

PreHevbrio versus Engerix-B in Healthy Adults
PROTECT Trial

PreHevbrio Vaccine vs Engerix-B Vaccine in Adults

PROTECT Trial: Design

- **Design**

- Phase 3, double-blind, randomized controlled trial, conducted at multiple sites in the USA, Finland, Canada, and Belgium that compared the safety and immunogenicity of PreHevbrio versus Engerix-B hepatitis B vaccines

- **Participants (n = 1,607)**

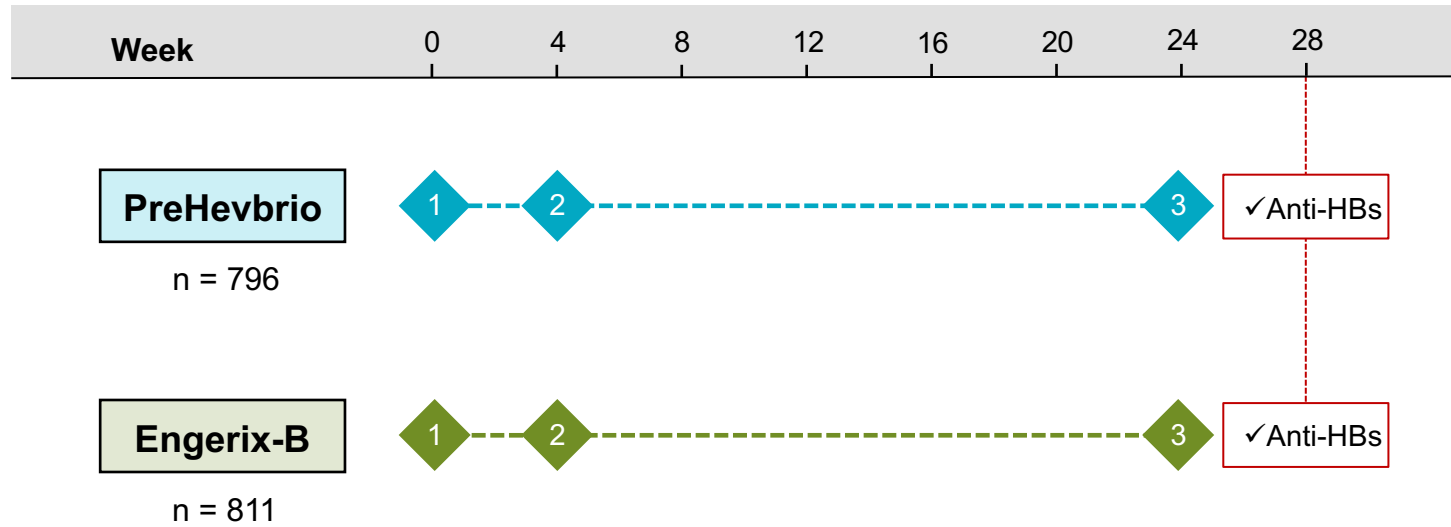
- Ages: ≥18 years
- HBV vaccine naïve
- Exclusions: current or past HBV infection; HIV; HCV; pregnancy; receipt of any live attenuated vaccine within 4 weeks of enrollment; receipt of inactivated vaccine within 2 weeks of enrollment; and uncontrolled comorbidities

- **Primary End Point**

- Anti-HBs seroprotection rate 4 weeks after 3rd dose of PreHevbrio or Engerix-B

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Vaccine Dosing

PreHevbrio: 1.0 mL dose of 10 μ g HBs antigens at weeks 0, 4, and 24

Engerix-B: 1 mL dose of 20 μ g recombinant HBsAg at weeks 0, 4, and 24

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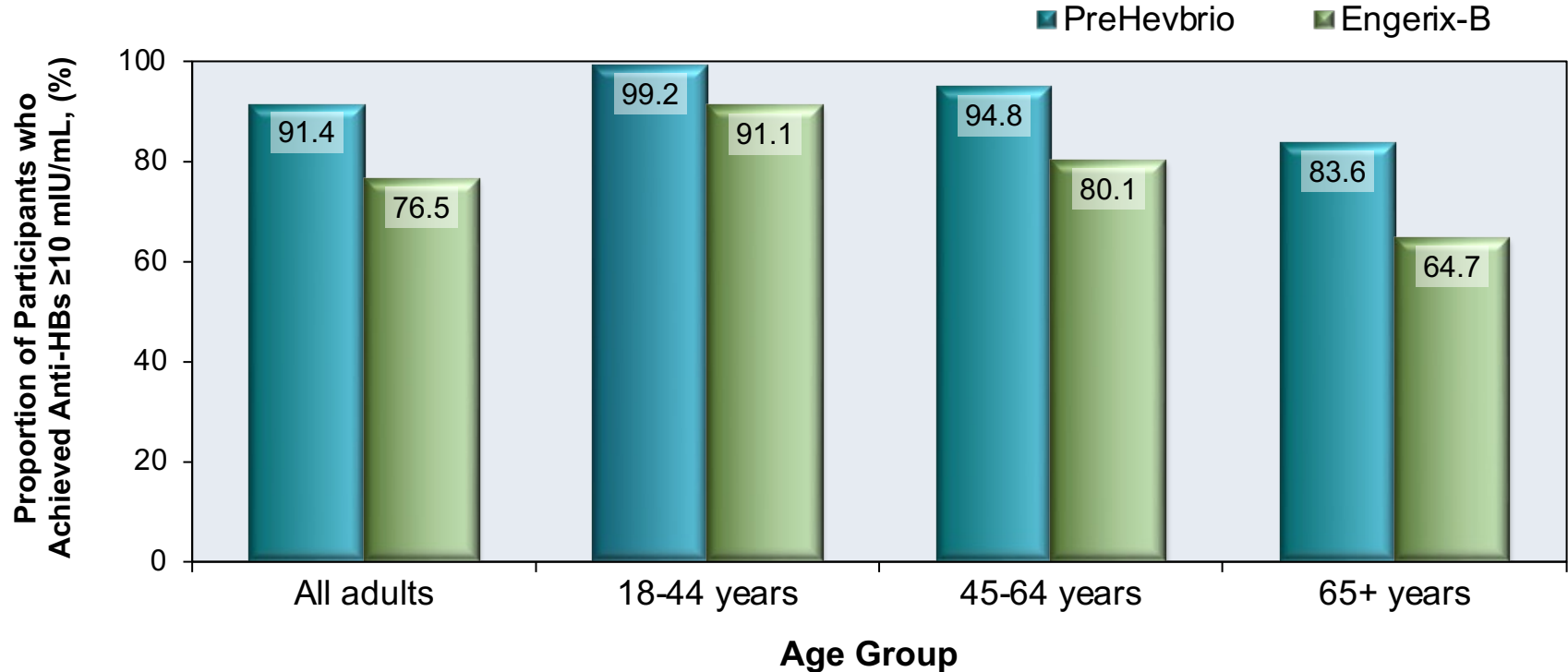
PROTECT Trial: Baseline Characteristics

Baseline Characteristic	PreHevbrio (n = 796)	Engerix-B (n = 811)
Age, mean (range), years	56.6 (18-86)	56.6 (18-90)
Male, no. (%)	315 (39.6)	303 (37.4)
Race, no. (%)		
White	715 (89.8)	730 (90.0)
Black/African American	66 (8.3)	65 (8.0)
Asian, Pacific Islander, Native Hawaiian, AI/AN	15 (1.8)	16 (2.0)
Current smoker, no. (%)	104 (13.1)	113 (13.9)
Type 2 diabetes, no. (%)	60 (7.5)	65 (8.0)
Country or region		
USA	338 (42.5)	342 (42.2)
Canada	126 (15.8)	133 (16.4)
Europe	332 (41.7)	336 (41.4)

Source: Vesikari T, et al. Lancet Infect Dis. 2021;21:1271-81.

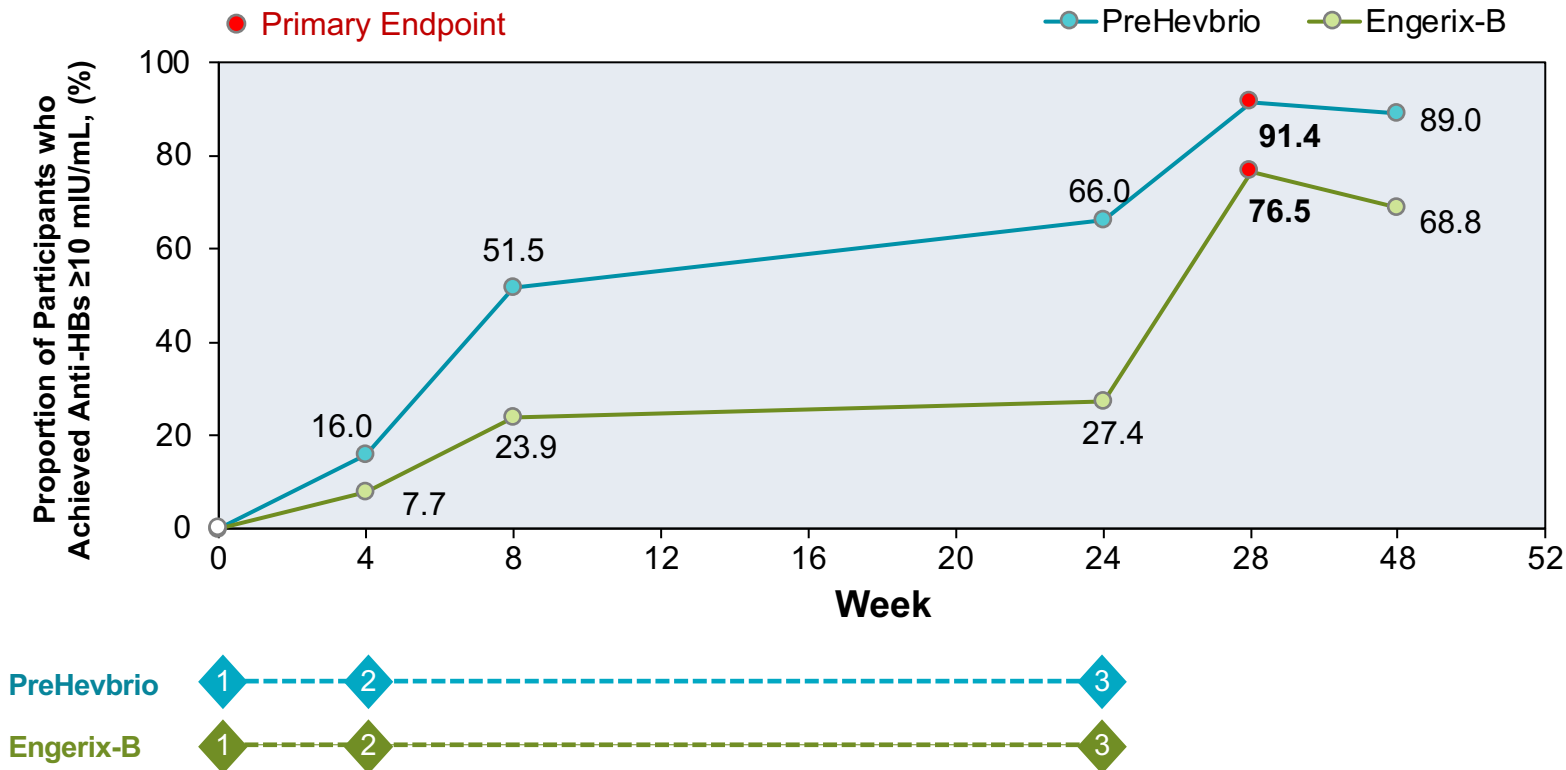
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PROTECT Trial: Week 28 Results (anti-HBs ≥ 10 mIU/mL), by Age Group



PreHevbrio Vaccine vs Engerix-B Vaccine in Adults Aged ≥ 18 Years

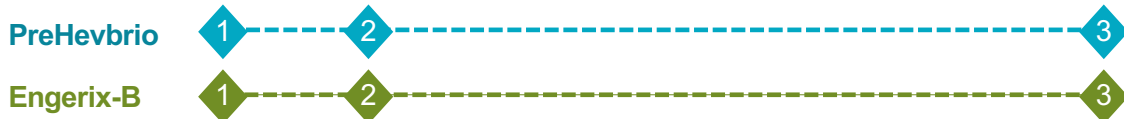
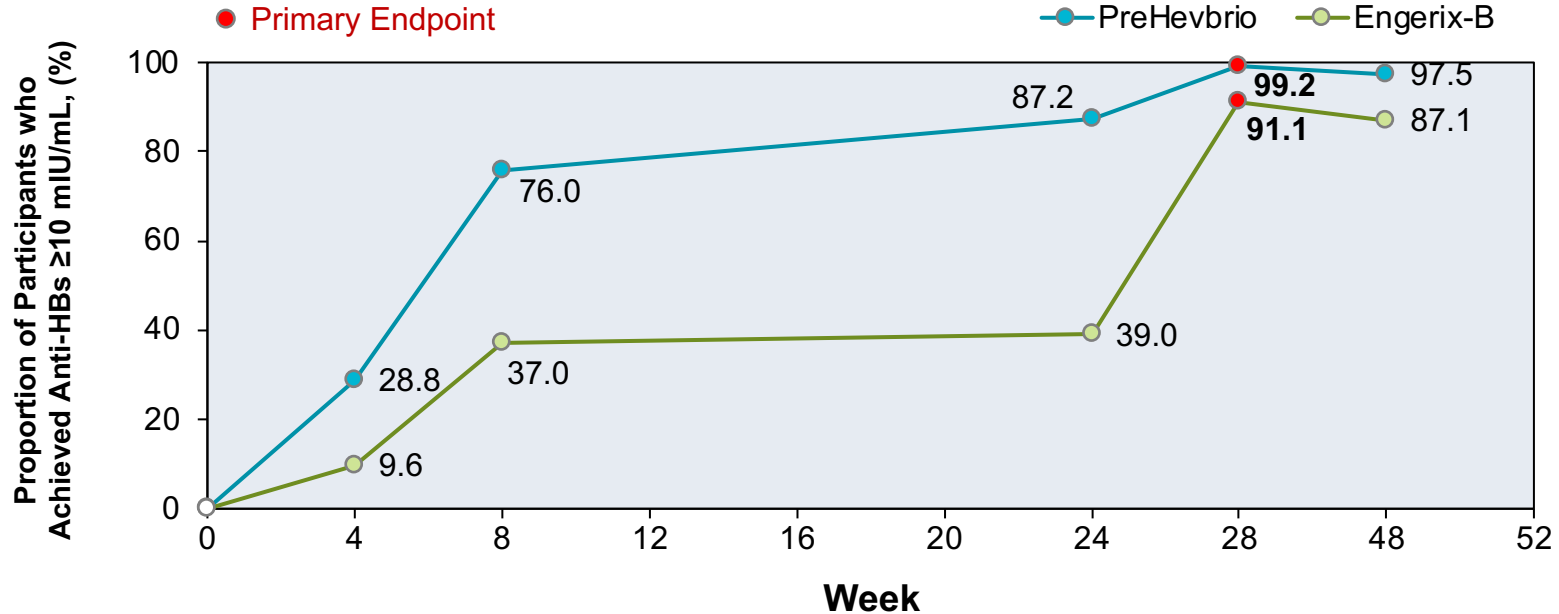
PROTECT Trial: Results



Source: Vesikari T, et al. Lancet Infect Dis. 2021;21:1271-81.

PreHevbrio Vaccine vs Engerix-B Vaccine in Adults Aged 18-44 Years

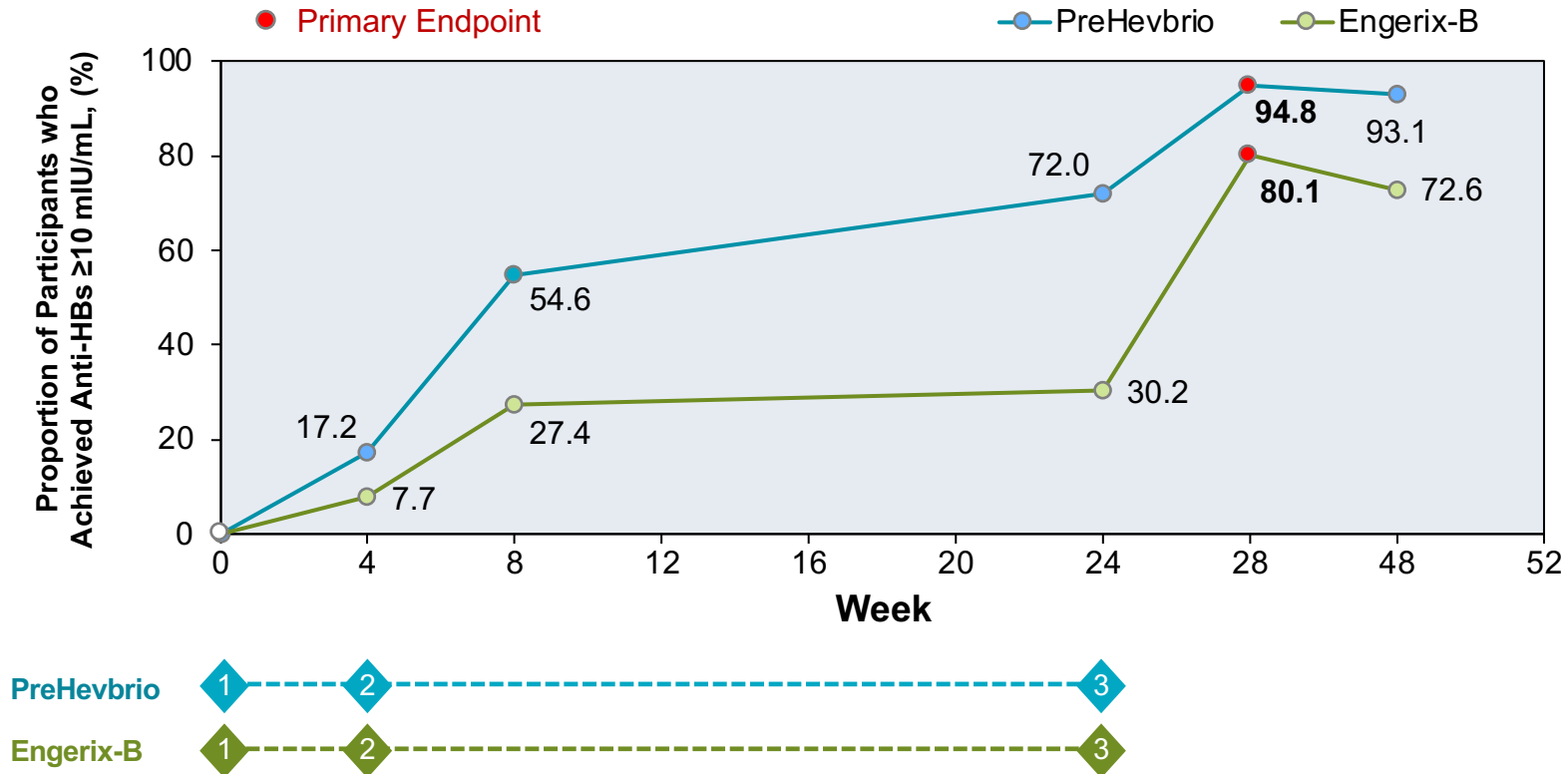
PROTECT Trial: Results



Source: Vesikari T, et al. Lancet Infect Dis. 2021;21:1271-81.

PreHevbrio Vaccine vs Engerix-B Vaccine in Adults Aged 45-64 Years

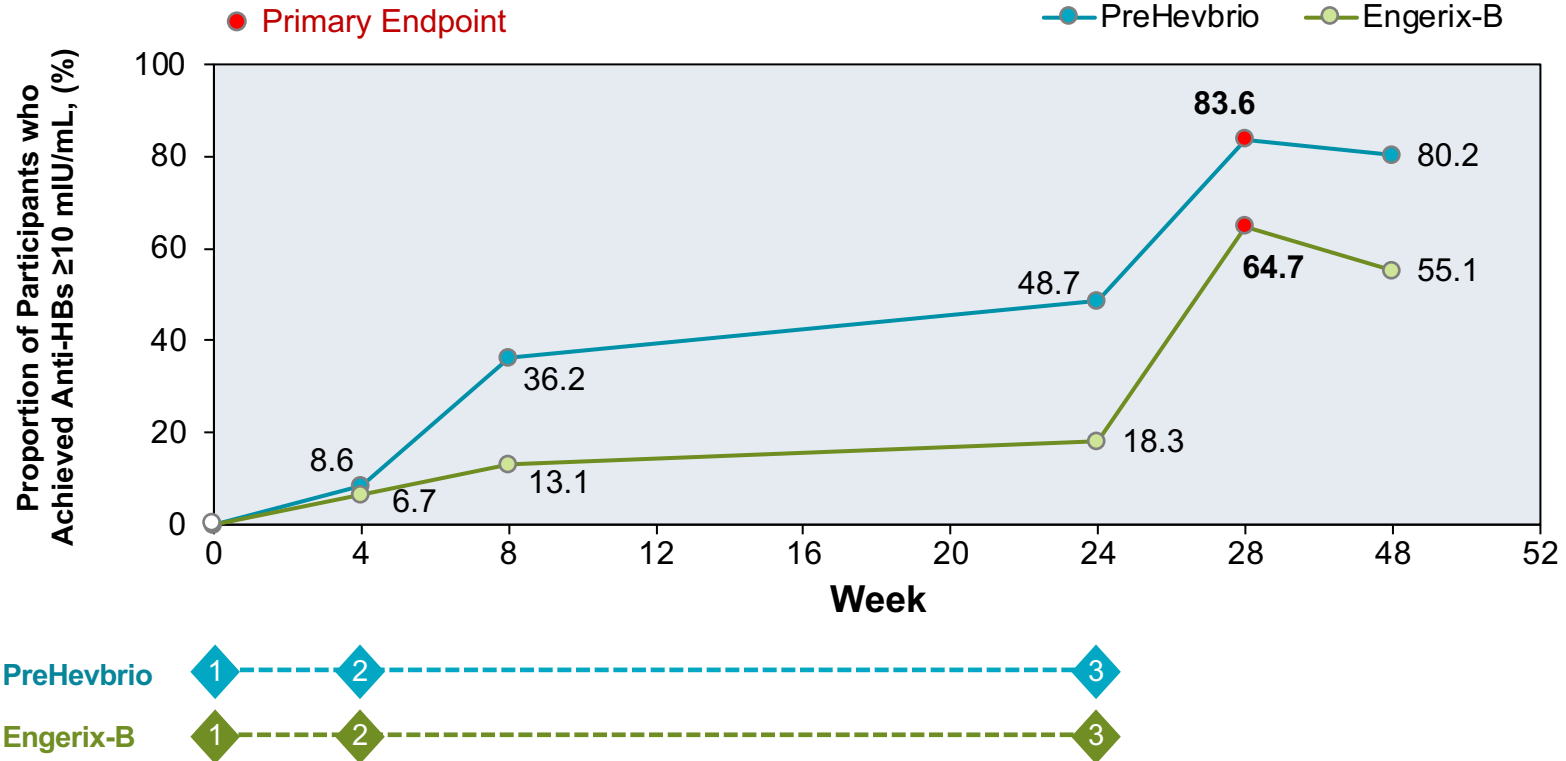
PROTECT Trial: Results



Source: Vesikari T, et al. Lancet Infect Dis. 2021;21:1271-81.

PreHevbrio Vaccine vs Engerix-B Vaccine in Adults Aged ≥ 65 Years

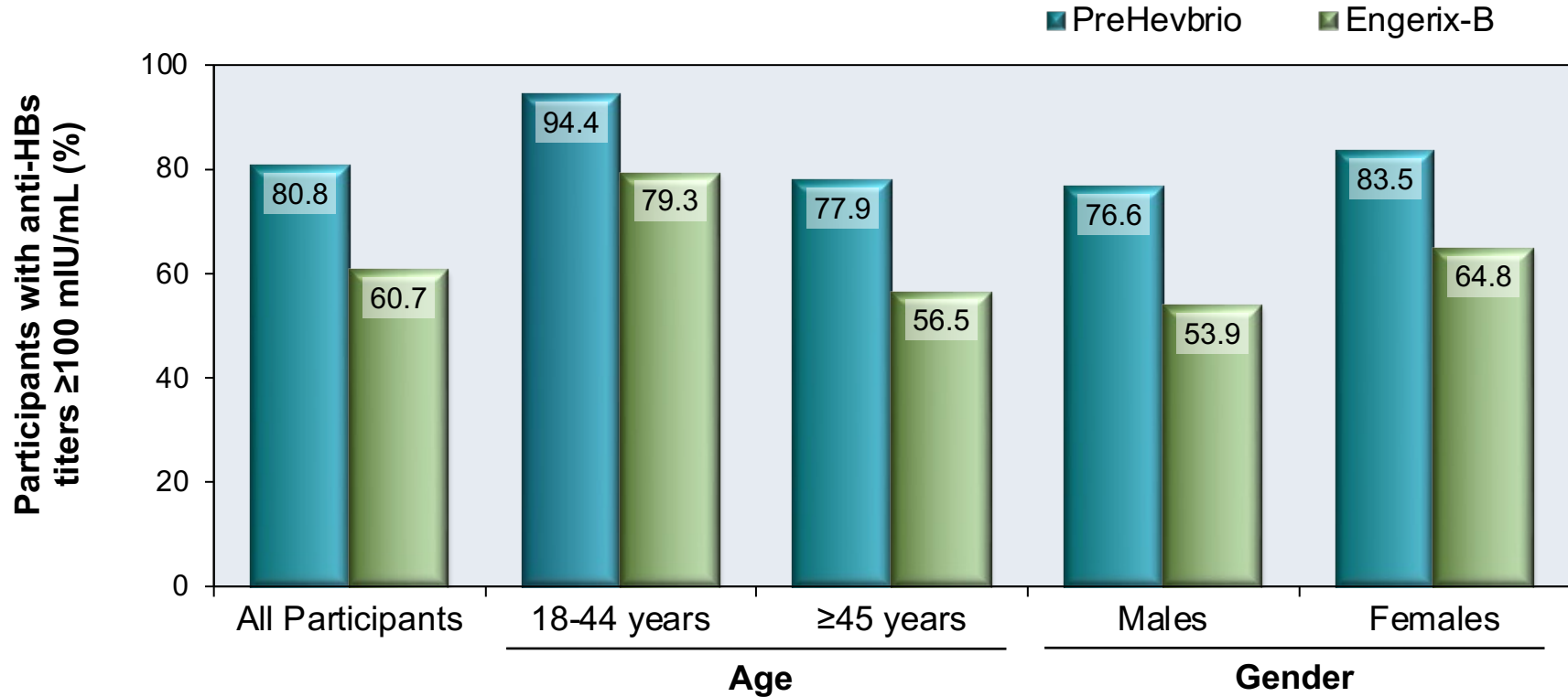
PROTECT Trial: Results



Source: Vesikari T, et al. Lancet Infect Dis. 2021;21:1271-81.

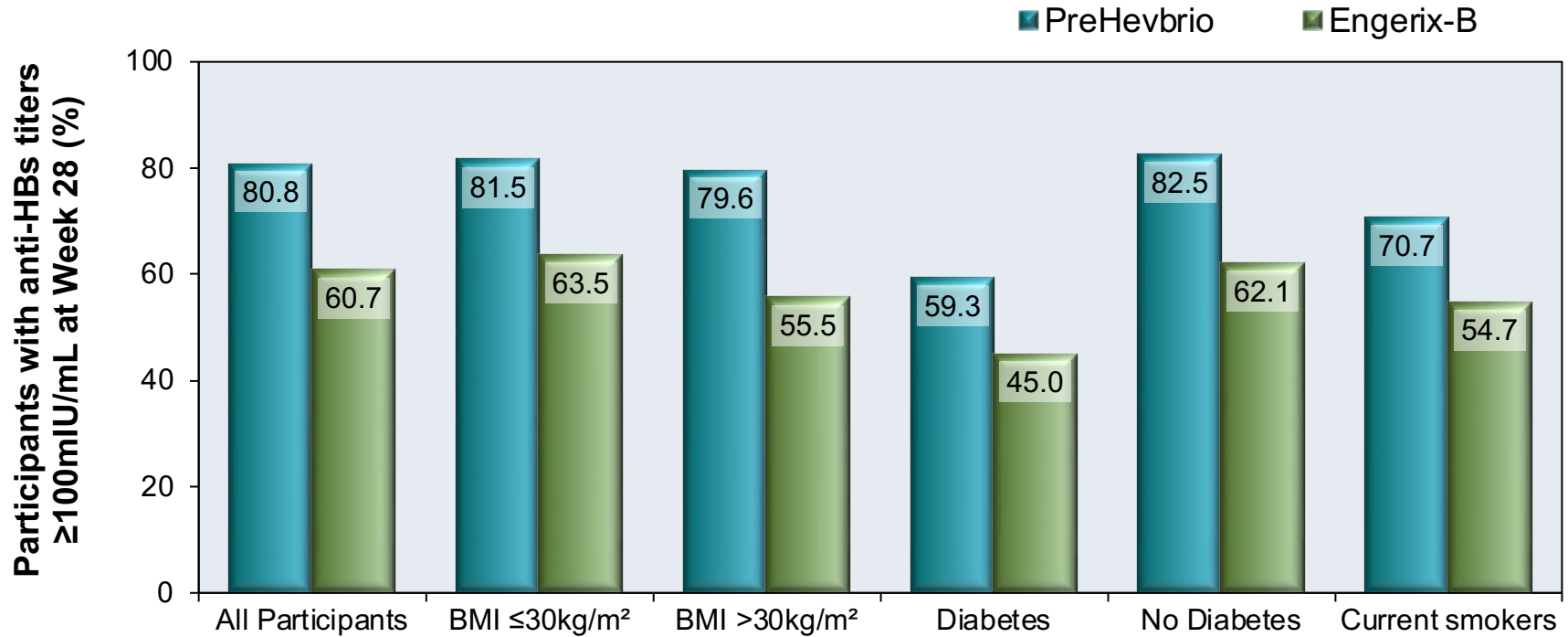
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PROTECT Trial: Results (anti-HBs ≥ 100 mIU/mL), by Age and Gender



PreHevbrio Vaccine vs Engerix-B Vaccine in Adults

PROTECT Trial: Results (anti-HBs ≥ 100 mIU/mL), by BMI, Diabetes, and Smoking



PreHevbrio Vaccine vs Engerix-B Vaccine in Adults ≥ 18 years

PROTECT Trial: Results

Conclusions: “PreHevbrio was non-inferior to Engerix-B and induced higher seroprotection in adults aged 18 years of age and older after three doses of vaccine.”

Acknowledgments

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