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Global approach to good pharmacovigilance and risk management

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Since its beginning, pharmacovigilance (PV) has undergone continuous transformation. Policy, legislation, and guidelines have continued to evolve over time to better ensure patient safety and improve monitoring of the safety of medicinal products. Since 2012, the European Medicines Agency (EMA) committed to continuously improve their guidance based on stakeholder experience. In 2013, the EMA released draft guidance on risk management systems for public consultation in February 2016. The guidance was further developed with feedback from a wide variety of stakeholders including marketing authorisation holders, industry associations, national healthcare system representatives, and individual citizens, among many others.This GVP guidance has a significant impact on how pharmacovigilance and risk management is conducted around the world. Recently, the EMA has published significant changes to European Union's PV guideline on risk management plans (GVP Module V). These updates aim to further clarify the activities on which a PV described in a risk management plan should focus to ensure optimal health promotion and protection based on a risk-proportionate planning of activities that directs resources to areas where the need for additional information and risk minimisation is greatest.The main topics presented include the definition and life cycle of safety concerns (important identified risk, important potential risk, and missing information) as well as removal of duplication within a RMP, and alignment with other regulatory documents.

Biography

Danny S Gonzalez is currently a Pharmacovigilance Process Leader at Genentech. He contributes to the development of innovative, global risk management strategies across the Roche/Genentech portfolio. Prior to joining Genentech, he was working with the Food and Drug Administration's (FDA) Office of Regulatory Policy where he consulted on the implementation of FDA risk management policies for both pre-approved and post-marketed products. Before this experience, he worked with the FDA's Division of Risk Management where he was responsible for developing risk management programs, assessing modifications to risk minimization strategies, reviewing proposals for single shared system risk evaluation and mitigation strategies (REMS), and designing research to examine current risk management practices. He began his career as a Safety Scientist in Sanofi's Global Pharmacovigilance and Epidemiology team where he contributed to the development of global risk management plans, assessed potential safety signals, and contributed to risk management research. He is originally from Miami, Florida and received his master's degree in Biomedical Engineering from Florida International University and a Doctor of Pharmacy degree from the University of Florida.

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