OCT CLINICAL

Case Study:

Data Management Solutions for a Clinical-Stage Cancer Immunotherapy Study

Study Details

Clinical first-in-human study evaluating the safety and tolerability of an investigational cancer immunotherapy in patients with advanced melanoma.

About the Sponsor

The Sponsor of the study is a biotechnology company based in Europe that specializes in the development of cancer immunotherapies.

Phase: I • **Duration:** 2014 to 2023 • **Location of sites:** Europe

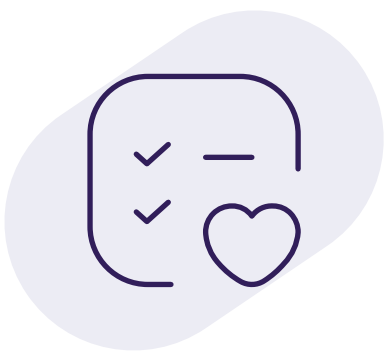
Main Milestones

Database setup

complete

Data processing after each study cohort

complete



Subjects treatment

in proccess

Database lock

in proccess

Key Stages, Challenges and Solutions

1 Challenges

OCT Clinical Data Management team managed a wide range of CRFs and Database development despite the complexity of the study design and treatment schema. In collaboration with the Sponsor's team, the first version of CRF was created with the utmost quality, in order to negate the need for major changes as a result of subsequent updates of the Protocol related to new study cohort additions.

2 Workflow in numbers

There were 14 versions of Study Protocol, 9 main CRF versions. More than 26,000 completed electronic forms, >5,000 closed queries, >10,000 coded medical terms; 51 SDTM and FDA compliant datasets.

3 Efficient communication

The OCT Clinical team holds regular team discussions on both current project issues and future tasks. This type of communication and team structure allows for the best solution to be found in the case of difficult technical tasks related to the design of databases and other issues. Clearly, careful scheduling ensures that deadlines are firmly adhered to.

4 Multilevel verification

All collected data go through several stages of validation, not only carried out by the OCT DM team, but also with the involvement of the Sponsor, which promotes confidence in the quality of received data.
At OCT no request goes unanswered.

The extensive duration of the trial has meant that new team members from both OCT DM and the Sponsor have joined the team over time. Nevertheless, what remains unchanged is how each member of the team is completely dedicated to the project.

Reach out to OCT Clinical experts to explore your clinical trials options

oct-clinicaltrials.com