Infants with at least 1 dose (n=34,644)

Randomized but not vaccinated (n=609)

Infants included in MITT analysis (n=33,163)
- Vaccinated infants excluded
  - No follow-up (n=10)
  - Not evaluable for case definition (n=862)
- No stool specimens (n=747)
- Late positive (n=6)
- Late negative (n=46)
- Insufficient clinical symptoms (n=3)
- Multiple reasons (n=60)

Randomized but not vaccinated (n=627)

Infants with at least 1 dose (n=34,035)
- Vaccinated infants excluded
  - No follow-up (n=13)
  - Not evaluable for case definition (n=975)
- No stool specimens (n=851)
- Late positive (n=20)
- Late negative (n=46)
- Insufficient clinical symptoms (n=5)
- Multiple reasons (n=53)

Placebo group
Infants randomized (n=34,630)

Vaccine group
Infants randomized (n=34,644)