PRECISION
for medicine

Diagnostic Development Reinvented

Comprehensive services from early development through product launch

Our experienced team of diagnostics experts helps you through every stage from discovery to commercial success. All at one company.

At Precision for Medicine we understand that the route from assay development to commercialization is complex. So, our comprehensive suite of solutions is designed expressly to help your advanced in vitro, laboratory-developed, and companion diagnostics take the shortest path from test concept through clinical trial development, and over regulatory hurdles to reimbursement and market uptake.

We focus on the end from the very beginning, cutting through clutter and helping you reach your goal faster. Our integrated team understands how the pieces fit together and ensures that learnings from each stage inform the rest of the process. **The result: We've delivered more than 250 market clearances and approvals along with numerous favorable coverage and payment decisions for hundreds of diagnostic products—including many game-changing, first-to-market innovations.**

Constant, clear communication: Since we are one organization dedicated to diagnostics, we eliminate your need to manage multiple vendors.

Integrated planning: A unified approach—from biomarker research and discovery through regulatory approval, payer acceptance, and commercial uptake—creates efficiencies and speeds results.

Global expertise: We work where you work—and where your samples are stored, your trials held, your products sold—everywhere across the globe.

End-to-end expertise.
All under one roof. All across the globe.

Regulatory Strategy and Submissions

- US FDA advisory
- Regulatory approval strategies
- Submission development and management
- Meetings, appeals, and negotiations
- Quality/compliance
- Expert recruitment for reports, panels, and advisory boards
- EU and global approval programs
- IDE assessment
- Risk/benefit analysis

Biostatistics and Data Management

- Analysis of complex datasets, including NGS and 'omic data, and digital biomarker data
- Data management and EDC builds
- Strategic data development plans
- Study reports and publication support
- Statistical Analysis Plans (SAPs)
- Execution of analysis programs to support submission packages

Market Access and Reimbursement

- Landscape assessment and stakeholder insights
- Coding and payment strategy
- Value story development
- Evidence strategy for coverage
- Reimbursement strategy and execution
- Health economics and budget impact
- Market landscape assessment

Clinical Trial Services

- Clinical trial design, including advanced study designs
- Evidence development plans
- Clinical trial document development
- Site identification and investigator recruitment
- Site training and study initiation
- Site monitoring
- Study management and execution

Branding and Marketing

- Brand development
- Positioning
- Corporate identity
- Strategic planning
- HCP marketing
- Direct-to-consumer marketing
- Tradeshow activation
- Digital communication
- Metrics and analysis

Laboratory Solutions

- Pre-analytical services
- Molecular assays
- Cellular and immunological assays
- Custom assay development
- Biobanking
- Clinical sample identification and procurement
- Clinical sample collection, kitting, and logistics

True global expertise means that wherever you are in the world, so are we.

One team. Integrated across functions. Streamlining test development and speeding global product launches.

THERAPEUTIC AREAS

- Infectious Diseases
- Oncology
- Immunology
- Neurology
- Women's Health
- Cardiology
- Gastroenterology
- General and Plastic Surgery
- Peripheral and Neurovasculature
- Urology
- Pathology
- Hematology
- Toxicology
- Microbiology
- Clinical Chemistry

SPECIALIZED TECHNOLOGIES/ APPROACHES

IVD/LDT

- Sequencing
- IHC, FISH, Immunoassays
- PCR and RT-PCR
- ELISA
- Flow Cytometry
- Liquid Biopsy/ctDNA

CDx

- Dx Partnering Strategy
- Global CDx Regulatory
- Global Market Access

Digital

- Digital Biomarkers & Dx Apps
- AI/Machine Learning Algorithms

FIRST-IN-CLASS PRODUCTS

- Clinical utility evidence strategy for a molecular LDT in obstructive CAD
- Expedited Access Program (EAP) for an innovative NGS assay
- Digital biomarker strategy for an interactive mobile application
- Integrated market access and regulatory strategy for a first-in-class non-oncology complementary Dx
- Conversion of a suite of advanced LDTs to FDA-ready assays
- Reimbursement strategy and coding application for first labeled CDx
- Reimbursement and market access landscape for first pan-cancer NGS test
- Access strategy and tactics for first bladder cancer FISH test

labs data trials

About Precision for Medicine

Precision for Medicine, founded in 2012, is uniquely positioned to offer you a one-stop, turnkey solution to develop and commercialize your diagnostic test. Our more than 1000 experts across 27 campuses means we offer you leading expertise at every stage on the path to market. We provide comprehensive project management, early-phase research and assay development support, forward-looking regulatory and market access solutions, integrated reimbursement and commercialization strategy, and extensive industry and business experience.

Discover the Precision Difference

Consult with our experts about your situation and needs. Once you've experienced our thinking, you'll understand the Precision difference.

To set up an appointment or to learn more, email us at info@precisionformedicine.com, call us at +1 855.222.5010, or visit precisionformedicine.com/contact.

For more information about our clinical trial solutions, please contact us at info@precisionformedicine.com or visit precisionformedicine.com.

PRECISION for medicine
shift the curve

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