Hemacord AE Monitoring Agreement, November 8, 2011 - Hemacord

In addition, you have agreed to do the following:

1. Implement a safety outcomes monitoring and analysis plan. This plan will include a) maintenance of an observational database to include, for all hematopoietic progenitor cell, cord blood units released, information including but not limited to, time to neutrophil recovery, graft failure, survival, cause of death, infusion reactions, and other adverse experiences, and b) aggregate analyses of interval and cumulative adverse experience reports, and c) safety outcomes analyses of interval and cumulative data that address early mortality, graft failure-related mortality, graft failure, time to neutrophil recovery, infusion-related events, and other adverse experiences. Reports will include a description of the population analyzed, results of the analyses, whether outcomes indicators were triggered and, if so, what actions were implemented as a result.

2. Submit a 15-day “alert report” for each serious infusion reaction associated with administration of hematopoietic progenitor cells, cord blood.