A scientist at Q2 Solutions' Edinburgh genomics laboratory prepares a sample for sequencing. Photo by Alec Brown

In Edinburgh, taking comprehensive genomic profiling to the next level

Having validated TSO Comp EU, Q² Solutions is supporting international clinical trials

Q² SOLUTIONS IS a global laboratory supporting clinical trials as well as research and development, companion diagnostic studies, and more.* These clinical trials span a broad range of indications from cardiovascular to infectious disease, but just over half of them have an oncology focus—either solid tumor or hematological malignancies. Since 2016, Q² Solutions has supported more than 3400 oncology projects involving over 250 sponsors. It has also contributed to the development of over 85% of FDA-approved therapies that have a companion diagnostic.

Q² Solutions operates four main central laboratories—in Edinburgh, Scotland; Beijing, China; Valencia, California; and Singapore—in addition to several specialty labs around the world. It operates genomics laboratories in its Edinburgh and Beijing sites, and its flagship genomics laboratory is located in North Carolina's Research Triangle Park.

The Edinburgh site serves as the company's testing hub for the United Kingdom, Europe, Africa, and the Middle East, and it is currently gaining prominence for being the first to validate Illumina TruSight Oncology Comprehensive (EU), or TSO Comp.** This assay is the first CE-marked in vitro diagnostic solution for comprehensive genomic profiling (CGP) of DNA and RNA variants, plus microsatellite instability and tumor mutational burden, for multiple solid tumor types.

To date, Q² Solutions has provided its clients with biomarker analysis by employing the research-use-only TruSight Oncology 500 (TSO 500) assay. Using TSO Comp, they can now provide tumor profiling information with a CE-marked IVD assay—an important consideration with the advent of the European Union's In Vitro Diagnostic Regulation (IVDR)—and immediately select European patients for enrollment in clinical trials based on specific biomarkers covered by the test.

"Having a CE-marked assay for tumor genomic profiling of European patients in oncology clinical trials makes things much simpler for everyone involved," says Patrick Hurban, PhD, vice president and general manager of the Genomics division at Q² Solutions.

Since 2018, Q² Solutions has been an extensive user of

**q2labsolutions.com*
***emea.illumina.com/products/by-type/ivd-products/trusight-oncology-comprehensive.html*

Illumina's oncology portfolio of assays (including TruSight Tumor 170, TSO 500, TSO 500 ctDNA, and TSO Comp), but it's the CE-IVD marked assay that excites Hurban, since it provides a clear bridge between patient care, biomarker discovery, and companion diagnostic development.

"We see a really nice continuum," he says, "between initial studies using an assay like TSO 500 in a research or clinical trial setting to identify biomarkers or build evidence around their utility, to prospective studies using TSO Comp to determine whether patients are eligible for clinical trials based upon a specific biomarker. And of course, because it has a CE-IVD mark, and many of those biomarkers have known therapies associated with them, it provides the clinical site care team with rich biomarker information that will allow them to treat their patient to the best of their ability."

Reaching large, geographically diverse patient populations

Clinical trials commonly include multiple sites across several geographic regions. When a biomarker is used to determine patient eligibility for a trial, biomarker testing can be conducted using local laboratories or through a central laboratory. While local laboratory testing has some apparent advantages, variability in test quality, delivery, and even composition can add unwanted uncertainty to a trial. Hurban says, "Biopharma companies have to weigh the risks entailed by enrolling patients based on results obtained from various tests performed in multiple local laboratories, against those obtained from a centralized testing laboratory with a single test performed using globally harmonized standard operating procedures."

As a global laboratory, Q^2 Solutions can serve biopharma clients with diverse oncology clinical development programs that target the broad array of biomarkers covered by TSO Comp. With the addition of TSO Comp in the Edinburgh laboratory, and soon the TSO Comp that was just approved by the FDA in the US,* clinical trial sponsors that approach Q^2 Solutions with planned trials featuring clinical sites in Europe and the US will have access to a uniform testing solution and consistent quality of results. Hurban says, "Because we have solutions available to them in so many regions, we can emphatically say, 'Yes, we can support this trial.'"

The success of clinical trials hinges on data submitted to the FDA, most of which is laboratory testing data. "The more you can do to ensure the quality, the integrity, and thus the utility of that data, the less risk you are introducing into your submission," Hurban says, "which ultimately benefits the patients we all serve. We're excited to offer TSO Comp as a biomarker testing and comprehensive genomic profiling solution that we conduct uniformly within our global laboratories."

CGP for all

Comprehensive genomic profiling is a powerful tool that can provide actionable insights to improve patient care. Pharma companies, central laboratories, and large health care systems are taking advantage of this technology. Hurban sees a future where even clinics and hospitals in rural and community care settings have the staffing, equipment, and expertise for solutions based on next-generation sequencing. But to realize that outcome, he believes that clinical trial data must be obtained under the best conditions to build the necessary evidence to advance the field. Advanced clinical laboratories like Q^2 Solutions are well positioned to facilitate the pursuit and development of therapies and companion diagnostics that could ultimately improve health outcomes and benefit a broader set of patients. ◆

To learn more about the first US FDA-approved distributable CGP IVD with pan-cancer CDx claims, go to illumina.com/products/by-brand/trusight-oncology/ivd-solutions.html

*illumina.com/company/news-center/press-releases/press-release-details.html?newsid=cca694db-8cc7-4b6a-9449-38ccd9329816