From: Tarb,Allen, Joan
Sent: Tuesday, October 17, 2006 10:28 AM
To: [snipped]
Subject: RE: FDA questions

Dear Mr. [snipped]

Thank you for your inquiry regarding the term "pivotal clinical study."

As you have already discovered, this term is not used in FDA regulations. However, in my experience, when it is used it commonly refers to the clinical study or studies that are intended to provide the main supporting evidence for a marketing application or submission that is submitted to FDA. As a former CDRH RMO reviewer, I know it is commonly used by device personnel. Unlike pharmaceutical clinical studies, device studies rarely, if ever, are conducted in phases. However, clinical device studies may start with a small "feasibility" or "pilot" in regulatory sense). These small, initial clinical studies do require an IDE. If subsize safety and effectiveness are demonstrated, a larger "pivotal" study may then be planned and approved - either as a supplement to the original IDE or as a new IDE study. These terms appear in CDRH guidance documents at least as far back as 1995 where they can be found in the Blue Book guidance entitled "Goals and Initiatives for the IDE Program" which can be found at http://www.fda.gov/cdrh/df51.html. They are frequently used in presentations by FDA device staff as a means to consistently describe the different IDE studies that can and do occur.

I have also heard the terms used to refer to aspects of FDA-regulated studies of pharmaceuticals and animals products, but not quite so often. It is important to note that any and all studies of investigational products on human subjects, no matter how small or preliminary, must have IRB and, for pharmaceuticals, FDA approval prior to initiation. Device studies that are determined to be non-significant risk (NSR) studies or exempt from the need for an IDE (mainly IVD studies) do not need FDA approval but do need IRB review and approval before the first subject is entered into the study.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official CCP mailbox, gcpquestions@cder.fda.gov, in lieu of responding to my personal e-mail address.
Sincerely yours,

Joan Tarb,Allen, Ph.D.
Good Clinical Practices Program
OSRE, Office of the Commissioner, US FDA

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(j), which represents the best judgement 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.

-----Original Message-----
From: [snipped]
Sent: Monday, October 16, 2006 12:59 PM
To: OC-GCP Questions
Subject: Re: FDA questions

-----Original Message-----
From: [snipped]
Sent: Monday, October 16, 2006 12:03 PM
To: OC Webmail
Subject: FDA questions

Name: [snipped]
E-Mail: [snipped]
Address: [snipped]

Phone: [snipped]

URL:

Comments: I keep hearing the term "Pivotal Clinical Study" being used, but I've not been able to find a definition of what type of study that is, what it would be used for, or what criteria would be used to create one. Please advise.

Regards,

[snipped]