



NEWS RELEASE

Foundation Medicine and Natera Announce Broad Clinical Launch and Medicare Coverage of FoundationOne®Tracker

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FoundationOne® Tracker is now available to all physicians in the United States seeking personalized monitoring of their patients' response to treatment

Several recent publications demonstrate clinical validity of ctDNA monitoring using FoundationOne®Tracker

CAMBRIDGE, Mass. & AUSTIN, Texas--(BUSINESS WIRE)-- **Foundation Medicine, Inc.**, and Natera, Inc., today announced the broad clinical launch of FoundationOne®Tracker, a personalized tissue-informed circulating tumor DNA (ctDNA) test to monitor cancer patients' response to therapy. FoundationOne Tracker is now available to all U.S. healthcare providers for treatment response monitoring (TRM).

Additionally, the Centers for Medicare & Medicaid Services' (CMS) Palmetto GBA Molecular Diagnostics Program (MoIDX) has determined, effective June 17, 2023, that FoundationOne Tracker is covered for monitoring of response to immune-checkpoint inhibitor (ICI) therapy, for qualifying Medicare beneficiaries with all solid tumors. FoundationOne Tracker is also approved by the Clinical Laboratory Evaluation Program (CLEP) of New York, which is the only U.S. state that requires an independent regulatory review process for laboratory developed tests.

FoundationOne Tracker is a tissue-informed ctDNA monitoring test for patients with advanced cancer across all solid tumors. The test uses genomic information derived from FoundationOne®CDx, Foundation Medicine's tissue-based comprehensive genomic profiling test, with personalized assay design and ctDNA analysis from Natera. FoundationOne Tracker is performed serially to monitor patients' response to therapy and helps physicians identify



patients who are resistant to current treatment and may need alternate therapy, or those who are responding well to therapy and may benefit from dose reduction or therapy discontinuation.

Although imaging, such as CT scans and MRIs, is the standard of care for monitoring cancer patients' response to treatment, it has known limitations depending on the type of cancer and the treatment being prescribed.¹⁻⁴ When used as a complement to imaging, tissue-informed ctDNA monitoring with FoundationOne Tracker can provide more confidence than imaging alone.⁵

"Tissue-informed ctDNA monitoring is a natural extension of Foundation Medicine's current genomic testing portfolio, and we believe this new offering will further enable oncologists to make the best possible decisions about their patients' care through actionable and personalized data," said Foundation Medicine's Chief Executive Officer, Brian Alexander, M.D. "The insights provided by FoundationOne Tracker, along with Medicare coverage of the test for patients undergoing immunotherapy, position us to broaden the impact of genomic profiling and bring personalized cancer care to more patients."

"This is a big win for patients," said Natera's Chief Executive Officer, Steve Chapman. "Our partnership with Foundation Medicine, together with the recent Medicare coverage decision, enables even greater access to Natera's core technology for personalized immunotherapy monitoring."

Several recent publications demonstrate the clinical validity of FoundationOne Tracker in late-stage monitoring. In a **study presented** at this year's American Society of Clinical Oncology (ASCO) annual meeting and recently published in **Clinical Cancer Research**, investigators found that FoundationOne Tracker can inform outcomes of maintenance immunotherapy in patients with advanced non-small cell lung cancer from the IMpower131 trial.

Research published in Molecular Oncology features results from the OMICO-MoST study, which showed that as early as four weeks after treatment, a decline in ctDNA was predictive of improved overall survival. In two patients with complete response, ctDNA clearance, or complete removal of ctDNA, preceded any response by scan with a median lead time of 11.5 months, a potential advantage in the use of ctDNA for response assessment.

These studies are part of the extensive body of evidence both Foundation Medicine and Natera are generating to support the value of integrating tissue-informed ctDNA monitoring into clinical practice.

Foundation Medicine® and FoundationOne® are registered trademarks of Foundation Medicine, Inc.

About Foundation Medicine: Your Essential Partner in Cancer Care

Foundation Medicine is a pioneer in molecular profiling for cancer, working to shape the future of clinical care and

research. We collaborate with a broad range of partners across the cancer community and strive to set the standard for quality, scientific excellence, and regulatory leadership. Our deep understanding of cancer biology helps physicians make informed treatment decisions for their patients and empowers researchers to develop new medicines. Every day, we are driven to help our partners find answers and take action, enabling more people around the world to benefit from precision cancer care. For more information, please visit us on www.FoundationMedicine.com and follow us on [Twitter](#) and [LinkedIn](#).

About Natera

Natera™ is a global leader in cell-free DNA testing, dedicated to oncology, women's health, and organ health. Our aim is to make personalized genetic testing and diagnostics part of the standard of care to protect health and enable earlier and more targeted interventions that help lead to longer, healthier lives. Natera's tests are validated by more than 100 peer-reviewed publications that demonstrate high accuracy. Natera operates ISO 13485-certified and CAP-accredited laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) in Austin, Texas and San Carlos, California. For more information, visit www.natera.com.

Forward-Looking Statements (Natera)

All statements other than statements of historical facts contained in this press release are forward-looking statements and are not a representation that Natera's plans, estimates, or expectations will be achieved. These forward-looking statements represent Natera's expectations as of the date of this press release, and Natera disclaims any obligation to update the forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual results to differ materially, including with respect to our efforts to develop and commercialize new product offerings, whether the results of clinical or other studies will support the use of our product offerings, the impact of results of such studies, our collaborations with commercial partners, or our expectations of the benefits of our tests and product offerings to patients, providers and payers. Additional risks and uncertainties are discussed in greater detail in "Risk Factors" in Natera's recent filings on Forms 10-K and 10-Q and in other filings Natera makes with the SEC from time to time. These documents are available at www.natera.com/investors and www.sec.gov.

Source: Foundation Medicine

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5. Data on File, Foundation Medicine, 2022

Media:

Foundation Medicine:

Abigail Alderman, 781-534-3210

newsroom@foundationmedicine.com

Natera:

Lesley Bogdanow

PR@natera.com

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