Long-Term Antibody Persistence After Primary Vaccination With MenACWY-TT and Immunogenicity of a Booster Dose in Individuals Aged 11–55 Years

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Disclosure: Paula Peyrani

Company Name	*Honoraria/ Expenses*	*Consulting/ Advisory Board*	*Funded Research*	*Royalties/ Patent*	*Stock Options*	*Ownership/ Equity Position*	*Employee*	*Other (please specify)*
Pfizer Inc					×		×	

Background and Aim

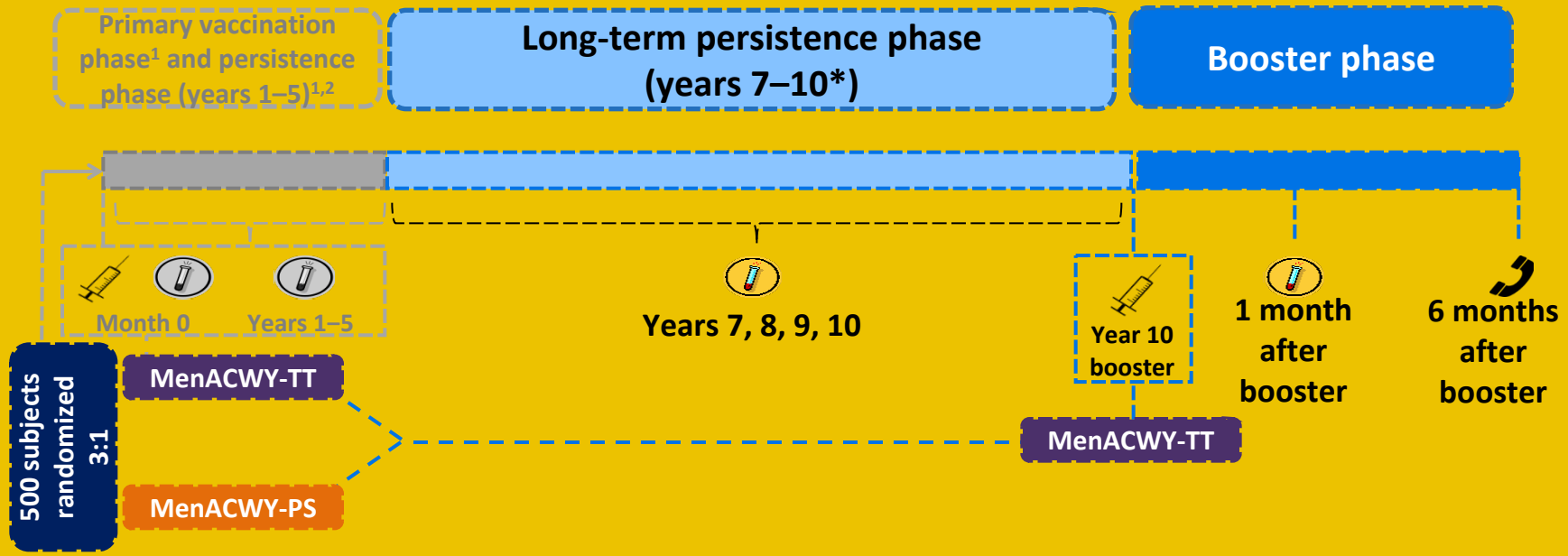
- Invasive meningococcal disease (IMD) caused by *Neisseria meningitidis* serogroups A, C, W, and Y is associated with substantial morbidity and mortality.[1]
- MenACWY-TT (Nimenrix®; Pfizer Inc) is a quadrivalent meningococcal polysaccharide conjugate vaccine using tetanus toxoid as the carrier protein; it is licensed for individuals aged ≥6 weeks.[2]
- In a previous phase 2 study (NCT00356369) conducted in the Philippines and Saudi Arabia, subjects received a single dose of MenACWY-TT or a quadrivalent meningococcal polysaccharide vaccine (Men-PS; Mencevax® ACWY; GlaxoSmithKline) and were followed up for 5 years after primary vaccination to evaluate antibody persistence.[3,4]

This study reports long-term antibody persistence up to 10 years after primary vaccination in Filippino individuals aged 11–55 years and the safety and immunogenicity of a MenACWY-TT booster dose at year 10.

MenACWY-TT=quadrivalent meningococcal ACWY polysaccharide conjugate vaccine using tetanus toxoid as a carrier protein; Men-PS=quadrivalent meningococcal polysaccharide vaccine

1. McCarthy PC, et al. *Vaccine* 2018;6:1-13. 2. Nimenrix® Summary of Product Characteristics. Pfizer Inc, 2019. 3. Borja-Tabora, et al. *BMC Infect Dis*. 2013;13:116. 4. Borja-Tabora, et al. *BMC Infect Dis*. 2015;15:409.

Study Design



*Although an evaluation at year 6 was originally included in the study design, no study visit occurred at year 6 because approval from authorities was not obtained until the end of the year 6 window.
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1. Borja-Tabora, et al. *BMC Infect Dis* 2013;13:116. 2. Borja-Tabora, et al. *BMC Infect Dis* 2015;15:409.

Endpoints

Long-term persistence phase

- **Immunogenicity**: subjects with rSBA titres ≥1:8 and ≥1:128 and GMTs 7–10 years after primary dose (*primary endpoint*)

Booster phase

- **Immunogenicity**: subjects with rSBA titres ≥1:8 and ≥1:128 and GMTs 1 month after booster dose (*secondary endpoint*)
- **Safety**: reactogenicity events, AEs, SAEs, new chronic illnesses (*secondary endpoints*)
  - Reactogenicity events included solicited local reactions (pain, redness, swelling at injection site) and general symptoms (fatigue, fever, gastrointestinal symptoms, headache) from 0–3 days after the booster dose.
  - Unsolicited AEs were reported from 0–30 days after the booster dose.
  - New chronic illnesses, Guillain-Barré syndrome, meningococcal disease, and SAEs* were reported from day 0 until end of study (6 months after booster).

*SAEs were also reported throughout the persistence phase.
AE=adverse event; GMT=geometric mean titre; rSBA=serum bactericidal assay using baby rabbit complement; SAE=serious adverse event.

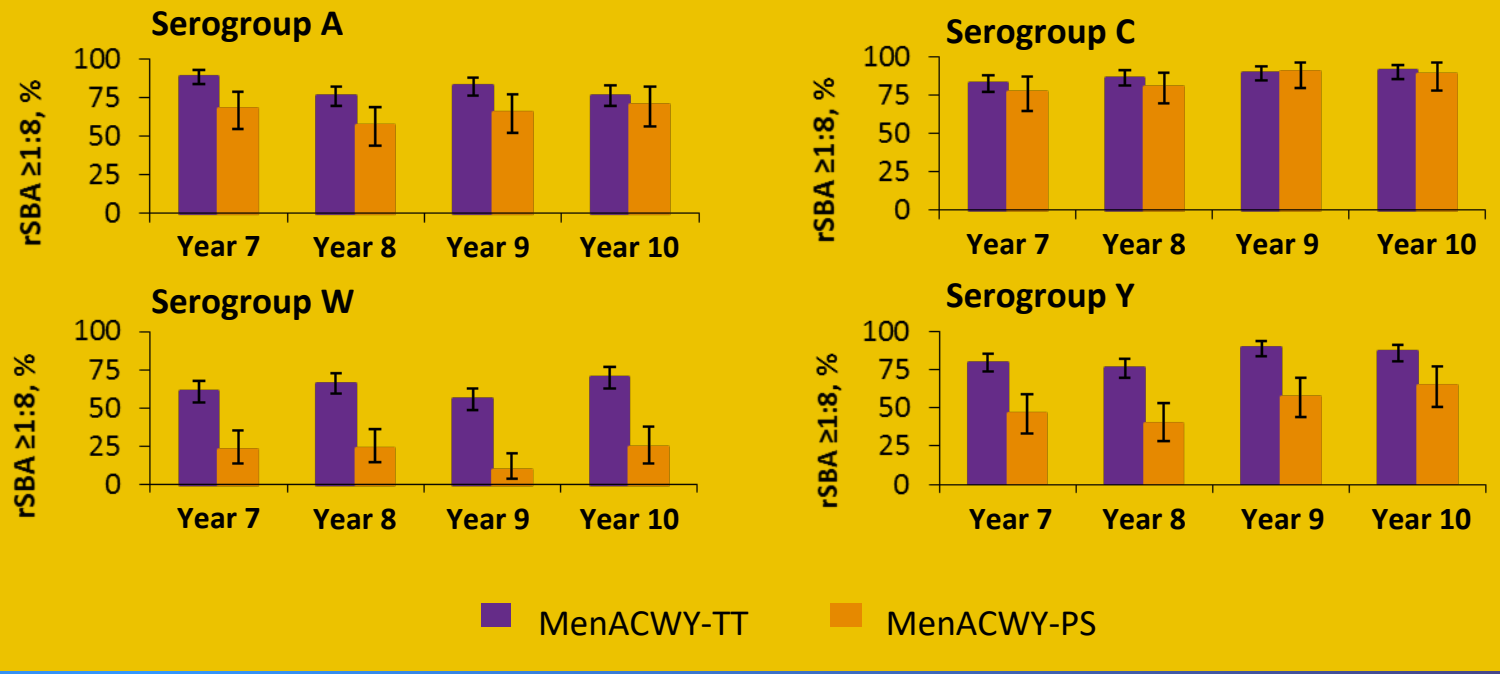
Subject Demographics

	Antibody Persistence Phase, Years 7–10		Booster Phase	
	MenACWY-TT	**MenACWY-PS**	**MenACWY-TT**	**MenACWY-PS**
Total enrolled cohort, n	235	76	164	56
Male, n (%)	127 (54.0)	36 (47.4)	93 (56.7)	29 (51.8)
Age at enrollment in persistence phase or at booster dose, y				
Mean ± SD	25.3±8.2	25.2±8.4	26.8±7.9	27.4±8.7
Median (range)	22.0 (18–60)	22.0 (18–55)	24.0 (21–63)	24.5 (21–56)
Asian/Southeast Asian, n (%)	235 (100)	76 (100)	164 (100)	56 (100)

MenACWY-TT=quadrivalent meningococcal ACWY polysaccharide conjugate vaccine using tetanus toxoid as a carrier protein; MenACWY-PS=quadrivalent polysaccharide vaccine.

Antibody Persistence Phase: High Percentages of Subjects Achieved rSBA Titres ≥1:8 Against All Serogroups

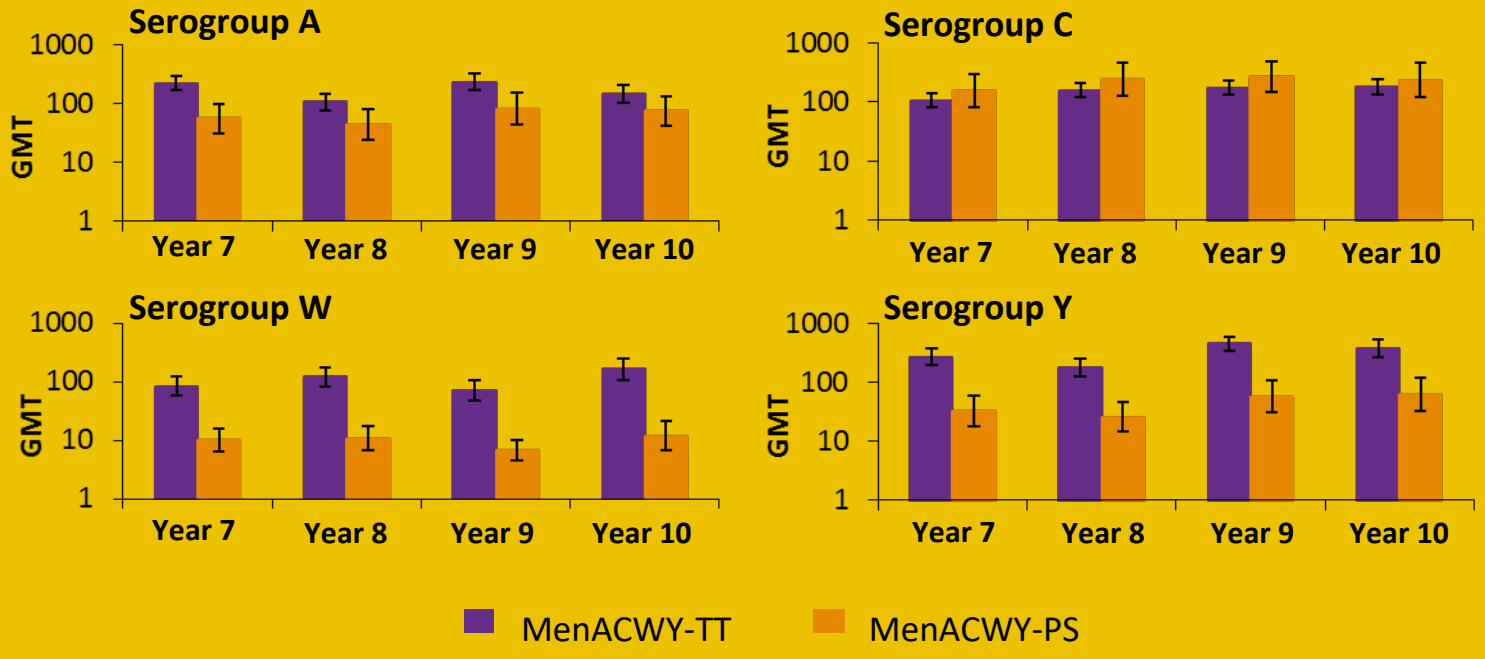
Adapted ATP Cohort



ATP=according to protocol; MenACWY-TT=quadrivalent meningococcal ACWY polysaccharide conjugate vaccine using tetanus toxoid as a carrier protein; MenACWY-PS=quadrivalent polysaccharide vaccine; rSBA=serum bactericidal assay using baby rabbit complement.

Antibody Persistence Phase: rSBA GMTs Were Generally Higher With MenACWY-TT vs MenACWY-PS

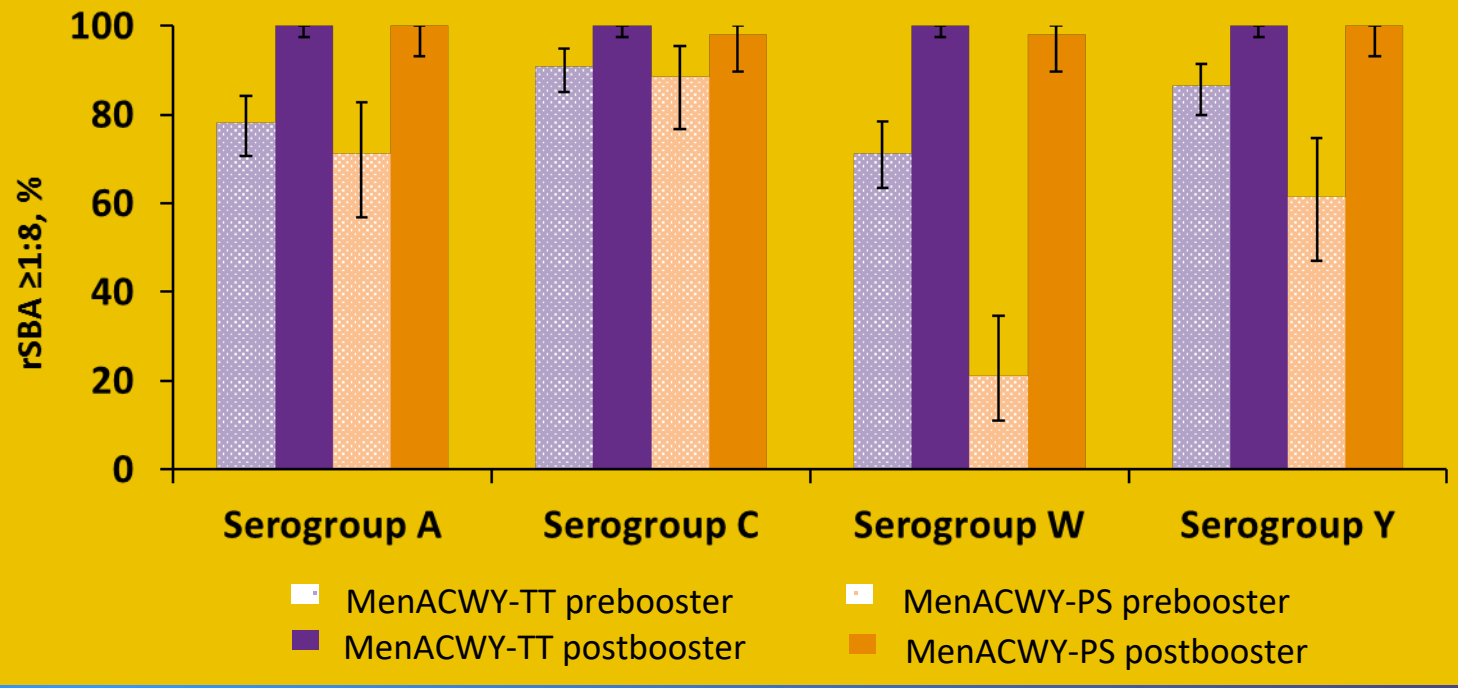
Adapted ATP Cohort



ATP=according to protocol; GMT=geometric mean titre; MenACWY-TT=quadrivalent meningococcal ACWY polysaccharide conjugate vaccine using tetanus toxoid as a carrier protein; MenACWY-PS=quadrivalent polysaccharide vaccine.

Booster Phase: High Percentages of Subjects Achieved rSBA Titres ≥1:8 Against All Serogroups

Booster ATP Cohort



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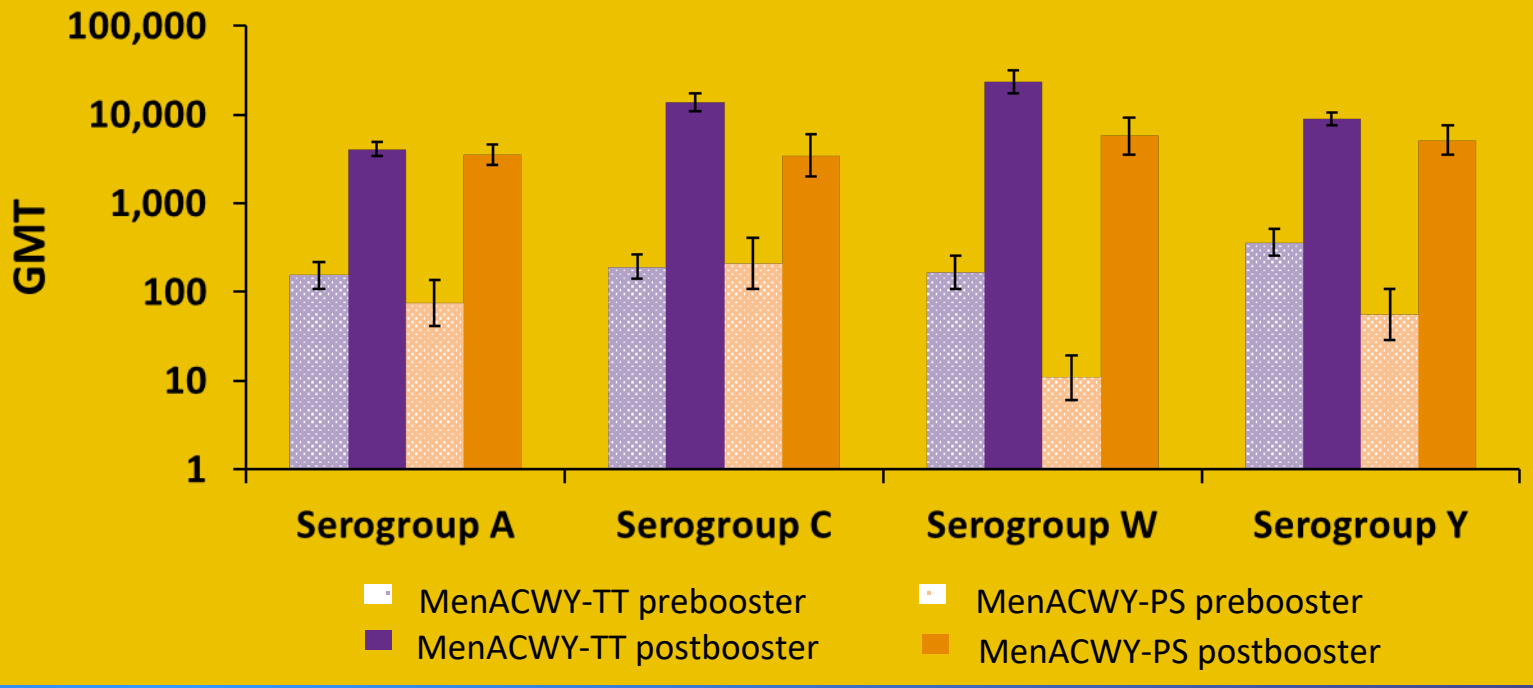
Booster Phase: rSBA GMTs Were Generally Higher With MenACWY-TT vs MenACWY-PS 1 Month After Booster

Booster ATP Cohort



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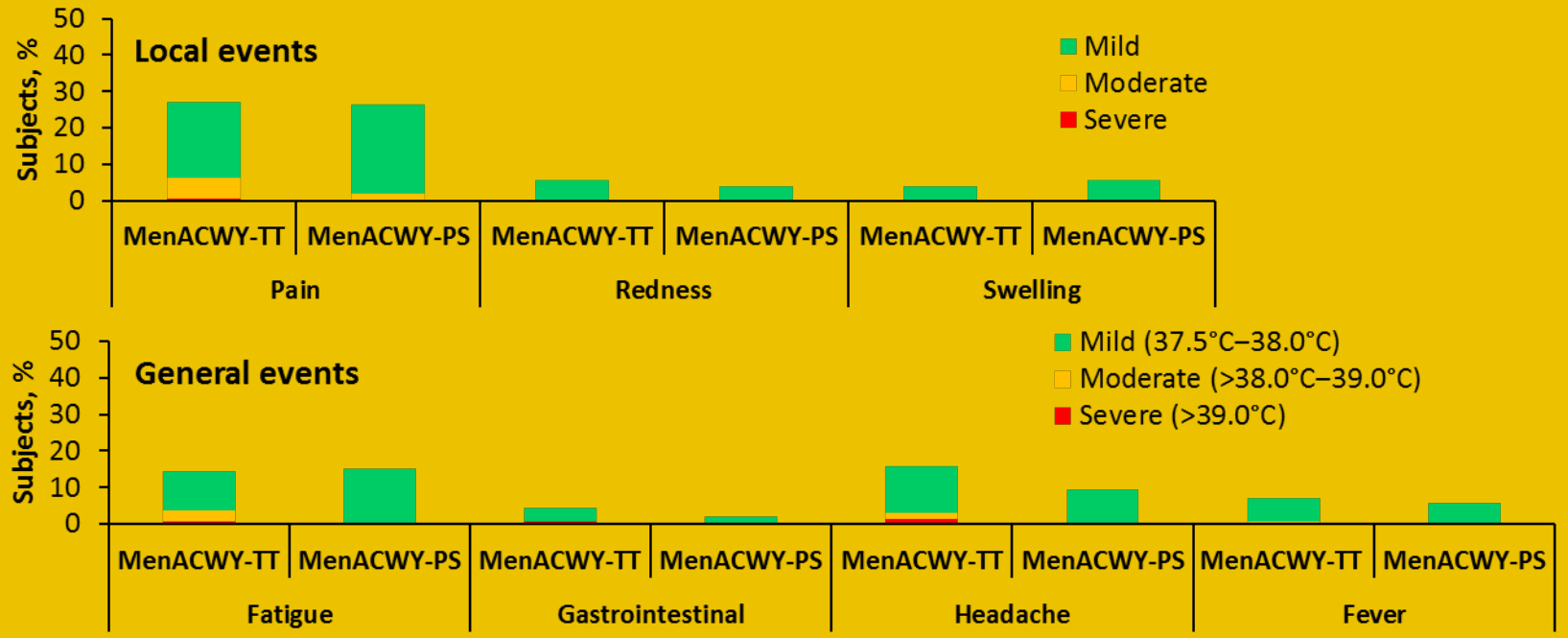
Booster Phase: Most Reactogenicity Events Were Mild or Moderate



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Adverse Events Were Few and Nonserious

- AEs were reported by 15 subjects (9.1%) in the MenACWY-TT group and 2 subjects (3.6%) in the MenACWY-PS group.
    - 3 (1.8%) AEs in the MenACWY-TT group were considered treatment-related, including 1 report each of dizziness, hypoesthesia, and oropharyngeal pain.
    - No treatment-related AEs were identified in the MenACWY-PS group.
- No instances of SAEs, new onset chronic illnesses, Guillain-Barré syndrome, or meningococcal disease were reported.

AE=adverse event; MenACWY-TT=quadrivalent meningococcal ACWY polysaccharide conjugate vaccine using tetanus toxoid as a carrier protein; MenACWY-PS=quadrivalent polysaccharide vaccine; SAE=serious adverse event.

Conclusions

Long-Term Persistence

- Functional antibody responses persisted 10 years after primary vaccination with MenACWY-TT, indicating long-term protection against IMD caused by meningococcal serogroups A, C, W, and Y.

MenACWY-TT Booster Dosing

- A MenACWY-TT booster dose administered at year 10 in individuals aged 11–55 years at the time of primary vaccination was safe and immunogenic, with no new safety signals observed.

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Acknowledgments

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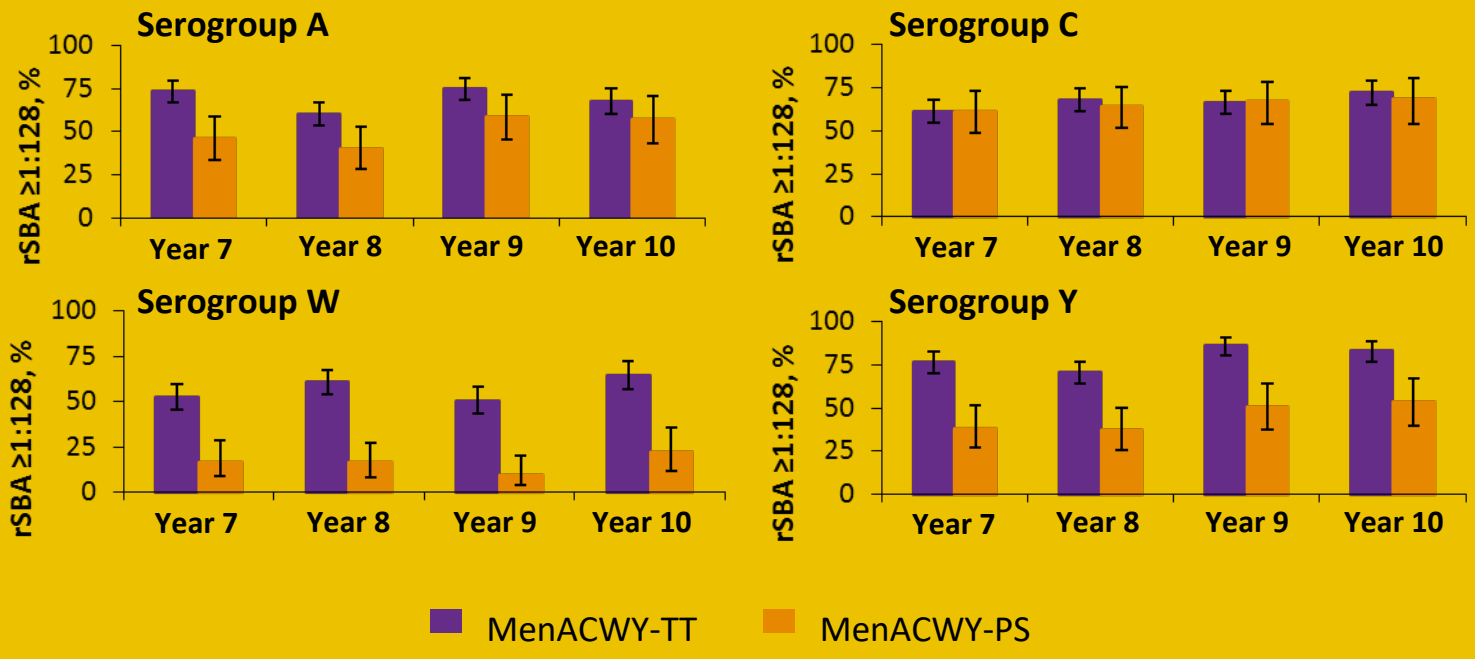
Backup Slide

Antibody Persistence Phase: Percentage of Subjects With rSBA Titres ≥1:128

Adapted ATP cohort



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