PRECISION for medicine | BIOSPECIMEN SOLUTIONS

Building a Diverse, Variant-rich Biobank to Fast-track CDx Development

PRECISION FOR MEDICINE | MOLECULAR & PRECISION MED TRI-CONFERENCE 2022

With the emergence of precision medicine, biomarkers have advanced from being exploratory endpoints to operating as clinical trial assays under fit-for-purpose validations to serve as inclusion and exclusion criteria. Genomic insights play a crucial role in the development of companion diagnostics (CDx) to support precision therapeutics. However, clinically meaningful, actionable mutations occur at very low frequency and securing biospecimens with those mutations is challenging.

Rob Fannon, MPH, MBA
General Manager,
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Rob Fannon, General Manager for Biospecimen Solutions at Precision for Medicine, delivered a presentation entitled *Advancing CDx Development with a Novel Next Generation Sequencing Initiative* at the *Association for Molecular Pathology Annual Meeting*-AMP 2021. Precision for Medicine, a global leader in supplying biospecimen, lab services, and CRO services to the life sciences industries, was pleased to have Fannon share his strategic insights with the AMP audience.

A Novel Next-Generation Sequencing Initiative

Generating data from real clinical samples, rather than contrived specimens, helps optimize biomarker and companion diagnostic development. In partnership with researchers and industry, Precision for Medicine has undertaken an ambitious next-generation sequencing (NGS) initiative called the Precision Oncology Sequencing Initiative (Project P.O.S.I.). The objective of Project P.O.S.I. is to provide annotated, profiled specimens to support biomarker discovery. The overarching goal is to create a precompetitive environment that is agnostic to sequencing panel, chemistry, or technique, thus enabling head-to-head analysis of different panels and facilitating the development of products across a range of technologies.

The first phase of this 2-phase initiative focuses on NGS screening of Precision's extensive library of formalin-fixed, paraffin-embedded (FFPE) specimens. These specimens are screened on the Thermo Fisher Ion Torrent Genexus System using the Oncomine Precision Assay, a clinically-curated cancer panel which features 2,768 of the most prevalent and potentially relevant cancer driver variants across 50 genes. Use of the Oncomine Precision Assay enables a total nucleic acid approach, as the panel can be run as a DNA or RNA-only assay, or both. To date, approximately 7,000 FFPE specimens have been screened.

OncomIne Precision Assay Content

The second phase of Project P.O.S.I. focuses on replicating the work of phase 1 in the liquid biopsy fraction. In addition to serving as a complement to tumor tissue, liquid biopsy offers the advantage of flexibility, as sample collection is less invasive and can be performed more frequently than tissue biopsy.

As part of phase 2, Precision for Medicine has collaborated with Pillar Biosciences, a company with a novel amplicon-based sequencing chemistry. Pillar recently received FDA approval for its oncoReveal™ lung and colon cancer assay, an NGS tissue-based CDx, and is now focused on developing cell-free DNA (cfDNA) diagnostics. This collaboration leverages Precision's clinical network of oncology sites and laboratory services for collection and processing of whole blood samples to obtain cfDNA specimens. These specimens are sent to Pillar Biosciences for sequencing. This effort yields an extremely rich data set as it is a prospective collection done under informed consent, where more phenotypic information can be gathered.

Data generated from both phases of Project P.O.S.I. are combined with key clinical information and biopsy metadata for interrogation using QuartzBio℠, Precision's proprietary multiomic data processing engine. QuartzBio utilizes artificial intelligence (AI) and computational biology

to find connections or relationships among diverse biological data to inform disease modeling, biomarker identification, pathway selection, and patient stratification.

A Purpose-Built Life Science Provider

Access to high-quality, data-rich specimens is just as—if not more—important as a regulatory pathway and commercialization strategy for optimizing the market for a companion diagnostic program. At Precision for Medicine, we understand that high-quality, ethically procured specimens that can be evaluated on a range of lab-based platforms and techniques must be combined with a comprehensive and thoughtful regulatory and commercialization plan to move innovations to market as quickly as possible.

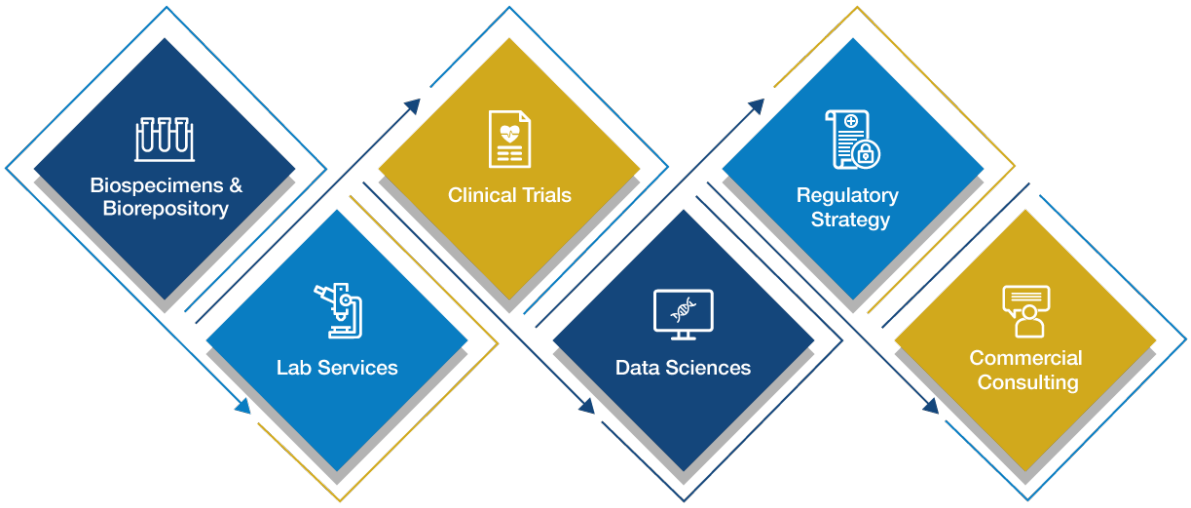
Precision Medicine Group, the parent company of Precision for Medicine, is a purpose-built life science provider focused on not only accelerating time to market for innovative tests and products, but also optimizing commercialization. We offer a full-service solution, from biospecimens, biorepositories, and sample management expertise to assay development, specialty laboratory services, and clinical trial capabilities for biomarker-anchored studies. We also offer expertise in regulatory strategy, data sciences, and commercialization.

Our world-class laboratory network includes seven wholly owned laboratories across the world, 5 in North America and 2 in Europe, all operating under the same quality system. Designed to be biomarker and analyte agnostic, our laboratory network offers a spectrum of advanced tissue and liquid biopsy profiling techniques, including immunohistochemistry, pathology, quantitative multiplex immunofluorescence, circulating tumor cell (CTC) isolation and analysis, and next generation sequencing.

Precision for Medicine, our dedicated in-house specimen unit, was designed to align with this laboratory network and enable our laboratory service offerings. Our specimen product offerings comprise three primary categories—biofluids, tissues, and viable cells—which are available either through our pre-existing inventory or through prospective collections under IRB-approved protocols within our clinical network.

Precision for Medicine

Accelerating the Pace of Scientific Discovery and Approval



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