



NZX/ASX Announcement

12 June 2026

Milestone Markets Update

- **Chinese Society of Colposcopy and Cervical Pathology (CSCCP) to be requested by the Chinese Obstetricians and Gynaecologists Association (COGA) to issue an Expert Consensus specific to TruScreen following world's largest opto-electronic cervical screening study of 15,000 women validating TruScreen's efficacy**
- **India regulatory approval expected in 3-6 months**
- **Three UNITAID applications may add NZ\$4m to annual revenue¹ from FY2028 to FY2030, for public screening programs across 14 countries in Africa, Asia and Latin America**
- **Preparation underway for the first of the 10,000 women TruScreen Ultra screening programs planned for Zimbabwe for FY2027**
- **Uzbekistan pilot study to commence July 2026, with device and SUS shipment in transit**
- **Bill & Melinda Gates Foundation grant application made for study to validate TruScreen's integration into existing clinical settings in Nigeria**
- **Rapid market expansion activity continues with distributor appointments and product registrations completed or in progress across Asia, Africa and Europe**

TruScreen Group Limited (NZX/ASX: TRU) ("TruScreen" or "the Company"), a global leader in AI-enabled cervical cancer screening, is pleased to provide investors with an update on activities across its key markets.

The World Health Organization's 90-70-90 milestones to be met by its 194 member nations by 31 December 2030 has created a sense of urgency for countries to accelerate existing or to implement new cervical cancer screening programs for its citizens. Over the past year, TruScreen has broadened its distribution network and collaborated with global and national NGOs and global funders to bring its cervical cancer screening technology to its targeted low and middle income markets, to assist them to achieve the 70% WHO screening target by December 2030.



China

The results of the Chinese Obstetricians and Gynaecologists Association (COGA) clinical study, the world's [largest opto-electronic cervical screening study](#) conducted internationally, were published in February 2026 [in leading German journal BMC Cancer on Springer Nature Link](#). The three-year study, conducted across 64 hospitals in 9 provinces and involving 14,982 women, validates TruScreen as a superior primary cervical cancer screening tool compared with liquid-based cytology (LBC/Pap test) and high-risk human papillomavirus (hrHPV) testing.

- TruScreen's **sensitivity** was well above that for Liquid Based Cytology (Pap test) (87.5% v's 66.5%)
- TruScreen's **specificity** (88.4%) was higher than both Liquid Based Cytology (Pap test) (86.3%) and HPV testing (78.3%)
- The sensitivity of TruScreen-HPV co-testing was higher than that of Liquid Based Cytology (Pap test) -HPV co-testing, **98.4% vs 95.9%**

The significant result will enable the Chinese Society of Colposcopy and Cervical Pathology (CSCCP) to issue an Expert Consensus specific to TruScreen, a process that is presently in progress. Once achieved, this will accelerate product rollout across both public and private sectors and will allow TruScreen to be considered for government conducted national and regional population screening programs.

China has the world's largest absolute cervical cancer burden, with more than 150,000 new cases annually. Regional disparities are large, with rural and western provinces carrying higher burdens and lower screening access. TruScreen is well placed to serve these areas, *with the COGA study determining TruScreen to be an appropriate primary cervical cancer screening tool in regions with high morbidity and mortality to cervical cancer.*

Other notable publications in China include:

- the [Sichuan University clinical study](#) (n=297), which showed that TruScreen + hr-HPV showed superior diagnostic performance and accuracy versus cytology-based co-testing, and
- the [Guilin People's Hospital study](#), which supported TruScreen's clinical value as a preferred screening option for pregnant women.



Vietnam

TruScreen and its distributor GHS are in discussions with the Ho Chi Minh City government regarding the use of TruScreen in the city-wide health check-up program launched by the Health Department in April 2026. The second phase of the program will include cervical cancer screening, and GHS believes TruScreen is well positioned for selection for use in this program, particularly as the program expands into rural areas where laboratory facilities for Pap and HPV testing are limited.

GHS participated in the Smart Healthcare Exhibition in April, where TruScreen attracted strong interest and positive feedback. Building on endorsements from major public hospitals and key opinion leaders, GHS has also entered Vietnam's growing private sector market. The first of these private hospitals has integrated TruScreen into its clinical operations, while a further seven hospitals are pending government approval for installation.

Vietnam has a moderate-to-high cervical cancer burden relative to ASEAN peers. Screening coverage remains uneven, especially in the rural areas.

Singapore, Malaysia and Thailand

Product registration with Thailand's FDA was obtained in April 2026. Thailand has made strong progress through organized screening programs in recent years but cervical cancer remains a major women's health issue, particularly in underserved rural and regional provinces.

Product registration in Malaysia was submitted in March 2026, with approval expected in Q2 of FY2027. Screening participation remains inconsistent, with local and rural populations experiencing poor outcomes.

In Singapore the prominent key opinion leader Dr S. C. Quek has installed TruScreen at his Parkway Gynaecology Screening & Treatment Centre, Gleneagles Hospital. This clinic will serve as a key TruScreen reference centre for South East Asia.

India

An application for regulatory approval was submitted in April 2026, with approval expected within three to six months.

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10 devices were shipped to India following the appointment of distributor Renovate Biologicals Pvt Ltd in April 2025, and an interim product testing licence issued in July 2025. A consortium of private hospitals is evaluating the adoption of TruScreen upon receipt of regulatory approval.

China and India accounted for 42% of cervical cancer cases in 2022. India has the world's second-largest cervical cancer burden, with over 127,000 new cases annually and a disproportionately high share of deaths. Mortality remains high because many women are diagnosed late – due to extremely low screening rates (2% nationally, with regional variance).

Bangladesh

Xerox Medica Limited, was appointed distributor in May 2026, with projected first-year sales revenue of NZD 554,000¹. A government procurement application is being submitted in late June 2026 to meet the government budget deadline.

Bangladesh carries a very high cervical cancer burden, from limited screening access, low awareness, and constrained oncology infrastructure. Like India, most women present with advanced disease.

Sri Lanka

Product registration is almost completed, and discussions regarding sales and marketing plans commenced in May 2026.

Sri Lanka has a comparatively lower cervical cancer burden than India and Bangladesh, though it remains an important public health issue and screening coverage is still incomplete, particularly in rural and regional populations. Many women are diagnosed later than recommended by the World Health Organisation. Sri Lanka has an estimated 7.4m women of screening age*, representing significant market opportunity.

Uzbekistan

In May 2026. Albatros Health Care LLC a leading medical device distributor was appointed as TruScreen's distributor in Uzbekistan and potential revenue for the 30-month period through calendar year 2028 is NZD 1.27 million¹.

Following ethics approval, Professor Pakhomova, President of the Association of Obstetricians and Gynaecologists of Uzbekistan will conduct a pilot clinical study in Tashkent. The study will commence



in early July 2026. TruScreen Ultra devices and Single Use Sensors are in transit to Uzbekistan to commence this program.

Uzbekistan has a moderate but rising cervical cancer burden, from limited organized screening and historically low HPV vaccination uptake. Access to early diagnosis and treatment varies substantially between urban and rural regions.

Central Asia

Distributor IMSytem is conducting a multi-centre clinical study to support recognition of TruScreen as a primary screening method across government healthcare providers and screening programs. Two key women's health centres began screening 1,500 women in April, with two additional centres commencing in May 2026 to screen a remaining 500 women.

Product registrations have been submitted in Kyrgyzstan and Belarus, with approvals expected in Q3 FY2027.

Kyrgyzstan has high mortality compared with Western Europe because many cases are diagnosed at later stages. Screening infrastructure and pathology capacity remain limited. Belarus has a moderate cervical cancer burden by European standards. Screening access is broader than neighbouring Central Asian nations, but incidence is higher than in Western Europe.

Italy

A product introduction meeting was held at Borgo Trento Hospital in Verona in February 2026. Ten senior managers and professors from the hospital, the University of Verona and AIRC (Italian Association for Cancer Research) attended, and feedback was positive.

Following that meeting, distributor Chinni engaged AIRC to conduct a pilot clinical study to gain acceptance from local doctors and government policymakers. The protocol is to screen 650 to 800 women and compare TruScreen with the current screening methods.

Following expected favourable results, AIRC will support installation of TruScreen across the 17 committees it operates, with an estimated two to three devices per committee and approximately 40 screenings per device per month. This could result in up to 50 TruScreen Ultra devices being installed using 24,000 Single Use Sensors per annum. AIRC is awaiting ethics approval to commence the study.

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Dr Roberto Rulli, Head of the OBGYN Department at Bassano del Grappa Hospital, is the Company's key opinion leader to provide medical support and potentially establish his clinic as the clinical reference centre for Italy and Europe.

Italy has a comparatively low cervical cancer burden due to organized cytology and HPV-based screening programs and vaccine availability but see concentrations of cervical cancer incidence among under-screened populations and migrants with lower healthcare access. With an estimated 18.6m women of screening age* in the country, Italy represents a significant market opportunity.

Nigeria

TruScreen collaborated with Lagos State University Teaching Hospital (LASUTH) and Lagos State University College of Medicine (LASUCOM) in Nigeria on a Bill & Melinda Gates Foundation grant application. Dr Ayokunle Moses Olumodeji, Consultant Gynaecological Oncologist at LASUTH, selected TruScreen's AI-enabled cervical cancer screening device as the cornerstone of his proposed study to validate its integration into existing clinical settings.

The application was submitted in April 2026. The first clinical reference centre in Africa is planned to be established in Nigeria with Professor Chibuikwe Chigbu at the University of Nigeria Teaching Hospital in June 2026.

Professor Chigbu has received TruScreen Ultra devices and Single Use Sensors to conduct a pilot clinical study at his centre in support of market entry in Nigeria. This program will commence in July 2026.

Nigeria has one of the highest cervical cancer burdens in the world. Cervical cancer is among the leading causes of cancer death in women, from low screening coverage, limited HPV vaccination, and inadequate treatment access. HIV prevalence in some populations also contributes to risk.

Zimbabwe

Following the positive results of the re-validation study and the subsequent approval from the Ministry of Health to extend from one province to nationwide screening programs, preparation has commenced for the first of the 10,000 women TruScreen Ultra screening programs planned for Zimbabwe for FY2027.

Distributor Southern Skies Medical participated in the Zimbabwe Inaugural Reproductive, Maternal, Newborn, Child and Adolescent Health and Nutrition (RMNCAH+N) Conference 2026 under the theme "Ending Preventable Maternal and Perinatal Mortality: Lessons Learned and Future Directions" in March.



The TruScreen booth attracted more than 50 visitors, including the Health Minister, who spent 15 minutes reviewing the features and benefits of TruScreen, with positive feedback.

Zimbabwe faces an extremely high burden, worsened by high HIV prevalence, which substantially increases cervical cancer risk (a challenge faced by much of sub-Saharan Africa). Late diagnosis and treatment shortages contribute to high mortality.

South Africa

Product registration with the South African Health Products Regulatory Authority (SAHPRA) was submitted in March 2026, with approval expected in July 2026.

South Africa has a very high cervical cancer burden despite relatively advanced medical infrastructure compared with many African countries. HIV co-infection is a major cause. The country has expanded HPV vaccination and screening programs.

Other global market expansion opportunities

TruScreen is in a rapid market expansion phase. In addition to the countries outlined above, the Company is in discussions with distributors in Rwanda, Palestine and Jordan.

In addition, the Company is working with Austrade's African offices to accelerate the market entry to Africa. The first group of countries include Kenya and Tanzania.

The Global funders

UNITAID

Transformational opportunities have recently arisen through global funder UNITAID's Call for Proposals: Accelerating Cervical Cancer Elimination through Secondary Prevention in Low and Middle Income Countries. Three grant applications have been made to UNITAID to screen an additional 400-500,000 women over 3 years. If successful, additional public screening programs may add NZ\$4m¹ to annual revenue from FY2028 to FY 2030.

African countries: Zimbabwe, South Africa, Eswatini, Rwanda, Nigeria, Kenya

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Partners:

- National AIDS Council (NAC), Zimbabwe - Country implementation lead (Zimbabwe)
- PATH - Global technical partner (Program for Appropriate Technology in Health)
- Solina Centre for International Development and Research (SCIDaR) - Implementation partner (Nigeria)
- RedAid Nigeria - Community health delivery and outreach (Nigeria)
- Baylor College of Medicine Children's Foundation Eswatini - Implementation partner (Eswatini)

Asia and Latin America Countries: China, India, Indonesia, Vietnam, Uzbekistan, Mexico, Malaysia, Thailand

Partners:

- PATH (Program for Appropriate Technology in Health)
- Ho Chi Minh City Public Health Association
- Gordon Health Services Vietnam
- Beijing Siweixiangtai Tech Ltd Co
- Sunbird Mexico

TruScreen has also partnered with two global NGOs, as technology provider, in separate grant applications to UNITAID for cervical screening programmes. In total, TruScreen is the technology partner in five grant applications to UNITAID.

TruScreen has also submitted grant applications to both the Bill and Melinda Gates Foundation and to the Clinton Health Access Initiative to fund screening programs in Africa.

Bill and Melinda Gates Foundation

Partner:

1. Nigeria's Lagos State University Teaching Hospital (LASUTH)
2. Lagos State University College of Medicine (LASUCOM),
3. Dr. Ayokunle Moses Olumodeji, Consultant Gynaecological Oncologist at LASUTH

Country: Nigeria



Clinton Health Access Initiative

The **Clinton Health Access Initiative** have confirmed receipt of TruScreen's application for a US\$700,000 program to use AI enabled technology for cervical cancer screening in Africa.

This announcement has been approved by the Board.

* *Female population ages 15-64, Source: World Population Prospects, United Nations Population Division, World Bank*

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About TruScreen

TruScreen Group Limited (NZX/ASX: TRU) is a New Zealand and Australian listed company with a real-time, AI-enabled cervical cancer screening technology designed to detect pre-cancerous and cancerous changes of the cervix.

The TruScreen device is registered for use in multiple markets and has been used to screen more than 1,000,000 women worldwide.

TruScreen's technology is designed to support cervical cancer screening in settings where access to laboratory infrastructure and specialist pathology services may be limited, making it well suited to emerging markets and public screening initiatives.

Future performance

This announcement includes certain "forward-looking statements" about the Company and the environment in which the Company operates. Forward-looking information is inherently uncertain and subject to contingencies, known and unknown risks and uncertainties and other factors, many of which are outside of the Company's control, and may involve significant elements of subjective judgement and assumptions as to future events which may or may not be correct. A number of important factors could cause actual results or performance to differ materially from any forward-looking statements. No assurance can be given that actual outcomes or performance will not materially differ from the forward-looking statements. The forward-looking statements are based on information available to the Company as at the date of this presentation. Except as required by law or regulation (including the Listing Rules), the Company undertakes no obligation to provide any additional or updated information whether as a result of new information, future events or results or otherwise.