Appendices

Rapid evidence synthesis appendices

Efficacy and effectiveness of respiratory syncytial virus vaccines and monoclonal antibodies against lower respiratory tract disease in older adults and infants

1 April 2026

[MHF product code: RS 127.2]

Appendix 1: Detailed search strategy

Databases searched:

- EMBASE + MEDLINE via OVID
- Preprint via Web of Science (Preprint Citation Index includes arXiv, bioRxiv, chemRxiv, medRxiv, and Preprints.org.)
- Clinical trials registry: https://clinicaltrials.gov/search?cond=Respiratory%20Syncytial%20Virus&intr=RSV%20Vaccine&firstPost=2024-08-19_

Search limits: No

Database retrieval:

Databases	06/01/2026
EMBASE + MEDLINE via OVID	3683
Preprint	8
Clinical trials	62
Cochrane central	25
Duplicates	717
TOTAL	4495

EBM & MEDLINE via OVID search:

#1	exp respiratory syncytial virus vaccine/
#2	("respiratory syncytial virus vaccin*" or "RSV vaccin*" or "respiratory syncytial virus immunization" or "RSV immunization").ab,ti.
#3	(AREXVY or "GSK RSV vaccin*" or "GlaxoSmithKline RSV vaccin*").mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx]
#4	RSVPreF3.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx]
#5	(ABRYSVO or "Pfizer RSV vaccin*" or "Pfizer respiratory syncytial virus vaccin*").mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx]
#6	RSVpreF.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx]
#7	("mRESVIA" or "mRNA-1345" or "Moderna RSV vaccin*").mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx]
#8	nirsevimab or clesrovimab .mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx]
#9	monoclonal antibod*.ab,ti.

#10	exp respiratory syncytial virus/
#11	9 and 10
#12	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 11
#13	(effectiveness or efficacy or protection).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx]
#14	12 and 13
#15	remove duplicates from 14

Preprint citation search:

#1	(TS=(AREXVY OR rsvpref OR ABRYSVO OR RSVpreF OR BEYFORTUS OR Clesrovimab OR nirsevimab OR mRESVIA)) AND TS=(effectiveness OR efficacy OR protection)

Appendix 2: Summary of studies reporting on the effectiveness of RSV immunization products

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

Ares-Gómez 2024 (1)	• Population studied
	  ○ Children (0 to 2 years old)
	• Type of immunization product
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Nirsevimab effectiveness
	• RSV-related outcome
	  ○ Lower respiratory tract disease (LRTD) (lower respiratory tract illness)
	  ○ Hospitalization
	  ○ Severe LRTD (requiring oxygen support)
	• Timeframe (specimens collected timepoints)
	  ○ Baseline (all infants born from 1 April to 15 December 2023)
	  ○ Follow-up (25 September to 31 December 2023)
		Type of publication: Peer reviewed
		
		Study design: Longitudinal prospective study
		
		Analysis: This study employed Poisson regression and Cox proportional hazards models to estimate nirsevimab effectiveness against RSV-related hospitalizations in infants, adjusting for factors like enrollment group, sex, and residential area
		
		Setting and country: Hospitals, Galicia, Spain
			• The study focused on infants in Galicia, Spain, including 10,259 eligible for nirsevimab (6,919 in the catch-up group born between 1 April and 24 September 2023, and 3,340 in the seasonal group born between 25 September 25 and 15 December 2023), with 91.7% receiving the immunization, and 851 (8.3%) did not receive nirsevimab
			• Administration of nirsevimab, a long-acting monoclonal antibody against RSV
				• These effectiveness estimates were based on data collected during the first three months of the nirsevimab immunization campaign in Galicia, Spain
				  ○ Nirsevimab effectiveness against RSV-related lower respiratory tract illness (LRTI) hospitalizations: 82.0% (95% CI 65.6–90.2)
				  ○ Nirsevimab effectiveness against severe RSV-related LRTI requiring oxygen support: 86.9% (95% CI 69.1–94.2)
				  ○ Nirsevimab effectiveness against all-cause LRTI hospitalizations: 69.2% (95% CI 55.9–78.0)

Estrella-Porter 2024 (2)	• Population studied
	  ○ Children (0 to 2 years old, born from 1 April 2023 onwards)
	• Type of immunization product
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Relative risk
	  ○ Odds ratio
	• RSV-related outcome
	  ○ Infection
	  ○ Hospitalization
	• Follow-up
		Type of publication: Peer reviewed
		
		Study design: Observational retrospective study
		
		Analysis: Vaccine effectiveness was calculated using multivariate logistic regression, controlling for factors such as breastfeeding intention, mother's country of origin, gestational weeks, and campaign group, to derive an adjusted odds ratio comparing RSV infection rates between immunized and non-immunized infants
			• The study included 27,362 children born from 1 April 2023 onwards in the Valencian Community, Spain, with 24,223 receiving the intervention and 3,139 serving as non-immunized comparators
			• The intervention consisted of administering nirsevimab, as pre-exposure prophylaxis against RSV to newborns, infants under 6 months, and high-risk children up to 24 months old, starting from 1 October 2023, in various healthcare settings
				• Relative risk of RSV infection: 0.30 (95% CI 0.23–0.39)
				• Adjusted odds ratio for RSV infection: 0.26 (95% CI 0.20–0.35) and nirsevimab effectiveness: 73.7%

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ From 1 October 2023 onwards	Setting and country: Valencian Community (healthcare centres and maternity services) in Spain		
Ezpeleta 2024 (3)	• Population studied ○ Children (0 to 2 years old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Nirsevimab effectiveness ○ Incidence rate • RSV-related outcome ○ Hospitalization ○ Emergency department (ED) visits ○ ICU admission ○ Lower respiratory tract infection • Timeframe (specimens collected timepoints) ○ Baseline ○ Follow-up (from birth until 28 January 2024, or until the first confirmed RSV specimen)	Type of publication: Peer reviewed Study design: Population-based study, prospective cohort design Analysis: This study used epidemiological surveillance, assessing nirsevimab effectiveness using Cox regression models adjusted for sex and week of birth, with nirsevimab immunization as a time-dependent variable, estimating effectiveness as (1 – hazard ratio) × 100 for various RSV-related outcomes Setting and country: Navarre, Spain	• The study included 1,177 infants born in Navarre, Spain from October to December 2023, followed up until 28 January 2024 • Nirsevimab was administered at birth to 92% of the infants, with most receiving it within seven days after birth	• Nirsevimab effectiveness against RSV-LRTI related hospitalization: 88.7% (95% CI 69.6–95.8) ○ By sex: ▪ Male: 91.5% (95% CI 66.8–97.8) ▪ Female: 81.5% (95% CI 15.0–96.0) ○ By birth month: ▪ October: 88.2% (95% CI 40.2–97.7) ▪ November: 91.6% (95% CI 62.0–98.2) ▪ December: 80.6% (95% CI –143.0–98.5) • Vaccine efficacy (VE) against RSV-related emergency room consultations: 89.0% (95% CI 73.7–95.4) • VE against RSV-related ICU admissions: 85.9% (95% CI 13.2–97.7)
Moline 2024 (4)	• Population studied ○ Children (0 to two years old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic-acid testing RT-PCR • Outcome measures ○ Nirsevimab effectiveness • RSV-related outcome ○ Infection ○ Hospitalization • Timeframe (specimens collected timepoints)	Type of publication: Peer reviewed Study design: Test-negative case-control design Analysis: The study estimated nirsevimab effectiveness against RSV-associated hospitalization using multivariable logistic regression, adjusting for age at enrollment in months, month of illness, enrollment site, and presence of one or more high-risk medical conditions for severe RSV disease	• The New Vaccine Surveillance Network, a platform to monitor acute respiratory illness, was used to monitor data from children younger than 18 • Children were invited to participate in this study if they were younger than 6 months as of 1 October 2023 (or born after that date), were hospitalized with acute respiratory illness during 1 October 2023 to 29 February 2024 • A total of 699 infants were included in the study; 407 cases (58%) and 292 controls (42%)	• Nirsevimab against RSV-associated hospitalization: 90% (95% CI 75–96)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Baseline (1 October 2023 to 29 February 2024) ○ Follow-up	Setting and country: Seven pediatric academic medical centres, United States	• 59 (8%) of participants had previously received nirsevimab	
López-Lacort 2024 (5)	• Population studied ○ Children (0 to 2 years old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ If none of above, extract the information from the study • Testing ○ Other (extract the information from the study) • Outcome measures ○ Nirsevimab effectiveness • RSV-related outcome ○ Lower respiratory tract infection • Timeframe (specimens collected timepoints) ○ Baseline ○ Follow-up	Type of publication: Peer reviewed Study design: Test-negative design Analysis: Bayesian logistic regression was used and supported by a sensitivity analysis to estimate vaccine effectiveness Setting and country: Five hospitals in Spain	• Infants eligible for nirsevimab immunization were eligible for the study • Surveillance lasted between 1 October 2023 to 10 January 2024 • Immunisation was considered from data of vaccine, ranging from 26 September 2023 to 14 December 2025 • Proportion of infants immunized in hospital cases was compared to immunized infants in the general area	• Nirsevimab effectiveness against RSV-associated LRTI hospital admission (screening method): ○ 69.3% (95% CI 36.4–86.2) in Valencia ○ 86.9% (95% CI 77.1–92.9) in Murcia ○ 97% (95% CI 87.7–99.6) in Valladolid • Nirsevimab effectiveness against RSV lower respiratory tract infection hospital admission (overall from all three regions): 84.4% (95% CI 76.8–90.0) • RSV-LRTI hospitalizations (test-negative design): 70.2% (95% CI 38.3–88.5) in Valencia and Murcia • Nirsevimab effectiveness against RSV-negative lower respiratory tract infection hospital admissions (screening method – sensitivity analysis): ○ 19.6% (95% CI –18.0–82.3) in Valencia ○ 27.5% (95% CI –27.5–63.4) in Murcia ○ 32.4% (95% CI –27.5–63.4) for overall (Valencia and Murcia)
Lassoued 2024 (6)	• Population studied ○ Children (0 to 12 months) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Antigen • Outcome measures	Type of publication: Peer reviewed Study design: Test-negative case-control study Analysis: This study uses multivariate logistic regression to estimate the effectiveness of nirsevimab against RSV-positive bronchiolitis in infants aged <12	• 883 (453 case patients, 430 controls) infants in France aged <12 months who received a diagnosis of bronchiolitis within the PARI network; 62 (13.7) case patients and 177 (41.2%) control patients were immunized with nirsevimab • Administration of nirsevimab, a long-acting monoclonal antibody against RSV	• The nirsevimab effectiveness against RSV-positive bronchiolitis in outpatients: 79.7% (95% CI 67.7–87.3) • The nirsevimab effectiveness against RSV-positive bronchiolitis in outpatients by age: ○ For <3 months old, 65.5% (95% CI –0.8–94.0)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Nirsevimab effectiveness • RSV-related outcome ○ Bronchiolitis due to RSV • Timeframe (specimens collected timepoints) ○ Baseline (15 September 2023 to 1 February 2024)	months, adjusting for factors including age, sex, birth term, birth weight, previous bronchiolitis, number of children per household, month of diagnosis, childcare settings, and region; subgroup analyses were performed for effectiveness of nirsevimab based on infant's age and gestational age at birth Setting and country: Paediatric and Ambulatory Research in Infectious diseases surveillance network (PARI) involving 107 ambulatory paediatricians, France		○ For 3–6 months old, 87.8% (95% CI 66.9–95.5) ○ For >6 months old, 82.0% (95% CI 62.2–91.5) • Nirsevimab effectiveness against RSV-positive bronchiolitis in outpatients for preterm infants (gestational age <37 weeks) was 56.6% (95% CI –1.2–92.5) • Nirsevimab effectiveness against RSV-positive bronchiolitis in outpatients for full term-born infants (gestational age ≥37 weeks) was 77.7% (95% CI 62.5–86.8)
Assad 2024 (7)	• Population studied ○ Children (0 to 12 months old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Nirsevimab effectiveness • RSV-related outcome ○ Hospitalization ○ RSV-associated bronchiolitis • Timeframe (specimens collected timepoints) ○ Baseline (15 October 2023 to 10 December 2023)	Study design: Prospective matched case-control study Analysis: This study uses a conditional logistic-regression model and a multivariate regression model to estimate the effectiveness of nirsevimab against hospitalization for RSV-positive bronchiolitis in infants aged <12 months, adjusting for sex, gestational age at birth, birth weight, and risk factors for severe bronchiolitis; vaccine effectiveness was additionally estimated by age group, paediatric intensive care unit admission, ventilatory support, and present of at least one risk factor for severe bronchiolitis Setting and country: Six tertiary hospitals around metropolitan France	• 1,035 patients younger than 12 months (690 cases, 345 controls) from tertiary hospitals in France; 60 (8.7%) case patients and 97 (28.1%) control patients were immunized with nirsevimab • Administration of nirsevimab, a long-acting monoclonal antibody against RSV	• Nirsevimab effectiveness against hospitalization for RSV-associated bronchiolitis: 83.0% (95% CI 73.4–89.2) • Nirsevimab effectiveness against hospitalization for RSV-associated bronchiolitis by age: ○ For <3 months old, 82.4% (95% CI 69.3–89.9) ○ For ≥3 months old, 82.7% (95% CI 52.8–93.7) • Nirsevimab effectiveness against RSV-positive bronchiolitis leading to PICU admission: 69.6% (95% CI 42.9–83.8) • Nirsevimab effectiveness against RSV-positive bronchiolitis leading to ventilatory support: 67.2% (95% CI 38.6–82.5) • Nirsevimab effectiveness for infants with ≥ one risk factor for severe bronchiolitis: 64.8% (95% CI –17.2–89.4)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

Agüera 2024 (8)	• Population studied
	  ○ Children (0 to 12 months old)
	• Type of immunization product
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Nirsevimab effectiveness
	• RSV-related outcome
	  ○ Hospitalization
	  ○ Bronchiolitis Score of Sant Joan de Déu (BROSJOD)
	  ○ Need for oxygen support
	  ○ Lengths of hospital stay (LOS)
	• Timeframe (specimens collected timepoints)
	  ○ November 2023 to February 2024
		Type of publication: Peer reviewed
		
		Study design: Test-negative case-control
		
		Analysis: Multivariate analysis using a logistic regression model adjusted for age, weight, and presence of one or more preexisting conditions was used to estimate the effectiveness of nirsevimab against hospitalization due to RSV-associated bronchiolitis and severe RSV disease, BROSJOD score at admission, need for oxygen support, and LOS; subgroup analyses were performed by age and presence of comorbidities
		
		Setting and country: Hospital Sant Juan de Déu Barcelona, Hospital Universitari General de Catalunya, and Hospital Nostra Senyora Meritxell, Spain and Andorra
			• 234 children up to 12 months old, 141 cases and 93 controls; 181 patients were eligible for nirsevimab
			• 109 (46.6%) patients had received nirsevimab, 72 (30.8%) were eligible but had not been immunized, and 53 (22.6%) were not eligible
			• Administration of nirsevimab, a long-acting monoclonal antibody against RSV
				• Nirsevimab effectiveness against hospitalization for RSV-associated LRTI: 81.0% (95% CI 60.9–90.7)
				• Nirsevimab effectiveness against hospitalization for RSV-LRTI among patients by age group:
				  ○ <3 months old: 78.2% (95% CI 42.8–91.7)
				  ○ 3–6 months old: 85.3% (95% CI 22.5–97.2)
				• Nirsevimab effectiveness against hospitalization for RSV-LRTI for patients without comorbidities: 82.4% (95% CI 59.5–92.4)
				• Nirsevimab effectiveness against hospitalization for RSV-LRTI for patients born at a gestational age < 36 weeks (preterm): 98.9% (95% CI 33–100)
				• Nirsevimab effectiveness against severe disease (defined as needing non-invasive ventilation or conventional mechanical ventilation): 85.6% (95% CI 41.7–96.4)

Coma 2024 (9)	• Population studied
	  ○ Children (0 to 6 months old)
	• Type of immunization product
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Antigen
	• Outcome measures
	  ○ Nirsevimab effectiveness
	• RSV-related outcome
	  ○ Infection
	  ○ Hospitalization
	  ○ ED visits due to bronchiolitis
	  ○ ICU admission
		Type of publication: Peer reviewed
		
		Study design: Retrospective cohort study
		
		Analysis: The Kaplan-Meier estimator and Cox regression models were used to evaluate nirsevimab in preventing primary care attended bronchiolitis, RSV infection, viral pneumonia diagnosed in primary care, ED visits due to bronchiolitis, RSV-related hospitalization, and RSV-related ICU admission in infants; the analysis was adjusted for age
			• 26,525 infants born between April and September 2023
			• 23,127 (87.2%) had received nirsevimab
			• Administration of nirsevimab, a long-acting monoclonal antibody against RSV
				• Nirsevimab effectiveness against specified outcomes:
				  ○ Against RSV infection: 68. 9% (95% CI 51.7–80)
				  ○ Against primary care attended bronchiolitis: 48.1% (95% CI 42.4–53.3)
				  ○ Against viral pneumonia: 60.7% (95% CI 24.2–79.7)
				  ○ Against hospital emergency visits due to bronchiolitis: 55.4% (95% CI 48.4–61.5)
				  ○ Against hospital admission due to RSV bronchiolitis: 87.6% (95% CI 82.1–91.4)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Primary care attended bronchiolitis ○ Viral pneumonia diagnosed in primary care • Timeframe (specimens collected timepoints) ○ 1 October 2023 to 31 January 2024	at beginning of study, sex, area of residence, nationality, rurality, and socio-economic status; a final Cox regression model stratified by months of birth was performed Setting and country: Catalonia, Spain		○ Against ICU admission due to RSV bronchiolitis: 90.1% (95% CI 76.3–95.9)
Paireau 2024 (10)	• Population studied ○ Children (0 to 9 months old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Multiplex PCR • Outcome measures ○ Nirsevimab effectiveness • RSV-related outcome ○ ICU admission for RSV bronchiolitis • Timeframe (specimens collected timepoints) ○ 15 September 2023 to 31 January 2024	Type of publication: Peer reviewed Study design: Test-negative case-control Analysis: A logistic regression model was used to estimate the VE on hospitalization to paediatric intensive care unit (PICU) for RSV-bronchiolitis in infants <5 months old (or <9 months old if they had comorbidities), adjusting for age group, sex, presence of comorbidities, prematurity, and time period Setting and country: 20 PICUs, metropolitan France	• 288 infants (238 cases and 50 controls), 58 (20%) had received nirsevimab prior to treatment in the PICU • Administration of nirsevimab, a long-acting monoclonal antibody against RSV	• Nirsevimab effectiveness against severe RSV-bronchiolitis cases requiring paediatric intensive care unit (PICU) admission: 75.9% (95% CI 48.5–88.7)
Barbas Del Buey 2024 (11)	• Population studied ○ Children (0 to 10 months old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Antigen ○ Nucleic acid testing-RT-PCR ○ RSV isolation test • Outcome measures ○ Nirsevimab effectiveness • RSV-related outcome	Type of publication: Peer reviewed Study design: Prospective cohort study Analysis: A multivariable Cox regression model was used to estimate the effectiveness of nirsevimab. The model was adjusted for the following variables: sex, age, gestational age at birth, type of gestation, presence of comorbidities, net income of household, cumulative incidence of RSV infection in children aged 0 to 5 years old in	• 37,067 (80.8% immunized) infants born between April and December 2023 were included in the population eligible for immunization • 33,859 were included in the analysis of nirsevimab effectiveness • Administration of nirsevimab, a long-acting monoclonal antibody against RSV	• Nirsevimab effectiveness against emergency care: ○ 66.7% (95% CI 61.0–71.6) in first month of follow-up ○ 58.1% (95% CI 53.5–62.3) in second month of follow-up ○ 47.3% (95% CI 41.2–52.9) in third month of follow-up ○ 33.8% (95% CI 21.8–43.9) in fourth month of follow-up ○ 16.7% (95% CI –5.9–34.5) in fifth month of follow-up • Nirsevimab effectiveness against hospitalization: ○ 93.6% (95% CI 89.7–96.1) in first month of follow-up

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Medically attended bronchitis/bronchiolitis ○ Hospitalization ○ ED visits ○ ICU admission • Timeframe (specimens collected timepoints) ○ Baseline (1 October 2023 to 29 February 2024)	the area of residence, and epidemiological week Setting and country: Primary care or hospital settings in Madrid region, Spain		○ 92.5% (95% CI 89.9–94.4) in second month of follow-up ○ 91.1% (95% CI 86.9–94.0) in third month of follow-up ○ 89.5% (95% CI 79.8–94.6) in fourth month of follow-up ○ 87.6% (95% CI 67.7–95.3) in fifth month of follow-up • Nirsevimab effectiveness against intensive care: ○ 94.4% (95% CI 87.3–97.5) in first month of follow-up ○ 93.3% (95% CI 85.6–96.9) in second month of follow-up ○ 92.1% (95% CI 64.0–98.3) in third month of follow-up ○ 90.7% (95% CI –3.6–99.2) in fourth month of follow-up ○ 89.0% (95% CI –207.3–99.6) in fifth month of follow-up • Nirsevimab effectiveness against medically attended bronchitis/bronchiolitis: ○ At 15 days old: ▪ 69.0% (95% CI 63.5–73.7) in first month of follow-up ▪ 60.9% (95% CI 55.0–65.9) in second month of follow-up ▪ 50.6% (95% CI 43.6–56.7) in third month of follow-up ▪ 37.5% (95% CI 27.6–46.1) in fourth month of follow-up ▪ 21.1% (95% CI 5.5–34.1) in fifth month of follow-up ○ At 1 month old: ▪ 68.2% (95% CI 62.6–73.0) in first month of follow-up ▪ 59.8% (95% CI 54.1–64.9) in second month of follow-up ▪ 49.3% (95% CI 42.4–55.3) in third month of follow-up

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
				▪ 35.9% (95% CI 26.1–44.4) in fourth month of follow-up ▪ 19.0% (95% CI 3.5–32.0) in fifth month of follow-up ○ At 3 months old: ▪ 59.8% (95% CI 54.3–64.6) in first month of follow-up ▪ 49.2% (95% CI 44.4–53.6) in second month of follow-up ▪ 35.8% (95% CI 30.4–40.8) in third month of follow-up ▪ 18.9% (95% CI 10.0–27.0) in fourth month of follow-up ▪ –2.4% (95% CI –18.7–11.6) in fifth month of follow-up ○ At 5 months old: ▪ 48.3% (95% CI 40.9–54.9) in first month of follow-up ▪ 34.7% (95% CI 27.6–41.2) in second month of follow-up ▪ 17.5% (95% CI 9.1–25.2) in third month of follow-up ▪ –4.2% (95% CI –17.4–7.5) in fourth month of follow-up • Nirsevimab effectiveness against hospitalization at 150 days of follow-up: ○ 86.1% (95% CI 50.3–96.1) for 50 mg ○ 85.2% (95% CI 38.8–96.4) for 100 mg
Xu 2025 (12)	• Population studied ○ Children (0 to 2 years old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures	Type of Publication: Peer-reviewed Study design: Multicentre, case-control, test-negative study Analysis: Vaccine effectiveness (VE) was estimated using a test-negative design. Odds ratios (ORs) for prior nirsevimab receipt among RSV-positive cases versus RSV-negative controls were calculated	• The analytic sample included 3,090 infants, of whom 680 (22.0%) tested positive for RSV and were classified as cases, while 2,410 (78.0%) tested negative and served as controls. The median age at testing was 6.7 months (interquartile range [IQR], 3.6–9.7 months), and 57.3% of infants were male. In terms of race and ethnicity, 43.0% were Hispanic, 17.2% were non-Hispanic	• Nirsevimab effectiveness against medically attended RSV infection: 68.4% (95% CI 50.3–80.8) ○ By time since immunization: ▪ At two weeks post–immunization: 79% (95% CI 63–91) ▪ At four weeks post-immunization: 76% (95% CI 60–87)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Nirsevimab effectiveness • RSV-related outcome ○ Medically attended RSV infection ○ Hospitalization ○ Outpatient visits ○ Severe RSV ○ All-cause LRTI ○ All-cause LRTI hospitalization ○ RSV-associated LRTI • Timeframe (specimens collected timepoints) ○ Baseline (1 October to 9 May 2024)	using multivariable logistic regression. VE was computed as: VE = (1 − OR) × 100% Models were adjusted for age, calendar month, and selected confounders identified through backward selection using the Akaike information criterion. Setting and country: United States	Black, and 26% were non-Hispanic White. Nearly one-quarter of infants (24.3%) had at least one risk factor for severe RSV disease, and 13.5% were born prematurely (<37 weeks' gestation). • Overall uptake of nirsevimab was 10.7% (330 of 3,090 infants), including 21 RSV-positive cases and 309 RSV-negative controls who had received immunization prior to testing. Among the 680 RSV-positive infants, 166 (24.4%) were hospitalized; of those hospitalized, 97 (58.4%) required more than 2 liters of respiratory support, and 23 (13.8%) required admission to the intensive care unit. • The intervention was receipt of nirsevimab prior to RSV testing.	▪ At six weeks post-immunization: 73% (95% CI 56–84) ▪ At eight weeks post-immunization: 70% (95% CI 51–82) ▪ At 10 weeks post-immunization: 66% (95% CI 44–80) ▪ At 12 weeks post-immunization: 61% (95% CI 34–77) ▪ At 14 weeks post-immunization: 55% (95% CI 16–75) ▪ At 16 weeks post-immunization: 48% (95% CI –9–72) ▪ At 16+ weeks post-immunization: 39% (95% CI –53–70) ○ By dose: ▪ 50 mg: 66% (95% CI 42.1–81.4) ▪ 100 mg: 72.7% (95% CI 40.6–89.6) ▪ Any dosage: 68.4% (95% CI 50.3–80.8) • Nirsevimab effectiveness against outpatient visits: 61.6% (95% CI 35.6–78.6) ○ By time since immunization: ▪ At two weeks post-immunization: 75% (95% CI 53–89) ▪ At four weeks post-immunization: 71% (95% CI 48–86) ▪ At six weeks post-immunization: 67% (95% CI 44–83)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
				▪ At eight weeks post-immunization: 64% (95% CI 38–80) ▪ At 10 weeks post-immunization: 60% (95% CI 31–78) ▪ At 12 weeks post-immunization: 55% (95% CI 20–76) ▪ At 14 weeks post-immunization: 49% (95% CI 3–73) ▪ At 16 weeks post-immunization: 42% (95% CI –23-70) ▪ At 16+ weeks post-immunization: 33% (95% CI –63-68) o By dose: ▪ 50 mg: 58.1% (95% CI 21.5–79.5) ▪ 100 mg: 67.1% (95% CI 22.9–88.8) ▪ Any dosage: 61.6% (95% CI 35.6–78.6) • Nirsevimab effectiveness against hospitalization: 80.5% (95% CI 52.0–93.5) o By time since immunization ▪ At two weeks post-immunization: 91% (95% CI 71–98) ▪ At four weeks post-immunization: 88% (95% CI 67–97) ▪ At six weeks post-immunization: 86% (95% CI 61–96) ▪ At eight weeks post-immunization: 83% (95% CI 53–95)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
				▪ At 10 weeks post-immunization: 79% (95% CI 42–94) ▪ At 12 weeks post-immunization: 74% (95% CI 24–92) ▪ At 14 weeks post-immunization: 67% (95% CI –6–90) ▪ At 16 weeks post-immunization: 59% (95% CI –56–89) ▪ At 16+ weeks post-immunization: 49% (95% CI –149-88) o By dose: ▪ 50 mg: 77.8% (95% CI 39.6–93.7) ▪ 100 mg: 87.9% (95% CI 34.3–99.4) ▪ Any dosage: 80.5% (95% CI 52–93.5) • Nirsevimab effectiveness against severe RSV: 84.6% (95% CI 58.7–95.6) o By time since immunization: ▪ At two weeks post-immunization: 95% (95% CI 79–100) ▪ At four weeks post-immunization: 93% (95% CI 75–99) ▪ At six weeks post-immunization: 91% (95% CI 70–98) ▪ At eight weeks post-immunization: 88% (95% CI 61–97) ▪ At 10 weeks post-immunization: 84% (95% CI 48–96)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
				▪ At 12 weeks post-immunization: 78% (95% CI 21–94) ▪ At 14 weeks post-immunization: 69% (95% CI –25–93) ▪ At 16 weeks post-immunization: 58% (95% CI –99–91) ▪ At 16+ weeks post-immunization: 43% (95% CI –247–89) o By dose: ▪ 50 mg: 84.7% (95% CI 52.9–96.5) ▪ 100 mg: 85.8% (95% CI 17.9–99.3) ▪ Any dosage: 84.6% (95% CI 58.7–95.6) • Nirsevimab effectiveness against all-cause LRTI: o Full season (Oct.–May): 18.8% (95% CI –9.3–40.3) o Peak months (Oct.–Jan.): 38% (95% CI 4.7–60.9) o Peak months (Oct.–Dec.): 47.2% (95% CI 7.5–71.7) o Peak months (Nov.–Dec.): 49.4% (95% CI 10.7–72.9) o Off-peak months (Feb.–May): –14.2% (95% CI –75.6–26.7) • Nirsevimab effectiveness against all-cause LRTI hospitalization: o Full season (Oct.–May): 47.1% (95% CI 7.6–70.2) o Peak months (Oct.–Jan.): 78.3% (95% CI 50.8–91.1) o Peak months (Nov.–Dec.): 79.1% (95% CI 27.6–94.9) o Peak months (Oct.–Dec.): 80.5% (95% CI 36.8–95.1)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
				○ Off-peak months (Feb.–May): –59.5% (95% CI –287–32.6) • Nirsevimab effectiveness against RSV-associated LRTI: ○ At two weeks post-immunization: 84% (95% CI 62–95) ○ At four weeks post-immunization: 81% (95% CI 58–93) ○ At six weeks post-immunization: 79% (95% CI 54–91) ○ At eight weeks post-immunization: 76% (95% CI 49–89) ○ At 10 weeks post-immunization: 72% (95% CI 42–88) ○ At 12 weeks post-immunization: 68% (95% CI 32–86) ○ At 14 weeks post-immunization: 63% (95% CI 17–84) ○ At 16 weeks post-immunization: 58% (95% CI –1–82) ○ At 16+ weeks post-immunization: 52% (95% CI –29–81) • Waning effectiveness over time (Bayesian estimates): ○ 79.3% (95% CrI 63.4–90.6) at 2 weeks post-immunization ○ 54.8% (95% CrI 16.3–74.7) at 14 weeks post-immunization • VE during peak RSV season against all-cause LRTI: 49.4% (95% CI 10.7–72.9) • VE during peak season against all-cause LRTI hospitalization: 79.1% (95% CI 27.6–94.9)
López-Lacort 2025 (13)	• Population studied ○ Children (0 to <10 months old) • Type of immunization product	Type of publication: Pre-print Study design: Test-negative design (TND)	• 160 infants; 141 infants (88%) received nirsevimab • 29 infants (21%) were administered in hospital and 112 (79%)	• The overall adjusted Nirsevimab effectiveness against medically attended RSV-LRTI (respiratory syncytial virus lower respiratory tract

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals ○ Individuals who tested negative for RSV • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Nirsevimab effectiveness • RSV-related outcome ○ Medically attended RSV-LRTI (respiratory syncytial virus lower respiratory tract infections) in the primary care setting • Timeframe (specimens collected timepoints) ○ Baseline (1 November 2023 to 29 February 2024)	Analysis: A Bayesian logistic regression model was used to analyze the effectiveness of nirsevimab in preventing RSV-LRTI in infants <20 months of age (both overall and for catch-up infants); effectiveness was calculated using (1 – Odds Ratio) x 100% and random effects was calculated to account for primary care center variability Setting and country: Large primary care network in Valencia and Murcia regions of Spain	administered to catch-up group (targeted effort outside of hospital administration) • 44 infants (27.5%) tested positive for RSV, with the other 116 serving as controls • Administration of nirsevimab, a monoclonal antibody against RSV	infections): 75.8% (95% CI 40.04–92.7), and 80.2% (95% CI 44.3–95.4) in the catch-up group
Carbajal 2024 (14)	• Population studied ○ Children (0 to 12 months old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Nirsevimab effectiveness • RSV-related outcome ○ Hospitalization for all-cause bronchiolitis ○ Hospitalization for RSV-bronchiolitis ○ Severe RSV- bronchiolitis ○ ICU admission ○ ED visits for all-cause bronchiolitis ○ ED visits for RSV-bronchiolitis • Timeframe (specimens collected timepoints) ○ Baseline (14 October 2023 to 29 February 2024)	Type of publication: Peer reviewed Study design: Case-control study Analysis: The effectiveness of nirsevimab in reducing ED visits was calculated using odds ratio ((1 – Odds Ratio) x 100%) adjusted for week of ED visit, sex, and age; sensitivity analyses were also conducted including logistic regression analysis with age as a continuous variable; a Bayesian logistic model was used to predict RSV status in infants who did not undergo PCR sampling Setting and country: Paediatric emergency department, Armand Trousseau University Hospital, Paris, France	• 2,786 infants (864 case infants diagnosed with bronchiolitis, 1,922 control infants without bronchiolitis) • 178 (21%) case infants had received nirsevimab, 686 (79%) had not received • Of 864 infants diagnosed with bronchiolitis, 277 (32%) were RSV PCR tested • Of the 67 infants tested for RSV who had received nirsevimab, 22 (33%) tested positive	• VE against ED visits for all-cause bronchiolitis: 47% (95% CI 33–58) ○ By age: ▪ ≤3 months: 52% (95% CI 29–68) ▪ 3–6 months: 59% (95% CI 36–74) ▪ 6–12 months: 27% (95% CI –9-51) • Nirsevimab effectiveness against ED visits for RSV-associated bronchiolitis: 83% (95% CI 71–90) ○ By age groups: ▪ ≤3 months: 79% (95% CI 63–88) ▪ 3 to ≤6 months: 88% (95% CI 69–95) ▪ 6 to 12 months: 83% (95% CI 35–95) • Nirsevimab effectiveness against hospitalization for all-cause bronchiolitis: 59% (95% CI 42–72) ○ By age groups:

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
				▪ ≤3 months: 58% (95% CI 33–73) ▪ 3 to ≤6 months: 66% (95% CI 33–83) ▪ 6 to 12 months: 50% (95% CI –17–79) • Nirsevimab effectiveness against RSV-associated bronchiolitis hospitalizations: 83% (95% CI 72–90) ○ By age groups: ○ ≤3 months: 78% (95% CI 62–88) ○ 3 to ≤6 months: 88% (95% CI 71–97) ○ 6 to 12 months: 89% (95% CI 72–97) • Nirsevimab effectiveness against severe RSV-associated bronchiolitis: ○ Requiring supplemental oxygen: 91% (95% CI 78–96) ○ Requiring nasogastric tube feeding: 88% (95% CI 74–95) • Nirsevimab effectiveness against ICU admission: 67% (95% CI –100–95)
Rodríguez-Fernández 2024 (15)	• Population studied ○ Children (0 to <6 months old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Antigen ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Nirsevimab effectiveness • RSV-related outcome ○ Hospitalization	Type of publication: Peer reviewed Study design: Case-control study Analysis: The effectiveness of nirsevimab in reducing hospitalization was calculated using (1 – Odds Ratio) x 100%; sensitivity analyses were also performed to compare seasons with lower RSV and other factors	• 138 infants <6 months old, 32 admitted for bronchiolitis (21 with RSV bronchiolitis) • Of the 21 admitted for RSV bronchiolitis, six (28%) had received nirsevimab • Of the 11 admitted for bronchiolitis due to another cause, eight (72%) received nirsevimab	• Nirsevimab effectiveness against RSV hospitalization: 85% (95% CI 32–97)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	• Timeframe (specimens collected timepoints) ○ 1 October 2023 to 31 December 2023	Setting and country: Gregorio Marañón Children's Hospital, Madrid, Spain		

Tartof 2024 (16)	• Population studied
	  ○ Older adults (aged ≥65 years)
	• Type of immunization product
	  ○ ABRYSVO™ (RSVpreF) by Pfizer
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Other (Roche Diagnostics Cobas eplex respiratory pathogen panel 2)
	• Outcome measures
	  ○ RSVpreF effectiveness
	• RSV-related outcome
	  ○ Medically attended LRTD
	  ○ ED visits
	  ○ Severe LRTD
	  ○ Death
	• Timeframe (specimens collected timepoints)
	  ○ Baseline (24 November 2023 to 9 April 2024)
		Type of publication: Peer reviewed
		
		Study design: Test-negative case-control study
		
		Analysis: Vaccine effectiveness was assessed using 1 – Odds Ratio x 100%; the 95% confidence interval was reported; a multivariate logistic regression was used to calculate odds ratios, and the model was adjusted for month of encounter, age, sex, self-reported race and ethnicity, modified Charlson score, and healthcare use the year before recruitment
		
		Setting and Country: Kaiser Permanente Southern California, United States
			• A total of 10,566 patients, 60 years or older, who had LRTD hospitalizations or ED encounters
			• 8,085 (76.5%) patients had a nasal swab, 5,649 (69.7%) were tested for RSV, and 7,047 (64.2%) patients were included in the final analysis
			• 8.8% (n = 623) of participants tested positive for RSV, 3.2% (n = 223) had received RSVpreF
			• 3.4% (n = 221) of RSV-negative participants were vaccinated with RSVpreF
			• The analysis with strictly defined controls included 623 cases and 804 controls
				• RSVpreF vaccine effectiveness against RSV-related LRTD (hospitalizations and ED visits)
				  ○ With strictly defined controls: 91% (95% CI 59–98)
				  ○ With any controls: 90% (95% CI 59–97)
				• RSVpreF vaccine effectiveness against severe RSV-related LRTD hospitalizations and ED events (requiring oxygen supplementation): 89% (95% CI 13–99)
				• RSVpreF vaccine effectiveness against RSV-related LRTD hospitalizations: 87% (95% CI –8–98)
				• RSVpreF vaccine effectiveness against RSV-related LRTD hospitalizations in high-risk patients: 87% (95% CI –6–98)
				• RSVpreF vaccine effectiveness against RSV-related LRTD ED visits: 93% (95% CI 45–99)

Rius-Peris 2025 (17)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	• RSV related outcome
	  ○ Hospitalization
	• Timeframe (Specimens collected timepoints)
		Type of publication: Peer reviewed
		
		Study design: Test-negative case-control study
		
		Analysis: Effectiveness of nirsevimab was calculated as (1 – OR) x 100%. The odds ratio was determined using a multivariable logistic regression model adjusted for sex, age, presence of a comorbidity, epidemiological week of admission, and region where the hospital was located.
			• 2,656 patients up to 12 months old were included in the study
			• 426 patients in the 2023-2024 season were eligible for nirsevimab; 329 (77.23%) were immunized
			• Of patients eligible for nirsevimab in the 2023-2024 season, 52 unimmunized patients and 91 immunized patients tested positive for RSV
				• VE of nirsevimab against RSV-bronchiolitis hospitalization: 70.53% (95% CI: 49.58-82.77)
				  ○ Ague 4-6 months: 81.58% (95% CI: 50.00-93.21)
				  ○ Without comorbidities: 69.38% (95% CI: 45.50-82.80)
				  ○ Infected with RSV only: 72.58% (95% CI: 51.60-84.47)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Baseline (1 September 2021 to 15 June 2024)	Setting and country: 20 hospitals in Castilla-La Mancha and Comunidad Valenciana, Spain		
Moline 2024 (18)	• Population studied ○ Children (0 to two years old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing RT-PCR • Outcome measures ○ Nirsevimab effectiveness • RSV-related outcome ○ Medically attended acute respiratory infection ○ Hospitalization • Timeframe (specimens collected timepoints) ○ Baseline (1 October 2023 to 31 April 2024)	Type of publication: Peer reviewed Study design: Test-negative case-control design study Analysis: Multivariable logistic regression models were utilized and adjusted for site, age in months, month of enrollment, and presence of one or more high-risk medical conditions for severe RSV disease; nirsevimab effectiveness was calculated using (1 – adjusted odds ratio) x 100% Setting and country: Seven unnamed academic medical centres in the New Vaccine Surveillance Network, United States	• 1,616 infants younger than 8 months on 1 October 2023 or born after were included in the analysis of nirsevimab effectiveness; 765 were cases and 851 were controls • 1% (n = 10) of case patients and 15% (n = 126) of control patients had received nirsevimab	• Nirsevimab effectiveness: ○ RSV-associated hospitalization: 93% (95% CI 82–97) ○ RSV medically attended RSV-associated acute respiratory illness (ARI): 89% (95% CI 79–94)
Pérez Marc 2025 (19)	• Population studied ○ Children (0 to two years old) • Type of immunization product ○ Maternal ABRYSVO™ (RSVpreF) by Pfizer • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR ○ Other (indirect immunofluorescence) • Outcome measures ○ RSVpreF effectiveness • RSV-related outcome ○ Hospitalization ○ Severe LRTI • Timeframe (specimens collected timepoints)	Type of publication: Peer reviewed Study design: Multicentre, retrospective, test-negative, case-control study Analysis: Vaccine effectiveness was calculated as (1 - adjusted OR) x 100. Odds ratio was estimated using multilevel logistic regression with site-specific random effect, adjusting for conception date, calendar date of hospitalization, and infant age at hospitalization. Setting and country: 12 hospitals across Argentina	• Of 663 infants aged 0 to 6 months hospitalized for LRTD, 585 met eligibility criteria • 505 infants were included in the main vaccine effectiveness analyses; 286 (57%) case infants (RSV positive) and 219 (43%) control infants (RSV negative) • Of infants included in the vaccine effectiveness analyses 160 (32%) were born to RSVpreF-vaccinated pregnant women (51 (18%) case patients and 109 (50%) controls)	• RSVpreF effectiveness against RSV-associated LRTD hospitalization: ○ From birth to age three months: 78.6% (95% CI 62.1-87.9) ○ From birth to age six months: 71.3% (95% CI 53.3-82.3) • RSVpreF effectiveness against RSV-associated severe LRTD hospitalization: ○ From birth to age three months: 70.9% (95% CI 21.7-89.2) ○ From birth to age six months: 76.9% (95% CI 45.0-90.3)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Baseline (1 April to 30 September 2024)			
Lefferts 2024 (20)	• Population studied ○ Children (0 to 2 years old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Nirsevimab effectiveness • RSV-related outcome ○ Hospitalization ○ Acute respiratory infection ○ Acute respiratory disease ○ Outpatient visits • Timeframe (specimens collected timepoints) ○ Baseline (31 October 2023 to 30 June 2024)	Type of publication: Peer reviewed Study design: Test-negative case-control Analysis: Odds ratios of medically attended acute respiratory illness (ARI) associated with RSV was evaluated using multivariable logistic regression adjusted for age, sex, calendar month, residence community type, and presence of underlying conditions; effectiveness of nirsevimab was estimated as (1 – adjusted odds ratio) x 100% Setting and country: Yukon-Kuskokwim Delta region, Alaska, United States	• 472 children aged <20 months on 1 October 2023 or born after that date were included; 68 (14%) patients tested positive for RSV and 404 (86%) tested negative • 48% of included patients had received nirsevimab; 15% (n = 10) of patients testing positive for RSV had received nirsevimab compared to 54% (n = 217) of patients testing negative	• Nirsevimab effectiveness against medically attended ARI: 82% (95% CI 62–91) ○ Among children in their first RSV season: 76% (95% CI 42–90) ○ Among children in their second RSV season: 88% (95% CI 48–97) ○ Seven to 89 days after nirsevimab receipt: 90% (95% CI 68–97) ○ 90 to 179 days after nirsevimab receipt: 77% (95% CI 31–92) • Nirsevimab effectiveness against RSV-associated hospitalization: 93% (95% CI 64–99) ○ Among children in their first RSV season: 89% (95% CI 32–98)
Payne 2024 (21)	• Population studied ○ Older adults (aged ≥60 years) • Type of immunization effectiveness ○ AREXVY™ (RSVPreF3) by GlaxoSmithKline ○ ABRYSVO™ (RSVpreF) by Pfizer • Comparator ○ Unvaccinated individuals • Testing ○ Antigen ○ Nucleic acid testing-RT-PCR • Outcome measures ○ RSVPreF3 effectiveness • RSV-related outcome ○ Hospitalization ○ ED visits ○ ICU admission ○ Death • Timeframe (specimens collected timepoints)	Type of publication: Peer reviewed Study design: Test-negative design analysis study Analysis: VE against hospitalizations and emergency department encounters was calculated as (1 – adjusted odds ratio (OR)) x 100%; odds ratios were calculated with multivariable logistic regression models adjusted for age, race and ethnicity, sex, calendar day, Social Vulnerability Index quartile, non-respiratory underlying conditions, respiratory underlying conditions, and Health and Human services geographical region	• 36,706 hospitalizations of patients ≥60 years old with RSV-like illness and RSV testing during the study period were identified, with 34,780 (95%) being linked to RSV-negative tests and 1,926 (5%) being linked to RSV-positive tests • 3,275 (9%) had received an RSV vaccine, 3,230 (9%) of virus negative patients were vaccinated, and 45 (2%) of virus-positive patients were vaccinated • 37,842 emergency department patients ≥60 years old with RSV-like illness and RSV testing during the study period were identified, with 35,082 (93%) being linked to RSV negative tests and 2,760 (7%) being linked to RSV positive tests	• RSVPreF3 effectiveness against hospitalization for immunocompetent ≥60 years old: 80% (95% CI 71–85) • RSVPreF3 effectiveness against hospitalization for immunocompetent 60–74 years old: 81% (95% CI 66–90) • RSVPreF3 effectiveness against hospitalization for immunocompetent ≥75 years old: 79% (95% CI 68–86) • RSVPreF3 effectiveness for ≥60 year olds with critical illness (ICU admission or death): 81% (95% CI 52-92) • RSVPreF3 effectiveness against hospitalization for immunocompromised ≥60 year olds: 73% (95% CI 48–85)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Baseline (1 October 2023 to 31 March 2024)	Setting and country: VISION EHR network from Kaiser Permanente Northwest (Oregon and Washington), University of Colorado (Colorado), Intermountain Health (Utah), Regenstrief Institute (Indiana), HealthPartners (Minnesota and Wisconsin), and Kaiser Permanente Northern California (California) containing 230 hospitals and 245 emergency departments, United States	• 3,166 (8%) had received an RSV vaccine; 3,105 (9%) of virus-negative patients were vaccinated and 61 (2%) of virus-positive patients were vaccinated	• RSVPreF3 effectiveness against ED encounters for ≥60 year olds: 77% (95% CI 70–83) • RSVPreF3 effectiveness against ED encounters for 60–74 years: 75% (95% CI 62–84) • RSVPreF3 effectiveness against ED encounters for ≥75 year olds: 78% (95% CI 69–85) • By Time Since Vaccination: ○ Hospitalization: ▪ 14–59 days post-vaccination: 90% (95% CI 79–95) ▪ ≥60 days post-vaccination: 73% (95% CI 60–82) ○ Emergency Department Encounters: ▪ 14–59 days post-vaccination: 85% (95% CI 77–91) ▪ ≥60 days post-vaccination: 70% (95% CI 58–78)
Surie 2024 (22)	• Population studied ○ Older adults (aged ≥60 years) • Type of immunization product ○ AREXVY™ (RSVPreF3) ○ ABRYSVO™ (RSVpreF) • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ RSVPreF3 effectiveness ○ RSVpreF effectiveness • RSV-related outcome ○ Hospitalization • Timeframe (specimens collected timepoints) ○ Baseline (1 October 2023 to 31 March 2024)	Type of publication: Peer reviewed Study design: Test-negative, case-control study Analysis: Vaccine efficacy against hospitalization was estimated using the equation (1 – adjusted odds ratio) x 100%; multivariable logistic regression was used to determine the odds ratio; the model was adjusted for age, sex, race and ethnicity, region, and calendar month Setting and country: 24 hospitals in 19 states, United States	• 2,978 adults aged 60 years and older, 367 (12.3%) were RSV case patients and 2,611 (87.7%) were control patients • Median age was 72 years • Median Charlson Comorbidity Index score was 5 and 720 were immunocompromised • Nine (2.5%) of the 367 case patients and 256 (9.8%) of 2,611 control patients were vaccinated with a median interval between vaccination and illness onset of 84 days	• VE against RSV-associated hospitalization: 75% (95% CI 50–87) • VE against RSV-associated hospitalization with inverse probability of vaccination weighting: 79% (95% CI 56–90) • VE against RSV-associated hospitalization by age: ○ 60 to 74 years: 75% (95% CI 31–91) ○ 75 years and older: 76% (95% CI 40–91)
New studies included in 2026 January update				

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

Lassen 2026 (23)	• Population studied
	  ○ Older adults (aged ≥60 years)
	• Type of vaccine
	  ○ ABRYSVO™ (RSVpreF) by Pfizer
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Antigen
	• Outcome measures
	  ○ Vaccine effectiveness
	  ○ Incidence rate
	• RSV related outcome (more severe outcomes)
	  ○ Hospitalization
		Type of publication: Peer-reviewed
		Study design: Pragmatic, open-label parallel-group, randomized controlled, phase 4 trial
		
		Analysis: Vaccine effectiveness was calculated using incidence rate ratio to compare groups. 95% confidence intervals were constructed using the Clopper-Pearson model
		
		Setting and country:
		National population-based study with data linkages between the Danish Health Data Authority and national administrative health registries in Denmark
			• A total of 1,399,220 potentially eligible adults were invited to enroll in the trial, and 131,379 people who were 60 years or older underwent randomization
			• The mean age was 69 years and equal representation among men and women
			• This study included 131,276 intention-to-treat population, with 65,688 in the RSVpreF group and 65,691 in the control group
			• The median time from randomization to the initially scheduled trial visit was 13 days (interquartile range, 6 to 21)
			• Participants received the vaccine on, after, or before the initial scheduled visit date
				• VE against hospitalization for RSV-related respiratory tract disease 83.3% (95% CI 42.9–96.9)

Zambrano 2025 (24)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Test-negative
	• Testing
	  ○ Antigen
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Odds ratio
	• RSV related outcome (more severe outcomes)
	  ○ ICU admission
	• Timeframe (Specimens collected timepoints)
	  ○ Baseline
		Type of publication: Peer-reviewed
		Study design: Test-negative case-control
		
		Analysis: Unconditional multivariable logistic regression used to estimate odds ratios for the ICU admission
		
		Setting and country:
		United States
			• A total of 917 infants admitted to an ICU were enrolled, including 548 (60%) case-patients and 369 (40%) control patients. After the exclusion of 91 (17%) case-patients and 67 (18%) control patients, 457 case-patients and 302 control patients remained	• VE against RSV-associated ICU admission: 80% (95% CI 70–86%)
				• VE against RSV-associated ICU admission at 7-59 days after dose: 86% (95% CI 74–90%)
				• VE against RSV-associated ICE admission at 60-183 days after dose: 66% (95% CI 47–79%)

Vera-Punzano, 2025 (25)	• Population studied ○ Newborns • Type of immunization product	Type of publication: peer-reviewed Study design: prospective cohort study	• This study included 2,699 newborns, mostly male (53,1%)	• VE effectiveness against RSV-related acute respiratory infections hospital admissions in newborns

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Vaccine effectiveness • RSV related outcome ○ Hospitalization ○ Pediatric intensive care unit (PICU) admission • Timeframe (Specimens collected timepoints) ○ First season: October 1st 2023 to February 18 2024 • Second season: September 1st 2024 to January 26 2025	Analysis: Vaccine effectiveness was estimated using a Cox regression model, adjusted for sex and birth week. Hazard ratios (HR) and 95% confidence intervals were estimated. Effectiveness was estimated as (1 – HR) x 100. Setting and country: This population-based prospective cohort study included all children born between 2023 and 2024, and between 2024 and 2025. This study was conducted in Navarra, Spain.	• 1,183 newborns were included from the first season (2023-2024), and 1,516 from the second season (2024-2025). • 2,541(94,1%) were vaccinated (1,089 in the first season, and 1,452 in the second season). • 41 newborns were hospitalized (17 in the first season, and 24 in the second season). • 20 newborns were admitted to PICU	• General VE against RSV-related hospital admissions of 79.5% (95% CI 59.2–89.7) • First season VE against RSV-related hospital admissions of 89.9% (95% CI 73.5–96.1) • Second season VE against RSV-related hospital admissions of 52.8% (95% CI - 61.3–86.2) • General VE against RSV-related hospital admissions in females of 65.4% (95% CI - 7.0–88.8) • General VE against RSV-related hospital admissions in males of 86.2% (95% CI 65.4–94.5) • VE effectiveness against RSV-related acute respiratory infections PICU admissions in newborns • General VE against RSV-related PICU admissions of 70.3% (95% CI 9.4–90.2)
Tartof 2025 (26)	• Population studied ○ Older adults (aged ≥60 years) • Type of immunization product ○ ABRYSVO™ (RSVpreF) by Pfizer • Comparator ○ Other • Testing ○ Other • Outcome measures ○ Vaccine effectiveness ○ Odds ratio • RSV related outcome ○ Hospitalization • Timeframe (Specimens collected timepoints) ○ Baseline (24 November 2023 to 9 April 2024)	Type of publication: Peer-reviewed Study design: Test-negative case control Analysis: Vaccine effectiveness (VE) was estimated using adjusted odds ratio and multivariate logistic regression Setting and country: Hospitals Southern, California	• This study focused on older adults in Southern California including 15 452 patients aged 60 years or older, with hospitalization visits at the study sites and who received a nasal swab between (24 November 2023 to 9 April 2024) • Receival of ABRYSVO™ (RSVpreF)	• VE against hospitalizations • VE against hospitalization: 91% (95% CI 30–99) • VE against hospitalizations in persons older than 75: 95% (95% CI 60–99) • VE against hospitalizations in persons older than 80: 95% (95% CI 62–99) • VE against hospitalizations in persons with chronic medical conditions: 92% (95% CI 65–98)
Hsiao 2025 (27)	• Population studied ○ Children (0 to two years old) • Type of immunization product	Type of publication: Peer-reviewed Study design: Retrospective cohort study	• This study focused on 31 900 infants in Northern California, 49% had received the Nirsevimab vaccine	• VE against hospitalizations ○ VE against RSV LRTD: 87.2% (95% CI 81.7–91.1)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Vaccine effectiveness ○ Odds ratio • RSV related outcome ○ Lower respiratory tract disease (LRTD) ○ Hospitalization • Timeframe (Specimens collected timepoints) ○ October 1, 2023, to April 30, 2024	Analysis: Vaccine effectiveness (VE) was estimated using adjusted cox regression analysis and adjusted hazard ratios Setting and country: Hospitals Northern, California	• Mothers of all infants received prenatal care at the Northern California clinic • All infants were born at 37 or over weeks without any high-risk diagnoses • Nirsevimab vaccine was offered to all infants born at the clinic after October 19th, 2023 or who had visited for discharge or an out-patient visit	○ VE against hospitalization RSV LRTD: 98% (95% CI 85.1–99.7) ○ VE against PCR-confirmed RSV: 71% (95% CI 65.3–75.8)
Bermúdez-Barrezueta 2025 (28)	• Population studied ○ Children and adolescents aged two to 17 years • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Vaccine effectiveness • RSV related outcome ○ Lower respiratory tract disease (LRTD) ○ Hospitalization ○ ICU admission • Timeframe (Specimens collected timepoints) ○ October 2023 and March 2024	Type of publication: Peer-reviewed Study design: Observational study Analysis: Vaccine effectiveness (VE_ was analyzed using a Kruskal-Wallis test Setting and country: Tertiary hospitals, primary care centres, Spain	• This study focused on 311 children under five years of age receiving care at a tertiary hospital in Spain. • From 1 October 2023 to 31 March 2024, Nirsevimab was administered to all newborns (age 35 weeks) • Infants under six months born 1 April and 30 September 2023 or high-risk children under two years of age were vaccinated at primary care centre	• VE against hospitalizations • VE against hospitalization: 26.1% (95% CI 15–37.2) • VE against LRTI related hospitalization: 83.3% (95% CI 70.0–95.8) ○ VE against PICU admission: 54.2% (95% CI 58.4-88) • VE against PICU admission in infants under six months: 73.3% (95% CI 44.9–92.2)
Campos Mena 2025 (29)	• Population studied ○ Children (0 to two years old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator	Type of publication: Peer-reviewed Study design: Test-negative case–control study design	• This study focused on children born between 1 April 2024 and 31 March 2025 and hospitalized with severe respiratory infection between 16 September and 1 October 2024 • Children received an RT-PCR RSV-tested within 10 days of symptom	• VE against severe RSV associated hospitalization ○ VE overall against RSV associated hospitalization: 65.5% (95% CI 45.2–78.3) ○ VE against RSV associated hospitalization in the “catch up

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Vaccine effectiveness ○ Oddsratio • RSV related outcome ○ Hospitalization • Timeframe (Specimens collected timepoints) ○ September 16 and October 1 2024	Analysis: Vaccine effectiveness was analyzed using odds ratio and logistic regression Setting and country: Spain	onset and hospitalization to identify cases and controls	group": 63.6% (95% CI 26.9–81.9) ○ VE against RSV associated hospitalization in the "at birth group": 70.4% (95% CI 43.4–84.5)
Scruzzi 2025 (30)	• Population studied ○ Children (0 to two years old) • Type of immunization product ○ RSVpreF (Abrysvo®) • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Vaccine effectiveness ○ Odds ratio • RSV related outcome ○ Infection • Timeframe (Specimens collected timepoints) ○ March 31 and October 31, 2024	Type of publication: Peer-reviewed Study design: Retrospective case-control study Analysis: Vaccine effectiveness was assessed using logistic regression and odds ratios Setting and country: Argentina	• This study included 1249 children (180 cases and 1069 controls) born between March 31 and October 31, 2024 • RSV status was assessed using people with a positive laboratory test for RSV • Maternal vaccination against RSV during pregnancy (at least 14 days before birth) was assessed using the Civil Registry	• VE against severe RSV associated hospitalization • VE overall against RSV associated onset: (95% CI 0.11–0.23) • VE overall against likelihood of becoming ill: 74.0% (95% CI 0.17–0.39)
Razzini 2025 (31)	• Population studied ○ Children (0 to two years old) • Type of immunization product ○ RSVpreF • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Vaccine effectiveness • RSV related outcome ○ Hospitalization ○ Lower respiratory tract infection • Timeframe (Specimens collected timepoints) ○ March 1 and November 9, 2024	Type of publication: Peer-reviewed Study design: Multicentre, retrospective surveillance cohort study Analysis: Comparisons between groups were conducted a Pearson's $\chi 2$ test The impact of RSVpreF MI on hospitalizations was assessed using a Poisson regression mode Setting and country: Argentina	• This study included 8407 infants aged ≤18 months enrolled after being hospitalized with ALRTI • Infants younger than 6 months old who were born between March 1st and November 9th 2024 were eligible for this study and may have been a part of the national vaccination campaign. RSV infections were confirmed using a laboratory testing	• VE against RSV factors • VE against RSV associated PICU admissions: 87.2% (95% CI 52.6–97.0) • VE against RSV associated prolonged hospital admission stays (>11 days): 88·6% (95% CI 62.3–97.1)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

Consolati 2024 (32)	• Population studied
	  ○ Children (0 to two years old)
	• Type of immunization product
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Other
	• Outcome measures
	  ○ Vaccine effectiveness
	• RSV related outcome
	  ○ Hospitalization
	• Timeframe (Specimens collected timepoints)
	  ○ 1 May 2023 to 15 February 2024
		Type of publication:
		Peer-reviewed
		
		Study design:
		Prospective observational cohort study
		
		Analysis:
		Differences between groups was completed using chi-square test
		
		Setting and country:
		Italy
			• This study included 556 infants born between 1 May 2023 and 15 February 2024
			• A vaccine administration campaign was ran across hospitals to encourage infant vaccination
				• VE against RSV bronchiolitis factors: 98.4% (95% CI 73.8–99.9)
				  ○ Associate risk ratio reported as 0.016 (95% CI 0.001–0.262)
				  ○ Risk difference reported as −8.33 percentage points (i.e., absolute reduction from 8.33% to 0%)
				  ○ None of the vaccinated children received treatment (0 of 369), p <0.001
				  ○ Hospitalization risk decreased from, 7 to 3.2% p <0.001.

Symes 2025 (33)	• Population studied
	  ○ Older adults (aged ≥65 years)
	• Type of immunization product
	  ○ ABRYSVO™ (RSVpreF) by Pfizer
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	  ○ Odds ratio
	• RSV related outcome
	  ○ Lower respiratory tract disease
	  ○ Hospitalization
	• Timeframe (Specimens collected timepoints)
	  ○ Oct 1, 2024, and March 31, 2022
		Type of publication: Peer-reviewed
		Study design:
		Multicentre, test-negative, case–control study
		
		Analysis:
		VE was calculated by subtracting VE-odds ratio, with a 95% CI
		Setting and country:
		England
			• This study included 1006 older adults aged 75 to 79 who were admitted to hospital with acute respiratory infection
			• Within 48 hours of being admitted to the hospital, older adults received molecular diagnostic assays to confirm diagnosis
			• Vaccination status was obtained from the National Immunisation Information System
				• VE against hospitalization for RSV acute infection: 82.3% (95% CI 70.6–90.0)
				• VE against severe RSV associated disease: 86.7% (95% CI 75.4–93.6)
				• VE against hospitalization for RSV LRTI: 88.6% (95% CI 75.6–95.6)
				• VE against exacerbation of chronic lung disease: 77.4% (95% CI 42.4–92.8)
				• VE against exacerbation of any chronic illness including chronic lung disease: 78.8% (95% CI 47.8–93.0)
				• VE was explored in different populations
				  ○ VE in persons who were immunocompetent: 86.2% (95% CI 73.6–93.6)
				  ○ VE in persons with immunosuppression: 72.8% (95% CI 39.5–89.3)
				  ○ VE in persons with chronic heart and vascular disease: 77.0% (95% CI 59.1–88.0)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
				○ VE in persons with chronic respiratory disease: 80.1% (95% CI 62.4–90.6)
Godonou 2025 (34)	• Population studied ○ Children (0 to two years old) • Type of immunization product ○ ABRYSVO™ (RSVpreF) by Pfizer ○ AREXVY™ (RSVPreF3) by GlaxoSmithKline • Comparator ○ Unvaccinated individuals • Testing ○ Other • Outcome measures ○ Vaccine effectiveness ○ Incidence rate • RSV related outcome ○ Lower respiratory tract infection • Timeframe (Specimens collected timepoints) ○ Baseline (April 1, 2024, and Sept 30, 2024)	Type of publication: Peer-reviewed Study design: Cohort study Analysis: Vaccine effectiveness was estimated using a cox regression model Setting and country: United States	• This study included 281 participants (n=117 vaccinated) aged 60 or older • RSV-specific binding antibodies were measured using serum species • RSV infection was confirmed using PCR testing	• Unadjusted IR of RSV infections per 1000 person years: 121.3 (95% CI 69.5–198.1) • RSV cases not meeting symptomatic case per 1000 person-years: 34.7 (95% CI 11.6–82.4) • RSV cases meeting symptomatic case per 1000 person-years: 86.7 (95% CI 44.5–153.7) • RSV infections per 1000 person-years among vaccinated participants: 61.2 (95% CI 16.9–163.2) • RSV infections per 1000 person-years among non-vaccinated participants:165.8 (95% CI 88.0–287.0) • IR of symptomatic RSV among unvaccinated participants per 1000 person-years compared: 120.6 (95% CI 56.9–227.6) • IR of symptomatic RSV among vaccinated participants per 1000 person-years compared: 40.8 (95% CI 8.1–130.7) • Adjusted RSV VE against any RSV infection HR: 0.492 (95% CI: 0.135–1.791) and VE: 50.8% (95% CI −79.1%–86.5%)
Torres 2025 (35)	• Population studied ○ Children (0 to two years old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing	Type of publication: Peer-reviewed Study design: Retrospective cohort Analysis: Vaccine effectiveness was estimated using cox proportional hazards models and calculating the hazard ratio Setting and country:	• Data from 154173 infants was collected; 145087 infants received the vaccine and 9086 were not • Data was obtained from three government registries	• VE against RSV-related LRTI: 76.41% (95% CI 72.57–79.72) • Hazard ratio against RSV-related hospitalization: 1.31 (95% CI 1.43–1.61) • VE against RSV-related ICU admissions: 84.94% (95% CI 79.47–88.95)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Other • Outcome measures ○ Vaccine effectiveness • RSV related outcome ○ Lower respiratory tract infection ○ Hospitalization • Timeframe (Specimens collected timepoints) ○ Follow up (April 1, 2024, and Sept 30, 2024)	Chile		• VE against all-cause LRTI hospitalisations: 66.50% (95% CI 61.97–70.50) • VE against all-cause hospitalisations: 47.90% (44.35–51.21)
Fortunato 2025 (36)	• Population studied ○ Children (0 to two years old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Vaccine effectiveness ○ Odds ratio ○ Relative risk • RSV related outcome ○ Lower respiratory tract infection ○ Hospitalization • Timeframe (Specimens collected timepoints) ○ January 1, 2024 and March 31, 2025	Type of publication: Peer-reviewed Study design: Test-negative case-control design Analysis: VE was calculated using (PPI − PCI)/(PPI × (1 − PCI)). Odds ratio was calculated using (1 − odds ratio) × 100%. Relative risk was calculated (1 − relative risk) × 100%. Kruskal wallis was used to compare across groups Setting and country: Southern Italy	• This study included 4280 infants born in Southern Italy, 54.7% of those who received the Nirsevimab immunoprophylaxis vaccine • Infants who were admitted to the hospital with LRTI were confirmed to have RSV with a laboratory test. Date of vaccination was recorded using hospital documentation.	• Overall VE in preventing RSV-related LRTI hospitalisations: 84.4% (95% CI: 71.7–91.4) • Hospitalization risk in immunized group: 0.49% (13/2635) • Hospitalization risk in non-immunized group: 3.16% (69/2185)
Bajema 2026 (37)	• Population studied ○ Older adults (aged ≥65 years) • Type of immunization product ○ AREXVY™ (RSVPreF3) by GlaxoSmithKline • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Vaccine effectiveness ○ Incidence rate • RSV related outcome	Type of publication: Peer-reviewed Study design: Observational study Analysis: Incidence rates were calculated as the number of events per 1000 person-years, and 95% Cis VE was estimated as 100 × (1 – risk ratio)	• This study included 301 3000 Veterans 60 years or older who received the RSV vaccination and 288 111 matched controls • Veterans were included if they had a minimum of 1 primary care and blood pressure measurement within 12 months • RSV infection was confirmed using laboratory testing 0 to 13 days after the index date	• VE against documented RSV infections 0 to 1 month from day 14 after the index: 82.5% (95% CI 77.5–86.9) • VE against documented RSV infections 0 to 18months of follow-up: 59.4% (95% CI 55.6–63.5) • VE against RSV-associated ED and UC visits over 0 to 1 month: 84.9% (95% CI 78.4–90.2) • VE against RSV-associated ED and UC visits over 0 to 18 months: 57.3% (95% CI 47.3–66.4)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Infection ○ Hospitalization ○ ED visits ○ ICU admission • Timeframe (Specimens collected timepoints) ○ September 2023 to March 2024	Setting and country: United States		• VE against RSV-associated ICU admission over 0 to 1 month: 92.5% (95% CI 61.1–100.0) • VE against RSV-associated ICU admission over 0 to 18 months: 71.9% (95% CI 42.8–90.0) • Incidence rate of RSV infections: 6.2 vs 3.6 events per 1000 person-years over 18 months • VE of RSV infection at 0 to 1 month: 75.2% (95% CI 52.5–89.3) • VE of RSV infection at 18 months: 39.7% (95% CI 23.9–52.7) • VE among nonimmunocompromised individuals at 0 to 1 month: 83.9% (95% CI 78.1–88.8) • VE among nonimmunocompromised individuals over 18 months: 60.7% (95% CI 56.2–65.2) • RSVpreF effectiveness: 55.9% (95% CI 51.0–61.2) • RSVPreF3 effectiveness: 64.6% (95% CI 57.1–71.8)
Moline 2025 (38)	• Population studied ○ Children (0 to two years old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Vaccine effectiveness ○ Incidence rate • RSV related outcome ○ Acute respiratory infection • Timeframe (Specimens collected timepoints) ○ October 1, 2024, to April 30, 2025	Type of publication: Peer-reviewed Study design: Test-negative case-control design Analysis: VE was calculated using adjusted odds ratio Setting and country: United States	• This study included 5029 children younger than two years of age with medically attended ARI during October 1, 2024, to April 30, 2025 • Laboratory specimens were collected and analyzed using reverse transcription–polymerase chain reaction (RT-PCR) assays; positive tests were specified for RSV-A or RSV-B	• Maternal VE against medically attended RSV associated ARI: 64% (95% CI 37–79) ○ Maternal VE fewer than 14 days: 54% (95% CI 26–72) • Maternal VE against RSV associated hospitalization: 70% (95% CI 37–86) ○ Maternal VE fewer than 14 days: 57% (95% CI 19–77) • VE against any medically attended RSV-associated ARI: 77% (95% CI 69–83) • VE against RSV-associated hospitalization: 81% (95% CI 71–87) • VE against RSV-associated ICU admission: 90% (95% CI 68–97)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

				• VE against emergency department visit: 71% (95% CI 48–83)
				• RSV associated hospitalization incidence rate per 1000 children: 7.8 (95% CI 7.2-7.8)
				  ○ Newborn 0-2 month incidence rate: 12.7 (95% CI 10.2–15.2)
				  ○ Infants aged 3-5 months: 11.2 (95% CI 9.3–13.3)

Costantino 2025 (39)	• Population studied
	  ○ Children (0 to two years old)
	• Type of immunization product
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	  ○ Risk ratio
	  ○ Incidence rate
	• RSV related outcome
	  ○ Lower respiratory tract infection
	• Timeframe (Specimens collected timepoints)
	  ○ November 2024 to April 2025
		Type of publication:
		Peer-reviewed
		
		Study design:
		Retrospective, monocentric, real-world pilot study
		Analysis:
		Relative risk was calculated using the Katz log method
		
		Infection rates were calculated using two-sided Fisher exact tests
		
		Setting and country:
		Salerno, Italy
			• This study included 491 infants who were exposed to the Nirsevimab vaccine
			• RSV infection was confirmed with laboratory tests
				• Risk ratio of RSV infection for 2024–2025 vs. 2023–2024: 0.31 (95% CI 0.09–1.13)
				• Incidence rate in vaccinated infants: 0.41%
				• Incidence rate in unvaccinated infants: 1.09%
				• VE against RSV hospitalization 62% (95% CI -31–97)

Furgier 2025 (40)	• Population studied
	  ○ Children (0 to two years old)
	• Type of immunization product
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	• RSV related outcome
	  ○ Lower respiratory tract infection
		Type of publication:
		Peer-reviewed
		Study design:
		Test-negative case-control study
		
		Analysis:
		VE effectiveness was calculated a multivariate regression and the equation: 100% × (1 − adjusted odds ratio)
		
		Setting and country:
		France
			• This study included 127 infants, 22% of which tested for receipt of Nirsevimab vaccine during the October 10, 2024 to March 15, 2025 maternal vaccination campaign
			• Recommendations for maternal vaccination were between 32 and 36 weeks of pregnancy
			• RSV diagnosis was confirmed using a PCR test
				• VE against hospitalisation for RSV-bronchiolitis: 84.9% (95% CI 80.0–88.6)
				  ○ VE in infants aged <3: 86.0% (95% CI 79.0–90.7)
				  ○ VE in infants ≥3 months: 83.8% (95% CI 75.1–89.5)
				• VE against severe bronchiolitis in persons with one or more risk factor: 85.0% (95% CI 79.8–88.8)
				• VE against severe bronchiolitis in persons without one or more risk factor: 87.2% (95% CI 38.9–97.3)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Hospitalization • Timeframe (Specimens collected timepoints) ○ October 10, 2024 to March 15, 2025			
Coma 2025 (41)	• Population studied ○ Children (0 to two years old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Other • Outcome measures ○ Vaccine effectiveness ○ Incidence rate ○ Relative risk • RSV related outcome ○ Lower respiratory tract infection ○ Hospitalization ○ ICU admission • Timeframe (Specimens collected timepoints) ○ April 2023 and March 2024	Type of publication: Peer-reviewed Study design: Population-based retrospective cohort study Analysis: Cox proportional hazard models were used to calculated hazard ratios (HRs) and 95%CIs Setting and country: Catalonia, Spain	• This study included 51154 infants, 89.9% of which received the Nirsevimab vaccine before or during their first RSV season • Rapid antigen tests were used to confirm RSV in children with respiratory infection symptoms	• Cumulative incidence and relative risk in the first season ○ Cumulative Incidence of hospital admission for immunized participants: 5.33 per 1,000 individuals (95% CI 4.08–6.62) ○ Cumulative Incidence of hospital admission for non-immunized participants: 31.20 (95% CI 21.62–42.06) ○ Relative risk of hospital admission: 0.17 (95% CI 0.11–0.26) • Cumulative incidence for pediatric ICU admissions ○ Vaccination group: 1.90 per 1,000 (95% CI 1.27–2.76) ○ Non-immunized group: 9.08 (95% CI 4.41–15.55) ○ RR: 0.21 (95% CI 0.11–0.48) • Emergency department visits at the end of the second season: 0.35 (95% CI 0.24–0.56) • Primary care visits for bronchiolitis at the end of the second season: 0.56 (95% CI 0.35–1.01) • Cumulative incidence and relative risk in the second season ○ Cumulative Incidence of hospital admission for immunized participants: 9.57 per 1,000 infants (95% CI 7.92–11.20) ○ Cumulative Incidence of hospital admission for non-immunized participants: 35.56 per 1,000 (95% CI 25.69–47.58) ○ RR: 0.27 (95% CI: 0.20–0.40)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
				• Relative risk for PICU admission 1.90 vs. 9.08 per 1,000 (RR: 0.21, 95% CI 0.11–0.48) • Primary care infection rate RR: 0.81 (95% CI 0.57–1.29)

Ma 2025 (42)	• Population studied
	  ○ Children (0 to two years old)
	• Type of immunization product
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Other
	• Outcome measures
	  ○ Vaccine effectiveness
	• RSV related outcome
	  ○ Lower respiratory tract infection
	• Timeframe (Specimens collected timepoints)
	  ○ October 1, 2023 to March 31, 2024
		Type of publication:
		Peer-reviewed, correspondence
		
		Study design:
		Population-based cohort study
		
		Analysis:
		A cox proportional hazards model was used to calculate hazard ratios with a 95% confidence interval
		
		Setting and country:
		United States
			• This study included 192677 infants who received the Nirsevimab vaccination and 185625 who did not
			• Data was obtained from a de-identified electronic medical record database, consisting of 93 health-care organization
				• VE against RSV infection: HR: 0.24 (95% CI 0.17–0.33)
				• VE against wheezing risk: HR: 0.73 (95% CI 0.58–0.93)

Kitano, 2025 (43)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	  ○ Odds ratio
	• RSV related outcome
	  ○ Hospitalization
	  ○ Acute respiratory infection
	• Timeframe (Specimens collected timepoints)
	  ○ Baseline (1 July 2023 to 30 June 2025)
		Type of Publication: Peer-reviewed
		
		Study design: Multi-centre retrospective cohort study
		Analysis: Propensity score matching was performed using a 1:1 greedy nearest-neighbour methodMatching adjusted for age group, sex, race/ethnicity, and high-risk comorbidities. After matching, odds ratios (ORs) with 95% confidence intervals (CIs) for RSV infection were estimated using the TriNetX platform.
		
		Setting and country: TriNetX global database primarily contains North America (95%)
			• 4,627,861 children aged <24 months who underwent RSV nucleic acid testing between July 2023 and June 2025; 532 children had received nirsevimab prior to testing (stratified by time since administration), and 210,626 had not received nirsevimab	• VE against medically attended RSV infection (<6 months after dose): 47% (95% CI 0.41–0.53)
				• VE against medically attended RSV infection (6–11 months after dose): 41% (95% CI 0.30–0.55)
				• VE against medically attended RSV infection (≥12 months after dose): 1.25 (95% CI 0.92–1.70)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

Gaio, 2025 (44)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	  ○ Antigen
	• Outcome measures
	  ○ Vaccine effectiveness
	  ○ Odds ratio
	• RSV related outcome
	  ○ Hospitalizations
		Type of Publication: Peer-reviewed
		
		Study design: Test-negative case-control study
		
		Analysis: Odds ratios for RSV-positive hospitalisation among children admitted with acute respiratory infection were estimated using multivariable logistic regression in a test-negative design. Vaccine effectiveness of nirsevimab was calculated as (1 − adjusted odds ratio) × 100%, with stratified analyses by age group and time since immunisation
		
		Setting and country: Portugal
			• Children aged <24 months hospitalised with severe acute respiratory infection (SARI) and tested for RSV within the VigiRSV sentinel hospital network in Portugal (15 hospitals across mainland and Madeira) between Week 43/2024 and Week 16/2025.
			• All participants were tested using RT-PCR or rapid antigen tests, and only children eligible for national immunisation recommendations were include
				• VE against RSV-related hospitalizations: 78.5% (95% CI 59.3–89.0)
				  ○ Crude VE: 77.3 (95% CI 63.8–86.0)
				• VE against nirsevimab effectiveness: 82.0% (95% CI 62.0–91.8)
				  ○ Crude VE: 81.4 (95% CI 67.5–89.6)
				• VE against RSV-related hospitalizations (Immunisation at least 7 days before the onset date instead of 2 days: 76.2 (55.2–87.7)
				  ○ Crude VE: 77.3 (95% CI 63.8–86.0)
				• VE against RSV-related hospitalizations ARI (Without Madeira data (n = 329)): 79.1 (59.5–89.6)

Fusco, 2025 (45)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Antigen
	• Outcome measures
	  ○ Vaccine effectiveness
	  ○ Odds ratio
	• RSV related outcome
	  ○ Hospitalizations
	  ○ ICU admission
	• Timeframe (Specimens collected timepoints)
	  ○ Baseline (November 1 2024 to March 31 2025)
		Type of Publication: Peer-reviewed
		Study design: Test-negative case-control study
		
		Analysis: Odds ratios were calculated using unadjusted logistic regression, and vaccine effectiveness (VE) was estimated as (1 − odds ratio) × 100%. Separate analyses were conducted to estimate effectiveness against RSV infection, RSV-associated hospitalization, and PICU admission
		
		Setting and country: Italy (Lombardy region, Milan)
			• Infants aged 1–12 months diagnosed with bronchiolitis at Vittore Buzzi Children's Hospital in Milan. RSV testing was performed using rapid antigen assay on nasal aspirates. Only first ED visit included per patient
			• Receipt of nirsevimab was based on parental report
				• VE against RSV infection (ED bronchiolitis cases): 82% (95% CI 66–90)
				• VE against RSV-associated hospitalization: 78% (95% CI 50–89)
				  ○ OR reported as 0.22 (95% CI: 0.11–0.50)
				• VE against PICU admission: 84% (95% CI 33–97)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

McLachlan, 2025 (46)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	• RSV related outcomes
	  ○ Lower respiratory tract infections
	  ○ Hospitalizations
	• Timeframe (Specimens collected timepoints)
	  ○ Baseline (August 12 2024, to March 31 2025)
		Type of Publication: Peer-reviewed
		
		Study design: Retrospective nested case–control study
		Analysis: Cases (infants ≤90 days hospitalized with RSV-related LRTI confirmed by PCR) were matched 1:10 to controls by ISO week of birth and gestational age at birth. VE was calculated as 100 × (1 − adjusted OR).
		
		Setting and country: Scotland, United Kingdom
			• Infants aged ≤90 days from all singleton live births in Scotland between Aug 12, 2024, and March 31, 2025, identified using the Scottish Linked Pregnancy and Baby Dataset. A nested case–control study was conducted, including infants with RSV-related hospital admission for lower respiratory tract infection (LRTI) and a positive PCR test (cases), each matched to 10 controls by week of birth and gestational age. Controls had no prior RSV-positive test or RSV-related hospitalisation at the time of matching	• VE against RSV-related LRTI hospitalisation (vaccinated): 82.2% (95% CI 75.1–87.3)
				  ○ Adjusted (mothers received the RSV vaccine >14 days before delivery): 82.4% (95% CI 75.1–87.6)
				• VE against RSV-related LRTI hospitalisation (≥37 weeks): 81.5% (95% CI 73.9–87.0)
				  ○ Adjusted (mothers received the RSV vaccine >14 days before delivery): 81.7% (95% CI 73.8–87.2)
				• VE against RSV-related LRTI hospitalisation (<37 weeks): 89.9% (95% CI 55.3–97.7)
				  ○ Adjusted (mothers received the RSV vaccine >14 days before delivery): 90.5% (95% CI 56.3–97.9)
				• VE against RSV-related LRTI hospitalisation (suboptimally immunised): 31.7% (95% CI −15.2 to 59.5)
				  ○ Adjusted (mothers received the RSV vaccine >14 days before delivery): 30.2% (95% CI −18.9 to 59.0)

Cocchi, 2025 (47)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	  ○ Odds ratio
		Type of Publication: Peer-reviewed
		
		Study design: Prospective test-negative case–control study
		
		Analysis: Vaccine effectiveness was estimated using a test-negative design. Odds ratios (ORs) for prior nirsevimab receipt among RSV-positive cases versus RSV-negative controls were calculated using logistic regression. VE was computed as (1 − OR) × 100%.
			• The study included 13,624 children aged <20 months were tested for RSV. Cases were infants with PCR-confirmed RSV infection, and controls were RSV-negative infants presenting with ARI during the same period
			• Participants were infants presenting to participating Italian hospitals with symptoms of ARI who underwent RSV PCR testing. Vaccination
				• Nirsevimab prophylaxis was associated with a lower hazard of RSV hospitalization: 0.11 (95% CI 0.06–0.21)
				• Prematurity: 2.93 (95% CI 2.11–4.07)
				• Among hospitalized infants, nirsevimab was associated with reduced HFNC use: 0.33 (95% CI 0.11–0.97)
				• Among hospitalized infants, nirsevimab was associated with

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

	• RSV related outcome
	  ○ Hospitalizations
	• Timeframe (Specimens collected timepoints)
	  ○ Prenirsevimab: April 1, 2023, to March 31, 2024
	  ○ Postnirsevimab: April 1, 2024, to March 31, 2025
		Setting and country: Italy (Forlì, Cesena, Rimini, Faenza, and Ravenna)	status was verified through immunization records	shorter stays: 0.81 (95% CI 0.63–1.03)

Surie, 2025 (48)	• Population studied
	  ○ Older Adults (60 years and older)
	• Type of vaccine
	  ○ AREXVY™ (RSVPreF3) by GlaxoSmithKline
	  ○ ABRYSVO™ (RSVpreF) by Pfizer
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	• RSV related outcome
	  ○ Hospitalizations
	  ○ ICU admission
	  ○ Acute respiratory infection
	  ○ Any outcomes associated with due to RSV
	• Timeframe (Specimens collected timepoints)
	  ○ First Season: October 1, 2023, to March 31, 2024
	  ○ Second Season: October 1, 2024, to April 30, 2025
		Type of Publication: Peer-reviewed
		
		Study design: Multicenter, test-negative, case-control study
		
		Analysis: ORs for prior RSV vaccination among RSV-positive hospitalized cases versus RSV-negative controls were calculated using multivariable logistic regression. VE was computed as (1 − adjusted OR) × 100%.
		
		Setting and country: United States
			• A total of 6,958 adults were included in the analysis, comprising 821 RSV-positive cases (11.8%) and 6,137 RSV-negative controls (88.2%). The median age was 72 years (IQR, 66–80), and 50.8% of participants were female. Overall, 26.3% were classified as immunocompromised. RSV vaccination coverage was 7.7% (63/821) among cases and 15.7% (966/6,137) among controls. Among cases with known RSV subtype (n = 651), 45.9% were infected with RSV subtype A and 54.1% with RSV subtype B.
			• The intervention was receipt of a single dose of an RSV vaccine administered at least 14 days before illness onset. Vaccination status was stratified according to timing relative to hospitalization, distinguishing between same-season vaccination and prior-season vaccination.
				• Overall VE against RSV-associated hospitalization (≥60 years, 2 seasons): 58% (95% CI 45–68)
				• Overall VE against RSV-associated hospitalization 60-74, 2 seasons): 46% (95% CI 21–63)
				• Overall VE against RSV-associated hospitalization (≥75, 2 seasons): 68% (95% CI 52–79)
				• VE stratified by RSV vaccine product
				  ○ Arexvy (GSK): 64% (95% CI 47–76)
				  ○ Abrysvo (Pfizer): 61% (95% CI 41–74)
				• VE against RSV subtype A: 61% (95% CI 41–74)
				• VE against RSV subtype A: 65% (95% CI 43–78)
				• Same-season vaccination: 69% (95% CI 52–81)
				• Prior-season vaccination: 48% (95% CI 27–63)
				• VE against acute respiratory failure: 73% (95% CI 50–86)
				• VE against acute organ failure: 73% (95% CI 49–86)
				• VE against ICU admission: 67% (95% CI 37–83)
				• VE against Invasive mechanical ventilation or death: 72% (95% CI 7–91)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

Lenglart, 2025 (49)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Antigen
	• Outcome measures
	  ○ Vaccine effectiveness
	• RSV related outcome
	  ○ Hospitalizations
	  ○ ED visit
	  ○ Lower respiratory tract infection
	• Timeframe (Specimens collected timepoints)
	  ○ First season: October 5, 2023, to February 29, 2024
	  ○ Second season: October 15, 2024, to January 31, 2025
		Type of Publication: Peer-reviewed
		
		Study design: Multicenter, test-negative, case-control study
		
		Analysis: ORs for maternal RSV vaccination among RSV-positive hospitalized infants versus RSV-negative controls were calculated using multivariable logistic regression. VE was computed as (1 − adjusted OR) × 100%. Subgroup analyses were conducted according to gestational age at birth (preterm vs term) and adequacy of maternal immunization timing
		
		Setting and country: France
			• During the study period, 1,093 infants younger than 1 year presented to participating pediatric emergency departments with a first episode of bronchiolitis. After exclusions, 636 infants were included in the analysis. The median age was 3 months, 52% were boys, 6.6% were born prematurely, and 5.7% had an underlying chronic condition. About one-quarter (25.5%) had received nirsevimab more than 7 days before their visit. Overall, 71% tested positive for RSV, 52% required oxygen therapy, and 84% were hospitalized. Across the two seasons, RSV positivity remained consistent at about 71%, and hospitalization rates were high in both RSV-positive and RSV-negative infants.
			• The analysis included infants hospitalized for LRTI during the study period, classified into RSV-positive cases and RSV-negative controls based on PCR results. Infants were predominantly younger than 3 months of age, reflecting the highest RSV hospitalization risk period. A proportion were born preterm (<37 weeks' gestation). Maternal vaccination coverage was higher among controls than cases. Subgroup analyses were conducted by gestational age at birth (preterm vs term) and by timing/adequacy of maternal immunization.
			• Maternal receipt of a single dose of RSV vaccine during pregnancy, administered according to national recommendations during the third
				• VE against RSV-related Bronchiolitis in ED (First season): 83.2% (95% CI 68.0–91.4)
				• VE against RSV-related Bronchiolitis in ED (Second season): 89.3% (95% CI 77.8–95.1)
				• First season
				  ○ VE against RSV-related Bronchiolitis in ED (less than 3 months): 76.5% (95% CI 52.3–88.7)
				  ○ VE against hospitalization: 82.3% (95% CI 63.0–91.8)
				  ○ VE against respiratory support: 85.2% (95% CI 62.8–94.4)
				• Second season
				  ○ VE against RSV-related Bronchiolitis in ED (less than 3 months): 88.0% (95% CI 70.6–95.1)
				  ○ VE against hospitalization: 89.6% (95% CI 77.5–95.4)
				  ○ VE against respiratory support: 92.2% (95% CI 77.2–97.6)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
			trimester to provide passive immunity to the infant.	

Fry, 2025 (50)	• Population studied
	  ○ Older Adults (60 years and older)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	• RSV related outcome
	  ○ Hospitalizations
	• Timeframe (Specimens collected timepoints)
	  ○ October 1, 2023 to April 30, 2024
		Type of Publication: Peer-reviewed
		
		Study design: Retrospective test-negative case-control study
		
		Analysis: ORs for prior RSV vaccination among RSV-positive cases versus RSV-negative controls were calculated. VE was computed as (1 − OR) × 100%. Unadjusted ORs were supplemented with stratified analyses by age group (60–74 years vs ≥75 years), immunocompromised status, month of RSV testing, and state of residence to evaluate potential confounding.
		
		Setting and country: United States
			• A total of 787,822 adults with ARI and RSV testing were included in the VE analysis, comprising 53,963 RSV-positive cases and 733,859 RSV-negative controls. The median age was 74 years among cases and 73 years among controls; approximately half were aged 60–74 years and half ≥75 years. The majority were White (83.3%), followed by Black (11.6%) and Asian (2.5%) individuals. Comorbidities were common: 31% were immunocompromised, 30.9% had chronic lung disease, and 72.3% had cardiovascular disease.
			• Intervention was a receipt of a single dose of an RSV protein subunit vaccine (either RSVPreF3+AS01 or RSVPreF) administered at least 14 days before RSV testing.
				• VE against RSV-associated medically attended ARI (≥60 years): 75.1% (95% CI 73.6–76.4)
				• VE against RSV-associated medically attended ARI (Age 60–74 years): 75.2% (95% CI 73.0–77.2)
				• VE against RSV-associated medically attended ARI (Age ≥75 years): 75.6% (95% CI 73.7–77.3)
				• VE against RSV-associated ED/urgent care visits (≥60 years): 75.8% (95% CI 73.2–78.1)
				• VE against RSV-associated ED/urgent care visits (Age 60–74 years): 76.9% (95% CI 72.9–80.3)
				• VE against RSV-associated ED/urgent care visits (Age ≥75 years): 76.92% (95% CI 72.9–79.2)
				• VE against RSV-associated hospitalization (≥60 years): 75.5% (95% CI 73.1–77.6)
				• VE against RSV-associated hospitalization (Age 60–74 years): 75.2% (95% CI 71.0–78.8)
				• VE against RSV-associated hospitalization (Age ≥75 years): 76.1% (95% CI 73.2–78.7)
				• Immunocompromised individuals
				  ○ VE against RSV-associated medically attended ARI (≥60 years): 70.4% (95% CI 67.8–72.7)
				  ○ VE against RSV-associated medically attended ARI (Age 60–74 years): 67.0% (95% CI 62.6–70.9)
				  ○ VE against RSV-associated medically attended ARI (Age

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
				≥75 years): 73.1% (95% CI 69.8–76.0)

Payne, 2025 (51)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Antigen
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	• RSV related outcome
	  ○ Hospitalizations
	  ○ ED Visit
	• Timeframe (Specimens collected timepoints)
	  ○ October 8, 2023 to March 31, 2024
		Type of Publication: Peer-reviewed
		
		Study design: Retrospective test-negative study
		
		Analysis: ORs for prior nirsevimab receipt among RSV-positive cases versus RSV-negative controls were estimated using logistic regression, with adjustment for age, race and ethnicity, sex, calendar day, and geographic region. VE was computed as (1 − adjusted OR) × 100%.
		
		Setting and country: United States
			• A total of 5039 ED encounters with an RSV-like illness (RLI) were analysed; 2045 (41%) were RSV-positive. Among these, 446 encounters (9%) involved infants who received nirsevimab, with a median of 52 days since dose (interquartile range [IQR] 27–84 days). For hospitalisation outcomes, there were 1025 RLI hospitalisations, of which 605 (59%) were RSV-positive, and 95 (9%) had received nirsevimab (median 48 days since dose, IQR 24–82 days). Demographic characteristics included infants seen across diverse regions and settings; detailed covariates (age, sex, race/ethnicity) were adjusted in regression models to control for confounding in VE estimation.
			• The intervention was administration of nirsevimab, a long-acting monoclonal antibody given once to provide passive immunity against RSV for infants in their first RSV season.
				• VE against RSV-associated ED encounters (7-164 days after dose): 77% (95% CI 69–83)
				• VE against RSV-associated ED encounters (7-59 days after dose): 76% (95% CI 66–83)
				• VE against RSV-associated ED encounters (60-164 days after dose): 78% (95% CI 62–87)
				• VE against RSV-associated hospitalisation (7-145 days after dose): 98% (95% CI 95–99)

Williams, 2025 (52)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	• RSV related outcome
		Type of Publication: Peer-reviewed
		
		Study design: Multicentre test-negative, case-control study
		
		Analysis: ORs for prior nirsevimab receipt among RSV-positive hospitalized cases versus RSV-negative hospitalized controls were calculated using multivariable logistic regression. VE was computed as (1 − adjusted OR) × 100%.
			• Infants aged 0–5 months admitted to 30 hospitals across the UK with acute lower respiratory illness (bronchiolitis, LRTI, or first wheeze) during the 2024–2025 RSV season were included in a national multicentre prospective test-negative case–control study nested within the PERUKI BronchStart-Stop cohort. All infants were tested for RSV using RT-PCR; RSV-positive infants were cases and RSV-negative infants were controls	• VE against RSV-associated hospitalisation for ARLI: 58% (95% CI 28.0–75.0)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Hospitalizations • Timeframe (Specimens collected timepoints) ○ September 30, 2024, to January 20, 2025	Setting and country: England (United Kingdom)	• A single intramuscular dose of nirsevimab administered as part of the national infant RSV immunisation programme	
Perramon-Malavez, 2025 (53)	• Population studied ○ Children (0 to two years old) • Type of vaccine ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Vaccine effectiveness ○ Hospitalizations	Type of Publication: Peer-reviewed Study design: Retrospective cohort study Analysis: Hazard ratios (HRs) for RSV-related outcomes among infants who received nirsevimab versus those not immunized were estimated using Cox proportional hazards regression models with calendar time as the time scale, adjusted for confounders identified via standardized mean differences. Vaccine effectiveness (VE) was computed as (1 − adjusted HR) × 100%. Sensitivity analyses were conducted using 1:1 exact matching on date of birth, sex, nationality, and socioeconomic status. Setting and country: Spain (Catalonia)	• A total of 15,341 infants born between October 1, 2023 and January 21, 2024 were included in the study • 14,055 (92%) were immunized with nirsevimab, while 1,286 (8%) were non-immunized. Infants were followed from birth or from the date of immunization until the occurrence of an outcome, death or the end of the study period • The intervention consisted of a single dose of nirsevimab administered to infant during the RSV season as part of a regional immunization program	• RSV-associated bronchiolitis ○ VE against hospital admission: 74% (95% CI 61–83) ○ HRs: 0.26 (95% CI 0.17–0.39) ○ VE against PICU admission: 85% (95% CI 72–93) ○ HRs: 0.15 (95% CI 0.07–0.28) ○ VE against emergency department visits: 54% (95% CI 10–77) ○ HRs: 0.46 (95% CI 0.23–0.90) • All-cause bronchiolitis ○ VE against hospital admission: 55% (95% CI 37–69) ○ HRs: 0.45 (95% CI: 0.31–0.63) ○ VE against PICU admission: 77% (95% CI 59–87) ○ HRs: 0.23 (95% CI: 0.13–0.41) ○ VE against emergency department visits: 51% (95% CI 32–65) ○ HRs: 0.49 (95% CI: 0.35–0.68)
Guerrero-Del-Cueto, 2025 (54)	• Population studied ○ Children (0 to two years old) • Type of vaccine ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Vaccine effectiveness • RSV related outcome	Type of Publication: Peer-reviewed Study design: Retrospective, single-center, matched case-control design Analysis: Effectiveness of nirsevimab was estimated using a matched case-control design. Cases (infants hospitalized with PCR-confirmed RSV bronchiolitis) were matched 1:2 with controls by exact date of birth to control for	• The population included infants younger than 24 months hospitalized for PCR-confirmed RSV bronchiolitis during the first nirsevimab season. • For the case-control effectiveness analysis, infants hospitalized for RSV bronchiolitis were defined as cases and matched with controls born on the same day from the same province who were not admitted for RSV bronchiolitis during the season. Immunization	• VE against RSV-associated hospitalisation for bronchitis: 91.5% (95% CI 71.8–97.4)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Hospitalizations • Timeframe (Specimens collected timepoints) ○ October 1, 2023 to March 31, 2024	age and seasonal exposure. Logistic regression models estimated odds ratios comparing immunization status between cases and controls; immunization effectiveness was computed as (1 − OR) × 100% with 95% confidence intervals. Secondary analyses compared clinical outcomes between immunized and non-immunized cases using chi-squared tests for categorical variables and Mann–Whitney U tests for continuous outcomes. Setting and country: Malaga Regional University Hospital, Andalusia, Spain	status was determined by medical records, classifying infants as immunized if nirsevimab was administered ≥7 days before admission. • The intervention was immunization with Nirsevimab, administered intramuscularly at least 7 days before hospital admission during the 2023–2024 RSV season.	
Gentile, 2025 (55)	• Population studied ○ Children (0 to two years old) • Type of vaccine ○ ABRYSVO™ (RSVpreF) by Pfizer • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Vaccine effectiveness ○ Odds ratio • RSV related outcome ○ Hospitalizations ○ Acute respiratory infections • Timeframe (Specimens collected timepoints) ○ March 15, 2024 and October 31, 2024	Type of Publication: Peer-reviewed Study design: Multicentre, case-control, test-negative study Analysis: VE was estimated using a test-negative design with logistic regression. The odds of maternal RSV vaccination among RSV-positive cases were compared with RSV-negative controls. VE was calculated as (1 − adjusted odds ratio [aOR]) × 100% with 95% confidence intervals. Setting and country: Argentina	• A total of 1,340 children <18 years were hospitalized for ALRI in the study period; among these, 187 infants <6 months old born after 15 March 2024 were included in the VE analysis. Of these infants, 91 (48.7%) were RSV-positive cases and 96 (51.3%) were RSV-negative controls. RSV cases were significantly younger than controls and had lower rates of chronic respiratory disease, prematurity, and comorbidities. • Maternal RSV vaccination was significantly less common among cases compared with controls. Only 16 (17.6%) cases had documented maternal RSV vaccination vs. 43 (44.8%) controls. Maternal RSV vaccine administration at least 14 days before delivery was present in 12 (13.2%) cases vs. 31 (32.3%) controls.	• VE against RSV-associated hospitalisation in infants <6 months • Crude VE: 68.2% (95% CI 33.1–84.9) • Adjusted VE: 78.7% (95% CI 51.4–90.7), after adjusting for age <3 months, prematurity, and chronic respiratory disease

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
			• Maternal immunization with the bivalent RSV prefusion F vaccine (RSVpreF) administered between 32.0 and 36.6 weeks gestation during pregnancy.	

Bajema, 2025 (56)	• Population studied
	  ○ Older Adults (60 years and older)
	• Type of vaccine
	  ○ AREXVY™ (RSVPreF3) by GlaxoSmithKline
	  ○ ABRYSVO™ (RSVpreF) by Pfizer
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	• RSV associated outcomes
	  ○ Hospitalization
	  ○ ED visit
	  ○ ICU admission
	• Timeframe (Specimens collected timepoints)
	  ○ Enrolment: September 1, 2023 to December 31, 2023
	  ○ Follow-up: March 31, 2024
		Type of Publication: Peer-reviewed
		
		Study design: Retrospective observational study
		
		Analysis: Vaccinated individuals were exact-matched on age group, immunocompromised status, frailty (CAN score), region, and prior healthcare utilization, followed by 1:4 propensity score matching. Incidence rates were calculated per 1000 person-years. Cumulative incidence was estimated using the Aalen–Johansen estimator accounting for death as a competing risk. Vaccine effectiveness (VE) was estimated as: VE = 100 × (1 − risk ratio) where the risk ratio compared cumulative incidence between vaccinated and unvaccinated groups at the end of follow-up.
		
		Setting and country: United States
			• Among 4,956,973 VHA enrollees aged ≥60 years screened during the enrollment window, 148,319 received RSV vaccination. After matching, 146,852 vaccinated individuals were matched to 582,936 unique unvaccinated controls, weighted equally to represent 146,852 individuals in each group. Across matched participants (n=293,704 weighted), 94.0% were male and 6.0% were female, with a median age of 75.9 years (IQR 71.7–79.7).
			• Cardiovascular disease was present in 41.5%, chronic lung disease in 30.2%, and 5.2% were immunocompromised. Among vaccinated individuals, 69.2% received RSVpreF and 29.9% received RSVPreF3. Median follow-up from day 14 post-index was 124 days (IQR 102–150).
			• Receipt of a single dose of RSV vaccine (RSVpreF or RSVPreF3) during September–December 2023.
				• VE against documented RSV infection (60–69 years): 79.1% (95% CI 68.0–88.3)
				• VE against documented RSV infection (70–79 years): 78.0% (95% CI 70.3–84.0)
				• VE against documented RSV infection (≥80 years): 72.3% (95% CI 57.9–84.6)
				• VE against documented RSV infection (RSVpreF): 77.4% (95% CI 70.4–82.4)
				• VE against documented RSV infection (RSVPreF3): 76.7% (95% CI 66.0–86.7)
				• VE against RSV-associated emergency department or urgent care visits: 78.2% (95% CI 71.6–84.2)
				• VE against RSV-associated hospitalisations: 76.7% (95% CI 59.1–89.2)
				• RSV-associated ICU and RSV-associated death are not reported for VE effectiveness

Wadia, 2025 (57)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
		Type of Publication: Peer-reviewed
		
		Study design: Multicentre, case-control, test-negative study
		
		Analysis: Conditional logistic regression models were used to compare the odds of prior nirsevimab receipt among RSV-positive cases versus RSV-
			• A total of 284 nirsevimab-eligible children were enrolled, including: 184 RSV-positive cases (64.8%) and 100 RSV-negative controls (35.2%).
			• The median age among cases was 0.37 years (IQR 0.17–0.73) and 0.28 years (IQR 0.10–0.58) among controls. Approximately half of
				• VE against RSV-associated ARI hospitalisation (Y1 + Y2 combined): 88.2% (95% CI 73.5–94.7)
				• VE in first RSV season cohort (Y1): 86.4% (95% CI 68.0–94.3)
				• VE in second RSV season cohort (Y2): 98.7% (95% CI 60.1–99.9) (limited by small numbers)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Vaccine effectiveness • RSV related outcome ○ Hospitalizations ○ ICU admission • Timeframe (Specimens collected timepoints) ○ April 1, 2024 to October 30, 2024	negative controls. Effectiveness was calculated as: VE = (1 − adjusted odds ratio) × 100%. Setting and country: Australia (Western Australia; Perth metropolitan region)	participants were male (51.6% of cases; 58.0% of controls). • Aboriginal children comprised 16.9% of cases and 10.0% of controls. Most children were born at term (83.2% of cases; 81.0% of controls), with prematurity (<37 weeks gestation) present in approximately 17% overall. At least one medical risk factor was present in 16.3% of cases and 9.0% of controls. Overall, 106 of 284 children (37.3%) had received nirsevimab prior to admission. Coverage was substantially higher among controls (64.0%) compared with cases (22.8%). • Among RSV-positive cases, 42 (22.8%) represented breakthrough infections. The median time from nirsevimab receipt to hospitalisation was 75 days (IQR 28–103). Among RSV-positive cases: 13 (7.1%) required PICU admission, 35 (19.0%) required high-flow oxygen, non-invasive, or invasive ventilation, 92 (50.0%) required any oxygen or respiratory support and no deaths occurred • The intervention was receipt of nirsevimab prior to hospitalization.	• VE against RSV hospitalisation requiring oxygen and/or respiratory support: 61.8% (95% CI 16.4–82.5) • VE against PICU admission: 32.4% (95% CI −138.1–80.8) • VE 0–90 days post-immunisation: 83.8% (95% CI 63.2–95.3) • VE >90 days post-immunisation: 93.6% (95% CI 76.5–98.3)
Marouk, 2025 (58)	• Population studied ○ Children (0 to two years old) • Type of vaccine ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures	Type of Publication: Peer-reviewed Study design: Retrospective, multicentre, observational study Analysis: The association between nirsevimab immunization and clinical outcomes was evaluated using multivariable logistic regression models. Adjusted ORs for hospitalization and secondary	• A total of 739 infants younger than 3 months with a clinical diagnosis of bronchiolitis were included after screening ED visits across six university hospitals in Paris. Initially, 897 infants were identified, but exclusions were applied for repeated visits, coding errors, or other predefined criteria. Among the included infants, 531 (72%) had documented nirsevimab	• VE against hospitalization following ED visit for bronchiolitis: 53.5% (95% CI 34.1–67.3) ○ Neonates (<28 days): 37.5% (95% CI −64.7–76.2) ○ Infants 28 days–3 months: 54.5% (95% CI 33.5–69.1) ○ Preterm infants (<37 weeks gestation): 24.8% (95% CI −404.8–89.1)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Vaccine effectiveness • RSV related outcome ○ Hospitalizations ○ ICU admission • Timeframe (Specimens collected timepoints) ○ October 2, 2023 to December 31, 2023	outcomes were estimated comparing infants who received nirsevimab with those who did not. Vaccine effectiveness was calculated as (1 − adjusted OR) × 100%. Setting and country: France (Greater Paris region)	immunization status, while 28% had missing exposure data that were later addressed using statistical imputation methods. • Overall, 402 infants (54%) were hospitalized following their ED visit for bronchiolitis. Among infants who underwent viral testing (456 infants), 290 (64%) tested positive for RSV. Additionally, 70 infants (9%) required PICU admission, with a median age of 17 days at admission.	○ Term infants: 56.1% (95% CI 36.5–69.3) ○ Infants from deprived households: 31.1% (95% CI −24.2–62.1) ○ Non-deprived infants: 53.5% (95% CI 34.1–67.3) • VE against PICU admission: 51.1% (95% CI 10.7–74.3) • VE against hospitalization excluding ED observation unit stays: 54.7% (95% CI 36.1–68.2) • Effectiveness in reducing RSV positivity: 79.6% (95% CI 68.0–87.1)
Hammitt, 2025 (59)	• Population studied ○ Children (0 to two years old) • Type of vaccine ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Vaccine effectiveness • RSV related outcome ○ Hospitalizations • Timeframe (Specimens collected timepoints) ○ November 6, 2023 to May 31, 2024	Type of Publication: Peer-reviewed Study design: Observational test-negative case-control study Analysis: Vaccine effectiveness was calculated as (1 − adjusted OR) × 100%. Setting and country: United States, specifically AI/AN communities in Alaska and the Southwest United States (Navajo Nation, White Mountain Apache Tribal lands, Anchorage municipality, and Yukon-Kuskokwim Delta)	• The primary analysis included 291 hospitalized AI/AN children younger than 19 months of age, consisting of 136 RSV-positive cases and 155 RSV-negative controls. Overall, 64 children (22.0%) had received nirsevimab prior to illness, with the median time from immunization to presentation being 107 days (interquartile range 59–134 days) • Receipt of nirsevimab differed markedly by case status: 6.1% of RSV cases had received nirsevimab compared with 47.5% of controls. Children entering their first RSV season, those with high-risk medical conditions, those presenting later in the RSV season, and those living in Alaska were more likely to have received nirsevimab. Among infants entering their first RSV season, preterm infants were also more likely to receive prophylaxis	• VE against RSV-associated hospitalization (first RSV season): 86.0% (95% CI 55.9–95.6) • VE against RSV-associated hospitalization (second RSV season): 87.9% (95% CI 22.2–98.1) • Effectiveness in reducing RSV positivity: 79.6% (95% CI 68.0–87.1)
Manzoni, 2025 (60)	• Population studied ○ Children (0 to two years old) • Type of vaccine	Type of Publication: Peer-reviewed (Commentary)	• A total of 432 infants hospitalized for severe LRTD were initially identified across participating	• VE against RSV-associated LRTD hospitalization

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Vaccine effectiveness ○ Odds ratio • RSV related outcome ○ Lower respiratory tract infection ○ Hospitalizations • Timeframe (Specimens collected timepoints) ○ November 1, 2024 to April 30, 2025	Study design: Multicentre test-negative case-control study Analysis: Crude odds ratios (cORs) were initially calculated to estimate the association between immunization status and RSV hospitalization Immunization effectiveness was calculated using the formula IE = 100 × (1 − OR), where OR refers to either the crude or adjusted odds ratio derived from the regression models. Setting and country: Italy	hospitals. Of these, 123 infants were excluded because they were older than 5 months by 1 November 2024 and therefore not eligible for nirsevimab immunization under the universal program. An additional 16 infants were excluded due to missing information on nirsevimab administration. • The final sample consisted of 309 hospitalized infants, representing 71.5% of the initial sample. Among these, 140 infants were RSV-positive cases (45.3%), while 169 infants were RSV-negative controls (54.7%). Nirsevimab immunization was documented in 49 RSV-positive cases (35.0%) and 104 RSV-negative controls (61.5%). Among infants who had received nirsevimab, the mean time from injection to hospital admission was 42.1 days (SD 27.1).	○ Crude VE: 66.4% (95% CI 46.3–78.8) ○ Adjusted VE: 65.5% (95% CI 43.0–79.2)
Attaianese, 2025 (61)	• Population studied ○ Children (0 to two years old) • Type of vaccine ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Vaccine effectiveness ○ Odds ratio • RSV related outcome ○ Hospitalizations • Timeframe (Specimens collected timepoints) ○ November 1, 2024 to March 31, 2025	Type of Publication: Peer-reviewed Study design: Observational, multicenter matched case-control study Analysis: Case patients hospitalized with PCR-confirmed RSV bronchiolitis were matched with control patients hospitalized for non-respiratory conditions based on age and date of hospitalization. Conditional logistic regression models were used to estimate ORs for prior nirsevimab receipt among cases versus controls while accounting for the matched study design. Immunization effectiveness (IE)	• During the study period, 189 eligible infants were initially identified across participating hospitals. Fifty-one infants were excluded due to missing data or incomplete case-control matching, resulting in a final analytic sample of 138 infants younger than 12 months. The study included 46 RSV-positive cases and 92 matched controls hospitalized for non-respiratory conditions. The median age at admission was 4.0 months in both groups. • Overall, 83 infants (60.1%) had received nirsevimab prior to hospitalization. Nirsevimab immunization was documented in 19 cases (41.3%) and 64 controls (69.6%). Approximately 13% of	• VE against RSV-related hospitalization (all infants) • Adjusted IE: 89.5% (95% CI 60.3–97.2) • Unadjusted IE: 88.8% (95% CI 61.4–96.8) • VE against RSV-related hospitalizations • Infants born from April 1, 2024 (Base model): 87.9% (95% CI 57.8–96.5) • Infants born from April 1, 2024 (Adjusted model): 89.0% (95% CI 57.5–97.1) • Infants without risk factors (Base model): 88.4% (95% CI 47.4–97.4)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

		was calculated as IE = 100 × (1 − OR).
		
		Setting and country: Italy
			cases and 14.1% of controls had at least one risk factor for severe bronchiolitis, including prematurity, bronchopulmonary dysplasia, or congenital heart disease.	• Infants without risk factors (Adjusted model): 88.1% (95% CI 45.7–97.4)
				• Stratified effectiveness analyses
				  ○ Infants born after April 1, 2024: 88.4% (95% CI 56.5–96.9)
				  ○ Infants without clinical risk factors: 88.1% (95% CI 45.7–97.4)

Coma, 2025 (62)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	  ○ Risk ratio
	• RSV related outcome
	  ○ Hospitalizations
	• Timeframe (Specimens collected timepoints)
	  ○ October 1, 2024 to February 16, 2025
		Type of Publication: Peer-reviewed (Commentary)
		
		Study design: Observational cohort study (Letter to Editor)
		
		Analysis: Effectiveness was estimated using a population cohort design comparing immunised and non-immunised infants. Cox proportional hazards regression models using calendar time as the time scale were fitted to estimate hazard ratios (HRs) and 95% confidence intervals for RSV-related outcomes according to nirsevimab immunisation status. Models were adjusted for covariates with a standardised mean difference greater than 0.1, including nationality and month of birth. Immunisation effectiveness was calculated as (1 − adjusted HR) × 100%. Because the number of paediatric intensive care unit admissions was very low (two events in the control group), effectiveness estimates for this outcome could not be calculated.
		
		Setting and country: Catalonia, Spain
			• A total of 25,736 infants born between April and September 2024 were included in the analysis. Among these infants, 24,115 (93.7%) received nirsevimab, while 1,621 infants remained non-immunised and served as the control group. The two cohorts were largely comparable, with the only notable differences observed for nationality and month of birth, both showing a standardised mean difference greater than 0.1. Overall immunisation coverage was higher than that observed in the previous Catalonian campaign (2023–2024).
			• Administration of nirsevimab immunisation as part of the regional RSV prevention campaign, delivered to infants born between April and September during October in primary care settings.
				• VE against RSV-related primary care infection: 76.1% (95% CI 60.3–85.6)
				• VE against RSV bronchiolitis diagnosed in primary care: 67.4% (95% CI 36.2–83.4)
				• VE against emergency visits due to RSV bronchiolitis: 80.9% (95% CI 67.5–88.8)
				• VE against RSV-related hospital admissions: 79.8% (95% CI 66.4–87.8)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

Reina 2025 (63)	• Population studied
	  ○ Children under 15 years of age
	• Type of immunization product
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	• RSV related outcome
	  ○ Acute respiratory infection
	• Time frame
	  ○ 27 November 2023 to 31 March 2024
		Type of publication:
		Peer-reviewed
		
		Study design:
		Comparative analysis
		
		Analysis:
		Incidences were compared across seasons; analysis not specified
		
		Setting and country:
		Balearic Islands
			• A total of 581 youth under the age of 15 were compared; 303 in 2022-2023 and 278 in 2023-2024
			• Infants under six months were prospectively studied and a real-time polymerase chain reaction was colletced
				• Of the 278 cases identified in 2023-2024, 69.1% received the vaccine
				• The percentage of positivity in persons who was immunised was 69.3%, compared to 73.3% of those not immunised

Alejandre 2024 (64)	• Population studied
	  ○ Children and adolescents aged two to 17 years
	• Type of immunization product
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	  ○ Relative risk
	• RSV related outcome
	  ○ ICU admission
	• Timeframe (Specimens collected timepoints)
	  ○ September 2010 and February 2024
		Type of publication: Peer-reviewed
		Study design:
		Prospective, descriptive, and observational study
		
		Analysis: Differences between groups were explored using a Mann-Whitney U-test.
		
		Setting and country:
		Spain
			• This study included 1531 children with severe bronchitis
			• Previous immunization history was documented and record for individuals who entered the pediatric intensive care unit
			• Causal viral agents were also diagnosed using polymerase chain reaction assays
				• Burden of RSV-bronchiolitis
				  ○ Burden of RSV-bronchiolitis admissions per 100 PICU admissions pre Nirsevimab vaccine: 9 (95% CI: 8.6–9.5)
				  ○ Burden of RSV-bronchiolitis admissions per 100 PICU admissions after Nirsevimab vaccine: 4.3 (95%CI: 3.2–6.1)
				  ○ P<0.001 difference between groups

Lassen 2025 (65)	• Population studied
	  ○ Older adults (aged ≥65 years)
	• Type of immunization product
	  ○ ABRYSVO™ (RSVpreF) by Pfizer
	• Comparator
	  ○ Unvaccinated individuals
		Type of publication:
		Peer-reviewed
		
		Study design:
		Pragmatic, open-label, individually randomized clinical trial
			• This study included 131276 older adults aged 60 or older
			• Participants were randomized 1:1 to receive RSVpreF (n = 65 642) or no vaccine (n = 65 634)
				• Vaccine effectiveness against all-cause cardiorespiratory hospitalizations: 9.9% (95% CI 0.3–18.7)
				• All-cause cardiovascular hospitalization incidence rate in

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	  ○ Incidence rate
	• RSV related outcome
	  ○ Infection
	  ○ Hospitalization
	  ○ ICU admission
	  ○ Acute respiratory infection
	• Timeframe (Specimens collected timepoints)
	  ○ 2024-2025 northern hemisphere winter season
		Analysis:
		Vaccine effectiveness was calculated using 1 − incidence rate ratio, with 95% confidence intervals
		
		Setting and country:
		Denmark
			• Participants attended a follow up 30 days after their original visit	RSVpreF compared to placebo: 6.4 vs 17.7 events per 1000 PY
				• Stroke incidence rate in RSVpreF compared to placebo: 3.0 vs 3.8 events per 1000 PY
				• Heart failure incidence rates: 1.65 vs 1.57 events per 1000 PY
				• Myocardial infarction incidence rate: 1.98 vs 2.01 events per 1000 PY
				• Atrial fibrillation incidence rate: 42.49 vs 41.50 events per 1000 PY
				• Vaccine effectiveness for RSV-related respiratory tract disease hospitalization: 83.3% (95% CI 42.9–96.9)

Pareek, 2025 (66)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ ABRYSVO™ (RSVpreF) by Pfizer
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine effectiveness
	• RSV related outcome
	  ○ Hospitalizations
		Type of Publication: Peer-reviewed
		
		Study design: Pragmatic, open-label, parallel-group, individually randomized clinical trial
		
		Analysis: Analyses followed the intention-to-treat principle. Vaccine effectiveness was calculated as: VE = [1 − (incidence rate in vaccine group ÷ incidence rate in control group)] × 100%, with 95% CIs using the Clopper–Pearson method. Outcome incidence rates and VE were summarized by ASCVD status and treatment arm. Heterogeneity in effectiveness by ASCVD status was assessed with Poisson regression models including treatment–subgroup interaction terms. Continuous and categorical baseline variables were compared with Mann–Whitney U or χ^2 tests, respectively. All analyses were exploratory in nature due to secondary analysis design.
			• A total of 131 276 participants were randomized: 65 642 to the RSVpreF vaccine and 65 634 to no vaccine (control). The median follow-up included data captured through registries for hospitalizations and other outcomes. Among the total, 14 241 (10.8 %) had a history of ASCVD, defined using ICD-10 codes for conditions like ischaemic heart disease, cerebrovascular disease, or peripheral artery disease. Those with ASCVD tended to be older and have a higher cardiovascular risk profile, but characteristics were balanced between vaccine and control groups.
			• A single intramuscular dose of the bivalent RSV prefusion F protein-based vaccine (RSVpreF) containing 60 µg each of stabilized prefusion F antigens from RSV subgroups A and B was administered to the intervention group.
				• VE against RSV-related hospitalization:
				• Individuals without ASCVD: 80.0% (95% CI 29.3–96.3)
				• Individuals with ASCVD: 100.0% (95% CI −141.3–100.0)
				• VE against all-cause cardiorespiratory hospitalization (Without ASCVD): 10.6% (95% CI −0.5–20.5)
				• VE against all-cause cardiorespiratory hospitalization (With ASCVD): 7.4% (95% CI −14.1–25.8)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
		Setting and country: Denmark		

Jabagi 2025 (67)	• Population studied
	  ○ Children (0 to two years old)
	• Type of immunization product
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Nirsevimab effectiveness
	• RSV-related outcome
	  ○ Hospitalization
	  ○ ICU admission
	  ○ Severe LRTI
	  ○ Lower respiratory tract infection
	• Timeframe (specimens collected timepoints)
	  ○ Baseline (15 September 2023 to 31 January 2024)
		Type of publication: Peer reviewed
		
		Study design: Population-based cohort study
		
		Analysis: Vaccine effectiveness was calculated using the Cox proportional hazard ratio: (1 – hazard ratio) x 100.
		
		Setting and country: Mainland France
			• 82,474 infants (41,237 each in immunized and unimmunized group) age 0 to 12 months old were included in the analysis
			• 379 (0.8%) infants in the immunized group and 1,012 (2.4%) infants in the unimmunized group were hospitalized for RSV-LRTI
				• Nirsevimab effectiveness against RSV-LRTI associated hospitalization: 65% (95% CI: 61-69)
				  ○ By sex:
				  ▪ Male: 66% (95% CI: 60-71)
				  ▪ Female: 65% (95% CI: 57-71)
				  ○ By age:
				  ▪ ≤3 months: 64% (95% CI: 57-70)
				  ▪ > 3 months: 63% (95% CI: 55-69)
				  ○ By gestational age at birth:
				  ▪ <37 weeks: 70% (95% CI: 53-81)
				  ▪ ≥37 weeks: 65% (95% CI: 60-69)
				  ○ By medical history:
				  ▪ No known comorbidity: 65% (95% CI: 60-70)
				  ▪ With a comorbidity: 62% (95% CI: 28-80)
				  ○ By time since nirsevimab administration:
				  ▪ 0 to 75 days: 65% (95% CI: 60-70)
				  ▪ >75 days: 65% (95% CI: 53-75)
				  ○ By intensity of RSV circulation:
				  ▪ Low circulation (Sept. 15 to Nov. 14): 57% (95% CI: 47-65)
				  ▪ High circulation (Nov. 15 to Dec. 14): 71% (95% CI: 65-76)
				  ▪ Low circulation (Dec. 15 to Jan. 31): 63% (95% CI: 51-72)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
				• Nirsevimab effectiveness against RSV-LRTI associated PICU admission: 74% (95% CI: 56-85) • Nirsevimab effectiveness against RSV-LRTI associated high dependency unit admission: 64% (95% CI: 55-71) • Nirsevimab effectiveness against RSV-LRTI associated hospitalization requiring ventilation: 66% (95% CI: 51-76) • Nirsevimab effectiveness against RSV-LRTI associated hospitalization requiring oxygen therapy: 67% (95% CI: 57-75)

Jeziorski 2025 (68)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Antigen
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Nirsevimab effectiveness
	• RSV related outcome
	  ○ Hospitalization
	  ○ Bronchiolitis
	• Timeframe (Specimens collected timepoints)
	  ○ Baseline (October 27, 2023 to February 29, 2024)
		Type of publication: Peer reviewed
		
		Study design: Multicentre prospective study with test-negative design post-hoc analysis
		
		Analysis: Vaccine effectiveness was estimated using the following equation: effectiveness = 100% x (1 – OR). Odds of RSV infection was estimated using a multivariable logistic regression model.
		
		Setting and country: Six pediatric wards in France
			• 1,015 infants 12 months old or younger were included in the RSV analysis (724 cases and 291 controls)
			• 230 (22.7%) had received nirsevimab including 102 (14.1%) cases and 128 controls (44.9%)
				• Nirsevimab effectiveness against hospitalization for RSV-bronchiolitis: 79.5% (95% CI: 71.4-85.3)

Núñez 2025 (69)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
		Type of publication: Peer-reviewed
		
		Study design: Population-based matched case-control study
		
		Analysis: Pragmatic nirsevimab effectiveness was estimated from
			• 4,757 infants born after April 1, 2023 were included; this included 2,029 in the catch-up immunisation cohort (406 cases and 1,623 controls) and 2,728 in the at-birth immunisation cohort (546 cases and 2,182 controls)	• Effectiveness of nirsevimab against RSV-LRTI hospitalization by ITT analysis:
				  ○ Catch-up immunization: 71.0% (95% CI: 64.6-76.2)
				  ○ At-birth immunization: 78.0% (95% CI: 72.7-82.3)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Nirsevimab effectiveness
	• RSV related outcome
	  ○ Hospitalization
	  ○ Lower respiratory tract infection
	• Timeframe (Specimens collected timepoints)
	  ○ Baseline (September 25, 2023 to March 31, 2024)
		conditional logistic regression models adjusted for sex, gestational age, birth weight, multiple pregnancy, previous non-RSV related hospitalization, and previous comorbidities. Intention to treat (ITT) and per protocol (PP) causal estimates used inverse-probability-of-censoring weighted conditional logistic models based on assigned immunisation among uncensored clones at the end of the intervention period and up to the matching date, respectively.
		
		Setting and country: Public hospitals in Spain
			• Within the catch-up immunization cohort 50.5% (n=205) of cases and 83.7% (n=1,359) of controls received nirsevimab Within the at-birth immunization cohort 73.1% (n=n=399) of cases and 93.4% (n=2,039) of controls received nirsevimab	• Effectiveness of nirsevimab against RSV-LRTI hospitalization by PP analysis:
				  ○ Catch-up immunization: 80.3% (95% CI: 75.3-84.4)
				  ○ At-birth immunization: 83.1% (95% CI: 78.5-86.8)
				• Effectiveness of nirsevimab against RSV-LRTI hospitalization by pragmatic analysis:
				  ○ Catch-up immunization: 87.5% (95% CI: 83.1-90.8)
				• At-birth immunization: 85.5% (95% CI: 80.5-89.2)

Mallah 2025 (70)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Nirsevimab effectiveness
	• RSV related outcome
	  ○ Hospitalization
	  ○ Severe LRTD
	  ○ Lower respiratory tract infection
	• Timeframe (Specimens collected timepoints)
	  ○ Baseline (September 25, 2023 to April 15, 2024)
		Type of publication: Correspondence
		
		Study design: Population-based longitudinal study
		
		Analysis: Vaccine effectiveness was estimated with Cox proportional hazard regression models adjusted for sex and health district area.
		
		Setting and country: Galicia, Spain
			• Effectiveness outcomes included only data from the catch-up cohort of 7,062 infants age 0 to 24 months old born between April 1 to September 24, 2023
			• 88.5% (n=6,249) of infants in the catch-up cohort had received nirsevimab
				• Nirsevimab effectiveness against RSV-LRTI hospitalization: 70.7% (95% CI: 42.4-85.1)
				• Nirsevimab effectiveness against RSV-LRTI hospitalization with oxygen support: 80.3% (95% CI: 54.6-91.5)

Lenglart 2025 (71)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
		Type of publication: Peer-reviewed
		
		Study design: Test-negative study
			• 383 infants younger than one year were included; 274 were RSV-positive
			• 9.8% (n=27) of RSV-positive patients and 46.2% (n=50) of RSV-
				• Nirsevimab effectiveness against RSV-bronchiolitis in PEDs: 82.5% (95% CI: 68.0-90.8)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (Type of publication, Vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Antigen
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Nirsevimab effectiveness
	• RSV related outcome
	  ○ Hospitalization
	  ○ ED visits
	  ○ Bronchiolitis
	• Timeframe (Specimens collected timepoints)
	  ○ Baseline (October 1, 2023 to February 29, 2024)
		Analysis: A multivariate logistic regression model adjusted for sex, age, underlying chronic disease, prematurity, type of childcare, month and centre of inclusion was used. Vaccine effectiveness was calculated as 100 x (1 – adjusted odds ratio).
		
		Setting and country: Pediatric emergency department (PED) of five university hospitals, France
			negative patients had received nirsevimab	• Nirsevimab effectiveness against hospitalization for RSV-bronchiolitis: 80.5% (95% CI: 60.5-90.3)

Appendix 3: Summary of studies reporting on the efficacy of RSV immunization products

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (type of publication, vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

Curran 2024 (72)	• Population studied
	  ○ Older adults (aged ≥60 years)
	• Type of immunization product
	  ○ AREXVY™ (RSVPreF3 OA)
	• Comparator
	  ○ Individuals receiving placebo
	• Testing
	  ○ Nucleic acid testing RT-PCR
	• Outcome measures
	  ○ Nirsevimab efficacy
	• RSV-related outcome
	  ○ Infection
	  ○ Lower respiratory tract disease (LRTD)
	  ○ Medically attended LRTD
	  ○ Acute respiratory infection (ARI)
	  ○ Hospitalization
	• Timeframe (specimens collected timepoints)
	  ○ One RSV season
		Type of publication: Peer reviewed
		
		Study design: Observer blind, multi-country, randomized trial
		
		Analysis: Vaccine efficacy (VE) was estimated using the conditional exact binomial method based on the Poisson model
		
		Setting and country: Not reported
			• 24,960 adults over the age of 60 were included in the analysis; participants were randomized to receive placebo (n = 12,494) or the vaccine (RSVPreF3 OA) (n = 12,466)	• VE against RSV-confirmed ARI with medically attended visits was 79.0% (95% CI 54.3–91.5)
				• VE against RSV-confirmed LRTD with medically attended visits: 87.5% (95% CI 58.9–97.6)

Walsh 2023 (73)	• Population studied
	  ○ Older adults (aged ≥60 years)
	• Type of immunization product
	  ○ ABRYSVO™ (RSVpreF) by Pfizer
	• Comparator
	  ○ Individuals receiving placebo
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ RSVpreF efficacy
	• RSV-related outcome
	  ○ Lower respiratory tract illness (LRTI)
	• Timeframe (specimens collected timepoints)
	  ○ Baseline (31 August 2021 to 14 July 2022)
		Type of publication: Peer reviewed
		
		Study design: Phase three, multinational, double-blinded, randomized, placebo-controlled trial
		
		Analysis: Used a risk ratio-based approach to calculate vaccine efficacy, comparing the incidence of RSV-associated LRTI and acute respiratory illness between the vaccine and placebo groups, with confidence intervals calculated using a conditional exact test adjusted for interim analysis using Pocock error spending
		
		Setting and country:
		240 sites located in Argentina, Canada, Finland, Japan, the
			• 34,284 participants received one intramuscular 120 ug dose of RSVpreF (n = 17,215) or placebo (n = 17,069)	• The authors reported on the efficacy against RSV-associated LRTI based on signs and symptoms and overall
				  ○ RSVpreF efficacy against RSV-associated LRTI with two signs or symptoms: 66.7% (96.66% CI 28.8–85.8)
				  ○ RSVpreF efficacy against RSV-associated LRTI with three signs or symptoms: 85.7% (96.66% CI 32.0–98.7)
				  ○ RSVpreF efficacy against RSV-associated ARI: 62.1% (95% CI 37.1–77.9)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (type of publication, vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
		Netherlands, South Africa, and the United States		
Kampmann 2023 (74)	• Population studied ○ Children (0 to 2 years old) • Type of immunization product ○ Maternal ABRYSVO™ (RSVpreF) by Pfizer • Comparator ○ Individuals receiving placebo • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ RSVpreF efficacy • RSV-related outcome ○ Medically attended severe RSV-associated LRTI ○ Medically attended RSV-associated LRTI ○ Hospitalization ○ All-cause medically attended lower respiratory illness • Timeframe (specimens collected timepoints) ○ Baseline (17 June 2020 to 2 October 2022) ○ Followed up (from 72 hours to 1 or 2 years after birth)	Type of publication: Peer reviewed Study design: Phase three, multinational, randomized, placebo-controlled trial Analysis: Binominal distribution of the number of cases of disease in the RSV vaccine group and given the total number of cases in both groups, with adjusted confidence intervals to account for interim analyses and multiple endpoints, while also employing sensitivity analyses and subgroup assessments for comprehensive evaluation of the vaccine's effects Setting and country: Multicentre, 18 countries (Argentina, Australia, Brazil, Canada, Chile, Denmark, Finland, Gambia, Japan, Mexico, the Netherlands, New Zealand, Philippines, South Korea, South Africa, Spain, Taiwan, and the United States)	• The study randomized 7,358 pregnant women at 24–36 weeks' gestation who received a single 120 µg intramuscular injection of bivalent RSVpreF vaccine (n = 3,682) or placebo (n = 3,676) • 3,570 infants whose mothers received RSVpreF and 3,558 infants whose mothers received placebo were included	• VE against medically attended severe RSV-associated LRTI ○ Within 90 days after birth: 81.8% (99.5% CI 40.6–96.3) ○ Within 120 days after birth: 73.9% (97.58% CI 45.6–88.8) ○ Within 150 days after birth: 70.9% (97.58% CI 44.5–85.9) ○ Within 180 days: 69.4% (97.58% CI 44.3–84.1) • VE against medically attended RSV-associated LRTI ○ Within 90 days after birth: 57.1% (99.5% C 14.7–79.8) ○ Within 120 days after birth: 56.8% (97.58% C 31.2–73.5) ○ Within 150 days after birth: 52.5% (97.58% C 28.7–68.9) ○ Within 180 days after birth: 51.3 (97.58% C 29.4–66.8) • VE against RSV-associated hospitalization: ○ Within 90 days after birth: 67.7% (99.17% CI 15.9–89.5) ○ Within 180 days after birth: 56.8% (99.17% CI 10.1–80.7) • VE against medically attended RSV-associated respiratory tract illness (exploratory analysis): ○ Within 90 days after birth: 39.1% (95% CI 16.7–55.7) ○ Within 180 days after birth: 37.9% (95% CI 24.0–49.5) • VE against medically attended LRTI from any cause: ○ Within 90 days after birth: 7.0% (99.17% CI −22.3–29.3)
Papi 2023 (75)	• Population studied ○ Older adults (aged ≥60 years)	Type of publication: Peer reviewed	• The trial included 24,966 adults aged 60 years or older (mean age 69.5	• VE against LRTD: 82.6% (96.95% CI 57.9–94.1)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (type of publication, vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

	• Type of immunization product
	  ○ AREXVY™ (RSVPreF3-OA) by GlaxoSmithKline
	• Comparator
	  ○ Individuals receiving placebo
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ RSVPreF3-OA efficacy
	• RSV-related outcome
	  ○ LRTD
	  ○ Acute respiratory infection (ARI)
	  ○ Severe LRTD
	• Timeframe (specimens collected timepoints)
	  ○ Enrollment between 25 May 2021 to 31 January 2022
	  ○ Maximum follow-up 10.1 months
		Study design: Phase three, multinational, randomized, placebo-controlled trial
		
		Analysis: One minus the relative risk with the use of the conditional exact binomial method based on the Poisson model
		
		Setting and country: Multinational including 17 countries in Africa, Asia, Australia, Europe and North America
			years), with approximately 39% having coexisting conditions associated with increased risk of severe RSV disease
			• Participants were randomly assigned in a 1:1 ratio to receive either a single 0.5 ml dose of the RSVPreF3 OA vaccine (containing 120 µg of RSVPreF3 antigen and the AS01E adjuvant system) (n = 12,467) or placebo (n = 12,499), injected into the deltoid muscle of the non-dominant arm before the RSV season
				• VE against severe LRTD: 94.1% (95% CI 62.4–99.9)
				• VE against RSV-related ARI: 71.7% (95% CI 56.2–82.3)
				• VE against RSV-LRTD by RSV subtype:
				  ○ RSV A: 84.6% (95% CI 32.1–98.3)
				  ○ RSV B: 80.9% (95% CI 49.4–94.3)
				• VE against RSV-ARI by RSV subtype:
				  ○ RSV A-related: 71.9% (95% CI 39.7–88.2)
				  ○ RSV B: 70.6% (95% CI 49.6- 83.7)
				• VE against RSV-LRTD by age group:
				  ○ 60-69 years: 81.0% (95% CI 43.6–95.3)
				  ○ 70-79 years: 93.8% (95% CI 60.2–99.9)
				  ○ ≥70 years: 84.4% (95% CI, 46.9–97.0)
				  ○ ≥80 years: 33.8% (95% CI –477.7–94.5)
				• VE against RSV-LRTD by baseline characteristics:
				  ○ With coexisting conditions: 94.6% (95% CI 65.9–99.9)
				  ○ Prefrail: 92.9% (95% CI 53.4–99.8)
				  ○ Fit: 80.0% (95% CI 46.7–94.0)

Simões 2023 (76)	• Population studied
	  ○ Infants born preterm (≥29 to <35 weeks gestational age)
	  ○ healthy infants born at term or late preterm (≥35 weeks gestational age)
	• Type of immunization product
	  ○ Anti-RSV monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Individuals receiving placebo
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Nirsevimab efficacy
	• RSV-related outcome
		Type of publication: Peer reviewed
		
		Study design: Double-blind, randomised, placebo-controlled controlled trials
		
		Analysis: VE was estimated in the intention-to-treat population using a Poisson regression model with robust variance adjusted for age and location and multiple imputation; a pre-specified subgroup analysis assessed data by hemisphere, age at randomisation, sex, ancestry or ethnic group, weight at baseline,
			• The study included 2,350 infants (1,564 receiving nirsevimab, 786 receiving placebo), with gestational ages ranging from 29 weeks to full term, and a median age of 2 months at randomization
			• Nirsevimab was administered as a single intramuscular injection before the RSV season, with weight-based dosing of 50 mg for infants <5 kg and 100 mg for infants ≥5 kg, compared to placebo
				• Nirsevimab efficacy (Relative Risk Reduction, RRR) against medically attended RST-LRTI: 79.5% (95% CI 65.9–87.7)
				• Nirsevimab efficacy against hospital admission for medically attended RST-LRTI: 77.3% (95% CI 50.3–89.7)
				• Nirsevimab efficacy against very severe RST-LRTI: 86.0% (95% CI 62.5–94.8)
				• Nirsevimab efficacy against medically attended LRTI of any cause: 35.4% (95% CI 21.5–46.9)
				• Nirsevimab efficacy against hospital admission for respiratory illness of any cause: 43.8% (95% CI 18.8–61.1)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (type of publication, vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Medically attended RSV lower respiratory tract infection (LRTI) ○ Hospital admission • Timeframe (specimens collected timepoints) ○ Follow-up (infants were followed up for 150 days post-dose)	country, and geographical region; post-hoc exploratory endpoints of health resource use, outpatient visits, and antibiotic use were also assessed. Setting and country: Multinational • Phase 2b trial: 164 sites across 23 countries in Europe, North America, South America, and Australasia • MELODY primary cohort: 160 sites across 21 countries in Europe, North America, Asia, South Africa • MEDLEY: 126 sites across 25 countries in Europe, North America, Asia, and South Africa		• Reduction in outpatient visits for LRTI: 41.9% (95% CI 25.7–54.6)
Drysdale 2023 (77)	• Population studied ○ Children (0 to 12 months old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Diagnostic testing using a test designated by hospital policy • Outcome measures ○ Nirsevimab efficacy • RSV-related outcome ○ Hospitalization ○ LRTI ○ Severe RSV-LRTI ○ Hospitalization from all-cause LRTI • Timeframe (specimens collected timepoints) ○ Baseline (8 August 2022 to 28 February 2023) ○ Follow-up (6 months, with intention to follow-up again on day 366)	Type of publication: Peer reviewed Study design: Phase 3b, open-label, two-group, randomized trial Analysis: A time-to-first event analysis and Cox proportional-hazard regression model was used adjusted for age group and country; P values and Bonferroni corrections were calculated for primary and secondary endpoints Setting and country: 235 sites in France, Germany, and the United Kingdom	• Healthy infants 12 months or younger, born at gestational age ≥29 weeks who were entering their first RSV season, were invited to participate • A total of 8,058 infants participated in this study (4,037 vaccinated, 4,021 standard care) • Infants were randomized to receive the nirsevimab vaccine or standard care ○ Doses were 50 mg for children weighing less than 5 kg or 100 mg for children weighing over 5 kg	• Nirsevimab efficacy against RSV-LRTI hospitalization: 83.2% (95% CI 67.8–92.0) ○ By age at randomization: ▪ ≤3 months: 89.6% (95% CI 73.8–96.8) ▪ >3 to 6 months: 58.7% (95% CI –47.9–90.7) ▪ >6 months: 76.5% (95% CI –17.9–97.6) ○ By weight at randomization: ▪ <5 kg: 82.1% (95% CI 59.1–93.3) ▪ ≥5 kg: 85.2% (95% CI 57.0–96.2) ○ By gestational age: ▪ <37 weeks: 78.3% (95% CI 33.5–94.7) ▪ ≥37 weeks: 84.4% (95% CI 64.9–94.1) ○ By sex: ▪ Male: 82.4% (95% CI 60.0–93.4)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (type of publication, vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
				▪ Female: 84.4% (95% CI 54.2–96.1) ○ By timing of randomization: ▪ During the RSV season: 83.0% (95% CI 67.3–91.9) • Nirsevimab efficacy against severe RSV-LRTI: 75.7% (95% CI 32.8–92.9) • The vaccinated group showed superior efficacy to standard care 75.4% (95% CI 34.0–90.8) • Nirsevimab efficacy against hospitalization for RSV-LRTI by country: ○ France: 89.6% (95% CI 58.8–98.7) ○ Germany: 74.2% (95% CI 27.9–92.5) ○ United Kingdom: 83.4% (95% CI 34.3–97.6) • The efficacy of standard care against hospitalization for RSV-LRTI by country: ○ France: 89.4% (95% CI 54.1–97.5) ○ Germany: 74.2% (95% CI 30.6–90.4) ○ United Kingdom: 83.5% (95% CI 32.9–96.0) • VE against all-cause-LRTI hospitalization: 58.0% (95% CI 39.7–71.2)
Ison 2024 (78)	• Population studied ○ Older adults (aged ≥60 years) • Type of immunization product ○ AREXVY™ (RSVPreF3 OA) by GlaxoSmithKline • Comparator ○ Individuals receiving placebo • Testing ○ Quantitative RT-PCR • Outcome measures ○ RSVPreF3 efficacy • RSV-related outcome ○ LRTD ○ Medically attended LRTD ○ Severe LRTD ○ Acute respiratory infection	Type of publication: Peer reviewed Study design: Randomized, placebo-controlled trial Analysis: This study uses the conditional exact binomial method based on a Poisson model to estimate over the course of two seasons the efficacy of 1 RSVPreF3 OA dose followed by revaccination a year later against RSV-associated LRTD, severe RSV-LRTD, and RSV-associated acute respiratory infection (ARI) in adults ≥60 years old; season, age, and region were covariates in	• Season one the study included 24,973 participants; 12,470 received RSVPreF3 OA and 12,503 received placebo • In season two 19,990 of the original participants were included; 4,966 (24.8%) were revaccinated, 4,991 (25.0%) received a placebo as their second dose (but had previously received the first vaccine dose), and 10,033 (50.2%) received their second placebo dose • Administration of RSVPreF3 OA or a placebo over the course of two seasons; this resulted in three interventions: RSV_revaccination	• RSVPreF3 efficacy of one dose of RSVPreF3 OA over two seasons: ○ 67.2% (97.5 % CI 48.2–80.0) against RSV-LRTD ○ 78.8% (95% CI 52.6–92.0) against severe RSV-LRTD ○ 52.7% (95% CI 40.0–63.0) against RSV-ARI ○ 73.1% (95% CI 49.4–86.9) against medically attended RSV-LRTD ○ 52.0% (95% CI 27.3–69.1) against medically attended RSV-ARI • RSVPreF3 efficacy of one dose of RSVPreF3 OA over two seasons against RSV-LRTD by virus subtype: ○ 80.5% (95% CI 54.0–93.2) for RSV-A

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (type of publication, vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	• Timeframe (specimens collected timepoints) ○ April 2022 to 31 March 2023 ○ Follow up (two RSV seasons, median follow-up of 17.8 months)	the model; secondary analyses were performed for efficacy based on RSV subtype, season, year, age, comorbidities, and frailty Setting and country: 17 countries (Belgium, Canada, Estonia, Finland, Germany, Italy, Japan, Mexico, Poland, South Korea, Russian Federation, Spain, United Kingdom, United States, Australia, New Zealand, and South Africa)	group with two doses of the vaccine; RSV_1dose group with one dose of the vaccine followed by one placebo; and the placebo group that received two placebo doses.	○ 59.7% (95% CI 35.8–75.5) for RSV-B • RSVPreF3 efficacy of one dose of RSVPreF3 OA over two seasons against RSV-LRTD by age group: ○ 60–69 years: 65.4% (95% CI 40.4–80.9) ○ 70–79 years: 74.9% (95% CI 48.4–89.2) ○ ≥70 years: 69.3% (95% CI 43.4–84.6) ○ ≥80 years: 38.4% (95% CI –118.2–86.1) • RSVPreF3 efficacy of one dose of RSVPreF3 OA by presence of coexisting conditions (for RSV-LRTD over 2 seasons): ○ ≥1 coexisting condition: 66.7% (95% CI 41.8–82.0) ○ ≥1 cardiorespiratory condition: 73.8% (95% CI 47.9–88.2) ○ ≥1 endocrine or metabolic condition: 63.1% (95% CI 17.4–85.4) • RSVPreF3 efficacy of one dose of RSVPreF3 OA over two seasons against RSV-LRTD among: ○ Pre–frail participants: 73.3% (95% CI 42.4–89.2) ○ Fit participants: 66.2% (95% CI 44.3–80.4) • VE of one dose of RSVPreF3 OA against RSV-LRTD: ○ Over one season (6.7 months median follow-up): 82.6% (95% CI 57.9–94.1) ○ Over one year: 78.9% (95% CI 57.6–90.5) ○ until mid-season 2 (13.9 months median follow-up): 77.3% (95% CI 60.2–87.9) ○ Over 2 seasons (17.8 months median follow-up): 67.2% (95% CI 48.2–80.0)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (type of publication, vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

				• Over season two only, VE of one dose of RSVPReF3 OA:
				  ○ Against RSV-LRTD: 56.1% (95% CI 28.2–74.4)
				  ○ Against severe RSV-LRTD: 64.2% (95% CI 6.2–89.2)
				  ○ Against RSV-ARI: 40.6% (95% CI 19.0–57.0)
				  ○ RSV-A: 76.4% (95% CI 33.8–93.9)
				  ○ RSV-B: 43.9% (95% CI 1.0–69.9)
				  ○ Age ≥70 years: 62.1% (95% CI 18.4–84.6)
				  ○ Age 60–69 years: 50.9% (95% CI 6.1–76.3)
				  ○ Age 70–79 years: 66.2% (95% CI 18.9–88.3)
				  ○ ≥1 co-existing condition: 51.5% (95% CI 7.4–76.6)
				  ○ ≥1 cardiorespiratory condition: 66.5% (95% CI 24.2–87.4)
				
				RSVPreF3-Mat efficacy of RSV (revaccination regimen)
				• The VE of two doses of RSVPreF3 OA (second dose is given one year following the first dose) over two seasons:
				  ○ Against RSV-LRTD: 67.1% (97.5% CI 48.1–80.0)
				  ○ Against severe RSV-LRTD: 78.8% (95% CI 52.5–92.0)
				  ○ Against RSV-ARI: 60.3% (95% CI 48.8–69.5)
				• RSVPreF3-Mat efficacy of two doses of RSVPreF3 OA over two seasons against RSV-LRTD by virus subtype was:
				  ○ 55.9% (95% CI 16.8–78.2) for RSV-A
				  ○ 72.1% (95% CI 52.5–84.5) for RSV-B
				• RSVPreF3-Mat efficacy of two doses of RSVPreF3 OA over two seasons against RSV-LRTD by age group:
				  ○ 60–69 years: 71.6% (95% CI 48.9–85.2)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (type of publication, vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
				○ 70–79 years: 66.2% (95% CI 35.7–83.6) ○ ≥70 years: 61.9% (95% CI 33.0–79.6) ○ ≥80 years: 38.6% (95% CI –117.2–86.2) • RSVPreF3-Mat efficacy of two doses of RSVPreF3 OA over two seasons against RSV-LRTD by co-existing conditions ○ ≥1 condition: 75.1% (95% CI 53.6–87.8) ○ ≥1 cardiorespiratory condition: 81.3% (95% CI 58.6–92.9) ○ ≥1 endocrine or metabolic condition: 67.5% (95% CI 24.2–88.0) • RSVPreF3-Mat efficacy of two doses of RSVPreF3 OA over two seasons against RSV-LRTD by frailty status: ○ Pre-frail participants: 77.3% (95% CI 49.1–91.4) ○ Fit participants: 62.2% (95% CI 38.8–77.5) • Over season two only, VE of two doses of RSVPReF3 OA: ○ 55.9% (95% CI 27.9–74.3) against RSV-LRTD ○ 64.1% (95% CI 5.9–89.2) against severe RSV-LRTD ○ 55.8% (95% CI 37.5–69.5) against RSV-ARI
Griffin 2020 (79)	• Population studied ○ Children (0 to one year old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Individuals receiving placebo • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Nirsevimab efficacy	Type of publication: Peer reviewed Study design: Randomized, placebo-controlled trial Analysis: This study uses a Poisson regression model to evaluate nirsevimab against RSV-associated medically attended LRTI and RSV-associated hospitalization in infants ≤1 year old who were born preterm (gestational age at birth of 29 weeks	• 1,453 infants ≤1 year old included; 969 (66.7%) received nirsevimab, 484 (33%) received placebo • Administration of nirsevimab, a long-acting monoclonal antibody against RSV	• Nirsevimab efficacy against medically attended RSV-associated lower respiratory tract infection: 70.1% (95% CI 52.3–81.2) • Nirsevimab efficacy against hospitalization for RSV-associated lower respiratory tract infection: 78.4% (95% CI 51.9–90.3) • Nirsevimab efficacy against all-cause medically attended lower respiratory tract infection: 23.5% (95% CI 7.1–37.0)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (type of publication, vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

	• RSV-related outcome
	  ○ Hospitalization
	  ○ Medically attended LRTI
	• Timeframe (specimens collected timepoints)
	  ○ Baseline (November 2016 to November 2017)
	  ○ Follow-up (days 8, 31, 91, 151, and 361 after receiving nirsevimab/placebo)
		0 days to 34 weeks 6 days); a Cochran-Mantel-Haenszel test and Kaplan-Meier curves were used for secondary analyses; subgroup analyses were performed for efficacy based on hemisphere, age, sex, race, gestational age, and siblings (twins/triplets)
		
		Setting and country: 164 sites in 23 countries (Argentina, Australia, Belgium, Brazil, Bulgaria, Canada, Chile, Czech Republic, Estonia, Finland, France, Hungary, Italy, Latvia, Lithuania, New Zealand, Poland, South Africa, Spain, Sweden, Turkey, United Kingdom, United States)
				• Nirsevimab efficacy against all-cause respiratory-related hospitalization: 42.5% (95% CI 16.3–60.5)
				• Nirsevimab efficacy against medically attended RSV-associated lower respiratory tract infection through 150 days post-dose:
				  ○ Hemisphere:
				  ▪ Northern: 76.0% (95% CI 52.9–87.1)
				  ▪ Southern: 69.0% (95% CI 39.9–84.1)
				  ○ Age at randomization:
				  ▪ ≤3 months: 84.2% (95% CI 51.9–87.3)
				  ▪ 3 to ≤6 months: 61.2% (95% CI 21.3–80.8)
				  ▪ >6 months: 65.2% (95% CI -2.5–88.2)
				  ○ Sex:
				  ▪ Female: 82.1% (95% CI 62.0–91.5)
				  ▪ Male: 62.3% (95% CI 29.4–79.8)
				  ○ Race:
				  ▪ Caucasian: 71.7 % (95% CI 52.5–83.1)
				  ▪ Non-Caucasian: 76.5% (95% CI 23.5–92.8)
				  ○ Gestational age:
				  ▪ ≥29 to ≤32 weeks: 75.7% (95% CI 49.5–88.3)
				  ▪ >32 weeks: 70.4% (95% CI 44.7–84.2)
				  ○ Sibling enrolled in study:
				  ▪ Yes: 74.4% (95% CI 33.0–90.2)
				  ▪ No: 72.5% (95% CI 52.5–84.0)

Otsuki 2024 (80)	• Population studied
	  ○ Children (0 to two years old)
	• Type of immunization product
	  ○ Maternal ABRYSVO™ (RSVpreF) by Pfizer
		Type of publication: Peer reviewed
		
		Study design: Randomized controlled trial
			• 462 maternal participants ≤49 years old at 24–36 weeks' gestation were vaccinated with RSVpreF (n = 230) or placebo (n = 232)	• VE against RSV-associated medically attended lower respiratory tract infection (RSV-MA-LRTI):
				  ○ Within 90 days after birth: 100.0% (95% CI 30.9–100.0)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (type of publication, vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

	• Comparator
	  ○ Individuals receiving placebo
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ RSVpreF efficacy
	• RSV-related outcome
	  ○ Medically attended LRTI
	  ○ Hospitalization
	  ○ Severe LRTI
	• Timeframe (specimens collected timepoints)
	  ○ Baseline (12 November 2020 to 2 September 2022)
	  ○ Follow-up (weekly up to 6 months after birth, then monthly up to 12 or 24 months after birth)
		Analysis: VE of maternal RSVpreF against medically attended RSV-LRTI (RSV-MA-LRTI), severe RSV-MA-LRTI, RSV-associated hospitalization, and all-cause medically attended LRTI (MA-LRTI) in infants was calculated using the equation 1-(hP/[1-P])
		
		Setting and country: Japan
			• 434 infants were followed after birth (218 were born to mothers who received RSVpreF, 216 were born to mothers who received placebo) until 12 or 24 months old
			• Maternal administration of RSVpreF
				○ Within 120/150/180/210/240/270 days after birth: 87.6% (95% CI 7.2–99.7)
				○ Within 360 days after birth: 75.1% (95% CI –24.7–97.4)
				• VE against severe RSV-MA-LRTI:
				○ Within 90 days after birth: 100.0% (95% CI –140.9–100.0)
				○ Within 120/150/180 days after birth: 75.1% (95% CI –151.5–99.5)
				• VE against RSV-associated hospitalization:
				○ Within 90 days after birth: 100.0% (95% CI –8.6–100.0)
				○ Within 120/150/180/360 days after birth: 80.1% (95% CI –77.9–99.6)
				• VE against all-cause MA-LRTI:
				○ 53.6% (95% CI –21.0–84.0) within 90 days after birth
				○ 16.2% (95% CI –72.1–59.7) within 120 days after birth
				○ 0.5% (95% CI –91.5–48.3) within 150 days after birth
				○ 4.3% (95% CI –72.4–47.0) within 180 days after birth
				○ 25.4% (95% CI –26.4–56.4) within 360 days after birth

Schmoele-Thoma 2022 (81)	• Population studied
	  ○ Adults (aged 18 to 50 years)
	• Type of immunization product
	  ○ ABRYSVO™ (RSVpreF) by Pfizer
	• Comparator
	  ○ Individuals receiving placebo
	• Testing
	  ○ Reverse-transcriptase – quantitative polymerase-chain-reaction (RT-qPCR)
	• Outcome measures
	  ○ RSVpreF efficacy
	• RSV-related outcome
	  ○ Infection
	• Timeframe (specimens collected timepoints)
		Type of publication: Peer reviewed
		
		Study design: Phase 2a, single-centre, randomized, double-blind, exploratory study
		
		Analysis: VE against RSV infection was estimated using the equation (1 – incidence rate ratio) x 100% using the intention to treat population
		
		Setting and country: Not reported
			• 70 participants were randomized to receive the RSVpreF vaccine (n = 35) or placebo (n = 35)
			• 62 participants (31 in each group) were challenged with the RSV A Memphis 37b preparation
			• 60 participants completed the full 12-day observation
				• VE against symptomatic RSV infection confirmed by viral detection on two consecutive days: 86.7% (95% CI 53.8–96.5)
				• VE against symptomatic RSV infection confirmed by two quantifiable RT-qPCR results on ≥2 consecutive days: 100.0% (95% CI 72.8–100.0)
				• VE against culture-confirmed symptomatic RSV infection: 100.0% (95% CI 67.7–100.0)
				• VE against RSV infection regardless of symptom:

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (type of publication, vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ Follow-up (days 1–12, 28, and 155 post-challenge)			○ With RT-qPCR results on ≥2 consecutive days: 75.0% (95% CI 38.4–90.6) ○ With a quantifiable culture-confirmed infection: 100.0% (95% CI 72.8–100.0)
Walsh 2024 (82)	• Population studied ○ Older adults (aged ≥60 years) • Type of immunization product ○ ABRYSVO™ (RSVpreF) by Pfizer • Comparator ○ Individuals receiving placebo • Testing ○ Quantitative RT-PCR • Outcome measures ○ RSVpreF efficacy • RSV-related outcome ○ LRTD ○ Acute respiratory infection • Timeframe (specimens collected timepoints) ○ Follow-up (days 2, 3, 7, and 15 and 1 month post-injection)	Type of publication: Letter to the editor Study design: International phase 3, double-blind, randomized, placebo-controlled trial Analysis: VE was calculated using case count ratio, calculated as 1 – (P/[1–P]), where P is the number of RSVpreF cases divided by the total number of cases; cases in season 1 and season 2 were pooled to estimate the VE across both seasons Setting and country: 240 sites across Argentina, Canada, Finland, Japan, the Netherlands, South Africa, and the United States	• 18,050 participants (aged ≥60 years) were at risk in the RSVpreF group at the end of season 1 • 16,164 participants were at risk in the RSVpreF group at the end of season 2 • Across both seasons, 18,050 participants in the RSVpreF group were at risk at some point • 18,074 participants (aged ≥60 years) were at risk in the placebo group at the end of season 1 • 16,059 participants in the placebo group remained at risk at the end of season 2 • Across both seasons, 18,074 participants in the placebo group were at risk at some point	• VE of RSVpreF vaccine across seasons one and two combined ○ RST-LRTI ≥3 symptoms: 81.5% (95% CI 63.3–91.6) ○ RST-LRTI ≥2 symptoms: 58.8% (95% CI 43.0–70.6) ○ RSV-associated acute respiratory illness (ARI): 44.3% (95% CI 33.2–53.7) • VE of RSVpreF vaccine end of season one ○ RST-LRTI ≥3 symptoms: 88.9% (95% CI 53.6–98.7) ○ RST-LRTI ≥2 symptoms: 65.1% (95% CI 35.9–82.0) ○ RSV-associated ARI: 62.2% (95% CI 44.4–74.9) • VE of RSVpreF vaccine end of season two ○ RST-LRTI ≥3 symptoms: 77.8% (95% CI 51.4–91.1) ○ RST-LRTI ≥2 symptoms: 55.7% (95% CI 34.7–70.4) ○ RSV-associated ARI: 36.9% (95% CI 22.2–48.9) • VE of RSVpreF vaccine against RSV-A and RSV-B ○ RSV-A: 80.6% (95% CI 52.9%–93.4) ○ RSV-B: 86.4% (95% CI 54.6%–97.4)
Wilson 2023 (83)	• Population studied ○ Adults (age 60 years and older) • Type of immunization product ○ mRNA-1345 • Comparator ○ Individuals receiving placebo	Type of publication: Peer reviewed Study design: Randomized, double-blind, placebo-controlled, phase 2–3 trial	• 35,541 participants were randomized, where 17,793 participants were assigned to the mRNA-1345 group and 17,748 were assigned to the placebo group	• Efficacy against RSV-associated lower respiratory disease with at least two signs or symptoms: 83.7% (95.88% CI 66.0–92.2) • Efficacy against RSV-associated lower respiratory disease with at least three

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (type of publication, vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

	• Testing
	  ○ Reverse transcription polymerase chain reaction
	• Outcome measures
	  ○ mRNA-1345 efficacy
	• RSV-related outcome
	  ○ RSV-associated lower respiratory disease
	  ○ RSV-associated acute respiratory disease
	• Timeframe (specimens collected timepoints)
	  ○ 17 November 2021 to 31 October 2022
		Analysis: VE against RSV-associated lower respiratory disease was estimated using the equation (1 – hazard ratio) x 100%
		
		Setting and country: 22 countries (not reported in detail)
			• The mean age of the participants at enrollment was 68.1 years, 49.0% were women, 36.1% were non-White, and 34.5% were Hispanic or Latino
			• One or more coexisting conditions were reported by 29.3% of the participants, with 1.1% reporting a history of congestive heart failure and 5.5% reporting a history of chronic obstructive pulmonary disease (COPD)
			• A total of 21.9% of the participants were assessed as vulnerable or frail, as defined according to the Edmonton Frailty score
			• All participants who had undergone randomization completed at least one visit or surveillance contact 14 days after injection
				signs or symptoms: 82.4% (96.36% CI 34.8–95.4)
				• Efficacy against RSV-associated acute respiratory disease with at least two signs or symptoms: 68.4% (95% CI 50.9–79.7)

New studies included in 2026 January update				

Zar 2025 (84)	• Population studied
	  ○ Children (0 to two years old)
	• Type of immunization product
	  ○ Clerovismab
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine efficacy
	  ○ Relative risk
	• RSV related outcome
	  ○ RSV-associated medically attended lower respiratory infection
		Type of publication: Peer-reviewed
		Study design:
		Double-blind, randomized, placebo-controlled trial
		
		Analysis:
		Vaccine efficacy was calculated using Poisson regression with robust variance
		
		Efficacy was calculated as 1 minus the relative risk (as estimated with the Poisson model)
		
		Incidence rates were calculated as the number of cases during the follow-up period divided by the total follow-up time, multiplied by the month rate
			• A total of 3614 infants under the age of one were included in this study; 2412 in the Clesrovimab group and 1202 in the placebo group
			• RSV infection was confirmed using reverse-transcriptase–polymerase-chain-reaction (RT-PCR) assay 7 or 12 days before symptom offset
				• VE against RSV-associated medically attended lower respiratory infection: 60.4% (95% CI 44.1–71.9)
				• VE against RSV-associated hospitalization: 84.2% (95% CI 66.6–92.6)
				• VE against RSV-associated medically attended lower respiratory infection that required at least one indicator of lower respiratory infection plus at least one indicator of disease severity: 88.0% (95% CI 76.1–94.0)
				• Through 180 days
				  • VE against RSV-associated severe medically attended lower respiratory infection: 91.7% (95% CI 62.9–98.1)
				  • VE against hospitalization for RSV-associated lower respiratory infection: 91.2% (95% CI 77.2–96.6)
				• Incidence rate of RSV- associated medically attended lower respiratory

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (type of publication, vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
		Setting and country: Argentina, Belgium, Canada, Chile, China, Colombia, Denmark, Finland, France, Italy, Japan, Korea, Malaysia, Mexico, Peru, Philippines, Poland, South Africa, Thailand, Turkiye, United Kingdom, United States		infection at 5-month period in the Clesrovimab: 5.5% (95% CI 4.1–7.1) • Incidence rate of RSV- associated medically attended lower respiratory infection at 5-month period in the placebo: 5.4% (96% CI 3.5–7.9)
Muller 2023 (85)	• Population studied ○ Children (0 to two years old) • Type of immunization product ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi • Comparator ○ Unvaccinated individuals • Testing ○ Other • Outcome measures ○ Vaccine efficacy ○ RSV related outcome ○ Hospitalization	Type of publication: Peer-reviewed Study design: Commentary Analysis: NA Setting and country: United States	• This commentary focused on infants who were term or late term • In all studies included in this commentary, participants were randomized assigned to receive either the Nirsevimab vaccine or a placebo	• RSV-associated LRTI infection in 1490 participants: 74.5% (95% CI 49.6–87.1) • Hospitalization for RSV-associated LRTI: 76.8% (95% CI 49.4–89.4) • Vaccine efficacy for severe medically attended RSV-associated LRTI: 78.6% (95% CI 48.4–91.0)
Feldman 2024 (79; 86)	• Population studied ○ Adults (aged ≥60 years) • Type of immunization product ○ RSVPreF3-OA vaccine • Comparator ○ Individuals receiving placebo • Testing ○ Reverse-transcriptase—quantitative polymerase-chain-reaction (RT-qPCR) • Outcome measures ○ Vaccine efficacy • RSV related outcome ○ Infection ○ Medically attended RSV-LRTI (respiratory syncytial virus lower respiratory tract infections) in the primary care setting • Timeframe (Specimens collected timepoints)	Type of publication: Peer-reviewed Study design: Phase 3, randomized, placebo-controlled trial Analysis: Vaccine efficacy was calculated as 1 minus the relative risk with the conditional exact binomial method based on a Poisson model Setting and country: 17 countries in Africa, Asia, Australia, Europe, and North America	• 26 664 adults aged ≥60 years old were enrolled in the trial, of whom 24 966 were part of the exposed population (12 467 received RSVPreF3 OA and 12 499 received placebo) • 39.6% (RSVPreF3 OA) and 38.9% (placebo) of participants had at least 1 of the coexisting medical conditions of interest (i.e., associated with severe RSV disease); 20.0% and 19.4% had at least 1 cardiorespiratory condition of interest, and 25.7% and 25.9% had at least 1 endocrine or metabolic condition of interest	• VE against RSV-LRTD: 82.6% (95% CI 57.9–94.1) • VE against RSV-ARI: 71.7% (95% CI 56.2–82.3)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (type of publication, vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome
	○ 1 October 2021 to 30 April 2022 (Northern hemisphere); 1 March 2022 to 30 September 2022 (Southern hemisphere)			
Ison 2025 (87)	• Population studied ○ Other • Type of immunization product ○ ABRYSVO™ (RSVpreF) by Pfizer • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR • Outcome measures ○ Vaccine efficacy ○ Incidence rate • RSV related outcome ○ Hospitalization ○ Lower respiratory tract disease • Timeframe (Specimens collected timepoints) ○ May 25, 2021, and Jan 31, 2022	Type of publication: Peer-reviewed Study design: Randomised, observer-blind, placebo-controlled, phase 3 trial Analysis: Cumulative efficacy was analyzed in RSV-related acute respiratory illness within 15 days post-dose one Efficacy was defined as 1 – the incidence rate ratio Setting and country: Africa, Asia, Oceania, Europe, and North America	• This study included participants 60 years across 275 centres in 17 countries • Participants were randomized to receive either the RSVPreF3 (n=12 468) OA or placebo (n=12 498)	• Cumulative vaccine efficacy across three RSV seasons against LRTD: 62.9% (97.5% CI 46.7–74.0) ○ Vaccine efficacy against RSV-LRTD due to RSV A: 69.8% (97.5% CI 42.2–85.7) ○ Vaccine efficacy against RSV-LRTD due to RSV B: 58.6% % (97.5% CI 35.9–74.1) • Cumulative vaccine efficacy across three RSV seasons against RSV-related acute respiratory illness: 51.1% (95% CI 40.3–60.2) • Cumulative vaccine efficacy across three RSV seasons against severe RSV-LRTD: 67.4% (95% CI 42.4–82.7) • Cumulative vaccine efficacy across three RSV seasons against medically attended RSV-LRTD: 70.2% (95% CI 50.1–83.1) • Cumulative vaccine efficacy of a single dose: 62 ○ Persons aged 60-69: 60.3% (95% CI 39.5–74.8) ○ Persons aged 70-79: 70.6% (95% CI 48.4–84.3) ○ Persons with pre-frail status: 70.1% (95% CI 43.9–85.3) ○ Pre-existing medical conditions:64.7% (95% CI 45.1-78.1)
Simoes 2025 (88)	• Population studied ○ Children (0 to two years old) • Type of immunization product ○ RSVpreF • Comparator ○ Unvaccinated individuals • Testing ○ Nucleic acid testing-RT-PCR	Type of publication: Peer-reviewed Study design: Phase 3, randomized, double-blinded, placebo-controlled trial Analysis:	• This study focused on 7420 healthy pregnant participants aged 49 years or younger, within the 24-36 week gestation period. Of these women, 7307 children were born and were explored for efficacy analysis. • From June 17, 2020, to October 27, 2022, pregnant women were randomly	• VE against severe RSV associated medically attended LRTI ○ VE against LRTI within 90-180 days of birth: 82.4% (95% CI 57.5–93.9) ○ VE against LRTI within 90 days of birth: 81.8% (99.5% CI 40.6–96.3) ○ VE against LRTI within 90 days of birth: 70% (95% CI 50.6–82.5)

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (type of publication, vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

	• Outcome measures
	  ○ Vaccine efficacy
	  ○ Relative risk
	• RSV related outcome
	  ○ Lower respiratory tract disease (LRTD)
	  ○ Hospitalization
	• Timeframe (Specimens collected timepoints)
	  ○ June 17, 2020, to October 27, 2022
		Vaccine efficacy was analyzed using relative risk ratio
		
		Setting and country: Hospitals, United States
			assigned to receive either the RSVpreF vaccine or a placebo	• VE against RSV associated medically attended LRTI
				  ○ VE against LRTI within 90-180 days of birth: 57.6% (95% CI 31.3–74.6)
				• VE against RSV associated hospitalization
				  ○ VE against hospitalization within 90 days of birth: 69.7% (95% CI 37.1–86.7)
				  ○ VE against hospitalization within 180 days of birth: 55.3% (95% CI 23.8–74.6)

Munro, 2025 (89)	• Population studied
	  ○ Children (0 to two years old)
	• Type of vaccine
	  ○ ABRYSVO™ (RSVpreF) by Pfizer
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine efficacy
	• RSV related outcome
	  ○ Hospitalizations
	• Timeframe (Specimens collected timepoints)
	  ○ Enrolment: August 8, 2022 to February 28, 2023
	  ○ Follow-up: 180 days post-randomization (efficacy)
		Type of Publication: Peer-reviewed
		
		Study design: Multicentre, open-label, parallel-group, randomized controlled phase 3b trial (HARMONIE trial)
		
		Analysis: Nirsevimab efficacy was defined as (1 − incidence rate ratio) × 100%, using exact binomial methods accounting for follow-up time. Kaplan–Meier analyses and log-rank tests stratified by country and age group were performed to compare time to first RSV hospitalization. Subgroup analyses were conducted by age at randomization, weight, and timing of dosing (before vs during RSV season).
		
		Setting and country: France, Germany, United Kingdom
			• The study included 8,057 infants aged ≤12 months who were born at ≥29 weeks' gestation, entering their first RSV season, and not eligible for palivizumab. Of these, 4,038 (50.1%) were randomized to receive nirsevimab and 4,019 (49.9%) to standard care. The median age at randomization was 4.0 months (IQR 1–7 months), 52.1% were male, 85.2% were born at ≥37 weeks' gestation, and 27% had at least one baseline medical condition.
			• Intervention used was Nirsevimab, a singular dose of either 50 mg for infants <5 kg or 100 mg for infants ≥5 kg
				• Efficacy against RSV-associated lower respiratory tract (less than 3 months): 90.3% (95% CI 75.2–96.98)
				  ○ 3 – 6 months: 60.69% (95% CI: -36.27–91.0)
				  ○ Greater than 6 months: 62.83% (-54.88–93.65)

Arbetter 2025 (90)	• Population studied
	  ○ Children (0 to two years old)
	• Type of immunization product
	  ○ Monoclonal antibody BEYFORTUS™ (nirsevimab) by Sanofi
	• Comparator
	  ○ Unvaccinated individuals
		Type of publication: Peer-reviewed
		
		Study design:
		Randomized clinical trial
		
		Analysis:
		Incidence rates were calculated using a pre-determined formula
			• A total of 3012 infants were randomized to receive the Nirsevimab vaccine (n = 2009) or placebo (n = 1003)
			• Participants who received medical attention for a respiratory illness received a nasopharyngeal swab within two days of a healthcare
				• RSV infections detection: 193 of 852 swabs (22.7%)
				• RSV severity was similar in placebo and intervention groups: P = .949

Reference (author year) with URL	Clinical trial characteristics	Study characteristics (type of publication, vaccine effectiveness analysis methods, setting and country)	Sample description and intervention	Summary of key findings in relation to the outcome

	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine efficacy
	  ○ Incidence rate
	• RSV related outcome
	  ○ Lower respiratory tract infection
	  ○ Hospitalization
	• Timeframe (Specimens collected timepoints)
	  ○ 23 July 2019 and 22 October 2021
		Setting and country:
		United States
			provider assessment and RSV infection was confirmed using real-time reverse-transcription polymerase chain reaction assay	

Walsh 2025 (91)	• Population studied
	  ○ Older adults over 60
	• Type of immunization product
	  ○ ABRYSVO™ (RSVpreF) by Pfizer
	• Comparator
	  ○ Unvaccinated individuals
	• Testing
	  ○ Nucleic acid testing-RT-PCR
	• Outcome measures
	  ○ Vaccine efficacy
	  ○ Relative risk
	• Time frame
	  ○ August 31st 2021 to December 18th 2023
		Type of publication:
		Peer-reviewed
		
		Study design:
		Phase 3 multicenter, randomized, double-blind, placebo-controlled trial
		
		Analysis:
		Vaccine effectiveness was defined as 1- relative risk
		
		Relative risk was defined as the ratio of the under of confirmed first-episode RSV-LRTI cases in the RSVpreF group to the number of confirmed cases in the placebo group
		
		Setting and country:
		United States
			• A total of 36 662 participants were randomized to receive the RSVpreF (n=18574) and placebo (n=18288)
			• RT-PCR was used to confirm RSV infection
				• VE against RSV-LRTI episode with ≥3 symptoms throughout 2 seasons: 88.9% (95% CI 53.6–98.7) and 77.8% (95% CI 51.4–91.1)
				• VE against medically attended RSV with ≥3 symptoms: 76.3% (95% CI 50.2–89.9)
				• VE against medically attended RSV with ≥2 symptoms: 60.0% (95% CI 37.2–75.2)
				• VE against medically attended RSV-ARI: 53.2% (95% CI 35.7–66.2)

Appendix 4: Documents excluded at the final stage of reviewing

Hyperlinked title	Reason for exclusion
Use of respiratory syncytial virus vaccines in adults aged ≥60 years: Updated recommendations of the advisory committee on immunization practices – United States, 2024	Wrong study design
A randomized, double-blind, placebo-controlled, phase 1 study to evaluate the safety, reactogenicity, and immunogenicity of single vaccination of Ad26.RSV.preF-based regimen in Japanese adults aged 60 years and older	Wrong outcome
Single-dose nirsevimab prevents RSV infection	Wrong study design
Abrysvo demonstrates continued efficacy in older adults through second RSV season	Wrong study design
Nirsevimab in the prevention of respiratory syncytial virus bronchiolitis	Unable to retrieve full text
Safety and efficacy of nirsevimab in a universal prevention program of respiratory syncytial virus bronchiolitis in newborns and infants in the first year of life in the Valle D'Aosta region, Italy, in the 2023–2024 epidemic season	Wrong outcome
Adjuvanted vaccine to prevent respiratory syncytial virus in adults ages 60 years and older	Wrong study design
RSVpreF vaccine (Abrysvo°) during pregnancy to prevent RSV infection in the woman's child after birth	Unable to retrieve full text
89. The impact of nirsevimab on an RSV season in all infants: Data from the HARMONIE study	Wrong study design
1936. Efficacy of one dose of the Respiratory Syncytial Virus (RSV) prefusion F protein vaccine (RSVPreF3 OA) in adults ≥ 60 years of age persists for 2 RSV seasons	Wrong study design
HARMONIE study: The next chapter in the respiratory syncytial virus story	Wrong study design
1634. Respiratory syncytial virus-associated health care utilization in the pivotal phase 3 trial RSV vaccine efficacy study in older adults immunized against RSV disease (RENOIR)	Wrong study design
1630. Clinical profile of Acute Respiratory Illness (ARI) events in the phase 3 trial the RSV vaccine efficacy study in older adults immunized against RSV disease (RENOIR)	Wrong study design
Two vaccines (Arexvy and Abrysvo) for prevention of RSV disease	Unable to retrieve full text
EPH154 modeled head-to-head comparison of nirsevimab and rsvpref maternal vaccine in the US	Wrong study design
Nirsevimab (Beyfortus) to prevent RSV infection in infants	Unable to retrieve full text
Respiratory syncytial virus candidate vaccine attenuates the severity of breakthrough infections	Wrong study design
The quest for a respiratory syncytial virus vaccine for older adults: Thinking beyond the F protein	Wrong study design
Efficacy and safety of bivalent respiratory syncytial virus (RSVpreF) vaccine in older adults	Wrong study design
Respiratory syncytial virus (RSV) prefusion F protein candidate vaccine (RSVpreF3 OA) is efficacious in adults >= 60 years of age (YOA)	Wrong study design
Three dose levels of a maternal respiratory syncytial virus vaccine candidate are well tolerated and immunogenic in a randomized trial in nonpregnant women	Wrong outcome
Effectiveness and cost-effectiveness of RSV infant and maternal immunization programs: A case study of Nunavik, Canada	Wrong study design
New long-acting monoclonal antibody reduces RSV infections in healthy preterm infants	Wrong study design
The efficacy and impact in heathy infants of nirsevimab on medically attended RSV lower respiratory tract infection	Wrong study design
901. MEDI8897 prevents serious RSV disease in healthy preterm infants	Wrong study design
Nirsevimab (Beyfortus) for prevention of severe RSV disease in young children	Unable to retrieve full text
A phase III, randomized, multi-country study to evaluate the lot-to-lot consistency of GSK's investigational RSV maternal vaccine and the immune response, safety and reactogenicity of RSV maternal vaccine when co-administered with GSK's quadrivalent influenza D-QIV vaccine in healthy non-pregnant women 18-49 years of age *	Unable to retrieve full text
A phase 3, observer-blind, randomized, placebo controlled study to evaluate the non inferiority of the immune response and safety of the RSVPreF3 OA investigational vaccine in adults 50-59 years of age, including adults at increased risk of respiratory syncytial virus lower respiratory tract disease, compared to older adults ≥60 years of age *	Unable to retrieve full text
A phase III, randomized, open-label, active vaccine-controlled crossover study to evaluate the reactogenicity, safety and immune response of unadjuvanted RSV maternal vaccine in healthy non-pregnant girls from 9 to 17 years of age, and in non-pregnant adult women from 18 to 49 years of age	Unable to retrieve full text

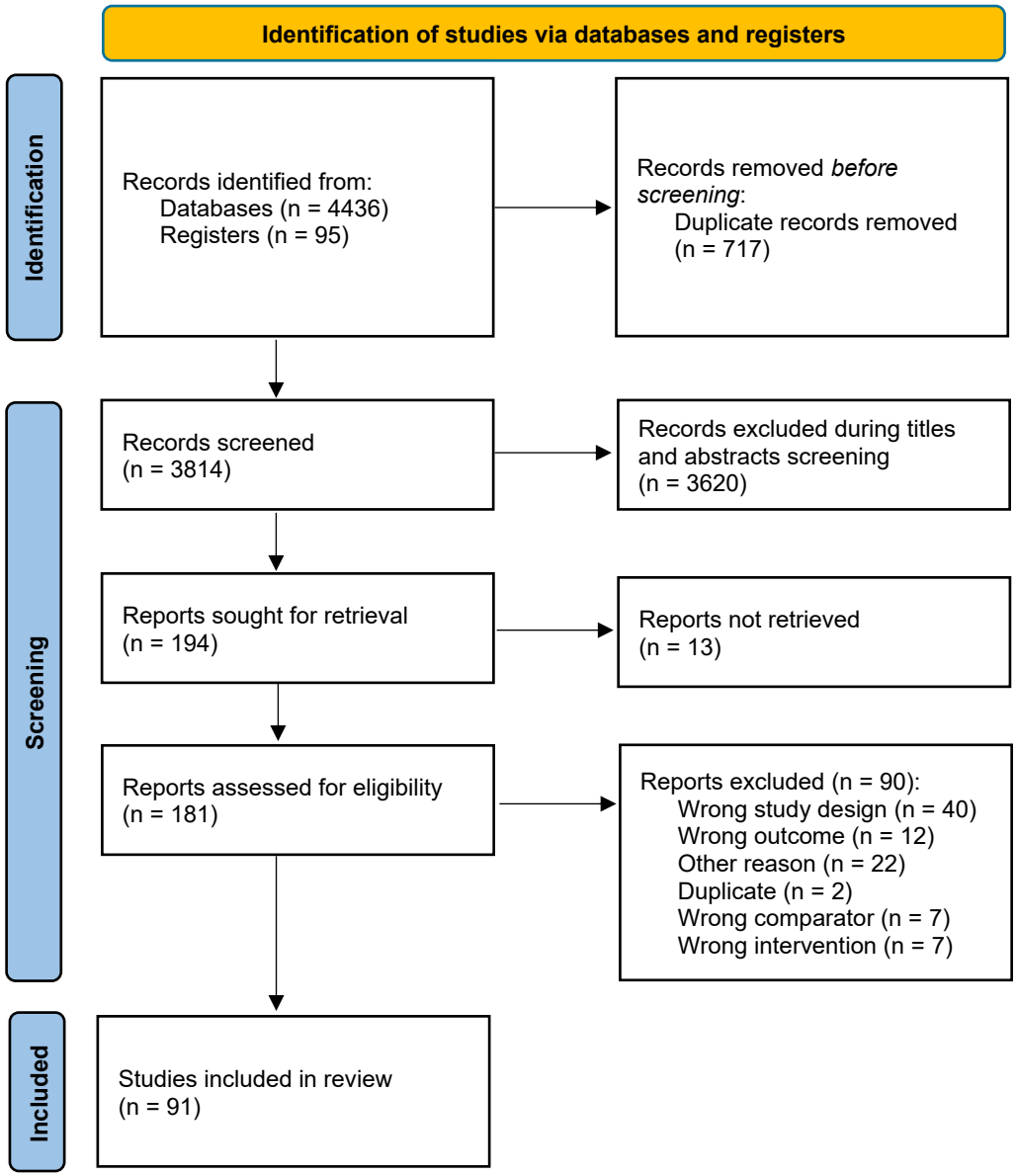
Hyperlinked title	Reason for exclusion
Phase II randomized, observer-blind, placebo-controlled, multi-country study in healthy non-pregnant women 18-45 years of age to evaluate the safety, reactogenicity and immunogenicity of a 1st intramuscular dose of GSK Biologicals' investigational RSV maternal vaccine (GSK388550A) when given alone and given in co-administration with a single intramuscular dose of Boostrix (US formulation SB776423 or exUS formulation SB263855) and to evaluate the safety, reactogenicity and immunogenicity of a 2nd dose of the RSV maternal vaccine *	Unable to retrieve full text
A phase 3, randomized, double blind, multi country study to evaluate consistency, safety, and reactogenicity of 3 lots of RSVPreF3 OA investigational vaccine administrated as a single dose in adults aged 60 years and above *	Unable to retrieve full text
A phase 3, open-label, randomized, controlled, multicountry study to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with FLU HD vaccine in adults aged 65 years and above *	Unable to retrieve full text
A phase III, open-label, randomized, controlled, multi-country study to evaluate the immune response, safety and reactogenicity of an RSVPreF3 OA investigational vaccine when co-administered with FLU aQIV (inactivated influenza vaccine – adjuvanted) in adults aged 65 years and above *	Unable to retrieve full text
A phase 3, open-label, randomized, controlled, multi-country study to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with FLU-QIV vaccine in adults aged 60 years and above	Unable to retrieve full text
A respiratory syncytial virus (RSV) prefusion F protein candidate vaccine (RSVPreF3-OA) is efficacious in adults ≥ 60 years of age (YOA)	Wrong Study Design
The efficacy and impact in heathy infants of nirsevimab on medically attended RSV lower respiratory tract infection	Wrong Study Design
Efficacy and safety of an Ad26.RSV.preF–RSV preF protein vaccine in older adults	Wrong Intervention
Live-attenuated vaccines prevent respiratory syncytial virus-associated illness in young children	Wrong Intervention
Long-term efficacy and immunogenicity of Ad26.RSV.preF-RSV preF protein vaccine (CYPRESS): a randomised, double-blind, placebo-controlled, phase 2b study	Wrong Intervention
Maternal Respiratory Syncytial Virus Vaccination and Preterm Birth: A Utah Statewide Retrospective Cohort Study	Wrong Outcome
Public health impact of nirsevimab and reduction of RSV hospitalisation in all infants: early real-world data from Tuscany (Italy) in the 2024-25 RSV season	Wrong Comparator
A Phase IIIb Randomized Open-label Study of Nirsevimab (Versus no Intervention) in Preventing Hospitalizations Due to Respiratory Syncytial Virus in Infants (HARMONIE)*	Other reason
Retrospective Study Evaluating ABRYSVO Vaccine Effectiveness Against Severe Lower Respiratory Tract Infection in Older Adults	Other reason
A Pragmatic Randomized Trial to Evaluate the Vaccine Effectiveness of Abrysvo for Preventing RSV Hospitalizations in Adults Aged 60 Years or Above	Other reason
A Phase 3, Randomized, Placebo-controlled, Observer-blind, Multi-country Study to Demonstrate the Efficacy of a Single Dose and Annual Revaccination Doses of GSK's RSVPreF3 OA Investigational Vaccine in Adults Aged 60 Years and Above*	Other reason
EPINIR-BRONCHIO : Evaluation Pragmatique de l'Impact du NIrsevimab Sur le Recours Aux uRgences Pour BRONCHIOlite Evaluation in Practice of the Impact of NIrsevimab on EmeRgency Use for BRONCHIOlitis*	Other reason
A Phase IIb, Randomized, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of an RSV Vaccine Candidate in Adult Participants 60 Years and Older	Other reason
Impact of Nirsevimab on RSV and Non-RSV Severe Respiratory Infections in Hospitalized Infants	Wrong Comparator
Treatment for paediatric respiratory syncytial virus infection	Wrong Study Design
Real world data show effectiveness of new respiratory syncytial virus (RSV) vaccines	Wrong Study Design
Early impact of RSV vaccination in older adults in England	Wrong Comparator
Early evidence of RSV vaccination impact on hospitalisation rates of older people in Scotland	Wrong Comparator
RSVPreF3 OA respiratory syncytial virus vaccine in older adults: a profile of its use	Wrong Study Design
Unequal impact of respiratory syncytial virus immunization in patients attending Spanish pediatric emergency departments.	Wrong Study Design
Acceptance and impact of Nirsevimab and the RSVpreF vaccine following implementation in Austria.	Wrong Outcome
Nirsevimab and Acute Bronchiolitis Admissions in Infants Under One Year of Age.	Wrong Outcome
Interim Evaluation of Respiratory Syncytial Virus Hospitalization Rates Among Infants and Young Children After Introduction of Respiratory Syncytial Virus Prevention Products - United States, October 2024-February 2025.	Wrong Comparator
Changes in Care in Spanish Pediatric Emergency Departments After the First Immunization With Nirsevimab.	Wrong Outcome

Hyperlinked title	Reason for exclusion
Comparative analysis of acute respiratory infections of viral etiology in children under 6 months with and without nirsevimab in the Balearic Islands (2022-2023 and 2023-2024).	Wrong Outcome
Nonadjuvanted Bivalent Respiratory Syncytial Virus Vaccination and Perinatal Outcomes.	Wrong Outcome
RSV Vaccine Effectiveness Against Hospitalization Among US Adults 60 Years and Older.	Other reason
Preliminary real-world Abrysvo vaccine effectiveness (VE) against Respiratory Syncytial Virus (RSV)-related lower respiratory tract disease (LRTD) hospitalizations and emergency department (ED) visits-Kaiser Permanente of Southern California (KPSC)	Wrong Study Design
A Study to Evaluate the Safety and Immune Response of mRNA-1345, a Vaccine Targeting Respiratory Syncytial Virus (RSV), When Co-administered With a Fluzone HD, in Adults 65 Years of Age	Wrong Study Design
Efficacy of a Bivalent RSVpreF Vaccine in Older Adults Across a Second RSV Seasonv	Wrong Study Design
RSVPreF3Â OA respiratory syncytial virus vaccine in older adults: a profile of its use: rSVPreF3Â OA respiratory syncytial virus vaccine in older adults: M. Shirley	Wrong Study Design
Efficacy of nirsevimab against respiratory syncytial virus lower respiratory tract infections in preterm and term infants, and pharmacokinetic extrapolation to infants with congenital heart disease and chronic lung disease: a pooled analysis of randomised	Wrong Study Design
Suptavumab for the Prevention of Medically Attended Respiratory Syncytial Virus Infection in Preterm Infants	Wrong Intervention
A Pragmatic Randomized Trial to Evaluate the Vaccine Effectiveness of Abrysvo for Preventing RSV Hospitalizations in Adults Aged 60 Years or Above (DAN-RSV)	Other reason
A study to investigate the reactogenicity, safety, and immunogenicity of mRNA-1345 in pregnant women, and safety and immunogenicity in their infants	Other reason
Does nirsevimab prevent lower respiratory infections caused by respiratory syncytial virus?	Wrong Study Design
A PHASE 3, RANDOMIZED, DOUBLE-BLINDED, PLACEBO-CONTROLLED TRIAL TO EVALUATE THE EFFICACY AND SAFETY OF A RESPIRATORY SYNCYTIAL VIRUS (RSV) PREFUSION F SUBUNIT VACCINE IN INFANTS BORN TO WOMEN VACCINATED DURING PREGNANCY Short title: a Phase 3 Trial*	Wrong Study Design
EFFICACY OF A RESPIRATORY SYNCYTIAL VIRUS (RSV) PREFUSION F PROTEIN VACCINE (RSVPREF3 OA) IN OLDER ADULTS WITH PRE-EXISTING MEDICAL CONDITIONS*	Wrong Study Design
Clinical Profile of Acute Respiratory Illness (ARI) Events in the Phase 3 Trial The RSV Vaccine Efficacy Study iN Older Adults Immunized against RSV Disease (RENOIR)	Wrong Study Design
Respiratory Syncytial Virus-Associated Health Care Utilization in the Pivotal Phase 3 Trial RSV Vaccine Efficacy Study In Older Adults Immunized Against RSV Disease (RENOIR)*	Wrong Study Design
Phase 2a Study of MVA-BN-RSV Vaccination and RSV Challenge in Healthy Adults	Wrong Intervention
Efficacy of a Respiratory Syncytial Virus (RSV) Prefusion F Protein Vaccine (RSVPreF3 OA) in Older Adults with Preexisting Medical Conditions	Wrong Study Design
EFFICACY OF A RESPIRATORY SYNCYTIAL VIRUS (RSV) PREFUSION F PROTEIN VACCINE (RSVPREF3 OA) IN OLDER ADULTS WITH PRE-EXISTING MEDICAL CONDITIONS*	Duplicate
A Respiratory Syncytial Virus (RSV) Prefusion F Protein Candidate Vaccine (RSVPreF3-OA) is Efficacious in Adults â‰¥ 60 Years of Age (YOA)	Wrong Study Design
A Respiratory Syncytial Virus (RSV) Prefusion F Candidate Vaccine (RSVPreF3 OA) is Efficacious in Adults â‰¥ 60 Years of Age (YOA)	Duplicate
Establishing Proof of Concept for a Bivalent RSVpreF Subunit Vaccine for Maternal Immunization	Wrong Study Design
Efficacy And Safety Of Bivalent Respiratory Syncytial Virus (RSVpreF) Vaccine In Older Adults	Wrong Study Design
Safety and Reactogenicity of an Investigational Respiratory Syncytial Virus (RSV) Prefusion F Protein Vaccine for Adults â‰¥ 60 Years of Age (RSVPreF3 OA): an Interim Analysis at 6 Months after Vaccination	Wrong Study Design
Respiratory syncytial virus vaccination in pregnancy is not effective enough at reducing infant infections	Wrong Study Design
A study to Evaluate the Safety and Efficacy of mRNA-1345, an mRNA Vaccine Targeting Respiratory Syncytial Virus (RSV), in Adults = 60 Years of Age	Other reason
A Phase 3 Study to Evaluate the Efficacy, Immunogenicity, and Safety of RSVpreF in Adults*	Other reason
Clinical Study to Evaluate the Safety and Efficacy of MEDI8897, an Experimental Drug, for Preventing Serious Respiratory Syncytial Virus Disease in Healthy Late Preterm and Term Infants*	Other reason

Hyperlinked title	Reason for exclusion
Clinical Study to Evaluate the Safety of MEDI8897, an Experimental Drug, for Preventing Serious Respiratory Syncytial Virus Disease in High-risk Children*	Other reason
A Phase III study to assess safety and efficacy of an RSV Maternal vaccine, in pregnant women and infants born to vaccinated mothers	Other reason
Vaccine effectiveness of the maternal RSVpre-F vaccine against severe disease in infants in Scotland, UK: national population-based case-control and cohort analyses	Other reason
A PHASE 3, RANDOMIZED, DOUBLE-BLINDED, PLACEBO-CONTROLLED TRIAL TO EVALUATE THE EFFICACY AND SAFETY OF A RESPIRATORY SYNCYTIAL VIRUS (RSV) PREFUSION F SUBUNIT VACCINE IN INFANTS BORN TO WOMEN VACCINATED DURING PREGNANCY*	Other reason
Multicentre study on nirsevimab: Bayesian analysis reveals persisting risk for preterm infants	Wrong Intervention
Effectiveness And Impact of Nirsevimab In A Nationwide Immunization Program During The 2024 Winter Campaign In Chile (Nirse-CL)	Other reason
A Phase 3 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody With an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Late Preterm and Term Infants (MELODY)*	Other reason
Real-world impact of nirsevimab immunisation against respiratory disease on emergency department attendances and admissions among infants: a multinational retrospective analysis	Wrong Intervention
Nirsevimab Prophylaxis for Reduction of Respiratory Syncytial Virus Complications in Hospitalised Infants: The Multi-Centre Study During the 2023-2024 Season in Andalusia, Spain (NIRSEGRAND)	Wrong Comparator
Impact of Nirsevimab in Its Second Season on Respiratory Syncytial Virus and Non-RSV Admissions in Children Under 5.	Wrong Comparator
Efficacy, Immunogenicity, and Safety of the Bivalent RSV Prefusion F (RSVpreF) Vaccine in Older Adults Over 2 RSV Seasons.*	Wrong Outcome
A Phase 1b/2a Trial of a Half-life Extended Respiratory Syncytial Virus Neutralizing Antibody, Clesrovimab, in Healthy Preterm and Full-term Infants.*	Wrong Outcome
Infants Receiving a Single Dose of Nirsevimab to Prevent RSV Do Not Have Evidence of Enhanced Disease in their Second RSV Season	Other reason
Efficacy of a respiratory syncytial virus (RSV) prefusion F protein vaccine (RSVPreF3 OA) in older adults with co-existing cardiorespiratory conditions	Other reason
Phase 2a Study of RSVpreF Vaccination and RSV Challenge in Healthy Adults *	Other reason
Efficacy, Immunogenicity, and Safety of the Bivalent RSV Prefusion F (RSVpreF) Vaccine in Older Adults Over 2 RSV Seasons.	Other reason
Changes in RSV-associated lower respiratory tract infections among hospitalized and outpatient children under 2 years in Northern Bavaria after general recommendation of Nirsevimab immunization in 2024	Wrong Outcome

*: We used the title on the Clinical Trial's official study protocol (linked PDF at the bottom of the trial page). Trials often update their names as studies evolve, so we used the protocol's title and the clinical trial link to ensure consistency and accuracy

Appendix 5: PRISMA flow diagram



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