



Real Time Trials

Real Time. Real Value.

clinical trials safety in no time

a cruise control

for *your* risk-benefit management

real time | real value | real trials

speeding-up your *safety* engine

Imagine Following Situations:

- > *You have a highly demanded new drug; the risk management issues are slowing down its approval, though.*
- > *Your already marketed product runs up against some unforeseen or changed post-marketing safety limitations.*
- > *You urgently need support to handle an adverse events reporting while still complying with the PSUR timelines or even run a call center.*

Put an increasingly tighter clinical trials budget on top and you'll get the challenges that unfortunately all are so familiar for the pharmaceutical companies nowadays. You certainly don't need all of them to make or break your product's success. And you will not likely find any relief by tackling the safety issues piece by piece.

The Solution is Holistic Approach to the Safety

You need one complete solution to address the regulatory, pharmacovigilance as well as your commercial needs while keeping you fully in charge. That's exactly what the RTTs' approach to the Clinical Trials Safety gives you: improved control over the operations, lower costs, expedited decision-making and as a result shorter time-to-market.

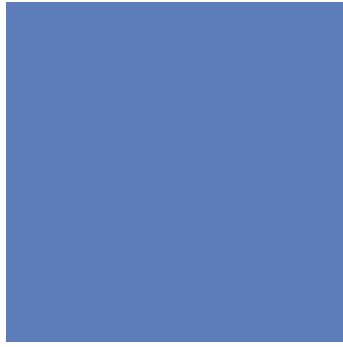
Reassuring Safety: The Lifecycle Model

Drug safety is crucial for its value. And with growing demand for transparency of the safety information as well as reliable risk management, you may need a better way to manage safety throughout the whole product development, along with the increasingly more important post-marketing surveillance period (phase IV Clinical Trials).

Thus we set up a new approach for you: Lifecycle Safety. It's a model that truly integrates the full scope of your safety activities in two ways:

- > *Horizontal: across different phases of the product lifecycle, from early-stage through post-marketing*
- > *Vertical: across different functions, which binds together everything happening simultaneously*

As you handle safety as a unified, coordinated approach, benefits accumulate quickly. No more gaps while transmitting data from one study phase to another. No more approvals get stuck because some of the safety functions aren't in sync for some reason. No more surprises because safety information is not fully consistent with risk-management measures. No more hesitation in calling stakeholders or authorities because the information in front of you isn't up-to-date or sufficient. Of course, to exercise such a comprehensive risk and safety management, you need a wide array of corresponding expertise, as well as a proven track record of delivering on safety monitoring. With RTT you get exactly that.



We Keep You Informed — and in Control

RTT acts as an integrated part of your team, bringing in just the right expert knowledge to complement the one you already have. We work on your behalf to ensure just as smooth knowledge transfer and the team orchestration. But steering wheel remains, of course, in your hands.

You get a single contact person, a dedicated manager who serves as your gateway to cross-trained safety and risk management experts, harmonized workflow and provides you real-time access to the data you need. That means more thorough analysis, greater level of transparency and more efficient decision-making.

We build Lifecycle Safety around your current needs, but it's also flexible enough to grow with them. As usual there is no one-size-fits-all solution. That's why Quintiles starts each project by careful listening.

Our solutions can target either an entire medicine lifecycle, or only those phases you need. It's up to you to use Lifecycle Safety as part of a larger RTT engagement or as a mere standalone service. In case your product is already making its way through the pipeline and what you need is just some extra support, we can jump even into a midstream.

Thus, through our comprehensive operational framework you get all the knowledge you need at every moment of the development and approval process. Consequently, your mission-critical decisions are being made easily and the risk-benefit profile of your products is managed effectively and to the benefit of the patients.

You need

We offer

Turning-point strategy

Unique, innovative approach to safety and risk management.

Optimized operations

Objectively measured and controlled, IT-supported, agile processes that eliminate gaps as well as excessive bureaucracy.

Timely decision-making

Seamless integration across the whole function stack so that all your information appears to be in one system, even if it's spread all over the globe (key word "service oriented IT architecture").

Proactive vs. reactive risk-benefit planning

A sound medically scientific (GxP) and financial focus that identifies potential shortcomings before they really come about.

Time-to-market

Industry-wide unmatched quality and compliance assurance system to enable timely approval and marketing.

Best commercial potential

Excellent post-marketing monitoring strategy to help you get the highest return on investment possible (ROI).

Put the Critical Data in the Right Hands

An appropriate safety approach makes the difference. The quality of safety services is vital. With the Lifecycle Safety solution from RTT and all the expertise and capacity that's made us a market leader you can be sure to get:

- > *Up-to-date notion of international reporting and regulatory requirements to keep your safety data fully compliant and available on-demand.*
- > *Reliable, smooth meeting customer and competent authority deadlines.*
- > *Streamlined processes, modern technology and unprecedented performance that ensure quality and reduce your costs.*

Lifecycle Safety Services

- > *Risk Management Plan implementation*
- > *Processing of Safety Data and Operational Pharmacovigilance*
- > *Audit Group Management*
- > *Training in Safety and Pharmacovigilance*
- > *Safety Publishing*
- > *Services of Qualified Person / Provision of Interim QPPV*
- > *Medical Information Management*
- > *Quality and Compliance Assurance*
- > *Endpoint Adjudication*

RTT ensures your *safety & regulatory* compliance in a single, coordinated activity – one solution, one point of contact and one less thing to worry about.

what do you need to bring safety *up* to the *next level*?

> *A company with know-how in managing the safety of your product throughout its whole lifecycle*

> *A dedicated team of professionals who is able to see things your way*

> *Best results due to the comprehensive information management*

Find the Way to Link Safety to the Real Value

Getting more value out of your products nowadays is probably more challenging than ever. But now you can be better off, to achieve efficiency, manage risks and increase returns on your investment — with our sophisticated Lifecycle Safety solution. Contact RTT today to learn more.

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