Cover sheet

- Title of the investigation
- Test center address
- Responsible testing physician
- Curriculum vitae

1 Summary/synopsis

2 Scientifically relevant background information for the study

3 Objective

- Primary and secondary study objective

4 Patient group

- Presentation of the patient data relevant to the study
- Inclusion criteria
- Exclusion criteria
- Procedure in the event of a premature termination

5 Study structure and methodology

- Multi-center, randomized, open, controlled, etc.
- Study duration (study flow chart)
- Treatment description (comparison and control group)
- Number of visits
- Primary and secondary parameters of the clinical results (outcome)
- Investigative methods
- Technology/measurement technology used

4 Biometrics and statistical analysis of the data

5 Bibliography and list of sources

6 Appendix

- Ethics committee approval
- Patient information
- Patient insurance
- Declaration of consent
- References

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¹ in line with ICH guidelines (Guidelines for Good Clinical Practice; www.ich.org)
² in accordance with the 2013 Helsinki Declaration