CONTENTS OF THE CLINICAL STUDY REPORT

The clinical study report should contain the following sections:

1. **Title page**

The title page should contain the following information:

- study title
- name of test drug/investigational product
- indication studied
- if not apparent from the title, a brief (1 to 2 sentences) description giving design (parallel, cross-over, blinding, randomised) comparison (placebo, active, dose/response), duration, dose, and patient population
- name of the sponsor
- protocol identification (code or number)
- development phase of study
- study initiation date (first patient enrolled, or any other verifiable definition)
- date of early study termination, if any
- study completion date (last patient completed)
- name and affiliation of principal or coordinating investigator(s) or sponsor's responsible medical officer
- name of company/sponsor signatory (the person responsible for the study report within the company/sponsor. The name, telephone number and fax number of the company/sponsor contact persons for questions arising during review of the study report should be indicated on this page or in the letter of application.)
- statement indicating whether the study was performed in compliance with Good Clinical Practices (GCP), including the archiving of essential documents
- date of the report (identify any earlier reports from the same study by title and date).

2. **Synopsis**
3. **Table of contents for the individual clinical study report**
4. **List of abbreviations and definition of terms**
5. **Ethics**
6. **Investigators and study administrative structure**
7. **Introduction**
8. **Study objectives**
9. **Investigational plan**
10. **Study patients**
11. **Efficacy evaluation**

12. Safety evaluation

13. Discussion and overall conclusions

14. Tables, figures and graphs referred to but not included in the text

15. Reference list

16. Appendices

The detailed content of this Instruction must be harmonised with ICH Guideline on Structure and Content of Clinical Study Reports E3, available at ICH web page that can be accessed from here.