18 YEARS OF EXCELLENCE IN RESEARCH

cliantha research

The keys to success in a Phase II Trial in Advanced Stage Non-Small Cell Lung Cancer (NSCLC)

Cliantha Research has now developed - a proven track record in complex patient-based trials such as outlined in this case study.

Cliantha's team of experts in oncology and clinical trial management are able to deliver clinical trial outcomes of high quality in a timely manner, that are required in late phase studies, where our clients require ef cient management to move them forward in their drug development program. These milestones are achieved by understanding the requirements and importance of technical excellence and operational expertise.

By leveraging our in-depth knowledge base and clinical research ef ciencies, Cliantha has broadened its horizon in the eld of Oncology by successfully conducting a Phase II clinical study for a Novel Aerosol Therapy in patients with advanced-stage Lung Cancer.

Molecule	NCE
Indication	Advanced-Stage Non-SmallCell Lung Cancer
Phase of the study	Phase II – Novel Therapy
Population	NSCLC who are - Not candidates for curative surgery, radiation or immunotherapy Receiving Standard of Care (SOC) Pemetrexed and Carboplatin Measurable disease as per RECIST and ECOG ≤ 2
Patients & Sites	60 Patients & 10 Sites in India

Challenges:

- Recruitment of NSCLC patients, who are not candidates for curative surgery, radiation or immunotherapy and who are receiving standard of care Pemetrexed and Carboplatin. While in the advanced stage of disease, these patients also required a high degree of self-management (ECOG ≤ 2).
- Retention and compliance of patients on SOC and SOC+NCE
- Attracting 10 high-quality sites with top KOLs in India where competition for resources and patients
- Regulatory complexity.

The Cliantha Advantage

- Regulatory expertise and knowledge led to early protocol approval, before agreed timelines.
- Scientfic and clinical research teams had a good understanding of NCEs and supported for study design and regulatory questions.
- Designation of a project management team, that was experienced in the conduct of successful Phase II oncology trials.
- Ensured selection of experienced and productive Investigator sites.
- The attraction of KOLs in Oncology in India.
- Provision of required and methodical training and standardization of PIs and site staff.
- Development of Nebulizer usage training modules for site staff and patients.
- Subject retention was maintained due to team's dedication, skill, know-how, and training. At this stage in the study, approximately 90 of subjects have completed 4 cycles of treatment or reached the 3-month stage.
- More evaluable subjects completed the trial than anticipated, which improved the power of this trial to evaluate this Novel Aerosol in the safe adjunctive treatment of NSCLC on SOC.

Conclusion:

Cliantha's knowledge and experience led to:

- An efficient study startup including regulatory support to drive streamlined approvals sooner than estimated.
- Standardized training of PIs and personnel in key study procedures and outcome measures led to high-quality outcomes.
- Successful recruitment of the right patient population and retaining patients in the study.
- Regular monitoring to keep PIs and their sites on track and to ensure high-quality outcomes to form a discriminative and robust study for our Sponsors.

Contact Cliantha for more information about how we can make your patient-based trial successful.

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