

Quintiles advances new approach to speed biomarker targeted therapies to cancer patients

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As a first step, Quintiles is undertaking a study with the participation of US Oncology Research, supported by McKesson Specialty Health and The US Oncology Network, to explore the operational feasibility and clinical benefits of an upfront approach to the genomic profiling of tumors from metastatic colorectal cancer (mCRC) patients.

The study will investigate how pre-profiling and genomic sequencing data may support physician treatment decisions, including the identification of appropriate clinical trials for patients.

"Today, the industry's approach to stratifying patients through genomic screening is sequential - testing for oncology biomarkers one at a time, and often only as part of screening for participation in a single clinical trial," explained Jeffrey Spaeder, M.D., chief medical and scientific officer for Quintiles. "Early indications from this study suggest that we can provide physicians and patients with early visibility on potentially clinically actionable biomarkers within a rapid two-week timeframe. This level and speed of analysis has promise to save valuable time in administering potentially life-saving therapies to patients, and reduce the development times of precision medicines."

As cancer research and care enter the era of precision medicine, Quintiles is actively transforming the model for testing new therapies. Pre-profiling may accelerate early testing of new biomarker-targeted therapies by enabling biopharmaceutical

companies to focus on molecules with high potential for safety and effectiveness. For cancer patients and physicians, pre-profiling enables the efficient matching of the right patients to the right clinical studies, and increases patient access to innovative therapies.

"Our work is taking a critical step toward making precision medicine a reality," continued Spaeder. "Quintiles' end-to-end design and delivery model for connecting genomic testing with clinical trials supports the needs of patients, physicians and drug developers. Our goal is to provide oncology investigators and their patients with access to effective, cutting-edge therapies through a model built upon experience and high-quality cancer care."

The primary objective of the study titled "Feasibility Study of Biomarker Analysis for Patients with Metastatic Colorectal Cancer", is to determine the number of genetic changes that occur within mCRC patients that are targeted by US Food and Drug Administration approved therapies, as well as those targeted by therapies in development. The study will perform a broad-based biomarker analysis on mCRC patients, and the results will be reported to the treating physicians in a clinically meaningful format to help identify higher-risk patients and aid in selecting better treatment options.