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ErlySign to launch oral cancer detection kit by April 2026

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ErlySign is now initiating the regulatory approval process with CDSCO

ErlySign, a Nagpur-based biotech startup developing India's first salivary biomarker–based screening test for early-stage oral cancer, has announced the successful completion of its large-scale clinical trial conducted across 1,000 patients. With this milestone achieved, the company is now gearing up to introduce its first product to the market by April 2026.

The multi-centre clinical study was conducted across leading cancer care institutions, including HCG Nagpur, Ranchi, Bangalore, and the Regional Cancer Hospital (Rashtrasant Tukdoji Cancer Hospital, Nagpur), a Government of India–recognised centre of excellence.

The interim analyses from this large-scale trial mirrored the findings of ErlySign's earlier small-scale study, providing strong confirmation that the results generated through the current funding and broader trial framework demonstrate consistent, reproducible, and scientifically validated performance. This consistency across studies reinforces the scientific validity of ErlySign's approach to early oral cancer detection.

A notable finding during the study was the identification of subjects flagged as high-risk by ErlySign's test despite being clinically marked healthy. Continuous monitoring over six months later confirmed these cases as positive, demonstrating the test's potential to uncover extremely early-stage abnormalities that would otherwise go undetected.

"This trial success strengthens our belief that early detection can truly change cancer outcomes. Oral cancer claims more than 1,45,000 lives annually in India, largely due to delayed diagnosis. With our upcoming product, detecting precancerous changes will be possible in a simple, painless 15-minute saliva test, long before tumors develop," said Shubhendra Singh, CEO, ErlySign.

With the successful trial outcomes, ErlySign is now initiating the regulatory approval process with CDSCO and simultaneously preparing for commercial rollout, manufacturing scale-up, and clinical partnerships.

ErlySign's upcoming screening kit will be the first Indian diagnostic solution enabling non-invasive, oral cancer risk assessment, offering results in the form of low, moderate, or high risk, empowering both clinicians and individuals with actionable insights.