Pharmacovigilance Expert Working Group

Chairperson: Linda Walter-Grimm (US FDA)

Introduction

The Pharmacovigilance Expert Working Group (formerly the Electronic Standards Implementation Expert Working Group) developed the five existing VICH pharmacovigilance guidelines. The working group is responsible for the revision and maintenance of those guidelines, including the technical requirements that support harmonized electronic submission and receipt of veterinary adverse event reports through standardized messages, field lengths, data types, cardinalities and vocabularies.

Pharmacovigilance Guidelines adopted

GL24 Management of Adverse Event Reports

GL29 Management of Periodic Summary Update Reports (PSURs)

GL42 Data Elements for Submission of Adverse Events – revised March 2023)

GL35 Electronic Standards for Transfer of Data (revised March 2023)

GL30 Controlled Lists of Terms (updated July 2023)

Status of implementation

Not all guidelines are currently implemented in all regions but are adopted as regulatory regions develop capacity. The technical PV guidelines (GL42, GL35) have recently been revised and GL30 now includes expanded and updated vocabularies.

Key benefits of the harmonized guidelines

It is important for all global stakeholders to develop harmonized pharmacovigilance systems, including common definitions and standardized terminology. Harmonization of electronic reporting requirements for adverse events enhances data quality, facilitates rapid exchange of important safety information between marketing authorization holders and regulatory authorities, reduces reporting burden, and protects veterinary patients and consumers from potential harm by facilitating rapid identification of potential safety issues related to drug use which in turn leads to better risk management and more informed, safer therapeutic choices.

New topics

The VICH Pharmacovigilance Expert Working Group continues to ensure that the implementation and maintenance of five pharmacovigilance guidelines will be run smoothly and that the defined lists and dictionaries are maintained. The group is also drafting a discussion paper to reflect on signal detection and management models currently in use by pharmacovigilance systems in several regulatory regions.

EWG Composition

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