Early Phase Trials
Overview and Case Study

Overview

For over 25 years, Pharmnet has excelled in helping our clients transition from pre-clinical development to the clinic. Having completed over 130 Phase I-II and First-in-Human clinical investigations, our experience can bring considerable value to your clinical development programs.

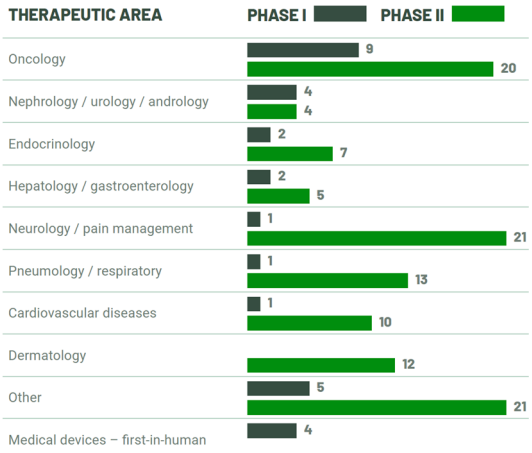
Pharmnet goes beyond just managing your early phase clinical trial. We offer a comprehensive approach that extends to supporting you as you secure financing for your study. Our team's combined scientific, statistical, and medical writing expertise and deep knowledge of the regulatory landscape, patient management, standards of care, and healthcare facilities, allow us to optimize your study design. Such an approach has the potential to accelerate the entire development process and reduce cost and risk.

Even though the primary goal of early phase clinical trials is to verify safety and efficacy, we always recommend thoroughly monitoring outcomes because such preliminary data and their detailed understanding can make subsequent trial designs more targeted and increase the likelihood of success. The correct approach and well-defined outcomes of early-stage protocols are critical because they lay the framework for succeeding phases of clinical development and contribute to the overall success of the drug development process.

Pharmnet's approach and experience

Over the last two decades, Pharmnet has undertaken 25 Phase I and 113 Phase II clinical trials. We have broad experience in designing regulatory-compliant protocols for early phase trials. We generally handle submissions to the regulatory authority using our considerable understanding of the regulatory environment.

We can provide a full Phase I clinical solution, including end-to-end services to run clinical trials in healthy volunteers within a fully equipped facility and bioanalytical testing in modern, GLP-compliant labs. We ensure that Phase II studies are conducted in clinical facilities with suitable scientific credentials, adequate trial resources, and extensive experience with GCP clinical trials.



Smooth transition from pre-clinical to clinical stage

Pharmnet prioritizes building long-term relationships with clients. We believe initial investment in understanding your needs leads to efficient project execution and a smooth transition from pre-clinical to clinical development.

We offer early consultations on Phase I/II trial design, typically while preclinical tests are still in progress. We focus on a few key scenarios, basic statistics, and initial top-line feasibility assessments. A preliminary budget

estimate helps you decide on your protocol design, target population, and overall strategy (conservative or rapid approach). Once you select a protocol outline, we develop the full protocol and supporting documents.

This streamlined process, initiated under a preliminary contract or a Letter of Intent, saves you money by avoiding complex contracts upfront and allows for flexibility based on emerging data. By only paying for start-up costs initially, Pharmnet makes budget planning more efficient, allowing you to fully define the protocol before committing to the full trial costs. By focusing on efficiency and collaboration, Pharmnet helps you navigate the early phase with confidence.

Case Study

Challenge: Our client, a biotech company, faced slow progress with their clinical program having only data from PK studies on healthy volunteers performed in India. In parallel to an ongoing Phase I trial conducted by another CRO, Pharmnet efficiently designed and prepared the trial documentation for Phase II and Phase IIb/III trials and got approvals for 4 EU countries within a short timeframe. Although Pharmnet was ready to start the Phase II study, the biotech was experiencing difficulties with patient recruitment in Phase I. Our client needed to accelerate data generation and secure early patient safety and efficacy insights to greenlight further development.

Pharmnet's solution: Despite the ongoing Phase I study, Pharmnet took a proactive approach:

- **Data Acceleration:** Recognizing the client's urgent need for real patient data, Pharmnet strategically amended the Phase II protocol to include a small, open-label cohort of 12 subjects to replace data from the unsuccessful Phase I study conducted by the other CRO (plan approved by client beginning of September 2023, submitted by Pharmnet to CA same month with all approvals available in late October).
- **Rapid Recruitment:** Utilizing its extensive network of clinical trial sites, Pharmnet recruited all 12 subjects within 2 months (November 2023 - January 2024), significantly outperforming the original Phase I study.

Results:

- **Early Data Insights:** The first interim report, delivered within 7 days of the last patient visit, provided valuable safety and efficacy data after 8 subjects reached a stable drug dose.
- **Favorable Risk-Benefit Ratio:** Based on the initial data, the study demonstrated a favorable risk-benefit profile for subjects, paving the way for a seamless transition into an extension study. Pharmnet developed this extension study concurrently and anticipates its approval in April 2024.
- **Streamlined Funding:** Leveraging two flexible contracts based on a Master Service Agreement, Pharmnet allowed the client to commit to specific project phases without needing upfront funding for the entire development program.

Conclusion: This case study demonstrates Pharmnet's ability to deliver efficient and cost-effective solutions for early phase clinical trials. By working in parallel with ongoing studies and utilizing strategic amendments, Pharmnet helped the client accelerate data generation and secure early insights to inform future development decisions.

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