Kardia/AliveCor

Scaling research operations to improve remote EKG devices

Eric Shumake: UX Research Lead, 2020

Context:

AliveCor is a $64 million medical device and AI company producing EKG hardware and software for a consumer smartphone-connected ECG recorder known as KardiaMobile - cleared by the FDA in 2012 for detecting atrial fibrillation and normal sinus rhythm. A professional product known as KardiaPro provides medical professionals with the ability to monitor their patients using Kardia devices.

Challenge:

To establish and lead a research practice of exceptional value and quality documented by product research operations to leverage research resources with full operational transparency, standards, protocols, and procedures.

Solution:

Developed internal teams of six part-time researchers and one full-time contract researcher to drive enterprise level results at a lower cost with actionable results; maintain compliance with HIPAA, FDA, legal, and ethical research.

Results:

- Authored 40+ reports and studies on formative and summative research with qualitative and quantitative methodologies regarding product research, FDA regulatory testing, usability, and accessibility.

- Key stakeholder in the FDA clearance process, helping the Regulatory and Quality Assurance teams in devising and driving user tests to support new filings.

- Delivering insights on product design, development, and iteration while scaling Alivecor from $24 million to $64 million in funding.