From: OC GCP Questions
To: [redacted]
[redacted]
Subject: Phase 1 site requirements for USA
Date: Thursday, September 13, 2018 8:54:00 AM
Attachments: [redacted]

Good morning –

FDA's regulations for the conduct of clinical trials involving investigational new drugs or biologics (21 CFR 312) and for human subject protection (21 CFR 50 and 56) apply, regardless of the "phase" of the trial. FDA's regulations for the conduct of clinical trials involving investigational devices (21 CFR 812) do not refer to "phases".

FDA's regulations at 21 CFR 312.21 contain the following definition of Phase 1 studies:

Sec. 312.21 Phases of an investigation.

An IND may be submitted for one or more phases of an investigation. The clinical investigation of a previously untested drug is generally divided into three phases. Although in general the phases are conducted sequentially, they may overlap. These three phases of an investigation are as follows:

(a) Phase 1. (1) Phase 1 includes the initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. The total number of subjects and patients included in Phase 1 studies varies with the drug, but is generally in the range of 20 to 80.

(2) Phase 1 studies also include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.

Phase 1 testing typically involves fewer than 100 subjects, and is often conducted in healthy volunteers, although there may be Phase 1 studies in oncology patients. Phase 1 studies typically last several months, and the purpose of these studies is primarily to evaluate a drug's safety when it is first introduced in humans. While these studies may be smaller or of short duration, Phase 1 studies still pose risks to the human volunteers.

Content and format of INDs for Phase 1 studies:

https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm071597.pdf

If your company sets up a Phase 1 facility, you or the clinical investigators who are conducting the Phase 1 studies would need to obtain the services of an institutional review board (IRB) to review the studies that will be conducted at the facility. The IRB's primary responsibility is to review the research (including protocols and informed consent documents and procedures), to ensure that subjects' rights and welfare are protected and that the provisions of 21 CFR 50 (informed consent) and 21 CFR part 56 (IRB review) are met.

Although FDA has not issued guidance directed specifically to Phase 1 facilities, facilities that are planning to conduct Phase 1 studies should consider the following:

What are the qualifications of the individuals who are in charge of the Phase 1 clinical trial center or who

will be conducting the actual studies?

Do they have any previous experience with clinical trials?

Has the staff received training in research ethics?

Will the facility have sufficient resources (e.g., staff, medical expertise), support services, and adequate facilities to respond to unanticipated problems that may arise while the study is ongoing?

Is the Phase 1 center affiliated with a nearby hospital, to ensure that any medical emergencies can be promptly handled (and subjects will be protected)?

If you have additional questions regarding Phase 1 studies, you can contact the Center for Drugs (CDER) directly at druginfo@fda.hhs.gov

Kind regards,

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

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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: Wednesday, September 12, 2018 5:05 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Phase 1 site requirements for USA

Hello,

Good day to you.
I hope this message finds you well.

I would like to ask if USA has guidelines/ requirements in clinical trials for sites conducting Phase 1 studies (eg: phase 1 sites need to be accredited by the government, etc.)?
If there is a guideline, where can I get a copy of that?

I look forward to your feedback.
Thank you so much.

Best regards,
[redacted]