MolecularMD
An ICON plc Company

ICON

Oncology Drug Approval **Accelerated**

Mitigating Risk

MolecularMD ensures that your biomarker assay will meet its intended purpose as a companion diagnostic with the focus on reducing clinical development cost and accelerating your timeline to market.

Our proven quality management system and regulatory affairs expertise enables us to help manage the regulatory process for the diagnostic with the FDA. We scientifically assess the biomarker(s) at the start of the project, propose a validation

Proven Methods and Techniques

We use the best tools for the clinical indication because we know how critical it is to accelerate the approval and commercialisation of your therapies. Our platform partnerships enable the selection of the most appropriate process and marry it with the diagnostic test, as well as submit it to the FDA for their feedback—accelerating the timeline and speeding up the review and approval process. MolecularMD is actively involved in all stages of oncology biomarker assay development and testing to support drug development programs. Our focus is on accelerating new oncology therapy development by providing innovative platform offerings, expertise in clinical testing services and trial support and demonstrated experience with successful regulatory and commercialisation CDx strategies.

Technology and methods to establish the desired specifications for assay performance and to meet the criteria for budget and patient management.

	Next Gen Sequencing	Sanger Sequencing	Droplet Digital PCR	Multiplex Genetic Analysis	RT-qPCR	qPCR	IHC/ISH	Digital Pathology
Mutation Detection	✓	✓	✓			✓		
Copy Number Variation	✓		✓	✓		✓	✓	
Gene Fusions	✓			✓	✓		✓	
Gene Expression	✓			✓	✓		✓	✓
Protein Analysis							✓	✓
Quantitative Biomarker Analysis			✓					✓

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Our Approach

Design

Establish test design requirements of analytical performance and clinical validation specific to the indication and clinical strategy of the targeted cancer therapy.

– Assess product requirements

– Determine the optimal platform and sample handling method to drive clinical and commercialisation strategy

– Develop the assay procedure and generate appropriate reference samples for use in validation studies for clinical delivery

Develop & Validate

Integrate the enabling technology with the right sample preparation, test workflow and study logistics. Develop and validate tests under ISO 13485:2003 and FDA QSR Part 820 design, development and product requirements.

– Assay transfer & appropriate method validation for clinical delivery

– Sample sourcing for validation

– Fit for purpose validation plan

Implement

Meet the requirements and timelines of the global clinical trial protocols.

– Regulatory pre-submission, risk assessment, and Investigational Device Exemption (if required)

– Supply chain/delivery of reference samples and kits

– Clinical trial data delivery and review

– Distribute and commercialise via centralised testing, CE/IVD kit distribution and Global OEM partners.

Commercialise & Distribute

Distribute and commercialise via centralised testing, CE/IVD kit distribution and Global OEM partners.

– cGMP manufacturing

– Custom kit configurations

– OEM platform partners

Biomarkers and Companion Diagnostics are a Routine Component of Drug Development Programs

An experienced and trusted advisor can be the difference between success or failure

The integration of biomarker research and oncology drug development, once considered an exception, is now becoming the rule. Currently, there are over 800 medicines and vaccines in clinical testing for cancer, 73% of which have the potential to be personalised medicines[1]. Many of the drugs that turn into personalised therapies will require the development of a companion diagnostic in order to demonstrate safety and efficacy and gain regulatory approval. In 2015 there were over 700 unique biomarkers used in clinical trials[2]. Companion Diagnostics is a rapidly evolving environment full of opportunity and risk for BioPharma Companies.

MolecularMD focuses on mitigating risks and is uniquely positioned to assist clients in accelerating oncology drug approval. For over a decade MolecularMD has delivered on service projects that span the continuum from clinical trial assay validation to the commercialisation of companion diagnostics. A cross-functional team, led by a highly experienced Program Director, ensures that the appropriate level of support is provided in key areas such as assay development and validation, documentation, clinical trial management, regulatory submission and kit manufacturing/ commercialisation.

Fulfilled ● **Deficiency** ○

Key Criteria for CDx Partnering Decisions	CAP-Accredited, CLIA-Certified Laboratories	Global Reach / Lab Network	ISO 13485:2003 Compliant	cGMP Manufacturing of IVD Kits	Expertise in CDx PMA Submissions & Clinical Trials	Competency in Assay Prototyping & Bridging	Multiple Tools-Platform Agnostic
MolecularMD	●	◑	●	◕	●	●	●
Oncology CROs	●	◕	◔	○	◔	◔	◕
Large Reference Labs	●	◔	○	○	◑	○	◕
Specialty Labs	●	◔	○	○	○	○	◔
IVD Manufacturers	○	◕	●	●	◕	◔	◑
Life Science Tools Companies	◔	◑	◔	○	○	○	◔

1. "Personalised Medicine, Targeted Therapeutics and Companion Diagnostic Market to 2019 – Strategic Analysis of Industry Trends, Technologies, Participants, and Environment." KellySciPub.
2. Amplion BioMarker Base (2-11-2016)

Quality Management System

MolecularMD's Quality Management System is compliant with the requirements of ISO 13485:2003 and FDA QSR Part 820 for the design, development and production of molecular diagnostic products. MolecularMD laboratories are CLIA certified and accredited by the College of American Pathologists (CAP). Individual state licenses are held in California, Florida, Maryland, Massachusetts, New York, Pennsylvania and Rhode Island.

ICON plc Corporate Headquarters

South County Business Park
Leopardstown, Dublin 18
Ireland
T: (IRL) +353 1 291 2000
T: (US) +1 215 616 3000
F: +353 1 247 6260

ICONplc.com

About ICON

ICON plc is a global provider of outsourced drug and device development and commercialisation services to pharmaceutical, biotechnology, medical device and government and public health organisations. The company specialises in the strategic development, management and analysis of programs that support clinical development - from compound selection to Phase I-IV clinical studies. With headquarters in Dublin, Ireland, ICON currently, operates from 90 locations in 37 countries and has approximately 13,920 employees. Further information is available at ICONplc.com