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GVP module V, GVP module XVI, and GVP module XVI addendums

At the end of a clinical trial, we may know about the drug's efficacy, but unfortunately, we know very little related to the drug's safety profile. Inclusion/exclusion criteria restrict the patient population to limited clinical trial participants. Also, many drugs have a long latency; drugs may develop their safety profile after a very long duration. Nevertheless, the benefit-risk balance of a particular medicinal product must always remain positive.

RMP is a detailed description of the risk management system of a drug. The RMP is prepared whenever there is a significant change to the benefit-risk balance of a drug or at the time of approval of a new drug. RMP identifies, characterizes, and minimises a medicinal product's risk. It includes only important identified and potential risks and missing information. RMP includes three major sections; safety specification, pharmacovigilance plan, and risk minimization measures. Good Pharmacovigilance Practices (GVP module V) entail RMP and must be read along with GVP module XVI- Risk minimisation measures and GVP module XVI addendum I- educational materials. Addendum I provide further guidance to the health care authorities and the national competent authorities to support the assessment of educational materials about format and content. GVP module XVI addendum II- Risk minimisation measures: selection of tools and effectiveness indicators, provide additional guidance to marketing authorisation holders and competent authorities on data sources and methodologies for monitoring outcomes of risk minimisation measures. GVP module XVI addendum III- Risk minimisation measures: pregnancy prevention programme and other pregnancy-specific risk minimisation measures aim to minimise exposure to a medicinal product during pregnancy. GVP module V and GVP module XVI and its various addendums provide a complete profile of the risk management system for all safety concerns. Both: GVP module XVI addendum II and III are still drafts for public consultation.

Biography

Joan D'souza is a freelance pharmacovigilance and medical writer also; she currently works as a Regulatory Intelligence Expert and Item Writer at the Institute of Pharmacovigilance. She is the Chair of Switzerland and Austria International Society of Pharmacovigilance (ISoP) chapters. She is also very active at different Special Interest Groups (SIGs) at ISoP such as the Risk communication, Geriatric, Medical Devices, and Ecopharmacovigilance SIGs. She is also active at the European Medical Writers Association (EMWA) Pharmacovigilance and the Medical Devices SIGs.

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