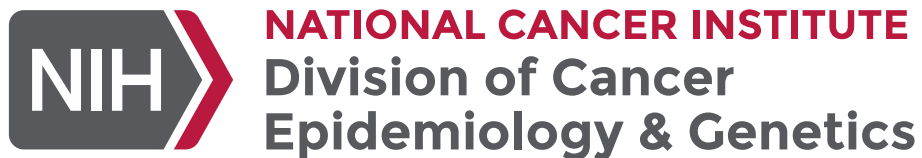


# RESEARCH AND IMPLEMENTATION OPPORTUNITIES TO ACCELERATE CERVICAL CANCER PREVENTION: COSTA RICA

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# Costa Rica HPV Vaccination Program

- Launched on June 3<sup>rd</sup>, 2019
- Target population: 10-year old girls only (N= 35,000 per year)
- Gardasil, 2-dose regimen
- School-based program
- Vaccination is mandatory by law and vaccines are applied by health care workers (ATAPs) from the Social Security System

Uptake per year

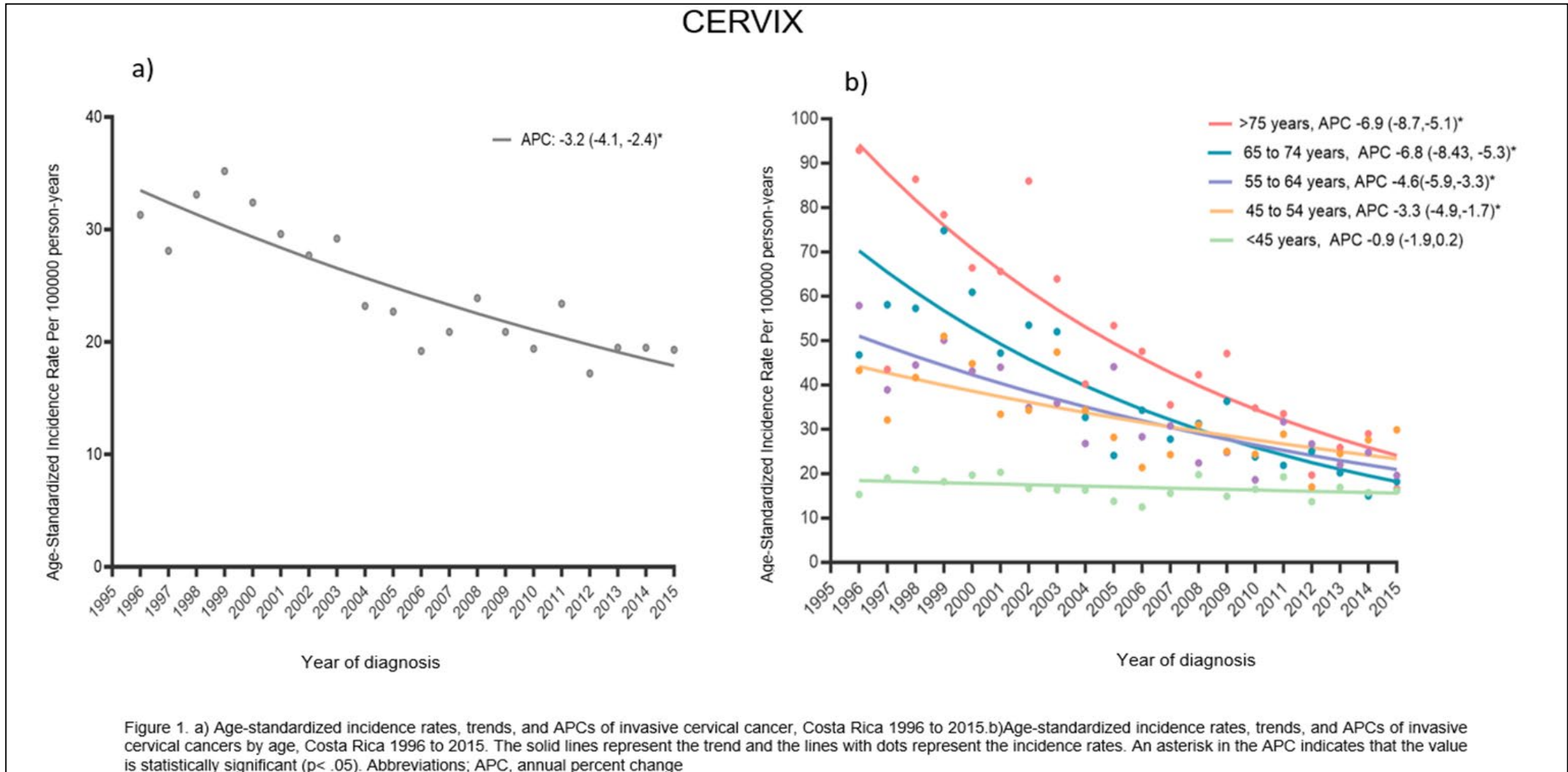
<b>Year</b>	<b>1st Dose</b>	<b>2nd Dose</b>
2019	98%	95%
2020	85%	75%
2021	55%	42%
2022	74%	69%
2023	80%	68%

Data from Epidemiological Surveillance Area, CCSS

# Cervical cancer screening program in Costa Rica

- Opportunistic program offered by the Social Security System and the private sector. Since 2006:
  - Any woman of  $\geq 20$  years of age a who has initiated vaginal sexual relations.
  - Method: cytology (mainly conventional cytology)
- New 'normative' signed in 2023 for the Comprehensive Management of Cervical Cancer.
  - Incorporates WHO guidelines for screening and treatment and ASCCP guidelines for abnormal cervical cancer screening
  - Primary screening methods:
    - Cytology: for women 20-29 years old
    - HPV test: for women 30 years and older (triage of with cytology and/or HPV-16/18)
  - Initiate HPV testing gradually and reach all geographic areas by the end of 2025

# Costa Rica cervical cancer incidence



# Two ideas for FASTER research in Costa Rica

- 1) Using the PRISMA trial, which (sort of) sets up for a FASTER evaluation (Aimee)
- 2) Country-wide assessment of cervical cancer incidence trends after implementation of single-dose HPV vaccination (up a broad age range) and HPV-based screening in a middle income country (Rolando)

# NCI/Costa Rica: Single-dose HPV vaccine trials

1. **ESCUDDO\*** (2018) – formal non-inferiority trial of 1 to 2 doses

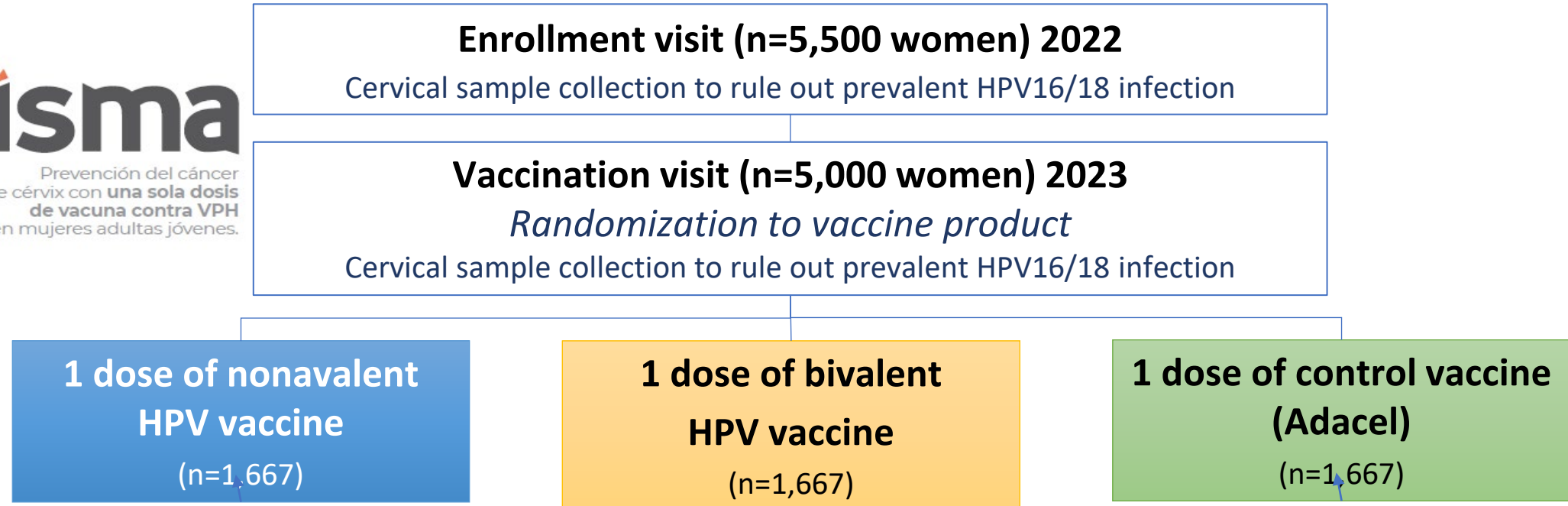
*Cancer Moonshot Initiative to Expand Use of Proven Cancer Prevention Strategies*

2. **PRIMAVERA\*** (2019) – immunobridging trial that could provide earlier and complementary results to ESCUDDO

3. **PRISMA\*** (2022) – 1 dose HPV vaccine efficacy in adult women to accelerate vaccine impact

4. **Original CVT** (2004) – 20-year duration of antibodies

# PRISMA: Single-dose HPV vaccine efficacy among adult women, to accelerate potential impact of HPV vaccination



**Active Follow-up: months 12, 18, 24, 30, 36 (2026)**

**Virologic (1<sup>o</sup>) and Immunologic (2<sup>o</sup>) endpoints**

Cervical samples collected at all study visits; Blood collected at vaccination and M12, M24, and M36

**Anal and oral samples collected at vaccination and M30 and M36**

# Is PRISMA an opportunity to investigate FASTER?

- 3 trial arms: 2v, 9v, non-HPV vax
- Women aged 21 to 33 at end of 3 year followup
- Safety exit procedures: At the final study visit, we can only release women if they do not have more than average risk of cervical precancer.
  - Risk-based algorithm(HPV data, other validated risk markers, etc)
  - Standard colposcopy for those who screen positive
  - Treatment will be provided to women with cervical precancer (work to safeguard against over-treatment given younger age).
- Could one additional post-screening cycle compare 'FASTER' (HPV vax and screening) to screening alone?
- Note: Sample size could be inadequate (n=~1600 per arm)



**What would a country-wide assessment of cervical cancer incidence trends after implementation of WHO recommendations for cervical cancer prevention look like?**