At a glance

**Precision medicine excellence**

*Innovative clinical strategies for better outcomes*

New genomic technologies and scientific advances are making it possible to deliver safer and more effective targeted therapies and diagnostics to patients worldwide.

Quintiles and Q² Solutions have developed an integrated approach which spans target and molecule characterization through commercialization. We work with you to design and deliver innovative, effective studies to help you identify predictive biomarkers, develop and deploy biomarker tests, and engage the most appropriate patient populations to demonstrate the safety, efficacy and value of your therapeutic and diagnostic products.

**The promise of precision medicine**

Precision medicine strategies can enable identification of an effective target, the optimal dose or exposure, and the right patients to better predict the safety and efficacy of new therapies and meaningfully improve patient outcomes. Rapidly advancing genomic understanding is arming researchers with the tools to better understand disease biology and underlying genetic contributors to disease. Already, these developments have had a tremendous impact on drug discovery, and incorporating genomics into clinical development can bring us even closer to realizing the value of precision medicine.

- **Early clinical development**: Genomics can help to identify patients who may respond most appropriately to a particular therapeutic. These results can help stratify populations in later phase trials.
- **Recruitment and enrollment**: Enriching study populations using predictive biomarkers may improve efficacy signals while reducing drug development costs and timelines.
- **Post approval**: Genomic insight can be used to optimize treatment decisions and ensure that the right drug is used to treat the right patient at the right time.

Through our partnership with Q² Solutions | EA Genomics, we can help you to apply genomic insights and integrate precision medicine strategies into your clinical trials, programs and portfolios to bring lifesaving or life-enhancing drugs and diagnostics to patients faster, while also improving patient safety, therapeutic efficacy and value.

**Spotlight: Q² Solutions Comprehensive Cancer Panel**

The Q² Solutions Comprehensive Cancer Panel is a targeted NGS panel covering over 220 genes known to be associated with cancer, DNA repair or other pharmacogenetic markers.

- The assay tests for the most actionable somatic alterations currently reported in tumors, and can identify pathways or other markers that may help to stratify patients into more effective therapy groups.
- The assay has been validated to CLIA standards and demonstrates high specificity and sensitivity (>99%) for low frequency variants (for SNVs our Limit of Detection is 4% and for Indels our Limit of Detection is 10%).
The path to precision medicine
Avoid obstacles along your path to developing new personalized medicines and associated diagnostics with a clinical partner who provides insight and innovation to drive tangible results.

**Insight**
- Draw from the scientific insights and commercial understanding of 14 Therapeutic Centers of Excellence
- Bioinformatics and scientists at Q² Solutions | EA Genomics have published over 150 peer-reviewed articles in leading scientific journals since 2001 & have taken major roles in the FDA-led MAQC & SEQC projects

**Innovation**
Adopt innovative new strategies for patient selection. We’ve developed dramatically more efficient means of enrolling rare, biomarker-defined patients – leveraging Q² Solutions next-generation sequencing and Quintiles’ established site relationships

**Results**
- Quintiles helped develop or commercialize all of the Top 75 best-selling products of 2014
- Q² Solutions helped develop or commercialize diagnostics for many of the biomarkers used today, including BCR-Abl, ALK, BRAF, C-KIT, EGFR, KRAS and HER2

End-to-end precision medicine integration
Quintiles’ and Q² Solutions’ approach to integrated precision medicine begins with the molecule and continues post market. Learn more about our integrated services:

<table>
<thead>
<tr>
<th>Target &amp; molecule characterization</th>
<th>Biomarker identification</th>
<th>Biomarker implementation through Q² Solutions</th>
<th>Clinical, regulatory &amp; commercial strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Client-directed studies involving:</strong></td>
<td><strong>Prospective</strong> – prior to clinical development, enabling patient stratification into studies or development of companion diagnostics</td>
<td><strong>Biomarker assay development</strong></td>
<td><strong>Patient stratification and segmentation analysis</strong></td>
</tr>
<tr>
<td>Disease biology</td>
<td></td>
<td><strong>Biomarker test technical/clinical validation</strong></td>
<td><strong>Commercial forecasting</strong></td>
</tr>
<tr>
<td>Mechanism of action (MOA)</td>
<td></td>
<td><strong>Patient screening &amp; profiling (pre-profiling)</strong></td>
<td><strong>Portfolio wide CDx strategy</strong></td>
</tr>
<tr>
<td>Markers of activity</td>
<td></td>
<td><strong>Central lab testing</strong></td>
<td><strong>Dx technology strategy and partnerships</strong></td>
</tr>
<tr>
<td>Markers of resistance</td>
<td></td>
<td><strong>Companion Diagnostic (CDx) development &amp; commercialization</strong></td>
<td><strong>HEOR, pricing, market access</strong></td>
</tr>
<tr>
<td>Markers of toxicity</td>
<td></td>
<td><strong>Drug CDx co-development</strong></td>
<td><strong>Regulatory submission strategy</strong></td>
</tr>
<tr>
<td>For the purposes of:</td>
<td><strong>Retrospective</strong> – data-enabled biomarker ID for molecules in development or on the market, e.g., in pursuit of:</td>
<td><strong>Next-generation sequencing (NGS) and CDx</strong></td>
<td><strong>Dx distribution and promotional strategy</strong></td>
</tr>
<tr>
<td>Go/no-go decision making</td>
<td>• Program rescue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Candidate selection or optimization</td>
<td>• Molecule (re)positioning</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical development planning</td>
<td>• Out-licensing prep</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Share optimization</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Quintiles helped develop or commercialize 98 of the Top 100 best-selling products of 2014

Contact us
**Toll free:** 1 866 267 4479  
**Direct:** +1 973 850 7571  
**Website:** www.quintiles.com/precision  
**Email:** clinical@quintiles.com