Fact Sheet

Translational Science and Innovation Laboratory (TSAIL)

Translational biomarker solutions to accelerate drug development through early test development and adoption of emerging technologies

In today's evolving, dynamic clinical development environment, IQVIA Laboratories must adapt to meet the growing demand for early biomarker evaluation before advancing into the clinical arena. Identifying novel biomarkers for predictive clinical use is becoming increasingly complex, withstanding the breadth and specialized nature of biomedical information. This often calls for experimentation and new technology development outside the regulatory confines of clinical trials, attended by specialized subject matter experts. At IQVIA Laboratories, our dedicated, state-of-the-art Translational Science and Innovation Laboratory (TSAIL) is designed to address these challenges by providing the agility and breadth of translational science capabilities and expertise required to bridge the gap between pre-clinical and early clinical trial drug development. TSAIL cradles the journey from biomarker discovery and characterization to assay development for clinical studies. This approach ensures that the most effective predictive biomarkers and technologies are deployed rapidly, accelerating the development of therapeutics.

TSAIL focuses on biomarker discovery activities, exploratory clinical sample testing and new technology evaluation. Scientific teams include anatomic, digital and molecular-genetic pathology, cellular immunology and ex-vivo/in-vitro immunoassays that **harmonize with methods from other IQVIA laboratories teams located in the same facility**.

IQVIA Laboratories Translational Science and Innovation Laboratory

TSAIL Accelerating Biomarker Discovery

Anatomic and Digital Pathology

- Histopathologic diagnostics and morphometry
- Single and multiplexed biomarker assessments
- Artificial intelligence (AI) and machine learning (ML) assisted whole slide imaging analytics
- Spatial RNA expression profiling

Immune Monitoring

- Intracellular Cytokine Staining (ICS) assays
- Multi-parametric ELISpot/FluoroSpot assays
- Cultured immune cell assays
- Alpha assays/Multimode plate assays
- Cytokine quantitation
- Spectral Flow Cytometry and Cell Sorting
- Novel assay development and POC biomarker validation

Knowledge Base

- Experienced biomarker development scientists
- Board-certified anatomic and molecular-genetic pathologists
- Experienced immunologists and ASCP certified flow cytometry scientists
- Vast experience immune monitoring pre-clinical and clinical vaccine, oncology and cell and gene therapy trials
- Off-the-shelf and custom informatic pipelines

Molecular-Genetic Pathology

- Fixed tissue and liquid DNA/RNA genetic profiling, with clinical variant curation
- Solid tumor molecular minimal residual disease

TSAIL's custom-designed, multidisciplinary space melds industry-leading expertise with numerous cutting-edge technology platforms to support all aspects of biomarker development and delivery. TSAIL supports state-of-the-art research and fit-for-purpose validation and by enabling customers to access a broad range of services, including bespoke biomarker assay development, bioinformatic pipeline builds, data and digital image analytics, and the flexibility to work-up emerging technologies.

Working with TSAIL additionally provides several ancillary benefits, including:

- Access to pre-clinical research technologies and exploratory data to guide clinical trial design
- Opportunities for team building and collaboration with IQVIA Laboratories' subject-matter experts to enhance clinical trial success

- Deployment and outsourcing of biomarker R&D projects that leverage the IQVIA Laboratories Global ecosystem
- Access to established *in vitro* diagnostic (IVD) and Companion Diagnostic (CDx) manufacturers in the IQVIA Laboratories network/portfolio
- Integration of holistic artificial intelligence/machine learning technologies

TSAIL's translational scientists can help you overcome many of the challenges associated with moving biomarkers and technologies from discovery into clinical trials.

Access to a diverse portfolio of capabilities and technology platforms

Anatomic and Digital Pathology

- Fully stocked histology laboratory for wet or formalin-fixed, paraffin embedded (FFPE) tissue processing
- End-to-end test oversight by board-certified pathologists
- Open chromogenic and fluorescence staining platforms, including Leica Bond Rx, Ventana Discovery and Agilent Omnis
- Aperlo and Epredia light and fluorescent whole slide imaging
- Goodness-of-fit AI/ML algorithm development for digital image analytics.
- RNAScope and Nanostring GeoMX RNA profiling
- Greater IQVIA Laboratories adjacencies and global deployment for scaling

Immune Monitoring

- Cytek Aurora(R) Spectral Flow Cytometers and CS Cell sorter (64 parameter, 5 lasers)
- MabTech IRIS (ELISpot/FluoroSpot reader)
- Meso Scale Discover (MSD) reader
- Victor Nivo Alpha assay/Multimode reader
- Curiox Pluto cellular assay automation system
- End-to-end assay development, qualification, testing, and analysis by a team of skilled and experienced Immunologists
- Greater IQVIA Laboratories adjacencies and global deployment for scaling

Molecular-Genetic Pathology

- Thermo Fisher Genexus System automated nucleic acid extraction and Next Generation Sequencing (NGS)
- Thermo Fisher Oncomine Precision and Comprehensive Assay amplicon-based FFPE tissue NGS panels
- Liquid DNA/RNA NGS for solid tumor molecular minimal residual disease (~0.1%)
- Board-certified molecular-genetic pathologist for variant curation and clinical interpretation

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