

Pipeline Vaccines for children

Update on „just licensed“ & phase 3 vaccine programs - EMA-countries

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As of September 27, 2022

I would be most grateful to receive any additional data, information, comments on any pipeline vaccine around the globe.

Please write to:

joe.schmitt@globalhealthpress.org

Presentation Outline

1. Introduction

- ▶ Current vaccines and vaccine development

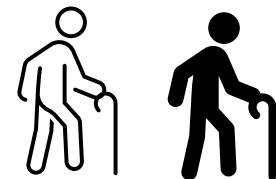
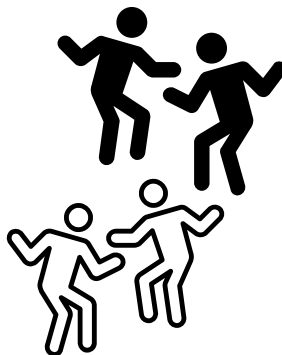
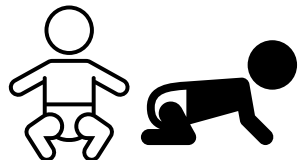
2. Coming soon (recently licensed & phase 3)

3. Think about the future!

- ▶ What do we need?

Current Vaccines

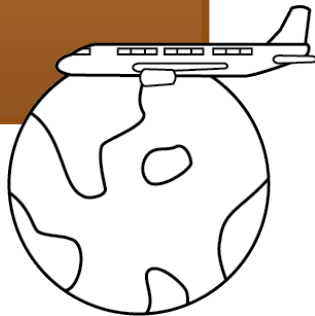
Maternal Immunization (5)	Infant, toddlers (≥11+4)	School Entry/ Adolescents (6)	Adults (>3)	≥65 yrs (9)
<ul style="list-style-type: none">- Tdap- Influenza- COVID19 <p>(Recommended, not licensed)</p>	<ul style="list-style-type: none">- DTaP-Hib-IPV-HBV- PCV- Rotavirus- Influenza- MenACWY,- Men B- (TBE >1 yr)- MMR-V	<ul style="list-style-type: none">- Boosters Tdap- Influenza- COVID19- Men ACWY- MenB- HPV- (TBE)	<ul style="list-style-type: none">- Boosters- Tdap-IPV- Influenza- HPV- TBE- „Workplace Vx“	<ul style="list-style-type: none">- Boosters- Tdap- TBE- COVID19- Influenza- PCV- Zoster- MenACWY- MenB



Medical need based on special host/exposure

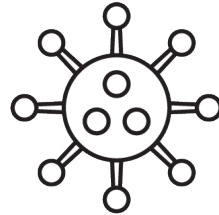
Traveller

- Boosters
- TBE (FSME)
- HAV
- HBV
- Influenza
- MenACWY
- MenB
- JE
- Typhoid
- Rabies
- Yellow fever
- Cholera
- Dengue



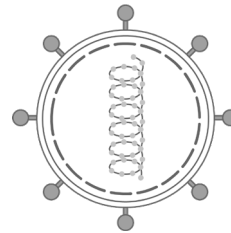
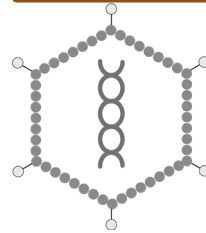
Underlying diseases

- Influenza
- Boosters
- (risk-based Vx)



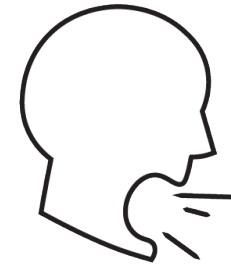
B-&T-cell Defect/ Cancer*

- Influenza
- PCV
- MenACWY
- MenB
- H. influenzae b
- HBV
- Boosters



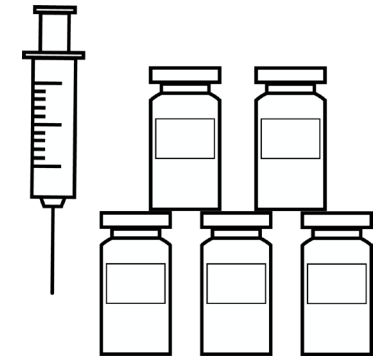
Emerging infections

- COVID19 VOCs
- Avian influenza
- Cholera
- Smallpox
- Monkeypox



Lack of health care resources

Monkeypox
Ebola



* If sufficient immune responses can be reasonably expected

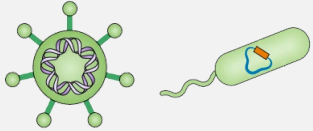
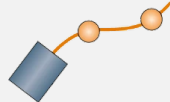
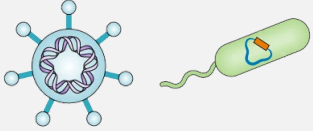



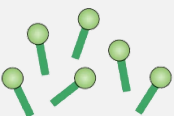

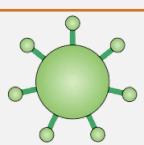
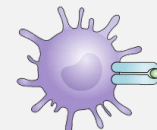
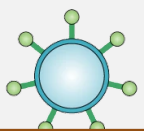
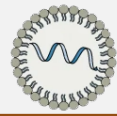
USA: Cases Prevented by Vaccination in 10 Years

1994–2013; Numbers x 1,000

Vaccine-preventable Disease	Illnesses	Hospitalizations	Deaths
Diphtheria	5,073	5,073	507.3
Tetanus	3	3	0.5
Pertussis	54,406	2,697	20.3
Invasive <i>Haemophilus influenzae</i> type b	361	334	13.7
Polio	1,244	530	14.8
Measles	70,748	8,877	57.3
Mumps	42,704	1,361	0.2
Rubella	36,540	134	0.3
Congenital rubella syndrome	12	17	1.3
Hepatitis B	4,007	623	59.7
Varicella	68,445	176	1.2
<i>Pneumococcus</i> -related diseases	26,578	903	55.0
Rotavirus	11,968	327	0.1
Total	322,089	21,055	731.7

Vaccine Types:

Empirical → Recombinant → Glyco-conjugation → Reverse Vaccinology → Next generation

Type of Vaccine	Licensed Vaccines Using This Technology	First Introduced	Type of Vaccine	Licensed Vaccines Using This Technology	First Introduced
Live attenuated (weakened or inactivated) 	Measles, mumps, rubella, yellow fever, influenza, oral polio, typhoid, Japanese encephalitis, rotavirus, BCG, varicella zoster	1798 (smallpox)	Protein-Polysaccharide Conjugate 	<i>Haemophilus influenzae</i> type b, pneumococcal, meningococcal, typhoid	1987 (<i>H. influenzae</i> type B)
Killed Whole Organism 	Whole-cell pertussis, polio, influenza, Japanese encephalitis, hepatitis A, rabies	1896 (typhoid)	Viral Vectored 	Ebola	2019 (Ebola)
Toxoid 	Diphtheria, tetanus	1923 (diphtheria)	Nucleic Acid Vaccine 	SARS-CoV-2	2020 (SARS-CoV-2)
Subunit (purified protein, recombinant protein, polysaccharide, peptide) 	Pertussis, influenza, hepatitis B, meningococcal, pneumococcal, typhoid, hepatitis A	1970 (anthrax)	Bacterial Vectored 	Experimental	—
Virus-Like Particle 	Human papillomavirus	1986 (hepatitis B)	Antigen-Presenting Cell 	Experimental	—
Outer Membrane Vesicle 	Group B meningococcal	1987 (group B meningococcal)	RNA Vaccine 	SARS-CoV-2	2020 (SARS-CoV-2)

Today there are >300 vaccine candidates in clinical trials

In 2016, There Were 271 New Vaccines in Big Pharma's Pipeline

sanofi pasteur prevention of Clostridium difficile ACE BioSciences prevention of traveler's diarrhea caused by Campylobacter jejuni ACE BioSciences prevention of traveler's diarrhea caused by Escherichia coli sanofi pasteur diphtheria, tetanus, pertussis Phase III DTP vaccine Aeras Global tuberculosis Novartis Vaccines prevention of influenza A infection (H5N1 subtype) Antigenics treatment of herpes simplex virus BioSante Pharmaceuticals anthrax Phase I/II vaccine InterCell USA anthrax KaloBios Pharmaceuticals Pseudomonas aeruginosa infections Aduro BioTech treatment of hepatitis C Emergent BioSolutions anthrax vaccine AlphaVax prevention of influenza virus infections in the elderly DynPort Vaccine botulism vaccine Inviragen Chikungunya virus vaccine Celldex Therapeutics cholera vaccine (live attenuated) ChronTech Pharma hepatitis C (DNA vaccine) Virionics prevention and treatment of hepatitis C Vical prevention of cytomegalovirus (DNA vaccine) AlphaVax prevention of cytomegalovirus infections Hawaii Biotech prevention of dengue fever GlaxoSmithKline prevention of dengue fever (tetravalent) Acambis mild to severe dengue fever sanofi pasteur DTP-Hep B sanofi pasteur diphtheria, tetanus, pertussis GlaxoSmithKline prevention of infectious diseases in adults and children sanofi pasteur rotavirus infections in infants GlaxoSmithKline prevention of Streptococcus pneumoniae infections in adults and children GlaxoSmithKline prevention of Haemophilus influenzae and pneumococcus influenza A virus (H1N1 subtype) for children West Nile virus infection Novartis Vaccines prevention of hepatitis B Pfizer treatment of hepatitis B prevention of influenza virus seasonal infections in adolescents, children and infants CSL Behring Baxter Healthcare prevention of influenza virus infections Vaxin influenza virus infections Naval Medical Research Center) Vical Sanaria malaria vaccine GenPhar malaria vaccine

„Vaccine“ vs. „Vaccine Candidate“

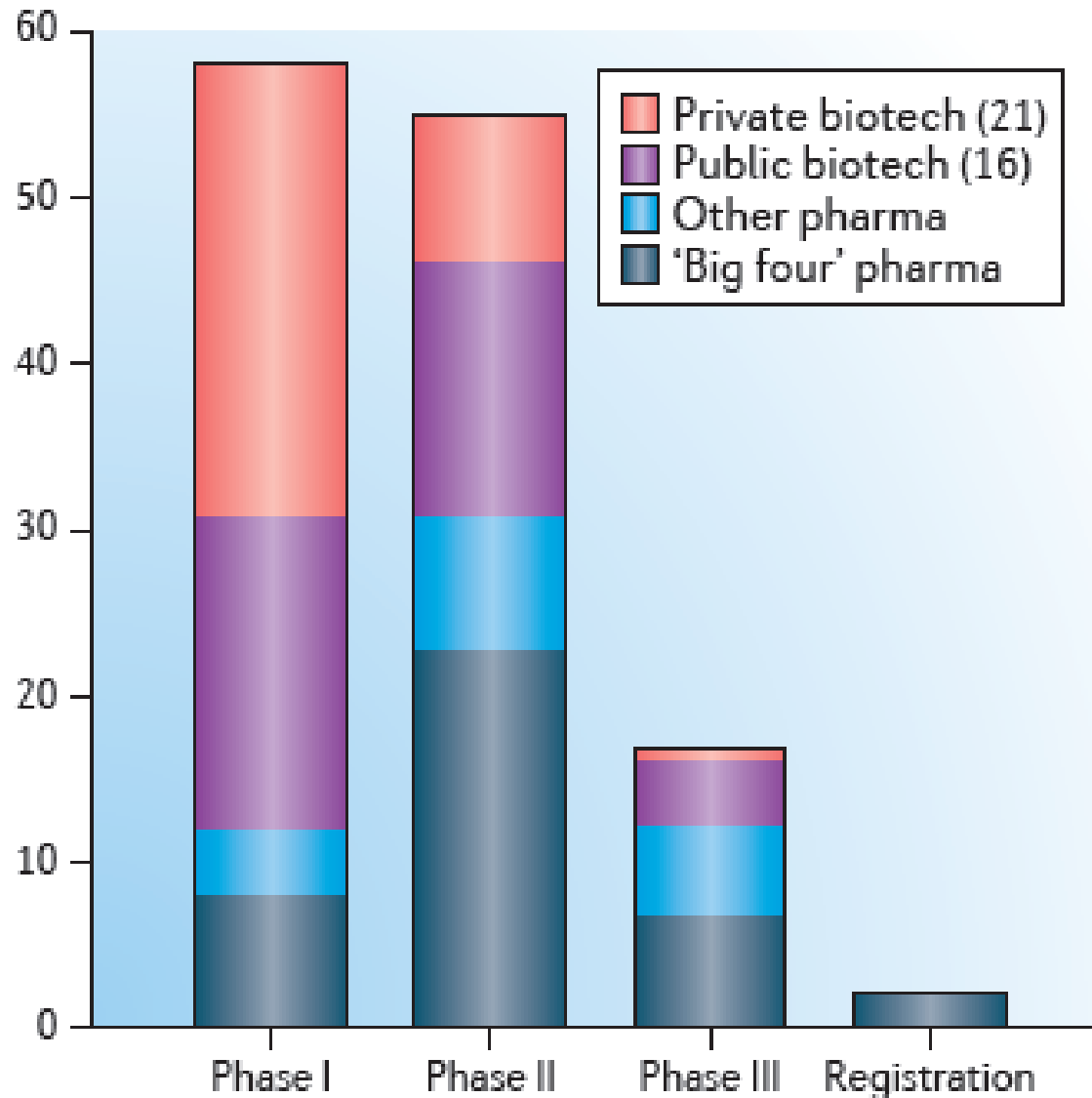
parainfluenza virus infections in children and infants MedImmune prevention of influenza virus (quadrivalent) for adolescents and children sanofi pasteur Neisseria meningitidis A, C in toddlers 9 months-12 months GlaxoSmithKline prevention of Neisseria meningitidis groups C and Y, Haemophilus influenzae type B, and tetanus toxoid sanofi pasteur meningitis in infants Novartis Vaccines meningococcal group B infections vaccine group B Novartis Vaccines meningococcal group A, C infections in children Novartis Vaccines meningococcal group A, C infections in infants GlaxoSmithKline prevention of malaria (recombinant vaccine) NanoBio prevention of influenza virus (intranasal) GlaxoSmithKline prevention of influenza virus inactivated split-trivalent vaccine GlaxoSmithKline prevention of Neisseria meningitidis groups A, C in children LigoCyte Pharmaceuticals norovirus infections (intranasal) Novartis Vaccines prevention of influenza virus Protein Sciences prevention of influenza A pandemic (H5N1 subtype) Meridian Biosciences parvovirus infections Crucell prevention of influenza virus infections Pfizer meningococcal group B infections (meningococcal "plague" vaccine) DynPort Vaccine Yersinia infections (injectable) Baxter Healthcare prevention of seasonal influenza virus GlaxoSmithKline prevention of influenza A virus ("pre-pandemic") Pfizer prevention of pneumococcal infection in the elderly (Prevnam 13 Adult™) sanofi pasteur rabies vaccine BioSante Pharmaceuticals ricin poisoning ("biodefense" vaccine) Soligenix ricin poisoning sanofi pasteur prevention of rotavirus infections Bharat Biotech prevention of rotavirus infections Emergent BioSolutions anthrax (Fast Track) "protective antigen" vaccine Inhibitex staphylococcal infections Vical prevention of severe acute respiratory syndrome (SARS) coronavirus infections Emergent BioSolutions shigella infections GlaxoSmithKline prevention of herpes simplex virus infections PharmAthene anthrax ("protective antigen" – rPA) BioSante Pharmaceuticals staphylococcal infections ("biodefense" vaccine) Nabi Biopharmaceutical prevention of staphylococcal aureus infections GlaxoSmithKline prevention of staphylococcal aureus infections Nabi Biopharmaceutical prevention of streptococcal B infections Emergent BioSolutions prevention of streptococcal infections Novartis Vaccines prevention of streptococcal infections sanofi pasteur prevention of meningitis and pneumonia (tetravalent) Inviragen treatment of dengue fever InterCell USA prevention of traveler's diarrhea due to E. coli ("patch" technology) GlaxoSmithKline tuberculosis Aeras Global TB prevention of tuberculosis in young children GlaxoSmithKline prevention of tuberculosis in adults sanofi pasteur prevention of tuberculosis DynPort Vaccine tularemia Emergent BioSolutions prevention of typhoid (live typhoid organisms – oral vaccine) Novartis Vaccines prevention of typhoid fever Celldex Therapeutics typhoid fever Merck prevention of herpes zoster (shingles) Merck hepatitis B in infants Merck human papillomavirus infections Merck staphylococcal infections GlaxoSmithKline prevention of varicella zoster virus VaxInnate prevention of influenza A virus VaxInnate influenza A virus infections in elderly patients VaxInnate prevention of influenza A virus (H1N1 subtype) Inovio Pharmaceuticals human papillomavirus infections Inovio Pharmaceuticals prevention of influenza A virus (H5N1 subtype) Xcellerex prevention of yellow fever - See more at: <http://healthimpactnews.com/2015/there-are-271-new-vaccines-in-big-pharmas-pipeline/#sthash.mrVonyMf.dpuf>

GenPhar Ebola virus vaccine
es prevention of influenza virus
virus infections GlaxoSmithKline
vention of influenza virus
is (infants) GlaxoSmithKline
oSmithKline prevention of
tion Hawaii Biotech prevention of
hepatitis E (recombinant) Dynavax
epatitis B, polio, Hib InterCell
influenza A virus (H1N1 subtype) in
A virus (DNA – H1N1 subtype)
vaccine) Dynavax prevention of
s Vaccines malaria vaccine (U.S.
ter) Crucell malaria vaccine
MedImmune prevention of

Criteria for Development of New Vaccines

Criterion	Comments
1 Medical Need	Often: Lack of data
2 Administrative Issues	
Pathway for License	Often main hurdle – PEI is excellent
Chance for Recommendation	Watch out for „late adaptors“
Health Economics:Reimbursement	
Acceptance: Actual Use	Adverse events is crucial
3 Chances for Success / Risks	Idea for new product and production platform
4 Know how	„Big pharma“ vs. start up
5 Investment Size: ≥ 1 bn	Overall failure rate 90%; Factory needed for phase 3
6 Return on Investment	Global economic and political situation

Commercial Landscape for New Vaccines (2018)



Success rates:

- ✓ Phase 1: 22%,
- ✓ Phase 2: 30%,
- ✓ Phase 3: 64%

Main Keys to success

- ✓ Pathway to licensure
- ✓ Global Expertise
- ✓ Financial resources

Presentation Outline

1. Introduction

- ▶ Current vaccines and vaccine development

2. Coming soon (recently licensed & phase 3)

3. Think about the future!

- ▶ What do we need?

Searching selected company- websites for phase 3 studies

Astra Zeneca	Cambridge, England
Bavarian Nordic	Hellerup, Denmark
Beijing Institute of Biological Products	China
Sinopharm	
Bharat Biotech	Hyderabad, India
Biological E. Limited	India
BionTech	Mainz, Germany
CanSinoBio	Tianjin, China
CSL Seqirus	Maidenhead, United Kingdom
Curevac	Tübingen, Germany
Daiichi-Sankyo	Tokyo, Japan
Dynavax	Emeryville, California, United States
Finlay Institute	Havana, Cuba
Gamaleya Institute	Moscow, Russia
Genova Biopharmaceuticals	Pune, India
GSK	Brentford, London, England
Inovio Pharmaceuticals	Pennsylvania, United States
J&J	New Jersey, United States
Merck	Kenilworth, New Jersey, United States
Moderna	Massachusetts, United States
Novavax	Maryland, United States
Pfizer	New York, New York, United States
Sanofi	Paris, France
Serum Institute of India	Pune, Maharashtra, India
Sinopharm	Beijing, China
Sinovac	Beijing, China
SK Bioscience	Seongnam, South Korea
Takeda	Tokyo, Japan
Valneva	Saint-Herblain, France
Walvax	Kunming, China
Wuhan Institute of Biological Products	China
Zydus	Ahmedabad, India

Coming soon ?

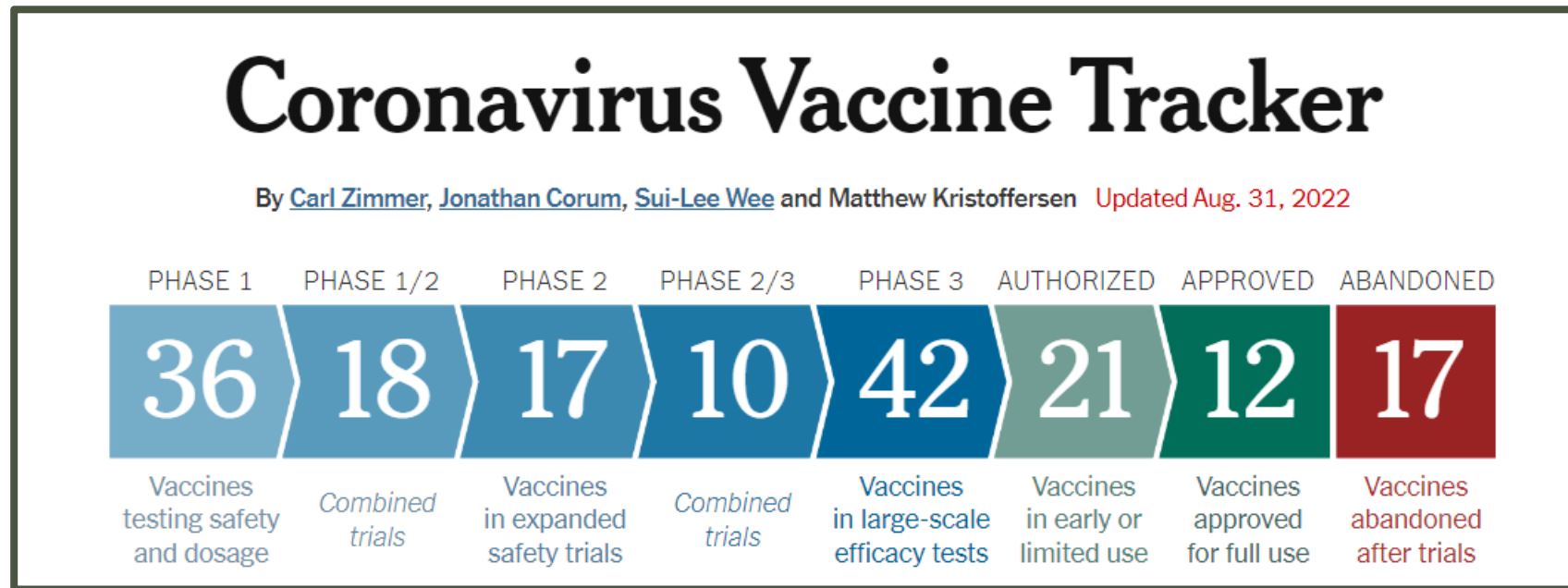
Selected recently licensed
or phase 3 vaccine
candidates for children

COVID new VOCs, PIP

- RSV MI
- RSV LamAb
- PCV 15; PCV 20
- Lyme Diseases
- Dengue Takeda
- Chikungunya

SARS-CoV2-vaccines

The New York Times



This tracker is no longer being updated. It followed the development of Covid vaccines from early 2020 through August 2022. More than 120 clinical trials were underway at that time.

The New York Times

Globally leading COVID-19 vaccines

Leading vaccines

Developer	How It Works	Phase	Status
 Pfizer-BioNTech	mRNA	3	Approved in U.S., other countries. Emergency use in many countries.
 Sinopharm	Inactivated	3	Approved in China, Bahrain. Emergency use in many countries.
 Oxford-AstraZeneca	ChAdOx1	2 3	Approved in Brazil, India. Emergency use in many countries.
 Sinovac	Inactivated	3	Approved in China. Emergency use in many countries.
 Moderna	mRNA	3	Approved in U.S., Canada, Switzerland. Emergency use in many countries.
 Novavax	Protein	3	Approved in Canada, South Korea. Emergency use in several countries.
 Bharat Biotech	Inactivated	3	Approved in India. Emergency use in other countries.
 Johnson & Johnson	Ad26	3	Approved in Canada. Limited in U.S. Emergency use in many countries.
 Baylor-Biological E	Protein	3	Emergency use in India, Botswana.
 Gamaleya	Ad26, Ad5	3	Approved in Russia. Emergency use in many countries.

Pediatric COVID19 Vaccines

- ▶ Companies must submit a “Pediatric Investigation Plan” (PIP)
 - ▶ Trials are underway with vaccination as early as 6 months
- ▶ Some countries: emergency use authorization for mRNA vaccines (Pfizer-BioNTech BNT162b2 and Moderna mRNA-1273) for use in the age groups **of 6 months and above.**
- ▶ Trials in children as young as age 3 years were completed **for two inactivated vaccines** (Sinovac-CoronaVac and BBIBP-CorV) and these products were approved by Chinese authorities for the age indication of 3-17 years.

[Interim statement on COVID-19 vaccination for children \(who.int\)](https://www.who.int/news/item/15-05-2021-interim-statement-on-covid-19-vaccination-for-children)

EMA-authorized COVID19 Vaccines (September 17th, 2022)



Authorised for use in the EU

- **Comirnaty** (BioNTech and Pfizer)
- **COVID-19 Vaccine Valneva**
- **Nuvaxovid** (Novavax)
- **Spikevax** (Moderna)
- **Vaxzevria** (AstraZeneca)
- **Jcovden** (Janssen)



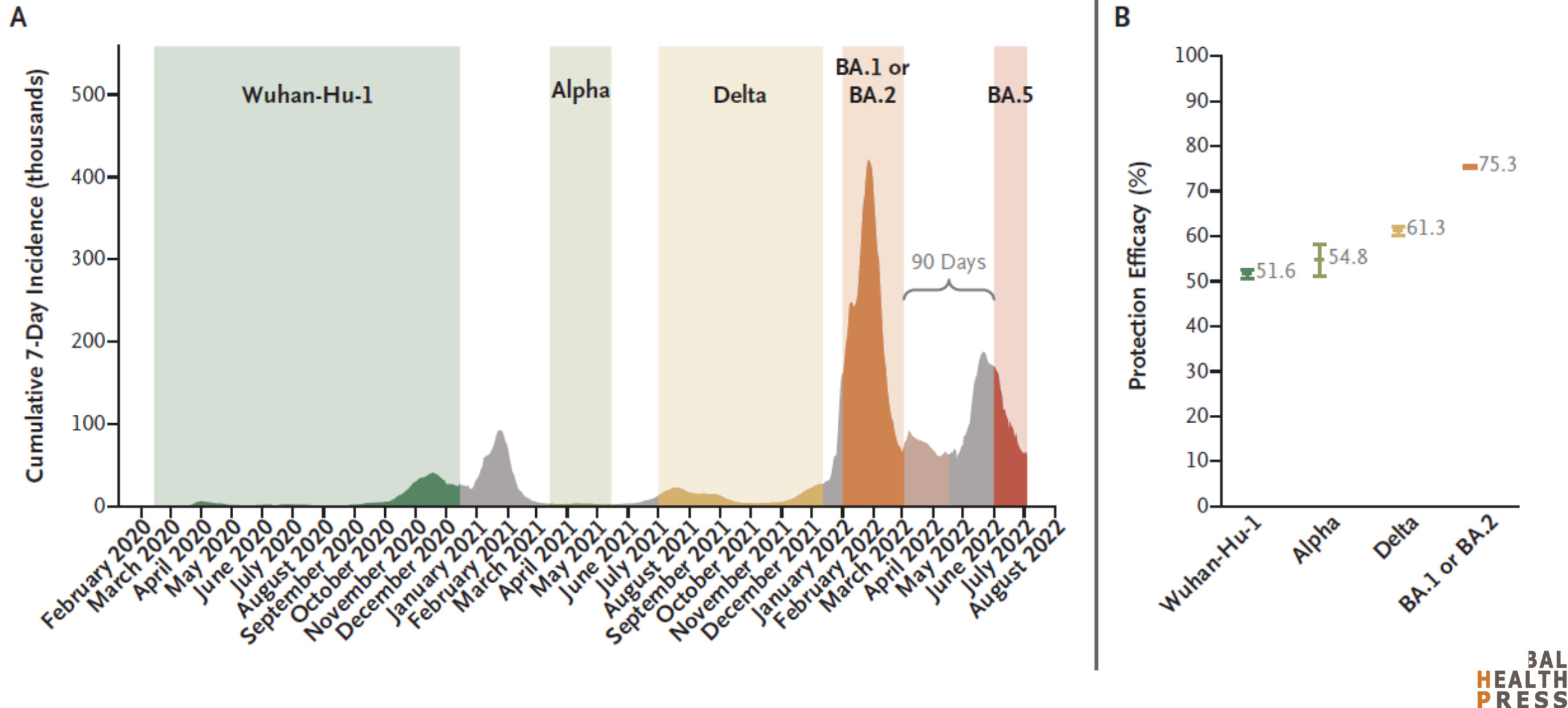
Adapted vaccines authorised for use as boosters in the EU

- **Comirnaty Original/Omicron BA.1** (BioNTech and Pfizer)
- **Comirnaty Original/Omicron BA.4/5** (BioNTech and Pfizer)
- **Spikevax bivalent Original/Omicron BA.1** (Moderna)

Comirnaty 5-11 yr: 10µg; ≥12 yr: 30µg
Nuvaxovid: n.a. ≥12 yr: 30µg
Spikevax: 6-11 yr: 50µg; ≥12yr: 100 µg

Not for children <12 yr

Portugal: Protection against BA.5 provided by vaccination followed by SARS-CoV2-infection



Respiratory Syncytial Virus, RSV

RSV-infection:

clinical manifestations vary within and across age groups

Repeated infections occur with an unknown frequency; NT-antibodies are known to protect infants (Palivizumab) but mechanisms of immune-mediated long-term protection are unknown

Common clinical manifestations



Infants

- **Bronchiolitis**²
- Pneumonia²
- Croup²
- Apnea²
- Upper respiratory tract infection²



Children

- Upper respiratory tract infection¹
- Bronchitis¹
- Exacerbation of asthma¹



Adults & pregnant women

- Nasal congestion³
- Fever³
- Irritating, non-productive cough³

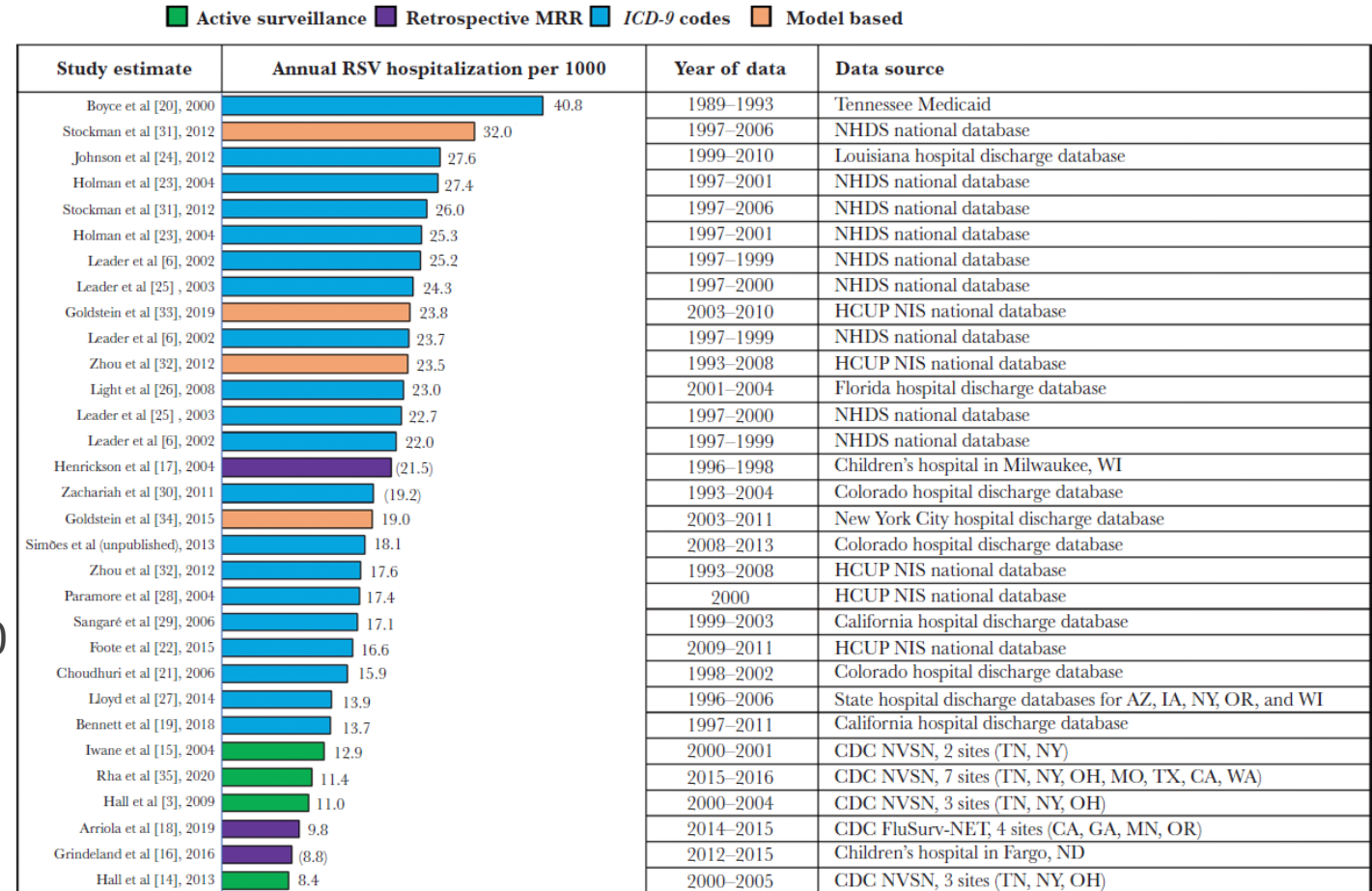


Older adults

- Upper respiratory tract infection²
- Bronchitis²
- Exacerbation of asthma², COPD⁴, CHF⁴
- Pneumonia²

Annual RSV-associated hospitalizations/1000 US infants (n=31 BoD estimates)

- ▶ Review of 3328 articles (<09/2020)
 - ▶ 25 relevant studies
 - ▶ 31 estimates of RSV-associated hospitalization rates
 - ▶ US infants <1 year of age, annual rates: 8.4 to 40.8/1000
 - ▶ **Pooled rate 19.4 (95% [CI], 17.9–20.9)**
 - ▶ Study type influenced rates ($P = 0.003$)
- ▶ Conclusions: applying pooled rates to 2020 US birth cohort suggests **79 850** (73,680–86,020) RSV-associated infant hospitalizations each year



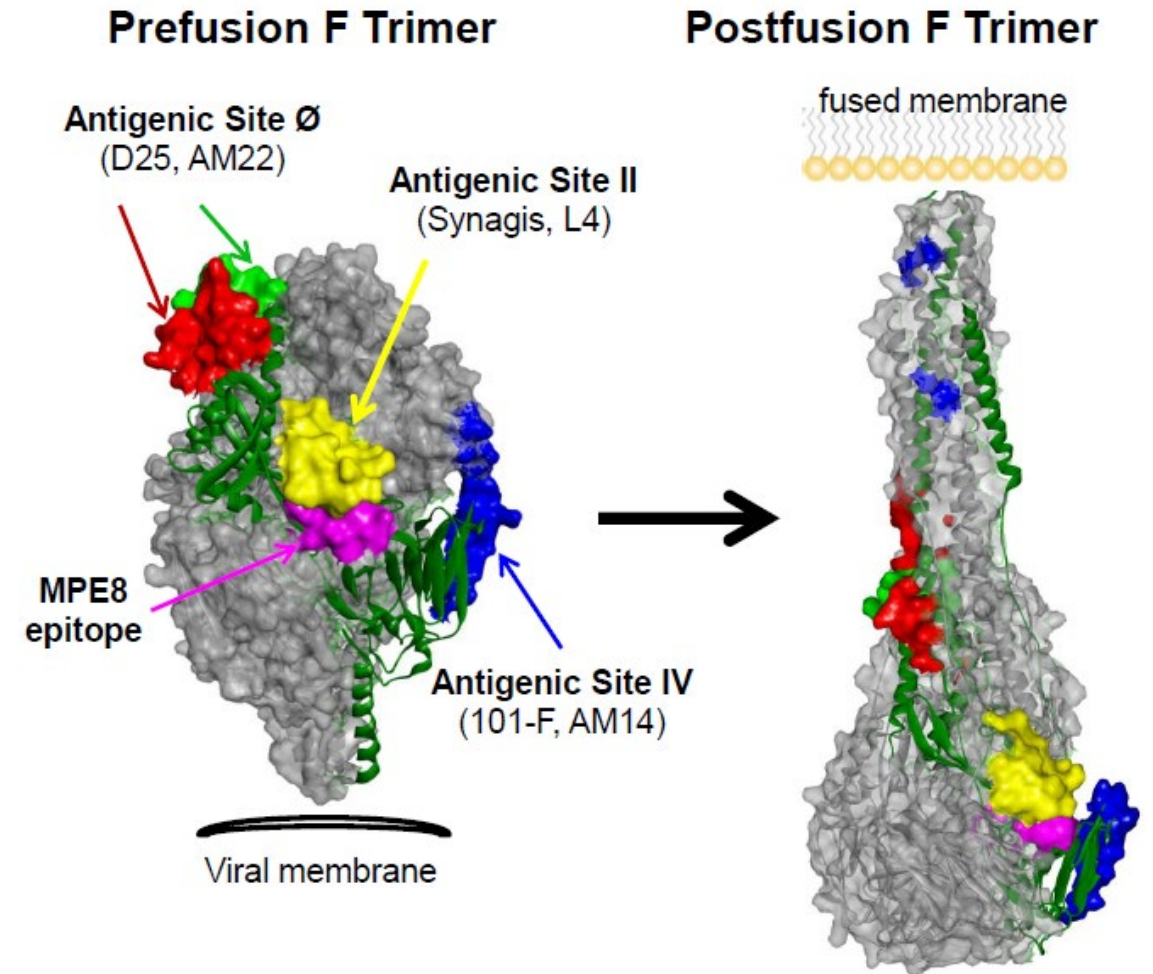
>75% of RSV-hospitalized children are <6 months old

Wyeth (now Pfizer) RSV vaccine experience
























































~1966 -1969	Formalin-inactivated RSV (FI-RSV)	Enhanced infant RSV disease
~1985 -2003	Purified F Protein (PFP)	Did not elicit high titer neutralizing antibody or protect humans from RSV
~1987 -2003	Live attenuated RSV viruses	Could not balance immunogenicity and tolerability in humans
~2003-2010	Vectored RSV vaccine (low level pre-clinical effort)	Did not elicit immune responses comparable to natural RSV infection in an animal model






RSV vaccines: The F-protein story




- ▶ New vaccine approaches are based on the breakthrough NIH determination of prefusion RSV F crystal structure (McLellan, Science 340:1113; 2013)
- ▶ Stabilization of **prefusion F** with rigorously monitored conformation
- ▶ There are subtypes **A-** and **B-F** proteins
- ▶ Pre-F antigens elicit **much higher nAb-titers** than postfusion F in non-human-primates and
 - ▶ Do not enhance respiratory pathology in cotton rats
- ▶ Currently in global **phase 3 studies**



RSV vaccine and monoclonal antibody agents by target population

	 Paediatric	 Maternal	 Older adults
Phase 3	 Nirsevimab  Clesrovimab 	 RSVPreF  RSVPreF3 	 RSVPreF  RSVPreF3   Ad26.RSV.PreF  MVA-BN-RSV   mRNA-1345 
Phase 2	 Ad26.RSV.PreF   MV-012-968  VAD00001  ΔNS2Δ131311314L   BARS13   Narsyn 		 BARS13 
Phase 1	 rBCG-N-hRSV  SeV/RSV  6120/ΔNS1  6120/ΔNS2/1030s  6120/F1/G2/ΔNS1   RSV-MinL4.0  IT-RSV-ΔG  LIDΔM2-2 1030s   RSM01   mRNA-1345 	 V306 VLP   DS-Cav1 	 IVX-121   DS-Cav1  DPX-RSV  VN-0200   RSV-MinL4.0 

 mAb
  Vector
  Live-attenuated vaccine
  Chimeric
  Nucleic acid

 Subunit
  Particle
  Route of administration

RSV Vaccines and Trial Names

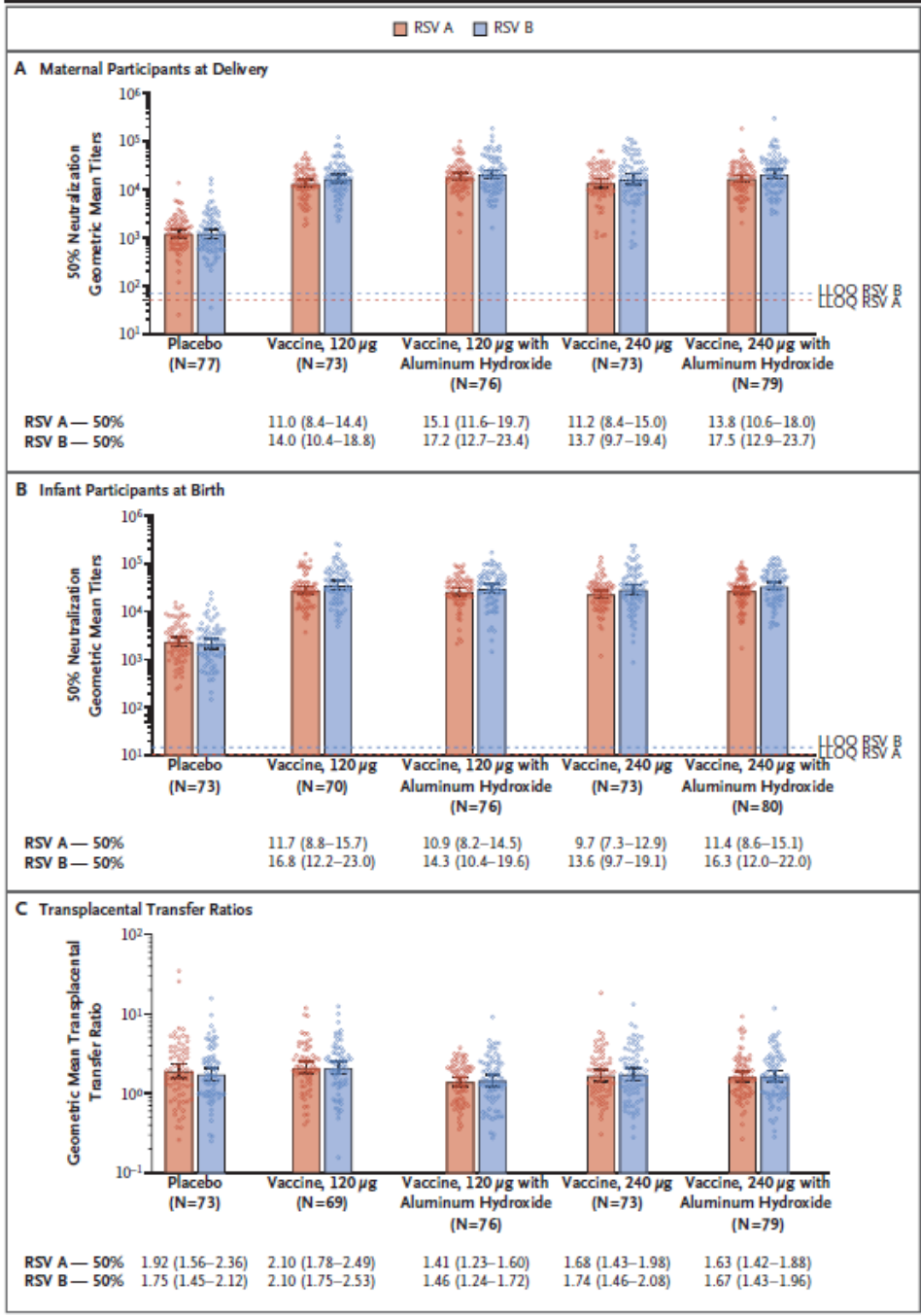
Late-stage RSV pipeline				
Project	Company	Description	Details	
Nirsevimab (SP0232)	Sanofi/Astrazeneca	Fusion antibody	Filed; accepted under accelerated assessment in EU	Medley, Melody
GSK3844766A	Glaxosmithkline	Protein subunit vaccine, adjuvanted	Aresvi 004 in adults ≥60, data due H1 2022	Aresvi
RSVPreF3 (GSK3888550A)	Glaxosmithkline	Protein subunit vaccine, unadjuvanted	Trials on pause; Grace maternal protection trial was due to read out H2 2022	Grace
RSVpreF (PF-06928316)	Pfizer	Protein subunit vaccine	Data from Renoir (adults ≥60) and maternal protection trial due H1 2022	Renoir, Matisse
Ad26.RSV.preF	Johnson & Johnson	Adenovirus type 26 viral vector vaccine	Evergreen in adults ≥60, data due H2 2022	Evergreen
Clesrovimab (MK-1654)	Merck & Co	Fusion antibody	MK-1654-007 in high-risk infants; ph2/3 MK-1654-004 in healthy infants, data due 2022	
Rilematovir (JNJ-53718678)	Johnson & Johnson	Oral RSV F-protein fusion inhibitor	Daisy in hospitalised children; Primrose in adult outpatients; trials started late 2021	Daisy, Primrose

ORIGINAL ARTICLE

Prefusion F Protein–Based Respiratory Syncytial Virus Immunization in Pregnancy

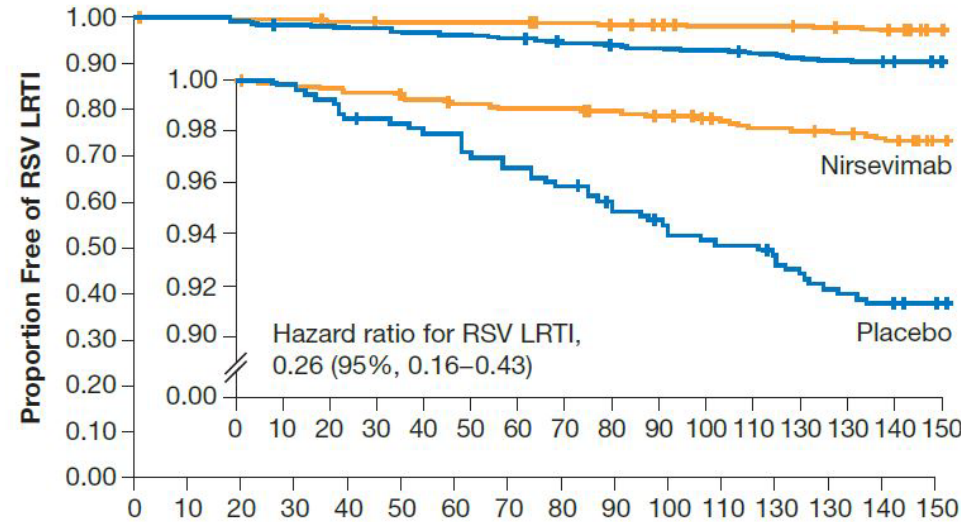
Conclusions:

RSVpreF vaccine elicited neutralizing antibody responses with efficient transplacental transfer and without evident safety concerns. (Funded by Pfizer; ClinicalTrials.gov number, NCT04032093.)

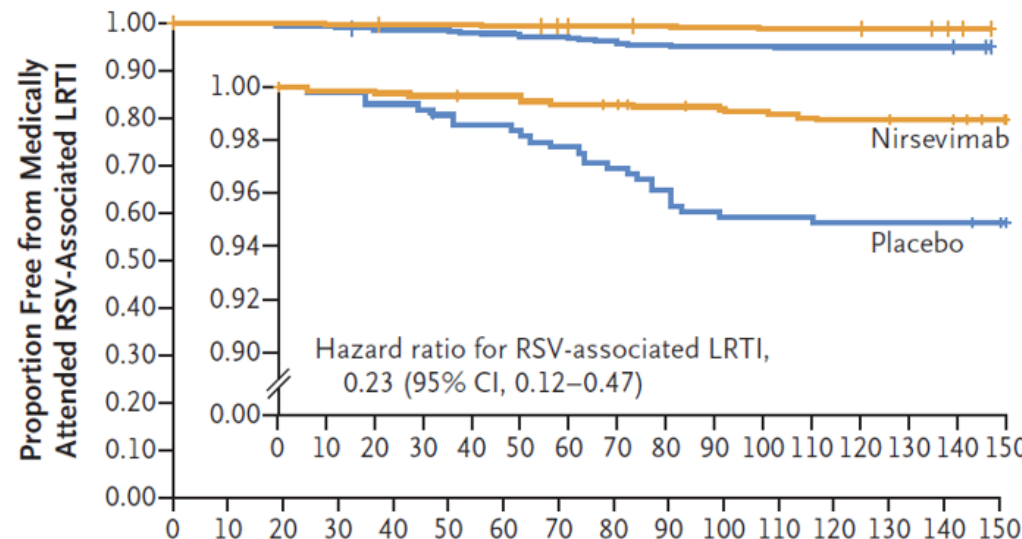


RSV-LRTIs in preterm (top) or term infants (bottom) with or without Beyfortus[®] (nirsevimab) (Sanofi/AZ)

- Two studies with similar design, definitions and procedures:
- 2:1 randomisation of infants
(1) GA 29 <35 weeks;
(2) >35 weeks
to a single i.m. injection of nirsevimab or placebo before the start of an RSV season
- Primary end point was medically attended RSV-LRTI within 150 days after injection
- Secondary end point was hospitalization for RSV-associated LRTI within 150 days after the injection



VE against RSV
- medically attended **70.1%**
- hospitalization: **78.4%**



VE against RSV
- medically attended **74.5%**
- hospitalization: **62.1%**

MI versus La-mAb?

OPTIONS

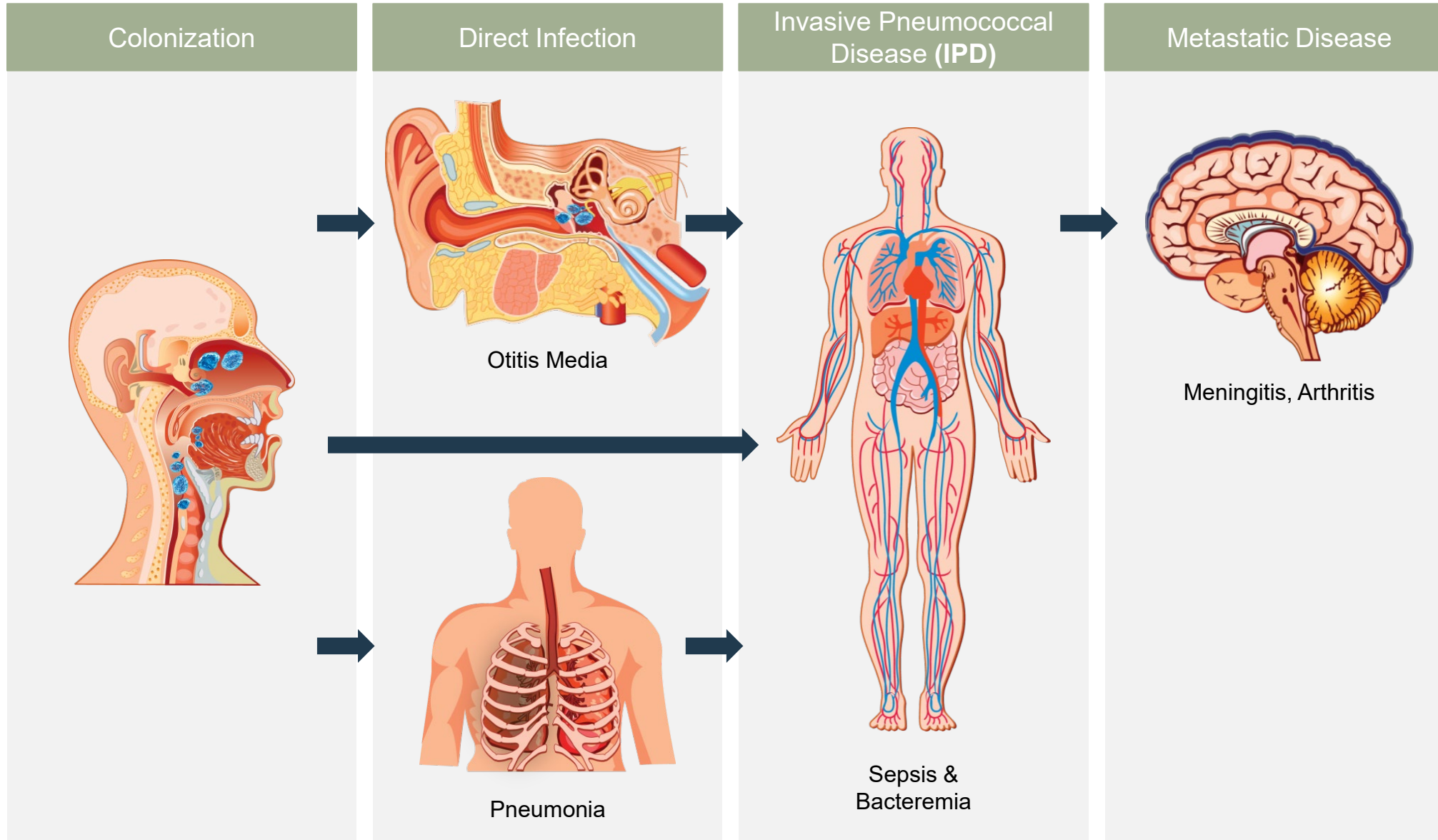
- 1) MI only (alone or in combination)
- 2) La-mAb only
- 3) Universal MI + La-mAb for pre-terms; (if antibody transfer-window too short);
- 4) Risk-children (1st + ?? 2nd winter);
- 5) Active toddler-vaccine?

KEY POINTS FOR DECISION

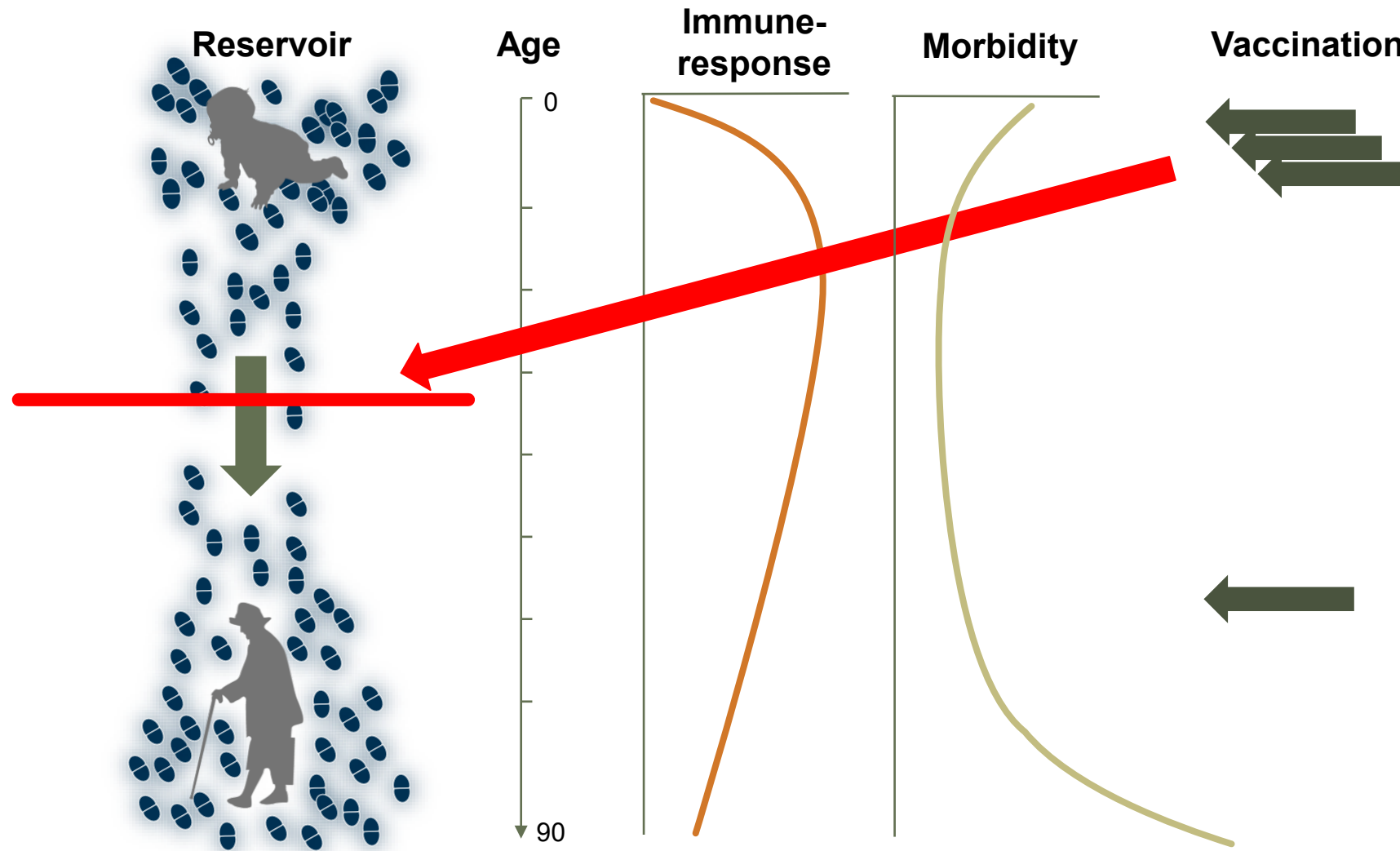
- 1) (herd protection likely not possible with any current vaccine)
- 2) Benefit (hospitalization!)
- 3) Price / annual cost / strategy
- 4) Product availability
- 5) Time from birth to LAmAb-dosing
- 6) Logistics, implementation
- 7) Availability of **RSV-surveillance

3rd Generation Pneumococcal Conjugate Vaccines (PCVs)

Pathogenesis of *S pneumoniae* Diseases



Infectious Pressure, Colonization, Immune Response & BoD



“OLD” Pneumococcal Vx: Antigens, Carriers, Doses

(PCV7, PCV10, PCV13, and PPV23)

PCV7	4	6B	9V	14	18C	19F	23F																
	CRM ₁₉₇																						
PCV10	<u>4</u>	6B	9V	14	<u>18C</u>	<u>19F</u>	23F	1	5	7F													
	Protein D				TT	D	Protein D																
PCV13	4	6B	9V	14	18C	19F	23F	1	5	7F	3	6A	19A										
	CRM ₁₉₇																						
PPV23	1	2	3	4	5	6B	7F	8	9N	9V	10A	11A	12F	14	15B	17F	18C	19F	19A	20	22F	23F	33F

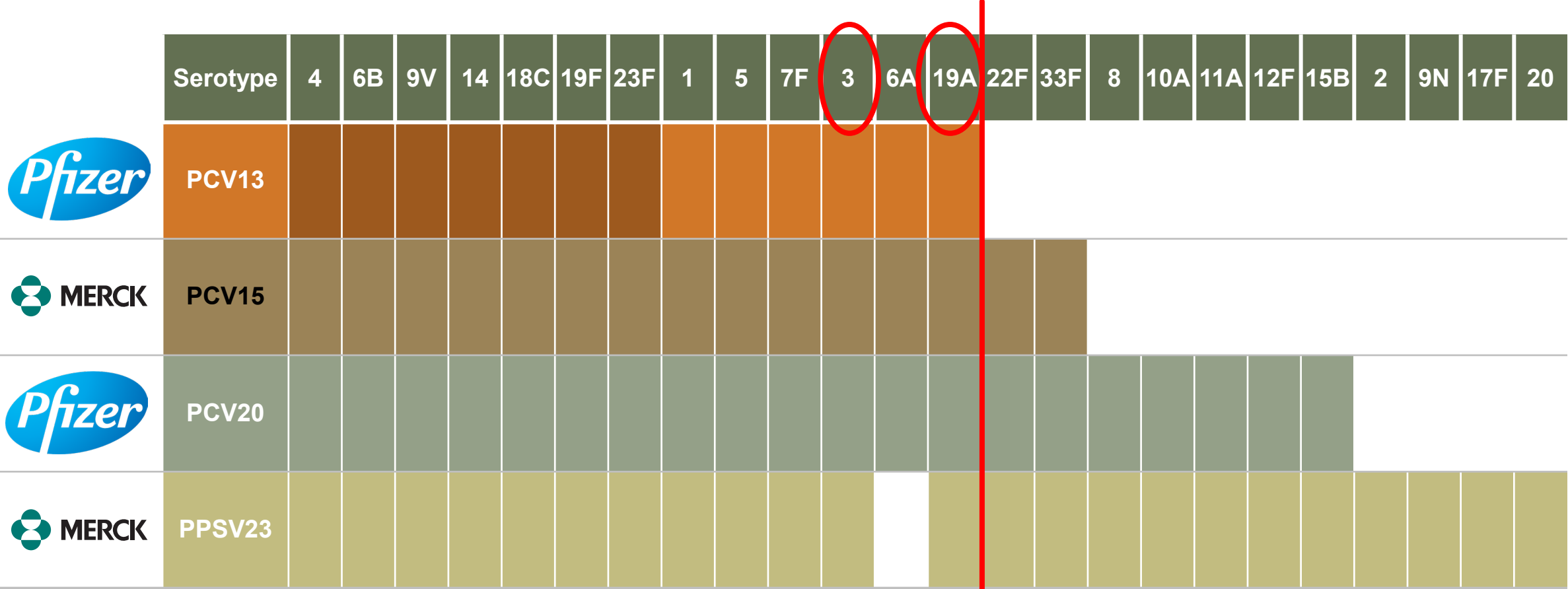
Amount of Antigen per Polysaccharide

PCV10: 1 µg, except serotypes 4, 18C, 19F (3 µg); D, T “protein D”-conjugates; only for pediatrics

PCV7, PCV13: 2.2 µg, except serotype 6B (4.4 µg) - PCV10: 1 µg, except serotypes 4, 18C, 19F (3 µg)

PPV23: 25 µg (no 6A)

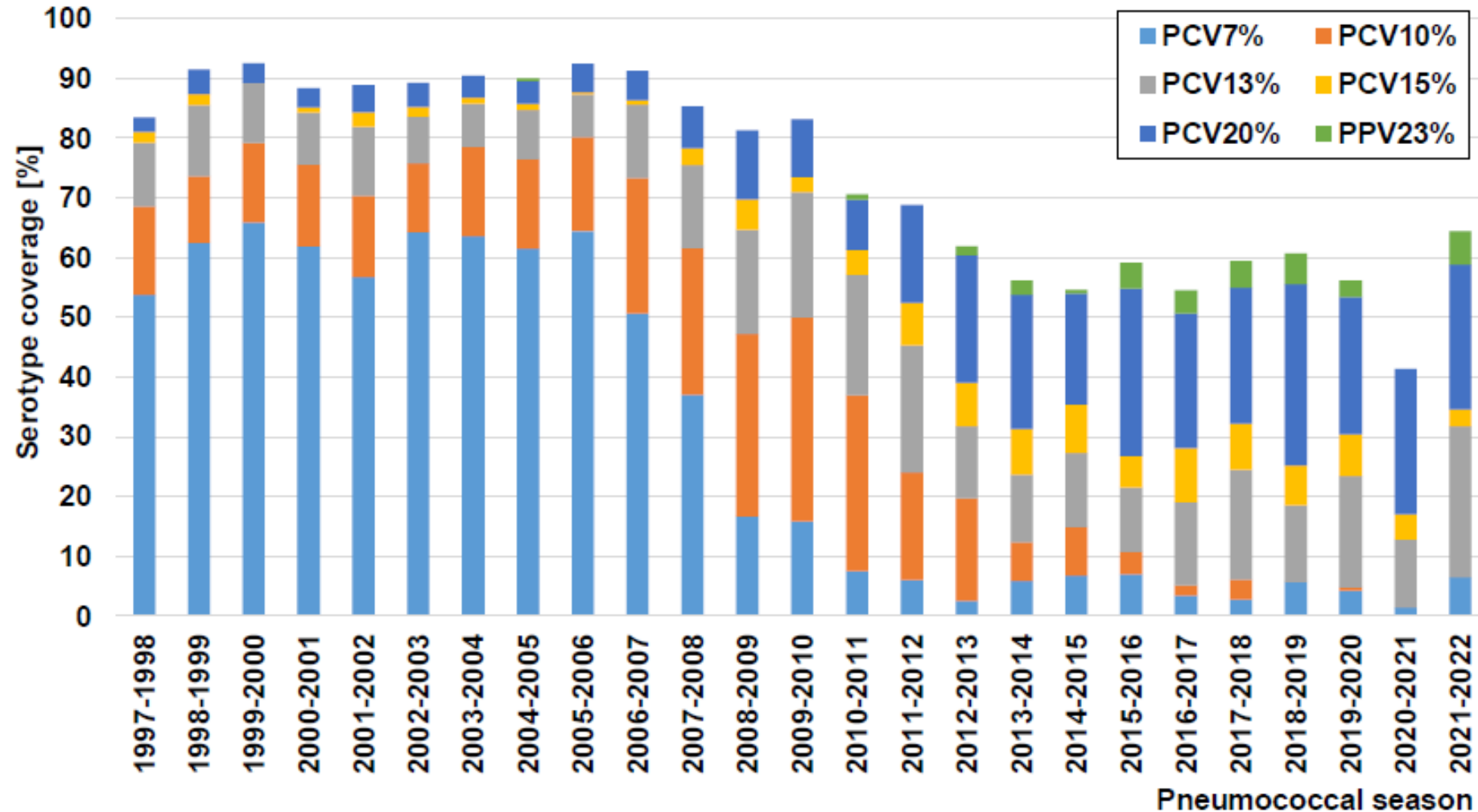
Pipelines of Vaccine Producers for Next-generation PCVs



PPV23: 25µg/polysaccharide („pure“
PCV15: 2.0 µg/polysaccharide (except serotype 4: 4.0 µg) individually conjugated to CRM₁₉₇
PCV13, PCV20: 2.2µg/polysaccharide (except serotype 4: 4.4 µg) individually conjugated to CRM₁₉₇

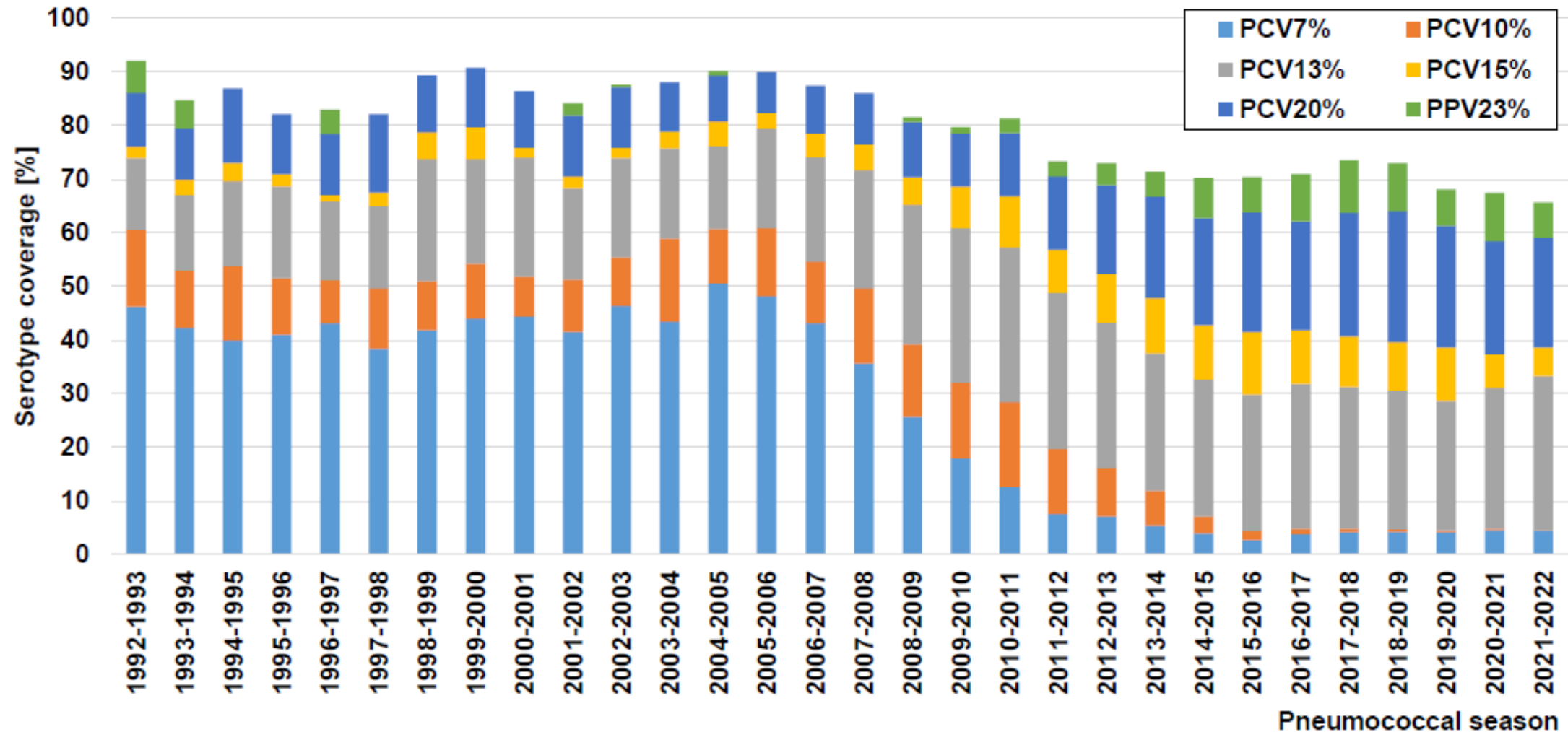
Serotype coverage by different PCVs - IPD isolates, <18 yr

Germany, ARI-season 1997-2022



Serotype coverage by different PCVs - IPD isolates, ≥ 60 yr

Germany, ARI-season 1997-2022



PCV15 (*Vaxneuvance*®) vs. PCV13 (*Prevnar13*®)

Immunogenicity in infants post dose 3

Table 9: Proportions of US Participants with IgG Response Rates ≥ 0.35 mcg/mL at 30 Days Following Dose 3 in Infants Administered VAXNEUVANCE at 2, 4 and 6 Months of Age (Study 8)

Pneumococcal Serotype	VAXNEUVANCE (n=452-455)	Prevnar 13 (n=426-430)	Percentage Point Difference (VAXNEUVANCE – Prevnar 13) (95% CI)* †
	Observed Response Percentage	Observed Response Percentage	
Serotype			
1	93.8	98.6	-4.8 (-7.5, -2.4)
3	93.1	74.0	19.1 (14.4, 24.0)
4	94.7	98.1	-3.4 (-6.1, -1.0)
5	93.4	96.0	-2.6 (-5.7, 0.3)
6A	92.7	99.3	-6.6 (-9.4, -4.2)
6B	86.7	89.9	-3.2 (-7.5, 1.1)
7F	98.7	100.0	-1.3 (-2.9, -0.4)
9V	96.7	97.2	-0.5 (-2.9, 1.9)
14	97.8	98.1	-0.3 (-2.4, 1.7)
18C	96.2	98.1	-1.9 (-4.3, 0.3)
19A	97.4	99.8	-2.4 (-4.3, -1.0)
19F	98.5	100.0	-1.5 (-3.2, -0.6)
23F	89.8	91.4	-1.5 (-5.4, 2.4)
Additional Serotypes			
22F	98.0	‡	8.1 (5.1, 11.5)
33F	84.8	‡	-5.1 (-9.5, -0.7)

PCV20 – Immunogenicity in infants post primary dose 3 (Phase 2 data)

Immune Measurement	Group	Serotype										23F
		1	3	4	5	6A	6B	7F	9V	14	18C	
Sero-responders	PCV20 (n† = 189)	87.8 (82.3–92.1)	87.8 (82.3–92.1)	87.8 (82.3–92.1)	87.8 (82.3–92.1)	93.7 (89.2–96.7)	86.8 (81.1–91.3)	98.9 (96.2–99.9)	89.4 (84.1–93.4)	94.2 (89.8–97.1)	92.6 (87.9–95.9)	79.9 (73.5–85.4)
	PCV13 (n† = 187)	87.7 (82.1–92.0)	87.7 (82.1–92.0)	87.7 (82.1–92.0)	87.7 (82.1–92.0)	92.5 (87.8–95.8)	90.4 (85.2–94.2)	97.9 (94.6–99.4)	89.3 (84.0–93.3)	95.7 (91.7–98.1)	95.2 (91.1–97.8)	81.8 (75.5–87.1)
IgG GMCs 1 month after Dose 3, % (95% CI‡)	PCV20 (n† = 189)	0.92 (0.81–1.05)	0.92 (0.81–1.05)	0.92 (0.81–1.05)	0.93 (0.79–1.11)	2.28 (1.94–2.67)	0.63 (0.49–0.80)	2.15 (1.92–2.40)	1.22 (1.05–1.42)	3.15 (2.69–3.70)	1.59 (1.37–1.84)	0.94 (0.78–1.14)
	PCV13 (n† = 187)	1.16 (1.00–1.33)	1.16 (1.00–1.33)	1.16 (1.00–1.33)	1.13 (0.96–1.34)	2.57 (2.16–3.05)	0.99 (0.77–1.27)	2.59 (2.28–2.93)	1.45 (1.24–1.70)	3.6 (3.07–4.21)	2.05 (1.76–2.38)	1.26 (1.03–1.55)
IgG GMC	PCV20 (n† = 189)	0.92 (0.81–1.05)	0.92 (0.81–1.05)	0.92 (0.81–1.05)	0.93 (0.79–1.11)	2.28 (1.94–2.67)	0.63 (0.49–0.80)	2.15 (1.92–2.40)	1.22 (1.05–1.42)	3.15 (2.69–3.70)	1.59 (1.37–1.84)	0.94 (0.78–1.14)
	PCV13 (n† = 187)	1.16 (1.00–1.33)	1.16 (1.00–1.33)	1.16 (1.00–1.33)	1.13 (0.96–1.34)	2.57 (2.16–3.05)	0.99 (0.77–1.27)	2.59 (2.28–2.93)	1.45 (1.24–1.70)	3.6 (3.07–4.21)	2.05 (1.76–2.38)	1.26 (1.03–1.55)
Serotype												
Participants achieving prespecified IgG concentration* 1 month after Dose 3, % (95% CI‡)	PCV20 (n† = 189)	99.5 (97.1–100.0)	99.5 (97.1–100.0)	99.5 (97.1–100.0)	99.5 (97.1–100.0)	99.5 (97.1–100.0)	99.5 (97.1–100.0)	99.5 (97.1–100.0)	99.5 (97.1–100.0)	99.5 (97.1–100.0)	99.5 (97.1–100.0)	92.1 (87.2–95.5)
	PCV13 (n† = 187)	3.7 (1.5–7.6)	3.7 (1.5–7.6)	3.7 (1.5–7.6)	3.7 (1.5–7.6)	3.7 (1.5–7.6)	3.7 (1.5–7.6)	3.7 (1.5–7.6)	3.7 (1.5–7.6)	3.7 (1.5–7.6)	3.7 (1.5–7.6)	1.6 (0.3–4.6)
IgG GMCs 1 month after Dose 3, % (95% CI§)	PCV20 (n† = 189)	2.09 (1.90–2.30)	2.09 (1.90–2.30)	2.09 (1.90–2.30)	2.09 (1.90–2.30)	2.09 (1.90–2.30)	2.09 (1.90–2.30)	2.09 (1.90–2.30)	2.09 (1.90–2.30)	2.09 (1.90–2.30)	2.09 (1.90–2.30)	2.21 (1.87–2.61)
	PCV13 (n† = 187)	0.04 (0.03–0.04)	0.04 (0.03–0.04)	0.04 (0.03–0.04)	0.04 (0.03–0.04)	0.04 (0.03–0.04)	0.04 (0.03–0.04)	0.04 (0.03–0.04)	0.04 (0.03–0.04)	0.04 (0.03–0.04)	0.04 (0.03–0.04)	0.05 (0.04–0.05)

Pneumococcal vaccines - Licensure SUMMARY.

Vaccine	Age group	EMA	FDA	Comment
PPV23 <i>Pneumovax</i> ® 23	≥ 2 years	Yes	Yes	Mainly booster in subjects ≥60 years or in „risk subjects“
PCV10 <i>Synflorix</i> ®	6 weeks – 5 years	Yes	No	
PCV13 (<i>Prevenar</i> ®13)	≥ 6 weeks	Yes	Yes	„ <i>Prevnar</i> ®“ in the USA
PCV15 <i>Vaxneuvance</i> ®	≥ 6 weeks, <18 years >18 years	No YES	YES YES	Watch for 2+1 (EU) vs. 3+1 (USA)
PCV20 <i>Appexnar</i> ®; <i>Prevnar20</i> ®	≥ 6 weeks, <18 years >18 years	No YES	No YES	Watch for 2+1 (EU) vs. 3+1 (USA)

Vaxneuvance[®] (PCV15), Appexnar[®] (PCV20): Use in Infants

USA: PCV15/PCV13 interchangeable as 3+1 (1 dose as of 3 yr)

▶ Licenses for children in Europe

- ▶ Based on non-inferior immunogenicity & safety vs. PCV13
- ▶ Schedule 3+1 or 2+1 or (off label in EU) in the UK: 1+1
 - ▶ Cave: immune responses decline with number of additional serotypes

▶ Decision criteria – for discussion (same price, 10 doses: € 767,35)

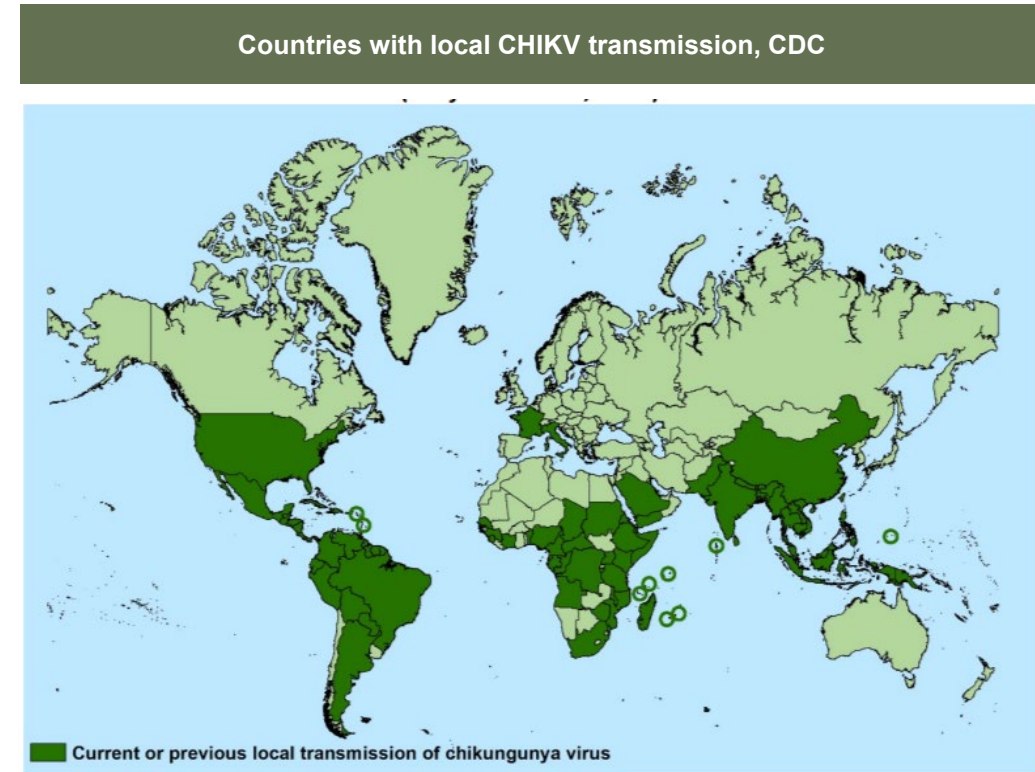
- ▶ What lower titer makes difference? - Herd protection more relevant?
- ▶ Impact/effectiveness against serotypes 3 and 19A
- ▶ Magnitude of local strain coverage regarding
 - ▶ 22F, 33F (PCV15) PLUS 8, 10A, 11A, 12F, 15B (PCV20)
- ▶ We will only know 1-5 years after licensure

Chikungunya (Valneva) Phase 3

Chikungunya: a major public health threat

► Mosquito-transmitted disease with potentially debilitating consequences

- Chikungunya virus (CHIKV): transmitted by *Aedes* mosquitoes¹
- Often: explosive outbreaks with high attack rates, affecting 30-75% of the population¹; difficult to predict next outbreaks²
- Outbreaks have occurred in **Asia, Africa and across Latin America**¹ with the potential for it to happen in the **U.S. and Europe**^{2,4}
- Highest areas of risk of infection for **travelers** include the Americas, parts of Africa, and Southeast Asia³
- Returning **infected travelers can trigger local transmission** in areas where relevant mosquitoes are established (e.g. Southern U.S. / Europe)²
- High burden of disease: outbreaks can have substantial health-economic impact; infection can progress to severe chronic symptoms in many patients⁴



No cure; treatment is symptomatic and supportive only

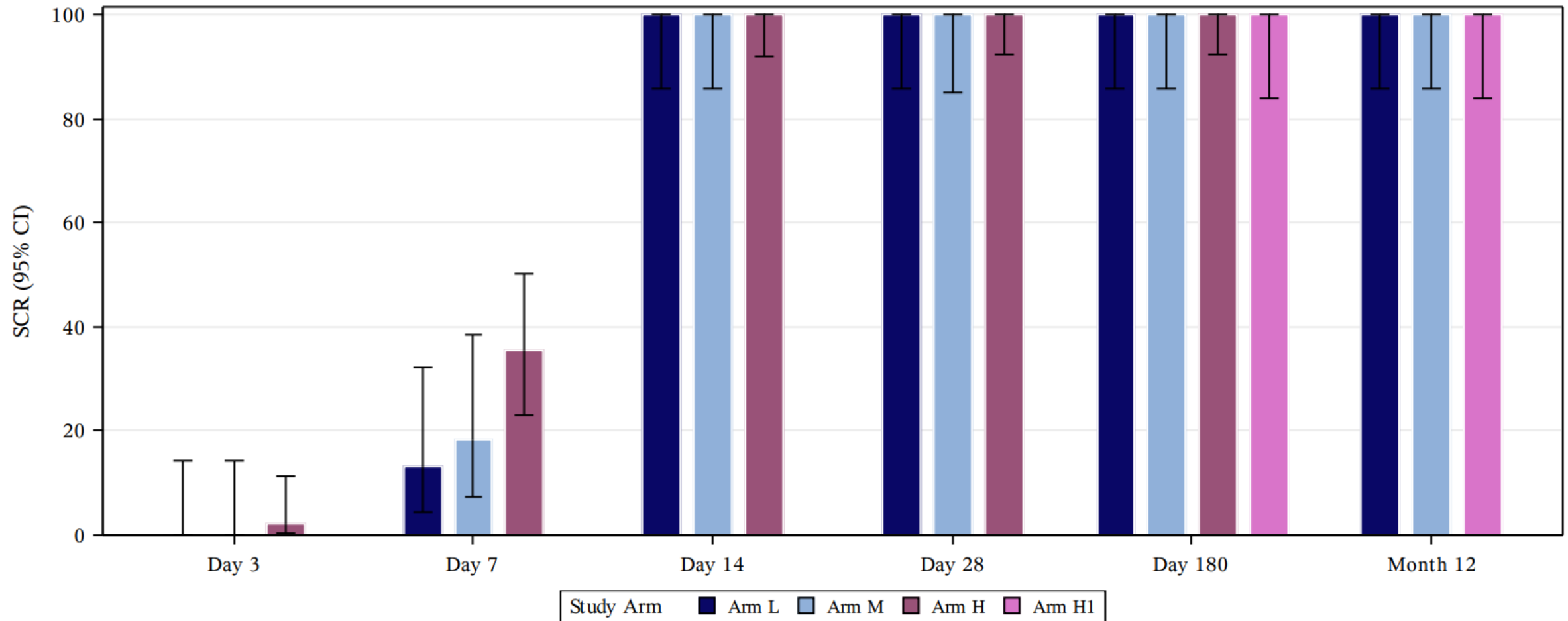
Without a vaccine, prevention is limited to protection against mosquito bites and vector control

Target Product Profile Phase 3: Valneva VLA1533 – Chikungunya vaccine (fast track)

Composition/Platform	Monovalent live-attenuated (CHIKV- LR2006-OPY1; deleted nsPr3 (replicase complex))
Indication	“Adults and children” – P3: ≥ 18 years in endemic regions
Dosing	Single dose i.m.
Immunogenicity	Descriptive only (100% responders after 1 dose);
Efficacy Endpoint(s) Phase 3	Immunogenicity (NT vs. surrogate) day 28
Efficacy data	Surrogate “protective titer”
Duration of protection	Lifelong?
Co-Administration	None
Reactogenicity	Target? Similar to Tdap or other?
Safety	N= 4,000 US adults
Vaccination Goal	Individual protection
Others	Fast Track and Breakthrough Designation (FDA), PRIME (EMA)

VAL1533 (Chikungunya) immunogenicity to L/M/H-doses

SCR for CHIKV-specific neutralizing antibodies after single vaccination



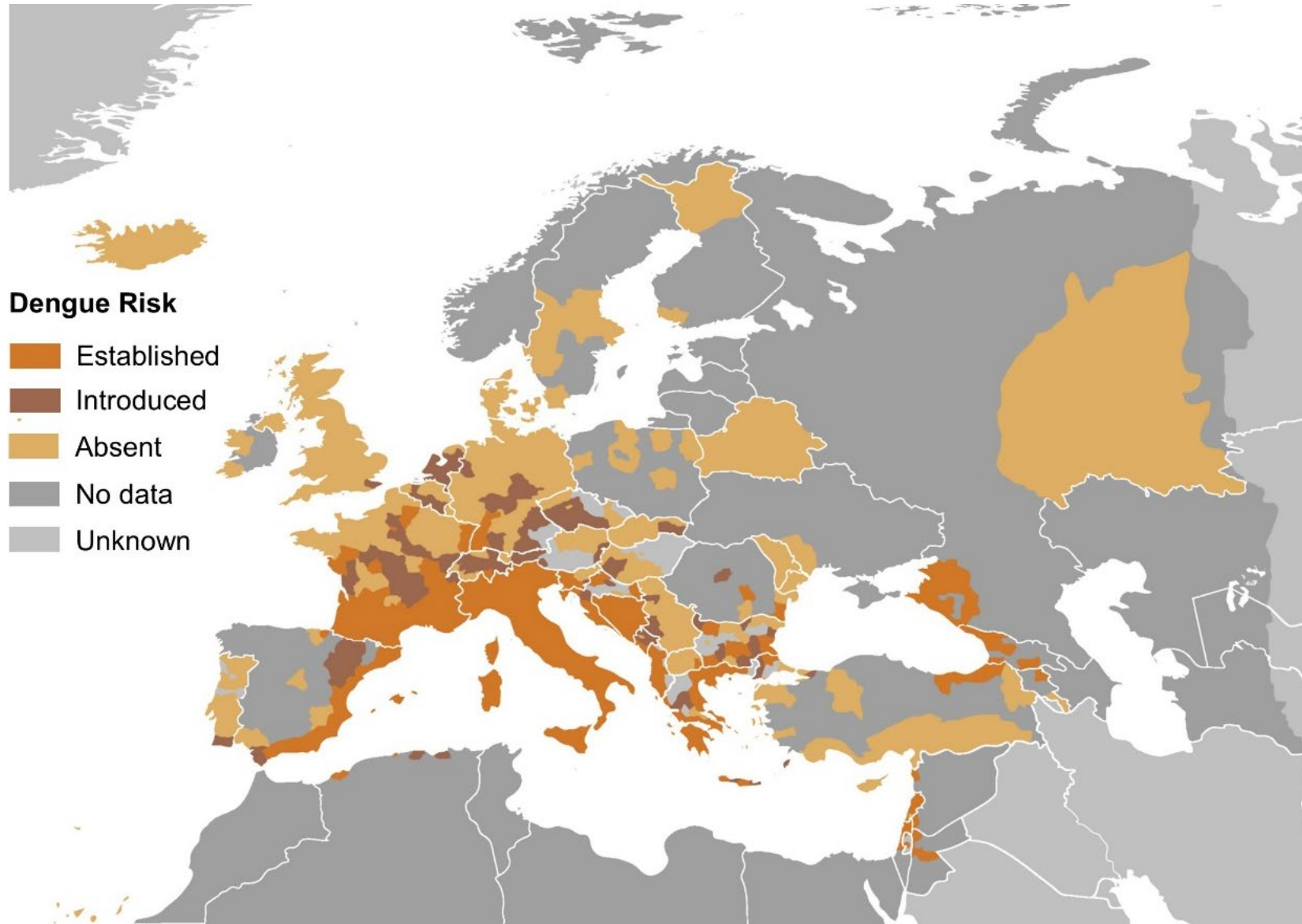
Valneva / Pfizer Lyme disease

Valneva/Pfizer

VALNEVA / PFIZER: Lyme Diseases

Composition/Platform	3 fusions proteins from 6 <i>Borrelia</i> OspA serotypes (ST1-ST6) (EU; USA); Al-adjuvanted
Indication	≥ 5 yr
Dose	Before 1 st season (2+1): 0-2-5 (-9) mo / booster @ 18 mo / + later boosters ?
Immunogenicity	Yes 😊
Efficacy data	Phase 3 ongoing (USA, EU)
„Seroprotetction“	No CoP
Duration of protection	Unknown
Reactogenicity	Acceptable
Safety	No safety concern to date
NOTABENE:	Prevents INFECTION by killing <i>Borreliae</i> in ticks

Dengue – Risk in Europe



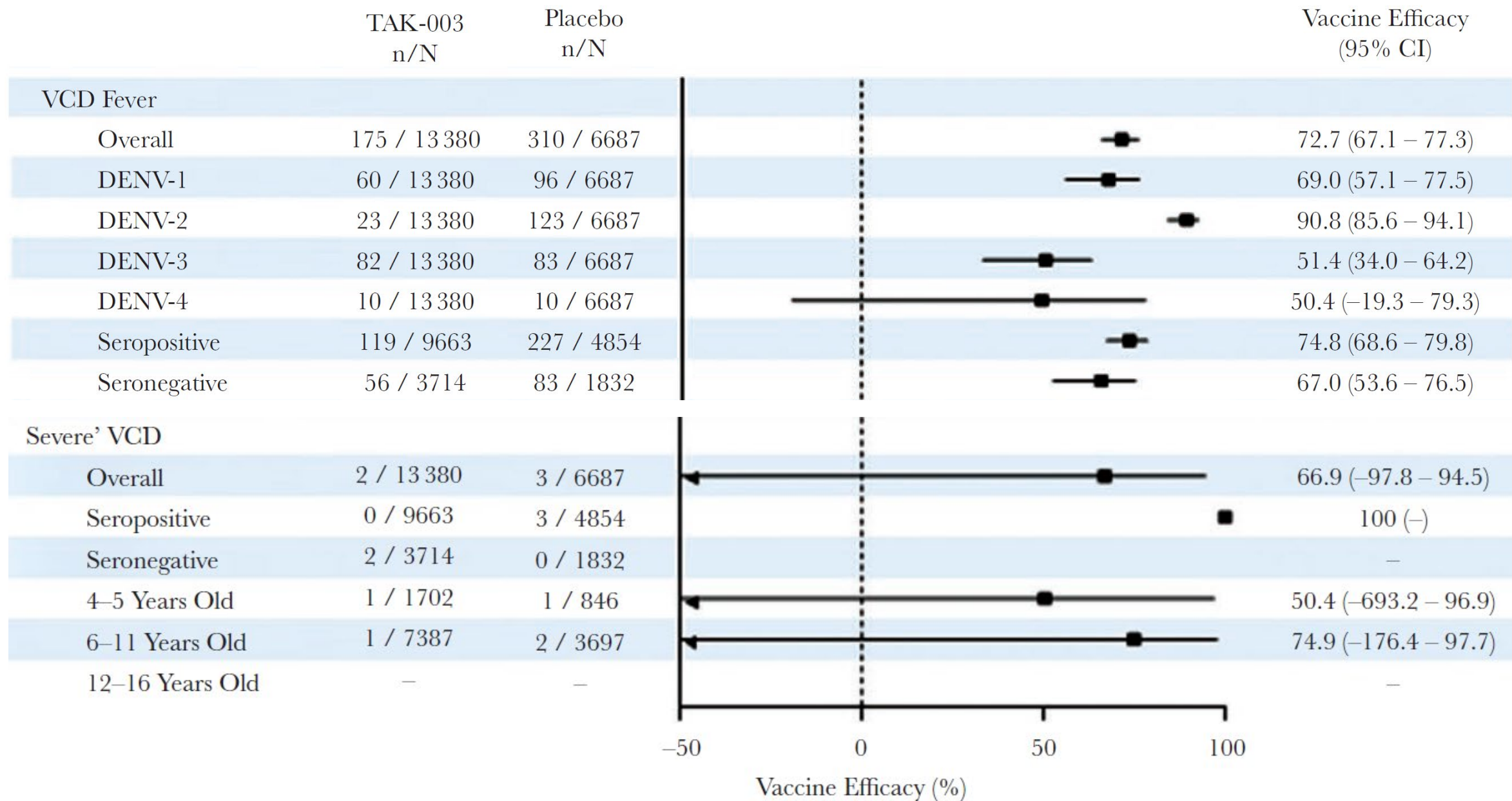
Target Product Profile (licensed): Dengvaxia (Sanofi)

Composition/Platform	Live-attenuated chimeric yellow-fever/Dengue-virus tetravalent (CYD-TDV)
Indication	EMA: 9-45 Yr FDA: 9-16 yr after first DEN-V infection WHO: in seropositive subjects (serological pre-screening); Approved in ~ 20 countries
Dosing	3 doses at 0 – 6mo – 12 mo
Immunogenicity	Available for ages 9-45 years
Efficacy data (9-16 years only)	VE 81.9% against symptomatic virologically confirmed DEN (sVCD) VE 89.2% DEN hospitalization VE 95.3% severe sVCD
„Seroprotection“	Age 17-45 yr
Duration of protection	?? Lifelong?
Reactogenicity	Acceptable;
Safety	?? ADE (retrospective analysis)

Target Product Profile TAKEDA “TAK-003” DEN-V Vx

Composition/Platform	Live attenuated chimeric (DENV-2 backbone) for DENV 1,2,3,4 (CDC-derived)
Indication	Children 4-16 years, no pre-screening before vx
Dosing	s.c. injection at 0 mo + 3 mo
Immunogenicity	
Efficacy data (“TIDES”) N >20,000 @27 mo	VE 72.7% hospitalized VCD VE Variation by age, serogroup, time VE decline in 2 nd yr
„Seroprotection“	
Duration of protection	≥2-3 yr?
Reactogenicity	Acceptable
Safety	No safety concern seen to date

TAK-003 VE (Phase 3)



Target Product Profile: Butantan/NIH DENV

Composition/Platform		DenV 1,3,4 attenuated vaccine + DENV 2 chimeric on DENV4 backbone
Indication		2-6, 7-17, 18-59 yr
Dosing		1 single dose s.c.
Immunogenicity		
Efficacy data		Phase 3 ongoing (28 days p.v. to 52 weeks p.v.; Brazil); to end 08/2024
„Seroprotetion“		
Duration of protection		
Reactogenicity		
Safety		

Last update found in 2020

FYI only – globally / traveler relevant

A novel tool to eradicate an ancient scourge: the novel oral polio vaccine type 2 story

Ananda S Bandyopadhyay, Simona Zipursky

The recent detection of vaccine-derived poliovirus (VDPV) in London (UK) and a case of paralytic polio in New York (USA) have highlighted how the scourge of poliomyelitis has not been totally overcome and remains an international problem, not confined to Afghanistan and Pakistan (where wild-type 1 poliovirus remains endemic) or as outbreaks of circulating VDPV in countries in Africa. To address the risk of circulating VDPVs, a global collaborative effort over the past decade has enabled the development of novel oral polio vaccine type 2 (nOPV2) that is as immunogenic as the current Sabin strain and so equally effective, while being less likely to revert to neurovirulence than Sabin oral polio vaccines. The successful development of nOPV2—the first such vaccine against type 2 poliovirus and the first vaccine ever authorised by the WHO Prequalification team through its Emergency Use Listing procedure—has led to the deployment of approximately 450 million doses of nOPV2 for outbreak control in 21 countries. It also paved the way for the subsequent Emergency Use Listing approval of COVID-19 vaccines in the global pandemic. Monitoring the use of nOPV2 has confirmed it is more genetically stable and less likely to result in VDPV than the Sabin strain, suggesting that the target of the global eradication of poliomyelitis might be a little more attainable than previously believed.



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Presentation Outline

1. Introduction

- ▶ Current vaccines and vaccine development

2. Coming soon (recently licensed & phase 3)

3. Think about the future!

- ▶ What do we need?

My Predictions: Vaccines in 3-5-10 years

Improved / available „new“ product

- MPX
- Men ABCWY
- Egg-free cell culture
- EV71
- Malaria next gen
- Rabies SAM
- PCV~~XY~~
- Various Combinations



Perhaps

- Ebola
- Lassa Fever
- MERS
- GBS
- *C. difficile*
- Lyme disease
- Broad influenza
- *Shigella*
- Therapeutic HBV
- CMV
- Norovirus
- *S. Paratyphi*
- HCV



My hope for the future

- Anti-cancer Vx
- Hep BD-
- HIV
- ~~Tuberculosis?~~
- Emerging diseases



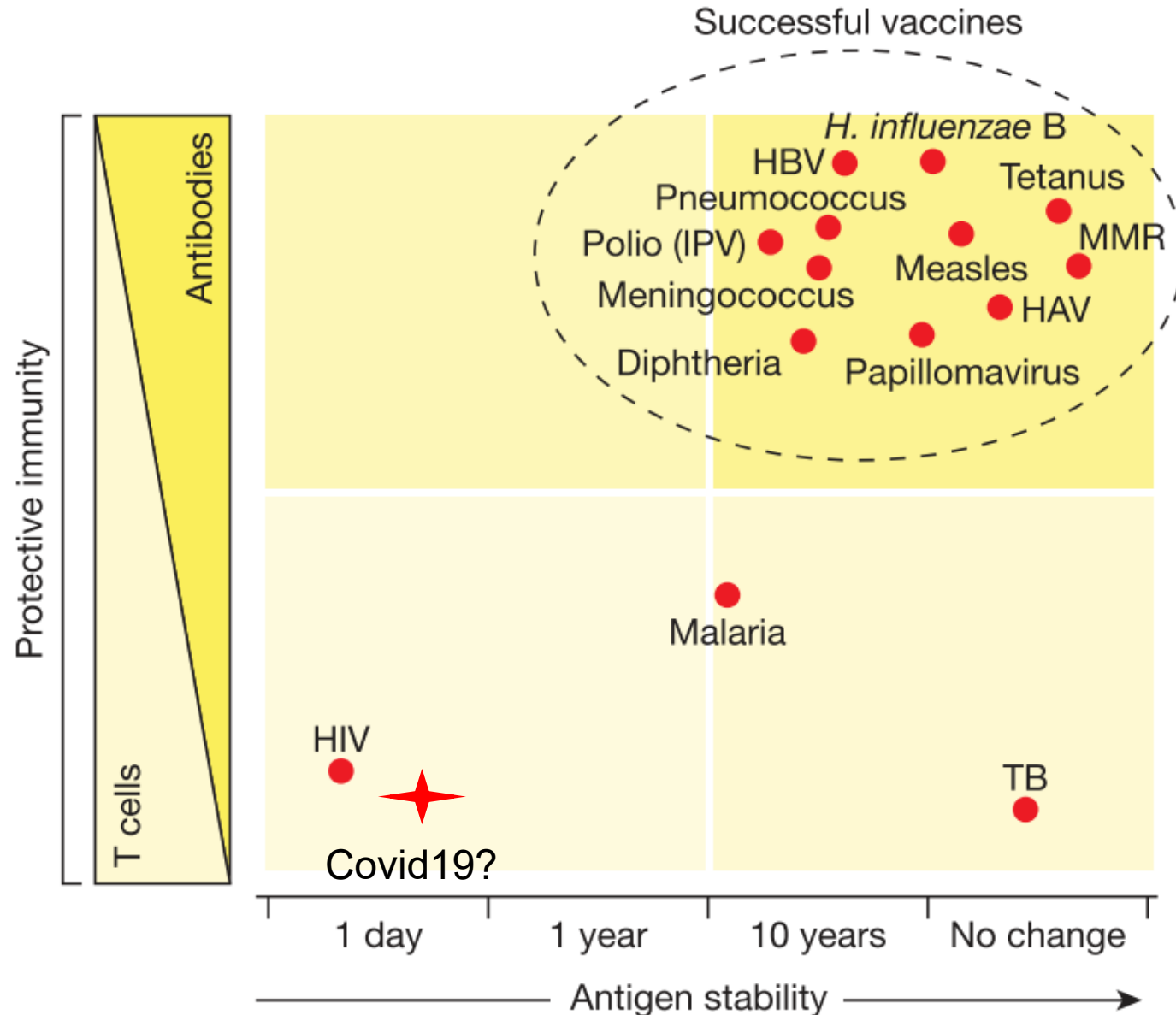
Platform safety – profiles: Specific for COVID-antigen or „Class-effect-AEs“?

Vaccine Type	Example	Event	Adverse Event (SmPC)
Whole cell, live	Varicella	Spread to vulnerable Population	Infection during pregnancy, ICH
	OPV	Spread in Population	VAPP
	DTwP	High reactogenicity	Fear (!) of brain damage, low acceptance
AdenoVector	COVID Vx	Coagulation diseases	Stroke (very rare, no estimate)
		CNS	GBS (very rare)
		nerval system involvement	transverse myelitis (very rare)
			Facial paralysis (rare)
			Capillary leakage (frequency unknown)
mRNA	COVID Vx	Myocarditis (natural: 1-10/10 ⁵)	Less frequent, no estimate; causality?
		Facial paralysis	1:1,000 – 1:10,000

Current Vaccine Platforms do not Always Work

**Sterilizing
mucosal
Immunity**

**Hib, PCV,
Mening.
D, HPV,
OPV**



Only 4 Out of 26 Vaccine Targets Identified as Priorities in 1999 by IOM Licensed to Date

Most
Favorable

- Cytomegalovirus vaccine for 12-year-olds
- Influenza virus vaccine for the general population (vaccine only needed every 5 years)
- Insulin-dependent diabetes mellitus therapeutic vaccine
- Multiple sclerosis therapeutic vaccine

To Successfully Get the Benefits of a New Vaccine You Need:

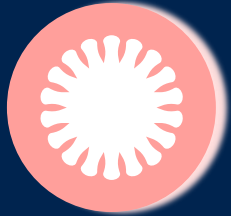
- Someone who wants to invest at high risk
- Transparent criteria for recommendations and reimbursement
- A national immunization program (NIP)

Less
Favorable

Costs >\$100k per
QALY saved

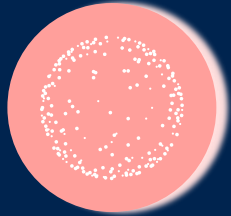
- *Borrelia burgdorferi* vaccine for resident infants and migrants of any age in high-risk geographic areas (*Vaccine licensed but removed from the market*)
- *Coccidioides immitis* vaccine for resident infants and migrants of any age in high-risk geographic areas
- Enterotoxigenic *Escherichia coli* vaccine for infants and travelers
- Epstein-Barr virus vaccine for 12-year-olds
- *Histoplasma capsulatum* vaccine for resident infants and migrants of any age in high-risk areas
- *Neisseria meningitidis* group B vaccine for infants
- *Shigella* vaccine for infants and travelers, or travelers only

CEPI's vaccine portfolio



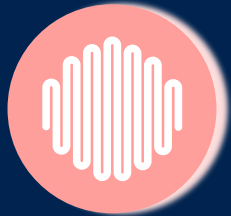
MERS

4 vaccine candidates



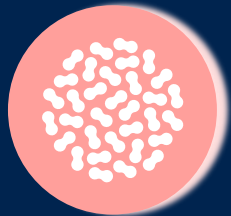
Lassa

5 vaccine candidates



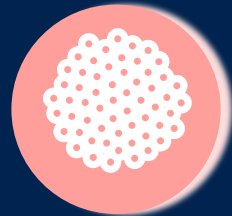
Nipah

4 vaccine candidates



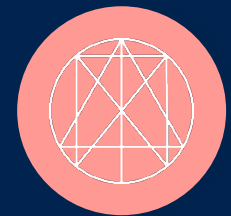
Chikungunya

3 vaccine candidates



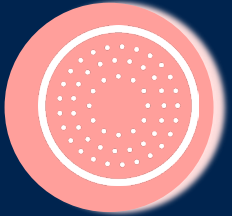
Rift Valley
fever

2 vaccine candidates



COVID-19

14 vaccine candidates



Disease X

3 platform technologies

Which vaccine would you/your country want to have in 3 -5 -10 years?

Most countries lack epidemiology data needed to determine the disease burden – as shown by the Country Vaccination Score (CVS):

See: [VacciNATION – Global Health Press \(id-ea.org\)](https://id-ea.org/VacciNATION)

More if you wish:
www.id-ea.org

Companies' Vaccine Pipelines

Download 2022-09

GSK PIPELINE, July 2022

Generic Name/ INN	Indication	Mechanism of Action / Vaccines Type	Phase	*)
Rotavirus vaccine	Rotavirus prophylaxis (US) (TN: Rotarix) infants	Live attenuated, porcine circovirus free	Phase III	no
Men B	Meningococcal B prophylaxis in infants (US) (TN:Bexsero)	Recombinant protein vaccine	Phase III	no
Men ABCWY (1st Gen)	Meningococcal A, B, C, W, Y prophylaxis, adolescents	Recombinant protein – conjugate	Phase III	no
RSV	MI against RSV-LRTI during first months of life	Recombinant protein	Phase III	yes
RSV	RSV prophylaxis in older adults	Recombinant protein – adjuvanted	Phase III	yes
COVID-19 VLP	COVID-19 (Medicago; plant derived)	recombinant protein-adjuvanted	Phase III	yes
COVID-19	COVID-19 (TN: Vidprevtyn), Sanofi	recombinant protein-adjuvanted	Phase III	yes
COVID-19	COVID-19 (SK Bioscience)	Recombinant protein nanoparticle-adjuvanted	Phase III	yes
Malaria next generation	Malaria (fractional dose) (P. falciparum)	Recombinant protein – adjuvanted	Phase II	yes
Shigella	Shigella diarrhea prophylaxis	Bioconjugated (tetraivalent) vaccine	Phase II	yes
Therapeutic HBV	Chronic hepatitis B treatment: controlling / resolving infection, reducing need for further treatment	Prime-boost viral vector vaccines, co- or sequentially given w. adjuvanted rec. proteins	Phase II^	yes
C. difficile	Prevention of primary /recurrent C. difficile diseases	Recombinant protein –adjuvanted	Phase I	yes
SAM (Rabies model)	Rabies prophylaxis	Self-Amplifying mRNA vaccine	Phase I	no
S. aureus	Prevention primary / recurrent soft-skin-tissue infections	Rec. protein – bioconjugated, adjuvanted	Phase II^	yes
COVID-19 SAM model	COVID-19	Self-Amplifying mRNA	Phase I	no
Men ABCWY (2nd Gen)	Meningococcal A, B, C, W, Y prophylaxis adolescents	Recombinant protein – conjugated	Phase II^	no
Klebsiella pneumoniae	Klebsiella pneumoniae prophylaxis	Rec. protein – bioconjugated, adjuvanted	Phase I	yes
CMV	CMV infection prophylaxis (females 16-49 yrs.)	Recombinant subunit- adjuvanted	Phase I^	no

*) in-licensed or other alliance

BCG Vaccine U.S.P.

[Prescribing Information](#)
[Instructions for Use](#)

ERVEBO[®]

(Ebola Zaire Vaccine, Live)
[Prescribing Information](#)
[Patient Product Information](#)

PRODUCT DETAILS



GARDASIL[®] 9

(Human Papillomavirus 9-valent Vaccine, Recombinant)
[Prescribing Information](#)
[Patient Product Information](#)

PRODUCT DETAILS



M-M-R[®] II

(Measles, Mumps, and Rubella Virus Vaccine Live)
[Prescribing Information](#)
[Patient Product Information](#)

PRODUCT DETAILS



PedvaxHIB[®]

[Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)]
[Prescribing Information](#)

PRODUCT DETAILS



PNEUMOVAX[®] 23

(Pneumococcal Vaccine Polyvalent)
[Prescribing Information](#)
[Patient Product Information](#)

PRODUCT DETAILS



ProQuad[®]

(Measles, Mumps, Rubella and Varicella Virus Vaccine Live)
[Prescribing Information](#)
[Patient Product Information](#)

PRODUCT DETAILS



RECOMBIVAX HB[®]

[Hepatitis B Vaccine (Recombinant)]
[Prescribing Information](#)

PRODUCT DETAILS



RotaTeq[®]

(Rotavirus Vaccine, Live, Oral, Pentavalent)
[Prescribing Information](#)
[Patient Product Information](#)

PRODUCT DETAILS



VAQTA[®]

(Hepatitis A Vaccine, Inactivated)
[Prescribing Information](#)
[Patient Product Information](#)

PRODUCT DETAILS



VARIVAX[®]

(Varicella Virus Vaccine Live)
[Prescribing Information](#)
[Patient Product Information](#)

PRODUCT DETAILS



VAXELIS[™]

(Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus, Haemophilus b Conjugate and Hepatitis B Vaccine)
[Prescribing Information](#)
[Patient Product Information](#)

PRODUCT DETAILS



VAXNEUVANCE[™]

(Pneumococcal 15-valent Conjugate Vaccine)
[Prescribing Information](#)
[Patient Product Information](#)

PRODUCT DETAILS



MSD

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Comirnaty (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection Booster (in collaboration with BioNTech) (U.S.; EU) ¹	Registration	Product Enhancement
Comirnaty (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection (in collaboration with BioNTech) (U.S.; EU – 5 to 11 years of age) ²	Registration	Product Enhancement
► Comirnaty (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection Booster (in collaboration with BioNTech) (U.S. – 5 to 11 years of age) ²	Registration	Product Enhancement
► Comirnaty (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection (in collaboration with BioNTech) (children 2 to 4 years of age) ³	Registration	Product Enhancement
► Comirnaty (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection (in collaboration with BioNTech) (infants 6 months to <24 months) ³	Registration	Product Enhancement
PF-06425090	Prophylactic Vaccine	Primary <i>Clostridioides difficile</i> infection (FAST TRACK)	Phase 3	New Molecular Entity
PF-06482077	Prophylactic Vaccine	Invasive and Non-Invasive Pneumococcal infections (pediatric) (BREAKTHROUGH, FAST TRACK)	Phase 3	Product Enhancement
PF-06928316	Prophylactic Vaccine	Respiratory Syncytial Virus Infection (maternal) (BREAKTHROUGH, FAST TRACK – U.S.)	Phase 3	New Molecular Entity
PF-06928316	Prophylactic Vaccine	Respiratory Syncytial Virus Infection (older adult) (BREAKTHROUGH - U.S.)	Phase 3	Product Enhancement
Omicron variant (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection (in collaboration with BioNTech) (adults)	Phase 3	New Molecular Entity
PF-06886992	Prophylactic Vaccine	Serogroups ABCWY Meningococcal Infections (adolescent and young adults)	Phase 3	New Molecular Entity
PF-06842433	Prophylactic Vaccine	Invasive and Non-Invasive Pneumococcal infections (infants and children)	Phase 2	New Molecular Entity
PF-06760805	Prophylactic Vaccine	Invasive Group B Streptococcus Infection (maternal) (FAST TRACK)	Phase 2	New Molecular Entity
PF-07307405	Prophylactic Vaccine	Lyme disease (FAST TRACK)	Phase 2	New Molecular Entity
PF-07252220	Prophylactic mRNA Vaccine	Influenza (adults)	Phase 1	New Molecular Entity


Sanofi Vaccine

Vaccines	<div><div>1</div><div>2</div><div>3</div><div>R</div></div>	SP0273	<div><div>i</div>mRNA vaccine</div>	Influenza
Vaccines	<div><div>1</div><div>2</div><div>3</div><div>R</div></div>	Fluzone® HD	<div><div>i</div>Inactivated influenza vaccine</div>	Pediatric
Vaccines	<div><div>1</div><div>2</div><div>3</div><div>R</div></div>	SP0125	<div><div>i</div>Live attenuated virus vaccine</div>	Respiratory (toddlers)
Vaccines	<div><div>1</div><div>2</div><div>3</div><div>R</div></div>	SP0202	<div><div>i</div>Next-generation conjugate vaccine</div>	Pneumonia
Collaboration		Notes		Expected
Developed in collaboration with SK				Not available
More about Vaccines →				

<div><div>i</div><div>Meningococcal (A,C,Y,W) conjugate vaccine</div></div>	Me
<div><div>i</div><div>Purified Vero rabies vaccine</div></div>	Pe
<div><div>i</div><div>Anti-RSV mAb</div></div>	Pe
<div><div>i</div><div>Recombinant baculovirus vaccine</div></div>	CO

SP0218	<div><div>i</div><div>Vaccine (Vero cell)</div></div>	Yellow Fever	
SP0230	<div><div>i</div><div>Multicomponent vaccine</div></div>	Meningitis B	
MenQuadfi™	<div><div>i</div><div>Meningococcal (A,C,Y,W) conjugate vaccine</div></div>	Meningitis, 6 weeks+ (USA / EU)	▼
VRVg	<div><div>i</div><div>Purified Vero rabies vaccine</div></div>	Rabies	▼
nirsevimab	<div><div>i</div><div>Anti-RSV mAb</div></div>	Respiratory syncytial virus	▼
SP0253	<div><div>i</div><div>Recombinant baculovirus vaccine</div></div>	COVID-19	▼

Moderna's Respiratory Vaccines (Pipeline 1/3)


Modality	Program	ID #	Preclinical development	Phase 1	Phase 2	Phase 3	Commercial	Moderna rights
<div>Adults</div> <div></div> <div>Prophylactic vaccines</div>	COVID-19 vaccine	mRNA-1273/Spikevax®						Worldwide
		mRNA-1273.351	Beta variant					Worldwide
		mRNA-1273.617	Delta variant					Worldwide
		mRNA-1273.211	Beta variant + wild-type					Worldwide
		mRNA-1273.213	Beta + Delta variant					Worldwide
		mRNA-1273.529	Omicron variant					Worldwide
		mRNA-1273.214	Omicron + wild-type					Worldwide
		mRNA-1283	Next generation (2-5 °C)					Worldwide
	Flu vaccine	mRNA-1010	Phase 3 prep					Worldwide
		mRNA-1011						Worldwide
		mRNA-1012						Worldwide
		mRNA-1020						Worldwide
		mRNA-1030						Worldwide
	COVID + Flu vaccine	mRNA-1073						Worldwide
Older adults RSV vaccine	mRNA-1345						Worldwide	
Adolescents & Pediatrics	COVID-19 vaccine (adolescents)	mRNA-1273	TeenCOVE					Worldwide
	COVID-19 vaccine (pediatrics)	mRNA-1273	KidCOVE					Worldwide
	Pediatric RSV vaccine	mRNA-1345					Worldwide	
	Pediatric hMPV + PIV3 vaccine	mRNA-1653	Phase 1b					Worldwide
	Pediatric RSV + hMPV vaccine	mRNA-1365					Worldwide	

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moderna

Moderna

Moderna's Latent & Public Health Vaccines (Pipeline 2/3)

Modality	Program	ID #	Preclinical development	Phase 1	Phase 2	Phase 3	Commercial	Moderna rights
Latent vaccines  Prophylactic vaccines	CMV vaccine	mRNA-1647						Worldwide
	EBV vaccine (to prevent infectious mononucleosis)	mRNA-1189						Worldwide
	EBV vaccine (to prevent EBV sequelae)	mRNA-1195						Worldwide
	HSV vaccine	mRNA-1608						Worldwide
	VZV vaccine	mRNA-1468						Worldwide
	HIV vaccines	mRNA-1644						Worldwide IAVI/others funded
		mRNA-1574						Worldwide BMGF/NIAID/others funded
Public health vaccines	Zika vaccine	mRNA-1893						Worldwide BARDA funded
	Nipah vaccine	mRNA-1215						Worldwide NIH funded

Slide 23

moderna















BioNTech Vaccine Candidates

Drug Class	Product Candidate	Indication (<i>Targets</i>)	Pre-clinical	Phase 1	Phase 2	Phase 3	Commercial	Rights/Collaborator
mRNA	BNT162b2	COVID-19						Fosun Pharma (China), Pfizer (Global, except China)
	BNT161	Influenza						Pfizer
	Un-named program	Shingles						Pfizer
	BNT164	Tuberculosis ⁴						Bill & Melinda Gates Foundation
	BNT165	Malaria						Fully-owned
	Un-named program	HSV 2						Fully-owned
	Un-named program	HIV ⁴						Bill & Melinda Gates Foundation
	Undisclosed programs	Additional mRNA vaccine programs ⁵						Fully-owned
	Undisclosed programs	Precision antibacterials						Fully-owned

AstraZeneca Vaccine Candidates

 Vaccine & Immune therapies (as of 29 July 2022)			
Phase I	Phase II	Phase III	LCM Projects
		<div>Evusheld <i>prevention and treatment of COVID-19</i></div> <div>nirsevimab <i>passive RSV immunisation</i></div> <div>Vaxzevria <i>COVID vaccine</i></div>	

Novavax Vaccine Candidates

Therapeutic area	Candidate	Technology	Phase of trial				Authorized use
			Preclinical	Phase 1	Phase 2	Phase 3	
Respiratory diseases COVID-19	Novavax COVID-19 vaccine (NVX-COV2373) Pipeline details						 Authorized*
Respiratory diseases COVID-19	Novavax COVID-19 Omicron vaccine Pipeline details					 Phase 3	
Respiratory diseases Seasonal influenza	NanoFlu Pipeline details					 Phase 3 in progress	
Respiratory diseases COVID-19 + seasonal influenza	Novavax COVID-NanoFlu combination candidate Pipeline details				 Phase 1/2		
Respiratory diseases Respiratory syncytial virus (RSV)	ResVax for infants via maternal immunization Pipeline details					 Phase 3†	
Respiratory diseases Respiratory syncytial virus (RSV)	RSV F vaccine for children between 2-6 years old Pipeline details			 Phase 1			
Respiratory diseases Respiratory syncytial virus (RSV)	RSV F vaccine for adults 60+ years old Pipeline details			 Phase 1			
Respiratory diseases Middle East Respiratory Syndrome (MERS)	MERS vaccine Pipeline details		 Preclinical				
Respiratory diseases Severe Acute Respiratory Syndrome (SARS)	SARS vaccine Pipeline details		 Preclinical				
Parasitic diseases Malaria	R21† Pipeline details				 Phase 2b in progress		
Parasitic diseases Ebola	Ebola GP vaccine Pipeline details			 Phase 1			

Takeda Vaccine Candidates

Collaborator	VC	Phase 1	Phase 2	Phase 3
-	Tetravalent live attenuated serotype 2 dengue-viurs backbone VC (TAK-003)			
BARDA	Inactivated adjuvanted, whole virus Zika VC			
NN	Hil-214, Norovirus VC (formerly TAK-214)			

Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA).

Curevac Vaccine Pipeline

Collaborator	Vaccine	Phase 1	Phase 2	Phase 3
GSK	Modified COVID19			
GSK	Unmodified COVID19			
GSK	FluSV mRNA, modified			
GSK	CVSQIV (Flu unmodified)			
CEPI	CVnCoV (Covid-19)			
CEPI	Lassa fever; Yellow fever			
	CV7202 (Rabies)			
	RSV			
BMG foundation	Various in preclinical			

Serum Institut of India

Combination Vaccines

[Diphtheria, Tetanus, Pertussis & Hepatitis B Vaccine Adsorbed](#)
1 dose, 10 dose

[Diphtheria, Tetanus, Pertussis, & Haemophilus influenzae Type b Conjugate Vaccine \(Freeze-dried\)](#)
1dose

[Diphtheria, Tetanus, Pertussis, Hepatitis B & Haemophilus influenzae Type b Conjugate Vaccine \(Freeze-dried\)](#)
1dose, 2 dose

[Diphtheria, Tetanus, Pertussis, Hepatitis B & Haemophilus influenzae Type b Conjugate Vaccine Adsorbed \(Liquid\)](#)
1dose, 10 dose

Recombinant Products

[Hepatitis B Vaccine \(rDNA\) \(Pediatric & Adult\)](#)
1 dose, 10 dose

[Hepatitis B Vaccine \(rDNA\) \(Pediatric & Adult\) \(Thiomersal Free\)](#)
1 dose

[REPOITIN \(Vial\)](#)
[Recombinant Human Erythropoietin \(rHuEPO\) Injection](#)
2000 IU, 4000 IU, 5000 IU, 10000 IU

[REPOITIN \(PFS\)](#)
[Recombinant Human Erythropoietin \(rHuEPO\) Injection](#)
2000 IU, 3000 IU, 4000 IU, 5000 IU, 6000 IU, 10000 IU

[RABISHIELD](#)
[Rabies Human Monoclonal Antibody](#)
100 IU, 250 IU

Bacterial Vaccines

[Diphtheria, Tetanus & Pertussis Vaccine Adsorbed](#)
1 dose, 10 dose, 20 dose

[Diphtheria & Tetanus Vaccine Adsorbed for Adults & Adolescents](#)
1 dose, 10 dose, 20 dose

[Diphtheria & Tetanus Vaccine Adsorbed \(Pediatric\)](#)
1 dose, 10 dose, 20 dose

[Diphtheria & Tetanus Vaccine Adsorbed \(Pediatric\) \(Thiomersal Free\)](#)
1 dose

[Tetanus Toxoid Vaccine Adsorbed](#)
1 dose, 10 dose, 20 dose

[BCG Vaccine \(Freeze-Dried\)](#)
10 dose, 20 dose

Viral Vaccines

[Measles Vaccine, Live, Attenuated \(Freeze-dried\)](#)
1 dose, 2 dose, 5 dose, 10 dose

[Mumps Vaccine Live, Attenuated \(Freeze-dried\)](#)
1 dose, 2 dose, 5 dose, 10 dose

[Rubella Vaccine, Live, Attenuated \(Freeze-dried\)](#)
1 dose, 2 dose, 5 dose, 10 dose

[Measles, Mumps & Rubella Vaccine, Live, Attenuated \(Freeze-dried\)](#)
1 dose, 2 dose, 5 dose, 10 dose

[Measles & Rubella Vaccine, Live, Attenuated \(Freeze-dried\)](#)
1 dose, 2 dose, 5 dose, 10 dose

[RABIVAX-S](#)
[Rabies Vaccine Inactivated \(Freeze-dried\)](#)
1 dose

[ROTASIIL - Rotavirus Vaccine, \(Live Attenuated Oral\), \(Freeze-Dried\)](#)
1 dose, 2 dose

[ROTASIIL-Liquid - Rotavirus Vaccine, \(Live Attenuated Oral\), \(Liquid\)](#)
1 dose, 2 ml

PRODUCTS SUPPLIED OVERSEAS

Coronavirus disease (COVID-19) Vaccines

[SARS-CoV-2 rS Protein \(COVID-19\) recombinant spike protein Nanoparticle Vaccine](#)
COVOVAX™

[ChAdOx1 nCoV-19 Corona Virus Vaccine \(Recombinant\)](#)
COVISHIELD™

Polysaccharide Conjugate Vaccines

[Haemophilus influenzae Type b Conjugate Vaccine \(Freeze-dried\)](#)
1 dose

[MenAfriVac](#)
[Meningococcal A Conjugate Vaccine \(Freeze-dried\)](#)
1 dose, 10 dose

[Pneumasil \(10-Valent with 6A & 19A\)](#)
[Pneumococcal Polysaccharide Conjugate Vaccine \(Adsorbed\)](#)
1 dose, 5 dose

Influenza Vaccines

[NASOVAC-S](#)
[Influenza Vaccine \(Human, Live Attenuated\), \(Freeze-dried\) Pandemic \(H1N1\), \(Intranasal\)](#)
1 dose

Anti Sera

[Tetanus Antitoxin 1500 IU, 3000 IU, 20000 IU](#)

[Anti-Rabies Serum 1000 IU, 1500 IU](#)

Uro-Oncology

[ONCO-BCG \(BCG LIVE\) \(Lyophilized\)](#)

Janssen (Johnson & Jonson)

INFECTIOUS DISEASES AND VACCINES, GLOBAL PUBLIC HEALTH

CABENUVA

HIV Adolescents

Registration

VAC52150

Monovalent Ebola Virus Vaccine

Registration

VAC31518

Janssen COVID-19 Vaccine

Registration

VAC18193

RSV Adult Vaccine

Phase 3

REMICADE (Infliximab)

COVID-19

Phase 3

VAC89220

HIV Px Vaccine

Phase 3

VAC52416

Multivalent ExPEC Vaccine

Phase 3

VAC31518

Janssen COVID-19 Vaccine Pediatrics

Phase 3

JNJ-3989

Hepatitis B/D Co-infection

Phase 2

JNJ-3989 Combination Therapy

Hepatitis B

Phase 2

JNJ-1802

Dengue Treatment

Phase 2

JNJ-1802

Dengue Prophylaxis

Phase 2

Ultra Long-Acting

HIV

Phase 1

JNJ-0953

Influenza

Phase 1

JNJ-3283 Combination Therapy

Hepatitis B

Phase 1

— Lyme Borreliose – VLA15



Lyme Borreliose ist die häufigste durch Vektoren übertragene Krankheit in der nördlichen Hemisphäre. Der Impfstoffkandidat von Valneva ist weltweit der einzige Impfstoff in der klinischen Entwicklung. Valnevas Impfstoffkandidat VLA15, der von der FDA den Fast Track-Status erhalten hat, ist ein multivalenter Impfstoff, der auf das äußere Oberflächenprotein A (OspA) von Borrelien abzielt.

Mehr lesen

+ Chikungunya – VLA1553

+ COVID-19 – VLA2001

+ Zika – VLA1601

+ Clostridium difficile – VLA84

[Home](#) > [Innovation](#) > [Pipeline Products](#)

Pipeline Products

The company currently has more than 10 varieties under research, mainly including DPT series combined vaccines, Hand-foot-mouth series vaccines, Pneumococcal series vaccines, MMR series live attenuated vaccine, Hepatitis B vaccine, Sabin strain inactivated polio vaccine, etc. These varieties will be successively listed over the next few years, serving China and even the global disease prevention and control.

CanSinoBio



Inovio

(DNA-based)

		INTERNALLY FUNDED				EXTERNALLY FUNDED
PRODUCT	INDICATION	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	PARTNER/COLLABORATOR/FUNDER
COVID-19						
INO-4800	COVID-19 (Heterologous Boost)					AdVaccine
	COVID-19 (Solidarity)					World Health Organization
INFECTIOUS DISEASES						
INO-4700	MERS					CEPI
INO-4500	Lassa Fever					CEPI
INO-4201	Ebola (Booster)					DARPA, UNIVERSITÉ DE GENÈVE, GuardRX
HPV-TARGETED						
VGX-3100	Cervical Dysplasia (HSIL)					Apollobio (China; INOVIO maintains global rights)
	Vulvar Dysplasia (HSIL)					
	Anal Dysplasia (HSIL)					
INO-3107	Recurrent Respiratory Papillomatosis (RRP)					
IMMUNO-ONCOLOGY						
INO-5401	Glioblastoma (GBM)					REGENERON
INO-5151	Prostate Cancer					CANCER RESEARCH INSTITUTE, FICCI, THE WISTAR INSTITUTE
dMAb™						
	COVID-19					AstraZeneca, DARPA, THE WISTAR INSTITUTE
INO-A002	Zika					BILL & MELINDA GATES foundation

Key product



R&D Pipeline

S.No	Vaccines	Product Development	Preclinical Testing	Phase I	Phase II	Phase III
1	Zika					
2	Chikungunya					
3	S. Paratyphi					
4	NTS Conjugates					
5	Human Papilloma Virus					
6	Acellular Pertussis					
7	Malaria PvRII					
8	Sabin IPV					
S. No.	Therapeutics	Product Development	Preclinical Testing	Phase I	Phase II	Phase III
1	THR-100					
2	lysostaphin Topical					
3	lysostaphin IV					

PIPELINE



VACCINES IN CLINICAL DEVELOPMENT

> MVA-BN freeze-dried / Smallpox / Phase 3 completed

.....

> MVA-BN RSV / Respiratory Syncytial Virus / Phase 3 ongoing

.....

> ABNCoV2 / SARS-CoV2 / Phase 3 ongoing

.....

> TAEK-VAC / Immuno-oncology / Phase 1/2 ongoing

.....

SK Bioscience

		Basic Research / Preclinical	Phase I Clinical Trial	Phase II Clinical Trial	Phase III Clinical Trial	Commercialization
Cell Culture Flu Trivalent (NDCK)						✓
Cell Culture Flu Quadrivalent (MDCK)						✓
Zoster Vaccine						✓
Varicella Vaccine						✓
COVID-19 Vaccine	CEPI <small>BILL & MELINDA GATES foundation</small>					✓ Achieved BLA / of SKYCoVone (KMFDS)
Combo Vaccine (COVID-19 + Flu)		✓				
Universal Coronavirus Vaccine (Sarbecovirus)	CEPI <small>INSTITUTE FOR Protein Design UNIVERSITY OF WASHINGTON</small>	✓				
Nasal Spray*	IAVI <small>BILL & MELINDA GATES foundation</small>	✓				
COVID-19 mRNA Vaccine		✓				
Next-Gen Pneumococcal Vaccine	sanofi			✓ U.S.		
RSV Vaccine		✓				
Cancer Immunotherapies, Obesity Vaccines, etc		✓				
Typhoid Conjugate Vaccine	<small>International Vaccine Institute</small> <small>BILL & MELINDA GATES foundation</small>					✓ Earned a biologics license for export
Cervical Cancer Vaccine (4-/10-valent)			✓ Phase I/II Clinical Trial			
Rotavirus Vaccine			✓			
iNTS ² Vaccine* (Non-Typhoidal Salmonella)		✓				
Hepatitis A, Recombinant Herpes Zoster Vaccines, etc.		✓				

The End

More to follow