

## Statistical Analysis Plan (SAP) template

<b>1. Administrative information</b>		
Study title	1.1	Descriptive title with study design, population, study acronym, if applicable
Roles and responsibilities	1.2	Names, affiliations, roles of contributors to the study and responsibilities, including statisticians, project manager, data manager
Signatures	1.3	Lead PI, Lead statistician, Lead data manager
<b>2. Introduction</b>		
Background and rationale	2.1	Description of the research and justification for undertaking the study
Objectives	2.2	Objectives, hypotheses, estimands
<b>3. Study level information</b>		
Study setting	3.1	Examples: retrospective, survey, etc
Study population	3.2	Inclusion/exclusion criteria
Data sources	3.3	Incl. sample sizes
Data collection processes	3.4	Incl. timeline
<b>4. Variable level information</b>		
Outcome definitions	4.1	Primary and secondary outcomes
Main variable(s) of interest	4.2	
Other variables	4.3	Variables used in at least one analysis, groups of variables, timing of measurements
Other variables to describe the study population	4.4	Variables that are not used in the analyses
Structural variables	4.5	
<b>5. Methods of analyses</b>		
<b>Statistical Analysis Plan (SAP)</b>	5.1	
Methods for analyzing primary outcomes	5.1.1	list of analyses A1, A2,..
Methods for analyzing secondary outcomes	5.1.2	list of analyses
Assumptions	5.1.3	Statistical significance, multiple testing, missing data
Sample size and power	5.1.4	Estimated number of data subjects and events, if applicable; domain and statistical assumptions support sample size calculations
<b>Initial Data Analysis Plan (IDAP)</b>	5.2	
Data subject profile	5.2.1	number of data subjects; time frame if applicable
Missing values	5.2.2	Explanatory and outcome variables
Univariate descriptions	5.2.3	Structural variables, explanatory and outcome variables
Multivariate descriptions	5.2.4	Explanatory and structural variables
Longitudinal aspects	5.2.5	If applicable

Timing of analyses	5.3	e.g. IDAP once data are extracted, ongoing with the data collection, SAP once IDA is completed and discussed with PIs.
Additional analyses	5.4	different statistical models, sensitivity analyses, subgroups, if applicable
<b>6. Data management plan</b>		
Data access	6.1	Statement who has access to data
Data storage	6.2	Statement to where data is stored
Data standards	6.3	Format, software,
Confidentiality and dissemination	6.4	Plans for granting public access, if any, to data or code, type of public license
<b>7. Protocol Amendments</b>		
Additional IDA	7.1	
Amended SAP	7.2	updated analysis plan after IDA or SAP, if no changes. With dates and rationale
Changes to the SAP	7.3	Description of changes with dates after starting the analysis; this may include changes to the analysis data set. Additional analyses
Subgroup/sensitivity analyses	7.4	
<b>8. Appendices</b>		
Data dictionary	8.1	Variable names, values, data source, standards
IRB materials	8.2	List and location of: ethics approval letter, consent forms, if applicable, IRB protocol related documents
Statistical software	8.3	
Key references	8.4	