



## CLINICAL EVALUATION STUDY



### CLISTEPROBE

ClisteProbe is a new venture emerging from University College Cork under Enterprise Ireland's Commercialisation fund programme. The team specialises in developing advanced biopsy devices to improve the accuracy and efficiency of disease detection with a current focus on breast and prostate cancer diagnosis. Their innovative technology aims to enhance the diagnostic process, reduce the workload on radiologists, and streamline patient care by providing quicker and more accurate biopsy results. ClisteProbe's ultimate mission is to become a leading provider of smart diagnostic solutions, thereby optimising disease detection and improving patient outcomes.



Dr Eric Moore, Dr Justina Ugwah and Dr Yineng Wang  
(ClisteProbe co-founders)

## About Femtech @ HIHI

FemTech focuses on women's health from birth to death and includes areas such as adolescent health, fertility, menstruation, menopause, gynaecological health, pregnancy, cancer, mental health, female wellness and health conditions that affect women disproportionately. Health Innovation Hub Ireland's FemTech initiative, FemTech @ HIHI, will stimulate and support the development of high potential new products, services and start-ups. This will impact the health and wellbeing of 50% of the Irish population, create a geographical FemTech focus and build an ecosystem of experts and entrepreneurs supporting, driving and innovating. There will be a unique pathway of access to clinical, research and business expertise. FemTech

entrepreneurs will have access to critical research expertise through University College Cork Innovation and business and enterprise support will be provided through our FemTech Advisors. Clinical expertise through a partnership with the Ireland South Women and Infants Directorate will provide invaluable access to discipline specific clinical teams.



## The Healthcare Challenge

Biopsy and subsequent diagnosis of cancer can take a significant amount of time. Before the patient can be informed of the results, the biopsy sample must be obtained, processed in pathology labs, and the results interpreted.

This period of time between biopsy and diagnosis can cause a large amount of anxiety and worry for patients, as they are left wondering about the results.

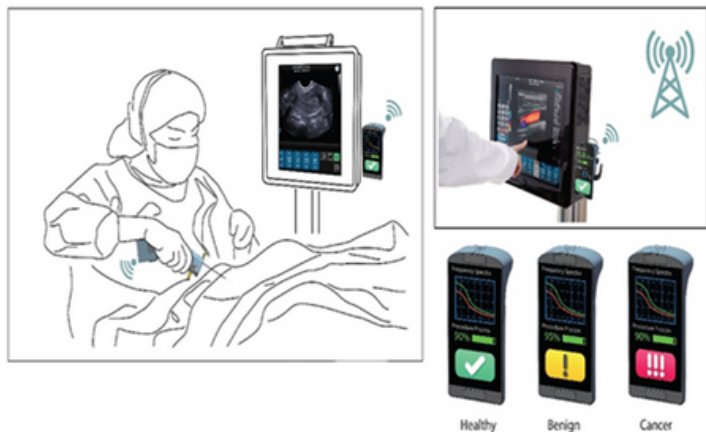
The majority of biopsies also have benign findings - meaning that the patient's distress is likely to have been unnecessary.

A method of separating benign from malignant cases at the time of biopsy would reduce the overall turnaround time in biopsies at large. This in turn

would allow patients to be informed of malignancies and start needed treatment much more quickly.



# The Healthcare Solution



ClisteProbe has developed a pioneering platform technology designed to revolutionise breast cancer diagnosis during biopsy procedures. The device, named CLISTEPROBE, enhances point-of-care capabilities by integrating sensors that provide real-time tissue assessment. This allows for more targeted biopsies, reducing the number of benign samples sent for histopathology and potentially minimising the need for multiple biopsy passes.

By offering real-time insights, the CLISTEPROBE device aims to reduce diagnosis time, lower healthcare costs, and improve patient management, particularly by promptly reassuring patients with benign results and fast-tracking those with suspicious lesions for further analysis.

## HIHI Role

Health Innovation Hub Ireland (HIHI) played a crucial role in the ClisteProbe project by facilitating part of the evaluation phase of their innovation pathway in breast cancer diagnosis. HIHI organised a series of focus groups and interviews with relevant healthcare professionals, including breast surgeons, oncologists, radiologists, and nurses, to gather feedback on the ClisteProbe device.

HIHI was responsible for recruiting participants, organising meetings, and moderating discussions. They also assisted ClisteProbe with preparing presentations, formulating pertinent questions, and analysing the feedback. HIHI's involvement ensured that ClisteProbe received comprehensive insights that could be integrated into their research and development processes to optimise the device for clinical use.



## Outcome Report

The project led to several key insights and opportunities for ClisteProbe. The feedback from clinical experts highlighted the device's potential to address significant pain points in breast cancer diagnosis, such as improving intraoperative margin assessments and providing immediate diagnostic results to reduce patient anxiety.

The discussions emphasised the importance of ensuring high diagnostic accuracy to prevent missed cancers and the need for ergonomic improvements to facilitate use in clinical settings. The feedback also underscored the necessity of stringent data protection compliance and cautious integration of AI technologies.

These insights provide ClisteProbe with a roadmap to optimise their device, enhance its clinical relevance, and facilitate its adoption in healthcare environments.

## Testimonials

*"Health Innovation Hub Ireland, HIHI provided invaluable support to the CLISTEPROBE team throughout a critical stage of our development. By organising and facilitating focus group interviews with a wide range of medical professionals, HIHI helped us validate the market fit and clinical relevance of our biopsy technology. Their expertise ensured that we gathered crucial feedback on key areas such as improving intraoperative margin assessments, enhancing the ergonomics of our device, and addressing the need for immediate diagnostic results."*

*Beyond their logistical and organisational support, HIHI offered a collaborative partnership, providing not just a listening ear but also insightful recommendations that have significantly informed our research and development."*

*Their ability to foster meaningful connections between research and the healthcare system was instrumental to ensure that our technology is tailored to meet real-world clinical needs. The comprehensive feedback we received, thanks to HIHI, has laid a solid foundation for optimising our device and promote its integration into healthcare environments."*

-Dr Justina Ugwah, ClisteProbe CEO.



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