From: OC GCP Questions
To: [redacted]
Subject: RE: Quick question
Date: Friday, June 15, 2018 2:47:00 PM
Attachments: [redacted]

Good afternoon,

The regulations at 42 CFR 11.10(a) define an applicable device clinical trial and applicable drug clinical trial as follows:

> *Applicable device clinical trial* means:
> (1) A prospective clinical study of health outcomes comparing an intervention with a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)) against a control in human subjects (other than a small clinical trial to determine the feasibility of a device product, or a clinical trial to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes);
> (2) A pediatric postmarket surveillance of a device product as required under section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 3601); or
>
> (3) A clinical trial of a combination product with a device primary mode of action under 21 CFR part 3, provided that it meets all other criteria of the definition under this part.
>
> *Applicable drug clinical trial* means:
> (1) A controlled clinical investigation, other than a phase 1 clinical investigation, of a drug product subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product subject to section 351 of the Public Health Service Act (42 U.S.C. 262), where ''clinical investigation'' has the meaning given in 21 CFR 312.3 and ''phase 1'' has the meaning given in 21 CFR 312.21; or
>
> (2) A clinical trial of a combination product with a drug primary mode of action under 21 CFR part 3 is also an applicable drug clinical trial, provided that it meets all other criteria of the definition under this part.

To further assist responsible parties in evaluating whether a study meets the definition of an applicable clinical trial, the NIH/National Library of Medicine has developed the attached checklist. Should you have additional questions regarding the applicability of the regulatory requirements, please contact the ClinicalTrials.gov staff at register@clinicaltrials.gov

I hope this information is helpful

Patrick J. McNeilly, Ph.D.
Senior Health Policy Analyst

Office of Good Clinical Practice
U.S. Food and Drug Administration

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Friday, June 15, 2018 10:05 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Quick question

Do post-marketed observational research studies need to register on clinical trials.gov?

Thank you in advance for your guidance.

Sincerely,
[redacted]

[redacted]

[redacted]

[redacted]