

BESPOKE study of ctDNA guided therapy in colorectal cancer (CRC)

Signatera detects and tracks circulating tumor DNA (ctDNA) using a personalized, tumor-informed assay.

First prospective, multi-center clinical study examining the role of ctDNA in:
MRD Assessment | Adjuvant Treatment Guidance | Recurrence Monitoring

Our goal: BESPOKE CRC study seeks to quantify the impact on treatment decisions and outcomes based on the results of Signatera™ residual disease test (MRD).

Signatera test Signatera is a tumor informed ctDNA assay for tracking 16 tumor-specific mutations in the blood for MRD determination and molecular monitoring.

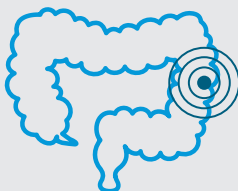
Description: BESPOKE CRC will measure changes in treatment decisions and clinical outcomes based on the use of Signatera in patients with stage II and III colorectal cancer. The study will enroll at least 1,000 patients. Natera and its collaborators will collect clinical utility and outcomes data on enrolled patients for two years.

Study sites: >50 sites will be selected

Date: Multicenter clinical trials will begin enrollment in March 2020

Funding: Budget will be sponsored by Natera's clinical trials department, with budget for Institutional Review Board (IRB) approval, on-site coordination, data collection, and analysis.

Initial protocol for
Colorectal cancer



>50
sites

Clinical utility and
outcome data

≥2
years

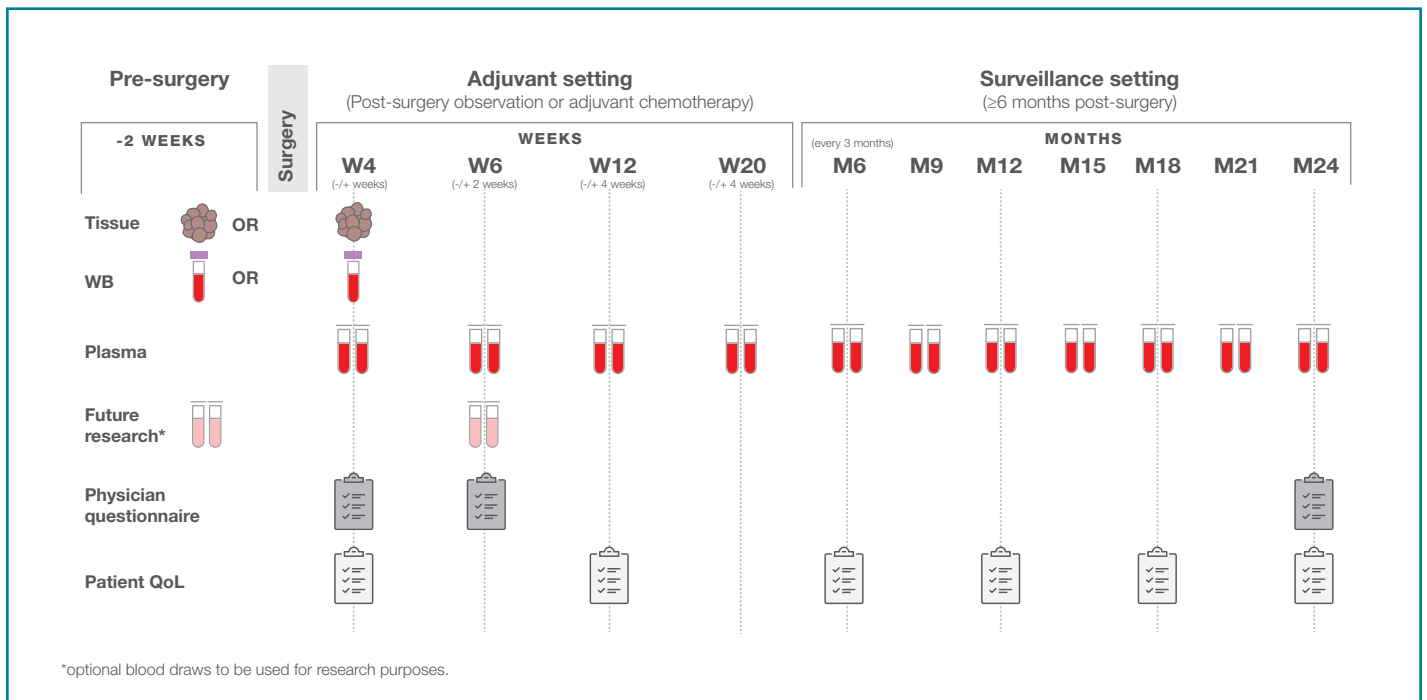
For additional information about the BESPOKE colorectal cancer study please contact the study team at: bespokecolonstudy@natera.com

Eligibility

- Pathologic Stage II and III
- Has residual surgically resected FFPE tissue from adenocarcinoma of the colon or rectum
- ECOG performance status ≤ 2
- Clinically eligible for chemotherapy
- Able to tolerate collection of up to 30 mL of blood via venipuncture
- 18 years or older
- Able to provide written informed consent

Endpoints

- 1°
 - Impact on adjuvant treatment decisions
 - Rates of CRC recurrence while asymptomatic
- 2°
 - Overall survival
 - Patient satisfaction
 - Physician utility
 - Rate of MRD clearance
 - Adjuvant treatment rates
 - Surgery rates for oligometastatic recurrence



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