Elisabeth BOTELHO-NEVERS

Country: *France*

Affiliation: *Infectious diseases department and Clinical investigational centre (CIC) 1408 at University Hospital of Saint-Etienne; GIMAP team at CIRI Lab (Inserm, U1111, CNRS, UMR530) University of Lyon; University of Saint-Etienne*

Function: *Head of Infectious Diseases department, Head of Vaccinology axis at CIC 1408*

Main expertise: *burden of vaccine preventable ID in older adults; vaccine clinical development; acceptability of vaccines in development and new vaccines*

RSV Specific topic: Need for revaccination? When and how to organize it?

Pr Elisabeth BOTELHO-NEVERS

Infectious diseases dpt, University of Saint-Etienne
Inserm CIC 1408- Vaccinology axis, I-Reivac, Covireivac
Team GIMAP, CIRI, Inserm, U1111, CNRS, UMR530
Prévention, Vaccination, Contrôle de l'Infection University Chair- PRESAGE Institute

Disclosure

- Speaker or participation in advisory boards:

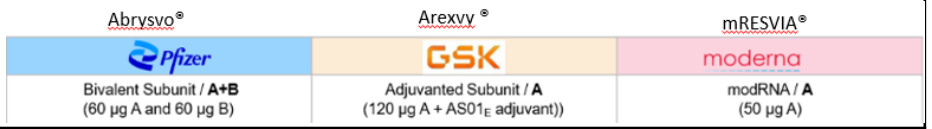
Pfizer, Sanofi-Pasteur, Merck, Janssen, Moderna, GSK

Honoraria payed to my Institution

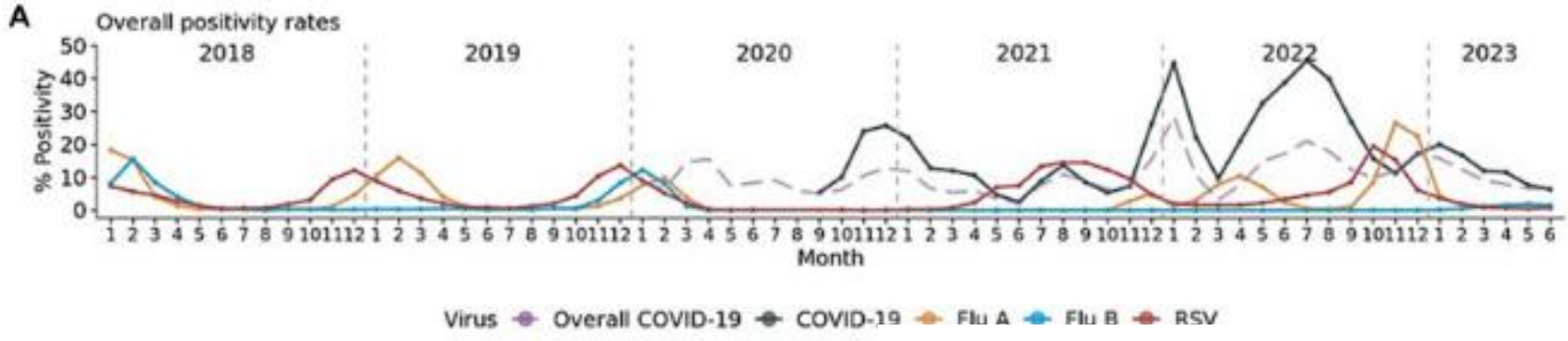
- Principal Investigator for vaccine clinical trials

Pfizer, Sanofi-Pasteur, Merck, Janssen, Moderna, GSK

Overview slide

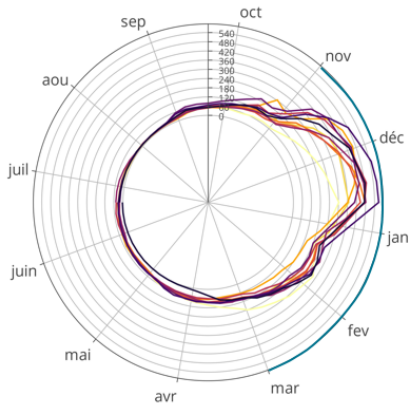
Vaccine information	Information
Which vaccines on the market	3 vaccines: 
Vaccine immunogenicity in older adults	Immune responses were similar across age groups
Vaccine efficacy / effectiveness in older adults	Efficacy from 88.9% to 83.7% according to different primary outcomes. **Effectiveness** USA from Abrysvo®+ Arexvy®: **1. 78·1%** (95% CI 72·6–83·5) against documented RSV infection, 78·7% (72·2–84·8) against RSV-associated emergency dep artment or urgent care encounters, and **80·3%** (65·8–90·1) against RSVassociated hospitalisation. **2. 80%** (95% CI 71–85) against RSV-associated hospitalisations, and 81% (52–92) against RSV-associated critical illness (ICU admission or death, or both). **73%** (48–85) immunocompromised against associated hospitalization. Arexvy® 83%, Abrysvo® 73%. **3.** Effectiveness 60-74y=**75% (31-91**), 75+= **76% (40-91**) against hospitalizations. **4.** Abrysvo® effectiveness 90% (95% CI, 59%-97%) (retrospective)
Vaccine safety in older adults	Good safety profile, warning for GBS
Long lasting protection in older adults	Persist over >2 seasons in all subgroups age
Vaccine co-administration in older adults	Arexvy®+Adjuvanted FLU-aQIV= I (lower H3N2 HAI titers) +S OK; Arexvy®+ SD FLU-QIV in high risk HF or in older adults= S OK mRESVIA®+ SD Flu-QIV= I (NAb RSVA inferior) S OK, mRESVIA®+ mRNA Covid= I+S Ok Abrysvo®+ SD Flu-QIV= I+S Ok Arexvy'®+ Shingrix®= I + S OK
Other relevant information in context of older adults?	Not yet data of effectiveness on other relevant outcomes such as cardiovascular events Not yet data of effectiveness over 2 seasons, nor effectiveness of revaccination

RSV a seasonal virus



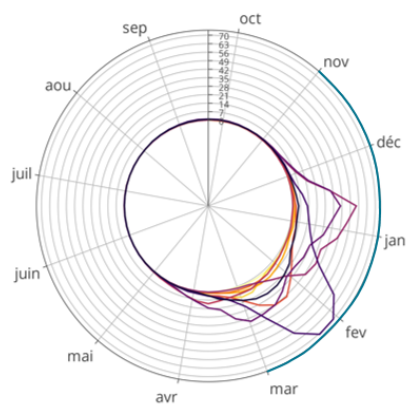
RSV and flu seasonalities overlap
Since SARS-CoV-2 emergence also overlaping
Great epidemic in 2022-2023 « triple epidemic » with SARS-COV-2

RSV



Hospitalizations for bronchiolitis in infants

Influenza



Hospitalizations for Influenza in 65 years+

Nuttens C, Estimation des hospitalisations et des décès attribuables aux infections par le VRS et à la grippe chez les adultes âgés de 65 ans et plus en France, ECCMID & JNI, 2023

Incidence/100 000 persons, 2010-2020, France

RSV vaccines available for older adults

Abrysvo®	Arexvy ®	mRESVIA®
Pfizer	GSK	moderna
Bivalent Subunit / **A+B** (60 µg A and 60 µg B)	Adjuvanted Subunit / **A** (120 µg A + $AS01_E$ adjuvant))	modRNA / **A** (50 µg A)

Approved FDA+ EMA
Recommanded in 75+ and 60-65+ with comorbidities

- Good efficacy against RSV-related lower respiratory tract diseases in phases III
- Data from USA in one season: very good effectiveness against RSV-related hospitalization and death for Abrysvo® and Arexvy®
- Including in elderly (75+), in immunocompromised and with chronic conditions people
- Co-administration with other vaccines evaluated
- Vaccination each year as flu and COVID-19 vaccines?

Data available for immune response after one dose of RSV vaccine in older people

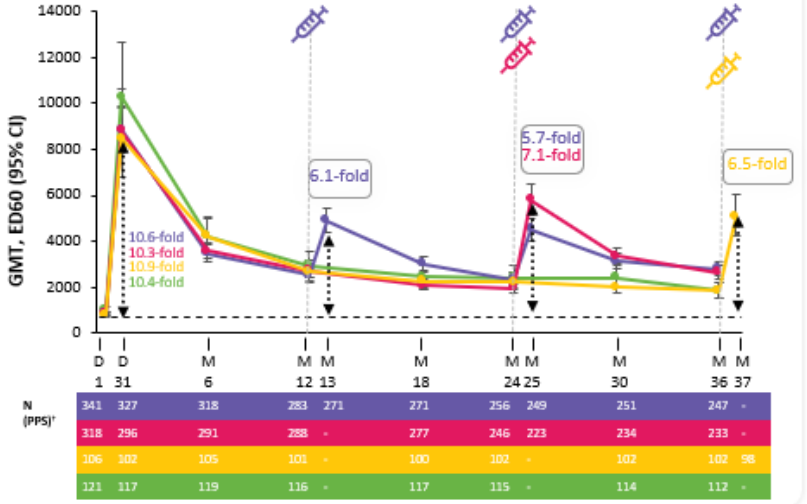
	GSK Arexvy® [1, 2]
Neutralizing Ab against RSVA and RSV B	Following 1 dose NAb responses reached a peak at D31 (1 month post-Dose 1) then decreased until M12 **with a plateau above baseline persisting until M36**. Including people with ≥ 1 comordibity and frailty
Specific CD4+ T cells	In adults ≥60 YOA, 1 adjuvanted RSVPreF3 dose induced immune responses that **persisted until M36, remaining above baseline.**

1. Schwarz TF et al. Immunogenicity and safety of the $AS01_E$-adjuvanted respiratory syncytial virus prefusion F protein vaccine (adjuvanted RSVPreF3) after different revaccination schedules up to 3 years post-first dose in adults aged 60 years and above. Presented at 13th International RSV Symposium, March 12–15, 2025, Iguazu Falls, Brazil . 2. Susan Gerber Medical director GSK-presentation at ACIP April 16 2025.
3. Ilangovan K et al., Modeling of the Persistence of RSV Neutralizing Titers and Vaccine Efficacy After a Single Dose of RSVpreF in Older Adults Poster 229. 4. Walsh EE, et al., . Efficacy, Immunogenicity, and Safety of the Bivalent RSV Prefusion F (RSVpreF) Vaccine in Older Adults Over 2 RSV Seasons. Clin Infect Dis. 2025 Feb 10:ciaf061. doi: 10.1093/cid/ciaf061.
5 . Frances Priddy Moderna presentation, at ACIP April 16 2025

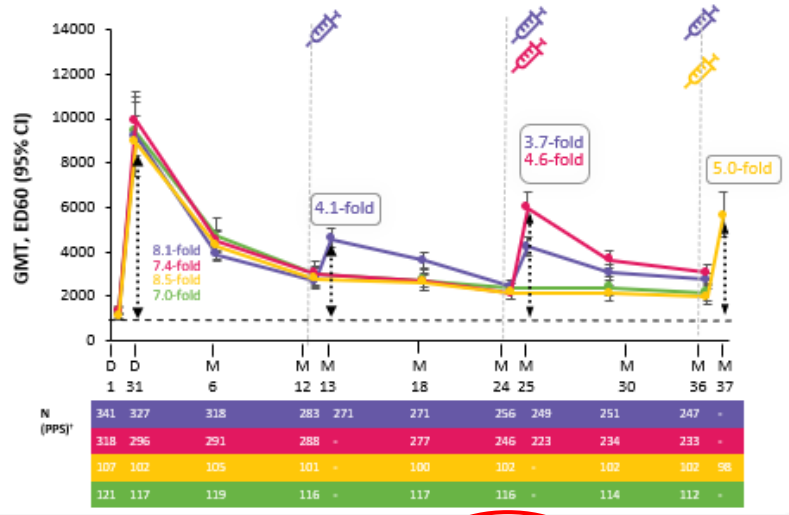
AReSVi-004

Durable RSV-A and RSV-B neutralizing antibody responses (NAb) were observed 36 months post vaccination[1]

RSV-A NAb*



RSV-B NAb*

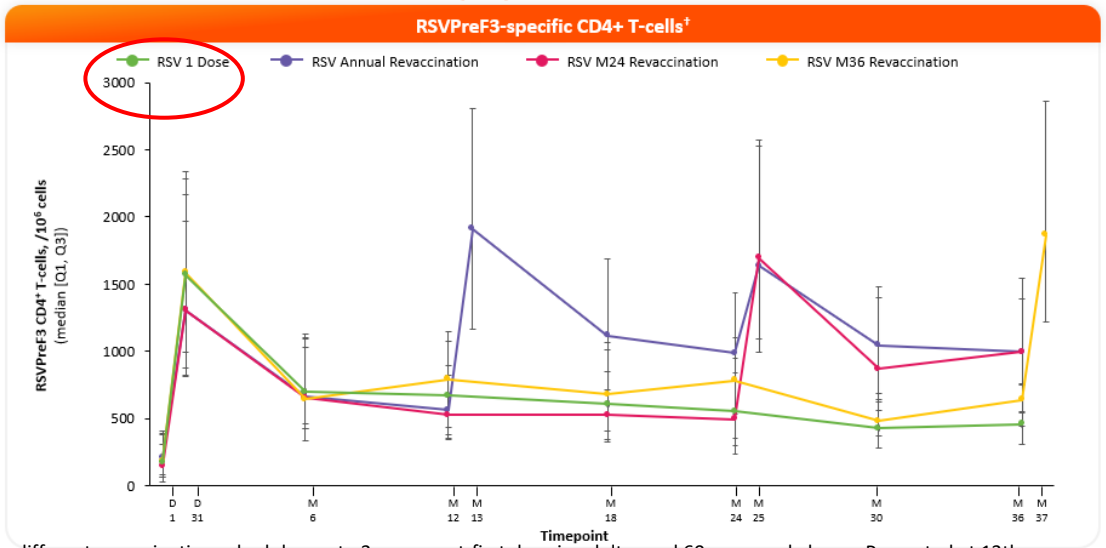


Adjuvanted RSVPreF3 vaccination schedule (ES)‡:
Annual revaccination (N=993)
M24 revaccination (N=329)
M36 revaccination (N=108)
1 Dose (N=126)

In green data after 1 dose

AReSVi-004

After revaccination with 1 or 2 doses, RSVPreF3-specific CD4+ T-cell median frequency increased at M13, M25 and M37 to levels similar to D31 levels (PPS)[1,*]



GSK

Schwarz TF et al. Immunogenicity and safety of the AS01$_E$-adjuvanted respiratory syncytial virus prefusion F protein vaccine (adjuvanted RSVPreF3) after different revaccination schedules up to 3 years post-first dose in adults aged 60 years and above. Presented at 13th International RSV Symposium, March 12–15, 2025, Iguazu Falls, Brazil

Data available for immune response after one dose of RSV vaccine in older people

	GSK Arexvy® [1, 2]	Pfizer Abrysvo® [3, 4]
Neutralizing Ab against RSVA and RSV B	Following 1 dose NAb responses reached a peak at D31 (1 month post-Dose 1) then decreased until M12 with a plateau above baseline persisting until M36. Including people with ≥ 1 comordibity and frailty	At the preseason 2 visit (occurring from **8–20 months** post-vaccination), **neutralizing GMTs decreased but remained substantially higher than baseline.** Across all age group and presence of comorbidities
Specific CD4+ T cells	In adults ≥60 YOA, 1 adjuvanted RSVPreF3 dose induced immune responses that persisted until M36, remaining above baseline.	/

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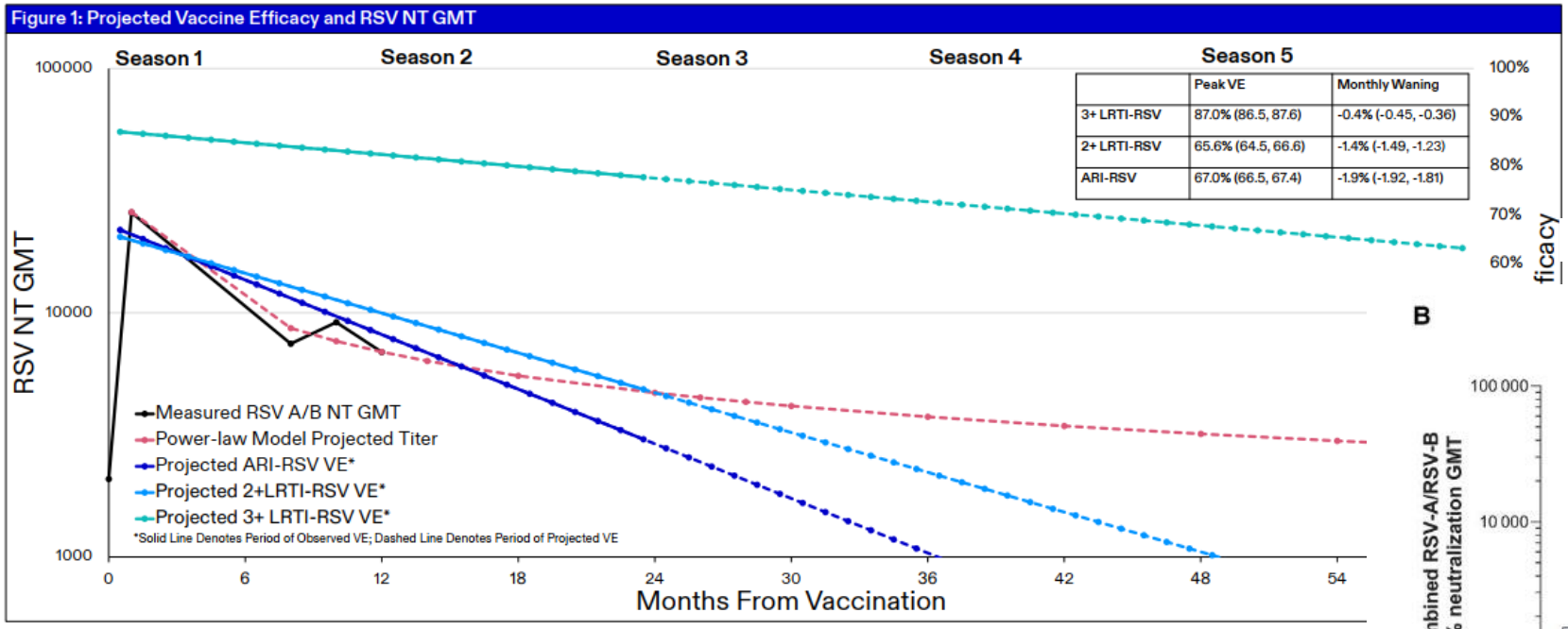

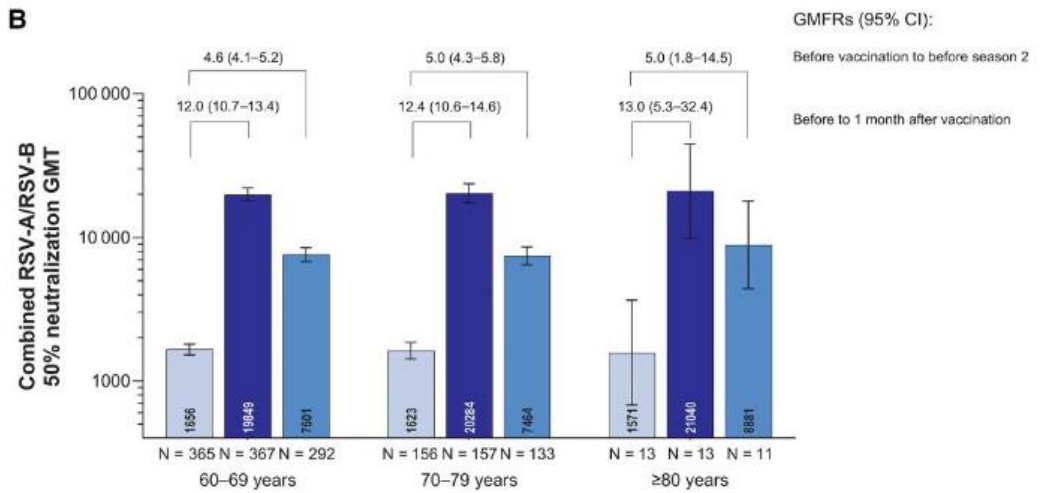

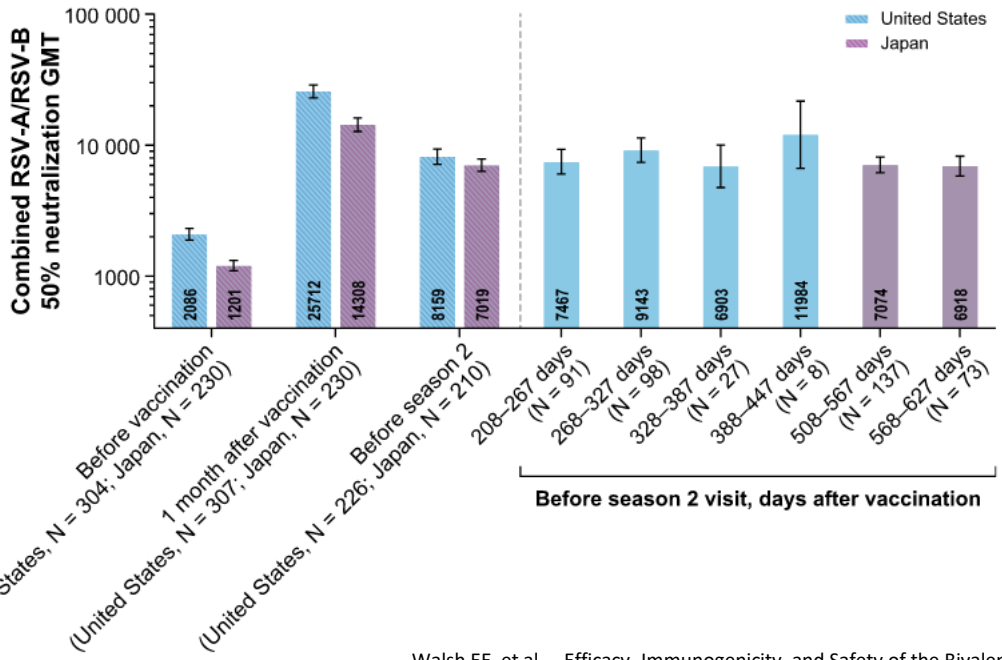

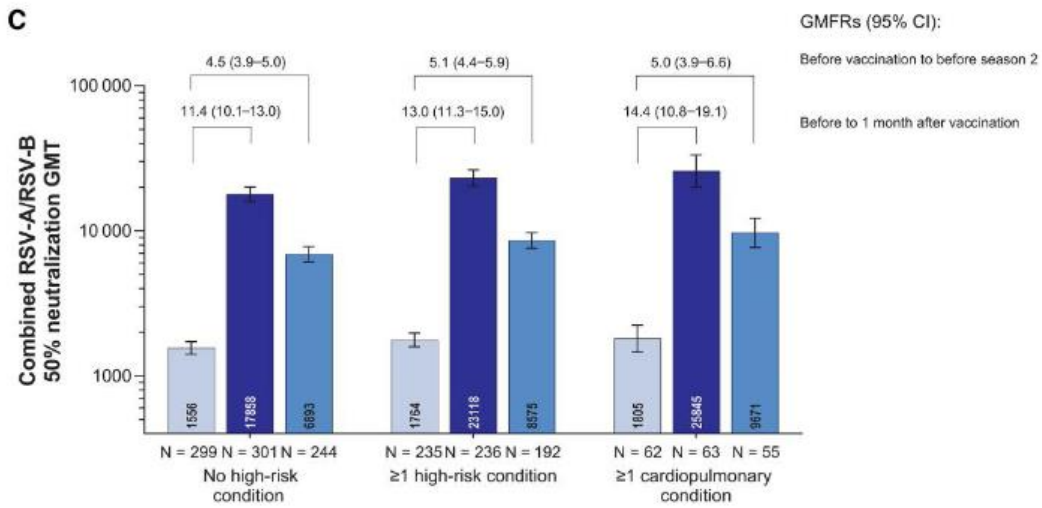

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Data available for immune response after one dose of RSV vaccine in older people

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Neutralizing Ab against RSVA and RSV B	Following 1 dose NAb responses reached a peak at D31 (1 month post-Dose 1) then decreased until M12 with a plateau above baseline persisting until M36. Including people with ≥ 1 comordibity and frailty	At the preseason 2 visit (occurring from **8–20 months** post-vaccination), neutralizing GMTs decreased but remained substantially higher than baseline. Across all age group and presence of comorbidities	RSV-A neutralizing antibodies **detectable at 24 months post-vaccination higher than baseline** (post 1 dose)
Specific CD4+ T cells	In adults ≥60 YOA, 1 adjuvanted RSVPreF3 dose induced immune responses that persisted until M36, remaining above baseline.	/	/

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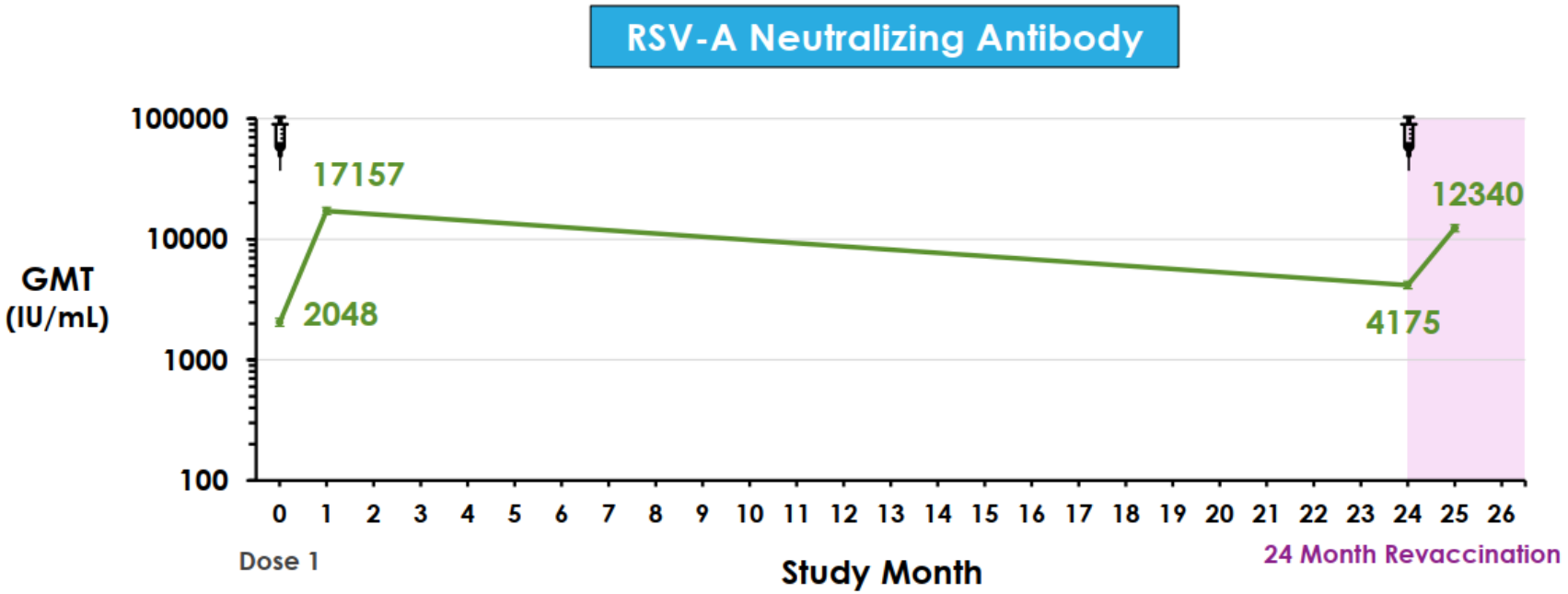
Revaccination at 24 Months with mRNA-1345 Meets Pre-Specified Noninferiority Criteria - RSV-A

Study 301B – Adults ≥60 Years – Per Protocol Set (N=956)



moderna

Data available for efficacy after one dose of RSV vaccine in older people

Different outcomes definitions

	GSK Arexvy® [1, 2]
Vaccine efficacy after 1 dose	VE against RSV-LRTD **over 2 seasons** was **67.2%** (97.5% CI: 48.2– 80.0) *(vs in S1=82.6% (57.9-94.1%),* ; VE against severe RSV-LRTD: **78.8%** *(vs in S1=94.1% (62.4 to 99.9%)* **In line by age** (60-69= 65.4%: 70-79=74.9%), by **presence of ≥ 1 comorbidity** (66.7%), **by frailty** (pre-frail 73.3%) VE against RSV-LRTD **over 3 seasons** was **62.9%** (97.5% CI: 46.7–74.8), VE against severe RSV-LRTD: **67.4%** (42.4–82.7%). VE clinically relevant in groups
Safety	Well tolerated acceptable safety profile. No cases of GBS or ADEM were reported up to study end.

1. Ison MG, et al., 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. Open Forum Infect Dis. 2023 Nov 27;10(Suppl 2):ofad500.2467.
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4 . Frances Priddy Moderna presentation, at ACIP April 16 2025 5. Rituparna Das Moderna Presentation ACIP June 26 2024

Figure 1. Vaccine efficacy against first occurrence of RSV-LRTD and RSV-ARI over 2 RSV seasons (modified exposed population)

	RSVPreF3 OA		Placebo		VE (%) with CI[a]
	N	n	N	n	
VE of 1 RSVPreF3 OA dose over 2 seasons					
RSV-LRTD					
Overall	12,469	30	12,498	139	67.2
Severe	12,469	7	12,498	48	78.8
By age[b]					
60–69 YOA	6,963	17	6,981	74	65.4
70–79 YOA	4,489	9	4,489	55	74.9
By baseline comorbidities					
≥1 comorbidity of interest[c]	4,983	16	4,919	72	66.7
By frailty[b]					
Pre-frail[d]	4,794	8	4,779	47	73.3
RSV-ARI					
Overall	12,469	94	12,498	292	52.7

Conclusions: A single RSVPreF3 OA dose provides clinically relevant protection against RSV disease over 3 RSV seasons in adults ≥60 YOA, regardless of RSV subtype, disease severity (RSV-LRTD, severe RSV-LRTD and RSV-ARI), baseline comorbidities or age, and in pre-frail participants, with an acceptable safety profile. This supports a favorable benefit-risk profile of RSVPreF3 OA over 3 RSV seasons.

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Different outcomes definitions

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Safety	Well tolerated acceptable safety profile. No cases of GBS or ADEM were reported up to study end.	Well tolerated acceptable safety profile. 2 cases of variants of GBS reported. IRR significant (O/E)

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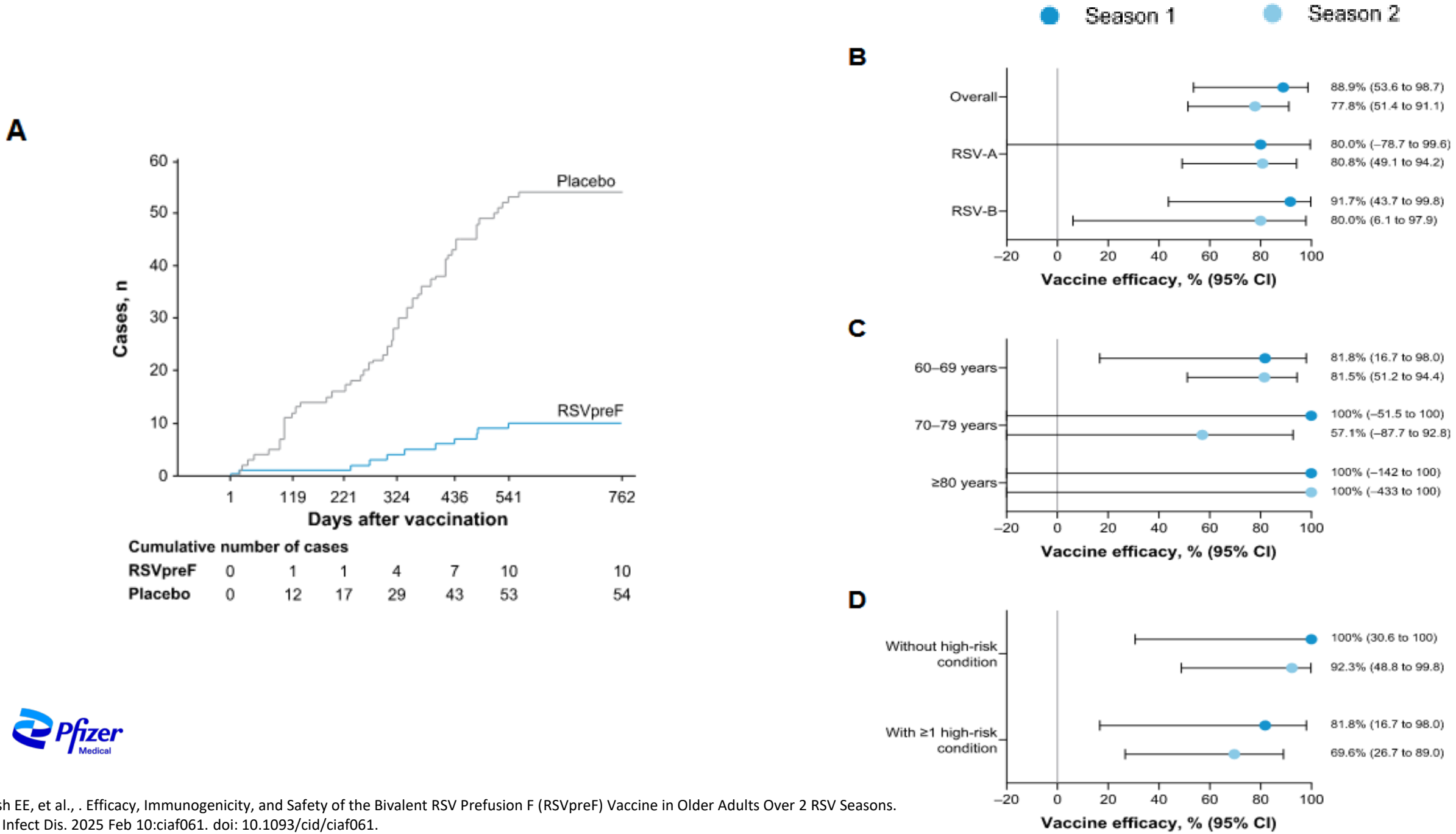

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Safety	Well tolerated acceptable safety profile. No cases of GBS or ADEM were reported up to study end.	Well tolerated acceptable safety profile. 2 cases of variants of GBS reported. IRR significant (O/E)	No reports of GBS, ADEM, acute myocarditis and/or pericarditis

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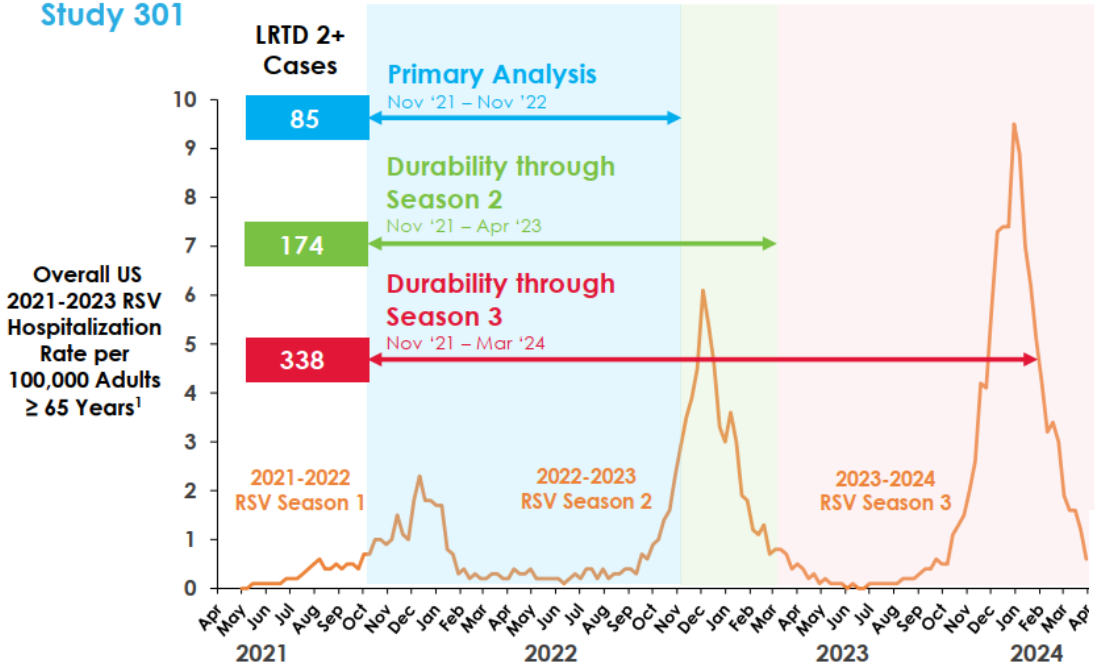
RSV Case Accrual and Efficacy Analyses through 3 Seasons in the Phase 2/3 Pivotal Trial

20

Study 301



1. CDC. Respiratory Syncytial Virus Hospitalization Surveillance Network (RSV-NET). https://www.cdc.gov/respiratory-viruses/data-research/das impacted-hospitalizations.html 2. Based on final FDA Package Insert

Efficacy[2]

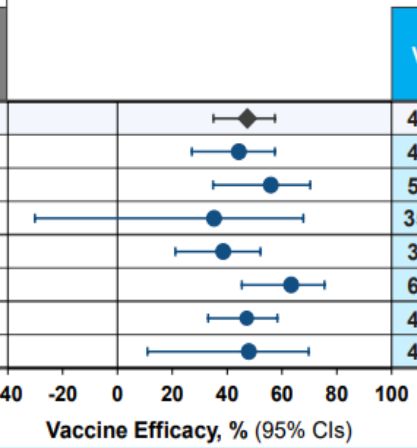
LRTD 2+	Severe RSV (shortness of breath)
78.7% (62.8%, 87.9%)	86.7% (41.9%, 97.0%)
62.5% (47.7%, 73.1%)	74.6% (50.7%, 86.9%)
50.3% (37.5%, 60.7%)	56.7% 33.1%, 72.6%)

Efficacy of mRNA-1345 by Age, Comorbidities, and Frailty Against RSV LRTD ≥ 2 Symptoms

15

Study 301 - Per-Protocol Efficacy Set through 24 Months

RSV LRTD with ≥ 2 Symptoms		Numbers of Events: RSV Vaccine (mRNA-1345) (N = 18,181)	Numbers of Events: Placebo (N = 18,132)	Vaccine Efficacy (95% CI)
Overall		132/18,181	248/18,132	47.4% (35.0, 57.4)
Age	60 – 69 Years	83/11,269	147/11,238	44.3% (27.1, 57.4)
	70 – 79 Years	36/5,487	81/5,459	56.0% (34.9, 70.3)
	≥ 80 Years	13/1,425	20/1,435	35.3% (-30.1, 67.8)
Comorbidities	No Comorbidities	99/12,788	160/12,856	38.6% (21.1, 52.2)
	≥ 1 Comorbidities	33/5393	88/5276	63.4% (45.4, 75.5)
Frailty Status	Fit (0-3)	106/13,491	197/13,366	47.2% (33.1, 58.3)
	Vulnerable/Frail (≥ 4)	20/3802	39/3872	48.0% (10.9, 69.7)

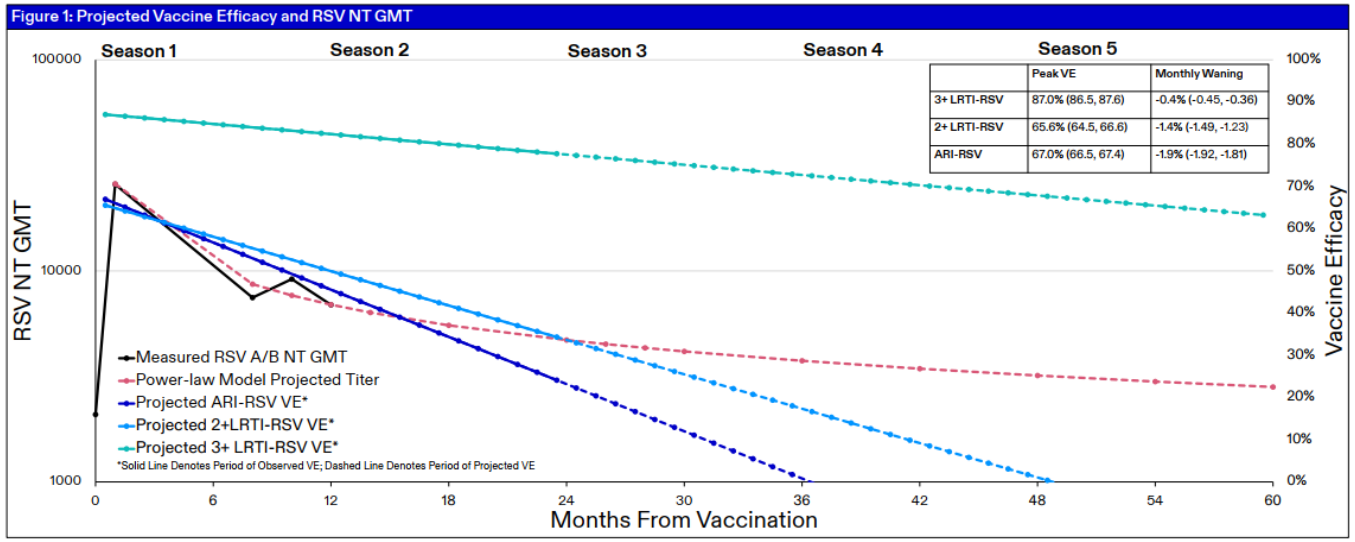


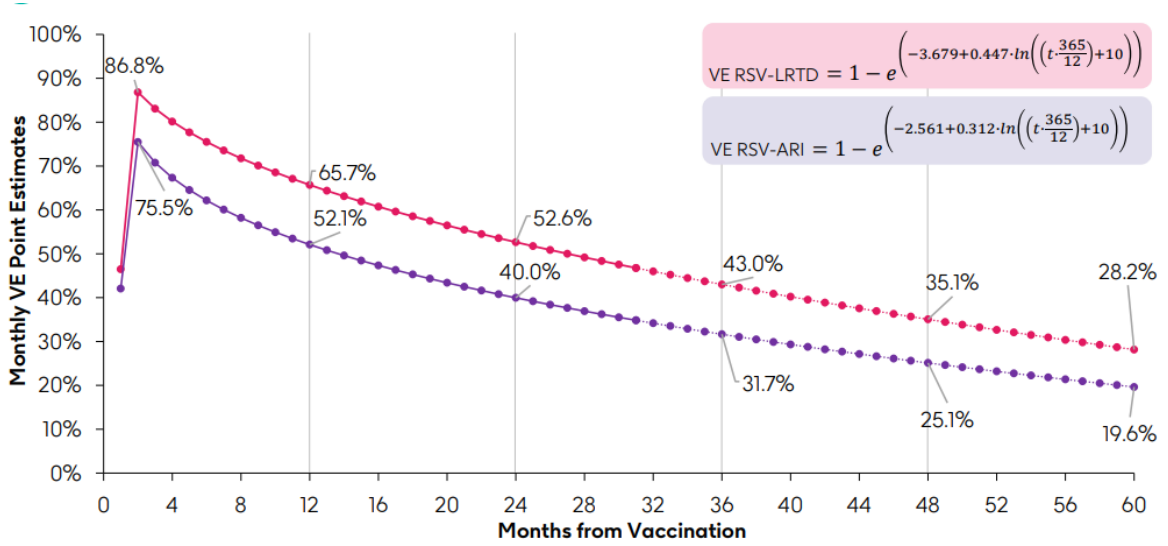
- Case splits favorable for mRNA-1345 with respect to age, comorbidities, and frailty through 24 months

Frances Priddy Moderna presentation, at ACIP April 16 2025
Rituparna Das Moderna Presentation ACIP June 26 2024
Available at https://www-cdc-gov.proxy.insermbiblio.inist.fr/acip/meetings/

Modelisation data of efficacy

- Using immunogenicity data, different models evaluate vaccine efficacy at 5 years after 1 dose RSV vaccine (Pfizer, GSK)





Ilangovan K et al., Modeling of the Persistence of RSV Neutralizing Titers and Vaccine Efficacy After a Single Dose of RSVpreF in Older Adults Poster 229.
Anna Puggina et al., The Potential Public Health Impact of the Adjuvanted Respiratory Syncytial Virus Prefusion F Protein Vaccine Among Older Adults in Italy. ISPOR Europe 2024 | 17-20 November 2024 | Barcelona, Spain

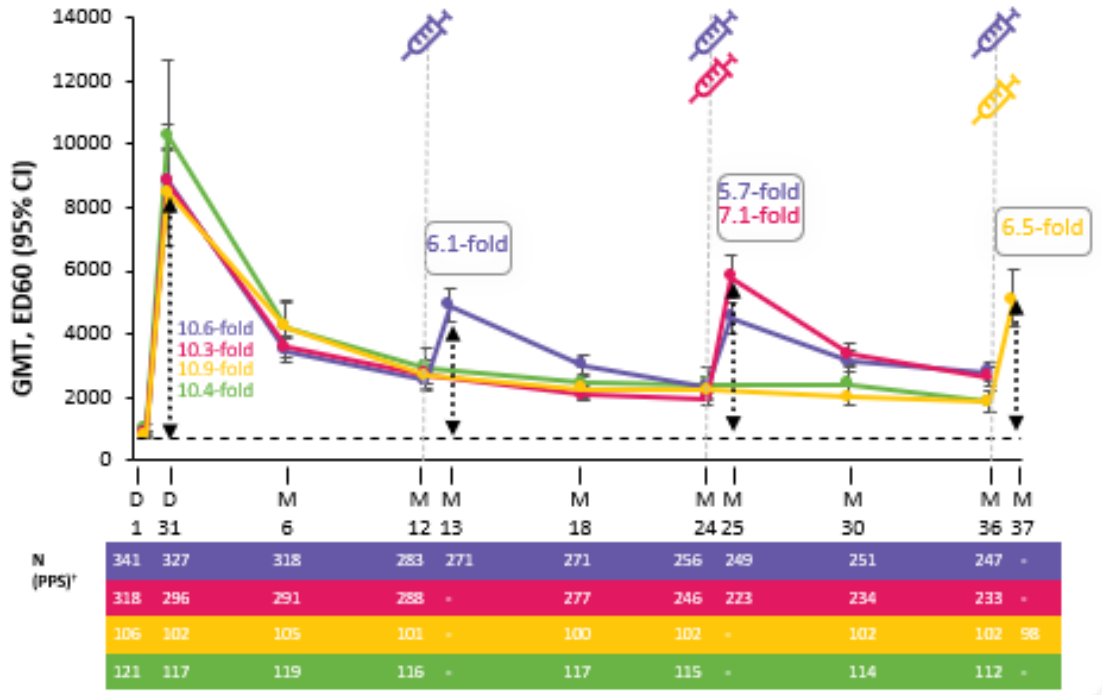
Role of RSV revaccination?

- Impact of one or more dose of RSV revaccination was studied by GSK and Moderna in older adults
- Impact of one dose studied by Pfizer but with a different vaccine formulation
- Increase in N Abs after each dose, inferior to titers obtain after first dose

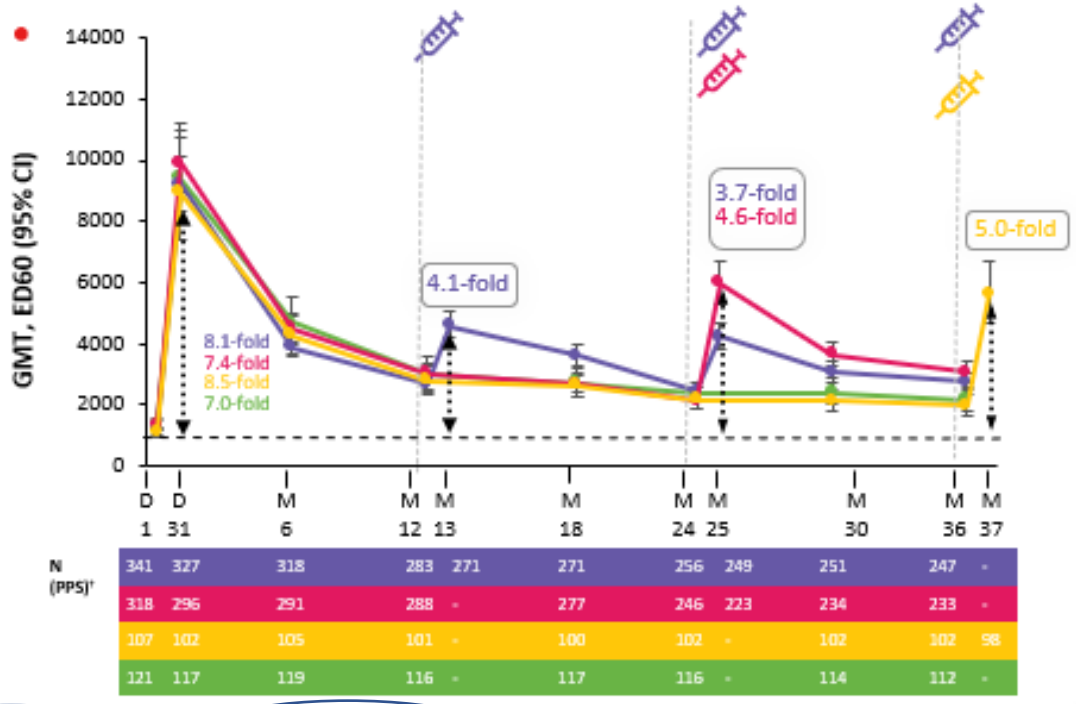
Schwarz TF et al. Immunogenicity and safety of the $AS01_E$-adjuvanted respiratory syncytial virus prefusion F protein vaccine (adjuvanted RSVPreF3) after different revaccination schedules up to 3 years post-first dose in adults aged 60 years and above. Presented at 13th International RSV Symposium, March 12–15, 2025, Iguazu Falls, Brazil .
Frances Priddy Moderna presentation, at ACIP April 16 2025, available at https://www-cdc-gov.proxy.insermbiblio.inist.fr/acip/meetings/
Walsh EE, et al. Respiratory Syncytial Virus Prefusion F Vaccination: Antibody Persistence and Revaccination. J Infect Dis. 2024 Oct 16;230(4):e905-e916. doi: 10.1093/infdis/jiae185.

Durable RSV-A and RSV-B neutralizing antibody responses (NAb) were observed 36 months post vaccination[1]

RSV-A NAb*



RSV-B NAb*



Adjuvanted RSVPreF3 vaccination schedule (ES)‡:

- Annual revaccination (N=993)
- M24 revaccination (N=329)
- M36 revaccination (N=108)
- 1 Dose (N=126)

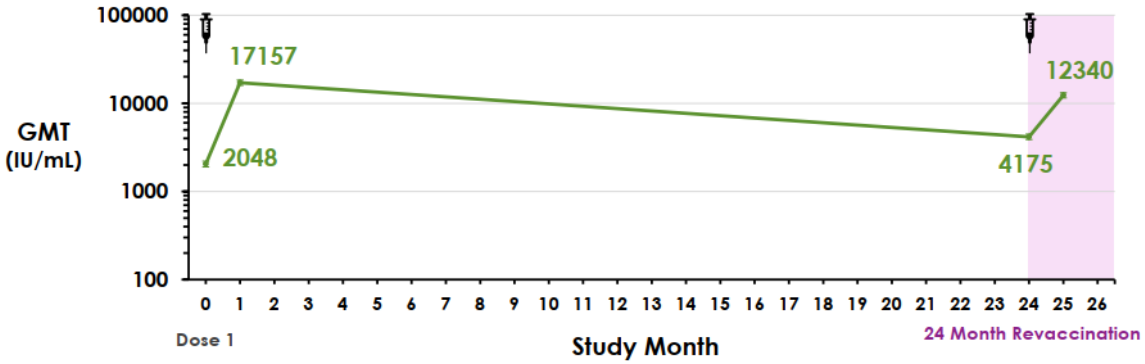
- Following 1 dose of adjuvanted RSVPreF3, NAb responses reached a peak at D31 (1 month post-Dose 1) then decreased until M12 with a plateau above baseline persisting until M36
- Revaccination at M36 increased NAb responses, but not to levels 1 month after Dose 1 (D31)
- Revaccination with 1 or 2 doses increased RSV-A/-B GMT levels at M13, M25 and M37 compared with pre-revaccination in all groups

Schwarz TF et al. Immunogenicity and safety of the AS01$_E$-adjuvanted respiratory syncytial virus prefusion F protein vaccine (adjuvanted RSVPreF3) after different revaccination schedules up to 3 years post-first dose in adults aged 60 years and above. Presented at 13th International RSV Symposium, March 12–15, 2025, Iguazu Falls, Brazil .

Revaccination at 24 Months with mRNA-1345 Meets Pre-Specified Noninferiority Criteria - RSV-A

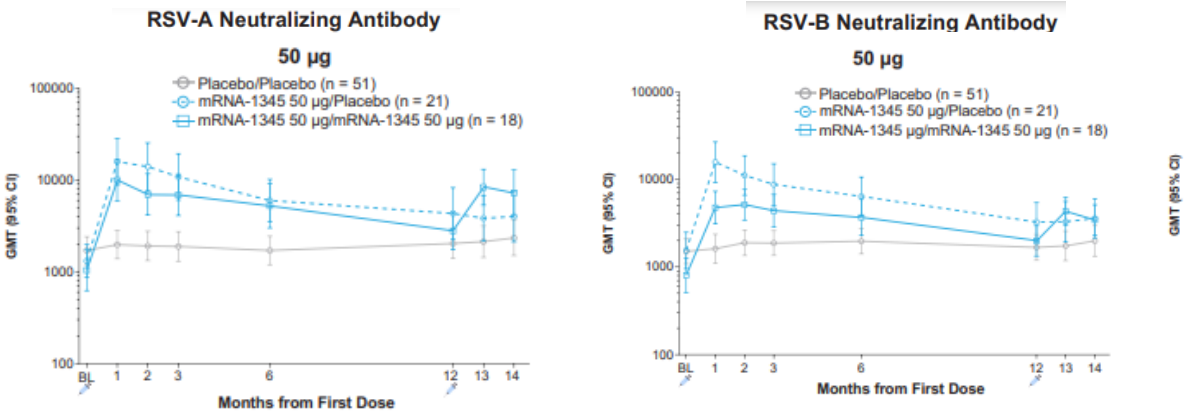
Study 301B – Adults ≥60 Years – Per Protocol Set (N=956)

RSV-A Neutralizing Antibody



- RSV-A neutralizing antibodies detectable at 24 months post-vaccination
- Revaccination at 24 months after primary vaccination elicits responses similar to those following primary dose
- Revaccination met non-inferiority success criteria for RSV-A & RSV-B (LB of 95% CI of GMR > 0.667)

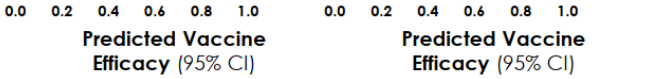
Revaccination at 12 months



Predicted Vaccine Efficacy for the 12-Month Period Following 24 Month Revaccination with mRNA-1345

Study P301 Part B Per-Protocol Set ≥60 Years, N = 956

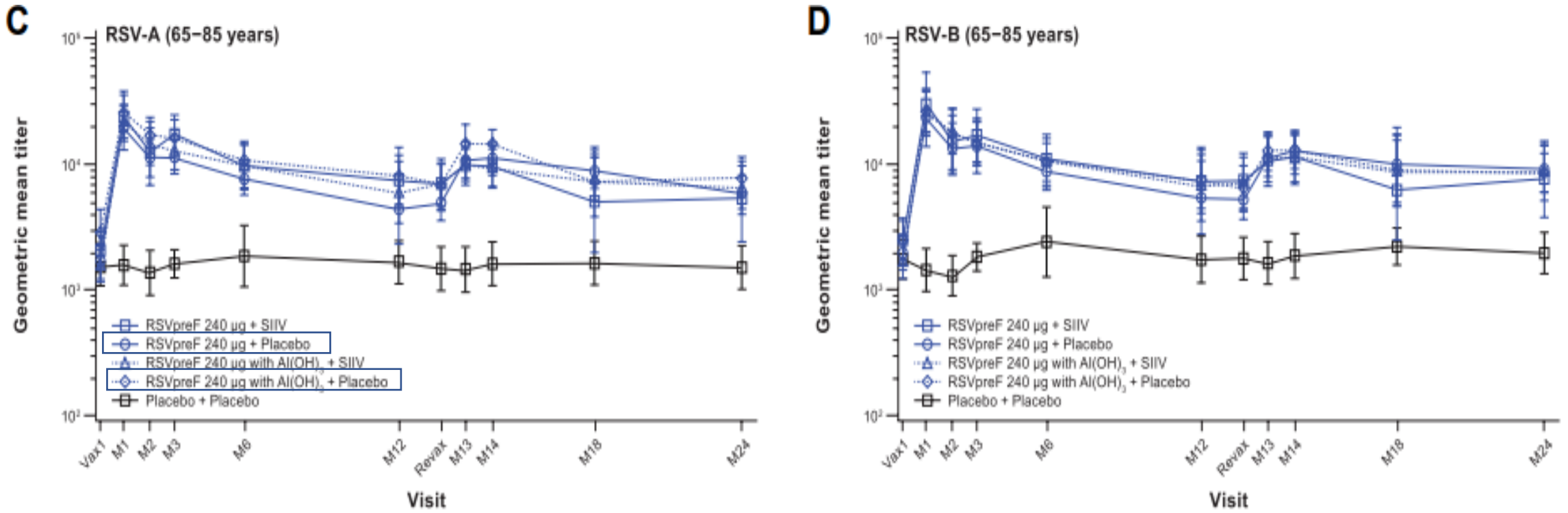
Neutralizing Antibody	Day 29 GMT After Revaccination	RSV-LRTD 2+	RSV-LRTD 3+
RSV-A (IU/mL)	12382	60% (43, 74)	68% (44, 84)
RSV-B (IU/mL)	4024	58% (40, 73)	67% (44, 84)



Correlate of protection model suggests revaccination restores vaccine efficacy

Shaw CA, et al., Safety and Immunogenicity of an mRNA-Based RSV Vaccine Including a 12-Month Booster in a Phase 1 Clinical Trial in Healthy Older Adults. J Infect Dis. 2024 Sep 23;230(3):e647-e656.
Frances Priddy Moderna presentation, at ACIP April 16 2025, available at https://www-cdc-gov.proxy.insermbiblio.inist.fr/acip/meetings/

moderna



Walsh EE, et al. Respiratory Syncytial Virus Prefusion F Vaccination: Antibody Persistence and Revaccination. J Infect Dis. 2024 Oct 16;230(4):e905-e916. doi: 10.1093/infdis/jiae185.

- Vaccine efficacy of an annual revaccination over 2 seasons does not bring higher protection than 1 dose (data GSK)

Figure 1. Vaccine efficacy against first occurrence of RSV-LRTD and RSV-ARI over 2 RSV seasons (modified exposed population)

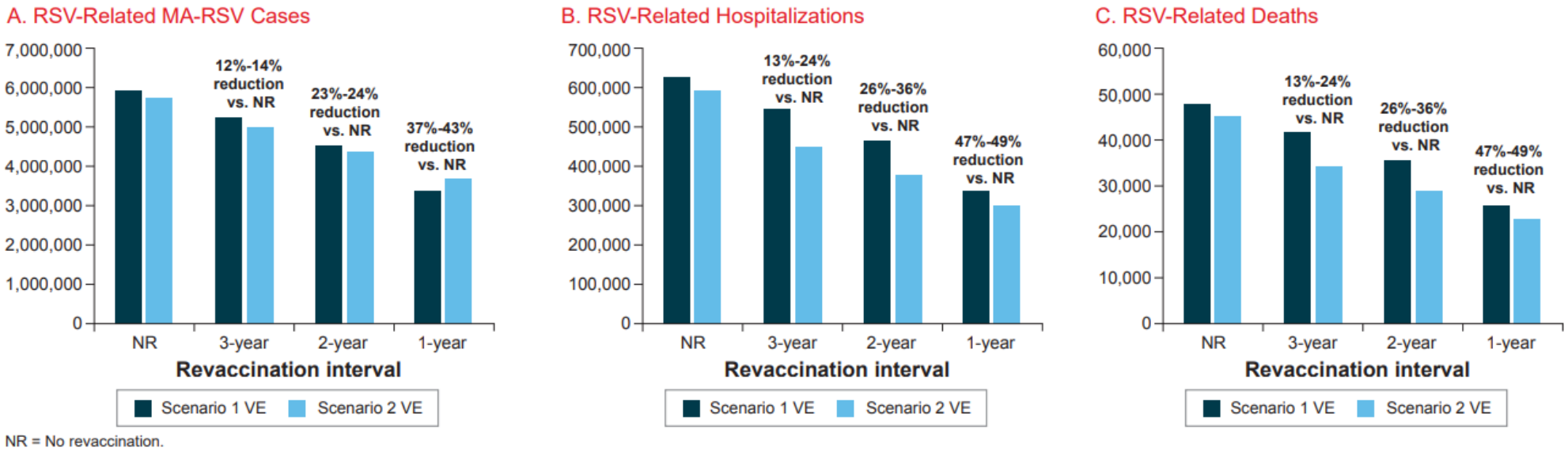
	RSVPreF3 OA		Placebo		VE (%) with CI[a]
	N	n	N	n	
VE of annual revaccination over 2 seasons					
RSV-LRTD					
Overall	12,469	30	12,498	139	67.1
Severe	12,469	7	12,498	48	78.8
By age[b]					
60–69 YOA	6,963	14	6,981	74	71.6
70–79 YOA	4,489	12	4,489	55	66.2
By baseline comorbidities					
≥1 comorbidity of interest[c]	4,983	12	4,919	72	75.1
By frailty[b]					
Pre-frail[d]	4,794	7	4,779	47	77.3
RSV-ARI					
Overall	12,469	80	12,498	292	60.3
VE of 1 RSVPreF3 OA dose over 2 seasons					
RSV-LRTD					
Overall	12,469	30	12,498	139	67.2
Severe	12,469	7	12,498	48	78.8
By age[b]					
60–69 YOA	6,963	17	6,981	74	65.4
70–79 YOA	4,489	9	4,489	55	74.9
By baseline comorbidities					
≥1 comorbidity of interest[c]	4,983	16	4,919	72	66.7
By frailty[b]					
Pre-frail[d]	4,794	8	4,779	47	73.3
RSV-ARI					
Overall	12,469	94	12,498	292	52.7

Ison MG, et al., 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. Open Forum Infect Dis. 2023 Nov 27;10 (Suppl 2):ofad500.2467.

Modelisation data of efficacy with revaccination

- Using vaccine effectiveness (no data on mRNA vaccine) and vaccine efficacy from trials, Moderna evaluate the vaccine efficacy of revaccination at 1, 2, 3 years versus no revaccination.

Figure 2. RSV-Related Outcomes With No Revaccination Versus 1-, 2-, and 3-Year Revaccination After Primary Vaccination: A 6-Year Time Horizon

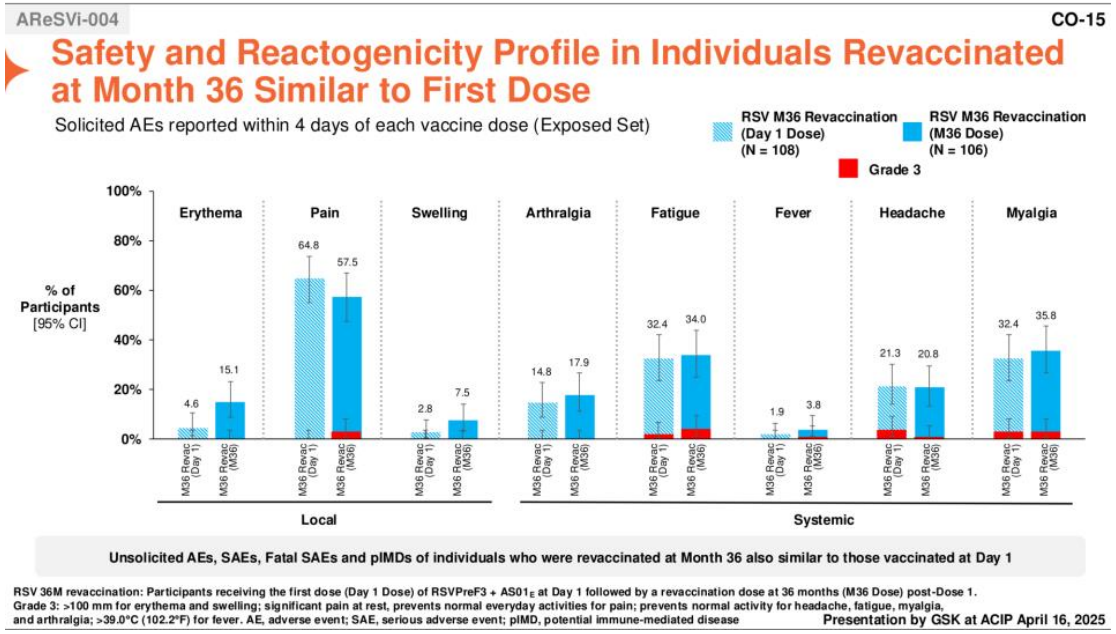


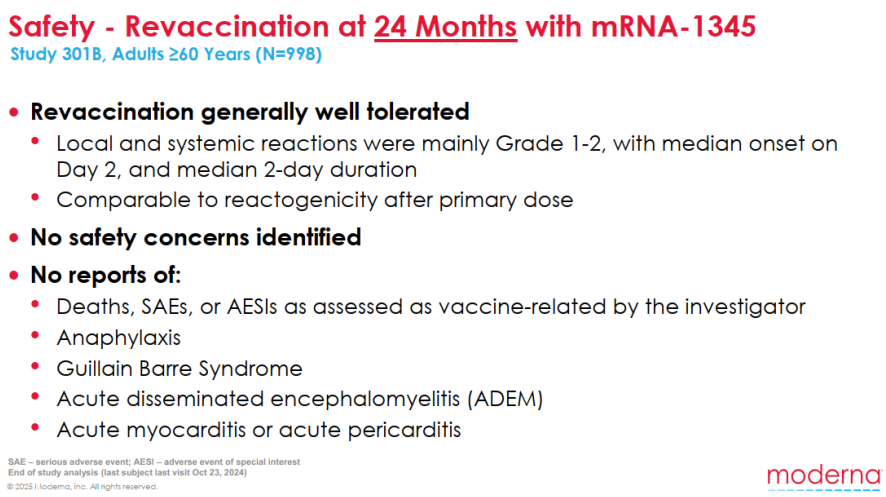
NR = No revaccination.

Hicks K et al., Optimal Revaccination Intervals for Sustained Public Health Impact Following Primary Respiratory Syncytial Virus (RSV) Vaccination in Older Adults in the US. ISIRV 2025. https://investors.modernatx.com/events-and-presentations/Scientific--Medical-Meetings/default.aspx

Safety of revaccination

- Data provided by GSK and Moderna are reassuring
- Safety profile after revaccination acceptable and consistent with first dose
- No GBS or ADEM reported
- No pericarditis, myocarditis reported





Susan Gerber Medical director GSK-presentation at ACIP April 16 2025
Frances Priddy Moderna presentation, at ACIP April 16 2025
Available at : https://www.cdc.gov/acip/meetings/presentation-slides-april-15-16-2025.html

Revaccination with RSV vaccines?

- **YES**
- **But not annualy!**
- When?
- **We don’t know**…. every 2 years?, every 3 years? every 5 years?
- Cost effectiveness models used these schedules
- The same for each vaccine available?
- Studies ongoing need to address these questions
- In USA, recommendations are to NOT vaccinate people that already received RSV shot, to increase target population > 50 years-old with comorbidities

ACIP Adult RSV Work Group Clinical Considerations

Diya Surie, MD
Michael Melgar, MD
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Coronavirus and Other Respiratory Viruses Division (CORVD)
Advisory Committee on Immunization Practices (ACIP)
April 16, 2025

RSV vaccination will have the most benefit if given in late summer or early fall.

- This means from **August to October in most of the United States.**
- Note this is not a formal seasonal recommendation for RSV vaccination. Eligible adults may continue to receive RSV vaccination year-round.

Adults who have already received a dose of RSV vaccine should NOT receive another dose at this time.

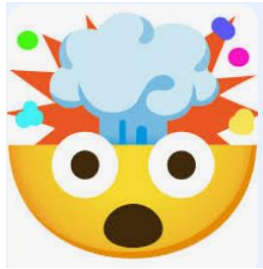
- RSV vaccination should be given ONLY to adults who have not yet received a dose of RSV vaccine.
- It is anticipated that adults may need additional doses of RSV vaccine in the future, but ideal revaccination timing is not yet known.

https://www-cdc-gov.proxy.insermbiblio.inist.fr/acip/meetings/

If not seasonal, if not yearly? When to revaccinate?

- Coadministration with other vaccines recommended in older people crucial+++
  - with Influenza vaccines: possible in some seasons
    - Immunogenicity can be different for RSV or Flu, clincally significant?
  - with mRNA COVID-19 vaccine (Moderna): possible in some seasons
  - with PCV-20 (GSK study complete no results available):?
  - with Zoster vaccine: ok (GSK)

- Need for a vaccine registry+++++, not available in all the countries!
- Need for a decision aid, helping HCWs for people < 75 years-old
- I hope that all vaccines have the same schedule of revaccination…..
- Or that preferential vaccine recommendation will be implemented
- Because, if it is not the case I am afraid that it will be a brainteaser for HCPs!



In conclusion,

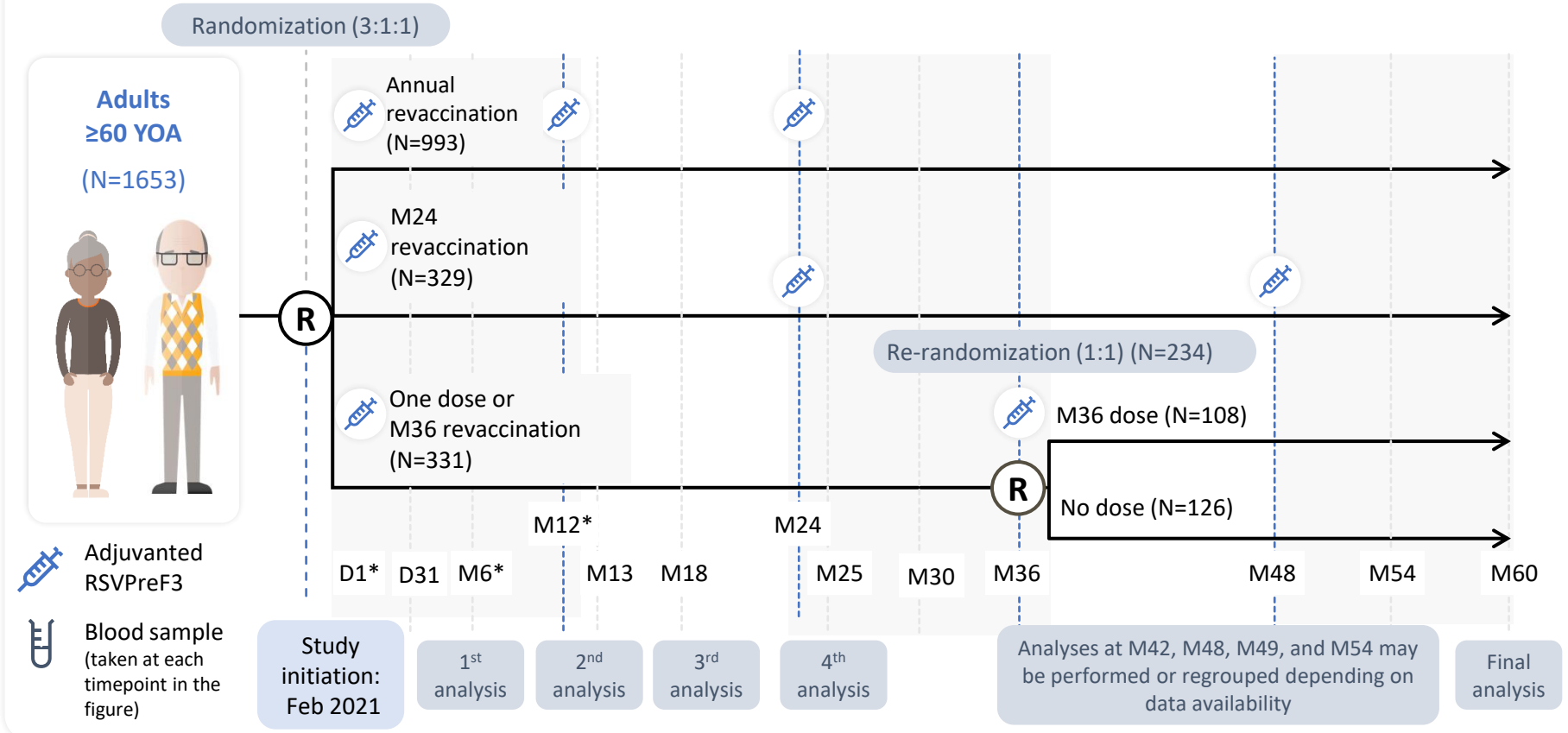
- RSV vaccines immune response and efficacy shown long lasting
- Data from different industrials continue to be heterogenous
- Effectiveness data of more than one season are expected
- Revaccination not annualy (safety, cost)
- Clinical impact of revaccination need to be shown
- Time between revaccination not defined at this time
- How to organize RSV revaccination not so easy….
  - Need for vaccine registry
  - Opportunity of co-administration
- Waiting for more data+++ and clear recommandations


Thank You!
Any questions?

Back-up slides

AReSVi-004 is a Phase 3 open-label study evaluating the immunogenicity, safety, reactogenicity, and persistence of adjuvanted RSVPreF3 vaccination

The study design includes analyses of both single dose and various revaccination schedules[1–5]



Primary objective: Evaluate humoral immune response following a 1-dose primary schedule up to 12 months post-dose 1[1,2,4]*

Key secondary confirmatory objectives: Evaluate humoral and CMI† responses following 1-dose primary schedule and revaccination doses, up to study end (M36). Safety and reactogenicity will also be assessed[2,4]

*Primary endpoints are NAb geometric mean titers (RSV-A and RSV-B) at Day 1 (pre-vaccination), D31, M6, and M12 post-dose 1;[1,2,4] †CMI response in terms of frequency of RSVPreF3-specific CD4+ and/or CD8+ T-cells expressing at least 2 activation markers;[2]
CD, cluster of differentiation; CMI response, cell-mediated immune response; D, day; M, month; NAb, neutralizing antibody; R, randomization; YOA, years of age

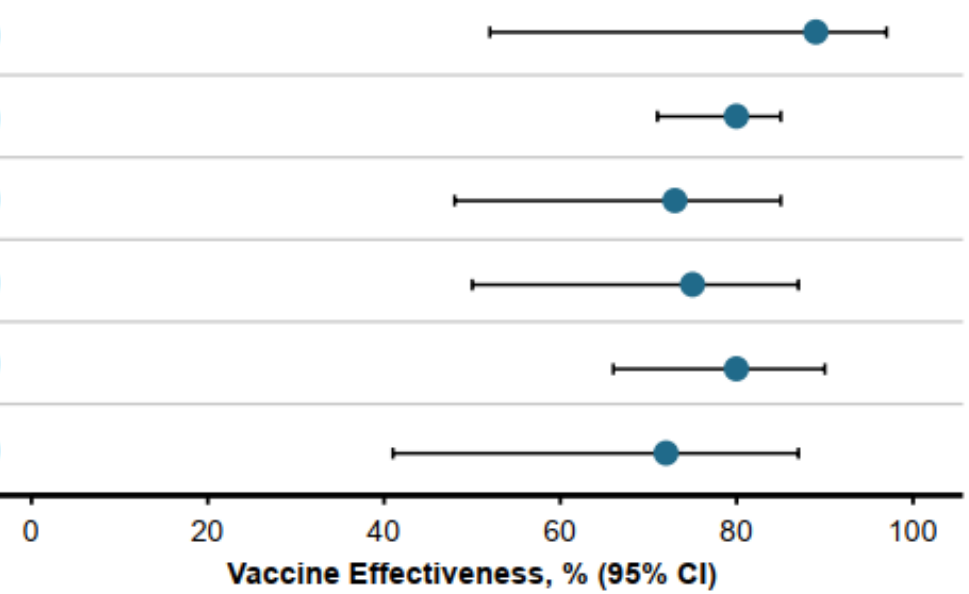
1. ClinicalTrials.gov. NCT04732871. https://clinicaltrials.gov/study/NCT04732871; 2. Schwarz TF *et al*. *J Infect Dis* 2024;230:e102-e110; 3. GSK, 2024. Immunogenicity, safety, reactogenicity and persistence of an investigational respiratory syncytial virus (RSV) vaccine in adults aged 60 years and above. https://www.gsk-studyregister.com/en/trial-details/?id=212496; 4. Gerber S. AREXVY (Adjuvanted RSVPreF3) 2-Year Update. Presented at ACIP, June 26, 2024 https://www.cdc.gov/acip/downloads/slides-2024-06-26-28/03-RSV-Adult-Gerber-508.pdf; 5. GSK, data on file; 2025N565740_00. All URLs accessed March 2025

Observational real-world evidence of VE for RSV Vaccines

For informational purposes only, no head-to-head trials completed

Under real-world conditions, RSV vaccines provide protection against severe RSV disease among US adults aged ≥60 years In the first season of use

RSV-associated vaccine effectiveness against hospitalization or ED/hospitalization	VE, % (95% CI)
KPSC Network,[1,2] adults aged ≥60 years[1*]	89 (52, 97)
VISION, adults aged ≥60 years, immunocompetent[3]	80 (71, 85)
VISION, immunocompromised[3]	73 (48, 85)
IVY Network, adults aged ≥60 years[4*]	75 (50, 87)
VHA, adults aged ≥60 years[5*]	80 (66, 90)
Medicare ESRD, otherwise immunocompetent, adults aged ≥65 years[6]	72 (41, 87)



*Includes patients with immunocompromising conditions in the displayed vaccine effectiveness estimate.
Adapted from the studies cited in references 1–5
CI, confidence interval; ED, emergency department; ESRD, end-stage renal disease; KPSC, Kaiser Permanente Southern California RSV, respiratory syncytial virus; VE, vaccine effectiveness; VHA, Veterans Health Administration.
1. Tartof SY et al. *JAMA Network Open*. 2024;7(12):e2450832. 2. Tartof S. Presented at 13th International RSV Symposium. March 14, 2025. 3. Payne AB et al. *The Lancet*. 2024; 404(10462):1547-1559. 4.Surie D et al. *JAMA*. 2024;332(13):1105–1107. 5. Bajema KL et al. The Lancet Inf Dis. 2025. Published online January 20, 2025. https://doi.org/10.1016/S1473-3099(24)00796-5; 6. Surie D. Effectiveness of adult respiratory syncytial virus (RSV) vaccines, 2023–2024. ACIP Meeting June 26, 2024. https://www.cdc.gov/acip/downloads/slides-2024-06-26-28/07-RSV-Adult-Surie-508.pdf. Accessed February 2025.