Deeper science to drive tailored solutions, optimized quality systems, delivery excellence and better insights
Meeting our customers’ needs today and tomorrow

Meeting the demands of today’s drug, device and diagnostics development environment requires a next generation laboratory. When looking for a long term central laboratory solution, it’s important to find a partner that can accommodate your needs for scientific expertise, lab services and esoteric testing, high quality data and analytics, sample management and logistics as your product pipeline evolves.

Q² Solutions helps biopharma, medical device and diagnostics customers improve human health through innovation that transforms science and data into actionable medical insights.

What we offer

Tailored solutions. We deliver end-to-end lab services, from central lab through precision medicine and biomarker discovery and development.

Delivery excellence. We enhance the drug, medical device and diagnostic development process, with global reach that provides superior customer access and an industry-leading footprint.

Shaping outcomes. We use advanced methods and technologies to help you turn clear insights into confident decisions.

Tailored solutions

Because the challenges faced by our clients are unique, one-size-fits-all solutions simply don’t work. This is why the solutions we offer are specifically designed and tailored to the needs of each client. Our customized solutions are powered by:

- A large, validated test menu and the ability to collaborate on developing customized tests
- Harmonized processes with clinical data management for full-service integration
- Expertise to develop a fit-for-purpose biomarker discovery and development strategy based on knowledge and experience, mitigating risks for improved clinical outcomes
- Early engagement scientific specialists for feasibility and methods review, assessment of regulatory requirements (e.g. IVD vs CLIA validation), and application of best practices for global scale-up and deployment
- Scientific acumen and resources to supplement and enhance your internal capabilities
- Quality from sample collection to data delivery
- Strategic operation models customized to integrate all your lab data, biosample tracking and storage needs with easy-to-use technology platforms that enable result reporting and trial oversight

Extending well beyond basic safety testing, our clinical laboratory services include highly specialized esoteric tests, as well as complex biomarkers.

>111 PhDs,
>34 Medical Doctors,
>25 expert pathologists

Access to

>1,500 ESOTERIC ASSAYS across all therapeutic areas

>9 MILLION TESTS managed annually for clinical trials

Constantly expanding menu of

>3,500 tests and assays
Testing overview by discipline:

<table>
<thead>
<tr>
<th>Discipline</th>
<th>Methodology</th>
<th>Example biomarker assays</th>
</tr>
</thead>
</table>
| Automated chemistry/urinalysis    | • Enzymatic analysis  
• Colorimetry  
• Turbidimetry  
• Spectrophotometry | • Routine chemistry  
• Urinalysis  
• Endocrinology  
• Tumor markers; thyroid functions |
| Hematology/coagulation            | • Automated cell counting  
• Leukocyte differential counting  
• Conductivity and light scatter  
• Chromatography  
• Clotting time | • CBC, WBC differential, Reticulocytes  
• HbA1c  
• Prothrombin time, aPTT, Fibrinogen  
• D-dimer, proteins S & C  
• Von Willebrand factor |
| Flow cytometry                    | • Light scatter  
• Cellular fluorescence  
• Custom panel development | • T cell subsets  
• Minimal residual disease  
• Phosphomarkers  
• Activated T and B cells  
• NK cells  
• Dendritic cells  
• Monocytes  
• Activated granulocytes |
| Anatomic and molecular pathology  | • Tissue processing (FFPE, cryo,TMAs)  
• H&E  
• Digital pathology  
• Assay and algorithm development  
• IHC, ISH, FISH  
• Mutation and expression analysis  
• (PCR, RT-qPCR) | • PI3K/EGFR/RTK pathways  
• Apoptosis/cell-death markers  
• MAPK pathway  
• Tumor stroma and infiltrating lymphocytes  
• Companion diagnostic (CDx) assays |
| Microbiology                      | • Direct inoculation  
• Molecular characterization | • Bacteria and yeast identification  
• Antimicrobial susceptibility  
• Ova and parasites  
• TB testing, Latent TB infection |
| Genomics                          | • PCR and variants  
• SNP Analysis  
• Universal array sorting  
• FISH  
• Next generation sequencing | • Viral loads and genotyping  
• ADME/PGx  
• HLA typing  
• GEP (array, RNAseq)  
• Whole or targeted exome sequencing |
| Mass spectrometry                 | • LC/MS/MS | • Drugs of abuse  
• Hormones  
• Metabolomics |
| Immunoassay                       | • Standard plate ELISA  
• Multiplexing  
• Immunoblotting (RIBA)  
• Automated immunoassay platforms | • Immunogenicity /ADAs/HAHA  
• Cytokines  
• Immunoglobulins  
• Cardiac and bone markers |
Delivery excellence
Each of our central laboratories delivers excellence through our six-sigma quality systems encompassing harmonized processes, instrumentation, tests and reagents, and integrated LIMS systems. Central laboratory solutions from Q² Solutions are flexible, drawing from our deep scientific expertise and far-reaching global network. Thus, we can help you meet the unique turnaround times and stability requirements of every protocol and ensure quality from sample collection to data delivery. Core solutions include:

- Project management
- Logistics and sample management
- Data management and analytics solutions
- Specimen management and storage
- Third-party lab data management
- Full service integration
- Global digital pathology

Project management
Not only are we committed to ensuring the quality and accuracy of your studies, we’re also dedicated to making the entire process – from startup to timely database lock – seamless and simple for you. Serving as the single source of contact, our veteran project managers will keep your study on-time and on-budget. They provide:

- Management of internal and global communications
- Local knowledge and expertise around the world
- Regional support for kits and logistics
- Detailed budget management
- Risk-and-solution focus with a customer service mindset
- Study specific monitoring for proactive oversight of all key parameters
- Proactive study planning and management

Network integration
Through our network integration model, not only can we manage your central laboratory, genomics and bioanalytical/ADME services, but we can also coordinate additional third-party external laboratories. Q² Solutions can manage and integrate data streams across our global labs as well as external labs through either Quintiles Infosario® or RESULTVIEW™ technology platforms. Data visualizations and on-demand reports from our technology platforms keep you in control of your study, while at the same time our governance and change management expertise means you can shift more of the day-to-day activities to us and focus on strategy.

Logistics
Your logistics strategy needs to take into account the increasing complexity of new testing methods, therapies and expanding geographies. Within and across clinical programs, shipping solutions for clinical trial kits and biological specimens can vary by shipment profiles (ambient, refrigerated, frozen, etc.) and by the number and location of kit delivery and specimen collection points. At Q² Solutions, our scientists, project managers and logistics experts understand your needs and are committed to helping you navigate this complexity to improve your probability of success through our comprehensive logistics solutions:

- Globally connected, regionally invested resources
  - 6 globally harmonized kit building facilities across North America, Europe and Asia-Pacific
  - Servicing >38k investigator sites in >85 countries
- Over >1.2 million shipments per year
- Predictable global logistics with 98-99% on-time delivery performance
- Proactive transportation cost review
- Proven logistics expertise with dedicated logistics professionals strategically positioned worldwide to deliver an optimized logistics solution to reduce logistics costs and turnaround time
- IATA certified in all regions

Specimen management and storage
As part of our commitment to quality our dedicated specimen management and storage team provide you with reliable tracking, chain of custody and storage of your study samples. We routinely retain clinical trial specimens for a period of time after the test results have been issued. This procedure enables the laboratory to run subsequent additional or repeat analyses on the same specimen. We have hundreds of specially designed freezers for short- and long-term specimen storage at -20°C and -70°C, as well as liquid nitrogen storage.

98–99% ON-TIME delivery performance

>38K investigators in >85 countries
Optimized network
We have the largest network of wholly owned, CAP-accredited central laboratories with presence in the Americas, Europe, Asia and Africa, including dedicated bioanalytical, ADME, genomics and specialty laboratories.

What does it mean to have more labs where you need them in more places? The right footprint in the right geographies with the right systems and the right technologies to deliver top-quality services and innovations that transform science and data into actionable medical insights. You can expect:

• **Innovation:** State of the art laboratory facilities with industry leading test menu and platforms and room for expansion to meet current and expanding customer needs for end-to-end laboratory solutions

• **Data integrity:** Clean, reliable and comparable globally harmonized data

• **Superior project management:** Site support that enables optimal study performance

• **Value:** Superior technology coupled with logistical and supply chain optimization that enables on-time and cost effective delivery of lab results

• **Quality:** Six Sigma Quality Systems and integrated LIMS system coupled with our seasoned scientific and operational experts that manage >9M lab tests each year, delivering the high quality data and informed insights needed for today’s complex drug development programs

• **Specimen management:** Proactive management of global logistics and biospecimens to ward off delays

• **Local language support:** More labs in more places mean our team is able to provide follow the clock coverage and local language support in many regions

An optimized network to support your global trial or local study

Shaping outcomes
Q2 Solutions brings together methods and technologies to help our customers turn clear insights into confident decisions. Customers across the biopharma world – including all of the top 20 largest...
biopharmaceutical companies, as well as innovative emerging biopharma, medical device, diagnostic companies and CROs – trust us for providing not only high quality lab services, but also accurate, quality data and analytics to shape better outcomes.

Technology platforms
Q² Solutions’ platforms (Quintiles Infosario®, RESULT:VIEW™ and more) use advanced analytics technology and reporting to give you near-real-time data access and analysis that allows you to quickly make important connections and proactively address issues to optimize drug, medical device and diagnostic development.

Up to 80 percent of the clinical trial data needed to support an NDA submission comes from the lab. How you manage the complexity and quantity of that data can make the difference in speeding your products safely through development and into the hands of patients.

With the Quintiles Infosario® and RESULT:VIEW™ technology platforms, you can see trial lab data at a deeper level to improve the quality of your studies. Our leading technology solutions give your study leads near-real-time access to metrics and trends for enhanced oversight.

Simplify how your sites manage lab materials, respond to queries and track samples through Infosario Site Gateway, a best-in-class online workspace. Interactive, easy-to-use tools can help your sites:

- Optimize lab kit materials management with electronic kit re-supply
- Receive and respond to queries electronically, eliminating time-intensive phone calls and faxes
- Access and ship samples, track sample receipts and obtain reports in a single online location
- Complete requisitions electronically – virtually eliminating queries

Scientific expertise
Our scientific experts also have deep expertise on many of the key methodologies and technologies that can be applied to your product across the developmental continuum including assay development expertise, flow cytometry, regulatory submission, biostatistics, anatomic pathology and more.

Our experts can bring years of clinical trial and central labs experience to your study and execution strategy, to ensure our wealth of knowledge and best practices translates into better delivery of your study.

Helped develop

> 32%
of all FDA-approved breakthrough drugs of 2016

Helped develop

> 33%
of all FDA-approved rare disease drugs of 2016

Conducted

> 980
oncology & hematology studies in the last 5 years

Conducted

> 370
immunological / infectious disease studies in the past 5 years
Therapeutic expertise
Complemented by our technology solutions, our internal experts represent a deep source of experience and expertise that can be applied to your study. We have specific expertise in the following therapeutic areas:

- Allergy
- Cardiovascular
- Dermatology
- Diabetes, endocrinology, metabolism
- Gastroenterology
- Genitourinary
- Immunology
- Infectious diseases
- Neurology
- Oncology and Immuno-oncology
- Ophthalmology
- Psychiatry
- Rare and Orphan diseases
- Respiratory

Clinical trial integration
Q² Solutions has broad experience running integrated clinical and lab studies across the therapeutic spectrum. This experience and knowledge allows us to effectively and efficiently integrate our labs services with your clinical services provider. With an integrated lab and clinical approach, you can benefit from:

- **Efficiency**: Coordinated project management and communication plans
- **Control**: Integrated data systems keep sponsor and study team in command of study execution
- **Insight**: Lab data and considerations factored in to protocol review, risk management plans, site selections and timelines

33% SHORTER TOTAL STUDY DURATION
Compared to stand-alone clinical studies, integrated clinical and lab studies result in up to 33% shorter total study duration in certain therapy areas since 2009

Your committed partner for today and tomorrow
Q² Solutions is committed to providing our customers an innovative, progressive and responsive partner with the quality focus, global experience and deep medical expertise integral to drug, medical device and diagnostic development.

To learn more visit [www.Q2LabSolutions.com](http://www.Q2LabSolutions.com) or contact us.

**Contact us**

Toll free: 1 855.277.9929
Direct: +1 919.998.7000
International: +44 (0) 1506 814000
Website: [www.Q2LabSolutions.com](http://www.Q2LabSolutions.com)