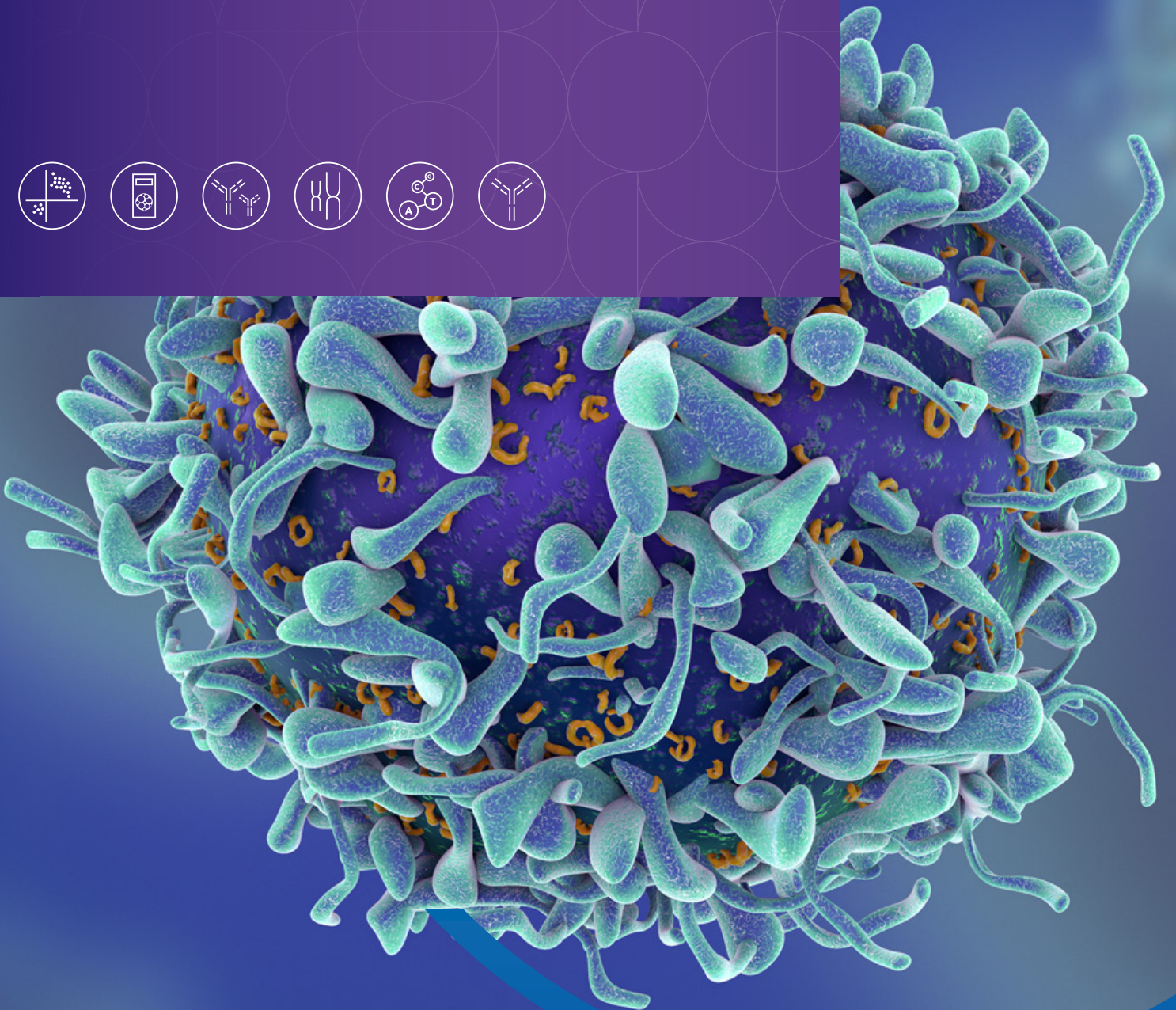




Companion Diagnostic Services



Company Overview

As the largest oncology-focused contract research organization (CRO) in the USA, with comprehensive and global one-stop testing and nearly two decades of cancer-testing experience, NeoGenomics has one of the most robust, analytically validated oncology diagnostic menus in the world. NeoGenomics Pharma Services takes pride in delivering an unparalleled level of expertise, flexibility, and scalability in our products. We can, and will, work with you to identify the best approach for your biomarker testing strategy because we are platform-agnostic.

NeoGenomics consists of three divisions that unify under a common purpose of saving lives by improving patient care:



Pharma Services

biomarker testing CRO specializing in assay development, validation, and clinical trial testing

- IHC, Flow Cytometry, Molecular, Cyto/FISH, Immunoassay, mIF
- Global lab sites in the U.S.A., Switzerland, Singapore, and China



Clinical

largest oncology-focused clinical reference laboratory in the U.S.A.

- >1M tests per year. >650K patients served per year. >120 MDs and PhDs
- Unrivalled ability to launch new companion diagnostics (CDx) assay for the US oncology market



Informatics

leveraging real-world data generated from NeoGenomics' Clinical division to accelerate clinical trial site and patient recruitment, diagnostic alerts, or real-world insights.

- Patient Demographics – Unique Patient ID, Age, Gender, Body Site
- Test Information – Test Name, Test Methodology, Result Value, and Explanation
- Provider Connections – Provider Name, Provider NPI, Provider Zip

CDx Services

Emphasis on personalized and precision medicines is driving partnerships between pharmaceutical and diagnostic organizations to develop CDx, with the goal of accelerating clinical trials and regulatory approval. Because CDx are regulated devices, there are additional development requirements beyond those for biomarker or diagnostic assays used in clinical trials. Careful consideration must be given to the regulatory strategy, design of the assay, and supporting technology platform to ensure that the device can be successfully commercialized.

As of January 2021, NeoGenomics has participated in more than 100 CDx-track projects, developing and deploying diagnostic tests intended to select and enroll patients in a clinical trial. These cover a broad range of technologies and platforms and stages of development, from preclinical through pivotal clinical trials. We have extensive experience with assay development, transfer, and analytical validation across a broad range of technologies.



CDx Team

Underpinning NeoGenomics’ CDx Services program are internal experts ensuring lockstep device development and submission to coincide with therapeutic approval. Quality and regulatory (QA/RA) teams oversee that Quality System Regulation (QSR) standards are followed and navigate regulatory interactions and filings. Scientific and medical staff provide guidance during assay development and validation approaches. CDx strategists to offer consultation on strategic IVD partnerships and platform choice to ensure an optimal commercialization pathway. Operations team to deploy robust testing solutions globally to support clinical trials. And lastly, a commercial launch team to ensure successful deployment and post-marketing surveillance for the U.S.A. market.

NeoGenomics’ CDx Services				
QA/RA	Medical & Scientific	CDx Strategy	Operations	Commercial Launch Team
24 personnel	>120 MDs/PhDs	2 PhDs	>120 lab scientists & technicians >44 Project management/support	>70 Clinical BDs, dedicated strategic reimbursement team, 3 Medical Science Liaisons

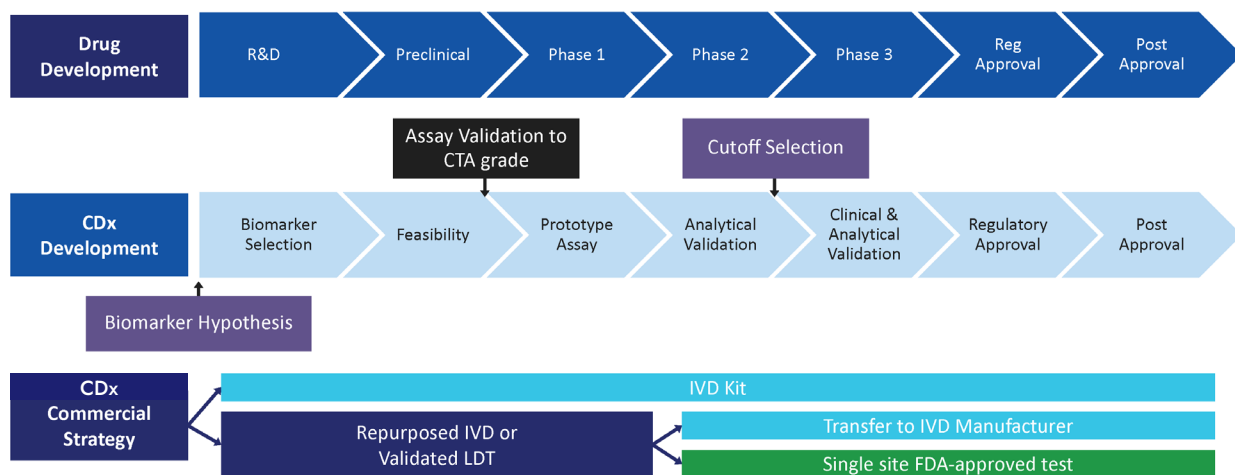
Our Approach

NeoGenomics adopts a technology and commercialization agnostic approach. This affords our partners the ability to pursue either a centralized (i.e., single site FDA approved test, or ssPMA) or decentralized (i.e., kitted) CDx approval pathway. We work with our sponsors to assess a multitude of factors, including timelines, budget, risk, competing technologies, and market opportunity to form an appropriate strategy.

- Platforms for IVD “kitted” development**
- IHC: Agilent, Leica, and Ventana
 - PCR: Qiagen and Roche Molecular
 - NGS: Thermo Fisher and Illumina
 - RNA: NanoString
 - Multiplex IF: Polaris/Akoya
 - Real-time PCR: Biocartis

- Platforms for single-site PMA development**
- Whole exome sequencing
 - 297 gene NGS panel for blood cancers
 - Custom PCR, IHC, ISH, or FISH tests

Note: Development of a novel assay or use of an existing NeoGenomics’ LDT menu assay can be utilized for ssPMA submission.



CDx Project Types

CDx projects come in many forms depending on the stage of the therapeutic program. NeoGenomics can provide support for CDx programs from early-stage research to support pivotal trial testing to commercialization. CDx projects we've supported at NeoGenomics' Pharma Services include:

- Assay development and analytical validation
- Inter/Intra-site reproducibility and orthogonal reproducibility
- Prospective clinical trial testing
- Device bridging studies
- Regulatory submissions and support
- Commercial Launch

Reduce Time and Cost with LDTs

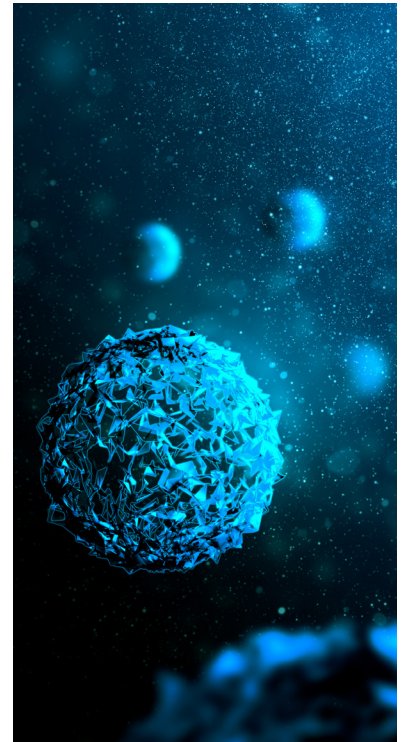
The rapid pace of drug development additionally requires timely development of assays to support early-phase clinical studies. Commitment to developing a kitted, manufactured solution may not be compatible with rapid development cycles and cost constraints associated with early phase clinical trials. NeoGenomics can deliver laboratory-developed tests to support early phase clinical studies, inexpensively and rapidly, that can readily be bridged to kitted IVD solutions for support of late-phase or pivotal studies. When developing assays, we utilize best practices provided by our manufacturing partners or can collaborate with them directly, utilizing IVD-capable platforms and reagents. This permits the design of a robust assay that can support early-phase development while minimizing any delays or bridging studies associated with developing a kitted solution.

NeoGenomics has worked with multiple IVD manufacturers to transfer an LDT to manufacture investigational use only (IUO) kits. We have multiple partners to manufacture the ISO13485 kitted solutions.

Single Site FDA-Approved Tests

While CDx were traditionally developed as distributed and kitted IVDs, the industry has rapidly adopted single site FDA-approved tests as a new mechanism to bring diagnostics quickly to market. This approach allows diagnostics to be developed and approved more rapidly and inexpensively than a distributed kit.

NeoGenomics provides a 21 CFR part 820 compliant Quality system for the development of single-site FDA-approved tests. We have two established testing solutions for sequencing-based solutions; WES for solid tumors and 297 gene NGS assay for blood cancers. Custom solutions for PCR, IHC, ISH, or other single-plex assays are also available.



Commercial Launch

As the largest oncology-focused clinical reference laboratory in the United States, NeoGenomics is an ideal commercial partner to support Day One Launch of CDx tests. We are one of the few CROs that offers integrated testing for clinical trials and commercial launch for the United States.

If NeoGenomics participates in the pivotal clinical trials for your diagnostic as a central testing site, we can readily support Day One CDx launch for the US market immediately following FDA approval. The CDx test will be added to our clinical services menu, and our sales force trained on appropriate use. As a full-service oncology laboratory, NeoGenomics can support all aspects of patient management, from diagnostic confirmation and additional molecular diagnostic and prognostic testing required as part of standard cancer care. We make it easy for physicians to order CDx testing.

Recent examples of Day One launch include the FDA-approved thescreen PIK3CA RGQ PCR test to support the launch of Novartis' PIQRAY® therapeutic, Thermo Fisher's OncoPrint Dx Target Test, and multiple PDL1 tests and indications.

Sponsored Test Programs

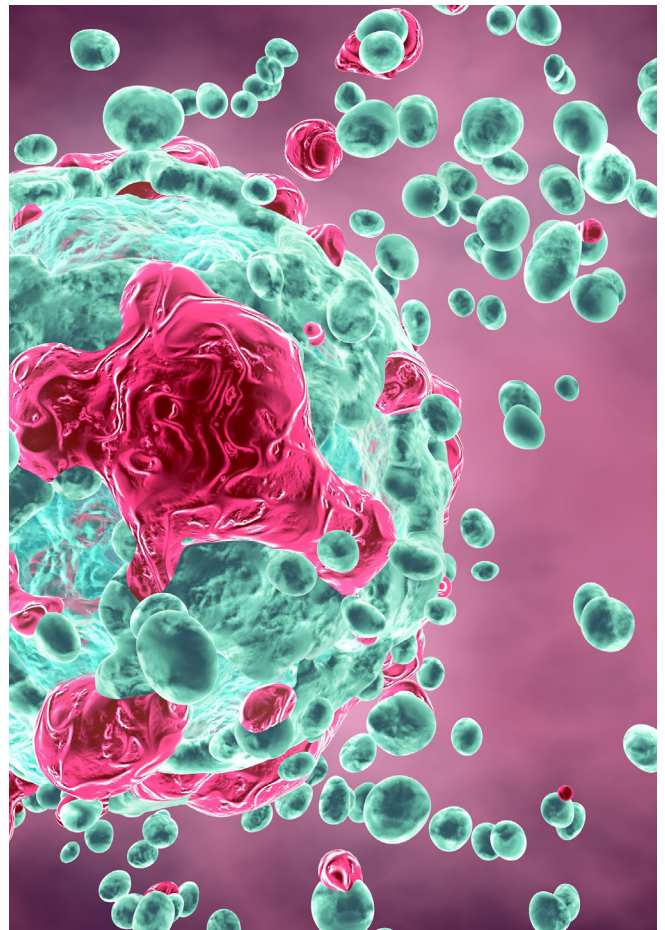
NeoGenomics has developed a Sponsored Test Program to eliminate this barrier to utilization and ensure that all patient care decisions are based on the best available medical science. A collaborative and integrated approach to maximize your product launch success. Through the NeoGenomics' Sponsored Testing Program (STP), we can help broaden your voice and amplify reach and frequency to pathologists and oncologists to build awareness and accelerate biomarker testing. An STP removes testing barriers and uses real-time data to identify the right patient at the right time for the right treatment. Sponsored Testing Programs are available for both companion diagnostics and genomic testing. Under this program, the pharma sponsor covers any testing not otherwise covered by Centers for Medicare and Medicaid.

Recent examples include the launch of PIK3CA, RET, and N-TRK testing to support launch of alpelisib, selpercatinib and larotrectinib, respectively.

Regulatory Support

Our regulatory and quality teams are an integral part of all CDx projects. Regulatory works closely with our scientists and medical teams to ensure that assays are sufficiently analytically validated for their intended use. Additionally, the NeoGenomics Regulatory Affairs group can support the following submissions and interactions with the Food and Drug Administration.

- Risk assessments
- Pre-submission meetings with CDRH
- IDE filings
- PMA filings
- HUD and HDE filings



NeoGenomics CDx Team



T. Scott Reid, PhD, MBA
Vice President, Alliances & CDx

Scott Reid heads up companion diagnostic services and strategic alliances at NeoGenomics. He has been with NeoGenomics since 2016 and previously covered Business Development for the New England territory. He has been working in oncology since graduate school with a focus on diagnostics and IVD commercialization that has included previous positions at LabCorp and Covance. Scott completed his PhD in Biochemistry and MBA at Duke University.



James Yen, PhD
Associate Director, CDx Strategy

James Yen is a Senior Scientific Manager within NeoGenomics' Pharma Services division. He completed his doctorate studies at UC Irvine studying the mechanism of protein degradation. Afterwards, he began working at Zymo Research (Irvine, CA) to lead the development of research reagents and kits for the study of epigenetics. He subsequently joined MDxHealth (Irvine, CA) in 2011 to setup their CLIA/CAP lab operations within the US and worked in both the clinical operations and product development teams as a senior scientist. In 2014, James joined Clariant (GE Healthcare) to manage the Pharma Services molecular and FISH operation teams. NeoGenomics acquired Clariant from GE Healthcare in 2015, and his current role is as a scientific liaison with a focus on NeoGenomics' molecular, FISH and companion diagnostic service offerings.

12701 Commonwealth Dr., Suite 9
Fort Myers, FL 33913
United States
Phone: 866.776.5907
Fax: 239.690.4237

31 Columbia
Aliso Viejo, CA 92656
United States
Phone: 800.720.4363
Fax: 949.425.5865

7256 S. Sam Houston Pkwy W. Suite 300
Houston, TX 77085
United States
Phone: 800.720.4363 / 713.528.4363
Fax: 713.668.3565

NeoGenomics Laboratories, Inc.
4570 Executive Drive, Suite 250
San Diego, CA 92121
Phone: 949.445.7300 5056
Fax: 713.668.3565

A-One Business Center
Bâtiment A5, 2nd Floor
Z.A. La Pièce / Route de l'Etraz 1
1180 Rolle, Switzerland
Phone: +41 (0)21 721 06 00
Fax: +41 (0)21 826 00 73

NeoGenomics Singapore Pte Ltd
61 Science Park Road, #02-11,
Singapore 117525
Phone: +65 6591 5200

Suzhou NeoGenomics Pharmaceutical
Research Co., Ltd Building 6, Block 19,
Yong'an Road Huguan Industrial Park,
Suzhou New District, China



neogenomics.com

© 2021 NeoGenomics Laboratories, Inc. All Rights Reserved. All other trademarks are the property of their respective owners. Rev. 042821