Begin With The End in Mind:
Top 5 Considerations on Your Critical Path to First-in-Human Clinical Trials

You have been moving steadily from discovery into preclinical, and based on the data, your molecule will be advancing into First-in-Human clinical trials. Congratulations are in order — but with limited funds, tight resources, and a myriad of conflicting priorities, how do you begin to make sure your organization is ready for clinical trials?

To help you prioritize what is most important, we have summarized the top five most important considerations on your critical path to FIH clinical trials.

1. Assembling Your Team

When assembling your drug development team, you will need to ensure you cover an array of disciplines and skillsets. Consultants or a CRO partnership can fill many roles. Start by looking at your core team and the strengths of those you have already assembled and then bring people onboard who fill your gaps.

- A strong business/financial person to manage contracts and represent your business interests with the investment community is important
- Chemistry, toxicology, and pharmacology disciplines are needed to guide animal studies, understand safety and efficacy of the drug, and help determine the starting dose for the human studies
- A solid regulatory strategy consultant will be critical - someone who knows what the IND enabling package needs to look like
- A strong Chemistry, Manufacturing and Controls (CMC) expert to help you produce a quality, administrable drug product will be worth their weight in gold
- Do not underestimate the importance of having a Drug Metabolism and Pharmacokinetics (DMPK) or Absorption, Distribution, Metabolism and Excretion (ADME) expert on your team — someone who understands the pharmacokinetics of the drug and how it will be eliminated from the body. Mid to large pharmaceutical companies or consulting organizations are the best place to find people with these skillsets.

2. Defining Your Regulatory Strategy

It will be critical in the months leading up to your FIH clinical trials to have a clear regulatory strategy. You will need to address many important questions to ensure you are on the right path:

- What will your indication be? This will help determine the division of the FDA with which you will be working.
- What will your FIH clinical trial look like?
- Will it be healthy volunteer or a patient study?

Too many drug companies become distracted by the potential efficacy of their new drug compound. However, the most important element to the regulatory authorities in phase I clinical trials is safety, safety and safety.

3. Preparing for FIH Trials

There are over a dozen ICH guidances on FIH studies. Understand the “minimum package required” for FIH. Also, consider what type of molecule you are developing. Small molecule, antibody, cell or gene therapy? The molecule type will dictate what types of studies you need to conduct for efficacy and safety. Consider how you will choose a starting dose. Note: the most common hold reasons during this early stage are CMC and toxicology.

4. Developing Your Protocol Synopsis

As you prepare to move forward, begin to flesh out a protocol synopsis that summarizes what your FIH clinical study will look like. What will the inclusion/exclusion criteria be? How long will the treatment period last? How much drug supply will be required? The protocol synopsis will be the first thing the investors ask for and the first documentation that you can share to demonstrate your organization is serious about advancing your compound forward.

5. Operationalizing Your Protocol

Numerous study team members will become essential as you plan to operationalize your clinical trial. This does not necessarily mean you need to staff-up. You can remain lean and outsource the bulk of your clinical study activities to a CRO or bring on key team members as consultants. You will need regulatory support to help manage FDA interactions such as document preparation submission and FDA meetings. Moreover, you will need a solid project team consisting of clinical operations, project management, safety, data management, biostatistics and medical personnel. The CRO can help manage other third-party vendors like analytical laboratories. It ultimately is up to you how much you want to outsource – depending on the size of your internal team, your in-house expertise and the bandwidth of your in-house team, taking into consideration how many compounds you have in your pipeline, etc. Don’t wait too late to get started on this piece. Ideally, you should start requesting proposals at least six months out and initiate discussions with CROs at least one year out.

Interested in learning more about how your organization can prepare for FIH clinical trials? Contact Aperio today at info@aperioclinical.com.

About Aperio Clinical Outcomes

Aperio Clinical Outcomes provides full, customized clinical research services across multiple therapeutic areas. More important, we offer what sponsors need most in today’s new world of healthcare: intelligence, honesty, and agility. We deliver comprehensive clinical research services with unmatched transparency and experience. That’s why we chose the name Aperio — Latin for uncover or reveal.

Aperio offers a full-range of Clinical Trial Services depending on your needs:

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