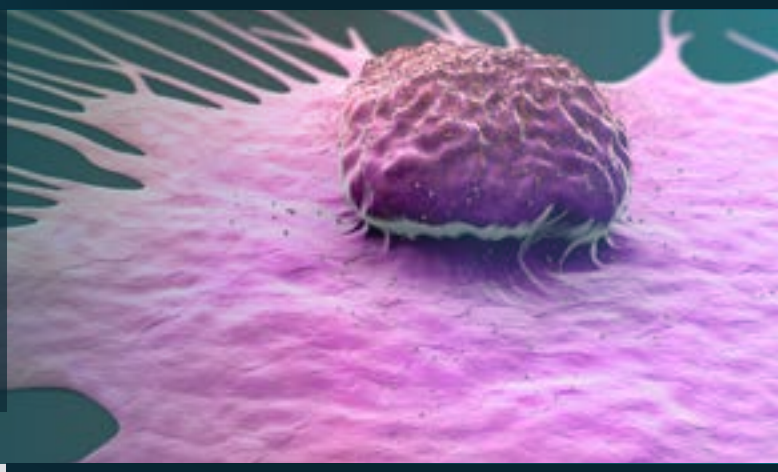
Case study

SIMBEC-ORION

Phase III rescue study: resolving site issues through CRO collaboration and on-site training



Metastatic breast cancer

An open-label, randomised, parallel, two arm, multicentre, international Phase III study in patients with recurrent or metastatic breast cancer previously treated with cytotoxic chemotherapy regimens.

Background

A sponsor that had previously worked with Simbec-Orion invited us to re-monitor a percentage of work being conducted by a mega CRO on their phase III breast cancer study. The sponsor was questioning why they were not seeing a normal level of background noise in the study (particularly protocol deviations) and wanted us to help investigate.

Objectives

- To review the active study sites and the monitoring practices and conduct of the existing CRAs.
- To identify any issues with the conduct of the study, including data collection and reporting, and report back to the sponsor.
- To work in partnership with the sponsor and existing CRO to rectify past issues and ensure the project remained within the inital projected timelines, and that high-quality, accurate data was obtained.

Potential problems were identified with the data collected by the existing CRO across one third of study sites

Worked with the existing CRO to rectify issues through mentoring and training

Tactful, honest and open communication with the existing CRO and the sponsor

After intervention the study was completed within the initial timelines with high-quality publishable data

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Challenges

Our initial review confirmed that there were substantial issues with one of the sites, especially with the level of source data verification. We were asked to examine more sites and review the RECIST assessment of tumours. We found that there were errors in the data collected, with potential problems across one-third of sites.

One site was highlighted by the sponsor as a potential fraud concern as data was constantly changing between visits.

Due to the size of the study, the sponsor wanted to continue the relationship with the mega CRO but wanted Simbec-Orion to work alongside them to resolve the issues identified.This required a tactful approach which relied on honest communication and teamwork from all parties.

Solutions

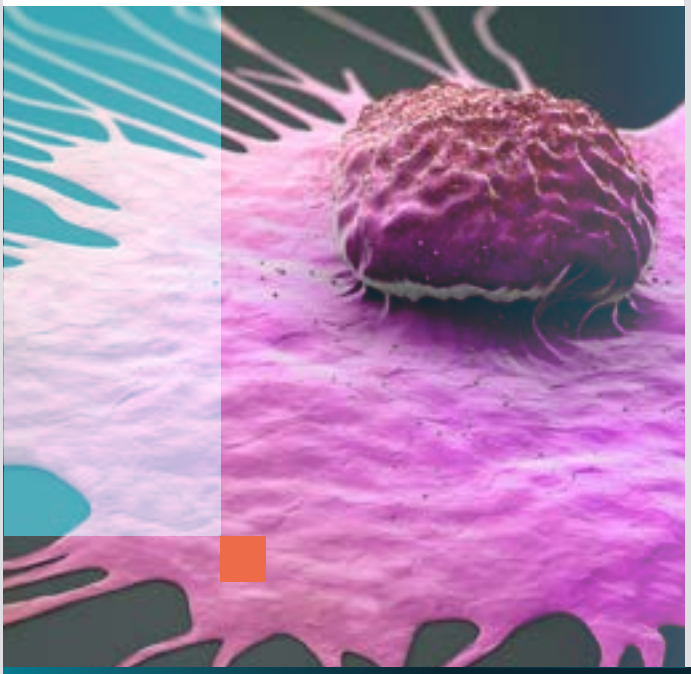
- Simbec-Orion set-up a team of senior, highly experienced CRAs (Clinical Research Associates) to attend sites alongside the existing site monitors. As a result of this preliminary work, re-monitoring was extended in selected areas, re-monitoring of tumour assessment data for a percentage of patients was requested and the highest recruiting site was judged to require 100% re-monitoring.
- We dedicated time to develop a relationship and rapport with the other CRO's team, developing a mentoring strategy to train junior CRAs. Senior CRA's from Simbec-Orion shared guidance and experience, which was well received and improved performance.
- For the potentially fraudulent site we conducted a 100% retrospective re-audit and re-SDV of all information. Significant data was found in the patient records which had not been uploaded to the eCRF, leading to concerns the site might be taking the fee without completing the work. We undertook a second Site Initiation Visit (SIV) for this site and retrained all staff, which remediated behaviour at the site.

Outcome

Simbec-Orion's high-quality monitoring by our experienced CRAs ensured that this large phase III study provided high quality, publishable data to support the further development of the drug.

Once additional attention was applied the study, it proceeded positively to completion and the sponsor was pleased with all parties' involvement.

Our collaborative approach and expertise helped the sponsor get the project back to original timelines, leading to a successful study after the rescue period, with all parties satisfied.



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