|  |  |
| --- | --- |
| **TITLE:** | **{TITLE** |
| **PROTOCOL NUMBER:** | {Number} |
| **VERSION NUMBER:** | 1.0 |
| **STUDIED MEDICAL PRODUCT:** |  |
| **AUTHOR:** | Name/profession:  Address:  Hospital:  City:  Country:  Phone/mobile:  E-mail: |
| **DATE FINAL:** |  |

**This protocol is approved:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Title and name

Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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# Rationale and Background

# Reseach Question and Objectives

# Study Design

Examples: Data Source, Study Limitations, Study Population, Demographic characteristics, rationale for study design

# Studied Medical Product

# Inclusion/Exclusion Criteria

Inclusion Criteria:

Exclusion Criteria:

# Study endpoints

# Randomization & Stratification (if applicable)

# Number of expected patients

# Variables

# Statistical Plan/methods

Analysis Population

Including number of sites

# Special protocol consideration (if applicable)

# IMP, non – IMP, Comparators (if applicable)

# Dose and route of administration (if applicable)

# Safety reporting

(An SDEA must be created for details of safety reporting in the study)

# Data Sources

# Plan for Monitoring

# Milestones for study

**Study period:**

|  |  |
| --- | --- |
| **Milestone** | **Planned Date** |
| Start date of study |  |
| End of study |  |
| Publication submission |  |

# Plan for Publication

# Submission to Authorities

# References

# Appendix