

Reported Pregnancy Outcomes Across NVX-CoV2373 COVID-19 Vaccine Primary Series and Booster Dose Clinical Studies

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BACKGROUND

- NVX-CoV2373 is a recombinant protein-based, adjuvanted COVID-19 vaccine that is authorized or approved for use in over 40 countries
- Limited data exist on the outcomes of identified pregnancies among the participants of COVID-19 vaccines clinical trials¹⁻⁶
- Pregnancy was an exclusion criterion for all NVX-CoV2373 trials; however, some female participants became pregnant during the program¹⁻⁶

OBJECTIVE

- Identify and characterize pregnancies among participants that received study vaccine or placebo in the NVX-CoV2373 COVID-19 vaccine clinical development program

1 Identification of pregnancies

- US/Mexico Phase 3^{2*}
n=29,949
- UK Phase 3³
n=15,187
- South Africa Phase 2b⁴
n=4,406
- US/Australia Phase 1/2^{5,6}
n=131 Phase 1
n=1,288 Phase 2



2 Examination of key pregnancy related data†

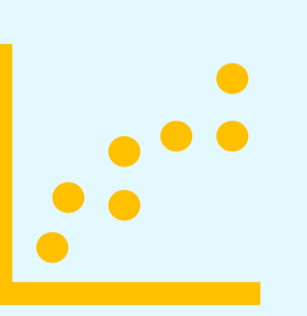
- Age
- Country
- Pregnancy outcome

†As of February 14, 2023



3 Analysis: demographics and outcomes

- Relative frequency of pregnancy outcomes were described in percentages

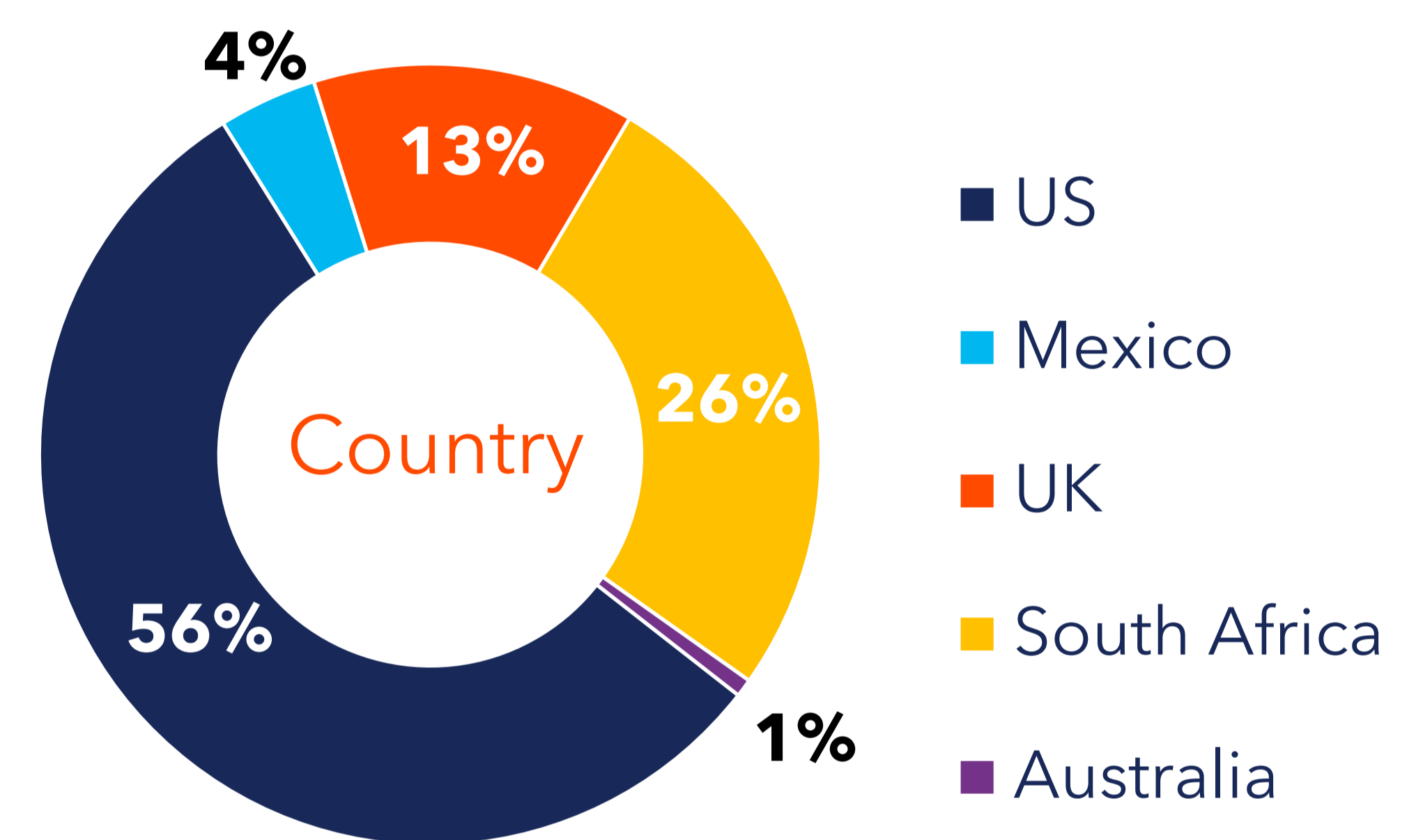


*Participants were randomly assigned in a 2:1 ratio to receive two doses of NVX-CoV2373 or placebo (all other studies randomized 1:1)

Frequency of Pregnancies by Country

% of total program-wide pregnancies

- Analysis included only blinded data
- 270** pregnancies identified among female participants across the NVX-CoV2373 COVID-19 vaccine clinical development program
- Mean (SD) age of 30.78 (6.22) years old¹
- 40 (14.8%) participants received a booster dose¹



Frequency of Pregnancy Outcomes

Pregnancy Outcome†	Total N=270	Percentage of Total (%)
Live Birth	124	45.9
Spontaneous Abortion/Miscarriage	36	13.3
Voluntary Termination	24	8.9
Termination Due to Pregnancy Abnormality	4	1.5
Termination Due to Fetal Abnormality	1	0.4
Ongoing/Withdrawn/Unknown	81	30.0

†No other birth outcomes were available

Average Spontaneous Abortion/Miscarriage Rates By Country

- US: 26%⁷⁻⁹
- UK: >20%¹⁰
- South Africa: 15-20%¹¹

Insights

- 30% of pregnancies had outcomes that were ongoing or unknown
- Program-wide observed spontaneous abortion/miscarriage rate seems to be similar to worldwide background data
- This analysis provides **preliminary descriptive data** on identified pregnancies and the associated outcomes across the NVX-CoV2373 COVID-19 vaccine clinical development program
- Continued follow up of ongoing pregnancies and future analysis of unblinded data can further inform the safety profile of NVX-CoV2373

Spontaneous Abortion/Miscarriage Rates

13.3%
Program-wide¹

15.30%
Worldwide¹²