A study is temporarily suspended based on sponsor decision.

A female participant exposed to study agent C due to her involvement in a phase I clinical trial gives birth to a child. Clinicians note a major cardiac defect at birth along with several clinically insignificant physical findings. The congenital anomaly is deemed not related to the study agent and is reported to DAIDS within 3 reporting days.

A participant involved in a two-arm comparison study of drug A versus drug B receives the wrong study agent. The participant is monitored for adverse effects and does not experience any.

The Data and Safety Monitoring Board (DSMB) for a phase II multi-center, randomized clinical trial convened for an annual review of accumulated safety and enrollment data. A summary report is written at the end of the meeting and provided to the investigator.

A participant involved in a phase II study reports the new onset of a migraine which lasted two days and caused the participant to remain bedridden and miss work.

A pediatric research protocol is amended to add allergy skin testing.

17 research sites are participating in a study comparing an investigational agent to standard therapy in subjects ages 18-25. Of those subjects receiving the investigational drug, an average of 35% of subjects across the 17 sites experience deep vein thrombosis.

The first implementation version of a trial protocol is distributed to your site.

Your site receives a clarification memo for a study that does not result in a change to the protocol informed consent document.

A participant involved in a double-blind study experiences a medical emergency. The investigator deems unblinding of the participant necessary, calls the site pharmacist to access unblinding codes, and identifies the investigational product assignment of the individual participant.