



Product Development: Due Diligence, Strategy & Study Management for NCE in EU.



Customer Understanding

Customer profile

Small European based Research and Development company intending to develop and register their first NCE targeting Non-Alcoholic Fatty Liver Disease (NAFLD) & Steatohepatitis (NASH).

This drug was not authorised anywhere in the world.

Customer Challenges

- Due to the size and nature of the company, they possessed expertise in drug development, but have very little expertise in pre-clinical and clinical regulations.
- Initial data collected had not been validated against the latest regulations for compliance.
- The client lacked experience in selecting Clinical Research Organisation (CRO) for pre-clinical & clinical studies.
- Client did not have in house pre-clinical & clinical experts to design a development plan for required studies.
- Client had limited ability to manage all the necessary studies and data analysis required for pre-clinical and clinical requirements.



PLG's Responsibilities & Activities

Scope of work provided:

Due Diligence

- With the client's existing data, PLG conducted a due diligence identifying possible gaps that could exist.
- PLG conducted robust literature searches using regulatory requirements and similar product types precedents to create a development plan for the product, inclusive of Good Laboratory and Good Clinical Practices (GLP & GCP).

Product Development

- PLG created the development plan and initiated contact with several CROs on behalf of the client to select the appropriate candidate to carry out the pre-clinical studies.
- Currently PLG is managing on behalf of the client the 180-day toxicology programme with upcoming studies, including 28 days of repeat dose toxicity, Safety Pharmacology, Metabolite Profiling, PK & Genotoxicity studies.



Solution provided by PLG

The client benefited from:

- A team of highly skilled and experienced pre-clinical & clinical experts to assess current data and design development plans.
- Qualification & Selection of CRO to conduct studies.
- A robust Project Management plan with allocated milestones to keep the project on track.
- In conjunction with the above SMEs, a dedicated Project Management team to assist in the collection of study data and keeping the client in constant communication for timely updates.



Added-value and customer benefits

II Customer benefits

Specific Subject Matter Expert resources dedicated to the client's project.

A cost-effective solution with centralized project management & offshore operational resources.

KPI: 80-90% reduction in the manpower needed due to automation instead of manual processes.

II PLG success factors

Flexibility in working with the client's preferred schedule of payment.

PLG's holistic understanding of the client's "wants and needs", while managing the client's realistic expectations.