

Outline of the MTN 004 Safety Reports

Table #	Table Title	Description	Type of Report	Recipients	When available
Table 1	Cumulative Adverse Event Listing	Listing of new/updated AEs with MedDRA preferred terms and AE verbatim text, as well as SAE and EAE flags. Other variables displayed include severity, relationship to study product, onset date, outcome date, duration of event, and treatment received for the AE. Modified AEs include those AEs whose MedDRA preferred term, onset date, severity, or relationship to study product have changed since the previous report	Individual Line Listing by PTID	All of PSRT	A week prior to the PSRT call
Table 2	Summary of Adverse Event Coding Progress	Tabulation of AEs awaiting MedDRA Coding by SCHARP Clinical Affairs staff. Subsumed records are AE CRF pages that have been marked for deletion by the study site. Subsumed AE CRF pages are excluded from analysis but retained in the study database. The subsumed category is included in this table in order to provide a full accounting of all AE CRF records received at the SDMC.	Tabulation	All of PSRT	A week prior to the PSRT call
Table 3	Pregnancy Report	This table displays a summary of the participants that have become pregnant on study. The table displays the number of participants currently enrolled, and the number of participants who became pregnant on study. It separates pregnancies into two groups: those pending outcomes and those with outcomes (resolved pregnancies).	Individual Line Listing by PTID	All of PSRT	A week prior to the PSRT call
Table 4	AE by Body System/MedDRA Preferred Term and Severity	Cumulative summary of all AEs reported to SCHARP– sorted by Body System/MedDRA preferred term and Severity.	Numeric summary	All of PSRT	A week prior to the PSRT call
Table 5	AE by Body System/MedDRA Preferred Term and Relationship to Study Product	Cumulative summary of all AEs reported to SCHARP – sorted by Body System/MedDRA term and Relationship to Study Product.	Numeric summary	All of PSRT	A week prior to the PSRT call

MTN 004 PSRT call is scheduled bi-monthly on the first and third Mondays at 10:00 Pacific Time. The PSRT reports will be posted to ATLAS on the Thursdays prior to the PSRT call.