

An FDA Insider's Guide to Pre-IND/IDE Meetings How to Avoid Clinical Trial Holds

**An RxTrials Institute audioconference
Thursday, July 19, 2007 • 1:30 p.m. — 3:00 p.m. EDT**

Register now!

Improve your power to prevent clinical trial holds and unnecessary studies by just 10 percent and you could add \$100 million to your bottom line. It could be as simple as meeting with the FDA before initiating your IND/IDE.

But there's a catch: Successful meetings require strategic preparation. Plus, as the FDA works up new pre-IND/IDE guidance, chances for face-to-face contact may be scarce.

So, what's the secret for getting pre-IND/IDE meetings - and turning them into lower costs and faster approvals?

Register now for this 90-minute audioconference and find out!

Former FDA medical officer **Dr. Jerri Perkins** reveals the best strategies for using pre-IND/IDE meetings to spot safety and efficacy shortfalls *early* — and get the ball rolling on clinical trials at the lowest possible cost. From preparing for meetings to using interaction with the FDA to map out (and negotiate) the critical path, Jerri helps you clear away problems with CMC information, insufficient pre-clinical support, dosage information and other costly obstacles.

Sign up your entire team to listen in on how to use pre-IND/IDE meetings to minimize costs and speed products to market:

- Seven situations in which pre-IND/IDE meetings are critical
- Meeting tactics that help you spot and avoid unnecessary studies
- Specific studies that will support the initiation of clinical trials
- Insider guidance on how to gain FDA support for a proposed strategy
- How to enhance development through strategies such as orphan drug designation, fast track designation or accelerated approval
- Practical tactics that can minimize the potential for clinical hold
- How to foster a creative — time-saving — exchange of ideas with the FDA
- Best practices for obtaining regulatory insights
- How to use meetings to define endpoints and goals of the development program
- Tips on how to enhance the success of your interactions and negotiations with the FDA

Don't miss this "early-phase" opportunity to win faster approvals and wider profit margins — **register today.**

Meet Your Speaker

Former FDA medical officer **Dr. Jerri Perkins** founded Perkins & Perkins, Inc. (PPI), an internationally recognized firm offering medical and regulatory assistance to the pharmaceutical and medical device industries. As president of PPI, Jerri writes protocols, prepares companies to meet with FDA staff, participates in FDA meetings and assists companies in preparing IND, NDA, ANDA, IDE, PA and 510(k) submissions. These submissions have included drug/device and biologic/device products, and she has developed a strategy for propelling a product from non approval to approval without additional data. Jerri has also served on data safety monitoring boards.

Jerri has conducted pre-FDA audit inspections in the US and Europe. Her audit reports have been

used successfully to prepare sites for FDA inspections.

[Register now!](#)

Who Will Benefit

The audioconference is a must for experts in drug, biotech, biologic, device and diagnostic companies, including:

- Clinical development
- Clinical trial project managers/leaders
- Regulatory affairs
- Chief scientific officer
- Medical/scientific affairs
- Protocol development

Audioconference Details

Date: Thursday, July 19, 2007

Location: Your office or conference room (*no need to travel!*)

Time: 1:30 p.m. – 3:00 p.m. EDT
12:30 p.m. – 2:00 p.m. CDT
11:30 a.m. – 1:00 p.m. MDT
10:30 a.m. – 12:00 p.m. PDT
6:30 p.m. – 8:00 p.m. BST

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time of day or night for three weeks, from July 23 — Aug. 10, 2007. You'll also receive all presentation materials.

Also Available from RxTrials Institute and FDAnews ... interactive training workshops for the clinical research team. [Click here](#) for more information, dates, locations and to register.

RxTrials Institute; cooperation between RxTrials and FDAnews.

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