

MTN 004 Study-Specific Procedures Manual (SSP)

Table of Contents

INTRODUCTION.....	1
PROTOCOL.....	2
DOCUMENT REQUIREMENTS.....	3
PARTICIPANT ACCRUAL.....	4
INFORMED CONSENT.....	5
PARTICIPANT FOLLOW-UP.....	6
VISIT CHECKLISTS.....	7
PARTICIPANT RETENTION.....	8
STUDY GEL CONSIDERATIONS FOR NON-PHARMACY STAFF.....	9
CLINICAL CONSIDERATIONS.....	10
ADVERSE EVENT REPORTING AND SAFETY MONITORING.....	11
LABORATORY CONSIDERATIONS.....	12
BEHAVIORAL MEASURES.....	13
DATA COLLECTION.....	14
DATA COMMUNIQUES.....	15
STUDY REPORTING PLAN.....	16