

Integrated Solutions to Define,  
Demonstrate and Communicate  
Product Value

Post-Marketing Studies

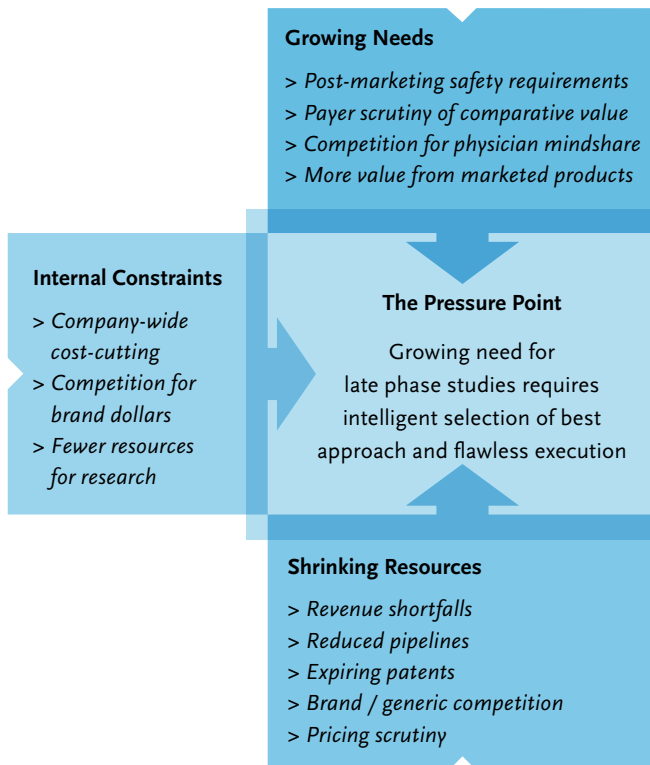


**New Challenges Need New Approaches**

The post-marketing environment is evolving rapidly — and without the right strategy, new challenges can squeeze precious value out of your investment. Regulatory agencies are requiring more data well past market approval. Payers are

tightening their reimbursement criteria. Competition to win the attention of prescribers and patients is tougher than ever. And with the multitude of study options available to collect real world data, selecting the optimal approach is critical.

Faced with these demands, you need an ally with proven late phase expertise to help you define the optimal approach, demonstrate your product’s safety and effectiveness in a real-world setting, and communicate value to your stakeholders. That’s where Quintiles can help. With experience in more than 800 late phase studies, we know how to combine unparalleled data quality with innovative strategies tailored to your objectives. The result? Maximized value for the life of your product.



**Engineered for Efficiency and Innovation**

While earlier development phases are built around regulatory and clinical requirements, late phase studies involve more variables, requiring more agility and ingenuity. So we are constantly looking for opportunities to maximize your research investment and provide cost and time savings. With data integrity firmly in our sights, we have adapted study processes and created flexible models to shorten timelines and reduce traditionally high cost centers.

We also look for more effective ways to collect data. Through collaborations with leading electronic health record service providers, we offer web-based platforms that integrate clinical research with clinical care to streamline interactions with busy physicians. Our relationship with over 2 million patients through our MediGuard platform allows rapidly mobilizing clinically and geographically targeted patients for protocol feasibility, outcomes research, and observational studies.

With Quintiles' global infrastructure and study site relationships, we can scale up to deliver large trials quickly and efficiently. Whether your project calls for aggressive recruitment timelines or staggered startup, we'll make it happen.

## The Right Experts Focused on Your Success

Experienced in every phase of drug development, Quintiles can help you proactively manage risk, address regulatory demands and realize value. Dedicated project managers are specially trained to anticipate the challenges unique to late phase and identify opportunities to improve operational success. With experts in epidemiology, biostatistics, health outcomes and post-marketing requirements, we can deliver design and operational efficiencies, mid-course adjustments and better results.

Of course, understanding the practical aspects of your therapeutic area can drive better decisions for your late phase research. With more than 80 physicians worldwide with research and clinical experience, we can help you create a smarter strategy to address the information needs of prescribers, patients and payers. Our physicians bring valuable insights into treatment and coverage decisions across all major areas of medicine including:

- > *Anti-Infectives*
- > *Cardiovascular*
- > *Diabetes / endocrinology*
- > *Gastroenterology*
- > *Genitourinary*
- > *Musculoskeletal*
- > *Neurology*
- > *Oncology*
- > *Psychiatry*
- > *Respiratory / allergy*

## Late Phase Studies for Every Objective

- > *New indication / label change*
- > *Product differentiation / publication*
- > *Regulatory commitment / safety surveillance*

Study types include:

- > *Phase IIIB and Phase IV clinical trials*
- > *Observational and epidemiological studies*
- > *Patient registries*
- > *Direct patient data capture (MediGuard)*
- > *Research addressing needs of RMPs and REMS*
- > *Comparative effectiveness; health economics outcomes research (HEOR)*
- > *Extended access programs (EAP)*

## Understanding Your Marketplace

The competitive market presents distinct challenges for every product, but finding out the issues for your drug once you get to market could be too late. No other CRO has the commercial breadth and expertise to understand market complexities and what resonates with all your different stakeholders. Focused on your market objectives, we can translate study design and data analytics into opportunities to realize your goals.

You've made a significant investment in your product's development, and late phase studies can make the difference in your product's success. To learn how you can get a post-market advantage, please contact our Late Phase team today.

### Contact Us:

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