IQVIA LABORATORIES

IQVIA Laboratories

A global drug discovery and development laboratory services organization

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Offering a comprehensive suite of central laboratory and specialty biomarker services

Our expertise spans genomics, immunoassays, flow cytometry, anatomic pathology, precision medicine assays, vaccine assays, ADME, and regulated bioanalytical services. IQVIA Laboratories also specializes in antibody and biomarker discovery and decentralized clinical trial laboratory solutions.

The right experts. The right solutions.

Committed to scientific rigor, operational excellence and advanced laboratory technologies, we support every phase of the drug discovery and development process across diverse regions and regulatory frameworks to ensure the highest standards of data integrity and accelerate the delivery of transformative therapies to patients.

Central laboratory services

Precision testing, seamless operations, delivered worldwide

Our comprehensive central laboratory services support clinical trials across the globe through the world's largest network of CAP-accredited central laboratories. With strategically located facilities, we offer routine safety and biomarker testing to ensure consistent methodologies, equipment and reporting standards, driving standardization, accuracy and reliable data across all studies.

FOCUSED ON PROJECT DELIVERY AND OPERATIONAL EXCELLENCE

Our commitment to project delivery and operational excellence empowers faster, more informed decisions through a robust laboratory trial management system. With globally standardized testing and centralized data visibility, sponsors benefit from an integrated, flexible solution to manage study data and operations seamlessly.

- **Enhanced investigator site experience:** A comprehensive suite of tools and dynamic site portal streamlines laboratory operations to meet the demands of global trials, enabling sponsors to track progress efficiently from start to finish.
- **Clinical trial sample and consent tracking:** Labmatrix® ensures samples are tracked throughout their lifecycle, from sites to labs and biorepositories.
- **Biorepository and specimen management:** Preserving the integrity of millions of biospecimens annually, meeting clients' needs for short- and long-term storage and logistics based on study requirement.
- **Kitting and logistics:** With over 25 years of expertise, we provide harmonized solutions to over 180,000 investigator sites across 90 countries.
- **Decentralized laboratory solutions:** Delivering high-quality results through transformative, patient-centric hybrid and remote approaches, ensuring efficient, safe trial participation from anywhere.

LEADING WITH SCIENCE — INTEGRATED TESTING FOR TODAY'S DRUG DEVELOPMENT

At IQVIA Laboratories, we go beyond traditional central labs, combining scientific expertise and cutting-edge technology to address the toughest challenges in drug development. Our globally harmonized network ensures seamless integration of core and specialty testing.

- **Anatomic pathology:** 30+ expert pathologists deliver traditional and digital pathology services — from histology to IHC and FISH analysis, guided by harmonized SOPs.
- **Spectral flow cytometry:** Integrates translational science with a global fleet of PMT and spectral cytometers, cloud-based analysis tools, and robust data reporting. Our harmonized instrument platforms and dedicated assay validation laboratories elevate research through comprehensive spectral solutions.
- **Immunoassays:** Utilizes ELISA, ultra-sensitive platforms, multiplexing technologies (e.g., bead-based detection, biochips, immunoblotting), and automated systems to deliver comprehensive, global immunoassay solutions.
- **Companion diagnostics:** Leverages global expertise in FISH, IHC, NGS, and quantitative PCR to develop harmonized companion diagnostics assays for protein and gene expression, mutation detection, copy number and translocations.
- **Translational Science and Innovation Laboratory (TSAIL):** Combines scientific expertise and technology evaluation to advance early translational biomarker development. TSAIL offers custom assays, bioinformatics, analytics, digital innovations and novel technology assessments to accelerate the adoption of assays and drive research forward.
- **Cell and gene therapies:** Provides flexible, integrated testing solutions for CAGT programs throughout the drug development journey, beginning with the preclinical phase and continuing through post-approval.
- **Pediatric services:** Implements tailored policies and procedures for pediatric sample collection, handling and testing to ensure reliable results, even from very low-volume samples.

BIOTECH LABORATORY SOLUTIONS

Tailoring lab solutions to navigate complex landscapes

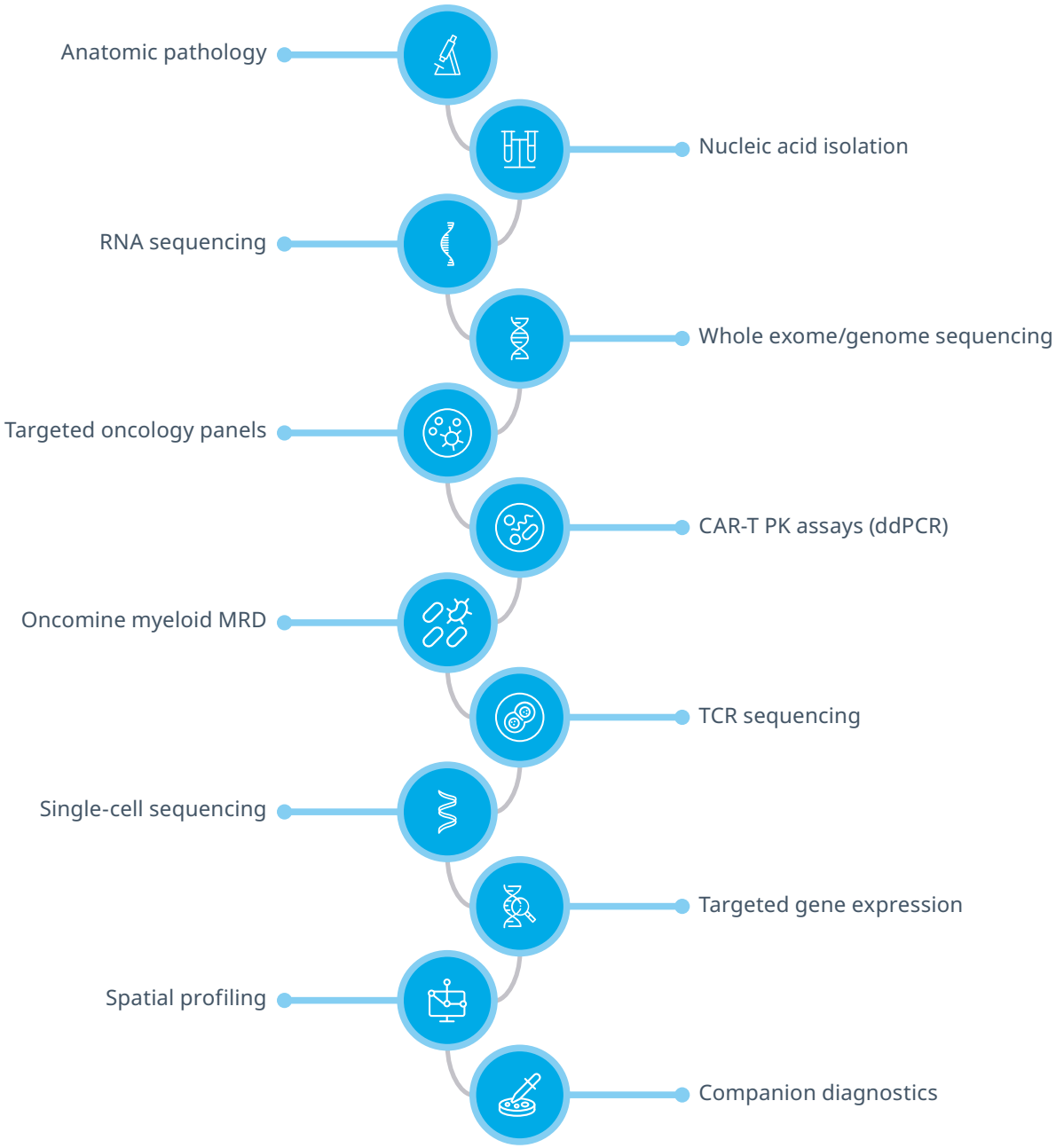
IQVIA Laboratories offers a comprehensive suite of flexible solutions tailored to meet the needs of small and mid-sized companies. With a track record of more than 2,000 biotech studies, we provide expansive expertise, operational efficiency and strategic insights that enable your team to remain lean and focused.

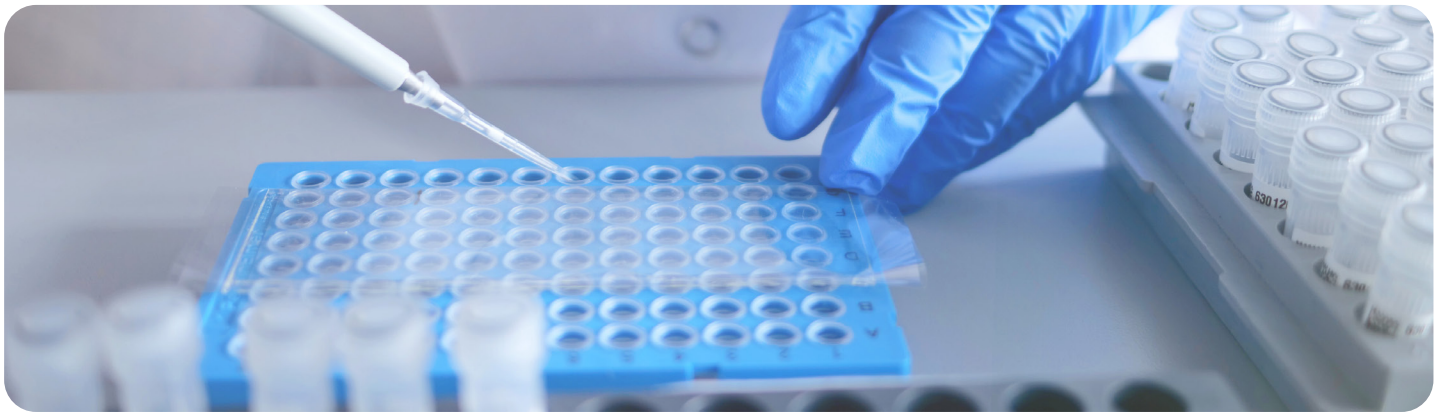
- **Simplicity:** A straightforward approach that streamlines complex processes and systems.
- **Value:** Early laboratory engagement to develop testing strategies that maximize return on investment.
- **Attention and Flexibility:** A dedicated operational point of contact with fit-for-purpose oversight tailored to ensure study success.
- **Confidence:** Access to scientific expertise across key therapeutic areas and technologies to support your clinical development, at any stage.

Genomics

Our experienced genomics team provides a wide range of laboratory and bioinformatics services to support drug discovery, clinical development, and precision medicine. With genomics laboratories in the U.S., U.K, China and Singapore, our expert capabilities span from custom assay design to development, validation, clinical sample analysis and bioinformatics data analysis. As industry leaders in high-complexity genomic testing, our cutting-edge technology and scientific insights maximize the value of your data and advance your research.

We offer end-to-end clinical genomics laboratory expertise with a range of specialized services, including but not limited to:





Discovery sciences

In a competitive R&D environment, IQVIA Laboratories brings expertise in protein production, antibody discovery and immunogenicity assessments to help you select the most promising candidates on the path toward IND-enabling studies, reducing risk of early abandonment and costly, lengthy add-on services.

Protein sciences

Our labs develop protein and antibody reagents tailored to your specifications in scale, purity and other desired characteristics. We are experienced with prokaryotic and eukaryotic recombinant proteins, and our monoclonal antibody reagents include the full sequence for future scalability. Delivering reagents as quickly as 12 weeks, our expert lab teams can customize and optimize proteins to support quality drug and vaccine development.

Antibody discovery

The team at Specifica, IQVIA's antibody discovery laboratory, constructs and delivers in vitro antibody libraries tailored to each client's specific needs. Specifica also performs dozens of de novo antibody discovery campaigns each year, as well as providing optimization services, including affinity maturation, developability and species cross-reactivity for all types of antibody leads. In contrast to in vivo antibodies, our platform allows selection of specific properties while still achieving the desired developability, diversity and affinity.

In vitro immunology and immunogenicity

Our in vitro immunology lab performs assays involving primary immune cells to evaluate candidate therapeutics. Our expert team also performs in silico and in vitro assays to help assess wanted or unwanted immunogenicity. These tests support the development of therapeutics for immuno-oncology, inflammation, autoimmunity, and cell and gene therapy, as well as prophylactic and therapeutic vaccines.

Bioanalytical and ADME services

IQVIA Laboratories leads with science and provides large pharmaceutical, specialty pharmaceutical and biotechnology companies with complete bioanalytical and ADME laboratory services for testing around the globe and across the spectrum of product development. With an industry-leading bioanalytical and ADME global laboratory network and central lab services, our team combines relevant expertise and services to deliver timely, high-quality data that allows you to make informed decisions for regulatory filings.

Regulated bioanalytical services (small and large molecules)

Bringing a promising drug candidate to market requires a well-planned strategy incorporating sensitive, specific and validated assays to inform development decisions.

Leading with science for more than three decades, our experts apply leading-edge technologies, automated platforms and state-of-the-art techniques to support a wide range of regulated bioanalytical services.

ADME/ DMPK

Identifying promising ADME and pharmacokinetic properties during the discovery stage can streamline the development process.

Our experts can help you make informed development decisions about your small and large molecule drug candidates via an array of high-throughput screening and drug metabolism services.

Biomarker analysis

Our biomarker testing laboratories develop and perform assays to assess a therapeutic's efficacy, safety and mechanism of action as well as biomarkers useful for prognosis and companion diagnostics for patient stratification and eligibility.

Biomarker testing

Our biomarker testing laboratories develop and perform assays to assess a therapeutic's efficacy, safety and mechanism of action as well as biomarkers useful for prognosis and companion diagnostics for patient stratification and eligibility.

Rules-Based Medicine (RBM) is the specialty immunoassay testing lab within IQVIA Laboratories. Through a dedicated assay development team, RBM internally develops, validates and manufactures multiplex immunoassays validated to clinical laboratory standards. RBM builds multi-analyte profiles for the Luminex® xMAP platform and ultrasensitive immunoassays on the Simoa® platform. RBM's newest platform is Olink®, which uses proximity extension assay (PEA) technology to delivers optimal specificity with the scalability of high-throughput, multiplex protein biomarker analysis. RBM delivers microsphere-based immunoassays with the precision and dependability of automated liquid handling systems, advanced quality monitoring and validated data reporting processes.

Vaccines

For more than 35 years, our deep bench of scientists, cutting-edge technology platforms and industry-leading laboratory services have come together to support clinical vaccine development, from discovery through late-stage phases. From candidate selection to assay development and vaccine testing, IQVIA Laboratories can provide a diverse range of vaccine platforms, in-house custom in vivo services and advanced protein sciences capabilities, including molecular biology, protein expression, purification, and characterization expertise. Understanding the importance of staying agile for vaccine development, our experienced team can rapidly produce custom antigen and pseudoparticle reagents in-house as recognized by leaders in the COVID-19 field.

Assay development

IQVIA Laboratories is a leading partner in fit-for-purpose assay development on a wide variety of platforms and related technology transfer, supporting your vaccine program through all phases. In addition, our team has deep experience with assay transfers, successfully developing 100 assays and transferring them to sponsors around the globe.

Early development assays

IQVIA Laboratories offers expert knowledge with monoclonal and bispecific antibodies, cell and gene therapies, RNA/DNA vaccines, viruses, small molecules, immune checkpoint inhibitors and more. We can adapt our programs to help ensure functionality in the most efficient way possible. Whether your require full assessments or a la carte solutions, our team can quickly adapt your protocol with flexible, quality solutions for assay optimization.

High throughput testing

Through our strategic investment in specialized robotics to support our expert scientists, IQVIA Laboratories uses automated systems for high throughput, generating more than 1.5 million results annually. Our extensive capacity through automation helps accelerate vaccine discovery and related clinical trial process, providing you with accurate, reproducible and precise deliverables with consistency.

Immunotherapy

At IQVIA Laboratories, we have in-depth scientific expertise with a wide range of assay development services with advanced instrumentation to support your efforts, from exploration onward. Through our leading translational capabilities, we can help increase efficiency in your effort and accelerate your novel therapies to patients who need them.

Preclinical

IQVIA Laboratories can design and develop disease specific in vivo models alongside bespoke personalized model development services. Our wealth of experience and capabilities allows us to help answer your unique research questions, resulting in tailored study design. Our experts can provide non-regulated, preclinical development solutions that include performing experiments, analysis, reporting and technical writing.

Therapeutic expertise

Navigating the complexities of different therapeutic areas requires a dedicated approach. At IQVIA Laboratories, we have the diverse therapeutic clinical lab expertise to meet those challenges head-on. With extensive experience in assay development across multiple therapeutic areas, including oncology, infectious diseases and rare diseases, our global team is well-equipped to support your individual clinical trial needs:

- Our deep knowledge in oncology clinical research enables us to help design genomics-based assays that account for the complex biology of solid and hematologic tumors.
- With more than 30 years of experience, our global vaccine laboratory network excels in infectious disease testing for bacterial pathogens and viruses, including vaccine immunogenicity and efficacy studies, vector-specific detection, and viral and bacterial neutralization assays.

In precision medicine, we are well-positioned to meet the complex needs of orphan drug development through optimal study design and accelerated regulatory approval. Whether navigating complex regulatory submissions or supporting proof of mechanisms and efficacy evaluations, we are committed to helping you accelerate drug development while upholding the highest standards of safety and quality.

Innovation

Through our dedicated Digital Innovation Department, IQVIA Laboratories focuses on driving operational improvements and quality of services. Our LabMatrix Clinical Trial and Sample Consent Tracking system provides comprehensive lifecycle support for in-study samples, next-generation biobanking, and data mining, and has been used in more than 1,000 trials to date.

In 2021, we opened our state-of-the-art custom-designed Innovation Laboratories facility. This scientific community incorporates a broad array of services and capabilities to support drug discovery and development under one roof. This facility houses our Vaccines Center of Excellence, Genomics Center of Excellence, Transitional Science and Innovations Laboratory Services (TSAIL) and other large-molecule bioanalytical services.

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