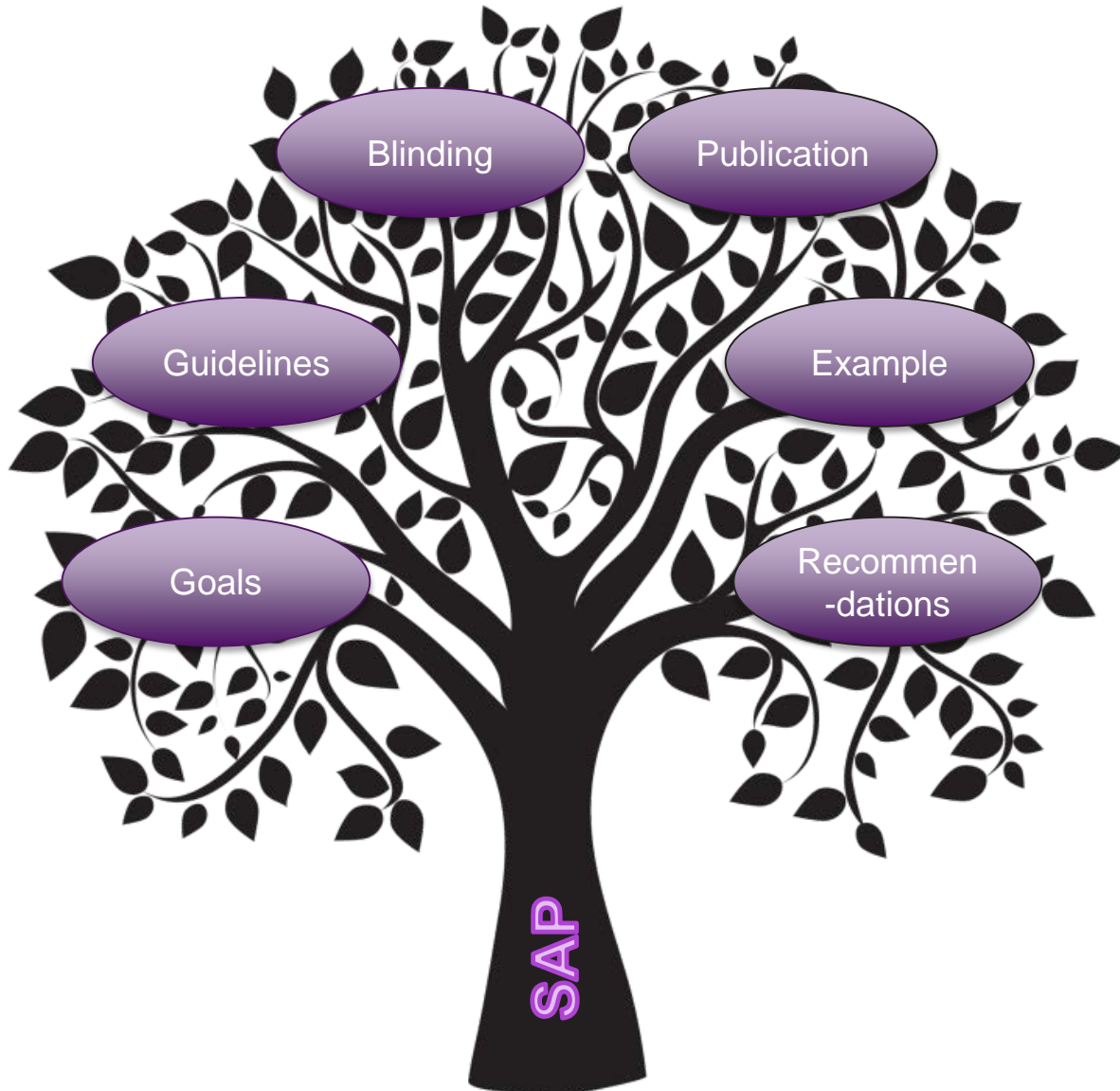
Statistical Analysis Planning (SAP)



2018 NHMRC Symposium on Research Translation
28 November 2018

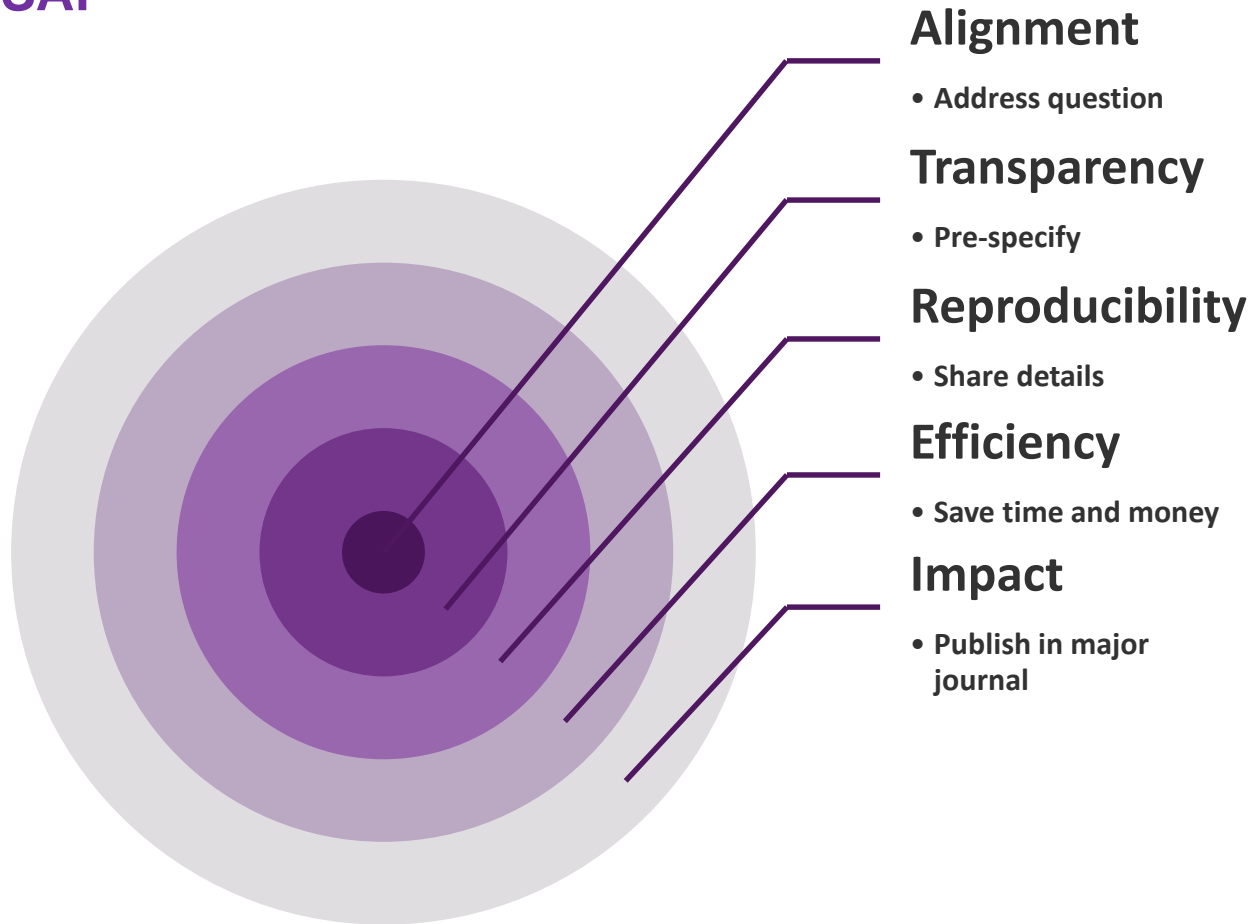
Associate Professor Laurent Billot

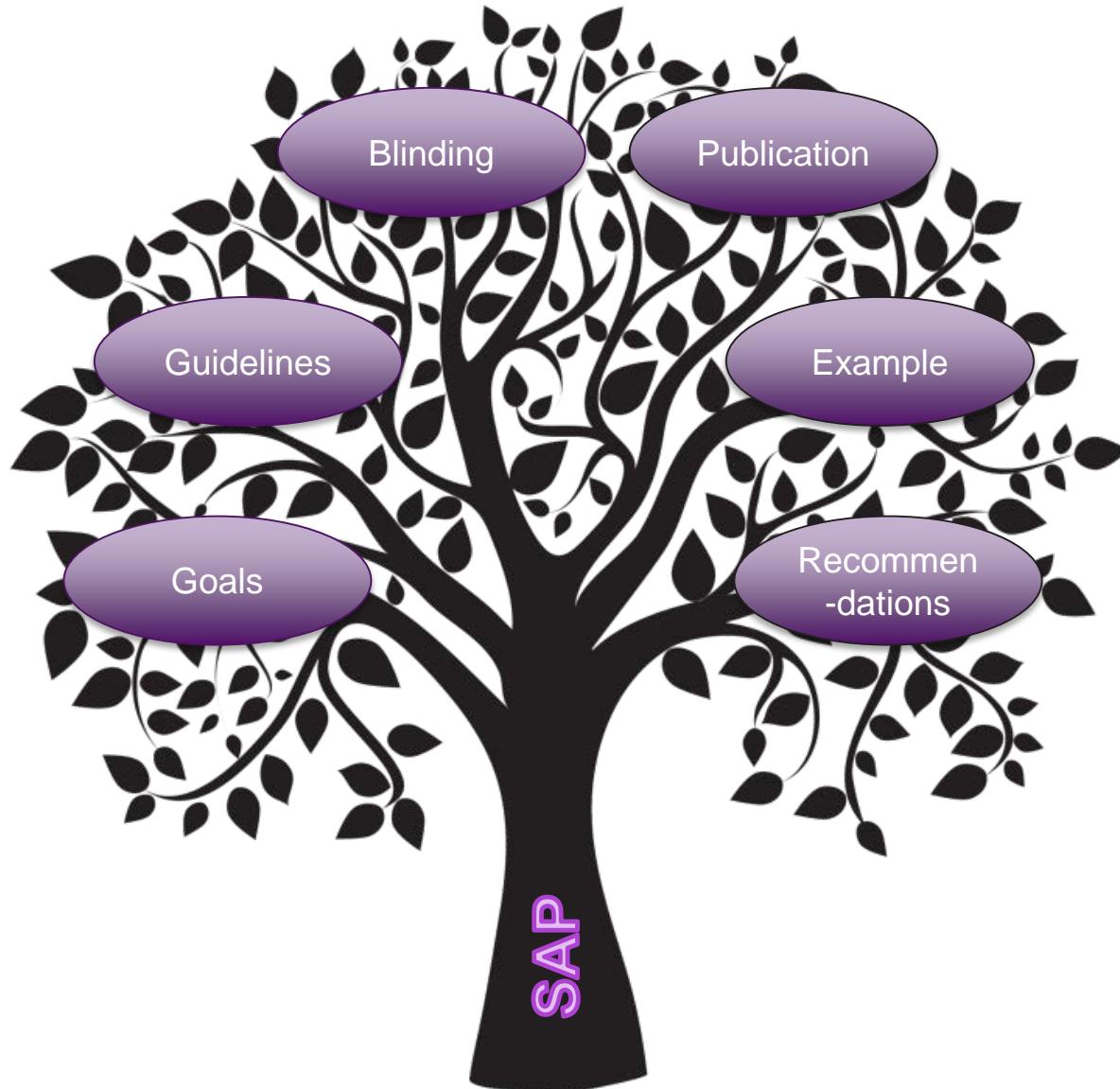
*Director, Statistics Division, the George Institute for Global Health
Conjoint Associate Professor, Faculty of Medicine, UNSW Sydney*





Goals of a SAP





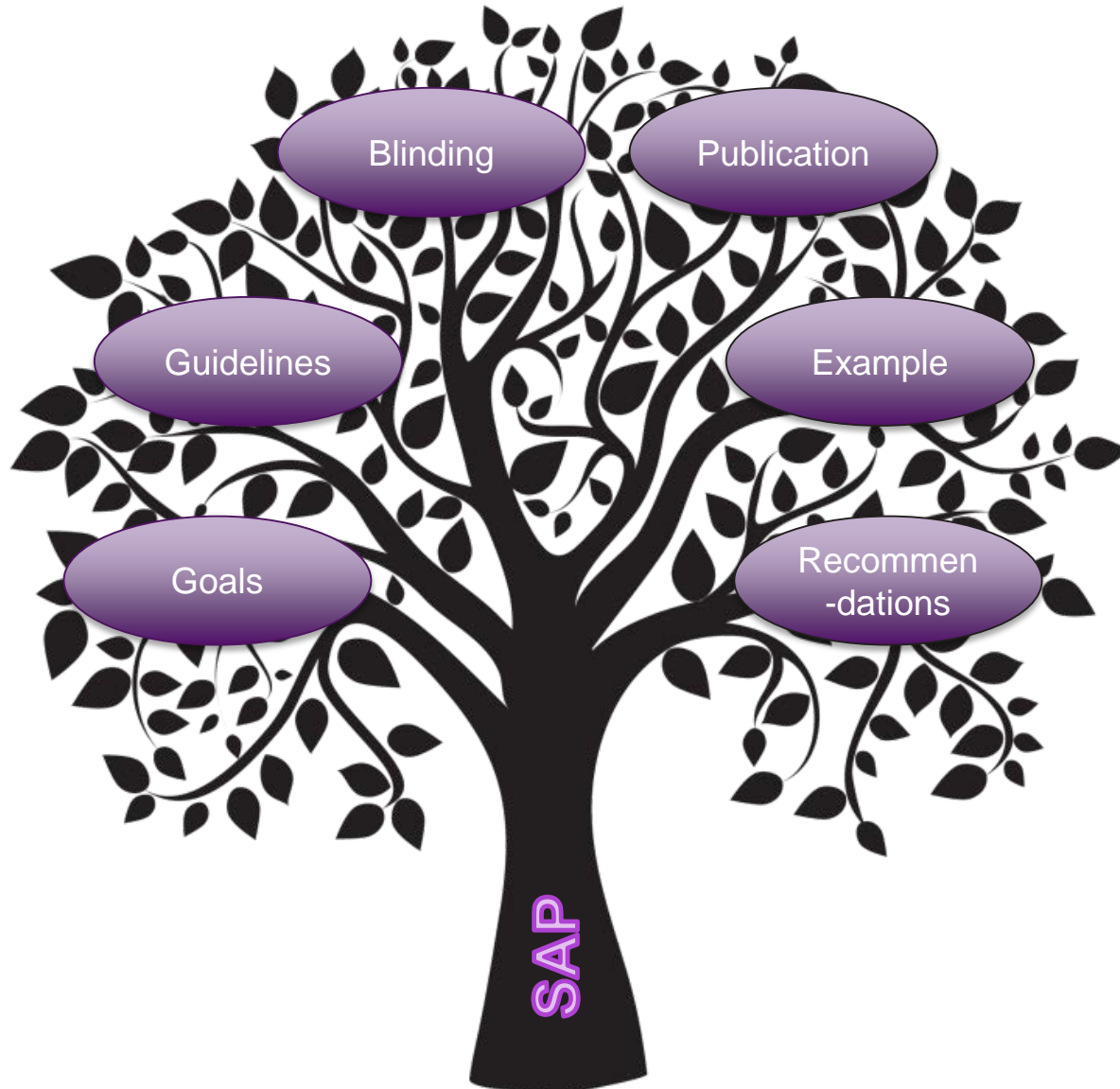
JAMA guideline

Section 6: Analysis	
Administrative information	26a
Introduction	26b
Study methods	26c
Statistical principles	27a
Trial population	27b
Analysis	27c

26a	List and describe each primary and secondary outcome including details of specification of outcomes and timings. If applicable include the order of importance of primary or key secondary end points (eg, order in which they will be tested)
26b	specific measurement and units (eg, glucose control, HbA _{1c} , [mmol/mol or %])
26c	any calculation or transformation used to derive the outcome (eg, change from baseline, QoL score, time to event)
27a	what analyses are planned to be presented
27b	any adjustment for covariates
27c	any alternative statistical methods
27d	details of any statistical methods used if standard assumptions do not hold, eg, normality, proportional hazards, etc
27e	any planned sensitivity analyses
27f	any planned subgroup analyses
28	any planned methods to handle missing data (eg, multiple imputation)
29	any planned methods to handle missing data (eg, multiple imputation)
30	any planned methods to handle missing data (eg, multiple imputation)
31	Details of any other methods to be used
32a	References to be provided for nonstandard statistical methods
32b	Reference to Data Management Plan
32c	Reference to the Trial Master File and Statistical Master File
32d	Reference to other standard operating procedures or documents to be adhered to

Source: <https://jamanetwork.com/journals/jama/fullarticle/2666509>





Blinding

Publication

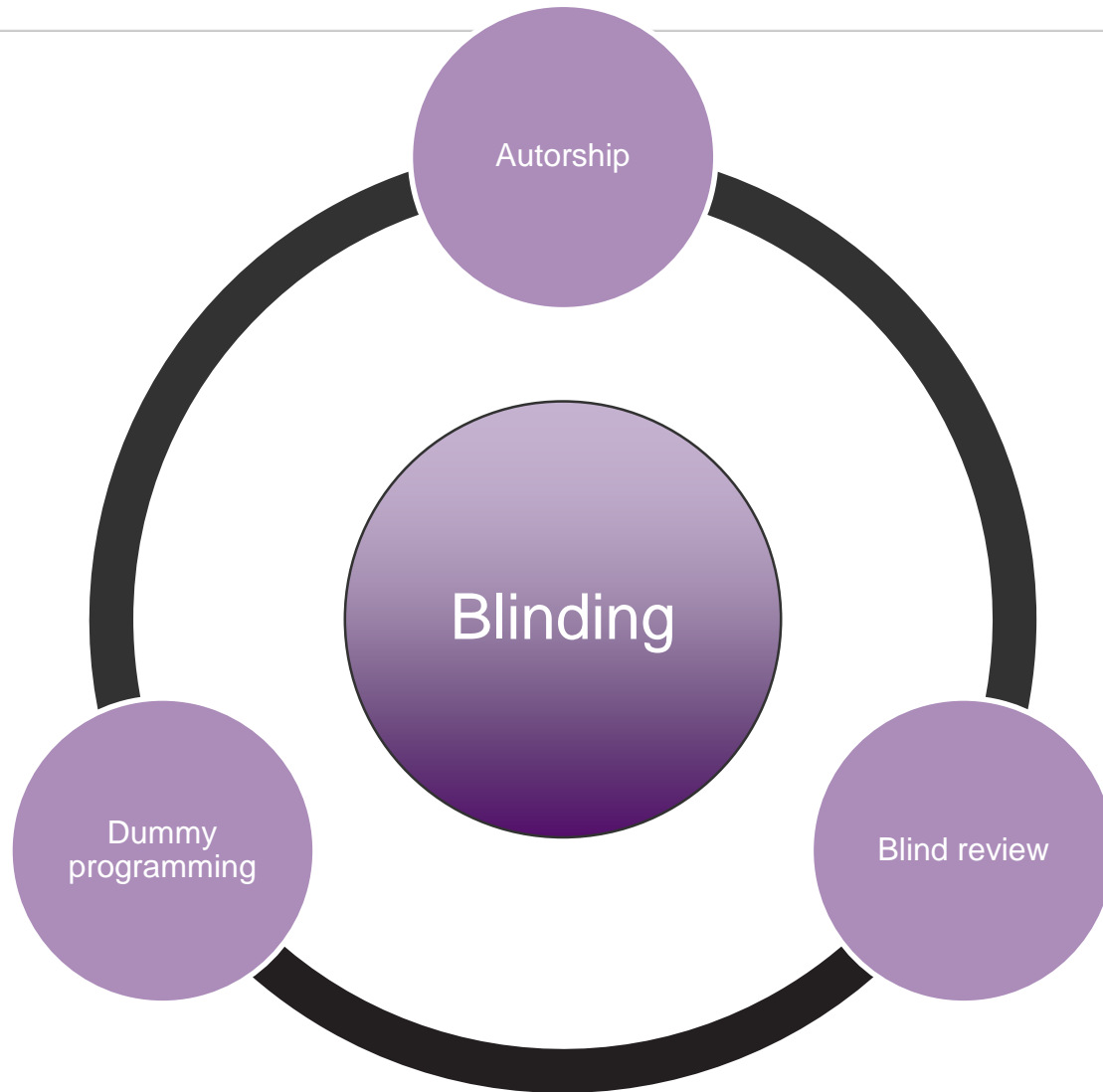
Guidelines

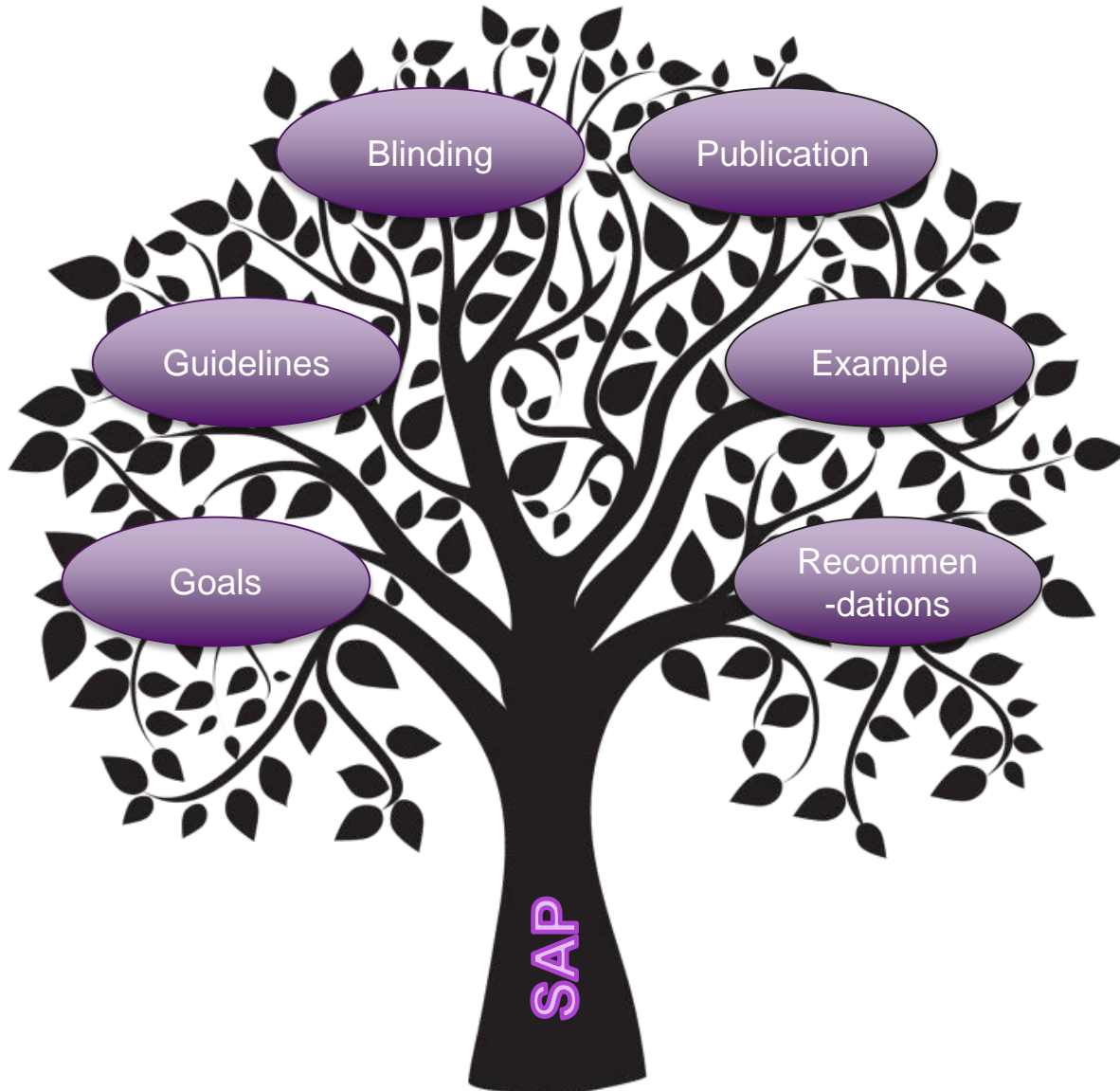
Example

Goals

Recommen
-dations

SAP





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)

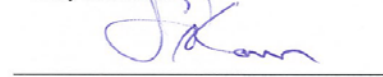
Version date: 23 August 2012

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

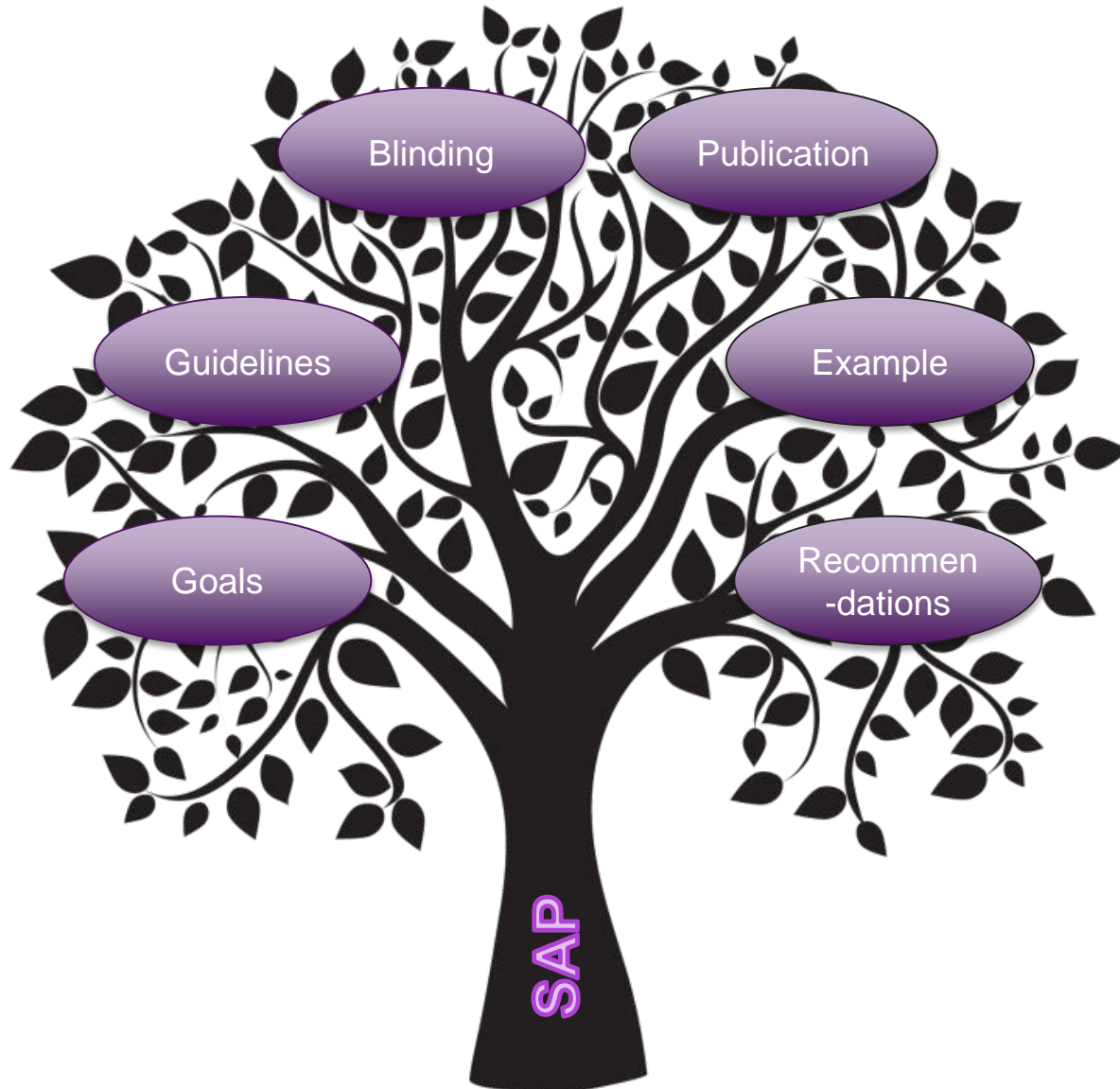
Open Access



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

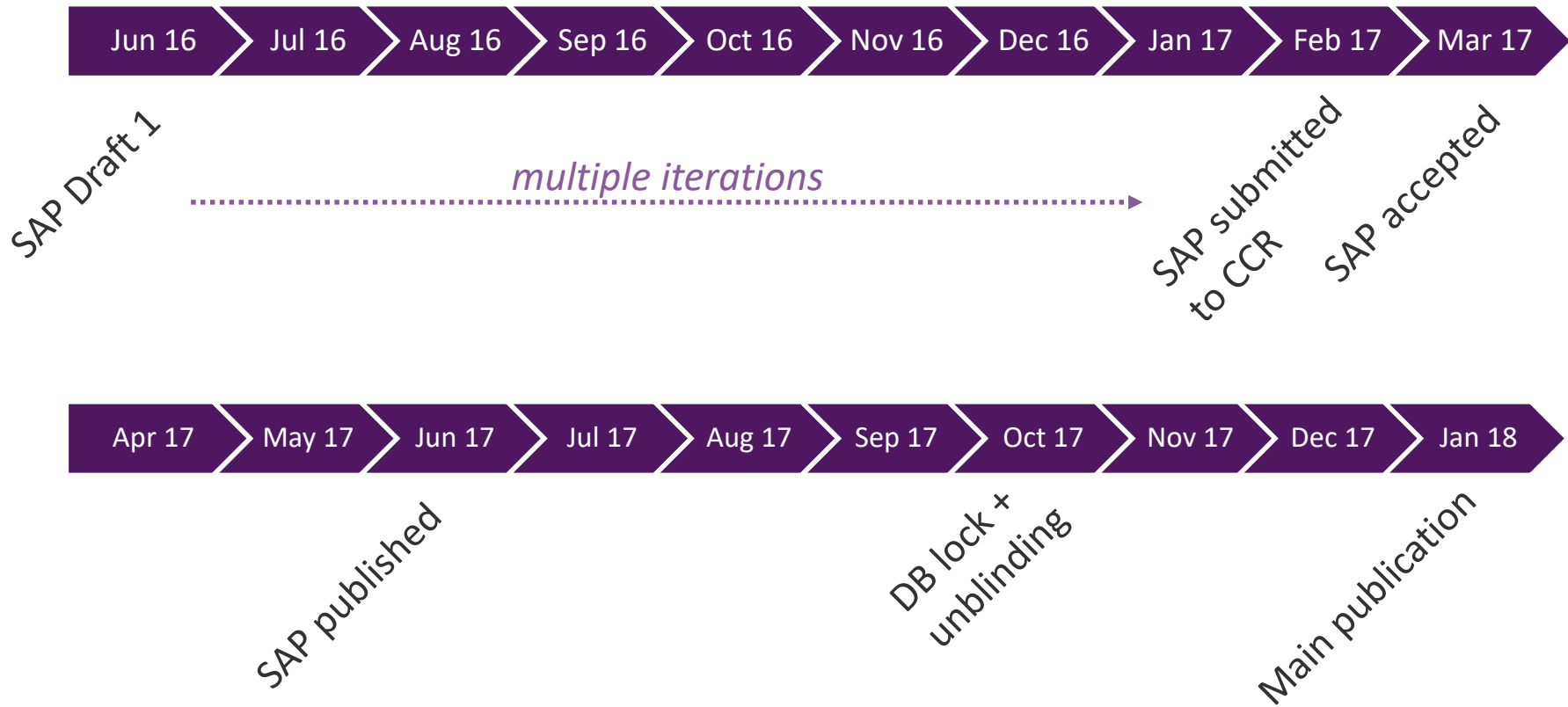
Stephanie Mathieson^{1*}, Laurent Billot¹, Christopher G. Maher¹, Andrew J. McLachlan², Jane Latimer¹, Bart W. Koes³, Mark J. Hancock⁴, Ian Harris⁵, Richard O. Day⁶, Justin Pik⁷, Stephen Jan¹ and Chung-Wei Christine Lin¹

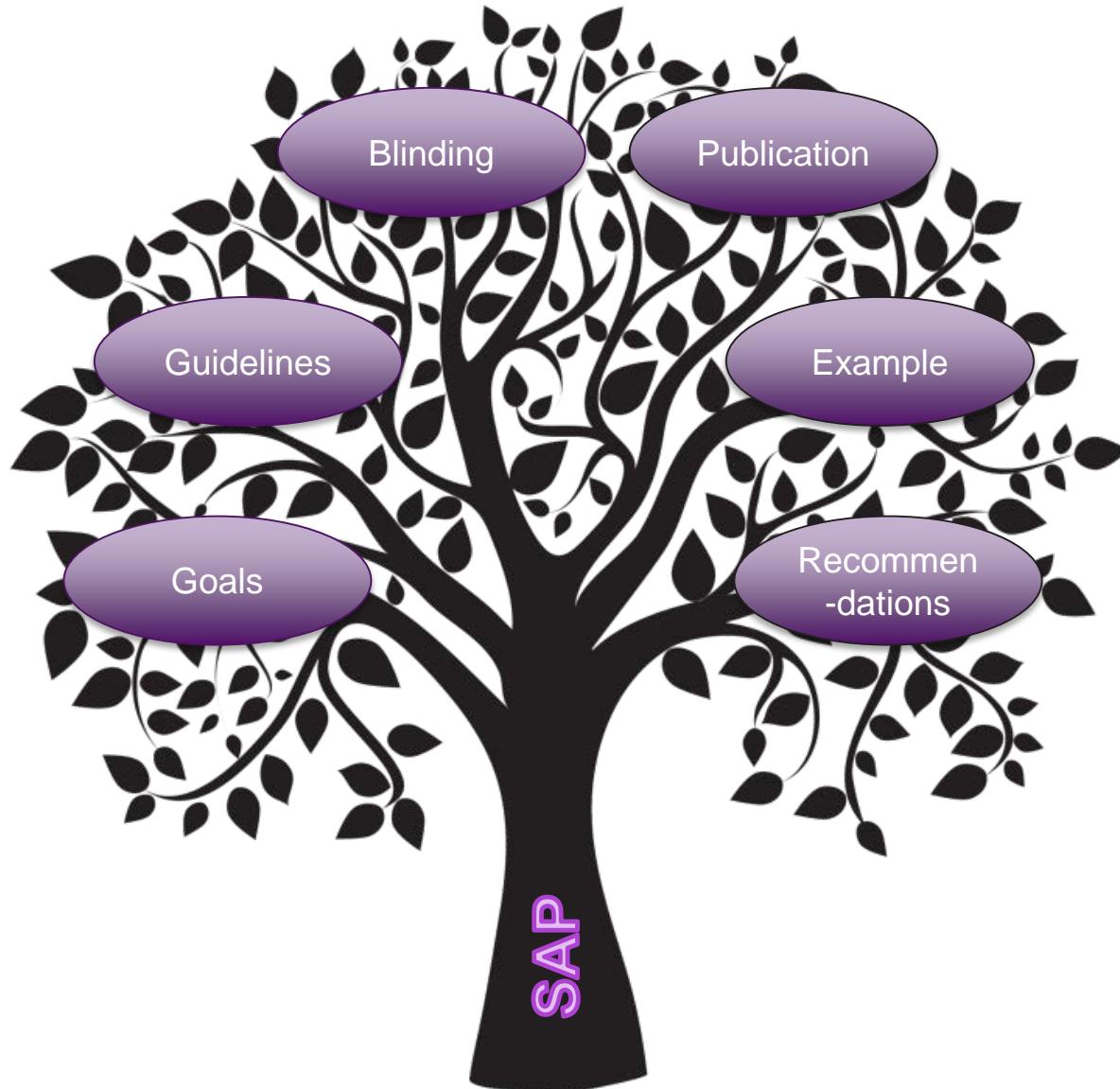






Case study: ADRENAL trial





Recommendations



- 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