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A **GenomeWeb Lunch and Learn**
Presented by **IQVIA Laboratories** Summary

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On October 7, 2025, IQVIA Laboratories hosted a GenomeWeb Virtual Lunch and Learn titled “Navigating Global Clinical Trials with Comprehensive Genomic Profiling,” featuring Jennifer Sims, director of genomics assay development at IQVIA Laboratories. The event drew attendees from across the biopharma industry eager to learn how IQVIA Laboratories’ global laboratories are advancing precision oncology through implementation of Illumina’s TruSight Oncology 500 (TSO500) next-generation sequencing (NGS) assay.

Sims began by framing IQVIA Laboratories’ mission: “We work to improve patients’ lives by treating every sample as if a life depends on it,” she said. IQVIA Laboratories is the first global CRO offering the TSO500 family of assays to support prospective testing of patient samples from clinical trials across Europe, the US, and China.

The TSO500 assay is a large tumor profiling assay covering more than 500 cancer-related genes, enabling both solid tumor profiling through the TSO500 tissue assay and liquid biopsy profiling using the TSO500 ctDNA v2 assay, thereby offering flexibility for clinical trial sponsors.

“TSO500 is a great example of a tumor profiling assay that can support your biomarker development and CDx testing,” she added.

The assay’s versatility makes it valuable both for biomarker discovery and companion diagnostic (CDx) development. Sims explained that by inputting 40 ng DNA or 80 ng RNA into the TSO500 tissue assay, IQVIA Laboratories can achieve a sensitivity of 4.5 percent variant allele frequency (VAF). For the TSO500 ctDNA test, 20ng cfDNA resulted in 0.3 percent VAF sensitivity.

IQVIA Laboratories’ TSO500 validation is fully CAP/CLIA compliant, with demonstrated accuracy, precision, and reproducibility across sites. “We looked at the New York State CAP requirements to tailor our validations in all of our locations,” she said. “We were able to see excellent accuracy for our variant detection, as well as high sensitivity and specificity of the assay.”

IQVIA Laboratories has validated TSO500 across multiple platforms, including Illumina’s NovaSeq 550Dx and NovaSeq 6000 achieving equivalent results.

TSO500: Speed, Coverage, and Regulatory Strength

During the Q&A session, Sims elaborated on why TSO500 is a compelling choice for global clinical trials.

“This panel has a wide range of biomarkers,” she said. These include broad coverage of variant classes, including SNV/CNV/MSI/fusions/TMB. “We can return results within about 10 business days so that we can support patient enrollment.”

She also noted that TSO500’s CE-IVD mark makes it one of the few large-scale NGS profiling assays suitable for clinical enrollment within the EU under In Vitro Diagnostic Regulations (IVDR). “This is important for being able to support patient-specific enrollment within the EU,” she said.

Comparing it to other assays, Sims added: “It is a larger panel that can serve a dual purpose: providing data back to sites for patient enrollment using a small subset of the panel and also deliver the remaining data to the pharma partner” which can be used for exploratory purposes.

Validation and the Use of Laboratory Developed Tests

When asked about validating laboratory-developed tests (LDTs) for use in clinical trials, Sims outlined IQVIA Laboratories' rigorous approach:

"We included more than 60 different clinical cases in our validation along with reference material, and we used a validated orthogonal method so that we would be able to evaluate accuracy using that orthogonal method as our ground truth."

Using the TSO500 assay, IQVIA Laboratories achieved nearly 100 percent accuracy in variant detection, specificity, and sensitivity, and intra- and inter-run precision. They validated the method both on an automated platform and manually. "We looked specifically at our tumor content, our tissue volume, and our nucleic acid yield," she said. For reliable results, IQVIA Laboratories determined that a minimum of 20 percent tumor content and approximately 4 millimeters cubed of total tissue volume are required.

On evolving FDA guidance around LDTs, Sims noted: "We definitely are always keeping our eyes on the evolving regulatory landscape to see how that might change our approach to validations and testing in the future."

Global Expertise and Seamless Operations

IQVIA Laboratories operates as a global network of CAP- and CLIA-accredited sites designed to deliver seamless and global support for clinical trials. Sims explained that their central genomics laboratory — based in North Carolina and CAP-accredited and CLIA-licensed in all 50 US states — serves as its Genomics Center of Excellence, with additional facilities in the UK, China, and Singapore enabling the company to support global testing.

This distributed infrastructure allows IQVIA Laboratories to mirror capabilities across continents, minimizing regional testing disparities and regulatory bottlenecks. For example, the company ensured that the same services are available at its China location as at its North Carolina facility.

IQVIA Laboratories' experience in companion diagnostics (CDx) is extensive, and the company has developed strong relationships with device manufacturers to enable a straightforward path to CDx testing for its pharma partners.

Sims highlighted the laboratory's track record: Within the genomics group, IQVIA Laboratories has performed testing for more than 15 next-generation sequencing CDx studies, and IQVIA as a whole has participated in more than 50 CDx studies.

Patient-Specific Custom Reporting

A standout feature of IQVIA Laboratories' offering is its custom reporting infrastructure, which ensures actionable insights reach clinical sites quickly and consistently. Sims explained:

"We can support patient-specific reporting back to sites from our laboratories that are located across the globe. Some of that testing may include comprehensive tumor profiling, which can be tailored to support your specific biomarker and in your therapeutic area."

Each report is reviewed by a board-certified molecular pathologist and medical director who verify results and identify clinically significant variants. Reports include sequencing quality metrics, variant interpretations, and potential clinical trials or treatment matches, enabling timely patient enrollment decisions.

Sims also detailed IQVIA Laboratories' meticulous approach to sample handling and quality control, underscoring that strong analytical performance begins with sample integrity.

Decades of Experience in Genomics and Bioinformatics

The IQVIA Laboratories genomics group draws on more than 25 years of continuous operation and deep experience in assay development with 140 staff professionals supporting genomics testing.

IQVIA Laboratories' strength lies not only in its laboratory footprint, which includes 19 laboratories on five continents, but also in its in-house bioinformatics expertise. The company established its bioinformatics group as early as 2002, a move that has enabled it to deliver advanced analytical and statistical support to clinical partners.

"Our bioinformatics group has over 20 scientists who work to support biostatistical work, custom pipeline development, as well as new product development," Sims said, noting that the group's principal bioinformatician is among the IQVIA Laboratories genomics group's longest-tenured scientists.

Harmonized Quality and Regulatory Compliance

Regulatory compliance is another cornerstone of IQVIA Laboratories' global strategy. Sims emphasized that all IQVIA Laboratories sites follow harmonized standard operating procedures (SOPs) and use aligned instrumentation to ensure consistency and remove site-to-site variability.

"We have harmonized SOPs as well as instrumentation across our laboratories so that we can remove some of the bias that may occur in testing in different locations," she said.

The company's global reach is matched by its deep regulatory knowledge. Sims explained that IQVIA Laboratories' regulatory team helps sponsors navigate complex frameworks, including IVDR in Europe and local testing requirements in China.

"We are able to provide study support and regulatory guidance to help you navigate the dynamic regulatory landscape of a global clinical trial," she said.

Ensuring Consistency Across Global Sites

Consistency is key when running large-scale global trials. Sims explained that IQVIA Laboratories ensures alignment across its laboratories by centralizing development and sending standardized test panels to satellite sites.

"We centralize our development activities in our North Carolina laboratory by performing feasibility and validation work there first, and then collaborate with our sister laboratories to transfer and validate the assay in place at that site," she explains.

Each location follows harmonized training, protocols, and pipelines.

"We do evaluate all validation results through the same validated pipelines," she said. "We also have the same performance metrics tracked and the same qualified positive and negative controls, so that we can ensure as much consistency as possible."

With 25 years of operational history, a fully global laboratory footprint, harmonized SOPs and instrumentation across laboratories, and expertise spanning assay design to regulatory navigation, IQVIA Laboratories' genomics group demonstrated how it serves as a comprehensive partner for biopharma companies conducting biomarker-driven and companion diagnostic trials.

From sample to answer, the organization delivers what Sims described as a seamless, scientifically rigorous, and globally coordinated approach to precision oncology testing — anchored by its expertise with assays like TSO500 and a steadfast commitment to "treating every sample as if a life depends on it."