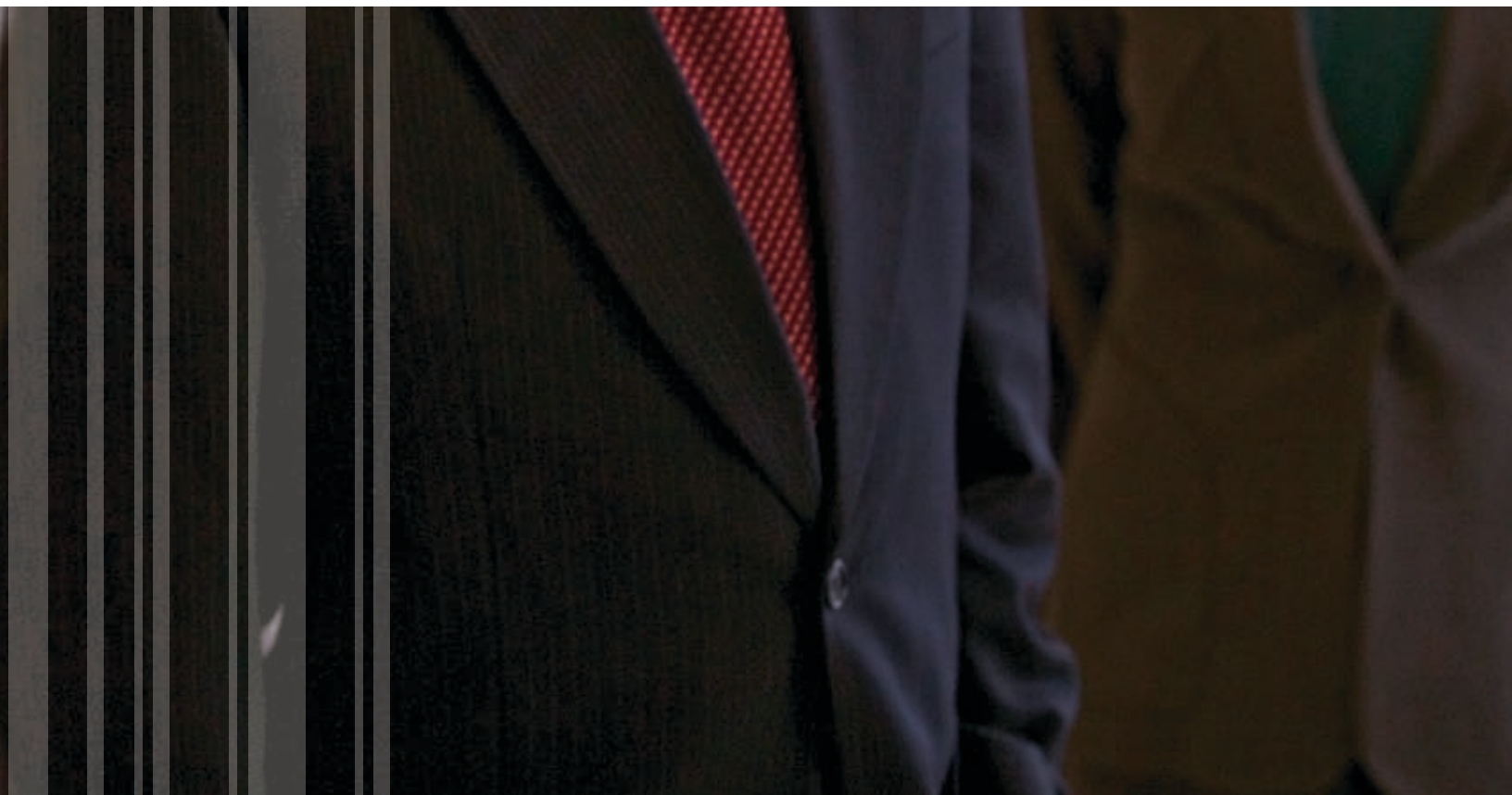




QUINTILES LATE PHASE & SAFETY SERVICES



Now More Than Ever, Experience Counts

As the leader in Phase IIIB/IV, Quintiles is well positioned to lead the way as the market becomes more and more driven by safety.



Recent and pending regulatory changes have created an atmosphere of watchful waiting throughout the industry. While it may seem premature to initiate post-marketing studies to collect more “intelligent” safety data, Quintiles Late Phase & Safety Services anticipates that the need for expanded studies will soon spread.

In preparation, we have expanded our highly experienced Late Phase & Safety Services team and developed a range of new services to help preserve the benefits of your drugs while minimizing risks.

At the Heart of it All: The Resources, Experience and Tools to Maximize Benefits and Minimize Risks

Quintiles Late Phase & Safety Services is ahead of the curve in offering comprehensive, efficient resources to meet expanding safety requirements. Our safety study specialists and regulatory strategists offer a well-informed, completely independent view, so we can help you analyze a drug’s benefit risk profile throughout its lifecycle. And because we understand the regulatory process so well, we can help you prepare solid responses to whatever new regulatory agency demands may arise.

Comprehensive Fit-for-Purpose Solutions

Quintiles Late Phase & Safety Services offers a complete spectrum of benefit and risk management capabilities, and readily bridges the gap between peri-approval and commercialization.

- > Phase IIIB/IV studies including safety surveillance and observational studies
- > Benefit risk advisory services to help you anticipate potential regulatory concerns and highlight the benefit side of your drug’s benefit risk profile
- > Clinical safety operations including pharmacovigilance, biovigilance, mature product outsourcing and oversight committee management
- > Risk management measures that can keep valuable drugs on the market, even after adverse events that might trigger a recall

*New Requirements,
Innovative Solutions*

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.™



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*Do You Know
How Exposed
You Are?*



Do You Know How Exposed You Are?

Quintiles benefit risk analysis can help you anticipate potential regulatory concerns and highlight the benefit side of your drug's benefit risk profile.

Strange things often happen after approval. Signals start coming in. Regulators start asking questions. And pharmaceutical companies are all too often caught by surprise.

There's no reason to be. Quintiles Late Phase & Safety Services has developed a new, expert benefit risk advisory service that holistically analyzes a drug's benefit risk profile from a lifecycle perspective. We'll help prepare you early on for regulatory agency demands that may arise, and put in place a portfolio of solutions that maximize the upside – the benefit side of the benefit risk equation – while fully characterizing potential risks.

What Secrets Are Your Data Holding Back?

Clinical and even pre-clinical data often have stories to tell that remain hidden despite the rigorous analysis involved in the approval process. Our experts take a fresh look at all your data, impartially, from every perspective, and



identify potential trouble areas that may have been overlooked in the rush to complete the submission dossier.

We have worked in virtually every therapeutic area, and we can leverage insights from around the globe. We know from experience the types of things that will attract regulators' attention; most often, it's a subtle pattern of data that is far from an obvious adverse event.

Introducing the Quintiles Readiness Assessment Check

Based on our analysis of your data, we prepare a thorough Readiness Assessment Check. It includes a detailed report of our findings, gaps and recommendations to fill the gaps. In short, it defines your safety needs far more precisely than the submission dossier can.



In addition to giving you valuable insights into potential trouble areas that deserve special scrutiny, the Readiness Assessment Check will suggest approaches for strengthening the evidence of your product's benefits despite its risks, perhaps by limiting the term of usage or excluding certain patient populations as prospects.

Follow-Up: Comprehensive Benefit Risk Management Planning

Even drugs that involve considerable risk can be extremely valuable if given to the right patients, administered properly and monitored carefully. The Quintiles Benefit Risk Advisory team can provide a complete benefit risk management plan to help ensure that every detail is covered both to maximize your drug's lifecycle potential and to minimize safety issues.

The regulators may say, for example, that in order to keep the drug on the market you have to take certain steps; we can call on a broad array of Quintiles tools and expertise to respond quickly and minimize the negative effects of their demands.

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Our Benefit Risk Advisory Service may be new, but we have 25 years' experience in the field of drug safety, and more than 850 team members globally whose collective experience and intellectual capital are unequalled in the industry.

When it comes to drug safety, the fewer surprises there are, the better. Please contact us today to learn more about this whole new approach to understanding and minimizing your exposure.

BENEFIT RISK ASSESSMENT SERVICES

- > Readiness Assessment Check
- > Benefit Risk Management Planning
 - Executive overview & recommendations
 - Signal detection and management
 - Crisis management
- > Medical/Therapeutic/Regulatory Services
 - Medical advisors
 - Medical surveillance
 - Genomics
 - Epidemiology

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*What's
Missing?*



What's Missing?

With Quintiles, you can choose a complete safety package or outsource the individual services you need.

Turnkey Biovigilance Services for Small Companies

Small companies that lack an internal pharmacovigilance infrastructure are likely to need a complete outsourced service. Quintiles Late Phase & Safety Services created Biovigilance Services specifically to meet this need and help you accelerate product submissions.

Our comprehensive program begins with the development of an optimal safety plan. Customized to your specific needs and continuously updated as the safety profile of your product unfolds, our plan goes on to cover every aspect of pharmacovigilance, safety surveillance, data processing, risk management and global regulatory reporting.

A Little or a Lot: Outsourcing Solutions for Large Companies

Large pharmaceutical companies can improve efficiency and transform fixed costs into flexible,



as-needed costs by outsourcing mature product management and safety oversight management to Quintiles Late Phase & Safety Services. We can act as a functional service provider to handle the totality of your case processing needs, or provide a range of individual safety services.

Comprehensive Safety Management for Lower Priority, Mature Products

Quintiles offers an extensive package of safety services for mature products that frees up your in-house resources to focus on new therapies. We provide skilled data capture, entry and coding, query resolution, pharmacovigilance, risk management and up-to-date mapping of global regulatory requirements with fully compliant reporting.



In addition, we can take over the voluminous business of spontaneous post-marketing case processing for large portfolios of mature products – another good way to lower fixed costs and apply your internal resources to higher-priority work.

Integrated Oversight Group Management

The requirements for even one oversight group – endpoint committee, data monitoring committee, core laboratory or advisory group – can add complexity to trial communication and data flow processes. Some studies include multiple groups of various types. Quintiles' CEVA department has the expertise to set up, integrate, coordinate and successfully deliver these oversight group processes.

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Our Medical Information safety call center provides a turnkey solution to the challenge of answering questions and capturing safety information from consumers and health professionals. Registered nurses, pharmacists and/or physicians staff a phone bank 24/7, and the call center records and tracks all reports in a 21 CFR Part 11 compliant database.

There's Safety in Numbers

Quintiles Late Phase & Safety Services has covered all phases of drug, biologic and device development for 25 years.

We operate nine offices in as many countries – a robust global presence that ensures we can manage your safety programs wherever you conduct clinical trials.

Whether you need a complete safety package or an individual service, Quintiles has the depth and breadth of experience to help you offer patients, physicians, regulators and legislators the highest possible level of confidence in your drugs' safety.

At Quintiles, it's all about results.™



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*Mitigating Risk to
Maintain Safe Utilization
and Drug Longevity*



Mitigating Risk to Maintain Safe Utilization and Drug Longevity

Risk mitigation measures can help keep valuable drugs on the market, even when their safety profile includes adverse events that might negatively affect the benefit risk balance.

Regulators recognize that all drugs cause side effects, and that some drugs that cause significant side effects should remain on the market because their benefits outweigh their risks – particularly when no comparable therapies are available.

The key to keeping your drug on the market is to maximize safe utilization throughout the product's lifecycle through an active and comprehensive benefit risk management plan.

Quintiles Late Phase & Safety Services can manage every aspect of both active benefit risk management programs and overall risk management for drugs across all therapeutic areas.

Drug Candidates for Risk Management Programs

The elements of a benefit risk management program vary considerably from one drug to



another, but every program must be tightly designed and executed, cover every known risk and be flexible enough to react as new information is received.

For example, your benefit risk management program might help clinicians mitigate risks by excluding patients with certain known conditions. It might provide information that enables providers and their patients to understand the benefit risk balance and make informed decisions about whether or not to use the drug. Or, it might improve correct usage by helping patients understand the importance of taking the drug exactly as instructed.

The Benefit Risk Management team of Quintiles Late Phase & Safety Services can help you evaluate the components of your drug's benefit risk program and ensure that every detail is covered properly for the lifecycle of the product.



COMPREHENSIVE BENEFIT RISK MANAGEMENT SERVICES

- > Benefit risk management plan design and execution
- > Safety partner integration
- > Active surveillance program & reporting
- > Provider/patient education
- > Appropriate use management/limited use programs
- > Independent monitoring boards for large Phase IV studies
- > Comprehensive program oversight
- > Partnership/alliance management
- > Protocol management by incorporating risk management strategies during development
- > Assistance at regulatory agency meetings
- > Independent Data Safety Monitoring Board (DSMB)
- > Strategic review of plans to fully demonstrate product benefits

The Safe Choice

The Benefit Risk Management team of Quintiles Late Phase & Safety Services has the therapeutic area expertise and global experience to implement management programs for virtually any drug, anywhere in the world.

We have 25 years' experience in the field of drug safety, and more than 850 team members globally whose collective experience and intellectual capital are unequalled in the industry. Our multi-disciplinary, global team of safety experts calls on and integrates the resources of Quintiles, Innovex and NovaQuest to execute many aspects of risk management programs.

Result: A comprehensive, proactive benefit risk management program that helps ensure safe utilization and extend product longevity on the market.

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