BEYOND SCREENING

TruScreen's news from around the globe



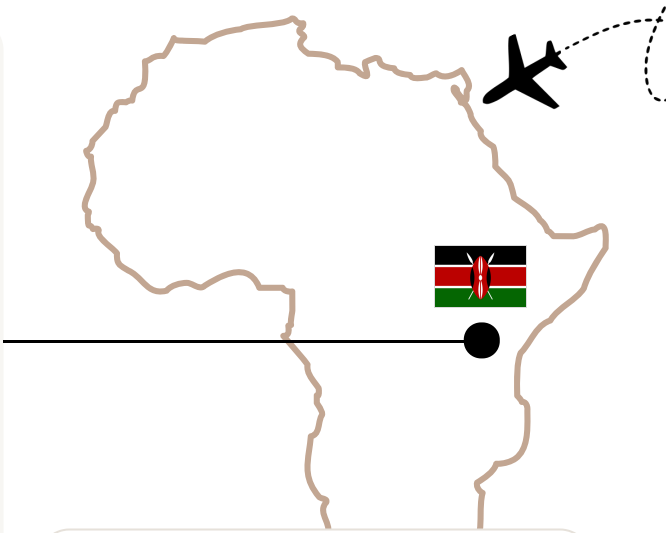
KENYA REGISTRATION SECURED AND FIRST ORDER EXPECTED

TruScreen Ultra® has received product registration in Kenya from the Ministry of Health Pharmacy and Poisons Board – much sooner than expected – clearing the way for sales into Kenya's public and private health sectors.

Cervical cancer is the leading cause of cancer death among Kenyan women, with around 6,000 new cases and 4,000 deaths each year. Only 6% of women aged 30–49 have been screened with a high-performance test, against the WHO and national target of 70% by 2030. TruScreen's real-time result at the point of care, with no laboratory or pathology infrastructure required, is well suited to screening at the scale Kenya needs.

Our distributor, Ansell Pharmaceuticals, will soon place its first order of 5 devices and 1,080 Single Use Sensors (SUS) for marketing and training, with a clear launch plan in place:

- **December–January:** two key opinion leaders (KOLs) will conduct a pilot study.
- **February:** a launch meeting where the pilot results will be presented, with senior officials from the Kenyan Government and the Australian mission invited to attend.
- **Market entry:** Ansell will initially focus on the private sector to build field knowledge and feedback, while engaging NGOs and government bodies on screening programs.



KENYAN DELEGATION IN SYDNEY

TruScreen will feature at the Kenya-Australia Healthcare Conference in Sydney in the last week of November, attended by Kenyan government officials and MPs.

The delegation will also visit TruScreen's office and the Royal Hospital for Women to meet Professor Mick Campion – a valuable opportunity to build Government support for TruScreen in national screening programs.

17m
Kenyan women of screening age

6%
currently screened with a high-performance test

70%
national screening target by 2030

5 + 1,080
devices and SUS order expected

NEWS FROM AROUND THE GLOBE....

BANGLADESH

TruScreen has received its first sale in Bangladesh, and a clinical evaluation has been agreed with the Ministry of Health and Family Welfare following a successful visit to Dhaka.

From 26–28 October, Dr Carolina Velasquez, Medical Affairs and Training Manager, and Ms Sumaya Mozumder, Business Development Manager for the Indian subcontinent, delivered three days of product presentations and training, supported by local distributor Xerox Medica Ltd.

Ministry of Health and Family Welfare

Dr Velasquez presented TruScreen's technology, clinical evidence and connected screening results portal to Dr Md. Nurul Islam and his team at the Directorate General of Health Services. Discussions focused on a proposed national community screening model led by an all-female team of nurses and midwives, with the portal giving Government population-level data down to upazila (sub-district) level.

National Institute of Cancer Research & Hospital

Presentations to senior clinicians at Bangladesh's national cancer institute helped build key opinion leader support for TruScreen's adoption.

DocTime

A hands-on demonstration and device training for DocTime and Xerox Medica staff opened a potential channel to women in the private health system.

Clinical evaluation agreed

Following the visit, Xerox Medica met again with the Ministry and agreed to conduct a clinical evaluation with a key opinion leader. Completing the evaluation is the Ministry's condition for approving a procurement request for **40 devices and 10,000 Single Use Sensors (SUS)** for government hospitals.

Xerox Medica has ordered 1 device and 240 SUS for the evaluation, which will be delivered in November. The evaluation will start in December and is expected to take 30 days.

With around 8,500 new cases and 5,000 deaths each year, and screening coverage below 10%, cervical cancer is a major burden for Bangladeshi women. TruScreen's non-invasive, AI-enabled device gives an immediate result and can be used by trained nurses and midwives in community clinics – supporting Bangladesh's path to the WHO 70% screening target by 2030.



Dr Carolina Velasquez and Ms Sumaya Mozumder with the TruScreen device



Dr Velasquez presenting to Dr Md. Nurul Islam and his team from the Ministry of Health and Family Welfare



Visit to the Office of the Director, NICRH, Dhaka



Hands-on training with the TruScreen device

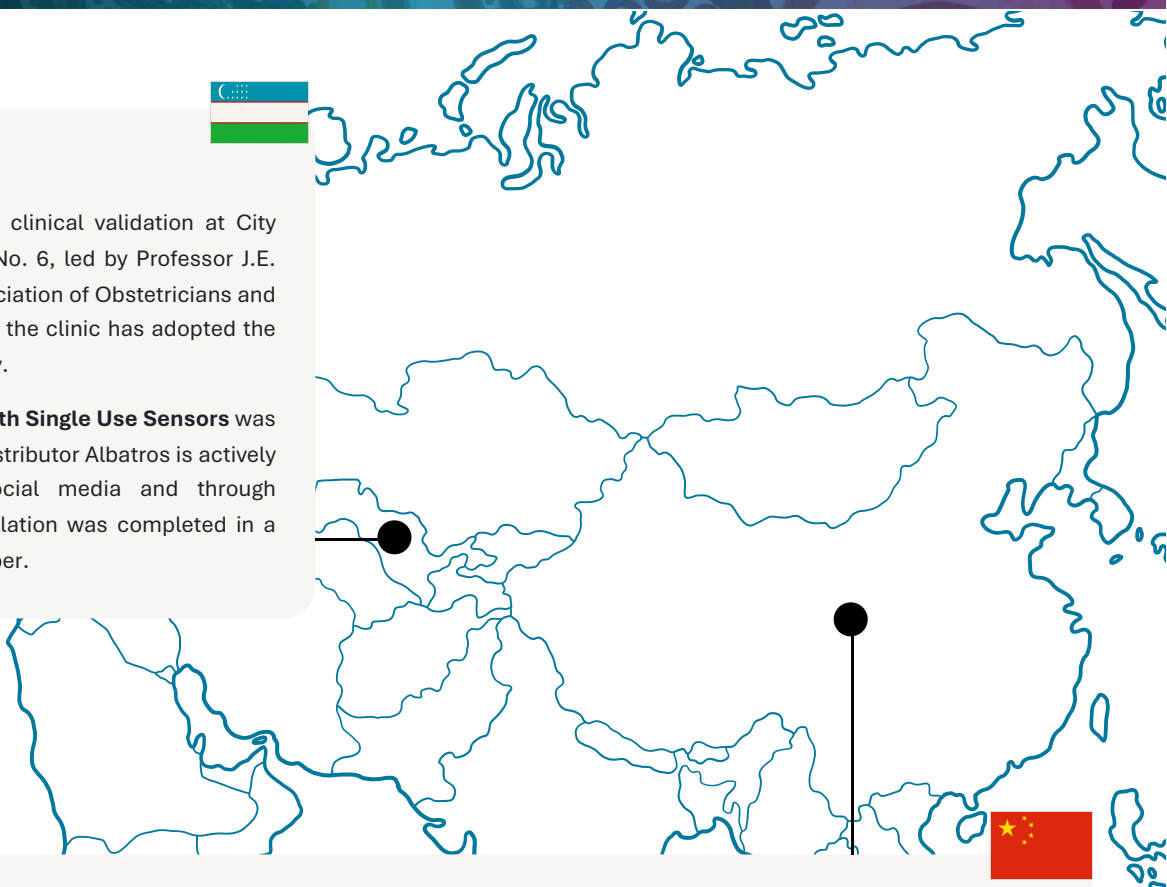


TruScreen and DocTime teams at DocTime's headquarters, Dhaka



Training participants with the TruScreen team

NEWS FROM AROUND THE GLOBE....



UZBEKISTAN

Following the success of the clinical validation at City Interdistrict Perinatal Centre No. 6, led by Professor J.E. Pakhomova, Chair of the Association of Obstetricians and Gynaecologists of Uzbekistan, the clinic has adopted the use of TruScreen commercially.

The **first order of 2 devices with Single Use Sensors** was delivered in November, and distributor Albatros is actively promoting TruScreen on social media and through doctors' visits. The first installation was completed in a private hospital in late November.

CHINA

Two more hospitals have won tenders for TruScreen, with installation expected by December.

Pricing approval

Building on the pricing approval progress reported last month, three provinces – Shanghai, Yunnan and Guizhou – are now undergoing the application process, and a further four – Liaoning, Guangdong, Hunan and Sichuan – are preparing to submit.

Three clinical studies underway

500
patients
First Affiliated Hospital of Jilin University

500
patients
Third Affiliated Hospital of Sun Yat-sen University

2,000
patients
Fourth Affiliated Hospital of Harbin Medical University

A busy conference season

Our distributor SiWeiXingTai Technology (SWXT) has been out in force, sponsoring and participating in the Annual OBGYN Meeting of Shantou City (17 October, Shantou, Guangdong) and the 14th Annual Academic Meeting of the China Cervical Cancer Prevention and Treatment Program (30 October – 1 November, Beijing). Still to come:

- 19th Academic Meeting of Reproductive Medicine of the Chinese Medical Association – 25–28 November, Kunming, Yunnan
- Asian Society for Gynaecologic Oncology Annual Meeting (ASGO 2026) – 4–6 December, Shanghai

NEWS FROM AROUND THE GLOBE....

CENTRAL AND SOUTH AMERICA

Mexico

A clinical trial with **Dr Fernando Río de la Loza**, one of Mexico's best-known and most influential gynaecologists, has been confirmed. Training was completed in September and the protocol is being finalised.

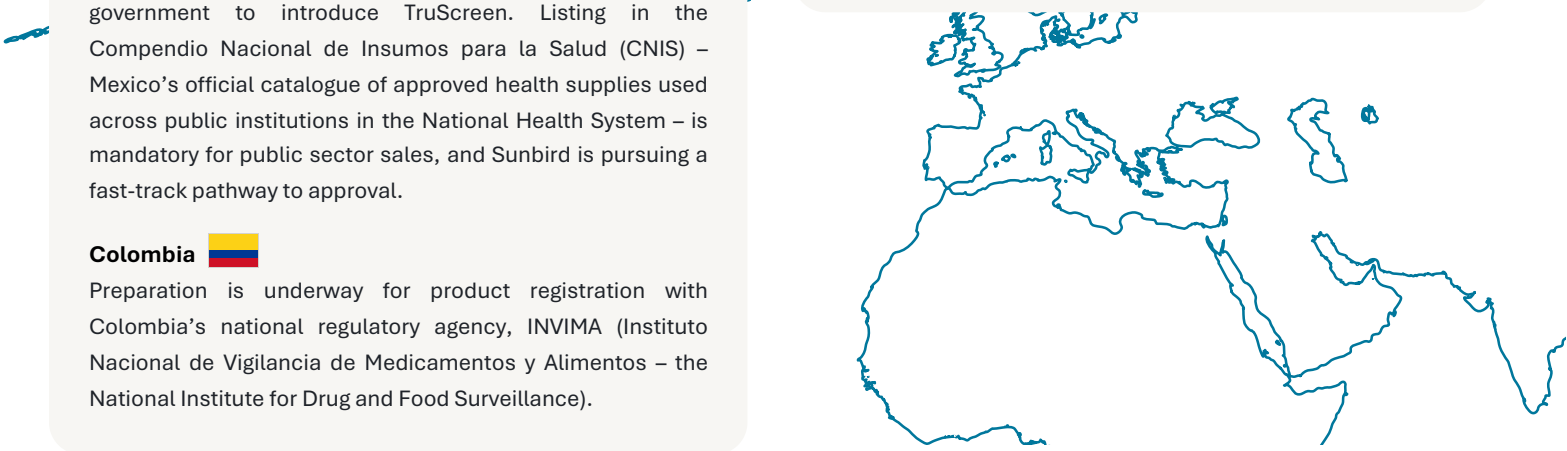
Our distributor Sunbird has secured several meetings with government to introduce TruScreen. Listing in the Compendio Nacional de Insumos para la Salud (CNIS) – Mexico's official catalogue of approved health supplies used across public institutions in the National Health System – is mandatory for public sector sales, and Sunbird is pursuing a fast-track pathway to approval.

Colombia

Preparation is underway for product registration with Colombia's national regulatory agency, INVIMA (Instituto Nacional de Vigilancia de Medicamentos y Alimentos – the National Institute for Drug and Food Surveillance).

MARKET GROWTH

TruScreen is exploring strategic partnerships to open up opportunities across a variety of countries. Paris-based **Hazex Partners** will work with TruScreen to facilitate access across multiple regions, and TruScreen will deliver training for their team in the first week of December. We look forward to sharing more as these opportunities develop.



GRANT OPPORTUNITIES

TruScreen continues to work with partners applying for grant funding to expand access to cervical cancer screening.

Live opportunities include:

Final round

UNITAID

A grant application submitted by AMREF in collaboration with PATH has progressed to the final round.

amref health africa

PATH The way to better health

220 women

BIG Cat – Nigeria

Dr Ayokunle Olumodeji of Lagos State University Teaching Hospital (LASUTH) and College of Medicine (LASUCOM) has applied for the Beginning Investigator Grant for Catalytic Research, backed by the American Association for Cancer Research. The study will evaluate TruScreen in women attending LASUTH's Gynaecological Oncology Unit, comparing it with high-risk HPV DNA testing and liquid-based cytology, using colposcopy and histology as the reference standard.

50,000–100,000 women

Pacific Corridor Project

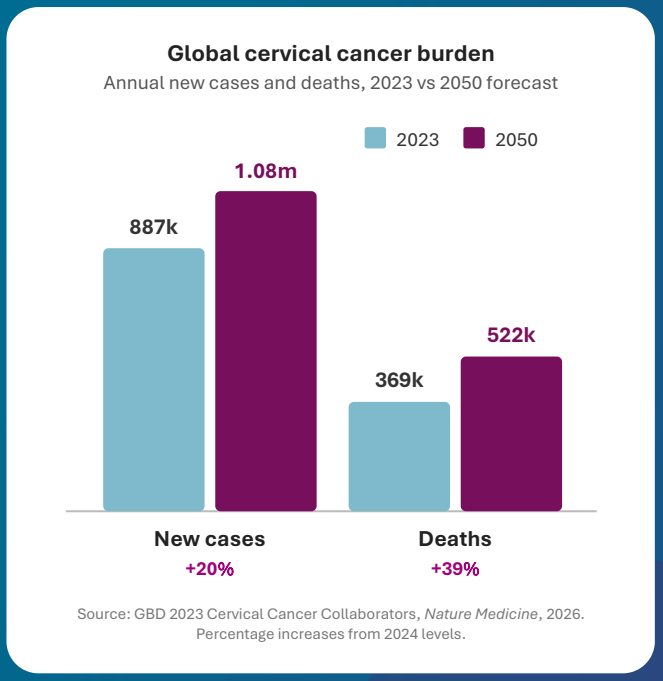
Dr Kelvin Billinghurst is preparing a tender for the Pacific Corridor Project with DFAT (Australia), in partnership with the Royal Australasian College of Medical Administrators (RACMA), which he chairs, Fiji National University and RANZCOG. The program would screen women starting in the outer Pacific islands and finishing in Fiji. The New Zealand Government is also looking to support screening across the Pacific. TruScreen's participation will validate the cost benefits of its AI-enabled, portable technology, which delivers real-time, instant results with no laboratory infrastructure.

DID YOU KNOW?

Global cervical cancer deaths are projected to rise by 39% by 2050.

A new Global Burden of Disease study published in *Nature Medicine*, involving researchers from NUS Medicine (National University of Singapore) and the Institute for Health Metrics and Evaluation (IHME), forecasts that the number of women affected will keep rising as populations grow and age.

The steepest rise is expected in sub-Saharan Africa, where deaths could almost double – underlining the need for screening at the point of care.



1.08 million new cases a year by 2050, up 20%

522,000 deaths a year by 2050, up 39%



NEWS FROM HQ...

Learn more about:

Denim Walker

TruScreen's Production and Technology Executive

Denim's interest in human biology and physiology began in high school science, grew through his HSC biology studies, and led him to the University of Wollongong, where he graduated with a Bachelor of Medical and Health Sciences.

He was drawn to TruScreen by its unique technology, which uses advanced optical fibre technology to screen for cervical cancer efficiently, and by its goal: a world without cervical cancer.

Denim joined TruScreen as an intern focused on quality assurance in medical devices, before moving into a part-time production role. Today he is Production and Technology Executive and AI Administrator, and is training in Regulatory Affairs. He is eager to keep growing with TruScreen and to make a meaningful impact on the early detection of cervical cancer.