Late-phase Clinical development

Our support to manage Regulatory Requests and enhance the Value proposition of your Product

Long-term safety and efficacy data are not detectable during the first phases of the Clinical Development process. Regulatory Agencies, healthcare professionals and payers are increasingly demanding for additional data for new products in a Real World Setting.
At GB Pharma, we have proven and long-term experience in managing:

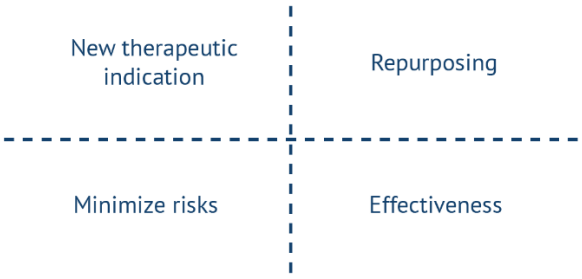
- Phase IIIb / Phase IV trials
- PASS & PAES;
- Comparative effectiveness research
- Observational (non-intervention) studies
- Patient registries
- Health-related quality of life studies
- Patient-reported Outcome (PRO)
- Pharmacoepidemiology
- Expanded access programs
- Health economics studies.

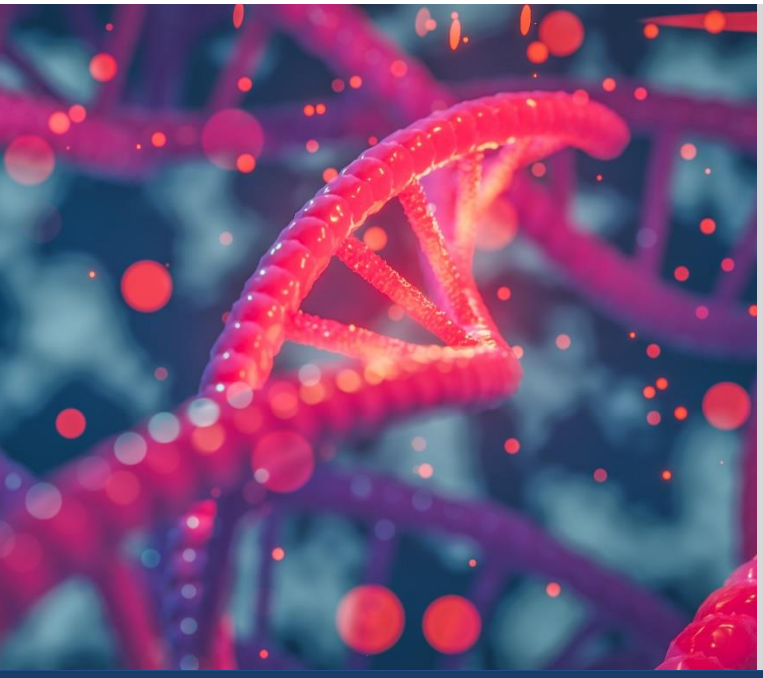
Our experts

Our late-phase development staff is made of clinical, regulatory and pharmacovigilance experts and is able to support your Company designing and conducting studies where observational methods and epidemiological methods apply.

Develop a late-phase program

Late-phase development is not about a study or a trial, it is about a program. We want to partner with our Clients to develop a late-stage clinical development program and enhance your Value proposition.





WHAT WE OFFER

- **A multi-disciplinary team**
- **Robust late-phase development experience**
- **Feasibility support**
- **A global coverage**

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Manage Regulatory request

As GB Pharma, we combine our regulatory and clinical know-how to support our Clients in designing studies and collecting data as requested by Regulatory Authorities during MA application procedures or post-authorization assessments.

- Conditional Marketing Authorization;
- Approval under exceptional circumstances;
- Risk Management Plan;
- PRAC recommendation;
- Referral;

Oberservational studies

Observational Studies have an important role in the comprehensive development and testing of a drug and, when conducted properly, provide valuable information to complete drug life-cycle. They provide evidence of effectiveness, tolerability and safety in real-life routine clinical practice. We have experience in managing the most common study designs (Cohort and Case Control studies, Cross Sectional studies, Case Series, hybrid design).

RWE

There is an increased need to understand the impact on disease and treatment options of new and existing drugs. Regulatory and payers are more demanding of Real World Data to assess patient's needs and proposed treatments. We provide our Clients with effective solutions to access to Real World Data and generate evidence to demonstrate the cost-benefit improvements, in order to reach market authorizations, pricing and reimbursement policies.

Feasibility support

Designing an observational project is a critical process. Several factors should be considered during the feasibility process. Through our network of Key Opinion Leaders, sites and local partner, our feasibility support allow our Clients to have an overview on all possible scenario, including milestone, sites, patient enrollment, cost, study design and milestone of your project. This is a service aimed at driving our Client in designing an added value project and collect on-purpose data.

Contacts

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