PRECISION for medicine®

CASE STUDY

A Customized Prospective Biospecimen Collection with Unique Subject and Timepoint Constraints

Prospective Biospecimen Collection for a Blood-Based Liquid Biopsy for Colorectal Cancer

Background

Precision for Medicine engaged with a sponsor conducting a program to develop a blood-based liquid biopsy diagnostic for colorectal cancer (CRC) with a goal to create and market a rapid blood test sensitive to pre-cancerous lesions and early-stage CRC, which could significantly improve patient outcomes. At this stage of development, the sponsor needed to determine the diagnostic accuracy of their assay: sensitivity, specificity, and negative/positive predictive value of the test as compared to standard screening.

This process required the use of a significant number of biospecimens conforming to highly specific subject criteria and timing of sample acquisition, coupled with rapid and simplified evaluation of data quality and downstream analysis of results. Due to the criteria, a custom, prospective biospecimens collection was needed to obtain the specimens required for this phase of the diagnostic development.

Developing the liquid biopsy diagnostic required tailored biospecimen collection and expert collaboration to ensure protocol execution, rapid data assessment, and streamlined analysis for timely, reliable results.

Challenge

The study required collecting biospecimens from a large cohort within a short time frame (700 subjects, less than 1 year), with extremely specific subject entry requirements and expeditious shipping of samples. No "off-the-shelf" sample inventory/standard collection sites were available, emphasizing the need to build cohort definitions and collection plans based on specific subject and logistical requirements.

Unique Constraints:

- Subjects had to be healthy individuals between the ages of 45 and 84 who had no personal or family history of colorectal cancer (CRC) or inflammatory bowel disease (IBD).
- The study required a large, U.S.-based cohort with broad geographic representation, consisting of subjects undergoing routine standard care, with strict adherence to specimen collection timing—specifically, standard care procedures had to be scheduled within 90 days of sample collection.

Impact If Unsolved:

- Without biospecimens collected from the required number of subjects, under the specific conditions, development and validation of the CRC liquid biopsy assay would not have been possible.
- A slower than target collection process could have led to delays in biomarker identification, assay development, and overall liquid biopsy development, leading to inflated project costs, lost time, and potential loss of revenue and market share.
- Samples collected without strict adherence to data quality—i.e., improper, or compromised sample/data integrity—could also have led to project failure.

Implementation

Utilizing an extensive network of collection sites, Precision for Medicine implemented a prospective biospecimen collection strategy that ensured the specimens were properly and ethically sourced, collected, transported, and ready for downstream analysis. Emphasis was placed on strict compliance with client standards and site-level protocols to ensure consistency of the targeted population pool and of the biospecimen collection process across a large, yet specific collection of sites and subjects. The following were implemented to ensure alignment with operational procedures, streamlined logistics, and client/sponsor expectations for deliverables:

- **Identified and qualified optimal collection sites**

  By vetting detailed accrual data to qualify the most relevant collection sites based on specific client criteria, Precision leveraged its network of more than 150 USA–based collection sites to quickly identify 26 sites that aligned with and had access to the target population.

- **Engaged and guided collection sites**

  Precision facilitated regular and detailed communication between the client and collection sites via a dedicated project manager assisted by in-house medical directors and study teams. Seamless support for collection sites including onboarding, virtual training, and troubleshooting was provided, with minimal disruptions to site operations.

- **Developed and delivered collection protocols and kits to sites**

  Collection and processing kits with tailored, quality-assured reagents and clear, detailed instructions for acquisition and processing of samples ensured consistency of specimen acquisition and quality across a large number of sites and subjects.

- **Managed specimen collection logistics and shipping**

  Precision's logistics team coordinated and maintained a chain of custody over sample shipping and delivery, ensuring receipt of samples in compliance with the biospecimen lifecycle, as well as best practice biosafety measures to ensure biospecimen quality.

- **Organized subject information and resulting data**

  Precision for Medicine facilitated data analysis by organizing de-identified subject collection and results data using a validated electronic data capture (EDC) system with real-time visibility, allowing for rapid and simplified data evaluation, analysis, and interpretation. Data integrity compliance was ensured through a combination of Good Documentation Practices (GDP) as outlined by the U.S. Food and Drug Administration (FDA) 21 Code of Federal Regulations (CFR), International Council for Harmonisation—Good Clinical Practice (ICH/GCP) guidelines, and Precision's standard operating procedures (SOP) for monitoring.

Results and Key Outcomes

- **Rapidly identified high-volume collection sites**

  Twenty-six geographically dispersed locations across the USA were onboarded within 4 weeks after being identified. Once the site was onboarded and project activated, the average time of receiving initial subject enrollment was 5 to 6 days.

- **Rapidly enrolled test subjects and expedited specimen/data turnaround**

  The study met the client's requirement of enrolling 700 subjects within less than one year, including the shipment of 300 samples within the first three months. Complete sample acquisition and shipment were achieved within seven months, resulting in a total of 874 subjects—approximately 125 subjects per month—all paired with both sample and clinical data.

- **Obtained low screen failure rates**

  The study maintained a screen failure rate of less than 5%.

- **Enrolled back-up subjects and extended prospective biospecimen collections**

  One hundred and thirty-nine subjects were enrolled for back-up purposes and 150 additional subjects were requested due to the depth of the target population pool. Based on this success, assistance was requested and provided with respect to a secondary prospective collection of 50 subjects with different requirements.

Conclusion

Precision for Medicine's extensive site network, paired with site training capabilities and processes to ensure consistent data, allowed the prospective collection of samples conforming to highly specific subject and logistical criteria for assessment of a blood-based liquid biopsy for CRC. This case study exemplifies the importance of engaging with an experienced partner—from protocol design to biospecimen collection to sample analysis—when study criteria are complex, ensuring optimal chances of success and avoiding the consequences of delayed collection and inferior quality specimens and data.

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For details on Precision's Prospective Collections, visit precisionformedicine.com/biospecimens

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