CASE STUDY

# A Lung Cancer Imaging Success Story

## A Multi-Stakeholder Lung Cancer Study That Uncovered Hidden Tumors and Achieved FDA Approval

### Situation

Caidya undertook a complex clinical research project of an **intra-operative lung imaging study** focused on **lung cancer patients**.

The objective was to provide **intra-operative identification** of cancer cells using a **novel imaging** system. This system incorporated a special camera, and a **folate analog combined with a fluorescent dye**, enabling surgeons to visualize tumours not detectable by the naked eye or standard imaging methods.

The project was executed in collaboration with medical device vendors Stryker and ISRG, with data collection support provided by On Target.

### Challenge

The study faced **several significant challenges**, particularly due to the constraints of the COVID-19 pandemic and the complexity of the trial. Key challenges included:

- **Real-Time Data Documentation:** Coordinating high volumes of data during surgeries required precise, real-time documentation to maintain study integrity.
- **Limited In-Person Access**: Pandemic restrictions reduced physical access to operating rooms, requiring the team to use video recordings to verify data remotely.
- **Surgery Classification as Elective**: Hospitals initially classified surgeries as elective, causing delays. The team worked closely with hospitals to reschedule procedures and minimize disruptions.
- **Vendor Coordination**: Integrating imaging technology from Stryker and ISRG added complexity, requiring seamless collaboration to ensure consistent use across surgeries.

Despite these hurdles, the team's ability to adapt quickly, maintain strong communication, and implement strategic solutions allowed the study to proceed successfully and achieve its objectives.

## Solution

To address the challenges posed by the COVID-19 pandemic and ensure smooth trial execution, Caidya employed a **combination of proactive strategies**.

On Target deployed representatives directly in the operating rooms to facilitate real-time data collection, ensuring adherence to the study's strict protocols. When pandemic restrictions limited in-person access, **video recordings of surgeries** were used to validate data and maintain study integrity.

The team also coordinated with hospital staff to reschedule surgeries that had been delayed due to the designation of the procedures as elective.

Throughout the trial, real-time eligibility assessments and randomization ensured that patients were appropriately included, and **seamless collaboration with vendors**, ensured that the imaging technology functioned effectively in the clinical setting, **revealing cancerous lesions** that would have otherwise gone unnoticed.

## Outcome

Despite the challenges, the trial was **completed ahead of schedule**, uncovering **23 previously undetected cancerous lesions**, which would have had significant impacts on the patients' lives.

Undetected primary lung tumors were identified in **19% of participants**. An additional 8% had one or more cancerous lesions **not visible on imaging** or to the surgeon during the procedure.

Without this detection, these lesions would have remained untreated, increasing the risk of disease progression. For these 23 patients, the findings likely prevented recurrence and significantly improved their prognosis.

The **FDA audit** concluded with zero findings and led to quick **FDA approval** of the imaging technology. The study provided life improving and/or life saving therapy for patients in the trial, and for other patients after its approval.

The sponsor expressed high satisfaction with the results and has recommended Caidya to other biopharma companies.

**23** The study uncovered 23 previously undetected cancerous lesions.

- **Ahead of Schedule Completion**
- **Successful FDA Approval**
- **Seamless collaboration with vendors**

**Caidya's real-time imaging process identified 23 clinically significant lesions, passed a 100% FDA audit. The study provided life improving and/or life saving therapy for patients in the trial, and with the treatment approval, opened the possibility for early detection and treatment in a number of patients.**