

A participant presents with Hodgkin's disease (HD) without predisposing risk factors for HD. Protocol-related documents and other relevant sources of information only refer to acute myelogenous leukemia as a potential adverse event.

A participant in a clinical trial dies because of a motor vehicle crash. The investigators conclude that the participant's death was unlikely to be related to the research interventions.

New protocol version 3.0 is released for a phase 2b study to evaluate the safety and efficacy of VRC01 in reducing HIV-1 acquisition.

A study is prematurely terminated based on sponsor decision.

A clinical research site located at a local HIV/AIDS clinic uses a text notification system for appointment reminders. Research staff send a text reminder to a participant regarding their upcoming visit at the clinic, however this participant did not previously consent to receiving text notifications. The participant is inadvertently outed when a work colleague sees the notification appear on their phone.

A new version of the Investigator Brochure for an enhanced anti-HIV-1 broadly neutralizing antibody becomes available through the electronic system for Investigator Brochure distribution.

A new study suggests an increased risk of birth defects in babies born to women taking dolutegravir at time of conception. The protocol study team for an in-progress phase III multicenter open label pharmacokinetic safety, tolerability, and antiviral activity of dolutegravir study in HIV-1 infected infants, children, and adolescents releases an amendment that includes protocol updates to ensure documented contraception use for female participants of childbearing potential.

A HIV/AIDS clinical trials network elects to reallocate enrollment slots among clinical research sites for Protocol X. Your site, originally approved to enroll 100 participants, is now granted 50 additional slots for a maximum of 150 participants.

A participant is hospitalized for
a grade 4 pancreatitis that is
unexpected and there is a
reasonable possibility that the
AE is related to participation in
the research.

A clinical research site receives
a call from the FDA/EMA to
schedule an inspection.