CASE STUDY
Immunology

Study
A randomized phase III study of the efficacy and safety of x the treatment of HAE acute attacks.

Study objective
The study objectives were efficacy, safety, immunogenicity after single and repeat administrations.

Investigational drug
A substitute therapy with replacement protein.

Primary Efficacy parameter
The study was designed to monitor subjective and objective clinical response.

Study details
Recruitment period: 15 months
Participating countries: Europe (Italy, UK, Romania, Israel) South America (Argentina)

Sintesi Research Services
Project management, regulatory, site coordination, investigators and CRA meetings, data management, QA QC, Statistics, final reports.

Key challenges

- Sintesi Research planned the activation of more experienced and motivated sites and maximized the potential of the on-going sites.
- Sintesi Research was asked to give a full service program to boost the enrolment.
- Sintesi Research was asked for a very detailed evaluation of the participating sites
- The Sponsor wanted a fast sites initiation to speed up the recruitment of a very limited population
- Sintesi was asked to run an interim analysis.
- The study plan was really challenging: it required the understanding of different medical cultures, different regulatory requirement, different drug/documents importation in addition of a very effective level of coordination. A capillary communication was needed.
- The existence of many registrative competitive trials in the same restricted population was also a challenging task.

- Trial related assessment required a very experienced staff and study team.
- The study procedures aimed to assess the tolerability and the efficacy required a very experienced staff and study team.

Keys of project success

Sintesi Research organized a local investigators with the participation CRAs and with the staff from the laboratory to familiarize them with the difficult study and drug administration procedures.

To maximize patients recruitment Sintesi Research performed a very precise country and sites evaluation and selected highly experienced and motivated investigators.

To keep constantly updated the sponsor about screenings and screening results Sintesi Research gave priority on team communication performing weekly teleconferences.

Sintesi Research team worked closely with each clinical site encouraging the investigators to complete enrolment and determining what resources were need to speed up enrolment.

Sintesi Research provided the sites with the study materials: booklets on study procedure, patients questionnaire, patients diaries, guidelines for performing tests and for completion of tolerability and efficacy assessment.

To discover Sintesi Research services contact us.
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