CASE STUDY
Oncology

Study description
A Prospective Observational study of neutropenia and anemia management in subjects with solid tumors receiving myelotoxic chemotherapy.

Key study objectives
Primary:

Description of the incidence of febrile neutropenia (FN) based on G-CSF (primary, secondary or no usage) in subjects receiving myelotoxic chemotherapy.

Secondary:

- Description of the management of patients receiving myelotoxic chemotherapy including G-CSF use, ESA use, anti-infective use, transfusions and hospitalizations
- Description of current chemotherapy administration practices
- Description of all outcomes associated with myelotoxic chemotherapy

Patient population
Subjects with solid tumors (breast, ovarian and lung) with a risk > 20%
Subjects ≥ 18 years old

Study details
Pan-European participation
Non-interventional study
Approximate number of patients: 1300
Approximate number of sites: 100- 150 sites
First site starting: May 2008

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 rapid sites selection to speed up recruitment to quickly open 13 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 period of five years or until failure/disease progression or death

Keys of project success
To speed-up the enrolment Sintesi Research supported the Investigators in entering data in the e-CRF
To meet study protocol follow-up period Sintesi Research has developed an exact management of all trial related procedures.

Sintesi Research

To discover Sintesi Research services contact us.

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