

Table 14.1.1.1
Disposition
All Enrolled Subjects

Age Group: Overall

	Menactra® n (%)	NmCV-5 n (%)	Total n (%)
TOTAL NUMBER OF SUBJECTS			
ENROLLED			1869
Mali			907
The Gambia			962
SCREEN FAILURE			61
Mali			7
The Gambia			54
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN BEFORE RANDOMIZATION			8
Mali			0
The Gambia			8
RANDOMIZED	600	1200	1800
Mali	300	600	900
The Gambia	300	600	900
VACCINATED	600	1200	1800
Mali	300	600	900
The Gambia	300	600	900
VACCINATED AS PER RANDOMIZATION	600	1200	1800
Mali	300	600	900
The Gambia	300	600	900
COMPLETED VISIT 1 (DAY 1)	600 (100.0)	1200 (100.0)	1800 (100.0)
HAVING BASELINE IMMUNOGENICITY RESULTS	597 (99.5)	1197 (99.8)	1794 (99.7)
COMPLETED VISIT 2 (DAY 8)	599 (99.8)	1199 (99.9)	1798 (99.9)
COMPLETED VISIT 3 (DAY 29)	597 (99.5)	1198 (99.8)	1795 (99.7)
HAVING IMMUNOGENICITY RESULTS	596 (99.3)	1198 (99.8)	1794 (99.7)
COMPLETED SAFETY FOLLOW-UP TILL VISIT 4 (DAY 169)	597 (99.5)	1198 (99.8)	1795 (99.7)
VISIT 4 ASSESSMENTS PERFORMED AT SITE	162 (27.0)	323 (26.9)	485 (26.9)
VISIT 4 ASSESSMENTS PERFORMED TELEPHONICALLY	435 (72.5)	875 (72.9)	1310 (72.8)

Percentages are based on the number of subjects vaccinated.

Subject 10705 has completed Visit 2 and Visit 4 safety assessment but did not attended Visit 3.

Source Data: Listing 16.2.1.1, 16.2.1.3 and 16.2.3.1

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DL1\TLF\t14010101.sas

Executed: 22OCT2021

Table 14.1.1.1
Disposition
All Enrolled Subjects

Age Group: Overall

	Menactra®		NmCV-5		Total	
	n	(%)	n	(%)	n	(%)
DISCONTINUED FROM VISIT 1 TILL VISIT 2	1	(0.2)	1	(0.1)	2	(0.1)
PRIMARY REASON FOR DISCONTINUATION						
ADVERSE EVENT	0	(0.0)	0	(0.0)	0	(0.0)
DEATH	0	(0.0)	0	(0.0)	0	(0.0)
LOST TO FOLLOW-UP	0	(0.0)	0	(0.0)	0	(0.0)
INVESTIGATOR DECISION	0	(0.0)	0	(0.0)	0	(0.0)
PROTOCOL DEVIATION	0	(0.0)	0	(0.0)	0	(0.0)
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN	1	(0.2)	1	(0.1)	2	(0.1)
STUDY TERMINATED BY SPONSOR	0	(0.0)	0	(0.0)	0	(0.0)
OTHER	0	(0.0)	0	(0.0)	0	(0.0)
DISCONTINUED POST VISIT 2 TILL VISIT 3	1	(0.2)	1	(0.1)	2	(0.1)
PRIMARY REASON FOR DISCONTINUATION						
ADVERSE EVENT	0	(0.0)	0	(0.0)	0	(0.0)
DEATH	0	(0.0)	0	(0.0)	0	(0.0)
LOST TO FOLLOW-UP	0	(0.0)	0	(0.0)	0	(0.0)
INVESTIGATOR DECISION	0	(0.0)	0	(0.0)	0	(0.0)
PROTOCOL DEVIATION	0	(0.0)	0	(0.0)	0	(0.0)
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN	1	(0.2)	1	(0.1)	2	(0.1)
STUDY TERMINATED BY SPONSOR	0	(0.0)	0	(0.0)	0	(0.0)
OTHER	0	(0.0)	0	(0.0)	0	(0.0)

Percentages are based on the number of subjects vaccinated.

Subject 10705 has completed Visit 2 and Visit 4 safety assessment but did not attended Visit 3.

Source Data: Listing 16.2.1.1, 16.2.1.3 and 16.2.3.1

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Table 14.1.1.1
Disposition
All Enrolled Subjects

Age Group: Overall

	Menactra®		NmCV-5		Total	
	n (%)		n (%)		n (%)	
DISCONTINUED POST VISIT 3 TILL VISIT 4 SAFETY ASSESSMENT	1	(0.2)	0	(0.0)	1	(0.1)
PRIMARY REASON FOR DISCONTINUATION						
ADVERSE EVENT	0	(0.0)	0	(0.0)	0	(0.0)
DEATH	1	(0.2)	0	(0.0)	1	(0.1)
LOST TO FOLLOW-UP	0	(0.0)	0	(0.0)	0	(0.0)
INVESTIGATOR DECISION	0	(0.0)	0	(0.0)	0	(0.0)
PROTOCOL DEVIATION	0	(0.0)	0	(0.0)	0	(0.0)
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN	0	(0.0)	0	(0.0)	0	(0.0)
STUDY TERMINATED BY SPONSOR	0	(0.0)	0	(0.0)	0	(0.0)
OTHER	0	(0.0)	0	(0.0)	0	(0.0)
FULL ANALYSIS POPULATION	596	(99.3)	1198	(99.8)	1794	(99.7)
PER-PROTOCOL POPULATION	595	(99.2)	1198	(99.8)	1793	(99.6)
SAFETY POPULATION	600	(100.0)	1200	(100.0)	1800	(100.0)

Percentages are based on the number of subjects vaccinated.

Subject 10705 has completed Visit 2 and Visit 4 safety assessment but did not attended Visit 3.

Source Data: Listing 16.2.1.1, 16.2.1.3 and 16.2.3.1

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Table 14.1.1.1
Disposition
All Enrolled Subjects

Age Group: Missing

	Menactra® n (%)	NmCV-5 n (%)	Total n (%)
TOTAL NUMBER OF SUBJECTS			
ENROLLED			8
Mali			0
The Gambia			8
SCREEN FAILURE			0
Mali			0
The Gambia			0
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN BEFORE RANDOMIZATION			8
Mali			0
The Gambia			8
RANDOMIZED	0	0	0
Mali	0	0	0
The Gambia	0	0	0
VACCINATED	0	0	0
Mali	0	0	0
The Gambia	0	0	0
VACCINATED AS PER RANDOMIZATION	0	0	0
Mali	0	0	0
The Gambia	0	0	0
COMPLETED VISIT 1 (DAY 1) HAVING BASELINE IMMUNOGENICITY RESULTS			
COMPLETED VISIT 2 (DAY 8)			
COMPLETED VISIT 3 (DAY 29) HAVING IMMUNOGENICITY RESULTS			
COMPLETED SAFETY FOLLOW-UP TILL VISIT 4 (DAY 169) VISIT 4 ASSESSMENTS PERFORMED AT SITE			
VISIT 4 ASSESSMENTS PERFORMED TELEPHONICALLY			

Percentages are based on the number of subjects vaccinated.

Subject 10705 has completed Visit 2 and Visit 4 safety assessment but did not attended Visit 3.

Source Data: Listing 16.2.1.1, 16.2.1.3 and 16.2.3.1

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Executed: 22OCT2021

Table 14.1.1.1
Disposition
All Enrolled Subjects

Age Group: Missing

	Menactra® n (%)	NmCV-5 n (%)	Total n (%)
DISCONTINUED FROM VISIT 1 TILL VISIT 2			
PRIMARY REASON FOR DISCONTINUATION			
ADVERSE EVENT			
DEATH			
LOST TO FOLLOW-UP			
INVESTIGATOR DECISION			
PROTOCOL DEVIATION			
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN			
STUDY TERMINATED BY SPONSOR			
OTHER			
DISCONTINUED POST VISIT 2 TILL VISIT 3			
PRIMARY REASON FOR DISCONTINUATION			
ADVERSE EVENT			
DEATH			
LOST TO FOLLOW-UP			
INVESTIGATOR DECISION			
PROTOCOL DEVIATION			
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN			
STUDY TERMINATED BY SPONSOR			
OTHER			

Percentages are based on the number of subjects vaccinated.

Subject 10705 has completed Visit 2 and Visit 4 safety assessment but did not attended Visit 3.

Source Data: Listing 16.2.1.1, 16.2.1.3 and 16.2.3.1

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Executed: 22OCT2021

Table 14.1.1.1
Disposition
All Enrolled Subjects

Age Group: Missing

	Menactra® n (%)	NmCV-5 n (%)	Total n (%)
DISCONTINUED POST VISIT 3 TILL VISIT 4 SAFETY ASSESSMENT			
PRIMARY REASON FOR DISCONTINUATION			
ADVERSE EVENT			
DEATH			
LOST TO FOLLOW-UP			
INVESTIGATOR DECISION			
PROTOCOL DEVIATION			
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN			
STUDY TERMINATED BY SPONSOR			
OTHER			
FULL ANALYSIS POPULATION			
PER-PROTOCOL POPULATION			
SAFETY POPULATION			

Percentages are based on the number of subjects vaccinated.

Subject 10705 has completed Visit 2 and Visit 4 safety assessment but did not attended Visit 3.

Source Data: Listing 16.2.1.1, 16.2.1.3 and 16.2.3.1

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Executed: 22OCT2021

Table 14.1.1.1
Disposition
All Enrolled Subjects

Age Group: 2 to 10 years

	Menactra® n (%)	NmCV-5 n (%)	Total n (%)
TOTAL NUMBER OF SUBJECTS			
ENROLLED			605
Mali			301
The Gambia			304
SCREEN FAILURE			5
Mali			1
The Gambia			4
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN BEFORE RANDOMIZATION			0
Mali			0
The Gambia			0
RANDOMIZED	200	400	600
Mali	100	200	300
The Gambia	100	200	300
VACCINATED	200	400	600
Mali	100	200	300
The Gambia	100	200	300
VACCINATED AS PER RANDOMIZATION	200	400	600
Mali	100	200	300
The Gambia	100	200	300
COMPLETED VISIT 1 (DAY 1) HAVING BASELINE IMMUNOGENICITY RESULTS	200 (100.0)	400 (100.0)	600 (100.0)
COMPLETED VISIT 2 (DAY 8)	200 (100.0)	399 (99.8)	599 (99.8)
COMPLETED VISIT 3 (DAY 29) HAVING IMMUNOGENICITY RESULTS	200 (100.0)	399 (99.8)	599 (99.8)
COMPLETED SAFETY FOLLOW-UP TILL VISIT 4 (DAY 169)	200 (100.0)	399 (99.8)	599 (99.8)
VISIT 4 ASSESSMENTS PERFORMED AT SITE	94 (47.0)	187 (46.8)	281 (46.8)
VISIT 4 ASSESSMENTS PERFORMED TELEPHONICALLY	106 (53.0)	212 (53.0)	318 (53.0)

Percentages are based on the number of subjects vaccinated.

Subject 10705 has completed Visit 2 and Visit 4 safety assessment but did not attended Visit 3.

Source Data: Listing 16.2.1.1, 16.2.1.3 and 16.2.3.1

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Table 14.1.1.1
Disposition
All Enrolled Subjects

Age Group: 2 to 10 years

	Menactra® n (%)	NmCV-5 n (%)	Total n (%)
DISCONTINUED FROM VISIT 1 TILL VISIT 2	0 (0.0)	1 (0.3)	1 (0.2)
PRIMARY REASON FOR DISCONTINUATION			
ADVERSE EVENT	0 (0.0)	0 (0.0)	0 (0.0)
DEATH	0 (0.0)	0 (0.0)	0 (0.0)
LOST TO FOLLOW-UP	0 (0.0)	0 (0.0)	0 (0.0)
INVESTIGATOR DECISION	0 (0.0)	0 (0.0)	0 (0.0)
PROTOCOL DEVIATION	0 (0.0)	0 (0.0)	0 (0.0)
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN	0 (0.0)	1 (0.3)	1 (0.2)
STUDY TERMINATED BY SPONSOR	0 (0.0)	0 (0.0)	0 (0.0)
OTHER	0 (0.0)	0 (0.0)	0 (0.0)
DISCONTINUED POST VISIT 2 TILL VISIT 3	0 (0.0)	0 (0.0)	0 (0.0)
PRIMARY REASON FOR DISCONTINUATION			
ADVERSE EVENT	0 (0.0)	0 (0.0)	0 (0.0)
DEATH	0 (0.0)	0 (0.0)	0 (0.0)
LOST TO FOLLOW-UP	0 (0.0)	0 (0.0)	0 (0.0)
INVESTIGATOR DECISION	0 (0.0)	0 (0.0)	0 (0.0)
PROTOCOL DEVIATION	0 (0.0)	0 (0.0)	0 (0.0)
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN	0 (0.0)	0 (0.0)	0 (0.0)
STUDY TERMINATED BY SPONSOR	0 (0.0)	0 (0.0)	0 (0.0)
OTHER	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of subjects vaccinated.

Subject 10705 has completed Visit 2 and Visit 4 safety assessment but did not attended Visit 3.

Source Data: Listing 16.2.1.1, 16.2.1.3 and 16.2.3.1

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Table 14.1.1.1
Disposition
All Enrolled Subjects

Age Group: 2 to 10 years

	Menactra® n (%)	NmCV-5 n (%)	Total n (%)
DISCONTINUED POST VISIT 3 TILL VISIT 4 SAFETY ASSESSMENT	0 (0.0)	0 (0.0)	0 (0.0)
PRIMARY REASON FOR DISCONTINUATION			
ADVERSE EVENT	0 (0.0)	0 (0.0)	0 (0.0)
DEATH	0 (0.0)	0 (0.0)	0 (0.0)
LOST TO FOLLOW-UP	0 (0.0)	0 (0.0)	0 (0.0)
INVESTIGATOR DECISION	0 (0.0)	0 (0.0)	0 (0.0)
PROTOCOL DEVIATION	0 (0.0)	0 (0.0)	0 (0.0)
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN	0 (0.0)	0 (0.0)	0 (0.0)
STUDY TERMINATED BY SPONSOR	0 (0.0)	0 (0.0)	0 (0.0)
OTHER	0 (0.0)	0 (0.0)	0 (0.0)
FULL ANALYSIS POPULATION	200 (100.0)	399 (99.8)	599 (99.8)
PER-PROTOCOL POPULATION	200 (100.0)	399 (99.8)	599 (99.8)
SAFETY POPULATION	200 (100.0)	400 (100.0)	600 (100.0)

Percentages are based on the number of subjects vaccinated.

Subject 10705 has completed Visit 2 and Visit 4 safety assessment but did not attended Visit 3.

Source Data: Listing 16.2.1.1, 16.2.1.3 and 16.2.3.1

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Table 14.1.1.1
Disposition
All Enrolled Subjects

Age Group: 11 to 17 years

	Menactra® n (%)	NmCV-5 n (%)	Total n (%)
TOTAL NUMBER OF SUBJECTS			
ENROLLED			607
Mali			301
The Gambia			306
SCREEN FAILURE			7
Mali			1
The Gambia			6
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN BEFORE RANDOMIZATION			0
Mali			0
The Gambia			0
RANDOMIZED	200	400	600
Mali	100	200	300
The Gambia	100	200	300
VACCINATED	200	400	600
Mali	100	200	300
The Gambia	100	200	300
VACCINATED AS PER RANDOMIZATION	200	400	600
Mali	100	200	300
The Gambia	100	200	300
COMPLETED VISIT 1 (DAY 1)	200 (100.0)	400 (100.0)	600 (100.0)
HAVING BASELINE IMMUNOGENICITY RESULTS	200 (100.0)	399 (99.8)	599 (99.8)
COMPLETED VISIT 2 (DAY 8)	200 (100.0)	400 (100.0)	600 (100.0)
COMPLETED VISIT 3 (DAY 29)	199 (99.5)	399 (99.8)	598 (99.7)
HAVING IMMUNOGENICITY RESULTS	199 (99.5)	399 (99.8)	598 (99.7)
COMPLETED SAFETY FOLLOW-UP TILL VISIT 4 (DAY 169)	200 (100.0)	399 (99.8)	599 (99.8)
VISIT 4 ASSESSMENTS PERFORMED AT SITE	33 (16.5)	69 (17.3)	102 (17.0)
VISIT 4 ASSESSMENTS PERFORMED TELEPHONICALLY	167 (83.5)	330 (82.5)	497 (82.8)

Percentages are based on the number of subjects vaccinated.

Subject 10705 has completed Visit 2 and Visit 4 safety assessment but did not attended Visit 3.

Source Data: Listing 16.2.1.1, 16.2.1.3 and 16.2.3.1

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Table 14.1.1.1
Disposition
All Enrolled Subjects

Age Group: 11 to 17 years

	Menactra® n (%)	NmCV-5 n (%)	Total n (%)
DISCONTINUED FROM VISIT 1 TILL VISIT 2	0 (0.0)	0 (0.0)	0 (0.0)
PRIMARY REASON FOR DISCONTINUATION			
ADVERSE EVENT	0 (0.0)	0 (0.0)	0 (0.0)
DEATH	0 (0.0)	0 (0.0)	0 (0.0)
LOST TO FOLLOW-UP	0 (0.0)	0 (0.0)	0 (0.0)
INVESTIGATOR DECISION	0 (0.0)	0 (0.0)	0 (0.0)
PROTOCOL DEVIATION	0 (0.0)	0 (0.0)	0 (0.0)
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN	0 (0.0)	0 (0.0)	0 (0.0)
STUDY TERMINATED BY SPONSOR	0 (0.0)	0 (0.0)	0 (0.0)
OTHER	0 (0.0)	0 (0.0)	0 (0.0)
DISCONTINUED POST VISIT 2 TILL VISIT 3	0 (0.0)	1 (0.3)	1 (0.2)
PRIMARY REASON FOR DISCONTINUATION			
ADVERSE EVENT	0 (0.0)	0 (0.0)	0 (0.0)
DEATH	0 (0.0)	0 (0.0)	0 (0.0)
LOST TO FOLLOW-UP	0 (0.0)	0 (0.0)	0 (0.0)
INVESTIGATOR DECISION	0 (0.0)	0 (0.0)	0 (0.0)
PROTOCOL DEVIATION	0 (0.0)	0 (0.0)	0 (0.0)
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN	0 (0.0)	1 (0.3)	1 (0.2)
STUDY TERMINATED BY SPONSOR	0 (0.0)	0 (0.0)	0 (0.0)
OTHER	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of subjects vaccinated.

Subject 10705 has completed Visit 2 and Visit 4 safety assessment but did not attended Visit 3.

Source Data: Listing 16.2.1.1, 16.2.1.3 and 16.2.3.1

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Table 14.1.1.1
Disposition
All Enrolled Subjects

Age Group: 11 to 17 years

	Menactra®		NmCV-5		Total	
	n	(%)	n	(%)	n	(%)
DISCONTINUED POST VISIT 3 TILL VISIT 4 SAFETY ASSESSMENT	0	(0.0)	0	(0.0)	0	(0.0)
PRIMARY REASON FOR DISCONTINUATION						
ADVERSE EVENT	0	(0.0)	0	(0.0)	0	(0.0)
DEATH	0	(0.0)	0	(0.0)	0	(0.0)
LOST TO FOLLOW-UP	0	(0.0)	0	(0.0)	0	(0.0)
INVESTIGATOR DECISION	0	(0.0)	0	(0.0)	0	(0.0)
PROTOCOL DEVIATION	0	(0.0)	0	(0.0)	0	(0.0)
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN	0	(0.0)	0	(0.0)	0	(0.0)
STUDY TERMINATED BY SPONSOR	0	(0.0)	0	(0.0)	0	(0.0)
OTHER	0	(0.0)	0	(0.0)	0	(0.0)
FULL ANALYSIS POPULATION	199	(99.5)	399	(99.8)	598	(99.7)
PER-PROTOCOL POPULATION	199	(99.5)	399	(99.8)	598	(99.7)
SAFETY POPULATION	200	(100.0)	400	(100.0)	600	(100.0)

Percentages are based on the number of subjects vaccinated.

Subject 10705 has completed Visit 2 and Visit 4 safety assessment but did not attended Visit 3.

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Table 14.1.1.1
Disposition
All Enrolled Subjects

Age Group: 18 to 29 years

	Menactra® n (%)	NmCV-5 n (%)	Total n (%)
TOTAL NUMBER OF SUBJECTS			
ENROLLED			649
Mali			305
The Gambia			344
SCREEN FAILURE			49
Mali			5
The Gambia			44
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN BEFORE RANDOMIZATION			0
Mali			0
The Gambia			0
RANDOMIZED	200	400	600
Mali	100	200	300
The Gambia	100	200	300
VACCINATED	200	400	600
Mali	100	200	300
The Gambia	100	200	300
VACCINATED AS PER RANDOMIZATION	200	400	600
Mali	100	200	300
The Gambia	100	200	300
COMPLETED VISIT 1 (DAY 1)	200 (100.0)	400 (100.0)	600 (100.0)
HAVING BASELINE IMMUNOGENICITY RESULTS	197 (98.5)	400 (100.0)	597 (99.5)
COMPLETED VISIT 2 (DAY 8)	199 (99.5)	400 (100.0)	599 (99.8)
COMPLETED VISIT 3 (DAY 29)	198 (99.0)	400 (100.0)	598 (99.7)
HAVING IMMUNOGENICITY RESULTS	197 (98.5)	400 (100.0)	597 (99.5)
COMPLETED SAFETY FOLLOW-UP TILL VISIT 4 (DAY 169)	197 (98.5)	400 (100.0)	597 (99.5)
VISIT 4 ASSESSMENTS PERFORMED AT SITE	35 (17.5)	67 (16.8)	102 (17.0)
VISIT 4 ASSESSMENTS PERFORMED TELEPHONICALLY	162 (81.0)	333 (83.3)	495 (82.5)

Percentages are based on the number of subjects vaccinated.

Subject 10705 has completed Visit 2 and Visit 4 safety assessment but did not attended Visit 3.

Source Data: Listing 16.2.1.1, 16.2.1.3 and 16.2.3.1

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Table 14.1.1.1
Disposition
All Enrolled Subjects

Age Group: 18 to 29 years

	Menactra® n (%)	NmCV-5 n (%)	Total n (%)
DISCONTINUED FROM VISIT 1 TILL VISIT 2	1 (0.5)	0 (0.0)	1 (0.2)
PRIMARY REASON FOR DISCONTINUATION			
ADVERSE EVENT	0 (0.0)	0 (0.0)	0 (0.0)
DEATH	0 (0.0)	0 (0.0)	0 (0.0)
LOST TO FOLLOW-UP	0 (0.0)	0 (0.0)	0 (0.0)
INVESTIGATOR DECISION	0 (0.0)	0 (0.0)	0 (0.0)
PROTOCOL DEVIATION	0 (0.0)	0 (0.0)	0 (0.0)
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN	1 (0.5)	0 (0.0)	1 (0.2)
STUDY TERMINATED BY SPONSOR	0 (0.0)	0 (0.0)	0 (0.0)
OTHER	0 (0.0)	0 (0.0)	0 (0.0)
DISCONTINUED POST VISIT 2 TILL VISIT 3	1 (0.5)	0 (0.0)	1 (0.2)
PRIMARY REASON FOR DISCONTINUATION			
ADVERSE EVENT	0 (0.0)	0 (0.0)	0 (0.0)
DEATH	0 (0.0)	0 (0.0)	0 (0.0)
LOST TO FOLLOW-UP	0 (0.0)	0 (0.0)	0 (0.0)
INVESTIGATOR DECISION	0 (0.0)	0 (0.0)	0 (0.0)
PROTOCOL DEVIATION	0 (0.0)	0 (0.0)	0 (0.0)
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN	1 (0.5)	0 (0.0)	1 (0.2)
STUDY TERMINATED BY SPONSOR	0 (0.0)	0 (0.0)	0 (0.0)
OTHER	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of subjects vaccinated.

Subject 10705 has completed Visit 2 and Visit 4 safety assessment but did not attended Visit 3.

Source Data: Listing 16.2.1.1, 16.2.1.3 and 16.2.3.1

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DL1\TLF\t14010101.sas

Executed: 22OCT2021

Table 14.1.1.1
Disposition
All Enrolled Subjects

Age Group: 18 to 29 years

	Menactra®		NmCV-5		Total	
	n (%)		n (%)		n (%)	
DISCONTINUED POST VISIT 3 TILL VISIT 4 SAFETY ASSESSMENT	1	(0.5)	0	(0.0)	1	(0.2)
PRIMARY REASON FOR DISCONTINUATION						
ADVERSE EVENT	0	(0.0)	0	(0.0)	0	(0.0)
DEATH	1	(0.5)	0	(0.0)	1	(0.2)
LOST TO FOLLOW-UP	0	(0.0)	0	(0.0)	0	(0.0)
INVESTIGATOR DECISION	0	(0.0)	0	(0.0)	0	(0.0)
PROTOCOL DEVIATION	0	(0.0)	0	(0.0)	0	(0.0)
WITHDRAWAL BY SUBJECT OR PARENT/GUARDIAN	0	(0.0)	0	(0.0)	0	(0.0)
STUDY TERMINATED BY SPONSOR	0	(0.0)	0	(0.0)	0	(0.0)
OTHER	0	(0.0)	0	(0.0)	0	(0.0)
FULL ANALYSIS POPULATION	197	(98.5)	400	(100.0)	597	(99.5)
PER-PROTOCOL POPULATION	196	(98.0)	400	(100.0)	596	(99.3)
SAFETY POPULATION	200	(100.0)	400	(100.0)	600	(100.0)

Percentages are based on the number of subjects vaccinated.

Subject 10705 has completed Visit 2 and Visit 4 safety assessment but did not attended Visit 3.

Source Data: Listing 16.2.1.1, 16.2.1.3 and 16.2.3.1

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DL1\TLF\t14010101.sas

Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: Overall

	Menactra® (N=600)	NmCV-5 (N=1,200)	Total (N=1,800)	p-value
AGE (Years) *				0.673
n	600	1200	1800	
MEAN (SD)	13.6 (7.19)	13.8 (7.12)	13.7 (7.14)	
MEDIAN	13.0	13.0	13.0	
MIN, MAX	2, 29	2, 29	2, 29	
SEX n (%) **				0.789
MALE	293 (48.8)	594 (49.5)	887 (49.3)	
FEMALE	307 (51.2)	606 (50.5)	913 (50.7)	
RACE AS COLLECTED n (%) **				NE
BLACK	600 (100.0)	1200 (100.0)	1800 (100.0)	
OTHER	0 (0.0)	0 (0.0)	0 (0.0)	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DL1\TLF\t14010104.sas

Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: Overall

	Menactra® (N=600)	NmCV-5 (N=1,200)	Total (N=1,800)	p-value
ETHNICITY n (%)**				0.224
MANDINKA/MALINKE	258 (43.0)	523 (43.6)	781 (43.4)	
WOLOF	25 (4.2)	35 (2.9)	60 (3.3)	
FULA/PEULH	78 (13.0)	151 (12.6)	229 (12.7)	
JOLA	27 (4.5)	76 (6.3)	103 (5.7)	
SERAHULE/SARAKOLE	35 (5.8)	51 (4.3)	86 (4.8)	
SERERE	6 (1.0)	22 (1.8)	28 (1.6)	
MANJANGO	2 (0.3)	1 (0.1)	3 (0.2)	
BAMBARA	123 (20.5)	234 (19.5)	357 (19.8)	
NOT REPORTED	0 (0.0)	0 (0.0)	0 (0.0)	
OTHER	46 (7.7)	107 (8.9)	153 (8.5)	
UNKNOWN	0 (0.0)	0 (0.0)	0 (0.0)	
HEIGHT (CM)***				0.179
n	600	1200	1800	
MEAN (SD)	144.4 (27.04)	145.3 (26.48)	145.0 (26.67)	
MEDIAN	154.0	153.0	154.0	
MIN, MAX	79, 192	76, 192	76, 192	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DL1\TLF\t14010104.sas

Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: Overall

	Menactra® (N=600)	NmCV-5 (N=1,200)	Total (N=1,800)	p-value
WEIGHT (KG) ***				0.440
n	600	1200	1800	
MEAN (SD)	41.46 (20.625)	41.87 (20.508)	41.73 (20.542)	
MEDIAN	41.70	43.25	42.35	
MIN, MAX	8.0, 127.6	8.7, 115.6	8.0, 127.6	
WEIGHT-FOR-HEIGHT Z-SCORE LESS THAN -3 [a]				NOT ASSESSED
NO	110 (18.3)	185 (15.4)	295 (16.4)	
YES	0 (0.0)	0 (0.0)	0 (0.0)	
NOT APPLICABLE	490 (81.7)	1015 (84.6)	1505 (83.6)	
CHILD-BEARING POTENTIAL [b]				NOT ASSESSED
NO	108 (35.2)	215 (35.5)	323 (35.4)	
YES	199 (64.8)	391 (64.5)	590 (64.6)	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DL1\TLF\t14010104.sas

Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: Overall

	Menactra® (N=600)	NmCV-5 (N=1,200)	Total (N=1,800)	p-value
TEMPERATURE (C)				NOT ASSESSED
n	600	1200	1800	
MEAN (SD)	36.27 (0.398)	36.28 (0.408)	36.28 (0.405)	
MEDIAN	36.20	36.20	36.20	
MIN, MAX	35.2, 37.3	34.7, 37.3	34.7, 37.3	
PULSE RATE (BEATS/MIN)				NOT ASSESSED
n	600	1200	1800	
MEAN (SD)	83.3 (13.82)	82.8 (13.76)	83.0 (13.78)	
MEDIAN	80.0	81.0	80.5	
MIN, MAX	50, 132	50, 138	50, 138	
RESPIRATORY RATE (BREATHS/MIN)				NOT ASSESSED
n	600	1200	1800	
MEAN (SD)	21.0 (3.68)	20.9 (3.58)	20.9 (3.62)	
MEDIAN	20.0	20.0	20.0	
MIN, MAX	14, 36	12, 40	12, 40	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DL1\TLF\t14010104.sas

Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: Overall

	Menactra® (N=600)	NmCV-5 (N=1,200)	Total (N=1,800)	p-value
SYSTOLIC BLOOD PRESSURE (mmHg) [c]				NOT ASSESSED
n	333	650	983	
MEAN (SD)	112.4 (10.33)	113.6 (10.51)	113.2 (10.46)	
MEDIAN	110.0	111.0	110.0	
MIN, MAX	86, 150	66, 140	66, 150	
DIASTOLIC BLOOD PRESSURE (mmHg) [c]				NOT ASSESSED
n	333	650	983	
MEAN (SD)	71.8 (8.29)	72.6 (8.29)	72.3 (8.30)	
MEDIAN	70.0	71.0	70.0	
MIN, MAX	44, 97	45, 100	44, 100	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DL1\TLF\t14010104.sas

Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: 2 to 10 years

	Menactra® (N=200)	NmCV-5 (N=400)	Total (N=600)	p-value
AGE (Years) *				0.099
n	200	400	600	
MEAN (SD)	5.4 (2.35)	5.8 (2.49)	5.7 (2.45)	
MEDIAN	5.0	6.0	6.0	
MIN, MAX	2, 10	2, 10	2, 10	
SEX n (%) **				0.602
MALE	106 (53.0)	221 (55.3)	327 (54.5)	
FEMALE	94 (47.0)	179 (44.8)	273 (45.5)	
RACE AS COLLECTED n (%) **				NE
BLACK	200 (100.0)	400 (100.0)	600 (100.0)	
OTHER	0 (0.0)	0 (0.0)	0 (0.0)	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DL1\TLF\t14010104.sas

Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: 2 to 10 years

	Menactra® (N=200)	NmCV-5 (N=400)	Total (N=600)	p-value
ETHNICITY n (%)**				0.893
MANDINKA/MALINKE	87 (43.5)	174 (43.5)	261 (43.5)	
WOLOF	6 (3.0)	12 (3.0)	18 (3.0)	
FULA/PEULH	30 (15.0)	55 (13.8)	85 (14.2)	
JOLA	9 (4.5)	26 (6.5)	35 (5.8)	
SERAHULE/SARAKOLE	10 (5.0)	15 (3.8)	25 (4.2)	
SERERE	5 (2.5)	6 (1.5)	11 (1.8)	
MANJANGO	0 (0.0)	0 (0.0)	0 (0.0)	
BAMBARA	41 (20.5)	92 (23.0)	133 (22.2)	
NOT REPORTED	0 (0.0)	0 (0.0)	0 (0.0)	
OTHER	12 (6.0)	20 (5.0)	32 (5.3)	
UNKNOWN	0 (0.0)	0 (0.0)	0 (0.0)	
HEIGHT (CM)***				0.131
n	200	400	600	
MEAN (SD)	111.3 (16.43)	113.5 (17.33)	112.8 (17.05)	
MEDIAN	112.0	114.0	114.0	
MIN, MAX	79, 169	76, 167	76, 169	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DL1\TLF\t14010104.sas

Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: 2 to 10 years

	Menactra® (N=200)	NmCV-5 (N=400)	Total (N=600)	p-value
WEIGHT (KG) ***				0.091
n	200	400	600	
MEAN (SD)	18.52 (5.779)	19.42 (6.799)	19.12 (6.486)	
MEDIAN	17.85	18.30	18.25	
MIN, MAX	8.0, 36.5	8.7, 64.6	8.0, 64.6	
WEIGHT-FOR-HEIGHT Z-SCORE LESS THAN -3 [a]				NOT ASSESSED
NO	110 (55.0)	185 (46.3)	295 (49.2)	
YES	0 (0.0)	0 (0.0)	0 (0.0)	
NOT APPLICABLE	90 (45.0)	215 (53.8)	305 (50.8)	
CHILD-BEARING POTENTIAL [b]				NOT ASSESSED
NO	94 (100.0)	179 (100.0)	273 (100.0)	
YES	0 (0.0)	0 (0.0)	0 (0.0)	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

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Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: 2 to 10 years

	Menactra® (N=200)	NmCV-5 (N=400)	Total (N=600)	p-value
TEMPERATURE (C)				NOT ASSESSED
n	200	400	600	
MEAN (SD)	36.31 (0.381)	36.28 (0.378)	36.29 (0.379)	
MEDIAN	36.30	36.20	36.30	
MIN, MAX	35.2, 37.2	35.2, 37.2	35.2, 37.2	
PULSE RATE (BEATS/MIN)				NOT ASSESSED
n	200	400	600	
MEAN (SD)	93.6 (13.60)	93.0 (13.89)	93.2 (13.79)	
MEDIAN	92.0	91.5	92.0	
MIN, MAX	66, 132	54, 138	54, 138	
RESPIRATORY RATE (BREATHS/MIN)				NOT ASSESSED
n	200	400	600	
MEAN (SD)	24.4 (3.65)	24.0 (3.77)	24.1 (3.73)	
MEDIAN	24.0	24.0	24.0	
MIN, MAX	17, 36	15, 40	15, 40	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DL1\TLF\t14010104.sas

Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: 11 to 17 years

	Menactra® (N=200)	NmCV-5 (N=400)	Total (N=600)	p-value
AGE (Years) *				0.653
n	200	400	600	
MEAN (SD)	13.6 (1.94)	13.5 (1.92)	13.5 (1.93)	
MEDIAN	13.0	13.0	13.0	
MIN, MAX	11, 17	11, 17	11, 17	
SEX n (%) **				0.326
MALE	98 (49.0)	213 (53.3)	311 (51.8)	
FEMALE	102 (51.0)	187 (46.8)	289 (48.2)	
RACE AS COLLECTED n (%) **				NE
BLACK	200 (100.0)	400 (100.0)	600 (100.0)	
OTHER	0 (0.0)	0 (0.0)	0 (0.0)	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DL1\TLF\t14010104.sas

Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: 11 to 17 years

	Menactra® (N=200)	NmCV-5 (N=400)	Total (N=600)	p-value
ETHNICITY n (%)**				0.223
MANDINKA/MALINKE	87 (43.5)	167 (41.8)	254 (42.3)	
WOLOF	9 (4.5)	12 (3.0)	21 (3.5)	
FULA/PEULH	26 (13.0)	52 (13.0)	78 (13.0)	
JOLA	9 (4.5)	29 (7.3)	38 (6.3)	
SERAHULE/SARAKOLE	8 (4.0)	14 (3.5)	22 (3.7)	
SERERE	0 (0.0)	8 (2.0)	8 (1.3)	
MANJANGO	2 (1.0)	0 (0.0)	2 (0.3)	
BAMBARA	42 (21.0)	84 (21.0)	126 (21.0)	
NOT REPORTED	0 (0.0)	0 (0.0)	0 (0.0)	
OTHER	17 (8.5)	34 (8.5)	51 (8.5)	
UNKNOWN	0 (0.0)	0 (0.0)	0 (0.0)	
HEIGHT (CM)***				0.926
n	200	400	600	
MEAN (SD)	155.0 (11.47)	154.9 (11.57)	155.0 (11.53)	
MEDIAN	155.0	155.0	155.0	
MIN, MAX	126, 185	126, 188	126, 188	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DL1\TLF\t14010104.sas

Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: 11 to 17 years

	Menactra® (N=200)	NmCV-5 (N=400)	Total (N=600)	p-value
WEIGHT (KG) ***				0.882
n	200	400	600	
MEAN (SD)	44.19 (12.068)	44.35 (12.784)	44.30 (12.540)	
MEDIAN	41.95	43.65	43.40	
MIN, MAX	21.0, 97.5	23.4, 115.6	21.0, 115.6	
CHILD-BEARING POTENTIAL [b]				NOT ASSESSED
NO	14 (13.7)	36 (19.3)	50 (17.3)	
YES	88 (86.3)	151 (80.7)	239 (82.7)	
TEMPERATURE (C)				NOT ASSESSED
n	200	400	600	
MEAN (SD)	36.26 (0.378)	36.27 (0.396)	36.27 (0.390)	
MEDIAN	36.20	36.20	36.20	
MIN, MAX	35.2, 37.3	35.1, 37.2	35.1, 37.3	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DBL1\TLF\t14010104.sas

Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: 11 to 17 years

	Menactra® (N=200)	NmCV-5 (N=400)	Total (N=600)	p-value
PULSE RATE (BEATS/MIN)				NOT ASSESSED
n	200	400	600	
MEAN (SD)	79.6 (10.81)	79.4 (10.09)	79.5 (10.32)	
MEDIAN	79.0	79.0	79.0	
MIN, MAX	53, 110	51, 113	51, 113	
RESPIRATORY RATE (BREATHS/MIN)				NOT ASSESSED
n	200	400	600	
MEAN (SD)	20.0 (2.18)	20.0 (2.18)	20.0 (2.18)	
MEDIAN	20.0	20.0	20.0	
MIN, MAX	15, 26	14, 28	14, 28	
SYSTOLIC BLOOD PRESSURE (mmHg) [c]				NOT ASSESSED
n	133	250	383	
MEAN (SD)	109.2 (9.30)	110.8 (10.00)	110.2 (9.78)	
MEDIAN	110.0	110.0	110.0	
MIN, MAX	88, 139	66, 139	66, 139	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DL1\TLF\t14010104.sas

Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: 11 to 17 years

	Menactra® (N=200)	NmCV-5 (N=400)	Total (N=600)	p-value
DIASTOLIC BLOOD PRESSURE (mmHg) [c]				NOT ASSESSED
n	133	250	383	
MEAN (SD)	68.8 (7.84)	70.4 (8.44)	69.8 (8.26)	
MEDIAN	70.0	70.0	70.0	
MIN, MAX	44, 84	45, 91	44, 91	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

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Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: 18 to 29 years

	Menactra® (N=200)	NmCV-5 (N=400)	Total (N=600)	p-value
AGE (Years) *				0.522
n	200	400	600	
MEAN (SD)	21.9 (3.25)	22.0 (3.17)	22.0 (3.20)	
MEDIAN	21.0	22.0	21.0	
MIN, MAX	18, 29	18, 29	18, 29	
SEX n (%) **				0.292
MALE	89 (44.5)	160 (40.0)	249 (41.5)	
FEMALE	111 (55.5)	240 (60.0)	351 (58.5)	
RACE AS COLLECTED n (%) **				NE
BLACK	200 (100.0)	400 (100.0)	600 (100.0)	
OTHER	0 (0.0)	0 (0.0)	0 (0.0)	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

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Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: 18 to 29 years

	Menactra® (N=200)	NmCV-5 (N=400)	Total (N=600)	p-value
ETHNICITY n (%)**				0.158
MANDINKA/MALINKE	84 (42.0)	182 (45.5)	266 (44.3)	
WOLOF	10 (5.0)	11 (2.8)	21 (3.5)	
FULA/PEULH	22 (11.0)	44 (11.0)	66 (11.0)	
JOLA	9 (4.5)	21 (5.3)	30 (5.0)	
SERAHULE/SARAKOLE	17 (8.5)	22 (5.5)	39 (6.5)	
SERERE	1 (0.5)	8 (2.0)	9 (1.5)	
MANJANGO	0 (0.0)	1 (0.3)	1 (0.2)	
BAMBARA	40 (20.0)	58 (14.5)	98 (16.3)	
NOT REPORTED	0 (0.0)	0 (0.0)	0 (0.0)	
OTHER	17 (8.5)	53 (13.3)	70 (11.7)	
UNKNOWN	0 (0.0)	0 (0.0)	0 (0.0)	
HEIGHT (CM)***				0.537
n	200	400	600	
MEAN (SD)	166.9 (8.67)	167.4 (8.86)	167.2 (8.79)	
MEDIAN	166.0	167.0	167.0	
MIN, MAX	137, 192	130, 192	130, 192	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

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Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: 18 to 29 years

	Menactra® (N=200)	NmCV-5 (N=400)	Total (N=600)	p-value
WEIGHT (KG) ***				0.864
n	200	400	600	
MEAN (SD)	61.66 (12.450)	61.84 (11.958)	61.78 (12.114)	
MEDIAN	60.40	60.55	60.50	
MIN, MAX	38.3, 127.6	34.6, 102.9	34.6, 127.6	
CHILD-BEARING POTENTIAL [b]				NOT ASSESSED
NO	0 (0.0)	0 (0.0)	0 (0.0)	
YES	111 (100.0)	240 (100.0)	351 (100.0)	
TEMPERATURE (C)				NOT ASSESSED
n	200	400	600	
MEAN (SD)	36.25 (0.434)	36.28 (0.448)	36.27 (0.443)	
MEDIAN	36.20	36.30	36.20	
MIN, MAX	35.2, 37.3	34.7, 37.3	34.7, 37.3	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

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Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: 18 to 29 years

	Menactra® (N=200)	NmCV-5 (N=400)	Total (N=600)	p-value
PULSE RATE (BEATS/MIN)				NOT ASSESSED
n	200	400	600	
MEAN (SD)	76.7 (10.39)	76.0 (10.63)	76.2 (10.55)	
MEDIAN	76.0	76.0	76.0	
MIN, MAX	50, 109	50, 113	50, 113	
RESPIRATORY RATE (BREATHS/MIN)				NOT ASSESSED
n	200	400	600	
MEAN (SD)	18.5 (1.92)	18.6 (2.02)	18.6 (1.99)	
MEDIAN	18.0	18.0	18.0	
MIN, MAX	14, 26	12, 26	12, 26	
SYSTOLIC BLOOD PRESSURE (mmHg) [c]				NOT ASSESSED
n	200	400	600	
MEAN (SD)	114.5 (10.45)	115.4 (10.46)	115.1 (10.45)	
MEDIAN	112.0	116.5	115.0	
MIN, MAX	86, 150	83, 140	83, 150	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

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Executed: 22OCT2021

Table 14.1.1.4
Demographics and Baseline Characteristics
Safety Population

Age Group: 18 to 29 years

	Menactra® (N=200)	NmCV-5 (N=400)	Total (N=600)	p-value
DIASTOLIC BLOOD PRESSURE (mmHg) [c]				NOT ASSESSED
n	200	400	600	
MEAN (SD)	73.8 (8.00)	74.0 (7.90)	73.9 (7.93)	
MEDIAN	74.0	74.0	74.0	
MIN, MAX	49, 97	48, 100	48, 100	

[a] Weight-for-height Z-scores are calculated only for subjects between 2-5 years of age.

[b] Female subjects only.

[c] Subjects of age 13 years and older only.

* p-value is calculated using t-test.

** p-value is calculated using Cochran-Mantel-Haenszel with age group as stratification factor for overall summary and using chi-square for by age group summary. For ethnicity, categories with 0 count in both treatment groups are not considered while calculating p-value.

*** p-value is calculated using generalized linear model with age group as independent effect for overall summary and t-test for by age group summary.

NE = Non-Estimable.

Source Data: Listing 16.2.4.1, 16.2.9.2

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Executed: 22OCT2021

Table 14.3.1.1.1
Overall Summary of Adverse Events
Safety Population

Age Group: Overall

Number Of Subjects With	Menactra® (N=600) n (%) [E]		NmCV-5 (N=1,200) n (%) [E]		Total (N=1,800) n (%) [E]	
NON-MISSING SOLICITED LOCAL AND SYSTEMIC AE CRF DATA	599	(99.8)	1199	(99.9)	1798	(99.9)
ANY IMMEDIATE SOLICITED LOCAL ADVERSE EVENT WITHIN THE AT LEAST 30-MINUTES POST-VACCINATION OBSERVATION PERIOD [a]*	10	(1.7) [10]	42	(3.5) [43]	52	(2.9) [53]
ANY IMMEDIATE SOLICITED SYSTEMIC ADVERSE EVENT WITHIN THE AT LEAST 30-MINUTES POST-VACCINATION OBSERVATION PERIOD [a]*	5	(0.8) [5]	10	(0.8) [12]	15	(0.8) [17]
ANY IMMEDIATE UNSOLICITED ADVERSE EVENT WITHIN THE AT LEAST 30-MINUTES POST-VACCINATION OBSERVATION PERIOD [b]	0	(0.0) [0]	0	(0.0) [0]	0	(0.0) [0]
ANY IMMEDIATE ADVERSE EVENT	15	(2.5) [15]	49	(4.1) [55]	64	(3.6) [70]
ANY SOLICITED LOCAL ADVERSE EVENT [a]	115	(19.2) [117]	312	(26.0) [315]	427	(23.7) [432]
ANY SOLICITED SYSTEMIC ADVERSE EVENT [a]	55	(9.2) [78]	133	(11.1) [193]	188	(10.5) [271]
ANY UNSOLICITED ADVERSE EVENT# [b]	99	(16.5) [117]	189	(15.8) [231]	288	(16.0) [348]
ANY NON-SERIOUS ADVERSE EVENT WITHIN 168 DAYS [b]	212	(35.3) [312]	482	(40.2) [739]	694	(38.6) [1051]

* Solicited AEs were collected on Visit 1 (Day 1) after the 30-minute observation period following administration of IP.
#Serious adverse events with onset after Day 29 are excluded from summary. There are 3 unsolicited adverse events with onset after Day 29 (2 onset on Day 30 and 1 onset on Day 32) included in summary.

n represents the number of subjects at each level of summarization.

[E] represents the number of events at each level of summarization. For unsolicited AEs, the number of events includes count of multiple occurrences of same event and count of different events. Whereas, for solicited AEs number of events includes count of different events only.

[a] Percentages are based on the subjects in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[b] Percentages are based on the safety population.

Source Data: Listings 16.2.7.1, 16.2.7.2, 16.2.7.4, 16.2.7.5

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Executed: 22OCT2021

Table 14.3.1.1.1
Overall Summary of Adverse Events
Safety Population

Age Group: Overall

Number Of Subjects With	Menactra® (N=600) n (%) [E]			NmCV-5 (N=1,200) n (%) [E]			Total (N=1,800) n (%) [E]		
ANY SERIOUS ADVERSE EVENT WITHIN 168 DAYS [b]	3	(0.5)	[3]	3	(0.3)	[3]	6	(0.3)	[6]
ANY IP-RELATED UNSOLICITED ADVERSE EVENT# [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
SOLICITED SYSTEMIC ADVERSE EVENT NOT RELATED TO IP [a]	2	(0.3)	[3]	6	(0.5)	[7]	8	(0.4)	[10]
ANY IP-RELATED SERIOUS ADVERSE EVENT WITHIN 168 DAYS [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
ANY STUDY PROCEDURE RELATED UNSOLICITED ADVERSE EVENT# [b]	1	(0.2)	[1]	0	(0.0)	[0]	1	(0.1)	[1]
ANY STUDY PROCEDURE RELATED SERIOUS ADVERSE EVENT WITHIN 168 DAYS [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
ANY UNSOLICITED ADVERSE EVENT LEADING TO TREATMENT GIVEN# [b]	90	(15.0)	[102]	166	(13.8)	[192]	256	(14.2)	[294]
ANY ADVERSE EVENT LEADING TO STUDY DISCONTINUATION [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
ANY ADVERSE EVENT LEADING TO DEATH [b]	1	(0.2)	[1]	0	(0.0)	[0]	1	(0.1)	[1]

* Solicited AEs were collected on Visit 1 (Day 1) after the 30-minute observation period following administration of IP.
#Serious adverse events with onset after Day 29 are excluded from summary. There are 3 unsolicited adverse events with onset after Day 29 (2 onset on Day 30 and 1 onset on Day 32) included in summary.

n represents the number of subjects at each level of summarization.

[E] represents the number of events at each level of summarization. For unsolicited AEs, the number of events includes count of multiple occurrences of same event and count of different events. Whereas, for solicited AEs number of events includes count of different events only.

[a] Percentages are based on the subjects in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[b] Percentages are based on the safety population.

Source Data: Listings 16.2.7.1, 16.2.7.2, 16.2.7.4, 16.2.7.5

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Executed: 22OCT2021

Table 14.3.1.1.1
Overall Summary of Adverse Events
Safety Population

Age Group: 2 to 10 years

Number Of Subjects With	Menactra® (N=200) n (%) [E]	NmCV-5 (N=400) n (%) [E]	Total (N=600) n (%) [E]
NON-MISSING SOLICITED LOCAL AND SYSTEMIC AE CRF DATA	200 (100.0)	399 (99.8)	599 (99.8)
ANY IMMEDIATE SOLICITED LOCAL ADVERSE EVENT WITHIN THE AT LEAST 30-MINUTES POST-VACCINATION OBSERVATION PERIOD [a]*	2 (1.0) [2]	15 (3.8) [15]	17 (2.8) [17]
ANY IMMEDIATE SOLICITED SYSTEMIC ADVERSE EVENT WITHIN THE AT LEAST 30-MINUTES POST-VACCINATION OBSERVATION PERIOD [a]*	0 (0.0) [0]	3 (0.8) [3]	3 (0.5) [3]
ANY IMMEDIATE UNSOLICITED ADVERSE EVENT WITHIN THE AT LEAST 30-MINUTES POST-VACCINATION OBSERVATION PERIOD [b]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
ANY IMMEDIATE ADVERSE EVENT	2 (1.0) [2]	17 (4.3) [18]	19 (3.2) [20]
ANY SOLICITED LOCAL ADVERSE EVENT [a]	19 (9.5) [20]	80 (20.1) [82]	99 (16.5) [102]
ANY SOLICITED SYSTEMIC ADVERSE EVENT [a]	8 (4.0) [9]	30 (7.5) [41]	38 (6.3) [50]
ANY UNSOLICITED ADVERSE EVENT# [b]	36 (18.0) [49]	81 (20.3) [100]	117 (19.5) [149]
ANY NON-SERIOUS ADVERSE EVENT WITHIN 168 DAYS [b]	57 (28.5) [78]	153 (38.3) [223]	210 (35.0) [301]

* Solicited AEs were collected on Visit 1 (Day 1) after the 30-minute observation period following administration of IP.
#Serious adverse events with onset after Day 29 are excluded from summary. There are 3 unsolicited adverse events with onset after Day 29 (2 onset on Day 30 and 1 onset on Day 32) included in summary.

n represents the number of subjects at each level of summarization.

[E] represents the number of events at each level of summarization. For unsolicited AEs, the number of events includes count of multiple occurrences of same event and count of different events. Whereas, for solicited AEs number of events includes count of different events only.

[a] Percentages are based on the subjects in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[b] Percentages are based on the safety population.

Source Data: Listings 16.2.7.1, 16.2.7.2, 16.2.7.4, 16.2.7.5

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Executed: 22OCT2021

Table 14.3.1.1.1
Overall Summary of Adverse Events
Safety Population

Age Group: 2 to 10 years

Number Of Subjects With	Menactra® (N=200)			NmCV-5 (N=400)			Total (N=600)		
	n	(%)	[E]	n	(%)	[E]	n	(%)	[E]
ANY SERIOUS ADVERSE EVENT WITHIN 168 DAYS [b]	2	(1.0)	[2]	0	(0.0)	[0]	2	(0.3)	[2]
ANY IP-RELATED UNSOLICITED ADVERSE EVENT# [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
SOLICITED SYSTEMIC ADVERSE EVENT NOT RELATED TO IP [a]	0	(0.0)	[0]	2	(0.5)	[2]	2	(0.3)	[2]
ANY IP-RELATED SERIOUS ADVERSE EVENT WITHIN 168 DAYS [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
ANY STUDY PROCEDURE RELATED UNSOLICITED ADVERSE EVENT# [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
ANY STUDY PROCEDURE RELATED SERIOUS ADVERSE EVENT WITHIN 168 DAYS [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
ANY UNSOLICITED ADVERSE EVENT LEADING TO TREATMENT GIVEN# [b]	31	(15.5)	[38]	70	(17.5)	[80]	101	(16.8)	[118]
ANY ADVERSE EVENT LEADING TO STUDY DISCONTINUATION [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
ANY ADVERSE EVENT LEADING TO DEATH [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]

* Solicited AEs were collected on Visit 1 (Day 1) after the 30-minute observation period following administration of IP.
#Serious adverse events with onset after Day 29 are excluded from summary. There are 3 unsolicited adverse events with onset after Day 29 (2 onset on Day 30 and 1 onset on Day 32) included in summary.

n represents the number of subjects at each level of summarization.

[E] represents the number of events at each level of summarization. For unsolicited AEs, the number of events includes count of multiple occurrences of same event and count of different events. Whereas, for solicited AEs number of events includes count of different events only.

[a] Percentages are based on the subjects in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[b] Percentages are based on the safety population.

Source Data: Listings 16.2.7.1, 16.2.7.2, 16.2.7.4, 16.2.7.5

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Executed: 22OCT2021

Table 14.3.1.1.1
Overall Summary of Adverse Events
Safety Population

Age Group: 11 to 17 years

Number Of Subjects With	Menactra® (N=200) n (%) [E]	NmCV-5 (N=400) n (%) [E]	Total (N=600) n (%) [E]
NON-MISSING SOLICITED LOCAL AND SYSTEMIC AE CRF DATA	200 (100.0)	400 (100.0)	600 (100.0)
ANY IMMEDIATE SOLICITED LOCAL ADVERSE EVENT WITHIN THE AT LEAST 30-MINUTES POST-VACCINATION OBSERVATION PERIOD [a]*	2 (1.0) [2]	12 (3.0) [12]	14 (2.3) [14]
ANY IMMEDIATE SOLICITED SYSTEMIC ADVERSE EVENT WITHIN THE AT LEAST 30-MINUTES POST-VACCINATION OBSERVATION PERIOD [a]*	3 (1.5) [3]	2 (0.5) [2]	5 (0.8) [5]
ANY IMMEDIATE UNSOLICITED ADVERSE EVENT WITHIN THE AT LEAST 30-MINUTES POST-VACCINATION OBSERVATION PERIOD [b]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
ANY IMMEDIATE ADVERSE EVENT	5 (2.5) [5]	13 (3.3) [14]	18 (3.0) [19]
ANY SOLICITED LOCAL ADVERSE EVENT [a]	45 (22.5) [45]	114 (28.5) [114]	159 (26.5) [159]
ANY SOLICITED SYSTEMIC ADVERSE EVENT [a]	24 (12.0) [29]	50 (12.5) [75]	74 (12.3) [104]
ANY UNSOLICITED ADVERSE EVENT# [b]	25 (12.5) [26]	44 (11.0) [53]	69 (11.5) [79]
ANY NON-SERIOUS ADVERSE EVENT WITHIN 168 DAYS [b]	72 (36.0) [100]	162 (40.5) [242]	234 (39.0) [342]

* Solicited AEs were collected on Visit 1 (Day 1) after the 30-minute observation period following administration of IP.
#Serious adverse events with onset after Day 29 are excluded from summary. There are 3 unsolicited adverse events with onset after Day 29 (2 onset on Day 30 and 1 onset on Day 32) included in summary.

n represents the number of subjects at each level of summarization.

[E] represents the number of events at each level of summarization. For unsolicited AEs, the number of events includes count of multiple occurrences of same event and count of different events. Whereas, for solicited AEs number of events includes count of different events only.

[a] Percentages are based on the subjects in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[b] Percentages are based on the safety population.

Source Data: Listings 16.2.7.1, 16.2.7.2, 16.2.7.4, 16.2.7.5

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Executed: 22OCT2021

Table 14.3.1.1.1
Overall Summary of Adverse Events
Safety Population

Age Group: 11 to 17 years

Number Of Subjects With	Menactra® (N=200)			NmCV-5 (N=400)			Total (N=600)		
	n	(%)	[E]	n	(%)	[E]	n	(%)	[E]
ANY SERIOUS ADVERSE EVENT WITHIN 168 DAYS [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
ANY IP-RELATED UNSOLICITED ADVERSE EVENT# [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
SOLICITED SYSTEMIC ADVERSE EVENT NOT RELATED TO IP [a]	1	(0.5)	[2]	1	(0.3)	[2]	2	(0.3)	[4]
ANY IP-RELATED SERIOUS ADVERSE EVENT WITHIN 168 DAYS [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
ANY STUDY PROCEDURE RELATED UNSOLICITED ADVERSE EVENT# [b]	1	(0.5)	[1]	0	(0.0)	[0]	1	(0.2)	[1]
ANY STUDY PROCEDURE RELATED SERIOUS ADVERSE EVENT WITHIN 168 DAYS [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
ANY UNSOLICITED ADVERSE EVENT LEADING TO TREATMENT GIVEN# [b]	23	(11.5)	[24]	39	(9.8)	[44]	62	(10.3)	[68]
ANY ADVERSE EVENT LEADING TO STUDY DISCONTINUATION [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
ANY ADVERSE EVENT LEADING TO DEATH [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]

* Solicited AEs were collected on Visit 1 (Day 1) after the 30-minute observation period following administration of IP.
#Serious adverse events with onset after Day 29 are excluded from summary. There are 3 unsolicited adverse events with onset after Day 29 (2 onset on Day 30 and 1 onset on Day 32) included in summary.

n represents the number of subjects at each level of summarization.

[E] represents the number of events at each level of summarization. For unsolicited AEs, the number of events includes count of multiple occurrences of same event and count of different events. Whereas, for solicited AEs number of events includes count of different events only.

[a] Percentages are based on the subjects in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[b] Percentages are based on the safety population.

Source Data: Listings 16.2.7.1, 16.2.7.2, 16.2.7.4, 16.2.7.5

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Executed: 22OCT2021

Table 14.3.1.1.1
Overall Summary of Adverse Events
Safety Population

Age Group: 18 to 29 years

Number Of Subjects With	Menactra® (N=200) n (%) [E]	NmCV-5 (N=400) n (%) [E]	Total (N=600) n (%) [E]
NON-MISSING SOLICITED LOCAL AND SYSTEMIC AE CRF DATA	199 (99.5)	400 (100.0)	599 (99.8)
ANY IMMEDIATE SOLICITED LOCAL ADVERSE EVENT WITHIN THE AT LEAST 30-MINUTES POST-VACCINATION OBSERVATION PERIOD [a]*	6 (3.0) [6]	15 (3.8) [16]	21 (3.5) [22]
ANY IMMEDIATE SOLICITED SYSTEMIC ADVERSE EVENT WITHIN THE AT LEAST 30-MINUTES POST-VACCINATION OBSERVATION PERIOD [a]*	2 (1.0) [2]	5 (1.3) [7]	7 (1.2) [9]
ANY IMMEDIATE UNSOLICITED ADVERSE EVENT WITHIN THE AT LEAST 30-MINUTES POST-VACCINATION OBSERVATION PERIOD [b]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
ANY IMMEDIATE ADVERSE EVENT	8 (4.0) [8]	19 (4.8) [23]	27 (4.5) [31]
ANY SOLICITED LOCAL ADVERSE EVENT [a]	51 (25.6) [52]	118 (29.5) [119]	169 (28.2) [171]
ANY SOLICITED SYSTEMIC ADVERSE EVENT [a]	23 (11.6) [40]	53 (13.3) [77]	76 (12.7) [117]
ANY UNSOLICITED ADVERSE EVENT# [b]	38 (19.0) [42]	64 (16.0) [78]	102 (17.0) [120]
ANY NON-SERIOUS ADVERSE EVENT WITHIN 168 DAYS [b]	83 (41.5) [134]	167 (41.8) [274]	250 (41.7) [408]

* Solicited AEs were collected on Visit 1 (Day 1) after the 30-minute observation period following administration of IP.
#Serious adverse events with onset after Day 29 are excluded from summary. There are 3 unsolicited adverse events with onset after Day 29 (2 onset on Day 30 and 1 onset on Day 32) included in summary.

n represents the number of subjects at each level of summarization.

[E] represents the number of events at each level of summarization. For unsolicited AEs, the number of events includes count of multiple occurrences of same event and count of different events. Whereas, for solicited AEs number of events includes count of different events only.

[a] Percentages are based on the subjects in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[b] Percentages are based on the safety population.

Source Data: Listings 16.2.7.1, 16.2.7.2, 16.2.7.4, 16.2.7.5

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Executed: 22OCT2021

Table 14.3.1.1.1
Overall Summary of Adverse Events
Safety Population

Age Group: 18 to 29 years

Number Of Subjects With	Menactra® (N=200)			NmCV-5 (N=400)			Total (N=600)		
	n	(%)	[E]	n	(%)	[E]	n	(%)	[E]
ANY SERIOUS ADVERSE EVENT WITHIN 168 DAYS [b]	1	(0.5)	[1]	3	(0.8)	[3]	4	(0.7)	[4]
ANY IP-RELATED UNSOLICITED ADVERSE EVENT# [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
SOLICITED SYSTEMIC ADVERSE EVENT NOT RELATED TO IP [a]	1	(0.5)	[1]	3	(0.8)	[3]	4	(0.7)	[4]
ANY IP-RELATED SERIOUS ADVERSE EVENT WITHIN 168 DAYS [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
ANY STUDY PROCEDURE RELATED UNSOLICITED ADVERSE EVENT# [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
ANY STUDY PROCEDURE RELATED SERIOUS ADVERSE EVENT WITHIN 168 DAYS [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
ANY UNSOLICITED ADVERSE EVENT LEADING TO TREATMENT GIVEN# [b]	36	(18.0)	[40]	57	(14.3)	[68]	93	(15.5)	[108]
ANY ADVERSE EVENT LEADING TO STUDY DISCONTINUATION [b]	0	(0.0)	[0]	0	(0.0)	[0]	0	(0.0)	[0]
ANY ADVERSE EVENT LEADING TO DEATH [b]	1	(0.5)	[1]	0	(0.0)	[0]	1	(0.2)	[1]

* Solicited AEs were collected on Visit 1 (Day 1) after the 30-minute observation period following administration of IP.
#Serious adverse events with onset after Day 29 are excluded from summary. There are 3 unsolicited adverse events with onset after Day 29 (2 onset on Day 30 and 1 onset on Day 32) included in summary.

n represents the number of subjects at each level of summarization.

[E] represents the number of events at each level of summarization. For unsolicited AEs, the number of events includes count of multiple occurrences of same event and count of different events. Whereas, for solicited AEs number of events includes count of different events only.

[a] Percentages are based on the subjects in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[b] Percentages are based on the safety population.

Source Data: Listings 16.2.7.1, 16.2.7.2, 16.2.7.4, 16.2.7.5

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Table 14.3.1.3.1.1
Solicited Adverse Events
Safety Population

Age Group: Overall

	Menactra® (N=600) n (%)	NmCV-5 (N=1,200) n (%)	Total (N=1,800) n (%)	p-value
SUBJECTS WITH NON-MISSING SOLICITED LOCAL AND SYSTEMIC AE CRF DATA	599	1199	1798	
BELOW 6 YEARS	110	185	295	
6 YEARS AND ABOVE	489	1014	1503	
SUBJECTS WITH SOLICITED ADVERSE EVENTS [a]	143 (23.9)	360 (30.0)	503 (28.0)	0.006
SOLICITED LOCAL ADVERSE EVENTS [a]	115 (19.2)	312 (26.0)	427 (23.7)	0.001
PAIN AT INJECTION SITE	115 (19.2)	311 (25.9)	426 (23.7)	0.001
SWELLING OR INDURATION AT INJECTION SITE	2 (0.3)	4 (0.3)	6 (0.3)	>0.999
SOLICITED SYSTEMIC ADVERSE EVENTS (COMMON IN ALL AGE GROUPS) [a]	15 (2.5)	36 (3.0)	51 (2.8)	0.652
FEVER	5 (0.8)	15 (1.3)	20 (1.1)	0.485
ANOREXIA	9 (1.5)	15 (1.3)	24 (1.3)	0.667
DIARRHEA	2 (0.3)	10 (0.8)	12 (0.7)	0.357

n represents the number of subjects at each level of summarization.

A subject is counted once under solicited local and systemic adverse events if a subject reported one or more events of a particular type.

[a] Percentages are based on the subjects in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[b] Percentages are based on the subjects below 6 years of age in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[c] Percentages are based on the subjects 6 years old and above (for age group 2 to 10 years percentages are based on the subjects 6 to 10 years of age) in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[d] Percentages are based on the subjects in corresponding age group in safety population with non-missing Solicited Local and Systemic AE CRF data.

p-value for comparison of percentages between treatments was calculated using Fisher's exact test at significance level of 0.05.

NE = Non-Estimable.

Source Data: Listings 16.2.7.1, 16.2.7.2

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DBL1\TLF\t140301030101.sas

Executed: 22OCT2021

Table 14.3.1.3.1.1
Solicited Adverse Events
Safety Population

Age Group: Overall

	Menactra® (N=600)		NmCV-5 (N=1,200)		Total (N=1,800)		p-value
	n	(%)	n	(%)	n	(%)	
SOLICITED SYSTEMIC ADVERSE EVENTS (BELOW 6 YEARS) [b]	4	(3.6)	9	(4.9)	13	(4.4)	0.773
FEVER	1	(0.9)	2	(1.1)	3	(1.0)	>0.999
DROWSINESS	0	(0.0)	3	(1.6)	3	(1.0)	0.296
IRRITABILITY	1	(0.9)	4	(2.2)	5	(1.7)	0.654
ANOREXIA	2	(1.8)	2	(1.1)	4	(1.4)	0.631
DIARRHEA	1	(0.9)	2	(1.1)	3	(1.0)	>0.999
SOLICITED SYSTEMIC ADVERSE EVENTS (6 YEARS AND ABOVE) [c]	51	(10.4)	124	(12.2)	175	(11.6)	0.345
FEVER	4	(0.8)	13	(1.3)	17	(1.1)	0.604
FATIGUE	16	(3.3)	38	(3.7)	54	(3.6)	0.768
HEADACHE	29	(5.9)	73	(7.2)	102	(6.8)	0.383
MUSCLE ACHES (MYALGIA)	13	(2.7)	22	(2.2)	35	(2.3)	0.585
JOINT ACHES (ARTHRALGIA)	3	(0.6)	13	(1.3)	16	(1.1)	0.293
ANOREXIA	7	(1.4)	13	(1.3)	20	(1.3)	0.813
DIARRHEA	1	(0.2)	8	(0.8)	9	(0.6)	0.286

n represents the number of subjects at each level of summarization.

A subject is counted once under solicited local and systemic adverse events if a subject reported one or more events of a particular type.

[a] Percentages are based on the subjects in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[b] Percentages are based on the subjects below 6 years of age in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[c] Percentages are based on the subjects 6 years old and above (for age group 2 to 10 years percentages are based on the subjects 6 to 10 years of age) in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[d] Percentages are based on the subjects in corresponding age group in safety population with non-missing Solicited Local and Systemic AE CRF data.

p-value for comparison of percentages between treatments was calculated using Fisher's exact test at significance level of 0.05.

NE = Non-Estimable.

Source Data: Listings 16.2.7.1, 16.2.7.2

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Executed: 22OCT2021

Table 14.3.1.3.1.1
Solicited Adverse Events
Safety Population

Age Group: 2 to 10 years

	Menactra® (N=200) n (%)	NmCV-5 (N=400) n (%)	Total (N=600) n (%)	p-value
SUBJECTS WITH NON-MISSING SOLICITED LOCAL AND SYSTEMIC AE CRF DATA	200	399	599	
BELOW 6 YEARS	110	185	295	
6 YEARS AND ABOVE	90	214	304	
SUBJECTS WITH SOLICITED ADVERSE EVENTS [d]	27 (13.5)	90 (22.6)	117 (19.5)	0.009
SOLICITED LOCAL ADVERSE EVENTS [d]	19 (9.5)	80 (20.1)	99 (16.5)	0.001
PAIN AT INJECTION SITE	19 (9.5)	79 (19.8)	98 (16.4)	0.001
SWELLING OR INDURATION AT INJECTION SITE	1 (0.5)	3 (0.8)	4 (0.7)	>0.999
SOLICITED SYSTEMIC ADVERSE EVENTS (BELOW 6 YEARS) [b]	4 (3.6)	9 (4.9)	13 (4.4)	0.773
FEVER	1 (0.9)	2 (1.1)	3 (1.0)	>0.999
DROWSINESS	0 (0.0)	3 (1.6)	3 (1.0)	0.296
IRRITABILITY	1 (0.9)	4 (2.2)	5 (1.7)	0.654
ANOREXIA	2 (1.8)	2 (1.1)	4 (1.4)	0.631
DIARRHEA	1 (0.9)	2 (1.1)	3 (1.0)	>0.999

n represents the number of subjects at each level of summarization.

A subject is counted once under solicited local and systemic adverse events if a subject reported one or more events of a particular type.

[a] Percentages are based on the subjects in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[b] Percentages are based on the subjects below 6 years of age in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[c] Percentages are based on the subjects 6 years old and above (for age group 2 to 10 years percentages are based on the subjects 6 to 10 years of age) in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[d] Percentages are based on the subjects in corresponding age group in safety population with non-missing Solicited Local and Systemic AE CRF data.

p-value for comparison of percentages between treatments was calculated using Fisher's exact test at significance level of 0.05.

NE = Non-Estimable.

Source Data: Listings 16.2.7.1, 16.2.7.2

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DL1\TLF\t140301030101.sas

Executed: 22OCT2021

Table 14.3.1.3.1.1
Solicited Adverse Events
Safety Population

Age Group: 2 to 10 years

	Menactra® (N=200)		NmCV-5 (N=400)		Total (N=600)		p-value
	n	(%)	n	(%)	n	(%)	
SOLICITED SYSTEMIC ADVERSE EVENTS (6 YEARS AND ABOVE) [c]	4	(4.4)	21	(9.8)	25	(8.2)	0.169
FEVER	0	(0.0)	5	(2.3)	5	(1.6)	0.327
FATIGUE	0	(0.0)	2	(0.9)	2	(0.7)	>0.999
HEADACHE	2	(2.2)	14	(6.5)	16	(5.3)	0.163
MUSCLE ACHES (MYALGIA)	1	(1.1)	3	(1.4)	4	(1.3)	>0.999
JOINT ACHES (ARTHRALGIA)	0	(0.0)	2	(0.9)	2	(0.7)	>0.999
ANOREXIA	1	(1.1)	1	(0.5)	2	(0.7)	0.505
DIARRHEA	0	(0.0)	1	(0.5)	1	(0.3)	>0.999

n represents the number of subjects at each level of summarization.

A subject is counted once under solicited local and systemic adverse events if a subject reported one or more events of a particular type.

[a] Percentages are based on the subjects in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[b] Percentages are based on the subjects below 6 years of age in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[c] Percentages are based on the subjects 6 years old and above (for age group 2 to 10 years percentages are based on the subjects 6 to 10 years of age) in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[d] Percentages are based on the subjects in corresponding age group in safety population with non-missing Solicited Local and Systemic AE CRF data.

p-value for comparison of percentages between treatments was calculated using Fisher's exact test at significance level of 0.05.

NE = Non-Estimable.

Source Data: Listings 16.2.7.1, 16.2.7.2

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Executed: 22OCT2021

Table 14.3.1.3.1.1
Solicited Adverse Events
Safety Population

Age Group: 11 to 17 years

	Menactra® (N=200) n (%)	NmCV-5 (N=400) n (%)	Total (N=600) n (%)	p-value
SUBJECTS WITH NON-MISSING SOLICITED LOCAL AND SYSTEMIC AE CRF DATA	200	400	600	
SUBJECTS WITH SOLICITED ADVERSE EVENTS [d]	55 (27.5)	137 (34.3)	192 (32.0)	0.114
SOLICITED LOCAL ADVERSE EVENTS [d]	45 (22.5)	114 (28.5)	159 (26.5)	0.141
PAIN AT INJECTION SITE	45 (22.5)	114 (28.5)	159 (26.5)	0.141
SWELLING OR INDURATION AT INJECTION SITE	0 (0.0)	0 (0.0)	0 (0.0)	NE
SOLICITED SYSTEMIC ADVERSE EVENTS [d]	24 (12.0)	50 (12.5)	74 (12.3)	0.896
FEVER	2 (1.0)	7 (1.8)	9 (1.5)	0.725
FATIGUE	4 (2.0)	11 (2.8)	15 (2.5)	0.783
HEADACHE	17 (8.5)	32 (8.0)	49 (8.2)	0.875
MUSCLE ACHES (MYALGIA)	3 (1.5)	11 (2.8)	14 (2.3)	0.405
JOINT ACHES (ARTHRALGIA)	1 (0.5)	5 (1.3)	6 (1.0)	0.669
ANOREXIA	1 (0.5)	5 (1.3)	6 (1.0)	0.669
DIARRHEA	1 (0.5)	4 (1.0)	5 (0.8)	0.669

n represents the number of subjects at each level of summarization.

A subject is counted once under solicited local and systemic adverse events if a subject reported one or more events of a particular type.

[a] Percentages are based on the subjects in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[b] Percentages are based on the subjects below 6 years of age in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[c] Percentages are based on the subjects 6 years old and above (for age group 2 to 10 years percentages are based on the subjects 6 to 10 years of age) in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[d] Percentages are based on the subjects in corresponding age group in safety population with non-missing Solicited Local and Systemic AE CRF data.

p-value for comparison of percentages between treatments was calculated using Fisher's exact test at significance level of 0.05.

NE = Non-Estimable.

Source Data: Listings 16.2.7.1, 16.2.7.2

Program: \\wilbtib\wilbtib08\PATH PTHACYWXCIVIA071_U\DL1\TLF\t140301030101.sas

Executed: 22OCT2021

Table 14.3.1.3.1.1
Solicited Adverse Events
Safety Population

Age Group: 18 to 29 years

	Menactra® (N=200) n (%)	NmCV-5 (N=400) n (%)	Total (N=600) n (%)	p-value
SUBJECTS WITH NON-MISSING SOLICITED LOCAL AND SYSTEMIC AE CRF DATA	199	400	599	
SUBJECTS WITH SOLICITED ADVERSE EVENTS [d]	61 (30.7)	133 (33.3)	194 (32.4)	0.578
SOLICITED LOCAL ADVERSE EVENTS [d]	51 (25.6)	118 (29.5)	169 (28.2)	0.337
PAIN AT INJECTION SITE	51 (25.6)	118 (29.5)	169 (28.2)	0.337
SWELLING OR INDURATION AT INJECTION SITE	1 (0.5)	1 (0.3)	2 (0.3)	0.554
SOLICITED SYSTEMIC ADVERSE EVENTS [d]	23 (11.6)	53 (13.3)	76 (12.7)	0.604
FEVER	2 (1.0)	1 (0.3)	3 (0.5)	0.257
FATIGUE	12 (6.0)	25 (6.3)	37 (6.2)	>0.999
HEADACHE	10 (5.0)	27 (6.8)	37 (6.2)	0.474
MUSCLE ACHES (MYALGIA)	9 (4.5)	8 (2.0)	17 (2.8)	0.114
JOINT ACHES (ARTHRALGIA)	2 (1.0)	6 (1.5)	8 (1.3)	>0.999
ANOREXIA	5 (2.5)	7 (1.8)	12 (2.0)	0.545
DIARRHEA	0 (0.0)	3 (0.8)	3 (0.5)	0.554

n represents the number of subjects at each level of summarization.

A subject is counted once under solicited local and systemic adverse events if a subject reported one or more events of a particular type.

[a] Percentages are based on the subjects in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[b] Percentages are based on the subjects below 6 years of age in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[c] Percentages are based on the subjects 6 years old and above (for age group 2 to 10 years percentages are based on the subjects 6 to 10 years of age) in the safety population with non-missing Solicited Local and Systemic AE CRF data.

[d] Percentages are based on the subjects in corresponding age group in safety population with non-missing Solicited Local and Systemic AE CRF data.

p-value for comparison of percentages between treatments was calculated using Fisher's exact test at significance level of 0.05.

NE = Non-Estimable.

Source Data: Listings 16.2.7.1, 16.2.7.2

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Executed: 22OCT2021

Table 22 Unsolicited adverse events by System Organ Class and Preferred Term (≥ 1.0% occurrence) – Safety Population

	2 to 10 years			11 to 17 years			18 to 29 years			Overall		
System Organ Class	Menactra (N=200)	NmCV-5 (N=400)	Total (N=600)	Menactra (N=200)	NmCV-5 (N=400)	Total (N=600)	Menactra (N=200)	NmCV-5 (N=400)	Total (N=600)	Menactra (N=600)	NmCV-5 (N=1200)	Total (N=1800)
Preferred Term	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]
Subjects With Unsolicited Adverse Events	36 (18.0) [49]	81 (20.3) [100]	117 (19.5) [149]	25 (12.5) [26]	44 (11.0) [53]	69 (11.5) [79]	38 (19.0) [42]	64 (16.0) [78]	102 (17.0) [120]	99 (16.5) [117]	189 (15.8) [231]	288 (16.0) [348]
Infections And Infestations	32 (16.0) [42]	70 (17.5) [83]	102 (17.0) [125]	14 (7.0) [14]	26 (6.5) [29]	40 (6.7) [43]	24 (12.0) [25]	43 (10.8) [45]	67 (11.2) [70]	70 (11.7) [81]	139 (11.6) [157]	209 (11.6) [238]
Upper Respiratory Tract Infection	16 (8.0) [19]	33 (8.3) [35]	49 (8.2) [54]	6 (3.0) [6]	9 (2.3) [10]	15 (2.5) [16]	5 (2.5) [5]	14 (3.5) [14]	19 (3.2) [19]	27 (4.5) [30]	56 (4.7) [59]	83 (4.6) [89]
Malaria	0 (0.0) [0]	3 (0.8) [3]	3 (0.5) [3]	3 (1.5) [3]	3 (0.8) [3]	6 (1.0) [6]	6 (3.0) [6]	8 (2.0) [8]	14 (2.3) [14]	9 (1.5) [9]	14 (1.2) [14]	23 (1.3) [23]
Pharyngitis	3 (1.5) [3]	4 (1.0) [4]	7 (1.2) [7]	1 (0.5) [1]	1 (0.3) [1]	2 (0.3) [2]	3 (1.5) [3]	3 (0.8) [3]	6 (1.0) [6]	7 (1.2) [7]	8 (0.7) [8]	15 (0.8) [15]
Bronchitis	5 (2.5) [5]	5 (1.3) [5]	10 (1.7) [10]	0 (0.0) [0]	1 (0.3) [1]	1 (0.2) [1]	0 (0.0) [0]	1 (0.3) [1]	1 (0.2) [1]	5 (0.8) [5]	7 (0.6) [7]	12 (0.7) [12]
Helminthic Infection	0 (0.0) [0]	5 (1.3) [5]	5 (0.8) [5]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.3) [1]	1 (0.2) [1]	0 (0.0) [0]	6 (0.5) [6]	6 (0.3) [6]
Gastroenteritis	2 (1.0) [2]	0 (0.0) [0]	2 (0.3) [2]	1 (0.5) [1]	5 (1.3) [5]	6 (1.0) [6]	0 (0.0) [0]	2 (0.5) [2]	2 (0.3) [2]	3 (0.5) [3]	7 (0.6) [7]	10 (0.6) [10]
Lower Respiratory Tract Infection	1 (0.5) [1]	1 (0.3) [1]	2 (0.3) [2]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.5) [1]	4 (1.0) [4]	5 (0.8) [5]	2 (0.3) [2]	5 (0.4) [5]	7 (0.4) [7]
Vulvovaginal Candidiasis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	2 (1.0) [2]	2 (0.5) [2]	4 (0.7) [4]	2 (0.3) [2]	2 (0.2) [2]	4 (0.2) [4]
Conjunctivitis	1 (0.5) [1]	0 (0.0) [0]	1 (0.2) [1]	0 (0.0) [0]	2 (0.5) [2]	2 (0.3) [2]	2 (1.0) [2]	1 (0.3) [1]	3 (0.5) [3]	3 (0.5) [3]	3 (0.3) [3]	6 (0.3) [6]
Gastrointestinal Disorders	3 (1.5) [3]	5 (1.3) [5]	8 (1.3) [8]	4 (2.0) [4]	8 (2.0) [9]	12 (2.0) [13]	5 (2.5) [6]	10 (2.5) [10]	15 (2.5) [16]	12 (2.0) [13]	23 (1.9) [24]	35 (1.9) [37]

	2 to 10 years			11 to 17 years			18 to 29 years			Overall		
System Organ Class	Menactra (N=200)	NmCV-5 (N=400)	Total (N=600)	Menactra (N=200)	NmCV-5 (N=400)	Total (N=600)	Menactra (N=200)	NmCV-5 (N=400)	Total (N=600)	Menactra (N=600)	NmCV-5 (N=1200)	Total (N=1800)
Preferred Term	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]	n (%) [E]
Dyspepsia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	2 (1.0) [2]	3 (0.8) [3]	5 (0.8) [5]	1 (0.5) [1]	6 (1.5) [6]	7 (1.2) [7]	3 (0.5) [3]	9 (0.8) [9]	12 (0.7) [12]
Abdominal Pain	0 (0.0) [0]	2 (0.5) [2]	2 (0.3) [2]	0 (0.0) [0]	2 (0.5) [2]	2 (0.3) [2]	2 (1.0) [2]	1 (0.3) [1]	3 (0.5) [3]	2 (0.3) [2]	5 (0.4) [5]	7 (0.4) [7]
Nervous System Disorders	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	3 (1.5) [3]	5 (1.3) [5]	8 (1.3) [8]	2 (1.0) [2]	4 (1.0) [4]	6 (1.0) [6]	5 (0.8) [5]	9 (0.8) [9]	14 (0.8) [14]
Headache	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	2 (1.0) [2]	2 (0.5) [2]	4 (0.7) [4]	1 (0.5) [1]	2 (0.5) [2]	3 (0.5) [3]	3 (0.5) [3]	4 (0.3) [4]	7 (0.4) [7]
Injury, Poisoning And Procedural Complications	0 (0.0) [0]	6 (1.5) [7]	6 (1.0) [7]	3 (1.5) [3]	2 (0.5) [2]	5 (0.8) [5]	0 (0.0) [0]	1 (0.3) [1]	1 (0.2) [1]	3 (0.5) [3]	9 (0.8) [10]	12 (0.7) [13]
Musculoskeletal And Connective Tissue Disorders	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	2 (0.5) [2]	2 (0.3) [2]	4 (2.0) [4]	6 (1.5) [6]	10 (1.7) [10]	4 (0.7) [4]	8 (0.7) [8]	12 (0.7) [12]
Back Pain	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.3) [1]	1 (0.2) [1]	4 (2.0) [4]	6 (1.5) [6]	10 (1.7) [10]	2 (0.3) [2]	3 (0.3) [3]	5 (0.3) [5]
General Disorders And Administration Site Conditions	2 (1.0) [2]	0 (0.0) [0]	2 (0.3) [2]	1 (0.5) [1]	2 (0.5) [2]	3 (0.5) [3]	2 (1.0) [2]	0 (0.0) [0]	2 (0.3) [2]	5 (0.8) [5]	2 (0.2) [2]	7 (0.4) [7]
Respiratory, Thoracic And Mediastinal Disorders	1 (0.5) [1]	0 (0.0) [0]	1 (0.2) [1]	0 (0.0) [0]	1 (0.3) [1]	1 (0.2) [1]	2 (1.0) [2]	2 (0.5) [2]	4 (0.7) [4]	3 (0.5) [3]	3 (0.3) [3]	6 (0.3) [6]
Reproductive System And Breast Disorders	0 (0.0) [0]	1 (0.3) [1]	1 (0.2) [1]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	4 (1.0) [5]	4 (0.7) [5]	0 (0.0) [0]	5 (0.4) [6]	5 (0.3) [6]

Serious adverse events with onset after Day 29 are excluded from summary.

There are 3 unsolicited adverse events with onset after Day 29 (2 onset on Day 30 and 1 onset on Day 32) included in summary.

n represents the number of subjects at each level of summarization.

[E] represents the number of events at each level of summarization.

Adverse Events were coded using MedDRA, Version 22.0.

Source: Section 14, [Table 14.3.1.4.1.1](#)

Table 14.3.2.1.1.1
Serious Adverse Events Within 168 Days by System Organ Class and Preferred Term
Safety Population

Age Group: Overall

SYSTEM ORGAN CLASS PREFERRED TERM	Menactra® (N=600)			NmCV-5 (N=1,200)			Total (N=1,800)		
	n	(%)	[E]	n	(%)	[E]	n	(%)	[E]
SUBJECTS WITH SERIOUS ADVERSE EVENTS WITHIN 168 DAYS	3	(0.5)	[3]	3	(0.3)	[3]	6	(0.3)	[6]
INFECTIONS AND INFESTATIONS	1	(0.2)	[1]	1	(0.1)	[1]	2	(0.1)	[2]
ABSCESS LIMB	0	(0.0)	[0]	1	(0.1)	[1]	1	(0.1)	[1]
CELLULITIS	1	(0.2)	[1]	0	(0.0)	[0]	1	(0.1)	[1]
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0)	[0]	1	(0.1)	[1]	1	(0.1)	[1]
ANAEMIA OF PREGNANCY	0	(0.0)	[0]	1	(0.1)	[1]	1	(0.1)	[1]
GASTROINTESTINAL DISORDERS	0	(0.0)	[0]	1	(0.1)	[1]	1	(0.1)	[1]
ENTERITIS	0	(0.0)	[0]	1	(0.1)	[1]	1	(0.1)	[1]
IMMUNE SYSTEM DISORDERS	1	(0.2)	[1]	0	(0.0)	[0]	1	(0.1)	[1]
HYPERSENSITIVITY	1	(0.2)	[1]	0	(0.0)	[0]	1	(0.1)	[1]
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1	(0.2)	[1]	0	(0.0)	[0]	1	(0.1)	[1]
INJURY	1	(0.2)	[1]	0	(0.0)	[0]	1	(0.1)	[1]

At each level of subject summarization, a subject is counted once if the subject reported one or more events.

n represents the number of subjects at each level of summarization.

[E] represents the number of events at each level of summarization.

Adverse Events were coded using MedDRA, Version 22.0.

Source Data: Listing 16.2.7.5

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Table 14.3.2.1.1.1
Serious Adverse Events Within 168 Days by System Organ Class and Preferred Term
Safety Population

Age Group: 2 to 10 years

SYSTEM ORGAN CLASS PREFERRED TERM	Menactra® (N=200)			NmCV-5 (N=400)			Total (N=600)		
	n	(%)	[E]	n	(%)	[E]	n	(%)	[E]
SUBJECTS WITH SERIOUS ADVERSE EVENTS WITHIN 168 DAYS	2	(1.0)	[2]	0	(0.0)	[0]	2	(0.3)	[2]
IMMUNE SYSTEM DISORDERS	1	(0.5)	[1]	0	(0.0)	[0]	1	(0.2)	[1]
HYPERSENSITIVITY	1	(0.5)	[1]	0	(0.0)	[0]	1	(0.2)	[1]
INFECTIONS AND INFESTATIONS	1	(0.5)	[1]	0	(0.0)	[0]	1	(0.2)	[1]
CELLULITIS	1	(0.5)	[1]	0	(0.0)	[0]	1	(0.2)	[1]

At each level of subject summarization, a subject is counted once if the subject reported one or more events.

n represents the number of subjects at each level of summarization.

[E] represents the number of events at each level of summarization.

Adverse Events were coded using MedDRA, Version 22.0.

Source Data: Listing 16.2.7.5

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Table 14.3.2.1.1.1
Serious Adverse Events Within 168 Days by System Organ Class and Preferred Term
Safety Population

Age Group: 11 to 17 years

	Menactra® (N=200)	NmCV-5 (N=400)	Total (N=600)
SYSTEM ORGAN CLASS PREFERRED TERM	n (%) [E]	n (%) [E]	n (%) [E]

No Data Reported

At each level of subject summarization, a subject is counted once if the subject reported one or more events.
n represents the number of subjects at each level of summarization.
[E] represents the number of events at each level of summarization.
Adverse Events were coded using MedDRA, Version 22.0.
Source Data: Listing 16.2.7.5
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Table 14.3.2.1.1.1
Serious Adverse Events Within 168 Days by System Organ Class and Preferred Term
Safety Population

Age Group: 18 to 29 years

SYSTEM ORGAN CLASS PREFERRED TERM	Menactra® (N=200)			NmCV-5 (N=400)			Total (N=600)		
	n	(%)	[E]	n	(%)	[E]	n	(%)	[E]
SUBJECTS WITH SERIOUS ADVERSE EVENTS WITHIN 168 DAYS	1	(0.5)	[1]	3	(0.8)	[3]	4	(0.7)	[4]
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0)	[0]	1	(0.3)	[1]	1	(0.2)	[1]
ANAEMIA OF PREGNANCY	0	(0.0)	[0]	1	(0.3)	[1]	1	(0.2)	[1]
GASTROINTESTINAL DISORDERS	0	(0.0)	[0]	1	(0.3)	[1]	1	(0.2)	[1]
ENTERITIS	0	(0.0)	[0]	1	(0.3)	[1]	1	(0.2)	[1]
INFECTIONS AND INFESTATIONS	0	(0.0)	[0]	1	(0.3)	[1]	1	(0.2)	[1]
ABSCESS LIMB	0	(0.0)	[0]	1	(0.3)	[1]	1	(0.2)	[1]
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1	(0.5)	[1]	0	(0.0)	[0]	1	(0.2)	[1]
INJURY	1	(0.5)	[1]	0	(0.0)	[0]	1	(0.2)	[1]

At each level of subject summarization, a subject is counted once if the subject reported one or more events.

n represents the number of subjects at each level of summarization.

[E] represents the number of events at each level of summarization.

Adverse Events were coded using MedDRA, Version 22.0.

Source Data: Listing 16.2.7.5

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Table 14.2.1.1.1
Percentage of Subjects with Seroresponse Measured by rSBA for Each Serogroup on Day 29 by Age Group
Per-Protocol Population

N Evaluated is the number of subjects with a non-missing value at Day 1 and Day 29. Seroresponse rates were calculated based on 'N Evaluated'.

Seroresponse is defined as a post-immunization (Day 29) rSBA titer of 32 or greater if the subject's pre-immunization (Day 1) rSBA titer was < 8; or at least a four-fold increase over baseline at Day 29 post-immunization if the subject's pre-immunization (Day 1) rSBA titer was ≥ 8 .

The 95% CIs for each treatment group were calculated by using the Clopper-Pearson method.

The two-sided 96% CIs for the difference (NmCV-5 - Menactra®) in percentages between the two groups were constructed using the Miettinen and Nurminen method.

For serogroup X, seroresponse rate in the NmCV-5 was compared with the lowest seroresponse rate among serogroups A, C, W, and Y of Menactra®.

Source: Listing 16.2.6.1

Table 14.2.1.1.1
Percentage of Subjects with Seroresponse Measured by rSBA for Each Serogroup on Day 29 by Age Group
Per-Protocol Population

Age Group: Overall

Serogroup	Statistics	Menactra® (N=595)	NmCV-5 (N=1,198)
A	N Evaluated	572	1154
	Seroresponse, n (%)	286 (50.0)	814 (70.5)
	95% CI	(45.8, 54.2)	(67.8, 73.2)
	Difference (96% CI)		20.5 (15.4, 25.6)
C	N Evaluated	556	1133
	Seroresponse, n (%)	531 (95.5)	1109 (97.9)
	95% CI	(93.4, 97.1)	(96.9, 98.6)
	Difference (96% CI)		2.4 (0.6, 4.7)
Y	N Evaluated	537	1051
	Seroresponse, n (%)	494 (92.0)	1019 (97.0)
	95% CI	(89.4, 94.1)	(95.7, 97.9)
	Difference (96% CI)		5.0 (2.5, 7.9)
W	N Evaluated	534	1097
	Seroresponse, n (%)	520 (97.4)	1081 (98.5)
	95% CI	(95.6, 98.6)	(97.6, 99.2)
	Difference (96% CI)		1.2 (-0.3, 3.1)
X	N Evaluated	507	1131
	Seroresponse, n (%)	48 (9.5)	1099 (97.2)
	95% CI	(7.1, 12.4)	(96.0, 98.1)
	Difference (96% CI)		47.2 (42.8, 51.6)

Notes are listed on page 1.

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Table 14.2.1.1.1
Percentage of Subjects with Seroresponse Measured by rSBA for Each Serogroup on Day 29 by Age Group
Per-Protocol Population

Age Group: 2 to 10 years

Serogroup	Statistics	Menactra® (N=200)	NmCV-5 (N=399)
A	N Evaluated	194	378
	Seroresponse, n (%)	115 (59.3)	274 (72.5)
	95% CI	(52.0, 66.3)	(67.7, 76.9)
	Difference (96% CI)		13.2 (4.7, 21.9)
C	N Evaluated	189	385
	Seroresponse, n (%)	183 (96.8)	379 (98.4)
	95% CI	(93.2, 98.8)	(96.6, 99.4)
	Difference (96% CI)		1.6 (-1.0, 5.5)
Y	N Evaluated	186	355
	Seroresponse, n (%)	173 (93.0)	349 (98.3)
	95% CI	(88.3, 96.2)	(96.4, 99.4)
	Difference (96% CI)		5.3 (1.8, 10.3)
W	N Evaluated	179	371
	Seroresponse, n (%)	178 (99.4)	368 (99.2)
	95% CI	(96.9, 100.0)	(97.7, 99.8)
	Difference (96% CI)		-0.2 (-2.0, 2.5)
X	N Evaluated	182	386
	Seroresponse, n (%)	19 (10.4)	376 (97.4)
	95% CI	(6.4, 15.8)	(95.3, 98.8)
	Difference (96% CI)		38.1 (30.9, 45.7)

Notes are listed on page 1.

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Table 14.2.1.1.1
Percentage of Subjects with Seroresponse Measured by rSBA for Each Serogroup on Day 29 by Age Group
Per-Protocol Population

Age Group: 11 to 17 years

Serogroup	Statistics	Menactra® (N=199)	NmCV-5 (N=399)
A	N Evaluated	190	383
	Seroresponse, n (%)	83 (43.7)	275 (71.8)
	95% CI	(36.5, 51.1)	(67.0, 76.3)
	Difference (96% CI)		28.1 (19.2, 36.7)
C	N Evaluated	182	371
	Seroresponse, n (%)	177 (97.3)	368 (99.2)
	95% CI	(93.7, 99.1)	(97.7, 99.8)
	Difference (96% CI)		1.9 (-0.3, 5.8)
Y	N Evaluated	174	352
	Seroresponse, n (%)	155 (89.1)	342 (97.2)
	95% CI	(83.5, 93.3)	(94.8, 98.6)
	Difference (96% CI)		8.1 (3.5, 14.1)
W	N Evaluated	174	356
	Seroresponse, n (%)	170 (97.7)	354 (99.4)
	95% CI	(94.2, 99.4)	(98.0, 99.9)
	Difference (96% CI)		1.7 (-0.3, 5.5)
X	N Evaluated	177	371
	Seroresponse, n (%)	14 (7.9)	364 (98.1)
	95% CI	(4.4, 12.9)	(96.2, 99.2)
	Difference (96% CI)		54.4 (46.8, 61.7)

Notes are listed on page 1.

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Table 14.2.1.1.1
Percentage of Subjects with Seroresponse Measured by rSBA for Each Serogroup on Day 29 by Age Group
Per-Protocol Population

Age Group: 18 to 29 years

Serogroup	Statistics	Menactra® (N=196)	NmCV-5 (N=400)
A	N Evaluated	188	393
	Seroresponse, n (%)	88 (46.8)	265 (67.4)
	95% CI	(39.5, 54.2)	(62.6, 72.0)
	Difference (96% CI)		20.6 (11.6, 29.4)
C	N Evaluated	185	377
	Seroresponse, n (%)	171 (92.4)	362 (96.0)
	95% CI	(87.6, 95.8)	(93.5, 97.8)
	Difference (96% CI)		3.6 (-0.5, 8.9)
Y	N Evaluated	177	344
	Seroresponse, n (%)	166 (93.8)	328 (95.3)
	95% CI	(89.2, 96.9)	(92.6, 97.3)
	Difference (96% CI)		1.6 (-2.5, 6.8)
W	N Evaluated	181	370
	Seroresponse, n (%)	172 (95.0)	359 (97.0)
	95% CI	(90.8, 97.7)	(94.7, 98.5)
	Difference (96% CI)		2.0 (-1.4, 6.7)
X	N Evaluated	148	374
	Seroresponse, n (%)	15 (10.1)	359 (96.0)
	95% CI	(5.8, 16.2)	(93.5, 97.7)
	Difference (96% CI)		49.2 (41.4, 56.8)

Notes are listed on page 1.

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Table 14.2.1.2.1
Geometric Mean Titers of Antibodies Measured by rSBA for Each Serogroup on Day 29 by Age Group
Per Protocol Population

n is the number of subjects with a non-missing value at Day 29.
For each treatment, the GMT of antibodies measured by rSBA against each of the five serogroups and 95% CI were calculated by exponentiating the corresponding log2-transformed mean and its two-sided 95% CI limits on Day 29.
The log2-transformed rSBA titers were used to construct a two-sided 98.98% CI for the mean difference between the two treatment groups (NmCV-5 - Menactra®) using analysis of covariance (ANCOVA). The mean difference and corresponding 98.98% CI limits were exponentiated to obtain the GMT ratio and the corresponding 98.98% CI.

ANCOVA included log2-transformed baseline titers, age, sex and study site as a covariate. Interaction term for treatment group and baseline titers, treatment group and age, treatment group and study site, baseline titer and age, baseline titer and study site were also included in the ANCOVA model.

Covariates were selected based on stepwise selection method with level of significance of 0.05 for entry and exit of covariate and scientific consideration.

For serogroup X, GMT in the NmCV-5 was compared with the lowest GMT among serogroups A, C, W, and Y of Menactra®.
rSBA titer values below lower limit of quantification (LLOQ) are set to LLOQ/2 for analysis.

Source Data: Listing 16.2.6.1

Table 14.2.1.2.1
Geometric Mean Titers of Antibodies Measured by rSBA for Each Serogroup on Day 29 by Age Group
Per Protocol Population

Age Group: Overall

Serogroup	Summary Statistic	Menactra® (N=595)	NmCV-5 (N=1,198)
A	n	583	1172
	GMT	4729.7	8009.9
	95% CI	(4420.0, 5061.2)	(7631.7, 8407.0)
	Ratio of GMTs (98.98% CI)		1.7 (1.5, 1.9)
C	n	588	1190
	GMT	1854.9	5587.2
	95% CI	(1619.6, 2124.4)	(5123.7, 6092.5)
	Ratio of GMTs (98.98% CI)		2.8 (2.3, 3.5)
Y	n	591	1186
	GMT	4815.6	10844.8
	95% CI	(4380.9, 5293.4)	(10260.2, 11462.8)
	Ratio of GMTs (98.98% CI)		2.2 (1.9, 2.5)
W	n	589	1185
	GMT	12294.6	28963.4
	95% CI	(10778.9, 14023.4)	(26804.6, 31295.9)
	Ratio of GMTs (98.98% CI)		2.5 (2.1, 3.0)
X	n	523	1187
	GMT	737.1	31290.4
	95% CI	(641.3, 847.4)	(29222.2, 33505.1)
	Ratio of GMTs (98.98% CI)		9.5 (7.1, 12.8)

Notes are listed on page 1.

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Table 14.2.1.2.1
Geometric Mean Titers of Antibodies Measured by rSBA for Each Serogroup on Day 29 by Age Group
Per Protocol Population

Age Group: 2 to 10 years

Serogroup	Summary Statistic	Menactra® (N=200)	NmCV-5 (N=399)
A	n	199	388
	GMT	5682.7	9250.1
	95% CI	(5079.4, 6357.6)	(8529.3, 10031.8)
	Ratio of GMTs (98.98% CI)		1.7 (1.4, 2.0)
C	n	197	396
	GMT	1020.4	3084.7
	95% CI	(814.6, 1278.3)	(2684.4, 3544.7)
	Ratio of GMTs (98.98% CI)		2.7 (2.0, 3.7)
Y	n	198	398
	GMT	4362.4	10768.1
	95% CI	(3701.0, 5142.0)	(9831.2, 11794.3)
	Ratio of GMTs (98.98% CI)		2.3 (1.9, 2.9)
W	n	199	396
	GMT	11208.2	28888.0
	95% CI	(8887.3, 14135.2)	(25399.7, 32855.3)
	Ratio of GMTs (98.98% CI)		2.4 (1.8, 3.4)
X	n	187	399
	GMT	1031.6	39737.0
	95% CI	(845.1, 1259.3)	(35838.0, 44060.2)
	Ratio of GMTs (98.98% CI)		17.5 (8.4, 36.6)

Notes are listed on page 1.

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Table 14.2.1.2.1
Geometric Mean Titers of Antibodies Measured by rSBA for Each Serogroup on Day 29 by Age Group
Per Protocol Population

Age Group: 11 to 17 years

Serogroup	Summary Statistic	Menactra® (N=199)	NmCV-5 (N=399)
A	n	192	389
	GMT	4871.0	9463.9
	95% CI	(4349.1, 5455.6)	(8762.4, 10221.7)
	Ratio of GMTs (98.98% CI)		2.0 (1.7, 2.4)
C	n	198	396
	GMT	2906.5	8021.7
	95% CI	(2322.2, 3637.8)	(6973.0, 9228.2)
	Ratio of GMTs (98.98% CI)		2.8 (2.0, 3.9)
Y	n	199	397
	GMT	5154.6	11256.2
	95% CI	(4359.4, 6095.0)	(10286.9, 12317.0)
	Ratio of GMTs (98.98% CI)		2.1 (1.7, 2.7)
W	n	197	395
	GMT	13453.9	30280.0
	95% CI	(10845.1, 16690.2)	(26538.4, 34549.0)
	Ratio of GMTs (98.98% CI)		2.4 (1.7, 3.4)
X	n	180	392
	GMT	835.0	44572.8
	95% CI	(682.6, 1021.4)	(39929.6, 49756.0)
	Ratio of GMTs (98.98% CI)		9.9 (6.3, 15.6)

Notes are listed on page 1.

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Executed: 22OCT2021

Table 14.2.1.2.1
Geometric Mean Titers of Antibodies Measured by rSBA for Each Serogroup on Day 29 by Age Group
Per Protocol Population

Age Group: 18 to 29 years

Serogroup	Summary Statistic	Menactra® (N=196)	NmCV-5 (N=400)
A	n	192	395
	GMT	3796.9	5900.3
	95% CI	(3363.2, 4286.7)	(5419.2, 6424.2)
	Ratio of GMTs (98.98% CI)		1.5 (1.2, 1.8)
C	n	193	398
	GMT	2153.6	7040.2
	95% CI	(1703.7, 2722.4)	(6036.8, 8210.5)
	Ratio of GMTs (98.98% CI)		3.1 (2.2, 4.5)
Y	n	194	391
	GMT	4967.7	10518.3
	95% CI	(4227.8, 5837.0)	(9450.9, 11706.2)
	Ratio of GMTs (98.98% CI)		2.0 (1.6, 2.6)
W	n	193	394
	GMT	12336.7	27773.5
	95% CI	(9713.9, 15667.8)	(24082.4, 32030.4)
	Ratio of GMTs (98.98% CI)		2.4 (1.7, 3.4)
X	n	156	396
	GMT	426.7	17327.5
	95% CI	(311.7, 584.2)	(15369.3, 19535.2)
	Ratio of GMTs (98.98% CI)		4.9 (3.3, 7.2)

Notes are listed on page 1.

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Table 14.2.2.1.1
Percentage of Subjects with rSBA Titers ≥ 8 for Each Serogroup by Age Group and Visit 1,3
Per-Protocol Population

Age Group: Overall

Serogroup	Statistics	Visit 1 (Day 1)		Visit 3 (Day 29)	
		Menactra® (N=595)	NmCV-5 (N=1,198)	Menactra® (N=595)	NmCV-5 (N=1,198)
A	N Evaluated	584	1179	583	1172
	rSBA titers ≥ 8 , n (%)	583 (99.8)	1175 (99.7)	583 (100.0)	1172 (100.0)
	95% CI	(99.0, 100.0)	(99.1, 99.9)	(99.4, 100.0)	(99.7, 100.0)
	Difference (96% CI)		-0.2 (-0.8, 0.7)		0.0 (-0.4, 0.7)
C	N Evaluated	563	1141	588	1190
	rSBA titers ≥ 8 , n (%)	176 (31.3)	382 (33.5)	586 (99.7)	1186 (99.7)
	95% CI	(27.5, 35.3)	(30.7, 36.3)	(98.8, 100.0)	(99.1, 99.9)
	Difference (96% CI)		2.2 (-2.8, 7.1)		0.0 (-0.6, 1.0)
Y	N Evaluated	541	1061	591	1186
	rSBA titers ≥ 8 , n (%)	471 (87.1)	911 (85.9)	590 (99.8)	1186 (100.0)
	95% CI	(83.9, 89.8)	(83.6, 87.9)	(99.1, 100.0)	(99.7, 100.0)
	Difference (96% CI)		-1.2 (-4.8, 2.6)		0.2 (-0.2, 1.0)
W	N Evaluated	539	1109	589	1185
	rSBA titers ≥ 8 , n (%)	322 (59.7)	631 (56.9)	586 (99.5)	1182 (99.7)
	95% CI	(55.5, 63.9)	(53.9, 59.8)	(98.5, 99.9)	(99.3, 99.9)
	Difference (96% CI)		-2.8 (-8.1, 2.5)		0.3 (-0.4, 1.3)
X	N Evaluated	568	1141	523	1187
	rSBA titers ≥ 8 , n (%)	526 (92.6)	1046 (91.7)	506 (96.7)	1187 (100.0)
	95% CI	(90.1, 94.6)	(89.9, 93.2)	(94.8, 98.1)	(99.7, 100.0)
	Difference (96% CI)		-0.9 (-3.6, 2.1)		0.5 (0.2, 1.6)

N Evaluated is the number of subjects with a non-missing value at corresponding visit. Percentages were calculated based on 'N Evaluated'.

The 95% CIs for each treatment group were calculated by using the Clopper-Pearson method.

The two-sided 96% CIs for the difference (NmCV-5 - Menactra®) in percentages between the two groups were constructed using the Miettinen and Nurminen method. When count of rSBA titers < 8 is 0 in both treatment groups, for the calculation of 96% CI between treatment groups, rSBA titers < 8 count of 10^{-11} is considered for one of the two treatments.

For serogroup X at Visit 3, rate in the NmCV-5 was compared with the lowest rate among serogroups A, C, W, and Y of Menactra®

Source Data: Listing 16.2.6.1

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Table 14.2.2.1.1
Percentage of Subjects with rSBA Titers ≥ 8 for Each Serogroup by Age Group and Visit 1,3
Per-Protocol Population

Age Group: 2 to 10 years

Serogroup	Statistics	Visit 1 (Day 1)		Visit 3 (Day 29)	
		Menactra® (N=200)	NmCV-5 (N=399)	Menactra® (N=200)	NmCV-5 (N=399)
A	N Evaluated	195	389	199	388
	rSBA titers ≥ 8 , n (%)	194 (99.5)	385 (99.0)	199 (100.0)	388 (100.0)
	95% CI	(97.2, 100.0)	(97.4, 99.7)	(98.2, 100.0)	(99.1, 100.0)
	Difference (96% CI)		-0.5 (-2.3, 2.1)		0.0 (-1.1, 2.1)
C	N Evaluated	192	388	197	396
	rSBA titers ≥ 8 , n (%)	23 (12.0)	67 (17.3)	196 (99.5)	395 (99.7)
	95% CI	(7.7, 17.4)	(13.6, 21.4)	(97.2, 100.0)	(98.6, 100.0)
	Difference (96% CI)		5.3 (-1.4, 11.2)		0.3 (-1.1, 2.8)
Y	N Evaluated	188	356	198	398
	rSBA titers ≥ 8 , n (%)	163 (86.7)	306 (86.0)	198 (100.0)	398 (100.0)
	95% CI	(81.0, 91.2)	(81.9, 89.4)	(98.2, 100.0)	(99.1, 100.0)
	Difference (96% CI)		-0.7 (-6.8, 6.0)		0.0 (-1.1, 2.1)
W	N Evaluated	179	373	199	396
	rSBA titers ≥ 8 , n (%)	77 (43.0)	158 (42.4)	199 (100.0)	395 (99.7)
	95% CI	(35.7, 50.6)	(37.3, 47.6)	(98.2, 100.0)	(98.6, 100.0)
	Difference (96% CI)		-0.7 (-9.9, 8.5)		-0.3 (-1.5, 1.8)
X	N Evaluated	195	386	187	399
	rSBA titers ≥ 8 , n (%)	187 (95.9)	369 (95.6)	184 (98.4)	399 (100.0)
	95% CI	(92.1, 98.2)	(93.0, 97.4)	(95.4, 99.7)	(99.1, 100.0)
	Difference (96% CI)		-0.3 (-3.7, 4.1)		0.5 (-0.5, 3.0)

N Evaluated is the number of subjects with a non-missing value at corresponding visit. Percentages were calculated based on 'N Evaluated'.

The 95% CIs for each treatment group were calculated by using the Clopper-Pearson method.

The two-sided 96% CIs for the difference (NmCV-5 - Menactra®) in percentages between the two groups were constructed using the Miettinen and Nurminen method. When count of rSBA titers < 8 is 0 in both treatment groups, for the calculation of 96% CI between treatment groups, rSBA titers < 8 count of 10^{-11} is considered for one of the two treatments.

For serogroup X at Visit 3, rate in the NmCV-5 was compared with the lowest rate among serogroups A, C, W, and Y of Menactra®

Source Data: Listing 16.2.6.1

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Executed: 22OCT2021

Table 14.2.2.1.1
Percentage of Subjects with rSBA Titers ≥ 8 for Each Serogroup by Age Group and Visit 1,3
Per-Protocol Population

Age Group: 11 to 17 years

Serogroup	Statistics	Visit 1 (Day 1)		Visit 3 (Day 29)	
		Menactra® (N=199)	NmCV-5 (N=399)	Menactra® (N=199)	NmCV-5 (N=399)
A	N Evaluated	197	393	192	389
	rSBA titers ≥ 8 , n (%)	197 (100.0)	393 (100.0)	192 (100.0)	389 (100.0)
	95% CI	(98.1, 100.0)	(99.1, 100.0)	(98.1, 100.0)	(99.1, 100.0)
	Difference (96% CI)		0.0 (-1.1, 2.1)		0.0 (-1.1, 2.2)
C	N Evaluated	183	374	198	396
	rSBA titers ≥ 8 , n (%)	64 (35.0)	129 (34.5)	197 (99.5)	395 (99.7)
	95% CI	(28.1, 42.4)	(29.7, 39.6)	(97.2, 100.0)	(98.6, 100.0)
	Difference (96% CI)		-0.5 (-9.4, 8.1)		0.3 (-1.1, 2.8)
Y	N Evaluated	174	354	199	397
	rSBA titers ≥ 8 , n (%)	154 (88.5)	309 (87.3)	198 (99.5)	397 (100.0)
	95% CI	(82.8, 92.8)	(83.4, 90.6)	(97.2, 100.0)	(99.1, 100.0)
	Difference (96% CI)		-1.2 (-7.1, 5.5)		0.5 (-0.6, 3.0)
W	N Evaluated	176	360	197	395
	rSBA titers ≥ 8 , n (%)	112 (63.6)	200 (55.6)	195 (99.0)	394 (99.7)
	95% CI	(56.1, 70.7)	(50.3, 60.8)	(96.4, 99.9)	(98.6, 100.0)
	Difference (96% CI)		-8.1 (-17.0, 1.3)		0.8 (-0.6, 3.6)
X	N Evaluated	193	377	180	392
	rSBA titers ≥ 8 , n (%)	180 (93.3)	348 (92.3)	176 (97.8)	392 (100.0)
	95% CI	(88.8, 96.4)	(89.1, 94.8)	(94.4, 99.4)	(99.1, 100.0)
	Difference (96% CI)		-1.0 (-5.4, 4.3)		1.0 (-0.1, 3.8)

N Evaluated is the number of subjects with a non-missing value at corresponding visit. Percentages were calculated based on 'N Evaluated'.

The 95% CIs for each treatment group were calculated by using the Clopper-Pearson method.

The two-sided 96% CIs for the difference (NmCV-5 - Menactra®) in percentages between the two groups were constructed using the Miettinen and Nurminen method. When count of rSBA titers < 8 is 0 in both treatment groups, for the calculation of 96% CI between treatment groups, rSBA titers < 8 count of 10^{-11} is considered for one of the two treatments.

For serogroup X at Visit 3, rate in the NmCV-5 was compared with the lowest rate among serogroups A, C, W, and Y of Menactra®

Source Data: Listing 16.2.6.1

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Executed: 22OCT2021

Table 14.2.2.1.1
Percentage of Subjects with rSBA Titers ≥ 8 for Each Serogroup by Age Group and Visit 1,3
Per-Protocol Population

Age Group: 18 to 29 years

Serogroup	Statistics	Visit 1 (Day 1)		Visit 3 (Day 29)	
		Menactra® (N=196)	NmCV-5 (N=400)	Menactra® (N=196)	NmCV-5 (N=400)
A	N Evaluated	192	397	192	395
	rSBA titers ≥ 8 , n (%)	192 (100.0)	397 (100.0)	192 (100.0)	395 (100.0)
	95% CI	(98.1, 100.0)	(99.1, 100.0)	(98.1, 100.0)	(99.1, 100.0)
	Difference (96% CI)		0.0 (-1.1, 2.2)		0.0 (-1.1, 2.2)
C	N Evaluated	188	379	193	398
	rSBA titers ≥ 8 , n (%)	89 (47.3)	186 (49.1)	193 (100.0)	396 (99.5)
	95% CI	(40.0, 54.7)	(43.9, 54.2)	(98.1, 100.0)	(98.2, 99.9)
	Difference (96% CI)		1.7 (-7.4, 10.8)		-0.5 (-1.9, 1.6)
Y	N Evaluated	179	351	194	391
	rSBA titers ≥ 8 , n (%)	154 (86.0)	296 (84.3)	194 (100.0)	391 (100.0)
	95% CI	(80.1, 90.8)	(80.1, 88.0)	(98.1, 100.0)	(99.1, 100.0)
	Difference (96% CI)		-1.7 (-8.1, 5.4)		0.0 (-1.1, 2.1)
W	N Evaluated	184	376	193	394
	rSBA titers ≥ 8 , n (%)	133 (72.3)	273 (72.6)	192 (99.5)	393 (99.7)
	95% CI	(65.2, 78.6)	(67.8, 77.1)	(97.1, 100.0)	(98.6, 100.0)
	Difference (96% CI)		0.3 (-7.7, 8.8)		0.3 (-1.1, 2.8)
X	N Evaluated	180	378	156	396
	rSBA titers ≥ 8 , n (%)	159 (88.3)	329 (87.0)	146 (93.6)	396 (100.0)
	95% CI	(82.7, 92.6)	(83.2, 90.3)	(88.5, 96.9)	(99.1, 100.0)
	Difference (96% CI)		-1.3 (-7.0, 5.3)		0.5 (-0.5, 3.1)

N Evaluated is the number of subjects with a non-missing value at corresponding visit. Percentages were calculated based on 'N Evaluated'.

The 95% CIs for each treatment group were calculated by using the Clopper-Pearson method.

The two-sided 96% CIs for the difference (NmCV-5 - Menactra®) in percentages between the two groups were constructed using the Miettinen and Nurminen method. When count of rSBA titers < 8 is 0 in both treatment groups, for the calculation of 96% CI between treatment groups, rSBA titers < 8 count of 10^{-11} is considered for one of the two treatments.

For serogroup X at Visit 3, rate in the NmCV-5 was compared with the lowest rate among serogroups A, C, W, and Y of Menactra®

Source Data: Listing 16.2.6.1

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Executed: 22OCT2021

Table 14.2.2.2.1
Percentage of Subjects with rSBA Titers \geq 128 for Each Serogroup by Age Group and Visit 1,3
Per-Protocol Population

Age Group: Overall

Serogroup	Statistics	Visit 1 (Day 1)		Visit 3 (Day 29)	
		Menactra® (N=595)	NmCV-5 (N=1,198)	Menactra® (N=595)	NmCV-5 (N=1,198)
A	N Evaluated	584	1179	583	1172
	rSBA titers \geq 128, n (%)	579 (99.1)	1167 (99.0)	583 (100.0)	1172 (100.0)
	95% CI	(98.0, 99.7)	(98.2, 99.5)	(99.4, 100.0)	(99.7, 100.0)
	Difference (96% CI)		-0.2 (-1.1, 1.1)		0.0 (-0.4, 0.7)
C	N Evaluated	563	1141	588	1190
	rSBA titers \geq 128, n (%)	97 (17.2)	221 (19.4)	556 (94.6)	1174 (98.7)
	95% CI	(14.2, 20.6)	(17.1, 21.8)	(92.4, 96.2)	(97.8, 99.2)
	Difference (96% CI)		2.1 (-2.0, 6.1)		4.1 (2.3, 6.4)
Y	N Evaluated	541	1061	591	1186
	rSBA titers \geq 128, n (%)	454 (83.9)	874 (82.4)	590 (99.8)	1186 (100.0)
	95% CI	(80.5, 86.9)	(79.9, 84.6)	(99.1, 100.0)	(99.7, 100.0)
	Difference (96% CI)		-1.5 (-5.5, 2.6)		0.2 (-0.2, 1.0)
W	N Evaluated	539	1109	589	1185
	rSBA titers \geq 128, n (%)	279 (51.8)	556 (50.1)	586 (99.5)	1182 (99.7)
	95% CI	(47.5, 56.1)	(47.2, 53.1)	(98.5, 99.9)	(99.3, 99.9)
	Difference (96% CI)		-1.6 (-7.0, 3.8)		0.3 (-0.4, 1.3)
X	N Evaluated	568	1141	523	1187
	rSBA titers \geq 128, n (%)	510 (89.8)	1015 (89.0)	482 (92.2)	1186 (99.9)
	95% CI	(87.0, 92.2)	(87.0, 90.7)	(89.5, 94.3)	(99.5, 100.0)
	Difference (96% CI)		-0.8 (-3.9, 2.6)		5.4 (3.7, 7.6)

N Evaluated is the number of subjects with a non-missing value at corresponding visit. Percentages were calculated based on 'N Evaluated'.

The 95% CIs for each treatment group were calculated by using the Clopper-Pearson method.

The two-sided 96% CIs for the difference (NmCV-5 - Menactra®) in percentages between the two groups were constructed using the Miettinen and Nurminen method. When count of rSBA titers < 128 is 0 in both treatment groups, for the calculation of 96% CI between treatment groups, rSBA titers < 128 count of 10^{-11} is considered for one of the two treatments.

For serogroup X at Visit 3, rate in the NmCV-5 was compared with the lowest rate among serogroups A, C, W, and Y of Menactra®

Source Data: Listing 16.2.6.1

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Executed: 22OCT2021

Table 14.2.2.2.1
Percentage of Subjects with rSBA Titers \geq 128 for Each Serogroup by Age Group and Visit 1,3
Per-Protocol Population

Age Group: 2 to 10 years

Serogroup	Statistics	Visit 1 (Day 1)		Visit 3 (Day 29)	
		Menactra® (N=200)	NmCV-5 (N=399)	Menactra® (N=200)	NmCV-5 (N=399)
A	N Evaluated	195	389	199	388
	rSBA titers \geq 128, n (%)	194 (99.5)	385 (99.0)	199 (100.0)	388 (100.0)
	95% CI	(97.2, 100.0)	(97.4, 99.7)	(98.2, 100.0)	(99.1, 100.0)
	Difference (96% CI)		-0.5 (-2.3, 2.1)		0.0 (-1.1, 2.1)
C	N Evaluated	192	388	197	396
	rSBA titers \geq 128, n (%)	10 (5.2)	37 (9.5)	181 (91.9)	389 (98.2)
	95% CI	(2.5, 9.4)	(6.8, 12.9)	(87.1, 95.3)	(96.4, 99.3)
	Difference (96% CI)		4.3 (-0.7, 8.7)		6.4 (2.7, 11.4)
Y	N Evaluated	188	356	198	398
	rSBA titers \geq 128, n (%)	155 (82.4)	296 (83.1)	198 (100.0)	398 (100.0)
	95% CI	(76.2, 87.6)	(78.8, 86.9)	(98.2, 100.0)	(99.1, 100.0)
	Difference (96% CI)		0.7 (-6.0, 8.1)		0.0 (-1.1, 2.1)
W	N Evaluated	179	373	199	396
	rSBA titers \geq 128, n (%)	62 (34.6)	141 (37.8)	199 (100.0)	395 (99.7)
	95% CI	(27.7, 42.1)	(32.9, 42.9)	(98.2, 100.0)	(98.6, 100.0)
	Difference (96% CI)		3.2 (-5.9, 11.9)		-0.3 (-1.5, 1.8)
X	N Evaluated	195	386	187	399
	rSBA titers \geq 128, n (%)	182 (93.3)	365 (94.6)	180 (96.3)	399 (100.0)
	95% CI	(88.9, 96.4)	(91.8, 96.6)	(92.4, 98.5)	(99.1, 100.0)
	Difference (96% CI)		1.2 (-2.8, 6.3)		8.1 (4.9, 13.1)

N Evaluated is the number of subjects with a non-missing value at corresponding visit. Percentages were calculated based on 'N Evaluated'.

The 95% CIs for each treatment group were calculated by using the Clopper-Pearson method.

The two-sided 96% CIs for the difference (NmCV-5 - Menactra®) in percentages between the two groups were constructed using the Miettinen and Nurminen method. When count of rSBA titers < 128 is 0 in both treatment groups, for the calculation of 96% CI between treatment groups, rSBA titers < 128 count of 10^{-11} is considered for one of the two treatments.

For serogroup X at Visit 3, rate in the NmCV-5 was compared with the lowest rate among serogroups A, C, W, and Y of Menactra®

Source Data: Listing 16.2.6.1

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Table 14.2.2.2.1
Percentage of Subjects with rSBA Titers \geq 128 for Each Serogroup by Age Group and Visit 1,3
Per-Protocol Population

Age Group: 11 to 17 years

Serogroup	Statistics	Visit 1 (Day 1)		Visit 3 (Day 29)	
		Menactra® (N=199)	NmCV-5 (N=399)	Menactra® (N=199)	NmCV-5 (N=399)
A	N Evaluated	197	393	192	389
	rSBA titers \geq 128, n (%)	197 (100.0)	389 (99.0)	192 (100.0)	389 (100.0)
	95% CI	(98.1, 100.0)	(97.4, 99.7)	(98.1, 100.0)	(99.1, 100.0)
	Difference (96% CI)		-1.0 (-2.7, 1.1)		0.0 (-1.1, 2.2)
C	N Evaluated	183	374	198	396
	rSBA titers \geq 128, n (%)	34 (18.6)	76 (20.3)	190 (96.0)	392 (99.0)
	95% CI	(13.2, 25.0)	(16.4, 24.8)	(92.2, 98.2)	(97.4, 99.7)
	Difference (96% CI)		1.7 (-5.9, 8.7)		3.0 (0.5, 7.1)
Y	N Evaluated	174	354	199	397
	rSBA titers \geq 128, n (%)	152 (87.4)	299 (84.5)	198 (99.5)	397 (100.0)
	95% CI	(81.5, 91.9)	(80.3, 88.1)	(97.2, 100.0)	(99.1, 100.0)
	Difference (96% CI)		-2.9 (-9.1, 4.1)		0.5 (-0.6, 3.0)
W	N Evaluated	176	360	197	395
	rSBA titers \geq 128, n (%)	102 (58.0)	177 (49.2)	195 (99.0)	394 (99.7)
	95% CI	(50.3, 65.3)	(43.9, 54.5)	(96.4, 99.9)	(98.6, 100.0)
	Difference (96% CI)		-8.8 (-18.0, 0.7)		0.8 (-0.6, 3.6)
X	N Evaluated	193	377	180	392
	rSBA titers \geq 128, n (%)	178 (92.2)	340 (90.2)	171 (95.0)	392 (100.0)
	95% CI	(87.5, 95.6)	(86.7, 93.0)	(90.7, 97.7)	(99.1, 100.0)
	Difference (96% CI)		-2.0 (-6.9, 3.6)		4.0 (2.0, 8.0)

N Evaluated is the number of subjects with a non-missing value at corresponding visit. Percentages were calculated based on 'N Evaluated'.

The 95% CIs for each treatment group were calculated by using the Clopper-Pearson method.

The two-sided 96% CIs for the difference (NmCV-5 - Menactra®) in percentages between the two groups were constructed using the Miettinen and Nurminen method. When count of rSBA titers < 128 is 0 in both treatment groups, for the calculation of 96% CI between treatment groups, rSBA titers < 128 count of 10^{-11} is considered for one of the two treatments.

For serogroup X at Visit 3, rate in the NmCV-5 was compared with the lowest rate among serogroups A, C, W, and Y of Menactra®

Source Data: Listing 16.2.6.1

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Table 14.2.2.2.1
Percentage of Subjects with rSBA Titers \geq 128 for Each Serogroup by Age Group and Visit 1,3
Per-Protocol Population

Age Group: 18 to 29 years

Serogroup	Statistics	Visit 1 (Day 1)		Visit 3 (Day 29)	
		Menactra® (N=196)	NmCV-5 (N=400)	Menactra® (N=196)	NmCV-5 (N=400)
A	N Evaluated	192	397	192	395
	rSBA titers \geq 128, n (%)	188 (97.9)	393 (99.0)	192 (100.0)	395 (100.0)
	95% CI	(94.8, 99.4)	(97.4, 99.7)	(98.1, 100.0)	(99.1, 100.0)
	Difference (96% CI)		1.1 (-1.0, 4.5)		0.0 (-1.1, 2.2)
C	N Evaluated	188	379	193	398
	rSBA titers \geq 128, n (%)	53 (28.2)	108 (28.5)	185 (95.9)	393 (98.7)
	95% CI	(21.9, 35.2)	(24.0, 33.3)	(92.0, 98.2)	(97.1, 99.6)
	Difference (96% CI)		0.3 (-8.2, 8.3)		2.9 (0.2, 7.0)
Y	N Evaluated	179	351	194	391
	rSBA titers \geq 128, n (%)	147 (82.1)	279 (79.5)	194 (100.0)	391 (100.0)
	95% CI	(75.7, 87.4)	(74.9, 83.6)	(98.1, 100.0)	(99.1, 100.0)
	Difference (96% CI)		-2.6 (-9.7, 5.1)		0.0 (-1.1, 2.1)
W	N Evaluated	184	376	193	394
	rSBA titers \geq 128, n (%)	115 (62.5)	238 (63.3)	192 (99.5)	393 (99.7)
	95% CI	(55.1, 69.5)	(58.2, 68.2)	(97.1, 100.0)	(98.6, 100.0)
	Difference (96% CI)		0.8 (-8.0, 9.8)		0.3 (-1.1, 2.8)
X	N Evaluated	180	378	156	396
	rSBA titers \geq 128, n (%)	150 (83.3)	310 (82.0)	131 (84.0)	395 (99.7)
	95% CI	(77.1, 88.5)	(77.8, 85.8)	(77.3, 89.4)	(98.6, 100.0)
	Difference (96% CI)		-1.3 (-8.0, 6.1)		3.9 (1.6, 8.0)

N Evaluated is the number of subjects with a non-missing value at corresponding visit. Percentages were calculated based on 'N Evaluated'.

The 95% CIs for each treatment group were calculated by using the Clopper-Pearson method.

The two-sided 96% CIs for the difference (NmCV-5 - Menactra®) in percentages between the two groups were constructed using the Miettinen and Nurminen method. When count of rSBA titers < 128 is 0 in both treatment groups, for the calculation of 96% CI between treatment groups, rSBA titers < 128 count of 10^{-11} is considered for one of the two treatments.

For serogroup X at Visit 3, rate in the NmCV-5 was compared with the lowest rate among serogroups A, C, W, and Y of Menactra®

Source Data: Listing 16.2.6.1

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