



CASE STUDY

PRAHEALTHSCIENCES

PRA RESCUES DIAGNOSTIC CANCER STUDY

Successfully Delivered On Time For The PMA Filing



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STUDY DESCRIPTION

A performance comparison study of a new in-vitro diagnostic test in patients with or at risk for colorectal cancer.

PRIMARY ENDPOINT

Comparison Test

PRA SERVICES

Project Management
Vendor Management
Startup Activities
Administer Investigator Payments
Site Recruitment
Negotiate Investigator Contracts
Site Management
Site Monitoring
Data Management with EDC
Document Management

INDICATION

Colorectal Cancer

BUSINESS SEGMENT

Clinical Diagnostic Services

STUDY DURATION

8
MONTHS

NO. OF CLINICAL SITES

75

PATIENT POPULATION

300

REGIONS

North America



SITUATION

A molecular diagnostics company with a novel in-vitro diagnostic test to detect colorectal cancer requested that PRA Health Sciences help transition a full-service study crucial to its premarket approval (PMA) filing. The previous CRO had missed site and patient enrollment milestones, potentially jeopardizing the study's PMA filing and Food and Drug Administration (FDA) approval.



CHALLENGES

The previous CRO's site selections were not yielding the patient enrollment necessary to meet the study's established timelines. Due to the inherent nature of non-interventional study designs, patients could not be recruited outside of the site practice or be seen at offices outside of their standard of care (SOC). The Clinical Diagnostics Services team needed to quickly identify sites and expedite study start-up to achieve on-time FDA submission.



PRA's Clinical Diagnostic Services group had to coordinate the study transition and get the project back on the correct path for success while maintaining the sponsor's original timelines. These challenges required PRA to:

- Quickly assess the current status of the project and each site to identify, reconcile, and resolve outstanding issues.
- Expediently transition sites from the previous CRO to PRA with minimal site disruption.
- Complete a quality check (QC) of study files and obtain any missing regulatory documentation from the sites.
- Identify new sites to be qualified and activated, as well as develop standardized training and retrain current sites.
- Re-engage and motivate active sites to deliver clean data and evaluable samples.
- Build a new electronic data capture (EDC) system and develop a process to transition from paper CRFs to electronic CRFs (eCRFs).
- Lock the database within a shortened time frame.

With the previous CRO achieving less than 2% of the enrollment goal, PRA also faced the challenge of fulfilling enrollment and sample targets (n=600) for 2 difficult cohorts of patients within 8 months from project rescue to data delivery.



SOLUTIONS

PRA's project team developed a number of strategies and executed a customized operational approach to meet the sponsor's requirements and overcome the study's challenges. Our steps involved:

EVIDENCED-BASED METHODOLOGY

- PRA's industry-leading Medical Informatics group supported the project by identifying additional sites for recruitment that had patients within their current practices.
- PRA conducted comprehensive quality control reviews of site start-up documents and training records.
- All samples were accounted for and documented accordingly, and any discrepancies were immediately addressed with sites and laboratory vendors.

PROACTIVE SITE SUPPORT

- Site management associates (SMAs) provided key site oversight and management, seamlessly transitioning sites and enhancing site motivation and engagement in the study.
- The SMAs averaged approximately:
 - **600 site contacts per month.**
 - **Over 5,000 site communication exchanges during project execution.**

OVERSIGHT & SUPPORT

- Senior management provided continual oversight and directed clear communication with the sponsor to ensure **high quality deliverables and full transparency.**
- Our direct engagement with the sponsor promoted prompt transitions and decision-making.
- The team demonstrated flexibility in resourcing SMAs and CRAs to complete site initiation visits (SIVs) to avoid impeding study progress or causing further delays due to scheduling conflicts.
- PRA's management and executive teams completed site calls to promote the study, integral logistics, and enrollment milestones.

INNOVATION

- Our team created new training modules, site motivation materials, and customized status alerts/notifications.
- Comprehensive blinding procedures were developed and sample tracking and reconciliation processes were put in place to meet regulatory requirements.
- PRA built the EDC database with an innovative tool (Medrio) to enable the design, testing, and production to occur **within 8 weeks of contact.**

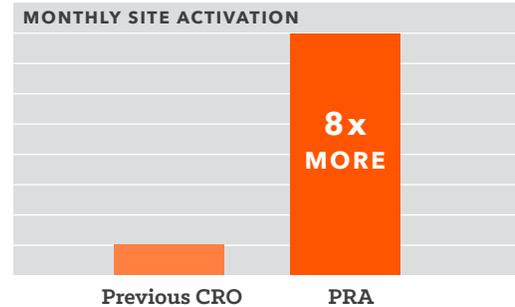


RESULTS

Thanks to the Clinical Diagnostic Services group's determination to meet the sponsor's aggressive timeline, commitment to quality, and tailored solutions for operational delivery, PRA and the sponsor achieved strategic study milestones and **successfully delivered the PMA filing**.

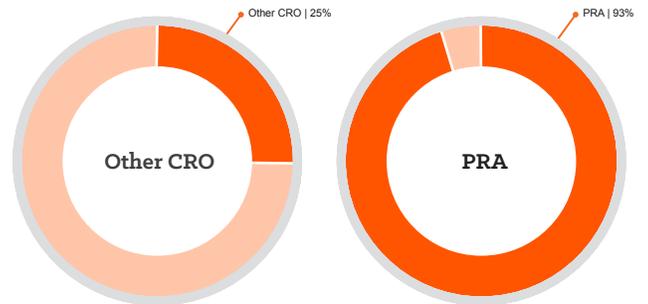
FASTER START-UP

- PRA activated 8 times the number of sites as the previous CRO within 1 month.
- Site motivation improved by selecting sites with a vested interest in the study.



MORE PATIENTS

- PRA's Medical Informatics group selected ideal study sites, with 93% enrolling more than 1 patient. The previous CRO's rate was approximately 25%.
- 70% of study patients enrolled in 12 weeks with all cohorts filled.



Sites without enrollment
 Sites with enrollment

HIGH QUALITY

- 100% of PRA's samples were reconciled.
- 90% of samples collected were evaluable.
- Database lock achieved within 1 week of last-patient-out date.
- Over 260 clinical, sample, and laboratory queries closed within 2 weeks.

COST REDUCTION

- PRA reduced laboratory costs by identifying sample-ready aliquots to initiate batch plasma testing.
- Closeout strategy saved the sponsor 5% of the overall budget.

- PRA's dedicated team accepted 100% ownership of tasks and provided strong project leaders who delivered effective solutions necessary to rescue the diagnostic study.
- PRA demonstrated our commitment to quality throughout project and promoted innovative methods and strategies to meet tight patient and site enrollment timelines.
- At the onset of the study transition to PRA, our team established clear communication pathways, senior management oversight, and direct sponsor engagement to expedite the decision-making process.
- Our committed executive and management teams operated strategically, leveraging prior experiences and lessons learned to provide meaningful oversight and ensure a seamless transition to the sites.
- Strong site relationships were imperative to meet the challenging milestones and expectations.

PRA Health Sciences provides comprehensive biopharmaceutical diagnostic research solutions.

To learn more about our solutions, please visit us at prahs.com or email us at prahealthsciences@prahs.com.