✦ DELIVERY DATE AI· FDA DE NOVO GRANTED · DEN250007

When delivery timing is uncertain, costs and quality variation follow.

Delivery Date AI™ provides an **image-based Predicted Delivery Date** for pregnancies without a reliable estimated delivery date, supporting more consistent maternity timing assessment, operational alignment, and network quality oversight.[1]

01 THE COST OF DELIVERY TIMING UNCERTAINTY

Pregnancies without a reliable delivery date carry measurably higher downstream costs. For a payor managing maternity networks at scale, that gap represents meaningful, recurring claims exposure concentrated in an identifiable population.

18.07%

NICU admission rate in suboptimally dated pregnancies vs. 13.25–13.30% in well-dated groups (p=0.01, N=2,113)[2]

Peer-reviewed association between dating quality and NICU admission rates. Not a causal claim for Delivery Date AI. Source: Reis et al. 2020.

$71,158

Avg NICU admission cost (employer-sponsored). Range $4,488 (P10) to $161,929 (P90)

Health Care Cost Institute (HCCI), 2023

02 THIS POPULATION EXISTS ACROSS YOUR NETWORK TODAY

Pregnancies without a reliable delivery date are not rare edge cases. They represent a recurring segment of any maternity network — disproportionately present among patients with late prenatal entry or limited early care access. These are exactly the pregnancies where timing variability is hardest to manage, document, and compare consistently across providers and sites.

03 PAYOR ACCOUNTABILITY & CONTRACT EXPOSURE

ACCOUNTABILITY LEVER	THREE STRATEGIC PAYOR PRESSURES
Network quality scorecards	Value-based maternity contracts depend on consistent documentation across providers. Where delivery timing varies, performance gaps compound and become difficult to measure or defend.
Employer and purchaser visibility	NICU admissions in employer-sponsored plans rose 8% between 2017 and 2021 — and children admitted to the NICU accumulate 5× more healthcare costs over their first two years than those who are not. Timing uncertainty concentrates in exactly the pregnancies driving that exposure.
Retrospective review and benchmarking	Where delivery timing documentation varies across providers, retrospective review becomes unreliable and network benchmarking loses validity.

04 WHAT DELIVERY DATE AI DELIVERS FOR YOUR NETWORK

Standardizing timing inputs across your networks

A consistent, FDA De Novo Granted Predicted Delivery Date for the pregnancies where conventional methods fall short — reducing the documentation variability that drives performance gaps across providers and sites.

Reduced downstream cost exposure

More consistent delivery timing assessment supports earlier, more appropriate care coordination for the highest-risk pregnancies in your network — the ones driving disproportionate NICU utilization.

Cleaner contract and purchaser performance

Consistent timing documentation supports more reliable case classification, retrospective quality review, and network benchmarking — giving you a stronger foundation for value-based contract performance and employer reporting.

Low-friction network deployment

FDA De Novo Granted. Compatible with most standard ultrasound systems. Integrates via DICOM/PACS. No new hardware, no protocol changes, no major IT redesign required.

Note: GE = 90.5% of validation cohort

Delivery timing is a foundational input to maternity network performance. When it's uncertain, costs and accountability gaps follow. Delivery Date AI closes that gap — standardized, FDA De Novo Granted, and deployable across your network today.

05 CLINICAL FOUNDATION

SOURCE	PERFORMANCE & POPULATION DETAIL
FDA De Novo Pivotal (N=247)[1]	Suboptimally dated singletons, GA 14 0/7–36 6/7 wks. AI MAE 15.22d (95% CI 13.67–16.77) vs. Hadlock 36.41d (CI 32.88–39.94), p<0.001 — 21.19-day improvement, 58% error reduction. Vendor: GE 90.5%, Philips small N.
PAIR Study (N=5,714)[4]	Patel et al., J Matern Fetal Neonatal Med 2025;38(1):2532099. 19,940 exams, up to 2,042,759 images. R^2=0.92 all births; term R^2=0.95 (V4); MAE 12.90d all / 10.76d term. Single-institution academic medical center.
Important distinction	PAIR validates the underlying AI across all pregnancies. The FDA De Novo Granted device (N=247) is specifically validated for suboptimally dated singletons.

U.S. regulatory note (DEN250007): Delivery Date AI™ is FDA De Novo Granted as an aid to clinical judgment for women 18+ with singleton pregnancies at 14 0/7–36 6/7 weeks gestation lacking a reliable EDD. Per FDA labeling, the output is not intended to predict or assess the risk of preterm birth. **[1] FDA Pivotal (N=247):** Suboptimally dated singletons only; do not generalize. Vendor: GE 90.5% of cohort; Philips N=24 (wider CI). **[2] Association, not causation.** Association, not causation. NICU admission statistics are peer-reviewed associations between dating quality and outcomes, not causal claims for Delivery Date AI. **[3] Staffing framing is directional** — institutional FTE impact data is emerging. **[4] PAIR Study:** Patel N, O'Brien J, Bunn R, Schanbacher B, Bauer J, Lam GK. J Matern Fetal Neonatal Med. 2025;38(1):2532099. Single-institution academic medical center; generalizability not established.