

Delphi Diagnostics's Software as a Medical Device (SaMD) is fast tracked with the Galen Cloud

CASE STUDY

Delphi Diagnostics is a diagnostics company based in Houston, Texas. They use groundbreaking machine learning technology to detect asymptomatic cancer earlier than ever when it is easiest to treat. Delphi takes the results of patient samples and runs them through an AI algorithm that helps predict the probability of success of a particular therapy for the individual patient. Their mission is to make this unique form of early cancer screening more accurate, affordable, and available than ever before, eliminating cost as a barrier to this novel form of cancer detection and treatment.

The challenge of choosing a trusted SaMD Partner

Software as a Medical Device (SaMD) startups like Delphi face unique challenges in navigating the regulatory process. All companies must undergo a rigorous independent risk analysis in order to obtain FDA approval. One of the main challenges for SaMD companies is controlling costs while simultaneously satisfying several stakeholder audiences and regulatory agencies.

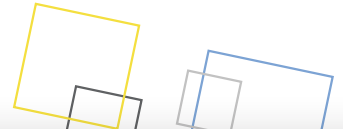
FDA compliance and regulatory approval hinge on secure data collection and accurate reporting. Choosing the wrong data partner increases unacceptable risks with adverse outcomes for patients and physicians.

Delphi therefore needed a potential partner with deep industry experience, high standards for data security certifications, algorithm development flexibility, and superior product output, all with a reasonable cost and timeline.

Galen Cloud is built for SaMD

After searching with their immediate network, Delphi soon learned that Galen Data had the experience, technical expertise and the highest levels of data security their company required. Todd Pappas, Delphi's Clinical Operations lead, puts it this way, "The security that Galen Data has and their expertise in this field was critical to us. Knowing that we were working with an experienced company that was patent protected, ISO 13485 certified, and HITRUST certified was important to us. Galen Data was the only solution that checked off all the boxes."

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On top of them having the best solution in the industry, with Galen Data, for me, it's the people. They have built trust with our team, I trust them, and that is invaluable for us.



Emily Granger, Chief Marketing Officer, Delphi



Time-savings and speed to submission



Increased accountability and faster decision-making



Project cost-savings

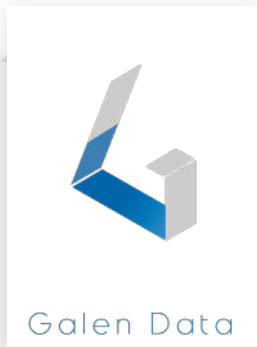
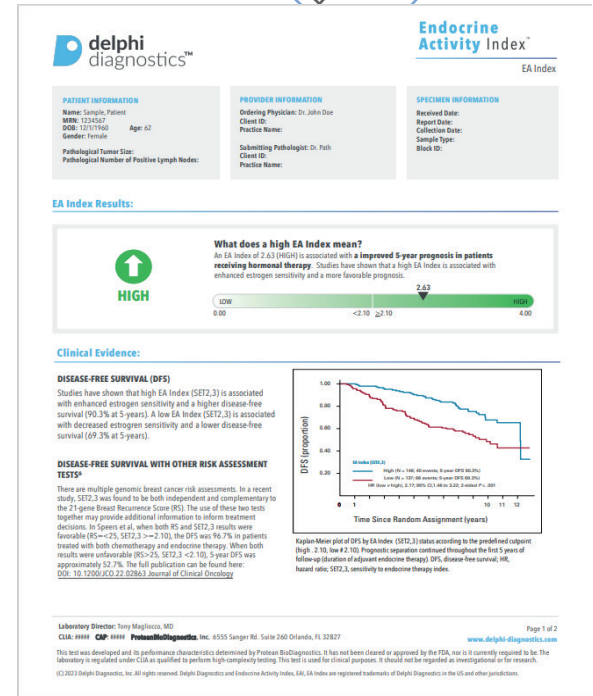
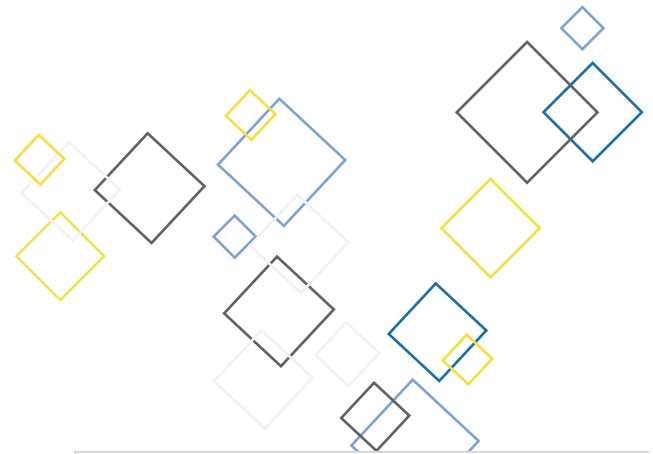
Delphi's Value Proposition

- Quickly processing patient samples using AI/ML
- Seamless algorithm refinement in the cloud
- Automatically generate reports for stakeholders

Delivering a fast, compliant solution

Initial conversations with the Delphi team centered around the Galen Cloud as an alternate modular solution. Instead of 6 to 9 months to build a custom solution, Galen Data could plug their application into Delphi's modules and get them up and running with a compliant system in a week or two.

Todd commented "They understood that we need development flexibility to host and validate algorithms, provide the workflow, and accommodate changes. Galen's solution provided all of the above with a startup-friendly rolling cost structure. The clincher was that their framework is already compliant with the medical device industry best practices, too."



Galen Data, Inc. provides a turnkey cloud solution for medical device makers that is configurable, secure, and compliant. The company was founded to make device-to-cloud connectivity possible in a matter of weeks instead of months, and at a fraction of the cost. The Galen Cloud™ collects and securely stores data, and includes tools to visualize and analyze that data. Dashboards and alerts for the manufacturer, medical team, and patients are also provided within the platform. The software platform is compliant to FDA, HIPAA, and CE Mark standards, and is ISO13485 and HITRUST certified. Dozens of companies have partnered with Galen Data to solve their medical device connectivity needs.

Contact us for more information on how Galen Data can quickly get your medical device connected to the cloud.



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