The study listed may include approved and non-approved uses, formulations or treatment regimens. The results reported in any single study may not reflect the overall results obtained on studies of a product. Before prescribing any product mentioned in this Register, healthcare professionals should consult prescribing information for the product approved in their country.

**Study Number:** 112595 (10PN-PD-DIT-053)

**Title:** Impact on nasopharyngeal carriage, acute otitis media, immunogenicity and safety of GSK Biologicals' pneumococcal conjugate vaccine 1024850A.
*Synflorix*™- GSK1024850A (10Pn): GlaxoSmithKline (GSK) Biologicals' 10-valent pneumococcal polysaccharide and non-typeable *Haemophilus influenzae* (*H. influenzae*) protein D conjugate (10Pn-PD-DiT) vaccine.

**Rationale:** The aim of this study was to assess the impact of 10Pn on nasopharyngeal carriage, acute otitis media (AOM), the immunogenicity and safety in subjects which 10Pn vaccine was given either as a 2-dose or 3-dose primary vaccination course in children below 7 months of age with a booster dose given early in the second year of life, or when given as a catch-up immunization dose in children 7 to 18 months of age. For all subjects enrolled in this study in combination with data collected for subjects enrolled in the 10PN-PD-DIT-043 (111442) study, within which this study is nested, vaccine effectiveness in preventing culture-confirmed or probable cases of ID and impact on hospital-diagnosed pneumonia cases, occurrence of tympanostomy tube placement and outpatient antimicrobial prescriptions was evaluated using data collected from the national registers. Control vaccines were GSK Biologicals' *Engerix B*™, in children below 12 months of age, and *Havrix 720 Junior*™, in children aged 12 months and above.
Duration of treatment in this study was of, approximately, 18 months for subjects enrolled between 6 weeks and 6 months of age, 15 months for subjects enrolled between 7 to 11 months of age, and 10 months for subjects enrolled between 12 to 18 months of age.
Refer to the 111442 CTRS for further details and results of the 10PN-PD-DIT-043 (111442) study.

*Engerix B*™ (HBV): GSK Biologicals' Hepatitis B vaccine.
*Havrix*™ *720 Junior* (HAV): GSK Biologicals' Hepatitis A vaccine.

**Phase:** III

**Study Period:** 18 February 2009 (Study start) to

- 22 December 2011 (Last Subject Last Visit in this 112595 study)
- 31 January 2012 (End time point for the Primary Objective and Outcome analysis common to both 111442 and 112595 studies)

**Study Design:** Double-blind, cluster-randomized, controlled study with 4 groups of clusters* (2:2:1:1)
This study was nested in 10PN-PD-DIT-043 (111442) study and was carried out in 50 clusters* out of total 78 study clusters, including 6 which recruited solely to this 112595 study.
** Refer to the Treatment section for definitions of the study clusters.*

**Centres:** 15 centres in Finland**.**

**Indication:** Active immunization against *S. pneumoniae* serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, and 23 F, and *H. influenzae* in children aged 6 to 18 months.

**Treatment:** Municipalities participating to the study were organised into the following 4 parallel groups of clusters (2:2:1:1):

- 10Pn 3+1 group of clusters: Subjects enrolled in the 10Pn 3+1 clusters received 10Pn vaccine. Children enrolled in these clusters between 6 weeks and 6 months of age received a 3-dose primary vaccination schedule.
- 10Pn 2+1 group of clusters: Subjects enrolled in the 10Pn 2+1 clusters received 10Pn vaccine. Children enrolled in these clusters between 6 weeks and 6 months of age received a 2-dose primary vaccination schedule.
- Control 3+1 group of clusters: subjects enrolled in the Control 3+1 clusters received HBV vaccine if < 12 months of age at the time of first study vaccination, or HAV vaccine if ≥ 12 months of age at the time of first study vaccination. Children enrolled in these clusters between 6 weeks and 6 months of age received a 3-dose primary vaccination schedule.
- Control 2+1 group of clusters: subjects enrolled in the Control 2+1 clusters received HBV vaccine if < 12 months of age at the time of first study vaccination, or HAV vaccine if ≥ 12 months of age at the time of first study vaccination. Children enrolled in these clusters between 6 weeks and 6 months of age received a 2-dose primary vaccination schedule.

Vaccination schedules and study groups depended on the age at enrolment:

- Infants enrolled between 6 weeks and 6 months of age: 3-dose primary vaccination with 10Pn vaccine ("10Pn3+1 Schedule") or HBV vaccine ("Ctrl3+1 Schedule") with an interval of at least 4 weeks, or 2-dose primary vaccination with 10Pn vaccine ("10Pn2+1 Schedule") or HBV vaccine ("Ctrl2+1 Schedule") with an interval of at least 8 weeks, followed by a booster dose of the same vaccine with an interval of preferably 6 months since the previous vaccine

dose (minimum 4 months).
This age group is also referred to as the "Infant cohort".

- Catch-up infants enrolled between 7 and 11 months of age: 2-dose primary vaccination with either 10Pn ("Catch-up 7-11M-10Pn") or HBV vaccine ("Catch-up 7-11M-Ctrl") with an interval of at least 4 weeks, followed by a booster dose of the same vaccine with an interval of preferably 6 months since the previous vaccine dose (minimum 4 months) ("7-11M Schedule").
- Catch-up toddlers enrolled between 12 and 18 months of age: 2-dose vaccination with 10Pn ("Catch-up 12-18M-10Pn") or HAV vaccine ("Catch-up 12-18M-Ctrl") with an interval of at least and preferably 6 months between doses ("12-18M Schedule").

The age group between 7 and 18 months of age is also referred to as the "Catch-up cohort"

All study vaccines were administered intramuscularly in the thigh, or in the deltoid region of upper arm in children aged ≥ 12 months, provided the muscle size was adequate.

**Objectives:***

- To demonstrate the effectiveness of 10Pn vaccine in preventing culture-confirmed Invasive Pneumococcal Disease (IPD) due to vaccine pneumococcal serotypes in children vaccinated with at least one dose of 10Pn within the first 7 months of life in clusters assigned to a 3-dose primary vaccination course.
  *Criterion for effectiveness:*
  *Effectiveness (VE) in preventing culture-confirmed IPD due to the 10 vaccine serotypes was demonstrated if the 2-sided p-value calculated for the null hypothesis H0 = (vaccine-type [VT] IPD VE = 0%) was lower than 5%.*

**This is the Primary Objective of the 111442 study in which this study was nested. Subjects enrolled to 112595 study contributed to this primary objective of the 111442 study as well as to its secondary objectives, and results are presented in the 111442 CTRS. All objectives of this nested 112595 study are secondary objectives and thus not listed here.*

**Primary Outcome/Efficacy Variable:**

In children starting vaccination within the first 7 months of life in clusters assigned to a 3-dose primary vaccination course:

- Occurrence of culture-confirmed IPD due to any of the 10 pneumococcal vaccine serotypes.

**This is the Primary Outcome of the 111442 study and subjects of the 112595 study, as nested within the 111442 study, are contributing to this primary outcome of the main 111442 study. Results for this Primary Outcome are presented in the 111442 CTRS. All outcomes in this nested 112595 study are secondary outcomes and listed in the Secondary Outcome section below*

**Secondary Outcome/Efficacy Variable(s):**

*Effectiveness*

In children starting vaccination within the first 7 months of life in clusters assigned to a 2-dose primary vaccination course:

- Occurrence of culture-confirmed IPD due to any of the 10 pneumococcal vaccine serotypes[µ].

In the vaccinated population:

- Occurrence of culture-confirmed ID due to any of the bacterial pathogens listed below[µ]:
  - any and each of the 10Pn vaccine serotypes
  - any and each of the vaccine-related pneumococcal serotypes
  - any and each of the other pneumococcal serotypes
  - any and each of the *H. influenzae* types
  - any other bacterial pathogen
- Occurrence of probable cases of ID caused by the bacterial pathogens as listed above[µ]
- Occurrence of hospital-diagnosed pneumonia cases[µ]
- Occurrence of hospital-diagnosed pneumonia cases with abnormal pulmonary infiltrates on the chest X-ray (CXR pneumonia) based on the chest X-ray (CXR) reading according to WHO criteria [µ]
- Occurrence of hospital-diagnosed pneumonia cases with alveolar consolidation/pleural effusion on the CXR (CXR-AC pneumonia) based on the CXR reading according to WHO criteria[µ]
- Occurrence of hospital-diagnosed pneumonia cases without alveolar infiltrates or pleural effusion on the CXR (CXR-NAC pneumonia) based on the CXR reading according to WHO criteria[µ]
- Occurrence of tympanostomy tube placements[µ]
- Occurrence of outpatient antibiotic prescriptions[µ]
- Antimicrobial susceptibility of *S. pneumoniae* and *H. influenzae* isolated from invasive disease[£]

*Carriage*

- Occurrence of *H. influenzae, S. pneumoniae* and/or other bacterial pathogens in the nasopharynx
- Acquisition of new *H. influenzae* and/or *S. pneumoniae* strains in the nasopharynx

*Immunogenicity (in the Immuno subset[%])*

- Subjects from 6 weeks to 6 months of age:
  - Concentration of antibodies and opsonophagocytic activity (OPA) against components of the 10Pn vaccine
    - Concentrations of antibodies and OPA against vaccine pneumococcal serotypes
    - Concentrations of antibodies and OPA against cross-reactive pneumococcal serotypes 6A and 19A
  - Antibody concentrations against protein D
- Subjects from 7-11 and 12-18 months of age:
  - Concentration of antibodies against components of the 10Pn vaccine
    - Concentrations of antibodies against vaccine pneumococcal serotypes.
    - Concentrations of antibodies against cross-reactive pneumococcal serotypes 6A and 19A.

*Clinical acute otitis media (AOM)*

- Occurrence of AOM with level 1 of diagnostic certainty.
- Occurrence of recurrent AOM based on level 1 of diagnostic certainty.
- Occurrence of AOM with level 1 of diagnostic certainty with documented antimicrobial prescription.

*Respiratory tract infection (RTI), including AOM (in a subset of subjects in Turku area)[X]:*

- Occurrence of lower respiratory tract infections (LRTIs).
- Occurrence of upper respiratory tract infections (URTIs), including AOM as specified below:
  - AOM with level 1-3 of diagnostic certainty.
  - Recurrent AOM based on level 1-3 of diagnostic certainty.
  - AOM by severity.
  - AOM with level 1-3 of diagnostic certainty with documented antimicrobial prescription.

*Safety**

- Occurrence of solicited local adverse events (AEs) (any, grade 3) within 4 days after each vaccination
- Occurrence of solicited general AEs (any, grade 3, related) within 4 days after each vaccination.
- Occurrence of unsolicited AEs within 31 days after each vaccination.
- Occurrence of serious adverse events (SAEs) following administration of the first vaccine dose up to study end.

*[μ]Results for these Secondary Outcomes concern subjects enrolled in this study as well as those enrolled in the 111442 study. These results are presented in the 111442 CTRS.*
*[£]Results on this outcome were not available at the time of writing of this CTRS. They will be posted in the 111442 CTRS when available.*
*[%]The Immuno subset was constituted of the first ± 1500 subjects from whom blood samples were collected, according to age and treatment groups. The Month 0 nasopharyngeal swab samples collected from subjects within their first 7 months of age were obtained solely from this Immuno subset.*
*[X]Exploratory analysis of outcomes related to impact on AOM severity, LRTI and URTI in the Turku area are not included in this CTRS because they are uninterpretable due to low sample size.*
**In addition, SAEs notified via passive surveillance were collected – from 31 January 2012 (end time point for the Primary Objective) till 05 October 2013 (the end of the 18-month period after study unblinding). Please refer to the 111442 CTRS for these results.*

**Statistical Methods:** The analyses were performed on cohorts defined as follows:

- The Total Vaccinated cohort for analysis of safety and carriage included all subjects with at least one vaccine administration documented.
- The Total Vaccinated cohort for analysis of carriage included all vaccinated subjects for whom data concerning carriage outcome measures were available.
- The Total Vaccinated cohort for analysis of AOM/RTI effectiveness included all vaccinated subjects for whom data concerning AOM/RTI effectiveness outcome measures were available. Note that the effectiveness analysis was performed considering cluster randomisation methodology and that wrongly randomised subjects for cluster randomisation effects were excluded from this analysis.
- The According-to-Protocol (ATP) cohort for immunogenicity included all evaluable subjects (i.e. those meeting all eligibility criteria, complying with the procedures and intervals defined in the protocol, with no elimination criteria during the study) for whom data concerning immunogenicity outcome measures were available.

Analyses of carriage, immunogenicity and safety were performed as per individually randomised subject9s attributed to the

actual treatment received.

*Analysis of Carriage*

The analysis was based on the Total Vaccinated cohort for analysis of carriage.

At each time point where a swab sample result was available, the following analyses were performed:

- Percentage of subjects with positive nasopharyngeal sample was tabulated with 95% confidence interval (CI)
- Vaccine efficacy estimated as [(1-relative risk)*100] with 95% CI was tabulated for carriage of *H. influenzae*, *S. pneumonia*e and other bacterial pathogens.

Cumulative acquisition of new bacteria/serotypes in the nasopharynx was also tabulated with 95% CI.

*Analysis of Immunogenicity*

The analysis of immunogenicity was performed on the ATP cohort for immunogenicity.

For each treatment group in each age range and at each time point where a blood sample result was available, the following parameters were tabulated with 95% CIs:

- Antibody geometric mean concentrations (GMCs), measured by 22F-inhibition enzyme-linked immunosorbent assay (ELISA), and seropositivity* rates for responses to each vaccine/cross-reactive pneumococcal serotype and protein D
- The percentage of subjects with pneumococcal antibody concentrations against serotypes 1, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F ≥ 0.05 µg/mL and ≥ 0.2 µg/mL
- The percentage of subjects with anti-PD antibody concentrations ≥ 100 EL.U/mL

For the subjects from 6 weeks to 6 months of age and for each treatment group, and at each time point where a blood sample result was available, the following parameters were tabulated with 95% CIs:

- Antibody geometric mean titres(GMTs)
- The percentage of subjects with OPA against pneumococcal serotypes 1, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F ≥8.

*A seropositive subject was a subject with antibody concentration ≥ 0.05 µg/mL and 100 EL.U/mL cut-off values for pneumococcal and anti-PD antibody concentrations, respectively.

*Analysis of Effectiveness*

The analysis of Effectiveness was performed on the Total Vaccinated cohort for analysis of AOM/RTI effectiveness.

An initial analysis of AOM/RTI was performed using one fixed calendar date as end of follow-up time for all subjects, similarly to what was applied for the effectiveness outcomes common with 111442 study in which effectiveness outcome collection was performed via national registers. A post-hoc re-analysis of AOM/RTI objectives with the corrected definition of follow-up taking into account individual end of follow-up time was performed; the results of re-analysis as the most prominent for AOM outcome are presented in this CTRS.

The AOM/RTI effectiveness outcomes were analysed descriptively applying the following algorithm:

- Using a negative binomial log-linear model favouring correction for the cluster effect by taking into account for over-dispersion associated to cluster.
- In case of convergence issue with the first model, a negative binomial log-linear model was applied.
- If the over-dispersion was null, the above models were replaced by a standard Poisson model

Any of these models was applied to derive the vaccine efficacy (VE), defined as 1-relative risk, and its 95% CI.

Exploratory analysis of outcomes related to impact on AOM severity, LRTI and URTI in the Turku area are not included in this CTRS because they are uninterpretable due to low sample size

*Analysis of Safety*

The analysis was performed on the Total Vaccinated cohort for analysis of safety and carriage.

The percentages of subjects reporting each individual solicited local and general AE during the 4-day (day 0-day 3) solicited follow-up period after vaccination were tabulated with exact 95% CIs. The same tabulation was performed for grade 3 AEs and for general AEs assessed by the investigators as causally related to the vaccination. The percentage of subjects with at least one unsolicited AE reported during the 31-day (Days 0-30) follow-up period and classified by the Medical Dictionary for Regulatory Activities (MedDRA) preferred term was tabulated. Serious adverse events during the entire study period were described in detail. Note that, to avoid inconsistency in the clinical database between the AE reporting and the AOM questionnaire, the questionnaire used for AOM report collection, otitis was not requested to be reported as an AE if already reported via the AOM questionnaire.

In addition to the above, SAEs notified via passive surveillance were collected –from 31 January 2012 (end time point for the Primary Objective) till 05 October 2013 (the end of the 18-month period after study unblinding).

**Study Population:** Male or female subjects between, and including, 6 weeks to 18 months of age at the time of the first

vaccination. Subjects who received previous vaccination with any registered, non-registered or investigational Hepatitis A or B virus or pneumococcal vaccines or for whom vaccination with such a vaccine other than the study vaccines was planned during the study period were excluded from the study, as well as subjects with any medical condition that would contraindicate the initiation of routine immunization outside a clinical trial context. Among others, subjects were excluded if they presented high risk of pneumococcal infections (such as anatomic or functional asplenia, HIV infection, chronic cardiac or respiratory disease (not asthma), diabetes, cochlear implant, CSF fistula or with significant immunodeficiency). Written informed consent was obtained from the parent(s) or from the guardian(s) of the subject.

**Number of subjects**:

Note regarding the tables presented here below: After the analysis had been performed, an error in treatment number allocation was identified. For 3 subjects, new subject numbers were allocated after administration of the first dose without excluding the initially allocated subject numbers from the Total Vaccinated cohort. Thus, for these 3 initially enrolled subjects, 2 subject numbers per each subject were used, while actually there were 3 subjects less enrolled among the 6181 subject numbers allocated. Therefore the actual total number of subjects enrolled was 6178 subjects in the Total Vaccinated cohort. This corresponds to 6174 subjects in the Total Vaccinated cohort for safety and carriage instead of the 6177 subjects presented in the demographic tables below. As these 3 subjects were part of separate age cohorts, the error would not be expected to have a significant impact on the overall data analysis; therefore re-analysis was not performed. The results presented below are based on the analysis including the 6 subject numbers pertaining to 3 enrolled subjects.

**Infants Enrolled between 6 Weeks and 6 Months of Age**

| **Number of subjects** | **10Pn3+1 Group** | **Ctrl3+1 Group** | **10Pn2+1 Group** | **Ctrl2+1 Group** |
|---|---|---|---|---|
| Planned, N | 1840 | 920 | 1840 | 920 |
| Randomized, N (Total Vaccinated cohort for analysis of safety and carriage) | 1849 | 1069 | 1316 | 859 |
| Completed, n (%) | 1696 (91.7) | 979 (91.6) | 1224 (93.0) | 797 (92.8) |
| Total Number Subjects Withdrawn, n (%) | 153 (8.3) | 90 (8.4) | 92 (7.0) | 62 (7.2) |
| Withdrawn due to Adverse Events, n (%) | 12 (0.7) | 3 (0.3) | 6 (0.5) | 5 (0.6) |
| Withdrawn due to Lack of Efficacy, n (%) | Not applicable | Not applicable | Not applicable | Not applicable |
| Withdrawn for other reasons, n (%) | 141 (7.6) | 87 (8.1) | 86 (6.5) | 57 (6.6) |
| **Demographics** | **10Pn3+1 Group** | **Ctrl3+1 Group** | **10Pn2+1 Group** | **Ctrl2+1 Group** |
| N (Total Vaccinated cohort for analysis of safety and carriage) | 1849 | 1069 | 1316 | 859 |
| Females: Males | 921:928 | 551:518 | 681:635 | 393:466 |
| Mean Age, months (SD) | 2.4 (1.02) | 2.6 (1.19) | 2.3 (0.95) | 2.4 (1.00) |
| White - Caucasian / European heritage, n (%) | 1822 (98.5) | 1058 (99.0) | 1303 (99.0) | 845 (98.4) |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with HBV vaccine
10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with HBV vaccine

**Children Enrolled between 7 and 11 Months of Age**

| **Number of Subjects:** | **10Pn Group** | **Ctrl Group** |
|---|---|---|
| Planned, N | 432 | 216 |
| Randomized, N (Total Vaccinated cohort for analysis of safety and carriage) | 241 | 204 |
| Completed, n (%) | 204 (84.6) | 178 (87.3) |
| Total Number Subjects Withdrawn, n (%) | 37 (15.4) | 26 (12.7) |
| Withdrawn due to Adverse Events, n (%) | 2 (0.9) | 1 (0.5) |
| Withdrawn due to Lack of Efficacy, n (%) | Not applicable | Not applicable |
| Withdrawn for other reasons, n (%) | 35 (14.5) | 25 (12.2) |
| **Demographics** | **10Pn Group** | **Ctrl Group** |
| N (Total Vaccinated cohort for analysis of safety and carriage) | 241 | 204 |
| Females: Males | 118:123 | 113:91 |
| Mean Age, months (SD) | 9.0 (1.44) | 8.7 (1.39) |
| White - Caucasian / European heritage, n (%) | 235 (97.5) | 201 (98.5) |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine

| **Children Enrolled between 12 and 18 Months of Age** | | |
|---|---|---|
| **Number of Subjects:** | **10Pn Group** | **Ctrl Group** |
| Planned, N | 432 | 216 |
| Randomized, N (Total Vaccinated cohort for analysis of safety and carriage) | 368 | 271 |
| Completed, n (%) | 340 (92.4) | 256 (94.5) |
| Total Number Subjects Withdrawn, n (%) | 28 (7.6) | 15 (5.5) |
| Withdrawn due to Adverse Events, n (%) | 0 (0.0) | 1 (0.4) |
| Withdrawn due to Lack of Efficacy, n (%) | Not applicable | Not applicable |
| Withdrawn for other reasons, n (%) | 28 (7.6) | 14 (5.1) |
| **Demographics** | **10Pn Group** | **Ctrl Group** |
| N (Total Vaccinated cohort for analysis of safety and carriage) | 368 | 271 |
| Females: Males | 173:195 | 142:129 |
| Mean Age, months (SD) | 15.0 (1.99) | 15.2 (1.99) |
| White - Caucasian / European heritage, n (%) | 362 (98.4) | 270 (99.6) |
| 10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine<br>Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine | | |
| **Primary Efficacy Results:** *Refer to the 111442 CTRS for these results.* | | |
| **Secondary Outcome Variable(s):** *Refer to the 111442 CTRS for results for secondary outcomes that are not presented in this summary.* | | |

**Secondary Outcome Variable(s):** Occurrence of *S. pneumoniae* (any) in nasopharyngeal swabs and vaccine efficacy for 10Pn3+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | **10Pn3+1 Group** | | | | | **Ctrl Group** | | | | | **Vaccine efficacy** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | **95% CI** | | | | | **95% CI** | | | **95% CI** | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 3 Months | PRE(M0) | 253 | 49 | 19.4 | 14.7 | 24.8 | 341 | 56 | 16.4 | 12.7 | 20.8 | -17.9 | -76.2 | 21.3 |
| 6 Months | PIII(M3) | 1803 | 412 | 22.9 | 20.9 | 24.9 | 1897 | 464 | 24.5 | 22.5 | 26.5 | 6.6 | -6.9 | 18.4 |
| 11-12 Months | PIII(M8) | 1784 | 500 | 28.0 | 26.0 | 30.2 | 1877 | 604 | 32.2 | 30.1 | 34.3 | 12.9 | 1.8 | 22.8 |
| 14-15 Months | PIV(M11) | 1727 | 512 | 29.6 | 27.5 | 31.9 | 1814 | 638 | 35.2 | 33.0 | 37.4 | 15.7 | 5.2 | 25.1 |
| 18-22 Months | PIV(M18) | 1686 | 503 | 29.8 | 27.7 | 32.1 | 1769 | 736 | 41.6 | 39.3 | 43.9 | 28.3 | 19.6 | 36.1 |
| - | Across time points | 1816 | 1041 | 57.3 | 55.0 | 59.6 | 1910 | 1237 | 64.8 | 62.6 | 66.9 | 11.5 | 3.8 | 18.6 |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl Group = Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
Nasopharyngeal swabs at PRE(M0) were only collected in the Immuno subset
PRE(M0) = Prior to dose 1
PIII(M3) = 1 month post dose 3
PIII(M8) = Pre booster dose
PIV(M11) = 3 months post-booster dose
PIV(M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Occurrence of *S. pneumoniae* (any) in nasopharyngeal swabs and vaccine efficacy for 10Pn2+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | **10Pn2+1 Group** | | | | | **Ctrl Group** | | | | | **Vaccine efficacy** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | **95% CI** | | | | | **95% CI** | | | **95% CI** | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 3 Months | PRE(M0) | 253 | 31 | 12.3 | 8.5 | 16.9 | 341 | 56 | 16.4 | 12.7 | 20.8 | 25.4 | -17.7 | 53.5 |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 6 Months | PII(M3) | 1289 | 323 | 25.1 | 22.7 | 27.5 | 1897 | 464 | 24.5 | 22.5 | 26.5 | -2.4 | -18.3 | 11.4 |
| 11-12 Months | PII(M8) | 1269 | 383 | 30.2 | 27.7 | 32.8 | 1877 | 604 | 32.2 | 30.1 | 34.3 | 6.2 | -6.8 | 17.7 |
| 14-15 Months | PIII(M11) | 1227 | 370 | 30.2 | 27.6 | 32.8 | 1814 | 638 | 35.2 | 33.0 | 37.4 | 14.3 | 2.4 | 24.8 |
| 18-22 Months | PIII(M18) | 1216 | 430 | 35.4 | 32.7 | 38.1 | 1769 | 736 | 41.6 | 39.3 | 43.9 | 15.0 | 4.1 | 24.7 |
| - | Across time points | 1297 | 774 | 59.7 | 56.9 | 62.4 | 1910 | 1237 | 64.8 | 62.6 | 66.9 | 7.9 | -0.9 | 15.9 |

10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit , UL = upper limit (conditional exact method)
Nasopharyngeal swabs at PRE(M0) were only collected in the Immuno subset
PRE(M0) = Prior to dose 1
PII(M3) = 1 month post-dose 2
PII(M8) = Prior to booster dose
PIII(M11) = 3 months post-booster dose
PIII(M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Occurrence of *S. pneumoniae* (any) in nasopharyngeal swabs and vaccine efficacy for 10Pn Group versus Ctrl Group in children enrolled between 7 and 11 months of age (Total Vaccinated cohort for analysis of carriage)

| | | **10Pn Group** | | | | | **Ctrl Group** | | | | | **Vaccine efficacy** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | **95% CI** | | | | | **95% CI** | | | **95% CI** | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 7-11 Months | PRE(M0) | 236 | 69 | 29.2 | 23.5 | 35.5 | 198 | 58 | 29.3 | 23.1 | 36.2 | 0.2 | -44.0 | 30.6 |
| 9-13 Months | PII(M2) | 230 | 79 | 34.3 | 28.2 | 40.9 | 200 | 56 | 28.0 | 21.9 | 34.8 | -22.7 | -76.0 | 14.0 |
| 13-17 Months | PII(M6) | 225 | 81 | 36.0 | 29.7 | 42.6 | 197 | 87 | 44.2 | 37.1 | 51.4 | 18.5 | -11.6 | 40.5 |
| 16-20 Months | PIII(M9) | 209 | 75 | 35.9 | 29.4 | 42.8 | 179 | 72 | 40.2 | 33.0 | 47.8 | 10.8 | -25.0 | 36.3 |
| 23-27 Months | PIII(M16) | 200 | 68 | 34.0 | 27.5 | 41.0 | 175 | 75 | 42.9 | 35.4 | 50.5 | 20.7 | -11.6 | 43.7 |
| - | Across time points | 240 | 154 | 64.2 | 57.7 | 70.2 | 203 | 146 | 71.9 | 65.2 | 78.0 | 10.8 | -12.7 | 29.3 |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PRE(M0) = Prior to dose 1
PII(M2) = 1 month post dose 2
PII(M6) = Pre booster dose
PIII(M9) = 3 months post booster dose
PIII(M16) = 10 months post booster dose

**Secondary Outcome Variable(s):** Occurrence of *S. pneumoniae* (any) in nasopharyngeal swabs and vaccine efficacy for 10Pn Group versus Ctrl Group in children enrolled between 12 and 18 months of age (Total Vaccinated cohort for analysis of carriage)

| | | **10Pn Group** | | | | | **Ctrl Group** | | | | | **Vaccine efficacy** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | **95% CI** | | | | | **95% CI** | | | **95% CI** | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 12-18 Months | PRE(M0) | 358 | 125 | 34.9 | 30.0 | 40.1 | 265 | 88 | 33.2 | 27.6 | 39.2 | -5.1 | -39.7 | 20.6 |
| 19-25 Months | PII(M7) | 340 | 152 | 44.7 | 39.3 | 50.2 | 255 | 112 | 43.9 | 37.7 | 50.2 | -1.8 | -31.1 | 20.8 |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 21-27 Months | PII(M9) | 338 | 132 | 39.1 | 33.8 | 44.5 | 254 | 105 | 41.3 | 35.2 | 47.7 | 5.5 | -23.3 | 27.4 |
| - | Across time points | 365 | 236 | 64.7 | 59.5 | 69.6 | 271 | 176 | 64.9 | 58.9 | 70.6 | 0.4 | -21.7 | 18.4 |

10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PRE(M0) = Prior to dose 1
PII(M7) = 1 month post dose 2
PII(M9) = 3 months post dose 2

**Secondary Outcome Variable(s):** Occurrence of *S. pneumoniae* (10Pn vaccine serotypes) in nasopharyngeal swabs and vaccine efficacy for 10Pn3+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | **10Pn3+1 Group** | | | | | **Ctrl Group** | | | | | **Vaccine efficacy** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | **95% CI** | | | | | **95% CI** | | | **95% CI** | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 3 Months | PRE(M0) | 253 | 29 | 11.5 | 7.8 | 16.0 | 341 | 30 | 8.8 | 6.0 | 12.3 | -30.3 | -124.7 | 24.5 |
| 6 Months | PIII(M3) | 1803 | 183 | 10.1 | 8.8 | 11.6 | 1897 | 237 | 12.5 | 11.0 | 14.1 | 18.8 | 1.1 | 33.4 |
| 11-12 Months | PIII(M8) | 1784 | 229 | 12.8 | 11.3 | 14.5 | 1877 | 342 | 18.2 | 16.5 | 20.0 | 29.6 | 16.5 | 40.7 |
| 14-15 Months | PIV(M11) | 1727 | 209 | 12.1 | 10.6 | 13.7 | 1814 | 364 | 20.1 | 18.2 | 22.0 | 39.7 | 28.3 | 49.4 |
| 18-22 Months | PIV(M18) | 1686 | 169 | 10.0 | 8.6 | 11.6 | 1769 | 404 | 22.8 | 20.9 | 24.9 | 56.1 | 47.3 | 63.5 |
| - | Across time points | 1816 | 476 | 26.2 | 24.2 | 28.3 | 1910 | 802 | 42.0 | 39.8 | 44.2 | 37.6 | 30.0 | 44.4 |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl Group = Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
Nasopharyngeal swabs at PRE(M0) were only collected in the Immuno subset
PRE(M0) = Prior to dose 1
PIII(M3) = 1 month post dose 3
PIII(M8) = Pre booster dose
PIV(M11) = 3 months post-booster dose
PIV(M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Occurrence of *S. pneumoniae* (10Pn vaccine serotypes) in nasopharyngeal swabs and vaccine efficacy for 10Pn2+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | **10Pn2+1 Group** | | | | | **Ctrl Group** | | | | | **Vaccine efficacy** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | **95% CI** | | | | | **95% CI** | | | **95% CI** | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 3 Months | PRE(M0) | 253 | 18 | 7.1 | 4.3 | 11.0 | 341 | 30 | 8.8 | 6.0 | 12.3 | 19.1 | -49.9 | 57.5 |
| 6 Months | PII(M3) | 1289 | 159 | 12.3 | 10.6 | 14.3 | 1897 | 237 | 12.5 | 11.0 | 14.1 | 1.3 | -21.2 | 19.8 |
| 11-12 Months | PII(M8) | 1269 | 178 | 14.0 | 12.2 | 16.1 | 1877 | 342 | 18.2 | 16.5 | 20.0 | 23.0 | 7.5 | 36.1 |
| 14-15 Months | PIII(M11) | 1227 | 153 | 12.5 | 10.7 | 14.4 | 1814 | 364 | 20.1 | 18.2 | 22.0 | 37.9 | 24.7 | 48.9 |
| 18-22 Months | PIII(M18) | 1216 | 176 | 14.5 | 12.5 | 16.6 | 1769 | 404 | 22.8 | 20.9 | 24.9 | 36.6 | 24.2 | 47.2 |
| - | Across time points | 1297 | 390 | 30.1 | 27.6 | 32.6 | 1910 | 802 | 42.0 | 39.8 | 44.2 | 28.4 | 19.1 | 36.7 |

10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine

For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit , UL = upper limit (conditional exact method)
Nasopharyngeal swabs at PRE(M0) were only collected in the Immuno subset
PRE(M0) = Prior to dose 1
PII(M3) = 1 month post-dose 2
PII(M8) = Prior to booster dose
PIII(M11) = 3 months post-booster dose
PIII(M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Occurrence of *S. pneumoniae* (10Pn vaccine serotypes) in nasopharyngeal swabs and vaccine efficacy for 10Pn Group versus Ctrl Group in children enrolled between 7 and 11 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 7-11 Months | PRE(M0) | 236 | 44 | 18.6 | 13.9 | 24.2 | 198 | 34 | 17.2 | 12.2 | 23.2 | -8.6 | -75.2 | 32.2 |
| 9-13 Months | PII(M2) | 230 | 43 | 18.7 | 13.9 | 24.3 | 200 | 35 | 17.5 | 12.5 | 23.5 | -6.8 | -72.0 | 33.2 |
| 13-17 Months | PII(M6) | 225 | 43 | 19.1 | 14.2 | 24.9 | 197 | 55 | 27.9 | 21.8 | 34.7 | 31.5 | -3.9 | 55.2 |
| 16-20 Months | PIII(M9) | 209 | 34 | 16.3 | 11.5 | 22.0 | 179 | 47 | 26.3 | 20.0 | 33.3 | 38.0 | 1.6 | 61.4 |
| 23-27 Months | PIII(M16) | 200 | 28 | 14.0 | 9.5 | 19.6 | 175 | 48 | 27.4 | 21.0 | 34.7 | 49.0 | 17.0 | 69.2 |
| - | Across time points | 240 | 96 | 40.0 | 33.8 | 46.5 | 203 | 109 | 53.7 | 46.6 | 60.7 | 25.5 | 1.1 | 44.0 |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PRE(M0) = Prior to dose 1
PII(M2) = 1 month post dose 2
PII(M6) = Pre booster dose
PIII(M9) = 3 months post booster dose
PIII(M16) = 10 months post booster dose

**Secondary Outcome Variable(s):** Occurrence of *S. pneumoniae* (10Pn vaccine serotypes) in nasopharyngeal swabs and vaccine efficacy for 10Pn Group versus Ctrl Group in children enrolled between 12 and 18 months of age (Total vaccinated cohort for analysis of carriage)

| | | 10Pn Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 12-18 Months | PRE(M0) | 358 | 70 | 19.6 | 15.6 | 24.0 | 265 | 57 | 21.5 | 16.7 | 27.0 | 9.1 | -31.3 | 36.8 |
| 19-25 Months | PII(M7) | 340 | 69 | 20.3 | 16.1 | 25.0 | 255 | 70 | 27.5 | 22.1 | 33.4 | 26.1 | -4.6 | 47.8 |
| 21-27 Months | PII(M9) | 338 | 64 | 18.9 | 14.9 | 23.5 | 254 | 53 | 20.9 | 16.0 | 26.4 | 9.3 | -33.2 | 37.9 |
| - | Across time points | 365 | 129 | 35.3 | 30.4 | 40.5 | 271 | 117 | 43.2 | 37.2 | 49.3 | 18.1 | -6.1 | 36.8 |

10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:

N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PRE(M0) = Prior to dose 1
PII(M7) = 1 month post dose 2
PII(M9) = 3 months post dose 2

**Secondary Outcome Variable(s):** Cumulative acquisition of *S. pneumoniae* (any) detected in nasopharyngeal swabs and vaccine efficacy for 10Pn3+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn3+1 Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 11-12 Months | PIII(M8) | 1780 | 331 | 18.6 | 16.8 | 20.5 | 1874 | 415 | 22.1 | 20.3 | 24.1 | 16.0 | 2.7 | 27.5 |
| 14-15 Months | PIV(M11) | 1723 | 562 | 32.6 | 30.4 | 34.9 | 1807 | 692 | 38.3 | 36.0 | 40.6 | 14.8 | 4.7 | 23.9 |
| 18-22 Months | PIV(M18) | 1675 | 818 | 48.8 | 46.4 | 51.3 | 1752 | 1023 | 58.4 | 56.0 | 60.7 | 16.4 | 8.2 | 23.8 |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl Group = Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
N = number of subjects with swabs cultured and available bacteria up to the considered time point
n/% = number/percentage of subjects with new acquisition associated to the specified bacteria at the considered time point
VE (%) = Vaccine Efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PIII(M8) = Prior to booster dose
PIV(M11) = 3 months post-booster dose
PIV(M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Cumulative acquisition of *S. pneumoniae* (any) detected in nasopharyngeal swabs and vaccine efficacy for 10Pn2+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn2+1 Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 11-12 Months | PII(M8) | 1269 | 246 | 19.4 | 17.2 | 21.7 | 1874 | 415 | 22.1 | 20.3 | 24.1 | 12.5 | -2.7 | 25.5 |
| 14-15 Months | PIII(M11) | 1222 | 400 | 32.7 | 30.1 | 35.4 | 1807 | 692 | 38.3 | 36.0 | 40.6 | 14.5 | 3.2 | 24.6 |
| 18-22 Months | PIII(M18) | 1200 | 609 | 50.8 | 47.9 | 53.6 | 1752 | 1023 | 58.4 | 56.0 | 60.7 | 13.1 | 3.8 | 21.5 |

10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
N = number of subjects with swabs cultured and available bacteria up to the considered time point
n/% = number/percentage of subjects with new acquisition associated to the specified bacteria at the considered time point
VE (%) = Vaccine Efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PII(M8) = Prior to booster dose
PIII(M11) = 3 months post-booster dose
PIII(M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Cumulative acquisition of *S. pneumoniae* (any) detected in nasopharyngeal swabs and vaccine efficacy for 10Pn Group versus Ctrl Group in children enrolled between 7 and 11 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 9-13 Months | PII(M2) | 226 | 36 | 15.9 | 11.4 | 21.4 | 195 | 30 | 15.4 | 10.6 | 21.2 | -3.5 | -74.0 | 38.0 |
| 13-17 Months | PII(M6) | 221 | 78 | 35.3 | 29.0 | 42.0 | 192 | 83 | 43.2 | 36.1 | 50.6 | 18.4 | -12.6 | 40.8 |
| 16-20 Months | PIII(M9) | 205 | 95 | 46.3 | 39.4 | 53.4 | 175 | 100 | 57.1 | 49.5 | 64.6 | 18.9 | -8.5 | 39.4 |
| 23-27 Months | PIII(M16) | 194 | 117 | 60.3 | 53.1 | 67.2 | 170 | 116 | 68.2 | 60.7 | 75.2 | 11.6 | -15.3 | 32.2 |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine
N = number of subjects with swabs cultured and available bacteria up to the considered time point
n/% = number/percentage of subjects with new acquisition associated to the specified bacteria at the considered time point

VE (%) = Vaccine Efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PII(M2) = 1 month post dose 2
PII(M6) = Prior to booster dose
PIII(M9) = 3 months post booster dose
PIII(M16) = 10 months post booster dose

**Secondary Outcome Variable(s):** Cumulative acquisition of S. *pneumoniae* (any) detected in nasopharyngeal swabs and vaccine efficacy for 10Pn Group versus Ctrl Group in children enrolled between 12 and 18 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 19-25 Months | PII(M7) | 333 | 130 | 39.0 | 33.8 | 44.5 | 249 | 94 | 37.8 | 31.7 | 44.1 | -3.4 | -36.3 | 21.3 |
| 21-27 Months | PII(M9) | 330 | 166 | 50.3 | 44.8 | 55.8 | 246 | 133 | 54.1 | 47.6 | 60.4 | 7.0 | -17.8 | 26.4 |

10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine
N = number of subjects with swabs cultured and available bacteria up to the considered time point
n/% = number/percentage of subjects with new acquisition associated to the specified bacteria at the considered time point
VE (%) = Vaccine Efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PII(M7) = 1 month post dose 2
PII(M9) = 3 months post dose 2

**Secondary Outcome Variable(s):** Cumulative acquisition of *S. pneumoniae* (10Pn vaccine serotypes) detected in nasopharyngeal swabs and vaccine efficacy - 10Pn3+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn3+1 Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **N** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 11-12 Months | PII(M8) | 1780 | 131 | 7.4 | 6.2 | 8.7 | 1874 | 223 | 11.9 | 10.5 | 13.5 | 38.2 | 22.9 | 50.5 |
| 14-15 Months | PIII(M11) | 1723 | 221 | 12.8 | 11.3 | 14.5 | 1807 | 387 | 21.4 | 19.5 | 23.4 | 40.1 | 29.2 | 49.5 |
| 18-22 Months | PIII(M18) | 1675 | 326 | 19.5 | 17.6 | 21.4 | 1752 | 626 | 35.7 | 33.5 | 38.0 | 45.5 | 37.6 | 52.5 |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
For time point considered:
N = number of subjects with swabs cultured and available bacteria up to the considered time point
n/% = number/percentage of subjects with new acquisition associated to the specified bacteria at the considered time point
VE (%) = Vaccine Efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PII(M8) = Prior to booster dose
PIII(M11) = 3 months post-booster dose
PIII(M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Cumulative acquisition of *S. pneumoniae* (10Pn vaccine serotypes) detected in nasopharyngeal swabs and vaccine efficacy - 10Pn2+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn2+1 Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 11-12 Months | PII(M8) | 1269 | 97 | 7.6 | 6.2 | 9.2 | 1874 | 223 | 11.9 | 10.5 | 13.5 | 35.8 | 18.1 | 49.9 |
| 14-15 Months | PIII(M11) | 1222 | 156 | 12.8 | 10.9 | 14.8 | 1807 | 387 | 21.4 | 19.5 | 23.4 | 40.4 | 28.0 | 50.8 |
| 18-22 Months | PIII(M18) | 1200 | 269 | 22.4 | 20.1 | 24.9 | 1752 | 626 | 35.7 | 33.5 | 38.0 | 37.3 | 27.5 | 45.8 |

10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
For time point considered:
N = number of subjects with swabs cultured and available bacteria up to the considered time point
n/% = number/percentage of subjects with new acquisition associated to the specified bacteria at the considered time point
VE (%) = Vaccine Efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)

PII(M8) = Prior to booster dose
PIII(M11) = 3 months post-booster dose
PIII(M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Cumulative acquisition of *S. pneumoniae* (10Pn vaccine serotypes) detected in nasopharyngeal swabs and vaccine efficacy - 10Pn Group versus Ctrl Group in children enrolled between 7 and 11 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 9-13 Months | PII(M2) | 226 | 18 | 8.0 | 4.8 | 12.3 | 195 | 17 | 8.7 | 5.2 | 13.6 | 8.6 | -88.7 | 55.6 |
| 13-17 Months | PII(M6) | 221 | 41 | 18.6 | 13.7 | 24.3 | 192 | 51 | 26.6 | 20.5 | 33.4 | 30.2 | -7.5 | 54.9 |
| 16-20 Months | PIII(M9) | 205 | 50 | 24.4 | 18.7 | 30.9 | 175 | 70 | 40.0 | 32.7 | 47.7 | 39.0 | 11.1 | 58.5 |
| 23-27 Months | PIII(M16) | 194 | 62 | 32.0 | 25.5 | 39.0 | 170 | 88 | 51.8 | 44.0 | 59.5 | 38.3 | 13.6 | 56.1 |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine
For time point considered:
N = number of subjects with swabs cultured and available bacteria up to the considered time point
n/% = number/percentage of subjects with new acquisition associated to the specified bacteria at the considered time point
VE (%) = Vaccine Efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PII(M2) = 1 month post dose 2
PII(M6) = Prior to booster dose
PIII(M9) = 3 months post booster dose
PIII(M16) = 10 months post booster dose

**Secondary Outcome Variable(s):** Cumulative acquisition of *S. pneumoniae* (10Pn vaccine serotypes) detected in nasopharyngeal swabs and vaccine efficacy – 10Pn Group versus Ctrl Group in children enrolled between 12 and 18 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 19-25 Months | PII(M7) | 333 | 53 | 15.9 | 12.2 | 20.3 | 249 | 55 | 22.1 | 17.1 | 27.8 | 27.9 | -7.0 | 51.5 |
| 21-27 Months | PII(M9) | 330 | 78 | 23.6 | 19.2 | 28.6 | 246 | 74 | 30.1 | 24.4 | 36.2 | 21.4 | -9.5 | 43.6 |

10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn-PD-DiT vaccine
Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine
For time point considered:
N = number of subjects with swabs cultured and available bacteria up to the considered time point
n/% = number/percentage of subjects with new acquisition associated to the specified bacteria at the considered time point
VE (%) = Vaccine Efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PII(M7) = 1 month post dose 2
PII(M9) = 3 months post dose 2

**Secondary Outcome Variable(s):** Occurrence of *H. influenzae*** in nasopharyngeal swabs and vaccine efficacy for 10Pn3+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn3+1 Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 3 Months | PRE(M0) | 253 | 6 | 2.4 | 0.9 | 5.1 | 341 | 10 | 2.9 | 1.4 | 5.3 | 19.1 | -145.6 | 75.8 |
| 6 Months | PIII(M3) | 1803 | 57 | 3.2 | 2.4 | 4.1 | 1897 | 46 | 2.4 | 1.8 | 3.2 | -30.4 | -96.6 | 13.1 |
| 11-12 Months | PIII(M8) | 1784 | 84 | 4.7 | 3.8 | 5.8 | 1877 | 87 | 4.6 | 3.7 | 5.7 | -1.6 | -38.7 | 25.6 |
| 14-15 Months | PIV(M11) | 1726 | 121 | 7.0 | 5.9 | 8.3 | 1814 | 92 | 5.1 | 4.1 | 6.2 | -38.2 | -83.3 | -4.5 |
| 18-22 Months | PIV(M18) | 1684 | 211 | 12.5 | 11.0 | 14.2 | 1768 | 190 | 10.7 | 9.3 | 12.3 | -16.6 | -42.6 | 4.6 |
| - | Across time points | 1816 | 408 | 22.5 | 20.6 | 24.5 | 1910 | 372 | 19.5 | 17.7 | 21.3 | -15.4 | -33.1 | 0.0 |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine

**Data presented only include results from samples confirmed as positive for Hi/NTHi after differentiation from *H. haemolyticus* by PCR assay
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
Nasopharyngeal swabs at PRE (M0) were only collected in the Immuno subset.
PRE(M0) = Prior to dose 1
PIII(M3) = 1 month post-dose 3
PIII(M8) = Prior to booster dose
PIV(M11) = 3 months post-booster dose
M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Occurrence of *H. influenzae*** in nasopharyngeal swabs and vaccine efficacy for 10Pn2+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn2+1 Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 3 Months | PRE(M0) | 253 | 4 | 1.6 | 0.4 | 4.0 | 341 | 10 | 2.9 | 1.4 | 5.3 | 46.1 | -86.9 | 87.7 |
| 6 Months | PII(M3) | 1289 | 36 | 2.8 | 2.0 | 3.8 | 1897 | 46 | 2.4 | 1.8 | 3.2 | -15.2 | -82.1 | 27.7 |
| 11-12 Months | PII(M8) | 1269 | 72 | 5.7 | 4.5 | 7.1 | 1877 | 87 | 4.6 | 3.7 | 5.7 | -22.4 | -69.2 | 11.7 |
| 14-15 Months | PIII(M11) | 1227 | 84 | 6.8 | 5.5 | 8.4 | 1814 | 92 | 5.1 | 4.1 | 6.2 | -35.0 | -83.5 | 0.8 |
| 18-22 Months | PIII(M18) | 1212 | 128 | 10.6 | 8.9 | 12.4 | 1768 | 190 | 10.7 | 9.3 | 12.3 | 1.7 | -23.6 | 22.1 |
| - | Across time points | 1297 | 276 | 21.3 | 19.1 | 23.6 | 1910 | 372 | 19.5 | 17.7 | 21.3 | -9.3 | -28.0 | 6.8 |

10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
**Data presented only include results from samples confirmed as positive for Hi/NTHi after differentiation from *H. haemolyticus* by PCR assay.
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
Nasopharyngeal swabs at PRE(M0) were only collected in the Immuno subset
PRE(M0) = Prior to dose 1
PII(M3) = 1 month post-dose 2
PII(M8) = Pre booster dose
PIII(M11) = 3 months post-booster dose
PIII(M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Occurrence of *H. influenzae*** in nasopharyngeal swabs and vaccine efficacy for 10Pn Group versus Ctrl Group in children enrolled between 7 and 11 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 7-11 Months | PRE(M0) | 236 | 6 | 2.5 | 0.9 | 5.5 | 198 | 8 | 4.0 | 1.8 | 7.8 | 37.1 | -106.8 | 82.0 |
| 9-13 Months | PII(M2) | 230 | 8 | 3.5 | 1.5 | 6.7 | 200 | 9 | 4.5 | 2.1 | 8.4 | 22.7 | -125.7 | 74.1 |
| 13-17 Months | PII(M6) | 225 | 22 | 9.8 | 6.2 | 14.4 | 197 | 14 | 7.1 | 3.9 | 11.6 | -37.6 | -190.8 | 32.7 |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 16-20 Months | PIII(M9) | 209 | 17 | 8.1 | 4.8 | 12.7 | 179 | 13 | 7.3 | 3.9 | 12.1 | -12.0 | -150.7 | 48.8 |
| 23-27 Months | PIII(M16) | 200 | 21 | 10.5 | 6.6 | 15.6 | 175 | 15 | 8.6 | 4.9 | 13.7 | -22.5 | -155.4 | 39.8 |
| - | Across time points | 240 | 66 | 27.5 | 22.0 | 33.6 | 203 | 45 | 22.2 | 16.7 | 28.5 | -24.1 | -85.4 | 16.3 |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine
**Data presented only include results from samples confirmed as positive for Hi/NTHi after differentiation from *H. haemolyticus* by PCR assay.
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PRE(M0) = Prior to dose 1
PII(M2) = 1 month post-Dose 2
PII(M6) = Pre-booster dose
PIII(M9) = 3 months post-booster dose
PIII(M16) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Occurrence of *H. influenzae*** in nasopharyngeal swabs and vaccine efficacy for 10Pn Group versus Ctrl Group in children enrolled between 12 and 18 months of age (Total Vaccinated cohort for analysis of carriage)

| | | **10Pn Group** | | | | | **Ctrl Group** | | | | | **Vaccine efficacy** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | **95% CI** | | | | | **95% CI** | | | **95% CI** | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 12-18 Months | PRE(M0) | 358 | 21 | 5.9 | 3.7 | 8.8 | 265 | 12 | 4.5 | 2.4 | 7.8 | -29.5 | -188.8 | 39.1 |
| 19-25 Months | PII(M7) | 340 | 24 | 7.1 | 4.6 | 10.3 | 255 | 21 | 8.2 | 5.2 | 12.3 | 14.3 | -61.9 | 54.3 |
| 21-27 Months | PII(M9) | 338 | 27 | 8.0 | 5.3 | 11.4 | 254 | 29 | 11.4 | 7.8 | 16.0 | 30.0 | -22.4 | 60.1 |
| - | Across time points | 365 | 60 | 16.4 | 12.8 | 20.6 | 271 | 54 | 19.9 | 15.3 | 25.2 | 17.5 | -21.4 | 43.8 |

10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine
**Data presented only include results from samples confirmed as positive for Hi/NTHi after differentiation from *H. haemolyticus* by PCR assay
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PRE(M0) = Prior to dose 1
PII(M7) = 1 month post-dose 2
PII(M9) = 3 months post-dose 2

**Secondary Outcome Variable(s):** Cumulative acquisition of *H. influenzae*** detected in nasopharyngeal swabs and vaccine efficacy for 10Pn3+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | **10Pn3+1 Group** | | | | | **Ctrl Group** | | | | | **Vaccine efficacy** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | **95% CI** | | | | | **95% CI** | | | **95% CI** | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 11-12 Months | PIII(M8) | 1780 | 77 | 4.3 | 3.4 | 5.4 | 1874 | 83 | 4.4 | 3.5 | 5.5 | 2.3 | -34.8 | 29.3 |
| 14-15 Months | PIV(M11) | 1722 | 176 | 10.2 | 8.8 | 11.7 | 1807 | 157 | 8.7 | 7.4 | 10.1 | -17.6 | -46.8 | 5.7 |
| 18-22 Months | PIV(M18) | 1672 | 349 | 20.9 | 18.9 | 22.9 | 1751 | 313 | 17.9 | 16.1 | 19.8 | -16.8 | -36.5 | 0.0 |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine

Ctrl Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
** Data presented only include results from samples confirmed as positive for Hi/NTHi after differentiation from *H. haemolyticus* by PCR assay
N = number of subjects with swabs cultured and available bacteria up to the considered time point
n/% = number/percentage of subjects with new acquisition associated to the specified bacteria at the considered time point
VE (%) = Vaccine Effectiveness as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PIII(M8) = Prior to booster dose
PIV(M11) = 3 months post-booster dose
PIV(M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Cumulative acquisition of *H. influenzae*** detected in nasopharyngeal swabs and vaccine efficacy for 10Pn2+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | **10Pn2+1 Group** | | | | | **Ctrl Group** | | | | | **Vaccine efficacy** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | **95% CI** | | | | | **95% CI** | | **95% CI** | | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 11-12 Months | PII(M8) | 1269 | 65 | 5.1 | 4.0 | 6.5 | 1874 | 83 | 4.4 | 3.5 | 5.5 | -15.6 | -62.0 | 17.7 |
| 14-15 Months | PIII(M11) | 1222 | 139 | 11.4 | 9.6 | 13.3 | 1807 | 157 | 8.7 | 7.4 | 10.1 | -30.9 | -65.5 | -3.4 |
| 18-22 Months | PIII(M18) | 1196 | 240 | 20.1 | 17.8 | 22.5 | 1751 | 313 | 17.9 | 16.1 | 19.8 | -12.3 | -33.2 | 5.5 |

10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
**Data presented only include results from samples confirmed as positive for Hi/NTHi after differentiation from *H. haemolyticus* by PCR assay
Ctrl 6W-6M Group = pooling of the Ctrl3+1 6W-6M Group and Ctrl2+1 6W-6M Group
N = number of subjects with swabs cultured and available bacteria up to the considered time point
n/% = number/percentage of subjects with new acquisition associated to the specified bacteria at the considered time point
VE (%) = Vaccine Effectiveness as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PII(M8) = Prior to booster dose
PIII(M11) = 3 months post-booster dose
PIII(M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Cumulative acquisition of *H. influenzae*** detected in nasopharyngeal swabs and vaccine efficacy for 10Pn Group versus Ctrl Group in children enrolled between 7 and 11 months of age (Total Vaccinated cohort for analysis of carriage)

| | | **10Pn Group** | | | | | **Ctrl Group** | | | | | **Vaccine efficacy** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | **95% CI** | | | | | **95% CI** | | **95% CI** | | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 9-13 Months | PII(M2) | 226 | 8 | 3.5 | 1.5 | 6.9 | 195 | 9 | 4.6 | 2.1 | 8.6 | 23.3 | -124.0 | 74.3 |
| 13-17 Months | PII(M6) | 221 | 29 | 13.1 | 9.0 | 18.3 | 192 | 19 | 9.9 | 6.1 | 15.0 | -32.6 | -150.3 | 28.1 |
| 16-20 Months | PIII(M9) | 205 | 37 | 18.0 | 13.0 | 24.0 | 175 | 28 | 16.0 | 10.9 | 22.3 | -12.8 | -91.4 | 32.8 |
| 23-27 Months | PIII(M16) | 194 | 55 | 28.4 | 22.1 | 35.2 | 170 | 39 | 22.9 | 16.9 | 30.0 | -23.6 | -91.3 | 19.5 |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine
**Data presented only include results from samples confirmed as positive for Hi/NTHi after differentiation from *H. haemolyticus* by PCR assay
N = number of subjects with swabs cultured and available bacteria up to the considered time point
n/% = number/percentage of subjects with new acquisition associated to the specified bacteria at the considered time point
VE % = Vaccine Effectiveness as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PII(M2) = 1 month post dose 2
PII(M6) = Prior to booster dose
PIII(M9) = 3 months post booster dose
PIII(M16) = 10 months post booster dose

**Secondary Outcome Variable(s):** Cumulative acquisition of *H. influenzae*** detected in nasopharyngeal swabs and vaccine efficacy for 10Pn Group versus Ctrl Group in children enrolled between 12 and 18 months of age (Total Vaccinated cohort for analysis of carriage)

| | **10Pn Group** | **Ctrl Group** | **Vaccine efficacy** |
|---|---|---|---|

| | | | | | 95% CI | | | | | 95% CI | | 95% CI | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 19-25 Months | PII(M7) | 333 | 19 | 5.7 | 3.5 | 8.8 | 249 | 20 | 8.0 | 5.0 | 12.1 | 29.0 | -40.2 | 64.1 |
| 21-27 Months | PII(M9) | 330 | 37 | 11.2 | 8.0 | 15.1 | 246 | 41 | 16.7 | 12.2 | 21.9 | 32.7 | -7.6 | 58.1 |

10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine
** Data presented only include results from samples confirmed as positive for Hi/NTHi after differentiation from H. haemolyticus by PCR assay
N = number of subjects with swabs cultured and available bacteria up to the considered time point
n/% = number/percentage of subjects with new acquisition associated to the specified bacteria at the considered time point
VE % = Vaccine Effectiveness as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PII(M7) = 1 month post dose 2
PII(M9) = 3 months post dose 2

**Secondary Outcome Variable(s):** Occurrence of *Moraxella catarrhalis* in nasopharyngeal swabs and vaccine efficacy for 10Pn3+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn3+1 Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 3 Months | PRE(M0) | 253 | 57 | 22.5 | 17.5 | 28.2 | 341 | 76 | 22.3 | 18.0 | 27.1 | -1.1 | -44.4 | 29.6 |
| 6 Months | PIII(M3) | 1803 | 459 | 25.5 | 23.5 | 27.5 | 1897 | 486 | 25.6 | 23.7 | 27.6 | 0.6 | -13.1 | 12.7 |
| 11-12 Months | PIII(M8) | 1784 | 671 | 37.6 | 35.4 | 39.9 | 1877 | 733 | 39.1 | 36.8 | 41.3 | 3.7 | -7.1 | 13.4 |
| 14-15 Months | PIV(M11) | 1727 | 612 | 35.4 | 33.2 | 37.7 | 1814 | 668 | 36.8 | 34.6 | 39.1 | 3.8 | -7.5 | 13.9 |
| 18-22 Months | PIV(M18) | 1686 | 794 | 47.1 | 44.7 | 49.5 | 1769 | 780 | 44.1 | 41.8 | 46.4 | -6.8 | -18.1 | 3.4 |
| - | Across time points | 1816 | 1403 | 77.3 | 75.3 | 79.2 | 1910 | 1470 | 77.0 | 75.0 | 78.8 | -0.4 | -8.1 | 6.8 |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
Nasopharyngeal swabs at PRE(M0) were only collected in the Immuno subset
PRE(M0) = Prior to dose 1
PIII(M3) = 1 month post dose 3
PIII(M8) = Pre booster dose
PIV(M11) = 3 months post-booster dose
PIV(M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Occurrence of *Moraxella catarrhalis* in nasopharyngeal swabs and vaccine efficacy for 10Pn2+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn2+1 Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 3 Months | PRE(M0) | 253 | 58 | 22.9 | 17.9 | 28.6 | 341 | 76 | 22.3 | 18.0 | 27.1 | -2.9 | -46.7 | 28.2 |
| 6 Months | PII(M3) | 1289 | 345 | 26.8 | 24.4 | 29.3 | 1897 | 486 | 25.6 | 23.7 | 27.6 | -4.5 | -20.2 | 9.3 |
| 11-12 Months | PII(M8) | 1269 | 493 | 38.8 | 36.2 | 41.6 | 1877 | 733 | 39.1 | 36.8 | 41.3 | 0.5 | -11.7 | 11.4 |
| 14-15 Months | PIII(M11) | 1227 | 466 | 38.0 | 35.3 | 40.8 | 1814 | 668 | 36.8 | 34.6 | 39.1 | -3.1 | -16.3 | 8.6 |
| 18-22 Months | PIII(M18) | 1216 | 566 | 46.5 | 43.7 | 49.4 | 1769 | 780 | 44.1 | 41.8 | 46.4 | -5.6 | -17.8 | 5.4 |
| - | Across time points | 1297 | 1014 | 78.2 | 75.8 | 80.4 | 1910 | 1470 | 77.0 | 75.0 | 78.8 | -1.6 | -10.1 | 6.3 |

10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
Nasopharyngeal swabs at PRE(M0) were only collected in the Immuno subset
PRE(M0) = Prior to dose 1
PII(M3) = 1 month post dose 2
PII(M8) = Prior to booster dose
PIII(M11) = 3 months post-booster dose
PIII(M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Occurrence of *Moraxella catarrhalis* in nasopharyngeal swabs and vaccine efficacy for 10Pn Group versus Ctrl Group in children enrolled between 7 and 11 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 7-11 Months | PRE(M0) | 236 | 69 | 29.2 | 23.5 | 35.5 | 198 | 59 | 29.8 | 23.5 | 36.7 | 1.9 | -41.3 | 31.7 |
| 9-13 Months | PII(M2) | 230 | 73 | 31.7 | 25.8 | 38.2 | 200 | 61 | 30.5 | 24.2 | 37.4 | -4.1 | -48.7 | 26.9 |
| 13-17 Months | PII(M6) | 225 | 109 | 48.4 | 41.8 | 55.2 | 197 | 98 | 49.7 | 42.6 | 56.9 | 2.6 | -29.3 | 26.6 |
| 16-20 Months | PIII(M9) | 209 | 91 | 43.5 | 36.7 | 50.6 | 179 | 81 | 45.3 | 37.8 | 52.8 | 3.8 | -31.5 | 29.5 |
| 23-27 Months | PIII(M16) | 200 | 83 | 41.5 | 34.6 | 48.7 | 175 | 63 | 36.0 | 28.9 | 43.6 | -15.3 | -62.6 | 17.9 |
| - | Across time points | 240 | 202 | 84.2 | 78.9 | 88.5 | 203 | 167 | 82.3 | 76.3 | 87.3 | -2.3 | -26.4 | 17.1 |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PRE(M0) = Prior to dose 1
PII(M2) = 1 month post dose 2
PII(M6) = Prior to booster dose
PIII(M9) = 3 months post booster dose
PIII(M16) = 10 months post booster dose

**Secondary Outcome Variable(s):** Occurrence of *Moraxella catarrhalis* in nasopharyngeal swabs and vaccine efficacy for 10Pn Group versus Ctrl Group in children enrolled between 12 and 18 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 12-18 Months | PRE(M0) | 358 | 143 | 39.9 | 34.8 | 45.2 | 265 | 72 | 27.2 | 21.9 | 33.0 | -47.0 | -98.0 | -10.0 |
| 19-25 Months | PII(M7) | 340 | 167 | 49.1 | 43.7 | 54.6 | 255 | 129 | 50.6 | 44.3 | 56.9 | 2.9 | -23.1 | 23.3 |
| 21-27 Months | PII(M9) | 338 | 143 | 42.3 | 37.0 | 47.8 | 254 | 120 | 47.2 | 41.0 | 53.6 | 10.4 | -15.1 | 30.2 |
| - | Across time points | 365 | 263 | 72.1 | 67.1 | 76.6 | 271 | 198 | 73.1 | 67.4 | 78.3 | 1.4 | -19.2 | 18.3 |

10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine

For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PRE(M0) = Prior to dose 1
PII(M7) = 1 month post dose 2
PII(M9) = 3 months post dose 2

**Secondary Outcome Variable(s):** Occurrence of Group A *Streptococcus* in nasopharyngeal swabs and vaccine efficacy for 10Pn3+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn3+1 Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 3 Months | PRE(M0) | 253 | 0 | 0.0 | 0.0 | 1.4 | 341 | 1 | 0.3 | 0.0 | 1.6 | 100 | -5156.5 | 100 |
| 6 Months | PIII(M3) | 1803 | 10 | 0.6 | 0.3 | 1.0 | 1897 | 8 | 0.4 | 0.2 | 0.8 | -31.5 | -283.5 | 53.3 |
| 11-12 Months | PIII(M8) | 1784 | 9 | 0.5 | 0.2 | 1.0 | 1877 | 5 | 0.3 | 0.1 | 0.6 | -89.4 | -619.4 | 43.0 |
| 14-15 Months | PIV(M11) | 1727 | 4 | 0.2 | 0.1 | 0.6 | 1814 | 10 | 0.6 | 0.3 | 1.0 | 58.0 | -45.7 | 90.4 |
| 18-22 Months | PIV(M18) | 1686 | 5 | 0.3 | 0.1 | 0.7 | 1769 | 7 | 0.4 | 0.2 | 0.8 | 25.1 | -174.3 | 81.2 |
| - | Across time points | 1816 | 26 | 1.4 | 0.9 | 2.1 | 1910 | 27 | 1.4 | 0.9 | 2.1 | -1.3 | -80.3 | 43.2 |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl Group = Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
Nasopharyngeal swabs at PRE(M0) were only collected in the Immuno subset
PRE(M0) = Prior to dose 1
PIII(M3) = 1 month post dose 3
PIII(M8) = Pre booster dose
PIV(M11) = 3 months post-booster dose
PIV(M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Occurrence of Group A *Streptococcus* in nasopharyngeal swabs and vaccine efficacy for 10Pn2+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn2+1 Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 3 Months | PRE(M0) | 253 | 0 | 0.0 | 0.0 | 1.4 | 341 | 1 | 0.3 | 0.0 | 1.6 | 100 | -5156.5 | 100 |
| 6 Months | PII(M3) | 1289 | 5 | 0.4 | 0.1 | 0.9 | 1897 | 8 | 0.4 | 0.2 | 0.8 | 8.0 | -218.9 | 76.3 |
| 11-12 Months | PII(M8) | 1269 | 8 | 0.6 | 0.3 | 1.2 | 1877 | 5 | 0.3 | 0.1 | 0.6 | -136.7 | -819.4 | 31.7 |
| 14-15 Months | PIII(M11) | 1227 | 5 | 0.4 | 0.1 | 0.9 | 1814 | 10 | 0.6 | 0.3 | 1.0 | 26.1 | -137.4 | 80.2 |
| 18-22 Months | PIII(M18) | 1216 | 5 | 0.4 | 0.1 | 1.0 | 1769 | 7 | 0.4 | 0.2 | 0.8 | -3.9 | -280.3 | 74.0 |
| - | Across time points | 1297 | 23 | 1.8 | 1.1 | 2.6 | 1910 | 27 | 1.4 | 0.9 | 2.1 | -25.4 | -127.2 | 31.3 |

10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
For each time point:
N = number of swabs cultured at the considered time point

n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
Nasopharyngeal swabs at PRE(M0) were only collected in the Immuno subset
PRE(M0) = Prior to dose 1
PII(M3) = 1 month post dose 2
PII(M8) = Prior to booster dose
PIII(M11) = 3 months post-booster dose
PIII(M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Occurrence of Group A *Streptococcus* in nasopharyngeal swabs and vaccine efficacy for 10Pn Group versus Ctrl Group in children enrolled between 7 and 11 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 7-11 Months | PRE(M0) | 236 | 1 | 0.4 | 0.0 | 2.3 | 198 | 1 | 0.5 | 0.0 | 2.8 | 16.1 | -6485.8 | 98.9 |
| 9-13 Months | PII(M2) | 230 | 0 | 0.0 | 0.0 | 1.6 | 200 | 3 | 1.5 | 0.3 | 4.3 | 100 | -110.4 | 100 |
| 13-17 Months | PII(M6) | 225 | 0 | 0.0 | 0.0 | 1.6 | 197 | 1 | 0.5 | 0.0 | 2.8 | 100 | -3314.7 | 100 |
| 16-20 Months | PIII(M9) | 209 | 0 | 0.0 | 0.0 | 1.7 | 179 | 2 | 1.1 | 0.1 | 4.0 | 100 | -356.0 | 100 |
| 23-27 Months | PIII(M16) | 200 | 2 | 1.0 | 0.1 | 3.6 | 175 | 1 | 0.6 | 0.0 | 3.1 | -75.0 | -10224.5 | 90.9 |
| - | Across time points | 240 | 3 | 1.3 | 0.3 | 3.6 | 203 | 6 | 3.0 | 1.1 | 6.3 | 57.7 | -98.0 | 93.2 |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PRE(M0) = Prior to dose 1
PII(M2) = 1 month post dose 2
PII(M6) = Prior to booster dose
PIII(M9) = 3 months post booster dose
PIII(M16) = 10 months post booster dose

**Secondary Outcome Variable(s):** Occurrence of Group A *Streptococcus* in nasopharyngeal swabs and vaccine efficacy for 10Pn Group versus Ctrl Group in children enrolled between 12 and 18 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 12-18 Months | PRE(M0) | 358 | 3 | 0.8 | 0.2 | 2.4 | 265 | 0 | 0.0 | 0.0 | 1.4 | I | I | 69.4 |
| 19-25 Months | PII(M7) | 340 | 2 | 0.6 | 0.1 | 2.1 | 255 | 0 | 0.0 | 0.0 | 1.4 | I | I | 85.9 |
| 21-27 Months | PII(M9) | 338 | 0 | 0.0 | 0.0 | 1.1 | 254 | 2 | 0.8 | 0.1 | 2.8 | 100 | -300.1 | 100 |
| - | Across time points | 365 | 5 | 1.4 | 0.4 | 3.2 | 271 | 2 | 0.7 | 0.1 | 2.6 | -85.6 | -1849.2 | 69.6 |

10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:

N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PRE(M0) = Prior to dose 1
PII(M7) = 1 month post dose 2
PII(M9) = 3 months postdose 2
I = negative infinity

**Secondary Outcome Variable(s):** Occurrence of *Staphylococcus aureus* in nasopharyngeal swabs and vaccine efficacy for 10Pn3+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn3+1 Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 3 Months | PRE(M0) | 253 | 111 | 43.9 | 37.7 | 50.2 | 341 | 144 | 42.2 | 36.9 | 47.7 | -3.9 | -34.0 | 19.6 |
| 6 Months | PIII(M3) | 1803 | 762 | 42.3 | 40.0 | 44.6 | 1897 | 796 | 42.0 | 39.7 | 44.2 | -0.7 | -11.4 | 8.9 |
| 11-12 Months | PIII(M8) | 1784 | 468 | 26.2 | 24.2 | 28.3 | 1877 | 462 | 24.6 | 22.7 | 26.6 | -6.6 | -21.5 | 6.5 |
| 14-15 Months | PIV(M11) | 1727 | 387 | 22.4 | 20.5 | 24.5 | 1814 | 373 | 20.6 | 18.7 | 22.5 | -9.0 | -26.0 | 5.7 |
| 18-22 Months | PIV(M18) | 1686 | 255 | 15.1 | 13.4 | 16.9 | 1769 | 266 | 15.0 | 13.4 | 16.8 | -0.6 | -19.9 | 15.6 |
| - | Across time points | 1816 | 1190 | 65.5 | 63.3 | 67.7 | 1910 | 1222 | 64.0 | 61.8 | 66.1 | -2.4 | -11.0 | 5.5 |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
Nasopharyngeal swabs at PRE(M0) were only collected in the Immuno subset
PRE(M0) = Prior to dose 1
PIII(M3) = 1 month post dose 3
PIII(M8) = Prior to booster dose
PIV(M11) = 3 Months post-booster dose
PIV(M18) = 10 months post-booster dose

**Secondary Outcome Variable(s):** Occurrence of *Staphylococcus aureus* in nasopharyngeal swabs and vaccine efficacy for 10Pn2+1 Group versus Ctrl Group in infants enrolled between 6 weeks and 6 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn2+1 Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 3 Months | PRE(M0) | 253 | 108 | 42.7 | 36.5 | 49.0 | 341 | 144 | 42.2 | 36.9 | 47.7 | -1.1 | -30.6 | 22.0 |
| 6 Months | PII(M3) | 1289 | 515 | 40.0 | 37.3 | 42.7 | 1897 | 796 | 42.0 | 39.7 | 44.2 | 4.8 | -6.5 | 14.9 |
| 11-12 Months | PII(M8) | 1269 | 306 | 24.1 | 21.8 | 26.6 | 1877 | 462 | 24.6 | 22.7 | 26.6 | 2.0 | -13.4 | 15.5 |
| 14-15 Months | PIII(M11) | 1227 | 282 | 23.0 | 20.7 | 25.4 | 1814 | 373 | 20.6 | 18.7 | 22.5 | -11.8 | -30.8 | 4.6 |
| 18-22 Months | PIII(M18) | 1216 | 182 | 15.0 | 13.0 | 17.1 | 1769 | 266 | 15.0 | 13.4 | 16.8 | 0.5 | -20.6 | 18.0 |
| - | Across time points | 1297 | 838 | 64.6 | 61.9 | 67.2 | 1910 | 1222 | 64.0 | 61.8 | 66.1 | -1.0 | -10.4 | 7.6 |

10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:

N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
Nasopharyngeal swabs at PRE(M0) were only collected in the Immuno subset
PRE(M0) = Prior to dose 1
PII(M3) = 1 month post dose 2
PII(M8) = Prior to booster dose
PIII(M11) = 3 months post-booster dose
PIII(M18) = 10 Months post-booster dose

**Secondary Outcome Variable(s):** Occurrence of *Staphylococcus aureus* in nasopharyngeal swabs and vaccine efficacy for 10Pn Group versus Ctrl Group in children enrolled between 7 and 11 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 7-11 Months | PRE(M0) | 236 | 60 | 25.4 | 20.0 | 31.5 | 198 | 53 | 26.8 | 20.7 | 33.5 | 5.0 | -40.1 | 35.5 |
| 9-13 Months | PII(M2) | 230 | 53 | 23.0 | 17.8 | 29.0 | 200 | 63 | 31.5 | 25.1 | 38.4 | 26.8 | -7.1 | 50.2 |
| 13-17 Months | PII(M6) | 225 | 32 | 14.2 | 9.9 | 19.5 | 197 | 26 | 13.2 | 8.8 | 18.7 | -7.8 | -88.3 | 37.8 |
| 16-20 Months | PIII(M9) | 209 | 34 | 16.3 | 11.5 | 22.0 | 179 | 31 | 17.3 | 12.1 | 23.7 | 6.1 | -58.0 | 44.0 |
| 23-27 Months | PIII(M16) | 200 | 30 | 15.0 | 10.4 | 20.7 | 175 | 36 | 20.6 | 14.8 | 27.3 | 27.1 | -21.8 | 56.6 |
| - | Across time points | 240 | 132 | 55.0 | 48.5 | 61.4 | 203 | 132 | 65.0 | 58.0 | 71.6 | 15.4 | -8.5 | 34.1 |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points:
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point
VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PRE(M0) = Prior to dose 1
PII(M2) = 1 month post dose 2
PII(M6) = Prior to booster dose
PIII(M9) = 3 months post booster dose
PIII(M16) = 10 months post booster dose

**Secondary Outcome Variable(s):** Occurrence of *Staphylococcus aureus* in nasopharyngeal swabs and vaccine efficacy for 10Pn Group versus Ctrl Group in children enrolled between 12 and 18 months of age (Total Vaccinated cohort for analysis of carriage)

| | | 10Pn Group | | | | | Ctrl Group | | | | | Vaccine efficacy | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95% CI | | | | | 95% CI | | | 95% CI | |
| **Age** | **Timing** | **N** | **N** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** | **%** | **LL** | **UL** |
| 12-18 Months | PRE(M0) | 358 | 45 | 12.6 | 9.3 | 16.5 | 265 | 38 | 14.3 | 10.4 | 19.1 | 12.3 | -38.7 | 44.3 |
| 19-25 Months | PII(M7) | 340 | 47 | 13.8 | 10.3 | 18.0 | 255 | 41 | 16.1 | 11.8 | 21.2 | 14.0 | -34.0 | 44.7 |
| 21-27 Months | PII(M9) | 338 | 39 | 11.5 | 8.3 | 15.4 | 254 | 40 | 15.7 | 11.5 | 20.8 | 26.7 | -16.8 | 54.1 |
| - | Across time points | 365 | 104 | 28.5 | 23.9 | 33.4 | 271 | 96 | 35.4 | 29.7 | 41.4 | 19.6 | -7.3 | 39.6 |

10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine
For each time point:
N = number of swabs cultured at the considered time point
n/% = number/percentage of swabs associated to the specified bacteria at the considered time point
Across time points
N = number of swabs cultured after at least one time point
n/% = number/percentage of subjects with swabs associated to the specified bacteria after at least one time point

VE (%) = Vaccine efficacy estimated as 1-Relative Risk
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit (conditional exact method)
PRE(M0) = Prior to dose 1
PII(M7) = 1 month post dose 2
PII(M9) = 3 Months post dose 2

**Secondary Outcome Variable(s):** Seropositivity rates and GMCs for anti-ANTI-1, anti-ANTI-4, anti-ANTI-5, anti-ANTI-6B, anti-ANTI-7F, anti-ANTI-9V, anti-ANTI-14, anti-ANTI-18C, anti-ANTI-19F and anti-ANTI-23F antibodies (22F-inhhibition ELISA) (ATP cohort for immunogenicity)

| | | | | ≥ 0.05 µg/mL | | | | ≥ 0.2 µg/mL | | | | GMC (µg/mL) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 95% CI | | | | 95% CI | | | 95% CI | |
| **Antibody** | **Group** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **n** | **%** | **LL** | **UL** | **value** | **LL** | **UL** |
| ANTI-1 | 10Pn3+1 | PIII(M3) | 208 | 208 | 100 | 98.2 | 100 | 208 | 100 | 98.2 | 100 | 1.86 | 1.68 | 2.05 |
| | | PIII(M8) | 202 | 202 | 100 | 98.2 | 100 | 181 | 89.6 | 84.5 | 93.4 | 0.54 | 0.48 | 0.61 |
| | | PIV(M9) | 189 | 189 | 100 | 98.1 | 100 | 189 | 100 | 98.1 | 100 | 2.13 | 1.88 | 2.41 |
| | | PIV(M18) | 185 | 183 | 98.9 | 96.1 | 99.9 | 162 | 87.6 | 81.9 | 92.0 | 0.50 | 0.44 | 0.57 |
| | Ctrl3+1 | PIII(M3) | 121 | 15 | 12.4 | 7.1 | 19.6 | 6 | 5.0 | 1.8 | 10.5 | 0.03 | 0.03 | 0.04 |
| | | PIII(M8) | 122 | 16 | 13.1 | 7.7 | 20.4 | 3 | 2.5 | 0.5 | 7.0 | 0.03 | 0.03 | 0.03 |
| | | PIV(M9) | 119 | 27 | 22.7 | 15.5 | 31.3 | 2 | 1.7 | 0.2 | 5.9 | 0.03 | 0.03 | 0.04 |
| | | PIV(M18) | 113 | 50 | 44.2 | 34.9 | 53.9 | 5 | 4.4 | 1.5 | 10.0 | 0.04 | 0.04 | 0.05 |
| | 10Pn2+1 | PII(M3) | 205 | 205 | 100 | 98.2 | 100 | 201 | 98.0 | 95.1 | 99.5 | 1.37 | 1.25 | 1.52 |
| | | PII(M8) | 209 | 209 | 100 | 98.3 | 100 | 169 | 80.9 | 74.9 | 86.0 | 0.42 | 0.37 | 0.47 |
| | | PIII(M9) | 193 | 193 | 100 | 98.1 | 100 | 193 | 100 | 98.1 | 100 | 1.91 | 1.72 | 2.12 |
| | | PIII(M18) | 189 | 188 | 99.5 | 97.1 | 100 | 145 | 76.7 | 70.0 | 82.5 | 0.36 | 0.32 | 0.40 |
| | Ctrl2+1 | PII(M3) | 142 | 10 | 7.0 | 3.4 | 12.6 | 2 | 1.4 | 0.2 | 5.0 | 0.03 | 0.03 | 0.03 |
| | | PII(M8) | 132 | 24 | 18.2 | 12.0 | 25.8 | 5 | 3.8 | 1.2 | 8.6 | 0.03 | 0.03 | 0.04 |
| | | PIII(M9) | 127 | 37 | 29.1 | 21.4 | 37.9 | 4 | 3.1 | 0.9 | 7.9 | 0.04 | 0.03 | 0.04 |
| | | PIII(M18) | 122 | 55 | 45.1 | 36.1 | 54.3 | 8 | 6.6 | 2.9 | 12.5 | 0.05 | 0.04 | 0.06 |
| ANTI-4 | 10Pn3+1 | PIII(M3) | 208 | 208 | 100 | 98.2 | 100 | 207 | 99.5 | 97.4 | 100 | 2.47 | 2.23 | 2.75 |
| | | PIII(M8) | 203 | 203 | 100 | 98.2 | 100 | 201 | 99.0 | 96.5 | 99.9 | 0.97 | 0.86 | 1.09 |
| | | PIV(M9) | 189 | 189 | 100 | 98.1 | 100 | 189 | 100 | 98.1 | 100 | 3.61 | 3.20 | 4.06 |
| | | PIV(M18) | 185 | 184 | 99.5 | 97.0 | 100 | 168 | 90.8 | 85.7 | 94.6 | 0.62 | 0.54 | 0.71 |
| | Ctrl3+1 | PIII(M3) | 122 | 5 | 4.1 | 1.3 | 9.3 | 0 | 0.0 | 0.0 | 3.0 | 0.03 | 0.03 | 0.03 |
| | | PIII(M8) | 122 | 8 | 6.6 | 2.9 | 12.5 | 2 | 1.6 | 0.2 | 5.8 | 0.03 | 0.03 | 0.03 |
| | | PIV(M9) | 116 | 10 | 8.6 | 4.2 | 15.3 | 3 | 2.6 | 0.5 | 7.4 | 0.03 | 0.03 | 0.03 |
| | | PIV(M18) | 113 | 12 | 10.6 | 5.6 | 17.8 | 4 | 3.5 | 1.0 | 8.8 | 0.03 | 0.03 | 0.03 |
| | 10Pn2+1 | PII(M3) | 204 | 204 | 100 | 98.2 | 100 | 202 | 99.0 | 96.5 | 99.9 | 1.87 | 1.68 | 2.07 |
| | | PII(M8) | 209 | 209 | 100 | 98.3 | 100 | 199 | 95.2 | 91.4 | 97.7 | 0.72 | 0.64 | 0.81 |
| | | PIII(M9) | 193 | 193 | 100 | 98.1 | 100 | 193 | 100 | 98.1 | 100 | 3.16 | 2.84 | 3.52 |
| | | PIII(M18) | 189 | 189 | 100 | 98.1 | 100 | 170 | 89.9 | 84.7 | 93.8 | 0.59 | 0.52 | 0.67 |
| | Ctrl2+1 | PII(M3) | 141 | 13 | 9.2 | 5.0 | 15.3 | 3 | 2.1 | 0.4 | 6.1 | 0.03 | 0.03 | 0.03 |
| | | PII(M8) | 134 | 16 | 11.9 | 7.0 | 18.7 | 3 | 2.2 | 0.5 | 6.4 | 0.03 | 0.03 | 0.03 |
| | | PIII(M9) | 125 | 23 | 18.4 | 12.0 | 26.3 | 5 | 4.0 | 1.3 | 9.1 | 0.03 | 0.03 | 0.04 |
| | | PIII(M18) | 122 | 16 | 13.1 | 7.7 | 20.4 | 3 | 2.5 | 0.5 | 7.0 | 0.03 | 0.03 | 0.04 |
| ANTI-5 | 10Pn3+1 | PIII(M3) | 208 | 208 | 100 | 98.2 | 100 | 208 | 100 | 98.2 | 100 | 2.73 | 2.47 | 3.01 |
| | | PIII(M8) | 201 | 201 | 100 | 98.2 | 100 | 197 | 98.0 | 95.0 | 99.5 | 1.07 | 0.95 | 1.19 |
| | | PIV(M9) | 189 | 188 | 99.5 | 97.1 | 100 | 188 | 99.5 | 97.1 | 100 | 3.27 | 2.87 | 3.73 |
| | | PIV(M18) | 185 | 185 | 100 | 98.0 | 100 | 176 | 95.1 | 91.0 | 97.8 | 0.85 | 0.75 | 0.97 |
| | Ctrl3+1 | PIII(M3) | 121 | 24 | 19.8 | 13.1 | 28.1 | 2 | 1.7 | 0.2 | 5.8 | 0.03 | 0.03 | 0.03 |
| | | PIII(M8) | 123 | 49 | 39.8 | 31.1 | 49.1 | 8 | 6.5 | 2.8 | 12.4 | 0.04 | 0.04 | 0.05 |
| | | PIV(M9) | 120 | 62 | 51.7 | 42.4 | 60.9 | 8 | 6.7 | 2.9 | 12.7 | 0.05 | 0.04 | 0.06 |
| | | PIV(M18) | 113 | 90 | 79.6 | 71.0 | 86.6 | 25 | 22.1 | 14.9 | 30.9 | 0.10 | 0.08 | 0.13 |
| | 10Pn2+1 | PII(M3) | 204 | 204 | 100 | 98.2 | 100 | 201 | 98.5 | 95.8 | 99.7 | 1.97 | 1.76 | 2.19 |
| | | PII(M8) | 209 | 208 | 99.5 | 97.4 | 100 | 198 | 94.7 | 90.8 | 97.3 | 0.71 | 0.63 | 0.80 |
| | | PIII(M9) | 193 | 193 | 100 | 98.1 | 100 | 193 | 100 | 98.1 | 100 | 2.82 | 2.52 | 3.15 |
| | | PIII(M18) | 189 | 189 | 100 | 98.1 | 100 | 182 | 96.3 | 92.5 | 98.5 | 0.83 | 0.73 | 0.94 |
| | Ctrl2+1 | PII(M3) | 139 | 33 | 23.7 | 16.9 | 31.7 | 4 | 2.9 | 0.8 | 7.2 | 0.03 | 0.03 | 0.04 |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | PII(M8) | 133 | 52 | 39.1 | 30.8 | 47.9 | 7 | 5.3 | 2.1 | 10.5 | 0.04 | 0.04 | 0.05 |
| | | PIII(M9) | 128 | 78 | 60.9 | 51.9 | 69.4 | 16 | 12.5 | 7.3 | 19.5 | 0.06 | 0.05 | 0.08 |
| | | PIII(M18) | 122 | 93 | 76.2 | 67.7 | 83.5 | 19 | 15.6 | 9.6 | 23.2 | 0.09 | 0.08 | 0.11 |
| ANTI-6B | 10Pn3+1 | PIII(M3) | 208 | 193 | 92.8 | 88.4 | 95.9 | 165 | 79.3 | 73.2 | 84.6 | 0.51 | 0.43 | 0.62 |
| | | PIII(M8) | 203 | 194 | 95.6 | 91.8 | 98.0 | 182 | 89.7 | 84.6 | 93.5 | 0.58 | 0.50 | 0.67 |
| | | PIV(M9) | 189 | 184 | 97.4 | 93.9 | 99.1 | 179 | 94.7 | 90.5 | 97.4 | 1.43 | 1.22 | 1.68 |
| | | PIV(M18) | 185 | 181 | 97.8 | 94.6 | 99.4 | 162 | 87.6 | 81.9 | 92.0 | 0.60 | 0.50 | 0.72 |
| | Ctrl3+1 | PIII(M3) | 122 | 14 | 11.5 | 6.4 | 18.5 | 3 | 2.5 | 0.5 | 7.0 | 0.03 | 0.03 | 0.03 |
| | | PIII(M8) | 123 | 11 | 8.9 | 4.5 | 15.4 | 1 | 0.8 | 0.0 | 4.4 | 0.03 | 0.03 | 0.03 |
| | | PIV(M9) | 120 | 20 | 16.7 | 10.5 | 24.6 | 1 | 0.8 | 0.0 | 4.6 | 0.03 | 0.03 | 0.03 |
| | | PIV(M18) | 113 | 42 | 37.2 | 28.3 | 46.8 | 7 | 6.2 | 2.5 | 12.3 | 0.04 | 0.04 | 0.05 |
| | 10Pn2+1 | PII(M3) | 205 | 192 | 93.7 | 89.4 | 96.6 | 136 | 66.3 | 59.4 | 72.8 | 0.32 | 0.27 | 0.37 |
| | | PII(M8) | 209 | 201 | 96.2 | 92.6 | 98.3 | 173 | 82.8 | 77.0 | 87.6 | 0.42 | 0.36 | 0.48 |
| | | PIII(M9) | 193 | 190 | 98.4 | 95.5 | 99.7 | 187 | 96.9 | 93.4 | 98.9 | 1.43 | 1.25 | 1.65 |
| | | PIII(M18) | 189 | 187 | 98.9 | 96.2 | 99.9 | 158 | 83.6 | 77.5 | 88.6 | 0.58 | 0.48 | 0.70 |
| | Ctrl2+1 | PII(M3) | 142 | 16 | 11.3 | 6.6 | 17.7 | 2 | 1.4 | 0.2 | 5.0 | 0.03 | 0.03 | 0.03 |
| | | PII(M8) | 133 | 14 | 10.5 | 5.9 | 17.0 | 3 | 2.3 | 0.5 | 6.5 | 0.03 | 0.03 | 0.03 |
| | | PIII(M9) | 127 | 23 | 18.1 | 11.8 | 25.9 | 5 | 3.9 | 1.3 | 8.9 | 0.03 | 0.03 | 0.04 |
| | | PIII(M18) | 124 | 57 | 46.0 | 37.0 | 55.1 | 17 | 13.7 | 8.2 | 21.0 | 0.06 | 0.05 | 0.07 |
| ANTI-7F | 10Pn3+1 | PIII(M3) | 209 | 209 | 100 | 98.3 | 100 | 209 | 100 | 98.3 | 100 | 2.90 | 2.62 | 3.20 |
| | | PIII(M8) | 202 | 202 | 100 | 98.2 | 100 | 202 | 100 | 98.2 | 100 | 1.56 | 1.40 | 1.74 |
| | | PIV(M9) | 189 | 189 | 100 | 98.1 | 100 | 189 | 100 | 98.1 | 100 | 4.25 | 3.80 | 4.75 |
| | | PIV(M18) | 185 | 185 | 100 | 98.0 | 100 | 184 | 99.5 | 97.0 | 100 | 1.19 | 1.07 | 1.32 |
| | Ctrl3+1 | PIII(M3) | 120 | 23 | 19.2 | 12.6 | 27.4 | 5 | 4.2 | 1.4 | 9.5 | 0.03 | 0.03 | 0.04 |
| | | PIII(M8) | 122 | 28 | 23.0 | 15.8 | 31.4 | 8 | 6.6 | 2.9 | 12.5 | 0.04 | 0.03 | 0.04 |
| | | PIV(M9) | 120 | 29 | 24.2 | 16.8 | 32.8 | 8 | 6.7 | 2.9 | 12.7 | 0.04 | 0.03 | 0.04 |
| | | PIV(M18) | 113 | 36 | 31.9 | 23.4 | 41.3 | 12 | 10.6 | 5.6 | 17.8 | 0.05 | 0.04 | 0.05 |
| | 10Pn2+1 | PII(M3) | 205 | 204 | 99.5 | 97.3 | 100 | 202 | 98.5 | 95.8 | 99.7 | 1.76 | 1.57 | 1.97 |
| | | PII(M8) | 209 | 209 | 100 | 98.3 | 100 | 204 | 97.6 | 94.5 | 99.2 | 0.96 | 0.86 | 1.07 |
| | | PIII(M9) | 193 | 193 | 100 | 98.1 | 100 | 193 | 100 | 98.1 | 100 | 3.62 | 3.28 | 4.01 |
| | | PIII(M18) | 189 | 189 | 100 | 98.1 | 100 | 189 | 100 | 98.1 | 100 | 1.27 | 1.15 | 1.41 |
| | Ctrl2+1 | PII(M3) | 140 | 27 | 19.3 | 13.1 | 26.8 | 5 | 3.6 | 1.2 | 8.1 | 0.03 | 0.03 | 0.04 |
| | | PII(M8) | 132 | 21 | 15.9 | 10.1 | 23.3 | 7 | 5.3 | 2.2 | 10.6 | 0.03 | 0.03 | 0.04 |
| | | PIII(M9) | 129 | 27 | 20.9 | 14.3 | 29.0 | 6 | 4.7 | 1.7 | 9.8 | 0.03 | 0.03 | 0.04 |
| | | PIII(M18) | 122 | 40 | 32.8 | 24.6 | 41.9 | 10 | 8.2 | 4.0 | 14.6 | 0.04 | 0.04 | 0.05 |
| ANTI-9V | 10Pn3+1 | PIII(M3) | 208 | 208 | 100 | 98.2 | 100 | 207 | 99.5 | 97.4 | 100 | 2.23 | 2.00 | 2.48 |
| | | PIII(M8) | 203 | 203 | 100 | 98.2 | 100 | 201 | 99.0 | 96.5 | 99.9 | 1.35 | 1.20 | 1.51 |
| | | PIV(M9) | 188 | 188 | 100 | 98.1 | 100 | 188 | 100 | 98.1 | 100 | 3.98 | 3.56 | 4.46 |
| | | PIV(M18) | 185 | 185 | 100 | 98.0 | 100 | 182 | 98.4 | 95.3 | 99.7 | 1.32 | 1.16 | 1.50 |
| | Ctrl3+1 | PIII(M3) | 122 | 9 | 7.4 | 3.4 | 13.5 | 2 | 1.6 | 0.2 | 5.8 | 0.03 | 0.03 | 0.03 |
| | | PIII(M8) | 121 | 6 | 5.0 | 1.8 | 10.5 | 1 | 0.8 | 0.0 | 4.5 | 0.03 | 0.03 | 0.03 |
| | | PIV(M9) | 119 | 10 | 8.4 | 4.1 | 14.9 | 1 | 0.8 | 0.0 | 4.6 | 0.03 | 0.03 | 0.03 |
| | | PIV(M18) | 113 | 22 | 19.5 | 12.6 | 28.0 | 5 | 4.4 | 1.5 | 10.0 | 0.03 | 0.03 | 0.04 |
| | 10Pn2+1 | PII(M3) | 205 | 204 | 99.5 | 97.3 | 100 | 201 | 98.0 | 95.1 | 99.5 | 1.38 | 1.24 | 1.54 |
| | | PII(M8) | 209 | 209 | 100 | 98.3 | 100 | 203 | 97.1 | 93.9 | 98.9 | 0.87 | 0.77 | 0.97 |
| | | PIII(M9) | 193 | 193 | 100 | 98.1 | 100 | 193 | 100 | 98.1 | 100 | 3.88 | 3.47 | 4.33 |
| | | PIII(M18) | 189 | 189 | 100 | 98.1 | 100 | 185 | 97.9 | 94.7 | 99.4 | 0.92 | 0.82 | 1.03 |
| | Ctrl2+1 | PII(M3) | 140 | 14 | 10.0 | 5.6 | 16.2 | 3 | 2.1 | 0.4 | 6.1 | 0.03 | 0.03 | 0.03 |
| | | PII(M8) | 133 | 8 | 6.0 | 2.6 | 11.5 | 1 | 0.8 | 0.0 | 4.1 | 0.03 | 0.03 | 0.03 |
| | | PIII(M9) | 127 | 16 | 12.6 | 7.4 | 19.7 | 3 | 2.4 | 0.5 | 6.7 | 0.03 | 0.03 | 0.03 |
| | | PIII(M18) | 122 | 24 | 19.7 | 13.0 | 27.8 | 8 | 6.6 | 2.9 | 12.5 | 0.04 | 0.03 | 0.04 |
| ANTI-14 | 10Pn3+1 | PIII(M3) | 209 | 209 | 100 | 98.3 | 100 | 209 | 100 | 98.3 | 100 | 5.00 | 4.46 | 5.61 |
| | | PIII(M8) | 202 | 202 | 100 | 98.2 | 100 | 198 | 98.0 | 95.0 | 99.5 | 2.52 | 2.19 | 2.91 |
| | | PIV(M9) | 189 | 189 | 100 | 98.1 | 100 | 189 | 100 | 98.1 | 100 | 6.40 | 5.62 | 7.29 |
| | | PIV(M18) | 185 | 185 | 100 | 98.0 | 100 | 184 | 99.5 | 97.0 | 100 | 1.98 | 1.70 | 2.30 |
| | Ctrl3+1 | PIII(M3) | 121 | 64 | 52.9 | 43.6 | 62.0 | 22 | 18.2 | 11.8 | 26.2 | 0.07 | 0.06 | 0.09 |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | PIII(M8) | 121 | 53 | 43.8 | 34.8 | 53.1 | 12 | 9.9 | 5.2 | 16.7 | 0.05 | 0.04 | 0.06 |
| | | PIV(M9) | 118 | 59 | 50.0 | 40.7 | 59.3 | 11 | 9.3 | 4.7 | 16.1 | 0.06 | 0.05 | 0.07 |
| | | PIV(M18) | 113 | 76 | 67.3 | 57.8 | 75.8 | 13 | 11.5 | 6.3 | 18.9 | 0.08 | 0.06 | 0.11 |
| | 10Pn2+1 | PII(M3) | 205 | 205 | 100 | 98.2 | 100 | 202 | 98.5 | 95.8 | 99.7 | 3.31 | 2.92 | 3.75 |
| | | PII(M8) | 209 | 208 | 99.5 | 97.4 | 100 | 197 | 94.3 | 90.2 | 97.0 | 1.32 | 1.13 | 1.54 |
| | | PIII(M9) | 193 | 193 | 100 | 98.1 | 100 | 192 | 99.5 | 97.1 | 100 | 4.84 | 4.26 | 5.51 |
| | | PIII(M18) | 189 | 189 | 100 | 98.1 | 100 | 185 | 97.9 | 94.7 | 99.4 | 1.57 | 1.32 | 1.86 |
| | Ctrl2+1 | PII(M3) | 140 | 70 | 50.0 | 41.4 | 58.6 | 22 | 15.7 | 10.1 | 22.8 | 0.06 | 0.05 | 0.07 |
| | | PII(M8) | 131 | 37 | 28.2 | 20.7 | 36.8 | 9 | 6.9 | 3.2 | 12.6 | 0.04 | 0.04 | 0.05 |
| | | PIII(M9) | 120 | 56 | 46.7 | 37.5 | 56.0 | 16 | 13.3 | 7.8 | 20.7 | 0.06 | 0.05 | 0.07 |
| | | PIII(M18) | 122 | 91 | 74.6 | 65.9 | 82.0 | 29 | 23.8 | 16.5 | 32.3 | 0.12 | 0.09 | 0.15 |
| ANTI-18C | 10Pn3+1 | PIII(M3) | 209 | 208 | 99.5 | 97.4 | 100 | 207 | 99.0 | 96.6 | 99.9 | 6.51 | 5.63 | 7.54 |
| | | PIII(M8) | 202 | 200 | 99.0 | 96.5 | 99.9 | 198 | 98.0 | 95.0 | 99.5 | 2.45 | 2.10 | 2.86 |
| | | PIV(M9) | 189 | 187 | 98.9 | 96.2 | 99.9 | 187 | 98.9 | 96.2 | 99.9 | 10.43 | 8.94 | 12.18 |
| | | PIV(M18) | 185 | 184 | 99.5 | 97.0 | 100 | 183 | 98.9 | 96.1 | 99.9 | 2.18 | 1.89 | 2.53 |
| | Ctrl3+1 | PIII(M3) | 121 | 25 | 20.7 | 13.8 | 29.0 | 3 | 2.5 | 0.5 | 7.1 | 0.03 | 0.03 | 0.04 |
| | | PIII(M8) | 123 | 5 | 4.1 | 1.3 | 9.2 | 3 | 2.4 | 0.5 | 7.0 | 0.03 | 0.03 | 0.03 |
| | | PIV(M9) | 119 | 10 | 8.4 | 4.1 | 14.9 | 2 | 1.7 | 0.2 | 5.9 | 0.03 | 0.03 | 0.03 |
| | | PIV(M18) | 113 | 23 | 20.4 | 13.4 | 29.0 | 8 | 7.1 | 3.1 | 13.5 | 0.04 | 0.03 | 0.04 |
| | 10Pn2+1 | PII(M3) | 205 | 205 | 100 | 98.2 | 100 | 203 | 99.0 | 96.5 | 99.9 | 3.38 | 2.88 | 3.95 |
| | | PII(M8) | 209 | 209 | 100 | 98.3 | 100 | 204 | 97.6 | 94.5 | 99.2 | 1.49 | 1.29 | 1.73 |
| | | PIII(M9) | 193 | 193 | 100 | 98.1 | 100 | 193 | 100 | 98.1 | 100 | 10.60 | 9.48 | 11.84 |
| | | PIII(M18) | 189 | 189 | 100 | 98.1 | 100 | 189 | 100 | 98.1 | 100 | 2.16 | 1.89 | 2.48 |
| | Ctrl2+1 | PII(M3) | 141 | 33 | 23.4 | 16.7 | 31.3 | 7 | 5.0 | 2.0 | 10.0 | 0.04 | 0.03 | 0.04 |
| | | PII(M8) | 132 | 4 | 3.0 | 0.8 | 7.6 | 1 | 0.8 | 0.0 | 4.1 | 0.03 | 0.02 | 0.03 |
| | | PIII(M9) | 124 | 20 | 16.1 | 10.1 | 23.8 | 2 | 1.6 | 0.2 | 5.7 | 0.03 | 0.03 | 0.03 |
| | | PIII(M18) | 120 | 32 | 26.7 | 19.0 | 35.5 | 9 | 7.5 | 3.5 | 13.8 | 0.04 | 0.03 | 0.05 |
| ANTI-19F | 10Pn3+1 | PIII(M3) | 209 | 209 | 100 | 98.3 | 100 | 206 | 98.6 | 95.9 | 99.7 | 5.91 | 5.06 | 6.89 |
| | | PIII(M8) | 202 | 202 | 100 | 98.2 | 100 | 200 | 99.0 | 96.5 | 99.9 | 2.73 | 2.36 | 3.16 |
| | | PIV(M9) | 189 | 189 | 100 | 98.1 | 100 | 189 | 100 | 98.1 | 100 | 8.04 | 7.04 | 9.17 |
| | | PIV(M18) | 185 | 185 | 100 | 98.0 | 100 | 183 | 98.9 | 96.1 | 99.9 | 2.17 | 1.84 | 2.55 |
| | Ctrl3+1 | PIII(M3) | 122 | 59 | 48.4 | 39.2 | 57.6 | 16 | 13.1 | 7.7 | 20.4 | 0.06 | 0.05 | 0.07 |
| | | PIII(M8) | 122 | 27 | 22.1 | 15.1 | 30.5 | 16 | 13.1 | 7.7 | 20.4 | 0.05 | 0.04 | 0.06 |
| | | PIV(M9) | 116 | 30 | 25.9 | 18.2 | 34.8 | 12 | 10.3 | 5.5 | 17.4 | 0.04 | 0.03 | 0.05 |
| | | PIV(M18) | 113 | 49 | 43.4 | 34.1 | 53.0 | 24 | 21.2 | 14.1 | 29.9 | 0.07 | 0.05 | 0.08 |
| | 10Pn2+1 | PII(M3) | 205 | 205 | 100 | 98.2 | 100 | 200 | 97.6 | 94.4 | 99.2 | 3.40 | 2.92 | 3.97 |
| | | PII(M8) | 209 | 209 | 100 | 98.3 | 100 | 200 | 95.7 | 92.0 | 98.0 | 1.51 | 1.29 | 1.75 |
| | | PIII(M9) | 193 | 193 | 100 | 98.1 | 100 | 192 | 99.5 | 97.1 | 100 | 7.41 | 6.54 | 8.40 |
| | | PIII(M18) | 189 | 189 | 100 | 98.1 | 100 | 187 | 98.9 | 96.2 | 99.9 | 2.10 | 1.79 | 2.47 |
| | Ctrl2+1 | PII(M3) | 140 | 64 | 45.7 | 37.3 | 54.3 | 21 | 15.0 | 9.5 | 22.0 | 0.06 | 0.05 | 0.07 |
| | | PII(M8) | 133 | 19 | 14.3 | 8.8 | 21.4 | 9 | 6.8 | 3.1 | 12.5 | 0.03 | 0.03 | 0.04 |
| | | PIII(M9) | 124 | 37 | 29.8 | 22.0 | 38.7 | 11 | 8.9 | 4.5 | 15.3 | 0.04 | 0.04 | 0.05 |
| | | PIII(M18) | 123 | 42 | 34.1 | 25.8 | 43.2 | 30 | 24.4 | 17.1 | 33.0 | 0.07 | 0.05 | 0.10 |
| ANTI-23F | 10Pn3+1 | PIII(M3) | 208 | 192 | 92.3 | 87.8 | 95.5 | 175 | 84.1 | 78.4 | 88.8 | 0.68 | 0.56 | 0.83 |
| | | PIII(M8) | 202 | 192 | 95.0 | 91.1 | 97.6 | 178 | 88.1 | 82.8 | 92.2 | 0.73 | 0.62 | 0.87 |
| | | PIV(M9) | 189 | 183 | 96.8 | 93.2 | 98.8 | 179 | 94.7 | 90.5 | 97.4 | 2.30 | 1.90 | 2.77 |
| | | PIV(M18) | 185 | 184 | 99.5 | 97.0 | 100 | 171 | 92.4 | 87.6 | 95.8 | 0.95 | 0.79 | 1.13 |
| | Ctrl3+1 | PIII(M3) | 121 | 18 | 14.9 | 9.1 | 22.5 | 2 | 1.7 | 0.2 | 5.8 | 0.03 | 0.03 | 0.03 |
| | | PIII(M8) | 123 | 10 | 8.1 | 4.0 | 14.4 | 4 | 3.3 | 0.9 | 8.1 | 0.03 | 0.03 | 0.03 |
| | | PIV(M9) | 119 | 16 | 13.4 | 7.9 | 20.9 | 6 | 5.0 | 1.9 | 10.7 | 0.03 | 0.03 | 0.04 |
| | | PIV(M18) | 113 | 37 | 32.7 | 24.2 | 42.2 | 15 | 13.3 | 7.6 | 20.9 | 0.05 | 0.04 | 0.06 |
| | 10Pn2+1 | PII(M3) | 205 | 195 | 95.1 | 91.2 | 97.6 | 158 | 77.1 | 70.7 | 82.6 | 0.54 | 0.45 | 0.65 |
| | | PII(M8) | 209 | 194 | 92.8 | 88.4 | 95.9 | 158 | 75.6 | 69.2 | 81.3 | 0.42 | 0.35 | 0.50 |
| | | PIII(M9) | 193 | 190 | 98.4 | 95.5 | 99.7 | 188 | 97.4 | 94.1 | 99.2 | 2.18 | 1.88 | 2.54 |
| | | PIII(M18) | 189 | 187 | 98.9 | 96.2 | 99.9 | 169 | 89.4 | 84.1 | 93.4 | 0.75 | 0.63 | 0.88 |
| | Ctrl2+1 | PII(M3) | 142 | 38 | 26.8 | 19.7 | 34.8 | 7 | 4.9 | 2.0 | 9.9 | 0.04 | 0.03 | 0.04 |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | PII(M8) | 134 | 10 | 7.5 | 3.6 | 13.3 | 2 | 1.5 | 0.2 | 5.3 | 0.03 | 0.03 | 0.03 |
| | | PIII(M9) | 123 | 23 | 18.7 | 12.2 | 26.7 | 3 | 2.4 | 0.5 | 7.0 | 0.03 | 0.03 | 0.04 |
| | | PIII(M18) | 122 | 38 | 31.1 | 23.1 | 40.2 | 8 | 6.6 | 2.9 | 12.5 | 0.04 | 0.04 | 0.05 |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with HBV vaccine
10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl2+1 Group = Infants enrolled 6 weeks-6 months of age: infant primed with 2 doses and boosted with HBV vaccine
GMC = geometric mean antibody concentration
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(M3) = 1 month after dose 2 at Month 3
PII(M8) = pre-booster vaccination blood sample at Month 8
PIII(M3) = 1 month after dose 3
PIII(M8) = pre-booster vaccination blood sample at Month 8
PIII(M9) = 1 month post-booster vaccination at Month 9
PIII(M18) = 10 months post-booster vaccination at Month 18
PIV(M9) = 1 month post-booster vaccination at Month 9
PIV(M18) = 10 months post-booster vaccination at Month 18

**Secondary Outcome Variable(s):** Seropositivity rates and GMCs for anti-ANTI-6A and anti-ANTI-19A antibodies (22F-inhhibition ELISA) (ATP cohort for immunogenicity)

| | | | | **≥ 0.05 µg/mL** | | | | **≥ 0.2 µg/mL** | | | | **GMC (µg/mL)** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **95% CI** | | | | **95% CI** | | | **95% CI** | |
| **Antibody** | **Group** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **n** | **%** | **LL** | **UL** | **value** | **LL** | **UL** |
| ANTI-6A | 10Pn3+1 | PIII(M3) | 208 | 151 | 72.6 | 66.0 | 78.5 | 80 | 38.5 | 31.8 | 45.4 | 0.13 | 0.11 | 0.15 |
| | | PIII(M8) | 202 | 169 | 83.7 | 77.8 | 88.5 | 94 | 46.5 | 39.5 | 53.7 | 0.19 | 0.16 | 0.23 |
| | | PIV(M9) | 189 | 178 | 94.2 | 89.8 | 97.1 | 145 | 76.7 | 70.0 | 82.5 | 0.53 | 0.43 | 0.65 |
| | | PIV(M18) | 185 | 175 | 94.6 | 90.3 | 97.4 | 112 | 60.5 | 53.1 | 67.6 | 0.30 | 0.25 | 0.36 |
| | Ctrl3+1 | PIII(M3) | 120 | 22 | 18.3 | 11.9 | 26.4 | 4 | 3.3 | 0.9 | 8.3 | 0.03 | 0.03 | 0.04 |
| | | PIII(M8) | 121 | 5 | 4.1 | 1.4 | 9.4 | 2 | 1.7 | 0.2 | 5.8 | 0.03 | 0.03 | 0.03 |
| | | PIV(M9) | 120 | 18 | 15.0 | 9.1 | 22.7 | 3 | 2.5 | 0.5 | 7.1 | 0.03 | 0.03 | 0.03 |
| | | PIV(M18) | 113 | 38 | 33.6 | 25.0 | 43.1 | 8 | 7.1 | 3.1 | 13.5 | 0.04 | 0.03 | 0.05 |
| | 10Pn2+1 | PII(M3) | 203 | 132 | 65.0 | 58.0 | 71.6 | 57 | 28.1 | 22.0 | 34.8 | 0.09 | 0.08 | 0.11 |
| | | PII(M8) | 209 | 163 | 78.0 | 71.8 | 83.4 | 78 | 37.3 | 30.7 | 44.3 | 0.14 | 0.12 | 0.17 |
| | | PIII(M9) | 193 | 184 | 95.3 | 91.3 | 97.8 | 150 | 77.7 | 71.2 | 83.4 | 0.50 | 0.42 | 0.60 |
| | | PIII(M18) | 189 | 171 | 90.5 | 85.4 | 94.3 | 110 | 58.2 | 50.8 | 65.3 | 0.27 | 0.22 | 0.33 |
| | Ctrl2+1 | PII(M3) | 140 | 27 | 19.3 | 13.1 | 26.8 | 6 | 4.3 | 1.6 | 9.1 | 0.03 | 0.03 | 0.04 |
| | | PII(M8) | 133 | 10 | 7.5 | 3.7 | 13.4 | 4 | 3.0 | 0.8 | 7.5 | 0.03 | 0.03 | 0.03 |
| | | PIII(M9) | 125 | 22 | 17.6 | 11.4 | 25.4 | 5 | 4.0 | 1.3 | 9.1 | 0.03 | 0.03 | 0.04 |
| | | PIII(M18) | 124 | 49 | 39.5 | 30.9 | 48.7 | 16 | 12.9 | 7.6 | 20.1 | 0.05 | 0.04 | 0.06 |
| ANTI-19A | 10Pn3+1 | PIII(M3) | 208 | 165 | 79.3 | 73.2 | 84.6 | 86 | 41.3 | 34.6 | 48.4 | 0.15 | 0.12 | 0.18 |
| | | PIII(M8) | 202 | 172 | 85.1 | 79.5 | 89.8 | 116 | 57.4 | 50.3 | 64.3 | 0.23 | 0.19 | 0.28 |
| | | PIV(M9) | 188 | 177 | 94.1 | 89.8 | 97.0 | 158 | 84.0 | 78.0 | 89.0 | 0.95 | 0.75 | 1.19 |
| | | PIV(M18) | 185 | 181 | 97.8 | 94.6 | 99.4 | 138 | 74.6 | 67.7 | 80.7 | 0.46 | 0.38 | 0.55 |
| | Ctrl3+1 | PIII(M3) | 120 | 37 | 30.8 | 22.7 | 39.9 | 15 | 12.5 | 7.2 | 19.8 | 0.04 | 0.04 | 0.05 |
| | | PIII(M8) | 122 | 17 | 13.9 | 8.3 | 21.4 | 4 | 3.3 | 0.9 | 8.2 | 0.03 | 0.03 | 0.03 |
| | | PIV(M9) | 117 | 38 | 32.5 | 24.1 | 41.8 | 8 | 6.8 | 3.0 | 13.0 | 0.04 | 0.03 | 0.05 |
| | | PIV(M18) | 113 | 47 | 41.6 | 32.4 | 51.2 | 18 | 15.9 | 9.7 | 24.0 | 0.06 | 0.05 | 0.08 |
| | 10Pn2+1 | PII(M3) | 204 | 153 | 75.0 | 68.5 | 80.8 | 86 | 42.2 | 35.3 | 49.3 | 0.13 | 0.11 | 0.16 |
| | | PII(M8) | 209 | 158 | 75.6 | 69.2 | 81.3 | 89 | 42.6 | 35.8 | 49.6 | 0.15 | 0.13 | 0.19 |
| | | PIII(M9) | 193 | 189 | 97.9 | 94.8 | 99.4 | 167 | 86.5 | 80.9 | 91.0 | 0.89 | 0.74 | 1.07 |
| | | PIII(M18) | 189 | 179 | 94.7 | 90.5 | 97.4 | 130 | 68.8 | 61.7 | 75.3 | 0.36 | 0.30 | 0.43 |
| | Ctrl2+1 | PII(M3) | 142 | 51 | 35.9 | 28.0 | 44.4 | 12 | 8.5 | 4.4 | 14.3 | 0.04 | 0.04 | 0.05 |
| | | PII(M8) | 132 | 17 | 12.9 | 7.7 | 19.8 | 3 | 2.3 | 0.5 | 6.5 | 0.03 | 0.03 | 0.03 |
| | | PIII(M9) | 125 | 29 | 23.2 | 16.1 | 31.6 | 5 | 4.0 | 1.3 | 9.1 | 0.04 | 0.03 | 0.04 |
| | | PIII(M18) | 118 | 49 | 41.5 | 32.5 | 51.0 | 21 | 17.8 | 11.4 | 25.9 | 0.06 | 0.05 | 0.08 |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with HBV vaccine

10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl2+1 Group = Infants enrolled 6 weeks-6 months of age: infant primed with 2 doses and boosted with HBV vaccine
GMC = geometric mean antibody concentration
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(M3) = 1 month after dose 2 at Month 3
PII(M8) = pre-booster vaccination blood sample at Month 8
PIII(M3) = 1 month after dose 3
PIII(M8) = pre-booster vaccination blood sample at Month 8
PIII(M9) = 1 month post-booster vaccination at Month 9
PIII(M18) = 10 months post-booster vaccination at Month 18
PIV(M9) = 1 month post-booster vaccination at Month 9
PIV(M18) = 10 months post-booster vaccination at Month 18

**Secondary Outcome Variable(s):** Seropositivity rates and GMTs for OPA-1, OPA-4, OPA-5, OPA-6B, OPA-7F, OPA-9V, OPA-14, OPA-18C, OPA-19F and OPA-23F (ATP cohort for immunogenicity)

| | | | | ≥ 8 | | | | GMT | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 95% CI | | | 95% CI | |
| **Antibody** | **Group** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **value** | **LL** | **UL** |
| OPA-1 | 10Pn3+1 | PIII(M3) | 202 | 145 | 71.8 | 65.0 | 77.9 | 52.8 | 40.7 | 68.4 |
| | | PIII(M8) | 199 | 76 | 38.2 | 31.4 | 45.3 | 13.8 | 10.8 | 17.6 |
| | | PIV(M9) | 184 | 173 | 94.0 | 89.6 | 97.0 | 305.6 | 238.9 | 390.8 |
| | | PIV(M18) | 184 | 98 | 53.3 | 45.8 | 60.6 | 20.9 | 16.1 | 27.1 |
| | Ctrl3+1 | PIII(M3) | 118 | 1 | 0.8 | 0.0 | 4.6 | 4.1 | 3.9 | 4.2 |
| | | PIII(M8) | 119 | 4 | 3.4 | 0.9 | 8.4 | 4.4 | 4.0 | 4.9 |
| | | PIV(M9) | 120 | 7 | 5.8 | 2.4 | 11.6 | 4.6 | 4.1 | 5.1 |
| | | PIV(M18) | 112 | 1 | 0.9 | 0.0 | 4.9 | 4.1 | 3.9 | 4.2 |
| | 10Pn2+1 | PII(M3) | 196 | 131 | 66.8 | 59.8 | 73.4 | 38.3 | 30.0 | 49.0 |
| | | PII(M8) | 205 | 60 | 29.3 | 23.1 | 36.0 | 9.8 | 8.0 | 12.0 |
| | | PIII(M9) | 185 | 160 | 86.5 | 80.7 | 91.1 | 256.9 | 194.6 | 339.2 |
| | | PIII(M18) | 187 | 68 | 36.4 | 29.5 | 43.7 | 13.0 | 10.2 | 16.6 |
| | Ctrl2+1 | PII(M3) | 139 | 1 | 0.7 | 0.0 | 3.9 | 4.1 | 3.9 | 4.2 |
| | | PII(M8) | 132 | 5 | 3.8 | 1.2 | 8.6 | 4.6 | 4.0 | 5.3 |
| | | PIII(M9) | 125 | 1 | 0.8 | 0.0 | 4.4 | 4.2 | 3.9 | 4.5 |
| | | PIII(M18) | 119 | 3 | 2.5 | 0.5 | 7.2 | 4.2 | 4.0 | 4.5 |
| OPA-4 | 10Pn3+1 | PIII(M3) | 199 | 199 | 100 | 98.2 | 100 | 845.6 | 746.8 | 957.4 |
| | | PIII(M8) | 190 | 158 | 83.2 | 77.1 | 88.2 | 78.7 | 61.1 | 101.3 |
| | | PIV(M9) | 184 | 184 | 100 | 98.0 | 100 | 1745.7 | 1476.3 | 2064.1 |
| | | PIV(M18) | 172 | 127 | 73.8 | 66.6 | 80.2 | 105.1 | 75.2 | 146.8 |
| | Ctrl3+1 | PIII(M3) | 112 | 3 | 2.7 | 0.6 | 7.6 | 4.6 | 3.9 | 5.5 |
| | | PIII(M8) | 119 | 9 | 7.6 | 3.5 | 13.9 | 6.0 | 4.6 | 7.7 |
| | | PIV(M9) | 115 | 8 | 7.0 | 3.1 | 13.2 | 5.8 | 4.5 | 7.5 |
| | | PIV(M18) | 109 | 11 | 10.1 | 5.1 | 17.3 | 6.6 | 4.9 | 8.8 |
| | 10Pn2+1 | PII(M3) | 192 | 191 | 99.5 | 97.1 | 100 | 553.0 | 484.9 | 630.5 |
| | | PII(M8) | 195 | 132 | 67.7 | 60.6 | 74.2 | 43.4 | 32.9 | 57.3 |
| | | PIII(M9) | 187 | 186 | 99.5 | 97.1 | 100 | 1143.4 | 961.9 | 1359.0 |
| | | PIII(M18) | 181 | 114 | 63.0 | 55.5 | 70.0 | 51.9 | 37.5 | 72.0 |
| | Ctrl2+1 | PII(M3) | 134 | 5 | 3.7 | 1.2 | 8.5 | 4.8 | 4.1 | 5.6 |
| | | PII(M8) | 125 | 4 | 3.2 | 0.9 | 8.0 | 4.6 | 4.0 | 5.2 |
| | | PIII(M9) | 122 | 4 | 3.3 | 0.9 | 8.2 | 4.7 | 4.0 | 5.6 |
| | | PIII(M18) | 115 | 14 | 12.2 | 6.8 | 19.6 | 6.3 | 5.0 | 7.9 |
| OPA-5 | 10Pn3+1 | PIII(M3) | 199 | 185 | 93.0 | 88.5 | 96.1 | 65.9 | 55.8 | 77.7 |
| | | PIII(M8) | 197 | 139 | 70.6 | 63.7 | 76.8 | 20.6 | 16.9 | 25.0 |
| | | PIV(M9) | 185 | 179 | 96.8 | 93.1 | 98.8 | 191.6 | 155.9 | 235.4 |
| | | PIV(M18) | 179 | 139 | 77.7 | 70.8 | 83.5 | 26.9 | 22.1 | 32.8 |
| | Ctrl3+1 | PIII(M3) | 118 | 1 | 0.8 | 0.0 | 4.6 | 4.0 | 4.0 | 4.1 |
| | | PIII(M8) | 119 | 0 | 0.0 | 0.0 | 3.1 | 4.0 | 4.0 | 4.0 |
| | | PIV(M9) | 120 | 1 | 0.8 | 0.0 | 4.6 | 4.1 | 3.9 | 4.2 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PIV(M18) | 112 | 0 | 0.0 | 0.0 | 3.2 | 4.0 | 4.0 | 4.0 |
| | 10Pn2+1 | PII(M3) | 195 | 172 | 88.2 | 82.8 | 92.4 | 48.5 | 40.5 | 58.0 |
| | | PII(M8) | 204 | 127 | 62.3 | 55.2 | 68.9 | 15.6 | 13.1 | 18.6 |
| | | PIII(M9) | 186 | 179 | 96.2 | 92.4 | 98.5 | 145.6 | 120.2 | 176.2 |
| | | PIII(M18) | 187 | 123 | 65.8 | 58.5 | 72.5 | 21.2 | 17.3 | 26.1 |
| | Ctrl2+1 | PII(M3) | 135 | 0 | 0.0 | 0.0 | 2.7 | 4.0 | 4.0 | 4.0 |
| | | PII(M8) | 132 | 1 | 0.8 | 0.0 | 4.1 | 4.1 | 3.9 | 4.3 |
| | | PIII(M9) | 126 | 1 | 0.8 | 0.0 | 4.3 | 4.1 | 3.9 | 4.3 |
| | | PIII(M18) | 119 | 0 | 0.0 | 0.0 | 3.1 | 4.0 | 4.0 | 4.0 |
| OPA-6B | 10Pn3+1 | PIII(M3) | 195 | 175 | 89.7 | 84.6 | 93.6 | 740.6 | 558.3 | 982.4 |
| | | PIII(M8) | 195 | 163 | 83.6 | 77.6 | 88.5 | 220.3 | 161.1 | 301.1 |
| | | PIV(M9) | 181 | 171 | 94.5 | 90.1 | 97.3 | 736.3 | 576.2 | 941.0 |
| | | PIV(M18) | 179 | 129 | 72.1 | 64.9 | 78.5 | 75.0 | 51.6 | 109.0 |
| | Ctrl3+1 | PIII(M3) | 111 | 2 | 1.8 | 0.2 | 6.4 | 4.4 | 3.8 | 5.0 |
| | | PIII(M8) | 116 | 6 | 5.2 | 1.9 | 10.9 | 5.5 | 4.2 | 7.2 |
| | | PIV(M9) | 117 | 8 | 6.8 | 3.0 | 13.0 | 6.1 | 4.6 | 8.2 |
| | | PIV(M18) | 106 | 12 | 11.3 | 6.0 | 18.9 | 7.4 | 5.3 | 10.4 |
| | 10Pn2+1 | PII(M3) | 186 | 149 | 80.1 | 73.6 | 85.6 | 268.6 | 193.3 | 373.3 |
| | | PII(M8) | 191 | 139 | 72.8 | 65.9 | 79.0 | 121.6 | 85.9 | 172.3 |
| | | PIII(M9) | 183 | 176 | 96.2 | 92.3 | 98.4 | 879.1 | 695.4 | 1111.2 |
| | | PIII(M18) | 173 | 108 | 62.4 | 54.8 | 69.7 | 62.0 | 41.6 | 92.3 |
| | Ctrl2+1 | PII(M3) | 132 | 1 | 0.8 | 0.0 | 4.1 | 4.2 | 3.8 | 4.7 |
| | | PII(M8) | 130 | 4 | 3.1 | 0.8 | 7.7 | 4.8 | 4.0 | 5.9 |
| | | PIII(M9) | 117 | 7 | 6.0 | 2.4 | 11.9 | 5.3 | 4.3 | 6.6 |
| | | PIII(M18) | 115 | 16 | 13.9 | 8.2 | 21.6 | 7.9 | 5.7 | 11.1 |
| OPA-7F | 10Pn3+1 | PIII(M3) | 197 | 197 | 100 | 98.1 | 100 | 3894.8 | 3320.2 | 4569.0 |
| | | PIII(M8) | 199 | 199 | 100 | 98.2 | 100 | 1960.7 | 1654.4 | 2323.7 |
| | | PIV(M9) | 184 | 184 | 100 | 98.0 | 100 | 5219.7 | 4440.2 | 6136.0 |
| | | PIV(M18) | 183 | 183 | 100 | 98.0 | 100 | 2124.5 | 1813.8 | 2488.5 |
| | Ctrl3+1 | PIII(M3) | 103 | 71 | 68.9 | 59.1 | 77.7 | 87.6 | 56.8 | 135.1 |
| | | PIII(M8) | 114 | 103 | 90.4 | 83.4 | 95.1 | 349.0 | 252.2 | 483.0 |
| | | PIV(M9) | 117 | 110 | 94.0 | 88.1 | 97.6 | 436.7 | 324.7 | 587.4 |
| | | PIV(M18) | 109 | 103 | 94.5 | 88.4 | 98.0 | 643.3 | 479.5 | 863.0 |
| | 10Pn2+1 | PII(M3) | 190 | 189 | 99.5 | 97.1 | 100 | 2553.5 | 2124.7 | 3069.0 |
| | | PII(M8) | 202 | 202 | 100 | 98.2 | 100 | 1454.9 | 1235.2 | 1713.7 |
| | | PIII(M9) | 185 | 185 | 100 | 98.0 | 100 | 4863.2 | 4211.1 | 5616.3 |
| | | PIII(M18) | 186 | 186 | 100 | 98.0 | 100 | 2182.7 | 1910.6 | 2493.5 |
| | Ctrl2+1 | PII(M3) | 118 | 70 | 59.3 | 49.9 | 68.3 | 59.6 | 38.3 | 92.6 |
| | | PII(M8) | 124 | 114 | 91.9 | 85.7 | 96.1 | 364.8 | 270.9 | 491.3 |
| | | PIII(M9) | 117 | 108 | 92.3 | 85.9 | 96.4 | 522.2 | 372.4 | 732.3 |
| | | PIII(M18) | 113 | 106 | 93.8 | 87.7 | 97.5 | 856.5 | 617.2 | 1188.6 |
| OPA-9V | 10Pn3+1 | PIII(M3) | 194 | 194 | 100 | 98.1 | 100 | 2798.0 | 2411.9 | 3246.0 |
| | | PIII(M8) | 198 | 198 | 100 | 98.2 | 100 | 735.3 | 625.6 | 864.3 |
| | | PIV(M9) | 183 | 183 | 100 | 98.0 | 100 | 3491.2 | 3049.2 | 3997.3 |
| | | PIV(M18) | 181 | 180 | 99.4 | 97.0 | 100 | 809.1 | 677.0 | 966.9 |
| | Ctrl3+1 | PIII(M3) | 112 | 14 | 12.5 | 7.0 | 20.1 | 6.5 | 5.1 | 8.3 |
| | | PIII(M8) | 105 | 41 | 39.0 | 29.7 | 49.1 | 19.4 | 12.9 | 29.1 |
| | | PIV(M9) | 110 | 45 | 40.9 | 31.6 | 50.7 | 24.7 | 16.0 | 38.0 |
| | | PIV(M18) | 100 | 61 | 61.0 | 50.7 | 70.6 | 73.0 | 44.9 | 118.5 |
| | 10Pn2+1 | PII(M3) | 186 | 186 | 100 | 98.0 | 100 | 1687.2 | 1442.7 | 1973.1 |
| | | PII(M8) | 198 | 198 | 100 | 98.2 | 100 | 509.4 | 431.3 | 601.6 |
| | | PIII(M9) | 179 | 179 | 100 | 98.0 | 100 | 3196.0 | 2718.4 | 3757.6 |
| | | PIII(M18) | 185 | 183 | 98.9 | 96.1 | 99.9 | 700.1 | 592.5 | 827.1 |
| | Ctrl2+1 | PII(M3) | 130 | 10 | 7.7 | 3.8 | 13.7 | 5.3 | 4.5 | 6.4 |
| | | PII(M8) | 123 | 46 | 37.4 | 28.8 | 46.6 | 19.3 | 13.2 | 28.4 |
| | | PIII(M9) | 109 | 46 | 42.2 | 32.8 | 52.0 | 24.5 | 15.9 | 37.6 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PIII(M18) | 108 | 62 | 57.4 | 47.5 | 66.9 | 55.9 | 35.4 | 88.2 |
| OPA-14 | 10Pn3+1 | PIII(M3) | 198 | 197 | 99.5 | 97.2 | 100 | 1831.3 | 1572.5 | 2132.7 |
| | | PIII(M8) | 198 | 194 | 98.0 | 94.9 | 99.4 | 529.4 | 446.6 | 627.6 |
| | | PIV(M9) | 185 | 185 | 100 | 98.0 | 100 | 2657.2 | 2280.6 | 3096.1 |
| | | PIV(M18) | 180 | 175 | 97.2 | 93.6 | 99.1 | 639.0 | 524.6 | 778.4 |
| | Ctrl3+1 | PIII(M3) | 106 | 27 | 25.5 | 17.5 | 34.9 | 10.5 | 7.5 | 14.7 |
| | | PIII(M8) | 105 | 40 | 38.1 | 28.8 | 48.1 | 18.9 | 12.6 | 28.3 |
| | | PIV(M9) | 109 | 29 | 26.6 | 18.6 | 35.9 | 14.1 | 9.3 | 21.3 |
| | | PIV(M18) | 101 | 51 | 50.5 | 40.4 | 60.6 | 45.2 | 27.4 | 74.4 |
| | 10Pn2+1 | PII(M3) | 191 | 188 | 98.4 | 95.5 | 99.7 | 1146.3 | 944.2 | 1391.8 |
| | | PII(M8) | 198 | 178 | 89.9 | 84.8 | 93.7 | 233.5 | 185.1 | 294.7 |
| | | PIII(M9) | 187 | 187 | 100 | 98.0 | 100 | 1724.2 | 1475.5 | 2014.8 |
| | | PIII(M18) | 182 | 174 | 95.6 | 91.5 | 98.1 | 463.8 | 380.9 | 564.7 |
| | Ctrl2+1 | PII(M3) | 124 | 18 | 14.5 | 8.8 | 22.0 | 7.3 | 5.5 | 9.5 |
| | | PII(M8) | 123 | 48 | 39.0 | 30.4 | 48.2 | 22.2 | 14.8 | 33.1 |
| | | PIII(M9) | 114 | 50 | 43.9 | 34.6 | 53.5 | 26.2 | 17.3 | 39.9 |
| | | PIII(M18) | 104 | 74 | 71.2 | 61.4 | 79.6 | 99.2 | 64.2 | 153.3 |
| OPA-18C | 10Pn3+1 | PIII(M3) | 192 | 188 | 97.9 | 94.8 | 99.4 | 543.3 | 444.5 | 664.2 |
| | | PIII(M8) | 195 | 146 | 74.9 | 68.2 | 80.8 | 50.0 | 38.0 | 65.7 |
| | | PIV(M9) | 183 | 181 | 98.9 | 96.1 | 99.9 | 1066.1 | 890.3 | 1276.6 |
| | | PIV(M18) | 179 | 148 | 82.7 | 76.3 | 87.9 | 70.4 | 53.7 | 92.2 |
| | Ctrl3+1 | PIII(M3) | 116 | 0 | 0.0 | 0.0 | 3.1 | 4.0 | 4.0 | 4.0 |
| | | PIII(M8) | 118 | 1 | 0.8 | 0.0 | 4.6 | 4.1 | 3.9 | 4.3 |
| | | PIV(M9) | 118 | 0 | 0.0 | 0.0 | 3.1 | 4.0 | 4.0 | 4.0 |
| | | PIV(M18) | 110 | 1 | 0.9 | 0.0 | 5.0 | 4.1 | 3.9 | 4.4 |
| | 10Pn2+1 | PII(M3) | 184 | 168 | 91.3 | 86.3 | 94.9 | 230.6 | 177.0 | 300.4 |
| | | PII(M8) | 197 | 118 | 59.9 | 52.7 | 66.8 | 28.9 | 21.6 | 38.6 |
| | | PIII(M9) | 183 | 183 | 100 | 98.0 | 100 | 1052.2 | 881.8 | 1255.5 |
| | | PIII(M18) | 179 | 147 | 82.1 | 75.7 | 87.4 | 84.9 | 63.4 | 113.6 |
| | Ctrl2+1 | PII(M3) | 132 | 0 | 0.0 | 0.0 | 2.8 | 4.0 | 4.0 | 4.0 |
| | | PII(M8) | 131 | 1 | 0.8 | 0.0 | 4.2 | 4.1 | 3.9 | 4.3 |
| | | PIII(M9) | 125 | 1 | 0.8 | 0.0 | 4.4 | 4.2 | 3.9 | 4.5 |
| | | PIII(M18) | 119 | 22 | 18.5 | 12.0 | 26.6 | 6.2 | 5.2 | 7.4 |
| OPA-19F | 10Pn3+1 | PIII(M3) | 196 | 191 | 97.4 | 94.1 | 99.2 | 649.6 | 522.7 | 807.4 |
| | | PIII(M8) | 198 | 165 | 83.3 | 77.4 | 88.2 | 63.5 | 49.2 | 81.9 |
| | | PIV(M9) | 183 | 177 | 96.7 | 93.0 | 98.8 | 1026.0 | 807.3 | 1303.9 |
| | | PIV(M18) | 181 | 155 | 85.6 | 79.7 | 90.4 | 80.1 | 60.2 | 106.6 |
| | Ctrl3+1 | PIII(M3) | 118 | 0 | 0.0 | 0.0 | 3.1 | 4.0 | 4.0 | 4.0 |
| | | PIII(M8) | 117 | 2 | 1.7 | 0.2 | 6.0 | 4.2 | 3.9 | 4.6 |
| | | PIV(M9) | 119 | 3 | 2.5 | 0.5 | 7.2 | 4.4 | 3.9 | 4.8 |
| | | PIV(M18) | 110 | 4 | 3.6 | 1.0 | 9.0 | 4.4 | 4.0 | 4.8 |
| | 10Pn2+1 | PII(M3) | 187 | 163 | 87.2 | 81.5 | 91.6 | 197.6 | 148.6 | 262.8 |
| | | PII(M8) | 204 | 135 | 66.2 | 59.2 | 72.6 | 30.1 | 23.6 | 38.5 |
| | | PIII(M9) | 186 | 180 | 96.8 | 93.1 | 98.8 | 854.6 | 672.1 | 1086.6 |
| | | PIII(M18) | 187 | 151 | 80.7 | 74.4 | 86.1 | 56.7 | 42.7 | 75.3 |
| | Ctrl2+1 | PII(M3) | 138 | 2 | 1.4 | 0.2 | 5.1 | 4.1 | 4.0 | 4.2 |
| | | PII(M8) | 132 | 2 | 1.5 | 0.2 | 5.4 | 4.2 | 3.9 | 4.5 |
| | | PIII(M9) | 125 | 0 | 0.0 | 0.0 | 2.9 | 4.0 | 4.0 | 4.0 |
| | | PIII(M18) | 116 | 4 | 3.4 | 0.9 | 8.6 | 4.3 | 4.0 | 4.7 |
| OPA-23F | 10Pn3+1 | PIII(M3) | 196 | 182 | 92.9 | 88.3 | 96.0 | 1900.7 | 1440.0 | 2508.7 |
| | | PIII(M8) | 191 | 154 | 80.6 | 74.3 | 86.0 | 457.1 | 313.4 | 666.8 |
| | | PIV(M9) | 184 | 183 | 99.5 | 97.0 | 100 | 3248.2 | 2705.9 | 3899.2 |
| | | PIV(M18) | 174 | 137 | 78.7 | 71.9 | 84.6 | 398.6 | 265.6 | 598.3 |
| | Ctrl3+1 | PIII(M3) | 111 | 9 | 8.1 | 3.8 | 14.8 | 7.0 | 4.9 | 10.1 |
| | | PIII(M8) | 111 | 24 | 21.6 | 14.4 | 30.4 | 15.9 | 9.6 | 26.3 |
| | | PIV(M9) | 119 | 31 | 26.1 | 18.4 | 34.9 | 21.8 | 12.9 | 37.0 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PIV(M18) | 109 | 43 | 39.4 | 30.2 | 49.3 | 56.4 | 29.9 | 106.3 |
| | 10Pn2+1 | PII(M3) | 188 | 168 | 89.4 | 84.0 | 93.4 | 897.1 | 663.5 | 1212.9 |
| | | PII(M8) | 202 | 138 | 68.3 | 61.4 | 74.7 | 237.2 | 156.6 | 359.3 |
| | | PIII(M9) | 184 | 179 | 97.3 | 93.8 | 99.1 | 2630.7 | 2047.9 | 3379.2 |
| | | PIII(M18) | 181 | 118 | 65.2 | 57.8 | 72.1 | 222.7 | 139.3 | 356.1 |
| | Ctrl2+1 | PII(M3) | 131 | 8 | 6.1 | 2.7 | 11.7 | 5.6 | 4.4 | 7.1 |
| | | PII(M8) | 129 | 29 | 22.5 | 15.6 | 30.7 | 17.3 | 10.6 | 28.0 |
| | | PIII(M9) | 121 | 28 | 23.1 | 16.0 | 31.7 | 17.3 | 10.6 | 28.2 |
| | | PIII(M18) | 113 | 41 | 36.3 | 27.4 | 45.9 | 43.4 | 23.8 | 79.0 |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with HBV vaccine
10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl2+1 Group = Infants enrolled 6 weeks-6 months of age: infant primed with 2 doses and boosted with HBV vaccine
GMT = geometric mean antibody titre
n/% = number/percentage of subjects with titre equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(M3) = 1 month after dose 2 at Month 3
PII(M8) = pre-booster vaccination blood sample at Month 8
PIII(M3) = 1 month after dose 3
PIII(M8) = pre-booster vaccination blood sample at Month 8
PIII(M9) = 1 month post-booster vaccination at Month 9
PIII(M18) = 10 months post-booster vaccination at Month 18
PIV(M9) = 1 month post-booster vaccination at Month 9
PIV(M18) = 10 months post-booster vaccination at Month 18

**Secondary Outcome Variable(s):** Seropositivity rates and GMTs for OPA-6A and OPA-19A (ATP cohort for immunogenicity)

| | | | | **≥ 8** | | | | **GMT** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **95% CI** | | | **95% CI** | |
| **Antibody** | **Group** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **value** | **LL** | **UL** |
| OPA-6A | 10Pn3+1 | PIII(M3) | 191 | 137 | 71.7 | 64.8 | 78.0 | 90.8 | 66.4 | 124.3 |
| | | PIII(M8) | 188 | 120 | 63.8 | 56.5 | 70.7 | 70.9 | 50.7 | 99.1 |
| | | PIV(M9) | 177 | 138 | 78.0 | 71.1 | 83.8 | 173.8 | 125.7 | 240.4 |
| | | PIV(M18) | 179 | 87 | 48.6 | 41.1 | 56.2 | 32.9 | 23.2 | 46.7 |
| | Ctrl3+1 | PIII(M3) | 116 | 1 | 0.9 | 0.0 | 4.7 | 4.1 | 3.9 | 4.4 |
| | | PIII(M8) | 117 | 6 | 5.1 | 1.9 | 10.8 | 5.2 | 4.2 | 6.4 |
| | | PIV(M9) | 115 | 7 | 6.1 | 2.5 | 12.1 | 5.3 | 4.3 | 6.5 |
| | | PIV(M18) | 109 | 17 | 15.6 | 9.4 | 23.8 | 8.0 | 5.9 | 11.0 |
| | 10Pn2+1 | PII(M3) | 183 | 104 | 56.8 | 49.3 | 64.1 | 43.1 | 31.2 | 59.5 |
| | | PII(M8) | 195 | 115 | 59.0 | 51.7 | 66.0 | 59.0 | 42.0 | 82.9 |
| | | PIII(M9) | 168 | 141 | 83.9 | 77.5 | 89.1 | 285.9 | 205.3 | 398.2 |
| | | PIII(M18) | 167 | 87 | 52.1 | 44.2 | 59.9 | 41.8 | 28.8 | 60.8 |
| | Ctrl2+1 | PII(M3) | 135 | 2 | 1.5 | 0.2 | 5.2 | 4.4 | 3.8 | 5.0 |
| | | PII(M8) | 132 | 7 | 5.3 | 2.2 | 10.6 | 5.1 | 4.3 | 6.2 |
| | | PIII(M9) | 113 | 7 | 6.2 | 2.5 | 12.3 | 5.3 | 4.3 | 6.6 |
| | | PIII(M18) | 110 | 25 | 22.7 | 15.3 | 31.7 | 10.5 | 7.4 | 14.8 |
| OPA-19A | 10Pn3+1 | PIII(M3) | 193 | 82 | 42.5 | 35.4 | 49.8 | 25.2 | 18.3 | 34.8 |
| | | PIII(M8) | 197 | 46 | 23.4 | 17.6 | 29.9 | 8.6 | 7.0 | 10.7 |
| | | PIV(M9) | 181 | 142 | 78.5 | 71.7 | 84.2 | 145.0 | 104.7 | 200.9 |
| | | PIV(M18) | 182 | 52 | 28.6 | 22.1 | 35.7 | 12.2 | 9.2 | 16.1 |
| | Ctrl3+1 | PIII(M3) | 118 | 3 | 2.5 | 0.5 | 7.3 | 4.3 | 3.9 | 4.8 |
| | | PIII(M8) | 118 | 4 | 3.4 | 0.9 | 8.5 | 4.3 | 3.9 | 4.8 |
| | | PIV(M9) | 119 | 4 | 3.4 | 0.9 | 8.4 | 4.3 | 4.0 | 4.8 |
| | | PIV(M18) | 111 | 7 | 6.3 | 2.6 | 12.6 | 4.8 | 4.1 | 5.7 |
| | 10Pn2+1 | PII(M3) | 190 | 55 | 28.9 | 22.6 | 36.0 | 11.9 | 9.2 | 15.5 |
| | | PII(M8) | 204 | 25 | 12.3 | 8.1 | 17.6 | 5.8 | 5.0 | 6.9 |
| | | PIII(M9) | 183 | 127 | 69.4 | 62.2 | 76.0 | 78.9 | 55.5 | 112.2 |
| | | PIII(M18) | 181 | 37 | 20.4 | 14.8 | 27.1 | 8.5 | 6.6 | 10.9 |
| | Ctrl2+1 | PII(M3) | 137 | 2 | 1.5 | 0.2 | 5.2 | 4.1 | 4.0 | 4.3 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PII(M8) | 129 | 1 | 0.8 | 0.0 | 4.2 | 4.0 | 4.0 | 4.1 |
| | | PIII(M9) | 125 | 2 | 1.6 | 0.2 | 5.7 | 4.1 | 4.0 | 4.2 |
| | | PIII(M18) | 118 | 7 | 5.9 | 2.4 | 11.8 | 5.1 | 4.2 | 6.3 |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with HBV vaccine
10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl2+1 Group = Infants enrolled 6 weeks-6 months of age: infant primed with 2 doses and boosted with HBV vaccine
GMT = geometric mean antibody titre
n/% = number/percentage of subjects with titre equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(M3) = 1 month after dose 2 at Month 3
PII(M8) = pre-booster vaccination blood sample at Month 8
PIII(M3) = 1 month after dose 3
PIII(M8) = pre-booster vaccination blood sample at Month 8
PIII(M9) = 1 month post-booster vaccination at Month 9
PIII(M18) = 10 months post-booster vaccination at Month 18
PIV(M9) = 1 month post-booster vaccination at Month 9
PIV(M18) = 10 months post-booster vaccination at Month 18

**Secondary Outcome Variable(s):** Seropositivity rates and GMCs for ANTI-PD antibodies (ATP cohort for immunogenicity)

| | | | | **≥ 100 EL.U/mL** | | | | **GMC (EL.U/mL)** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **95% CI** | | | **95% CI** | |
| **Antibody** | **Group** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **value** | **LL** | **UL** |
| ANTI-PD | 10Pn3+1 | PIII(M3) | 209 | 208 | 99.5 | 97.4 | 100 | 1869.4 | 1670.7 | 2091.7 |
| | | PIII(M8) | 203 | 201 | 99.0 | 96.5 | 99.9 | 955.2 | 837.1 | 1089.9 |
| | | PIV(M9) | 188 | 188 | 100 | 98.1 | 100 | 2734.7 | 2406.0 | 3108.3 |
| | | PIV(M18) | 185 | 184 | 99.5 | 97.0 | 100 | 1030.0 | 884.3 | 1199.7 |
| | Ctrl3+1 | PIII(M3) | 121 | 16 | 13.2 | 7.8 | 20.6 | 60.5 | 54.8 | 66.7 |
| | | PIII(M8) | 123 | 18 | 14.6 | 8.9 | 22.1 | 62.7 | 56.4 | 69.7 |
| | | PIV(M9) | 118 | 15 | 12.7 | 7.3 | 20.1 | 61.6 | 55.0 | 69.0 |
| | | PIV(M18) | 113 | 18 | 15.9 | 9.7 | 24.0 | 65.5 | 57.4 | 74.8 |
| | 10Pn2+1 | PII(M3) | 203 | 202 | 99.5 | 97.3 | 100 | 1062.9 | 936.0 | 1207.0 |
| | | PII(M8) | 209 | 201 | 96.2 | 92.6 | 98.3 | 505.6 | 439.2 | 582.1 |
| | | PIII(M9) | 193 | 192 | 99.5 | 97.1 | 100 | 1903.9 | 1642.7 | 2206.6 |
| | | PIII(M18) | 188 | 179 | 95.2 | 91.1 | 97.8 | 687.7 | 577.8 | 818.4 |
| | Ctrl2+1 | PII(M3) | 139 | 32 | 23.0 | 16.3 | 30.9 | 66.1 | 60.3 | 72.4 |
| | | PII(M8) | 131 | 22 | 16.8 | 10.8 | 24.3 | 62.9 | 57.0 | 69.5 |
| | | PIII(M9) | 127 | 30 | 23.6 | 16.5 | 32.0 | 68.2 | 61.1 | 76.1 |
| | | PIII(M18) | 124 | 37 | 29.8 | 22.0 | 38.7 | 78.6 | 68.8 | 89.8 |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with HBV vaccine
10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl2+1 Group = Infants enrolled 6 weeks-6 months of age: infant primed with 2 doses and boosted with HBV vaccine
GMC = geometric mean antibody concentration
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(M3) = 1 month after dose 2 at Month 3
PII(M8) = pre-booster vaccination blood sample at Month 8
PIII(M3) = 1 month after dose 3
PIII(M8) = pre-booster vaccination blood sample at Month 8
PIII(M9) = one month post-booster vaccination at Month 9
PIII(M18) = ten months post-booster vaccination at Month 18
PIV(M9) = 1 month post-booster vaccination at Month 9
PIV(M18) = 10 months post-booster vaccination at Month 18

**Secondary Outcome Variable(s):** Seropositivity rates and GMCs for anti-ANTI-1, anti-ANTI-4, anti-ANTI-5, anti-ANTI-6B, anti-ANTI-7F, anti-ANTI-9V, anti-ANTI-14, anti-ANTI-18C, anti-ANTI-19F and anti-ANTI-23F antibodies (22F-inhhibition ELISA) (ATP cohort for immunogenicity)

| | **≥ 0.05 µg/mL** | **≥ 0.2 µg/mL** | **GMC (µg/mL)** |
|---|---|---|---|

| | | | | | | | 95% CI | | | | 95% CI | | | 95% CI | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Antibody** | **Sub-Group** | **Group** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **n** | **%** | **LL** | **UL** | **value** | **LL** | **UL** |
| ANTI-1 | Catch-up 7-11M | 10Pn | PII(M2) | 151 | 151 | 100 | 97.6 | 100 | 149 | 98.7 | 95.3 | 99.8 | 1.96 | 1.72 | 2.23 |
| | | | PII(M6) | 144 | 144 | 100 | 97.5 | 100 | 139 | 96.5 | 92.1 | 98.9 | 0.66 | 0.58 | 0.75 |
| | | | PIII(M7) | 137 | 137 | 100 | 97.3 | 100 | 137 | 100 | 97.3 | 100 | 2.62 | 2.33 | 2.94 |
| | | | PIII(M16) | 124 | 124 | 100 | 97.1 | 100 | 117 | 94.4 | 88.7 | 97.7 | 0.59 | 0.51 | 0.68 |
| | | Ctrl | PII(M2) | 100 | 14 | 14.0 | 7.9 | 22.4 | 1 | 1.0 | 0.0 | 5.4 | 0.03 | 0.03 | 0.03 |
| | | | PII(M6) | 97 | 30 | 30.9 | 21.9 | 41.1 | 6 | 6.2 | 2.3 | 13.0 | 0.04 | 0.03 | 0.05 |
| | | | PIII(M7) | 90 | 24 | 26.7 | 17.9 | 37.0 | 6 | 6.7 | 2.5 | 13.9 | 0.04 | 0.03 | 0.05 |
| | | | PIII(M16) | 88 | 45 | 51.1 | 40.2 | 61.9 | 9 | 10.2 | 4.8 | 18.5 | 0.05 | 0.04 | 0.06 |
| | Catch-up 12-18M | 10Pn | PI(M1) | 181 | 180 | 99.4 | 97.0 | 100 | 167 | 92.3 | 87.4 | 95.7 | 0.73 | 0.63 | 0.84 |
| | | | PII(M7) | 167 | 167 | 100 | 97.8 | 100 | 166 | 99.4 | 96.7 | 100 | 1.87 | 1.67 | 2.09 |
| | | | PII(M9) | 162 | 162 | 100 | 97.7 | 100 | 158 | 97.5 | 93.8 | 99.3 | 0.95 | 0.84 | 1.08 |
| | | Ctrl | PI(M1) | 138 | 50 | 36.2 | 28.2 | 44.8 | 3 | 2.2 | 0.5 | 6.2 | 0.04 | 0.04 | 0.05 |
| | | | PII(M7) | 134 | 39 | 29.1 | 21.6 | 37.6 | 2 | 1.5 | 0.2 | 5.3 | 0.04 | 0.03 | 0.04 |
| | | | PII(M9) | 132 | 49 | 37.1 | 28.9 | 46.0 | 4 | 3.0 | 0.8 | 7.6 | 0.04 | 0.04 | 0.05 |
| ANTI-4 | Catch-up 7-11M | 10Pn | PII(M2) | 150 | 150 | 100 | 97.6 | 100 | 150 | 100 | 97.6 | 100 | 5.85 | 5.16 | 6.63 |
| | | | PII(M6) | 144 | 144 | 100 | 97.5 | 100 | 144 | 100 | 97.5 | 100 | 1.55 | 1.36 | 1.76 |
| | | | PIII(M7) | 135 | 135 | 100 | 97.3 | 100 | 135 | 100 | 97.3 | 100 | 5.45 | 4.85 | 6.14 |
| | | | PIII(M16) | 124 | 124 | 100 | 97.1 | 100 | 124 | 100 | 97.1 | 100 | 1.21 | 1.07 | 1.38 |
| | | Ctrl | PII(M2) | 101 | 3 | 3.0 | 0.6 | 8.4 | 0 | 0.0 | 0.0 | 3.6 | 0.03 | 0.02 | 0.03 |
| | | | PII(M6) | 96 | 6 | 6.3 | 2.3 | 13.1 | 2 | 2.1 | 0.3 | 7.3 | 0.03 | 0.02 | 0.03 |
| | | | PIII(M7) | 90 | 7 | 7.8 | 3.2 | 15.4 | 1 | 1.1 | 0.0 | 6.0 | 0.03 | 0.02 | 0.03 |
| | | | PIII(M16) | 88 | 8 | 9.1 | 4.0 | 17.1 | 2 | 2.3 | 0.3 | 8.0 | 0.03 | 0.03 | 0.03 |
| | Catch-up 12-18M | 10Pn | PI(M1) | 181 | 181 | 100 | 98.0 | 100 | 181 | 100 | 98.0 | 100 | 4.64 | 4.11 | 5.25 |
| | | | PII(M7) | 167 | 167 | 100 | 97.8 | 100 | 167 | 100 | 97.8 | 100 | 5.28 | 4.77 | 5.84 |
| | | | PII(M9) | 162 | 162 | 100 | 97.7 | 100 | 161 | 99.4 | 96.6 | 100 | 2.57 | 2.29 | 2.87 |
| | | Ctrl | PI(M1) | 143 | 8 | 5.6 | 2.4 | 10.7 | 2 | 1.4 | 0.2 | 5.0 | 0.03 | 0.03 | 0.03 |
| | | | PII(M7) | 134 | 12 | 9.0 | 4.7 | 15.1 | 3 | 2.2 | 0.5 | 6.4 | 0.03 | 0.03 | 0.03 |
| | | | PII(M9) | 133 | 22 | 16.5 | 10.7 | 24.0 | 3 | 2.3 | 0.5 | 6.5 | 0.03 | 0.03 | 0.03 |
| ANTI-5 | Catch-up 7-11M | 10Pn | PII(M2) | 151 | 151 | 100 | 97.6 | 100 | 151 | 100 | 97.6 | 100 | 2.40 | 2.13 | 2.72 |
| | | | PII(M6) | 144 | 144 | 100 | 97.5 | 100 | 144 | 100 | 97.5 | 100 | 1.19 | 1.06 | 1.34 |
| | | | PIII(M7) | 137 | 137 | 100 | 97.3 | 100 | 137 | 100 | 97.3 | 100 | 4.11 | 3.71 | 4.56 |
| | | | PIII(M16) | 123 | 123 | 100 | 97.0 | 100 | 123 | 100 | 97.0 | 100 | 1.30 | 1.12 | 1.51 |
| | | Ctrl | PII(M2) | 99 | 34 | 34.3 | 25.1 | 44.6 | 2 | 2.0 | 0.2 | 7.1 | 0.04 | 0.03 | 0.04 |
| | | | PII(M6) | 96 | 55 | 57.3 | 46.8 | 67.3 | 8 | 8.3 | 3.7 | 15.8 | 0.06 | 0.05 | 0.07 |
| | | | PIII(M7) | 89 | 52 | 58.4 | 47.5 | 68.8 | 12 | 13.5 | 7.2 | 22.4 | 0.07 | 0.05 | 0.08 |
| | | | PIII(M16) | 87 | 68 | 78.2 | 68.0 | 86.3 | 21 | 24.1 | 15.6 | 34.5 | 0.13 | 0.09 | 0.17 |
| | Catch-up 12-18M | 10Pn | PI(M1) | 181 | 181 | 100 | 98.0 | 100 | 164 | 90.6 | 85.4 | 94.4 | 0.77 | 0.67 | 0.88 |
| | | | PII(M7) | 167 | 167 | 100 | 97.8 | 100 | 167 | 100 | 97.8 | 100 | 3.45 | 3.05 | 3.90 |
| | | | PII(M9) | 162 | 162 | 100 | 97.7 | 100 | 162 | 100 | 97.7 | 100 | 2.14 | 1.88 | 2.44 |
| | | Ctrl | PI(M1) | 140 | 92 | 65.7 | 57.2 | 73.5 | 19 | 13.6 | 8.4 | 20.4 | 0.07 | 0.06 | 0.08 |
| | | | PII(M7) | 133 | 95 | 71.4 | 63.0 | 78.9 | 13 | 9.8 | 5.3 | 16.1 | 0.07 | 0.06 | 0.08 |
| | | | PII(M9) | 133 | 96 | 72.2 | 63.7 | 79.6 | 21 | 15.8 | 10.0 | 23.1 | 0.08 | 0.07 | 0.10 |
| ANTI-6B | Catch-up 7-11M | 10Pn | PII(M2) | 151 | 131 | 86.8 | 80.3 | 91.7 | 91 | 60.3 | 52.0 | 68.1 | 0.27 | 0.21 | 0.33 |
| | | | PII(M6) | 144 | 136 | 94.4 | 89.3 | 97.6 | 123 | 85.4 | 78.6 | 90.7 | 0.49 | 0.40 | 0.58 |
| | | | PIII(M7) | 137 | 128 | 93.4 | 87.9 | 97.0 | 124 | 90.5 | 84.3 | 94.9 | 1.06 | 0.85 | 1.31 |
| | | | PIII(M16) | 124 | 120 | 96.8 | 91.9 | 99.1 | 105 | 84.7 | 77.1 | 90.5 | 0.52 | 0.42 | 0.65 |
| | | Ctrl | PII(M2) | 100 | 5 | 5.0 | 1.6 | 11.3 | 0 | 0.0 | 0.0 | 3.6 | 0.03 | 0.03 | 0.03 |
| | | | PII(M6) | 97 | 24 | 24.7 | 16.5 | 34.5 | 2 | 2.1 | 0.3 | 7.3 | 0.03 | 0.03 | 0.04 |
| | | | PIII(M7) | 90 | 23 | 25.6 | 16.9 | 35.8 | 3 | 3.3 | 0.7 | 9.4 | 0.03 | 0.03 | 0.04 |
| | | | PIII(M16) | 88 | 41 | 46.6 | 35.9 | 57.5 | 11 | 12.5 | 6.4 | 21.3 | 0.06 | 0.04 | 0.07 |
| | Catch-up 12-18M | 10Pn | PI(M1) | 181 | 125 | 69.1 | 61.8 | 75.7 | 57 | 31.5 | 24.8 | 38.8 | 0.11 | 0.09 | 0.13 |
| | | | PII(M7) | 167 | 160 | 95.8 | 91.6 | 98.3 | 144 | 86.2 | 80.1 | 91.1 | 0.69 | 0.57 | 0.83 |
| | | | PII(M9) | 162 | 156 | 96.3 | 92.1 | 98.6 | 130 | 80.2 | 73.3 | 86.1 | 0.48 | 0.40 | 0.57 |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Ctrl | PI(M1) | 136 | 35 | 25.7 | 18.6 | 33.9 | 7 | 5.1 | 2.1 | 10.3 | 0.04 | 0.03 | 0.04 |
| | | | PII(M7) | 133 | 50 | 37.6 | 29.3 | 46.4 | 15 | 11.3 | 6.5 | 17.9 | 0.05 | 0.04 | 0.06 |
| | | | PII(M9) | 133 | 60 | 45.1 | 36.5 | 54.0 | 22 | 16.5 | 10.7 | 24.0 | 0.06 | 0.05 | 0.07 |
| ANTI-7F | Catch-up 7-11M | 10Pn | PII(M2) | 150 | 150 | 100 | 97.6 | 100 | 150 | 100 | 97.6 | 100 | 3.61 | 3.21 | 4.06 |
| | | | PII(M6) | 144 | 144 | 100 | 97.5 | 100 | 144 | 100 | 97.5 | 100 | 2.22 | 1.97 | 2.51 |
| | | | PIII(M7) | 137 | 137 | 100 | 97.3 | 100 | 137 | 100 | 97.3 | 100 | 5.44 | 4.80 | 6.15 |
| | | | PIII(M16) | 123 | 123 | 100 | 97.0 | 100 | 123 | 100 | 97.0 | 100 | 2.08 | 1.82 | 2.39 |
| | | Ctrl | PII(M2) | 100 | 9 | 9.0 | 4.2 | 16.4 | 3 | 3.0 | 0.6 | 8.5 | 0.03 | 0.03 | 0.03 |
| | | | PII(M6) | 97 | 16 | 16.5 | 9.7 | 25.4 | 6 | 6.2 | 2.3 | 13.0 | 0.03 | 0.03 | 0.04 |
| | | | PIII(M7) | 89 | 16 | 18.0 | 10.6 | 27.5 | 6 | 6.7 | 2.5 | 14.1 | 0.04 | 0.03 | 0.05 |
| | | | PIII(M16) | 88 | 28 | 31.8 | 22.3 | 42.6 | 9 | 10.2 | 4.8 | 18.5 | 0.05 | 0.04 | 0.06 |
| | Catch-up 12-18M | 10Pn | PI(M1) | 181 | 181 | 100 | 98.0 | 100 | 180 | 99.4 | 97.0 | 100 | 2.53 | 2.22 | 2.89 |
| | | | PII(M7) | 167 | 167 | 100 | 97.8 | 100 | 167 | 100 | 97.8 | 100 | 3.95 | 3.58 | 4.35 |
| | | | PII(M9) | 162 | 162 | 100 | 97.7 | 100 | 162 | 100 | 97.7 | 100 | 2.73 | 2.48 | 3.01 |
| | | Ctrl | PI(M1) | 142 | 26 | 18.3 | 12.3 | 25.7 | 4 | 2.8 | 0.8 | 7.1 | 0.03 | 0.03 | 0.04 |
| | | | PII(M7) | 134 | 35 | 26.1 | 18.9 | 34.4 | 11 | 8.2 | 4.2 | 14.2 | 0.04 | 0.03 | 0.05 |
| | | | PII(M9) | 133 | 36 | 27.1 | 19.7 | 35.5 | 15 | 11.3 | 6.5 | 17.9 | 0.05 | 0.04 | 0.06 |
| ANTI-9V | Catch-up 7-11M | 10Pn | PII(M2) | 151 | 151 | 100 | 97.6 | 100 | 146 | 96.7 | 92.4 | 98.9 | 1.42 | 1.24 | 1.64 |
| | | | PII(M6) | 144 | 144 | 100 | 97.5 | 100 | 137 | 95.1 | 90.2 | 98.0 | 0.88 | 0.76 | 1.02 |
| | | | PIII(M7) | 137 | 137 | 100 | 97.3 | 100 | 137 | 100 | 97.3 | 100 | 2.81 | 2.44 | 3.23 |
| | | | PIII(M16) | 123 | 123 | 100 | 97.0 | 100 | 119 | 96.7 | 91.9 | 99.1 | 1.16 | 0.99 | 1.37 |
| | | Ctrl | PII(M2) | 100 | 1 | 1.0 | 0.0 | 5.4 | 0 | 0.0 | 0.0 | 3.6 | 0.03 | 0.02 | 0.03 |
| | | | PII(M6) | 96 | 12 | 12.5 | 6.6 | 20.8 | 3 | 3.1 | 0.6 | 8.9 | 0.03 | 0.03 | 0.04 |
| | | | PIII(M7) | 90 | 12 | 13.3 | 7.1 | 22.1 | 4 | 4.4 | 1.2 | 11.0 | 0.03 | 0.03 | 0.04 |
| | | | PIII(M16) | 88 | 17 | 19.3 | 11.7 | 29.1 | 3 | 3.4 | 0.7 | 9.6 | 0.03 | 0.03 | 0.04 |
| | Catch-up 12-18M | 10Pn | PI(M1) | 181 | 179 | 98.9 | 96.1 | 99.9 | 168 | 92.8 | 88.0 | 96.1 | 0.84 | 0.73 | 0.97 |
| | | | PII(M7) | 167 | 167 | 100 | 97.8 | 100 | 166 | 99.4 | 96.7 | 100 | 1.60 | 1.42 | 1.81 |
| | | | PII(M9) | 163 | 163 | 100 | 97.8 | 100 | 161 | 98.8 | 95.6 | 99.9 | 1.22 | 1.07 | 1.39 |
| | | Ctrl | PI(M1) | 140 | 18 | 12.9 | 7.8 | 19.6 | 3 | 2.1 | 0.4 | 6.1 | 0.03 | 0.03 | 0.03 |
| | | | PII(M7) | 134 | 20 | 14.9 | 9.4 | 22.1 | 6 | 4.5 | 1.7 | 9.5 | 0.03 | 0.03 | 0.04 |
| | | | PII(M9) | 129 | 22 | 17.1 | 11.0 | 24.7 | 7 | 5.4 | 2.2 | 10.9 | 0.03 | 0.03 | 0.04 |
| ANTI-14 | Catch-up 7-11M | 10Pn | PII(M2) | 150 | 150 | 100 | 97.6 | 100 | 150 | 100 | 97.6 | 100 | 3.81 | 3.34 | 4.35 |
| | | | PII(M6) | 144 | 144 | 100 | 97.5 | 100 | 144 | 100 | 97.5 | 100 | 3.06 | 2.69 | 3.49 |
| | | | PIII(M7) | 137 | 137 | 100 | 97.3 | 100 | 137 | 100 | 97.3 | 100 | 8.38 | 7.42 | 9.47 |
| | | | PIII(M16) | 123 | 123 | 100 | 97.0 | 100 | 123 | 100 | 97.0 | 100 | 2.91 | 2.44 | 3.48 |
| | | Ctrl | PII(M2) | 100 | 38 | 38.0 | 28.5 | 48.3 | 9 | 9.0 | 4.2 | 16.4 | 0.05 | 0.04 | 0.06 |
| | | | PII(M6) | 95 | 48 | 50.5 | 40.1 | 60.9 | 21 | 22.1 | 14.2 | 31.8 | 0.08 | 0.06 | 0.11 |
| | | | PIII(M7) | 89 | 56 | 62.9 | 52.0 | 72.9 | 18 | 20.2 | 12.4 | 30.1 | 0.10 | 0.07 | 0.14 |
| | | | PIII(M16) | 88 | 68 | 77.3 | 67.1 | 85.5 | 21 | 23.9 | 15.4 | 34.1 | 0.13 | 0.09 | 0.19 |
| | Catch-up 12-18M | 10Pn | PI(M1) | 181 | 181 | 100 | 98.0 | 100 | 169 | 93.4 | 88.7 | 96.5 | 1.07 | 0.90 | 1.28 |
| | | | PII(M7) | 167 | 167 | 100 | 97.8 | 100 | 167 | 100 | 97.8 | 100 | 6.04 | 5.37 | 6.79 |
| | | | PII(M9) | 161 | 161 | 100 | 97.7 | 100 | 161 | 100 | 97.7 | 100 | 3.73 | 3.30 | 4.21 |
| | | Ctrl | PI(M1) | 143 | 76 | 53.1 | 44.6 | 61.5 | 19 | 13.3 | 8.2 | 20.0 | 0.06 | 0.05 | 0.08 |
| | | | PII(M7) | 132 | 89 | 67.4 | 58.7 | 75.3 | 19 | 14.4 | 8.9 | 21.6 | 0.09 | 0.07 | 0.12 |
| | | | PII(M9) | 133 | 102 | 76.7 | 68.6 | 83.6 | 45 | 33.8 | 25.9 | 42.5 | 0.21 | 0.15 | 0.29 |
| ANTI-18C | Catch-up 7-11M | 10Pn | PII(M2) | 150 | 150 | 100 | 97.6 | 100 | 149 | 99.3 | 96.3 | 100 | 10.03 | 8.67 | 11.61 |
| | | | PII(M6) | 144 | 144 | 100 | 97.5 | 100 | 144 | 100 | 97.5 | 100 | 4.70 | 4.01 | 5.50 |
| | | | PIII(M7) | 137 | 137 | 100 | 97.3 | 100 | 137 | 100 | 97.3 | 100 | 19.87 | 17.08 | 23.12 |
| | | | PIII(M16) | 123 | 123 | 100 | 97.0 | 100 | 123 | 100 | 97.0 | 100 | 5.46 | 4.61 | 6.46 |
| | | Ctrl | PII(M2) | 101 | 8 | 7.9 | 3.5 | 15.0 | 0 | 0.0 | 0.0 | 3.6 | 0.03 | 0.03 | 0.03 |
| | | | PII(M6) | 97 | 12 | 12.4 | 6.6 | 20.6 | 4 | 4.1 | 1.1 | 10.2 | 0.03 | 0.03 | 0.04 |
| | | | PIII(M7) | 90 | 12 | 13.3 | 7.1 | 22.1 | 5 | 5.6 | 1.8 | 12.5 | 0.03 | 0.03 | 0.04 |
| | | | PIII(M16) | 88 | 25 | 28.4 | 19.3 | 39.0 | 10 | 11.4 | 5.6 | 19.9 | 0.04 | 0.03 | 0.06 |
| | Catch-up 12-18M | 10Pn | PI(M1) | 181 | 181 | 100 | 98.0 | 100 | 180 | 99.4 | 97.0 | 100 | 3.76 | 3.35 | 4.22 |
| | | | PII(M7) | 166 | 166 | 100 | 97.8 | 100 | 166 | 100 | 97.8 | 100 | 21.27 | 18.70 | 24.19 |
| | | | PII(M9) | 162 | 162 | 100 | 97.7 | 100 | 162 | 100 | 97.7 | 100 | 12.44 | 10.88 | 14.22 |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Ctrl | PI(M1) | 142 | 32 | 22.5 | 16.0 | 30.3 | 5 | 3.5 | 1.2 | 8.0 | 0.04 | 0.03 | 0.04 |
| | | | PII(M7) | 134 | 27 | 20.1 | 13.7 | 27.9 | 6 | 4.5 | 1.7 | 9.5 | 0.04 | 0.03 | 0.04 |
| | | | PII(M9) | 133 | 28 | 21.1 | 14.5 | 29.0 | 10 | 7.5 | 3.7 | 13.4 | 0.04 | 0.03 | 0.05 |
| ANTI-19F | Catch-up 7-11M | 10Pn | PII(M2) | 151 | 149 | 98.7 | 95.3 | 99.8 | 147 | 97.4 | 93.4 | 99.3 | 6.64 | 5.41 | 8.15 |
| | | | PII(M6) | 144 | 144 | 100 | 97.5 | 100 | 140 | 97.2 | 93.0 | 99.2 | 3.41 | 2.81 | 4.14 |
| | | | PIII(M7) | 137 | 137 | 100 | 97.3 | 100 | 136 | 99.3 | 96.0 | 100 | 11.73 | 9.73 | 14.13 |
| | | | PIII(M16) | 124 | 124 | 100 | 97.1 | 100 | 123 | 99.2 | 95.6 | 100 | 3.69 | 3.06 | 4.44 |
| | | Ctrl | PII(M2) | 100 | 21 | 21.0 | 13.5 | 30.3 | 9 | 9.0 | 4.2 | 16.4 | 0.04 | 0.03 | 0.05 |
| | | | PII(M6) | 93 | 26 | 28.0 | 19.1 | 38.2 | 16 | 17.2 | 10.2 | 26.4 | 0.05 | 0.04 | 0.07 |
| | | | PIII(M7) | 86 | 29 | 33.7 | 23.9 | 44.7 | 17 | 19.8 | 12.0 | 29.8 | 0.06 | 0.04 | 0.08 |
| | | | PIII(M16) | 87 | 45 | 51.7 | 40.8 | 62.6 | 25 | 28.7 | 19.5 | 39.4 | 0.09 | 0.07 | 0.13 |
| | Catch-up 12-18M | 10Pn | PI(M1) | 181 | 180 | 99.4 | 97.0 | 100 | 179 | 98.9 | 96.1 | 99.9 | 2.63 | 2.24 | 3.10 |
| | | | PII(M7) | 166 | 166 | 100 | 97.8 | 100 | 166 | 100 | 97.8 | 100 | 12.10 | 10.38 | 14.11 |
| | | | PII(M9) | 162 | 162 | 100 | 97.7 | 100 | 162 | 100 | 97.7 | 100 | 8.49 | 7.39 | 9.74 |
| | | Ctrl | PI(M1) | 143 | 50 | 35.0 | 27.2 | 43.4 | 26 | 18.2 | 12.2 | 25.5 | 0.06 | 0.05 | 0.08 |
| | | | PII(M7) | 134 | 59 | 44.0 | 35.5 | 52.9 | 37 | 27.6 | 20.2 | 36.0 | 0.09 | 0.07 | 0.12 |
| | | | PII(M9) | 132 | 61 | 46.2 | 37.5 | 55.1 | 46 | 34.8 | 26.8 | 43.6 | 0.11 | 0.08 | 0.15 |
| ANTI-23F | Catch-up 7-11M | 10Pn | PII(M2) | 151 | 139 | 92.1 | 86.5 | 95.8 | 117 | 77.5 | 70.0 | 83.9 | 0.55 | 0.44 | 0.70 |
| | | | PII(M6) | 144 | 140 | 97.2 | 93.0 | 99.2 | 128 | 88.9 | 82.6 | 93.5 | 0.64 | 0.54 | 0.77 |
| | | | PIII(M7) | 137 | 135 | 98.5 | 94.8 | 99.8 | 134 | 97.8 | 93.7 | 99.5 | 2.04 | 1.71 | 2.43 |
| | | | PIII(M16) | 123 | 120 | 97.6 | 93.0 | 99.5 | 115 | 93.5 | 87.6 | 97.2 | 0.80 | 0.66 | 0.96 |
| | | Ctrl | PII(M2) | 100 | 8 | 8.0 | 3.5 | 15.2 | 3 | 3.0 | 0.6 | 8.5 | 0.03 | 0.03 | 0.03 |
| | | | PII(M6) | 94 | 22 | 23.4 | 15.3 | 33.3 | 7 | 7.4 | 3.0 | 14.7 | 0.04 | 0.03 | 0.05 |
| | | | PIII(M7) | 88 | 25 | 28.4 | 19.3 | 39.0 | 10 | 11.4 | 5.6 | 19.9 | 0.04 | 0.03 | 0.05 |
| | | | PIII(M16) | 87 | 35 | 40.2 | 29.9 | 51.3 | 16 | 18.4 | 10.9 | 28.1 | 0.06 | 0.05 | 0.08 |
| | Catch-up 12-18M | 10Pn | PI(M1) | 181 | 150 | 82.9 | 76.6 | 88.1 | 78 | 43.1 | 35.8 | 50.6 | 0.16 | 0.13 | 0.19 |
| | | | PII(M7) | 167 | 165 | 98.8 | 95.7 | 99.9 | 157 | 94.0 | 89.3 | 97.1 | 1.27 | 1.07 | 1.50 |
| | | | PII(M9) | 162 | 160 | 98.8 | 95.6 | 99.9 | 147 | 90.7 | 85.2 | 94.7 | 0.83 | 0.70 | 0.99 |
| | | Ctrl | PI(M1) | 138 | 26 | 18.8 | 12.7 | 26.4 | 4 | 2.9 | 0.8 | 7.3 | 0.03 | 0.03 | 0.04 |
| | | | PII(M7) | 134 | 47 | 35.1 | 27.0 | 43.8 | 14 | 10.4 | 5.8 | 16.9 | 0.05 | 0.04 | 0.06 |
| | | | PII(M9) | 132 | 54 | 40.9 | 32.4 | 49.8 | 16 | 12.1 | 7.1 | 18.9 | 0.05 | 0.04 | 0.06 |

Groups part of the Catch-up 7-11M sub-group:
- 10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
- Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine

Groups part of the Catch-up 12-18M sub-group:
- 10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
- Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine

GMC = geometric mean antibody concentration
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(M1) = 1 month after dose 1 at Month 1
PII(M2) = 1 month after dose 2 at Month 2
PII(M7) = 1 month after dose 2 at Month 7
PII(M9) = 3 months after dose 2 at month 9
PII(M6) = pre-booster vaccination blood sample at Month 6
PIII(M7) = 1 month post-booster vaccination at Month 7
PIII(M16) = 10 months post-booster vaccination at Month 16

**Secondary Outcome Variable(s):** Seropositivity rates and GMCs for anti-ANTI-6A and anti-ANTI-19A antibodies (22F-inhhibition ELISA) (ATP cohort for immunogenicity)

| | | | | | **≥ 0.05 µg/mL** | | | | **≥ 0.2 µg/mL** | | | | **GMC (µg/mL)** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | **95% CI** | | | | **95% CI** | | | **95% CI** | |
| **Antibody** | **Sub-group** | **Group** | **Timing** | **N** | **n** | **%** | **LL** | **UL** | **n** | **%** | **LL** | **UL** | **value** | **LL** | **UL** |
| ANTI-6A | Catch-up 7-11M | 10Pn | PII(M2) | 150 | 90 | 60.0 | 51.7 | 67.9 | 56 | 37.3 | 29.6 | 45.6 | 0.11 | 0.09 | 0.14 |
| | | | PII(M6) | 144 | 123 | 85.4 | 78.6 | 90.7 | 85 | 59.0 | 50.5 | 67.1 | 0.23 | 0.18 | 0.29 |
| | | | PIII(M7) | 137 | 130 | 94.9 | 89.8 | 97.9 | 113 | 82.5 | 75.1 | 88.4 | 0.70 | 0.55 | 0.90 |
| | | | PIII(M16) | 123 | 121 | 98.4 | 94.2 | 99.8 | 79 | 64.2 | 55.1 | 72.7 | 0.33 | 0.26 | 0.41 |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Ctrl | PII(M2) | 99 | 7 | 7.1 | 2.9 | 14.0 | 0 | 0.0 | 0.0 | 3.7 | 0.03 | 0.03 | 0.03 |
| | | | PII(M6) | 96 | 13 | 13.5 | 7.4 | 22.0 | 4 | 4.2 | 1.1 | 10.3 | 0.03 | 0.03 | 0.04 |
| | | | PIII(M7) | 89 | 17 | 19.1 | 11.5 | 28.8 | 4 | 4.5 | 1.2 | 11.1 | 0.03 | 0.03 | 0.04 |
| | | | PIII(M16) | 88 | 39 | 44.3 | 33.7 | 55.3 | 12 | 13.6 | 7.2 | 22.6 | 0.06 | 0.04 | 0.07 |
| | Catch-up 12-18M | 10Pn | PI(M1) | 181 | 89 | 49.2 | 41.7 | 56.7 | 34 | 18.8 | 13.4 | 25.2 | 0.06 | 0.05 | 0.08 |
| | | | PII(M7) | 167 | 145 | 86.8 | 80.7 | 91.6 | 106 | 63.5 | 55.7 | 70.8 | 0.32 | 0.26 | 0.41 |
| | | | PII(M9) | 162 | 145 | 89.5 | 83.7 | 93.8 | 102 | 63.0 | 55.0 | 70.4 | 0.29 | 0.23 | 0.36 |
| | | Ctrl | PI(M1) | 143 | 32 | 22.4 | 15.8 | 30.1 | 8 | 5.6 | 2.4 | 10.7 | 0.04 | 0.03 | 0.04 |
| | | | PII(M7) | 134 | 55 | 41.0 | 32.6 | 49.9 | 18 | 13.4 | 8.2 | 20.4 | 0.05 | 0.04 | 0.06 |
| | | | PII(M9) | 132 | 65 | 49.2 | 40.4 | 58.1 | 23 | 17.4 | 11.4 | 25.0 | 0.06 | 0.05 | 0.08 |
| ANTI-19A | Catch-up 7-11M | 10Pn | PII(M2) | 151 | 136 | 90.1 | 84.1 | 94.3 | 94 | 62.3 | 54.0 | 70.0 | 0.33 | 0.26 | 0.42 |
| | | | PII(M6) | 144 | 133 | 92.4 | 86.7 | 96.1 | 107 | 74.3 | 66.4 | 81.2 | 0.49 | 0.39 | 0.62 |
| | | | PIII(M7) | 137 | 132 | 96.4 | 91.7 | 98.8 | 128 | 93.4 | 87.9 | 97.0 | 1.98 | 1.53 | 2.56 |
| | | | PIII(M16) | 123 | 116 | 94.3 | 88.6 | 97.7 | 101 | 82.1 | 74.2 | 88.4 | 0.93 | 0.70 | 1.23 |
| | | Ctrl | PII(M2) | 100 | 19 | 19.0 | 11.8 | 28.1 | 4 | 4.0 | 1.1 | 9.9 | 0.04 | 0.03 | 0.04 |
| | | | PII(M6) | 97 | 31 | 32.0 | 22.9 | 42.2 | 10 | 10.3 | 5.1 | 18.1 | 0.05 | 0.04 | 0.06 |
| | | | PIII(M7) | 90 | 26 | 28.9 | 19.8 | 39.4 | 8 | 8.9 | 3.9 | 16.8 | 0.04 | 0.04 | 0.06 |
| | | | PIII(M16) | 88 | 43 | 48.9 | 38.1 | 59.8 | 17 | 19.3 | 11.7 | 29.1 | 0.08 | 0.06 | 0.11 |
| | Catch-up 12-18M | 10Pn | PI(M1) | 181 | 153 | 84.5 | 78.4 | 89.5 | 82 | 45.3 | 37.9 | 52.9 | 0.20 | 0.16 | 0.25 |
| | | | PII(M7) | 167 | 166 | 99.4 | 96.7 | 100 | 160 | 95.8 | 91.6 | 98.3 | 2.61 | 2.12 | 3.22 |
| | | | PII(M9) | 162 | 161 | 99.4 | 96.6 | 100 | 150 | 92.6 | 87.4 | 96.1 | 1.72 | 1.41 | 2.10 |
| | | Ctrl | PI(M1) | 136 | 45 | 33.1 | 25.3 | 41.7 | 16 | 11.8 | 6.9 | 18.4 | 0.05 | 0.04 | 0.06 |
| | | | PII(M7) | 134 | 57 | 42.5 | 34.0 | 51.4 | 16 | 11.9 | 7.0 | 18.7 | 0.06 | 0.05 | 0.07 |
| | | | PII(M9) | 132 | 67 | 50.8 | 41.9 | 59.6 | 20 | 15.2 | 9.5 | 22.4 | 0.07 | 0.05 | 0.09 |

Groups part of the Catch-up 7-11M sub-group:
- 10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
- Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine

Groups part of the Catch-up 12-18M sub-group:
- 10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
- Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine

GMC = geometric mean antibody concentration
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(M1) = 1 month after dose 1 at Month 1
PII(M2) = 1 month after dose 2 at Month 2
PII(M7) = 1 month after dose 2 at Month 7
PII(M9) = 3 months after dose 2 at Month 9
PII(M6) = pre-booster vaccination blood sample at Month 6
PIII(M7) = 1 month post-booster vaccination at Month 7
PIII(M16) = 10 months post-booster vaccination at Month 16

**Secondary Outcome Variable(s):** Vaccine effectiveness in reducing the number of subjects reporting at least one AOM episode with level 1 of diagnosis certainty for the infants enrolled between 6 weeks and 6 months of age any time after the administration of the first vaccine dose in the 112595 study – 3+1 and 2+1 schedules (Total Vaccinated cohort for analysis of AOM/RTI effectiveness)

| | | | | | | Person-year rate | | | VE | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Event Type** | **Group** | **N** | **n+** | **n** | **T(year)** | **n/T (Per 1000)** | **LL** | **UL** | **%** | **LL** | **UL** |
| Subjects with at least one AOM episode with level 1 of diagnosis certainty [with documented AOM questionnaire] | 10Pn3+1 | 1846 | 16 | 1163 | 2764.80 | 420.645 | 396.814 | 445.534 | 6.1 | -2.7 | 14.1 |
| | 10Pn2+1 | 942 | 17 | 589 | 1417.36 | 415.560 | 382.673 | 450.518 | 7.4 | -2.8 | 16.6 |
| | Ctrl | 1329 | 17 | 892 | 2011.68 | 443.411 | 414.786 | 473.491 | - | - | - |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
AOM episode with level 1 of diagnostic certainty = AOM episode defined as AOM event diagnosed by a physician according to

the Finnish AOM management guidelines (confirmed cases) and reported by subjects' Parent(s)/guardian(s) regardless the documentation in medical records or other source document.
VE (%) = Vaccine effectiveness (1 minus Relative Risk)
N = total number of subjects
T (year) = sum of follow-up period expressed in years taking into account a defined per-subject end of follow-up
n = number of subjects reporting a AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose
n+ = number of clusters with at least one event AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose
n/T (%) = percentage of subjects reporting a AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose expressed in 1000-child year
95% CI = 95% confidence interval, LL = lower limit, UL = upper limit
Note: A classical log linear Poisson regression model with strata was used to compute the VE and its 95% CI

**Secondary Outcome Variable(s):** Vaccine effectiveness in reducing the number of subjects reporting at least one AOM episode with level 1 of diagnosis certainty for the children enrolled between 7 and 11 months of age any time after the administration of first vaccine dose in the 112595 study – 7-11M Schedule (Total Vaccinated cohort for analysis of AOM/RTI effectiveness)

| | | | | | | Person-year rate | | | VE | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Event Type** | **Group** | **N** | **n+** | **n** | **T(year)** | **n/T (Per 1000)** | **LL** | **UL** | **%** | **LL** | **UL** |
| Subjects with at least one AOM episode with level 1 of diagnosis certainty [with documented AOM questionnaire] | 10Pn | 191 | 19 | 117 | 229.24 | 510.388 | 422.105 | 611.686 | 15.2 | -14.6 | 36.8 |
| | Ctrl | 96 | 8 | 71 | 120.31 | 590.118 | 460.887 | 744.354 | - | - | - |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine
AOM episode with level 1 of diagnostic certainty = AOM episode defined as AOM event diagnosed by a physician according to the Finnish AOM management guidelines (confirmed cases) and reported by subjects' Parent(s)/guardian(s) regardless the documentation in medical records or other source document.
VE (%) = Vaccine effectiveness (1 minus Relative Risk)
N = total number of subjects
T (year) = sum of follow-up period expressed in years taking into account a defined per-subject end of follow-up
n = number of subjects reporting a AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose
n+ = number of clusters with at least one event AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose
n/T (%) = percentage of subjects reporting a AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose expressed in 1000-child year
95% CI = 95% confidence interval, LL = lower limit, UL = upper limit
Note: A classical log linear Poisson regression model with strata was used to compute the VE and its 95% CI

**Secondary Outcome Variable(s):** Vaccine effectiveness in reducing the number of subjects reporting at least one AOM episode with level 1 of diagnosis certainty for the children enrolled between 12 and 18 months of age any time after the administration of first vaccine dose in the 112595 study – 12-18M Schedule (Total Vaccinated cohort for analysis of AOM/RTI effectiveness)

| | | | | | | Person-year rate | | | VE | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Event Type** | **Group** | **N** | **n+** | **n** | **T(year)** | **n/T (Per 1000)** | **LL** | **UL** | **%** | **LL** | **UL** |
| Subjects with at least one AOM episode with level 1 of diagnosis certainty [with documented AOM questionnaire] | 10Pn | 286 | 20 | 139 | 232.42 | 598.065 | 502.777 | 706.159 | -6.1 | -49.0 | 23.1 |
| | Ctrl | 106 | 8 | 49 | 86.39 | 567.194 | 419.613 | 749.861 | - | - | - |

10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine
AOM episode with level 1 of diagnostic certainty = AOM episode defined as AOM event diagnosed by a physician according to the Finnish AOM management guidelines (confirmed cases) and reported by subjects' Parent(s)/guardian(s) regardless the documentation in medical records or other source document.

VE (%) = Vaccine effectiveness (1 minus Relative Risk)N = total number of subjects
T (year) = sum of follow-up period expressed in years taking into account a defined per-subject end of follow-up
n = number of subjects reporting a AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose
n+ = number of clusters with at least one event AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose
n/T (%) = percentage of subjects reporting a AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose expressed in 1000-child year
95% CI = 95% confidence interval, LL = lower limit, UL = upper limit
Note: A classical log linear Poisson regression model with strata was used to compute the VE and its 95% CI

**Secondary Outcome Variable(s):** Vaccine effectiveness in reducing the number of subjects reporting recurrent AOM episode with level 1 of diagnosis certainty for the children enrolled between 6 weeks and 6 months of age any time after the administration of first vaccine dose in the 112595 study – 3+1 and 2+1 schedules (Total Vaccinated cohort for analysis of AOM/RTI effectiveness)

| | | | | | | Person-year rate | | | VE | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Event Type** | **Group** | **N** | **n+** | **n** | **T(year)** | **n/T (Per 1000)** | **LL** | **UL** | **%** | **LL** | **UL** |
| Subjects with recurrent AOM episodes with level 1 of diagnosis certainty [with documented AOM questionnaire] | 10Pn3+1 | 1846 | 16 | 278 | 2764.80 | 100.550 | 89.076 | 113.091 | -5.4 | -27.4 | 12.6 |
| | 10Pn2+1 | 942 | 17 | 146 | 1417.36 | 103.008 | 86.977 | 121.137 | -5.9 | -32.0 | 18.8 |
| | Ctrl | 1329 | 16 | 191 | 2011.68 | 94.946 | 81.957 | 109.407 | - | - | - |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
AOM episode with level 1 of diagnostic certainty = AOM episode defined as AOM event diagnosed by a physician according to the Finnish AOM management guidelines (confirmed cases) and reported by subjects' Parent(s)/guardian(s) regardless the documentation in medical records or other source document.
VE (%) = Vaccine effectiveness (1 minus Relative Risk)
N = total number of subjects
T (year) = sum of follow-up period expressed in years taking into account a defined per-subject end of follow-up
n = number of subjects reporting recurrent AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose
n+ = number of clusters with recurrent AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose
n/T (%) = percentage of subjects reporting recurrent AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose expressed in 1000-child year
95% CI = 95% confidence interval, LL = lower limit, UL = upper limit
Note:

- For 3+1 schedule, a classical log linear Poisson regression model with strata was used to compute the VE and its 95% CI
- For the 2+1 schedule a Negative Binomial regression model with strata was used to compute the VE and its 95% CI

**Secondary Outcome Variable(s):** Vaccine effectiveness in prevention of recurrent AOM episode with level 1 of diagnosis certainty for the children enrolled between 7 and 11 months of age any time after the administration of first vaccine dose in the 112595 study – 7-11M Schedule (Total Vaccinated cohort for analysis of AOM/RTI effectiveness)

| | | | | | | Person-year rate | | | VE | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Event Type** | **Group** | **N** | **n+** | **n** | **T(year)** | **n/T (Per 1000)** | **LL** | **UL** | **%** | **LL** | **UL** |
| Subjects with recurrent AOM episode with level 1 of diagnosis certainty [with documented AOM questionnaire] | 10Pn | 191 | 10 | 18 | 229.24 | 78.521 | 46.537 | 124.097 | 44.2 | -11.5 | 71.8 |
| | Ctrl | 96 | 8 | 16 | 120.31 | 132.984 | 76.012 | 215.958 | - | - | - |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine
AOM episode with level 1 of diagnostic certainty = AOM episode defined as AOM event diagnosed by a physician according to the Finnish AOM management guidelines (confirmed cases) and reported by subjects' Parent(s)/guardian(s) regardless the

documentation in medical records or other source document.
Recurrent AOM episode = at least 3 AOM episodes within 6 months or 4 episodes or more within one year. Recurrent AOM was considered to have the diagnostic certainty equal to the minimum level of diagnostic certainty of the individual episodes taken into account for the definition of recurrence.
VE (%) = Vaccine effectiveness (1 minus Relative Risk)
N = total number of subjects
T (year) = sum of follow-up period expressed in years taking into account a defined per-subject end of follow-up
n = number of subjects reporting recurrent AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose
n+ = number of clusters with recurrent AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose
n/T (%) = percentage of subjects reporting recurrent AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose expressed in 1000-child year
95% CI = 95% confidence interval, LL = lower limit, UL = upper limit
Note: a classical log linear Poisson regression model with strata was used to compute the VE and its 95% CI

**Secondary Outcome Variable(s):** Vaccine effectiveness in prevention of recurrent AOM episode with level 1 of diagnosis certainty for the children enrolled between 12 and 18 months of age any time after the administration of first vaccine dose in the 112595 study – 12-18M Schedule (Total Vaccinated cohort for analysis of AOM/RTI effectiveness)

| | | | | | | Person-year rate | | | VE | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Event Type** | **Group** | **N** | **n+** | **n** | **T(year)** | **n/T (Per 1000)** | **LL** | **UL** | **%** | **LL** | **UL** |
| Recurrent AOM episode with level 1 of diagnosis certainty [with documented AOM questionnaire] | 10Pn | 286 | 11 | 21 | 232.42 | 90.355 | 55.931 | 138.117 | -69.5 | -486.2 | 36.4 |
| | Ctrl | 106 | 2 | 4 | 86.39 | 46.302 | 12.616 | 118.550 | - | - | - |

10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine
AOM episode with level 1 of diagnostic certainty = AOM episode defined as AOM event diagnosed by a physician according to the Finnish AOM management guidelines (confirmed cases) and reported by subjects' Parent(s)/guardian(s) regardless the documentation in medical records or other source document.
Recurrent AOM episode = at least 3 AOM episodes within 6 months or 4 episodes or more within one year. Recurrent AOM was considered to have the diagnostic certainty equal to the minimum level of diagnostic certainty of the individual episodes taken into account for the definition of recurrence.
VE (%) = Vaccine effectiveness (1 minus Relative Risk)
N = total number of subjects
T (year) = sum of follow-up period expressed in years taking into account a defined per-subject end of follow-up
n = number of subjects reporting recurrent AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose
n+ = number of clusters with recurrent AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose
n/T (%) = percentage of subjects reporting recurrent AOM episode with level 1 of diagnosis certainty after the administration of first vaccine dose expressed in 1000-child year
95% CI = 95% confidence interval, LL = lower limit, UL = upper limit
Note: a classical log linear Poisson regression model with strata was used to compute the VE and its 95% CI

**Secondary Outcome Variable(s):** Vaccine effectiveness in reducing the number of subjects reporting at least one AOM episode with level 1 of diagnosis certainty and with antimicrobial prescription for the children enrolled between 6 weeks and 6 months of age any time after the administration of the first vaccine dose in the 112595 study – 3+1 and 2+1 schedules (Total Vaccinated cohort for analysis of AOM/RTI effectiveness)

| | | | | | | Person-year rate | | | VE | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Event Type** | **Group** | **N** | **n+** | **n** | **T(year)** | **n/T (Per 1000)** | **LL** | **UL** | **%** | **LL** | **UL** |
| Subjects with at least one AOM episode with level 1 of diagnosis certainty [with documented AOM questionnaire] and with at least one antibiotic taken | 10Pn3+1 | 1846 | 16 | 1133 | 2764.80 | 409.795 | 386.277 | 434.369 | 6.1 | -2.8 | 14.2 |
| | 10Pn2+1 | 942 | 17 | 579 | 1417.36 | 408.505 | 375.904 | 443.176 | 6.4 | -4.0 | 15.8 |
| | Ctrl | 1329 | 17 | 867 | 2011.68 | 430.984 | 402.769 | 460.653 | - | - | - |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine

10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Infants enrolled 6 weeks -6 months of age: infants primed with 2 or 3 doses and boosted with HBV vaccine
AOM episode with level 1 of diagnostic certainty = AOM episode defined as AOM event diagnosed by a physician according to the Finnish AOM management guidelines (confirmed cases) and reported by subjects' Parent(s)/guardian(s) regardless the documentation in medical records or other source document.
VE (%) = Vaccine effectiveness (1 minus Relative Risk)
N = total number of subjects
T (year) = sum of follow-up period expressed in years taking into account a defined per-subject end of follow-up
n = number of subjects reporting a AOM episode with level 1 of diagnosis certainty and with antimicrobial prescription after the administration of first vaccine dose
n+ = number of clusters with at least one event AOM episode with level 1 of diagnosis certainty and with antimicrobial prescription after the administration of first vaccine dose
n/T (%) = percentage of subjects reporting a AOM episode with level 1 of diagnosis certainty and with antimicrobial prescription after the administration of first vaccine dose expressed in 1000-child year
95% CI = 95% confidence interval, LL = lower limit, UL = upper limit
Note: A classical log linear Poisson regression model with strata was used to compute the VE and its 95% CI

**Secondary Outcome Variable(s):** Vaccine effectiveness in reducing the number of subjects reporting at least one AOM episode with level 1 of diagnosis certainty and with antimicrobial prescription for the children enrolled between 7 and 11 months of age any time after the administration of first vaccine dose in the 112595 study – 7-11M Schedule (Total Vaccinated cohort for analysis of AOM/RTI effectiveness)

| | | | | | | Person-year rate | | | VE | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Event Type** | **Group** | **N** | **n+** | **n** | **T(year)** | **n/T (Per 1000)** | **LL** | **UL** | **%** | **LL** | **UL** |
| Subjects with at least one AOM episode with level 1 of diagnosis certainty [with documented AOM questionnaire] and with at least one antibiotic taken | 10Pn | 191 | 19 | 114 | 229.24 | 497.301 | 410.212 | 597.410 | 16.3 | -13.4 | 37.8 |
| | Ctrl | 96 | 8 | 70 | 120.31 | 581.807 | 453.547 | 735.078 | - | - | - |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine
AOM episode with level 1 of diagnostic certainty = AOM episode defined as AOM event diagnosed by a physician according to the Finnish AOM management guidelines (confirmed cases) and reported by subjects' Parent(s)/guardian(s) regardless the documentation in medical records or other source document.
VE (%) = Vaccine effectiveness (1 minus Relative Risk)
N = total number of subjects
T (year) = sum of follow-up period expressed in years taking into account a defined per-subject end of follow-up
n = number of subjects reporting a AOM episode with level 1 of diagnosis certainty and with antimicrobial prescription after the administration of first vaccine dose
n+ = number of clusters with at least one event AOM episode with level 1 of diagnosis certainty and with antimicrobial prescription after the administration of first vaccine dose
n/T (%) = percentage of subjects reporting a AOM episode with level 1 of diagnosis certainty and with antimicrobial prescription after the administration of first vaccine dose expressed in 1000-child year
95% CI = 95% confidence interval, LL = lower limit, UL = upper limit
Note: a classical log linear Poisson regression model with strata was used to compute the VE and its 95% CI

**Secondary Outcome Variable(s):** Vaccine effectiveness in reducing the number of subjects reporting at least one AOM episode with level 1 of diagnosis certainty and with antimicrobial prescription for the children enrolled between 12 and 18 months of age any time after the administration of first vaccine dose in the 112595 study – 12-18M Schedule (Total Vaccinated cohort for analysis of AOM/RTI effectiveness)

| | | | | | | Person-year rate | | | VE | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Event Type** | **Group** | **N** | **n+** | **n** | **T(year)** | **n/T (Per 1000)** | **LL** | **UL** | **%** | **LL** | **UL** |
| Subjects with at least one AOM episode with level 1 of diagnosis certainty [with documented AOM questionnaire] and with at least one antibiotic taken | 10Pn | 286 | 20 | 138 | 232.42 | 593.763 | 498.833 | 701.499 | -7.5 | -51.4 | 22.3 |
| | Ctrl | 106 | 8 | 48 | 86.39 | 555.619 | 409.670 | 736.670 | - | - | - |

10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine
AOM episode with level 1 of diagnostic certainty = AOM episode defined as AOM event diagnosed by a physician according to the Finnish AOM management guidelines (confirmed cases) and reported by subjects' Parent(s)/guardian(s) regardless the documentation in medical records or other source document.
VE (%) = Vaccine effectiveness (1 minus Relative Risk)
N = total number of subjects
T (year) = sum of follow-up period expressed in years taking into account a defined per-subject end of follow-up
n = number of subjects reporting a AOM episode with level 1 of diagnosis certainty and with antimicrobial prescription after the administration of first vaccine dose
n+ = number of clusters with at least one event AOM episode with level 1 of diagnosis certainty and with antimicrobial prescription after the administration of first vaccine dose
n/T (%) = percentage of subjects reporting a AOM episode with level 1 of diagnosis certainty and with antimicrobial prescription after the administration of first vaccine dose expressed in 1000-child year
95% CI = 95% confidence interval, LL = lower limit, UL = upper limit
Note: a classical log linear Poisson regression model with strata was used to compute the VE and its 95% CI

**Secondary Outcome Variable(s):** Number (%) of subjects reporting solicited local symptoms during the 4-day (Days 0-3) post-primary vaccination following each dose and across doses – Subjects in the 3+1 Schedule enrolled aged 6 weeks to 6 months (Total Vaccinated cohort for analysis of safety and carriage)

| | | 10Pn3+1 Group | | | | | Ctrl3+1 Group | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95 % CI | | | | | 95 % CI | |
| **Symptom** | **Intensity** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** |
| **Dose 1** | | | | | | | | | | | |
| Pain | Any | 1846 | 807 | 43.7 | 41.4 | 46.0 | 1066 | 146 | 13.7 | 11.7 | 15.9 |
| | Grade 3 | 1846 | 60 | 3.3 | 2.5 | 4.2 | 1066 | 2 | 0.2 | 0.0 | 0.7 |
| Redness | Any | 1846 | 936 | 50.7 | 48.4 | 53.0 | 1066 | 270 | 25.3 | 22.7 | 28.1 |
| | >30 mm | 1846 | 56 | 3.0 | 2.3 | 3.9 | 1066 | 3 | 0.3 | 0.1 | 0.8 |
| Swelling | Any | 1846 | 636 | 34.5 | 32.3 | 36.7 | 1066 | 88 | 8.3 | 6.7 | 10.1 |
| | >30 mm | 1846 | 89 | 4.8 | 3.9 | 5.9 | 1066 | 4 | 0.4 | 0.1 | 1.0 |
| **Dose 2** | | | | | | | | | | | |
| Pain | Any | 1827 | 662 | 36.2 | 34.0 | 38.5 | 1056 | 114 | 10.8 | 9.0 | 12.8 |
| | Grade 3 | 1827 | 23 | 1.3 | 0.8 | 1.9 | 1056 | 2 | 0.2 | 0.0 | 0.7 |
| Redness | Any | 1827 | 996 | 54.5 | 52.2 | 56.8 | 1056 | 254 | 24.1 | 21.5 | 26.7 |
| | >30 mm | 1827 | 48 | 2.6 | 1.9 | 3.5 | 1056 | 3 | 0.3 | 0.1 | 0.8 |
| Swelling | Any | 1827 | 686 | 37.5 | 35.3 | 39.8 | 1056 | 114 | 10.8 | 9.0 | 12.8 |
| | >30 mm | 1827 | 67 | 3.7 | 2.9 | 4.6 | 1056 | 4 | 0.4 | 0.1 | 1.0 |
| **Dose 3** | | | | | | | | | | | |
| Pain | Any | 1808 | 538 | 29.8 | 27.7 | 31.9 | 1052 | 102 | 9.7 | 8.0 | 11.6 |
| | Grade 3 | 1808 | 12 | 0.7 | 0.3 | 1.2 | 1052 | 2 | 0.2 | 0.0 | 0.7 |
| Redness | Any | 1808 | 963 | 53.3 | 50.9 | 55.6 | 1052 | 300 | 28.5 | 25.8 | 31.4 |
| | >30 mm | 1808 | 52 | 2.9 | 2.2 | 3.8 | 1052 | 0 | 0.0 | 0.0 | 0.4 |
| Swelling | Any | 1808 | 676 | 37.4 | 35.2 | 39.7 | 1052 | 144 | 13.7 | 11.7 | 15.9 |
| | >30 mm | 1808 | 62 | 3.4 | 2.6 | 4.4 | 1052 | 1 | 0.1 | 0.0 | 0.5 |
| **Across Doses** | | | | | | | | | | | |
| Pain | Any | 1846 | 1163 | 63.0 | 60.8 | 65.2 | 1067 | 253 | 23.7 | 21.2 | 26.4 |
| | Grade 3 | 1846 | 82 | 4.4 | 3.5 | 5.5 | 1067 | 5 | 0.5 | 0.2 | 1.1 |
| Redness | Any | 1846 | 1414 | 76.6 | 74.6 | 78.5 | 1067 | 479 | 44.9 | 41.9 | 47.9 |
| | >30 mm | 1846 | 135 | 7.3 | 6.2 | 8.6 | 1067 | 6 | 0.6 | 0.2 | 1.2 |
| Swelling | Any | 1846 | 1098 | 59.5 | 57.2 | 61.7 | 1067 | 259 | 24.3 | 21.7 | 27.0 |
| | >30 mm | 1846 | 175 | 9.5 | 8.2 | 10.9 | 1067 | 9 | 0.8 | 0.4 | 1.6 |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl3+1 Group= Infants enrolled 6 weeks -6 months of age: infants primed with 3 doses and boosted with HBV vaccine
N= number of subjects with at least one documented dose
n/%= number/percentage of subjects reporting the symptom at least once
Any = occurrence of any solicited local symptom regardless of intensity grade
Grade 3 Pain = cried when limb was moved/spontaneously painful.
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

**Secondary Outcome Variable(s):** Number (%) of subjects reporting solicited local symptoms during the 4-day (Days 0-3) post-primary vaccination following each dose and across doses – Subjects in the 2+1 Schedule enrolled aged 6 weeks to 6 months groups (Total Vaccinated cohort for analysis of safety and carriage)

| | | 10Pn2+1 Group | | | | | Ctrl2+1 Group | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95 % CI | | | | | 95 % CI | |
| **Symptom** | **Intensity** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** |
| **Dose 1** | | | | | | | | | | | |
| Pain | Any | 1302 | 611 | 46.9 | 44.2 | 49.7 | 852 | 106 | 12.4 | 10.3 | 14.8 |
| | Grade 3 | 1302 | 43 | 3.3 | 2.4 | 4.4 | 852 | 3 | 0.4 | 0.1 | 1.0 |
| Redness | Any | 1302 | 675 | 51.8 | 49.1 | 54.6 | 852 | 214 | 25.1 | 22.2 | 28.2 |
| | >30 mm | 1302 | 48 | 3.7 | 2.7 | 4.9 | 852 | 0 | 0.0 | 0.0 | 0.4 |
| Swelling | Any | 1302 | 471 | 36.2 | 33.6 | 38.9 | 852 | 64 | 7.5 | 5.8 | 9.5 |
| | >30 mm | 1302 | 69 | 5.3 | 4.1 | 6.7 | 852 | 1 | 0.1 | 0.0 | 0.7 |
| **Dose 2** | | | | | | | | | | | |
| Pain | Any | 1287 | 509 | 39.5 | 36.9 | 42.3 | 847 | 94 | 11.1 | 9.1 | 13.4 |
| | Grade 3 | 1287 | 28 | 2.2 | 1.5 | 3.1 | 847 | 1 | 0.1 | 0.0 | 0.7 |
| Redness | Any | 1287 | 690 | 53.6 | 50.8 | 56.4 | 847 | 203 | 24.0 | 21.1 | 27.0 |
| | >30 mm | 1287 | 63 | 4.9 | 3.8 | 6.2 | 847 | 0 | 0.0 | 0.0 | 0.4 |
| Swelling | Any | 1287 | 536 | 41.6 | 38.9 | 44.4 | 847 | 79 | 9.3 | 7.5 | 11.5 |
| | >30 mm | 1287 | 91 | 7.1 | 5.7 | 8.6 | 847 | 1 | 0.1 | 0.0 | 0.7 |
| **Across Doses** | | | | | | | | | | | |
| Pain | Any | 1303 | 790 | 60.6 | 57.9 | 63.3 | 852 | 159 | 18.7 | 16.1 | 21.4 |
| | Grade 3 | 1303 | 63 | 4.8 | 3.7 | 6.1 | 852 | 4 | 0.5 | 0.1 | 1.2 |
| Redness | Any | 1303 | 923 | 70.8 | 68.3 | 73.3 | 852 | 303 | 35.6 | 32.3 | 38.9 |
| | >30 mm | 1303 | 100 | 7.7 | 6.3 | 9.3 | 852 | 0 | 0.0 | 0.0 | 0.4 |
| Swelling | Any | 1303 | 707 | 54.3 | 51.5 | 57.0 | 852 | 127 | 14.9 | 12.6 | 17.5 |
| | >30 mm | 1303 | 140 | 10.7 | 9.1 | 12.6 | 852 | 2 | 0.2 | 0.0 | 0.8 |

10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl 2+1 Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 doses and boosted with HBV vaccine
N= number of subjects with at least one documented dose
n/%= number/percentage of subjects reporting the symptom at least once
Any = occurrence of any solicited local symptom regardless of intensity grade
Grade 3 Pain = cried when limb was moved/spontaneously painful.
95% CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit

**Secondary Outcome Variable(s):** Number (%) of subjects reporting solicited local symptoms reported during the 4-day (Days 0-3) post-primary vaccination following each dose and across doses – Subjects enrolled aged 7 to 11 months (Total Vaccinated cohort for analysis of safety and carriage)

| | | 10PnGroup | | | | | Ctrl Group | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 95 % CI | | | | | 95 % CI | |
| **Symptom** | **Intensity** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** |
| **Dose 1** | | | | | | | | | | | |
| Pain | Any | 237 | 120 | 50.6 | 44.1 | 57.2 | 202 | 33 | 16.3 | 11.5 | 22.2 |
| | Grade 3 | 237 | 6 | 2.5 | 0.9 | 5.4 | 202 | 0 | 0.0 | 0.0 | 1.8 |
| Redness | Any | 237 | 137 | 57.8 | 51.2 | 64.2 | 202 | 48 | 23.8 | 18.1 | 30.2 |
| | >30 mm | 237 | 17 | 7.2 | 4.2 | 11.2 | 202 | 0 | 0.0 | 0.0 | 1.8 |
| Swelling | Any | 237 | 107 | 45.1 | 38.7 | 51.7 | 202 | 19 | 9.4 | 5.8 | 14.3 |
| | >30 mm | 237 | 20 | 8.4 | 5.2 | 12.7 | 202 | 0 | 0.0 | 0.0 | 1.8 |
| **Dose 2** | | | | | | | | | | | |
| Pain | Any | 229 | 108 | 47.2 | 40.6 | 53.8 | 199 | 38 | 19.1 | 13.9 | 25.3 |
| | Grade 3 | 229 | 11 | 4.8 | 2.4 | 8.4 | 199 | 0 | 0.0 | 0.0 | 1.8 |
| Redness | Any | 229 | 124 | 54.1 | 47.5 | 60.7 | 199 | 57 | 28.6 | 22.5 | 35.5 |
| | >30 mm | 229 | 21 | 9.2 | 5.8 | 13.7 | 199 | 0 | 0.0 | 0.0 | 1.8 |
| Swelling | Any | 229 | 98 | 42.8 | 36.3 | 49.5 | 199 | 18 | 9.0 | 5.4 | 13.9 |
| | >30 mm | 229 | 19 | 8.3 | 5.1 | 12.7 | 199 | 0 | 0.0 | 0.0 | 1.8 |
| **Across Doses** | | | | | | | | | | | |
| Pain | Any | 237 | 148 | 62.4 | 55.9 | 68.6 | 202 | 58 | 28.7 | 22.6 | 35.5 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Grade 3 | 237 | 15 | 6.3 | 3.6 | 10.2 | 202 | 0 | 0.0 | 0.0 | 1.8 |
| Redness | Any | 237 | 165 | 69.6 | 63.3 | 75.4 | 202 | 77 | 38.1 | 31.4 | 45.2 |
| | >30 mm | 237 | 32 | 13.5 | 9.4 | 18.5 | 202 | 0 | 0.0 | 0.0 | 1.8 |
| Swelling | Any | 237 | 138 | 58.2 | 51.7 | 64.6 | 202 | 29 | 14.4 | 9.8 | 20.0 |
| | >30 mm | 237 | 34 | 14.3 | 10.1 | 19.5 | 202 | 0 | 0.0 | 0.0 | 1.8 |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the symptom at least once
Any = occurrence of any solicited local symptom regardless of intensity grade
Grade 3 Pain = cried when limb was moved/spontaneously painful.
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

**Secondary Outcome Variable(s):** Number (%) of subjects reporting solicited local symptoms reported during the 4-day (Days 0-3) post-vaccination following each dose and across doses – Subjects enrolled aged 12 to 18 months (Total Vaccinated cohort for analysis of safety and carriage)

| | | **10Pn Group** | | | | | **Ctrl Group** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | **95 % CI** | | | | | **95 % CI** | |
| **Symptom** | **Intensity** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** |
| **Dose 1** | | | | | | | | | | | |
| Pain | Any | 363 | 220 | 60.6 | 55.4 | 65.7 | 270 | 65 | 24.1 | 19.1 | 29.6 |
| | Grade 3 | 363 | 19 | 5.2 | 3.2 | 8.1 | 270 | 0 | 0.0 | 0.0 | 1.4 |
| Redness | Any | 363 | 203 | 55.9 | 50.6 | 61.1 | 270 | 93 | 34.4 | 28.8 | 40.4 |
| | >30 mm | 363 | 39 | 10.7 | 7.8 | 14.4 | 270 | 0 | 0.0 | 0.0 | 1.4 |
| Swelling | Any | 363 | 142 | 39.1 | 34.1 | 44.3 | 270 | 25 | 9.3 | 6.1 | 13.4 |
| | >30 mm | 363 | 35 | 9.6 | 6.8 | 13.2 | 270 | 1 | 0.4 | 0.0 | 2.0 |
| **Dose 2** | | | | | | | | | | | |
| Pain | Any | 345 | 242 | 70.1 | 65.0 | 74.9 | 260 | 78 | 30.0 | 24.5 | 36.0 |
| | Grade 3 | 345 | 45 | 13.0 | 9.7 | 17.1 | 260 | 0 | 0.0 | 0.0 | 1.4 |
| Redness | Any | 345 | 193 | 55.9 | 50.5 | 61.3 | 260 | 85 | 32.7 | 27.0 | 38.8 |
| | >30 mm | 345 | 49 | 14.2 | 10.7 | 18.3 | 260 | 1 | 0.4 | 0.0 | 2.1 |
| Swelling | Any | 345 | 148 | 42.9 | 37.6 | 48.3 | 260 | 26 | 10.0 | 6.6 | 14.3 |
| | >30 mm | 345 | 34 | 9.9 | 6.9 | 13.5 | 260 | 0 | 0.0 | 0.0 | 1.4 |
| **Across Doses** | | | | | | | | | | | |
| Pain | Any | 363 | 300 | 82.6 | 78.3 | 86.4 | 270 | 116 | 43.0 | 37.0 | 49.1 |
| | Grade 3 | 363 | 61 | 16.8 | 13.1 | 21.1 | 270 | 0 | 0.0 | 0.0 | 1.4 |
| Redness | Any | 363 | 265 | 73.0 | 68.1 | 77.5 | 270 | 129 | 47.8 | 41.7 | 53.9 |
| | >30 mm | 363 | 76 | 20.9 | 16.9 | 25.5 | 270 | 1 | 0.4 | 0.0 | 2.0 |
| Swelling | Any | 363 | 209 | 57.6 | 52.3 | 62.7 | 270 | 42 | 15.6 | 11.4 | 20.4 |
| | >30 mm | 363 | 60 | 16.5 | 12.9 | 20.8 | 270 | 1 | 0.4 | 0.0 | 2.0 |

10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the symptom at least once
Any = occurrence of any solicited local symptom regardless of intensity grade
Grade 3 Pain = cried when limb was moved/spontaneously painful.
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

**Secondary Outcome Variable(s):** Number (%) of subjects reporting solicited local symptoms during the 4-day (Days 0-3) post-booster vaccination – Subjects enrolled aged 6 weeks to 6 months and 7 to 11 months (Total Vaccinated cohort for analysis of safety and carriage)

| | | **Subjects enrolled aged 6 weeks to 6 months** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **10Pn3+1 Group** | | | | | **Ctrl3+1 Group** | | | | |
| | | | | | **95 % CI** | | | | | **95 % CI** | |
| **Symptom** | **Intensity** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** |
| Pain | Any | 1758 | 888 | 50.5 | 48.1 | 52.9 | 1024 | 250 | 24.4 | 21.8 | 27.2 |
| | Grade 3 | 1758 | 66 | 3.8 | 2.9 | 4.8 | 1024 | 2 | 0.2 | 0.0 | 0.7 |
| Redness | Any | 1758 | 913 | 51.9 | 49.6 | 54.3 | 1024 | 345 | 33.7 | 30.8 | 36.7 |
| | >30 mm | 1758 | 102 | 5.8 | 4.8 | 7.0 | 1024 | 13 | 1.3 | 0.7 | 2.2 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Swelling | Any | 1758 | 716 | 40.7 | 38.4 | 43.1 | 1024 | 229 | 22.4 | 19.8 | 25.0 |
| | >30 mm | 1758 | 102 | 5.8 | 4.8 | 7.0 | 1024 | 10 | 1.0 | 0.5 | 1.8 |
| | | **10Pn2+1 Group** | | | | | **Ctrl2+1 Group** | | | | |
| | | | | | **95 % CI** | | | | | **95 % CI** | |
| **Symptom** | **Intensity** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** |
| Pain | Any | 1258 | 710 | 56.4 | 53.6 | 59.2 | 827 | 171 | 20.7 | 18.0 | 23.6 |
| | Grade 3 | 1258 | 41 | 3.3 | 2.3 | 4.4 | 827 | 2 | 0.2 | 0.0 | 0.9 |
| Redness | Any | 1258 | 702 | 55.8 | 53.0 | 58.6 | 827 | 238 | 28.8 | 25.7 | 32.0 |
| | >30 mm | 1258 | 103 | 8.2 | 6.7 | 9.8 | 827 | 2 | 0.2 | 0.0 | 0.9 |
| Swelling | Any | 1258 | 586 | 46.6 | 43.8 | 49.4 | 827 | 118 | 14.3 | 12.0 | 16.8 |
| | >30 mm | 1258 | 111 | 8.8 | 7.3 | 10.5 | 827 | 3 | 0.4 | 0.1 | 1.1 |
| | | **Subjects enrolled aged 7 to 11 months** | | | | | | | | | |
| | | **10Pn Group** | | | | | **Ctrl Group** | | | | |
| | | | | | **95 % CI** | | | | | **95 % CI** | |
| **Symptom** | **Intensity** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** |
| Pain | Any | 216 | 123 | 56.9 | 50.1 | 63.6 | 188 | 40 | 21.3 | 15.7 | 27.8 |
| | Grade 3 | 216 | 14 | 6.5 | 3.6 | 10.6 | 188 | 2 | 1.1 | 0.1 | 3.8 |
| Redness | Any | 216 | 106 | 49.1 | 42.2 | 55.9 | 188 | 54 | 28.7 | 22.4 | 35.8 |
| | >30 mm | 216 | 18 | 8.3 | 5.0 | 12.9 | 188 | 0 | 0.0 | 0.0 | 1.9 |
| Swelling | Any | 216 | 85 | 39.4 | 32.8 | 46.2 | 188 | 31 | 16.5 | 11.5 | 22.6 |
| | >30 mm | 216 | 14 | 6.5 | 3.6 | 10.6 | 188 | 0 | 0.0 | 0.0 | 1.9 |

Groups for subjects enrolled aged 6 weeks to 6 months

- 10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
- Ctrl3+1 Group= Infants enrolled 6 weeks -6 months of age: infants primed with 3 doses and boosted with HBV vaccine
- 10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
- Ctrl 2+1 Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 doses and boosted with HBV vaccine

Groups for subjects enrolled aged 7 to 11 months

- 10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
- Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine

N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
Any = occurrence of any solicited local symptom regardless of their intensity grade
Grade 3 Pain = cried when limb was moved/spontaneously painful.
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

**Secondary Outcome Variable(s):** Number (%) of subjects reporting solicited general symptoms reported during the 4-day (Days 0-3) post-primary vaccination following each dose and across doses – Subjects in the 3+1 Schedule enrolled aged 6 weeks to 6 months (Total Vaccinated cohort for analysis of safety and carriage)

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **10Pn3+1 Group** | | | | | **Ctrl3+1 Group** | | | | |
| | | | | | **95 % CI** | | | | | **95 % CI** | |
| **Symptom** | **Intensity/Relationship** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** |
| **Dose 1** | | | | | | | | | | | |
| Drowsiness | Any | 1846 | 1070 | 58.0 | 55.7 | 60.2 | 1066 | 462 | 43.3 | 40.3 | 46.4 |
| | Grade 3 | 1846 | 11 | 0.6 | 0.3 | 1.1 | 1066 | 5 | 0.5 | 0.2 | 1.1 |
| | Related | 1846 | 1054 | 57.1 | 54.8 | 59.4 | 1066 | 453 | 42.5 | 39.5 | 45.5 |
| Irritability | Any | 1846 | 1325 | 71.8 | 69.7 | 73.8 | 1066 | 577 | 54.1 | 51.1 | 57.2 |
| | Grade 3 | 1846 | 76 | 4.1 | 3.3 | 5.1 | 1066 | 20 | 1.9 | 1.1 | 2.9 |
| | Related | 1846 | 1298 | 70.3 | 68.2 | 72.4 | 1066 | 565 | 53.0 | 50.0 | 56.0 |
| Loss of appetite | Any | 1846 | 499 | 27.0 | 25.0 | 29.1 | 1066 | 202 | 18.9 | 16.6 | 21.4 |
| | Grade 3 | 1846 | 1 | 0.1 | 0.0 | 0.3 | 1066 | 2 | 0.2 | 0.0 | 0.7 |
| | Related | 1846 | 480 | 26.0 | 24.0 | 28.1 | 1066 | 196 | 18.4 | 16.1 | 20.8 |
| Temperature (Rectally) | ≥ 38.0°C | 1846 | 388 | 21.0 | 19.2 | 22.9 | 1066 | 82 | 7.7 | 6.2 | 9.5 |
| | > 40.0°C | 1846 | 2 | 0.1 | 0.0 | 0.4 | 1066 | 1 | 0.1 | 0.0 | 0.5 |
| | Related | 1846 | 381 | 20.6 | 18.8 | 22.6 | 1066 | 78 | 7.3 | 5.8 | 9.0 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Dose 2** | | | | | | | | | | | |
| Drowsiness | Any | 1828 | 868 | 47.5 | 45.2 | 49.8 | 1056 | 332 | 31.4 | 28.6 | 34.3 |
| | Grade 3 | 1828 | 7 | 0.4 | 0.2 | 0.8 | 1056 | 1 | 0.1 | 0.0 | 0.5 |
| | Related | 1828 | 855 | 46.8 | 44.5 | 49.1 | 1056 | 329 | 31.2 | 28.4 | 34.0 |
| Irritability | Any | 1828 | 1254 | 68.6 | 66.4 | 70.7 | 1056 | 532 | 50.4 | 47.3 | 53.4 |
| | Grade 3 | 1828 | 73 | 4.0 | 3.1 | 5.0 | 1056 | 13 | 1.2 | 0.7 | 2.1 |
| | Related | 1828 | 1236 | 67.6 | 65.4 | 69.8 | 1056 | 523 | 49.5 | 46.5 | 52.6 |
| Loss of appetite | Any | 1828 | 434 | 23.7 | 21.8 | 25.8 | 1056 | 187 | 17.7 | 15.5 | 20.1 |
| | Grade 3 | 1828 | 4 | 0.2 | 0.1 | 0.6 | 1056 | 1 | 0.1 | 0.0 | 0.5 |
| | Related | 1828 | 419 | 22.9 | 21.0 | 24.9 | 1056 | 181 | 17.1 | 14.9 | 19.6 |
| Temperature (Rectally) | ≥ 38.0°C | 1828 | 380 | 20.8 | 18.9 | 22.7 | 1056 | 78 | 7.4 | 5.9 | 9.1 |
| | > 40.0°C | 1828 | 2 | 0.1 | 0.0 | 0.4 | 1056 | 0 | 0.0 | 0.0 | 0.3 |
| | Related | 1828 | 373 | 20.4 | 18.6 | 22.3 | 1056 | 78 | 7.4 | 5.9 | 9.1 |
| **Dose 3** | | | | | | | | | | | |
| Drowsiness | Any | 1808 | 645 | 35.7 | 33.5 | 37.9 | 1052 | 293 | 27.9 | 25.2 | 30.7 |
| | Grade 3 | 1808 | 2 | 0.1 | 0.0 | 0.4 | 1052 | 2 | 0.2 | 0.0 | 0.7 |
| | Related | 1808 | 638 | 35.3 | 33.1 | 37.5 | 1052 | 285 | 27.1 | 24.4 | 29.9 |
| Irritability | Any | 1808 | 1115 | 61.7 | 59.4 | 63.9 | 1052 | 496 | 47.1 | 44.1 | 50.2 |
| | Grade 3 | 1808 | 41 | 2.3 | 1.6 | 3.1 | 1052 | 14 | 1.3 | 0.7 | 2.2 |
| | Related | 1808 | 1100 | 60.8 | 58.5 | 63.1 | 1052 | 492 | 46.8 | 43.7 | 49.8 |
| Loss of appetite | Any | 1808 | 349 | 19.3 | 17.5 | 21.2 | 1052 | 178 | 16.9 | 14.7 | 19.3 |
| | Grade 3 | 1808 | 3 | 0.2 | 0.0 | 0.5 | 1052 | 0 | 0.0 | 0.0 | 0.4 |
| | Related | 1808 | 336 | 18.6 | 16.8 | 20.5 | 1052 | 172 | 16.3 | 14.2 | 18.7 |
| Temperature (Rectally) | ≥ 38.0°C | 1808 | 347 | 19.2 | 17.4 | 21.1 | 1052 | 110 | 10.5 | 8.7 | 12.5 |
| | > 40.0°C | 1808 | 1 | 0.1 | 0.0 | 0.3 | 1052 | 1 | 0.1 | 0.0 | 0.5 |
| | Related | 1808 | 336 | 18.6 | 16.8 | 20.5 | 1052 | 106 | 10.1 | 8.3 | 12.1 |
| **Across Doses** | | | | | | | | | | | |
| Drowsiness | Any | 1846 | 1395 | 75.6 | 73.5 | 77.5 | 1067 | 658 | 61.7 | 58.7 | 64.6 |
| | Grade 3 | 1846 | 18 | 1.0 | 0.6 | 1.5 | 1067 | 6 | 0.6 | 0.2 | 1.2 |
| | Related | 1846 | 1386 | 75.1 | 73.0 | 77.0 | 1067 | 649 | 60.8 | 57.8 | 63.8 |
| Irritability | Any | 1846 | 1697 | 91.9 | 90.6 | 93.1 | 1067 | 861 | 80.7 | 78.2 | 83.0 |
| | Grade 3 | 1846 | 168 | 9.1 | 7.8 | 10.5 | 1067 | 43 | 4.0 | 2.9 | 5.4 |
| | Related | 1846 | 1689 | 91.5 | 90.1 | 92.7 | 1067 | 854 | 80.0 | 77.5 | 82.4 |
| Loss of appetite | Any | 1846 | 858 | 46.5 | 44.2 | 48.8 | 1067 | 409 | 38.3 | 35.4 | 41.3 |
| | Grade 3 | 1846 | 8 | 0.4 | 0.2 | 0.9 | 1067 | 3 | 0.3 | 0.1 | 0.8 |
| | Related | 1846 | 839 | 45.4 | 43.2 | 47.8 | 1067 | 398 | 37.3 | 34.4 | 40.3 |
| Temperature (Rectally) | ≥ 38.0°C | 1846 | 819 | 44.4 | 42.1 | 46.7 | 1067 | 240 | 22.5 | 20.0 | 25.1 |
| | > 40.0°C | 1846 | 5 | 0.3 | 0.1 | 0.6 | 1067 | 2 | 0.2 | 0.0 | 0.7 |
| | Related | 1846 | 807 | 43.7 | 41.4 | 46.0 | 1067 | 232 | 21.7 | 19.3 | 24.3 |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl3+1 Group= Infants enrolled 6 weeks -6 months of age: infants primed with 3 doses and boosted with HBV vaccine
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the symptom at least once
Any = occurrence of any solicited general symptom regardless of their intensity grade or relationship to vaccination
Related = event assessed by the investigator as causally related to the study vaccination
Grade 3 Drowsiness = drowsiness that prevented normal activity.
Grade 3 Loss of appetite = not eating at all.
Grade 3 Irritability = crying that could not be comforted/ prevented normal activity.
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

**Secondary Outcome Variable(s):** Number (%) of subjects reporting solicited general symptoms during the 4-day (Days 0-3) post-primary vaccination following each dose and across doses – Subjects in the 2+1 Schedule enrolled aged 6 weeks to 6 months (Total Vaccinated cohort for analysis of safety and carriage)

| | | **10Pn2+1 Group** | | | | | **Ctrl2+1 Group** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | **95 % CI** | | | | | **95 % CI** | |
| **Symptom** | **Intensity/Relationship** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** |
| **Dose 1** | | | | | | | | | | | |
| Drowsiness | Any | 1302 | 742 | 57.0 | 54.2 | 59.7 | 852 | 384 | 45.1 | 41.7 | 48.5 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Grade 3 | 1302 | 8 | 0.6 | 0.3 | 1.2 | 852 | 1 | 0.1 | 0.0 | 0.7 |
| | Related | 1302 | 738 | 56.7 | 53.9 | 59.4 | 852 | 374 | 43.9 | 40.5 | 47.3 |
| Irritability | Any | 1302 | 942 | 72.4 | 69.8 | 74.8 | 852 | 468 | 54.9 | 51.5 | 58.3 |
| | Grade 3 | 1302 | 56 | 4.3 | 3.3 | 5.5 | 852 | 14 | 1.6 | 0.9 | 2.7 |
| | Related | 1302 | 937 | 72.0 | 69.4 | 74.4 | 852 | 460 | 54.0 | 50.6 | 57.4 |
| Loss of appetite | Any | 1302 | 335 | 25.7 | 23.4 | 28.2 | 852 | 147 | 17.3 | 14.8 | 20.0 |
| | Grade 3 | 1302 | 3 | 0.2 | 0.0 | 0.7 | 852 | 0 | 0.0 | 0.0 | 0.4 |
| | Related | 1302 | 332 | 25.5 | 23.2 | 28.0 | 852 | 140 | 16.4 | 14.0 | 19.1 |
| Temperature (Rectally) | ≥ 38.0°C | 1302 | 289 | 22.2 | 20.0 | 24.6 | 852 | 78 | 9.2 | 7.3 | 11.3 |
| | > 40.0°C | 1302 | 0 | 0.0 | 0.0 | 0.3 | 852 | 0 | 0.0 | 0.0 | 0.4 |
| | Related | 1302 | 284 | 21.8 | 19.6 | 24.2 | 852 | 74 | 8.7 | 6.9 | 10.8 |
| **Dose 2** | | | | | | | | | | | |
| Drowsiness | Any | 1287 | 572 | 44.4 | 41.7 | 47.2 | 847 | 258 | 30.5 | 27.4 | 33.7 |
| | Grade 3 | 1287 | 6 | 0.5 | 0.2 | 1.0 | 847 | 3 | 0.4 | 0.1 | 1.0 |
| | Related | 1287 | 564 | 43.8 | 41.1 | 46.6 | 847 | 247 | 29.2 | 26.1 | 32.4 |
| Irritability | Any | 1287 | 822 | 63.9 | 61.2 | 66.5 | 847 | 408 | 48.2 | 44.8 | 51.6 |
| | Grade 3 | 1287 | 44 | 3.4 | 2.5 | 4.6 | 847 | 14 | 1.7 | 0.9 | 2.8 |
| | Related | 1287 | 816 | 63.4 | 60.7 | 66.0 | 847 | 396 | 46.8 | 43.4 | 50.2 |
| Loss of appetite | Any | 1287 | 323 | 25.1 | 22.7 | 27.6 | 847 | 149 | 17.6 | 15.1 | 20.3 |
| | Grade 3 | 1287 | 2 | 0.2 | 0.0 | 0.6 | 847 | 3 | 0.4 | 0.1 | 1.0 |
| | Related | 1287 | 318 | 24.7 | 22.4 | 27.2 | 847 | 135 | 15.9 | 13.5 | 18.6 |
| Temperature (Rectally) | ≥ 38.0°C | 1287 | 382 | 29.7 | 27.2 | 32.3 | 847 | 80 | 9.4 | 7.6 | 11.6 |
| | > 40.0°C | 1287 | 0 | 0.0 | 0.0 | 0.3 | 847 | 0 | 0.0 | 0.0 | 0.4 |
| | Related | 1287 | 378 | 29.4 | 26.9 | 31.9 | 847 | 71 | 8.4 | 6.6 | 10.5 |
| **Across Doses** | | | | | | | | | | | |
| Drowsiness | Any | 1303 | 909 | 69.8 | 67.2 | 72.2 | 852 | 472 | 55.4 | 52.0 | 58.8 |
| | Grade 3 | 1303 | 13 | 1.0 | 0.5 | 1.7 | 852 | 3 | 0.4 | 0.1 | 1.0 |
| | Related | 1303 | 904 | 69.4 | 66.8 | 71.9 | 852 | 459 | 53.9 | 50.5 | 57.3 |
| Irritability | Any | 1303 | 1118 | 85.8 | 83.8 | 87.7 | 852 | 615 | 72.2 | 69.0 | 75.2 |
| | Grade 3 | 1303 | 91 | 7.0 | 5.7 | 8.5 | 852 | 27 | 3.2 | 2.1 | 4.6 |
| | Related | 1303 | 1114 | 85.5 | 83.5 | 87.4 | 852 | 606 | 71.1 | 68.0 | 74.2 |
| Loss of appetite | Any | 1303 | 521 | 40.0 | 37.3 | 42.7 | 852 | 248 | 29.1 | 26.1 | 32.3 |
| | Grade 3 | 1303 | 5 | 0.4 | 0.1 | 0.9 | 852 | 3 | 0.4 | 0.1 | 1.0 |
| | Related | 1303 | 517 | 39.7 | 37.0 | 42.4 | 852 | 233 | 27.3 | 24.4 | 30.5 |
| Temperature (Rectally) | ≥ 38.0°C | 1303 | 521 | 40.0 | 37.3 | 42.7 | 852 | 140 | 16.4 | 14.0 | 19.1 |
| | > 40.0°C | 1303 | 0 | 0.0 | 0.0 | 0.3 | 852 | 0 | 0.0 | 0.0 | 0.4 |
| | Related | 1303 | 515 | 39.5 | 36.9 | 42.2 | 852 | 129 | 15.1 | 12.8 | 17.7 |

10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl 2+1 Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 doses and boosted with HBV vaccine
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the symptom at least once
Any = occurrence of any solicited general symptom regardless of their intensity grade or relationship to vaccination
Related = event assessed by the investigator as causally related to the study vaccination
Grade 3 Drowsiness = drowsiness that prevented normal activity.
Grade 3 Loss of appetite = not eating at all.
Grade 3 Irritability = crying that could not be comforted/ prevented normal activity
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

**Secondary Outcome Variable(s):** Number (%) of subjects reporting solicited general symptoms during the 4-day (Days 0-3) post-primary vaccination following each dose and across doses – Subjects enrolled aged 7 to 11 months (Total Vaccinated cohort for analysis of safety and carriage)

| | | **10Pn Group** | | | | | **Ctrl Group** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | **95 % CI** | | | | | **95 % CI** | |
| **Symptom** | **Intensity/Relationship** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** |
| **Dose 1** | | | | | | | | | | | |
| Drowsiness | Any | 237 | 106 | 44.7 | 38.3 | 51.3 | 202 | 62 | 30.7 | 24.4 | 37.6 |
| | Grade 3 | 237 | 1 | 0.4 | 0.0 | 2.3 | 202 | 0 | 0.0 | 0.0 | 1.8 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Related | 237 | 103 | 43.5 | 37.1 | 50.0 | 202 | 57 | 28.2 | 22.1 | 35.0 |
| Irritability | Any | 237 | 157 | 66.2 | 59.8 | 72.2 | 202 | 90 | 44.6 | 37.6 | 51.7 |
| | Grade 3 | 237 | 3 | 1.3 | 0.3 | 3.7 | 202 | 2 | 1.0 | 0.1 | 3.5 |
| | Related | 237 | 157 | 66.2 | 59.8 | 72.2 | 202 | 83 | 41.1 | 34.2 | 48.2 |
| Loss of appetite | Any | 237 | 84 | 35.4 | 29.4 | 41.9 | 202 | 56 | 27.7 | 21.7 | 34.4 |
| | Grade 3 | 237 | 0 | 0.0 | 0.0 | 1.5 | 202 | 1 | 0.5 | 0.0 | 2.7 |
| | Related | 237 | 81 | 34.2 | 28.2 | 40.6 | 202 | 48 | 23.8 | 18.1 | 30.2 |
| Temperature (Rectally) | ≥ 38.0°C | 237 | 38 | 16.0 | 11.6 | 21.3 | 202 | 16 | 7.9 | 4.6 | 12.5 |
| | > 40.0°C | 237 | 0 | 0.0 | 0.0 | 1.5 | 202 | 0 | 0.0 | 0.0 | 1.8 |
| | Related | 237 | 35 | 14.8 | 10.5 | 19.9 | 202 | 13 | 6.4 | 3.5 | 10.8 |
| **Dose 2** | | | | | | | | | | | |
| Drowsiness | Any | 229 | 88 | 38.4 | 32.1 | 45.1 | 198 | 52 | 26.3 | 20.3 | 33.0 |
| | Grade 3 | 229 | 2 | 0.9 | 0.1 | 3.1 | 198 | 1 | 0.5 | 0.0 | 2.8 |
| | Related | 229 | 85 | 37.1 | 30.8 | 43.7 | 198 | 51 | 25.8 | 19.8 | 32.4 |
| Irritability | Any | 229 | 139 | 60.7 | 54.0 | 67.1 | 198 | 94 | 47.5 | 40.4 | 54.7 |
| | Grade 3 | 229 | 7 | 3.1 | 1.2 | 6.2 | 198 | 1 | 0.5 | 0.0 | 2.8 |
| | Related | 229 | 137 | 59.8 | 53.2 | 66.2 | 198 | 93 | 47.0 | 39.9 | 54.2 |
| Loss of appetite | Any | 229 | 69 | 30.1 | 24.3 | 36.5 | 198 | 56 | 28.3 | 22.1 | 35.1 |
| | Grade 3 | 229 | 2 | 0.9 | 0.1 | 3.1 | 198 | 0 | 0.0 | 0.0 | 1.8 |
| | Related | 229 | 64 | 27.9 | 22.2 | 34.2 | 198 | 52 | 26.3 | 20.3 | 33.0 |
| Temperature (Rectally) | ≥ 38.0°C | 229 | 44 | 19.2 | 14.3 | 24.9 | 198 | 20 | 10.1 | 6.3 | 15.2 |
| | > 40.0°C | 229 | 0 | 0.0 | 0.0 | 1.6 | 198 | 1 | 0.5 | 0.0 | 2.8 |
| | Related | 229 | 43 | 18.8 | 13.9 | 24.4 | 198 | 15 | 7.6 | 4.3 | 12.2 |
| **Across Doses** | | | | | | | | | | | |
| Drowsiness | Any | 237 | 135 | 57.0 | 50.4 | 63.4 | 202 | 89 | 44.1 | 37.1 | 51.2 |
| | Grade 3 | 237 | 3 | 1.3 | 0.3 | 3.7 | 202 | 1 | 0.5 | 0.0 | 2.7 |
| | Related | 237 | 133 | 56.1 | 49.5 | 62.5 | 202 | 84 | 41.6 | 34.7 | 48.7 |
| Irritability | Any | 237 | 191 | 80.6 | 75.0 | 85.4 | 202 | 134 | 66.3 | 59.4 | 72.8 |
| | Grade 3 | 237 | 10 | 4.2 | 2.0 | 7.6 | 202 | 3 | 1.5 | 0.3 | 4.3 |
| | Related | 237 | 191 | 80.6 | 75.0 | 85.4 | 202 | 130 | 64.4 | 57.3 | 71.0 |
| Loss of appetite | Any | 237 | 118 | 49.8 | 43.3 | 56.3 | 202 | 86 | 42.6 | 35.7 | 49.7 |
| | Grade 3 | 237 | 2 | 0.8 | 0.1 | 3.0 | 202 | 1 | 0.5 | 0.0 | 2.7 |
| | Related | 237 | 111 | 46.8 | 40.3 | 53.4 | 202 | 80 | 39.6 | 32.8 | 46.7 |
| Temperature (Rectally) | ≥ 38.0°C | 237 | 73 | 30.8 | 25.0 | 37.1 | 202 | 36 | 17.8 | 12.8 | 23.8 |
| | > 40.0°C | 237 | 0 | 0.0 | 0.0 | 1.5 | 202 | 1 | 0.5 | 0.0 | 2.7 |
| | Related | 237 | 70 | 29.5 | 23.8 | 35.8 | 202 | 28 | 13.9 | 9.4 | 19.4 |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the symptom at least once
Any = occurrence of any solicited general symptom regardless of their intensity grade or relationship to vaccination
Related = event assessed by the investigator as causally related to the study vaccination
Grade 3 Drowsiness = drowsiness that prevented normal activity
Grade 3 Loss of appetite = not eating at all.
Grade 3 Irritability = crying that could not be comforted/ prevented normal activity.
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

**Secondary Outcome Variable(s):** Number (%) of subjects reporting solicited general symptoms during the 4-day (Days 0-3) post-vaccination following each dose and across doses – Subjects enrolled aged 12 to 18 months (Total Vaccinated cohort for analysis of safety and carriage)

| | | **10Pn Group** | | | | | **Ctrl Group** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | **95 % CI** | | | | | **95 % CI** | |
| **Symptom** | **Intensity/Relationship** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** |
| **Dose 1** | | | | | | | | | | | |
| Drowsiness | Any | 363 | 155 | 42.7 | 37.6 | 48.0 | 270 | 87 | 32.2 | 26.7 | 38.2 |
| | Grade 3 | 363 | 1 | 0.3 | 0.0 | 1.5 | 270 | 2 | 0.7 | 0.1 | 2.7 |
| | Related | 363 | 152 | 41.9 | 36.7 | 47.1 | 270 | 81 | 30.0 | 24.6 | 35.8 |
| Irritability | Any | 363 | 210 | 57.9 | 52.6 | 63.0 | 270 | 103 | 38.1 | 32.3 | 44.2 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Grade 3 | 363 | 6 | 1.7 | 0.6 | 3.6 | 270 | 4 | 1.5 | 0.4 | 3.7 |
| | Related | 363 | 201 | 55.4 | 50.1 | 60.6 | 270 | 96 | 35.6 | 29.8 | 41.6 |
| Loss of appetite | Any | 363 | 128 | 35.3 | 30.3 | 40.4 | 270 | 82 | 30.4 | 24.9 | 36.2 |
| | Grade 3 | 363 | 2 | 0.6 | 0.1 | 2.0 | 270 | 4 | 1.5 | 0.4 | 3.7 |
| | Related | 363 | 123 | 33.9 | 29.0 | 39.0 | 270 | 73 | 27.0 | 21.8 | 32.8 |
| Temperature (Rectally) | ≥ 38.0°C | 363 | 74 | 20.4 | 16.4 | 24.9 | 270 | 28 | 10.4 | 7.0 | 14.6 |
| | > 40.0°C | 363 | 2 | 0.6 | 0.1 | 2.0 | 270 | 2 | 0.7 | 0.1 | 2.7 |
| | Related | 363 | 69 | 19.0 | 15.1 | 23.4 | 270 | 25 | 9.3 | 6.1 | 13.4 |
| **Dose 2** | | | | | | | | | | | |
| Drowsiness | Any | 345 | 126 | 36.5 | 31.4 | 41.8 | 260 | 58 | 22.3 | 17.4 | 27.9 |
| | Grade 3 | 345 | 2 | 0.6 | 0.1 | 2.1 | 260 | 1 | 0.4 | 0.0 | 2.1 |
| | Related | 345 | 123 | 35.7 | 30.6 | 41.0 | 260 | 55 | 21.2 | 16.4 | 26.6 |
| Irritability | Any | 345 | 193 | 55.9 | 50.5 | 61.3 | 260 | 72 | 27.7 | 22.3 | 33.6 |
| | Grade 3 | 345 | 3 | 0.9 | 0.2 | 2.5 | 260 | 0 | 0.0 | 0.0 | 1.4 |
| | Related | 345 | 191 | 55.4 | 49.9 | 60.7 | 260 | 71 | 27.3 | 22.0 | 33.2 |
| Loss of appetite | Any | 345 | 109 | 31.6 | 26.7 | 36.8 | 260 | 57 | 21.9 | 17.0 | 27.5 |
| | Grade 3 | 345 | 2 | 0.6 | 0.1 | 2.1 | 260 | 1 | 0.4 | 0.0 | 2.1 |
| | Related | 345 | 105 | 30.4 | 25.6 | 35.6 | 260 | 54 | 20.8 | 16.0 | 26.2 |
| Temperature (Rectally) | ≥ 38.0°C | 345 | 55 | 15.9 | 12.2 | 20.2 | 260 | 11 | 4.2 | 2.1 | 7.4 |
| | > 40.0°C | 345 | 2 | 0.6 | 0.1 | 2.1 | 260 | 1 | 0.4 | 0.0 | 2.1 |
| | Related | 345 | 53 | 15.4 | 11.7 | 19.6 | 260 | 8 | 3.1 | 1.3 | 6.0 |
| **Across Doses** | | | | | | | | | | | |
| Drowsiness | Any | 363 | 214 | 59.0 | 53.7 | 64.1 | 270 | 118 | 43.7 | 37.7 | 49.8 |
| | Grade 3 | 363 | 3 | 0.8 | 0.2 | 2.4 | 270 | 3 | 1.1 | 0.2 | 3.2 |
| | Related | 363 | 212 | 58.4 | 53.1 | 63.5 | 270 | 111 | 41.1 | 35.2 | 47.2 |
| Irritability | Any | 363 | 282 | 77.7 | 73.0 | 81.9 | 270 | 140 | 51.9 | 45.7 | 57.9 |
| | Grade 3 | 363 | 9 | 2.5 | 1.1 | 4.7 | 270 | 4 | 1.5 | 0.4 | 3.7 |
| | Related | 363 | 280 | 77.1 | 72.5 | 81.4 | 270 | 137 | 50.7 | 44.6 | 56.9 |
| Loss of appetite | Any | 363 | 190 | 52.3 | 47.1 | 57.6 | 270 | 117 | 43.3 | 37.3 | 49.5 |
| | Grade 3 | 363 | 4 | 1.1 | 0.3 | 2.8 | 270 | 5 | 1.9 | 0.6 | 4.3 |
| | Related | 363 | 185 | 51.0 | 45.7 | 56.2 | 270 | 109 | 40.4 | 34.5 | 46.5 |
| Temperature (Rectally) | ≥ 38.0°C | 363 | 110 | 30.3 | 25.6 | 35.3 | 270 | 38 | 14.1 | 10.2 | 18.8 |
| | > 40.0°C | 363 | 4 | 1.1 | 0.3 | 2.8 | 270 | 3 | 1.1 | 0.2 | 3.2 |
| | Related | 363 | 105 | 28.9 | 24.3 | 33.9 | 270 | 32 | 11.9 | 8.2 | 16.3 |

10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the symptom at least once
Any = occurrence of any solicited general symptom regardless of their intensity grade or relationship to vaccination
Related = event assessed by the investigator as causally related to the study vaccination
Grade 3 Drowsiness = drowsiness that prevented normal activity
Grade 3 Loss of appetite = not eating at all.
Grade 3 Irritability = crying that could not be comforted/ prevented normal activity
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

**Secondary Outcome Variable(s):** Number (%) of subjects reporting solicited general symptoms during the 4-day (Days 0-3) post-booster vaccination – Subjects enrolled aged 6 weeks to 6 months and 7 to 11 months (Total Vaccinated cohort for analysis of safety and carriage)

| | | **Subjects enrolled aged 6 weeks to 6 months** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **10Pn3+1 Group** | | | | | **Ctrl3+1 Group** | | | | |
| | | | | | **95 % CI** | | | | | **95 % CI** | |
| **Symptom** | **Intensity/Relationship** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** |
| Drowsiness | Any | 1757 | 721 | 41.0 | 38.7 | 43.4 | 1024 | 307 | 30.0 | 27.2 | 32.9 |
| | Grade 3 | 1757 | 8 | 0.5 | 0.2 | 0.9 | 1024 | 3 | 0.3 | 0.1 | 0.9 |
| | Related | 1757 | 699 | 39.8 | 37.5 | 42.1 | 1024 | 300 | 29.3 | 26.5 | 32.2 |
| Irritability | Any | 1757 | 1124 | 64.0 | 61.7 | 66.2 | 1024 | 491 | 47.9 | 44.9 | 51.1 |
| | Grade 3 | 1757 | 47 | 2.7 | 2.0 | 3.5 | 1024 | 14 | 1.4 | 0.7 | 2.3 |
| | Related | 1757 | 1085 | 61.8 | 59.4 | 64.0 | 1024 | 481 | 47.0 | 43.9 | 50.1 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Loss of appetite | Any | 1757 | 549 | 31.1 | 29.1 | 33.5 | 1024 | 260 | 25.4 | 22.7 | 28.2 |
| | Grade 3 | 1757 | 12 | 0.7 | 0.4 | 1.2 | 1024 | 6 | 0.6 | 0.2 | 1.3 |
| | Related | 1757 | 513 | 29.2 | 27.1 | 31.4 | 1024 | 253 | 24.7 | 22.1 | 27.5 |
| Temperature (Rectally) | ≥ 38.0°C | 1757 | 391 | 22.3 | 20.3 | 24.3 | 1024 | 142 | 13.9 | 11.8 | 16.1 |
| | > 40.0°C | 1757 | 3 | 0.2 | 0.0 | 0.5 | 1024 | 0 | 0.0 | 0.0 | 0.4 |
| | Related | 1757 | 371 | 21.1 | 19.2 | 23.1 | 1024 | 134 | 13.1 | 11.1 | 15.3 |
| | | **10Pn2+1 Group** | | | | | **Ctrl2+1 Group** | | | | |
| | | | | | **95 % CI** | | | | | **95 % CI** | |
| **Symptom** | **Intensity/Relationship** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** |
| Drowsiness | Any | 1257 | 561 | 44.6 | 41.9 | 47.4 | 827 | 243 | 29.4 | 26.3 | 32.6 |
| | Grade 3 | 1257 | 8 | 0.6 | 0.3 | 1.3 | 827 | 4 | 0.5 | 0.1 | 1.2 |
| | Related | 1257 | 548 | 43.6 | 40.8 | 46.4 | 827 | 233 | 28.2 | 25.1 | 31.4 |
| Irritability | Any | 1257 | 816 | 64.9 | 62.2 | 67.6 | 827 | 410 | 49.6 | 46.1 | 53.0 |
| | Grade 3 | 1257 | 33 | 2.6 | 1.8 | 3.7 | 827 | 7 | 0.8 | 0.3 | 1.7 |
| | Related | 1257 | 801 | 63.7 | 61.0 | 66.4 | 827 | 395 | 47.8 | 44.3 | 51.2 |
| Loss of appetite | Any | 1257 | 411 | 32.7 | 30.1 | 35.4 | 827 | 186 | 22.5 | 19.7 | 25.5 |
| | Grade 3 | 1257 | 5 | 0.4 | 0.1 | 0.9 | 827 | 3 | 0.4 | 0.1 | 1.1 |
| | Related | 1257 | 398 | 31.7 | 29.1 | 34.3 | 827 | 173 | 20.9 | 18.2 | 23.9 |
| Temperature (Rectally) | ≥38.0°C | 1257 | 333 | 26.5 | 24.1 | 29.0 | 827 | 120 | 14.5 | 12.2 | 17.1 |
| | >40.0°C | 1257 | 0 | 0.0 | 0.0 | 0.3 | 827 | 1 | 0.1 | 0.0 | 0.7 |
| | Related | 1257 | 319 | 25.4 | 23.0 | 27.9 | 827 | 110 | 13.3 | 11.1 | 15.8 |
| | | **Subjects enrolled aged 7 to 11 months** | | | | | | | | | |
| | | **10Pn Group** | | | | | **Ctrl Group** | | | | |
| | | | | | **95 % CI** | | | | | **95 % CI** | |
| **Symptom** | **Intensity/Relationship** | **N** | **n** | **%** | **LL** | **UL** | **N** | **n** | **%** | **LL** | **UL** |
| Drowsiness | Any | 216 | 92 | 42.6 | 35.9 | 49.5 | 188 | 47 | 25.0 | 19.0 | 31.8 |
| | Grade 3 | 216 | 2 | 0.9 | 0.1 | 3.3 | 188 | 1 | 0.5 | 0.0 | 2.9 |
| | Related | 216 | 87 | 40.3 | 33.7 | 47.1 | 188 | 46 | 24.5 | 18.5 | 31.3 |
| Irritability | Any | 216 | 129 | 59.7 | 52.9 | 66.3 | 188 | 84 | 44.7 | 37.4 | 52.1 |
| | Grade 3 | 216 | 2 | 0.9 | 0.1 | 3.3 | 188 | 1 | 0.5 | 0.0 | 2.9 |
| | Related | 216 | 124 | 57.4 | 50.5 | 64.1 | 188 | 80 | 42.6 | 35.4 | 50.0 |
| Loss of appetite | Any | 216 | 64 | 29.6 | 23.6 | 36.2 | 188 | 46 | 24.5 | 18.5 | 31.3 |
| | Grade 3 | 216 | 2 | 0.9 | 0.1 | 3.3 | 188 | 1 | 0.5 | 0.0 | 2.9 |
| | Related | 216 | 60 | 27.8 | 21.9 | 34.3 | 188 | 43 | 22.9 | 17.1 | 29.5 |
| Temperature (Rectally) | ≥ 38.0°C | 216 | 42 | 19.4 | 14.4 | 25.4 | 188 | 11 | 5.9 | 3.0 | 10.2 |
| | > 40.0°C | 216 | 1 | 0.5 | 0.0 | 2.6 | 188 | 0 | 0.0 | 0.0 | 1.9 |
| | Related | 216 | 41 | 19.0 | 14.0 | 24.9 | 188 | 8 | 4.3 | 1.9 | 8.2 |

Groups for subjects enrolled aged 6 weeks to 6 months

- 10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
- Ctrl3+1 Group= Infants enrolled 6 weeks -6 months of age: infants primed with 3 doses and boosted with HBV vaccine
- 10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
- Ctrl 2+1 Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 doses and boosted with HBV vaccine

Groups for subjects enrolled aged 7 to 11 months

- 10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
- Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine

N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
Any = occurrence of any solicited general symptom regardless of their intensity grade or relationship to vaccination
Related = event assessed by the investigator as causally related to the study vaccination
Grade 3 Drowsiness = drowsiness that prevented normal activity
Grade 3 Loss of appetite = not eating at all.
Grade 3 Irritability = crying that could not be comforted/ prevented normal act.
95% CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

**Safety Results:** Number (%) of subjects with unsolicited AEs occurring within the 31-day (Days 0-30) after primary vaccination – Subjects enrolled aged 6 weeks to 6 months (Total Vaccinated cohort for analysis of safety and carriage)

| **Most frequent adverse events - On-Therapy (occurring within Days 0-30 following vaccination)** | **10Pn3+1 Group N = 1849** | **Ctrl3+1 Group N = 1069** | **10Pn2+1 Group N = 1316** | **Ctrl2+1 Group N = 859** |
|---|---|---|---|---|
| Subjects with any AE(s), n (%) | 1105 (59.8) | 554 (51.8) | 598 (45.4) | 337 (39.2) |
| Injection site induration | 376 (20.3) | 47 (4.4) | 203 (15.4) | - |
| Upper respiratory tract infection | 172 (9.3) | 98 (9.2) | 74 (5.6) | 29 (3.4) |
| Rhinitis | 121 (6.5) | 90 (8.4) | 57 (4.3) | 49 (5.7) |
| Diarrhoea | 106 (5.7) | 65 (6.1) | 52 (4.0) | 39 (4.5) |
| Nasopharyngitis | 84 (4.5) | 48 (4.5) | - | 35 (4.1) |
| Flatulence | - | - | 43 (3.3) | - |
| Cough | - | - | - | 21 (2.4) |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl3+1 Group= Infants enrolled 6 weeks -6 months of age: infants primed with 3 doses and boosted with HBV vaccine
10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl 2+1 Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 doses and boosted with HBV vaccine
Counting rule applied: As there were more than 30 subjects per treatment group and > 3 groups, only the 5 most frequent events in each treatment group are to be listed.
-: Implies that adverse event was not reported in the particular group or that the adverse event was reported in the particular group but did not fall within the pre-defined counting rule of 5 most frequent events for that group.

**Safety Results:** Number (%) of subjects with unsolicited AEs occurring within the 31-day (Days 0-30) after primary vaccination – Subjects enrolled aged 7 to 11 months (Total Vaccinated cohort for analysis of safety and carriage)

| **Most frequent adverse events - On-Therapy (occurring within Days 0-30 following vaccination)** | **10Pn Group N = 241** | **Ctrl Group N = 204** |
|---|---|---|
| Subjects with any AE(s), n (%) | 157 (65.1) | 132 (64.7) |
| Upper respiratory tract infection | 28 (11.6) | 42 (20.6) |
| Rhinitis | 21 (8.7) | 32 (15.7) |
| Pyrexia | 25 (10.4) | 20 (9.8) |
| Otitis media* | 23 (9.5) | 16 (7.8) |
| Diarrhoea | 17 (7.1) | 16 (7.8) |
| Teething | 10 (4.1) | 18 (8.8) |
| Injection site induration | 27 (11.2) | - |
| Nasopharyngitis | 15 (6.2) | 10 (4.9) |
| Gastroenteritis | 11 (4.6) | 13 (6.4) |
| Vomiting | 9 (3.7) | 7 (3.4) |
| Cough | - | 9 (4.4) |
| Exanthema subitum | 9 (3.7) | - |
| Injection site haematoma | 9 (3.7) | - |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine
Counting rule applied: As there were more than 30 subjects per treatment group and ≤ 3 groups, only the 10 most frequent events in each treatment group are to be listed.
-: Implies that adverse event was not reported in the particular group or that the adverse event was reported in the particular group but did not fall within the pre-defined counting rule of 10 most frequent events for that group.
*Note that, to avoid inconsistency in the clinical database, between the AE reporting and the AOM questionnaire, otitis was not requested to be reported as an AE if already reported via the AOM questionnaire.

**Safety Results:** Number (%) of subjects with unsolicited AEs occurring within the 31 days (Days 0-30) after vaccination – Subjects enrolled aged 12 to 18 months (Total Vaccinated cohort for analysis of safety and carriage)

| **Most frequent adverse events - On-Therapy (occurring within Days 0-30 following vaccination)** | **10Pn Group N = 368** | **Ctrl Group N = 271** |
|---|---|---|
| Subjects with any AE(s), n (%) | 221 (60.1) | 174 (64.2) |
| Upper respiratory tract infection | 36 (9.8) | 40 (14.8) |
| Rhinitis | 29 (7.9) | 25 (9.2) |
| Diarrhoea | 26 (7.1) | 25 (9.2) |
| Otitis media* | 25 (6.8) | 22 (8.1) |
| Injection site induration | 45 (12.2) | - |

| | | |
|---|---|---|
| Pyrexia | 14 (3.8) | 26 (9.6) |
| Cough | 14 (3.8) | 15 (5.5) |
| Nasopharyngitis | 18 (4.9) | 10 (3.7) |
| Gastroenteritis | 13 (3.5) | 13 (4.8) |
| Vomiting | - | 12 (4.4) |
| Injection site haematoma | - | 9 (3.3) |
| Injection site haemorrhage | 9 (2.4) | - |
| Teething | 9 (2.4) | - |

10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine
Counting rule applied: As there were more than 30 subjects per treatment group and ≤ 3 groups, only the 10 most frequent events in each treatment group are to be listed.
-: Implies that adverse event was not reported in the particular group or that the adverse event was reported in the particular group but did not fall within the pre-defined counting rule of 10 most frequent events for that group.
*Note that, to avoid inconsistency in the clinical database, between the AE reporting and the AOM questionnaire, otitis was not requested to be reported as an AE if already reported via the AOM questionnaire.

**Safety Results:** Number (%) of subjects with unsolicited AEs occurring within the 31 days (Days 0-30) after booster vaccination – Subjects enrolled aged 6 weeks and 6 months (Total Vaccinated cohort for analysis of safety and carriage)

| **Most frequent adverse events - On-Therapy (occurring within Days 0-30 following vaccination)** | **10Pn3+1 Group N = 1786** | **Ctrl3+1 Group N = 1043** | **10Pn2+1 Group N = 1275** | **Ctrl2+1 Group N = 837** |
|---|---|---|---|---|
| Subjects with any AE(s), n (%) | 521 (29.2) | 277 (26.6) | 363 (28.5) | 244 (29.2) |
| Injection site induration | 118 (6.6) | 29 (2.8) | 81 (6.4) | - |
| Upper respiratory tract infection | 89 (5.0) | 47 (4.5) | 47 (3.7) | 21 (2.5) |
| Pyrexia | 33 (1.8) | 29 (2.8) | 29 (2.3) | 35 (4.2) |
| Diarrhoea | 41 (2.3) | - | 30 (2.4) | 16 (1.9) |
| Rhinitis | 41 (2.3) | - | - | 27 (3.2) |
| Teething | - | 22 (2.1) | 29 (2.3) | 16 (1.9) |
| Nasopharyngitis | - | 22 (2.1) | - | 34 (4.1) |

10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine
Ctrl3+1 Group = Infants enrolled 6 weeks -6 months of age: infants primed with 3 doses and boosted with HBV vaccine
10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl 2+1 Group = Infants enrolled 6 weeks -6 months of age: infants primed with 2 doses and boosted with HBV vaccine
N = number of subjects with the documented dose
Counting rule applied: As there were more than 30 subjects per treatment group and > 3 groups, only the 5 most frequent events in each treatment group are to be listed.
-: Implies that adverse event was not reported in the particular group or that the adverse event was reported in the particular group but did not fall within the pre-defined counting rule of 5 most frequent events for that group.

**Safety Results:** Number (%) of subjects with unsolicited AEs occurring within the 31 days (Days 0-30) after booster vaccination – Subjects enrolled aged 7 to 11 months (Total Vaccinated cohort for analysis of safety and carriage)

| **Most frequent adverse events – On-Therapy (occurring within Days 0-30 following vaccination)** | **10Pn Group N = 226** | **Ctrl Group N = 197** |
|---|---|---|
| Subjects with any AE(s), n (%) | 51 (22.6) | 48 (24.4) |
| Upper respiratory tract infection | 13 (5.8) | 11 (5.6) |
| Diarrhoea | 8 (3.5) | 3 (1.5) |
| Injection site induration | 8 (3.5) | 3 (1.5) |
| Pyrexia | 2 (0.9) | 7 (3.6) |
| Nasopharyngitis | 3 (1.3) | 3 (1.5) |
| Otitis media* | 3 (1.3) | 3 (1.5) |
| Rhinitis | - | 6 (3.0) |
| Bronchitis | 3 (1.3) | 2 (1.0) |
| Cough | 2 (0.9) | 2 (1.0) |
| Laryngitis | 3 (1.3) | - |
| Teething | - | 3 (1.5) |
| Vomiting | 3 (1.3) | - |
| Exanthema subitum | - | 2 (1.0) |
| Injection site haematoma | - | 2 (1.0) |

10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine
Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine
N = number of subjects with the documented dose
Counting rule applied: As there were more than 30 subjects per treatment group and ≤ 3 groups, only the 10 most frequent events in each treatment group are to be listed.
-: Implies that adverse event was not reported in the particular group or that the adverse event was reported in the particular group but did not fall within the pre-defined counting rule of 10 most frequent events for that group.
*Note that, to avoid inconsistency in the clinical database, between the AE reporting and the AOM questionnaire, otitis was not requested to be reported as an AE if already reported via the AOM questionnaire.

**Safety Results:** Number (%) of subjects with SAEs reported during the entire study period (Study Months 0-18) for subjects enrolled aged 6 weeks to 6 months (Total Vaccinated cohort for analysis of safety and carriage)

**Serious adverse event, n (%) [n considered by the investigator to be related to study medication]**

| **All SAEs** | **10Pn3+1 Group N = 1849** | **Ctrl3+1 Group N = 1069** |
|---|---|---|
| Subjects with any SAE(s), n (%) [n assessed by the investigator as related] | 163 (8.8) [4] | 77 (7.2) [1] |
| Bronchitis | 33 (1.8) [0] | 19 (1.8) [0] |
| Otitis media* | 22 (1.2) [0] | 9 (0.8) [0] |
| Bronchiolitis | 9 (0.5) [0] | 5 (0.5) [0] |
| Gastroenteritis | 15 (0.8) [0] | 5 (0.5) [0] |
| Laryngitis | 12 (0.6) [0] | 4 (0.4) [0] |
| Respiratory syncytial virus bronchiolitis | 11 (0.6) [0] | 4 (0.4) [0] |
| Pneumonia | 10 (0.5) [0] | 3 (0.3) [0] |
| Pyelonephritis | 10 (0.5) [0] | 2 (0.2) [0] |
| Febrile convulsion | 5 (0.3) [0] | 1 (0.1) [0] |
| Pyrexia | 4 (0.2) [1] | 4 (0.4) [0] |
| Upper respiratory tract infection | 5 (0.3) [0] | 3 (0.3) [0] |
| Asthma | 4 (0.2) [0] | 4 (0.4) [0] |
| Otitis media acute* | 5 (0.3) [0] | 1 (0.1) [0] |
| Convulsion | 5 (0.3) [2] | 2 (0.2) [0] |
| Viral infection | 1 (0.1) [0] | 4 (0.4) [0] |
| Pyelonephritis acute | 4 (0.2) [0] | 1 (0.1) [0] |
| Concussion | 3 (0.2) [0] | 0 (0.0) [0] |
| Sepsis | 2 (0.1) [1] | 2 (0.2) [0] |
| Femur fracture | 2 (0.1) [0] | 2 (0.2) [0] |
| Respiratory syncytial virus infection | 4 (0.2) [0] | 0 (0.0) [0] |
| Urinary tract infection | 2 (0.1) [0] | 1 (0.1) [0] |
| Infection | 2 (0.1) [0] | 1 (0.1) [0] |
| Pneumonia respiratory syncytial viral | 1 (0.1) [0] | 0 (0.0) [0] |
| Tonsillitis | 2 (0.1) [0] | 0 (0.0) [0] |
| Adenovirus infection | 2 (0.1) [0] | 1 (0.1) [0] |
| Bacterial infection | 0 (0.0) [0] | 2 (0.2) [0] |
| Dyspnoea | 0 (0.0) [0] | 1 (0.1) [0] |
| Foreign body | 1 (0.1) [0] | 0 (0.0) [0] |
| Pneumococcal sepsis | 0 (0.0) [0] | 2 (0.2) [0] |
| Amaurotic familial idiocy | 1 (0.1) [0] | 0 (0.0) [0] |
| Anal abscess | 1 (0.1) [0] | 1 (0.1) [0] |
| Diarrhoea | 1 (0.1) [0] | 1 (0.1) [0] |
| Enteritis | 2 (0.1) [0] | 0 (0.0) [0] |
| Enterovirus infection | 2 (0.1) [0] | 0 (0.0) [0] |
| H1N1 influenza | 2 (0.1) [0] | 0 (0.0) [0] |
| Influenza | 1 (0.1) [0] | 0 (0.0) [0] |
| Intussusception | 2 (0.1) [0] | 0 (0.0) [0] |
| Milk allergy | 1 (0.1) [0] | 1 (0.1) [0] |
| Patent ductus arteriosus | 2 (0.1) [0] | 0 (0.0) [0] |
| Respiratory syncytial virus bronchitis | 0 (0.0) [0] | 2 (0.2) [0] |
| Thermal burn | 0 (0.0) [0] | 1 (0.1) [0] |

| | | |
|---|---|---|
| Tibia fracture | 1 (0.1) [0] | 0 (0.0) [0] |
| Type 1 diabetes mellitus | 1 (0.1) [0] | 0 (0.0) [0] |
| Urticaria | 0 (0.0) [0] | 1 (0.1) [0] |
| Ventricular septal defect | 1 (0.1) [0] | 0 (0.0) [0] |
| Abscess neck | 1 (0.1) [0] | 0 (0.0) [0] |
| Aplasia pure red cell | 1 (0.1) [0] | 0 (0.0) [0] |
| Bacterial sepsis | 1 (0.1) [0] | 0 (0.0) [0] |
| Cardiac murmur | 1 (0.1) [0] | 0 (0.0) [0] |
| Combined immunodeficiency | 1 (0.1) [0] | 0 (0.0) [0] |
| Contusion | 0 (0.0) [0] | 1 (0.1) [0] |
| Craniosynostosis | 1 (0.1) [0] | 0 (0.0) [0] |
| Croup infectious | 1 (0.1) [0] | 0 (0.0) [0] |
| Cyanosis | 1 (0.1) [0] | 0 (0.0) [0] |
| Ear infection | 1 (0.1) [0] | 0 (0.0) [0] |
| Electric shock | 1 (0.1) [0] | 0 (0.0) [0] |
| Epilepsy | 0 (0.0) [0] | 1 (0.1) [0] |
| Erythema | 1 (0.1) [0] | 0 (0.0) [0] |
| Gastroenteritis adenovirus | 0 (0.0) [0] | 1 (0.1) [0] |
| Gastroenteritis rotavirus | 1 (0.1) [0] | 0 (0.0) [0] |
| Gastrooesophageal reflux disease | 1 (0.1) [0] | 0 (0.0) [0] |
| Groin abscess | 0 (0.0) [0] | 1 (0.1) [0] |
| Herpes zoster | 0 (0.0) [0] | 1 (0.1) [0] |
| Hyperreflexia | 1 (0.1) [0] | 0 (0.0) [0] |
| Inguinal hernia | 0 (0.0) [0] | 1 (0.1) [0] |
| Inguinal hernia strangulated | 1 (0.1) [0] | 0 (0.0) [0] |
| Joint dislocation | 0 (0.0) [0] | 1 (0.1) [0] |
| Juvenile arthritis | 1 (0.1) [0] | 0 (0.0) [0] |
| Laryngitis viral | 0 (0.0) [0] | 1 (0.1) [0] |
| Laryngomalacia | 1 (0.1) [0] | 0 (0.0) [0] |
| Loss of consciousness | 0 (0.0) [0] | 1 (0.1) [0] |
| Lymph gland infection | 1 (0.1) [0] | 0 (0.0) [0] |
| Meningococcal sepsis | 1 (0.1) [0] | 0 (0.0) [0] |
| Neck pain | 1 (0.1) [0] | 0 (0.0) [0] |
| Nervous system disorder | 1 (0.1) [0] | 0 (0.0) [0] |
| Petit mal epilepsy | 0 (0.0) [0] | 1 (0.1) [1] |
| Pharyngitis | 1 (0.1) [0] | 0 (0.0) [0] |
| Pneumococcal bacteraemia | 0 (0.0) [0] | 1 (0.1) [0] |
| Pneumococcal infection | 0 (0.0) [0] | 1 (0.1) [0] |
| Pneumonia bacterial | 0 (0.0) [0] | 1 (0.1) [0] |
| Poisoning | 1 (0.1) [0] | 0 (0.0) [0] |
| Pyloric stenosis | 1 (0.1) [0] | 0 (0.0) [0] |
| Respiratory tract infection viral | 1 (0.1) [0] | 0 (0.0) [0] |
| Staphylococcal sepsis | 1 (0.1) [0] | 0 (0.0) [0] |
| Streptococcal infection | 0 (0.0) [0] | 1 (0.1) [0] |
| Subcutaneous abscess | 1 (0.1) [0] | 0 (0.0) [0] |
| Tracheitis | 1 (0.1) [0] | 0 (0.0) [0] |
| Vomiting | 1 (0.1) [0] | 0 (0.0) [0] |
| Weight gain poor | 0 (0.0) [0] | 1 (0.1) [0] |
| **Fatal SAEs** | **10Pn3+1 Group N = 1849** | **Ctrl3+1 Group N = 1069** |
| Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related] | 0 (0.0) [0] | 0 (0.0) [0] |
| **All SAEs** | **10Pn2+1 Group N = 1316** | **Ctrl2+1 Group N = 859** |
| Subjects with any SAE(s), n (%) [n assessed by the investigator as related] | 96 (7.3) [0] | 74 (8.6) [1] |

| | | |
|---|---|---|
| Bronchitis | 13 (1.0) [0] | 20 (2.3) [0] |
| Otitis media* | 7 (0.5) [0] | 13 (1.5) [0] |
| Bronchiolitis | 8 (0.6) [0] | 9 (1.0) [0] |
| Gastroenteritis | 7 (0.5) [0] | 4 (0.5) [0] |
| Laryngitis | 6 (0.5) [0] | 7 (0.8) [0] |
| Respiratory syncytial virus bronchiolitis | 7 (0.5) [0] | 4 (0.5) [0] |
| Pneumonia | 5 (0.4) [0] | 5 (0.6) [0] |
| Pyelonephritis | 7 (0.5) [0] | 2 (0.2) [0] |
| Febrile convulsion | 6 (0.5) [0] | 2 (0.2) [0] |
| Pyrexia | 4 (0.3) [0] | 2 (0.2) [1] |
| Upper respiratory tract infection | 3 (0.2) [0] | 3 (0.3) [0] |
| Asthma | 2 (0.2) [0] | 3 (0.3) [0] |
| Otitis media acute* | 2 (0.2) [0] | 3 (0.3) [0] |
| Convulsion | 2 (0.2) [0] | 1 (0.1) [0] |
| Viral infection | 3 (0.2) [0] | 1 (0.1) [0] |
| Pyelonephritis acute | 0 (0.0) [0] | 3 (0.3) [0] |
| Concussion | 2 (0.2) [0] | 2 (0.2) [0] |
| Sepsis | 1 (0.1) [0] | 2 (0.2) [0] |
| Femur fracture | 1 (0.1) [0] | 1 (0.1) [0] |
| Respiratory syncytial virus infection | 0 (0.0) [0] | 2 (0.2) [0] |
| Urinary tract infection | 2 (0.2) [0] | 1 (0.1) [0] |
| Infection | 1 (0.1) [0] | 0 (0.0) [0] |
| Pneumonia respiratory syncytial viral | 2 (0.2) [0] | 1 (0.1) [0] |
| Tonsillitis | 2 (0.2) [0] | 0 (0.0) [0] |
| Bacterial infection | 1 (0.1) [0] | 0 (0.0) [0] |
| Dyspnoea | 2 (0.2) [0] | 0 (0.0) [0] |
| Foreign body | 2 (0.2) [0] | 0 (0.0) [0] |
| Pneumococcal sepsis | 1 (0.1) [0] | 0 (0.0) [0] |
| Amaurotic familial idiocy | 0 (0.0) [0] | 1 (0.1) [0] |
| Dehydration | 2 (0.2) [0] | 0 (0.0) [0] |
| Influenza | 1 (0.1) [0] | 0 (0.0) [0] |
| Streptococcal sepsis | 1 (0.1) [0] | 1 (0.1) [0] |
| Thermal burn | 0 (0.0) [0] | 1 (0.1) [0] |
| Tibia fracture | 0 (0.0) [0] | 1 (0.1) [0] |
| Type 1 diabetes mellitus | 0 (0.0) [0] | 1 (0.1) [0] |
| Urticaria | 0 (0.0) [0] | 1 (0.1) [0] |
| Varicella | 1 (0.1) [0] | 1 (0.1) [0] |
| Ventricular septal defect | 1 (0.1) [0] | 0 (0.0) [0] |
| Altered state of consciousness | 0 (0.0) [0] | 1 (0.1) [0] |
| Anaphylactic reaction | 0 (0.0) [0] | 1 (0.1) [0] |
| Apnoea | 0 (0.0) [0] | 1 (0.1) [0] |
| Bacteraemia | 0 (0.0) [0] | 1 (0.1) [0] |
| Balance disorder | 1 (0.1) [0] | 0 (0.0) [0] |
| Breath holding | 0 (0.0) [0] | 1 (0.1) [0] |
| Burns second degree | 1 (0.1) [0] | 0 (0.0) [0] |
| Cerebral infarction | 1 (0.1) [0] | 0 (0.0) [0] |
| Chemical poisoning | 1 (0.1) [0] | 0 (0.0) [0] |
| Coarctation of the aorta | 1 (0.1) [0] | 0 (0.0) [0] |
| Cognitive disorder | 0 (0.0) [0] | 1 (0.1) [0] |
| Crying | 1 (0.1) [0] | 0 (0.0) [0] |
| Cystitis | 1 (0.1) [0] | 0 (0.0) [0] |
| Developmental delay | 0 (0.0) [0] | 1 (0.1) [0] |
| Dysarthria | 0 (0.0) [0] | 1 (0.1) [0] |
| Eczema infected | 1 (0.1) [0] | 0 (0.0) [0] |
| Eczema nummular | 0 (0.0) [0] | 1 (0.1) [0] |
| Exanthema subitum | 1 (0.1) [0] | 0 (0.0) [0] |

| | | |
|---|---|---|
| Gastroenteritis norovirus | 1 (0.1) [0] | 0 (0.0) [0] |
| Haemangioma | 0 (0.0) [0] | 1 (0.1) [0] |
| Hand-foot-and-mouth disease | 1 (0.1) [0] | 0 (0.0) [0] |
| Hypertension | 1 (0.1) [0] | 0 (0.0) [0] |
| Hypoglycaemia | 1 (0.1) [0] | 0 (0.0) [0] |
| Impetigo | 0 (0.0) [0] | 1 (0.1) [0] |
| Krabbe's disease | 0 (0.0) [0] | 1 (0.1) [0] |
| Lobar pneumonia | 1 (0.1) [0] | 0 (0.0) [0] |
| Lymphadenitis | 0 (0.0) [0] | 1 (0.1) [0] |
| Mastoiditis | 1 (0.1) [0] | 0 (0.0) [0] |
| Melaena | 0 (0.0) [0] | 1 (0.1) [0] |
| Mitochondrial encephalomyopathy | 0 (0.0) [0] | 1 (0.1) [0] |
| Osteomyelitis | 1 (0.1) [0] | 0 (0.0) [0] |
| Parainfluenzae virus infection | 1 (0.1) [0] | 0 (0.0) [0] |
| Pericardial effusion | 1 (0.1) [0] | 0 (0.0) [0] |
| Respiratory tract infection | 1 (0.1) [0] | 0 (0.0) [0] |
| Septic arthritis streptococcal | 0 (0.0) [0] | 1 (0.1) [0] |
| Skull fracture | 0 (0.0) [0] | 1 (0.1) [0] |
| Sudden death | 1 (0.1) [0] | 0 (0.0) [0] |
| **Fatal SAEs** | **10Pn2+1 Group N = 1316** | **Ctrl2+1 Group N = 859** |
| Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related] | 1 (0.1) [0] | 0 (0.0) [0] |
| Sudden death | 1 (0.1) [0] | 0 (0.0) [0] |
| 10Pn3+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 3 doses and boosted with 10Pn vaccine<br>Ctrl3+1 Group= Infants enrolled 6 weeks -6 months of age: infants primed with 3 doses and boosted with HBV vaccine<br>10Pn2+1 Group = Infants enrolled 6 weeks-6 months of age: infants primed with 2 doses and boosted with 10Pn vaccine<br>Ctrl 2+1 Group= Infants enrolled 6 weeks -6 months of age: infants primed with 2 doses and boosted with HBV vaccine<br>*Note that, to avoid inconsistency in the clinical database, between the AE reporting and the AOM questionnaire, otitis was not requested to be reported as an AE if already reported via the AOM questionnaire. | | |
| **Safety Results:** Number (%) of subjects with SAEs reported during the entire study period (Study Months 0-16) for subjects enrolled aged 7 to 11 months (Total Vaccinated cohort for analysis of safety and carriage) | | |
| **Serious adverse event, n (%) [n considered by the investigator to be related to study medication]** | | |
| **All SAEs** | **10Pn Group N = 241** | **Ctrl Group N = 204** |
| Subjects with any SAE(s), n (%) [n assessed by the investigator as related] | 24 (10.0) [0] | 18 (8.8) [0] |
| Bronchitis | 9 (3.7) [0] | 5 (2.5) [0] |
| Asthma | 4 (1.7) [0] | 1 (0.5) [0] |
| Gastroenteritis | 3 (1.2) [0] | 1 (0.5) [0] |
| Bronchiolitis | 1 (0.4) [0] | 2 (1.0) [0] |
| Convulsion | 1 (0.4) [0] | 1 (0.5) [0] |
| Otitis media acute* | 2 (0.8) [0] | 0 (0.0) [0] |
| Pneumonia | 1 (0.4) [0] | 1 (0.5) [0] |
| Pyelonephritis acute | 0 (0.0) [0] | 2 (1.0) [0] |
| Thermal burn | 1 (0.4) [0] | 1 (0.5) [0] |
| Bacterial infection | 1 (0.4) [0] | 0 (0.0) [0] |
| Bacterial sepsis | 0 (0.0) [0] | 1 (0.5) [0] |
| Concussion | 1 (0.4) [0] | 0 (0.0) [0] |
| Cough | 0 (0.0) [0] | 1 (0.5) [0] |
| Diarrhoea | 1 (0.4) [0] | 0 (0.0) [0] |
| Diarrhoea infectious | 1 (0.4) [0] | 0 (0.0) [0] |
| Epilepsy | 1 (0.4) [0] | 0 (0.0) [0] |
| Escherichia sepsis | 0 (0.0) [0] | 1 (0.5) [0] |
| Exanthema subitum | 1 (0.4) [0] | 0 (0.0) [0] |
| Febrile convulsion | 0 (0.0) [0] | 1 (0.5) [0] |

| | | |
|---|---|---|
| Gastroenteritis adenovirus | 1 (0.4) [0] | 0 (0.0) [0] |
| Gastroenteritis rotavirus | 1 (0.4) [0] | 0 (0.0) [0] |
| Laryngitis | 1 (0.4) [0] | 0 (0.0) [0] |
| Otitis media* | 1 (0.4) [0] | 0 (0.0) [0] |
| Otitis media fungal* | 0 (0.0) [0] | 1 (0.5) [0] |
| Pharyngitis | 1 (0.4) [0] | 0 (0.0) [0] |
| Pneumonia viral | 1 (0.4) [0] | 0 (0.0) [0] |
| Pyelonephritis | 0 (0.0) [0] | 1 (0.5) [0] |
| Respiratory syncytial virus bronchiolitis | 1 (0.4) [0] | 0 (0.0) [0] |
| Respiratory syncytial virus bronchitis | 0 (0.0) [0] | 1 (0.5) [0] |
| Respiratory tract infection | 1 (0.4) [0] | 0 (0.0) [0] |
| Roseola | 0 (0.0) [0] | 1 (0.5) [0] |
| Rotavirus infection | 1 (0.4) [0] | 0 (0.0) [0] |
| Tonsillitis | 1 (0.4) [0] | 0 (0.0) [0] |
| Urinary tract infection | 0 (0.0) [0] | 1 (0.5) [0] |
| **Fatal SAEs** | **10Pn Group N = 241** | **Ctrl Group N = 204** |
| Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related] | 0 (0.0) [0] | 0 (0.0) [0] |
| 10Pn Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with 10Pn vaccine<br>Ctrl Group = Catch-up infants 7-11 months of age: infants primed with 2 doses and boosted with HBV vaccine<br>*Note that, to avoid inconsistency in the clinical database, between the AE reporting and the AOM questionnaire, otitis was not requested to be reported as an AE if already reported via the AOM questionnaire. | | |
| **Safety Results:** Number (%) of subjects with SAEs reported during the entire study period (Study Months 0-9) for subjects enrolled aged 12 to 18 months (Total Vaccinated cohort for analysis of safety and carriage) | | |
| **Serious adverse event, n (%) [n considered by the investigator to be related to study medication]** | | |
| **All SAEs** | **10Pn Group N = 368** | **Ctrl Group N = 271** |
| Subjects with any SAE(s), n (%) [n assessed by the investigator as related] | 23 (6.3) [0] | 14 (5.2) [0] |
| Bronchitis | 5 (1.4) [0] | 2 (0.7) [0] |
| Asthma | 4 (1.1) [0] | 2 (0.7) [0] |
| Febrile convulsion | 2 (0.5) [0] | 1 (0.4) [0] |
| Gastroenteritis | 2 (0.5) [0] | 1 (0.4) [0] |
| Otitis media* | 1 (0.3) [0] | 2 (0.7) [0] |
| Pneumonia | 2 (0.5) [0] | 1 (0.4) [0] |
| Pyelonephritis | 2 (0.5) [0] | 1 (0.4) [0] |
| Gastroenteritis rotavirus | 1 (0.3) [0] | 1 (0.4) [0] |
| Gastroenteritis viral | 2 (0.5) [0] | 0 (0.0) [0] |
| Laryngitis | 2 (0.5) [0] | 0 (0.0) [0] |
| Accidental drug intake by child | 1 (0.3) [0] | 0 (0.0) [0] |
| Accidental poisoning | 1 (0.3) [0] | 0 (0.0) [0] |
| Cellulitis | 0 (0.0) [0] | 1 (0.4) [0] |
| Cellulitis orbital | 1 (0.3) [0] | 0 (0.0) [0] |
| Confusional state | 0 (0.0) [0] | 1 (0.4) [0] |
| Femur fracture | 1 (0.3) [0] | 0 (0.0) [0] |
| Pneumococcal sepsis | 0 (0.0) [0] | 1 (0.4) [0] |
| Respiratory syncytial virus bronchiolitis | 1 (0.3) [0] | 0 (0.0) [0] |
| Type 1 diabetes mellitus | 0 (0.0) [0] | 1 (0.4) [0] |
| Upper respiratory tract infection | 1 (0.3) [0] | 0 (0.0) [0] |
| Urinary tract infection | 1 (0.3) [0] | 0 (0.0) [0] |
| Urticaria | 0 (0.0) [0] | 1 (0.4) [0] |
| Viral upper respiratory tract infection | 0 (0.0) [0] | 1 (0.4) [0] |
| **Fatal SAEs** | **10Pn Group N = 368** | **Ctrl Group N = 271** |
| Subjects with fatal SAE(s), n (%) [n assessed by the | 0 (0.0) [0] | 0 (0.0) [0] |

| | | |
|---|---|---|
| investigator as related] | | |

10Pn Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of 10Pn vaccine
Ctrl Group = Catch-up toddlers 12-18 months of age: toddlers vaccinated with 2 doses of HAV vaccine
*Note that, to avoid inconsistency in the clinical database, between the AE reporting and the AOM questionnaire, otitis was not requested to be reported as an AE if already reported via the AOM questionnaire.

**Conclusion:**
For conclusion on primary and secondary results on vaccine effectiveness in the prevention of Invasive Disease, please refer to the 111442 CTRS.

Among subjects in the Infant cohort enrolled between 6 weeks and 6 months of age, during the 31-day follow-up period post primary vaccination, at least one unsolicited AE was reported for 1105 (59.8%), 554 (51.8%), 598 (45.4%) and 337 (39.2%) subjects assigned to the 10Pn3+1, Ctrl3+1, 10Pn2+1 and Ctrl2+1 groups, respectively.
Among subjects in the Catch-up cohort enrolled between 7 and 11 months of age, during that same period, at least one unsolicited AE was reported for 157 (65.1%) and 132 (64.7%) subjects in the Catch-up 7-11M-10Pn and Catch-up 7-11M-Ctrl groups, respectively.
Among subjects in the Catch-up cohort enrolled between 12 and 18 months of age, during that same period, at least one unsolicited AE was reported for 221 (60.1%) and 174 (64.2%) subjects in the Catch-up 12-18M-10Pn and Catch-up 12-18M-Ctrl groups, respectively.
Among subjects in the Infant cohort enrolled between 6 weeks and 6 months of age, during the 31-day follow-up period post booster vaccination, at least one unsolicited AE was reported for 521 (29.2%), 277 (26.6%), 363 (28.5%) and 244 (29.2%) subjects in the 10Pn3+1, Ctrl3+1, 10Pn2+1 and Ctrl2+1 groups, respectively. Among subjects in the Catch-up cohort enrolled between 7 and 11 months of age, during that same period, at least one unsolicited AE was reported for 51 (22.6%) and 48 (24.4%) subjects in the Catch-up 7-11M-10Pn and Catch-up 7-11M-Ctrl schedules, respectively.

Among subjects in the Infant cohort enrolled between 6 weeks and 6 months of age, from study start to study end (Month 18), SAEs were reported for 163 (8.8%), 77 (7.2%), 96 (7.3%) and 74 (8.6%) subjects in the 10Pn3+1, Ctrl3+1, 10Pn2+1 and Ctrl2+1 groups, respectively. 6 of these SAEs, of which none were fatal, were assessed by the investigators to be causally related to vaccination (4 in the 10Pn3+1 Group, 1 in the Ctrl3+1Group and 1 in the Ctrl2+1 Group). One fatal SAE (sudden death) was reported for the 10Pn2+1 Group. This SAE was assessed by the investigators as not causally related to vaccination.
Among subjects in the Catch-up cohort enrolled between 7-11 months of age, from study start to study end (Month 16), SAEs were reported for reported for 24 (10.0%) and 18 (8.8%) subjects in the Catch-up 7-11M-10Pn and Catch-up 7-11M-Ctrl groups, respectively, with none assessed causality to the vaccination. No fatal SAEs were reported for subjects in this age group.
Among subjects in the Catch-up cohort enrolled between 12 and 18 months of age, from study start to study end (Month 9), SAEs were reported for reported for 23 (6.3%) and 14 (5.2%) subjects in the in the Catch-up 12-18M-10Pn and Catch-up 12-18M-Ctrl groups, respectively, out of which none were assessed by the investigators to be causally related to vaccination. No fatal SAEs were reported for subjects in this age group.

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