

BUSINESS CASE

Case Study Analysis: Enhancing Safety in Clinical Trials



CHALLENGE

A leading pharmaceutical company launched one of the most widely used vaccines in the post-COVID era

The client's decision to outsource the safety activities resulted in our management of over 5 clinical trials concerning a COVID vaccine. This presented us with significant challenges, stemming from the urgent need to secure vaccine approval and the substantial volume of enrolled patients.

1. **High volume of safety data** which required a more **efficient workflow** to be properly processed.
2. Unexpected **surges of workload**, given that **recruitment and vaccination** for each study occurred at **different times**.
3. **Complex communication flows** and continued **collaboration with all parties**: Sponsor, CROs and clinical sites.



SOLUTION

Proactive initiatives were performed by Asphalion aimed at meeting the Authorities' deadlines and ensuring high-quality deliveries

1. **Identifying** relevant safety information and setting up **criteria and filters** for exchanging only **relevant safety data**. Asphalion agreed to implement **more frequent** reconciliations of safety data processed by all parties and **logical mismatch** resolution for minor discrepancies.
2. Asphalion developed a **back up system** to fix unexpected peaks of work and to **anticipate** start and closure of the studies.
3. **Periodic meetings** with the other parties were proposed and internal procedures were improved with more effective workflows.



OUTCOME

Successful outcomes achieved

- **Deadlines met**
On-Time SAEs management.
- **No mismatches**
Found in the periodic and final reconciliations.
- **Capacity to manage difficult projects and a high volume of work**
Working tools and key points identified.
- **Calendars**
Unforeseen spikes in workload were anticipated, and adequate resources were promptly allocated. Establishing an initial calendar proved to be essential.
- **Enhanced Safety standards within Asphalion's clinical trial system**
 - Internal procedures more complete and efficient.
 - Templates and workflows created to address the various possible scenarios based on the needs of the client.