Table. SAP Guidance Document: Recommended Items to Address in a Clinical Trial SAPa

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| Section/Item | Index | Description Section | Page |
| 1: Administrative Information | | | |
| Title and trial registration | 1a | Descriptive title that matches the protocol, with SAP either as a forerunner or subtitle, and trial acronym (if applicable) | 1 |
| 1b | 1b Trial registration number | 3 |
| SAP version | 2 | SAP version number with dates | 1 |
| Protocol version | 3 | Reference to version of protocol being used | 1 |
| SAP revisions | 4a | SAP revision history | 2 |
| 4b | Justification for each SAP revision | 2 |
| 4c | Timing of SAP revisions in relation to interim analyses, etc. | 2 |
| Roles and responsibility | 5 | Names, affiliations, and roles of SAP contributors | 1 |
| Signatures of: | 6a | Person writing the SAP | 17 |
| 6b | Senior statistician responsible | 17 |
| 6c | Chief investigator/clinical lead Section | 17 |
| Section 2: Introduction | | | |
| Background and rationale | 7 | Synopsis of trial background and rationale including a brief description of research question and brief justification for undertaking the trial | 4-6 |
| Objectives | 8 | Description of specific objectives or hypotheses | 4 |
| Section 3: Study Methods | | | |
| Trial design | 9 | Brief description of trial design including type of trial (eg, parallel group, multiarm, crossover, factorial) and allocation ratio and may include brief description of interventions | 6 |
| Randomization | 10 | Randomization details, eg, whether any minimization or stratification occurred (including stratifying factors used or the location of that information if it is not held within the SAP) | 6 |
| Sample size | 11 | Full sample size calculation or reference to sample size calculation in protocol (instead of replication in SAP) | See published protocol |
| Framework | 12 | Superiority, equivalence, or noninferiority hypothesis testing framework, including which comparisons will be presented on this basis | NA |
| Statistical interim analyses and stopping guidance | 13a | Information on interim analyses specifying what interim analyses will be carried out and listing of time points | NA |
| 13b | Any planned adjustment of the significance level due to interim analysis | NA |
| 13c | Details of guidelines for stopping the trial early | NA |
| Timing of final analysis | 14 | Timing of final analysis, eg, all outcomes analyzed collectively or timing stratified by planned length of follow-up | 9 |
| Timing of outcome assessments | 15 | Time points at which the outcomes are measured including visit “windows” | 9 |
| Section 4: Statistical Principles | | | |
| Confidence intervals and P values | 16 | Level of statistical significance | 10-11 |
|  | 17 | Description and rationale for any adjustment for multiplicity and, if so, detailing how the type 1 error is to be controlled | 10-11 |
|  | 18 | Confidence intervals to be reported | 10 |
| Adherence and protocol deviations | 19a | Definition of adherence to the intervention and how this is assessed including extent of exposure | 7 and table 2 |
| 19b | Description of how adherence to the intervention will be presented | 7 and table 2 |
| 19c | Definition of protocol deviations for the trial | 7 |
| 19d | Description of which protocol deviations will be summarized | 7 |
| Analysis populations | 20 | Definition of analysis populations, eg, intention to treat, per protocol, complete case, safety | 9 |
| Section 5: Trial Population | | | |
| Screening data | 21 | Reporting of screening data (if collected) to describe representativeness of trial sample | NA |
| Eligibility | 22 | Summary of eligibility criteria | 7 |
| Recruitment | 23 | Information to be included in the CONSORT flow diagram | See published protocol |
| Withdrawal/follow-up | 24a | Level of withdrawal, eg, from intervention and/or from follow-up | 12 |
| 24b | Timing of withdrawal/lost to follow-up data | 12 |
| 24c | Reasons and details of how withdrawal/lost to follow-up data will be presented | 12 |
| Baseline patient characteristics | 25a | List of baseline characteristics to be summarized | Table 1 |
| 25b | Details of how baseline characteristics will be descriptively summarized | 9 |
| Section 6: Analysis | | | |
| Outcome definitions |  | List and describe each primary and secondary outcome including details of: |  |
| 26a | 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) | 10-11 |
| 26b | specific measurement and units (eg, glucose control, hbA1c [mmol/mol or %]) | NA |
| 26c | any calculation or transformation used to derive the outcome (eg, change from baseline, QoL score, time to event, logarithm, etc) | 8 |
| Analysis methods | 27a | what analysis method will be used and how the treatment effects will be presented | 9-11 |
|  | 27b | any adjustment for covariates | 9-11 |
|  | 27c | methods used for assumptions to be checked for statistical methods | 9 |
|  | 27d | details of alternative methods to be used if distributional assumptions do not hold, eg, normality, proportional hazards, etc | 11 |
|  | 27e | any planned sensitivity analyses for each outcome where applicable | 9 |
|  | 27f | any planned subgroup analyses for each outcome including how subgroups are defined | NA |
| Missing data | 28 | Reporting and assumptions/statistical methods to handle missing data (eg, multiple imputation) | 12 |
| Additional analyses | 29 | Details of any additional statistical analyses required, eg, complier-average causal effect analysis | NA |
| Harms | 30 | Sufficient detail on summarizing safety data, eg, information on severity, expectedness, and causality; details of how adverse events are coded or categorized; how adverse event data will be analyzed, ie, grade 3/4 only, incidence case analysis, intervention emergent analysis | 7 |
| Statistical software | 31 | Details of statistical packages to be used to carry out analyses | 9 |
| References | 32a | References to be provided for nonstandard statistical methods | 10; Trial sequential analysis |
|  | 32b | Reference to Data Management Plan | 18 |
|  | 32c | Reference to the Trial Master File and Statistical Master File | 18 |
|  | 32d | Reference to other standard operating procedures or documents to be adhered to | 18 |

Abbreviations: CONSORT, Consolidated Standards of Reporting Trials; hbA1c, hemoglobin A1c; QoL, quality of life; SAP, statistical analysis plan. a Reproduced with permission from the authors