Our client, a pioneer in AI-based early cancer detection, needed regulatory guidance to secure FDA clearance and launch its product.

Emerging AI-enabled cancer screening startup

Situation

Advised an emerging digital health company developing AI-powered cancer screening tools, to develop the FDA regulatory strategy and commercialization planning for its device. Key activities included:

- Conducting a current state assessment to evaluate regulatory and technical documentation.
- Developing a comprehensive regulatory strategy aligned with FDA expectations.
- Defining and executing a roadmap to FDA submission via the appropriate regulatory pathway (De Novo or 510(k)).

Our approach

- Evaluated potential regulatory pathways (De Novo vs. 510(k)), considering device classification, risk level, and potential predicate devices.
- Developed a Regulatory Strategy Document that outlined submission timelines, data generation needs, and risk mitigation strategies.
- Led preparation for the FDA Q-Submission meeting, including drafting device descriptions, summarizing preliminary clinical data, and formulating targeted questions for FDA feedback.
- Conducted mock meetings with the client team to ensure alignment and preparation.
- Provided support during the pre-submission meeting, ensuring all interactions were documented and follow-up actions were defined

Impact and outcomes

- Enabled our client to confidently select between De Novo and 510(k) by evaluating classification and predicate device options.
- Delivered a robust regulatory strategy, guiding the client team from current state to submission readiness.
- Identified key documentation and data gaps, helping the team prioritize efforts ahead of submission.
- Effectively prepared the client for a successful Q-Submission meeting, ensuring productive dialogue with the FDA.
- Enabled the company to align technical, clinical, and regulatory milestones with market entry goals.

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