OCT CLINICAL

Mabscale Biotech

Case Study:
Mabscale Biotech & OCT Clinical

Maximizing Efficiency in Data Management Services in a Breast Cancer Study

Study Details

Multicenter, prospective, double-blind, randomized, comparative, clinical study of the efficacy and tolerability of trastuzumab drugs in combination with neoadjuvant chemotherapy and subsequent adjuvant monotherapy in patients with HER2-positive operable breast cancer.

Mabscale Biotech

Mabscale LLC is an innovative biopharmaceutical company engaged in the development and production of medicines based on monoclonal antibodies and other recombinant proteins. The company is a biotechnological project of Ozon Pharmaseuticals, which offers generic products, antivirals, antibiotics, oxidase inhibitors, calcium, and other drugs.

Main Milestones

Development of the electronic CRF

Data validation

Database lock

Key Stages, Challenges and Solutions

1

Workflow in numbers

596 subjects to be randomized in the study at 35 sites. The study is in the active phase now, and more than 30,000 CRFs have already been completed, and are subsequently being processed by OCT Clinical's DM team.

2

Prepare a detailed CRF:

2 Detailed CRFs

The design of the study is quite complex with two stages of research (neoadjuvant and adjuvant treatment) and specific procedures and assessments. Therefore, a detailed CRF was developed by OCT's DM department with the support of the CRO's Clinical Team and the Sponsor.

3 Key solutions introduced

The DM team managed to implement a complex setting in the Trial Supply module for additional deliveries depending on the stage of subjects' treatment. A number of automatic calculations were set up using EDC to simplify work at study sites. Other automatic settings and timely manual checks by the DM team were set to reduce the number of errors and the chance of the inclusion of non-eligible subjects.

The OCT DM team have been preparing detailed trackers and status checks for each study site and taking part in project team meetings with colleagues from the Clinical department. This assists them in tracking problematic data and correcting it in a timely manner.