

# Validation of GeneXpert testing for Human Papillomavirus (HPV) and Self-Sample Collection for Cervical Cancer Screening in Gutu District, Zimbabwe

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# Background 1/4

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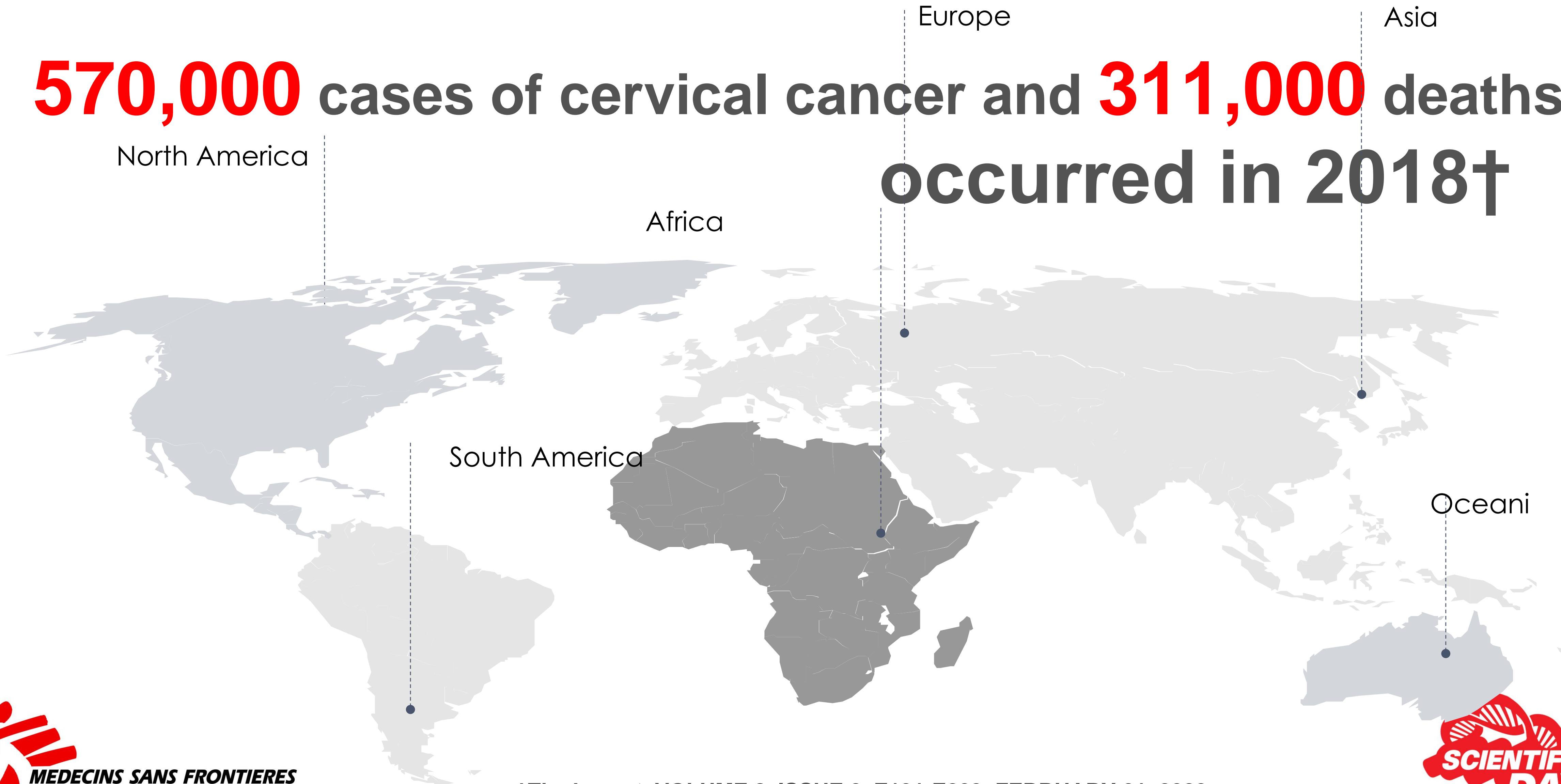
**Cervical cancer ranked in the top three cancers affecting women younger than 45 years**

# Background 1/4

**570,000** cases of cervical cancer and **311,000** deaths occurred in 2018†

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# Background 1/4



North America

Africa

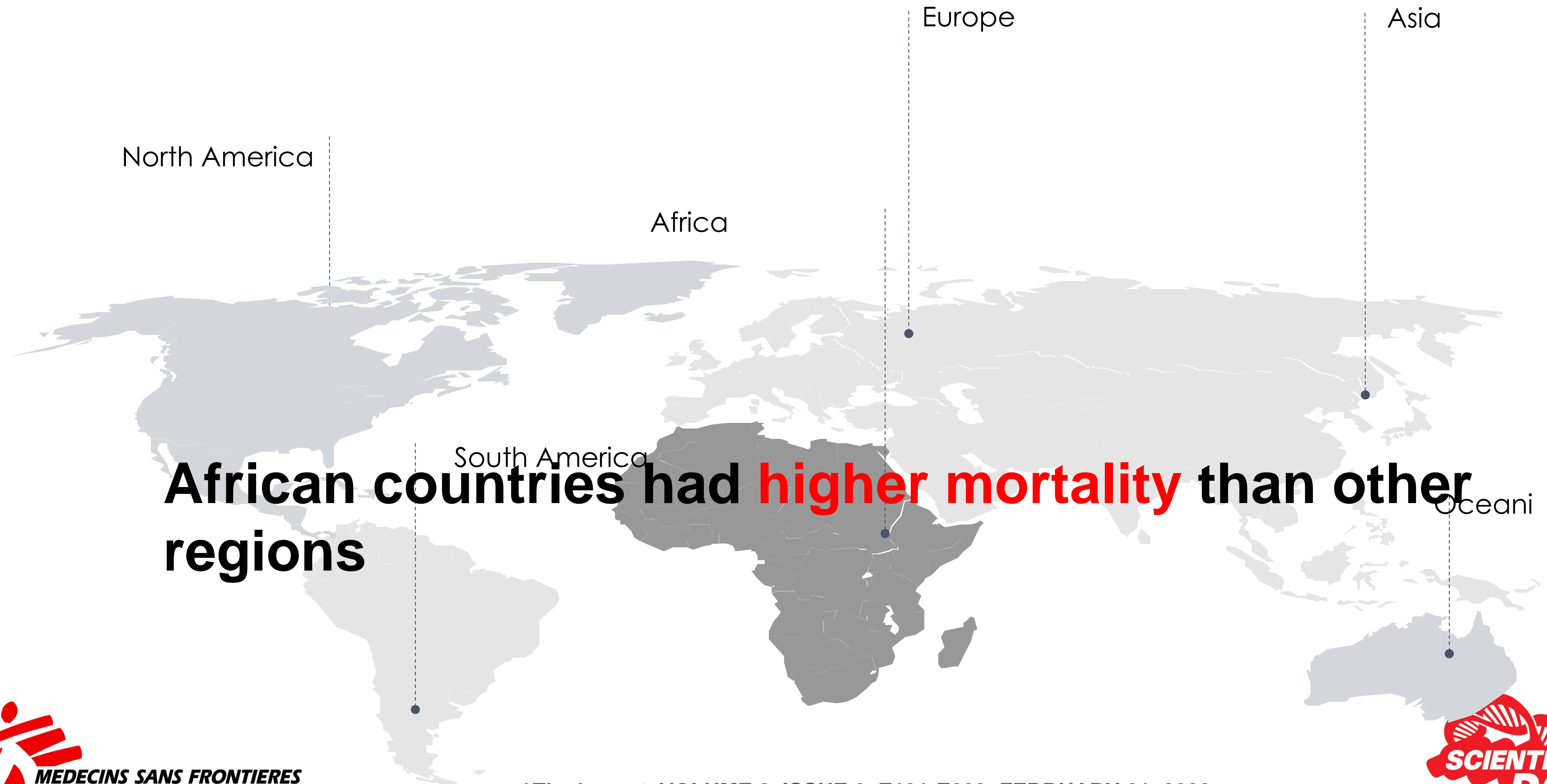
Europe

Asia

South America

Oceania

# Background 1/4



North America

Africa

Europe

Asia

South America

**African countries had higher mortality than other regions**

Oceania



†The Lancet VOLUME 8, ISSUE 2, E191-E203, FEBRUARY 01, 2020



# Background 1/4



North America

Africa

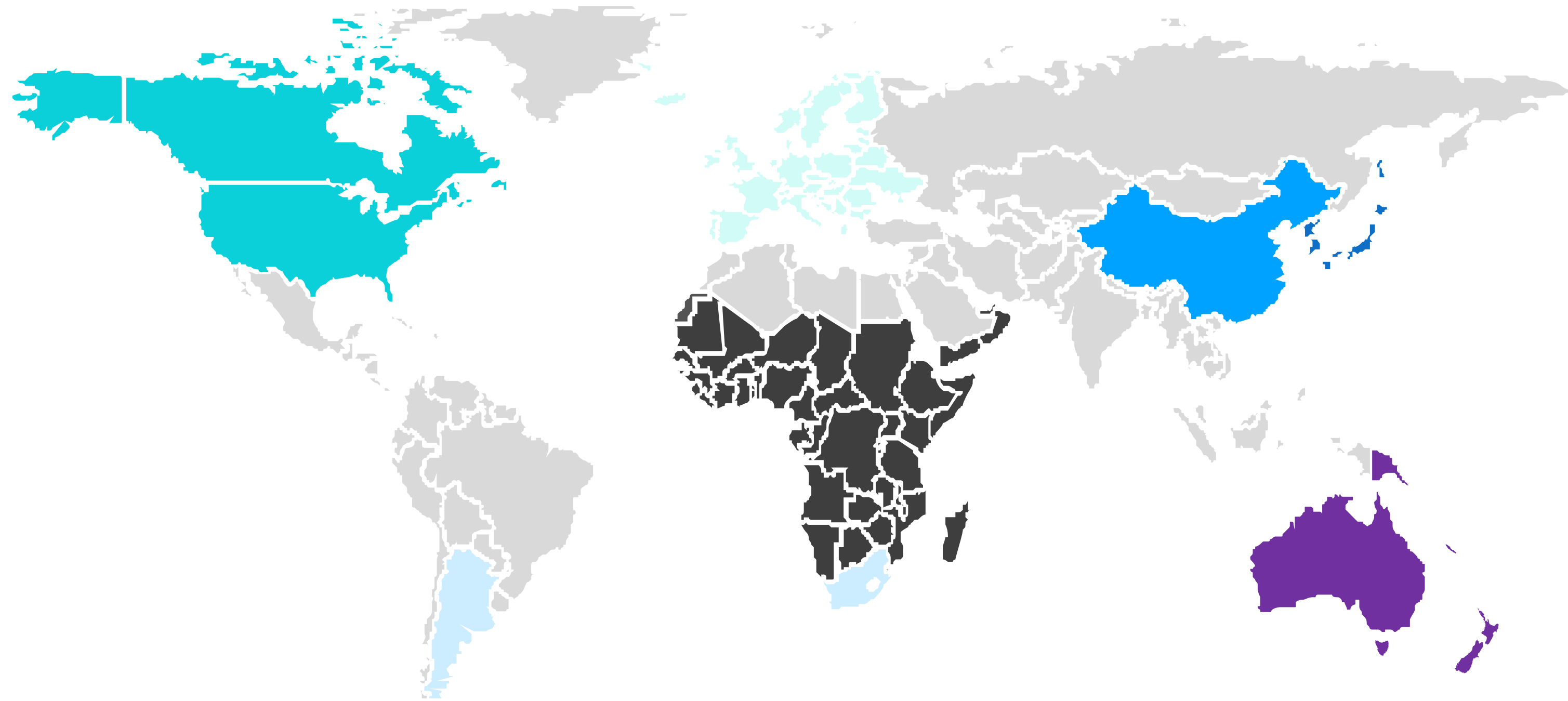
Europe

Asia

South America

Oceania

# Background 2/4





# Background 2/4

Screen and treat approaches reduce the burden in high-income countries **through cytology-based screening** that detects pre-cancerous abnormal cells

# Background 2/4

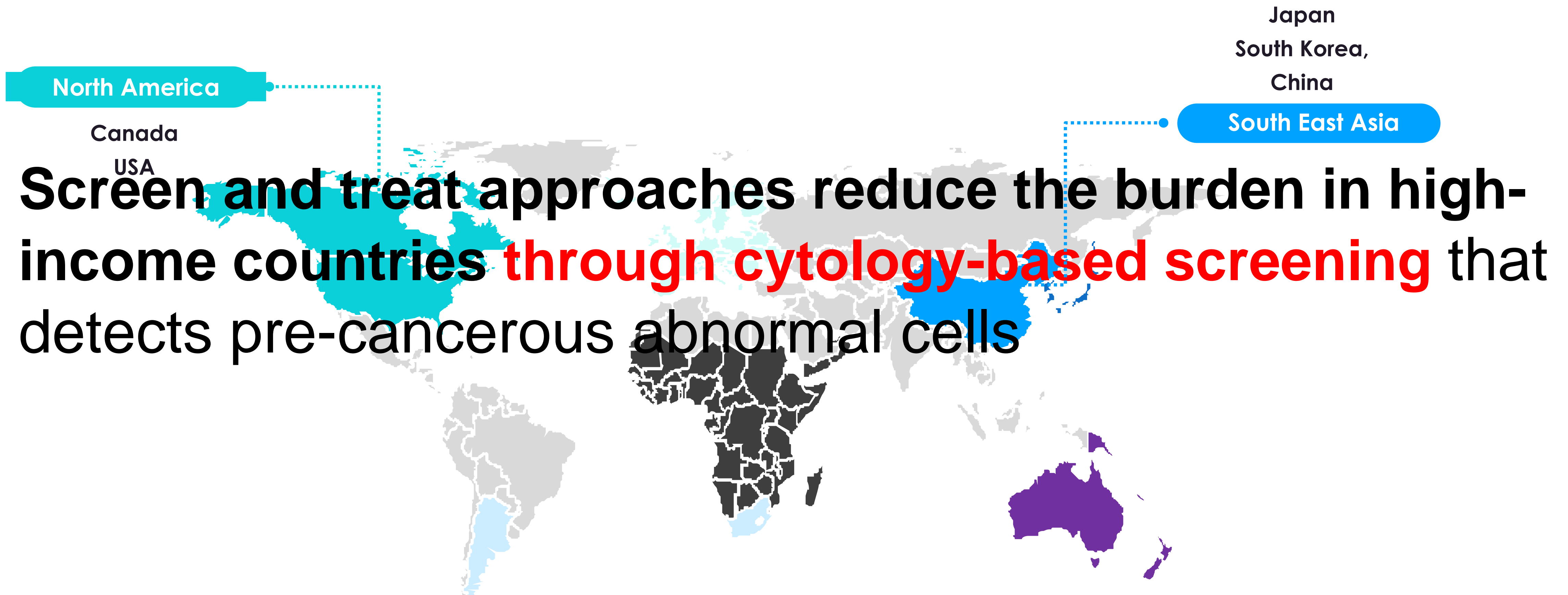
North America

Canada

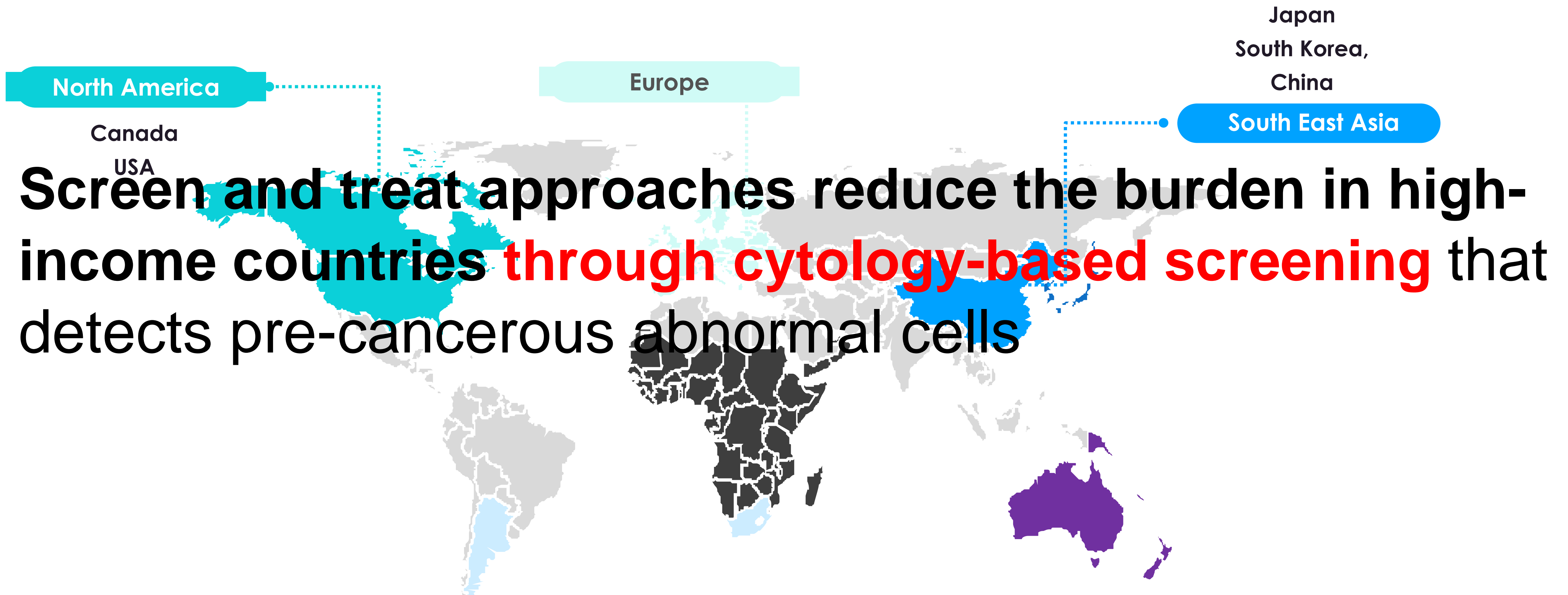
USA

Screen and treat approaches reduce the burden in high-income countries through cytology-based screening that detects pre-cancerous abnormal cells

# Background 2/4

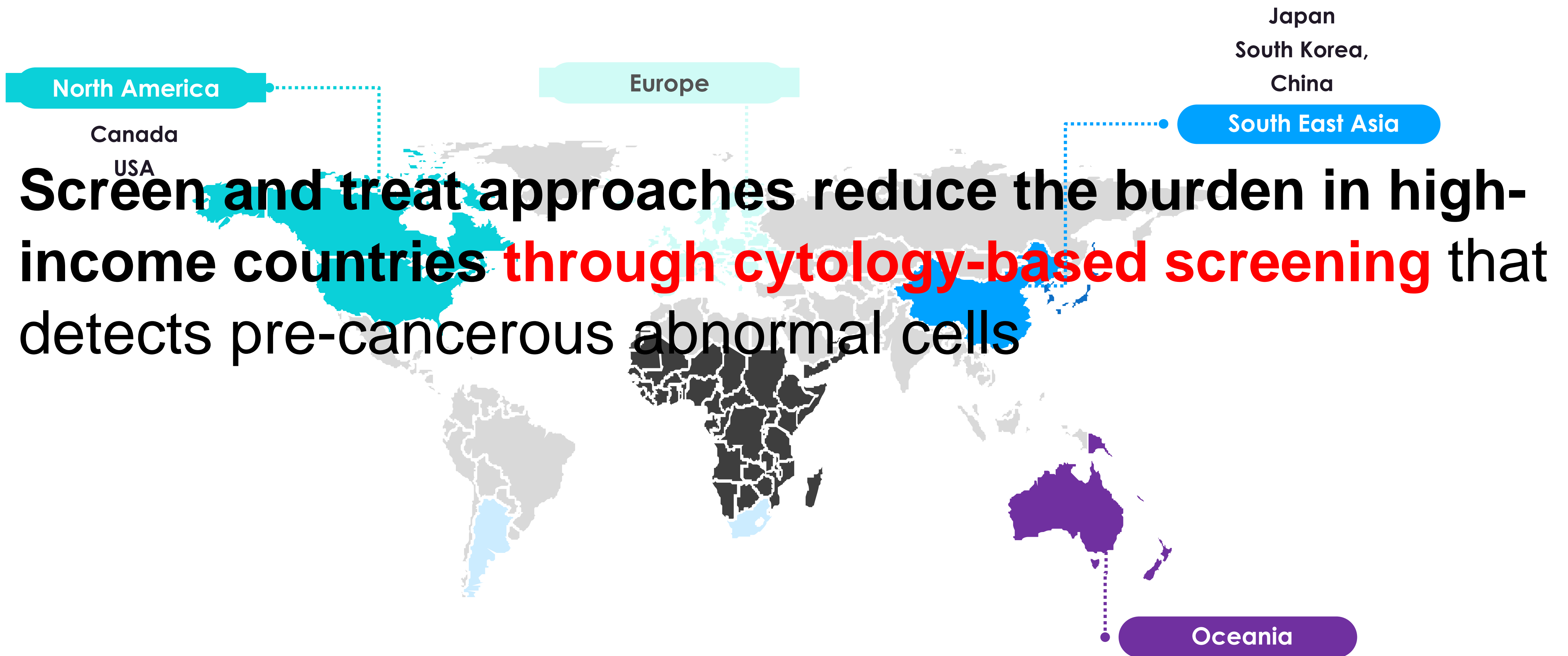


# Background 2/4

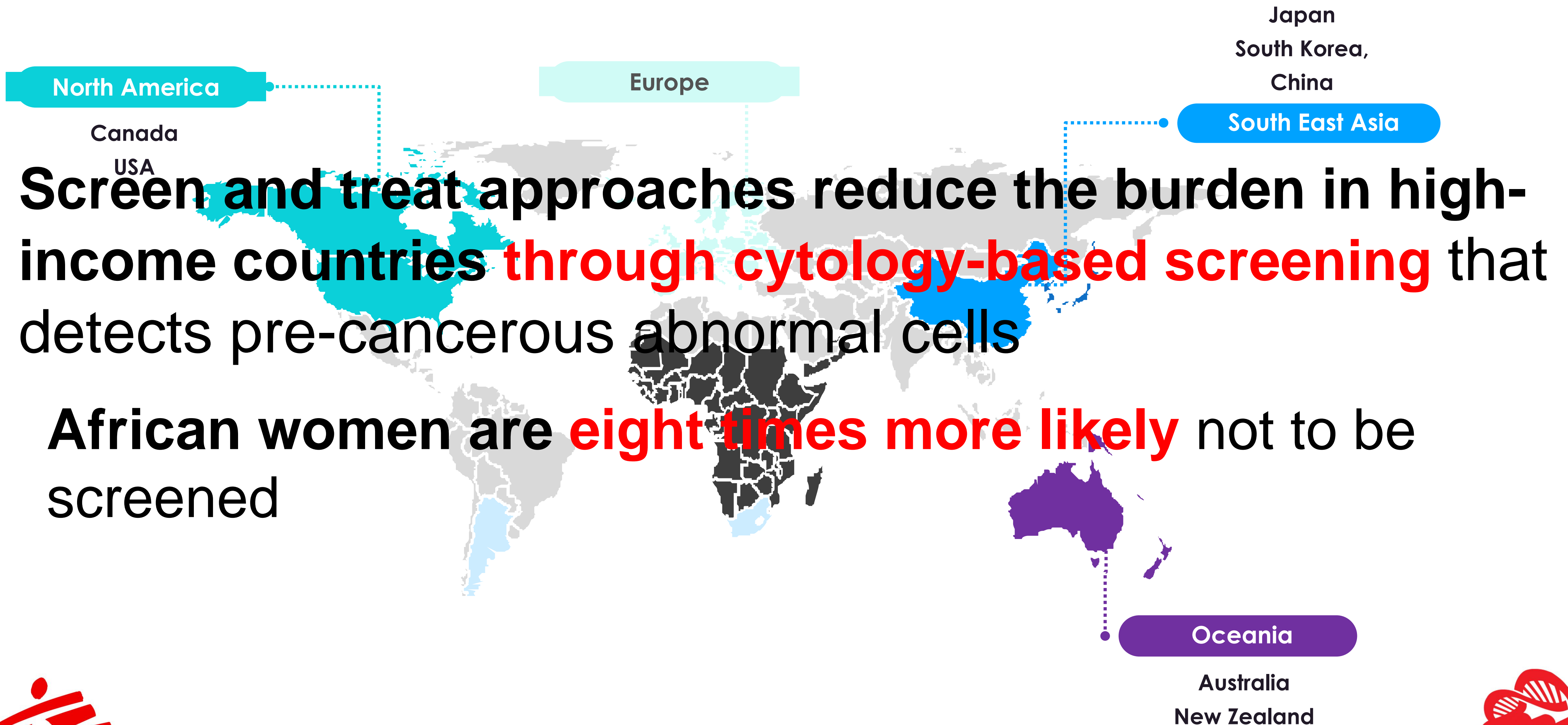




# Background 2/4



# Background 2/4



# Background 3/4

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**African countries have limited resources to replicate these strategies**

**Visual inspection with acetic acid and cervicography (VIAC)**

**Could be more visible and practical!**

# Background 4/4

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## GeneXpert

- TB and HIV viral load testing
- Early infant diagnosis

Leveraging existing GeneXpert machine to detect HPV - **the virus that causes cervical cancer**



# Objectives

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## **1. To determine the accuracy of diagnostic tests for HPV**

GeneXpert was compared with Cobas HPV, which was used as the reference test.

## **2. To determine diagnostic accuracy of 'self-collected' vs 'nurse-collected' samples using high vaginal swabs (HVS)**

HVS samples were tested for HPV. Nurse-collected HVS samples were used as the reference sample type.

# Methods 1/2

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**Study design:** Prospective diagnostic accuracy at four health facilities

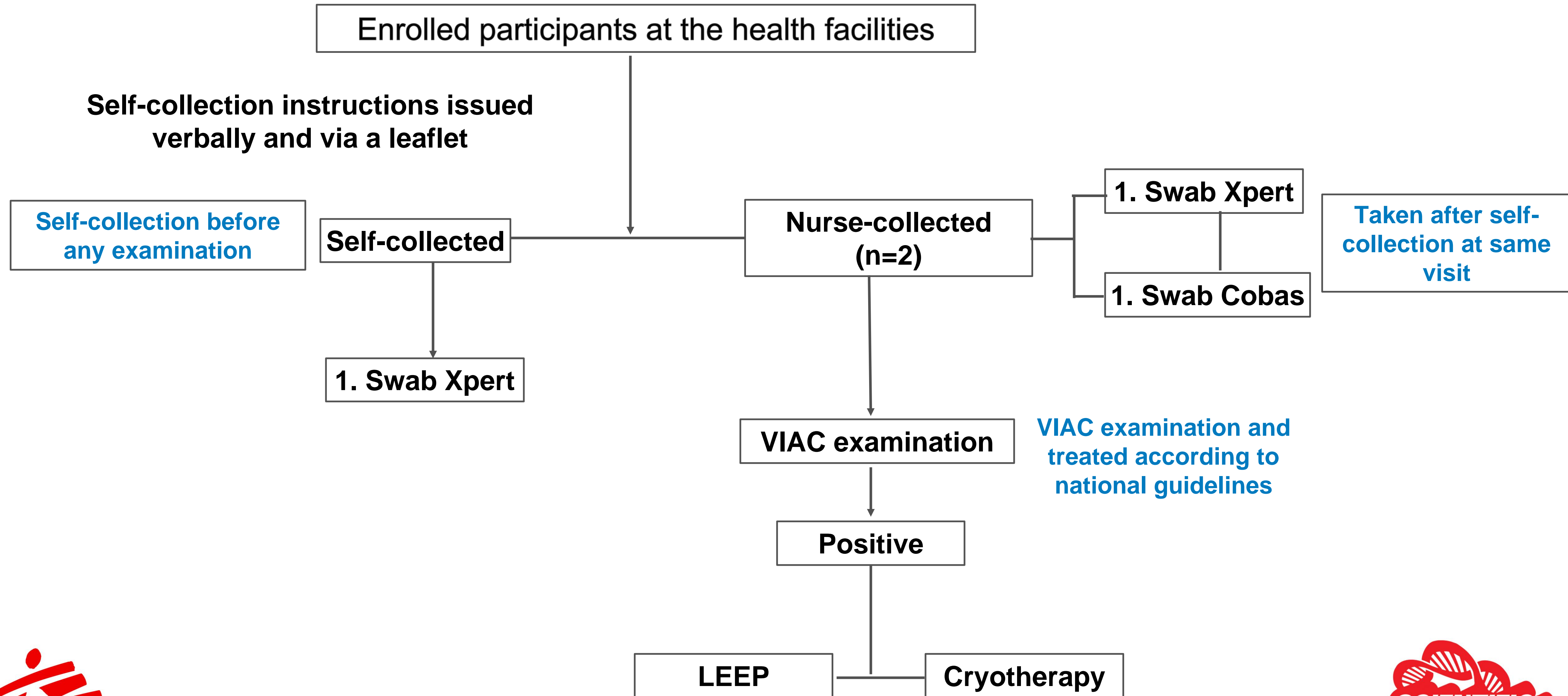
**Study group:** Women aged 18 to 65

**Sample size :** 316 participants

**Recruited :** 279 participants

**Ethical statement:** Study approved by MSF and Zimbabwean ERB

# Methods 2/2



# Results 1/4

## Demographic information

Characteristic	Participants enrolled (n=279)	Proportion (%)
Age Years		
19-29	62	22
30-39	86	31
40-49	77	28
50-59	42	15
60-65	12	4
HIV Status		
Negative	189	65
<b>Positive</b>	<b>97</b>	<b>35</b>

**47%**



# Results 2/4

## Comparison of test and swab type

Method	Swab type	Total enrolled	Invalid	HPV 16+	HPV 1845+
GeneXpert	Self-collected	279	8	10	15
GeneXpert	Nurse-collected	279	10	10	8
Cobas HPV	Nurse-collected	279	2	11	8

# Results 3/4

## Cobas HPV test vs GeneXpert HPV test

HPV sub-type detected	Performance (95% CI)		
	Sensitivity	Specificity	Kappa
HPV 16	91% (59-100)	100% (99-100)	0.95 (0.85-1.00)
HPV 1845	63% (25-92)	99% (97-100)	0.61 (0.33-0.90)

# Results 4/4

## Self-collected vs nurse-collected

HPV sub-type detected	Performance (95% CI)		
	Sensitivity	Specificity	Kappa
HPV 16	90% (56-100)	100% (98-100)	0.90 (0.75-1.00)
HPV 1845	88% (47-100)	97% (94-100)	0.61 (0.35-0.83)

# Conclusions

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## Comparable results

- GeneXpert vs Cobas HPV
- Self-collected vs nurse-collected samples

## GeneXpert availability is a plus

- TB and HIV viral load testing integrated in a single machine

## Self-collection and testing by GeneXpert reduces

- Turn-around time
- Workload for health workers



# Recommendations

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## **In progress - phase II of study**

Feasibility and acceptability of self-collected samples at on-site and off-site primary healthcare facilities

Advocate to change policy and guidelines to include GeneXpert as first-line test for HPV detection

# Acknowledgements

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## **Participants:**

Ministry of Health Staff

Zimbabwe National Medical Reference Lab

LANCET Laboratories (SA and Zimbabwe)

Zimbabwe Ministry of Health and Child Care

Zimbabwe Medical Research Council

MSF ERB Board