

## 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.

### Contact Us:

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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.™*



The Development Group of  
Quintiles Transnational