|  |  |
| --- | --- |
| **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\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Table of content:

[1. Rationale and Background 3](#_Toc522111258)

[2. Reseach Question and Objectives 3](#_Toc522111259)

[3. Study Design 3](#_Toc522111260)

[4. Studied Medical Product 3](#_Toc522111261)

[5. Inclusion/Exclusion Criteria 3](#_Toc522111262)

[6. Study endpoints 3](#_Toc522111263)

[7. Randomization & Stratification (if applicable) 3](#_Toc522111264)

[8. Number of expected patients 3](#_Toc522111265)

[9. Variables 3](#_Toc522111266)

[10. Statistical Plan/methods 3](#_Toc522111267)

[11. Special protocol consideration (if applicable) 3](#_Toc522111268)

[12. IMP, non – IMP, Comparators (if applicable) 3](#_Toc522111269)

[13. Dose and route of administration (if applicable) 3](#_Toc522111270)

[14. Safety reporting 3](#_Toc522111271)

[15. Data Sources 4](#_Toc522111272)

[16. Plan for Monitoring 4](#_Toc522111273)

[17. Milestones for study 4](#_Toc522111274)

[18. Plan for Publication 4](#_Toc522111275)

[19. Submission to Authorities 4](#_Toc522111276)

[References 4](#_Toc522111277)

[Appendix 4](#_Toc522111278)

1. Rationale and Background
2. Reseach Question and Objectives
3. Study Design

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

1. Studied Medical Product
2. Inclusion/Exclusion Criteria

 Inclusion Criteria:

 Exclusion Criteria:

1. Study endpoints
2. Randomization & Stratification (if applicable)
3. Number of expected patients
4. Variables
5. Statistical Plan/methods

 Analysis Population

 Including number of sites

1. Special protocol consideration (if applicable)
2. IMP, non – IMP, Comparators (if applicable)
3. Dose and route of administration (if applicable)
4. Safety reporting

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

1. Data Sources
2. Plan for Monitoring
3. Milestones for study

**Study period:**

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

1. Plan for Publication
2. Submission to Authorities

References

Appendix