CASE STUDY
Oncology

Study description
Observational chart review launched with the aim to collect data from patients treated for Non-Hodgkin's Lymphoma with two different chemotherapy regimens.

Key study objectives
- Description of the proportion of patients with an investigator assessed risk of febrile Neutropenia (FN) ≥20% who receive primary prophylaxis G-CSF
- Description of the current treatment practice with CHOP chemotherapy including G-CSF, ESA use, anti-infective use, transfusions and hospitalizations
- Toxicities description including Febrile Neutropenia and anaemia
- Outcome measures of two different chemotherapy regimens

Patient population
Subjects diagnosed with NHL
Subjects ≥ 18 years old
Subjects planned to receive a minimum of 3 cycles of CHOP-14 or CHOP-21 with or without X.
(Include Retrospective subjects planned to receive 3 cycles– regardless of what they eventually received)

Participating countries
Pan-European participation

Study details
Non-interventional study
Approximate number of patients: 1800
Approximate number of sites: 120 sites
First site starting: January 2007

Sintesi Research Services
Project management, sites coordination and monitoring activities.

Key challenges
- Sintesi Research was asked to perform a competitive countries selection.
- The Sponsor wanted a prompt sites selection to speed up recruitment to quickly open 11 sites in Italy.
- The sponsor imposed that sites not enrolling subjects within two months from site initiation were to be closed.
- The study protocol required a to follow-up subjects for a minimum of five years or until treatment failure/disease progression or death).

Keys of project success
Since the study also aimed to include data from retrospective subjects, Sintesi Research supported the Investigators in reviewing their data base.
To meet study protocol follow-up period Sintesi Research has developed an exact management of all trial related procedures.
The study procedures and the numerous tests for the assessment of the tolerability and the efficacy required a very experienced staff and study team.
A particular attention to the population under study: since the most of the subject include were children a very careful approach was need.

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 exact country and sites evaluation and selected highly experienced and motivated investigators.

To keep constantly update 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 assessments.

Sintesi Research

To discover Sintesi Research services contact us.

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