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 (if applicable) 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\(^1\)

- 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 (optional)

5 Bibliography and list of sources

6 Appendix (if available)

- Ethics committee approval\(^2\)
- 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