



Clinical Lifecycle Support

STRONGER EVIDENCE | SMARTER COMPLIANCE | FASTER MARKET ACCESS

A fully integrated approach to Clinical Evaluation, Risk Management, and Post-Market Surveillance, designed to support medical device manufacturers throughout the entire clinical lifecycle of their products.



PRO-LIANCE
GLOBAL SOLUTIONS



A unified framework for continuous compliance

Clinical Lifecycle Support is a structured, evidence-based service that integrates Clinical Evaluation, RiskManagement (RM), and Post-Market Surveillance (PMS), into one continuous lifecycle framework.

Rather than managing these activities in isolation, we align them into a single, traceable system that evolves with your device, from pre-market strategy through long-term post-market monitoring.

This integrated approach enables manufacturers to establish, maintain, and optimize compliance with Regulation (EU) 2017/745 (MDR), ISO 13485, ISO 14971, ISO/TR 20416 and the coming ISO/DIS 18969.

Why clinical lifecycle support matters

Our service ensures that clinical evidence, risk management activities, and post-market feedback are consistently aligned with:

- The intended use of the device
- Safety and performance claims
- Ongoing regulatory compliance with the MDR

Outcomes

Integrated clinical lifecycle support that enables:

	Transparent and interconnected lifecycle activities
	Consistent generation and evaluation of clinical evidence across the entire lifecycle
	Clear demonstration of device safety and performance
	Sustainable, audit-ready regulatory compliance
	More efficient documentation, reporting, and regulatory interactions
	Increased market confidence and product credibility



From compliance obligation to strategic advantage

We develop MDR-compliant Clinical Evaluations aligned with current Notified Body expectations. Our Clinical Evaluation Reports (CERs) follow MDR and best practices from MDCG and MEDDEV 2.7/1 Rev. 4, and are designed to support ISO 18969 readiness.

By integrating lifecycle thinking and clear evidence traceability, we help reduce delays, rework, and uncertainty during conformity assessment.



A PMS engine that builds market confidence

Beyond documentation, we implement a living PMS system aligned with MDR, ISO/TR 20416 and MDCG guidance. Continuous analysis of real-world data, performance of PMCF activities, creation of PMCF, PMS reports and PSURs, turns post-market information into a strategic asset.

End-to-End risk management you can trust

Our MDR and ISO 14971-compliant Risk Management support systematically helps you integrate clinical and post-market insights. Risks are continuously reassessed, controlled, and documented, providing clear traceability for audits and a sound basis for benefit-risk evaluation.





A structured, integrated process

1. Assessment

Structured gap analysis of existing Clinical Evaluation, Risk Management and PMS/PMCF documentation, focusing on both compliance and integration.

2. Design

Development of a tailored clinical lifecycle framework aligned with your Quality Management System, defining clear interfaces between clinical, risk management, and post-market activities.

3. Implementation

Establishment of procedures, templates, reports, and traceability links across CERs, Risk Management Files, PMS/PMCF documentation, and Technical Documentation.

4. Monitoring & continuous improvement

Ongoing analysis of clinical and post-market data, with systematic feedback into risk management to ensure continuous MDR compliance.

The power of full integration

When Clinical Evaluation, Risk Management, and Post-Market Surveillance operate as one integrated framework, manufacturers gain:

- Transparent and traceable clinical evidence across the lifecycle
- Reduced regulatory friction and fewer review cycles
- Faster and more predictable market access
- Evidence-based decision-making
- Strong, defensible safety and performance claims

WHO WE ARE

Florian Tolkmitt and Dr. Thomas Brzoska are the founders of PRO-LIANCE and experts in regulatory, clinical, and scientific affairs with more than 20 years of experience.



FLORIAN TOLKMITT



DR. THOMAS BRZOSKA

Alongside them, a multidisciplinary and international team of experts works to support each project, adapting to the specific needs of your project and medical device.



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