



GeneDx Showcases Leadership in Genomic Newborn Screening at ICoNS 2025

October 22, 2025

Data from more than 22,000 newborns reinforce GeneDx's role spearheading the adoption of genomic newborn screening (gNBS) from research to clinical practice

GAITHERSBURG, Md.--(BUSINESS WIRE)--Oct. 22, 2025-- GeneDx (Nasdaq: WGS), a leader in delivering improved health outcomes through genomic insights, today announced data and presentations at the International Consortium on Newborn Sequencing (ICoNS), underscoring the company's leadership in driving genomic newborn screening (gNBS) from research into real-world clinical implementation.

As the laboratory partner behind the leading gNBS programs – including the [Genomic Uniform-screening Against Rare Diseases In All Newborns \(GUARDIAN\)](#) Study, [Early Check](#)'s pilot phase, the NIH's [Building Evidence and Collaboration for GenOmics in Nationwide Newborn Screening \(BEACONS\)](#) Network, and Florida's Sunshine Genetics Program – GeneDx is powering the future of genomic sequencing from research to real-world clinical adoption. Collectively, these programs represent the largest and most comprehensive gNBS efforts in the U.S., with approximately 22,000 newborns screened to date.

Earlier this year GeneDx acquired Fabric Genomics enabling flexible solutions – from comprehensive end to end testing to interpretation-as-a-service – supporting partners and health systems globally and accelerating GeneDx's international expansion and driving further adoption of gNBS.

"GeneDx is proud to be the trusted partner behind major gNBS programs in the U.S.," said Katherine Stueland, President and Chief Executive Officer of GeneDx. "Our leadership in this space – from supporting pioneering research to enabling clinical adoption in Florida – reflects our mission to make genomic insights available to every family at birth and drive true longevity from the earliest moment possible. Genomic newborn screening represents the next frontier in preventive medicine, and GeneDx is uniquely equipped to deliver it at scale."

At ICoNS, Britt Johnson, PhD, FACMG, Senior Vice President of Medical Affairs at GeneDx, will present during the **Fast Track session: Laboratory Insights from GUARDIAN: Scalable, Equitable Approach to Genomic Newborn Screening in over 17,000 Newborns Reveals Actionable Insights**. The presentation will highlight real-world learnings from GeneDx's laboratory implementation of gNBS for the GUARDIAN study, including the operational, technical, and equity frameworks that are informing national and state-level programs. Powered by GeneDx Infinity™ and advanced clinical analysis automation, the GUARDIAN study demonstrates that gNBS can be performed with short turnaround times, equitable access, and high diagnostic yield.

"Through GUARDIAN, GeneDx's experience confirms that large-scale genomic newborn screening is feasible, scalable, and ready for real-world adoption to drive meaningful clinical impact," said Dr. Johnson. "Our findings show that early use of genomic newborn screening identifies conditions that traditional newborn screening doesn't include – offering families answers before symptoms, leading to accelerate treatment pathways and significant cost savings for our healthcare system."

"Enrolling more than 20,000 newborns in the GUARDIAN study marks a pivotal milestone in demonstrating the feasibility and impact of genomic newborn screening," said Wendy Chung, MD, PhD, Principal Investigator of the GUARDIAN Study and Chief of the Department of Pediatrics at Boston Children's Hospital. "We've shown that genomic screening can identify serious conditions early, often before symptoms appear, allowing families to begin life-saving interventions. Just as importantly, we've learned invaluable lessons that continue to refine and strengthen this approach, bringing us one step closer to making genomic newborn screening part of standard care for every baby."

Built on GeneDx Infinity™, the largest and most diverse rare-disease dataset – comprising nearly one million sequenced exomes and genomes and more than seven million phenotypic datapoints – GeneDx's platform delivers the clinical accuracy, speed, and scalability required to make gNBS a standard of care.

GeneDx collaborated on the following projects that will be presented at ICoNS:

- Thursday, October 23 – Laboratory Insights from GUARDIAN Scalable Equitable Approach to gNBS in over 17,000 Newborns Reveals Actionable Insights, *Britt Johnson, PhD, FACMG, GeneDx*
- Thursday, October 23 – GUARDIAN expanded NBS study: short and medium-term follow up with the first 15,000 participants enrolled, *Brenna Boyd, MS, CGC (Columbia University Irving Medical Center)*
- Thursday, October 23 – Top 10 lessons learned since launch of the GUARDIAN expanded newborn screening (NBS) study, *Wendy Chung, MD, PhD*
- Thursday, October 23 – Content analyses of New York Times' reader comments regarding expanded gNBS, *Brenna Boyd, MS, CGC (Columbia University Irving Medical Center)*
- Thursday, October 23 – FirstSteps: The newborn genome screening initiative in Greece, *Petros Tsipouras, Petros Tsipouras, MD, Managing Partner of PlumCare RWE and Scientific Director of FirstSteps*

- Friday, October 24 – Health Workforce Readiness, *Mimi Lee, MD, PhD, GeneDx*
- Friday, October 24 – Variant Interpretation and Reporting Approaches in the GUARDIAN Study of Genomic Newborn Screening, *Wendy Chung, MD, PhD*

About GeneDx

GeneDx (Nasdaq: WGS) is the global leader in rare disease diagnosis, transforming the way medicine is practiced by making genomics the starting point for health, not the last resort. We bring together unmatched clinical expertise, advanced technology, and the power of GeneDx Infinity™ – the largest rare disease dataset – built over 25 years from millions of genomic tests and deep clinical insights. This unparalleled foundation powers our ExomeDx™ and GenomeDx™ tests, giving clinicians the highest likelihood of delivering a timely, accurate diagnosis. GeneDx is shaping the future of healthcare by moving the standard of care from sick care to proactive healthcare. While our roots are in rare disease diagnosis, our commitment extends beyond – growing with the families we serve – as a trusted partner at every stage of life. For more information, visit [genedx.com](https://www.genedx.com) and connect with us on [LinkedIn](#), [Facebook](#), and [Instagram](#).

Forward Looking Statements

This press release may contain “forward-looking statements” within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements generally are identified by the words “believe,” “project,” “expect,” “anticipate,” “estimate,” “intend,” “strategy,” “future,” “opportunity,” “plan,” “may,” “should,” “will,” “would,” “will be,” “will continue,” “will likely result,” and similar expressions. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this press release, including but not limited to: (i) our ability to implement plans to accelerate scientific discoveries and unlock other value in the rare disease space, (ii) the risk of downturns and a changing regulatory landscape in the highly competitive healthcare industry, (iii) the size and growth of the market in which we operate, (iv) our ability to pursue our new strategic direction. The foregoing list of factors is not exhaustive. A further list and description of risks, uncertainties and other matters can be found in the “Risk Factors” section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 and our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2025 and June 30, 2025, and other documents filed by us from time to time with the SEC. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and we assume no obligation and do not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise. We do not give any assurance that we will achieve our expectations.

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