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SECTION

I

Risk Management Regulations

1 Risk Management Regulations in the US

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Introduction

The role of risk management in the drug development and postmarket environment is to optimize user benefits while minimizing risk and maintaining appropriate access. Managing risk involves many diverse individuals, including scientists, regulators, policymakers, physicians, healthcare providers, and patients. In early development, nonclinical study data are used to initiate the development of a human testing safety profile. During Phase 1 development, risks are managed at the individual patient level through careful monitoring and observation. As the drug progresses further into Phase 2 and 3 clinical trials, safety data are aggregated to assess risk at a population level. Following approval, the population exposed to the drug becomes more diverse, expanding the breadth and complexity of data and information on the drug's benefits and risks.

The science and process of risk management have evolved over time. This evolution is reflected in the activities conducted as well as the governing regulations and guidelines. Risk management is becoming increasingly complex, with the globalization of requirements, increased availability of potential data sources through advanced technology, digitization, and changes to the healthcare delivery system. The complexity and nature of clinical development and postmarket experience require a proactive, systematic, and scientific approach to measuring or assessing risk and developing strategies to manage or mitigate it.

Risk Management Concepts

Pharmacovigilance Overview

Pharmacovigilance (PV) refers to scientific activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.[1] One PV objective is to maintain a current safety profile, which includes information regarding the drug's known and potential risks in the context of its efficacy information, forming the benefit-risk profile under which the product is used. When discussing risk, it is important to differentiate between harm (the damage resulting from taking the drug) and risk (the probability that harm could result from taking the drug).

Safety information is collected to monitor and maintain biopharmaceutical products' safety profile. In the US and many other countries,