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Managing challenges and complexities in pharmacovigilance in oncology trials

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Oncology studies are required to be very intensively monitored than studies from many of the other therapeutic areas, because of the nature and severity of the disease and the complexity and potential toxicity of the treatment or the use of newer approaches such as biologics and personalized medicine. In oncology trials unlike the clinical trials in many of the other therapeutic areas, a higher number of subjects are likely to develop serious adverse events and these cases are often complex. The evaluation of drug event relationship and distinguishing from underlying disease and concomitant therapies can be very challenging. Many oncology trials are conducted in high mortality diseases and at times have efficacy endpoints that could also be reportable adverse reactions. The breaking of the blind for such cases as required for expedited reporting to regulatory authorities could compromise the integrity of the clinical trial. In such scenarios, it is advisable to reach agreement with regulatory authorities in advance concerning serious adverse events (SAEs) that would be considered disease related and not subject to systematic unblinding and expedited reporting. Making sure patient compliance with the necessities of a clinical study is quintessential to the success of a study meeting its intended objectives. Therefore, it is imperative to have experienced medical oversight throughout the design, implementation and reporting throughout all phases of a clinical development program. Safety monitors provide tactical drug development guidance as well as review key study documents and safety information and act as the prime medical resource to support the investigators and sites involved in the clinical trials. This session will describe the importance of safety in oncology trials, and how a rigorous and thorough monitoring can lead to the smooth conduct of oncology clinical trials.

Biography

Mugdha Chopra is a dentist by qualification and has over 14 years of experience in the field of dentistry, and pharmacovigilance. She is associate vice president for US PV and clinical safety at APCER and oversees the delivery and operations from India which includes but not limited to case processing aggregate reporting, literature monitoring and signal detection. Before joining APCER, she was with Ranbaxy as a manager in the Department of Medical Affairs and pharmacovigilance. She comes with an extensive experience in various safety databases like Argus Safety and ARISg for case processing, reporting, and product/license management and has also met the challenges of business continuity planning and data restoration..

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