



BMT CTN PROTOCOL #0401

A Phase III Rituxan/BEAM vs. Bexxar/BEAM with Autologous Hematopoietic Stem Cell Transplantation (ASCT) for Persistent or Relapsed Chemotherapy Sensitive Diffuse Large B-Cell Non-Hodgkin's Lymphoma

Deletions are noted in strike-out text and additions are noted in italicized text.

Minor Changes/Clarifications to Version 7.0 of the Protocol

- §4.2.2 *Adverse Event reporting*

Revised to read (new text highlighted in *italics*): Unexpected, grade 3-5 adverse events (AE) will be reported through an expedited AE reporting system via AdvantageEDC. Unexpected, grade 4-5 AEs must be reported within 24 hours of knowledge of the event. Unexpected, grade 3 AEs must be reported within three business days of knowledge of the event. *Unexpected, grade 3-5 AEs will be reported using NCI's Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0.* Expected AEs will be reported using NCI's Common Terminology Criteria for Adverse Events (CTCAE) Version 3.0 at regular intervals as defined on the Form Submission Schedule.