

From 2D to 3D: Charting a new course in imaging analytics in the US Oncology market

About Lunit

Lunit develops artificial intelligence (AI) that detects early-stage cancer and optimizes cancer treatment. Their mission is to conquer cancer through AI.

- [Lunit INSIGHT CXR Triage](#)
- [Lunit INSIGHT DBT](#)
- [Lunit INSIGHT MMG](#)
- [Lunit SCOPE](#)



The opportunity

- Lunit has established itself as a leader in medical imaging innovation, evidenced by the **FDA's clearances** of its [chest X-ray triage](#) and AI solutions for [mammography analysis](#).
- In response to the rising demand for advanced diagnostic methods in the US, Lunit saw an opportunity to build a state-of-the-art 3D breast cancer screening AI solution, **aiming for quicker and more accurate diagnoses** than conventional 2D imaging can provide.

The challenge

Advancements in computer-assisted detection and diagnosis software for 3D mammograms support clinicians with identifying breast cancer lesions in digital breast tomosynthesis (DBT) exams. However, ensuring these software products **meet regulatory standards for accuracy, reliability, and repeatability** introduces an extra layer of complexity.

The approach

- The regulatory intelligence and **proactive approach of engaging with the US FDA** in the early stages, as well as prior lessons learned from Lunit's INSIGHT MMG submission process, helped Lunit understand and **align with the agency's expectations**. Incorporating the agency's perspectives enabled Lunit to develop a comprehensive [510\(k\) submission](#) package for Lunit INSIGHT DBT. The requirements provided by the FDA facilitated Lunit's preparation for a swift regulatory authorization process, ensuring a **robust product development pipeline**.
- Lunit INSIGHT DBT is an AI algorithm to analyze 3D images generated by DBT equipment. DBT imaging offers a faster and more accurate breast cancer diagnosis compared to traditional 2D mammography screenings.

The success

- ✓ With DBT's precision in breast cancer examinations driving its demand—[over 64% of which comes from the US's advanced medical institutions](#)—**88% of the 8,850 facilities in US MQSA-certified US facilities** are certified units with DBT. Lunit INSIGHT DBT is expanding its presence in the US breast screening market to meet this growing demand.

“Given this substantial market influence, achieving FDA clearance for Lunit INSIGHT DBT solidifies our presence in the largest market. It marks a significant milestone in our mission to revolutionize breast cancer diagnosis and, ultimately, save more lives.”

— **Brandon Suh**

CEO, Lunit