**Research Project [number]**

**[Research Project title]**

**Statistical Analysis Plan (SAP)**

**[DRAFT/FINAL] version y.x**

**Date:**

**[DD MM YYYY]**

**🟅 Statistical Analysis Plan prepared by:**

[Name and title of trial statistician]

**🟅 With the collaboration of:**

[Names and title of collaborators]

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# Background

* Resume of the medical background for the study

# Objectives

## Primary objectives

* Description of the primary objectives of the Translational research

## Secondary objectives

* List of the secondary objectives of the Translational research

# Datasets and definition

## Databases used for the analysis

* Name and date of lock of the database(s) used in the analysis.

## Study population

* Inclusion and Exclusion criteria for the study population

## Definition of outcomes and covariates of interest

* Description of the different covariates used in the statistical analyses
* Details of the data provenance if external data are used in the study

# Definition of endpoints

* Description of the primary and secondary endpoints used in the planned analysis (definition of the corresponding events and baseline time)

# Statistical Analyses

## Primary analyses

* Description of the primary analyses (statistical method, endpoint, results/p-values displayed, potential power analysis)

## Secondary analyses

* Description of the secondary analyses

# References

* Main references used in the SAP development (optional)

# Annexes

* Example: preliminary descriptive results, table/graph templates, additional definition details…