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Definitions

Unanticipated Adverse Device Effect (UADE)

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\(s\)](#)

Serious

A UADE is serious if it led to:

- **Death**
- **Life-threatening situation** - participant was at substantial risk of dying at the time of the event, or use or continued use of the device might have resulted in the death of the patient
- **Hospitalization (initial or prolonged)** - admission to the hospital or prolongation of hospitalization. Emergency room visits that do not result in hospital admission should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage)
- **Disability or Permanent Damage** - substantial disruption of a person's ability to conduct normal life functions, i.e., resulted in a significant, persistent or permanent change, impairment, damage or disruption in body function/structure, physical activities and/or quality of life
- **Congenital Anomaly/Birth Defect** - suspect that exposure to the device prior to conception or during pregnancy may have resulted in an adverse outcome in the child
- **Required Intervention to Prevent Permanent Impairment or Damage** - medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, either situation suspected to be due to the use of the device.

(FDA Guidance: [What is a Serious Adverse Event?](#))

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Reporting requirements

UADEs must be reported by the clinical investigator to the sponsor and the reviewing IRB, as described below:

- to the sponsor and the reviewing IRB as soon as possible, but in no event later than 10 working days after the investigator first learns of the event. [21 CF 812.150 \(a\)\(1\)](#)
- ***Sponsors** must immediately conduct an evaluation of a UADE and must report the results of the evaluation to FDA, all reviewing IRBs, and participating investigators within 10 working days after the sponsor first receives notice of the effect. [21 CFR 812.46\(b\)](#); [21 CF 812.150 \(b\)\(1\)](#)
- A sponsor who determines that an unanticipated adverse device effect presents an unreasonable risk to subjects shall terminate all investigations or parts of investigations presenting that risk as soon as possible. Termination shall occur not later than 5 working days after the sponsor makes this determination and not later than 15 working days after the sponsor first received notice of the effect. [21 CFR 812.46\(b\)\(2\)](#)

The UADE reporting requirements apply to both [significant risk](#) and [nonsignificant risk](#) (NSR) studies.

***Sponsor-Investigators** assume the regulatory responsibilities of the research sponsor, including the reporting requirements to the FDA:

- **Investigator-held IDEs - Significant Risk Devices**
A sponsor-investigator for an IDE protocol must follow the FDA regulations in [21 CFR 812](#).
- **Nonsignificant Risk Device Studies when Investigator Acts as Sponsor**
Investigators conducting a nonsignificant risk device study, regulated by the abbreviated IDE regulations, have abbreviated sponsor responsibilities when there is no industry sponsor. [21 CFR 812.140\(b\)\(4\)](#)