



truscreen
a world without
cervical cancer

NZX/ASX Announcement

5 April 2022

COGA TRIAL VALIDATES SUPERIORITY OF TRUSCREEN CERVICAL CANCER SCREENING METHOD

- **COGA Trial screened 15,661 women across 64 hospitals in 9 provinces over 3 years**
- **TruScreen specificity surpassed Liquid Based Cytology (LBC) and hrHPV**
- **TruScreen was determined to be a simple, effective and rapid real-time cervical cancer screening method**
- **TruScreen was determined to be an appropriate primary cervical cancer screening tool in regions with high morbidity and mortality to cervical cancer**

TruScreen Group Limited (NZX/ASX: TRU) ('TruScreen' or 'the Company') is pleased to announce the release of a China-based cervical cancer screening trial which validated the superiority of TruScreen's screening method.

The Chinese Obstetricians and Gynaecologists Association (COGA) completed a much anticipated, detailed cervical cancer screening trial that commenced in September 2018 and concluded in July 2021. The results of this trial have just been released and presented at a research conference organised by ASCCP (American Society of Colposcopy and Cervical Pathology) held in San Diego, USA. It compared the relative effectiveness of TruScreen against two other cervical cancer screening methods of HPV DNA testing (HPV) and Liquid Based Cytology (LBC).

Chinese trial highlights superiority of TruScreen screening method

The released results of the COGA trial, like those for earlier TruScreen studies, determined TruScreen to be a simple, effective and rapid real-time method to screen for cervical cancer. The COGA trial results also highlighted the superiority of TruScreen against alternative screening methods as well as the potential benefits of a TruScreen-HPV co-testing.

The size of the COGA study, which was TruScreen's largest clinical evaluation to date, lends extra significance to its results and broad conclusions. It involved the screening in a clinical setting of 15,661 women aged 21 years and older across 64 teaching hospitals in 9 Chinese provinces. All the women included in the trial underwent primary screening with TruScreen, HPV and LBC, where levels of sensitivity and specificity were computed. The results of the study found:

- TruScreen's sensitivity¹ was well above that for LBC (**87.5%** v's 66.5%), with a high degree of statistical significance ($p < 0.001$).
- TruScreen's specificity² (**88.4%**) was higher than both LBC (86.3%) and hrHPV testing (78.3%) (also at $p < 0.001$).
- The sensitivity of TruScreen-hrHPV co-testing (carrying out with multiple types of screening tests at the same time, as opposed to a single type) was higher than that of LBC-hrHPV co-testing, **98.4% vs 95.9%** (statistically significant at $p = 0.006$).

COGA concluded that the study highlighted the superiority of TruScreen's screening method, with the Association noting that:

- ***Due to resource restrictions, cytology cannot be effective in mass population screening programs in the areas with high morbidity and mortality of cervical cancer***
- ***TruScreen minimizes the need for training and facilities and offers a real-time result***
- ***Given the above two points, TruScreen is appropriate as a primary screening tool in regions with high morbidity and mortality to cervical cancer.***

¹ **Sensitivity** measures correctly a positive result for patients who have the condition that is being tested for (also known as the "true positive" rate). A test that is highly sensitive will indicate patients who have the disease.

² **Specificity** measures correctly a negative result for people who do not have the condition that is being tested for (also known as the "true negative" rate). A high-specificity test will correctly rule out patients who do not have the disease.



Juliet Hull, TruScreen’s Chief Executive Officer said: *“Our thanks to Beijing Siweixiangtai Tech Co Ltd (SWXT), our Chinese distributor for their dedication and management of the 3-year clinical trial of our TruScreen cervical cancer screening technology. SWXT and TruScreen have achieved a significant milestone in the commercialisation of our technology in China. The validation of our technology by COGA together with the recent national price approval of our TruScreen device (NZX announcement 3 March 2022) have provided opportunities for SWXT to further expand distribution of our TruScreen cervical cancer screening technology in China. Importantly, the study’s results also point to the potential benefits of TruScreen-HPV co-testing. This is another opportunity for growth as the Company continues its successful expansion into China and other overseas markets.”*

This announcement was approved for release by the Board.

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

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About TruScreen:

TruScreen cervical cancer screening device offers the latest technology in cervical screening, providing real-time, accurate detection of precancerous and cancerous cervical cells to help improve the health and well-being of women around the world.

TruScreen’s real-time cervical cancer technology utilises a digital wand which is placed on the surface of the cervix to measure electrical and optical signals from the surrounding tissues. A sophisticated proprietary algorithm framework is utilised to detect pre-cancerous change, or cervical intra-epithelial neoplasia (CIN), by optical and electrical measurement of cervical tissue.

TruScreen offers an alternative approach to cervical screening, resolving many of the ongoing issues with conventional Pap tests, including failed samples, poor patient follow-up, patient discomfort and the need for supporting laboratory infrastructure. As such, TruScreen’s target market is low and middle-income countries where no large-scale cervical cancer screening programs and infrastructure are in place, such as China, Mexico, Africa, Russia and India. TruScreen’s cervical cancer screening device is CE-marked and certified for use throughout Europe and NMPA (formerly CFDA) approved for sale in China. The global market potential for TruScreen is significant.