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# Highlights FY2026 Outlook for FY2027



May 2026



# Who is TruScreen

**Enabled by AI, TruScreen provides an accurate, real time cervical cancer screening solution**



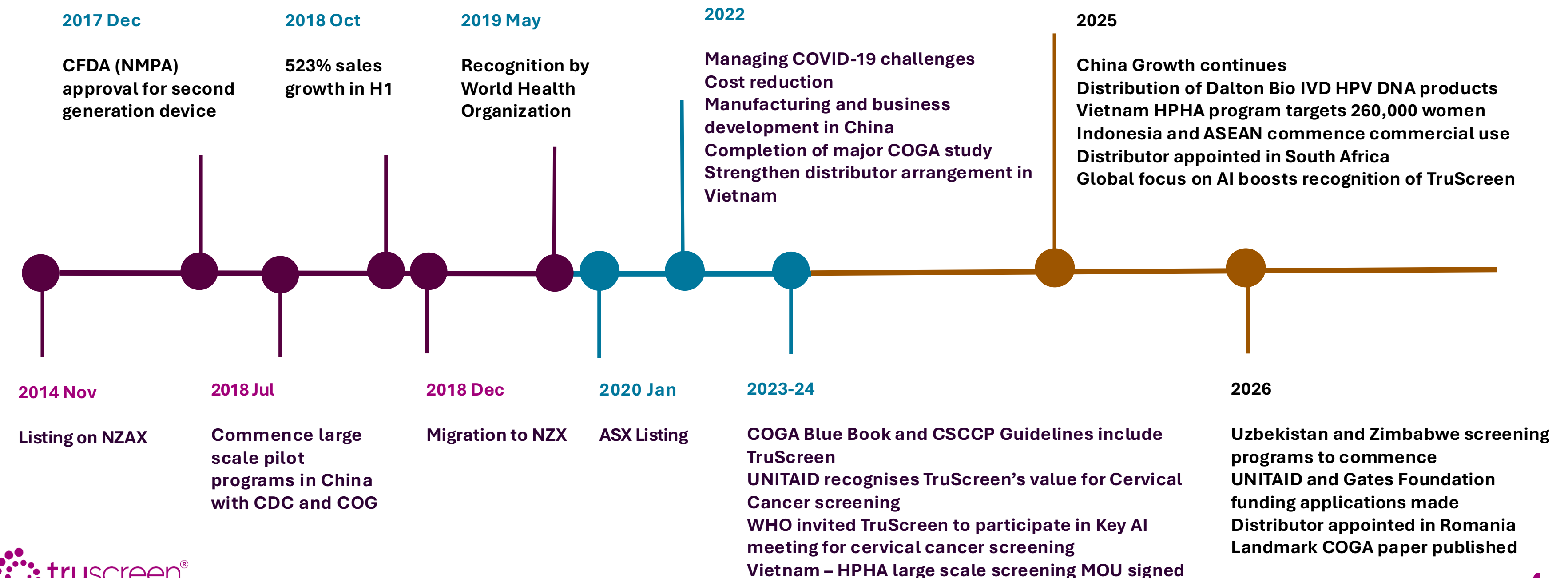
**TruScreen Group Ltd is a revenue generating Life Science company with a unique, AI-enabled real-time cervical cancer screening device.**

**FY26 annual sales exceeded NZD \$2.4m  
- 42% YOY growth.**

**TruScreen Group Ltd owns TruScreen Pty Ltd, the Australian operating company that manufactures and markets the TruScreen cervical cancer screening system.**



# The TruScreen Journey



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# TruScreen Sales Strategy



# Device installations and SUS Sales

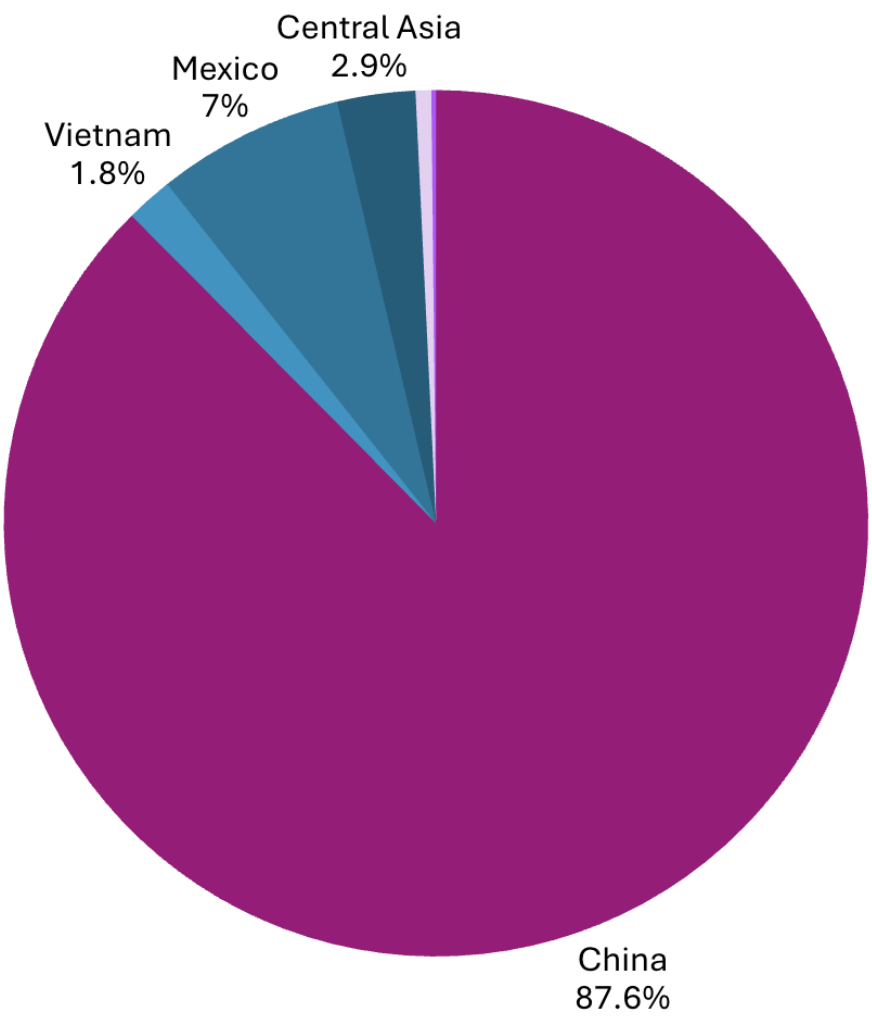
KEY FINANCIALS NZD (m)	FY 23 Actual	FY 24 Actual	FY25 Actual	FY26 Actual (unaudited)
Sales	1.66	2.1	1.7	2.4
Total Revenue	2.2	2.6	2.1	2.8
COGS	1.3	1.4	1.2	1.7
R&D	0.9	0.9	0.8	0.9
EBITDA	-2.4	-2.0	-2.2	-2.2
Write off of Non-Current Assets	-0.05	-	-	-
Amortisation & Depreciation	-	-	-	-
LOSS FOR YEAR	-2.4	-2.0	-2.2	-2.2
Net Assets	2.5	3.2	1.0	2.6
Cash	2.2	2.7	0.04	1.5

## From FY25 to FY26:

- Sales increased 42% YOY
- SUS Sales increased 1% YOY
- Revenue increased 33% YOY
- EBITDA – no change YOY
- Net Assets increased 160% YOY
- China SUS/Device Pull Through -4% YOY

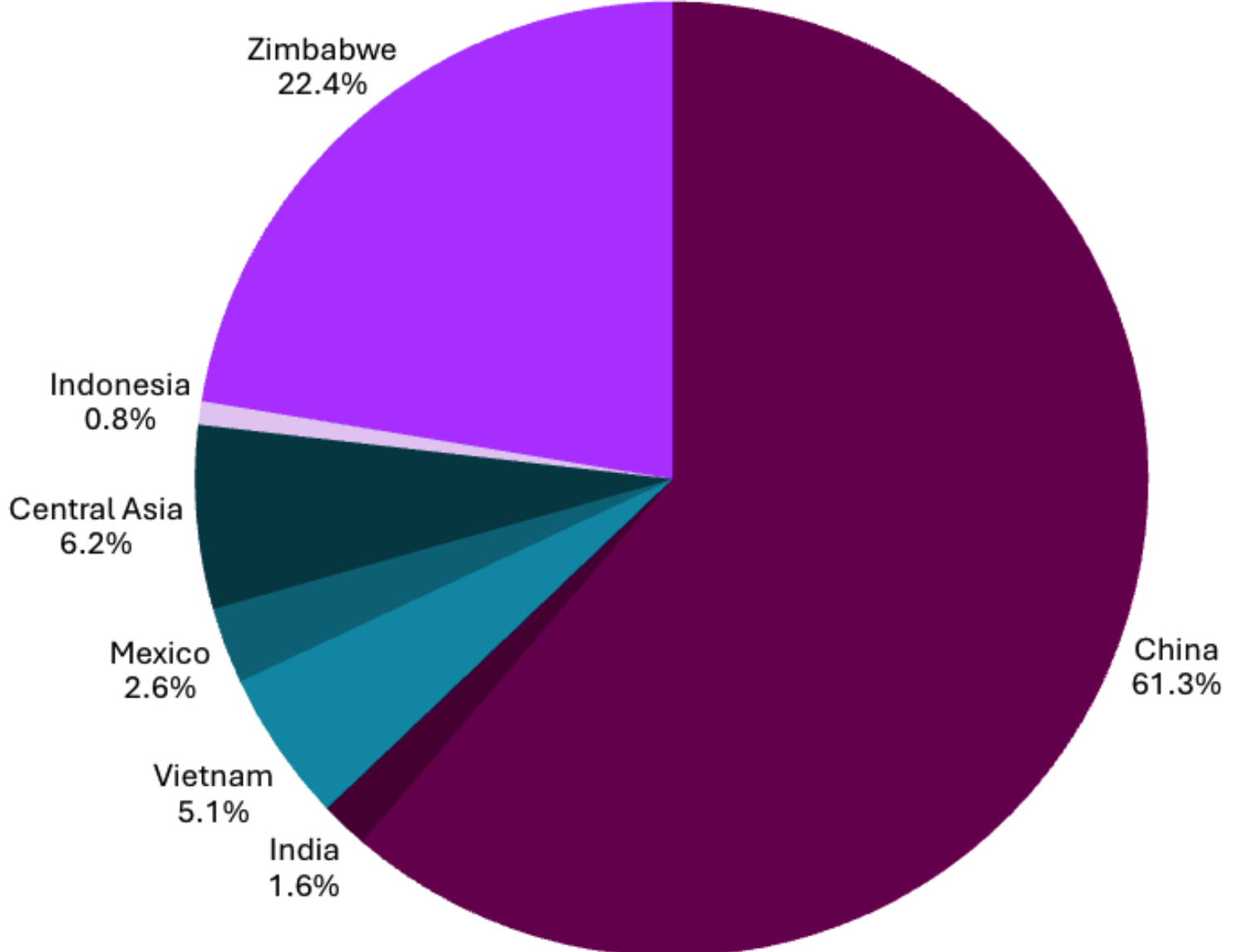
# FY25 ACTUAL

NZ\$1.7m



# FY26 ACTUAL

Unaudited sales NZ\$2.4m



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# Recurring Revenue Model

- **TruScreen manufactures two devices –**
  - **one made in China for use in China, where locally manufactured products have preferential market access**
  - **one made in Australia for other markets**
- **For each patient screened with the TruScreen device a new disposable Single Use Sensor (SUS) must be used. This creates a recurring revenue model with a consumable sale for each patient screened with TruScreen.**

# TruScreen Sales Strategy

- Whilst many other medical technology companies seek to commercialize their devices in developed countries, TruScreen focuses on Low and Middle Income Countries (LMICs) such as China, Mexico, Vietnam, India, Indonesia and Zimbabwe.
- Working with global and national NGOs, to manage large scale public health screening programs
- These countries and other LMICs have no or minimal large-scale cervical cancer screening programs and infrastructure. This creates a gap in the market for TruScreen that is not available in the developed markets and allows quicker market access from a relative lack of existing competition.
- In comparison with cytology and HPV DNA screening TruScreen is 'capital light', not requiring lab infrastructure to be established prior to commencing screening.

# TruScreen Regulatory Approvals

## Recognized by

- World Health Organisation (WHO)
- UNITAID
- Clinton Health Access Initiative
- Daffodil Foundation - Australia
- China Obstetricians and Gynaecologists Association
- China Society for Colposcopy and Cervical Pathology
- Russia Cervical Cancer Screening Guideline
- Vietnam Hospital Technical List

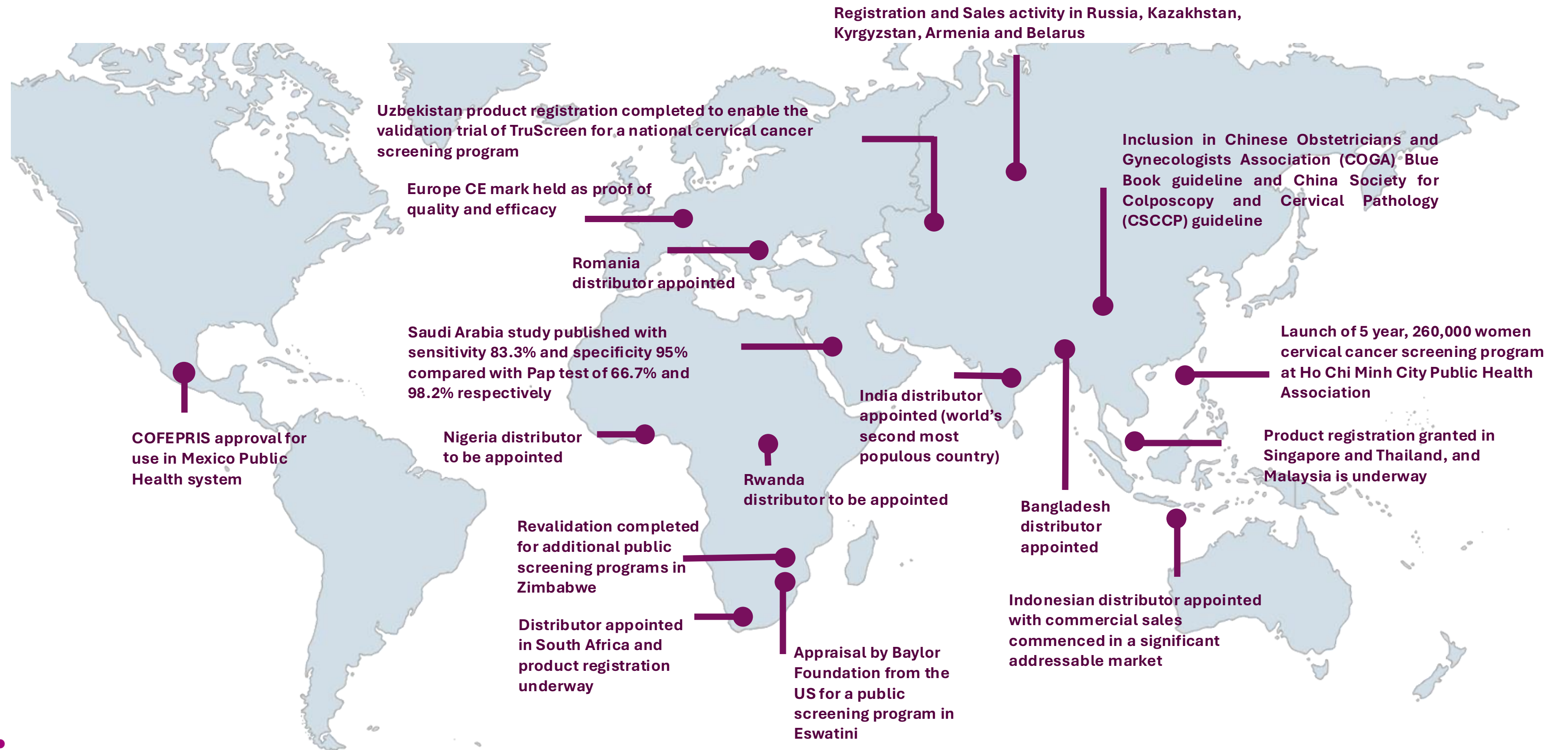
## International Approvals:

- CE Mark, European Union
- NMPA, China
- TGA, Australia
- MHRA, UK
- SFDA, Saudi Arabia
- Roszdravnadzor, Russia
- COFEPRIS, Mexico
- WAND New Zealand
- Zimbabwe Ministry of Health
- IEAKI Indonesia
- Vietnam MOH
- India (Test Licence)
- Uzbekistan
- HSA, Singapore
- Thai FDA

## International Quality Accreditation:

- ISO 13485
- IEC 60601-1
- IEC 60601-1-2
- CE Mark

# Global presence



# TruScreen Highlights FY 2026



# FY2026 Highlights — Five Marquee Wins

## 01 260,000-woman Vietnam programme

5-year cervical cancer screening programme launched in Ho Chi Minh City with HPHA & Gorton Health Services. Planned national expansion in a market of 35M women of screening age.

## 02 India re-entry

Renovate Biologicals Pvt Ltd appointed as distributor. Interim product testing licence (Jul-25), 10 devices shipped. Full regulatory submission Apr-26.

## 03 BMC Cancer landmark study

14,982 women, 64 hospitals, 9 provinces. CIN2+ sensitivity 87%, CIN3+ sensitivity 90%. Largest opto-electronic cervical screening study ever published.

## 04 UNITAID — 3 proposals submitted

14 high-burden countries, 1Bn women addressable market, up to US\$18.4m potential revenue as consortium lead.

## 05 Distributor footprint expanded

New distributors signed in South Africa, Uzbekistan, Bangladesh, Romania and Italy. Pending in Nigeria, Rwanda and Palestine.

# A Diversified Global Footprint

## Active markets

- China (61.3% of FY26 sales)
- Vietnam (4 public hospitals + private)
- Zimbabwe (national expansion)
- Mexico (lab-system entry)
- Central Asia / Russia (multi-centre)

## Launching FY27

- India (regulatory approval pending)
- Indonesia (POGI launch · July 2026)
- Singapore · Thailand · Malaysia
- Bangladesh (Xerox Medica)
- Kazakhstan (commercial use early FY27)

## Pipeline / new signings

- South Africa (AIR · pilot study)
- Uzbekistan (Albatros Health Care)
- Romania · Italy (signed)
- Nigeria (LASUTH · Gates Foundation app.)
- Rwanda · Sri Lanka · Palestine (in negotiations)

# China — The Anchor Market

# 61.3%

of FY2026 product sales

Consumable sales volumes met expectations despite challenging economic conditions.

### Anticipated guideline integration into:

- CSCCP guidelines update
- COGA Blue Book — 2nd edition (2026)
- Expert Consensus on opto-electronic screening

## Landmark BMC Cancer publication · Feb 2026

# 14,982

women

# 64

hospitals

# 9

provinces

### Clinical performance vs Liquid-Based Cytology & hrHPV

# 87%

CIN2+ sensitivity

# 90%

CIN3+ sensitivity

# 0.72

AUC for CIN2+

"TruScreen has the highest AUC for both CIN2+ and CIN3+, indicating it was the most accurate test overall." — Study authors, BMC Cancer (2026)

# Vietnam & Indonesia — South-East Asia Growth Engine

## Vietnam

# 260,000

women to be screened in Ho Chi Minh City over 5 years (with HPHA & Gorton Health Services)

- Adopted by 4 leading public hospitals in South Vietnam.
- Private-sector entry: 1 hospital integrated into daily clinic; 4 awaiting approval; 3 more preparing applications.
- Planned national expansion — Vietnam has ~35M women of screening age.
- Foundation for broader public-sector hospital acceptance now established.

## Indonesia

# 95M

women of screening age — government-funded mass screening program creates enormous opportunity

- Pilot clinical study underway with Marwa Mitra Medika.
- Results to be presented at POGI Annual Scientific Meeting — July 2026.
- TruScreen & distributor sponsoring the conference and product launch symposium.
- Collaboration planned with Ministry of Health for inclusion in public screening programmes.

# India Re-Entry & South-East Asia Regulatory Progress

## India

# 468M

women of screening age

Renovate Biologicals Pvt Ltd appointed distributor (Apr-25). Interim product testing licence (Jul-25) — 10 devices shipped. Regulatory submission filed Apr-26, approval expected within 3-6 months. Consortium of private hospitals lined up to adopt TruScreen subject to approval.

## Regulatory & market-entry milestones — South-East Asia

● India ● South-East Asia



SE Asia reference centre established with Dr. S. C. Quek at Parkway Gynaecology Screening & Treatment Centre, Gleneagles Hospital, Singapore.



# Africa — Three Growth Stories

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## Zimbabwe

# 20,000

screenings planned in CY2026

Re-validation by the National Microbiology Reference Lab (Aug-25) led the Ministry of Health to approve TruScreen as a primary screening test where HPV DNA testing is unavailable, and as a confirmatory test for HPV-positive women nationwide. 30,000+ women already screened since 2022 with the National AIDS Council.

## South Africa

# Jul 26

SAHPRA approval expected

New distributor AIR appointed (Nov-25). Product registration with the South African Health Products Regulatory Authority submitted Mar-26. A pilot clinical study has been planned to commence on receipt of regulatory approval, supporting market entry.

## Nigeria

# Gates

Foundation grant application

Collaboration with LASUTH and LASUCOM on a Bill & Melinda Gates Foundation grant application, TruScreen selected as the cornerstone device. First African clinical reference centre to be established with Prof. Chibuiké Chigbu, University of Nigeria Teaching Hospital. NGO partnerships with SCIDaR and RedAid.

# Central Asia, LatAm & New Distributors

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### Uzbekistan

**NZD 1.26m**

Albatros Health Care LLC appointed (May-26) a leading medical device distributor. Pilot clinical study commencing June 2026 with ethics approval, led by a senior government medical advisor.

30-mo revenue potential through CY2028

### Central Asia

**2,000**

women in multi-centre study

IMSystem multi-centre clinical study to secure recognition as a primary screening method in government healthcare. Kazakhstan to commence commercial use early FY27. Kyrgyzstan & Belarus registrations expected Q3 FY27.

### Mexico

**FY27**

Distributor Sunbird ran social media and digital campaigns and established online training centres. Now entering the laboratory system and in discussions with major laboratory chains.

sales expected to commence

### Bangladesh

**NZD 554k**

projected first-year sales

New distributor Xerox Medica Limited appointed (May-26). Government procurement application to be submitted June 2026 to meet the budget deadline.



# UNITAID — A Step-Change Opportunity

**14**

high-burden countries  
across Africa, Asia-Pacific & LatAm

**1Bn**

addressable screening-age  
women across target geographies

**US\$18.4m**

potential revenue to TruScreen  
as consortium lead

## Why TruScreen fits the UNITAID brief

- Point-of-care, portable AI technology — purpose-built for low-resource settings where laboratories, pathologists and patient recall are unavailable.
- Primary screening where labs are absent · HPV triage where HPV (incl. Dalton Bio) is primary · same-visit complement in screen-and-treat settings.
- Complementary, not competitive, to HPV-DNA expansion under the WHO 90-70-90 elimination strategy.

**Track record: 30,000+ women already screened in Zimbabwe since 2022 with the National AIDS Council · regulatory approvals across all 14 target countries.**

# Clinical & Scientific Milestones

Jan 2025

## WHO AI Collaboration

TruScreen invited to present at WHO Global AI Collaboration Meeting on cervical cancer screening.

May 2025

## Saudi Arabia study

Published Saudi Arabia study confirms TruScreen sensitivity and specificity vs. pap smear.

Jan 2026

## Pregnancy safety

Clinical study validates TruScreen efficacy and safety for pregnant women — broadens use cases.

Feb 2026

## BMC Cancer landmark

World's largest opto-electronic study — 14,982 women, 64 hospitals. CIN2+ 87%, CIN3+ 90%, AUC 0.72.

Mar 2026

## Sichuan University

297-patient study shows TruScreen + hr-HPV co-testing is superior to either modality alone.

Through 2026

## 30+ trials cumulative

TruScreen now backed by 30+ peer-reviewed studies covering 40,000+ women across 20+ countries.

# Commercial & Distributor Expansion

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## Asia-Pacific

**Jan 2025**

Indonesia distributor appointed (95M women).

**Apr 2025**

India re-entry — Renovate Biologicals Pvt Ltd.

**Apr 2025**

Vietnam — 260,000-woman public programme launches in HCMC.

**May 2025**

Dalton Bio HPV distribution rights for India.

**Aug 2025**

Public screening — Northeast India.

**May 2026**

Uzbekistan distributor formally appointed.

## Africa & Middle East

**Nov 2025**

South Africa — AIR Group appointed as distributor.

**Mar 2026**

South Africa — SAHPRA registration submission filed.

**May 2026**

Nigeria — LASUTH / Gates Foundation grant submitted.

**Dec 2025**

Western Europe & Middle East commercial scoping.

## Pipeline & Studies

**Feb 2025**

MOU with Hangzhou Dalton Bioscience.

**Aug 2025**

Public screening programme — Uzbekistan.

**2026**

New distributors signed in Romania and Italy.

**2026**

Pending in Rwanda, Sri Lanka, Palestine, Bangladesh.

# **TruScreen Outlook: FY2027 & Growth Strategies**



# What's Coming Next

FY2027 outlook	
■ <b>India</b>	Full regulatory approval expected within 3–6 months of Apr-26 filing.
■ <b>South Africa</b>	SAHPRA approval expected Jul 2026; pilot study to follow.
■ <b>Indonesia</b>	Commercial use targeted in FY27.
■ <b>Uzbekistan</b>	Scale-up under new distributor + public programme.
■ <b>UNITAID</b>	Funding decisions on three proposals through CY2026.
■ <b>Margin</b>	Country mix expected to lift gross margin above FY26's 31.5%.

Catalyst Drivers	
<b>H2 CY2026</b>	India regulatory approval; first commercial shipments.
<b>H2 CY2026</b>	South Africa SAHPRA approval and pilot study start.
<b>H2 CY2026</b>	UNITAID consortium decisions.
<b>H2 CY2026</b>	Indonesia / ME market activation.
<b>CY2026</b>	Nigeria — first African clinical reference centre opens.
<b>CY2027</b>	Vietnam — national expansion beyond HCMC.

# Growth Strategies



Market expansion to continue with China the key focus



Focus on key growth provinces (Shandong, Jiangsu,, Hunan, Zhejiang, Guangdong, Guangxi) - Total population 496m



Enter huge African market collaborating with NGOs



Strengthen vertical Asian market from Indonesia through China, and capitalise on Indian distribution network



Target Govt and NGO funded programs in Zimbabwe, Vietnam, Mexico and Uzbekistan



**Build on International NGO Recognition (WHO, UNITAID, CHAI, COGA , CSCCP) to build acceptance and remove barriers to sale**



**Focus on countries with limited or nil cervical screening capability**



**Developing strategic partnerships for complementary woman's health services**



**Capitalise on global focus on AI enabled cervical cancer technologies – e.g. WHO**



**Expand product portfolio to include Dalton Bio HPV related IVD products, including HPV DNA tests and self sampling**



**Reduce SUS and Device COGS and increase margins**

# The Game Changer

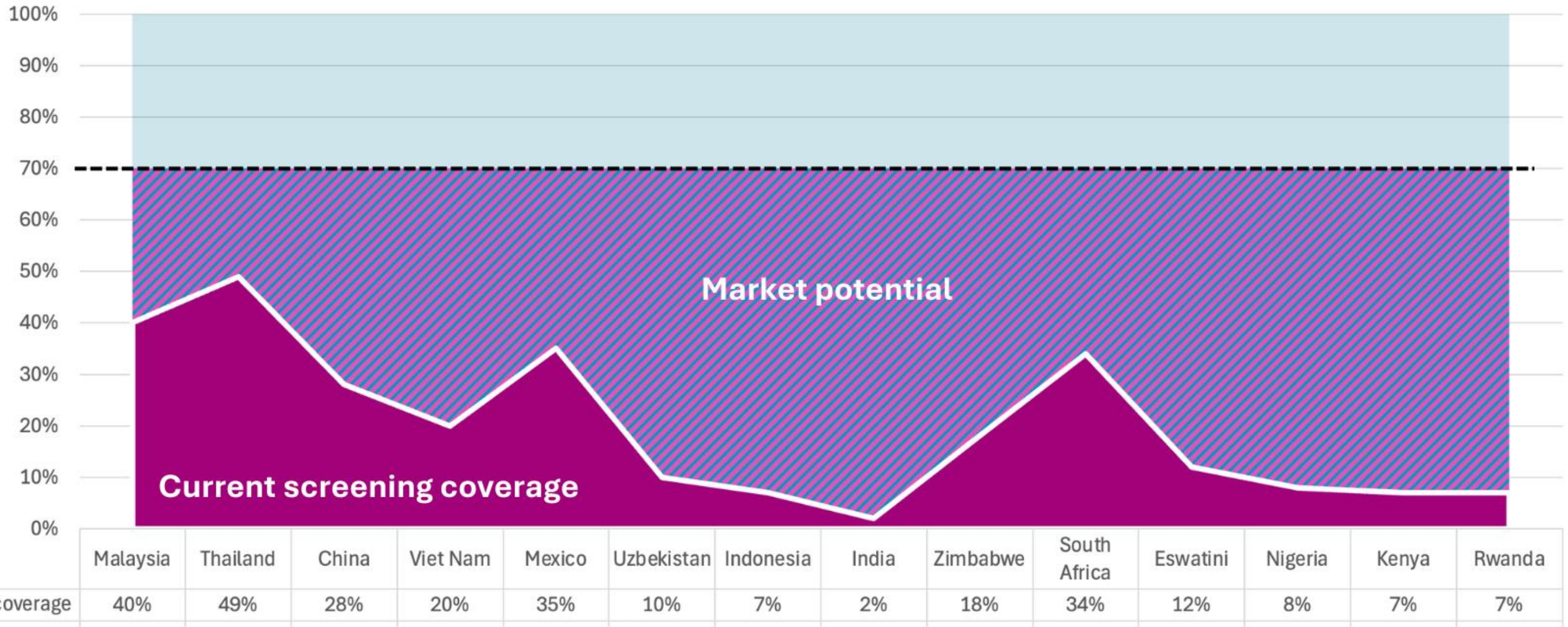
- 1 The timeline compression of WHO's 90-70-90 milestones<sup>1</sup> to December 2030 - Sense of Urgency
- 2 UNITAID and global NGOs funding by late 2026 to drive cervical cancer screening



<sup>1</sup> <https://www.who.int/initiatives/cervical-cancer-elimination-initiative>

# TruScreen Market Potential

**WHO 70%  
SCREENING  
TARGET**



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# DaltonBio Strategic Alliance

- **Q4 FY25** - Memorandum of Understanding signed with Dalton Biosciences (DaltonBio)
- **Q1 FY26** - TruScreen and Dalton Bio sign Distribution Agreement for HPV products in India



1. TruScreen to be appointed a global distributor of DaltonBio HPV related IVD products (excluding U.S.A. and Canada).
2. DaltonBio to explore opportunities to assist sales of TruScreen's AI enabled real time cervical screening device within its distribution network, notably in its selected distributors in China and South America. DaltonBio have 200 sub distributors in China which may augment TruScreen's current distribution network in it's largest market.

The collaboration will enhance access to innovative cervical cancer screening and detection solutions by leveraging the technology strengths of both companies. As demonstrated in the COGA landmark study (2023) and Beijing Obstetrics and Gynecology Hospital study (Dovepress, May 2025), co-testing improved TruScreen's already impressive standalone sensitivity significantly.

# Thank you.

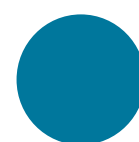


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