

Supplemental Material

Immunogenicity and safety of a quadrivalent meningococcal conjugate vaccine (MenACYW-TT) administered with routine pediatric vaccines: a European randomized controlled trial

Federico Martinon-Torres,^{1–3} Miia M Virta,⁴ Susanna Koski,^{5,6} Ignacio Salamanca de la Cueva,⁷ Henryk T Szymanski,⁸ Samantha Bosis,⁹ Anca C Drăgănescu,^{10,11} Sven-Arne Silfverdal,¹² Betzana Zambrano,¹³ Mandeep S Dhingra,¹⁴ Siham B’Chir,¹⁵ Olga Syrkina,¹⁶ Olga Lyabis,¹⁷ Gustavo A Vasquez,¹⁴ Christine Rehm^{14*} for the MET58 Study Group[‡]

1. Translational Paediatrics and Infectious Diseases Section, Paediatrics Department, Hospital Clínico Universitario de Santiago de Compostela, Santiago de Compostela 15701, Spain

2. Genetics, Vaccines, and Infections Research Group (GENVIP), Healthcare Research Institute of Santiago de Compostela, University of Santiago de Compostela, Santiago de Compostela 15701, Spain

3. CIBER of Respiratory Diseases (CIBERES), Instituto de Salud Carlos III, Madrid 28222, Spain

4. Finnish Vaccine Research, Järvenpää Clinic, Mannilantie, Järvenpää, Finland

5. Finnish Vaccine Research, Helsinki South Clinic, Vuorikatu, Helsinki, Finland

6. Finnish Vaccine Research, Helsinki East Clinic, Itäkeskuksen kauppakeskus, Agenttitalo, Turunlinnantie, Helsinki, Finland

7. Unidad de Investigación. Grupo IHP (Instituto Hispalense de Pediatría), Seville, Spain

8. Szpital im. Swietej Jadwigi Slaskiej w Trzebnicy, Department of Pediatrics,
Prusicka 53–55, 55–100 Trzebnica, Poland
9. Pneumology and Infectious Diseases Unit, Fondazione IRCCS Ca' Granda
Ospedale Maggiore Policlinico, Milano, Italy
10. National Institute for Infectious Diseases "Prof. Dr. Matei Bals", Bucharest,
Romania
11. Department of Pediatrics, Faculty of Medicine, Carol Davila University of
Medicine and Pharmacy, Bucharest, Romania
12. Clinical Sciences, Pediatrics, Umeå University, Umeå, Sweden
13. Global Clinical Development Strategy, Sanofi, Montevideo, Uruguay
14. Global Clinical Development Strategy, Sanofi, Swiftwater, PA, USA
15. Global Biostatistical Sciences, Sanofi, Marcy L'Étoile, France
16. Patient Safety and Pharmacovigilance, Sanofi R&D, Cambridge, USA
17. Global Clinical Development Strategy, Sanofi, Marcy L'Étoile, France

***Corresponding author**

Gustavo Vasquez

Global Clinical Development Strategy, Sanofi, Swiftwater, PA, USA

E-mail: Gustavo.Vasquez@sanofi.com

Section S1: Supplementary methods

MET58 study group

Investigators

Name	Institute	City/Town; Country
Renata Polackova	Doubletake 1211/54	Ostrava-Hrabuvka, Czech Republic
Jirina Dvorakova	Zdravotnicke stredisko Dubina v.o.s	L.Malé 656, Pardubice 12, Czech Republic
Stefan Hrunka	Prakticky lekar pro deti a dorost; Pernstynska 127/1	Chlumec nad Cidlinou, Czech Republic
Jiri Jarolimek	PED MED s.r.o., Palackeho 48	Smrice, Czech Republic
Iva Madejova	Kosmonautu 399	Pardubice, Czech Republic
Daniela Verdanova	U nemocnice 380/III	Jindrichuv Hradec, Czech Republic
Věra Ždímalová*	Dr. Jana Malíka 781	Chrudim, Czech Republic
Ludmila Plockova	Sidliste Vajgar 724/III	Jindrichuv Hradec, Czech Republic
Jana Schejbalova	PL pro deti a dorost, Luženická 678	Domažlice, Czech Republic
Hana Zelenáková*	Rákosníkova 225	Neveklov, Czech Republic
Miia Virta	Finnish Vaccine Research, Järvenpää Clinic Mannilantie 44, 2nd floor	Järvenpää, Finland,
Ilkka Seppä	Finnish Vaccine Research, Pori Clinic rokotetutkimusklinikka, Yrjönkatu 23	Pori, Finland
Susanna Koski	Finnish Vaccine Research, Helsinki South Clinic, Vuorikatu 18, Finnish Vaccine Research, Helsinki East Clinic, Itäkeskuksen kauppakeskus, Agenttitalo, Turunlinnantie 8, Helsinki	Helsinki, Finland
Satu Kokko	Finnish Vaccine Research, Oulu Clinic, Kiviharjunlenkki 6	Oulu, Finland

Pauliina Paavola	Finnish Vaccine Research, Kokkola Clinic, Rantakatu 7, Maximin liikekeskus	Kokkola, Finland
Benita Ukkonen	Finnish Vaccine Research, Espoo Clinic, Piispansilta 11, Ison Omenan toimistotorni	Espoo, Finland
Ilkka Seppä	Finnish Vaccine Research, Turku Clinic, Lemminkäisenkatu 14-18 B	Turku, Finland
Outi Laajalahti	Finnish Vaccine Research, Seinäjoki Clinic, Keskuskatu 6	Seinäjoki, Finland
Oskari Pitkanen	Finnish Vaccine Research, Tampere Clinic, Tullikatu 6	Tampere, Finland
Paola Marchisio	Fondazione IRCCS CA' Granda Ospedale Maggiore Policlinico (Clinica Mangiagalli), Via della Commenda, 9/12	Milano, Italy
Piotr Korbal	In Vivo Bydgoszcz, ul. Kaszubska 17H	Bydgoszcz, Poland
Barbara Pajek	Niepubliczny Zakład Lecznictwa Ambulatoryjnego Michalkowice, Ul. Koscielna 32	Siemianowice Śląskie, Poland
Henryk Szymanski	Szpital im. Świętej Jadwigi Śląskiej w Trzebnicy, Prusicka 53-55	Trzebnica, Poland
Elzbieta Kopinska	MICS Centrum Medyczne Torun, ul. Batorego 18-22	Torun, Poland
Anca Draganescu	Institutul de Boli Infectioase "Prof. Dr. Matei Bals", Str. Dr. Calistrat Grozovici nr. 1	Bucuresti, Romania
Alexandra Cara	Sc Med Fam Apolo srl, Strada Luceafarului 13	Calarasi, Romania
Oana-Gabriela Falup-Pecurariu	Spitalul Clinic de Copii Brasov, Str. Nicopole nr. 45, Judet Brasov	Brasov, Romania
Adrian Sarbu*	Centrul Medical Sana SRL, Str. Sergiu Dumitru nr.3, Etaj 1, Ap.2, Sector 1	Bucuresti, Romania
Elena Andrea Neculau*	Cabinet Medical de Medicina de Familie, Str. Alexandru cel Bun Nr. 21	Brasov, Romania
Carmen Tocea	Spitalul Municipal Caracal, Calea Plevnei nr. 36, Judet Olt	Caracal, Romania
Federico Martinon Torres	Complejo Hospitalario Universitario de Santiago, Travesia da Choupana s/n, Pediatria, Santiago de Compostela	La Coruña, Spain
Susana Ares Segura	Hospital Universitario La Paz, Paseo de la Castellana, 261, Servicio de Microbiología, Madrid	Madrid, Spain

Maria Luisa Navarro Gomez	Hospital General Universitario Gregorio Marañón, c/ Dr. Esquerdo, 46, Pediatría, Madrid	Madrid, Spain
Ignacio Salamanca de la Cueva	Grupo IHP (Instituto Hispalense de Pediatría) Calle Jardín de la isla, nº 6. Edificio Expolocal. 41014, Sevilla.	Sevilla, Spain
Alfonso Carmona Martinez	Grupo IHP (Instituto Hispalense de Pediatría) Calle Jardín de la isla, nº 6. Edificio Expolocal. 41014, Sevilla.	Sevilla, Spain
Sven-Arne Silfverdal	Umea University Hospital, Umeå universitet	Umeå, Sweden

List of independent ethics committees and institutional review boards

IEC/IRB Name, Chairperson, and Address	Center Number(s)	Principal Investigator(s)
Etická komise Fakultní nemocnice Kralovské Vinohrady, Šrobárova 1150/50, 100 34 Praha 10, Chairperson: Prof. MUDr. Jan Páchl, CSc.	2031003	Polackova, Renata
Etická komise Fakultní nemocnice Kralovské Vinohrady, Šrobárova 1150/50, 100 34 Praha 10, Chairperson: Prof. MUDr. Jan Páchl, CSc.	2031005	Dvorakova, Jirina
Etická komise Fakultní nemocnice Kralovské Vinohrady, Šrobárova 1150/50, 100 34 Praha 10, Chairperson: Prof. MUDr. Jan Páchl, CSc.	2031006	Hrunka, Stefan
Etická komise Fakultní nemocnice Kralovské Vinohrady, Šrobárova 1150/50, 100 34 Praha 10, Chairperson: Prof. MUDr. Jan Páchl, CSc.	2031007	Jarolimek, Jiri
Etická komise Fakultní nemocnice Kralovské Vinohrady, Šrobárova 1150/50, 100 34 Praha 10, Chairperson: Prof. MUDr. Jan Páchl, CSc.	2031008	Polackova, Renata
Etická komise Fakultní nemocnice Kralovské Vinohrady, Šrobárova 1150/50, 100 34 Praha 10, Chairperson: Prof. MUDr. Jan Páchl, CSc.	2031009	Madejova, Iva
Etická komise Fakultní nemocnice Kralovské Vinohrady, Šrobárova 1150/50, 100 34 Praha 10, Chairperson: Prof. MUDr. Jan Páchl, CSc.	2031010	Verdanova, Daniela
Etická komise Fakultní nemocnice Kralovské Vinohrady, Šrobárova 1150/50, 100 34 Praha 10, Chairperson: Prof. MUDr. Jan Páchl, CSc.	2031011	Ždímalová, Věra *
Etická komise Fakultní nemocnice Kralovské Vinohrady, Šrobárova 1150/50, 100 34 Praha 10, Chairperson: Prof. MUDr. Jan Páchl, CSc.	2031012	Plockova, Ludmila
Etická komise Fakultní nemocnice Kralovské Vinohrady, Šrobárova 1150/50, 100 34 Praha 10, Chairperson: Prof. MUDr. Jan Páchl, CSc.	2031013	Schejbalova, Jana
Etická komise Fakultní nemocnice Kralovské Vinohrady, Šrobárova 1150/50, 100 34 Praha 10, Chairperson: Prof. MUDr. Jan Páchl, CSc.	2031014	Zelenáková, Hana *
Varsinais-Suomen sairaanhoitopiiri, Sirkku Jyrkkiö , physical address: Kiinamyllynkatu 4-8, Turku, Rakennus 9 B (2.krs), mailing address: Varsinais-Suomen hyvinvointialue, Eettinen toimikunta / Tutkimuspalvelut, Tyks, Rakennus 9 B, PL 52, 20521 Turku	2462001	Virta, Miia
Varsinais-Suomen sairaanhoitopiiri, Sirkku Jyrkkiö , physical address: Kiinamyllynkatu 4-8, Turku, Rakennus 9 B (2.krs), mailing address: Varsinais-Suomen hyvinvointialue, Eettinen toimikunta / Tutkimuspalvelut, Tyks, Rakennus 9 B, PL 52, 20521 Turku	2462002	Seppä, Ilkka

Varsinais-Suomen sairaanhoitopiiri, Sirkku Jyrkkiö , physical address: Kiinamylynkatu 4-8, Turku, Rakennus 9 B (2.krs), mailing address: Varsinais- Suomen hyvinvointialue, Eettinen toimikunta / Tutkimuspalvelut, Tyks, Rakennus 9 B, PL 52, 20521 Turku	2462003	Koski, Susanna
Varsinais-Suomen sairaanhoitopiiri, Sirkku Jyrkkiö , physical address: Kiinamylynkatu 4-8, Turku, Rakennus 9 B (2.krs), mailing address: Varsinais- Suomen hyvinvointialue, Eettinen toimikunta / Tutkimuspalvelut, Tyks, Rakennus 9 B, PL 52, 20521 Turku	2462004	Koski, Susanna
Varsinais-Suomen sairaanhoitopiiri, Sirkku Jyrkkiö , physical address: Kiinamylynkatu 4-8, Turku, Rakennus 9 B (2.krs), mailing address: Varsinais- Suomen hyvinvointialue, Eettinen toimikunta / Tutkimuspalvelut, Tyks, Rakennus 9 B, PL 52, 20521 Turku	2462005	Kokko, Satu
Varsinais-Suomen sairaanhoitopiiri, Sirkku Jyrkkiö , physical address: Kiinamylynkatu 4-8, Turku, Rakennus 9 B (2.krs), mailing address: Varsinais- Suomen hyvinvointialue, Eettinen toimikunta / Tutkimuspalvelut, Tyks, Rakennus 9 B, PL 52, 20521 Turku	2462006	Paavola, Pauliina
Varsinais-Suomen sairaanhoitopiiri, Sirkku Jyrkkiö , physical address: Kiinamylynkatu 4-8, Turku, Rakennus 9 B (2.krs), mailing address: Varsinais- Suomen hyvinvointialue, Eettinen toimikunta / Tutkimuspalvelut, Tyks, Rakennus 9 B, PL 52, 20521 Turku	2462007	Ukkonen, Benita
Varsinais-Suomen sairaanhoitopiiri, Sirkku Jyrkkiö , physical address: Kiinamylynkatu 4-8, Turku, Rakennus 9 B (2.krs), mailing address: Varsinais- Suomen hyvinvointialue, Eettinen toimikunta / Tutkimuspalvelut, Tyks, Rakennus 9 B, PL 52, 20521 Turku	2462008	Seppä, Ilkka
Varsinais-Suomen sairaanhoitopiiri, Sirkku Jyrkkiö , physical address: Kiinamylynkatu 4-8, Turku, Rakennus 9 B (2.krs), mailing address: Varsinais- Suomen hyvinvointialue, Eettinen toimikunta / Tutkimuspalvelut, Tyks, Rakennus 9 B, PL 52, 20521 Turku	2462009	Laajalahti, Outi
Varsinais-Suomen sairaanhoitopiiri, Sirkku Jyrkkiö , physical address: Kiinamylynkatu 4-8, Turku, Rakennus 9 B (2.krs), mailing address: Varsinais- Suomen hyvinvointialue, Eettinen toimikunta / Tutkimuspalvelut, Tyks, Rakennus 9 B, PL 52, 20521 Turku	2462010	Pitkanen, Oskari
Comitato Etico Milano Area 2 Fond. IRCCS Ca'Granda Ospedale Maggiore Policlinico	3803002	Marchisio, Paola

Via F. Sforza, 28 20122
Milano

Chairperson: **Fabrizio Forini**

Komisja Bioetyczna przy Dolnośląskiej Izbie
Lekarskiej in Wrocław ul. Kazimierza Wielkiego
45, 50 - 077 Wrocław

6167002

Korbal, Piotr

Chairperson: Włodzimierz Bednorz, MD, PhD

Komisja Bioetyczna przy Dolnośląskiej Izbie
Lekarskiej in Wrocław ul. Kazimierza Wielkiego
45, 50 - 077 Wrocław

6167003

Pajek, Barbara

Chairperson: Włodzimierz Bednorz, MD, PhD

Komisja Bioetyczna przy Dolnośląskiej Izbie
Lekarskiej in Wrocław ul. Kazimierza Wielkiego
45, 50 - 077 Wrocław

6167004

Szymanski, Henryk

Chairperson: Włodzimierz Bednorz, MD, PhD

Komisja Bioetyczna przy Dolnośląskiej Izbie
Lekarskiej in Wrocław ul. Kazimierza Wielkiego
45, 50 - 077 Wrocław

6167006

Kopinska, Elzbieta

Chairperson: Włodzimierz Bednorz, MD, PhD

National Bioethics Committee of Medicines and
Medical Devices
BUCHAREST, Colentina Hospital, corp exterior C,
str. Dr. Grozovici no. 6, Sector 2 Web: www.bioetica-medicala.ro email: secretariat@bioetica-medicala.ro
Name of chair person of IRB/IEC: President of the
NBCMMD: **Prof. Doina Draganescu**, Pharm.D.

6424001

Draganescu, Anca

National Bioethics Committee of Medicines and
Medical Devices
BUCHAREST, Colentina Hospital, corp exterior C,
str. Dr. Grozovici no. 6, Sector 2 Web: www.bioetica-medicala.ro email: secretariat@bioetica-medicala.ro
Name of chair person of IRB/IEC: President of the
NBCMMD: **Prof. Doina Draganescu**, Pharm.D.

6424002

Cara, Alexandra

National Bioethics Committee of Medicines and
Medical Devices
BUCHAREST, Colentina Hospital, corp exterior C,
str. Dr. Grozovici no. 6, Sector 2 Web: www.bioetica-medicala.ro email: secretariat@bioetica-medicala.ro
Name of chair person of IRB/IEC: President of the
NBCMMD: **Prof. Doina Draganescu**, Pharm.D.

6424003

Falup-Pecurariu,
Oana-Gabriela

National Bioethics Committee of Medicines and
Medical Devices

6424004

Sarbu, Adrian*

BUCHAREST, Colentina Hospital, corp exterior C, str. Dr. Grozovici no. 6, Sector 2 Web: www.bioetica-medicala.ro email: secretariat@bioetica-medicala.ro Name of chair person of IRB/IEC: President of the NBCMMD: Prof. Doina Draganescu, Pharm.D. National Bioethics Committee of Medicines and Medical Devices		
BUCHAREST, Colentina Hospital, corp exterior C, str. Dr. Grozovici no. 6, Sector 2 Web: www.bioetica-medicala.ro email: secretariat@bioetica-medicala.ro Name of chair person of IRB/IEC: President of the NBCMMD: Prof. Doina Draganescu, Pharm.D. National Bioethics Committee of Medicines and Medical Devices	6424005	Neculau, Elena Andrea*
BUCHAREST, Colentina Hospital, corp exterior C, str. Dr. Grozovici no. 6, Sector 2 Web: www.bioetica-medicala.ro email: secretariat@bioetica-medicala.ro Name of chair person of IRB/IEC: President of the NBCMMD: Prof. Doina Draganescu, Pharm.D.	6424006	Tocea, Carmen
SERGAS Chairperson Name: Susana María Romero Yuste		
CEIm de Galicia XERENCIA DO SERVIZO GALEGO DE SAÚDE Complexo Administrativo de San Lázaro 15781 Santiago de Compostela T. 881 546425 ceic@sergas.gal https://acis.sergas. SERGAS Chairperson Name: Susana María Romero Yuste	7245001	Martinon Torres, Federico
CEIm de Galicia XERENCIA DO SERVIZO GALEGO DE SAÚDE Complexo Administrativo de San Lázaro 15781 Santiago de Compostela T. 881 546425 ceic@sergas.gal https://acis.sergas. SERGAS Chairperson Name: Susana María Romero Yuste	7245002	Ares Segura, Susana
CEIm de Galicia XERENCIA DO SERVIZO GALEGO DE SAÚDE Complexo Administrativo de San Lázaro 15781 Santiago de Compostela T. 881 546425 ceic@sergas.gal https://acis.sergas.	7245003	Navarro Gomez, Maria Luisa

SERGAS

Chairperson Name: **Susana María Romero Yuste**

CEIm de Galicia

XERENCIA DO SERVIZO GALEGO DE SAÚDE

7245006

Carmona Martinez,
Alfonso

Complexo Administrativo de San Lázaro

15781 Santiago de

Compostela T. 881 546425

ceic@sergas.gal

<https://acis.sergas.>

Regionala etikprövningsnämnden i Umeå, **Anders**

7526001

Silfverdal, Sven-
Arne

Iacobaeus address: Samverkanshuset,

Universitetssområdet, 901 87 Umeå

Etikprövningsmyndigheten, **Magnus Forsberg,**

physical address: Etikprövningsmyndigheten, FE

7854, 831 90 Östersund, mailing address:

7526001

Silfverdal, Sven-
Arne

Etikprövningsmyndigheten,

Box 2110, 750 02 Uppsala

*Investigator did not enroll any participants.

Procedures

Each dose of DTaP-IPV-HB-Hib (Hexyon[®], Hexacima[®], Sanofi Pasteur, Marcy L'Etoile, France) was presented as a ready-to-use suspension containing at least 20 IU of diphtheria toxoid, 40 IU tetanus toxoid, *Bordetella pertussis* antigens (25 µg pertussis toxoid, 25 µg filamentous haemagglutinin), inactivated poliovirus antigens (40 D antigen units of type 1 [Mahoney strain], 8 D antigen units of type 2 [MEF-1 strain], and 32 D antigen units of type 3 [Saukett strain]), 10 µg of hepatitis B surface antigens, 12 µg of *Haemophilus influenzae* type b polysaccharide, and 22–36 µg of polyribosylribitol phosphate conjugated to tetanus protein. PCV10 (Synflorix[®], GlaxoSmithKline Biologicals, Rixensart, Belgium) was presented as a ready-to-use suspension containing 1 µg of pneumococcal polysaccharide serotypes 1^{ab}, 5^{ab}, 6B^{ab}, 7F^{ab}, 9V^{ab}, 14^{ab}, and 23F^{ab} and 3 µg of serotypes 4^{ab}, 18C^{ab}, and 19F^{ab}. PCV13 (Prevenar 13[®], Pfizer Limited, Sandwich, UK) was presented as a ready-to-use suspension containing 2.2 µg of pneumococcal polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, and 23F and 4.4 µg of serotype 6B, conjugated to CRM₁₉₇ carrier protein and absorbed on aluminum phosphate (0.125 mg aluminum). M-M-RVAXPRO[®] (referred to as the MMR vaccine; Merck Sharp & Dohme B.V., Haarlem, The Netherlands) was provided as a powder and solvent for resuspension and contained at least 1×10^3 cell culture infection dose 50% (CCID₅₀) of live, attenuated measles virus (Enders' Edmonston strain), 12.5×10^3 CCID₅₀ of live, attenuated mumps virus (Jeryl LynnTM Level B stain) and 1×10^3 CCID₅₀ of live, attenuated rubella virus (Wistar RA 27/3 strain). All routine vaccinations were administered as 0.5 mL doses by intramuscular (IM) injection into the anterolateral area of the thigh.

Three doses each of DTaP-IPV-HB-Hib and PCV10/PCV13 were administered at approximately 2 months (V1), 4 months (V2), and 12–18 months (V4/5) of age. One dose of M-M-RVAXPRO was administered at 12–18 months of age (V4/5), or at least 4 weeks before any study vaccines or at the end of the study.

Immunogenicity assessment

Anti-diphtheria, tetanus, and pertussis antibodies

Antibodies against diphtheria, tetanus, and pertussis were measured by electrochemiluminescence (ECL), a multiplexed serological assay allowing for the simultaneous quantification of human antibodies to six specific antigens: diphtheria toxoid, tetanus toxoid, and four pertussis antigens (PT, FHA, FIM, and PRN). The LLOQ for diphtheria was 0.005 IU/mL, the LLOQ for tetanus was 0.01 IU/mL, and the LLOQ for pertussis antigens was 2.00 EU/mL.

Anti-Haemophilus influenzae type b (anti-PRP) antibodies

Anti-PRP concentrations were measured using a Farr-type radioimmunoassay (RIA). The LLOQ of the anti-PRP RIA was 0.06 µg/mL.

Anti-pneumococcal antibodies

Anti-*Streptococcus pneumoniae* antibodies for 21 serotypes, including all 10 serotypes in PCV10 and 13 serotypes in PCV13 (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F) were measured by pneumococcal capsular PS (PnPS) IgG ECL assay. The LLOQ for all PnPS serotypes was 0.15 µg/mL.

Anti-hepatitis B antibodies

Anti-HB antibodies were measured using the commercially available VITROS ECi/ECiQ Immunodiagnostic System using chemiluminescence detection technology.

The LLOQ was 5 mIU/mL.

Anti-poliovirus (types 1, 2, and 3) antibodies

Anti-poliovirus types 1, 2, and 3 were measured by neutralization assay. The LLOQ of the anti-poliovirus types 1, 2, and 3 assays was 4 (1/dil).

MMR antibodies

Total IgG antibodies against the measles virus were detected using the Bulk Measles IgG enzyme immunoassay (EIA). The clinical endpoint for the measles assay was 255 mIU/mL, and the LLOQ was 60 mIU/mL.

IgG antibodies against the mumps virus were detected using the mumps enzyme-linked immunosorbent assay. The clinical endpoint and the LLOQ for the mumps assay was 10 Mumps Ab units/mL.

Total IgG antibodies against the rubella virus were detected using the Bulk Rubella IgG EIA. The clinical endpoint for the rubella assay was 10 U/mL and the LLOQ was 5 IU/mL.

Table S1. Vaccination and blood sampling schedule by study group

Visit		1	2		3		4		5*
Group (Countries)	BS1 [†]	Vaccinations	Vaccinations	BS2	Vaccinations	BS3 [†]	Vaccinations	BS4	Vaccinations
1 (Czech Republic, Romania, Sweden, Finland and Poland)	✓	MenACYW conjugate vaccine Hexavalent vaccine [‡] PCV10 [‡]	MenACYW conjugate vaccine Hexavalent vaccine PCV10	✓	-	✓	MenACYW conjugate vaccine Hexavalent vaccine [‡] PCV10 [‡] MMR vaccine [#]	✓	-
2 (Czech Republic, Romania, Sweden, Finland and Poland)	✓	Nimenrix Hexavalent vaccine [‡] PCV10 [‡]	Nimenrix Hexavalent vaccine [‡] PCV10 [‡]	✓	-	✓	Nimenrix Hexavalent vaccine [‡] PCV10 [‡] MMR vaccine [#]	✓	-
3 (Italy and Spain)	✓	MenACYW conjugate vaccine	MenACYW conjugate vaccine	✓	-	✓	MenACYW conjugate vaccine	✓	-

		Hexavalent vaccine [‡]	Hexavalent vaccine [‡]			Hexavalent vaccine [‡]	
		PCV13 [‡]	PCV13 [‡]			PCV13 [‡]	
						MMR vaccine [#]	
		MenACYW conjugate vaccine	MenACYW conjugate vaccine			MenACYW conjugate vaccine [¶]	MenACYW conjugate vaccine
4	✓	Hexavalent vaccine [‡]	Hexavalent vaccine	-	✓	-	✓
(Italy and Spain)		PCV13 [‡]	PCV13				PCV13
							MMR vaccine

[#]MMR vaccine could be received concomitantly with other vaccines at Visit 4.

^{*}Last study visit for Groups 1, 2, and 3. Other routine vaccines could be administered as per standard of care after study procedures were completed.

[†]Blood was drawn prior to vaccinations.

[‡]The hexavalent (diphtheria, tetanus, acellular pertussis, inactivated poliovirus, hepatitis B, and *Haemophilus influenzae* type b [DTaP-IPV-HB-Hib]) vaccine and PCV10 or PCV13 were administered according to a 2+1 regimen, concomitantly with the first and second doses in infancy and the toddler dose of MenACYW conjugate vaccine. Participants in Finland, Sweden or Poland received the licensed rotavirus vaccine concomitantly with study vaccines at Visit 1 and Visit 2. No serological testing was done for rotavirus immunogenicity.

[¶]The 3rd dose of MenACYW conjugate vaccine was administered alone, without any other routine pediatric vaccines.

BS, blood sample; PCV10, 10-valent pneumococcal conjugate vaccine; PCV13, 13-valent pneumococcal conjugate vaccine.

Group 1: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV10) administered at 2, 4, and 12–18 months of age.

Group 2: MCV4-TT and routine pediatric vaccines (including hexavalent and PCV10) administered at 2, 4, and 12–18 months of age.

Group 3: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age.

Group 4: MenACYW-TT administered at 2, 4, 6 and 12–18 months of age. Routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age.

Section S2: Supplementary data

Table S2. Summary of hSBA GMTs at D0 before the 2-month vaccination and at D30 after the 4-month vaccination, and before and at D30 after the 12 to 18-month booster, for Group 3 (PPAS).

Serogroup	Time Point	MenACYW-T+MMR+PCV13	
		(2+1 regimen; Group 3)	
		(N=94)	
		M	GMT (95% CI)
A	D0 before dose 1	94	3.0 (2.6; 3.5)
	D30 after dose 2	91	14.8 (10.6; 20.8)
C	D0 before dose 1	94	3.9 (3.2; 4.8)
	D30 after dose 2	95	309 (235; 407)
Y	D0 before dose 1	94	2.9 (2.5; 3.3)
	D30 after dose 2	96	73.4 (57.7; 93.5)
W	D0 before dose 1	94	2.7 (2.4; 3.0)
	D30 after dose 2	96	102 (79.7; 131)

A	D0 before booster dose (Dose 3)	91	5.2 (4.2; 6.4)
	D30 after booster dose (Dose 3)	92	104 (67.9; 161)
C	D0 before booster dose (Dose 3)	94	26.2 (18.7; 36.8)
	D30 after booster dose (Dose 3)	93	819 (622; 1078)
Y	D0 before booster dose (Dose 3)	94	33.0 (25.0; 43.5)
	D30 after booster dose (Dose 3)	94	589 (470; 737)
W	D0 before booster dose (Dose 3)	93	39.1 (29.6; 51.8)
	D30 after booster dose (Dose 3)	87	1049 (782; 1406)

CI, confidence interval; D, day; GMT, geometric mean titer; hSBA, serum bactericidal antibody assay using human complement; M: number of participants with valid serology results for the particular serogroup and timepoint; MenACYW-TT, quadrivalent meningococcal polysaccharide

tetanus toxoid-conjugate vaccine; MMR, measles-mumps-rubella; N, number of participants who received vaccination; PCV13, 13-valent pneumococcal conjugate vaccine; PPAS, per-protocol analysis set.

95% CI calculated using calculation for normal distribution on $\log_{10}(\text{titer})$ followed by antilog transformation.

Group 3: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age.

Table S3. Summary of hSBA geometric mean titers at D0 before the 2-month vaccination and at D30 after the 6-month vaccination, and before and D30 after the 12 to 18-month booster for Group 4 (PPAS).

Serogroup	Time Point	MenACYW-TT+MMR+PCV13 (3+1 regimen; Group 4) (N=90)	
		M	GMT (95% CI)
A	D0 before dose 1	89	2.9 (2.5; 3.3)
	D30 after dose 3	88	23.0 (17.1; 30.9)
C	D0 before dose 1	90	3.9 (3.3; 4.6)
	D30 after dose 3	90	481 (376; 616)
Y	D0 before dose 1	90	2.8 (2.4; 3.2)
	D30 after dose 3	90	150 (116; 195)
W	D0 before dose 1	90	3.1 (2.6; 3.6)
	D30 after dose 3	90	196 (156; 245)

A	D0 before booster dose (Dose 4)	89	8.1 (6.3; 10.4)
	D30 after booster dose (Dose 4)	89	62.0 (39.9; 96.4)
C	D0 before booster dose (Dose 4)	89	56.9 (42.4; 76.4)
	D30 after booster dose (Dose 4)	86	791 (608; 1029)
Y	D0 before booster dose (Dose 4)	90	85.8 (68.2; 108)
	D30 after booster dose (Dose 4)	89	632 (512; 780)
W	D0 before booster dose (Dose 4)	90	92.6 (74.3; 115)
	D30 after booster dose (Dose 4)	86	1024 (806; 1301)

CI, confidence interval; D, day; GMT, geometric mean titer; hSBA, serum bactericidal antibody assay using human complement M, number of participants with valid serology results for the particular serogroup and timepoint; N, number of participants who received vaccination;

MenACYW-TT, quadrivalent meningococcal polysaccharide tetanus toxoid-conjugate vaccine; MMR, measles-mumps-rubella; PCV13, 13-valent pneumococcal conjugate vaccine; PPAS, per-protocol analysis set

95% CI calculated using calculation for normal distribution on $\log_{10}(\text{titer})$ followed by antilog transformation.

Group 4: MenACYW-TT administered at 2, 4, 6 and 12–18 months of age. Routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age.

Table S4. Percentage of participants with hSBA titers $\geq 1:4$ (a) and $\geq 1:8$ (b) at D0 before the 2-month vaccination and at D30 after the 6-month vaccination, and at D0 before and at D30 after dose 4 at 12 to 18-months for Group 4.

MenACYW-TT+MMR+PCV13				
Serogroup	Time Point	hSBA titers	(3+1 regimen; Group 4) (N=90)	
			n/M	% (95% CI)
A	D0 before dose 1	$\geq 1:4$	29/89	32.6 (23.0; 43.3)
		$\geq 1:8$	10/89	11.2 (5.5; 19.7)
	D30 after dose 3	$\geq 1:4$	81/88	92.0 (84.3; 96.7)
		$\geq 1:8$	72/88	81.8 (72.2; 89.2)
C	D0 before dose 1	$\geq 1:4$	44/90	48.9 (38.2; 59.7)
		$\geq 1:8$	29/90	32.2 (22.8; 42.9)
	D30 after dose 3	$\geq 1:4$	89/90	98.9 (94.0; 100)
		$\geq 1:8$	89/90	98.9 (94.0; 100)
Y	D0 before dose 1	$\geq 1:4$	20/90	22.2 (14.1; 32.2)
		$\geq 1:8$	11/90	12.2 (6.3; 20.8)
	D30 after dose 3	$\geq 1:4$	89/90	98.9 (94.0; 100)
		$\geq 1:8$	89/90	98.9 (94.0; 100)

W	D0 before dose 1	$\geq 1:4$	32/90	35.6 (25.7; 46.3)
		$\geq 1:8$	15/90	16.7 (9.6; 26.0)
	D30 after dose 3	$\geq 1:4$	89/90	98.9 (94.0; 100)
		$\geq 1:8$	89/90	98.9 (94.0; 100)
A	D0 before booster dose (Dose 4)	$\geq 1:4$	72/89	80.9 (71.2; 88.5)
		$\geq 1:8$	47/89	52.8 (41.9; 63.5)
	D30 after booster dose (Dose 4)	$\geq 1:4$	73/89	82.0 (72.5; 89.4)
		$\geq 1:8$	73/89	82.0 (72.5; 89.4)
C	D0 before booster dose (Dose 4)	$\geq 1:4$	87/89	97.8 (92.1; 99.7)
		$\geq 1:8$	82/89	92.1 (84.5; 96.8)
	D30 after booster dose (Dose 4)	$\geq 1:4$	86/86	100 (95.8; 100)
		$\geq 1:8$	86/86	100 (95.8; 100)
Y	D0 before booster dose (Dose 4)	$\geq 1:4$	90/90	100 (96.0; 100)
		$\geq 1:8$	90/90	100 (96.0; 100)
	D30 after booster dose (Dose 4)	$\geq 1:4$	89/89	100 (95.9; 100)
		$\geq 1:8$	89/89	100 (95.9; 100)
W	D0 before booster dose (Dose 4)	$\geq 1:4$	90/90	100 (96.0; 100)
		$\geq 1:8$	90/90	100 (96.0; 100)

D30 after booster dose	$\geq 1:4$	86/86	100 (95.8; 100)
(Dose 4)	$\geq 1:8$	86/86	100 (95.8; 100)

n: number of participants experiencing the endpoint.

M: number of participants with valid serology results for the particular serogroup and timepoint.

N: number of participants who received vaccination.

CI, confidence interval; D, day; GMT, geometric mean titer; hSBA, serum bactericidal antibody assay using human complement.

95% CI of the single proportion calculated from the exact binomial method.

Group 4: MenACYW-TT administered at 2, 4, 6 and 12–18 months of age. Routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age

Table S5. Summary of rSBA geometric mean titers at D0 before the 2-month vaccination and D30 after the 4-month vaccination, and before and at D30 after the 12 to 18-month vaccination for Groups 1–3

Serogroup	Time Point	MenACYW-TT+MMR+PCV10 (2+1 regimen; Group 1) (N=522)			MCV4-TT+MMR+PCV10 (2+1 regimen; Group 2) (N=524)			MenACYW-T+MMR+PCV13 (2+1 regimen; Group 3) (N=96)		
		M	GMT	95% CI	M	GMT	95% CI	M	GMT	95% CI
A	D0 before dose 1	84	2.0	(NC; NC)	73	2.0	(2.0; 2.1)	38	2.1	(1.9; 2.4)
	D30 after dose 2	79	17.8	(12.0; 26.4)	72	57.0	(39.3; 82.7)	31	40.0	(20.9; 76.5)
C	D0 before dose 1	86	2.3	(1.9; 2.6)	74	2.4	(2.0; 2.9)	38	2.9	(2.0; 4.1)
	D30 after dose 2	81	553	(433; 705)	72	264	(201; 345)	37	678	(488; 942)
Y	D0 before dose 1	84	2.0	(2.0; 2.1)	70	2.0	(NC; NC)	37	2.2	(1.8; 2.8)
	D30 after dose 2	36	683	(441; 1060)	30	315	(199; 500)	3	2048	(65.4; 64111)
W	D0 before dose 1	86	2.0	(NC; NC)	74	2.1	(2.0; 2.2)	37	2.0	(NC; NC)
	D30 after dose 2	69	1726	(1234; 2416)	56	894	(600; 1331)	19	4406	(2326; 8345)
A	D0 before booster dose (Dose 3)	72	6.6	(4.0; 10.8)	66	17.8	(9.9; 32.0)	35	8.0	(3.5; 18.2)

	D30 after booster dose (Dose 3)	71	447	(299; 668)	70	1522	(1188; 1950)	37	542	(288; 1018)
C	D0 before booster dose (Dose 3)	74	32.0	(20.9; 49.0)	69	11.0	(7.5; 16.2)	36	14.5	(8.0; 26.5)
	D30 after booster dose (Dose 3)	71	1269	(951; 1695)	70	883	(657; 1185)	37	1796	(1136; 2841)
Y	D0 before booster dose (Dose 3)	43	51.9	(29.3; 91.9)	41	10.5	(6.1; 18.0)	25	64.0	(30.6; 134)
	D30 after booster dose (Dose 3)	62	906	(716; 1146)	67	586	(444; 772)	37	1382	(1018; 1876)
W	D0 before booster dose (Dose 3)	64	85.7	(53.7; 137)	59	25.9	(15.8; 42.5)	33	58.8	(26.7; 129)
	D30 after booster dose (Dose 3)	70	2812	(2154; 3670)	70	1680	(1273; 2217)	37	3396	(2360; 4887)

M: number of participants with valid serology results for the particular serogroup and timepoint.

N: number of participants who received vaccination.

CI, confidence interval; D, day; GMT, geometric mean titer.

95% CI calculated using calculation for normal distribution on log10(titer) followed by antilog transformation.

Group 1: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV10) administered at 2, 4, and 12–18 months of age.

Group 2: MCV4-TT and routine pediatric vaccines (including hexavalent and PCV10) administered at 2, 4, and 12–18 months of age.

Group 3: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age.

Table S6. Summary of rSBA geometric mean titers at D0 before the 2-month vaccination and D30 after the 6-month vaccination, and before and at D30 after the 6-month vaccination for Group 4 (PPAS1)

Serogroup	Time Point	MenACYW-TT+MMR+PCV13 (3+1 regimen; Group 4) (N=90)		
		M	GMT	95% CI
A	D0 before dose 1	43	2.3	(1.8; 2.9)
	D30 after dose 3	39	124	(68.2; 224)
C	D0 before dose 1	43	4.4	(2.9; 6.8)
	D30 after dose 3	45	1393	(950; 2044)
Y	D0 before dose 1	43	2.2	(1.8; 2.7)
	D30 after dose 3	22	1863	(964; 3602)
W	D0 before dose 1	42	2.4	(2.1; 2.8)
	D30 after dose 3	34	8361	(5222; 13386)
A	D0 before booster dose (Dose 4)	41	15.2	(6.9; 33.7)
	D30 after booster dose (Dose 4)	41	660	(411; 1060)
C	D0 before booster dose (Dose 4)	41	82.5	(46.4; 146)
	D30 after booster dose (Dose 4)	41	2014	(1413; 2870)
Y	D0 before booster dose (Dose 4)	33	267	(163; 436)

	D30 after booster dose (Dose 4)	41	1882	(1142; 3101)
W	D0 before booster dose (Dose 4)	39	570	(349; 930)
	D30 after booster dose (Dose 4)	41	7156	(4880; 10493)

M: number of participants with valid serology results for the particular serogroup and timepoint.

N: number of participants who received vaccination.

CI, confidence interval; D, day; GMT, geometric mean titer.

95% CI calculated using calculation for normal distribution on log10(titer) followed by antilog transformation.

Group 4: MenACYW-TT administered at 2, 4, 6 and 12–18 months of age. Routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age.

Table S7. Percentage of participants with rSBA titers $\geq 1:8$ and $\geq 1:128$ at D0 before the 2-month vaccination and D30 after the 4-month vaccination, and before and at D30 after the 12 to 18-month vaccination for Groups 1–3.

Serogroup	Time Point	rSBA Titers	MenACYW-TT+MMR+PCV10 (2+1 regimen; Group 1) (N=522)			MCV4-TT+MMR+PCV10 (2+1 regimen; Group 2) (N=524)			MenACYW-T+MMR+PCV13 (2+1 regimen; Group 3) (N=96)		
			n/M	%	95% CI	n/M	%	95% CI	n/M	%	95% CI
A	D0 before dose 1	$\geq 1:8$	0/84	0	(0; 4.3)	1/73	1.4	(0; 7.4)	1/38	2.6	(0.1; 13.8)
		$\geq 1:128$	0/84	0	(0; 4.3)	0/73	0	(0; 4.9)	0/38	0	(0; 9.3)
	D30 after dose 2	$\geq 1:8$	52/79	65.8	(54.3; 76.1)	64/72	88.9	(79.3; 95.1)	25/31	80.6	(62.5; 92.5)
		$\geq 1:128$	19/79	24.1	(15.1; 35.0)	30/72	41.7	(30.2; 53.9)	11/31	35.5	(19.2; 54.6)
C	D0 before dose 1	$\geq 1:8$	2/86	2.3	(0.3; 8.1)	5/74	6.8	(2.2; 15.1)	3/38	7.9	(1.7; 21.4)
		$\geq 1:128$	2/86	2.3	(0.3; 8.1)	1/74	1.4	(0; 7.3)	2/38	5.3	(0.6; 17.7)
	D30 after dose 2	$\geq 1:8$	81/81	100	(95.5; 100)	70/72	97.2	(90.3; 99.7)	37/37	100	(90.5; 100)
		$\geq 1:128$	77/81	95.1	(87.8; 98.6)	63/72	87.5	(77.6; 94.1)	37/37	100	(90.5; 100)
Y	D0 before dose 1	$\geq 1:8$	1/84	1.2	(0; 6.5)	0/70	0	(0; 5.1)	1/37	2.7	(0.1; 14.2)
		$\geq 1:128$	0/84	0	(0; 4.3)	0/70	0	(0; 5.1)	1/37	2.7	(0.1; 14.2)
	D30 after dose 2	$\geq 1:8$	36/36	100	(90.3; 100)	29/30	96.7	(82.8; 99.9)	3/3	100	(29.2; 100)
		$\geq 1:128$	35/36	97.2	(85.5; 99.9)	28/30	93.3	(77.9; 99.2)	3/3	100	(29.2; 100)
W	D0 before dose 1	$\geq 1:8$	0/86	0	(0; 4.2)	1/74	1.4	(0; 7.3)	0/37	0	(0; 9.5)

		$\geq 1:128$	0/86	0	(0; 4.2)	0/74	0	(0; 4.9)	0/37	0	(0; 9.5)
	D30 after dose 2	$\geq 1:8$	69/69	100	(94.8; 100)	55/56	98.2	(90.4; 100)	19/19	100	(82.4; 100)
		$\geq 1:128$	68/69	98.6	(92.2; 100)	53/56	94.6	(85.1; 98.9)	19/19	100	(82.4; 100)
A	D0 before booster dose (Dose 3)	$\geq 1:8$	19/72	26.4	(16.7; 38.1)	33/66	50.0	(37.4; 62.6)	9/35	25.7	(12.5; 43.3)
		$\geq 1:128$	13/72	18.1	(10.0; 28.9)	23/66	34.8	(23.5; 47.6)	9/35	25.7	(12.5; 43.3)
	D30 after booster dose (Dose 3)	$\geq 1:8$	67/71	94.4	(86.2; 98.4)	70/70	100	(94.9; 100)	36/37	97.3	(85.8; 99.9)
C		$\geq 1:128$	64/71	90.1	(80.7; 95.9)	70/70	100	(94.9; 100)	32/37	86.5	(71.2; 95.5)
	D0 before booster dose (Dose 3)	$\geq 1:8$	55/74	74.3	(62.8; 83.8)	39/69	56.5	(44.0; 68.4)	21/36	58.3	(40.8; 74.5)
		$\geq 1:128$	27/74	36.5	(25.6; 48.5)	6/69	8.7	(3.3; 18.0)	8/36	22.2	(10.1; 39.2)
Y	D30 after booster dose (Dose 3)	$\geq 1:8$	71/71	100	(94.9; 100)	70/70	100	(94.9; 100)	37/37	100	(90.5; 100)
		$\geq 1:128$	70/71	98.6	(92.4; 100)	67/70	95.7	(88.0; 99.1)	36/37	97.3	(85.8; 99.9)
	D0 before booster dose (Dose 3)	$\geq 1:8$	36/43	83.7	(69.3; 93.2)	21/41	51.2	(35.1; 67.1)	22/25	88.0	(68.8; 97.5)
		$\geq 1:128$	21/43	48.8	(33.3; 64.5)	4/41	9.8	(2.7; 23.1)	13/25	52.0	(31.3; 72.2)
	D30 after booster dose (Dose 3)	$\geq 1:8$	62/62	100	(94.2; 100)	66/67	98.5	(92.0; 100)	37/37	100	(90.5; 100)

W	D0 before booster dose (Dose 3)	≥1:128	62/62	100	(94.2; 100)	65/67	97.0	(89.6; 99.6)	37/37	100	(90.5; 100)
		≥1:8	58/64	90.6	(80.7; 96.5)	41/59	69.5	(56.1; 80.8)	26/33	78.8	(61.1; 91.0)
	D30 after booster dose (Dose 3)	≥1:128	34/64	53.1	(40.2; 65.7)	17/59	28.8	(17.8; 42.1)	18/33	54.5	(36.4; 71.9)
		≥1:8	70/70	100	(94.9; 100)	70/70	100	(94.9; 100)	37/37	100	(90.5; 100)
		≥1:128	70/70	100	(94.9; 100)	70/70	100	(94.9; 100)	37/37	100	(90.5; 100)

n: number of participants experiencing the endpoint listed.

M: number of participants with valid serology results for the particular serogroup and timepoint.

N: number of participants who received vaccination.

CI, confidence interval; D, day; rSBA, serum bactericidal assay using rabbit complement.

95% CI of the single proportion calculated from the exact binomial method.

Group 1: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV10) administered at 2, 4, and 12–18 months of age.

Group 2: MCV4-TT and routine pediatric vaccines (including hexavalent and PCV10) administered at 2, 4, and 12–18 months of age.

Group 3: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age.

Table S8 Percentage of participants with rSBA titers $\geq 1:8$ and $\geq 1:128$ at D0 before the 2-month vaccination and D30 after the 6-month vaccination, and before and at D30 after the 12 to 18-month vaccination for Group 4.

Serogroup	Time Point	rSBA Titers	MenACYW-TT+MMR+PCV13 (3+1 regimen; Group 4) (N=90)		
			n/M	%	95% CI
A	D0 before dose 1	$\geq 1:8$	1/43	2.3	(0.1; 12.3)
		$\geq 1:128$	1/43	2.3	(0.1; 12.3)
	D30 after dose 3	$\geq 1:8$	36/39	92.3	(79.1; 98.4)
		$\geq 1:128$	27/39	69.2	(52.4; 83.0)
C	D0 before dose 1	$\geq 1:8$	11/43	25.6	(13.5; 41.2)
		$\geq 1:128$	3/43	7.0	(1.5; 19.1)
	D30 after dose 3	$\geq 1:8$	45/45	100	(92.1; 100)
		$\geq 1:128$	42/45	93.3	(81.7; 98.6)
Y	D0 before dose 1	$\geq 1:8$	1/43	2.3	(0.1; 12.3)
		$\geq 1:128$	1/43	2.3	(0.1; 12.3)
	D30 after dose 3	$\geq 1:8$	22/22	100	(84.6; 100)
		$\geq 1:128$	22/22	100	(84.6; 100)
W	D0 before dose 1	$\geq 1:8$	4/42	9.5	(2.7; 22.6)
		$\geq 1:128$	0/42	0	(0; 8.4)

	D30 after dose 3	≥1:8	34/34	100	(89.7; 100)
		≥1:128	34/34	100	(89.7; 100)
A	D0 before booster dose (Dose 4)	≥1:8	18/41	43.9	(28.5; 60.3)
		≥1:128	13/41	31.7	(18.1; 48.1)
	D30 after booster dose (Dose 4)	≥1:8	40/41	97.6	(87.1; 99.9)
		≥1:128	38/41	92.7	(80.1; 98.5)
C	D0 before booster dose (Dose 4)	≥1:8	37/41	90.2	(76.9; 97.3)
		≥1:128	23/41	56.1	(39.7; 71.5)
	D30 after booster dose (Dose 4)	≥1:8	41/41	100	(91.4; 100)
		≥1:128	41/41	100	(91.4; 100)
Y	D0 before booster dose (Dose 4)	≥1:8	32/33	97.0	(84.2; 99.9)
		≥1:128	28/33	84.8	(68.1; 94.9)
	D30 after booster dose (Dose 4)	≥1:8	40/41	97.6	(87.1; 99.9)
		≥1:128	40/41	97.6	(87.1; 99.9)

W	D0 before booster dose (Dose 4)	$\geq 1:8$	39/39	100	(91.0; 100)
		$\geq 1:128$	35/39	89.7	(75.8; 97.1)
	D30 after booster dose (Dose 4)	$\geq 1:8$	41/41	100	(91.4; 100)
		$\geq 1:128$	41/41	100	(91.4; 100)

n: number of participants experiencing the endpoint listed.

M: number of participants with valid serology results for the particular serogroup and timepoint.

N: number of participants who received vaccination.

CI, confidence interval; D, day; rSBA, serum bactericidal assay using rabbit complement.

95% CI of the single proportion calculated from the exact binomial method.

Group 4: MenACYW-TT administered at 2, 4, 6 and 12–18 months of age. Routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age.

Table S9. Summary of response rate to routine hexavalent and Pertussis (anti-PT and anti-FHA) vaccines at D30 after the 4-month vaccination for Groups 1–3

Antigens	Criterion	MenACYW-TT+MMR+PCV10 (2+1 regimen; Group 1) (N=522)			MCV4-TT+MMR+PCV10 (2+1 regimen; Group 2) (N=524)			MenACYW-T+MMR+PCV13 (2+1 regimen; Group 3) (N=96)		
		n/M	%	95% CI	n/M	%	95% CI	n/M	%	95% CI
Anti-tetanus	≥0.01 IU/mL	514/514	100	(99.3; 100)	520/520	100	(99.3; 100)	93/93	100	(96.1; 100)
	≥0.1 IU/mL	514/514	100	(99.3; 100)	519/520	99.8	(98.9; 100)	93/93	100	(96.1; 100)
	≥1.0 IU/mL	274/514	53.3	(48.9; 57.7)	293/520	56.3	(52.0; 60.7)	41/93	44.1	(33.8; 54.8)
Anti-diphtheria	≥0.01 IU/mL	514/514	100	(99.3; 100)	519/520	99.8	(98.9; 100)	93/93	100	(96.1; 100)
	≥0.1 IU/mL	465/514	90.5	(87.6; 92.9)	466/520	89.6	(86.7; 92.1)	88/93	94.6	(87.9; 98.2)
	≥1.0 IU/mL	168/514	32.7	(28.6; 36.9)	169/520	32.5	(28.5; 36.7)	31/93	33.3	(23.9; 43.9)
Anti-polio 1	≥1:8	423/486	87.0	(83.7; 89.9)	407/489	83.2	(79.6; 86.4)	82/83	98.8	(93.5; 100)
Anti-polio 2	≥1:8	470/482	97.5	(95.7; 98.7)	478/485	98.6	(97.0; 99.4)	79/79	100	(95.4; 100)
Anti-polio 3	≥1:8	468/488	95.9	(93.7; 97.5)	473/492	96.1	(94.0; 97.7)	81/82	98.8	(93.4; 100)
Anti-PRP	≥0.15 µg/mL	371/517	71.8	(67.7; 75.6)	390/521	74.9	(70.9; 78.5)	75/96	78.1	(68.5; 85.9)
	≥1 µg/mL	125/517	24.2	(20.5; 28.1)	142/521	27.3	(23.5; 31.3)	38/96	39.6	(29.7; 50.1)
Anti-HBsAg	≥10 mIU/mL	487/505	96.4	(94.4; 97.9)	499/510	97.8	(96.2; 98.9)	85/92	92.4	(84.9; 96.9)
	≥100 mIU/mL	433/505	85.7	(82.4; 88.7)	417/510	81.8	(78.1; 85.0)	67/92	72.8	(62.6; 81.6)

Anti-PT	484/512	94.5	(92.2; 96.3)	507/518	97.9	(96.2; 98.9)	76/92	82.6	(73.3; 89.7)
Anti-FHA	459/512	89.6	(86.7; 92.1)	474/518	91.5	(88.8; 93.8)	57/92	62.0	(51.2; 71.9)

n: number of participants with valid serology results for the particular antigen and who met the criterion.

M: number of participants with available data for the endpoint and timepoint. Percentages are based on M.

N: number of participants who received vaccination.

Pertussis vaccine seroresponse (anti-PT and anti-FHA) was defined as follows: if pre-primary vaccination concentration $<4 \times \text{LLOQ}$, post-primary vaccination concentration must be $\geq 4 \times \text{LLOQ}$; if pre-primary vaccination concentration is $\geq 4 \times \text{LLOQ}$, post-primary vaccination concentration must be $\geq$ pre-primary vaccination concentration.

CI, confidence interval; D, day; FHA, filamentous hemagglutinin; HBsAg, hepatitis B surface antigen; LLOQ, lower limit of quantitation; PRP, anti-polyribosyl-ribitol phosphate; PT, pertussis toxin.

95% CI of the single proportion calculated from the exact binomial method.

Group 1: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV10) administered at 2, 4, and 12–18 months of age.

Group 2: MCV4-TT and routine pediatric vaccines (including hexavalent and PCV10) administered at 2, 4, and 12–18 months of age.

Group 3: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age.

Table S10. Summary of response rate of routine hexavalent and Pertussis (anti-PT and anti-FHA) vaccines at D0 before and D30 after the 12 to 18-month vaccination for Groups 1–3

Antigens	Criterion	Time Point	MenACYW-TT+MMR+PCV10 (2+1 regimen; Group 1) (N=560)			MCV4-TT+MMR+PCV10 (2+1 regimen; Group 2) (N=584)			MenACYW-T+MMR+PCV13 (2+1 regimen; Group 3) (N=94)		
			n/M	%	95% CI	n/M	%	95% CI	n/M	%	95% CI
Anti-tetanus	≥0.01 IU/mL	D0 before booster dose (Dose 3)	542/542	100	(99.3; 100)	571/571	100	(99.4; 100)	92/92	100	(96.1; 100)
		D30 after booster dose (Dose 3)	551/551	100	(99.3; 100)	577/577	100	(99.4; 100)	92/92	100	(96.1; 100)
	≥0.1 IU/mL	D0 before booster dose (Dose 3)	510/542	94.1	(91.8; 95.9)	556/571	97.4	(95.7; 98.5)	77/92	83.7	(74.5; 90.6)
		D30 after booster dose (Dose 3)	551/551	100	(99.3; 100)	577/577	100	(99.4; 100)	92/92	100	(96.1; 100)
	≥1.0 IU/mL	D0 before booster dose (Dose 3)	58/542	10.7	(8.2; 13.6)	84/571	14.7	(11.9; 17.9)	6/92	6.5	(2.4; 13.7)
		D30 after booster dose (Dose 3)	551/551	100	(99.3; 100)	577/577	100	(99.4; 100)	92/92	100	(96.1; 100)

Anti-diphtheria	≥0.01 IU/mL	D30 after booster dose (Dose 3)	549/551	99.6	(98.7; 100)	575/577	99.7	(98.8; 100)	89/92	96.7	(90.8; 99.3)
		D0 before booster dose (Dose 3)	532/542	98.2	(96.6; 99.1)	561/569	98.6	(97.2; 99.4)	89/91	97.8	(92.3; 99.7)
	≥0.1 IU/mL	D30 after booster dose (Dose 3)	551/551	100	(99.3; 100)	577/577	100	(99.4; 100)	92/92	100	(96.1; 100)
		D0 before booster dose (Dose 3)	261/542	48.2	(43.9; 52.5)	235/569	41.3	(37.2; 45.5)	43/91	47.3	(36.7; 58.0)
	≥1.0 IU/mL	D30 after booster dose (Dose 3)	549/551	99.6	(98.7; 100)	576/577	99.8	(99.0; 100)	92/92	100	(96.1; 100)
		D0 before booster dose (Dose 3)	6/542	1.1	(0.4; 2.4)	4/569	0.7	(0.2; 1.8)	0/91	0	(0; 4.0)
		D30 after booster dose (Dose 3)	416/551	75.5	(71.7; 79.0)	418/577	72.4	(68.6; 76.1)	85/92	92.4	(84.9; 96.9)

Anti-polio 1 $\geq 1:8$	D0 before booster dose (Dose 3)	339/526	64.4	(60.2; 68.5)	356/559	63.7	(59.5; 67.7)	83/89	93.3	(85.9; 97.5)
	D30 after booster dose (Dose 3)	532/533	99.8	(99.0; 100)	547/553	98.9	(97.7; 99.6)	86/86	100	(95.8; 100)
Anti-polio 2 $\geq 1:8$	D0 before booster dose (Dose 3)	420/528	79.5	(75.8; 82.9)	453/560	80.9	(77.4; 84.1)	84/88	95.5	(88.8; 98.7)
	D30 after booster dose (Dose 3)	530/530	100	(99.3; 100)	554/554	100	(99.3; 100)	87/87	100	(95.8; 100)
Anti-polio 3 $\geq 1:8$	D0 before booster dose (Dose 3)	363/529	68.6	(64.5; 72.6)	368/560	65.7	(61.6; 69.6)	75/89	84.3	(75.0; 91.1)
	D30 after booster dose (Dose 3)	527/531	99.2	(98.1; 99.8)	556/557	99.8	(99.0; 100)	87/87	100	(95.8; 100)
Anti-PRP ≥ 0.15 $\mu\text{g/mL}$	D0 before booster dose (Dose 3)	308/545	56.5	(52.2; 60.7)	345/571	60.4	(56.3; 64.5)	56/93	60.2	(49.5; 70.2)

Anti-HBsAg	≥1 µg/mL	D30 after booster dose (Dose 3)	545/555	98.2	(96.7; 99.1)	576/583	98.8	(97.5; 99.5)	91/91	100	(96.0; 100)
		D0 before booster dose (Dose 3)	76/545	13.9	(11.1; 17.1)	85/571	14.9	(12.1; 18.1)	14/93	15.1	(8.5; 24.0)
		D30 after booster dose (Dose 3)	508/555	91.5	(88.9; 93.7)	553/583	94.9	(92.7; 96.5)	89/91	97.8	(92.3; 99.7)
		D0 before booster dose (Dose 3)	436/535	81.5	(77.9; 84.7)	449/565	79.5	(75.9; 82.7)	60/91	65.9	(55.3; 75.5)
Anti-HBsAg	≥10 mIU/mL	D30 after booster dose (Dose 3)	535/546	98.0	(96.4; 99.0)	563/571	98.6	(97.3; 99.4)	85/90	94.4	(87.5; 98.2)
	≥100 mIU/mL	D0 before booster dose (Dose 3)	207/535	38.7	(34.5; 43.0)	200/565	35.4	(31.5; 39.5)	24/91	26.4	(17.7; 36.7)

	D30 after booster dose (Dose 3)	510/546	93.4	(91.0; 95.3)	534/571	93.5	(91.2; 95.4)	72/90	80.0	(70.2; 87.7)
Anti-PT		517/533	97.0	(95.2; 98.3)	548/565	97.0	(95.2; 98.2)	84/90	93.3	(86.1; 97.5)
Anti-FHA		475/533	89.1	(86.2; 91.6)	509/565	90.1	(87.3; 92.4)	83/90	92.2	(84.6; 96.8)

n: number of participants with valid serology results for the particular antigen and who met the criterion.

M: number of participants with available data for the endpoint and timepoint. Percentages are based on M.

N: number of participants who received vaccination.

Pertussis vaccine seroresponse (anti-PT and anti-FHA) was defined as follows: if pre-primary vaccination concentration $<4 \times$ LLOQ, post-primary vaccination concentration must be $\geq 4 \times$ LLOQ; if pre-primary vaccination concentration is $\geq 4 \times$ LLOQ, post-primary vaccination concentration must be $\geq 2 \times$ pre-primary vaccination concentration.

CI, confidence interval; D, day; FHA, filamentous hemagglutinin; HBsAg, hepatitis B surface antigen; LLOQ, lower limit of quantitation; PRP, anti-polyribosyl-ribitol phosphate; PT, pertussis toxin.

95% CI of the single proportion calculated from the exact binomial method.

Group 1: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV10) administered at 2, 4, and 12–18 months of age.

Group 2: MCV4-TT and routine pediatric vaccines (including hexavalent and PCV10) administered at 2, 4, and 12–18 months of age.

Group 3: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age.

Table S11. Summary of response rate of MMR vaccination at D30 after the 12 to 18-month booster for Groups 1–3.

Antigens	Serostatus cutoff	MenACYW-TT+MMR+PCV10 (2+1 regimen; Group 1) (N=560)			MCV4-TT+MMR+PCV10 (2+1 regimen; Group 2) (N=584)			MenACYW-T+MMR+PCV13 (2+1 regimen; Group 3) (N=94)		
		n/M	%	95% CI	n/M	%	95% CI	n/M	%	95% CI
Anti-measles	≥255 mIU/mL	516/525	98.3	(96.8; 99.2)	548/553	99.1	(97.9; 99.7)	94/94	100	(96.2; 100)
Anti-mumps	≥10 Mumps Ab units/mL	518/525	98.7	(97.3; 99.5)	546/553	98.7	(97.4; 99.5)	94/94	100	(96.2; 100)
Anti-rubella	≥10 IU/mL	518/525	98.7	(97.3; 99.5)	538/553	97.3	(95.6; 98.5)	93/94	98.9	(94.2; 100)

n: number of participants with valid serology results for the particular antigen and who met the criterion.

M: number of participants with available data for the endpoint and timepoint. Percentages are based on M.

Ab, antibody; CI, confidence interval.

95% CI of the single proportion calculated from the exact binomial method.

Group 1: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV10) administered at 2, 4, and 12–18 months of age.

Group 2: MCV4-TT and routine pediatric vaccines (including hexavalent and PCV10) administered at 2, 4, and 12–18 months of age.

Group 3: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age.

Table S12. Summary of response rate of hexavalent and Pertussis (anti-PT and anti-FHA) vaccines at before and at D30 after the 12 to 18-month vaccination for Group 4

Antigens	Criterion	Time Point	MenACYW-TT+MMR+PCV13 (3+1 regimen; Group 4) (N=90)		
			n/M	%	95% CI
Anti-tetanus	≥0.01 IU/mL	D0 before booster dose (Dose 4)	90/90	100	(96.0; 100)
		D30 after booster dose (Dose 4)	89/89	100	(95.9; 100)
	≥0.1 IU/mL	D0 before booster dose (Dose 4)	83/90	92.2	(84.6; 96.8)
		D30 after booster dose (Dose 4)	89/89	100	(95.9; 100)
	≥1.0 IU/mL	D0 before booster dose (Dose 4)	14/90	15.6	(8.8; 24.7)
		D30 after booster dose (Dose 4)	88/89	98.9	(93.9; 100)
Anti-diphtheria	≥0.01 IU/mL	D0 before booster dose (Dose 4)	88/89	98.9	(93.9; 100)
		D30 after booster dose (Dose 4)	89/89	100	(95.9; 100)
	≥0.1 IU/mL	D0 before booster dose (Dose 4)	38/89	42.7	(32.3; 53.6)
		D30 after booster dose (Dose 4)	89/89	100	(95.9; 100)
	≥1.0 IU/mL	D0 before booster dose (Dose 4)	0/89	0	(0; 4.1)
		D30 after booster dose (Dose 4)	89/89	100	(95.9; 100)
Anti-polio 1	≥1:8	D0 before booster dose (Dose 4)	80/88	90.9	(82.9; 96.0)
		D30 after booster dose (Dose 4)	87/87	100	(95.8; 100)

Anti-polio 2	≥1:8	D0 before booster dose (Dose 4)	80/88	90.9	(82.9; 96.0)
		D30 after booster dose (Dose 4)	87/87	100	(95.8; 100)
Anti-polio 3	≥1:8	D0 before booster dose (Dose 4)	65/88	73.9	(63.4; 82.7)
		D30 after booster dose (Dose 4)	87/87	100	(95.8; 100)
Anti-PRP	≥0.15 µg/mL	D0 before booster dose (Dose 4)	60/90	66.7	(55.9; 76.3)
		D30 after booster dose (Dose 4)	90/90	100	(96.0; 100)
	≥1 µg/mL	D0 before booster dose (Dose 4)	11/90	12.2	(6.3; 20.8)
		D30 after booster dose (Dose 4)	87/90	96.7	(90.6; 99.3)
Anti-HBsAg	≥10 mIU/mL	D0 before booster dose (Dose 4)	58/90	64.4	(53.7; 74.3)
		D30 after booster dose (Dose 4)	79/86	91.9	(83.9; 96.7)
	≥100 mIU/mL	D0 before booster dose (Dose 4)	25/90	27.8	(18.9; 38.2)
		D30 after booster dose (Dose 4)	72/86	83.7	(74.2; 90.8)
Anti-PT		D30 after booster dose (Dose 4)	79/89	88.8	(80.3; 94.5)
Anti-FHA		D30 after booster dose (Dose 4)	81/89	91.0	(83.1; 96.0)

n: number of participants that met the criterion.

M: number of participants with available data for the endpoint. Percentages are based on M.

N: number of participants who received vaccination.

95% CI of the single proportion calculated from the exact binomial method.

Pertussis vaccine seroresponse (anti-PT and anti-FHA) was defined as follows: if pre-primary vaccination concentration $<4 \times \text{LLOQ}$, post-primary vaccination concentration must be $\geq 4 \times \text{LLOQ}$; if pre-primary vaccination concentration is $\geq 4 \times \text{LLOQ}$, post-primary vaccination concentration must be $\geq 2 \times$ pre-primary vaccination concentration.

CI, confidence interval; D, day; FHA, filamentous hemagglutinin; HBsAg, hepatitis B surface antigen; LLOQ, lower limit of quantification; PRP, anti-polyribosyl-ribitol phosphate; PT, pertussis toxin

Group 4: MenACYW-TT administered at 2, 4, 6 and 12–18 months of age. Routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age.

Table S13. Summary of response rate of MMR vaccination at D30 after the 12 to 18-month vaccination for Group 4

MenACYW-TT+MMR+PCV13 (3+1 regimen; Group 4) (N=90)				
Antigens	Serostatus cutoff	n/M	%	95% CI
Anti-measles	≥255 mIU/mL	88/90	97.8	(92.2; 99.7)
Anti-mumps	≥10 Mumps Ab units/mL	90/90	100	(96.0; 100)
Anti-rubella	≥10 IU/mL	90/90	100	(96.0; 100)

n: number of participants who met the criterion.

M: number of participants with available data for the endpoint and timepoint. Percentages are based on M.

N: number of participants who received vaccination.

CI, confidence interval; D, day.

95% CI of the single proportion calculated from the exact binomial method.

Group 4: MenACYW-TT administered at 2, 4, 6 and 12–18 months of age. Routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age.

Table S14. Summary of response to PCV10 vaccination at D30 after the 4-month vaccination for Groups 1 and 2.

Serotype	Criterion	MenACYW-TT+MMR+PCV10 (2+1 regimen; Group 1) (N=522)			MCV4-TT+MMR+PCV10 (2+1 regimen; Group 2) (N=524)		
		n/M	%	95% CI	n/M	%	95% CI
1	$\geq 0.35 \mu\text{g/mL}$	468/505	92.7	(90.0; 94.8)	479/512	93.6	(91.1; 95.5)
	$\geq 1 \mu\text{g/mL}$	370/505	73.3	(69.2; 77.1)	372/512	72.7	(68.6; 76.5)
4	$\geq 0.35 \mu\text{g/mL}$	489/505	96.8	(94.9; 98.2)	495/512	96.7	(94.7; 98.1)
	$\geq 1 \mu\text{g/mL}$	409/505	81.0	(77.3; 84.3)	426/512	83.2	(79.7; 86.3)
5	$\geq 0.35 \mu\text{g/mL}$	447/505	88.5	(85.4; 91.2)	464/512	90.6	(87.8; 93.0)
	$\geq 1 \mu\text{g/mL}$	293/505	58.0	(53.6; 62.4)	294/512	57.4	(53.0; 61.7)
6B	$\geq 0.35 \mu\text{g/mL}$	339/505	67.1	(62.8; 71.2)	357/511	69.9	(65.7; 73.8)
	$\geq 1 \mu\text{g/mL}$	191/505	37.8	(33.6; 42.2)	224/511	43.8	(39.5; 48.3)
7F	$\geq 0.35 \mu\text{g/mL}$	499/505	98.8	(97.4; 99.6)	503/512	98.2	(96.7; 99.2)
	$\geq 1 \mu\text{g/mL}$	417/505	82.6	(79.0; 85.8)	438/512	85.5	(82.2; 88.5)
9V	$\geq 0.35 \mu\text{g/mL}$	477/504	94.6	(92.3; 96.4)	487/512	95.1	(92.9; 96.8)
	$\geq 1 \mu\text{g/mL}$	370/504	73.4	(69.3; 77.2)	393/512	76.8	(72.9; 80.4)
14	$\geq 0.35 \mu\text{g/mL}$	494/505	97.8	(96.1; 98.9)	503/512	98.2	(96.7; 99.2)
	$\geq 1 \mu\text{g/mL}$	479/505	94.9	(92.5; 96.6)	479/512	93.6	(91.1; 95.5)

18C	≥0.35 µg/mL	366/505	72.5	(68.4; 76.3)	396/512	77.3	(73.5; 80.9)
	≥1 µg/mL	201/505	39.8	(35.5; 44.2)	219/512	42.8	(38.4; 47.2)
19F	≥0.35 µg/mL	415/505	82.2	(78.6; 85.4)	406/512	79.3	(75.5; 82.7)
	≥1 µg/mL	347/505	68.7	(64.5; 72.7)	320/512	62.5	(58.1; 66.7)
23F	≥0.35 µg/mL	393/505	77.8	(73.9; 81.4)	411/512	80.3	(76.6; 83.6)
	≥1 µg/mL	245/505	48.5	(44.1; 53.0)	256/512	50.0	(45.6; 54.4)

n: number of participants with anti-pneumococcal antibody concentrations that met the criterion.

M: number of participants with available data for the endpoint and timepoint. Percentages are based on M.

N: number of participants who received vaccination.

95% CI of the single proportion calculated from the exact binomial method.

CI, confidence interval; D, day; PCV10, pneumococcal conjugate vaccine 10.

Group 1: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV10) administered at 2, 4, and 12–18 months of age.

Group 2: MCV4-TT and routine pediatric vaccines (including hexavalent and PCV10) administered at 2, 4, and 12–18 months of age.

Table S15. Summary of response to PCV10 vaccination at D30 after the 12 to 18-month vaccination for Groups 1 and 2.

Serotype	Criterion	MenACYW-TT+MMR+PCV10 (2+1 regimen; Group 1) (N=560)			MCV4-TT+MMR+PCV10 (2+1 regimen; Group 2) (N=584)		
		n/M	%	95% CI	n/M	%	95% CI
1	≥0.35 µg/mL	544/545	99.8	(99.0; 100)	568/569	99.8	(99.0; 100)
	≥1 µg/mL	509/545	93.4	(91.0; 95.3)	526/569	92.4	(90.0; 94.5)
4	≥0.35 µg/mL	544/545	99.8	(99.0; 100)	567/569	99.6	(98.7; 100)
	≥1 µg/mL	523/545	96.0	(94.0; 97.5)	528/569	92.8	(90.4; 94.8)
5	≥0.35 µg/mL	534/544	98.2	(96.6; 99.1)	556/569	97.7	(96.1; 98.8)
	≥1 µg/mL	444/544	81.6	(78.1; 84.8)	448/569	78.7	(75.1; 82.0)
6B	≥0.35 µg/mL	539/545	98.9	(97.6; 99.6)	566/569	99.5	(98.5; 99.9)
	≥1 µg/mL	514/545	94.3	(92.0; 96.1)	534/569	93.8	(91.5; 95.7)
7F	≥0.35 µg/mL	543/545	99.6	(98.7; 100)	564/568	99.3	(98.2; 99.8)
	≥1 µg/mL	509/545	93.4	(91.0; 95.3)	532/568	93.7	(91.3; 95.5)
9V	≥0.35 µg/mL	544/545	99.8	(99.0; 100)	568/569	99.8	(99.0; 100)
	≥1 µg/mL	521/545	95.6	(93.5; 97.2)	540/569	94.9	(92.8; 96.6)
14	≥0.35 µg/mL	544/544	100	(99.3; 100)	564/568	99.3	(98.2; 99.8)
	≥1 µg/mL	539/544	99.1	(97.9; 99.7)	550/568	96.8	(95.0; 98.1)

18C	≥0.35 µg/mL	540/545	99.1	(97.9; 99.7)	561/569	98.6	(97.2; 99.4)
	≥1 µg/mL	461/545	84.6	(81.3; 87.5)	485/569	85.2	(82.1; 88.1)
19F	≥0.35 µg/mL	541/545	99.3	(98.1; 99.8)	565/569	99.3	(98.2; 99.8)
	≥1 µg/mL	531/545	97.4	(95.7; 98.6)	562/569	98.8	(97.5; 99.5)
23F	≥0.35 µg/mL	537/545	98.5	(97.1; 99.4)	553/569	97.2	(95.5; 98.4)
	≥1 µg/mL	467/545	85.7	(82.5; 88.5)	468/569	82.2	(78.9; 85.3)

n: number of participants with anti-pneumococcal antibody concentrations that met the criterion.

M: number of participants with available data for the endpoint and timepoint. Percentages are based on M.

N: number of participants who received vaccination.

95% CI of the single proportion calculated from the exact binomial method.

CI, confidence interval; D, day; PCV10, pneumococcal conjugate vaccine 10.

Group 1: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV10) administered at 2, 4, and 12–18 months of age.

Group 2: MCV4-TT and routine pediatric vaccines (including hexavalent and PCV10) administered at 2, 4, and 12–18 months of age.

Table S16. Summary of response to PCV13 vaccination at D30 after the 4-month vaccination for Group 3.

Serotype	Criterion	MenACYW-T+MMR+PCV13 (2+1 regimen; Group 3) (N=96)		
		n/M	%	95% CI
1	≥0.35 µg/mL	80/89	89.9	(81.7; 95.3)
	≥1 µg/mL	59/89	66.3	(55.5; 76.0)
3	≥0.35 µg/mL	73/89	82.0	(72.5; 89.4)
	≥1 µg/mL	30/89	33.7	(24.0; 44.5)
4	≥0.35 µg/mL	86/89	96.6	(90.5; 99.3)
	≥1 µg/mL	68/89	76.4	(66.2; 84.8)
5	≥0.35 µg/mL	68/89	76.4	(66.2; 84.8)
	≥1 µg/mL	47/89	52.8	(41.9; 63.5)
6A	≥0.35 µg/mL	79/89	88.8	(80.3; 94.5)
	≥1 µg/mL	59/89	66.3	(55.5; 76.0)
6B	≥0.35 µg/mL	36/89	40.4	(30.2; 51.4)
	≥1 µg/mL	18/89	20.2	(12.4; 30.1)
7F	≥0.35 µg/mL	87/89	97.8	(92.1; 99.7)
	≥1 µg/mL	83/89	93.3	(85.9; 97.5)

9V	≥0.35 µg/mL	79/89	88.8	(80.3; 94.5)
	≥1 µg/mL	54/89	60.7	(49.7; 70.9)
14	≥0.35 µg/mL	86/89	96.6	(90.5; 99.3)
	≥1 µg/mL	78/89	87.6	(79.0; 93.7)
18C	≥0.35 µg/mL	81/89	91.0	(83.1; 96.0)
	≥1 µg/mL	63/89	70.8	(60.2; 79.9)
19A	≥0.35 µg/mL	83/89	93.3	(85.9; 97.5)
	≥1 µg/mL	69/89	77.5	(67.4; 85.7)
19F	≥0.35 µg/mL	88/89	98.9	(93.9; 100)
	≥1 µg/mL	84/89	94.4	(87.4; 98.2)
23F	≥0.35 µg/mL	64/89	71.9	(61.4; 80.9)
	≥1 µg/mL	34/89	38.2	(28.1; 49.1)

n: number of participants with anti-pneumococcal antibody concentrations that met the criterion.

M: number of participants with available data for the endpoint and timepoint. Percentages are based on M.

N: number of participants who received vaccination.

95% CI of the single proportion calculated from the exact binomial method.

CI, confidence interval; D, day; PCV13, pneumococcal conjugate vaccine 13.

Group 3: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age.

Table S17. Summary of response rates for PCV13 vaccination at D30 after the 12 to 18-month vaccination for Group 3.

MenACYW-T+MMR+PCV13 (2+1 regimen; Group 3) (N=94)				
Serotype	Criterion	n/M	%	95% CI
1	≥0.35 µg/mL	91/91	100	(96.0; 100)
	≥1 µg/mL	87/91	95.6	(89.1; 98.8)
3	≥0.35 µg/mL	89/91	97.8	(92.3; 99.7)
	≥1 µg/mL	47/91	51.6	(40.9; 62.3)
4	≥0.35 µg/mL	91/91	100	(96.0; 100)
	≥1 µg/mL	90/91	98.9	(94.0; 100)
5	≥0.35 µg/mL	90/91	98.9	(94.0; 100)
	≥1 µg/mL	85/91	93.4	(86.2; 97.5)
6A	≥0.35 µg/mL	91/91	100	(96.0; 100)
	≥1 µg/mL	91/91	100	(96.0; 100)
6B	≥0.35 µg/mL	90/91	98.9	(94.0; 100)
	≥1 µg/mL	84/91	92.3	(84.8; 96.9)
7F	≥0.35 µg/mL	91/91	100	(96.0; 100)
	≥1 µg/mL	91/91	100	(96.0; 100)

9V	≥0.35 µg/mL	91/91	100	(96.0; 100)
	≥1 µg/mL	89/91	97.8	(92.3; 99.7)
14	≥0.35 µg/mL	91/91	100	(96.0; 100)
	≥1 µg/mL	91/91	100	(96.0; 100)
18C	≥0.35 µg/mL	91/91	100	(96.0; 100)
	≥1 µg/mL	85/91	93.4	(86.2; 97.5)
19A	≥0.35 µg/mL	91/91	100	(96.0; 100)
	≥1 µg/mL	90/91	98.9	(94.0; 100)
19F	≥0.35 µg/mL	91/91	100	(96.0; 100)
	≥1 µg/mL	91/91	100	(96.0; 100)
23F	≥0.35 µg/mL	91/91	100	(96.0; 100)
	≥1 µg/mL	84/91	92.3	(84.8; 96.9)

n: number of participants with anti-pneumococcal antibody concentrations that met the criterion.

M: number of participants with available data for the endpoint and timepoint. Percentages are based on M.

N: number of participants who received vaccination.

95% CI of the single proportion calculated from the exact binomial method.

CI, confidence interval; D, day; PCV13, pneumococcal conjugate vaccine 13.

Group 3: MenACYW-TT and routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age.

Table S18. Summary of response to PCV13 vaccination at D30 after the 12 to 18-month vaccination for Group 4.

Serotype	Criterion	MenACYW-TT+MMR+PCV13 (3+1 regimen; Group 4) (N=90)		
		n/M	%	95% CI
1	≥0.35 µg/mL	89/89	100	(95.9; 100)
	≥1 µg/mL	88/89	98.9	(93.9; 100)
3	≥0.35 µg/mL	82/89	92.1	(84.5; 96.8)
	≥1 µg/mL	47/89	52.8	(41.9; 63.5)
4	≥0.35 µg/mL	89/89	100	(95.9; 100)
	≥1 µg/mL	86/89	96.6	(90.5; 99.3)
5	≥0.35 µg/mL	89/89	100	(95.9; 100)
	≥1 µg/mL	86/89	96.6	(90.5; 99.3)
6A	≥0.35 µg/mL	89/89	100	(95.9; 100)
	≥1 µg/mL	88/89	98.9	(93.9; 100)
6B	≥0.35 µg/mL	89/89	100	(95.9; 100)
	≥1 µg/mL	89/89	100	(95.9; 100)
7F	≥0.35 µg/mL	89/89	100	(95.9; 100)
	≥1 µg/mL	88/89	98.9	(93.9; 100)

9V	≥0.35 µg/mL	89/89	100	(95.9; 100)
	≥1 µg/mL	88/89	98.9	(93.9; 100)
14	≥0.35 µg/mL	89/89	100	(95.9; 100)
	≥1 µg/mL	89/89	100	(95.9; 100)
18C	≥0.35 µg/mL	89/89	100	(95.9; 100)
	≥1 µg/mL	87/89	97.8	(92.1; 99.7)
19A	≥0.35 µg/mL	89/89	100	(95.9; 100)
	≥1 µg/mL	89/89	100	(95.9; 100)
19F	≥0.35 µg/mL	89/89	100	(95.9; 100)
	≥1 µg/mL	89/89	100	(95.9; 100)
23F	≥0.35 µg/mL	89/89	100	(95.9; 100)
	≥1 µg/mL	88/89	98.9	(93.9; 100)

n: number of participants with anti-pneumococcal antibody concentrations that met the criterion.

M: number of participants with available data for the endpoint and timepoint. Percentages are based on M.

N: number of participants who received vaccination.

95% CI of the single proportion calculated from the exact binomial method.

CI, confidence interval; D, day; PCV13, pneumococcal conjugate vaccine 13.

Group 4: MenACYW-TT administered at 2, 4, 6 and 12–18 months of age. Routine pediatric vaccines (including hexavalent and PCV13) administered at 2, 4, and 12–18 months of age.