

PHASE III CLINICAL TRIAL Study of Atopic Dermatitis

Achieving Stringent Study Timelines Despite Interim Regulatory Conditions

Study Background

A leading Indian Pharma company with expertise in discovering and developing a pipeline of first-in-class therapeutics wanted a partner to run a clinical trial with the ability to scale. The sponsor company was pressed on time since it wanted to be the first one to launch the drug in the Indian market. The results of this clinical trial would be key to the sponsor's DCGI approval of their drug candidate.



Problem

Site selection, recruitment, and enrollment are difficult under normal circumstances as the competitive timelines laid by the sponsor were very crucial.

Raptim would need to navigate different approaches and rules in response to meeting the timelines as well as all the regulations.

Sponsor Requirement

The sponsor wanted to get Clinical Trials done in the quickest possible timelines to get faster marketing authorization and first mover advantage in the market.

Challenges in the Study

- The SEC meeting asked the sponsor to provide interim safety data of the first 50 patients completed, as this was a new drug.
- The study deadlines did not budge despite the adversities.
- The sponsor and Raptim took the challenge and walked that path. The first 50 patients were recruited in 30 days' time.
- Despite the overall delay of 55 days, Raptim had to meet the stringent timelines to complete the project so that the sponsor had the edge over its competitors.

Strategy of Raptim

Raptim selected 15 sites for the Phase III trial with robust feasibility conducted across all of India from our database. Out of that, only 14 sites actively participated and still the requirements were fulfilled.

With the skills of project managers and with proper direction to the team, the Raptim team achieved the recruitment target of 184 patients in 2.5 months despite the special condition put by DCGI.



Conclusion

- Raptim provides sponsors with Clinical Trials expertise despite contingencies.
- Once again in a challenging environment, Raptim team achieved the enrollment goals.

When a sponsor needs a partner with the experience to run a difficult trial, Raptim knows how to execute and meet their expectations.

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