

FINAL STUDY REPORT MODULES

This report consists of 5 modules

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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 Patient 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 PATIENT LISTINGS OF DEMOGRAPHIC AND EFFICACY DATA Demographic Data Listings Previous and Concomitant Diseases Previous and Concomitant Medications Efficacy Listings
MODULE IV:	INDIVIDUAL PATIENT LISTINGS OF SAFETY DATA Laboratory Parameters Vital Signs Data
MODULE V:	STATISTICAL REPORT

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