Worldwide Clinical Trials

Partnering for the Success of Your Full Development Journey

Taking your investigational product from first-in-human (FIH) to commercialization requires collaboration with a CRO partner who has a strategic focus and global operational capabilities in your therapeutic area. Worldwide Clinical Trials offers more than just transactional study delivery services, prioritizing generation of quality data while aiming to become a trusted extension of your team on your drug development journey.

Worldwide's integrated teams work cross-functionally to deliver end-to-end drug development services to test your molecule from start to finish. From science to methodology, to regulatory, and through to operational and study delivery, we have integrated teams that think comprehensively and work strategically to your advantage. Our approach is personalized, adapting to your specific needs, and tapping into our global internal and external resources as needed for the unique requirements of your development program.

Case Study: Global Support That Helped Lead to Approval of Lecanemab

A leading global neuroscience sponsor came to Worldwide for delivery of their complex FIH study to establish the viability of their product, lecanemab, for Alzheimer's disease. After reassuring study results and establishing a proven and trusted partnership, the sponsor came back to us to help finish the open label portion of their Phase II study which has been the basis for accelerated approval.

We then delivered the pivotal Phase III study, applying our scientific and methodological expertise to enroll the right patients and deliver the study design in accordance with the sponsor's development plan, strategy, and timelines, making this one of the fastest enrolling studies in this indication. Additionally, we leveraged our robust clinical and medical monitoring practices and our data management oversight to ensure reporting of high integrity data.

On top of the main studies within the development lifecycle, we continue to conduct additional Phase III studies to support potential label extension.

Our Program Involvement

- **4** Studies
- **520+** Sites
- **4,100+** Patients
- **15+** Countries (NA/EMEA/APAC)

Endpoint Measures

- Clinical Assessment Technologies
- Neuro-Imaging

Drug Classification

- Monoclonal Antibody
- IV Administration Every 2 Weeks

Patient Population

- 2,700 Early Disease
- 1,400 Preclinical Disease

Regulatory Considerations

- Accelerated Review by FDA
- FDA Inspection of Study Conduct

We were an ideal fit for this large, global development program because of our flexible approach, global footprint, extensive expertise, and focus on quality delivery in support of our sponsor's development lifecycle.

Let's talk about how our personalized approach, development expertise, and global resources make us a strong partner for your development program.

Contact Us

worldwide.com