BUSINESS CASE

Bridging EU and US: IND preparation and submission

CHALLENGE

A small European biotech company focused on drug discovery and development, investigating the clinical potential of a novel compound (new chemical entity) in various autoimmune diseases, interested in engaging with the FDA and submitting an IND.

The product had: a complete set of **non-clinical studies,** completed **phase I and phase II clinical studies**, as well as available **IMPD and IB.**

The project presented the following challenges:

- Client **without prior regulatory experience** in the **US**
- **Critical deadlines** for timely approval of an additional Phase II clinical trial in the US

SOLUTION

The activities performed by Asphalion included:

- A **screening, cleaning and mapping exercise** to identify the non-clinical studies to be considered in the preparation of the IND sections
- Writing of the **non-clinical, drug substance and drug product IND sections** based on an existing IMPD
- Provision of **IND word template**s: up-to-date, ICH compliant CTD templates, including headers and footers according to client´s preference, active elements for creating Tables of Contents, List of Tables and List of Figures
- **Complete IND eCTD publishing**
- **Submission to FDA** through FDA electronic submissions gateway
- Asphalion appointed a **project manager** to coordinate the different teams and activities to ensure a timely delivery

OUTCOME

Successful results regarding:

- **IND templates** can be used for future submissions
- **Streamlining nonclinical studies** package to ensure an effective submission and a more focused evaluation
- Preparation of a robust **CMC package:** received no questions from FDA
- All tasks delivered within defined timeframe and **high quality of deliverables** that ensured a **successful IND approval** and led to a currently ongoing phase II study

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