Q² Solutions®

Turning Hope Into Help™

Anatomic Pathology

Q² Solutions' comprehensive in-house end-to-end anatomic pathology and adjunct molecular services are designed to meet your clinical trial needs.

Anatomic pathology is a vital part of any study that requires the assessment of tissue prior to downstream biomarker testing or molecular testing. Additionally, anatomical pathology capabilities can serve to confirm the original diagnosis, ensuring that the correct disease type is being assessed and enrolled for the study. Consequently, clinical development programs require a laboratory partner who can deliver the services needed to realize a successful biomarker strategy. Therefore, a comprehensive anatomic pathology offering that provides service, solutions and innovation is crucial to ensuring clinical and commercial success of your product.

Q² Solutions helps biopharma and diagnostics customers improve human health through innovation to turn hope into health. Q² Solutions delivers on this promise by offering tailored anatomic pathology solutions, by providing delivery excellence, and by bringing together our knowledge and expertise to help you make better decisions and shape better outcomes.

Tailored anatomic pathology solutions

With access to commercial clinical laboratories and a full in-house global Anatomic Pathology (AP) service with a footprint in the Americas, Europe, Asia-Pac and China, including 29 expert pathologists, and a lab operations team who are adept at assay transfer and validation, we have the ability to support your clinical development needs and have the flexibility to respond as science evolves. We often create tailored solutions as often – client requirements are unique. Our capabilities include:

- Co-localized central laboratories with AP and tissue-based molecular testing including China
- Centralized study set-up with flexible database configuration
- Tissue sample accessioning and processing
- Able to receive fresh-in-formalin tissues, formalin-fixed paraffin-embedded (FFPE) blocks, unstained slides, stained slides, or digital images
- Routine histology, immunohistochemistry (IHC), and ISH offered in various iterations
- Licensed histo-technologists
- Digital and remote pathology services
- Redundant labs for business continuity and management of peak volumes
- Deep companion diagnostics experience and solid relationships with several manufacturers
- Access to oncology, pathology, technology experts
- Access to commercial clinical laboratories
- Certified pathologists covering a broad range of pathology sub-specialties (including CDx, molecular, and hematopathology, as well as virtually every organ system), who can provide scientific oversight as principal investigator for your companion diagnostics study
- Each pathologist has >10 years of diagnostic experience with immersion in clinical trials and regulatory submissions
- Robust process for Path Report Form (PRF) entry and result reporting

Our co-localized AP-molecular testing laboratories employ Quality Management Systems that ensure consistency and specimen integrity for the pre-analytic (specimen collection and preparation), analytic (testing), and post-analytic (reporting) phases of testing. Expert in-house pathologists specialized in general histopathology, as well as many sub-specialties including cytopathology, surgical pathology, dermatopathology, hematopathology and the pathology of virtually every organ system, help guide your project successfully through regulatory submission.

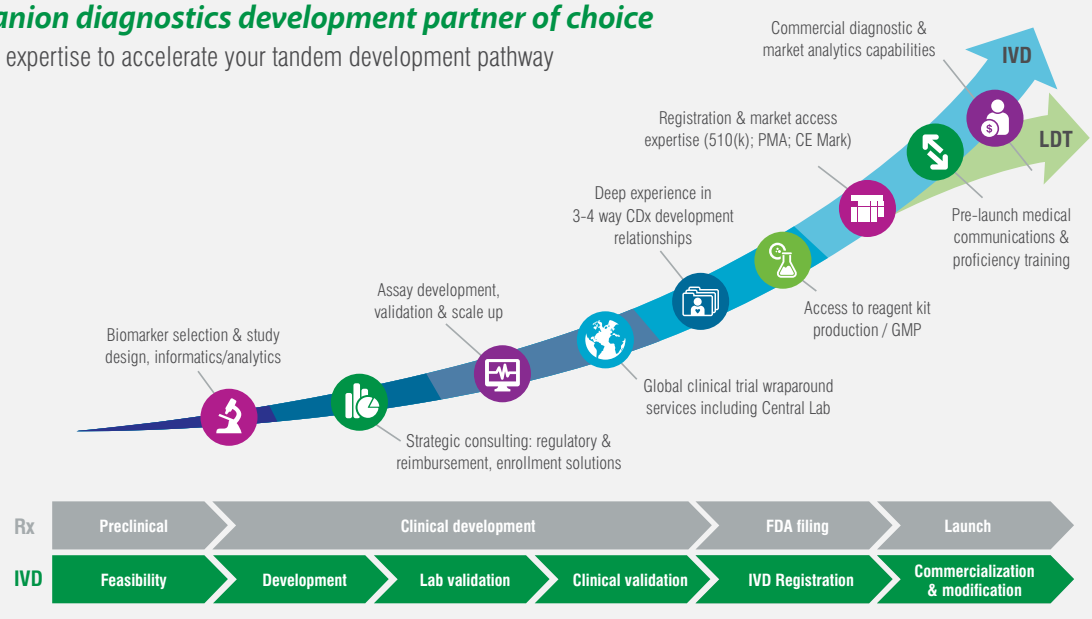
Companion diagnostics experience – Our scientific experts provide you with an optimal path to co-develop your companion diagnostic with clinical development of the therapeutic, regulatory submission and market launch. Our integrated approach is designed so you optimize time to market and commercial success.

Real world anatomic pathology and companion diagnostics experience providing solutions to our customers across the globe including:

>280 AP and CDx engagements

Companion diagnostics development partner of choice

Extensive expertise to accelerate your tandem development pathway



With Q² Solutions' comprehensive solution for companion diagnostics development, we can take your therapeutic in tandem with the companion diagnostic to market faster. Our integrated solution provides flexible support across the development spectrum, from biomarker R&D services, assay development and optimization, to global execution, regulatory support, and commercial, diagnostics and late-phase expertise.

Through biomarker selection, assay design and development, clinical validation, regulatory and commercial phases, we have a centralized lab network, deep domain expertise and relationships with IVD companies which allow us to co-develop and commercialize drugs with complex diagnostics paradigms.

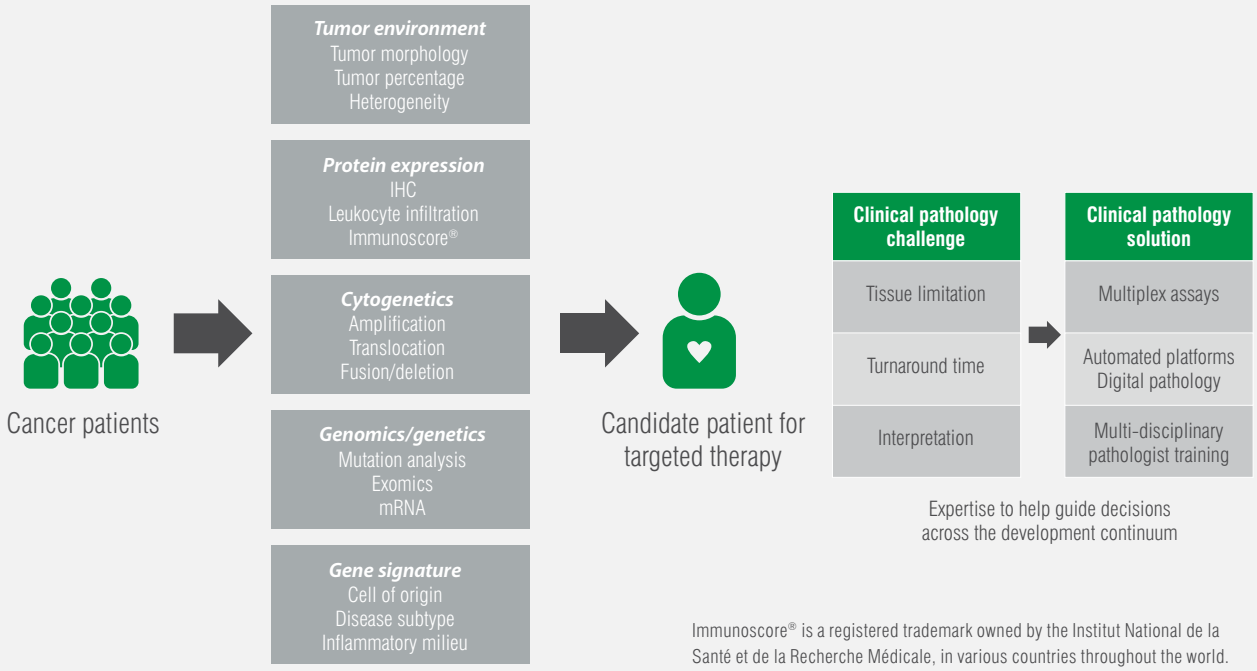
Q² Solutions has helped develop
40% of all **FDA-approved breakthrough/ first-in-class drugs since 2011**

Q² Solutions has helped develop
67% of all **FDA-approved precision medicine drugs of 2016**

29 expert pathologists

Anatomic pathology and companion diagnostics

Co-development and commercialization of drugs with complex diagnostic paradigms



Expertise to help guide decisions across the development continuum

Immunoscore® is a registered trademark owned by the Institut National de la Santé et de la Recherche Médicale, in various countries throughout the world.

Innovation – Promoting faster, more collaborative analysis through the use of innovative, leading-edge products and services to enable communication of richer efficacy signals faster and more cost-effectively.

- *Innovative technology:* Incorporation of image analysis validation in addition to remote pathology (telepathology) services are integral for quality review and proficiency testing and analysis.
- *Automation in FISH:* BioView allows for automated scanning for scoring and archiving images that improves productivity, accuracy, and reproducibility compared to manual scoring. This eliminates double data entry, which increases the efficacy of our labs. Additionally, by performing a combined IHC and FISH analysis, the number of samples needed from the patient is reduced.
- *Digital pathology:* Q² Solutions has an extensive fleet of Aperio AT2 slide imagers to ensure quality, speed, and reliability of slide digitization. The images can be accessed through our portal and delivered to sponsors for documentation, reviewed internally or externally for quality assurance, or used for image analysis.

Anatomic pathology and molecular testing services –
We showcase a full spectrum of comprehensive in-house end-to-end anatomic pathology and molecular testing services to meet today's drug development needs, including:

- DNA/RNA extraction/purification
- qPCR/RT-PCR open system
- qPCR/RT-PCR closed system
- Sanger Sequencing
- Next Generation Sequencing
- Pyro Sequencing
- RNA Sequencing Illumina
- Array-based genotyping
- PCR-based gene expression analysis
- Array-based gene expression analysis
- Nanostring – gene expression analysis
- Circulating Free DNA (cfDNA) mutation analysis
- Circulating Tumor Cell (CTC) analysis

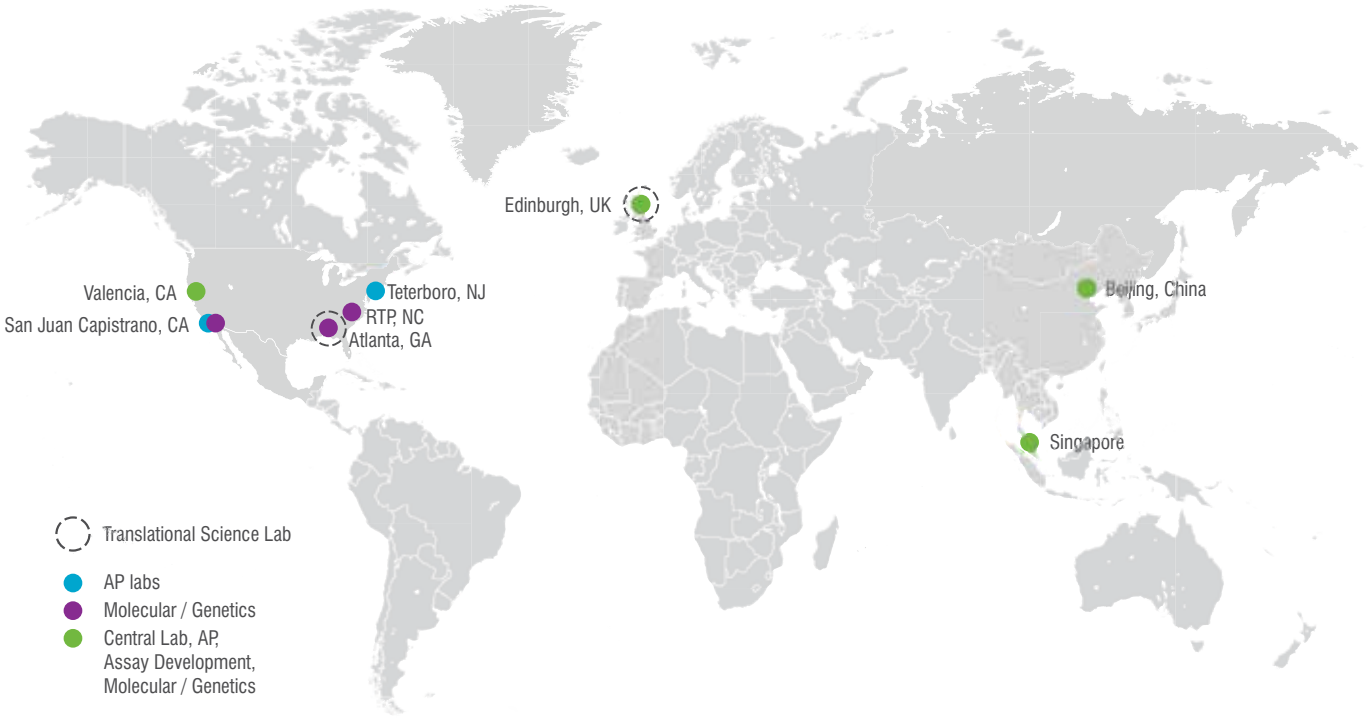
These services are led by our Chief Pathologist, who has >22 years anatomic and clinical pathology experience. He oversees global quality assurance within AP, focusing on harmonization of testing modalities, training of pathologists, assay validations and verifications, regulatory requirements, interpretation of biomarkers, proficiency testing, and study design with our sponsors.

Delivery excellence

Metrics are captured for turnaround time in each of our labs, with a goal of at least 95% achievement of turnaround time for each study. Backed by the scientific expertise of our in-house pathologists, our AP laboratories also participate in an accuracy-driven external quality assurance program (CAP Proficiency Testing) that supports our goal of achieving global harmonization, standardization and high quality results across the globe for every study.

Q² Solutions global footprint

Anatomic pathology capabilities across the globe providing rapid testing, harmonized data, and optimized logistics costs.



*Supporting more than 180,000 investigative sites worldwide

Spotlight on oncology

With experience in **anatomic and molecular pathology, flow cytometry, immunoassay and genomics-based assay development and testing**, Q² Solutions can provide customized and comprehensive global laboratory solutions specifically suited for the unique combinations of therapeutic indication and targeted mechanism-of-action driving modern oncology drug development.

Immuno-oncology – Experience predicting and assessing a patient's response to checkpoint inhibitors is an integral function in anatomic pathology (AP) as it relates to immuno-oncology drug development. Once a tissue sample is received, central AP testing is performed and data can be mined for immune-oncology characterizations, such as PD-L1 proteins or tumor-infiltrating lymphocytes. We then take those characterizations and apply them to drug studies, such as the creation of predictive biomarkers for patient selection.

Q² Solutions has helped develop

61% of all **FDA-approved oncology pharmacogenomics products to date**

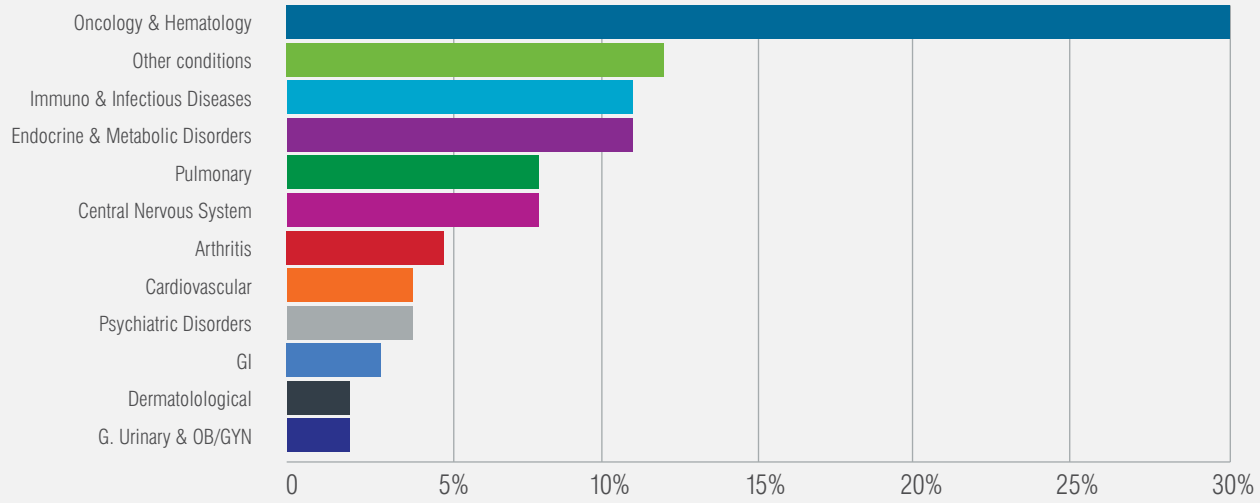
Q² Solutions has helped develop

54% of all **FDA-approved oncology precision medicine drugs since 2014**

Shaping outcomes

Q² Solutions has the breadth and depth of scientific experience and expertise across all major therapeutic areas to give drug developers a competitive advantage – helping ensure your success in clinical trials, regulatory approvals and new product launches.

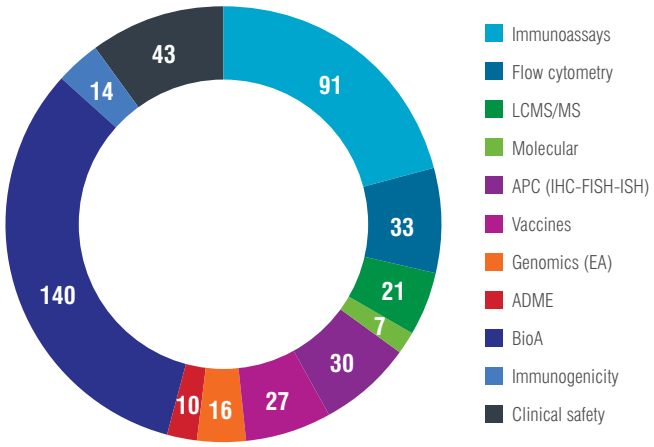
>3,300 laboratory studies conducted since 2011



We're able to go a step further with our capability to validate, transfer and employ new assays to meet today's development opportunities. These abilities add significant value as we develop new assays for your trials.

>400 assays validated in 2015

Q² Solutions is your partner of choice for any development program that requires anatomic pathology services because we're able to go a step further to help you understand how these capabilities can help turn hope into health.



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