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â??An affordable diagnostic kit can be a profitable business in India, but profitability and impact must go hand in handâ?•

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Cervical Cancer is the second leading cause of cancer deaths in India with more than 80,000 women losing their lives every year to the disease despite it being curable, if detected in early stages. Started in 2020, Pragmatech Healthcare Solutions, a biotech startup from Vadodara, launched CERVICHECK, India's first CDSCO approved at-home, self-sampling kit for HPV (Human Papillomavirus) screening to bring Cervical Cancer Screening to every woman across the country. Recently it received the Infosys Foundation Aarohan Social Innovations Award under the Juryâ??s Special Awards category. In an interview with BioSpectrum India Anirban Palit, Managing Director and Co-founder, Pragmatech shared his thoughts about the award and his plan and business model for the company.



What does this recognition mean to your team?

Recognition from the Infosys Foundation at the Aarohan Social Innovation Awards 2025 is a strong validation of the problem we are trying to solve and the approach we have taken. For our team, it reinforces the belief that innovation in preventive healthcare must be rooted in accessibility, dignity, and scientific rigor.

This recognition also highlights the importance of self-sampling as a scalable public health tool for cervical cancer screening in India, especially for women who are otherwise missed by conventional facility-based programs. It encourages us to continue working closely with public health systems, clinicians, and community partners to translate innovation into measurable population-level impact.

What makes CERVICHECK different from existing cervical cancer screening methods?

CERVICHECK is designed to address one of the biggest barriers to cervical cancer screening, low participation, by enabling women to collect cervical samples themselves with privacy and dignity, without compromising on sample quality. Unlike conventional screening methods that require pelvic examinations and trained clinicians, it can be used outside hospital settings, making it suitable for not just private use but also community and primary care programmes.

The kit has been clinically validated in the Indian context and is compatible with laboratory-based HPV testing, allowing it to integrate seamlessly into existing screening workflows rather than replace them. By improving access and compliance, it strengthens early detection efforts and supports national and global goals for cervical cancer elimination.

What does CERVICHECK do that a hospital-based Pap smear cannot?

While a hospital-based Pap smear is clinically effective, it depends heavily on women visiting a facility, undergoing a pelvic examination, and interacting with trained providers - factors that significantly limit participation at scale. CERVICHECK removes these barriers by allowing women to self-collect cervical samples in a private, non-clinical setting, making screening possible even outside hospitals.

This ability to decentralise sample collection enables outreach through primary health centers, NGOs, and community programmes, reaching women who are otherwise missed by conventional screening pathways. In doing so, it complements hospital-based screening by expanding coverage and strengthening early detection efforts rather than replacing existing

clinical practices.

Why is at-home HPV self-sampling a game changer for Indian women?

At-home HPV self-sampling is a game changer for Indian women because it directly addresses the social, cultural, and logistical barriers that have historically limited cervical cancer screening uptake. Many women avoid facility-based screening due to discomfort, lack of privacy, time constraints, or distance from healthcare facilities especially in semi-urban and rural settings.

By enabling women to collect samples themselves in a safe and dignified manner, at-home self-sampling significantly improves participation and early detection. This approach aligns closely with India's public health priorities and the WHO's screen-and-treat strategy, making large-scale cervical cancer prevention more feasible, equitable, and sustainable.

How did you ensure accuracy, safety, and regulatory compliance for CERVICHECK?

Accuracy, safety, and regulatory compliance were foundational to the development of CERVICHECK. The kit was validated through a bicentric clinical validation study conducted using the VALHUDES protocol, a globally recognised framework for evaluating HPV self-sampling devices. The study was led by renowned gynecologists and scientists from the AOGIN Network, a specialised international group focused exclusively on cervical cancer prevention and research.

Following successful clinical validation, CERVICHECK received approval from the Central Drugs Standard Control Organisation (CDSCO) as a non-predicate medical device, making it India's first clinically validated at-home cervical self-sampling kit. This rigorous clinical and regulatory pathway has been critical in ensuring the kit meets the highest standards of accuracy, safety, and trust required for population-level screening programmes.

What proof do you have that self-sampling works as well as clinician-led screening?

The effectiveness of self-sampling is best demonstrated through rigorous head-to-head clinical evidence. During CERVICHECK's bicentric clinical validation study, both self-collected samples using CERVICHECK and clinician-collected samples were blinded and sent to a centralised laboratory for analysis. Testing was performed using a WHO pre-qualified HPV assay, ensuring adherence to global benchmark standards.

The study demonstrated a greater than 95 per cent correlation between self-sampled and clinician-sampled results, with a kappa value of 0.9, indicating performance equivalence between the two methods. Importantly, these findings have been reviewed and published in an international peer-reviewed journal, providing independent scientific validation that self-sampling with CERVICHECK performs on par with clinician-led screening and is suitable for large-scale cervical cancer screening programmes.

Can an affordable diagnostic kit really be a profitable business in India?

Yes, an affordable diagnostic kit can be a profitable business in India, but profitability and impact must go hand in hand. The key lies in scalable distribution models, partnerships with hospitals, NGOs, and government programmes, and offering value through early detection that reduces long-term treatment costs.

For CERVICHECK, our approach combines B2B engagement with healthcare providers and D2C availability through lab partnerships, which allows us to maintain affordability while reaching a large population. In a market like India, where preventive health is gaining focus, there is a clear opportunity for businesses that deliver high-quality, accessible diagnostics at scale, proving that social impact and commercial sustainability can coexist.

How does Pragmatech balance affordability with sustainability?

At Pragmatech, we balance affordability with sustainability by designing cost-efficient, high-quality diagnostics. Our CERVICHECK at-home self-sampling kit is among the most affordable kits globally, while ensuring a high level of sample collection and reliability.

We achieve this by leveraging scalable distribution through hospitals, NGOs, primary health centres, and lab partners, which allows us to reach a large population without inflating costs, while maintaining strict quality and regulatory standards. By aligning social impact with operational efficiency, we ensure that women across India can access reliable cervical cancer screening, while keeping the business sustainable and capable of continuous innovation.

How scalable is your business model across India and other low-resource countries?

Our business model is designed to be highly scalable both across India and in other low-resource countries. By combining at-home self-sampling with lab-based HPV testing, we can decentralise screening without compromising on accuracy. Our CERVICHECK kit is more affordable than other at-home self-sampling kits globally, while ensuring high-quality sample collection.

Partnerships with hospitals, NGOs, primary health centers, and community health workers allow us to reach women in urban, semi-urban, and rural areas efficiently. We have already generated strong interest from several African countries, and pilot programmes are already underway, demonstrating the model's adaptability and potential to expand cervical cancer screening access at scale while keeping costs low and quality high.

Where do you envision Pragmatech in the next 5 years?

In the next five years, we envision Pragmatech as a leading preventive women's health company in India and other low-resource countries, driving large-scale cervical cancer screening. Immediately, we are focused on scaling in India through a combination of D2C outreach, partnerships with NGOs, and government screening programs, ensuring that CERVICHECK reaches women across urban, semi-urban, and rural areas.

Simultaneously, we are advancing the development of our lateral flow-based screening kit, which will complement HPV testing and help complete the end-to-end workflow of cervical cancer screening, from initial detection to risk stratification. Our goal is to create a comprehensive, scalable, and affordable screening ecosystem that strengthens early detection, enables timely intervention, and ultimately reduces cervical cancer incidence.

Should HPV self-sampling be part of India's national screening programme today?

Absolutely. HPV self-sampling, including at-home self-sampling, should be integrated into India's national cervical cancer screening program today. Self-sampling empowers women to collect samples overnight or at their convenience, increasing participation and compliance while reducing the burden on healthcare providers and sample collection infrastructure.

Incorporating self-sampling into national programmes can help achieve higher coverage, earlier detection, and more efficient use of public health resources, aligning closely with India's cervical cancer elimination goals and the WHO's screen-and-treat strategy.

What policy change would most accelerate cervical cancer elimination?

The most impactful policy change would be the formal integration of HPV self-sampling, including at-home self-sampling, into India's national cervical cancer screening programme. This would enable large-scale, accessible, and cost-effective screening, particularly for women who are currently missed by facility-based approaches.

Coupled with robust follow-up pathways and public awareness campaigns, such a policy would accelerate early detection, timely intervention, and ultimately drive India closer to the WHO goal of cervical cancer elimination.

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