Expanding access to cardiac ultrasound through AI-guided digital technology

About Caption Health's Caption Guidance™

Caption Health, now part of GE HealthCare, revolutionized the diagnostic imaging landscape by developing the first FDA-authorized AI software for cardiac ultrasound, Caption Guidance™. It enables healthcare providers without prior ultrasound experience to perform diagnostic-quality echocardiograms, addressing the national shortage of cardiac sonographers. By achieving FDA De Novo clearance and securing New Technology Add-on Payment (NTAP) status from CMS, Caption Health expanded access to life-saving diagnostics for Medicare patients. This case highlights Caption Health's strategic approach to regulatory authorization, clinical validation, and commercialization, demonstrating how effective regulatory navigation and rigorous clinical validation by Caption Guidance drive the broader adoption of AI in medical imaging.

Let's explore Caption Health's journey through the lens of the Integrated Evidence Plan for digital health technologies toolkit - Stage A, highlighting the process, key decisions, and concepts that shaped their success.

Stage A: Market need & product benchmarking

- **Market needs evaluation:** Heart disease is the leading cause of death in the U.S., responsible for approximately 702,880 deaths annually. The U.S. faces a 15% projected growth in demand for sonographers by 2031, intensifying the workforce shortage. Echocardiography is essential for diagnosing heart conditions, but sonographer shortages limit access, particularly in rural areas. For perspective, in the United States there are approximately 74,000 sonographers, of which only approximately 13,000 are cardiac trained.
- **Product benchmarking:** Traditional echocardiography requires specialized sonography training (2+ years), creating barriers to access.. Caption Guidance™ addresses this gap by leveraging AI to guide non-expert users in acquiring diagnostic-quality cardiac ultrasound images.
- **Competitive analysis:** Competing digital imaging solutions lacked FDA clearance or CMS reimbursement. No direct competitors offered scalable AI-assisted echocardiography solutions targeting non-specialist healthcare providers.
- **Stakeholder mapping:** Key stakeholders included **cardiologists**, **primary care**

physicians, **hospital systems**, and more. Early engagement with regulatory bodies and payors shaped their product development.

- **Initial business model development:** Targeted business priorities for hospital and rural areas as primary markets, identifying relevant workflows and needs in the care continuum where workforce shortages present opportunities to improve access to cardiac ultrasound diagnostics and ultimately facilitate proactive disease detection, surveillance and management.

By the end of stage A, Caption Health had:

✔ Identified the target geographic regions (US) and understood that the product would require regulatory authorization from the FDA.	✔ **Regulatory strategy**
✔ Recognized the novelty of the product and collaborated with the FDA to ensure compliance with regulatory requirements and to address evidence-generation needs.	✔ **Regulatory strategy**
✔ Conducted early stakeholder mapping and analyzed the reimbursement landscape to ensure economic viability for hospitals and healthcare providers.	✔ **Reimbursement pathway**
✔ Mapped out their initial strategy of reimbursement, including potential purchasers, and initiated discussions with payors and key opinion leaders to understand coverage requirements.	✔ **Reimbursement pathway**
✔ Kept track of market trends, including the increased demand for cardiac diagnostics, backlog and wait time for existing resources and the need for cost-effective solutions in underserved areas.	✔ **Business priorities**