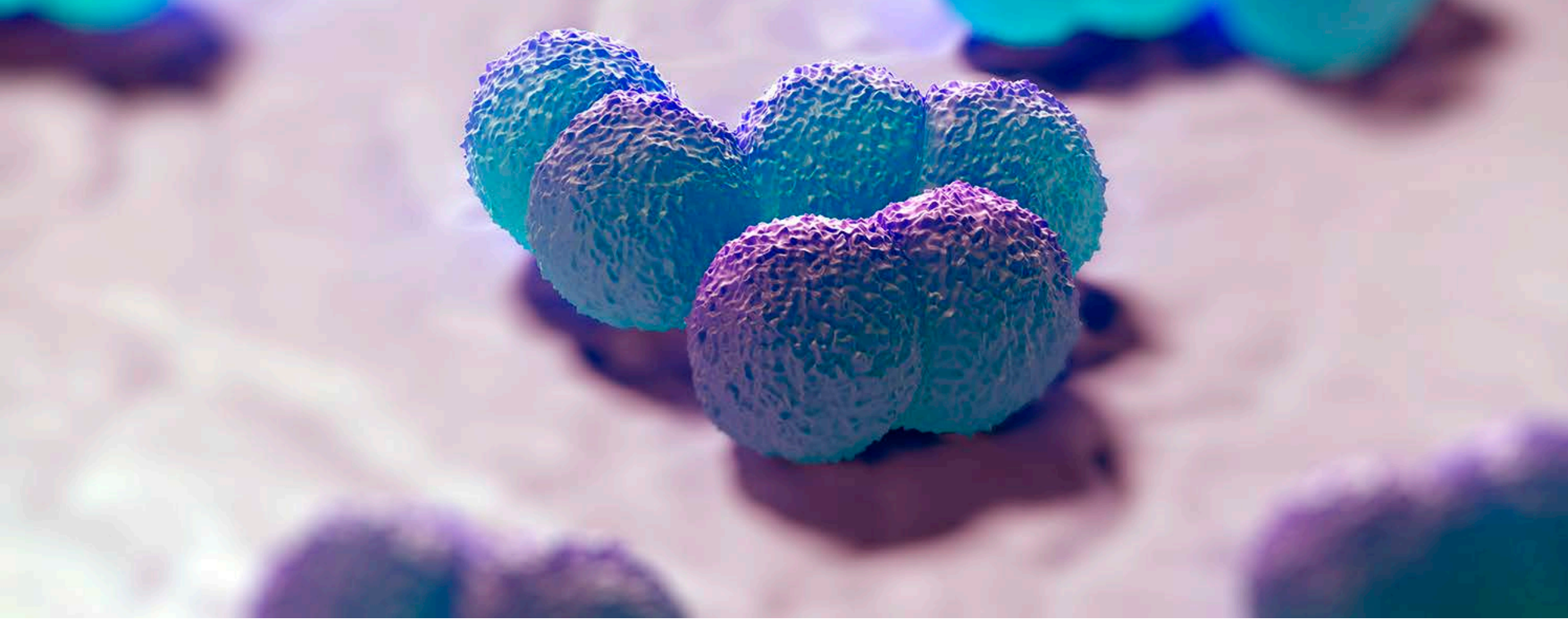

SANOFI PASTEUR

Safety and immunogenicity of MenQuadfi™ Meningococcal (Groups A, C, Y, W) Conjugate Vaccine

ACIP Meeting, 24 June 2020

Agenda

- Public health burden of invasive meningococcal disease
- Introduction of MenQuadfi
- Clinical data supporting approval of MenQuadfi by US FDA
- Summary

Public health burden of meningococcal disease

- Invasive meningococcal disease (IMD) remains a major global health challenge because it can strike quickly and with devastating effect, taking a life in < 24 hours [1,2]
- Case-fatality rate is ~10% to 15% even with appropriate treatment[2]
- ~1 in 5 survivors suffer permanent sequelae[3,4]
  - Limb amputation
  - Deafness
  - Brain damage
- Since introduction of the first MenACWY in 2005, MenACWY-D, IMD caused by serogroups C, W, and Y has declined by > 90% among adolescents and young adults[5]
- Despite impact of available MenACWY on meningococcal disease burden, there remains room for improvement

References: 1. Thompson MJ, et al. *Lancet*. 2006;367(9508):397-403. **2.** WHO. https://www.who.int/en/news-room/fact-sheets/detail/meningococcal-meningitis [accessed March 2020]. **3.** CDC. *MMWR*. 2013;62(RR-2):1-22. **4.** Rosenstein NE, et al. *N Engl J Med.* 2001;344(18):1378-1388. **5.** MacNeil JR, et al. *Clin Infect Dis* 2018; 66:1276–81.

What is MenQuadfi (MenACYW-TT)?

- A quadrivalent meningococcal conjugate vaccine to help **prevent invasive meningococcal disease caused by serogroups A, C, W, and Y**
- **FDA approved** on 23 April 2020 for use in **persons 2 years of age and older**
- Developed with the **ambition** of being:
  - Used across a **broad age range**
    - Studies to support expansion of age indication to include infants as young as 6 weeks of age are in progress
  - Incorporated in **various immunization schedules that exist worldwide**
- Conjugated to **tetanus toxoid** (approximately 55 µg)
  - Each 0.5-mL **intramuscular** dose contains 10 µg each of the 4 meningococcal polysaccharides
- Fully liquid solution that **does not require reconstitution** and supplied in a single-dose vial

Robust clinical development program led to initial US licensure of vaccine

Clinical Study Code	Phase	Title	Comparator	ClinicalTrials.gov Identifier
MET50	II	Immunogenicity and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine in Healthy Adolescents (NOTE: Coadministered vaccines were Tdap and HPV4)	MenACWY-CRM (Menveo)	NCT02199691
MET49	III	Immunogenicity and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine in Adults Age 56 Years and Older	MPSV4 (Menomune – A/C/Y/W-135)	NCT02842866
MET56	III	Immunogenicity and Safety of a Booster Dose of an Investigational Quadrivalent Meningococcal Conjugate Vaccine in Adolescents and Adults	MenACWY-D (Menactra)	NCT02752906
MET35	III	Immunogenicity and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine Administered in Healthy Children 2 to 9 Years of Age	MenACWY-CRM (Menveo)	NCT03077438
MET43	III	Immune Lot Consistency, Immunogenicity, and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine in Adolescents and Adults Aged 10 to 55 Years	MenACWY-D (Menactra)	NCT02842853

All trials were randomized, blinded, and active-controlled

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All trials were randomized, blinded, and active-controlled

MET50: Phase II study in MenACWY-naïve adolescents 10–17 years of age

Short Study Title	Immune Non-inferiority, Safety and Co-administration study in Adolescents	
Study Population	Age	10–17 years
	Number of subjects	1715
	Meningococcal-vaccine naïve	
Study Design	**Group 1:** MenACYW-TT **Group 2:** MenACWY-CRM	**Group 3:** MenACYW-TT+Tdap+HPV **Group 4:** Tdap+HPV
Vaccination Schedule	Single dose of MenACYW-TT or MenACWY-CRM Single dose of Tdap 3 doses of HPV (0,2,6 months)	
First subject visit	22 July 2014	
Last subject visit	02 October 2015	

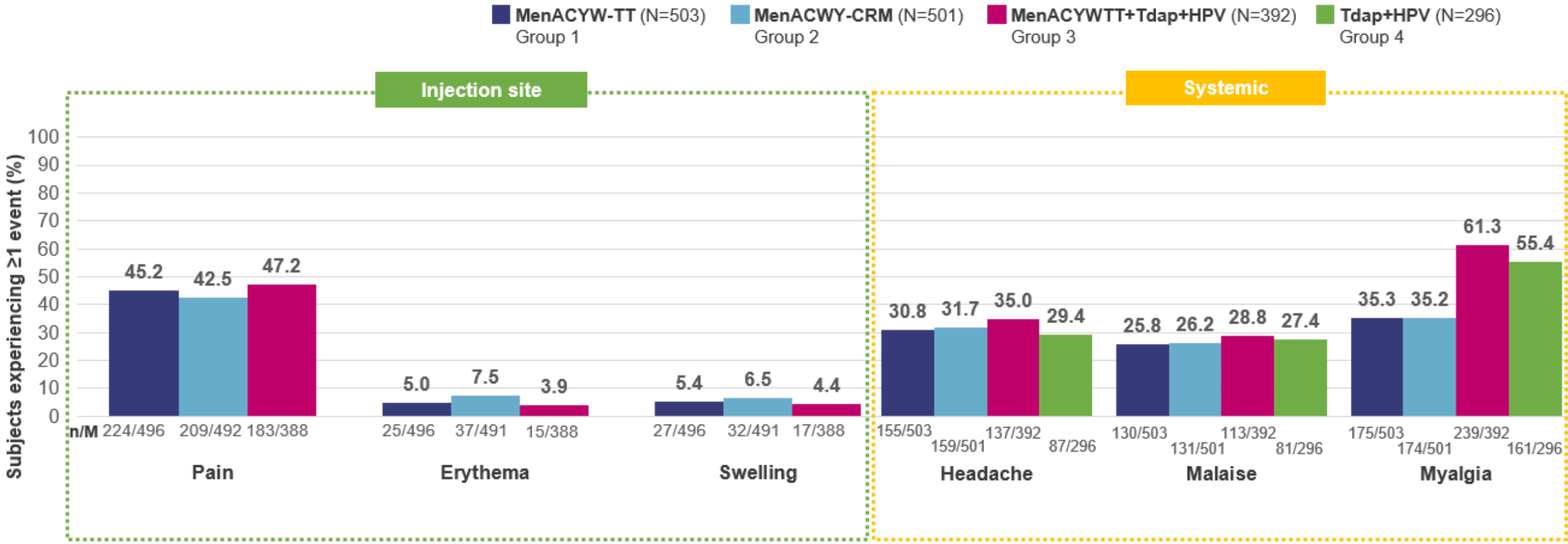
Baseline Demographics* (Safety Analysis Set)	
Characteristic ↓	**All** (N=1692)
Gender, n (%) Female	**821** (48.5)
Age in years, mean (std deviation)	**11.4** (1.33)
Race, n (%) White African-American Other	 **1498** (88.5) **85** (5.0) **107** (6.3)
Ethnicity, n (%) Hispanic or Latino	**326** (19.3)

*Demographic characteristics were balanced across vaccine groups (see back-up slide section)

REFERENCES: 1. Chang LJ et al. *Vaccine*. 2020 Apr 23:38(19): 3560-3569. **2**. Sanofi Pasteur Inc. Date on file (MET50 Clinical Study Report)

MET50: Frequency of solicited reactions

Within 7 days after vaccination, Safety Analysis Set

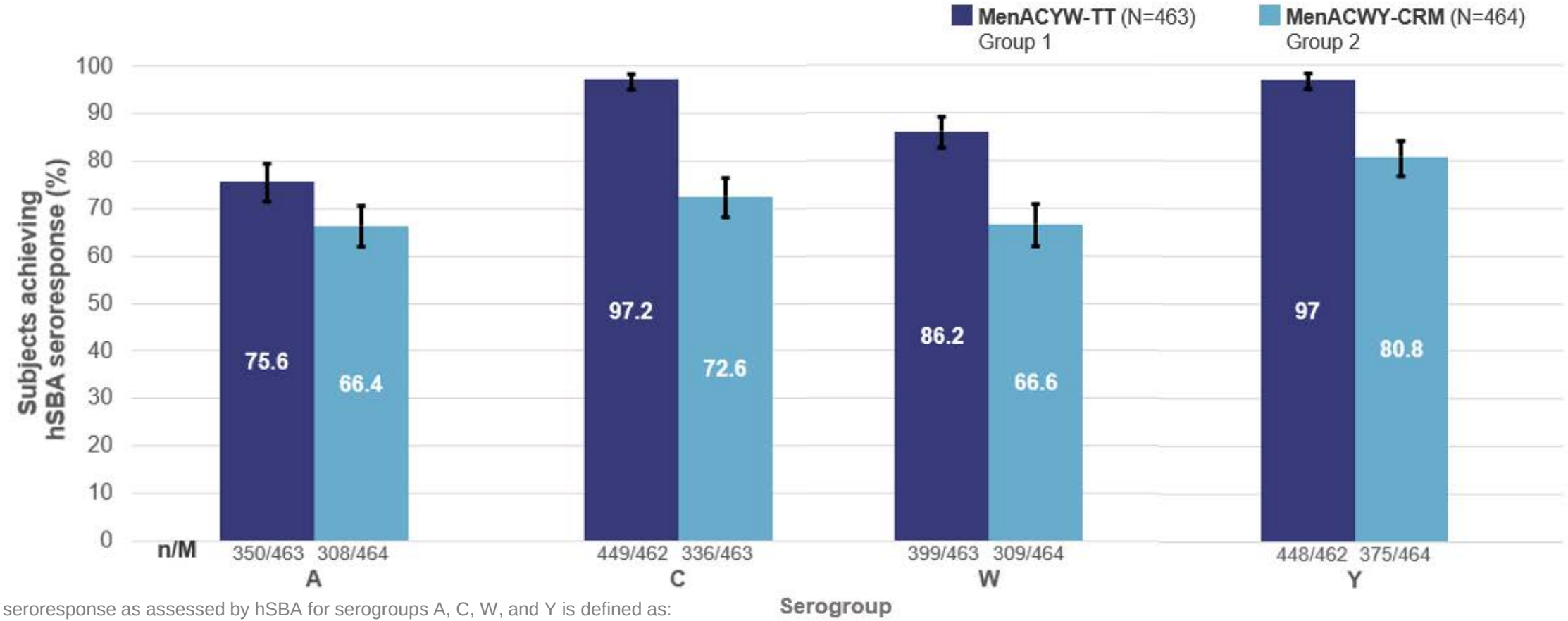


n, number of subjects experiencing endpoint; M, number of subjects with available data; N, total number of subjects in group.

References: 1. Chang LJ et al. *Vaccine*. 2020 Apr 23:38(19):3560-3569. **2.** Clinicaltrials.gov. NCT02199691 (MET50). Available at: https://clinicaltrials.gov/ct2/show/NCT02199691 [accessed June 2020].

MET50: Non-inferiority demonstrated, as assessed by SERORESPONSE rates at D30 in adolescents 10–17 years of age

Per-Protocol Analysis Set



Vaccine seroresponse as assessed by hSBA for serogroups A, C, W, and Y is defined as:

- For a subject with a pre-vaccination titer < 1:8, the post-vaccination titer must be ≥ 1:8
- For a subject with a pre-vaccination titer ≥ 1:8, the post-vaccination titer must be at least 4-fold greater than the pre-vaccination titer.

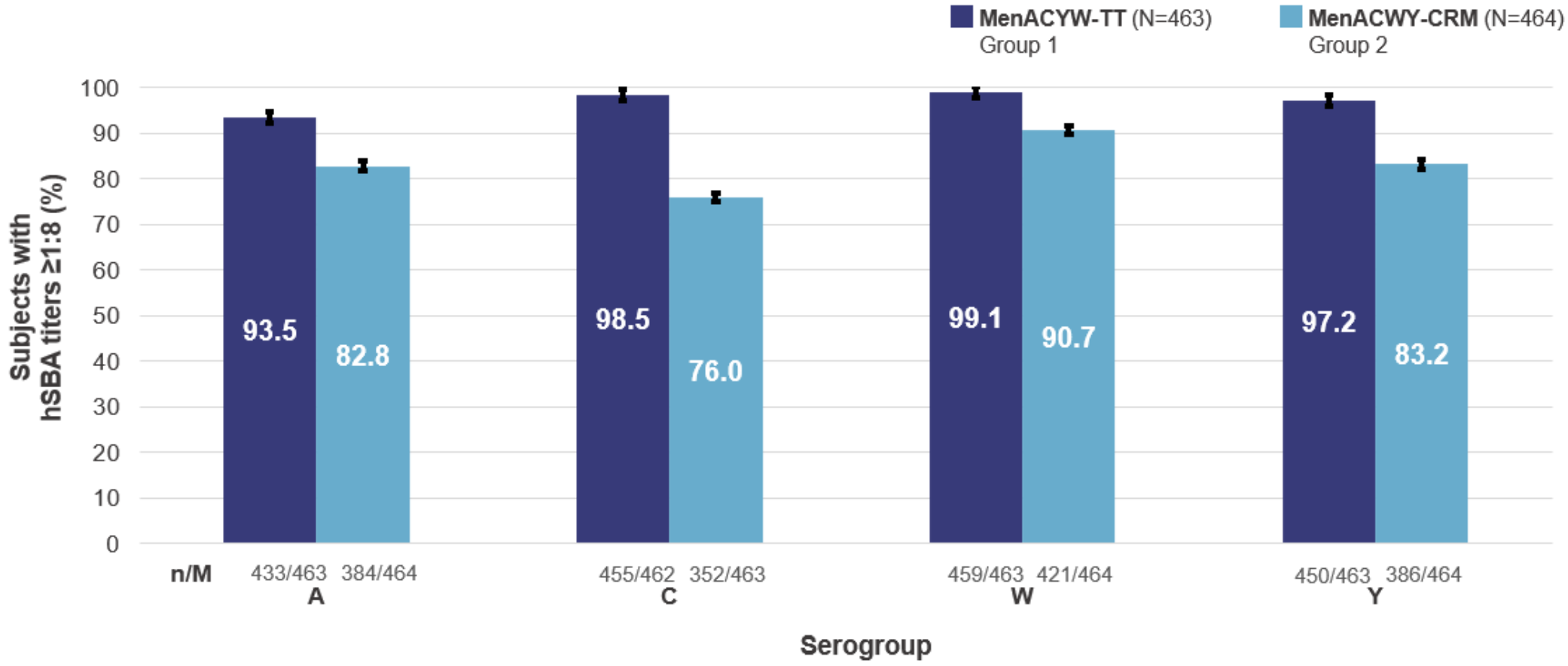
Non-inferiority concluded if the lower limit of the two-sided 95%CI of the proportion difference is >-10%.

CI, confidence interval; D30, day 30; hSBA, serum bactericidal assay using human complement; M, number of subjects with valid serology results; n, number of subjects achieving hSBA seroresponse; N, total number of subjects in group.

Reference: Chang LJ et al. *Vaccine*. 2020 Apr 23:38(19):3560-3569.

MET50: Percentage of subjects 10–17 years of age with hSBA TITERS ≥1:8 at D30

Per-Protocol Analysis Set

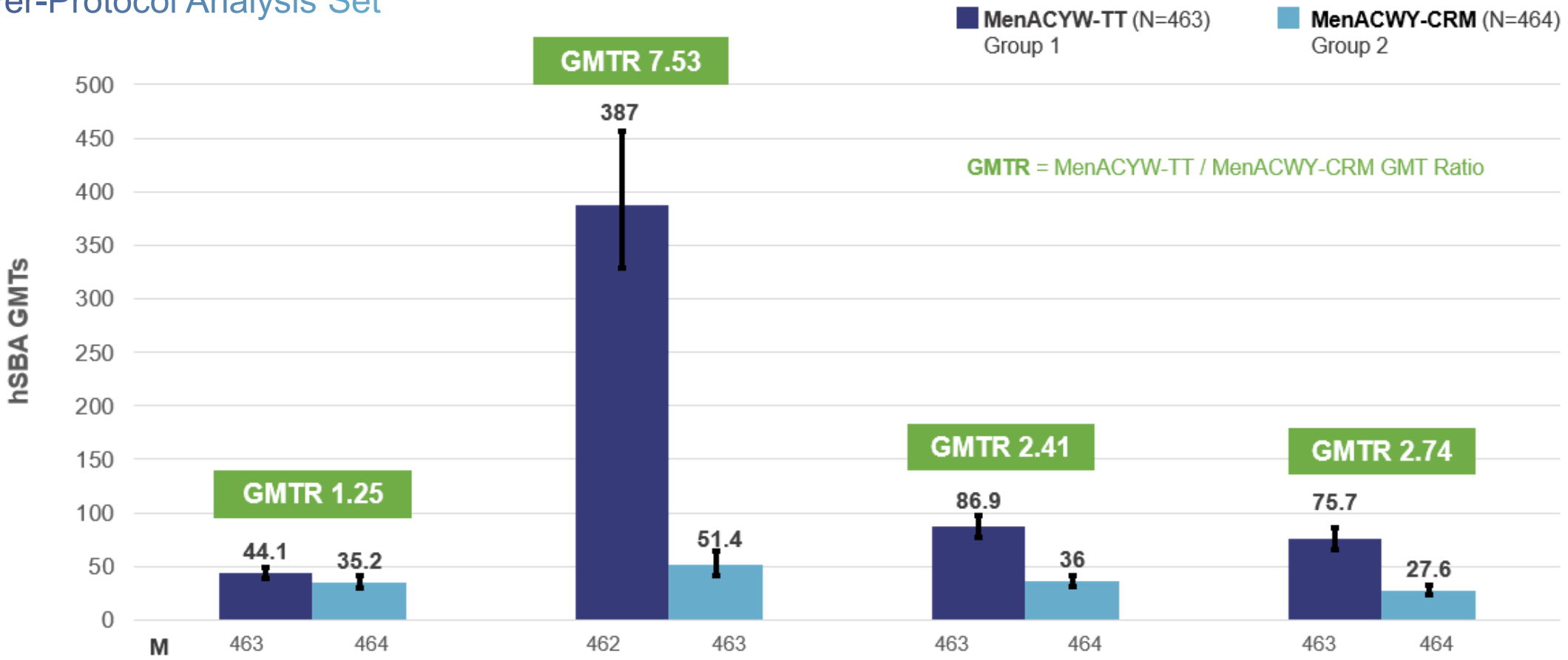


D30, day 30; hSBA, serum bactericidal assay using human complement; M, number of subjects with valid serology results; n, number of subjects with hSBA titers ≥1:8; N, total number of subjects in group

Reference: Chang LJ et al. *Vaccine*. 2020 Apr 23:38(19):3560-3569

MET50: hSBA GEOMETRIC MEAN TITERS at D30

Per-Protocol Analysis Set



D30, day 30; GMT, geometric mean titer; GMTR, GMT ratio; hSBA, serum bactericidal assay using human complement; M, number of subjects with valid serology results; N, total number of subjects in group

Reference: Chang LJ et al. *Vaccine.* 2020 Apr 23:38(19):3560-3569

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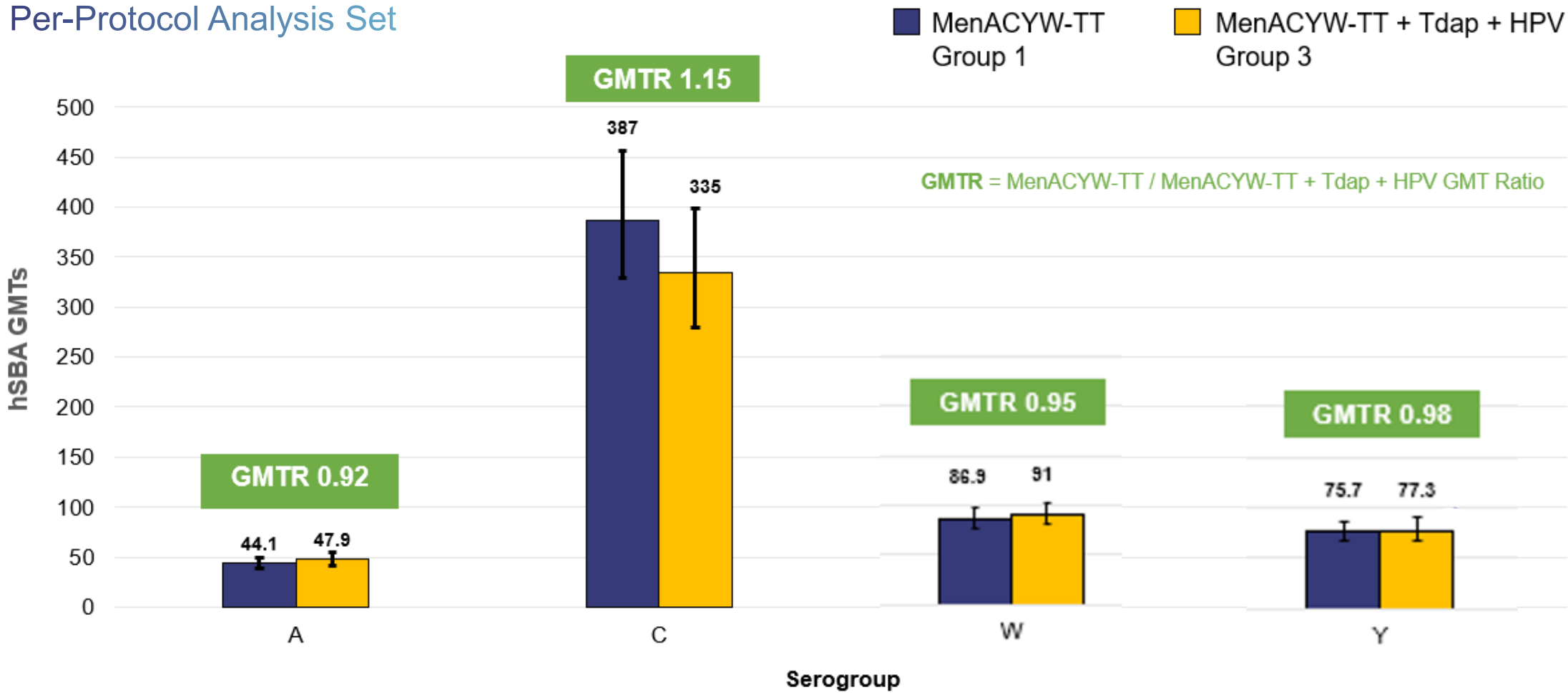
MET50: hSBA GEOMETRIC MEAN TITERS at D30

Per-Protocol Analysis Set

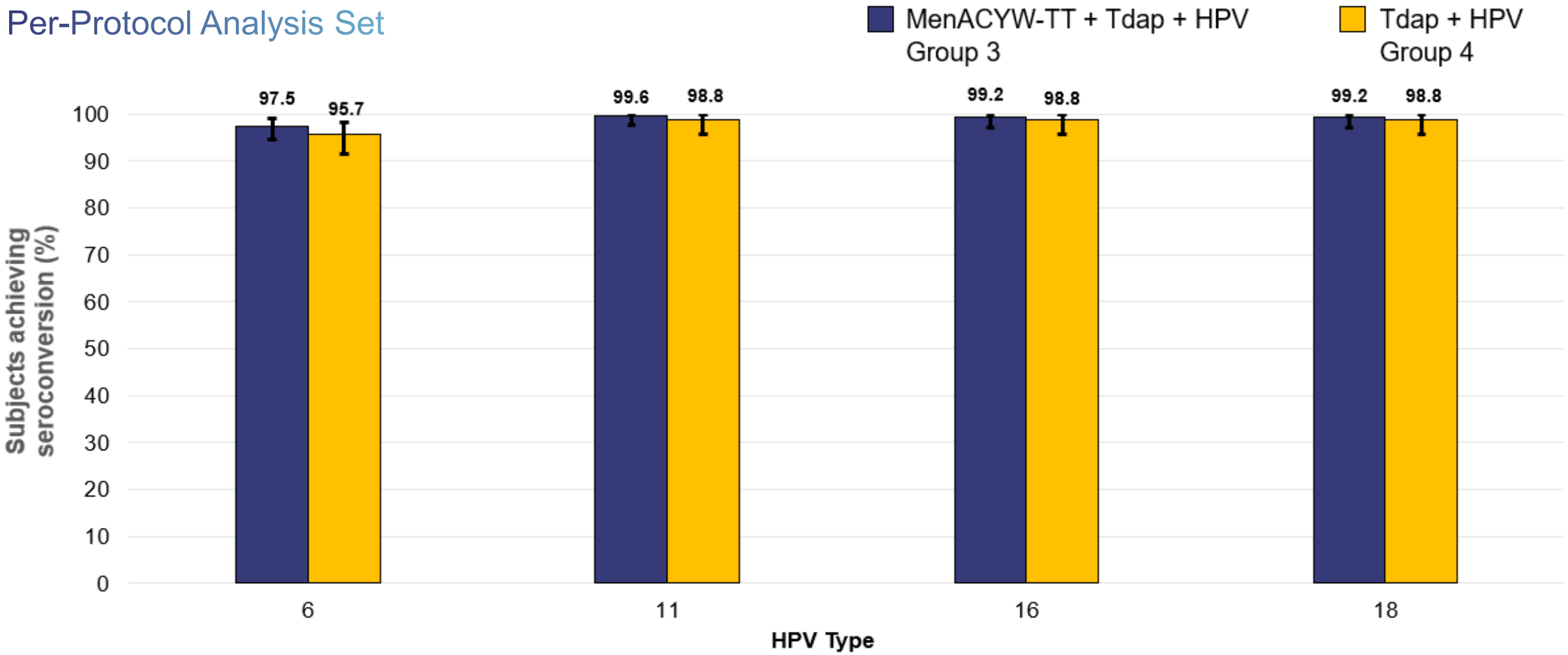


D30, day 30; GMT, geometric mean titer; GMTR, GMT ratio; hSBA, serum bactericidal assay using human complement

Reference: Chang LJ et al. *Vaccine.* 2020 Apr 23:38(19):3560-3569.

MET50: HPV type-specific SEROCONVERSION rates at D210

Per-Protocol Analysis Set

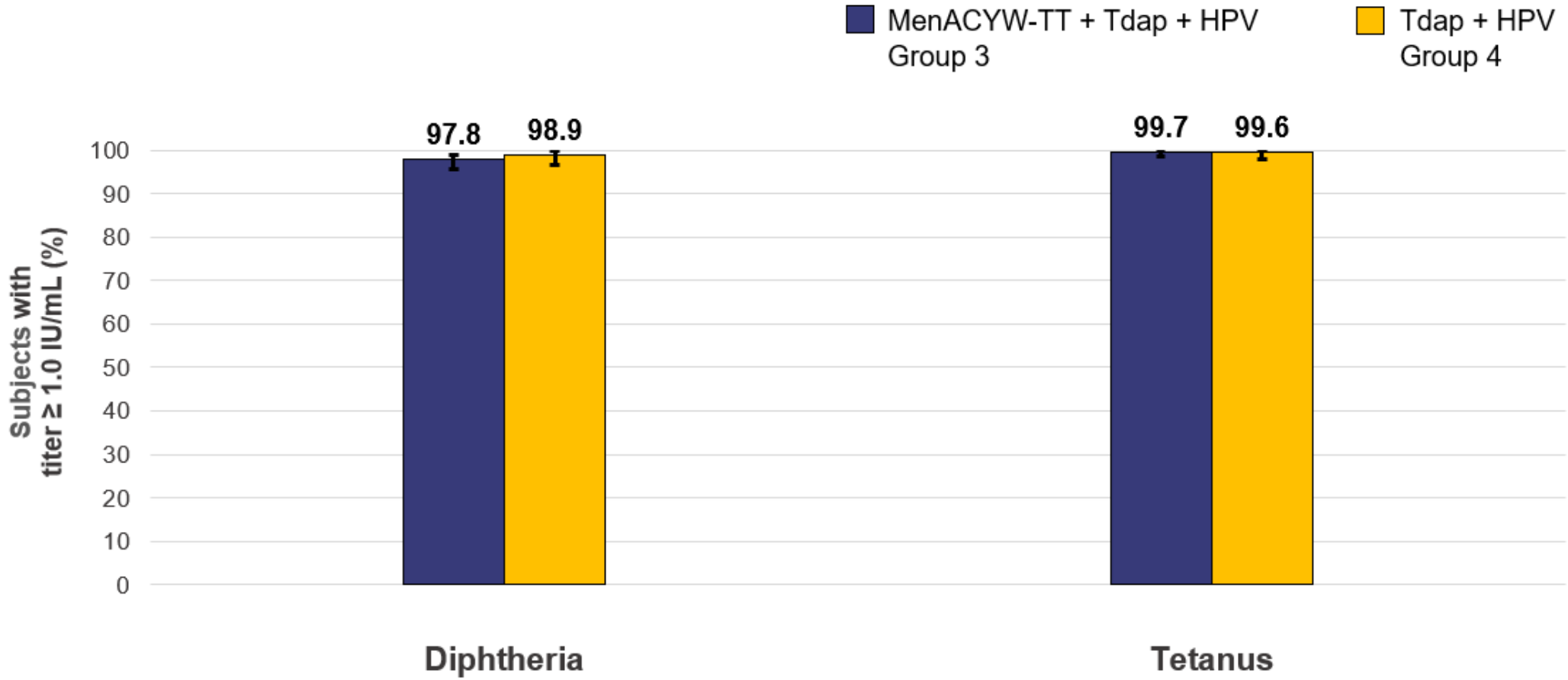


HPV seroconversion was defined as changing serostatus from seronegative to seropositive. Cutoff values for HPV seropositivity were ≥20 milli-Merck units/milliliter (mMU/mL) for types 6 and 16, ≥ 16 mMU/mL for type 11, and ≥ 24mMU/mL for type 18.
Non-inferiority concluded if the lower limit of the two-sided 95%CI of the proportion difference is >-10%.
D210, day 210

Reference: Chang LJ et al. *Vaccine.* 2020 Apr 23:38(19):3560-3569.

MET50: DIPHTHERIA and TETANUS SEROPROTECTION rates at D30

Per-Protocol Analysis Set

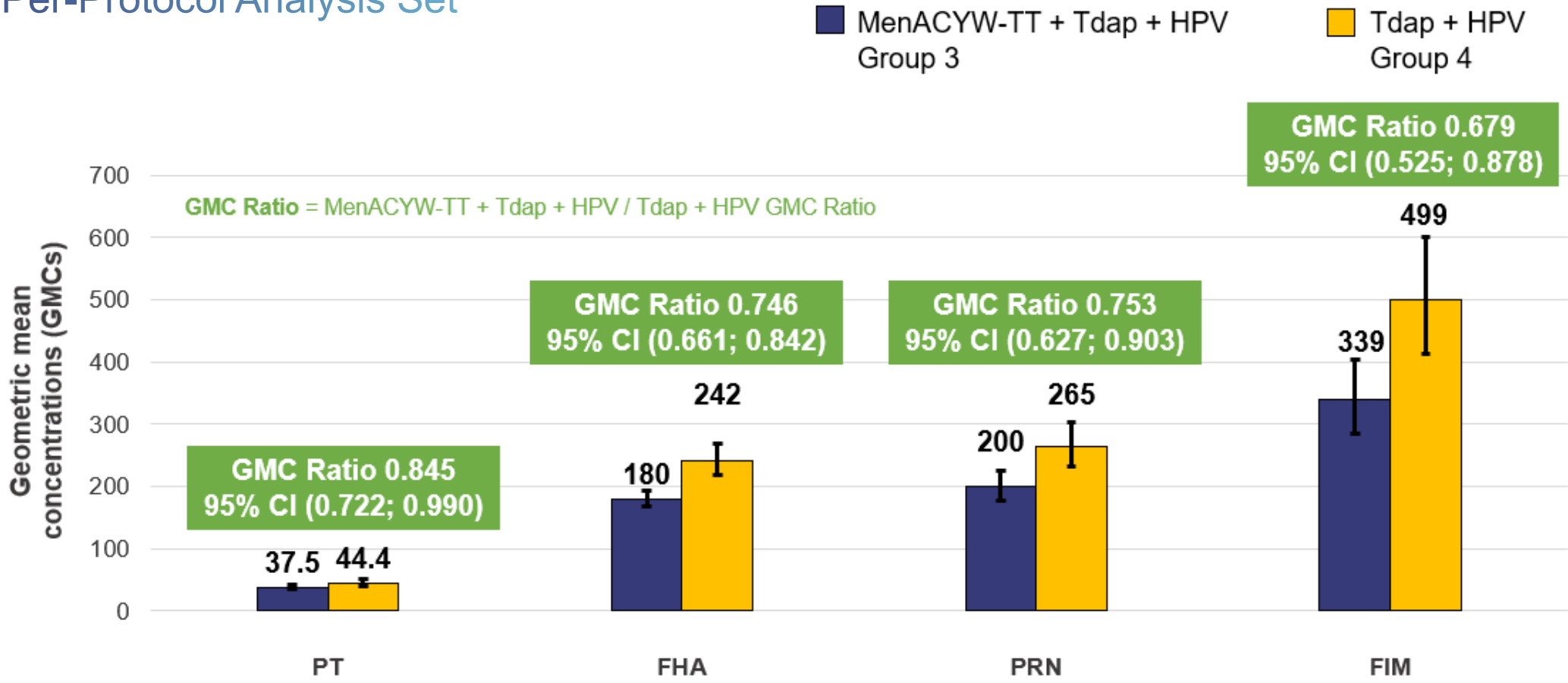


Seroprotection defined as titer ≥ 1.0 IU/mL.
Non-inferiority concluded if the lower limit of the two-sided 95%CI of the proportion difference is >-10%.
D30, day 30

Reference: Chang LJ et al. *Vaccine.* 2020 Apr 23:38(19):3560-3569.

MET50: PERTUSSIS Antigens
GEOMETRIC MEAN CONCENTRATIONS at D30

Per-Protocol Analysis Set

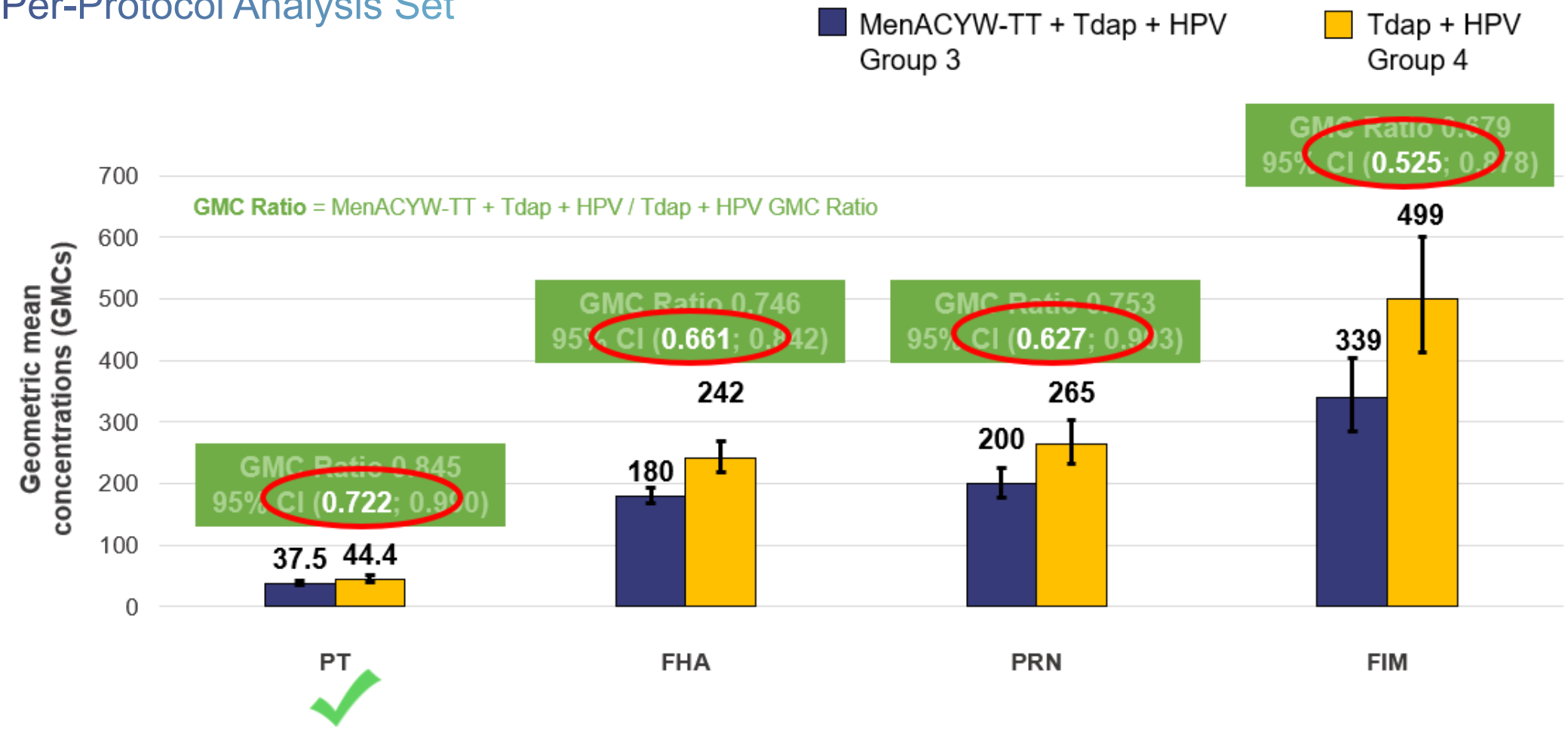


Non-inferiority concluded if the lower limit of the two-sided 95%CI of the ratio is > 0.667.
D30, day 30

Reference: Chang LJ et al. *Vaccine*. 2020 Apr 23:38(19):3560-3569.

MET50: PERTUSSIS Antigens
GEOMETRIC MEAN CONCENTRATIONS at D30

Per-Protocol Analysis Set



Non-inferiority concluded if the lower limit of the two-sided 95%CI of the ratio is > 0.667.
D30, day 30

Reference: Chang LJ et al. *Vaccine*. 2020 Apr 23:38(19):3560-3569.

MET49: Phase III study in MenACWY-naïve adults ≥ 56 years of age

Short Study Title	Immune Non-inferiority and Safety Study in Older Adults	
Study Population	Age	≥ 56 years
	Number of subjects	907
Study Design	**Group 1:** MenACYW-TT **Group 2:** MPSV4	
Vaccination Schedule	Single dose of MenACYW-TT or MPSV4	
First subject visit	15 July 2016	
Last subject visit	13 February 2017	

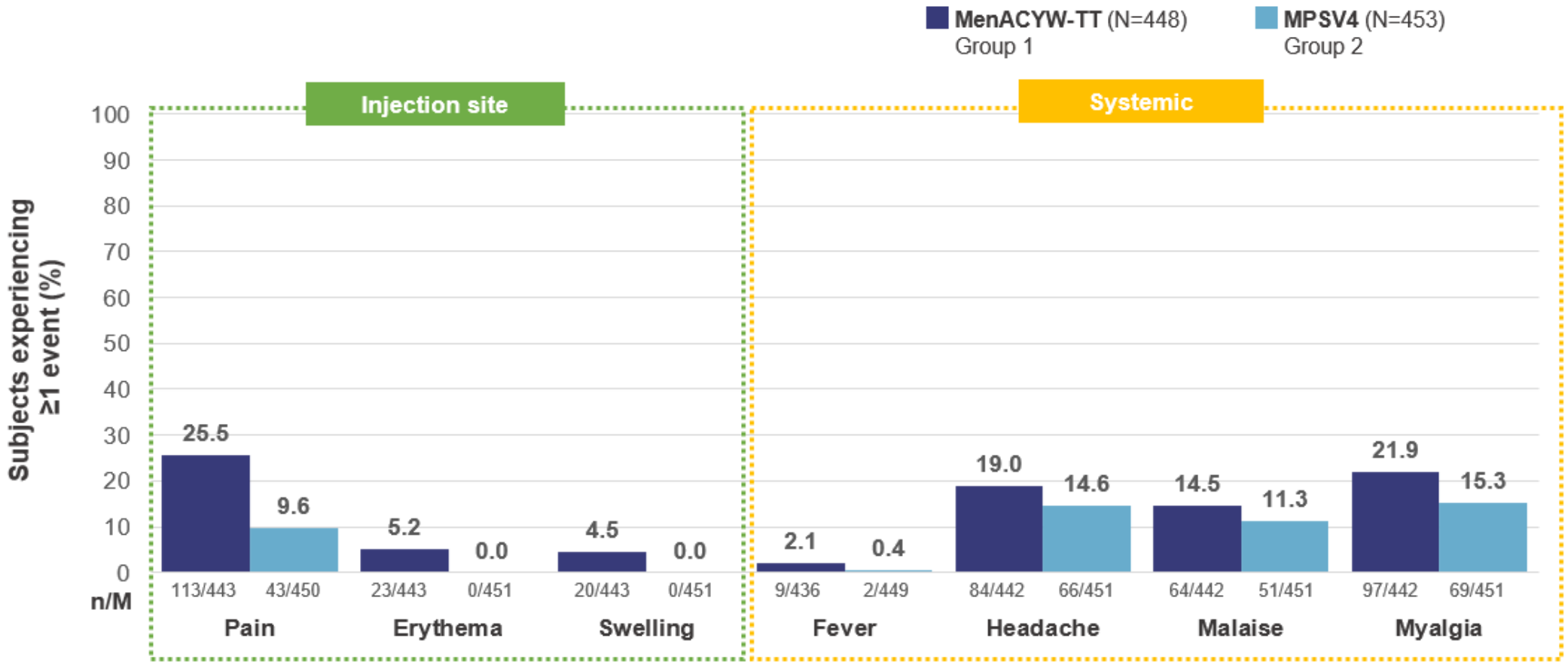
Baseline Demographics* (Safety Analysis Set)	
Characteristic ↓	**All (N=901)**
Gender, n (%) Female	**520** (57.4)
Age in years, mean (std deviation)	**72.4** (5.62)
Race, n (%) White African-American Other	 **793** (87.5) **101** (11.1) **11** (1.2)
Ethnicity, n (%) Hispanic or Latino	**67** (7.4)

*Demographic characteristics were balanced across vaccine groups (see back-up slide section)

References: 1. Esteves-Jaramillo A et al. *Vaccine*. 2020 Jun 9;38(28):4405-4411. **2.** Sanofi Pasteur Inc. Data on file (MET49 clinical study report).

MET49: Frequency of solicited reactions

Within 7 days of injection, Safety Analysis Set

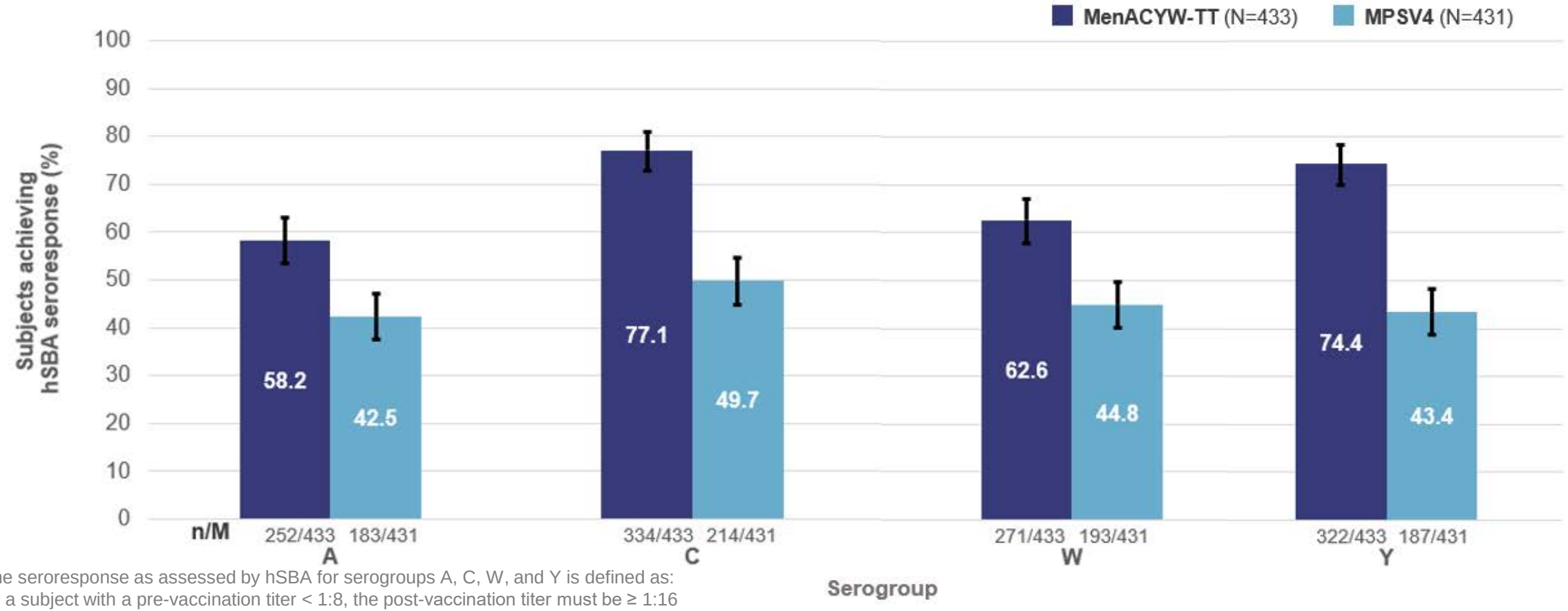


D0, day 0; D7, day 7; n, number of subjects experiencing endpoint; M, number of subjects with available data; N, total number of subjects in group.

References: 1. Esteves-Jaramillo A et al. *Vaccine*. 2020 Jun 9;38(28):4405-4411. **2.** Clinicaltrials.gov. NCT02842866 (MET49). Available at: https://clinicaltrials.gov/ct2/show/NCT02842866 [accessed June 2020].

MET49: Non-inferiority demonstrated, as assessed by SERORESPONSE rates at D30 in adults ≥ 56 years of age

Per-Protocol Analysis Set



Vaccine seroresponse as assessed by hSBA for serogroups A, C, W, and Y is defined as:

- For a subject with a pre-vaccination titer < 1:8, the post-vaccination titer must be ≥ 1:16
- For a subject with a pre-vaccination titer ≥ 1:8, the post-vaccination titer must be at least 4-fold greater than the pre-vaccination titer.

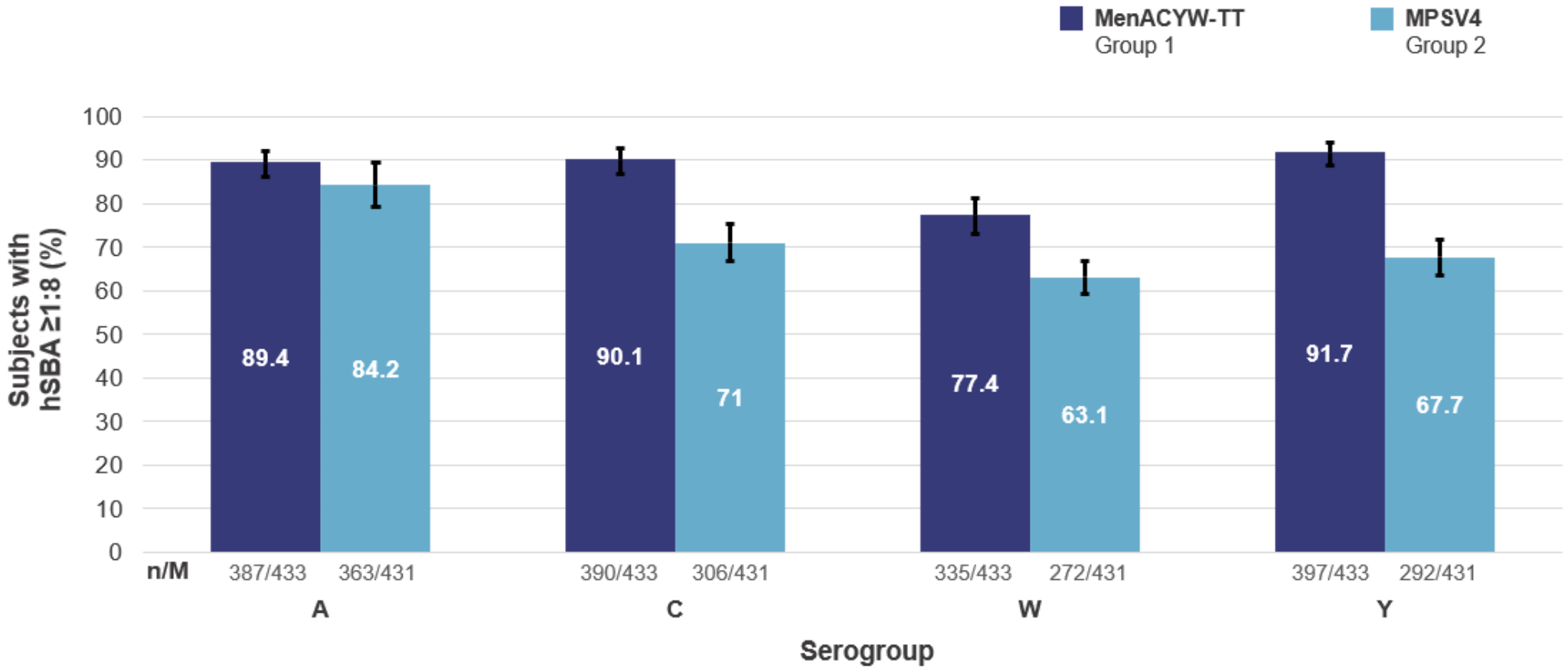
Non-inferiority concluded if the lower limit of the two-sided 95%CI of the proportion difference is >-10%.

CI, confidence interval; D30, day 30; hSBA, serum bactericidal assay using human complement; M, number of subjects with valid serology results; n, number of subjects achieving hSBA seroresponse; N, total number of subjects in group.

Reference: Esteves-Jaramillo A et al. *Vaccine*. 2020 Jun 9;38(28):4405-4411.

MET49: Percentage of adults ≥ 56 years of age with hSBA TITERS ≥1:8 at D30

Per-Protocol Analysis Set

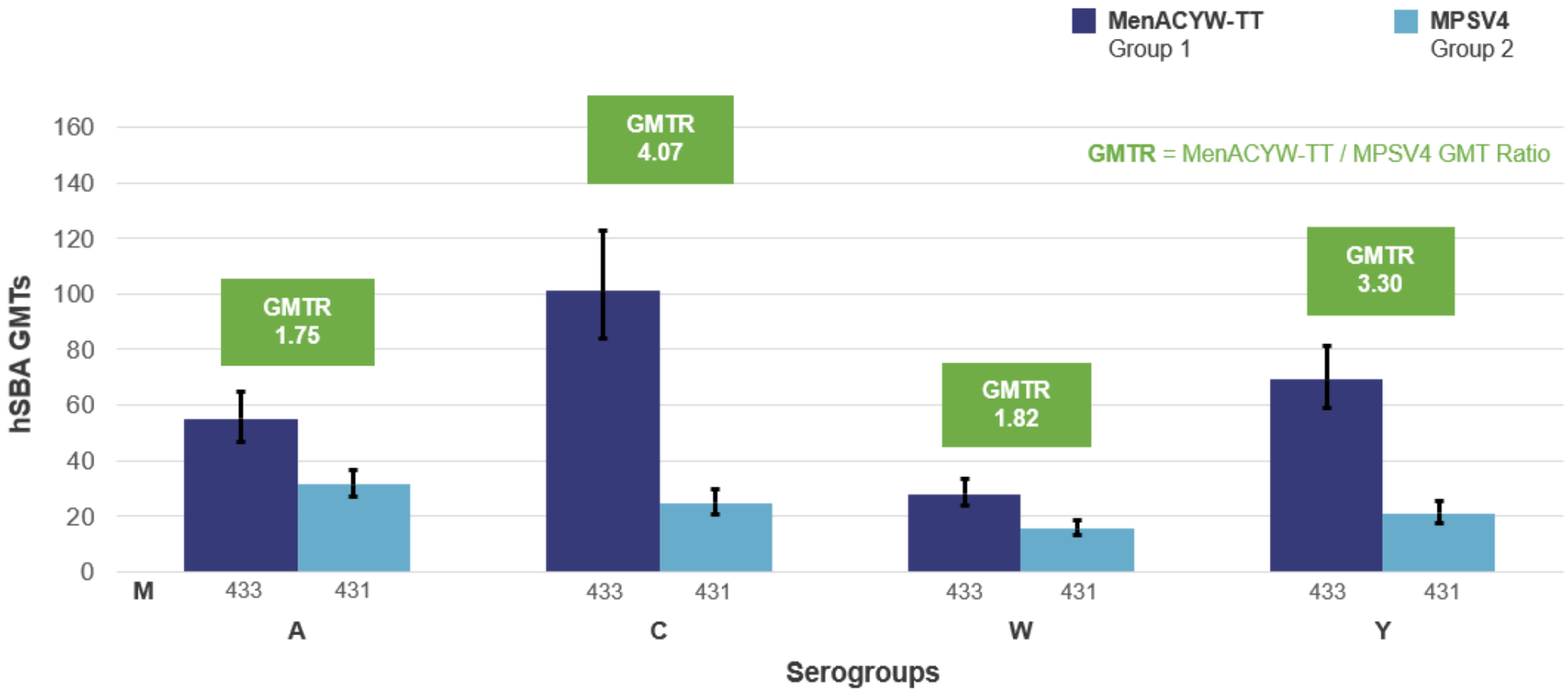


D30, day 30; hSBA, serum bactericidal assay using human complement; M, number of subjects with valid serology results; n, number of subjects with hSBA titers ≥1:8

Reference: Esteves-Jaramillo A et al. *Vaccine*. 2020 Jun 9;38(28):4405-4411.

MET49: hSBA GEOMETRIC MEAN TITERS at D30

Per-Protocol Analysis Set



D30, day 30; hSBA, serum bactericidal assay using human complement; GMT, geometric mean titer; GMTR, GMT ratio

Reference: Esteves-Jaramillo A et al. *Vaccine*. 2020 Jun 9;38(28):4405-4411.

MET56: Phase III study in MenACWY-primed persons ≥ 15 years of age

Short Study Title	Immune Non-Inferiority and Safety Study of a Booster Vaccine	
Study Population	Age	≥15 years
	Number of subjects	810
	Primed with MenACWY-D or MenACWY-CRM; 4 to 10 years before inclusion	
Study Design	**Group 1:** MenACYW-TT **Group 2:** MenACWY-D	
Vaccination Schedule	Single dose of MenACYW-TT or MenACWY-D	
First subject visit	15 April 2016	
Last subject visit	19 December 2016	

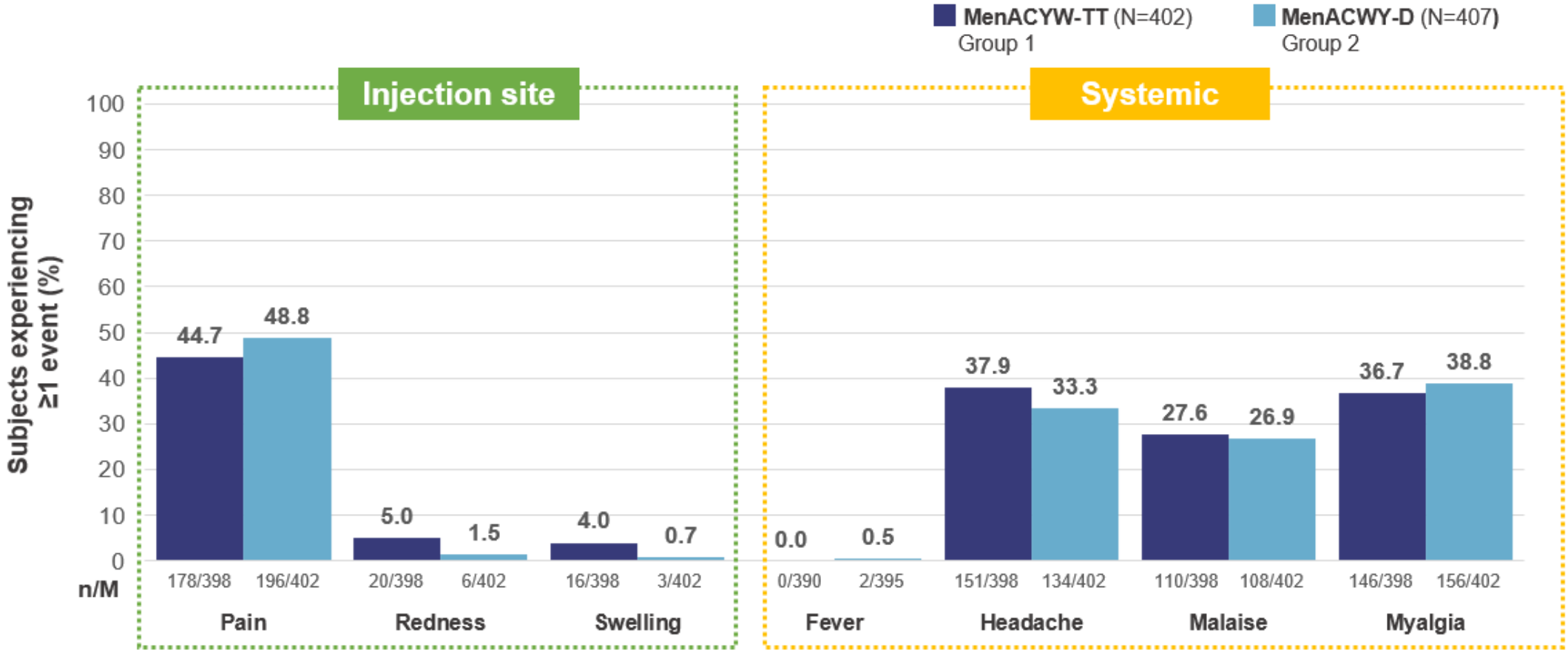
Baseline Demographics* (Safety Analysis Set)	
Characteristic ↓	**All (N=809)**
Gender, n (%) Female	**407** (50.2)
Age in years, mean (std deviation)	**20** (5.78)
Race, n (%) White African-American Other	682 (84.3) 85 (10.5) 41 (5.0)
Ethnicity, n (%) Hispanic or Latino	**134** (16.6)

*Demographic characteristics were balanced across vaccine groups (see back-up slide section)

References: 1. : Áñez G et al. *Hum Vaccin Immunother.* 2020 Mar 25:1-7 (ePub). **2.** Sanofi Pasteur Inc. Data on file (MET56 clinical study report).

MET56: Frequency of solicited reactions

within 7 days after vaccination, Safety Analysis Set

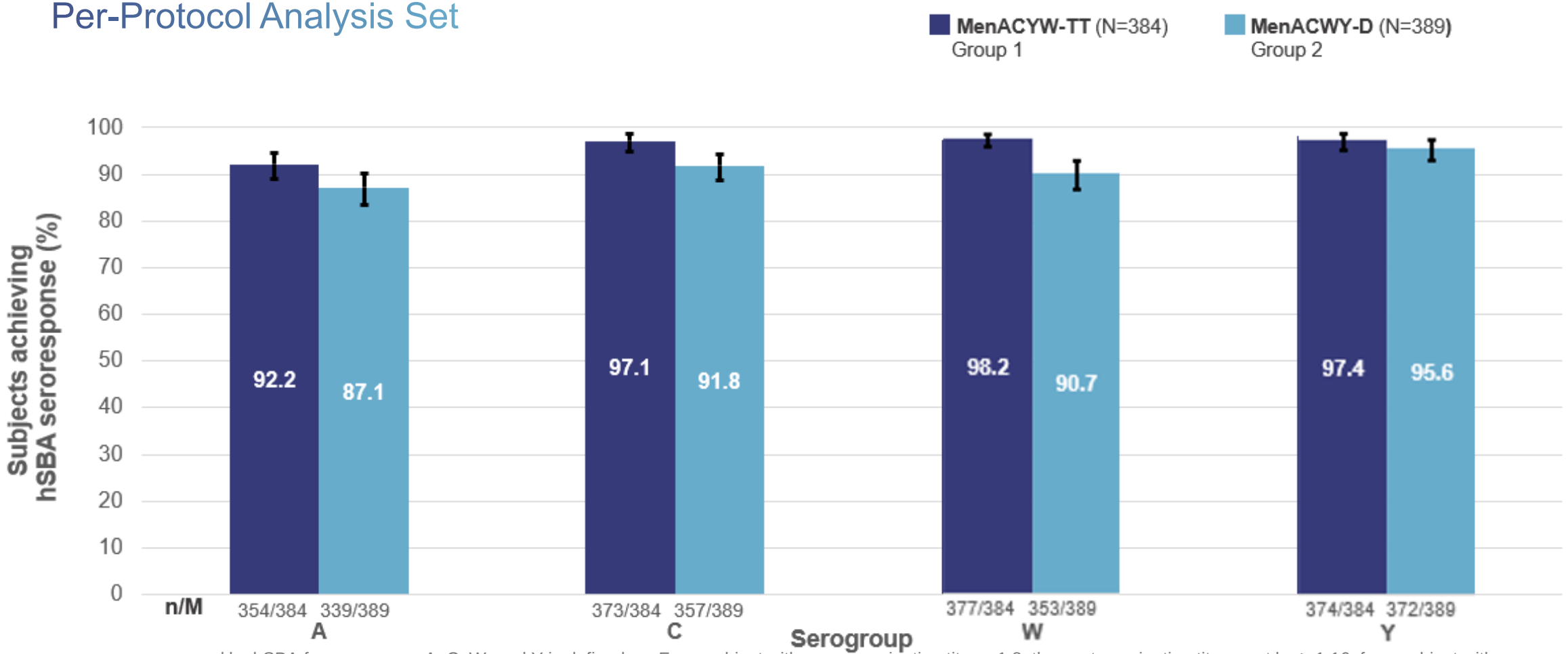


D0, day 0; D7, day 7; n, number of subjects experiencing endpoint; M, number of subjects with available data; N, total number of subjects in group.

References: 1. Áñez G et al. *Hum Vaccin Immunother.* 2020 Mar 25:1-7 (ePub). **2.** Clinicaltrials.gov. NCT02752906 (MET56). Available at: https://clinicaltrials.gov/ct2/show/NCT02752906 [accessed June 2020].

MET56: Non-inferiority demonstrated, as assessed by SERORESPONSE rates at D30 in MenACWY-primed persons ≥ 15 years of age

Per-Protocol Analysis Set



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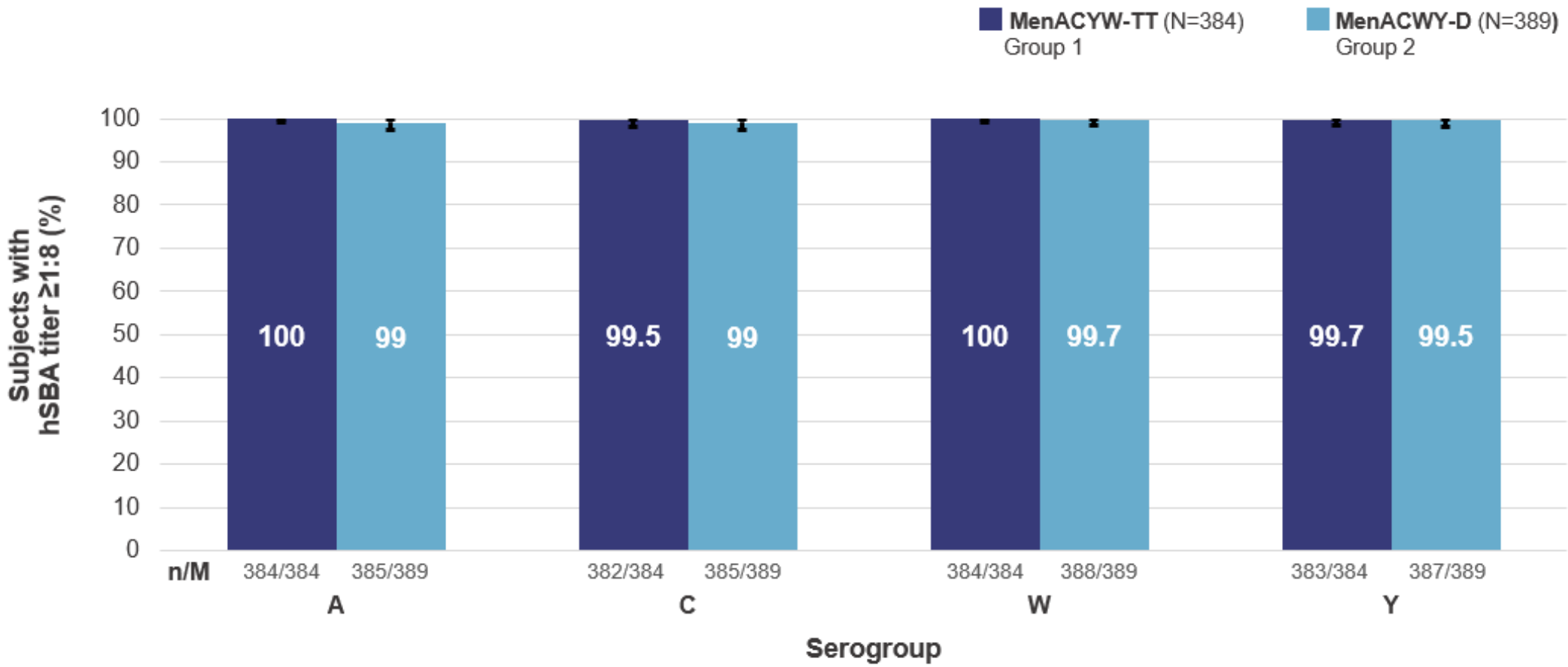
Non-inferiority concluded if the lower limit of the two-sided 95%CI of the proportion difference is >-10%.

CI, confidence interval; D30, day 30; hSBA, serum bactericidal assay using human complement; M, number of subjects with valid serology results; n, number of subjects achieving hSBA seroresponse; N, total number of subjects in group.

Reference: Áñez G et al. *Hum Vaccin Immunother.* 2020 Mar 25:1-7 (ePub).

MET56: MenACWY-primed persons ≥ 15 years of age with hSBA TITERS ≥1:8 at D30

Per-Protocol Analysis

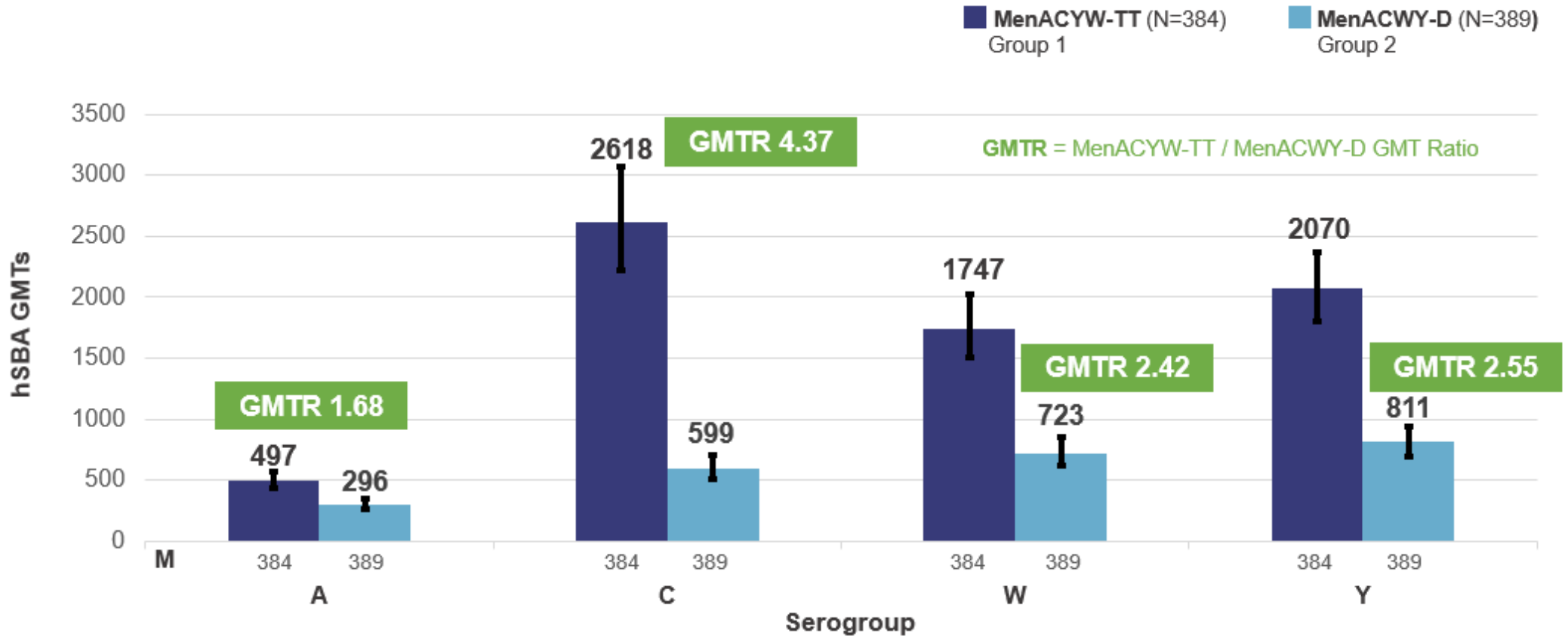


D30, day 30; hSBA, serum bactericidal assay using human complement; M, number of subjects with valid serology results; n, number of subjects with hSBA titers ≥1:8

References: 1. Áñez G et al. *Hum Vaccin Immunother.* 2020 Mar 25:1-7 (ePub). **2.** Clinicaltrials.gov. NCT02752906 (MET56). Available at: https://clinicaltrials.gov/ct2/show/NCT02752906 [accessed June 2020]

MET56: hSBA GEOMETRIC MEAN TITERS at D30

Per-Protocol Analysis Set



D30, day 30; GMT, geometric mean titer; GMTR, GMT ratio; hSBA, serum bactericidal assay using human complement; M, number of subjects with valid serology results; N, total number of subjects in group

Reference: Áñez G et al. *Hum Vaccin Immunother.* 2020 Mar 25:1-7 (ePub).

Robust clinical development program led to initial US licensure of vaccine

Clinical Study Code	Phase	Title	Comparator	ClinicalTrials.gov Identifier
MET50	II	Immunogenicity and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine in Healthy Adolescents (NOTE: Coadministered vaccines were Tdap and HPV4)	MenACWY-CRM (Menveo)	NCT02199691
MET56	III	Immunogenicity and Safety of a Booster Dose of an Investigational Quadrivalent Meningococcal Conjugate Vaccine in Adolescents and Adults	MPSV4 (Menomune)	NCT02752906
MET49	III	Immunogenicity and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine in Adults Age 56 Years and Older	MenACWY-D (Menactra)	NCT02842866
MET35	III	Immunogenicity and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine Administered in Healthy Children 2 to 9 Years of Age	MenACWY-CRM (Menveo)	NCT03077438
MET43	III	Immune Lot Consistency, Immunogenicity, and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine in Adolescents and Adults Aged 10 to 55 Years	MenACWY-D (Menactra)	NCT02842853

All trials were randomized, blinded, and active-controlled

MET35: Phase III study in MenACWY-naïve persons 2–9 years of age

Short Study Title	Immune Non-Inferiority and Safety Study in Children	
Study Population	Age	2-9 years
	Number of subjects	1000
Study Design	**Group 1:** MenACYW-TT **Group 2:** MenACWY-CRM	
Vaccination Schedule	Single dose of MenACYW-TT or MenACWY-CRM	
First subject visit	17 February 2017	
Last subject visit	10 October 2017	

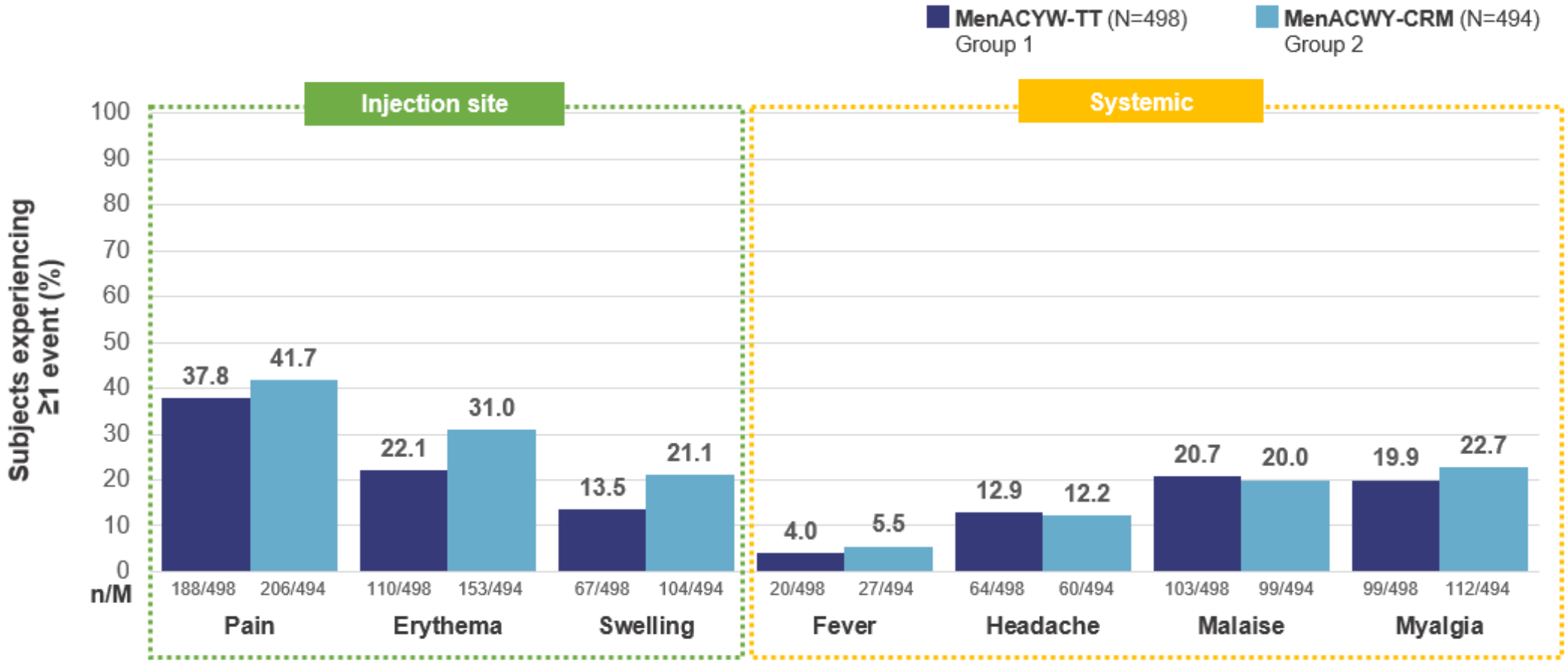
Baseline Demographics* (Safety Analysis Set)	
Characteristic ↓	All (N=992)
Gender, n (%) Female	**516** (52.0)
Age in years, mean (std deviation)	**6.0** (2.34)
Race, n (%) White African-American Other	 **812** (81.9) **126** (12.7) **51** (5.1)
Ethnicity, n (%) Hispanic or Latino	**229** (23.1)

*Demographic characteristics were balanced across vaccine groups (see back-up slide section)

References: 1. Clinicaltrials.gov. NCT03077438 (MET35). Available at: https://clinicaltrials.gov/ct2/show/NCT030774388 [accessed June 2020] **2.** Sanofi Pasteur Inc. Data on file (MET35 clinical study report).

MET35: Frequency of solicited reactions

Within 7 days of injection, Safety Analysis Set

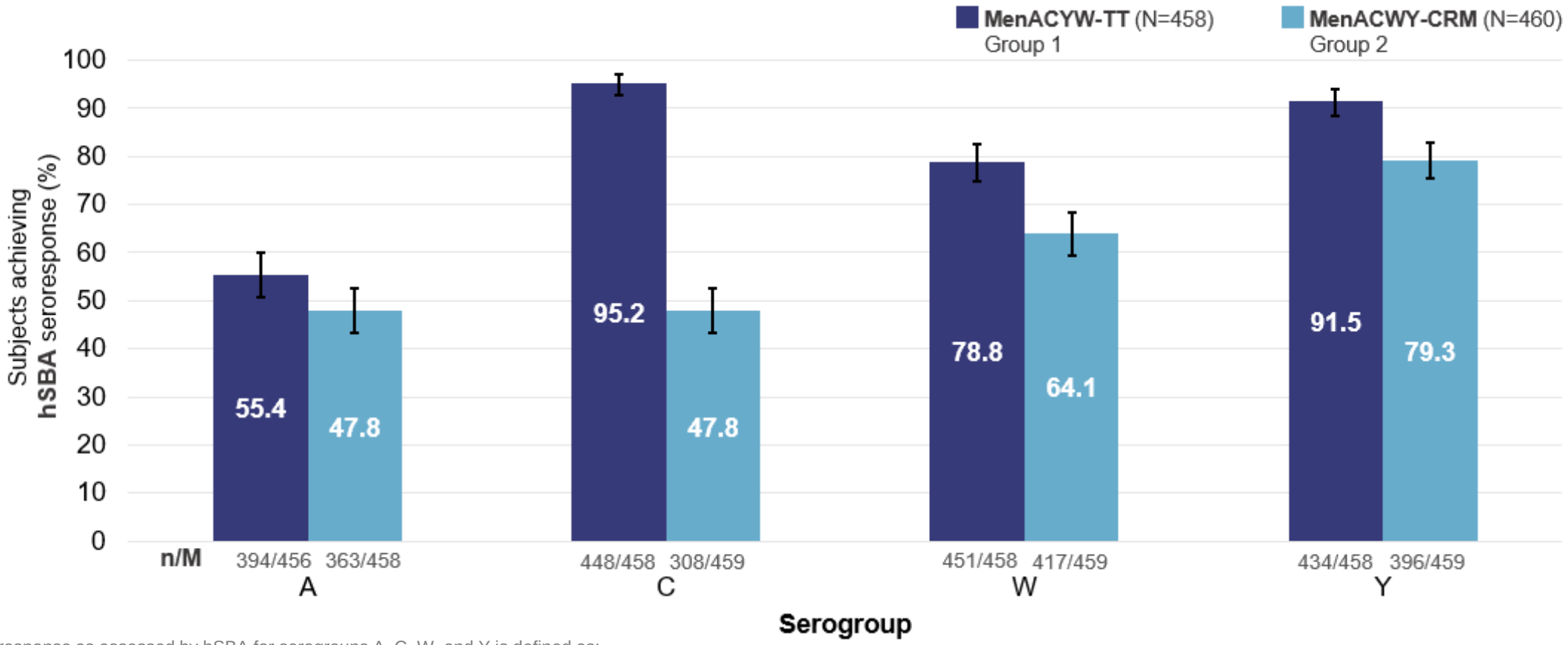


D0, day 0; D7, day 7; n, number of subjects experiencing endpoint; M, number of subjects with available data; N, total number of subjects in group.

Reference: Clinicaltrials.gov. NCT03077438 (MET35). Available at: https://clinicaltrials.gov/ct2/show/NCT030774388 [accessed June 2020].

MET35: Non-inferiority demonstrated, as assessed by SERORESPONSE rates at D30 in children 2–9 years of age

Per-Protocol Analysis Set

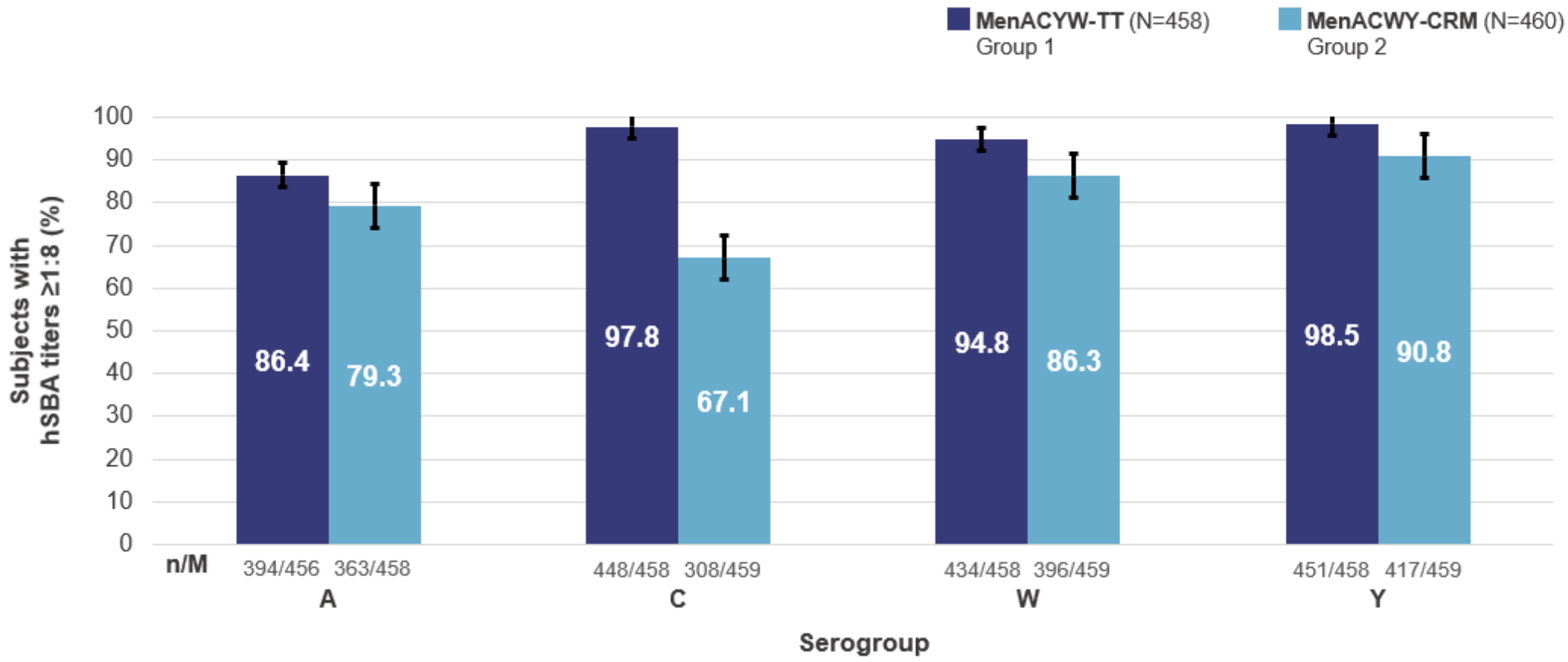


Vaccine seroresponse as assessed by hSBA for serogroups A, C, W, and Y is defined as:
For a subject with a pre-vaccination titer < 1:8, the post-vaccination titer must be ≥ 1:16
For a subject with a pre-vaccination titer ≥ 1:8, the post-vaccination titer must be at least 4-fold greater than the pre-vaccination titer.
Non-inferiority concluded if the lower limit of the two-sided 95%CI of the proportion difference is >-10%.
CI, confidence interval; D30, day 30; hSBA, serum bactericidal assay using human complement; M, number of subjects with valid serology results; n, number of subjects achieving hSBA seroresponse; N, total number of subjects in group.

Reference: Clinicaltrials.gov. NCT03077438 (MET35). Available at: https://clinicaltrials.gov/ct2/show/NCT03077438 [accessed June 2020].

MET35: Children 2–9 years of age with hSBA TITERS ≥1:8 at D30

Per-Protocol Analysis Set

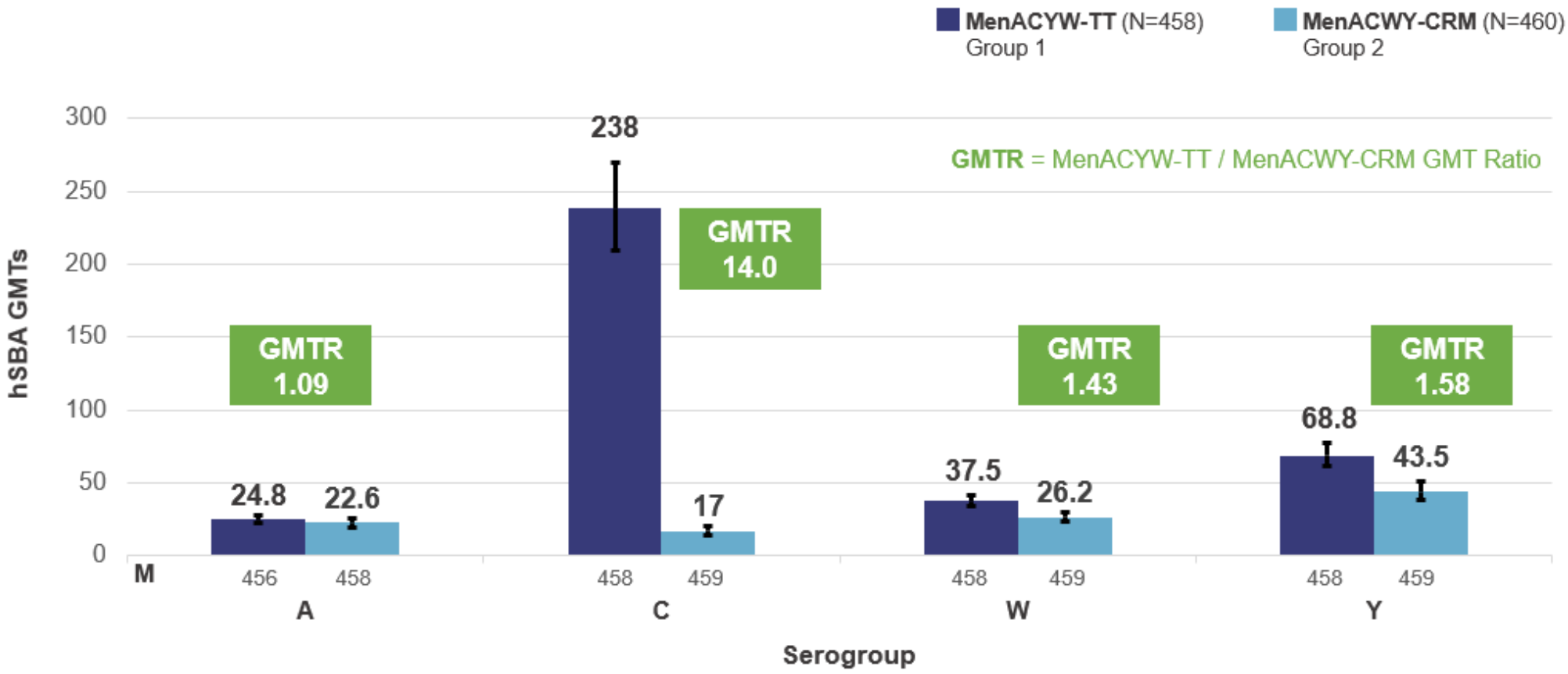


D30, day 30; hSBA, serum bactericidal assay using human complement; M, number of subjects with valid serology results; n, number of subjects with hSBA titers ≥1:8; N, total number of subjects in group.

Reference: Simon M, et al. Safety and immunogenicity of a quadrivalent meningococcal conjugate vaccine (MenACYW-TT) administered in healthy meningococcal vaccine naïve children (2-9 years). Poster presented at the 37th Annual meeting of the European Society for Paediatric Infectious Diseases, May 6-11 2019, Ljubljana. Slovenia [accessed June 2020].

MET35: hSBA GEOMETRIC MEAN TITERS at D30

Per-Protocol Analysis Set



D30, day 30; GMT, geometric mean titer; GMTR, GMT ratio; hSBA, serum bactericidal assay using human complement; M, number of subjects with valid serology results; N, total number of subjects in Group.

Reference: Clinicaltrials.gov. NCT03077438 (MET35). Available at: https://clinicaltrials.gov/ct2/show/NCT03077438 [accessed June 2020].

MET43: Phase III study in adolescents and adults aged 10–55 years

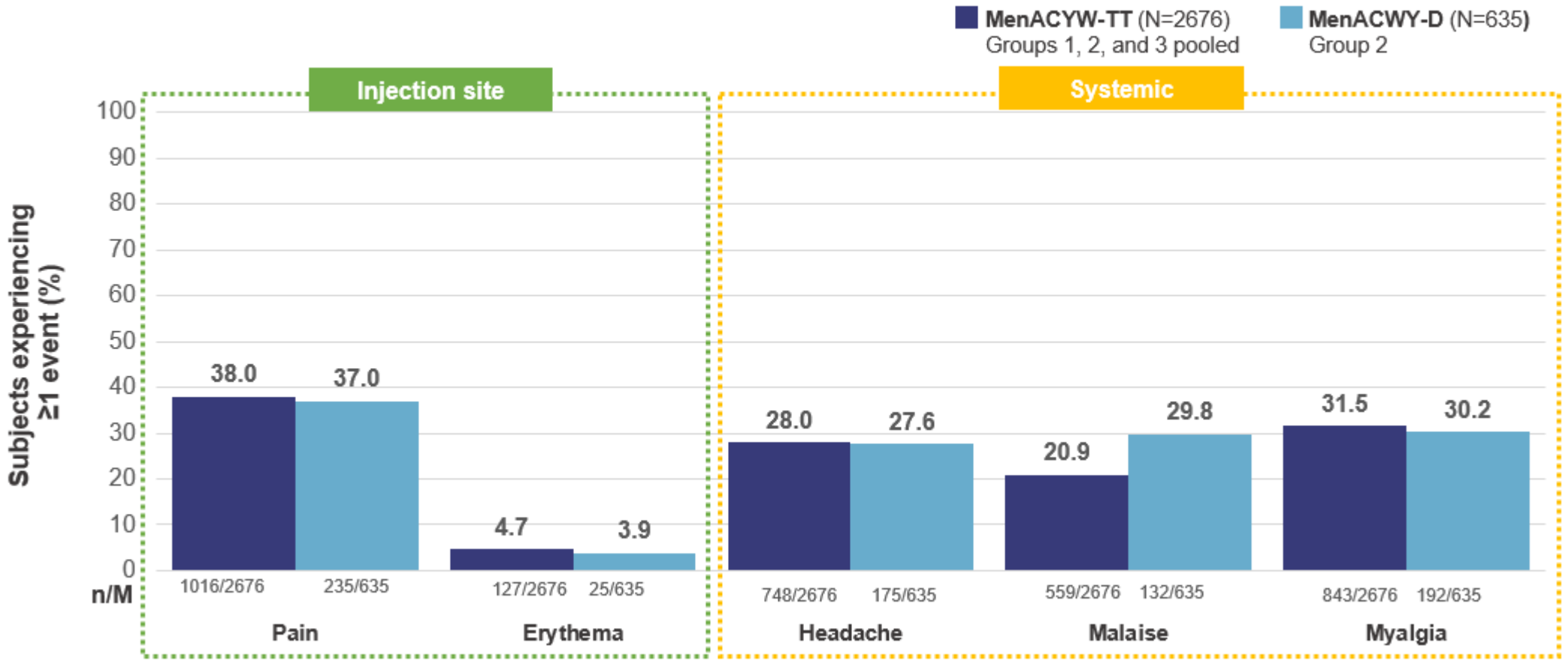
Short Study Title	Immune lot consistency, Immune Non-Inferiority and Safety Study in Adolescents and Adults	
Study Population	**Age**	10–55 years
	Number of subjects	3344
	Meningococcal vaccine-naïve	
Study Design	**Group 1:** MenACYW-TT – lot 1 **Group 3:** MenACYW-TT – lot 3	**Group 2:** MenACYW-TT – lot 2 **Group 4:** MenACWY-D
Vaccination Schedule	Single dose of MenACYW-TT or MenACWY-D	
First subject visit	15 July 2016	
Last subject visit	28 February 2017	

Baseline Demographics (Safety Analysis Set)	
Characteristic ↓	All (N=3311)
Gender, n (%) Female	**1904** (57.5)
Age in years, mean (std deviation)	**27.1** (15.6)
Race, n (%) White African-American Other	 **2462** (74.4) **643** (19.4) **201** (6.1)
Ethnicity, n (%) Hispanic or Latino	**709** (21.4)

References: 1. Dhingra MS et al. *Vaccine.* 2020 Jun 19:1-8 (ePub). **2.** Sanofi Pasteur Inc. Data on file (MET43 clinical study report).

MET43: Frequency of solicited reactions

Within 7 days of injection, Safety Analysis Set

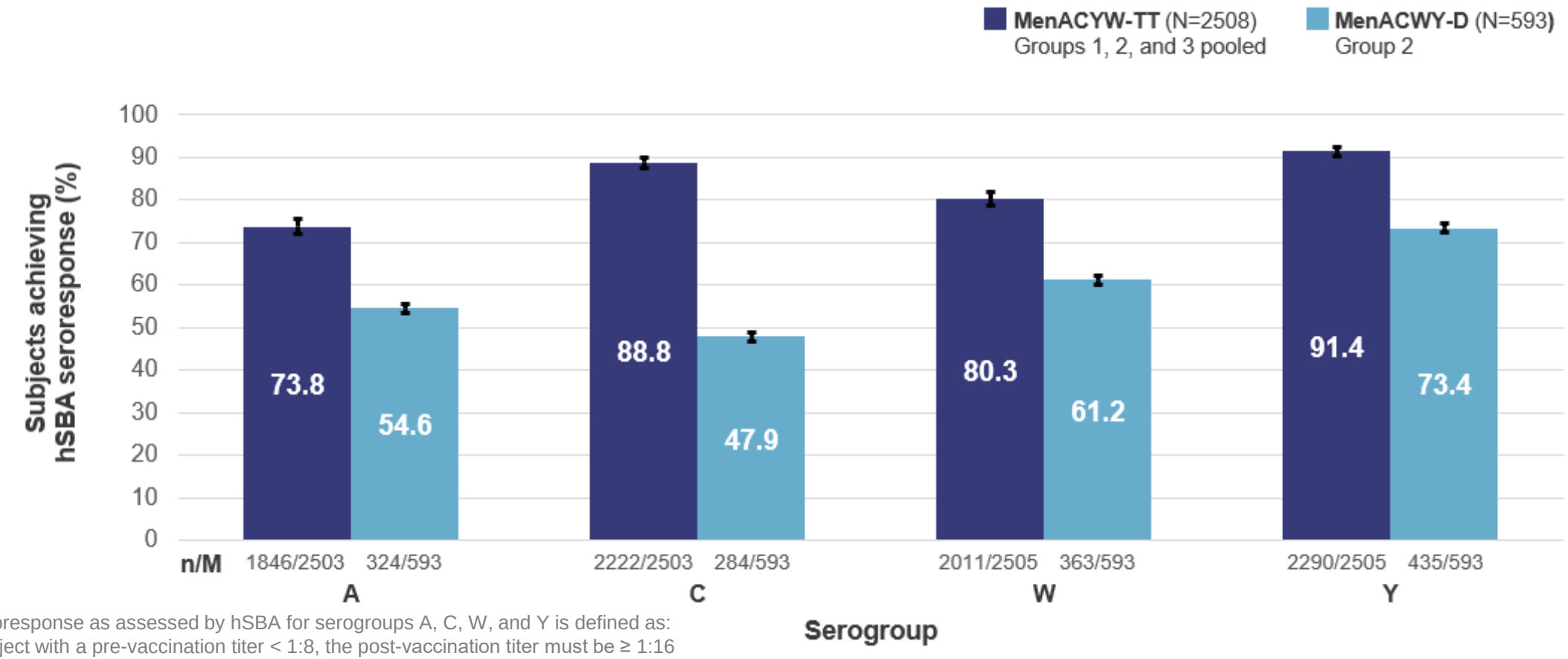


D0, day 0; D7, day 7; n, number of subjects experiencing endpoint; M, number of subjects with available data; N, total number of subjects in group.

References: 1. Dhingra MS et al. *Vaccine.* 2020 Jun 19:1-8 (ePub). **2.** Clinicaltrials.gov. NCT02842853 (MET43). Available at: https://clinicaltrials.gov/ct2/show/NCT02842853 [accessed June 2020].

MET43: Non-inferiority demonstrated, as assessed by SERORESPONSE rates at D30 in persons 10–55 years of age

Per-Protocol Analysis Set



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- For a subject with a pre-vaccination titer ≥ 1:8, the post-vaccination titer must be at least 4-fold greater than the pre-vaccination titer.

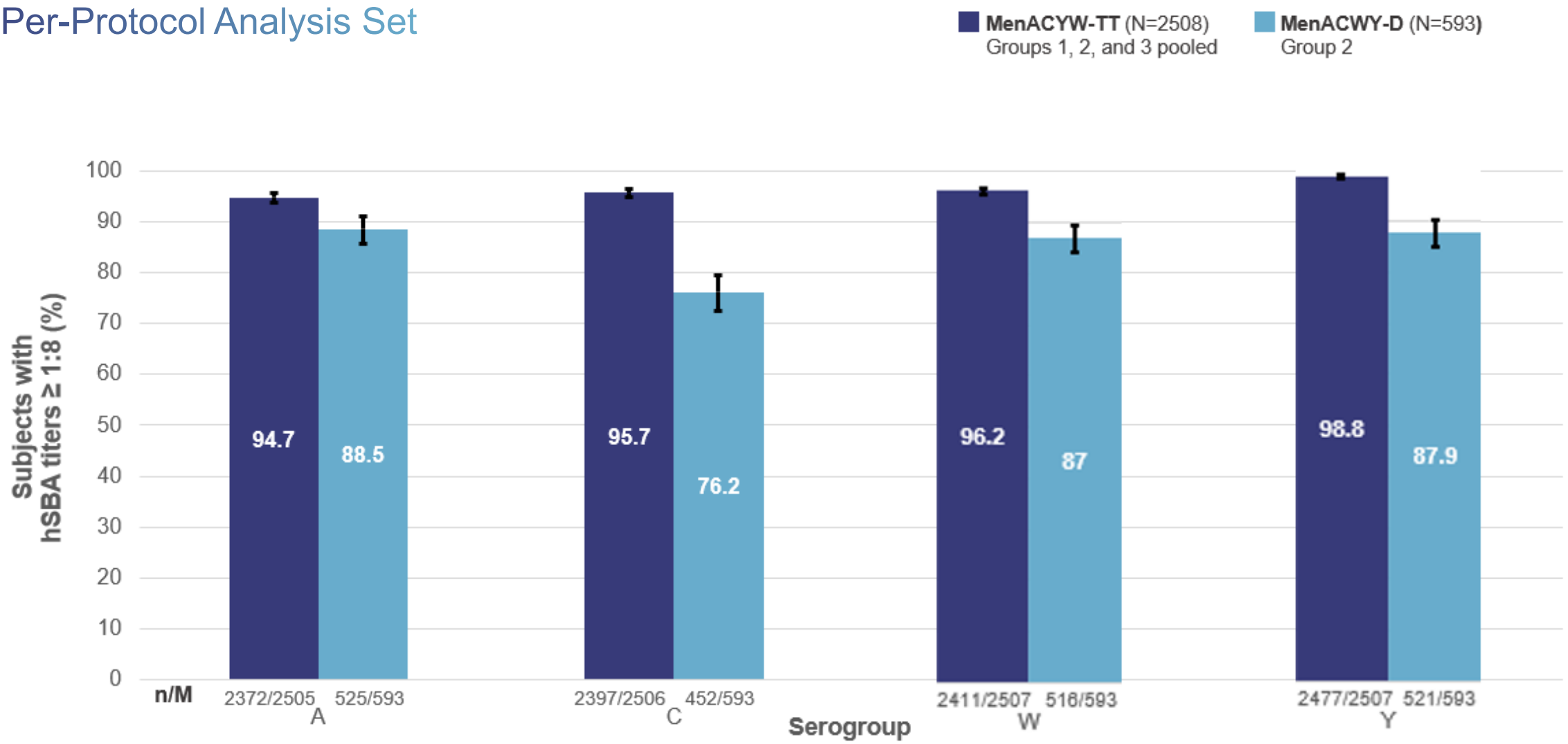
Non-inferiority concluded if the lower limit of the two-sided 95%CI of the proportion difference is >-10%.

CI, confidence interval; D30, day 30; hSBA, serum bactericidal assay using human complement; M, number of subjects with valid serology results; n, number of subjects achieving hSBA seroresponse; N, total number of subjects in group.

References: 1. Dhingra MS et al. *Vaccine.* 2020 Jun 19:1-8 (ePub). **2.** Clinicaltrials.gov. NCT02842853 (MET43). Available at: https://clinicaltrials.gov/ct2/show/NCT02842853 [accessed June 2020].

MET43: Persons 10–55 years of age with hSBA TITERS ≥1:8 at D30

Per-Protocol Analysis Set

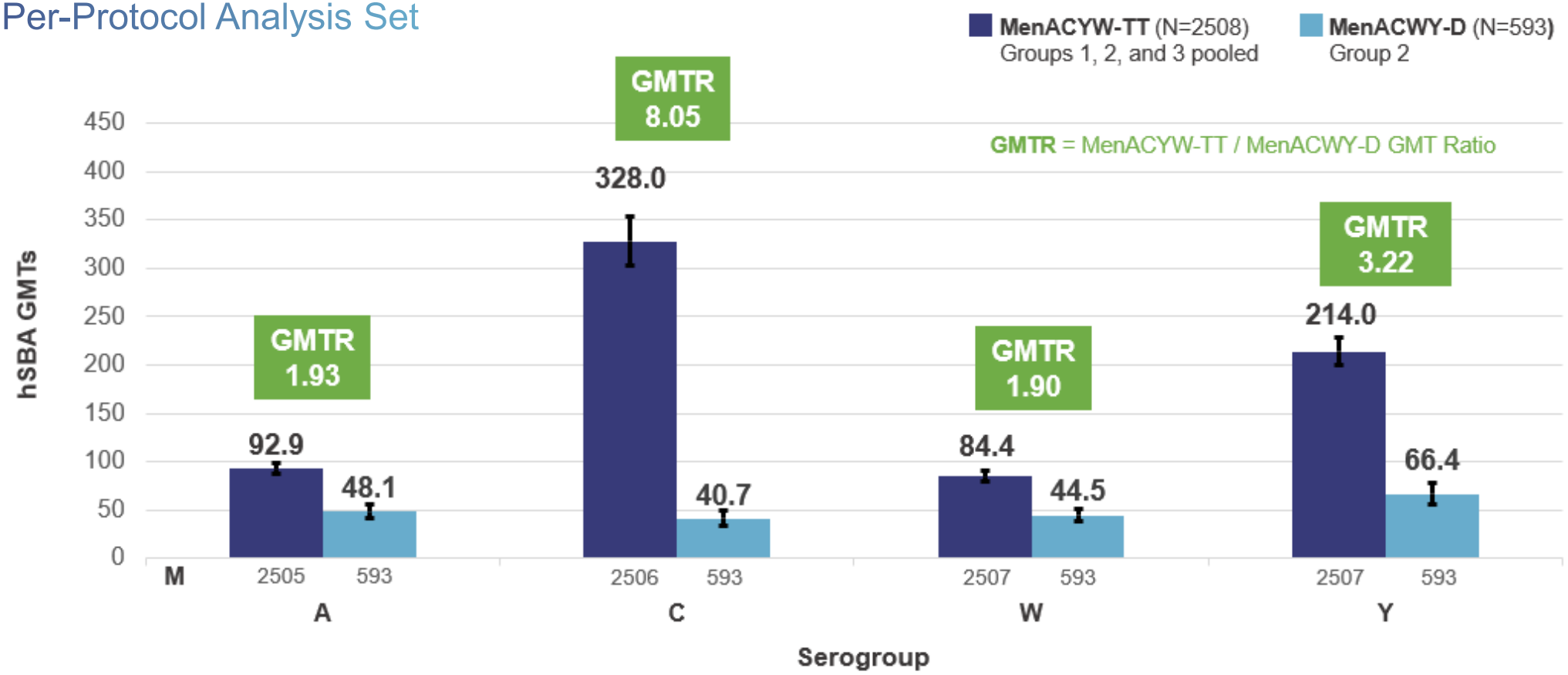


D30, day 30; hSBA, serum bactericidal assay using human complement; M, number of subjects with valid serology results; n, number of subjects with hSBA titers ≥1:8.

References: 1. Dhingra MS et al. *Vaccine.* 2020 Jun 19:1-8 (ePub). **2.** Clinicaltrials.gov. NCT02842853 (MET43). Available at: https://clinicaltrials.gov/ct2/show/NCT02842853 [accessed June 2020].

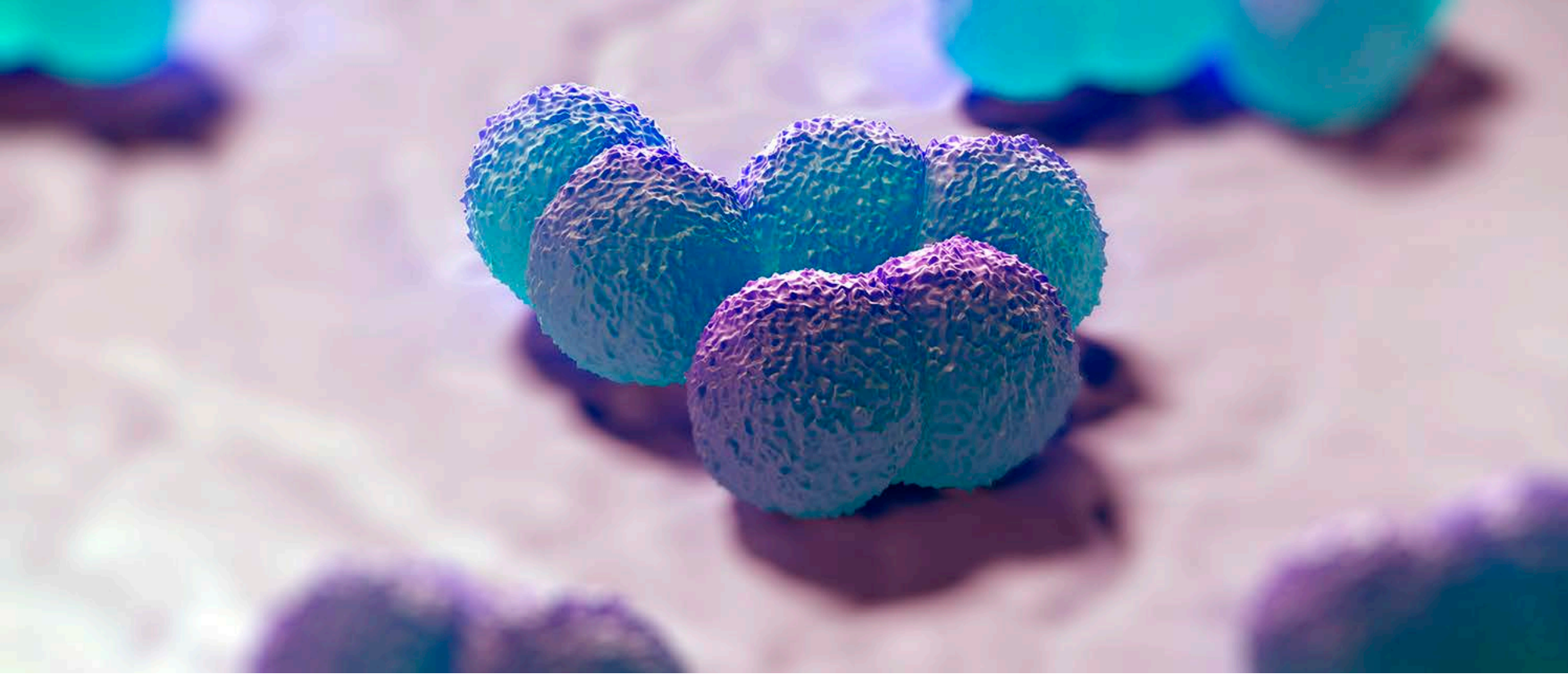
MET43: hSBA GEOMETRIC MEAN TITERS at D30

Per-Protocol Analysis Set



D30, day 30; GMT, geometric mean titer; GMTR, GMT ratio; hSBA, serum bactericidal assay using human complement; M, number of subjects with valid serology results; N, total number of subjects in group

References: 1. Dhingra MS et al. *Vaccine.* 2020 Jun 19:1-8 (ePub). **2.** Clinicaltrials.gov. NCT02842853 (MET43). Available at: https://clinicaltrials.gov/ct2/show/NCT02842853 [accessed June 2020].



SUMMARY

SANOFI PASTEUR

MenQuadfi Summary

- **MenQuadfi demonstrated to have an acceptable safety profile and to induce robust immune responses against serogroups A, C, W, and Y, especially serogroup C**
  - Immune responses were consistently non-inferior to standard-of-care vaccines across age groups ≥ 2 years for all 4 vaccine serogroups
  - MenQuadfi induced robust booster responses among persons previously primed with MenACWY-D or MenACWY-CRM
  - Clinical trial data show that MenQuadfi can be co-administered with routinely recommended adolescent vaccines (ie, Tdap and HPV)
- **On 23 April 2020, FDA approved MenQuadfi for use in persons 2 years of age and older**
- **Supply will become available in the US in 2021**
- **Trials are ongoing to seek expansion of the age indication to 6 weeks of age and to evaluate MenQuadfi according to different pediatric immunization schedules that exist worldwide**