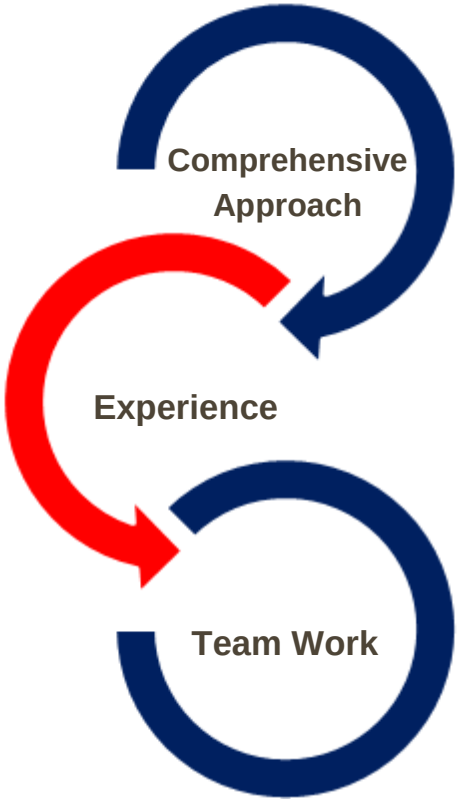

CLINICAL SERVICES

Therawis
Pharma | Diagnostics

Challenges

Clinical trial complexity has considerably increased during the past decades.

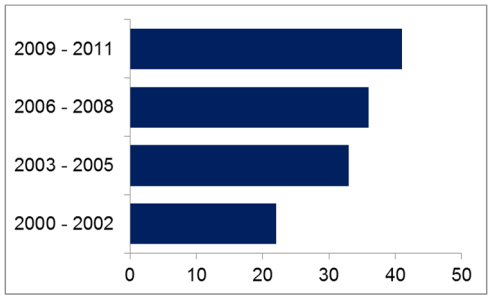

Figure: Increase in Trial Complexity for typical Phase II/III studies [Score by Medidata Solutions, 2012, Applied Clinical Trials, Vol 21, Issue 8]

The typical protocol in 2012 includes 13 endpoints, 167 procedures, 35 eligibility criteria and is conducted in 27 countries at 130 sites.

Highest complexity is seen in oncology trials and impacted trial performance can be measured as decreasing rates of screen-to-complete ratios and increased times from “protocol ready” to “last patient last visit”.

“Even in the hands of the most experienced project managers most international clinical trials will have unexpected peaks of workload with needs for external staff support”

Globalization and complexity have made the targeted timelines and global quality challenging.

We are a very *experienced team of clinical trial experts*.

We offer you a wide range of expert services to successfully complete your projects.

Clinical Services

Medical affairs / Consulting

Establish and optimize clinical development plans and study designs

Write / review the entire spectrum of study documents such as study protocols, study reports, publication manuscripts, posters and presentations

Write/review briefing packages for meetings with regulatory authorities such as FDA and EMA

Create scientific training modules and materials

Organize & conduct opinion leader & scientific advisory boards

Provide support and response to medical questions of clinical trials

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“Upfront optimization of clinical development plans and individual study protocols will drive speed and efficacy of development substantially”

Project management

We provide project management or project management support to:

Perform realistic feasibility studies

Develop & review study related documents and trackers

Manage & coordinate third party vendors (e.g. central labs/DSMB)

"If engaged on a scientific level and convinced of the trial, investigators will take ownership of the success of the study"

Clinical Trial Liaison

Clinical trial liaisons are highly trained, experienced professionals who:

Raise awareness of your trial to keep sites motivated & engaged during study participation

Develop, maintain and manage relationships with key opinion leaders and national coordinators

Ensure appropriate understanding of the study protocol and the drug's mechanism of action by all involved study personnel

Discuss enrolment potential and strategies with the sites

Identify enrolment barriers and develop strategies to overcome these barriers with sites and sponsors

Our Approach

Comprehensive approach based on the significant and broad experience of all team members

Customized design to meet your requirements in a manner that sets us apart from most clinical research service providers

Experienced & motivated team to support your project on an excellent scientific, medical and operational level

Ready to go on short-notice based on experience in consultancy, project management and clinical trial liaison

Clear and transparent communication

Diligent review and support to understand the needs of your project and translate into adequate solutions

Your Benefit

Provides an option to a faster and more efficient path to project completion

Save time and money by compensating your temporary in-house staffing shortage

About Us

Therawis Pharma GmbH is a privately held, profitable oncology-specialized company with offices located in Munich, Germany, and was founded in April 2014.

We are a very experienced group of clinical research experts with a track record of 15 years+ for each team member. As a team we work together in the oncology area since 10 years+.

All team members have experience on both sides - as sponsor and service provider. We are familiar with the needs of all involved parties and encompass work skills & scientific expertise to successfully support and execute your projects.

Contact

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