Clinical development pre-marketing

From clinical development to Marketing Authorization

Manage a clinical drug development program requires experience and expertise. We help our Clients to move from pre-clinical to clinical phases up to Marketing Authorization Application by providing clinical operation support to manage clinical trials. Our goal is to provide an efficient and cost-saving approach by applying a risk-based thinking and a successful process.

Early phase

We support our Clients to move from research to clinical development by fully managing clinical trials at this stage and providing effective advices to efficiently start *and ground* the clinical development. We can manage Phase I trials, as well as BE/BA studies. We also offer a flexible approach for Clients looking for a partner able to step in throughout the clinical development. We have experience in managing Phase I and Phase II clinical trials.

BE/BA studies

The deep knowledge of Phase I studies allows us to timely provide comprehensive quotations of studies/projects performed. Our support:

- Multiple dose tolerability & pharmacokinetics
- Local tolerability, Photo-toxicity and photo-sensitization
- QTc prolongation studies
- Drug-interaction studies
- Single / Multiple dose pharmacokinetics
- BA / BE

Registrative studies

Navigating the complexity of Phase III clinical trials can be challenging. We offer our proven expertise and a set of customized services to manage Phase III trials and maximize the chance of success. Our support starts from study feasibility to statistics and data analysis. Through our network we can manage clinical trials in multiple locations providing ad-hoc local expertise.

OUR PLUS

- **Proven experience**
- **20 year experience**
- **Flexible solutions**
- **A global coverage**

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Our approach

Through our Clinical development team we work to ensure the collection of high quality data from clinical trials. We are committed to plan in advance to identify risks and develop mitigation strategies.

How?

- **Project Plan:**

A detailed document to ensure a strategic planning of your trial. Through this plan we define project timelines, communication plans, project metrics and deliverables.

- **Monitoring Plan**

A tailored monitoring plan is implemented for each study. We combine compliance-oriented and risk-based solutions to set-up a plan that best fits with the study features.

- **Efficient issue escalation:**

As a mid-size CRO we can ensure our Sponsors that any issue is promptly and efficiently managed. No intermediate figure, but Sponsor dedicated Project Managers allow us to streamline issue escalation.

- **A Quality Risk Management Plan**

We identify risks associated with the trial and IMP / intervention, classify them and define measures to mitigate such risks. We take into account the study phase, the indication and IMP, the trial procedures, the number of countries and/or sites involved, the No. of patients and duration of the trial.

- **Highly-Trained personnel**

In addition to ongoing training, the staff allocated to clinical project is selected according to the experience and receive specific trainings on the project. Our flat organization structure allows a close coordination of the study team as well as a streamlined communication.

Our experience

Since 1999 we have managed more than 210clinical projects In almost all therapeutic areas. For details on projects and study phases visit our website (**gbpharma.it**).

Contacts

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