**What is Adverse Reaction?**

"Adverse reactions" are any medical problems or "adverse events" that are determined by the study physician to be likely to be caused by the drugs or treatments used in the study.

**Which types of adverse events?**

AEs are reported according to system organ categories and preferred terms using MedDRA version 14.0 and are classified according to severity, severity, and causal relationship with the study drug. See MedDRA version 14.0 for details.