

Nestmedic Selects Curavit Clinical Research as U.S. CRO Partner for Pioneering Prenatal Monitoring Trial

Boston, MA & Warsaw, Poland – [July 21, 2025] — *Curavit Clinical Research*, “The Innovation CRO”, is proud to announce its selection by **Nestmedic S.A.** to lead the U.S. clinical trial of **PregnaOne**, an innovative remote prenatal monitoring solution. This milestone partnership was recently shared on LinkedIn by Nestmedic CEO Jacek Gnich and Curavit leadership.

The upcoming **Non-Significant Risk (NSR)** study will enroll **50 expectant mothers** in the U.S.. to evaluate the safety and effectiveness of PregnaOne during home use. The study is designed to generate foundational evidence to support future regulatory approval in the U.S. **Curavit** will manage all aspects of the trial, including IRB submissions, site selection, contract and monitoring, data management, clinical data capture software selection, data analytics, and preparation of the Clinical Study Report (CSR).

“We are honored to support Nestmedic in bringing PregnaOne to market,” said **Joel Morse, CEO and Co-founder of Curavit Clinical Research**. “Their mission to improve prenatal care through remote monitoring perfectly aligns with Curavit’s vision to partner with innovative medical device companies that are working to expand access to healthcare.”

Trial Highlights:

- This FDA-required clinical study is designed to evaluate the safety and effectiveness of PregnaOne during home use, conducted under a Non-Significant Risk (NSR) device designation. The study will generate data to support future regulatory approval in the U.S.
- A minimum of three clinical sites will be selected, with an emphasis on enrolling participants that reflect geographic and demographic diversity.
- A centralized healthcare provider (HCP) data review and adjudication process will be implemented to ensure consistency and high quality data.
- The study will be conducted entirely in the United States, enrolling 50 expectant mothers over an 11 months period

“We are building technology with empathy at its core,” said **Jacek Gnich, CEO of Nestmedic**. “Curavit’s innovation forward approach, medical device expertise, and deep clinical trial experience make them the ideal partner to run this pivotal study in the U.S.”

About Curavit Clinical Research

Curavit Clinical Research, The Innovation-CRO, designs and executes modern clinical trials for medical devices, digital therapeutics, and novel pharmaceuticals. Headquartered in Boston, Curavit operates nationwide with additional offices in New York, Salt Lake City, and San Diego. Learn more at www.curavit.io.

About Nestmedic S.A.

Nestmedic is a Polish medtech company redefining prenatal care with **PregnaOne**, an AI-enabled remote monitoring solution that empowers patients and providers with real-time, continuous insight into fetal and maternal well-being.

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