From: OC GCP Questions
To: [redacted]
Subject: Clinical trial screening period eligibility
Date: Wednesday, August 08, 2018 9:20:00 AM
Attachments: [redacted]

Good morning -

I have discussed your question with a few of my OGCP colleagues. We think the labs must be within the I/E window on the first day of treatment.

The safety bounds for treatment generally apply only AFTER the first treatment of the investigational product is given; they determine whether or not a subject can continue to be treated, or if they hit the "stop treating" criteria. E.g., liver enzymes may be normal for I/E criteria, but they may be elevated slightly above normal with a chemotherapy agent. When the enzymes get above a certain level, or a percentage above that patient's normal level, treatment is stopped.

OGCP recommends that you discuss your question with the sponsor of the study.

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

Kind regards,

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From: [redacted]
Sent: Tuesday, August 07, 2018 2:30 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Clinical trial screening period eligibility

Hello,

I am an oncology physician investigator at [redacted] and have received some conflicting answers regarding clinical trial screening and eligibility. I have looked through the GCP guidelines and have not found one that addresses this question:

If a patient has screening labs that are within the inclusion/exclusion criteria for a study and

enrolls on that study, must their labs also be within the inclusion/exclusion criteria on the first day of treatment or only within the safety bounds for treatment?

I appreciate any guidance you can provide on this subject, thank you for your help.

[redacted]