PRA Health Sciences

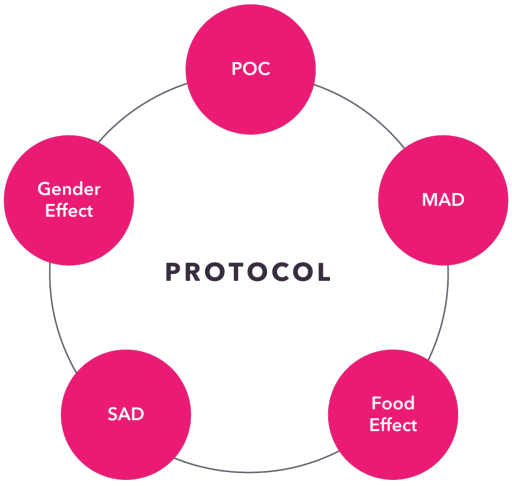
SLIP SHEET

Fast Track Development Program

For years, clinical pharmacology researchers have faced this critical challenge: how do you reach proof-of-concept (PoC) as early as possible using the best designed development program and without compromising subject safety?

Now, at PRA Health Sciences, our Early Development Services (EDS) group has created an innovative solution to that problem: the Fast Track Development Program. Beginning with an understanding of the overall development goal, our program employs an advanced approach that combines multiple clinical objectives into one study – while delivering high-quality data and substantial time and cost savings.

Fast Track in the Right Direction?



PRA works with the client to design a clinical strategy from product inception to regulatory approval that is tailored to meet clinical and regulatory expectations and is commercially appealing. This roadmap details the strategies for general clinical development, study design, and operational execution.

Furthermore, the roadmap focuses on the target product profile (TPP) that provides the product development team with valuable and measurable deliverables as well as the objectives for and guidance on the clinical development plan. The smart design of the sequential studies in the clinical development plan is the operational key to Fast Track Development.

Fast Track Makes the Complex Simple

The traditional, more costly early clinical development approach requires a lengthy program of separate single- and multiple-ascending dose (SAD/MAD) studies and numerous protocols. Conversely, PRA's cutting-edge Fast Track Development Program combines the SAD/MAD studies under one "umbrella" or "multi-purpose" (MP) protocol to provide clients with significant time (4-12 months) and financial (up to $1M) savings.

For instance, consider that a single protocol's development and approval cycle typically takes at least 3 months. But with the capability to combine 4 objectives into 1 protocol, we will help save 9-12 months.

The advantages are much greater when we incorporate adaptive design elements into the study. PRA's multipurpose protocols anticipate unforeseen outcomes that may affect study design and dosing regimens, enabling us to adapt the design to accommodate a closer clinical evaluation of specific dose levels or dose regimens, or modify endpoints or sample sizes.

Another way PRA delivers streamlined solutions is through our on-site GMP pharmacy, which specializes in preparing the study- and cohort-specific investigational medical product (IMP). With our in-house pharmacy, clients receive the benefit of no additional expensive CMO contracts and receiving inexpensive preparation of cohort-specific IMP within 24 hours.

How It Works

PRA's global Fast Track Program combines the following critical elements:

Seamless Drug Development Services – PRA offers clinical design services that encompass a collaborative strategic design process from product inception to regulatory approval. Our designs:

- Focus on meeting clinical and regulatory expectations.
- Are commercially appealing.
- Cover general clinical development, study design, and execution.

Clinical Development Time Optimization – PRA performs traditional SAD and MAD studies concurrently with significant time overlap. We administer the first dose for MAD studies to subjects after the initial doses in the ongoing SAD study have been proven safe.

Real-time Bioanalytical Results – We include our in-house bioanalytical solutions with your full-service project, ensuring that you get the PK data necessary for sound decision making.

Umbrella Protocols – PRA operates multiple studies within a "multi-purpose" protocol concept that combines multiple clinical objectives into a single document.

Next Steps

To learn more about how PRA's Fast Track Development approach, please contact:
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