

# New Requirements, Innovative Solutions

*New, more efficient delivery models help meet the increasing demands of Phase IIIB/IV Studies.*

Changing regulations are making it necessary to collect more “intelligent” safety data to answer increasingly detailed questions about drug risks. The Quintiles Late Phase & Safety Services team stands ready to provide alternative, innovative delivery mechanisms to capture better safety data and perform more comprehensive analyses within a cost containment/reduction environment.

And the industry knows we can do it. Quintiles exceeds customer expectations for our safety studies. By a margin of two to one, Quintiles holds the leadership position over the nearest challenger for peri- and post-approval services such as Phase IIIB studies, post-marketing safety surveillance and other Phase IV studies.

## Post-Marketing Safety Surveillance

Quintiles Late Phase & Safety Services coordinates safety surveillance studies that cumulatively involve more than 250,000 patients a year. That makes us one of the largest, most experienced and most reliable providers of worldwide safety surveillance services.



## Observational Studies

Observational studies require no specific treatment intervention, and therefore no randomization or mandated treatment protocol. They present little risk to patients, and therefore require less monitoring activity to ensure data quality and patient safety. This makes them an extremely cost-effective means of acquiring additional safety data.

Observational studies can still answer complex clinical questions. Using inclusion/exclusion criteria, Quintiles can design a prospective observational study that approximates a randomized design.



## New, Cost-Effective Delivery Models

Phase IIIB/IV trials are often conducted by clinicians rather than trained investigators, and we provide a wide range of support services to help them fulfill study requirements without interfering with patient care. Our proven site optimization methodology improves both efficiency and results.

Our Project Coordination Centers (PCCs) blend on-site and remote monitoring to generate significant productivity gains and improve data quality while improving site management efficiency.

The use of electronic data capture (EDC) ensures faster, less expensive, more accurate data. Quintiles does more of it than anyone else, with 400 EDC studies started to date. And our direct patient recruitment helps accelerate site start-up and ensure site productivity.

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## Expanded Access Programs and Health Economics/Outcomes Research

Our Late Phase offering also includes:

- > Expanded access (or compassionate use) programs to give patients with life-threatening or serious illnesses access to new treatments before they receive final regulatory approval
- > Health economics/outcomes research to measure clinical outcomes, economic outcomes and humanistic outcomes such as patient satisfaction and quality of life

Quintiles Late Phase & Safety Services has 25 years' experience in the field, and more than 850 team members globally whose collective experience and intellectual capital across all therapeutic areas are already at work devising the new services and strategies that will be critical to success in a market increasingly driven by safety concerns. There's no one better qualified to keep patients – and your company – safe.

*At Quintiles, it's all about results.™*



The Development Group of  
Quintiles Transnational