Biopharmaceutical Solutions

FOUNDATION MEDICINE®

Foundation Medicine® is your choice genomic partner, offering solutions that address your critical needs and core challenges including genomic profiling, clinical trial solutions, molecular database insights, and companion diagnostic development.

FOUNDATION MEDICINE®

We aim to improve patient care by serving the needs of clinicians, academic researchers, and drug developers to help advance the science of molecular-based medicine in cancer.

From discovery through commercialization, Foundation Medicine provides biopharma companies with actionable insights into the oncogenomics of both rare and common cancers.

WE PARTNER WITH YOU TO:

- **Profile patients** with leading comprehensive genomic profiling tests
- **Analyze populations** of patients to optimize development strategy
- **Accelerate development** of companion diagnostics with our established and validated platform
- **Facilitate design** of molecularly-guided clinical trials
- **Expedite enrollment** of genomically qualified patients to clinical trials
- **Query data** from one of the world's largest real-world cancer genomics databases of cancer patients in the world

Comprehensive Genomic Profiling (CGP)

Foundation Medicine offers both retrospective and prospective genomic profiling services to help identify patient cohorts, inform drug development decisions and clinical trial design, and increase patient access to appropriate investigational agents and trials.

Next-Generation Sequencing (NGS) Biomarker Discovery

Foundation Medicine offers a portfolio of comprehensive genomic profiling tests to facilitate sequencing of patient cohorts using multiple specimen types:

FOUNDATIONONE®CDx

- Profiles >300 genes (coding regions plus specific introns)
- Cancer type: solid tumors
- Alterations detected: base substitutions, insertions/deletions (indels), copy number alterations (CNAs), and select rearrangements
- Sample type: formalin-fixed paraffin-embedded (FFPE) tissue
- Advanced biomarkers: tumor mutational burden (TMB) and microsatellite instability (MSI) and Loss of Heterozygosity (LOH, for Ovarian Cancer only)

Foundation Medicine still offers the T7 baitset from our legacy test, **FoundationOne®**, for our biopharma partners.

FOUNDATIONONE®LIQUID

- Profiles 70 genes
- Cancer type: solid tumors
- Alterations detected: base substitutions, indels, CNAs, and select rearrangements
- Sample type: peripheral whole blood
- Advanced biomarkers: MSI*

** Reported when found to be high*

FOUNDATIONONE®HEME

- Profiles >400 genes (coding regions plus specific introns)
- Cancer type: hematologic malignancies and sarcomas
- Interrogates RNA of >250 commonly rearranged genes to assess gene fusions
- Alterations detected: base substitutions, indels, CNAs, and rearrangements
- Sample type: FFPE tissue, peripheral whole blood, or bone marrow aspirate
- Advanced biomarkers: TMB and MSI

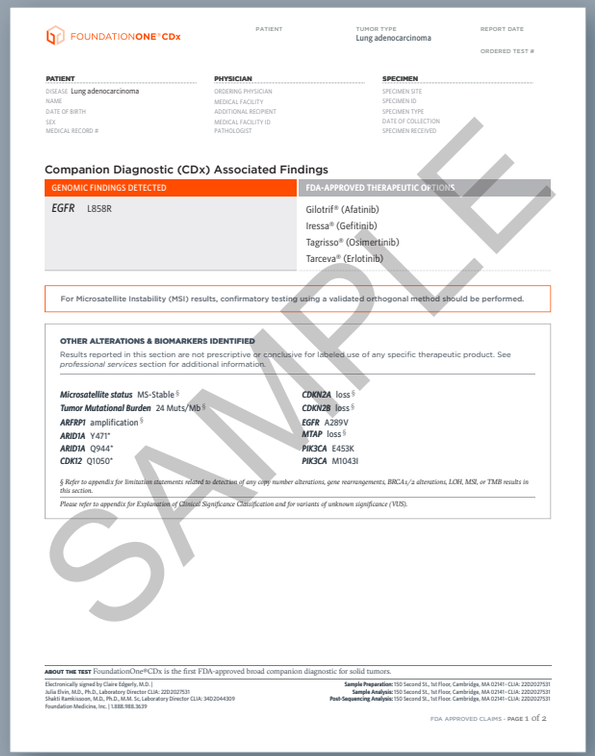
Foundation Medicine's validated portfolio of tests provides clinical-grade results appropriate for both biomarker discovery and clinical trial applications. Many of our tests can also provide other advanced genomic analyses. Identification of biomarkers TMB and MSI for immunotherapy decisions are validated using both conventional and non-parametric statistical methods.

RESULTS REPORTING

Test results can be provided in custom data formats with frequency of delivery tailored to customer requirements. For prospective utilization of any of our assays as a Clinical Trial Assay (CTA), results can be delivered directly to the clinical site via a dedicated partner-specific web portal.

RESEARCH AND DATA ANALYSIS

Foundation Medicine is a world leader in molecular data. We support prospective enrollment screening, retrospective analyses, and other sponsor-initiated research studies. We offer expert follow-up analysis of the genomic data we generate—including de novo biomarker discovery—with the goal of providing novel, data-driven insights that enhance your clinical programs.



FOUNDATIONONE® CDx

PATIENT

TUMOR TYPE
Lung adenocarcinoma

REPORT DATE
ORDERED TEST #

PATIENT
DISEASE Lung adenocarcinoma
NAME
DATE OF BIRTH
SEX
MEDICAL RECORD #

PHYSICIAN
ORDERING PHYSICIAN
MEDICAL FACILITY
ADDITIONAL RECIPIENT
MEDICAL FACILITY ID
PATHOLOGIST

SPECIMEN
SPECIMEN SITE
SPECIMEN ID
SPECIMEN TYPE
DATE OF COLLECTION
SPECIMEN RECEIVED

Companion Diagnostic (CDx) Associated Findings

GENOMIC FINDINGS DETECTED	FDA-APPROVED THERAPEUTIC OPTIONS
EGFR L858R	Gilotrif® (Afatinib) Iressa® (Gefitinib) Tagrisso® (Osimertinib) Tarceva® (Erlotinib)

For Microsatellite Instability (MSI) results, confirmatory testing using a validated orthogonal method should be performed.

OTHER ALTERATIONS & BIOMARKERS IDENTIFIED
Results reported in this section are not prescriptive or conclusive for labeled use of any specific therapeutic product. See *professional services* section for additional information.

Microsatellite status MS-Stable §
Tumor Mutational Burden 24 Muts/Mb §
ARFRP1 amplification §
ARID1A Y471*
ARID1A Q944*
CDK12 Q1050*
CDKN2A loss §
CDKN2B loss §
EGFR A289V
MTAP loss §
PIK3CA E453K
PIK3CA M1043I

§ Refer to appendix for limitation statements related to detection of any copy number alterations, gene rearrangements, BRCA1/2 alterations, LOH, MSI, or TMB results in this section.

Please refer to appendix for Explanation of Clinical Significance Classification and for variants of unknown significance (VUS).

SAMPLE

ABOUT THE TEST FoundationOne®CDx is the first FDA-approved broad companion diagnostic for solid tumors.

Electronically signed by Claire Edgerly, M.D. |
Julia Elvin, M.D., Ph.D., Laboratory Director CLIA: 22D2027531
Shakti Ramkissoon, M.D., Ph.D., M.M. Sc, Laboratory Director CLIA: 34D2044309
Foundation Medicine, Inc. | 1.888.988.3639

Sample Preparation: 150 Second St., 1st Floor, Cambridge, MA 02141 - CLIA: 22D2027531
Sample Analysis: 150 Second St., 1st Floor, Cambridge, MA 02141 - CLIA: 22D2027531
Post-Sequencing Analysis: 150 Second St., 1st Floor, Cambridge, MA 02141 - CLIA: 22D2027531

FDA APPROVED CLAIMS - PAGE 1 of 2

All of our testing for biopharma customers is performed in our CAP-accredited and CLIA-certified laboratories using the same platforms as our clinical diagnostic products. For prospective utilization in clinical trials, detailed sample requirement documents, test requisition forms, and specimen shipping kits can be supplied directly to your clinical sites or through your contract research organization.

Clinical Sample Report: FDA-Approved Claims

FOUNDATIONONE® CDx

PATIENT

TUMOR TYPE
Lung adenocarcinoma
COUNTRY CODE

REPORT DATE
ORDERED TEST #

ABOUT THE TEST FoundationOne®CDx is the first and only FDA-Approved comprehensive companion diagnostic for all solid tumors.

Interpretive content on this page and subsequent pages is provided as a professional service, and is not reviewed or approved by the FDA.

PATIENT
DISEASE Lung adenocarcinoma
NAME
DATE OF BIRTH
SEX
MEDICAL RECORD #

PHYSICIAN
ORDERING PHYSICIAN
MEDICAL FACILITY
ADDITIONAL RECIPIENT
MEDICAL FACILITY ID
PATHOLOGIST

SPECIMEN
SPECIMEN SITE
SPECIMEN ID
SPECIMEN TYPE
DATE OF COLLECTION
SPECIMEN RECEIVED

Biomarker Findings
Tumor Mutational Burden - 24 Muts/Mb
Microsatellite status - MS-Stable

Genomic Findings
For a complete list of the genes assayed, please refer to the Appendix.
EGFR A289V, L858R
PIK3CA E453K, M1043I
ARID1A Q944*, Y471*
ARFRP1 amplification - equivocal†
CDK12 Q1050*
CDKN2A/B loss
MTAP loss

7 Disease relevant genes with no reportable alterations: ***ALK, BRAF, ERBB2, KRAS, MET, RET, ROS1***

† See About the Test in appendix for details.

14 Therapies with Clinical Benefit
0 Therapies with Lack of Response
37 Clinical Trials

BIOMARKER FINDINGS	THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE)	THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE)
Tumor Mutational Burden - 24 Muts/Mb	Atezolizumab 1	Avelumab
	Durvalumab 1	Cemiplimab
10 Trials see p. 18	Pembrolizumab 1	
Microsatellite status - MS-Stable	Nivolumab 2A	
	No therapies or clinical trials. see Biomarker Findings section	

SAMPLE

The content provided as a professional service by Foundation Medicine, Inc., has not been reviewed or approved by the FDA.

Electronically signed by Claire Edgerly, M.D. |
Julia Elvin, M.D., Ph.D., Laboratory Director CLIA: 22D2027531
Shakti Ramkissoon, M.D., Ph.D., M.M. Sc, Laboratory Director CLIA: 34D2044309
Foundation Medicine, Inc. | 1.888.988.3639

Sample Preparation: 150 Second St., 1st Floor, Cambridge, MA 02141 - CLIA: 22D2027531
Sample Analysis: 150 Second St., 1st Floor, Cambridge, MA 02141 - CLIA: 22D2027531
Post-Sequencing Analysis: 150 Second St., 1st Floor, Cambridge, MA 02141 - CLIA: 22D2027531

PROFESSIONAL SERVICES - PAGE 1 of 25

Clinical Sample Report: Professional Services

Sample Report as of May 2020

Companion Diagnostic Development

The First FDA-Approved Broad Companion Diagnostic for All Solid Tumors

FOUNDATIONONE® CDx

BROAD CDX PLATFORM

Streamlines companion diagnostic (CDx) development by adding companion diagnostic claims to our clinically validated, comprehensive platform.

TARGETED & IMMUNOTHERAPY

Detection of substitutions, insertion and deletion alterations (indels), and copy number alterations in 324 genes, and select gene rearrangements, as well as genomic signatures including tumor mutational burden (TMB) and microsatellite instability (MSI) using DNA isolated from FFPE specimens.

Foundation Medicine's established platform may help accelerate CDx development, mitigate risk, and drive commercialization:

Lower Risks

Using our FDA-approved platform, FoundationOne CDx, can help **mitigate developmental, operational, and commercial risks** in companion diagnostics by utilizing our comprehensive profiling platform within our QSR-compliant laboratory.

Efficient Timelines for Commercial Development

Our existing FDA-approval as a broad companion diagnostic can potentially reduce CDx development timelines for your team. With our significant commercial footprint and ability to add diagnostic claims through supplemental pre-market approval applications to the FDA, we can help to minimize ramp-up time for novel biomarkers.

Post-Approval Support

Foundation Medicine provides integrated solution support for companion diagnostic development. Our platform contains the genes necessary to deploy nearly any cancer genomic biomarker.

Clinical Trial Solutions

Accelerating biomarker-driven clinical trials through better design, planning, and enrollment

The economic and logistical challenges presented by the need to recruit rare patient cohorts are a significant hurdle in bringing new cancer treatments to market.

Foundation Medicine has the tools to support biopharmaceutical companies in clinical trial enrollment in a molecularly-driven era. Every week, Foundation Medicine analyzes thousands of samples from patients who could be genomically eligible for your trial. With patient populations narrowly defined and widely distributed, we can help connect the right trial with the right patient.

RARE AND DIFFICULT-TO-RECRUIT PATIENT COHORTS

With the development of genomically-matched treatments in oncology, a patient's best or only targeted treatment option could be a clinical trial.

Unfortunately, physicians may not have the time, resources, or awareness to identify relevant trials for these patients, especially if the patient's cancer has rare genomic characteristics.

FOUNDATIONSMART TRIALS™

FoundationSmartTrials™ is an end-to-end program supporting clinical trials and helping partners run faster, smarter trials. We provide solutions to help identify new targets, optimize trial design, and screen patients for enrollment who meet specific genomic criteria.

Trial Expertise

We sit at an intersection of genomics and biopharmaceutical research, combining our talented scientific team, over 400,000 sequenced patient samples, and over 50 active biopharmaceutical partners.

Trial Design

With tailored access to more than 400,000 patient genomic profiles in our FoundationCore® knowledgebase, partners are able to define biomarker criteria, map certain geographic ordering patterns, and make informed decisions about site selection.

Expanded Reach

Over 20,000 providers across more than 5,000 facilities are using our reports to uncover therapy options including clinical trials, opening the pool of potentially matched patients to a nationwide search.

PRECISION ENROLLMENT

Foundation Medicine's Precision Enrollment solution helps to connect you with eligible patients that match your target profile and physicians interested in working with you on your trial.

Sponsors also gain insight into standard of care, prevalence trends, and trial expansion opportunities.

How it Works

1

Create Target Profile

We work with you to develop a target patient profile representing your trial's genomic, histologic, and demographic eligibility criteria.

2

Match Patients

Patients who match the target profile are identified from the pool of thousands of samples we evaluate and monitor each week.

3

Contact Physician

An oncologist from Foundation Medicine engages the patient's treating physician to provide details about relevant clinical trial option(s).

4

Connect Physician & Trial Sponsor

Sponsors and interested physicians are connected to exchange additional information regarding potential patient enrollment.

5

Evaluate & Enroll

The sponsor facilitates evaluation and enrollment of the patient in its clinical trial at the most appropriate location. We support Just-in-Time (JIT) Trial Access solutions for quick activation of additional sponsor trial sites near identified patients.

PLANNER

Foundation Planner provides real-world intelligence to your clinical trial design. With insights driven by more than 400,000 patient genomic profiles in the FoundationCore® knowledgebase, partners are able to more effectively:

- define biomarker criteria
- map geographic ordering patterns
- make informed decisions about site selection

Molecular Information Solutions

Extract and Visualize Key Data Insights via FoundationCore®

FoundationCore is our molecular information knowledgebase that is continuously evolving over time, informed by every clinical sample sequenced with Foundation Medicine's comprehensive genomic profiling tests.

In addition to detailed genomic data for all genes on our tests, basic patient demographics and several novel derived variables, such as tumor mutational burden (TMB) and microsatellite instability (MSI) status, are available.

FoundationCore is notably enriched with rare cancers relative to population prevalence, making it an invaluable source for identifying and analyzing populations with high unmet medical needs.

Applications for FoundationCore include:
- Profiling patient cohorts
- Identifying trends in complex biomarkers
- Informing clinical trial design
- Enabling commercial strategy and diligence

CLINICO-GENOMIC MOLECULAR OUTCOME ANALYSIS

Foundation Medicine offers access to unique clinico-genomic data resources through our partnership with Flatiron Health, a leading provider of clinical data. Through partnerships and via the FoundationCore knowledgebase, Foundation Medicine's comprehensive genomic profiling (CGP) data is linked on a de-identified basis to patients' detailed diagnoses, medication histories, and treatment outcomes including overall survival rates. By analyzing and integrating clinical treatment and outcomes data with matched comprehensive genomic profiling, we are able to support biomarker discovery, clinical trial planning, and commercial utilization analyses.

400k+
genomic profiles

150+
cancer subtypes

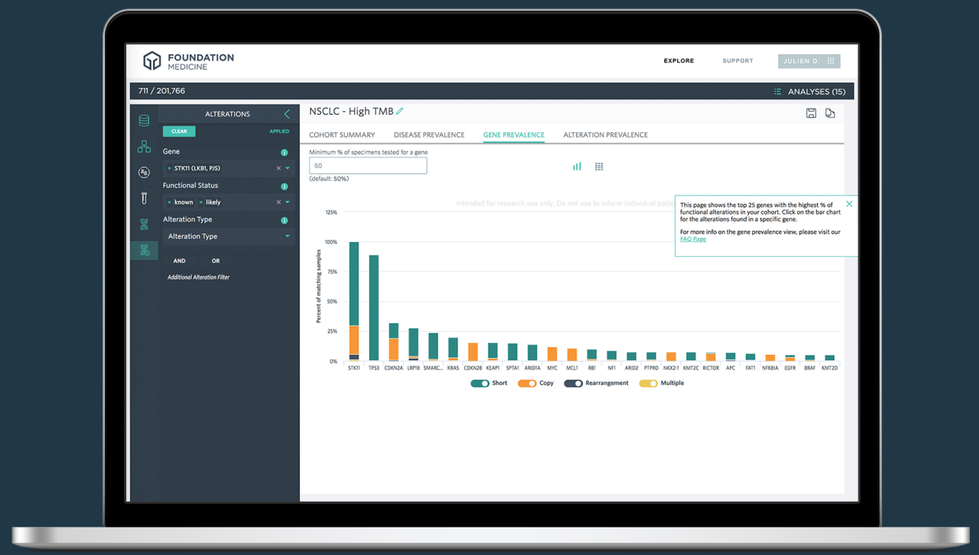
50k+
clinico-genomic cases

MOLECULAR INFORMATION SOLUTIONS

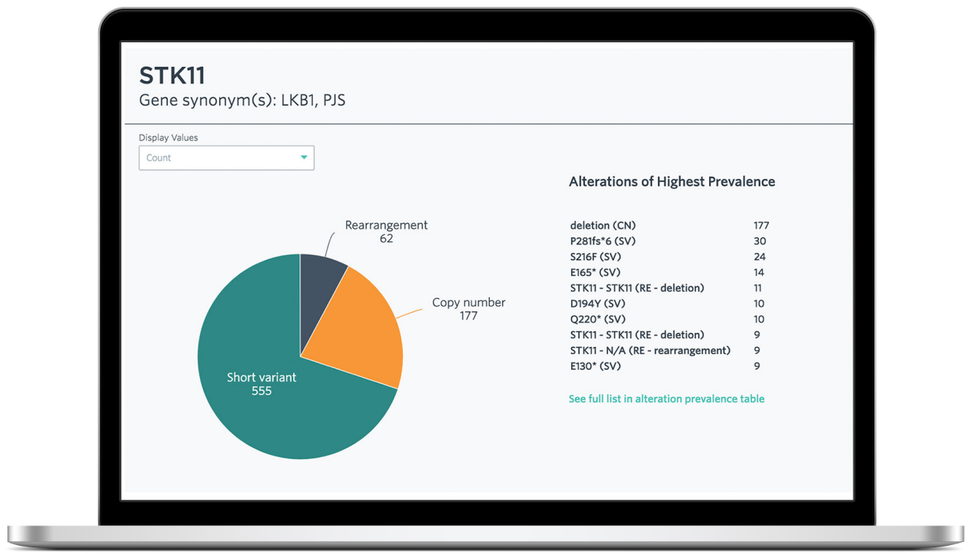
FOUNDATIONINSIGHTS®

SUBSCRIPTION ACCESS

FoundationInsights® is a web-based application that provides partners with flexible access to FoundationCore data via user-friendly, self-serve queries.



Gene Prevalence Example
How often does high TMB occur with *BRAF* or *STK11* alterations? Ask our data anything: with one of the largest databases of real-world genomic profiles coupled with a powerful analytics platform, we help provide insights to drive your goals.



Custom Queries
Ask Foundation Medicine experts for support with complex analyses, including markers not currently included in the FoundationInsights portal (e.g. LOH, SGZ) and an expanded assay list including FoundationOne®Liquid.

For more information contact us at:

biopharma@foundationmedicine.com
or visit www.foundationmedicine.com/partnerships

FOUNDATION MEDICINE®

© 2020 Foundation Medicine, Inc. | Foundation Medicine®, FoundationOne®, FoundationCore®, and FoundationInsights® are registered trademarks of Foundation Medicine, Inc.
www.foundationmedicine.com | Tel. 888.988.3639 | Fax 617.418.2290 | MKT-0311-03