



BESPOKE study of ctDNA guided immunotherapy (IO)

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

Prospective, multi-center clinical study examining the role of ctDNA in immune checkpoint blockade treatment response monitoring

Our goal:	BESPOKE IO study seeks to quantify the impact of Signatera molecular residual disease (MRD) test results on treatment decisions and outcomes.
Signatera test:	Signatera is a personalized, patient-specific, bespoke ctDNA assay for tracking tissue-derived clonal mutations in blood for MRD determination and molecular monitoring.
Description:	This is a prospective data collection study of patients with advanced solid tumors who will receive standard-of-care immunotherapy while being monitored with Signatera testing. The correlation between Signatera test results and subsequent treatment decisions will be examined. Over 1,500 patients will be prospectively enrolled from eligible study sites; additional information will be collected from historical control cases.
Study sites:	Up to 100 sites will be selected.
Date:	Multicenter clinical trials will begin enrollment in Q2 2021.
Funding:	The budget will be sponsored by Natera's clinical trials department. The budget will accommodate institutional review board (IRB) approval, on-site coordination, data collection, and analysis.

Tumor types enrolled:



Non-small cell lung cancer



Melanoma



Colorectal cancer



Eligible patients can enroll
up to four weeks before they
initiate immunotherapy.



Up to 100 sites



Clinical utility and
outcome data:
Up to 2 years

For additional information about the BESPOKE IO study,
please contact the study team at:

BESPOKEIOStudy@natera.com



BESPOKE IO trial design

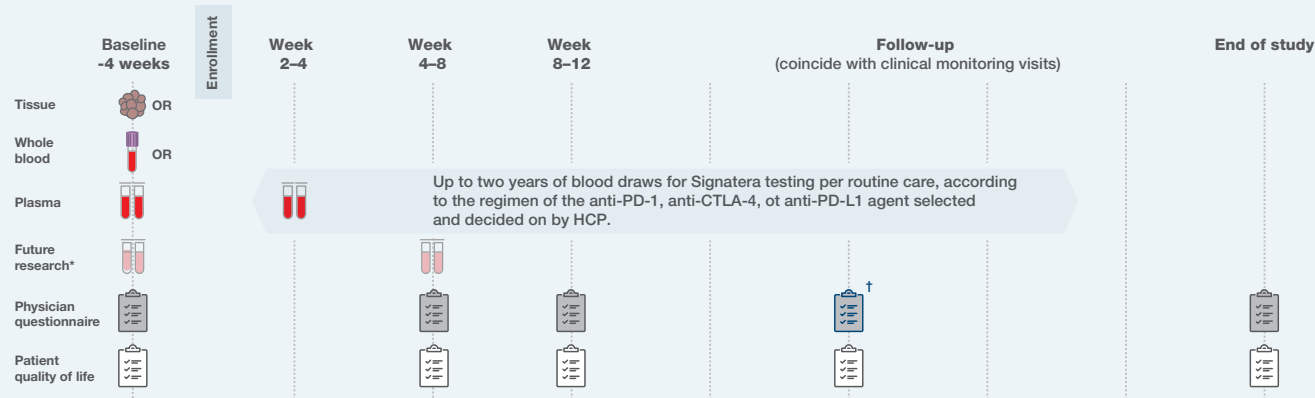
Eligibility

- › 18 years of age or older, with ECOG performance status 0–2
- › Documented metastatic or locally advanced cancer of the following types: melanoma, non-small cell lung cancer, colorectal cancer
- › Sufficient tumor tissue must be available for whole-exome sequencing
- › Clinically eligible, with a plan to receive therapy with an anti-neoplastic agent that works by immune checkpoint blockade (anti-PD-1, anti-CTLA-4, or anti-PD-L1)
- › At least one lesion that is measurable by RECIST criteria and that has at least one dimension >10 mm
- › Able to follow the study's visitation schedule and willing to provide up to 20 mL of peripheral blood samples at the indicated time points

Endpoints

- › **Primary**
Percentage of patients who continued or changed their immunotherapy treatment regimen because of a post-treatment Signatera ctDNA result
- › **Secondary**
Comparisons between patient cohorts as defined by change in ctDNA levels
 - Progression-free survival
 - Overall survival
 - Partial or complete response
 - Duration of response
 - Percentage of patients with six-month durable clinical response
 - Treatment confidence (patient and physician)
 - Anxiety levels and well-being in patients receiving Signatera ctDNA results

Study design



*Optional blood draws to be used for research purposes.

†To be completed when a change in treatment recommendation occurs.

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

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The tests described have been developed and their performance characteristics determined by the CLIA-certified laboratory performing the test. The tests have not been cleared or approved by the US Food and Drug Administration (FDA). Although FDA is exercising enforcement discretion of premarket review and other regulations for laboratory-developed tests in the US, certification of the laboratory is required under CLIA to ensure the quality and validity of the tests. CAP accredited, ISO 13485 certified, and CLIA certified. © 2021 Natera, Inc. All Rights Reserved.

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