

CRITICAL MILESTONES ACHIEVED AHEAD OF SCHEDULE IN LUNG CANCER STUDY

In a global, mutationally defined lung cancer study, low screen failures, strong communication and collaboration lead to swift site initiation and rapid enrollment

SITUATION

IQVIA™ Biotech was selected by a biotechnology company preparing to launch an international Phase III clinical trial for its investigational anaplastic lymphoma kinase (ALK) inhibitor in patients with non-small cell lung cancer (NSCLC). As this was a highly competitive space with more than five companies pursuing the same market, the sponsor's clinical operations team was seeking an oncology-focused partner who could support protocol design and accelerate the start-up process to meet enrollment milestones quickly. IQVIA Biotech's oncology team leveraged our extensive NSCLC operational experience, global footprint, and strategic resources to execute this large Phase III study.

Following a competitive review, the sponsor selected IQVIA Biotech to lead the study, managing Europe and Asia, while the sponsor managed North America (NA) in-house. This case study will focus on the ex-NA portion of the clinical trial covering more than 100 sites across nearly 20 countries.

Global study overview



CHALLENGES

The sponsor was motivated to quickly initiate and accrue the Phase III trial to beat competitive drugs to market. Other challenges included:

- Aggressive regulatory strategy and timelines for first site activated and first-patient-in
- A narrow window for accrual maximization, where a competitor's trial was ending and before that drug's anticipated approval
- Integrating site identification efforts from the sponsor, as referred by local medical science liaisons (MSLs)

"IQVIA Biotech's management and oversight of the trial have been very organized, efficient and collaborative, which have been instrumental in driving us toward the successful milestones we've already reached to date."

— Manager, Clinical Operations

SOLUTION

Following impressive Phase II results, IQVIA Biotech and the sponsor were eager to move forward with the Phase III study. IQVIA Biotech's study team worked to get enrollment started as soon as possible, beginning with strategic alignment, kick-off and data collection review meetings, and a focus on country prioritization. The team provided input on the protocol to anticipate potential FDA concerns related to lung cancer trials and guided the sponsor seamlessly through the start-up process globally. The EDC system was live within six weeks of the kick-off meeting.

STRATEGY

IQVIA BIOTECH EMPLOYED SPECIFIC STRATEGIES IN ORDER TO SPEED ENROLLMENT:

- IQVIA Biotech leveraged excitement and interest around Phase II results to motivate investigators and increase response times
- Our strategic feasibility team identified sites and PIs with a working knowledge of complex ALK inhibitors to ensure they could recruit appropriate patients. They leveraged competitive intelligence and advanced analytics to specifically minimize sites with potentially competing trials. Conversely, our team targeted centers where we knew a competing trial was ending, with direct outreach to offer a new trial so their patients would continue to have treatment options
- IQVIA Biotech's study start-up team provided training and tools to support each site
- IQVIA Biotech collaborated with the sponsor's MSL team to enhance site/PI conversations, work through the start-up process, and drive accrual
- Exceptional planning by the clinical operations team led to very low screen fails – a difficult task among advanced cancer patients
- Collaboration between regions provided complete operational coverage across North America, Europe and Asia Pacific, led by an IQVIA Biotech global project manager
- Teams with IQVIA Biotech and the sponsor developed strong working relationships and communication, paving the way for quick decision-making and preventing delays

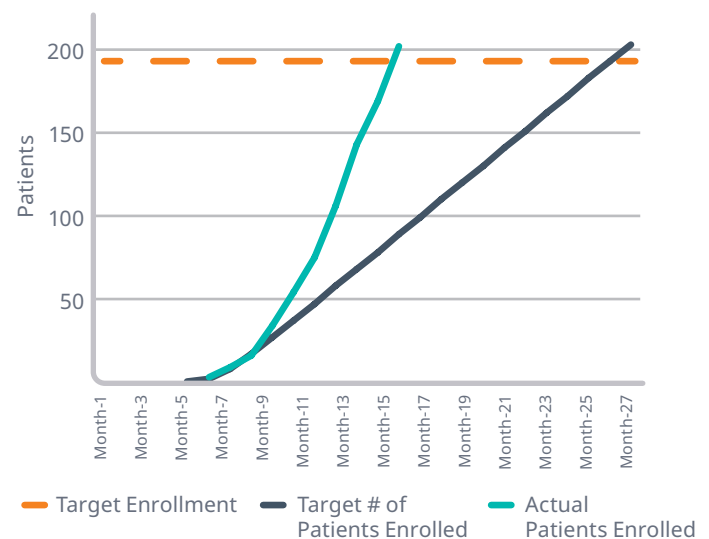


RESULTS

IQVIA Biotech exceeded the sponsor's expectations by reaching multiple milestones ahead of schedule, including last-patient-in (LPI). In fact, because our performance was so strong ex-NA, we over-enrolled our contracted target and took on a portion of the sponsor's NA accrual goals.

A SUMMARY OF ACHIEVEMENTS:

- Very low screen fail rate of 8%
- 25% patients enrolled – two months ahead of schedule
- 50% patients enrolled – four months ahead of schedule
- 75% patients enrolled – seven months ahead of schedule
- Global end of enrollment – met LPI milestone eight months ahead of schedule
- Over-enrolled ex-NA target, taking on a portion of sponsor's internal goal



Patient enrollment milestones for ex-NA sites managed by IQVIA Biotech were all met ahead of schedule.

CONTACT US
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