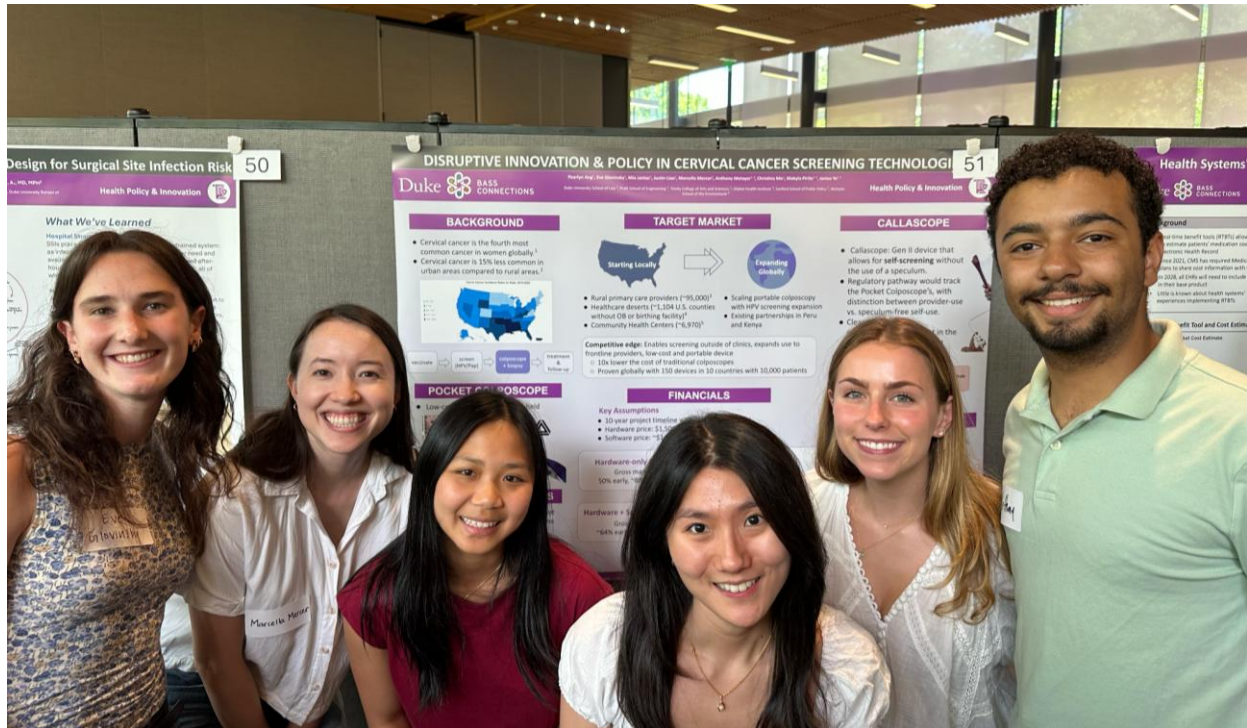


Disruptive Innovation and Policy for Cervical Cancer Prevention



Team members at the 2026 Fortin Foundation Bass Connections Showcase.

Bass Connections Student Team 2025-2026:

Pearlyn Ang, Eve Glovinsky, Mia Jantac, Justin Liao, Marcella Mercer, Anthony Metayer, Christina Mo, Makyla Pirtle, Janice Ye

Introduction

According to the American Cancer Society, cervical cancer incidence in the United States over the past 40 years has declined over 50%, largely due to implementation of standardized screening guidelines [1]. Despite nationwide progress, significant disparities persist between rural and urban areas, with cervical cancer incidence 25% higher and mortality 42% higher in rural counties compared to urban counties in recent years [2]. However, when detected early, cervical cancer is highly treatable, highlighting the need for improved cervical cancer screening initiatives in rural areas.

Duke's Center for Global Women's Health Technologies (GWHT) has developed two disruptive innovations for their global cervical cancer prevention initiative [3]. First, the Pocket Colposcope is a low-cost, portable, cervical cancer screening device that reduces structural barriers by shifting early detection from "physicians in urban centers" to "midwives in community settings." Additionally, a sister technology, the Callascope allows speculum-free physician-administered or patient self-exams for cervical cancer screening to reduce barriers related to fear of speculum and

feelings of vulnerability. These devices have been successfully implemented in midwife-run health clinics in Peru and Kenya, which has made screening available to thousands of women [4, 5]. To this end, we are interested in identifying how these same technologies may be adopted in the United States to encourage prevention efforts among underserved populations and reduce cervical cancer disparities.

Project Goals

This project's key research goals aimed to understand the market and policy strategies required for implementation of GWHT's two cervical screening devices in the United States. To this end, we were structured into three different teams to address key areas of focus: market analysis, regulatory and reimbursement, and business communication strategy.

- **Market analysis:** identify target customer profile, analyze market characteristics and competition, understand barriers to adoption.
- **Regulatory and reimbursement:** analyze FDA approval pathways, identify regulatory requirements, and evaluate insurance coverage and device coding practices.
- **Business and communication strategy:** develop product pricing model, deploy unit economics model, create investor pitch deck.

Our Approach

Target Market Analysis

The market analysis team conducted preliminary market research to understand the barriers to gynecological care and the healthcare system stakeholders in the rural United States to identify potential customers for the Pocket Colposcope. Based on these insights, we narrowed our focus on primary-care healthcare providers in rural community health centers. In the spring, we began field interviews, where we met with local gynecologists and rural family medicine physicians to validate our target audience and gain further insight into strategies for implementation in rural healthcare settings.

Regulatory and Reimbursement

The regulatory team wrote a regulatory brief highlighting the regulatory landscape for medical devices. We identified a key regulatory strategy to FDA-clear the Callascope. We also researched payment reimbursement considerations for the Pocket Colposcope, which has already been FDA-cleared.

Business and Communication Strategy

The business strategy team developed a comprehensive framework for the commercialization of the Pocket Colposcope, structuring a hardware-plus-software subscription revenue model designed to minimize adoption barriers while maximizing long-term recurring revenue. We built a detailed ten-year pro forma financial model projecting the company's path from initial seed financing through profitability. We also evaluated the unit economics of an experience-curve hardware pricing strategy alongside a fixed annual software subscription to determine project NPV. In the future, we look to identify different distribution channels and revenue diversification opportunities across direct institutional sales, global health partnerships, and value-added resellers to support the product's long-term commercial scale-up.

Key Deliverables

Go to Market Plan

Using our research on market size and growth, barriers to healthcare in the rural United States, competitor technologies, and return on investment, we outlined a Go to Market Plan for the Pocket Colposcope to highlight its value proposition and offer a guide for implementation for primary care providers in rural community-health centers the United States. Additionally, this document contained a customer decision roadmap and customer outreach and promotion plan to support the adoption of the Pocket Colposcope.

Regulatory Brief

Our regulatory brief identified a key strategy to streamline the FDA clearance process for the Callascope. We plan to first clear the trained healthcare professional-use Callascope through the Traditional 510(k) process, then modify its label to include self-use instead of proceeding through the De Novo pathway. This strategy is simpler than the De Novo pathway because we already have similar regulatory materials from the Pocket Colposcope, which we can easily adjust to the Callascope due to the devices' similarities. The brief also highlighted reimbursement considerations for the Pocket Colposcope: coding, coverage, and payment.

Financial Model

We developed a pro forma financial model to track the Pocket Colposcope's projected growth, demonstrating strong returns and a path to profitability (breakeven) by 2031.

MedTech Pitch Competition

The Pocket Colposcope pitch deck we created was selected for University of Minnesota's Great Medtech Pitch Competition in April 2026. Marcella represented our team at the competition and delivered a five-minute pitch highlighting the Pocket Colposcope's value proposition to a panel of medtech leaders. This pitch competition gave us the opportunity to increase awareness about the GWHT products and receive useful feedback from experienced medtech entrepreneurs from industry, academia, and venture capital.



Marcella delivers a 5 minute pitch of the Pocket Colposcope at the Great Medtech Pitch Competition at University of Minnesota.

Commercialization Plan

For our final deliverable, we compiled the findings from our work throughout the year to develop a commercialization plan encompassing both GWHT innovations to communicate potential for commercial impact of the technologies . In this plan, we outline the overall goals and objectives of the technologies, market reach and competition analysis, regulatory strategy, and production and marketing plan. This document serves to guide future development and implementation and to encourage investments into the technology.

References

- [1] American Cancer Society Cancer Action Network, *Cervical Cancer: General Factsheet*, Jan. 8, 2020.
- [2] T. L. Amboree, H. Damgacioglu, E. Y. Chiao, et al., “Rural-urban disparities in cervical cancer incidence and mortality among US women,” *JAMA Netw. Open*, vol. 8, no. 3, p. e2462634, 2025, doi: 10.1001/jamanetworkopen.2024.62634.
- [3] “Calla Health Foundation,” Calla Health Technologies, Sep. 28, 2021.
<https://callahealthfoundation.com/pocket-colposcope/>
- [4] J. L. Mueller, C. T. Lam, D. Dahl, et al., “Portable pocket colposcopy performs comparably to standard-of-care clinical colposcopy using acetic acid and Lugol’s iodine as contrast mediators—An investigational study in Perú,” *BJOG*, doi: 10.1111/1471-0528.15326.
- [5] C. M. Zeufack et al., “Feasibility of incorporating the Pocket colposcope into nurse-led cervical cancer screening programs in Western Kenya,” *ecancermedicalscience*, vol. 19, pp. 1925–1925, Jun. 2025, doi: <https://doi.org/10.3332/ecancer.2025.1925>.