Worldwide Clinical Trials

Stay on Track While Preparing for NDA Submission

Early phase studies can be complex, especially if you receive last-minute requests for supplemental studies from the FDA. Taking a proactive approach is ideal. But there is a chance you'll be required to submit results for certain studies you may not have originally considered when mapping out your clinical development program. It's crucial to anticipate what these possible requests might be so you can avoid delays.

Some of the most common last-minute mandated studies requested are Absorption, Metabolism, and Excretion (AME); Drug-Drug Interaction (DDI); Hepatic; Renal; and Thorough QT (TQT).

Clinical Conduct Timeframe

- Drug-Drug Interaction (DDI): 2 - 3 weeks
- TQT: 2 - 3 weeks
- Absorption, Metabolism & Excretion (AME): 1 month
- Hepatic: 3 - 4 months
- Renal: 3 - 4 months

Your NDA submission could be significantly delayed if you're required to complete additional studies. Not only do you need to consider clinical conduct time, but study start-up, analysis, and clinical study reporting time as well. A good rule of thumb is to double the clinical conduct time before you can get your final clinical study report (CSR) which can be a considerable hit to your program.

Additionally, not every CRO can complete these types of studies, so when selecting a partner, be sure to choose one that has the capability and proven track record so you can avoid delays and keep your asset moving forward.

To learn more about this topic, watch our presentation given at ASCPT titled, "**Sink or Swim: Successfully Executing NDA-Enabling Studies to Avoid Rough Waters.**"

We are here to help. Let's talk.