From: OC GCP Questions
To: [redacted]
Subject: GCP question
Date: Saturday, July 05, 2014 9:59:23 AM

Good morning --

Sorry for the delay in responding to your inquiry. I cannot specifically answer your question regarding the AE that you describe. FDA encourages investigators to report serious adverse events to the sponsor. As part of participating in a clinical trial, investigators agree to follow the protocol. The cut-off dates for adverse event reporting are described in the protocol and depend on a variety of factors, such as, pharmacokinetics of the test article, duration of use, potential for irreversible effects, etc. These dates may exceed the formal end of the study, especially for test articles with the potential for long-term effects. FDA's guidance, "Premarket Risk Assessment" (available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072002.pdf), discusses this issue:

G. Long-term Follow-up

In some cases, it is recommended that all subjects be followed to the end of the study or even after the formal end of the study (e.g., where the drug has a very long half-life, is deposited in an organ such as bone or brain, or has the potential for causing irreversible effects, such as cancer). The concern over adequate follow-up for ascertaining important safety events in such cases is particularly critical in long-term treatment and clinical outcome studies. In such cases, FDA recommends the follow-up for late safety events, even for subjects off therapy, include those subjects who drop out of the trial or who finish the study early due to meeting a primary outcome of interest. The duration of follow-up, however, would be dependent on the circumstances of the development and therefore should be discussed with the appropriate review division (e.g., during end-of-phase 2 meetings).

Following adverse events and their resolution is essential to developing the safety profile of the investigational product. Therefore the protocol and the sponsor should assist you in determining when an AE resolution date should be recorded and documented.

I hope this information was helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [Redacted]
Sent: Wednesday, July 02, 2014 9:05 PM
To: OC GCP Questions
Subject: GCP question

Hi there,

Our study team has a question regarding the resolution of an AE in a clinical trial. If the AE is an STD, what is the resolution date of the STD? Is it the date that the STD is treated? If its syphilis, is it the date of the first or third injection or is it when the rash goes away? Or does it stay open and ongoing as long as the RPR is positive?

Many thanks for any guidance you might provide.

Have a great July 4!

[Redacted]