

# Team 1 Presentation

## Introduction of a new Oral Live Attenuated Rotavirus Vaccine

Primary immunisation 3-dose scheme in newborn within 5 days and at 8 weeks and 14 weeks

- Team Lead: Patricia Mouta Nunes de Oliveira
- Presenter: Vanessa Infante
- Reporter: Reza Bosman
- Viska Indriani
- Aminata Diagne
- Fitriani Dewi



## Safety Issue/Research question

- New vaccine introduction into the EPI/NIP
- Change in EPI/NIP schedule
- Coadministration with other childhood vaccines etc. BCG(0), HepB(0), OPV(0)
- Vaccine composition – RV3 (G3P6)
- Intussusception is the main safety concern reported for other licensed Rotavirus vaccines

**Does the vaccine have the same safety profile in this age group for intussusception as the currently marketed vaccines?**



# Study design/methodology

- ▶ Review clinical development dossier to ensure the trials designs were able to identify rare adverse events such as intussusception – was it sufficiently powered to detect
  - ▶ Phase III trial was 1513 – which was considered a small sample size
  - ▶ This trial will be continued to include an additional 1400 participants
- ▶ Consider the incidence rate of the event in your country
  - ▶ Background incidence
  - ▶ Incidence of intussusception for other licensed vaccines
- ▶ Type of data collected will inform your decision of which method
- ▶ The frequency of intussusception in the exposed vs control group are similar
- ▶ Intussusception is an event that is medically attended in hospitals

A cohort event monitoring study was discussed as a potentially better option because the vaccine can be launched and the surveillance setup post-marketing to achieve the vaccinated numbers to power the study to identify the very rare risks of intussusception



# Data collection

- ▶ Strategy
  - ▶ Confirm cases of intussusception and then identify whether the patient was vaccinated and what vaccine they received and then determine whether the event occurred within the risk window or not
- ▶ Primary data
  - ▶ Standardized forms with required fields
  - ▶ Require informed consent for inclusion of participants
  - ▶ Ethical considerations is that it is a public health benefit



## Outcomes desired

- The frequency (rates) of intususception in the vaccinated (new borns) vs control group (currently marketed vaccines) are similar