From: OC GCP Questions
To: [redacted]
Subject: Pregnancy reporting in pharmacovigilance
Date: Friday, January 31, 2020 2:31:31 PM
Attachments: [redacted]

Good afternoon –

Unfortunately, I cannot specifically answer your follow-up questions. OGCP provided you general information regarding pregnancy during clinical trials. You will have to contact someone from the links provided in my previous email to seek specific information regarding your study.

You may also seek advice from FDA's Office of Pediatric Therapeutics. Please see their weblink below. There is a phone number and email address at the end of the first page.
https://www.fda.gov/about-fda/office-clinical-policy-and-programs/office-pediatric-therapeutics

Again, we strongly recommend that you contact the review division with jurisdiction over the product in question.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration

From: [redacted]
Sent: Friday, January 31, 2020 10:00 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Re: Pregnancy reporting in pharmacovigilance

Hi Dorren,

Thank you for providing us with this detailed information. Most of our concerns were addressed however we have few more questions for the same.

If the male partner is taking the study drug and the female partner becomes pregnant .is there a need to discontinue the male partner?

From the above statement what we derive is that pregnancy itself should not be reported to FDA . If there are safety concerns arise during pregnancy then that should be reported. Please advise if my understanding is correct? .

if there is no abnormality observed during the pregnancy and the subject deliver a healthy baby . this is also not re-portable, Please advise if my understanding is correct?

Please let me know if you have any questions

Thanks and Regard
[redacted]

On Fri, Jan 31, 2020 at 9:36 AM OC GCP Questions <gcpquestions@fda.hhs.gov> wrote:

> Good morning –
>
> Thank you for your email. 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, 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: (https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-8-general-considerations-clinical-trials-step-5_en.pdf)

Also, there is a new draft FDA guidance on pregnancy in clinical trials. https://www.fda.gov/media/112195/download

Please see other links below.

CDER's Division of Pediatric and Maternal Health. https://www.fda.gov/drugs/development-resources/division-pediatric-and-maternal-health

FDA's Office of Women Health. Please see the link. Office of Women's Health | FDA

We strongly recommend that you contact the review division with jurisdiction over the product in question.

Also, pharmacovigilance queries can be sent to Center for Drugs (CDER) CDER/OSIS CDER-OSIS-BEQ@fda.hhs.gov Although, I am not sure this office can answer your pregnancy question.

You may also contact the Center for Drugs (CDER) directly at druginfo@fda.hhs.gov

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration

From: [redacted]
Sent: Thursday, January 30, 2020 2:20 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Pregnancy reporting in pharmacovigilance

Hi All,

I would really appreciate if you guide us with pregnancy reporting guidance. We are working on a small molecule which under phase-2 clinical trail and now we received a report where the subjects spouse/partner became pregnant. Should this report be submitted as an ISCR .

Please advise

Thanks and Regards
[redacted]