

NZX/ASX Announcement

30 April 2025

TruScreen re-enters India

Appoints Renovate Biologicals Pvt Ltd as its distributor

- **TruScreen re-enters India and appoints Renovate Biologicals Pvt Ltd to distribute its AI enabled TruScreen cervical cancer screening system in India**
- **Cervical cancer is the second most common cancer among women in India, and it is estimated that one woman dies from cervical cancer every eight minutes in the country**
- **Cervical cancer screening currently covers only 2% of women in India**
- **India is the world's second most populous country, with an estimated screening population of over 468 million women***

TruScreen Group Limited (“TruScreen” or “the Company”) advises that it has re-entered the Indian sub-continent with the appointment of India medical products distributor Renovate Biologicals Pvt Ltd (RBL) to distribute its unique AI enabled TruScreen cervical cancer screening system in India. India is the second most populous country in the world, with one-sixth of the world's population – a total of 1.4 billion people – and an estimated screening population of over 468 million women*.

Cervical cancer is the second most common cancer among women in India, despite being the fourth most common globally. One woman dies from cervical cancer every eight minutes in the country, making it a significant public health concern, but with regional variations in incidence and mortality. According to 2023 estimates, 124,000 women are diagnosed with cervical cancer annually, and 77,000 die from the disease.**

The prevalence of cervical cancer screening is low at 2% in India***. Cervical cancer screening is substantially higher within the private health sector with Government Health insurance coverage. India conducted approximately 7 million screening tests last year with about 85% conducted in the private health sector with a focus on quality health outcome.

India's National Academy of Medical Sciences (NAMS) has recently recommended cervical cancer as a notifiable disease and to focus on early detection with a target to achieve a 70% screening rate for cervical cancer by 2030. TruScreen's unique AI enabled technology will directly contribute to this target.

TruScreen's portability and its AI enabled algorithm which provides real time results without the need of expensive laboratory infrastructure make it an ideal screening solution for such a populous nation with high mortality to cervical cancer. TruScreen technology is non-invasive and may be preferred by certain subgroups as it does not require a collection of cervical cells.

*CIA World Factbook women aged 15-64 = 467,593,7814

**Human Papilloma Virus and Related Cancers Fact Sheet 2023

**Muthuramalingam MR, Muraleedharan VR. Patterns in the prevalence and wealth-based inequality of cervical cancer screening in India. BMC Womens Health. 2023 Jun 26;23(1):337. doi: 10.1186/s12905-023-02504-y. PMID: 37365552; PMCID: PMC10291770.



RBL is an emerging leader in medical device distribution across India. Established in 2015 and based in Hyderabad, RBL has introduced gold standard, advanced and innovative technologies which have transformed clinical outcomes in Diagnostics (Gastroenterology, Gynaecology & Oncology), Therapeutics (oncology), Critical Care, Organ Transplantation, Hematology and Ophthalmology.

RBL's leadership team has a combined experience of over 50 years and are supported by a sales team of 22 and an additional 130 sub-distributors and/or partners. The team aim to gain a 70-80% share of the cervical cancer screening device market in 5 years.

TruScreen CEO, Martin Dillon commented:

"The appointment of Renovate Biologicals to distribute TruScreen in the world's second most populous country now means that we have distribution capability in 3 of the 4 most populous countries in the world - China, India and Indonesia. Renovate, has a focus on cutting edge technologies in medicine, approached TruScreen specifically to address their vision to bring the most advanced cervical cancer screening technology to India. In a country with very little access to high quality laboratory facilities, TruScreen is ideally suited to be part of the solution to Indias' objective to move from a screening coverage of 2% of eligible women to over 70% over the next 5 years."

This announcement has been approved by the Board.

Ends

For more information, visit www.truscreen.com or contact:

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About TruScreen:

TruScreen Group Limited (NZX/ASX: TRU) is a medical device company that has developed and manufactures an AI-enabled device for detecting abnormalities in the cervical tissue in real-time via measurements of the low level of optical and electrical stimuli.

TruScreen's cervical screening technology enables cervical screening, negating sampling and processing of biological tissues, failed samples, missed follow-up, discomfort, and the need for costly, specialised personnel and supporting laboratory infrastructure.

The TruScreen device, TruScreen Ultra[®], is typically registered as a primary screening device for cervical cancer screening.

The device is CE Marked/EC certified, ISO 13485 compliant and is registered for clinical use with the TGA (Australia), MHRA (UK), NMPA (China), SFDA (Saudi Arabia), Roszdravnadzor (Russia), and COFEPRIS (Mexico). It has Ministry of Health approval for use in Vietnam, Israel and the Philippines, among others and has distributors in over 20 countries. In 2021, TruScreen established a manufacturing facility in China for devices marketed and sold in China.

TruScreen technology has been recognised in CSCCP's (Chinese Society for Colposcopy and Cervical Pathology) China Cervical Cancer Screening Management Guideline.

TruScreen has been recognised in a China Blue Paper "Cervical Cancer Three Stage Standardized Prevent and Treatment" published on 28 April 2023.

In Dec 2023 TruScreen technology was added to the Vietnam Ministry of Health approved National Technical List, for use in Vietnam's public and private healthcare sectors and in 2024 was added to the Russian guidelines for the screening of cervical cancer.

In financial year 2024 alone, approximately 200,000¹ examinations were performed with the TruScreen device. To date, over 200 devices have been installed and used in China, Vietnam, Mexico, Zimbabwe, Russia, and Saudi Arabia. TruScreen's vision is "A world without the cervical cancer"[®].

To learn more, please visit: www.truscreen.com/.

¹Based on Single Use Sensor sales.

Glossary:

Pap smear (the Papanicolaou smear) test involves gathering a sample of cells from the cervix, with a special brush. The sample is placed on a glass slide or in a bottle containing a solution to preserve the cells. Then it is sent to a laboratory for a pathologist to examine under a microscope. <https://www.cancer.net/navigating-cancer-care/diagnosing-cancer/tests-and-procedures/pap-test>

LBC (the liquid-based cytology) test, transfers a thin layer of cells, collected with a brush from the cervix, onto a slide after removing blood or mucus from the sample. The sample is preserved so other tests can be done at the same time, such as the human papillomavirus (HPV) test <https://www.cancer.net/cancer-types/cervical-cancer/diagnosis>

HPV (human papilloma virus) test is done on a sample of cells removed from the cervix, the same sample used for the Pap test or LBC. This sample is tested for the strains of HPV most commonly linked to cervical cancer. HPV testing may be done by itself or combined with a Pap test and/or LBC. This test may also be done on a sample of cells which a person can collect on their own. <https://www.cancer.net/cancer-types/cervical-cancer/screening-and-prevention>

Sensitivity and specificity mathematically describe the accuracy of a test which reports the presence or absence of a condition. If individuals who have the condition are considered "positive" and those who don't are considered "negative", then sensitivity is a measure of how well a test can identify true positives and specificity is a measure of how well a test can identify true negatives:

- **Sensitivity** (true positive rate) is the probability of a positive test result, [conditioned](#) on the individual truly being positive.
- **Specificity** (true negative rate) is the probability of a negative test result, conditioned on the individual truly being negative ([Sensitivity and specificity – Wikipedia](#)).

For more information about the cervical cancer and cervical cancer screening in New Zealand and Australia, please see useful links:

New Zealand: [National Cervical Screening Programme](#) | [National Screening Unit \(nsu.govt.nz\)](#)

Australia: [Cervical cancer](#) | [Causes, Symptoms & Treatments](#) | [Cancer Council](#)