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 B, highlighting the process, key decisions, and concepts that shaped their success.

Stage B: Market need & product benchmarking

- **Purpose and strategic objectives:** Caption Health demonstrated that Caption Guidance™ enables novice users to obtain diagnostic-quality cardiac ultrasound images, ensuring clinical efficacy, safety, and economic value.
- **Evidence roadmap development:** The team worked backward from opportunity cost and the standard of care, ensuring Caption Guidance™ demonstrated clear, measurable benefits over traditional methods. Engaged cross-functional teams (clinical, commercial, and technical) to align evidence planning with regulatory and market goals and key user groups. Determined required data robustness, deciding the right strategy for clinical validation and real-world studies.
- **Evidence requirements:** Caption Health aligned with FDA De Novo pathway requirements, focusing on usability, diagnostic accuracy, and durability across diverse patient populations. Conducted pre-submission meetings to refine study designs and address potential gaps. Adjusted clinical protocols based on feedback from regulators and payors, ensuring alignment with their expectations.
- **Develop and implement the evidence plan and strategy:**

Pivotal study design (for FDA review process): Two independent studies evaluated Caption Guidance's performance by the FDA as a part of the De Novo process:

- **Study 1:** 50 trained sonographers scanned patients with and without Caption Guidance. The sonographers were able to capture comparable diagnostic quality images in both settings.
- **Study 2:** 8 registered nurses without prior ultrasonography experience used the Caption Guidance software and asked them to capture standard echocardiography images, followed by five cardiologists assessing the quality of the images acquired. The results showed that the Caption Guidance software enabled the registered nurses to acquire echocardiography images and videos of diagnostic quality. There was 92.5% agreement between the nurse and sonographer scans for the diagnostic assessments corresponding to the primary endpoints.

- **Generate robust evidence, monitor risks, and optimize outcomes:**
  - Delivered **comprehensive clinical data** to secure FDA De Novo clearance.
  - Monitored **post-market performance, validating long-term safety and usability** while addressing emerging risks or stakeholder concerns.
  - Performed extensive human factors testing to ensure **minimal risk of use errors** and optimized the software interface for real-world clinical environments.
  - Optimized features like **Auto-Capture and Prescriptive Guidance**, mimicking sonographer expertise to assist users.

Caption Health

By the end of Stage B, Caption Health had:

✔ Engaged with FDA multiple times and secured FDA De Novo grant as the first AI cardiac ultrasound software.	✔ **Regulatory strategy**
✔ Expanded device compatibility with additional 510(k) clearances.	✔ **Regulatory strategy**
✔ Initiated workstreams to take advantage of the Reimbursement Pathways opened via the "FDA Breakthrough Device" to support reimbursement incentives for adoption by hospital systems.	✔ **Reimbursement pathway**
✔ Explored considerations about NTAP application based on pivotal clinical data to ensure Medicare coverage.	✔ **Business priorities**
✔ Monitored key industry trends, including value-based care, increasing payor interest in AI-driven solutions, and evolving reimbursement policies for digital health technologies.	✔ **Business priorities**