

**Statistical Analysis Plan, Version 1.0 (Final)**

------ *Prepared by Anesthesia Biostatistics Consulting (ABC) based on SAP Guideline\**

Biostatistician: sign your name here

Senior Biostatistician: sign your name here

Principle Investigator: sign your name here

Date: date of signature

**Section 1: Administrative information**

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| Title and Trial registration  |
| Item 1a: Descriptive title that matches the protocol, with ‘Statistical analysis plan’ either as a fore runner or sub title, and trial acronym (if applicable).Item 1b: Trial registration number |

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| SAP Version |
| Item 2: SAP version number with dates |

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| Protocol Version |
| Item 3: Reference to version of Protocol being used |

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| SAP Revisions – revision history, with justification and timing |
| Item 4a/4b/4c: SAP Revision History Justification for each SAP revision Timing of SAP revisions in relation to interim analyses etc. |

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| Roles and Responsibility – non-signatory names and contribution |
| Item 5: Names, affiliations, and roles of SAP contributors |

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| Roles and Responsibility – signatures |
| Item 6a: Signature of person writing the SAPItem 6b: Signature of senior statistician responsibleItem 6c: Signature of chief investigator/clinical lead |

**Section 2: Introduction**

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| Background and rationale |
| Item 7: Synopsis of trial background and rationale including brief description of research question and brief justification for undertaking the trial |

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| Objectives |
| Item 8: Description of specific objectives or hypotheses |

**Section 3: Trial Methods**

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| Trial design – description of trial design |
| Item 9: Brief description of trial design including type of trial (e.g. parallel group, multiarm, crossover, factorial), allocation ratio and brief description of interventions |

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| Randomisation |
| Item 10: Randomisation details e.g. whether any dynamic allocation (e.g. minimisation) or stratification occurred (including stratifying factors used or the location of that information if not held within the SAP) |

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| Sample size |
| Item 11: Full details of the sample size calculation or alternatively reference to sample size calculation in protocol (instead of replication in SAP) |

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| Framework |
| Item 12: Superiority, equivalence or non-inferiority trial hypothesis testing framework, and which comparisons will be presented on this basis |

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| Statistical Interim analyses and stopping guidance |
| Item 13a: Information on Interim analyses specifying what interim analyses will be carried out and listing of time pointsItem 13b: Any planned adjustment of the significance level due to interim analysisItem 13c: Details of guidelines for stopping a trial early |

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| Timing of final analysis |
| Item 14: Timing of final analysis e.g. all outcomes analysed collectively or timing stratified by planned length of follow-up |

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| Timing of outcome assessments |
| Item 15: Time points at which the outcomes are measured |

**Section 4: Statistical Principles**

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| Confidence intervals and p-values |
| Item 16: Level of statistical significanceItem 17: Description of any planned adjustment for multiplicity, and if so, including how the type 1 error is to be controlledItem 18: Confidence intervals (CI) to be reported |

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| Adherence and Protocol Deviations |
| Item 19a: Definition of adherence to the intervention and how this is assessed including extent ofexposureItem 19b: Description of how adherence to the intervention will be presentedItem 19c: Definition of protocol deviation for the trialItem 19d: Description of which protocol deviations will be summarised (may include details of whether deviation is major or minor and impact on analysis populations and approach to summarising protocol deviations e.g. number and type of protocol deviation, per group) |

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| Analysis populations |
| Item 20: Definition of Analysis populations e.g. intention-to-treat (ITT), per-protocol, complete case, safety. |

**Section 4: Trial Population**

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| Screening Data |
| Item 21: Reporting of screening data (if collected) to describe representativeness of trial sample |

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| Eligibility |
| Item 22: Summary of eligibility criteria |

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| Recruitment |
| Item 23: Information to be included in the CONSORT flow diagram |

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| Withdrawal/Follow-up – level of withdrawal |
| Item 24a: Level of withdrawal e.g. from intervention and/or from follow upItem 24b: Timing of withdrawal/lost to follow up dataItem 24c: Reasons and details of how withdrawal/lost to follow up data will be presented |

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| Baseline patient characteristics |
| Item 25a: List of baseline characteristics to be summarizedItem 25b: Details of how baseline characteristics will be descriptively summarised |

**Section 5: Analysis**

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| Outcome definitions |
| List and describe each primary and secondary outcome including details of: Item 26a: Specification of outcomes and timings. Item 26b: Specific measurement and units (e.g. glucose control hbA1c (mmol/mol or %)) Item 26c: Any calculation or transformation used to derive the outcome (e.g. change from baseline, quality of life (QoL) score, time to event, logarithm etc). |

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| Analysis methods |
| Item 27a: - What analysis method will be used, and how the treatment effects will be presented |

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| Statistical Methods – adjustment for covariates |
| Item 27b: List and describe each primary and secondary outcome including details of: - any adjustment for covariatesItem 27c: List and describe each primary and secondary outcome including details of: - methods used for assumptions to be checked for statistical methodsItem 27d: List and describe each primary and secondary outcome including details of: -alternative methods to be used if distributional assumptions (e.g. normality, proportional hazards etc) do not hold |

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| Statistical Methods – sensitivity analyses |
| Item 27e: List and describe each primary and secondary outcome including details of: - any planned sensitivity analyses for each outcome |

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| Statistical Methods – subgroup analyses |
| Item 27f: List and describe each primary and secondary outcome including details of: - any planned subgroup analyses for each outcome |

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| Missing data |
| Item 28: Missing data- reporting and assumptions/statistical methods to handle missing data (e.g. multiple imputation) |

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| Additional Analyses |
| Item 29: Details of any additional statistical analyses required e.g. complier-average causal effect (CACE) analysis |

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| Harms |
| Item 30: Sufficient detail provided on summarising harms e.g. information on severity, expectedness and causality; details of how AE's are coded or categorised; how adverse events (AE’s) data will be analysed, i.e. grade 3/4 only, incidence case analysis, intervention emergent analysis |

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| Statistical Software |
| Item 31: Details of statistical packages to be used to carry out analyses (optional) |

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| References |
| Item 32a: References to be provided for non-standard statistical methodsItem 32b: Reference to Data Management PlanItem 32c: Reference to the Trial Master File and Statistical Master FileItem 32d: Reference to other Standard Operating Procedures or documents |