From: OC GCP Questions
To: [redacted]
Subject: RE: Study protocols given to clinicaltrials.gov
Date: Friday, April 25, 2014 2:11:00 PM

Good Afternoon,

The information contained on ClinicalTrials.gov is provided by the "responsible party" for the trial in question. The fields which are required to be included for each applicable clinical trial are outlined in Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) [available at http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf#page=82]. The field which you describe in your e-mail is not required by FDAAA. Such information may be voluntarily provided by the "responsible party," however, it is not required.

FDA does review information submitted to the Agency related to clinical trials. To use drugs as an example, the requirements for information which is to be submitted to FDA in support of an IND are outlined in 21 CFR part 312 [please see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312] . FDA will evaluate the information submitted and frequently requests clarification on various aspects of the submission, including sample size. However, many trials are not required to be submitted to FDA, as they may be exempt from the IND regulations. These trials may still be required to be registered on ClincialTrials.gov if they meet the definition of an applicable clinical trial in FDAAA.

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

Patrick J. McNeilly, Ph.D., C.I.P.
Office of Good Clinical Practice
Food and Drug Administration

From: [REDACTED]
Sent: Thursday, April 24, 2014 3:19 PM
To: OC GCP Questions
Subject: Study protocols given to clinicaltrials.gov

To whom it may concern:
I was referred to you by [REDACTED] regarding an issue I had respecting the study protocols filed with clinicaltrials.gov.

As one would, expect, those protocols specify the primary endpoint of the study, but I was

surprised to see that the studies do not specify a minimal clinically important difference (MCID) for those primary outcomes. The researchers say what they are going to measure when they compare their randomized groups, but they do not say how large a difference between groups they expect to find.

Since MCID is the driver of sample size calculations, and is a crucial piece of clinical trial transparency, I was astonished not to see any mention of MCID in a large number of protocols I examined at clinicaltrials.gov.

Do investigators supply MCID data to the FDA when they file their protocols? If so, is there a reason that the FDA does not pass this information along to the clinicaltrials.gov registry?

I look forward to receiving information that will increase my understanding of the protocol process.

Cordially,

[REDACTED]