

Attn: MTN Network, Peter Anton, and DAIDS Staff

From: Scott Proestel, M.D.
Director
DAIDS, Office for Policy in Clinical Research Operations (OPCRO)

Date: May 18, 2012

Re: "Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (Version 1.0 - December 2004 (Clarification dated August 2009), Addendum 3 - Rectal Grading Table for Use in Microbicide Studies (Clarification dated May 2012)"

The rectal grading table was initiated by a group of researchers who developed and used it. They subsequently discovered items that needed revision through use in several protocols. The revisions have been approved by DAIDS. A summary of the changes include the following and have been incorporated directly into the body of the rectal grading table for convenience.

Revisions were made to make the severity more standardized throughout the table (lesions, condyloma, incontinence and diarrhea specifically). The language regarding impairment of daily activities was standardized throughout the table. Missing "equals to" was added to "lesser than" and "greater than" signs throughout the table. Nausea and vomiting were removed as they were completely redundant with the main DAIDS grading table. Proctitis and proctalgia fugax were removed and were replaced by a revised proctalgia scale. Painful defecation was added.

Please be advised that there is no change in version number for the rectal grading table. Therefore, while this clarification to the rectal grading table may be used for protocols in development, there is no requirement to change any references to the same table in approved protocols.

The clarified Table is attached to this message and is now posted on the RSC web page (<http://rsc.tech-res.com/safetyandpharmacovigilance/gradingtables.aspx>).