

***MedDRA Term Selection: Points to Consider Release 3.2***  
**10 November 2003**

**Summary of Major Changes from Release 3.1**

The summary below indicates the main areas changed in release 3.2 compared to release 3.1. However, the user is advised to carefully read the whole document.

- **Changes applied throughout the document**
  - MedDRA version 6.1 is used for all specific examples of MedDRA terms.
  - Wording throughout the document was reviewed for consistency with guidelines for documents posted to the FDA website and changes were made where applicable.
  
- **Changes to Specific Term Selection Points**
  - **Section 3.2** - Death and Other Patient Outcomes. This section was expanded to cover outcomes other than death.
  - **Section 3.4** - Combination Terms. Additional section 3.4.5 was added for a combination of an event and an unchanged pre-existing condition
  - **Section 3.6** - Location vs Infectious agent. Examples given were changed to be more consistent
  - **Section 3.11** - Medication/administration errors and accidental exposures. A subsection was added for medication errors resulting in clinical consequences