

MedDRA Literature Commentary

Subject of commentary:

Hansen, RA, Gartlehner, G, Powell, GE, and Sandler, RS. Serious adverse events with infliximab: analysis of spontaneously reported adverse events. *Clinical Gastroenterology and Hepatology* 2007; 5: 729 - 735

Commentary:

This article describes use of signal detection approaches for adverse event reports from the FDA's spontaneous report database (AERS). The product studied was infliximab, and the study confirmed previous established safety signals for this product, including lymphoma, neuropathy, and granulomatous infections.

The aspect of interest to MedDRA users is the approach the authors used to generate safety signals. Because they were exploring already known issues, they initially "mapped" MedDRA terms into several categories to reflect their areas of interest. For example, into their category of "lymphoma", they grouped together multiple MedDRA Preferred Terms, such as PT *B-cell lymphoma*, PT *B-cell lymphoma stage II*, etc. (NOTE: The MedDRA Version used was not described). Once this step had been done, they then applied disproportionality analysis to assess associations between infliximab and the events of interest.

Standardised MedDRA Queries (SMQs) were not mentioned by the authors as part of their methodology. SMQs are groupings of terms from one or more System Organ Classes (SOCs) that relate to a defined medical condition or area of interest. Currently, there are 37 SMQs available to MedDRA users, including SMQs for cardiac failure and (peripheral) neuropathy, which are two of the infliximab issues examined by the authors. It is possible that, during the time frame of this study, certain SMQs were not yet available, but it would be interesting to know how corresponding SMQs for their issues of interest may have performed in their methodology.

From the MSSO's perspective, this study is important for two reasons: first, it explores how signal generation approaches could be applied to MedDRA-coded data; and second, it may serve as a model of applying SMQs for signal generation purposes. This is especially interesting because the EU's "Volume 9A of The Rules Governing Medicinal Products in the European Union" specifically recommends the use of SMQs for signal detection.

The MSSO is pleased to see research on how MedDRA is used for safety data analysis, and we continue to encourage further study and publications in this important area.

Summary:

This article describes use of signal detection approaches for adverse event reports for infliximab from the FDA's spontaneous report database (AERS). The approach of grouping MedDRA Preferred Terms into categories of interest is similar to how SMQs are designed. The approach may serve as a model for research into SMQs and signal detection.