From: OC GCP Questions
To: [redacted]
Subject: Sponsors reporting of pregnancies
Date: Monday, August 03, 2015 7:47:35 AM

Good morning --

This is what we have said in the past related to pregnancy and clinical trials.

Generally the collection of data related to the pregnancy is part of the clinical investigation would depend upon the specifics of the protocol. As is commonly the case, a complete response to your question is often dependent upon the particular details of a given protocol such as whether the protocol includes plans related to pregnancy during the study.

That said, if a pregnancy has been identified during a clinical trial, and no specific plans for handling such a pregnancy are included in the protocol, unblinding should occur so that counseling may be offered based on whether the fetus has been exposed to the investigational drug, placebo, or control. The risks and benefits of continuing versus stopping investigational treatment can be reviewed with the pregnant woman. Pregnant women who choose to continue in the clinical trial should undergo a second informed consent process that reflects these additional risk-benefit considerations. Given that fetal exposure has already occurred, women who become pregnant while enrolled in a clinical trial should be allowed to continue on the investigational drug if the potential benefits of continued treatment for the woman outweigh the risks of ongoing fetal exposure to the investigational drug, of discontinuing maternal therapy, and/or of exposing the fetus to additional drugs if placed on an alternative therapy. In the situation where the decision is for the pregnant woman to continue in the trial, FDA would consider all subsequent collection of data related to the pregnancy as part of the clinical investigation. Whereas, if the decision is for the pregnant woman to discontinue participating in the trial, FDA would not consider subsequent collection of data related to the pregnancy, and the resulting child, as part of the clinical investigation; however, the Agency expects that any safety information that might be obtained regarding the pregnancy or the child that results from the pregnancy would be reported to FDA by the study sponsor as part of important safety surveillance activity.

In keeping with ICH E8, FDA would expect sites to report the pregnancy of a female subject to the sponsor, the IRB/EC, and FDA. In the past, we have recommended that the female subject receive counseling (particularly if there is any information about the risks to the fetus, or if there is NO information about fetal exposure or information that can be derived from animal studies, ensuring that she is aware of that). If the female subject chooses to continue the pregnancy, then FDA routinely recommends that she be asked to allow the investigator to follow her pregnancy to term (or longer if possible for developmental sequelae), so that any important safety information could be obtained. If you want to read the ICH E8 guidance in its entirety, here is the link:
(
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E8/Step4/E8_Guideline.pdf
)

Additionally please see the guidance link below that discusses evaluating the risks of drug exposure in human pregnancies.

http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/WomensHealthResearch/UCM133359.pdf

You may wish to consult CDER's Maternal Health Staff.

Pediatric and Maternal Health Staff

Office of New Drugs

Center for Drug Evaluation and Research

Food and Drug Administration

Silver Spring, MD 20993

Tel 301-796-2200

FAX 301-796-9744

I hope this information is 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

-----Original Message-----
From: [redacted]
Sent: Saturday, August 01, 2015 9:32 AM
To: OC GCP Questions; CDER PMHS
Cc: [redacted]
Subject: Sponsors reporting of pregnancies

Hello

Can you provide the resource for guidance around sponsors responsibility of reporting pregnancies that occurred during clinical development to the agency? Is it even required at all?

Many thanks

[redacted]