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A Phase II study for an allergic asthma drug

Situation:

A Phase II study for an allergic asthma drug consisting of 60 patients across 5 sites.

Challenges:

Correction, confirmation and upload of electronic patient diary data onto the database by study site staff

Complex study design due to contraindication measurements (very strict timetables during patient visits)

SIRO Strategy:

SIRO conducted life-training with data of a test-patient during the initiation visit.

SIRO enhanced the e-diary system by incorporating changes in the E-Diary System (programming of checks etc.) during the study.

Investigator meeting and detailed initiation visits were performed to train the sites onto the study protocol and the urgent necessity to follow the timetable during patient visits.

All departments, investigator sites and sponsor worked in very close cooperation and had close communication lines.





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Result:

The patient diary data was of very good quality and became essential while showing the primary endpoint.

Despite the complexity of the protocol, all patient measurements were performed as stipulated.

At any time of the study, there was no backlog in any department. Study was set to high priority and as a result, the DB-lock was 5 days before timeline.

Sponsor Feedback:

“We really want to thank you and your team for the great efforts you have done in the study to keep the timelines and highly satisfied our needs within the study. We appreciate your proactive work and that potential hazards have been recognized, named and observed before they became a serious risk.”

-Sponsor PM

Investigator Feedback:

“My team and I want to thank you for the extraordinary good teamwork within the study and we would be glad to work with the SIRO Clinpharm Germany team again. We wish you all the best for the future.”

-Principle Investigator

“We enjoyed your competence and factual way of work during the study and we were pleased to work with you in such a good relationship.”

-Coordinating Investigator

