Get Ahead of the Game

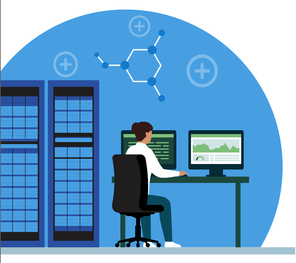
WITH FLEXIBLE PHASE I STUDY TIMING

Combining certain Phase II studies with the Phase I protocol gives you earlier access to data, enabling more informed go/no-go decisions early in the program. This strategy makes it possible to:

- **Accelerate drug development**
- **Potentially waive certain later-phase studies**
- **Better allocate resources to maximize revenues and balance timelines.**

LET'S IMAGINE...

That you're an early-stage biotech company with a promising small molecule showing potential as a novel analgesic...



The typical Phase I development program includes single ascending dose (SAD) and multiple ascending dose (MAD) studies in healthy normal populations.

A bare-bones, non-accelerated drug development program would stop there.

But you **can** get ahead of the game. **Think of the possibilities.**

YOU COULD...

Include special population cohorts (such as the elderly) in Phase I

Regulatory authorities recommend examining how other medications and age-related metabolism changes affect the safety and efficacy profiles of drugs in the elderly. You'll need these results to fully understand the product's risk-benefit ratio.

Include food effect studies in Phase I

The FDA requires food effect studies for any drug administered orally. Combining food effect assessment with other early studies will save time and make it easier to understand the dosage and administration parameters.

Begin cognitive assessments during Phase I

The FDA requires additional studies for any drug that may impact cognition, and you can save time and reduce costs by combining these studies with other Phase I assessments.

Include drug-drug interaction (DDI) studies in Phase I

Most new products will require at least one DDI study, so it makes sense to do this evaluation early on.

With early access to important data, you can make more informed decisions throughout the drug development journey. You will be empowered to make wiser investments and plan for the conduct, or waiving, of any specialized analyses later in the development pathway.

Every drug development pathway is different.

LET'S GET YOURS TO THE FRONT OF THE PACK.

Read *The Altascientist* for a more in-depth discussion on combined protocols, including **two scenarios**.

FIND OUT MORE

ALTASCIENCES BIOPHARMADIVE

Altasciences' integrated, customizable full-service solutions help sponsors save time and resources so that they can get better drugs to the people who need them, faster.

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