



## CASE STUDIES

# Accelerating Enrollment and Upholding Quality in Complex Oncology Trials

Below is a spotlight on two recent oncology trials where sponsors partnered our wholly owned oncology sites (Valkyrie Clinical Trials) to overcome challenges associated with complex trial design and execution. Across both studies, we delivered:

- **Faster startup and enrollment** in hard-to-recruit patient populations.
- Reduced operational friction in **biomarker-driven recruitment** involving **tissue procurement**.
- **High-quality data** delivery.

### CASE STUDY 1: Phase III double-blinded PD-L1 Lung Cancer Study

#### Challenge: Extremely Narrow Recruitment Window

This Phase III lung cancer study required newly diagnosed, **untreated patients with high PD-L1 expression**. These patients are typically initiated on standard-of-care therapy almost immediately, leaving a very limited window for identification and referral.

#### Our Strategy

We leveraged our well-established and unique rapid response physician network to identify eligible patients at the point of diagnosis and direct them toward the study.

#### Results

Our sites were:

- ✔ **First to enroll** patients among hundreds of global sites.
- ✔ **Strong enrollers** throughout the study.
- ✔ Recognized by the sponsor as **“Protocol Adherence Champion”** for highest quality among all sites.



#### Rapid Response Physician Network

We have built a robust and highly responsive network of 150+ physicians for rapid identification of trial participants. This enables real-time communication of eligibility criteria to providers to ensure timely and precise referrals. Patient pathway timelines can flow as follows:

- **24-hour network response**
- **Three days to patient visit**
- **Treatment within two weeks**

## CASE STUDY 2: Phase II – Phase III double-blinded Colorectal Cancer Biomarker Program

### Challenge: Complex Biomarker and Operational Requirements

While colorectal cancer recruitment is typically not a challenge, the combined factors below created substantial enrollment and operational barriers across participating sites.

- Inclusion criteria required a rare MMR/MSI assay, not commonly performed in standard oncology practice.
- Significant initial delays in tissue procurement from pathology labs.
- Requirement to rerun MMR testing despite prior negative results, creating resistance from referring physicians.

### Our Strategy

- Hands-On Operational Execution: Actively managed **tissue procurement**, including direct follow-up and escalation where needed and oversight of biomarker workflows end-to-end to minimize delays.
- Adaptive Enrollment Strategies: Incorporated **liquid biopsy (NGS)**, where permitted, to accelerate patient qualification, reducing sole reliance on slower tissue-based testing.

### Results

Our sites:

- ✔ Successfully overcame tissue and testing barriers that delayed enrollment elsewhere.
- ✔ Achieved **first patient treated, within two weeks of activation**, ahead of all sites globally.
- ✔ Enrolled the **first three patients globally** for the trial and hit enrollment goals for study.
- ✔ The sponsor used our processes as training for other sites in the study.

Flourish Research's dedicated oncology sites combine deep experience, strong referral networks, and adaptive clinical strategies to deliver superior performance in complex oncology trials. This approach accelerates enrollment timelines in both frontline and later line treatment scenarios, while maintaining the highest standards of quality and protocol adherence.



## Let's Get Your Oncology Trial Moving!

Learn more about our oncology capabilities or reach out today for a custom feasibility assessment.

**SEE OUR  
CAPABILITIES**