Rapid Molecular Diagnostic Platform for Sepsis and Acute Infection Detection

Inflammatix™

At A Glance

Customer
Inflammatix

Product
TriVerity™ Test System

Services/Market
Emergency Diagnostics, Molecular Diagnostics, Point-of-Care Testing

Challenge

Inflammatix aimed to develop a first-in-class, point-of-care diagnostic for infections and sepsis capable of delivering results in ~30 minutes. Success depended on tight coordination between software, hardware, and assay development—while meeting Class II FDA regulations, evolving cybersecurity guidance, and aligning with a pivotal multi-site clinical trial. Rapid execution and first-pass clearance were essential to market strategy and clinical impact.

Transforming Emergency Care: The Inflammatix Vision

In the fast-paced environment of an emergency room, time is a luxury that clinicians simply do not have, especially when confronted with critical infections like sepsis.

Every minute that passes without the right diagnosis increases the risk of complications and mortality. Traditionally, identifying the root cause of an infection—whether bacterial, viral, or another type—requires hours, if not days, of waiting for lab results. This delay forces medical professionals to make high-stakes decisions with limited information, often leading to broad-spectrum treatments that may not be effective. The need for a faster, more reliable diagnostic method was clear.

Recognizing this critical gap, Inflammatix set out to redefine how infections are diagnosed and treated. Their mission was clear: develop a rapid, point-of-care (POC) molecular diagnostic platform capable of delivering accurate actionable results in approximately 30 minutes—fast enough to guide treatment decisions in near real time. This bold vision aimed at giving clinicians the insights they need precisely when they need them, enabling targeted care that could save lives.

At the heart of this innovation is a rapid blood test that generates three critical diagnostic results:

- Bacterial infection score
- Viral infection score
- Illness severity score

Together, these scores offer unprecedented clarity in the early stages of patient evaluation—particularly for conditions like sepsis, which accounts for:

- 50% of all hospital deaths,
- 40% of ICU spending,
- And costs the U.S. healthcare system over $24 billion annually, making it the most expensive diagnosis.

The Challenge: Developing a First-In-Class Diagnostic Test System with Tight Timelines

The Inflammatix team's vision required advanced machine learning, bioinformatics, and robust integration between software, hardware, and a cartridge style consumable — all under tight timelines and evolving regulations.

Key challenges included:

- Regulatory Complexity: Development had to comply with FDA regulations (21 CFR Part 820), IEC 62304, ISO 13485, and ISO 14971 for a Class II device, while remaining adaptable to future changes.
- Cybersecurity Evolution: A new FDA cybersecurity guidance was expected mid-development, with the potential to delay key milestones if not addressed swiftly and effectively.
- Hiring & Scaling: Building an internal software team capable of FDA-compliant work would have required significant time and resources.
- Clinical Study Pressure: Timelines needed to align with the SEPSIS-SHIELD study - a pivotal multi-year clinical trial conducted by Inflammatix to validate the diagnostic and prognostic performance of its TriVerity™ test system for patients with suspected acute infections or sepsis (1,222 participants across 22 sites). This would be a key milestone before submission for FDA review.
- High Stakes: Straying too far from the 30-minute target to achieve acceptable result accuracy goals or failing the first FDA 510(k) submission could have derailed product and go to market strategies.
- HIPAA Compliance: Addressing HIPAA compliance for sensitive patient data would require proactive measures, including strong encryption and stringent access control protocols.

Choosing the Right Partner

Recognizing the pivotal role software would play in the success of the system, Inflammatix conducted a thorough evaluation to identify the right software development partner.

The RND Group - A Gener8 Company stood out for their deep regulatory expertise, proven track record in FDA-compliant software, and extensive experience with complex diagnostic instruments.

The RND Group's ability to design scalable, future-ready systems —combined with strong technical leadership—made them the clear and confident choice for this project.

Execution: Engineering for Agility and Compliance

Over a multi-year collaboration, The RND Group assembled a dedicated team of developers and verification engineers who worked shoulder-to-shoulder with Inflammatix. Developing the software within a robust design control framework, the team adapted to evolving priorities and overcame key challenges:

- Navigating Regulatory Change: When the FDA released new cybersecurity guidance in 2023, The RND Group's in-house cybersecurity team seamlessly incorporated the expanded assessments and documentation requirements—ensuring full compliance without disrupting the project timeline.
- Meeting the 30-Minute Test Completion Target: Tight integration between software, hardware, and assay development allowed the team to reach the critical goal of delivering test results in approximately 30 minutes, enabling emergency department adoption.
- Engineering a User-Friendly Platform: The team delivered a compact diagnostic system with pneumatic, thermal, motor, and optical controls—all operable through an intuitive touchscreen interface, with guided workflows, and barcode scanning to ensure ease of use in high-pressure clinical environments.
- Ensuring Compliance & Security: The software architecture included embedded HIPAA - compliant practices, encryption, and access control capabilities from the start. Further alignment to the best practices of medical software development assured alignment to FDA expectations.
- Streamlining Clinical Integration: Inflammatix utilized The RND Group's LIS connectivity solutions and added remote notification to streamline the experience for healthcare providers.
- FDA Clearance on First Attempt: The product submission succeeded on its first 510(k) attempt—a notable achievement considering the industry's 64% initial rejection rate.
- Programming for the Future: The software was built from the start to be able to handle future assays without having to update the platform code.

"We are so impressed at how well your QMS and your project plans line up with the FDA submission process, and thus paved the way to a much smoother submission. The technical excellence and attention to quality and detail that you all have always shown were a huge help."

Ambika Srinath
Director of Systems Engineering and Design Assurance, Inflammatix

Results: Strategic Wins and Long-Term ROI

The partnership yielded a powerful return on investment for Inflammatix:

- Exceptional Quality: Proven and rigorous software development lifecycle practices ensured that the product would operate at a high degree of quality and would be not only ready for FDA submission but also other regulatory markets.
- FDA Clearance: First-pass 510(k) submission success supported a timely market entry.
- Focus on Core Innovation: Inflammatix could concentrate on scientific breakthroughs while RND handled software execution and software regulatory compliance.
- DHF Documentation: RND's development of comprehensive Design History File (DHF) documentation saved Inflammatix an estimated 6 to 7 months of internal effort, eliminating the need to hire a dedicated team for this critical task.
- Study Alignment: On-time development allowed Inflammatix to align with the timing of the critical SEPSIS-SHIELD clinical study.
- Designed for Maintainability: Software features which include modular software design, remote update capability, built-in diagnostics, system self-checks, detailed error logging with reporting, and secured managed access reduces the burden of maintaining the system in a heavily regulated environment.
- Military Contract Win: Timely completion of key milestones was instrumental in securing a major defense contract.

Conclusion — A Winning Partnership

RND Group's disciplined engineering and regulatory experience were instrumental in delivering a compact user-friendly instrument that employs cutting-edge computational techniques. Inflammatix proprietary mRNA signature technology interprets the body's immune response with remarkable precision, enabling diagnostic insights that were not previously possible. More than just a single test, the Inflammatix platform is built for expansion and will be able to handle future assays. The collaboration between Inflammatix and RND Group stands as a strong example of how strategic partnerships can transform complex engineering concepts into successful, market-leading solutions.

Custom Software. Compliant Systems. Faster to Market.

Transforming diagnostics takes bold thinking, and the right partner to turn that vision into reality. Whether you're building a full product or need specialized software to power your platform, Gener8 brings the technical depth and regulatory expertise to move you forward.
Through collaborations with innovators like Inflammatix, we help teams navigate complexity and deliver market-ready solutions with confidence. From concept to code to clearance, we're here to accelerate what matters.

Innovation deserves follow-through. Let's build what's next — together.