A focus on personalized medicines and immune-modulating drugs has given rise to biomarker-focused oncology clinical studies. The use of biological signatures to identify patients that will benefit from a particular therapy has greatly accelerated the pace of drug development and approval. For this reason, there has been increased use of biomarkers and more specifically companion diagnostics, in current oncology drug development. With more than 30 active programs with pharmaceutical sponsors and IVD companies NeoGenomics has been a key player in this new approach to oncology drug development.

NeoGenomics has extensive experience working directly with large oncology IVD manufacturers across a multitude of platforms. These include Hoffmann-La Roche AG (Switzerland), Becton Dickinson, Agilent Technologies, Inc. (US), QIAGEN N.V. (acquired by Thermo Fisher Scientific) (Germany), Abbott Laboratories, Inc. (US), Danaher Corporation (US), Illumina, Inc. (US), NanoString (US), and Thermo Fisher Scientific Inc. (US). Because of these strategic relationships, NeoGenomics can engage in a collaborative enterprise with pharmaceutical organizations who are seeking to develop a companion diagnostic biomarker.

The global nature of clinical trials and drug development requires networks of harmonized laboratories and partners to ensure that assays developed in early phase development are scalable to the rest of the world. With NeoGenomics’ recent expansion into Singapore and China (laboratory) with a focus on supporting real-time companion diagnostic testing and established partnerships with global manufacturing partners, NeoGenomics is well positioned to continue our efforts in the global market to develop and commercialize companion diagnostics.

As the largest oncology-focused clinical reference laboratory in the United States, NeoGenomics uses a multitude of platforms and resources that not only supports companion diagnostic development but also commercial launch. Our Day One Launch program ensures that physicians and patients have access to companion diagnostic testing immediately following FDA approval of the drug/device combination.
In recent case studies associated with Merck and Novartis, NeoGenomics lead all other diagnostic companies in the development and commercialization of at least two successful companion diagnostics for targeted cancer therapies, KeyTruda and Piqray to support drug launch.

With known development and regulatory expertise NeoGenomics has created defined processes associated with each aspect of the program that involves coordinated efforts in the areas of Consultation; Customization; Commercialization; and Consolidation. Development of companion diagnostics is complex and time consuming. Our team of scientists, pathologists and business development professionals are here to help.

### Consultation
- Platform and technology selection
- Study design
- Regulatory support and submission
- Pathology
- Commercial Strategy

### Customization
- Assay Development
- Fit for purpose assay design and validation
- Global harmonization. Clinical trial testing (Phase 1-3)
- Project management
- Data management

### Commercialization
- IVD Partnerships
- Single-site FDA approved test
- USA commercial launch
- Partnerships for Ex-US launch
- Day One Launch Program
- Sponsored testing program
- Data services

### Consolidation
- Consolidate specialty testing with one CRO

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**Novartis CDx Case Study – Piqray.**

NeoGenomics Becomes First to Launch PIK3CA CDx as Part of ‘Day One’ Program

**NeoGenomics and QIAGEN Collaborate to Offer Companion Diagnostic Test for HR+/HER2- Advanced Breast Cancer Patients to Detect a PIK3CA Mutation**

FDA approves Novartis Piqray® - the first and only treatment specifically for patients with a PIK3CA mutation in HR+/HER2- advanced breast cancer

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