



Biomarker Roadmap to Success

A biomarker-driven approach to developing targeted therapies

Q² Solutions helps customers identify predictive biomarkers and plan a biomarker strategy for an optimized path to developing new personalized medicines.

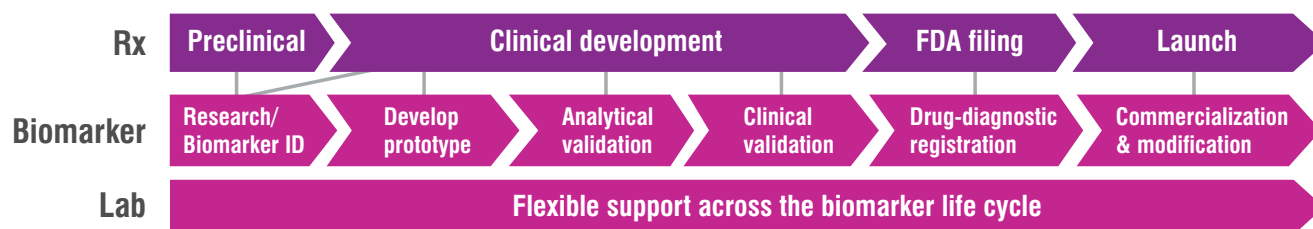
Precision medicine and sophisticated technologies have caused a paradigm shift in drug development, leading to programs with narrower indications, shorter development times and decreased costs. This shift in development has enabled programs to identify patients likely to respond to treatment, determine best dose, provide proof of biological mechanism, and present data in the exploratory setting for further downstream testing. Biomarkers are now an essential part of the immuno-oncology drug discovery and development processes, with more R&D investment allocated towards these targeted immune therapies. A biomarker-driven approach to developing targeted therapies enables risk mitigation throughout the drug development and commercialization process.

End-to-end biomarker solutions begin with early strategic planning

Biomarkers are key decision enablers, and it is important to select a biomarker and an appropriate technology platform early in clinical development with the possibility that biomarker assays could become standard of care or companion diagnostics assays following therapeutic approval. In fact, when developing cancer therapeutics, organizations must think of their full life cycle needs, from discovery through diagnostics, to develop biomarkers that support their clinical trial and commercial objectives.

Therapeutic and biomarker co-development life cycle

From discovery to commercialization



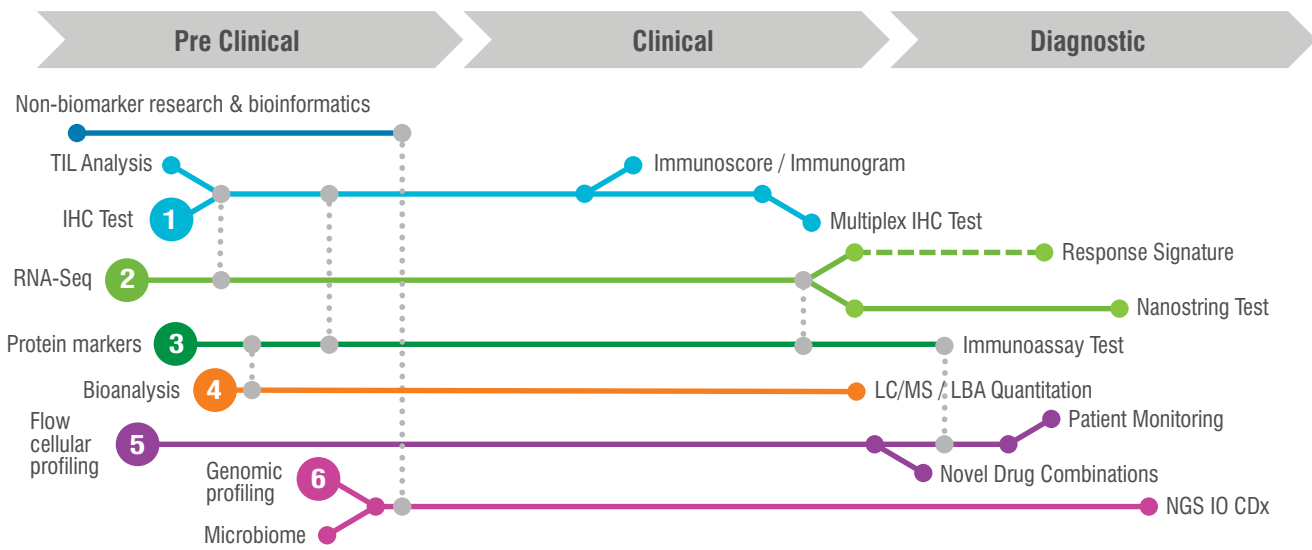
We understand there are certain pitfalls to avoid in planning biomarkers for your study. For more, read our insight brief [The End to End Importance of Selecting the Right Biomarker in Cancer Studies](#).

Within the immuno-oncology therapy area, drug developers should partner with a central laboratory that provides validation and verification studies and clinical trial testing. Because many programs are global clinical studies, it is important that the central laboratory is able to harmonize these activities across the globe. At Q² Solutions, we recommend creating a roadmap during the preclinical stage to develop optimal biomarker solutions. For immuno-oncology applications, there are several prioritized biomarker activities to consider during the preclinical phase, which are listed here and can be found in the roadmap below:

- 1 Develop next-gen IHC tests
- 2 RNA-Seq gene expression analysis
- 3 Immunoassays for soluble protein markers
- 4 Live Blood Analysis (LBA) and LC/MS bioanalysis
- 5 Flow cytometry immune cell population profiling
- 6 Genomic profiling for DNA repair defects/mutation load and microbiome profile

Biomarker strategic roadmap to achieve long-term therapeutic differentiation

Multiple parallel and synergistic pathways maximize immediate lab opportunities as well as long term clinical differentiation



A key success factor in this roadmap is the availability of multiple technologies to service the many biomarker requirements. These technologies include [anatomic pathology](#), [flow cytometry](#), [immunoassays](#) and [genomics](#). Q² Solutions has a [central lab approach](#) which is platform agnostic, providing objectivity based on extensive experience of various technologies and methodologies across discovery, clinical trials and [clinical diagnostics](#).



Q² Solutions has helped develop a number of biomarkers commonly used today, including

BCR-ABL, ALK, BRAF, C-KIT, EGFR, KRAS, HER2, MET and PD-L1

Q² Solutions has helped develop **61%** of all FDA-approved oncology pharmacogenomics

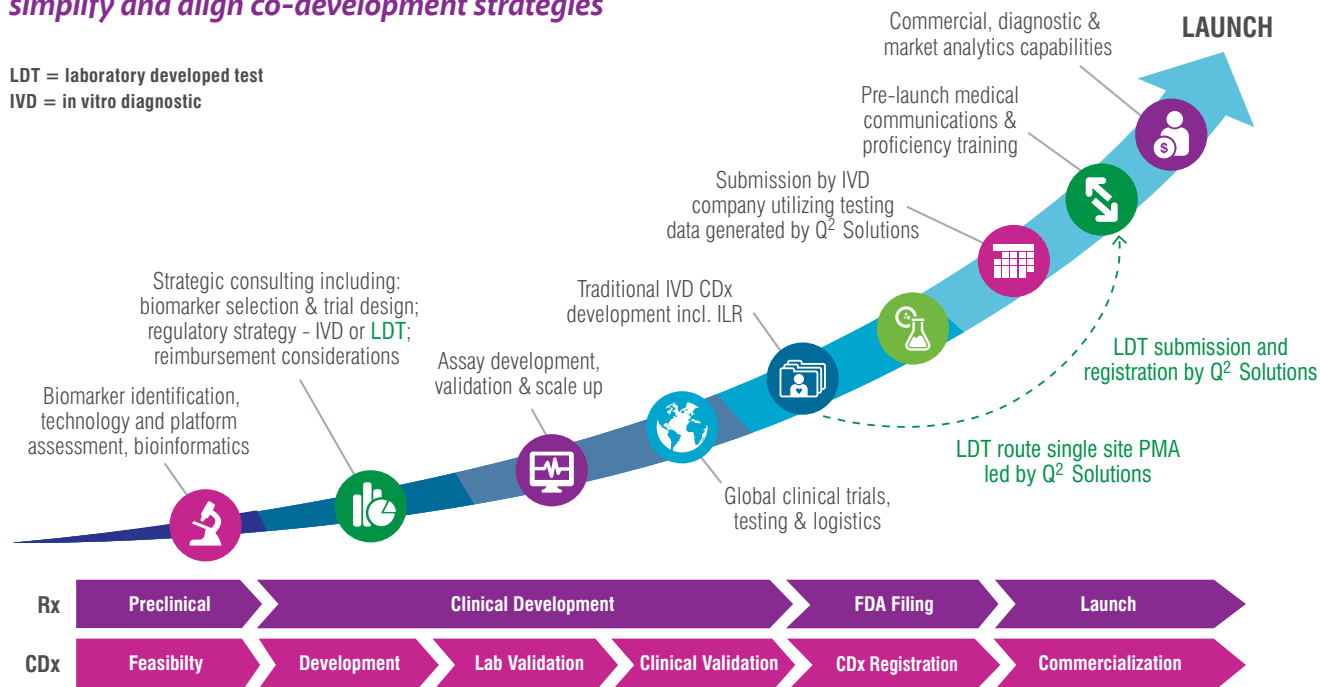


Integrated biomarker / companion diagnostic (CDx) solutions

Q² Solutions has the expertise, experience, and tools to validate, develop and implement patient selection of biomarkers throughout a product's development cycle, speeding development and driving clinical and commercial product success. Contingent on intended use, these can be developed as CDx. Depending on certain factors, recommendations for traditional IVD or Single Site Lab PMA routes can be made, as seen below.

Q² Solutions integrated biomarker and CDx solutions help simplify and align co-development strategies

LDT = laboratory developed test
IVD = in vitro diagnostic



At Q² Solutions, we help develop and use biomarkers in oncology trials across the development spectrum. Having assisted in developing some of the industry's most well-known biological markers for personalized medicine, we have the experience to incorporate these tools across the drug development process, from early clinical development through pre-launch and commercialization.

Our experience in biomarker discovery, through clinical trials and clinical diagnostics, has enabled the successful deployment of biomarkers across all therapeutic areas, enabling better outcomes for clinical trials and patients. Our multi-disciplinary team of scientific experts in AP/molecular, biomarker, CDx, IVD, genomics, and bioinformatics brings end-to-end biomarker solutions to mitigate risk throughout the drug development and commercialization process.

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The right biomarker approach for successful cancer trials

Q² Solutions has the breadth and depth of expertise, tools and capabilities to prepare and implement biomarker strategies to help drug developers effectively gain a competitive advantage – helping ensure your success in clinical trials, regulatory approvals and new product launches.

Companies that do not have in-house experience in biomarker strategy should partner with experienced laboratory service providers such as Q² Solutions to drive their project and integrate biomarkers across the drug development continuum. Working with a strategic partner with a broad spectrum of subject matter experts – with experience in the biopharma, CRO, central lab and IVD industries – will help deliver a successful biomarker plan that in turn can help optimize patient outcomes. **Choose Q² Solutions** as a partner for any development program which requires identifying, designing and/or validating biomarkers.

