From: OC GCP Questions
To: [redacted]
Subject: Question on open label study- Please help
Date: Monday, June 04, 2018 9:27:00 AM

Good morning -

"Open Label" studies are usually uncontrolled studies, carried out to obtain additional safety data. They are typically used when the controlled trial has ended and treatment is continued so that the subjects and the controls may continue to receive the benefits of the investigational drug until marketing approval is obtained. These studies require prospective Institutional Review Board (IRB) review and informed consent.

I am not sure that all open-label studies need to be blinded that would be up to the sponsor and or the institution. As you are aware, blinding reduces bias in a study. This office does not generally comment on specifics of IP labeling.

You might want to try the Center for Drugs (CDER) at druginfo@fda.hhs.gov

Kind regards,

The OGCP Group

From: [redacted]
Sent: Friday, June 01, 2018 7:25 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: [redacted]
Subject: Question on open label study- Please help

Good afternoon,

The study is Phase 1 and an Open Label Study. The Clinical samples are tested in a University Lab settings.

The clinical samples has the following information on the vial label:

1) Subject ID: XXX-XXXX
2) Date of Collections: DD-MMM-YYYY

According to the Head, Laboratory Research Department of Medicine, the Doctor in charge states that his Laboratory Technician handling the samples is required to be blinded when conducting and testing clinical samples from an open label study. Because he states that the laboratory technician will find out the data points of each subject. Therefore, he requested that samples must have a unique coded numbering system for all samples received from the Clinical Investigator Site and replace the information in numbers 1 and 2 above labeled by the site. Is this an FDA requirement in an Open Label Study? Please help.

Thank you very much.