Cohort study

A cohort study is an observational study design, starting from a patient sample without the disease and typically comparing between exposed and unexposed people or assessing risk factors for a disease/ outcome. It can be prospective or retrospective.

- ☐ **Background**
  - Explain the research topic to a non-expert
  - Present prior research, evidence and/ or guidelines on the topic, as relevant
  - Explain the rationale for the current study
- ☐ **Study significance**
- ☐ **Objectives and hypothesis** (if relevant)
- ☐ **Study design**:
  In addition to general definition of retrospective or prospective, define what was retrospective or prospective – was the aim defined before data collection, were patients identified prospectively, was data collection prospective and if prospective were there required assessments for the study?
- ☐ **Setting and dates:**
  - Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.
  - In studies based on secondary use of data describe the data sources that will be used.
- ☐ **Patients** (Study population)
  - Eligibility
    Inclusion and exclusion criteria. Give diagnostic criteria, if applicable
  - Patient sampling. Define how patients were identified and sampled from those potentially eligible
  - In studies based on secondary use of data the methods of study population selection such as codes or algorithms used to identify subjects, should be listed in detail. If this is not possible, an explanation should be provided.
- ☐ **Variables**
  - Independent (or exposure) variables,. The exposure variable is the treatment, test or patient characteristic of interest, on which the

study hypothesis is based. The exposure should be defined clearly (start time, duration, min/ max values and operative definition, measurement methods or data sources)

- Dependent (outcome) variable: study outcome or measurement of interest .Described follow up period and end of follow up events. Give sources of data and details of methods and criteria of assessment (measurement). Describe comparability of assessment methods between exposed and unexposed, if relevant.
- Other study variables: confounders and risk factors for the study outcome, other than the exposure variable. Other descriptive data collected.
- In studies based on secondary use of data a complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided.

☐ **Data sources, measurements and study flow:**
From where and how will data be collected? If relevant, describe patient follow-up, measurements and/ or study schedule and methods of assessment for each variable of interest. Describe comparability of assessment methods of outcome variables for exposed and unexposed if relevant.

☐ **Sample size or power.** If the sample size is known in advance calculate the power of this sample to answer the study question. Otherwise compute the needed sample size. Discuss the feasibility of reaching the needed sample size supported by relevant data.

☐ **Statistical analysis.**

- Describe all statistical methods, including those used to control for confounding.
- Describe any methods used to examine subgroups and interactions
- Explain how missing data were addressed.
- In studies based on secondary use of data information on the data cleaning methods used in the study should also be provided.

☐ **Ethical considerations**

☐ **Potential sources of bias:** describe the planned study limitations, potential bias and, if relevant, methods to address these.