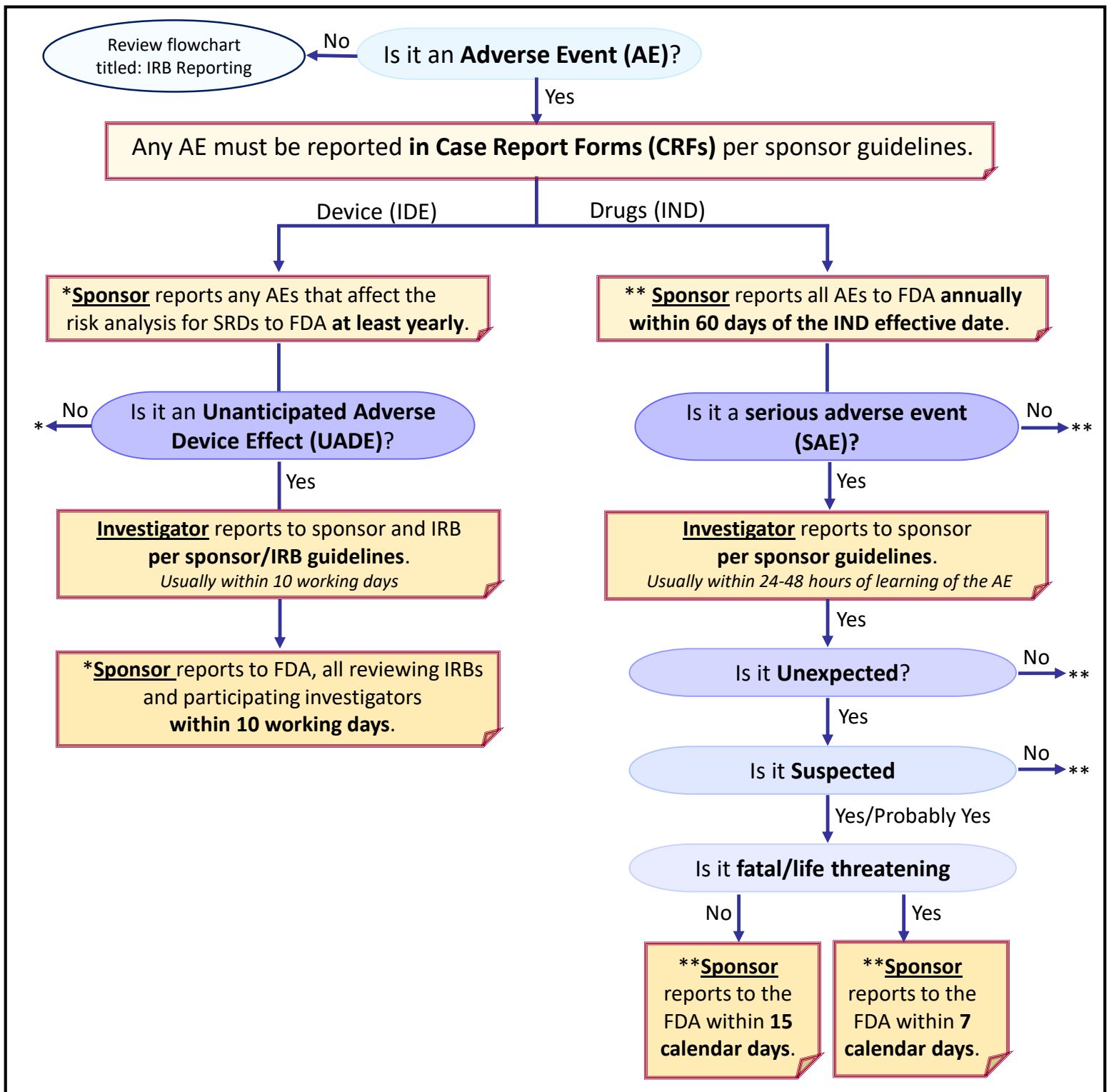


# Adverse Event (AE) Reporting



**AE: Adverse Event:** Any untoward medical occurrence associated with the use of a medical product in humans, whether or not considered medical product. All AE should be reported on CRFs (case report forms) per sponsor guidelines.  
21 CFR 312.32 & 21 CFR 803.3

**SAE: Serious Adverse Event:** An adverse event that in the view of either the investigator or sponsor, results in one of these outcomes:  
21 CFR 312.32

- Death
- Life-threatening situation
- Hospitalization/prolonged hospitalization
- Disability
- Congenital anomaly/birth defect
- Other important medical event

**UADE: Unexpected Adverse Device Effect:** An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product).  
*Integrated Addendum to ICH E6(R2): Guideline for Good Clinical Practice*

# Adverse Event (AE) Reporting Definitions

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**Significant Risk Device (SRD):** an investigational device that:

- 1) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- 2) Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- 3) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- 4) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

*21 CFR 812.3*

**UADE: Unanticipated Adverse Device Effect:** Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

*21 CFR 812.3 & 21 CFR 812.150*

**SAR: Suspected Adverse Reaction:** Any adverse event for which there is a reasonable possibility that the drug caused the adverse event. For the purposes of IND safety reporting, "reasonable possibility" means there is evidence to suggest a causal relationship between the drug and the adverse event.

*21CFR312.32*

**SUSAR: Suspected Unexpected Serious Adverse Reaction**

Reporting: Not fatal or life-threatening, sponsor must report to FDA within 15 calendar days. *21CFR312.32*

Reporting: Fatal or life-threatening, sponsor must report to FDA within 7 calendar days. *21CFR312.32*

**Unexpected:** Any research event occurring in one or more participants or others involved in a research protocol, the nature, severity, or frequency of which is not consistent with either: the known or foreseeable risk of research events associated with the procedures involved in the research that are described in

- a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and
- b) other relevant sources of information, such as product labeling and package inserts; or the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

*HHS Unanticipated Problems Involving Risks & Adverse Events Guidance (2007)*

**Related:** Any research event related or possibly related (there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research) to participation or role in the research.

*HHS Unanticipated Problems Involving Risks & Adverse Events Guidance (2007)*

**Unanticipated Problem (UP):** Any incident, experience, or outcome that meets all of the following criteria: unexpected, related, and greater risk. UPs from external sites must also be reported to by internal site investigator to internal site IRB promptly.

There may be additional safety reporting requirements for sponsors who hold INDs to report to the FDA within 15 calendar days.

These may include

- 1) an aggregate analysis of specific events observed in a clinical trial (such as known consequences of the underlying disease or condition under investigation or other events that commonly occur in the study population independent of drug therapy) that indicates those events occur more frequently in the drug treatment group than in a concurrent or historical control group,
- 2) findings from other studies,
- 3) findings from animal or in vitro testing, or
- 4) increased rate of occurrence of serious suspected adverse reactions.

*21 CFR 312.32*