



## CLINICAL EVALUATION STUDY

# Daye

Founded in 2017, Daye was created to address unmet needs in women's health through the development of medical and diagnostic devices. Valentina Milanova is the founder and CEO of Daye. Valentina has a background in public health, medical device law and economics. Daye is registered in Ireland with a multidisciplinary team of 38 staff spanning R&D, clinical operations, manufacturing, and commercial functions. Daye's products are developed and manufactured to ISO 13485, MDR and GMP standards.



Valentina Milanova

## About Femtech @ HIHI

FemTech focuses on women's health and includes conditions that affect **women only** such as fertility, menstruation, menopause, gynaecological health; conditions that affect **women disproportionately** to men (neurological, autoimmune conditions, osteoporosis etc) and conditions that affect **women differently** to men (heart disease, osteoporosis etc).

Health Innovation Hub Ireland's FemTech initiative stimulates and supports the development of high potential new products, services and start-ups. Impacting the health and wellbeing of 50% of the Irish population and is building an ecosystem of experts and entrepreneurs supporting, driving and innovating in women's health.

Femtech @HIHI provides access to key clinical experts through our partnership with Ireland South Women and Infants Directorate (CUMH) and supports development of new products at idea stage, prototype stage and delivers pilots of market ready products.



## The Healthcare Challenge

Human Papillomavirus (HPV) is a very common group of more than 100 viruses. Most people will be infected with a form of HPV in their lifetime. HPV infection is most common in people in their late teens and early 20s and can be transmitted by being sexually active with another person who already has the virus. Most HPV infections do not need treatment, however in some people, the HPV infection can develop into cervical cancer. Current HPV screening methods can be invasive, uncomfortable, and deter participation, particularly among certain populations. Barriers include lack of access, embarrassment, and suboptimal uptake among under-screened groups. Improving accessibility and acceptability of screening is crucial for increasing coverage and early detection.



# The Healthcare Solution



The Daye Diagnostic Tampon is a self-sampling device designed to collect high-quality specimens for HPV testing in a manner that is familiar and comfortable for most women. The device is validated for use with Roche, Hologic, BD and Abbott systems and has demonstrated high sensitivity and user acceptability, including among South Asian, Muslim, first-time tampon users, and peri- and post-menopausal women.

## HIHI Role

Health Innovation Hub Ireland (HIHI) runs clinical evaluations that connect companies with key opinion leaders and end-users. These evaluations provide vital feedback on product need, application, and market approach, while helping build a cohort of clinical champions. HIHI adds value through its structured, stage-gated framework that ensures meaningful insights and engagement with healthcare professionals.



## Outcome Report

This evaluation contained three consultants, one GP and one specialist registrar in Obs & Gynae. Valentina of Daye provided an in-depth presentation on the Daye Diagnostic Tampon, a sterile, CE marked product, that detects 14 high risk strains of HPV including HPV 16 and 18. The clinicians demonstrated great interest in the Day Diagnostic Tampon and its unique features. Some of the main benefits that emerged included (i) Patient preference (ii) User friendliness and cost effectiveness and (iii) Sustainability.

### Patient Preference

Clinicians praised the design of the tampon and how the product is favourably received by diverse patient populations including: First-time tampon users, Menopause and perimenopause patients, Vaginal atrophy patients, Sexual assault survivors and South-Asian & Muslim populations

### Cost Effectiveness and User Friendliness

The clinicians were also highly enthusiastic about the cost effectiveness and user friendliness of the tampon which is superior to other self-sampling methods currently available.

### Sustainability

Finally, the clinicians were hugely impressed with Daye's commitment to sustainability as the tampon is made from 100% cotton, while the sterile applicator is made of bio-based sugarcane in lieu of petrol-derived plastics. Daye is a carbon neutral, certified B corporation.

## Testimonials

*"Collaborating with the Health Innovation Hub Ireland team has been an invaluable experience. Their structured evaluation framework and support in connecting us with Irish clinicians have strengthened the clinical and economic case for Daye's Diagnostic Tampon - a CE-marked, MHRA-registered self-sampling device that can make cervical cancer prevention more accessible and equitable."*

*Valentina Milanova  
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Daye*



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