



CASE STUDY

PRAHEALTHSCIENCES

PRA RESCUES DIAGNOSTIC CANCER STUDY

Successfully Delivered On Time For The PMA Filing



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STUDY DESCRIPTION

Comparison of the performance of a new in vitro diagnostic test for post-colonoscopy in subjects with colorectal cancer and pre-colonoscopy in subjects from a guideline-eligible screening population

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

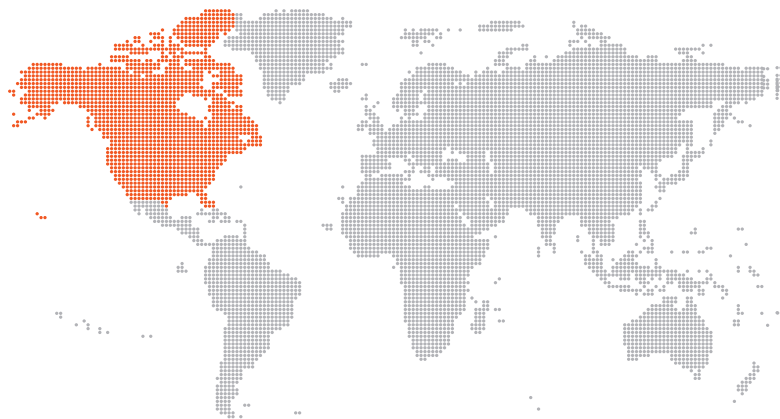
75

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 help rescue 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

Sponsors are reluctant to transition a study to another CRO because the transition often presents unique clinical, operational, and financial challenges. Typically, sponsors will make this move after the study experiences service failures that they cannot correct despite their best efforts. Therefore, the new service provider must deliver prompt transition and issue resolution.



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 to identify, reconcile, and resolve outstanding issues.
- Complete a quality check (QC) of study files and obtain missing regulatory documentation.
- 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 case report forms (CRFs) to electronic CRFs (eCRFs).
- Lock the database within a shortened time frame.

Considering that the previous CRO had achieved 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.
- We 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.

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 decision-making.
- We demonstrated flexibility in resourcing CRAs to complete Site Initiation Visits (SIVs) to avoid impeding study progress or cause further delays due to scheduling conflicts.
- PRA's management and executive teams completed site calls to promote study, integral logistics, and enrollment milestones.

INNOVATION

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

PROACTIVE SITE SUPPORT

- Site Management Associates (SMAs) provided key site oversight and management, which established strong relationships and actively engaged site staff.
- The SMAs averaged approximately:
 - **600 site contacts per month.**
 - **Over 5,000 site communications during project execution.**

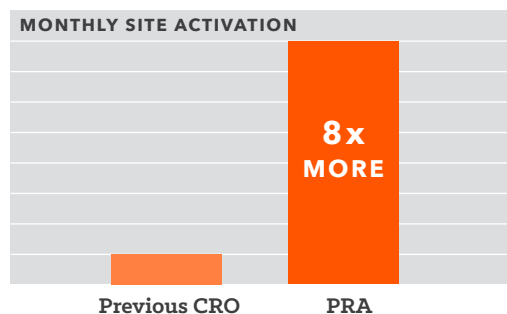


RESULTS

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**.

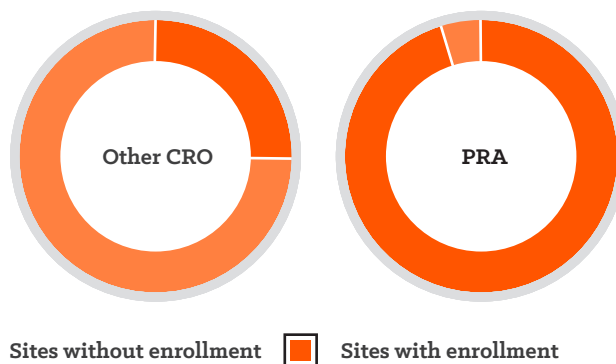
FASTER START-UP

- PRA activated 8 times the number of sites as the previous CRO within 1 month.



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.



HIGH QUALITY

- 100% of PRA's samples reconciled.
- 90% of samples collected 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 decision-making.
- 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 conducts comprehensive Phase I-IV biopharmaceutical drug development.

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