From: OC GCP Questions
To: [redacted]
Subject: Subject participation in multiple trials
Date: Friday, June 13, 2014 9:59:05 AM

Good morning–

There is nothing against FDA regulations for subjects enrolling in consecutive trials as long as the protocol and washout period are followed. Below is what we have said in the past for subjects enrolling in multiple trials at once.

I am not aware of any FDA regulation regarding enrollment of a subject in more than one clinical trial. However, FDA does strongly discourage this practice as enrollment in more than one clinical investigation could increase risks to the subject, particularly because the subject may be exposed to more than one investigational product for which the safety profile may not be well understood. In addition, the subject may find it difficult to understand all the risks and proposed benefits, much less meet the demands, of multiple protocols. There also may be potential drug or device interactions, and the simultaneous use of more than one investigational product may confound the results of the clinical investigations.

Sponsors generally include prohibitions related to the use of concomitant medications in the protocol or restrict (via exclusion criteria) inclusion of subjects who have participated in another clinical investigation within a specified period of time (for example, the washout period before a subject can enroll in a new clinical investigation). Implied in the prohibitions on concomitant medications is the idea that subjects should not participate in more than one clinical investigation at a time.

I hope this information is useful to you. If you need further information and/or have additional questions, please feel free to contact us at gcp.questions@fda.hhs.gov.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, June 13, 2014 9:35 AM
To: OC GCP Questions
Subject: Subject participation in multiple trials

Hello

What is the view on consecutive subject participation in clinical trials? Once our subjects end a trial, they are always eager to start participation in a new trial since there may be no approved treatment available for them. This is allowable in most protocols with a wash out period between studies. Is

there a point when using the same subject repeatedly in consecutive trials (for example 3 or more) becomes a red flag, even if allowable in the protocol? This seems like a really gray area to me. Thank you.

[redacted]