OCT CLINICAL

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Case Study:
Samsung Bioepis & OCT Clinical

Completing 100% recruitment 7 months ahead of schedule for a lung cancer study

OCT Clinical, a mid-sized European contract research organization, was contracted by Samsung Bioepis to run a Phase 3 lung cancer clinical study jointly with a global CRO. The CRO successfully completed its part of the study having reached 100% recruitment 7 months ahead of the global target.

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Study Details

Samsung Bioepis, one of the world's leading biopharmaceutical companies, ran a clinical trial for its own biosimilar product in 13 countries. OCT Clinical was contracted as a local CRO and was responsible for running full-scale clinical trial activities with the recruitment goal of 254 patients across 21 research sites in Russia. Whereas the Global CRO recruited 509 patients at 79 sites in other countries, including Germany, Spain, Serbia, Georgia, South Korea and Taiwan.

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Established in 2012, Samsung Bioepis is a biopharmaceutical company committed to making healthcare accessible to everyone. Through innovations in product development and a firm commitment to quality, Samsung Bioepis aims to become the world's leading biopharmaceutical company. Samsung Bioepis continues to advance a broad pipeline of biosimilar candidates that cover a spectrum of therapeutic areas, including immunology, oncology, ophthalmology, hematology, endocrinology and gastroenterology.

This was a Phase III, randomized, comparative, double-blind, two-parallel group, multicenter study in subjects with metastatic or recurrent non-squamous non-small cell lung cancer.
The aim of the study was to demonstrate the efficacy, safety, pharmacokinetics, and immunogenicity of the investigational drug (biosimilar) compared to a comparator during a 24-week chemotherapy period.

Lung cancer is the second most common cancer in men and the third most common in women, accounting for about 13% of all cancer diagnoses, but it is the leading cause of cancer-related deaths in industrialized countries. About 10–15% of cases occur in people who have never smoked. These cases are often caused by a combination of genetic factors and exposure to radon gas, asbestos, second-hand smoke, or other forms of air pollution.

- Recruitment goal: 763 subjects in total (254 in Russia and 509 in other countries)
- Two CROs: a Global CRO and a Local CRO (OCT Clinical)
- Combination of CROs' and the Sponsor's SOPs
- 100 research sites across 13 countries

OCT Clinical's Scope of Responsibilities

OCT Clinical was contracted by the Sponsor to perform clinical trial activities and enroll 254 patients. This was a full-service clinical project in which OCT Clinical provided the full range of regulatory and clinical research activities including site selection, regulatory support, submissions to local ethics committees, execution of contracts with research sites and principal investigators, organizing

investigators' meeting, as well as activities related to project management, monitoring, quality assurance and logistics, obtaining of an import license for the study drug and an export license for the biosamples shipment. The CRO was also in charge of selecting and dealing with the local warehouse. In total, OCT was responsible for 21 active research sites.

Challenges

The OCT Clinical team faced several challenges during the study and had to come up with a swift and effective set of actions to ensure continuity and success of the trial.

1

Large amount of data

The major challenge for the OCT Clinical team lay in the size of the enrollment target it was responsible for, which amounted to a third of the total number of patients for this study. Big recruitment goal meant a large amount of data for CRAs to process and send to the Sponsor.

2

Strict timelines

Due to a large amount of data, the team had to be able to plan and foresee how much of this data was expected at every given point in time in order to process and send those data cuts and interim project results to the Sponsor in a timely manner.

3

Penalty system

Failure to meet milestones within the project could result in fines for the CROs.

Key Solutions

To address the issues described above and ensure the success of the trial OCT Clinical incorporated the following measures:

Back-up CRAs

To ensure timely and compliant execution of study goals, the OCT team introduced a back-up clinical team. Three additional CRAs with an extensive Oncology background were trained and prepared to be available on stand-by mode. The back-up team underwent the same training as the core team and took part in all project meetings and maintained related correspondence in order to stay in the loop.
They were occasionally required to take over various tasks, for instance, during monitoring visits or when another set of data cuts was due. When the core CRAs were fully occupied workingon tasks like data verification and could not deal with such activities as accountability and study file checks, back-up CRAs were assigned to take over these parallel assignments. This approach helped to ensure timely data cuts delivery and data clearance.

Flexible CRA visits

This system presumed adaptive frequency of CRA visits based on a set of key metrics developed specifically for this study. Upon the occurrence of a certain event within the metrics, the monitoring schedule would be adjusted accordingly. When necessary, not only the frequency, but also the make-up of the team could be altered by engaging the back-up CRAs.

Site by site analysis and data extrapolation

During regular teleconference calls every incoming piece of metrics and analytics from Data Management was discussed on a site-by-site basis. Based on this analysis, a set of measures for every case was then introduced. Afterwards, the solutions for individual sites were presented during global discussions so that every team member was aware of these scenarios, knew how to deal with them and was able to extrapolate individual solutions and apply them when needed.

High engagement and close communication

OCT Clinical introduced regular experience exchange and project discussions in between project meetups to achieve maximum engagement of each team member. All team members participated in every TC, where each issue, query and overall progress were collectively discussed.
This allowed everyone to have a clear understanding of the project status at any given moment. Additionally, the team did collective problem-solving to ensure that everyone knew how to deal with certain challenges, and could share their recommendations on handling various issues.

Major Drivers for Success

1. Core team. A well-balanced project team was hand-picked and put together for this trial based on their portfolios and experience in Oncology. The OCT Clinical project team consisted of one Project Manager, one CRA Lead, four Senior CRAs and one Coordinator.

2. Sponsor's involvement. The Sponsor's team was actively involved in all stages of the project, which enabled streamlined communication and seamless CRO data management. The Samsung team consisted of two Country Managers, one Global Project Manager and one Head Officer.

3. Quick onboarding. Due to the effective knowledge management system and data storage set-up, all project information was easy to access and operate for the OCT Clinical team. That, together with their professional background, allowed the back-up team members to have a quick and smooth introduction to the project.

4. CRO's background. With 17 years of experience in Oncology, OCT Clinical has in-depth expertise in organization and conducting of phase III (pivotal) clinical trials. Since it was founded in 2005, OCT has successfully completed 71 phase III Oncology studies, including studies in non-small cell lung cancer patients.

5. Well-established collaboration with specialized sites. Due to exclusive long-term partnerships with 300 leading Oncology clinics in 10 countries OCT Clinical has access to tens of thousands targeted patients in cancer indications.
This allows the achievement of high enrollment rates and impeccable quality of clinical data.

6. Risk-management approach. Implementation of and adherence to effective risk-management strategy before the start of the study.

“We were honored when the Sponsor turned to us to conduct such an important study. We did our best to draft our most effective resources and deliver maximum performance to achieve the Sponsor’s goals while ensuring patients’ safety”

Project Manager, OCT Clinical

“We're pleased with the OCT team for having successfully completed our study and achieving patient recruitment target ahead of the schedule”

Luke Oh, Ph.D., Product Evaluation Team Leader, Samsung Bioepis

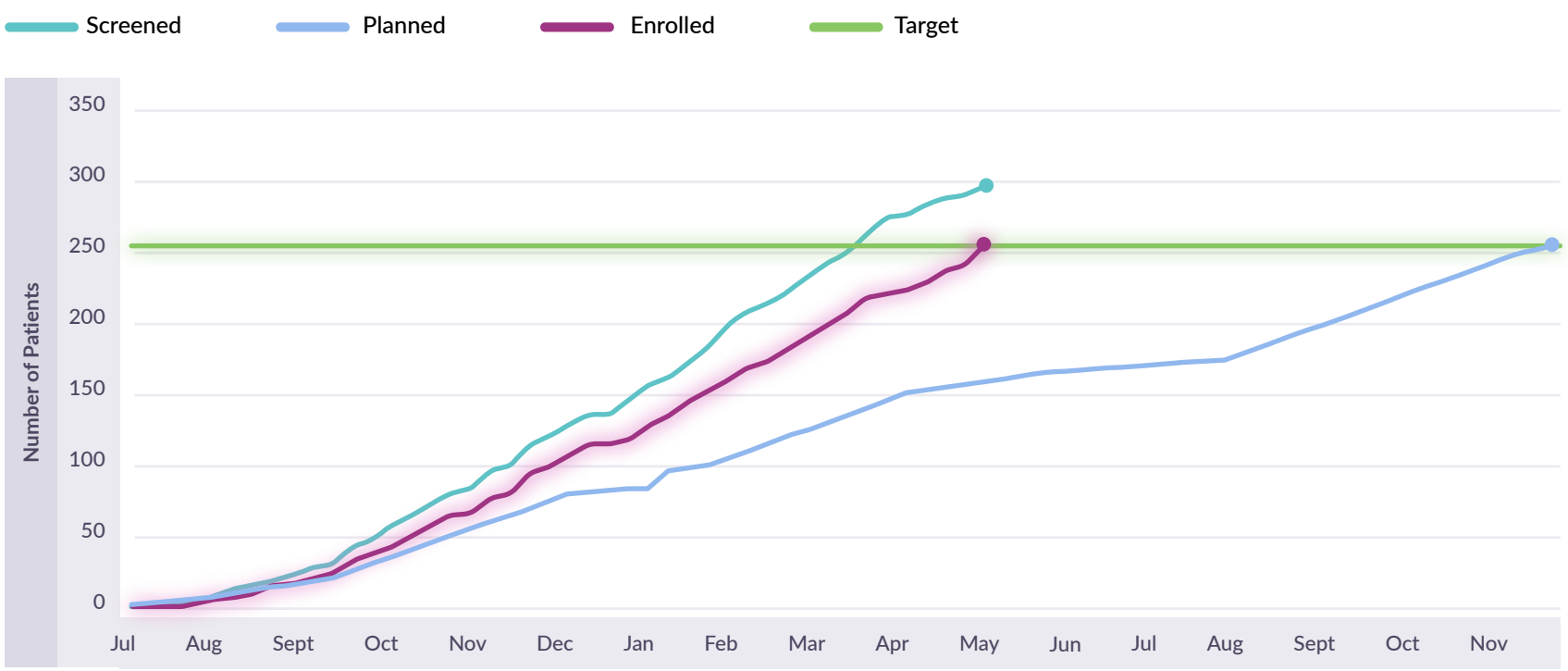
Outcomes & Key Study Metrics

All milestones set by the Sponsor (e.g. CTA/EC submission, CTA/EC approval, site initiation, first subject randomized, last subject last visit, data base lock, final clinical study report, transfer of all documents to Sponsor) were achieved by the OCT Clinical team ahead of schedule. Among the most critically important achievement is the fact that the enrollment target of 254 randomized patients was reached by the CRO within an impressive 8 months at a 14% screen failure rate and 7 months ahead of schedule.

Key Metrics	Outcome Achieved by OCT Clinical
Total enrollment, subjects	254
Active sites	21
Average enrollment by site, subjects	12.09
Screening failure rate	14%
Data queries per patient	149
Protocol deviations per patient	1.4

Milestones	Service Delivered by OCT Clinical
IDMC	2 weeks ahead of the stipulated timeline
First Database Lock	2 weeks ahead of the stipulated timeline
100% enrollment complete for a Country (254 randomized subjects)	7 months ahead of schedule
Final Database Lock	1 week ahead of the stipulated timeline

Enrollment Timeline



OCT Clinical conducted its part of the trial according to ethical and GCP standards and successfully passed an EMA inspection. The OCT Clinical team was also engaged by the Sponsor to provide necessary information for the inspection run by the Ministry of Health and Welfare of the Republic of Korea.

Apart from the immediate contribution to the overall research, the study has extended the knowledge of therapeutic strategies in the treatment of non-small cell lung cancer.

Reach out to OCT experts to explore your clinical trials options

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