

**United States Department of Agriculture
Center for Veterinary Biologics**

Standard Operating Procedure

Guidelines for Coding Adverse Event Reports

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Guidelines for Coding Adverse Event Reports

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Guidelines for Coding Adverse Event Reports

1. Purpose and Scope

This Standard Operating Procedure (SOP) provides a basis for a uniform approach to the assignment of VedDRA terms and causality assessment to adverse event reports (AERs) received by the Center for Veterinary Biologics (CVB).

2. Definitions

VedDRA: Veterinary Dictionary for Drug Regulatory Activities. A coding scheme adopted by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and applied to adverse event information that converts free text into standardized medical terminology

3. Responsibilities

AERs are coded for VedDRA terms and causality by the Biologics Epidemiologist(s).

4. The VedDRA Coding Process

When performing data entry of adverse event information, use an autoencoder to assign VedDRA's Lowest Level Term. The intent is to capture the specificity of information on the source document.

There is an automatic assignment of the Preferred Term, High Level Term, and High Level Group Term and location in primary System Organ Class

If there is not an exact match to the Lowest Level Term then conduct a search for words or parts of words in VedDRA, which are similar to the verbatim term. Another solution is to search likely locations in the terminology, based on suitable High Level Terms or High Level Group Terms.

5. Causality Assessment Coding Process

Six main factors should be taken into account: associative connection, immunological explanation, clinical or pathological phenomena, previous knowledge, other causes, and reliability of data. In regards to causality assessment, no distinction should be made between products administered in accordance with label recommendations and those used off-label. A system for assessment (e.g. ABON system) is recognized as a useful tool to help achieve consistency but should not serve as a replacement for experienced expert judgment.

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Four categories indicating the assessment of the likelihood of this association can be made.

5.1 Probable

For inclusion in the category 'probable', all of the following minimum criteria should be met:

- There should be a reasonable association in time between the administration of the VMP and onset and duration of the reported AE.
- The description of the clinical phenomena should be consistent with, or at least plausible, given the known pharmacology and toxicology of the VMP.
- There should be no other equally plausible explanations for the AE.

When any of the above criteria cannot be satisfied (due to lack of sufficient information or conflicting data) then the association cannot be assessed as 'probable'.

5.2 Possible

For inclusion in the category 'possible', association of the AE with administration of the primarily suspect VMP(s) is one of other possible and equally plausible explanations for the described event.

5.3 Unlikely

Where sufficient information exists to establish that the described event was not likely to have been associated with administration of the VMP(s), or other more plausible explanations exist, the assessment should be categorized as 'unlikely'.

5.4 Unknown

All events where reliable data is either unavailable or is insufficient to make an assessment should be categorized as 'unknown'.