IND to IMPD adaptation to open sites in Europe and Israel

BACKGROUND

The client, a US Biotechnology company, was running clinical trials in the US. With these existing trials going well, they wanted to expand their research program. They required a written IMPD within two weeks to adhere to their investors' ambitious site initiation timelines. An Investigational New Drug (IND) was already in place, with all the required data readily available and completed to a high standard.

HIGHLIGHTS

- Final draft of Investigational Medical Product Dossier (IMPD) ready within 2 weeks
- Application in the hands of an expert medical writer with 10 years' experience
- Qualified MD and QP - Assistance from the experts for the best outcome

CHALLENGE

The funding was in place for boosting recruitment and opening sites in Europe and Israel, but they didn't have the resources or knowledge to operate in line with European regulations. All their existing documentation was written to follow US guidelines, and they needed help to adapt to a new location and expand their research quickly and efficiently.

It was important to adhere to the short timelines as failure to do so could cause a delay in opening clinical trial sites and access to the drug for patients.

SOLUTION AND RESULTS

With our team of experienced writers, Morula Health were able to offer a rapid solution. We assigned a Medical Writer in the UK, who is also a QP with extensive experience writing CTD Module 3 and IMPDs. Using our secure file-sharing system, the source documents were uploaded and readily accessed and reviewed by the Medical Writer.

Within one week our writer began work, adapting the IND to IMPD. Working across time zones, we used the time more efficiently. It enabled the writer's questions to be sent at the end of their day and the answers to be in the client's inbox the following morning. The IMPD was finalized within two weeks, needing just one round of review. With these documents in place, the client's chosen CRO could move forward in seeking regulatory submission and contacting sites. Due to Morula Health's innovative solution, the research program was in an excellent position to expand.

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