Appendix 3. Index and expected content of a Roche clinical study report.

**FINAL STUDY REPORT MODULES**

*This report consists of 5 modules*
*Those not supplied in this submission are obtainable from the sponsor on request*

**MODULE I: CORE REPORT AND STUDY PUBLICATIONS**
- Introduction
- Rationale
- Objectives
- Methodology
- Efficacy Results
- Safety Results
- Discussion / Conclusions
- Appendices

**MODULE II: PRESTUDY DOCUMENTS AND STUDY METHODOLOGY**
- Protocol and Amendment History
- Blank CRF
- Subject Information Sheet
- Glossary of Original and Preferred Terms
- Randomization List
- Reporting Analysis Plan (RAP)
- Certificates of Analysis
- List of Investigators
- List of Responsible Ethics Committees

**MODULE III: INDIVIDUAL SUBJECT LISTINGS OF DEMOGRAPHIC AND EFFICACY DATA**
- Demographic Data Listings
- Previous and Concomitant Diseases
- Previous and Concomitant Medications
- Efficacy Listings

**MODULE IV: INDIVIDUAL SUBJECT LISTINGS OF SAFETY DATA**
- Laboratory Parameters
- Vital Signs Data

**MODULE V: STATISTICAL REPORT**