



lifecycle safety
a *new* standard
for risk-benefit management



bringing *safety* up to speed

Imagine These Scenarios:

- > You have a promising new product, but risk management issues are holding up approval
- > Your marketed product runs up against unexpected post-marketing safety requirements
- > You need urgent support to process and report adverse events, comply with PSUR timelines or staff a call center — all on a tight budget

Challenges like these are all too real. They can make or break a product's success. And you won't find the solution by approaching safety issues piecemeal.

The Solution is Lifecycle Safety

You need one safety solution that addresses your regulatory and commercial needs while keeping you firmly in charge. That's what Quintiles' approach to Lifecycle Safety provides — enhanced control, streamlined operations, more agile decision-making and faster speed to market.

Reinventing Safety: The Lifecycle Model

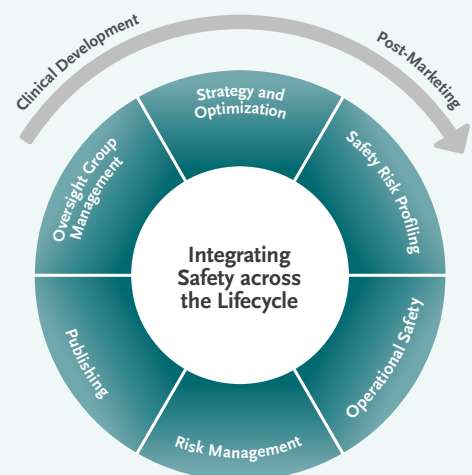
Product safety is a critical link to product value. And with growing demands for safety information and holistic risk management, you need a better way to manage safety throughout your overall product development, including the increasingly important post-marketing phase.

So we designed a new approach: Lifecycle Safety. It's a new model that integrates the full scope of your safety activities in two ways:

- > Across different phases of the product lifecycle, from early-stage through post-marketing
- > Across functions, to tie together everything that's happening at every moment

When you approach safety as a single, coordinated operation, the benefits add up fast. No more disconnects handing data off from one phase to another. No more delays to approval because different safety functions aren't in sync. No more surprises because safety information is disconnected from risk-management measures. No more hesitation making tough calls because the information in front of you isn't perfectly clear.

Of course, to manage such a comprehensive approach to safety, you need a wide array of safety expertise, as well as a proven history of delivering on safety monitoring and strategy. With Quintiles, that's exactly what you get.



You Need:

We Deliver:

Game-changing strategy

An exclusive, innovative approach to safety and risk management

Streamlined operations

Metrics-controlled, efficient, agile processes that eliminate duplication and inconsistency

Fast decision-making

Integration across functions and silos so all your information comes from one system

Proactive risk-benefit planning

A medical / scientific and commercial focus that identifies potential pitfalls before they happen

Speed to market

Industry-leading quality and compliance systems to aid in timely approval

Top commercial potential

Unique post-marketing integration that helps you get the most out of your investment

Keeping You Informed — and in Control

Quintiles functions as an integrated part of your team, bringing in the right expertise to complement what you already have in-house. We work as your ally to ensure knowledge transfer and team coordination. But the power stays in your hands.

You get a single point of contact — a dedicated manager who serves as your gateway to cross-trained safety and risk management experts, harmonized processes and real-time access to the data you rely on. That means more sophisticated analysis, greater adaptability and more agile decision-making.

Lifecycle Safety is built around what you need today, and it's flexible enough to grow with you. There are no one-size-fits-all solutions. That's because Quintiles starts every engagement by listening.

Our solutions can span an entire product lifecycle, or only the phases you need. You can use Lifecycle Safety as part of a larger Quintiles engagement or as a standalone service. If your product is already on its way through the pipeline and you need extra support, we can even jump in midstream.

Now, through our integrated operational framework, you'll have the complete, accessible knowledge you need at every step of the way. So you can make mission-critical decisions in stride — and manage the risk-benefit profile of your products effectively, and to the benefit of your patients.

Put Your Safety Data in the Best Hands

An innovative safety model is important. The quality of safety services is just as crucial. With Lifecycle Safety solutions from Quintiles, you can be confident knowing we have the breadth, expertise and capacity that's made us a market leader:

- > *Up-to-date mapping of international reporting requirements to keep your safety data fully compliant wherever it's used*
- > *Reliable, sanction-free performance against client and regulatory deadlines*
- > *Optimized processes, technology and efficiency that ensure quality and save you money*

Lifecycle Safety Services

- > *Risk Management Planning*
- > *Safety Operations*
- > *Oversight Group Management*
- > *Safety Training and Education*
- > *Safety Publishing*
- > *Qualified / Responsible Person Services*
- > *Quality Assurance*
- > *Medical Information*
- > *Endpoint Adjudication*



Quintiles helps you manage safety as a single, coordinated operation — giving you one solution, one point of contact and one less thing to worry about.

what do you need to take safety to the *next* level?

- > *A company with expertise in managing the safety of your product throughout its lifecycle*
- > *A dedicated team who sees things from your point of view*
- > *Robust results from comprehensive information management*

Find the Better Way to Link Safety to Value

Creating more value in your products is more challenging than ever. But now you can be better equipped to increase efficiencies, manage risk and ensure returns on your investment — with our comprehensive Lifecycle Safety solution. Contact Quintiles today to learn more.

Contact Us:

In the U.S.: 1 877 988 2100

In Europe: +44 (0) 1344 708000

In other areas: +1 877 998 2100

On the web: www.quintiles.com/safety

Email: safety@quintiles.com