500 subjects randomized

250 subjects assigned to PCV13 + P80 group
250 subjects received dose 1; 246 dose 2; 246 dose 3

- 4 withdrawals during infant series
  - 1 adverse event
  - 3 parent/legal guardian request

246 completed infant series

12 excluded from evaluable immunogenicity population
(Some subjects due to more than one reason)
- 4 did not receive all PCV13 vaccines
- 6 blood draw >42 days after infant series
- 5 excluded from all-available immunogenicity population*
  - 1 not eligible for study
  - 1 received vaccine other than randomized

238 subjects in infant evaluable immunogenicity population

6 withdrawn before toddler dose
- 3 parent/legal guardian request
- 2 adverse event
- 1 lost to follow-up

240 started toddler dose

1 withdrawn after toddler dose
- 1 lost to follow-up

239 completed study

19 excluded from evaluable immunogenicity population
(Some subjects due to more than one reason)
- 6 withdrawn before toddler vaccination
- 3 age >425 days on day of toddler dose
- 2 received vaccine other than randomized
- 8 blood draw >43 days after toddler dose
- 5 excluded from the all-available immunogenicity population

227 subjects in toddler evaluable immunogenicity population

250 subjects assigned to PCV13 w/o P80
250 subjects received dose 1; 249 dose 2; 247 dose 3

- 5 withdrawals during infant series
  - 3 adverse event
  - 1 protocol violation
  - 1 parent/legal guardian request

245 completed infant series

12 excluded from evaluable immunogenicity population
(Some subjects due to more than one reason)
- 3 did not receive all PCV13 vaccines
- 5 blood draw >42 days after infant series
- 5 excluded from all-available immunogenicity population*
  - 1 not eligible for study
  - 1 received vaccine other than randomized
  - 1 received prohibited vaccines†

238 subjects in infant evaluable immunogenicity population

1 withdrawn before toddler dose
- 1 parent/legal guardian request

244 started toddler dose

2 withdrawn after toddler dose
- 1 lost to follow-up
- 1 parent/legal guardian request

242 completed study

7 excluded from evaluable immunogenicity population
(Some subjects due to more than one reason)
- 1 withdrawn before toddler vaccination
- 1 received vaccine other than randomized
- 4 blood draw >43 days after toddler dose
- 1 excluded from all-available immunogenicity population
- 1 not eligible for study

238 subjects in toddler evaluable immunogenicity population

*5 subjects from each group were excluded from the all-available immunogenicity populations for having no postinfant assay results for any serotype
†Received meningococcal vaccine during the infant series