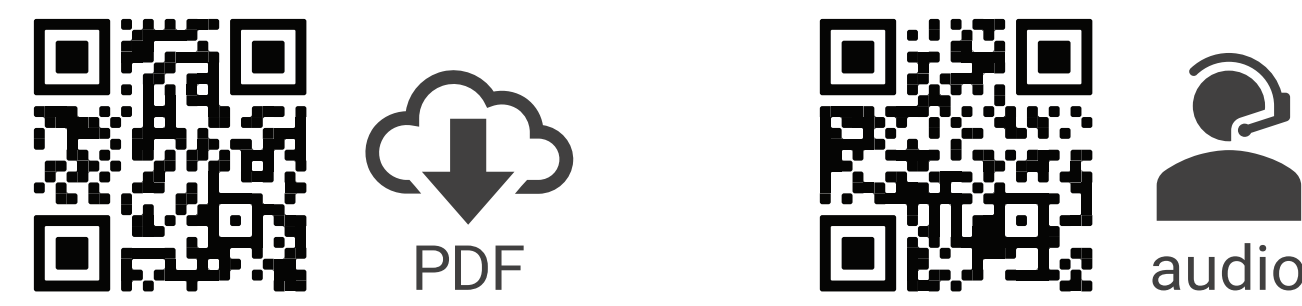


Prospective study evaluating pregnancy outcomes and pregnancy-related events of interest

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Interactive version available

Introduction

- Maternal immunisation can greatly reduce the burden of respiratory and other diseases in infants.
- For a better interpretation of safety data from clinical trials, it is paramount to understand the background rates of pregnancy outcomes and neonatal events of interest.
- Yet, such data are scarce and their collection is not standardised in low- and middle-income (LMI) regions.

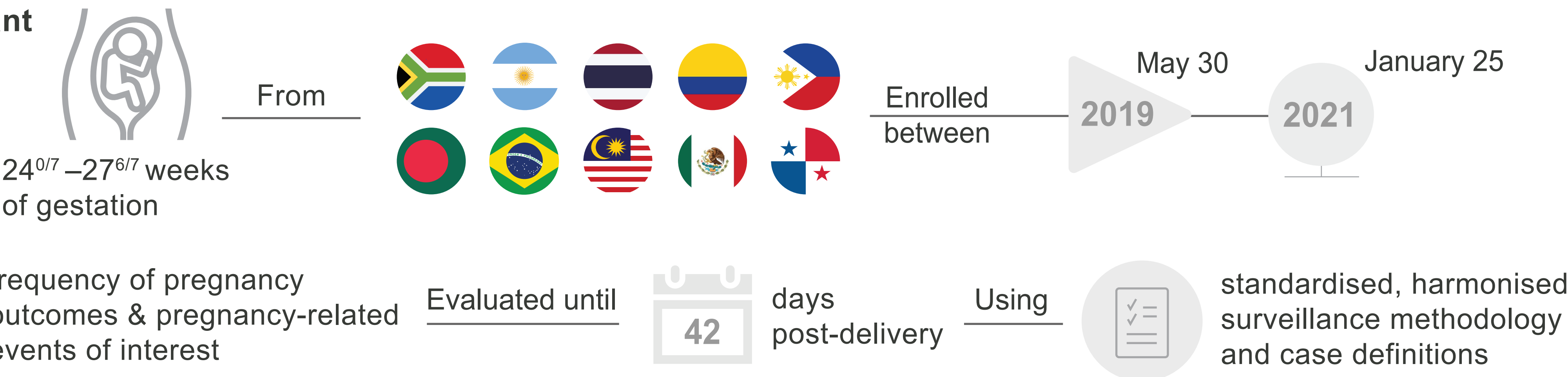
Objective

To estimate the incidence of pregnancy outcomes and pregnancy-related events of interest that may be considered adverse events if they occur after vaccination in healthy pregnant women in LMI regions.

Methods

Prospective, multi-country, low-interventional (without administration of medicines), cohort study (NCT03614676)

Healthy pregnant women aged 18–45 years

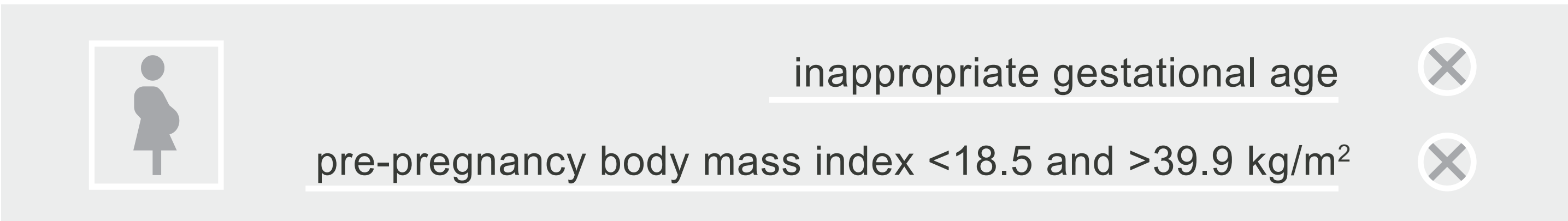


Endpoints

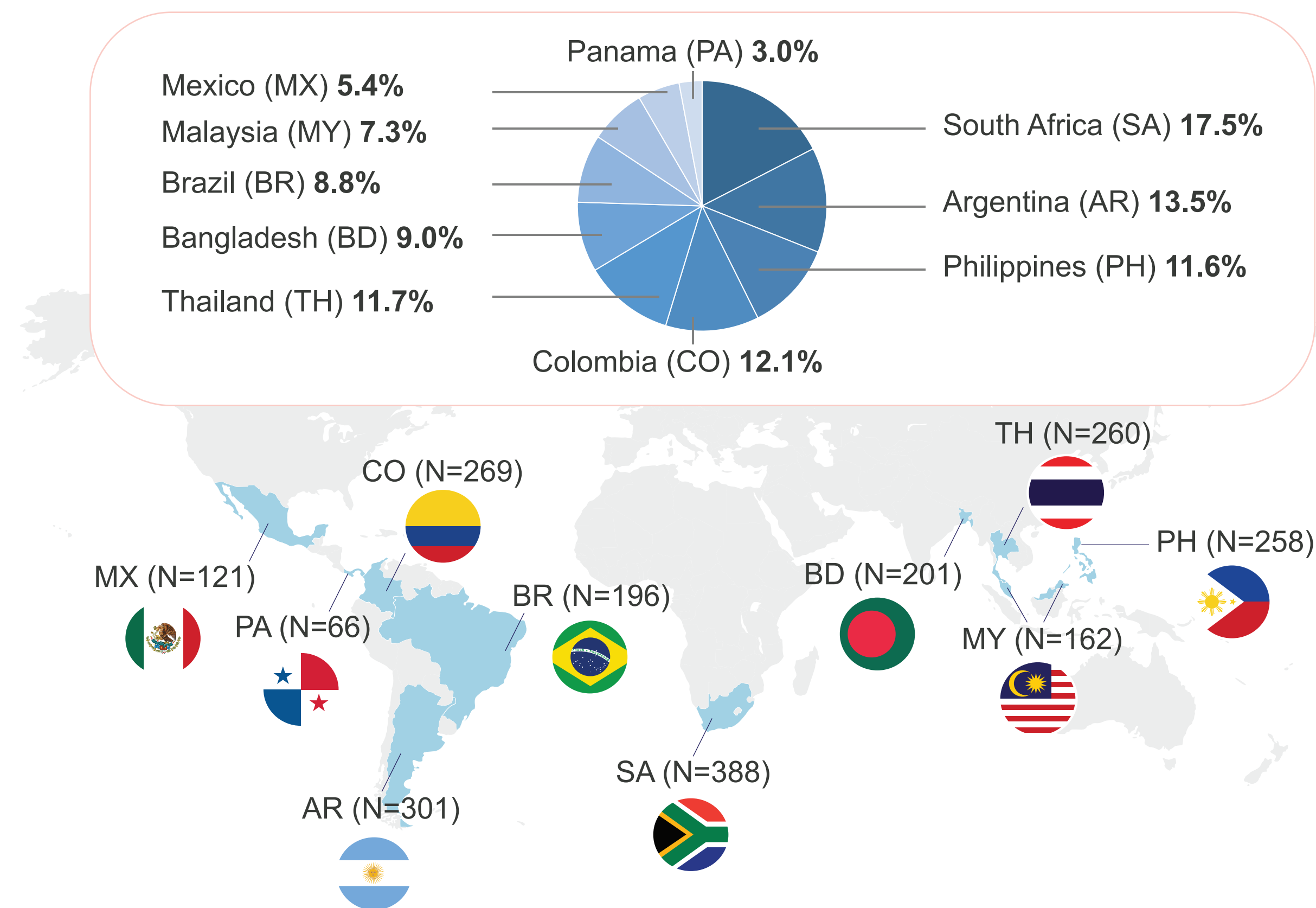
frequency of pregnancy outcomes & pregnancy-related events of interest

Results

Of **2311** women enrolled, **2222** were included in the analyses (per-protocol set); 89 did not meet the eligibility criteria, the **main exclusion reasons** being:

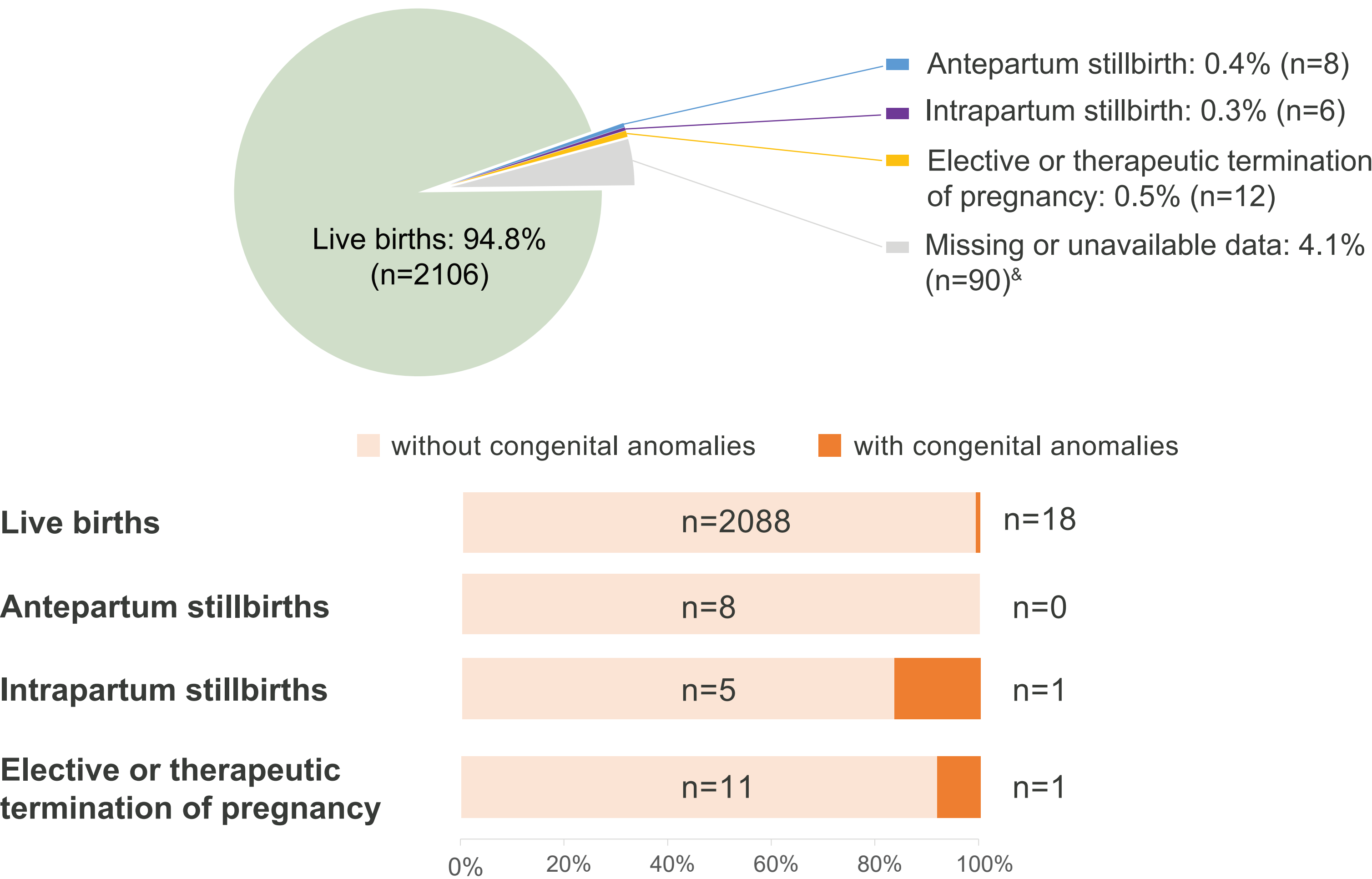


Number of women included (N) by country



Type and frequency of pregnancy outcomes

(% of a total of 2222 women included in the per-protocol analyses)



Key findings

The frequency of pregnancy outcomes was relatively similar across countries, although some variability was noted.

Overall, the most frequently reported pregnancy-related events were preterm delivery, non-reassuring fetal status and hypertensive disorders of pregnancy.

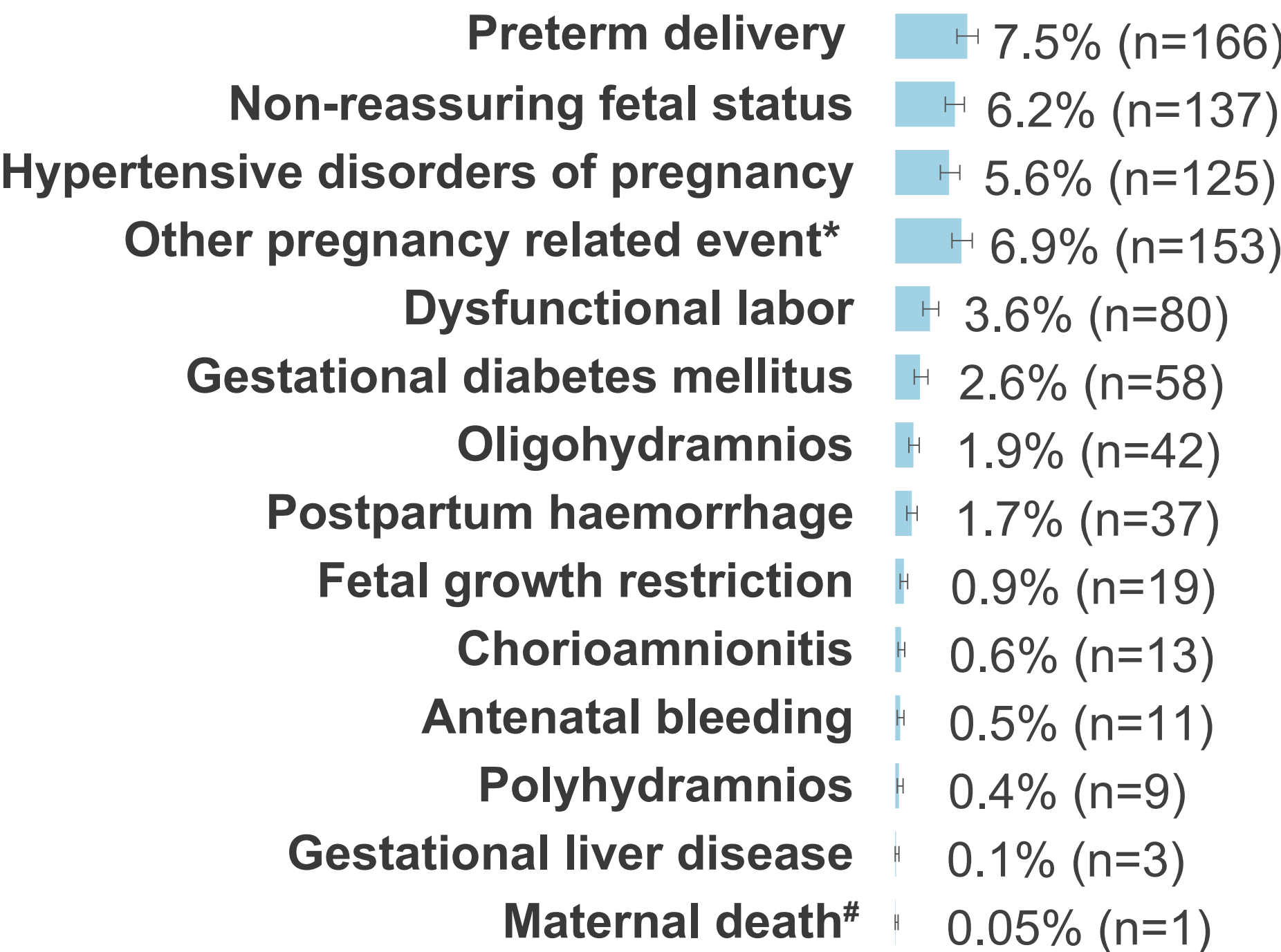
Conclusions

The **incidence of pregnancy outcomes and pregnancy-related events of interest** in healthy pregnant women in LMI regions was estimated, using a standardised and harmonised approach.

This study may facilitate the interpretation of safety data in **vaccine trials** or other studies in **pregnant women** and their **neonates**.

Pregnancy-related events of interest

(% of a total of 2222 women included in the per-protocol analyses)



*not specified but considered of interest by the investigators; #1 maternal death (due to postpartum haemorrhage with eclampsia) was recorded for a woman aged between 18–34 years in Bangladesh.
No maternal sepsis was reported. Confidence intervals are depicted as error bars.

Affiliations, Disclosures: available via the QR code
Funding: GlaxoSmithKline Biologicals SA

Acknowledgements: medical writing and editorial support provided by Lucia Adina Truta and Ana Vanessa Ferreira (Modis c/o GSK). The authors thank the study participants and their families, the investigators and staff, and the GSK clinical and serological laboratory teams.