Biopharma Partnership Solutions

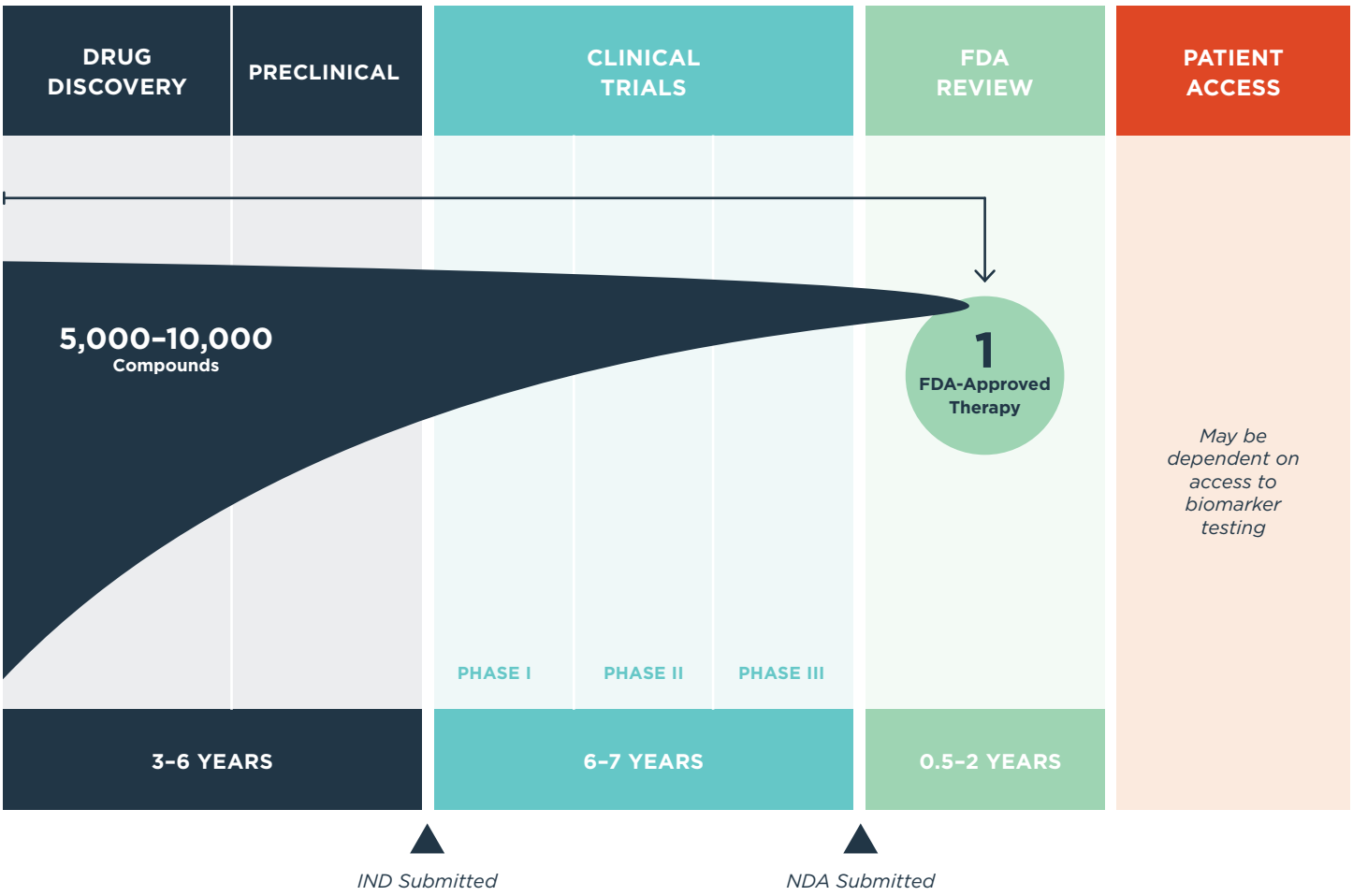
Shaping the forefront of cancer care together.

FOUNDATION MEDICINE®

Foundation Medicine is Your **Essential Partner** Across the **Global Therapy Development Lifecycle**

Traditional therapy discovery and development is long, slow, and costly—but studies have shown that **biomarkers can significantly reduce cost and accelerate the approval process**.[1]

The process can require **10+ years** and **over $2B from discovery to approval**[2]



Adapted from Figure 1 in Kloda, J. "FDA's Expedited Review Process: The Need for Speed." 2015. https://www.appliedclinicaltrialsonline.com/view/fda-s-expedited-review-process-need-speed

Our **comprehensive portfolio of tests** and **data solutions** can help your global therapy development programs **reach patients faster with fewer costs.**

Genomic Profiling + Real-World Data (RWD) Solutions Across Solid Tumors and Heme Malignancies

• DNA • RNA • ctDNA • RWD

Foundation Medicine is the Global Leader in Approved CDx Indications

FOUNDATIONONE®CDx

FOUNDATIONONE®LIQUID CDx

Trials using biomarkers exhibit almost twice the overall probability of success compared to trials without biomarkers.[3]

1. Gromova M, Vaggelas A, Dallmann G, Seimetz D. Biomarkers: Opportunities and Challenges for Drug Development in the Current Regulatory Landscape. Biomark Insights. 2020 Dec 8;15:1177271920974652. doi: 10.1177/1177271920974652. PMID: 33343195; PMCID: PMC7727038
2. Research and Development in the Pharmaceutical Industry. Congressional Budget Office. April 2021. https://www.cbo.gov/publication/57126
3. Wong CH, Siah KW, Lo AW. Estimation of clinical trial success rates and related parameters. Biostatistics. 2019 Apr 1;20(2):273-286. doi: 10.1093/biostatistics/kxx069. Erratum in: Biostatistics. 2019 Apr 1;20(2):366. PMID: 29394327; PMCID: PMC6409418.

Genomic Profiling and Real-World Data for Discovery and Clinical Trials

SOLID TUMORS + HEME MALIGNANCIES

GENOMIC PROFILING

Discover new biomarkers or enroll your **clinical trials** with our **comprehensive portfolio of clinical trial assays.**

DNA RNA ctDNA IHC

Detect common and complex biomarkers across 300+ genes, including genomic signatures like TMB or HRD

TMB = Tumor Mutational Burden
HRD = Homologous Recombination Deficiency

Include PD-L1 for immunotherapy programs

IUO NOW AVAILABLE

ctDNA MONITORING

Gain insights on treatment response and **dose activity** with ctDNA monitoring to complement standard imaging.[1]

TISSUE-NAÏVE

CLINICAL TRIAL ASSAY BASED ON

FOUNDATIONONE® MONITOR

- Evaluate changes in ctDNA levels over time and quantify using ctDNA tumor fraction, which incorporates multi-omic information[2]
- Monitor individual variants or assess resistance across 300+ genes

REAL-WORLD DATA SOLUTIONS

Inform clinical trial design and **accelerate enrollment** with our trial services and data solutions.

TrialBoost™

Use existing data from clinical reports for fast, efficient patient enrollment

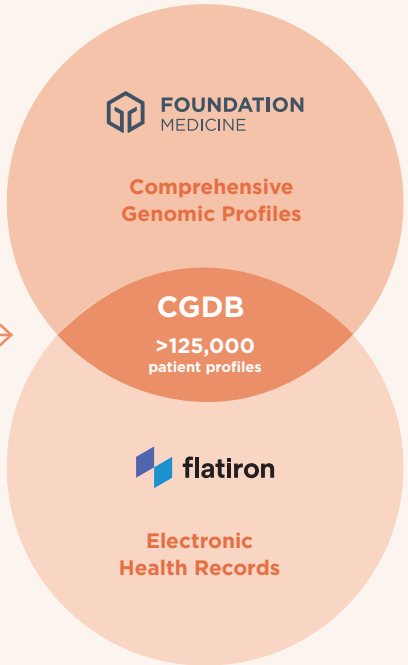
FOUNDATIONREACH™

Weekly alerts on biomarker-positive patients to enable focused outreach for potential trial enrollment

Clinico-Genomic Database (CGDB)

Get answers to your questions with a data subscription or for individual projects through our CGDB Analytical Services model

Data with Scale + Completeness:
Every sample tested with CGP

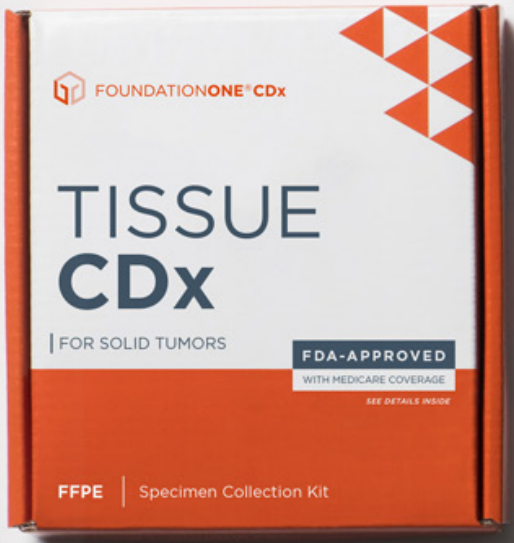


1. For Investigational Use Only. The performance characteristics of this product have not been established.
2. ctDNA tumor fraction is reported as a laboratory professional service which has not been reviewed or approved by the FDA.

Global Leader in Approved CDx Indications

APPROVED CDx TESTS FOR TISSUE OR LIQUID BIOPSY IN USA AND JAPAN*

* Test names in Japan are FoundationOne®CDx Cancer Genomic Profile and FoundationOne®Liquid CDx Cancer Genomic Profile



Why start from scratch? Our **established platforms with existing approvals** can make your **path to approval faster** compared to a new submission.

CDx Approvals Across Solid Tumors:

- Pan-Tumor
- Non-Small Cell Lung
- Breast
- Colorectal
- Prostate
- Ovarian
- Cholangiocarcinoma
- Melanoma

Nearly

60%

of all approved CDx indications for NGS testing in US and Japan†

† Data on File, Foundation Medicine, Inc., as of April 2023

Our **Regulatory Experience** Can Support You in **Additional Areas** of **Therapy Development**

As the **only company with an FDA-approved portfolio of tissue and blood-based CGP tests,** we have experience to **support submissions** with new **broad NGS assays**.

HEME MALIGNANCIES

CLINICAL TRIAL ASSAY BASED ON

FOUNDATIONONE® HEME

RARE FUSIONS

CLINICAL TRIAL ASSAY BASED ON

FOUNDATIONONE® RNA

CGDB powered CDx: our newest **RWD solution** can **supplement** your **regulatory submission.**

CLINICO-GENOMIC

REAL-WORLD DATA

GENOMIC DATA

Reanalyzed CGP data using current analytical pipeline in the genomic platform in order to harmonize to the latest scientific understanding of cancer genomics.

CLINICAL DATA

Reanalyzed and abstracted additional covariates.

+

REAL-WORLD

EVIDENCE STUDY

RWE STUDY STATISTICAL ANALYSIS PLAN

RWE STUDY EXECUTION + RESULTS

→

Regulatory service to align with health authority and support your CDx strategy.

Our Global Experience for Commercial Collaborations

Foundation Medicine Lab Lab Partnership

>1M
Patient CGP reports delivered

Advance your global trials and commercial launch plans with our global regulatory experience and commercial footprint and services.

FOUNDATIONREACH™

Weekly alerts on biomarker-positive results to enable timely physician engagement after commercial launch of a new therapy

CLINICAL TRIALS
850+ clinical trials supported, including 350+ prospective studies

EUROPE
CDx readiness planned for in vitro diagnostics regulations (IVDR)

CHINA
New partnership to support **clinical trials in China** and use the data for **global regulatory filings**

JAPAN
Dedicated Chugai team in country across functions

FOR MORE INFORMATION:

Send us an **email**

Visit our **website**

FoundationOne®CDx | FoundationOne®Liquid CDx | FoundationOne®Heme | FoundationOne®RNA

Look for your **gene of interest**

Clinical Trial Assays: For Investigational Use Only. The performance characteristics of these products have not been established.

FoundationOne®CDx and FoundationOne®Liquid CDx are qualitative next-generation sequencing based *in vitro* diagnostic tests for advanced cancer patients with solid tumors and are for prescription use only. FoundationOne CDx utilizes FFPE tissue and analyzes 324 genes as well as genomic signatures. FoundationOne Liquid CDx analyzes 324 genes utilizing circulating cell-free DNA and is FDA-approved to report short variants in 311 genes. The tests are companion diagnostics to identify patients who may benefit from treatment with specific therapies in accordance with the therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the tests does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Some patients may require a biopsy for testing with FoundationOne CDx when archival tissue is not available which may pose a risk. Patients being considered for eligibility for therapy based on detection of *NTRK1/2/3* and *ROS1* fusions should only be tested if tissue is unavailable. Patients who are tested with FoundationOne Liquid CDx and are negative for other companion diagnostic mutations should be reflexed to tumor tissue testing and mutation status confirmed using an FDA-approved tumor tissue test, if feasible.

For the complete label, including companion diagnostic indications and important risk information, please visit www.F1CDxLabel.com and http://www.F1LCDxLabel.com.

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