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## MTN-008 Data Communiqué #6

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8 February 2012

This is official study documentation for MTN-008. Please circulate it among relevant staff for their review, print it, and place it in your MTN-008 SSP Manual in the Data Communiqués section.

This document is considered part of the MTN-008 SSP manual.

### UPDATES

None.

### CLARIFICATIONS

#### 1. Adverse Experience reporting regarding Rupture of Membranes (ROM)

With regard to AE reporting and rupture of membranes, please note that while both “preterm premature rupture of membranes (prior to onset of labor)” and “term premature rupture of membranes (prior to onset of labor)” are considered specific pregnancy complications, only preterm premature ROM is considered an adverse event. The AE text for these should be recorded on the AE Log form as “preterm rupture of membranes,” and graded using the “preterm rupture of membranes” row on the DAIDS Female Genital Grading Table for Use in Microbicide Studies (Addendum 1). Do not complete an AE Log form for “term premature rupture of membranes.”

### REMINDERS

None.