

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 methodology¹
 - 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 approval²
 - Patient information
 - Patient insurance
 - Declaration of consent
 - References

¹ in line with ICH guidelines (*Guidelines for Good Clinical Practice; www.ich.org*)

² in accordance with the 2013 Helsinki Declaration