PHARMACOVIGILANCE

How adverse events are detected, assessed, and understood throughout a product's life cycle[1]

Overview of safety in **clinical trials** … * VS … **the real-world setting**

Trial participants are selected according to **pre-specified eligibility criteria**[2,3]

In randomized controlled trials (RCTs), incidence of adverse events (AEs) with a product is **compared with a control** (eg, placebo)[4-6]

In clinical trials, all **AEs are reported for the study duration** (including controlled and open-label phases) **regardless of causality**[2,3,5,6-8]

A **larger and more heterogenous patient population** use the approved/marketed product in the real-world setting (eg, patients with more complex comorbidities)[9,10]

Establishing whether a causal relationship exists between real-world AEs and the drug **is challenging because:**

- There may be **unidentified or unaccounted for confounding factors**[10]
- The incidence of real-world AEs includes **background rates of the affected population**[10]

In the post-marketing setting, **the manufacturer must communicate all AEs** that are reported to them to regulatory agencies **regardless of causality**[11]

AEs are **communicated to regulatory agencies** according to specified timelines[11,12]

*Refers specifically to manufacturer/company-sponsored clinical trials.[5,7]

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See reverse for information on safety signal detection, evaluation, and management ❯