

Clinical Brief

Executive Summary

The Preemie System is a pioneering, privacy-preserving, federated AI platform built to unlock the collective power of neonatal data without sharing sensitive patient information. We are building a collaborative network to tackle the most pressing challenges in neonatology: predicting and preventing life-altering complications in premature infants.

We invite you to join this groundbreaking initiative to accelerate research, validate interventions, and set new standards for data-driven, personalized care in the NICU.

The Critical Unmet Need

Despite advances in neonatology, premature infants remain at high risk for devastating complications, including:

- Neonatal Sepsis (early and late onset)
- Bronchopulmonary Dysplasia (BPD)
- Necrotizing Enterocolitis (NEC)
- Growth Failure

Current research is hampered by data silos. Individual hospitals hold valuable data, but alone, their datasets are too small to power robust AI models for rare events or to understand nuanced patient subgroups.

Our Solution: The Preemie System

The Preemie System leverages Federated AI to create a collaborative learning network.

The process is secure, ethical, and compliant:

- **Your Data Stays with You:** Patient data never leaves your firewall.
 - **The Model Travels:** An AI algorithm is sent to your secure server.
 - **Local Learning:** The model learns from your local, de-identified dataset.
 - **Shared Intelligence:** Only the model's "learnings" (mathematical updates) are aggregated to create a smarter, globally-informed model, which is then shared back with all participants.
- This is not a data-sharing platform. It is an intelligence-sharing consortium.

Key Features and Goals of the Preemie System

Here are the key features of our system:

- **Federated Learning:** As described above, this is the core architecture.
- **Predictive Analytics:** The AI model is designed to predict critical health risks for preemies, such as neonatal late-onset sepsis, bronchopulmonary dysplasia (BPD), and necrotising enterocolitis (NEC).

Why This Combination is So Powerful

The combination of the Preemie System's mission and Federated AI technology is a perfect solution for modern healthcare challenges:

- **Privacy-Preserving:** It overcomes the biggest hurdle to medical AI: using sensitive data without exposing it.
- **Regulatory Compliance:** It is inherently more compliant with data protection laws.
- **Unlocks "Silent Data":** It allows the value to be extracted from vast amounts of data that was previously locked away in individual hospital silos.

The Preemie System uses federated learning to build a collaborative, intelligent system that aims to directly improve the lives of vulnerable premature infants, all while rigorously protecting their privacy.

Unique Value Proposition for Each Partner

FOR NICU TEAMS AND HOSPITAL SYSTEMS:

- **Gain a Predictive Edge:** Access AI-powered risk scores for sepsis, BPD, and NEC, enabling earlier interventions and personalized care pathways.
- **Improve Outcomes & Quality Metrics:** Directly impact key clinical outcomes, reduce length of stay, and improve survival without morbidity.
- **Benchmark Performance Anonymously:** Compare your unit's outcomes and practices against a global network, all while maintaining complete data privacy.
- **Lead in Clinical Innovation:** Position your institution at the forefront of ethical, data-driven medicine.

FOR PHARMACEUTICAL COMPANIES:

- **Revolutionize Trial Design:** Identify ideal patient cohorts for clinical trials more efficiently across a vast, virtual network.
- **Generate Real-World Evidence (RWE):** Use the platform to study the long-term effectiveness and safety of your therapies in a real-world setting.
- **Discover Novel Biomarkers & Endpoints:** Collaborate to identify digital biomarkers and refine patient stratification for neonatal drug development.

FOR NUTRITION COMPANIES:

- **Objectively Evaluate Nutritional Impact:** Partner to study how specific nutritional formulations affect growth, neurodevelopment, and the risk of complications like NEC.
- **Drive Personalized Nutrition:** Move towards tailoring nutritional strategies based on AI-driven insights into an infant's unique metabolic and growth trajectory.
- **Strengthen Product Claims with Data:** Generate robust, clinical evidence to support the role of your products in improving neonatal health.

Review of Evidence and Preliminary Data

- **Validation of Federated Learning in Healthcare:** Federated learning has been successfully validated in other medical domains, demonstrating performance comparable to models trained on centralized data while preserving privacy. Seminal studies in areas like brain tumor segmentation (e.g., the Federated Tumor Segmentation (FeTS) initiative) have proven its feasibility and accuracy.
- **Proof-of-Concept in Neonatology:** Initial pilot studies on retrospective, multi-site NICU data have shown that federated models can effectively predict the onset of conditions like late-onset sepsis hours before clinical suspicion, with performance metrics (AUC-ROC) matching those of models trained on a theoretically pooled dataset.
- **Growing Regulatory Acceptance:** Regulatory bodies, including the FDA, are actively developing frameworks for evaluating AI-based models that are “locked” as well as those that continuously learn, acknowledging the potential of approaches like federated learning to maintain model quality and safety across diverse populations.

Discussion and Potential Impact

The Premie System represents a paradigm shift in how we approach clinical research and care delivery in neonatology. By enabling secure, multi-institutional collaboration, it addresses the fundamental limitation of small sample sizes that has plagued rare disease research.

- **Accelerating Discovery:** This platform can significantly shorten the time required to generate clinically actionable evidence for preventing and treating complex conditions like BPD and NEC.
- **Democratizing Data Science:** It empowers individual hospitals, regardless of their size or resources, to contribute to and benefit from cutting-edge AI, leveling the playing field in pediatric healthcare innovation.
- **Building a Learning Health System:** The Premie System is the foundational infrastructure for a true learning health system in neonatology, where every patient encounter contributes to collective knowledge, which is then immediately fed back to improve care for the next infant. The primary challenge ahead is network growth, which is why engaging founding partners is critical to its success and validation.

Join our Premie Consortium

We are seeking partners to improve and validate this platform. Your involvement will ensure the system addresses the most critical clinical and research questions.

Please reach out to us at Info@preemiesensor.com and let's start our collaboration.

Together, we can move beyond isolated data silos to create a collective intelligence that gives every premature infant their best chance at a healthy life.