RAPTIM RESEARCH PVT. LTD.

A CONTRACT RESEARCH ORGANIZATION

PHASE II CLINICAL TRIAL

Treatment of Symptomatic Internal Hemorrhoids

Study Background

A US based company had a very promising novel mechanism corticosteroid in symptomatic treatment for Internal Hemorrhoids. The objective of the company was to finish the Phase II trial in the shortest possible time, to decide **"Go"** or **"No Go"** for further development.

Study Type: Randomized, Double Blinded Placebo Controlled Phase-II study.

Problem

Study was started in USA, where they decided to enroll 100 patients from US sites but recruitment was not progressing well. They were struggling to complete the patient numbers from US sites. Hence, they selected India as a destination to conduct this trial.

Raptim Research became their "Rescue Partner" in India.

Sponsor Requirement

Sponsor wanted to enroll from India as a part of their competitive recruitment strategy. Study ended with enrollment of 37 subjects.

Challenges in the Study

- **Covid-19 pandemic:** Project management of the entire study from start-up to completion including recruitment was in Covid-19 pandemic period.
- Internal Hemorrhoids patients' off-treatment for 2 weeks prior to randomization along with placebo control study.
- **Anoscopy procedure: Anoscopy was performed in a different manner not routinely done in India.** Anoscope was inserted 4 times to inspect and take videos of all 4 quadrants of affected area. Uploading video on central server also had unique process.
- **Adherence of Patients:** To achieve 100% patient compliance to two daily questionnaires.Literate subjects were enrolled but to retain them in study and ensuring they adhere to their study related responsibilities became a challenge.
- **Route of Administration:** Mode of drug administration through suppositories was not so common in India.

Strategy of Raptim

- Robust feasibility at 30 sites based on the experience of Project Manager.
- Subject compliance was maintained due to adopting following measures:
  - + Enrolling only literate subjects, who can use ePRO. Approximately 40% subjects enrolled used English ePRO questionnaires.
  - + Created mechanism, where CRA ensured that site CRC did twice a day follow up with the subjects and kept them motivated.
  - + CRC were provided the script and their conversation was documented in Telephonic conversation log.
- Dedicated site coordinator at each site
- Monitoring during Covid-19 Pandemic:
  - + Created remote monitoring plan and a platform
  - + CRAs ensured that site team completed source and CRF in timely manner and were uploaded on shared platform.
- QA audit was done for all sites
- Explanation about usage of suppositories:
  - + Pictorial laminates demonstrating suppository insertion in local language were provided to subjects as a guide.

Performance

	Agreed Timelines (as per Contract)	Actual Achievement
No. of Patients	37	37
No. of Sites	5	3
Recruitment Period	3 months	3 months
GCP Compliance	Yes	Yes

Conclusion

- In India, within record time and adhering to all quality standards, the project was completed as per agreed timelines despite the Covid-19 pandemic which was not considered in the proposal.
- This was the first suppository study in India of its kind.
- Based on the data from the study, they decided to move for future development program

Needless to mention that the GCP compliance and Quality was delivered at the fastest speed Fastest enrollment from lesser sites translated into cost savings for them.

Raptim Research Pvt. Ltd.

(INDIA):
A-226 / A-242, TTC Industrial Area,
Mahape MIDC, Navi Mumbai 400 710
Phone: +91-22-2778 1887/1889

(INDIA):
401, 406 to 408, Super Mall - 2,
Infocity Campus, Near Gh. Zero Circle,
Gandhinagar, Gujarat 382 009
Phone: +91-79-2321-3211 / 3212

(USA):
1378 Rt. 206, STE 6/280,
Skillman, NJ 08558
Phone: +1 609-333-9660

contact@raptimresearch.com | www.raptimresearch.com