From: OC GCP Questions
To: [redacted]
Subject: RE: Question
Date: Monday, May 05, 2014 4:53:44 PM

Dana,

I would recommend providing the following response to [redacted]:

FDA recognizes that you may wish to know which drug you received in the STRIVE trial as it might make a difference in your eligibility for future trials.

Some research is "double-blinded" meaning that both the individual enrolled in the research and the investigator conducting the research do not know which drug the individual is receiving. This is done to help maintain the scientific integrity of the research. For research that is double-blinded, the sponsor of the study may not inform the investigator of individual study drug assignments until after all the study is concluded and the research data is analyzed.

We recommend that you contact the investigator and ask to know the name of the drug you were given when enrolled in the STRIVE trial. If he/she is not able to provide you with this information then we recommend you contact the sponsor (Medivation) directly.

Informed consent documents usually provide study enrollees with more than one contact number. In addition to the investigator (or the investigator's designee) the other person listed usually represents the Human Research Protection Program or the Institutional Review Board. That individual may also be of help to you in navigating the system.

Hope this is helpful.

Sara F. Goldkind, MD, MA
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From: Walters, Dana L
Sent: Monday, May 05, 2014 9:58 AM
To: OC GCP Questions
Subject: Question

Good morning,

Please see the attached question. Would your office respond to this person?

Thanks.