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|  | Statistical Analysis Plan |
| Date | DD/MM/YYYY |
| Authors | 1. SURNAME, Given name
2. SURNAME, Given name
3. SURNAME, Given name
4. SURNAME, Given name
5. SURNAME, Given name
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| **Title of Proposed Research (with subtitle specifying the design, e.g., case-control)** |
| This Statistical Analysis Plan describes definitions and outcomes in this study, which will… (state objectives briefly, specifying the PICO, <100 words)  |

 |
| title page |
|  |
| Principal investigator(s): |  |
| Nominated main analyst(s): |  |
| Nominated second/third independent analyst(s): |  |
| Publicly available on CSMPR or other websites? | Yes [ ]  Date:  |  | No [ ]  |

List Of Abbreviations

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| **Abbreviation or special term** | **Explanation** |
| CDARS | Clinical Data Analysis and Reporting System |
| ICD-9-CM | International Classification of Diseases, Ninth Revision, Coding Manual |
| IRR | Incidence rate ratio |
| PICO | Population, Intervention (or exposure), comparator, and Outcome |
| STROBE | STrengthening the Reporting of OBservational studies in Epidemiology |

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| 1. | BACKGROUND |
|  | Importance of the study. Specify research gaps and clinical significance.  |
| 2. | [OBJECTIVES](#_Toc351646345) |
|  | State 1-3 numbered objectives. Be concise. Provide hypotheses if any. |
| 3. | [STUDY](#_Toc351646344) DESIGN |
| 3a | Design: name the design. |
| 3b | Data source: name data sources e.g., Hospital Authority CDARS, with brief description what information is available for the analysis and up to what date. Importantly, how precise the information provided is (e.g., date is provided as calendar day/only month?).Specify the setting in which the data were collected, extracted, and/or coded (e.g inpatient, outpatient, or A&E) (Specify here or under Study Population) |
| 3c | Details of data handling: index date, follow-up endpoints, etc. For (nested) case control study, the underlying cohort can be described here. |
| 4. | STUDY POPULATION |
|  | e.g., Adult Hospital Authority service users living with depression. For case-control design, state case and control selection here. Specify the setting in which the data were collected, extracted, and/or coded (e.g., inpatient, outpatient, or A&E) (Specify here or under Study Design) |
| 4a | Inclusion criteria: e.g., i. Aged ≥18; ii. ICD-9-CM 311 ever recorded before index date |
| 4b | Exclusion criteria: e.g., i. ICD-9-CM 303 ever recorded before index date |
| 5 | STUDY OUTCOME |
| 5a | Primary outcome: e.g., all-cause mortality |
| 5b | Secondary outcomes: e.g., cardiovascular mortality with causes of death coded with ICD-9-CM 390-459 |
| 6 | EXPOSURE |
| 6a | Primary exposure: e.g. metformin use (specify details of operationalization such as duration and comparator, etc.)  |
| 6b | Secondary exposure: e.g. insulin use |
| 7 | CONFOUNDERS/COVARIATES |
|  | List all confounders to be considered and how they are operationalized. e.g., medication use specific generic name and the period based on which they are defined. Can be a numbered list.1. Age
2. Sex
3. ……
 |
| 8 | EFFECT MODIFICATION/STRATIFICATION |
|  | All sub-group or stratified analysis to be specified here. Also describe the potential effect modifiers to be tested. |
| 9 | ANALYSIS |
| 9a | Main analysis: Name the statistical models to be used. State the statistic(s), e.g., IRR, used to quantify any associations. Specify the exposure and outcome again. Provide references for uncommon methods. |
| 9b | Sub-group analysis: analyses corresponding to the stratifiers specified under Section 8. |
| 9c | Sensitivity analysis: analyses with alternative assumptions or operationalizations used to check the robustness of the findings. |
| 10 | SAMPLE SIZE CONSIDERATION |
|  | Provide justifications for the sample size that will result from the specified design and procedures. |
| 11 | ANTICIPATED PITFALLS |
|  | Any possible ways the results could fail to achieve one or more of the study objectives.1. Missing data (smoking, alcohol use, lifestyle factors, etc.)
2. Potential violation of assumptions, like SCCS event independence assumption, Cox proportional hazard assumption
3. Assumption on date and timing of exposure and events
4. Modest sample size anticipated
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| 12 | RELEVANT RESEARCH CHECKLIST |
|  | Research checklist to be used to enhance the reporting of the study. e.g., STROBE. |

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| **REFERENCES:** |

* Please save the completed protocol in share drive where the dataset and programming codes are stored
* No restrictions on the file name and exact location to store this protocol but it is recommended that its name contains the word ‘protocol’ and stored in the same location as the programming codes