Adverse Event

What Is an Adverse Event (AE)?

An Adverse Event is any untoward medical occurrence during a study—this could be symptoms, signs, or disease—regardless of causal relationship to the study drug or intervention. Salesforce's Life Sciences Cloud supports tracking these via objects like Adverse Event Entry, Outcome, Cause, Contributing Factor, Action, Party, etc., enabling rich documentation and reporting.

Example Scenario: AE in Clinical Trial Monitoring

Context

Your organization runs a clinical trial for a new rheumatoid arthritis (RA) medication. You've built a study management system using Salesforce Life Sciences Cloud.

Scenario Steps

1. **Patient Enrollment & Baseline Recording**
    a. Their baseline medical conditions (e.g., mild hypertension) are recorded in their **Patient Account.**
2. **Symptoms During the Trial**
    a. A few weeks into treatment, the patient reports heart palpitations, prompting an unscheduled clinic visit.
3. **Documenting an AE in Salesforce**
    a. Adverse Event Entry is created for "heart palpitations."
    b. The Adverse Event Outcome might be "resolved with no sequelae."
    c. The Adverse Event Cause might be marked as "investigational product—possible relation," or "unknown."
    d. The contributing factor could note "intake of new over-the-counter antihistamine," if relevant.
    e. Adverse Event Action could record whether treatment was paused, dosage adjusted, or follow-up scheduled**.**
4. **Investigator Review & Severity**
    a. The clinical investigator determines whether this constitutes a Serious Adverse Event (SAE)—for example, if hospitalization or life-threatening risk occurred. If deemed serious, regulatory teams are notified promptly; otherwise, the event is documented in aggregate safety reports

5. **Sponsors and Safety Monitoring**
    a. Using dashboards and reports, safety monitors or the sponsor review the AE alongside others to detect trends. If multiple participants report similar palpitations, the study team might investigate, adjust monitoring protocols, or modify the informed consent documentation.

Why This Matters

- **Safety & Compliance**: Capturing AEs—even minor ones—is critical. Regulatory guidelines require documentation for both serious and non-serious AEs, though timelines for reporting differ.

- **Risk Identification**: Documenting all AEs allows sponsors and researchers to identify patterns that may reveal safety signals or emerging risks.

- **Data Traceability**: Salesforce's Life Sciences data model allows full traceability—from patient to event, outcome, cause, and actions—ideal for audit readiness and pharmacovigilance.

Real-World Perspective: Capturing Everything Matters

A researcher on a clinical trial subreddit shared:

"If you enroll ten patients, and one bumps their head, it may seem insignificant. But if one in ten patients, at 100 sites globally, report bumping their heads on things, this could represent a new, drug-related problem that impacts the safety and well-being of everyone on the drug."

In other words: what appears trivial at the site level may reveal a broader safety concern when aggregated in a system like Salesforce—making comprehensive AE capture essential.

Quick Reference Table

Element	Salesforce Entity	Role in AE Tracking
Adverse Event Entry	Adverse Event Entry	Records initial details (type, timing, description)
Outcome	Adverse Event Outcome	Captures resolution or impact
Cause	Adverse Event Cause	Potential attribution (e.g., drug-related, unknown)
Contributing Factor	Adverse Event Contributing Factor	Contextual factors impacting the AE
Action	Adverse Event Action	Responses like dosage changes, referrals
AE Party	Adverse Event Party	involved parties (patient, investigator, etc.)