



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 October 2026
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Public Health Threats

Immunogenicity and efficacy of pneumococcal vaccines:

knowledge building from
the past and future
regulatory directions



16-17 November 2026, EMA, Amsterdam

Hybrid workshop – WebEx & Room **1D** EMA Building

Background and objectives

Streptococcus pneumoniae, a gram-positive bacterium with more than 100 known serotypes, is responsible for a wide spectrum of illnesses, among young children, the elderly, and immunocompromised subjects. The introduction of pneumococcal conjugate vaccines (PCVs) has significantly reduced the global burden of pneumococcal disease and mortality. Because infants have developing immune systems and are at higher risk of severe disease, such as pneumonia, meningitis and sepsis, pneumococcal vaccination is incorporated early into the already busy infant immunization schedule. In this context, the dynamic nature of pneumococcal epidemiology still poses significant challenges.

Pressing issues which shape the future of pneumococcal vaccination are many and includes, among the others: serotype dynamics and replacement, limitations of currently used surrogates of protection, evidence gaps, vaccine effectiveness across diverse populations and geographies, growing complexity of next generation vaccines development.

Despite ongoing efforts to develop and implement vaccines that cover more pneumococcal serotypes to combat pneumococcal disease and, as consequence, antibiotic resistance, there are continuous discussions in many jurisdictions worldwide on how to best develop and authorize new effective vaccines.

Informed decision making and collaborative approaches should be fostered to ensure that pneumococcal vaccines remain an effective tool for global disease prevention in the face of continuing pathogen evolution.

Objectives of the workshop:

The workshop will convene academics, vaccine developers, public health authorities and regulators with the following objectives:

- Advance understanding of immunobiology and epidemiology across pneumococcal serotypes.
- Critically assess strengths and limitations of current regulatory criteria, including the absence of correlates for non-invasive disease, inference of efficacy for new serotypes, non-inferiority criteria, consequences of not meeting success criteria in clinical trials, considerations on primary versus booster, and risk of bio-creep.
- Assessing how vaccine responses correlate with protection and the contribution of immune memory.
- Discuss opportunities to refine approval approaches, including feasibility of serotype specific criteria.
- Revising the latest data on vaccines effectiveness, tackling recurrent issues of serotypes expansion in the vaccines, reflecting on the herd effect and impact as part of the benefit/risk evaluation.
- Identify priorities and opportunities for novel and improved vaccines design and development, including novel technologies as well as regular update of vaccines and regional customization of the composition.

Immunogenicity and efficacy of pneumococcal vaccines

Day 1: 16 November 2026, 09:00 – 17:00 (CET)

09:00 Joining and technical checks

09:30 Welcome and objectives

Outline of the day and objectives <i>Alessandra Buoninfante (EMA)</i>	10'
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09:40 Session 1: Current pneumococcal vaccines and disease epidemiology

Chair: Maja Sommerfelt Grønvold (NOMA)

09:40	Regulatory perspective on current gaps <i>Eleonora Wijnans (MEB)</i>	20'
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10:00	Disease epidemiology in children and elderly <i>Maria Deloria Knoll (Johns Hopkins Bloomberg School of Public Health)</i>	20'
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10:20	Clinical aspects of pneumococcal disease endpoints <i>Ron Dagan (Ben-Gurion University of the Negev, Israel)</i>	20'
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10:40 Coffee break 20'

11:00 Session 2: Mechanistic insights in serotype-specific invasive and vaccine evasive capacity

Chair: Alessandra Buoninfante (EMA)

11:00	Mechanism of pneumococcal colonization and infection-induced immunity <i>Simon Jochems (LUMC, The Netherlands)</i>	20'
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11:20	Biological insights in serotype specific escape mechanisms including the molecular biology of pneumococcal surface proteins and host interactions <i>James Paton (Adelaide University, Australia)</i>	20'
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Immunogenicity and efficacy of pneumococcal vaccines

11:40	Impact of vaccines on serotype 3 <i>Bradford D. Gessner (EPIVAC)</i>	20'
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12:00	Learnings from CHIM studies <i>Daniela Ferreira (University of Oxford, United Kingdom)</i>	20'
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12:20 Lunch		60'
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13:20 Session 3: Serology and Correlates of protection

Chair: Marco Cavaleri (EMA)

13:20	Serology criteria used for pneumococcal vaccines <i>David Goldblatt (University College London)</i>	20'
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13:40	Regulatory criteria for licensing pneumococcal vaccines <i>Eleonora Wijnans (MEB)</i>	20'
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14:00	Serotype specific correlates <i>Merryn Voysey (University of Oxford)</i>	20'
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14:20	Industry perspective - Developing Reference Standards for Pneumococcal IgG Assays: Approach and Challenges for New Serotypes , Jennifer Rainho (Sanofi) - Balancing serotype expansion with global dosing paradigms , Julie Skinner (Pfizer)	40'
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15:00 Coffee break		20'
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15:20	Moderated discussion (Marco Cavaleri)	40'
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16:00 Closing remarks

Wrap up: take-home messages and next steps Marco Cavaleri (EMA)	30'
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16:30 End of Day 1	
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Day 2: 17 November 2026, 09:00 – 17:00 (CET)

09:00 Joining and technical checks

09:30 Welcome and objectives

Welcome, outline of the day 5'
Alessandra Buoninfante (EMA)

09:40 Session 1: Vaccines effectiveness and public health recommendations

Chair: Mathijs Goossens (EMA), Nicholas Perombleron (EMA)

09:40 **Estimation of vaccine effectiveness** 20'
Liz Miller (London School of Hygiene & Tropical Medicine)

10:00 **Assessment of serotype replacement** 20'
Germaine Hanquet (External expert)

10:20 **Methods to evaluate vaccination programmes and their interactions to inform vaccination strategies** 20'
Anneke Steens (RIVM)

11:00 **Industry perspective** 40'
– **Industry perspective on post-licensure vaccine effectiveness and vaccine impact studies**, *Alejandro Cane (Pfizer)*
– **Evaluating Next-Generation Pneumococcal Conjugate Vaccines: Integrating Serotype-Specific Immunogenicity and Public-Health Value**, *Luis Jodar (Vaxcyte)*

11:00 Coffee break 15'

11:15 **VE and US perspective** 20'
Miwako Kobayashi (US CDC)

11:35 **VE and the African perspective** 20'
Anthony Scott (KEMRI-Wellcome Trust Research Programme)

11:55 **VE and the European perspective** 20'
Camelia Savulescu (ECDC)

12:15 **VE and the UK perspective** 20'
Adam Finn (University of Bristol)

12:35 Lunch 55'

13:30 Session 2: Innovation and governance for new vaccines

Chair: Nicholas Perombleron (EMA)

13:30 **Innovative approaches in vaccines development** 20'

Bill Hausdorff (PATH)

13:50 **Modular approach and vaccines per geography** 20'

Peter Dull (Gates Foundation)

14:10 **Pragmatic trials** 20'

Arto Palmu (FVR – Finnish Vaccine Research)

14:30 Coffee break 15'

14:45 Session 3: Regulatory panel with moderated discussion and agreed next steps

Chair: Marco Cavaleri (EMA)

Panellists (David Kaslow, Dean Smith, Hanna Nohynek, Branda Gomes, Keith Klugman, Poonepalli ANURADHA, Shin Jinyoung, Nathaniel Nana Kwabena Nkrumah)

16:15 Closing remarks

Wrap up: take-home messages and next steps

Marco Cavaleri (EMA)

15'

16:30 End of meeting