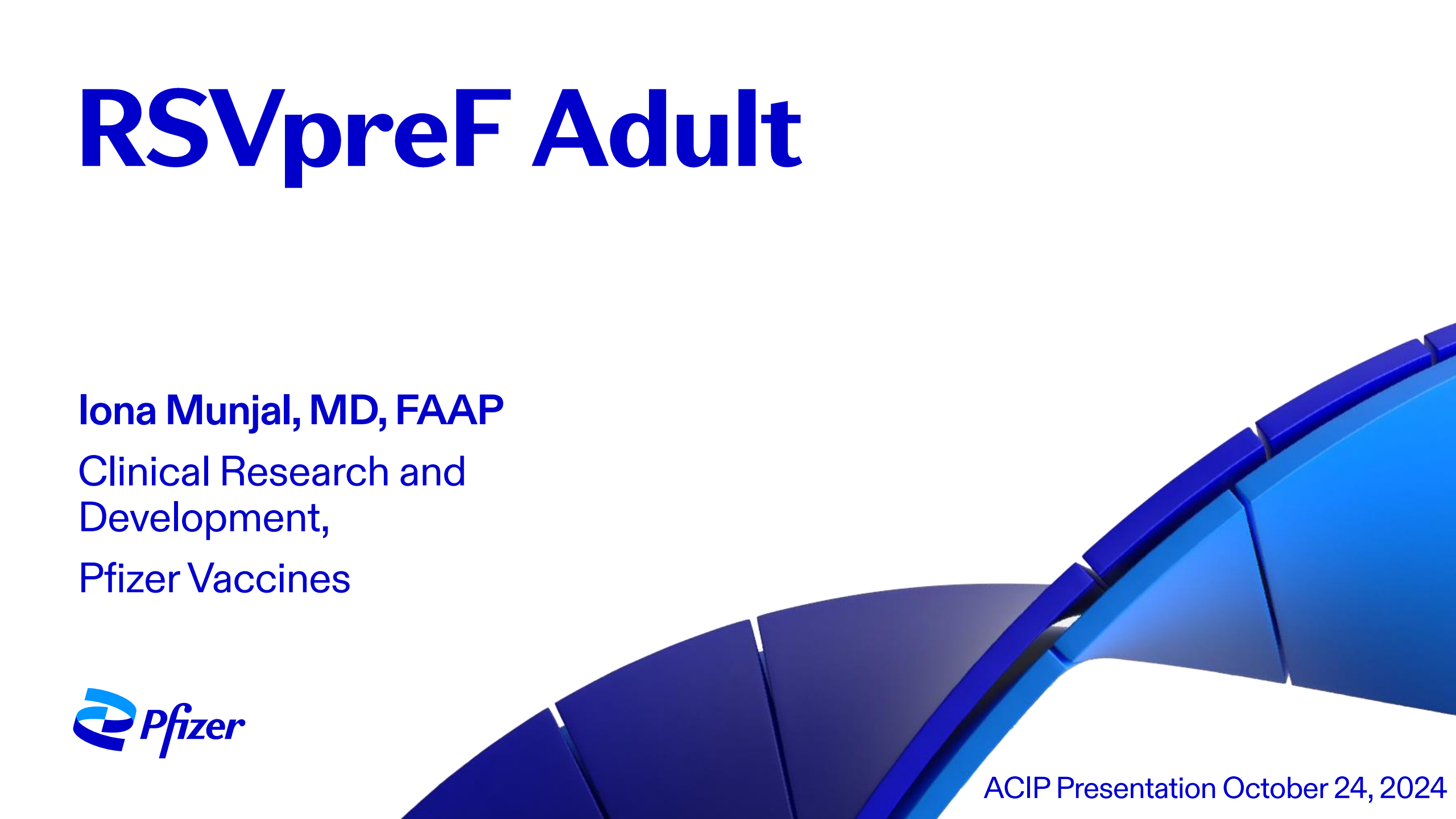
RSVpreF Adult

Iona Munjal, MD, FAAP

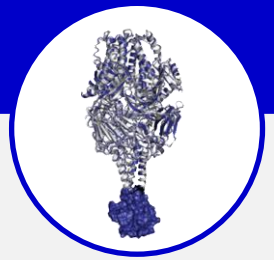
Clinical Research and Development,

Pfizer Vaccines



ACIP Presentation October 24, 2024

RSVpreF Adult – Clinical Development Program Updates



ABRYSVO®
(Respiratory Syncytial Virus Vaccine)

Bivalent Stabilized Prefusion F

RSV A and RSV B strains

Current Indications for ABRYSVO

Adult

Active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older.

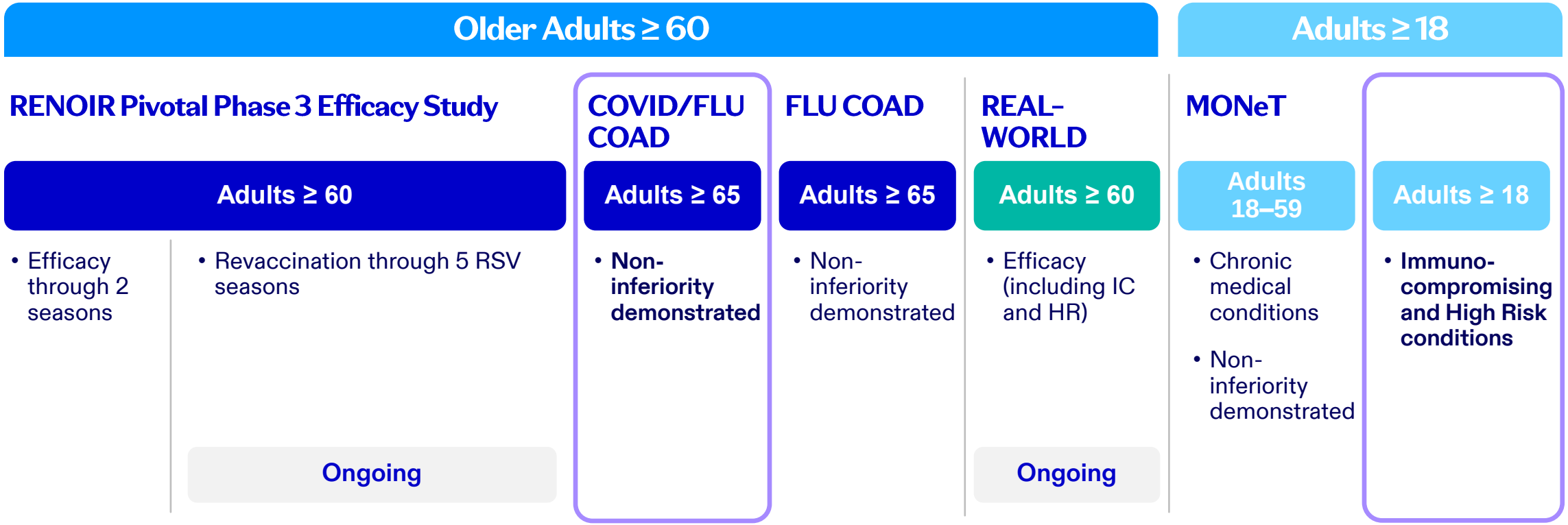
Maternal

Active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age.

NEW APPROVED INDICATION

Active immunization for the prevention of LRTD caused by RSV in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV

RSVpreF Adult – Clinical Development Program

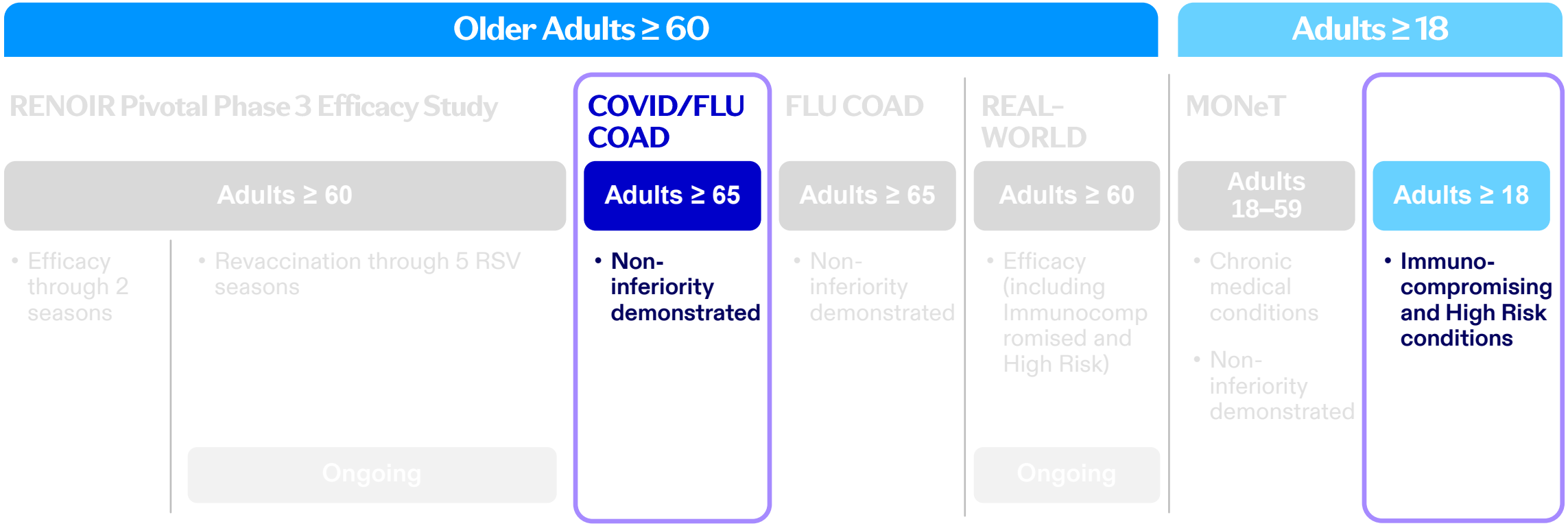


Post-Authorization Safety Studies in Adults

Immunocompromised, or renal, or hepatic impaired in EU	Guillain-Barré Syndrome in US	Atrial Fibrillation in US among VA patients	Near Real-time Guillain-Barré Syndrome in US

KPSC, Kaiser Permanente Southern California; IC, Immunocompromised; HR, High Risk

RSVpreF Adult – Clinical Development Program



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KPSC, Kaiser Permanente Southern California; IC, Immunocompromised; HR, High Risk

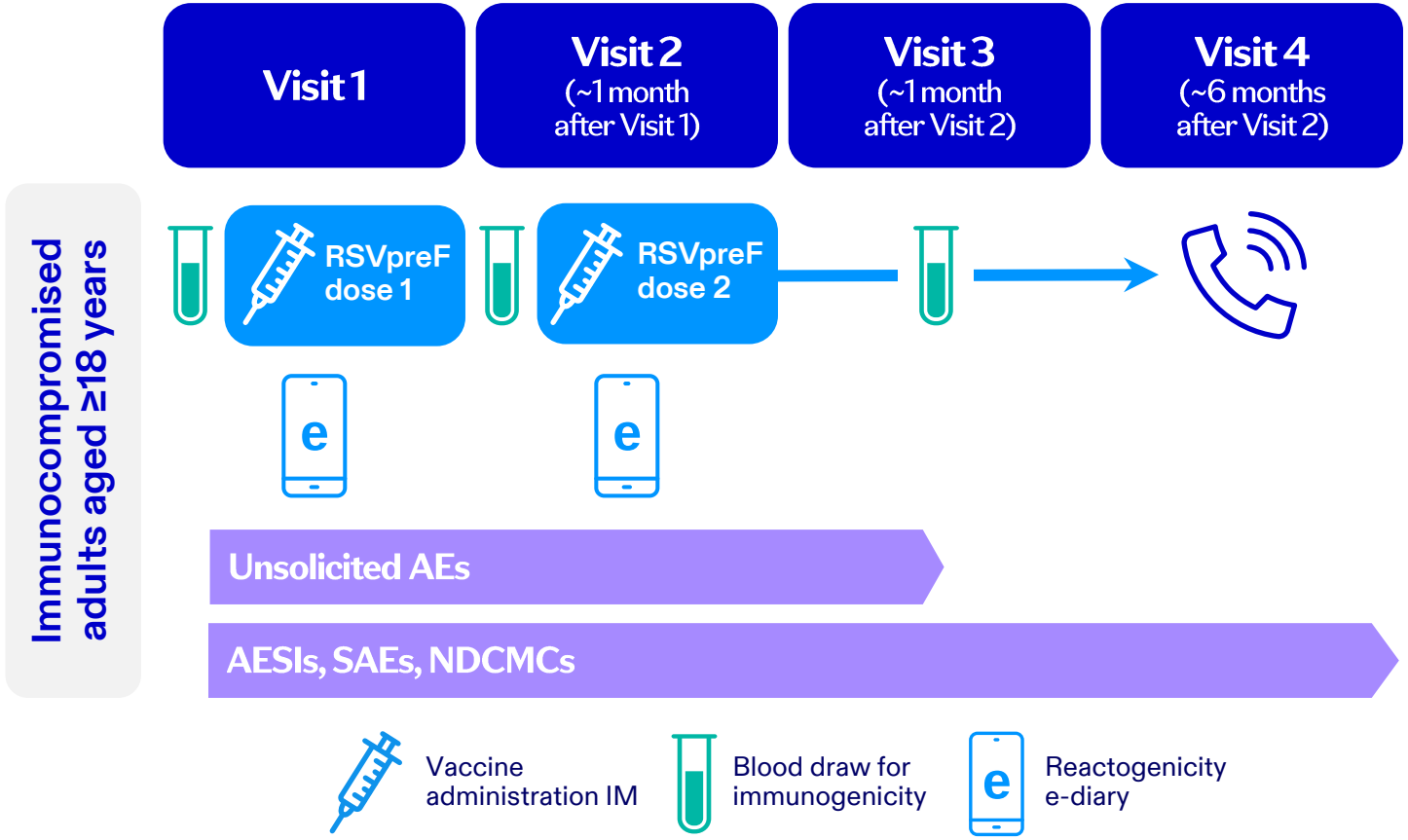
Unmet Need: Immunocompromised and Immunosuppressed Patients (IC) Are at Highest Risk of Severe RSV-Related Disease

Incidence rate and risk for severe complications from RSV infection (hospitalization, mortality, etc.) are higher among immunocompromised adults and those with at risk conditions[1,2,3]

1. Belongia EA, King JP, Kieke BA, et al. Clinical features, severity, and incidence of RSV illness during 12 consecutive seasons in a community cohort of adults ≥60 years old. *Open Forum Infect Dis.* 2018;5(12):ofy316.
2. Wyffels V, Kariburyo F, Gavart S, et al. A real-world analysis of patient characteristics and predictors of hospitalization among US Medicare beneficiaries with respiratory syncytial virus infection. *Adv Ther.* 2020;37(3):1203-17.
3. Rates of Lower Respiratory Tract Illness in US Adults by Age and Comorbidity Profile | Infectious Diseases and Therapy (springer.com).

Assessing Safety, Tolerability, and Immunogenicity of RSVpreF in Immunocompromised At Risk Adults ≥18 Years of Age

- Phase 3, single-arm, open-label, multicenter, descriptive study
- 200 immunocompromised participants aged ≥18 years (~half aged ≥60 years)
- 11 sites in the USA
- May 2023 – March 2024



Abbreviations: AE, adverse event; AESIs, adverse event of special interest; NDCMC, newly diagnosed chronic medical condition; SAE, serious adverse event.
Clinicaltrials.gov NCT05842967

Immunocompromised and High Risk Conditions Included in Study

1. **Non-small cell lung cancer** participants on per protocol therapy

2. **Solid organ transplant** recipients at least 3 months prior to enrollment

   Including:

   - Kidney (19%)
   - Lung (10%)
   - Liver (7%)
   - Heart (2%)

3. Participants with **autoimmune inflammatory disorders** on active immuno-modulator therapy

   Including:

   - Rheumatoid arthritis
   - Systemic lupus erythematosus (SLE)
   - Sjogren's syndrome
   - Ulcerative colitis/Crohn's disease
   - Psoriasis/psoriatic arthritis
   - Multiple sclerosis

4. Participants on **hemodialysis** due to ESRD

Demographics and Baseline Characteristics

	Age: 18 to <60 Years (N=96)	Age: ≥60 Years (N=107)	Total (N=203)
Sex	**n (z%)**	**n (%)**	**n (%)**
Female	56 (58.3)	53 (49.5)	109 (53.7)
Race			
White	63 (65.6)	87 (81.3)	150 (73.9)
Asian	6 (6.3)	2 (1.9)	8 (3.9)
American Indian or Alaska Native	1 (1.0)	3 (2.8)	4 (2.0)
Black or African American	25 (26.0)	15 (14.0)	40 (19.7)
Ethnicity			
Non-Hispanic/ non-Latino	88 (91.7)	101 (94.4)	189 (93.1)
Hispanic/Latino	8 (8.3)	3 (2.8)	11 (5.4)
Age at Dose 1			
Median (min, max)	51 (23, 59)	66 (60, 80)	60 (23, 80)

	Age: 18 to <60 Years (N=96)	Age: ≥60 Years (N=107)	Total (N=203)
Immunocompromised and High Risk Conditions			
Solid Organ Transplant	32 (33.3)	43 (40.2)	75 (36.9)
Autoimmune Inflammatory Disorders on Immunomodulator Therapy	44 (45.8)	53 (49.5)	97 (47.8)
Advanced NSCLC on Therapy	3 (3.1)	2 (1.9)	5 (2.5)
ESRD on Hemodialysis	20 (20.8)	11 (10.3)	31 (15.3)

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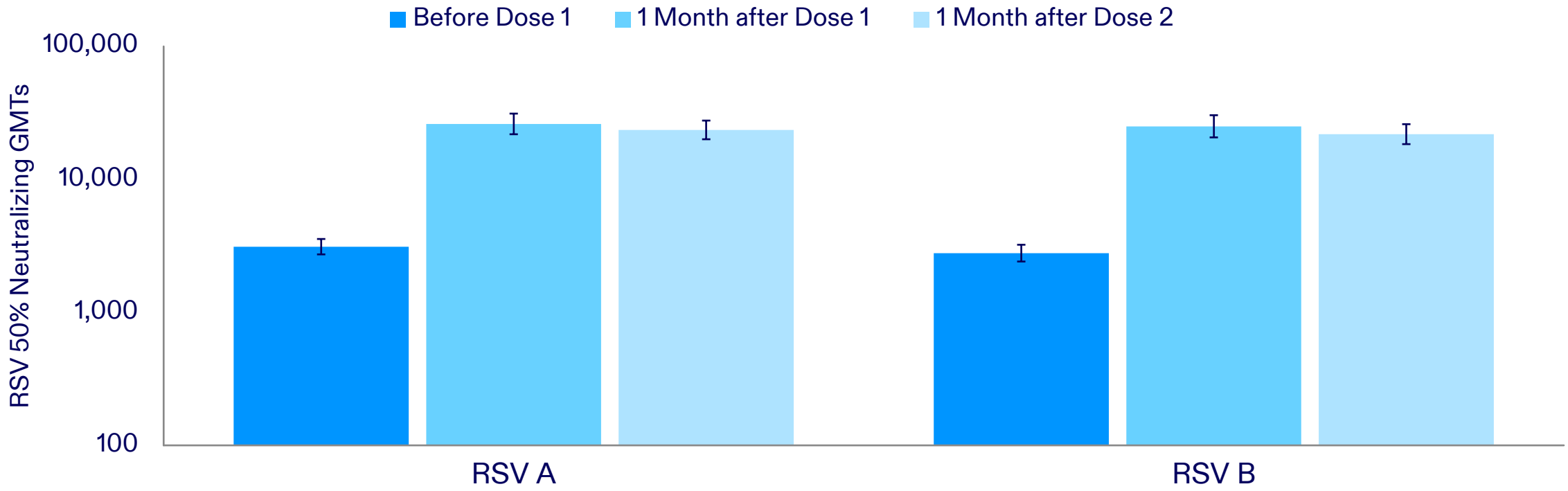
High Neutralizing GMTs 1 Month–post Dose 1, with No Additional Increase After 2nd Dose

GMT (n=188, 95% CI)

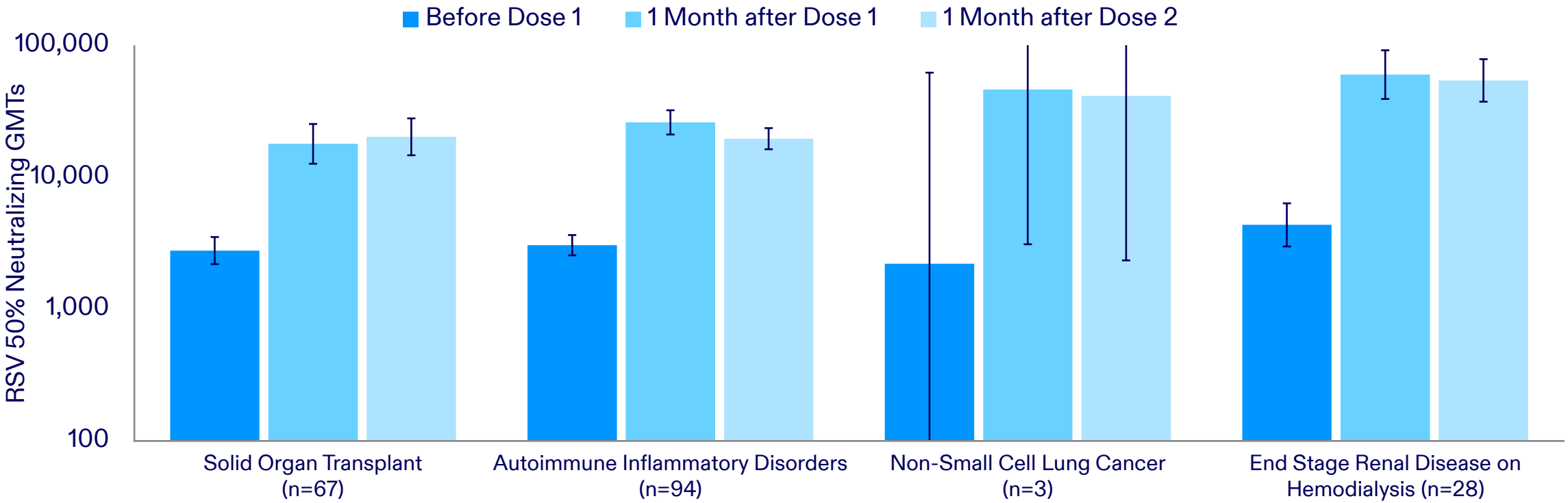


GMFR	8.3	7.5	9.0	7.8

Abbreviations: GMFR = geometric mean fold rise; GMT = geometric mean titer; NA = not applicable; RSV = respiratory syncytial virus.

Robust Neutralizing GMTs and GMFRs in Subgroups for RSV A

GMT (95% CI)

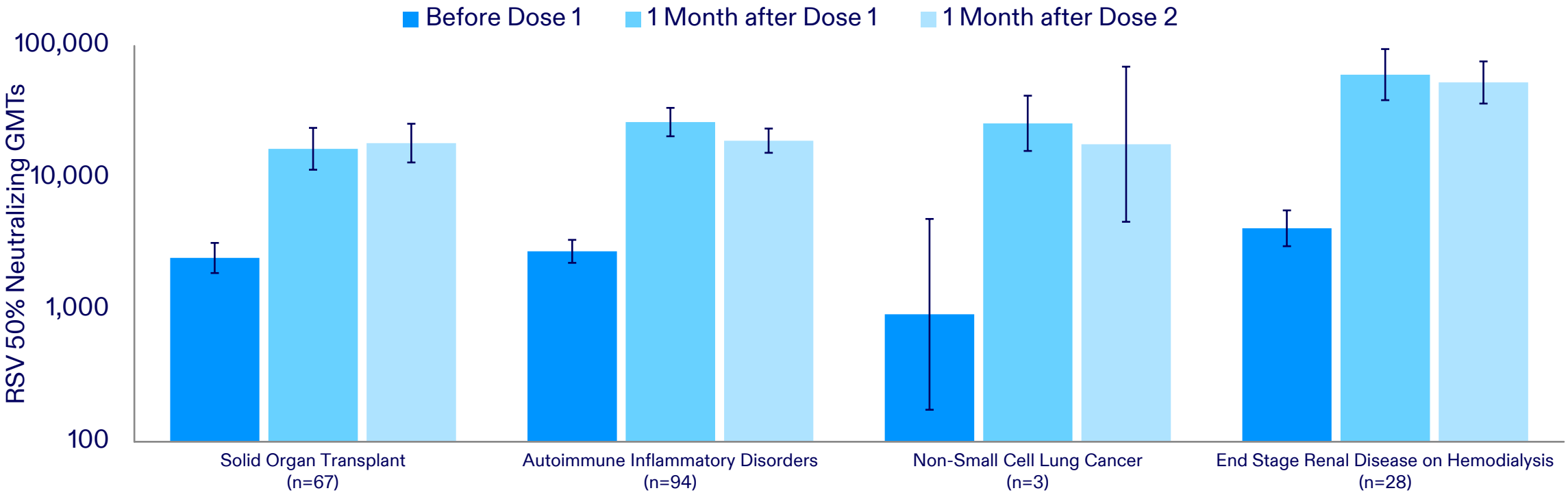


GMFR	6.4	7.2	8.6	6.4	21.0	18.8	13.8	12.5

Abbreviations: GMFR = geometric mean fold rise; GMT = geometric mean titer; NA = not applicable; RSV = respiratory syncytial virus.

Robust Neutralizing GMTs and GMFRs in Subgroups for RSV B

GMT (95% CI)

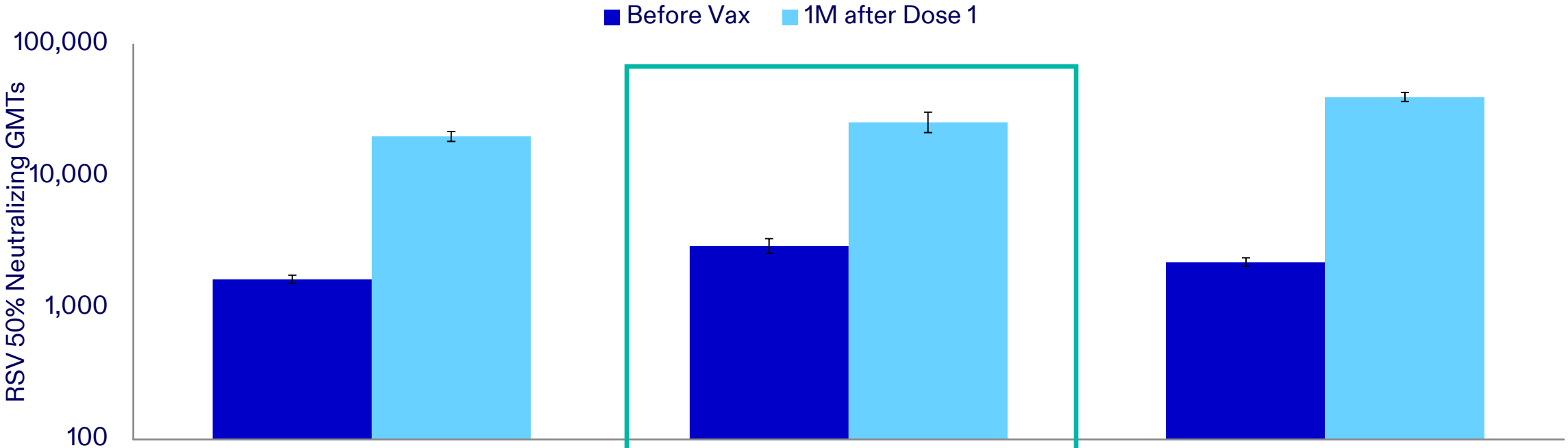


GMFR	6.7	7.4	9.5	6.9	28.0	19.5	14.6	12.7

Abbreviations: GMFR = geometric mean fold rise; GMT = geometric mean titer; NA = not applicable; RSV = respiratory syncytial virus.

Immunocompromised Population Immune Response Similar to Pivotal Efficacy "RENOIR" Study After One Dose

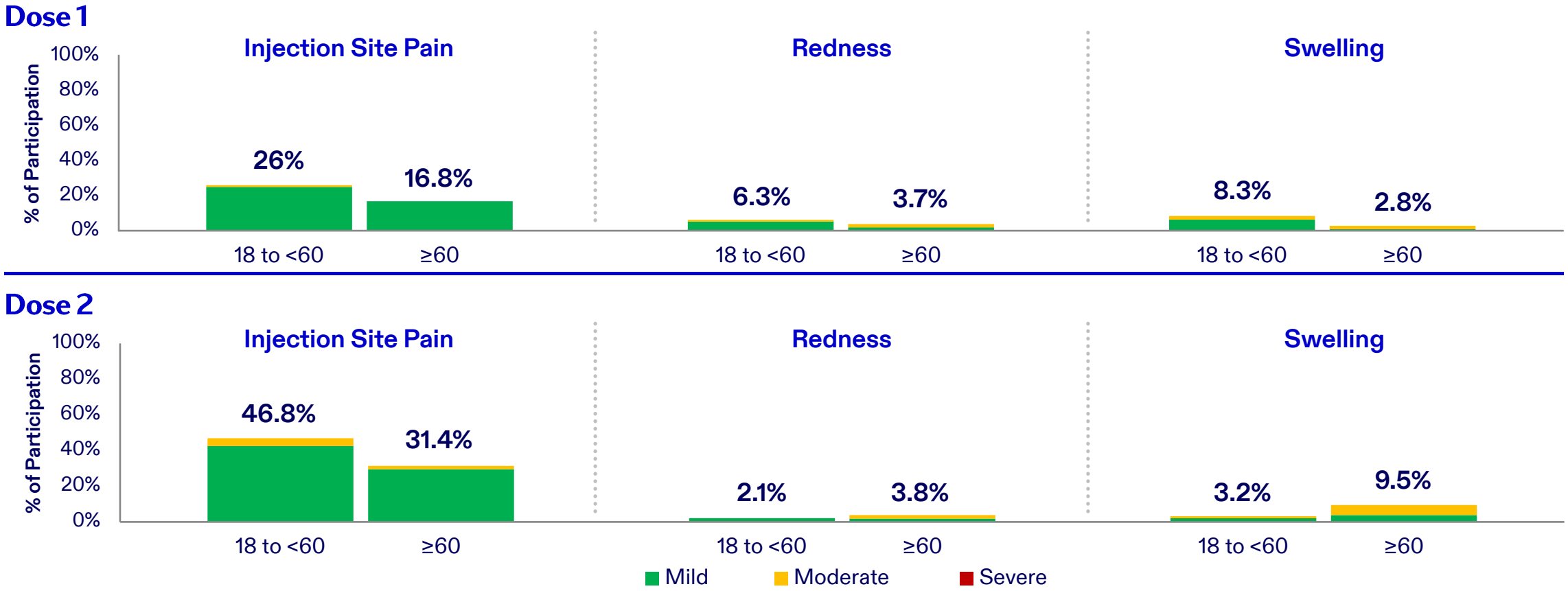
Neutralizing GMTs (by Study/Group)



	Pivotal Efficacy Study "RENOIR" ≥ 60 Years	Immunocompromised and High Risk Study ≥ 18 Years	At Risk Immunobridging Study 18–59 Years
GMFR	12.1	8.7	17.9

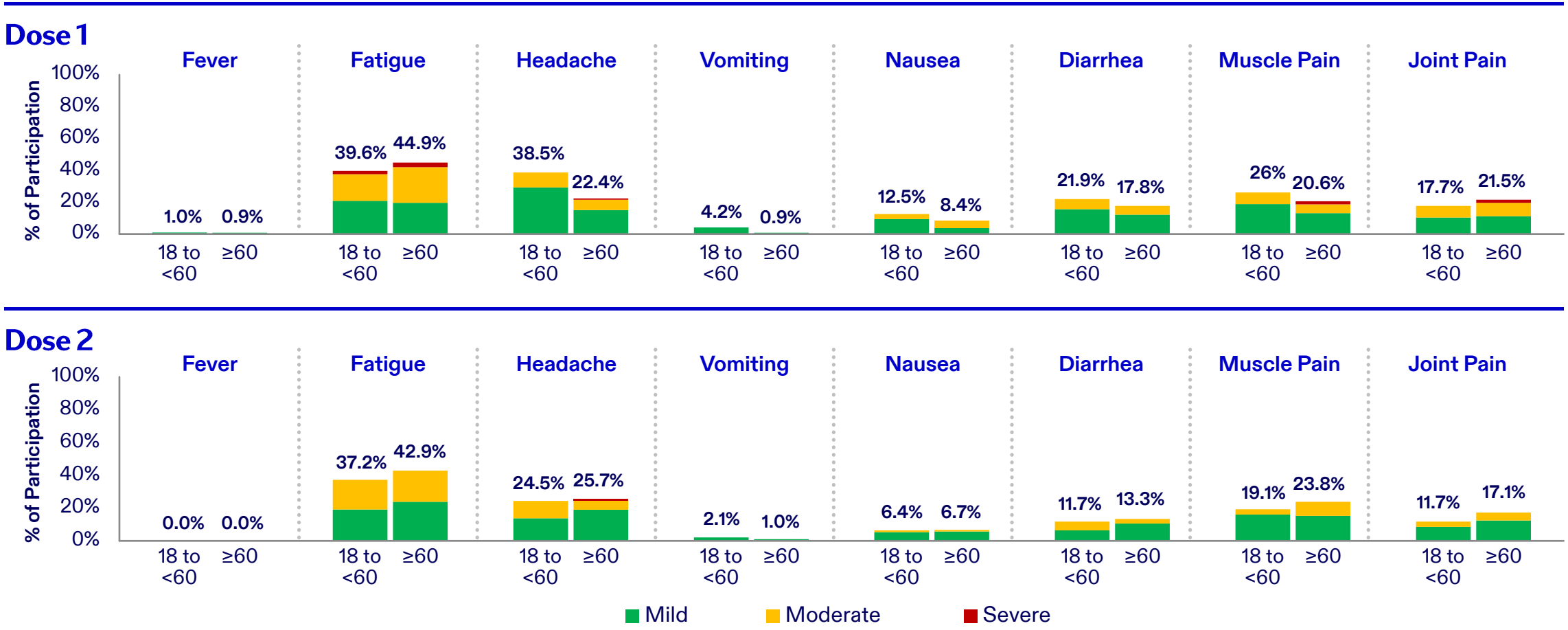
Abbreviations: GMFR = geometric mean fold rise; GMT = geometric mean titer; NA = not applicable; RSV = respiratory syncytial virus; HR: High-risk; IC: Immunocompromised; PD1: Post dose 1.

Local Reactions Within 7 Days After Vaccination Were Mild to Moderate in Immunocompromised Adults



1. Severity definition: mild = no interference with daily activity; moderate = some interference with daily activity; severe = prevents daily activity.
2. Severity definition: mild = >2–5 cm, moderate = >5–10 cm; severe = >10 cm.

Systemic Events Within 7 Days After Vaccination Were Mostly Mild to Moderate in Immunocompromised Adults



Adverse Events Across Study Populations

Adverse Event Category	Age 18 to <60 Years (N=96)	≥60 Years (N=107)
From Vaccination Through 1-Month after Dose 2 Follow-Up Visit		
Any Event	13 (13.5)	24 (22.4)
Severe	2 (2.1)	4 (3.7)
Related	0	2 (1.9)
From Vaccination Throughout the Study		
AE of Special Interest	0	2 (1.9)
SAE	7 (7.3)	15 (14.0)
AEs leading to withdrawal after Dose 1	2 (2.1)	0
AE Leading to Death	0	0
NDCMCs	2 (2.1)	7 (6.5)

AE: Adverse Event, AESI: Adverse Event of Special Interest (Guillain-Barré Syndrome, Acute polyneuropathy without an underlying etiology, Atrial Fibrillation, Preterm delivery, Hypertensive disorder of pregnancy), SAE: Serious Adverse Event, NDCMC: Newly Diagnosed Chronic Medical Condition.

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1 | Pain in the extremity
2 | Atrial Fibrillation

AE: Adverse Event, AESI: Adverse Event of Special Interest (Guillain-Barré Syndrome, Acute polyneuropathy without an underlying etiology, Atrial Fibrillation, Preterm delivery, Hypertensive disorder of pregnancy), SAE: Serious Adverse Event, NDCMC: Newly Diagnosed Chronic Medical Condition.

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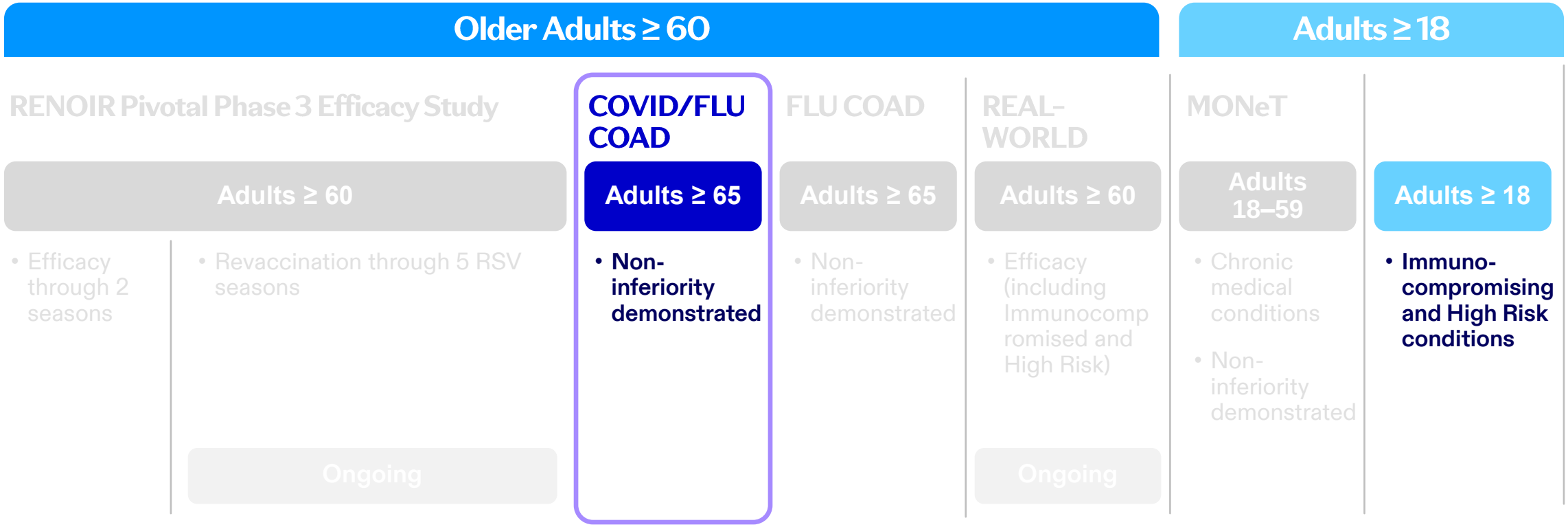
Summary

RSVpreF was **well-tolerated with no safety concerns** among immunocompromised adults aged 18 years or older

1 dose of RSVpreF elicited **high GMTs and GMFRs** in the immunocompromised study populations with **no additional increase after a second dose 1 month apart**

RSVpreF Adult – Clinical Development Program



Post-Authorization Safety Studies in Adults

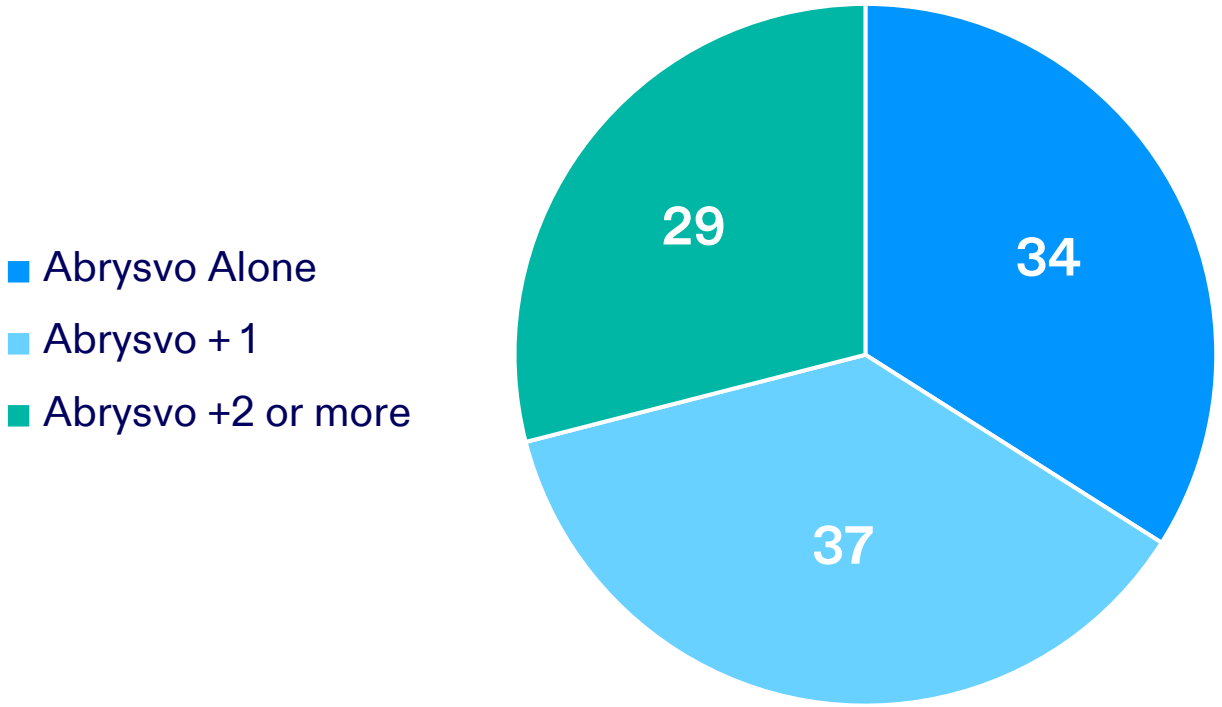
Immunocompromised, or renal, or hepatic impaired in EU	Guillain-Barré Syndrome in US	Atrial Fibrillation in US among VA patients	Near Real-time Guillain-Barré Syndrome in US

KPSC, Kaiser Permanente Southern California

RSV Vaccine Coadministration in Practice

Administration Claims: October 2023

(n= 855, 200)



Abrysvo was most commonly co-administered with influenza and COVID vaccine

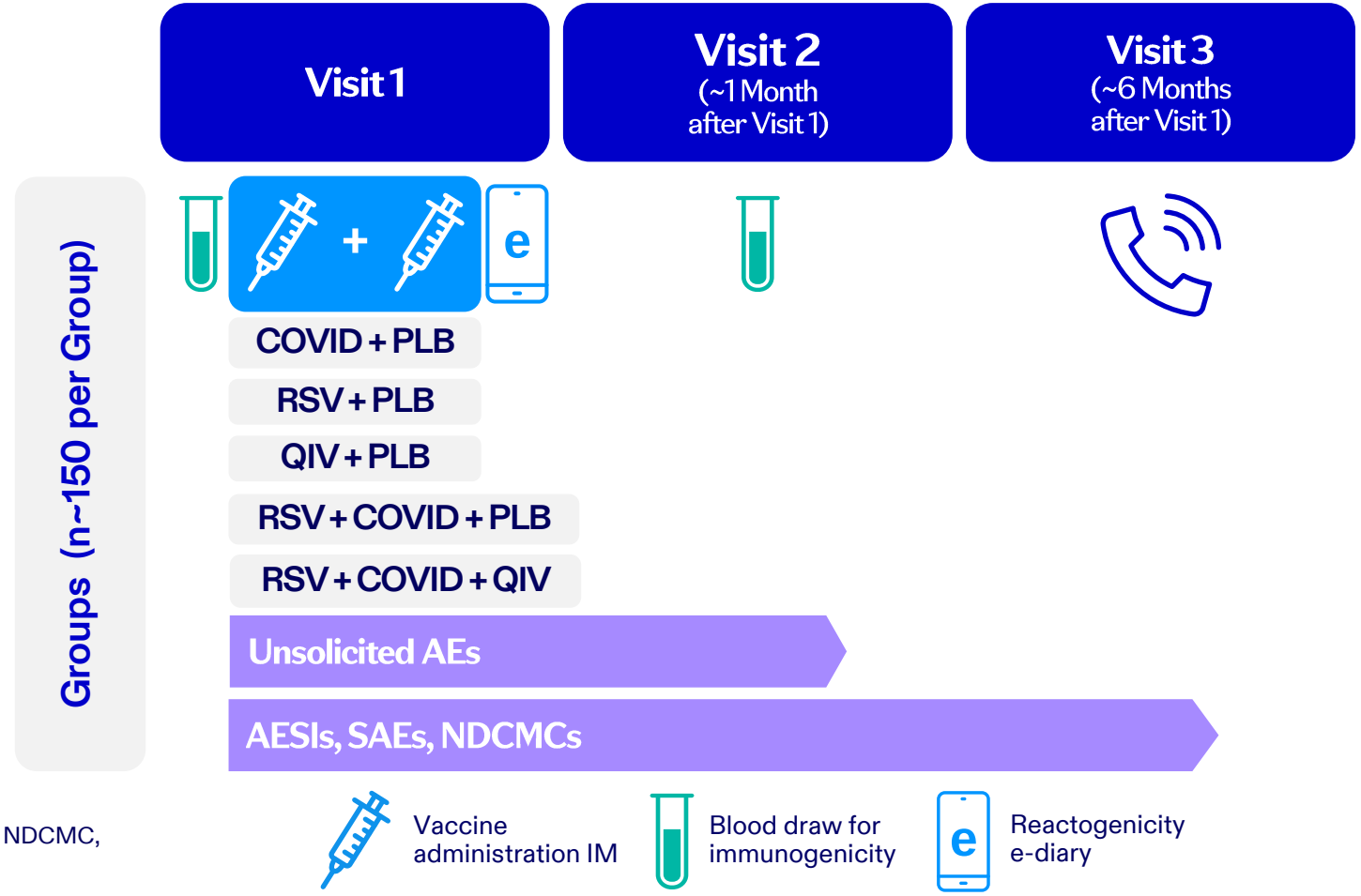
MedAdvisor Solutions. Abrysvo coadministration with 2 vaccines in adults 60 years of age and older in Retail Pharmacies for October 2023. Unpublished data. October 2024 MedAdvisor Solutions network covers about 65% of the US population (around 218 million patients) through 33,500 retail or grocer pharmacies.

Coadministration in Adults ≥65 Years of Age

Assessing Safety, Tolerability and Non-inferiority Immunogenicity

Study Vaccinations:
COVID = Comirnaty
RSVpreF: Abrysvo
QIV: Fluzone HD Quad
PLB = Placebo

- Randomized, parallel group, observer-blinded study
- 30 sites in the USA
- ~750 participants aged ≥65 years
- No Prior RSV Vaccine
- No Flu vaccine ≤120 days
- At least 3 prior COVID-19 vaccines ≥150 days prior



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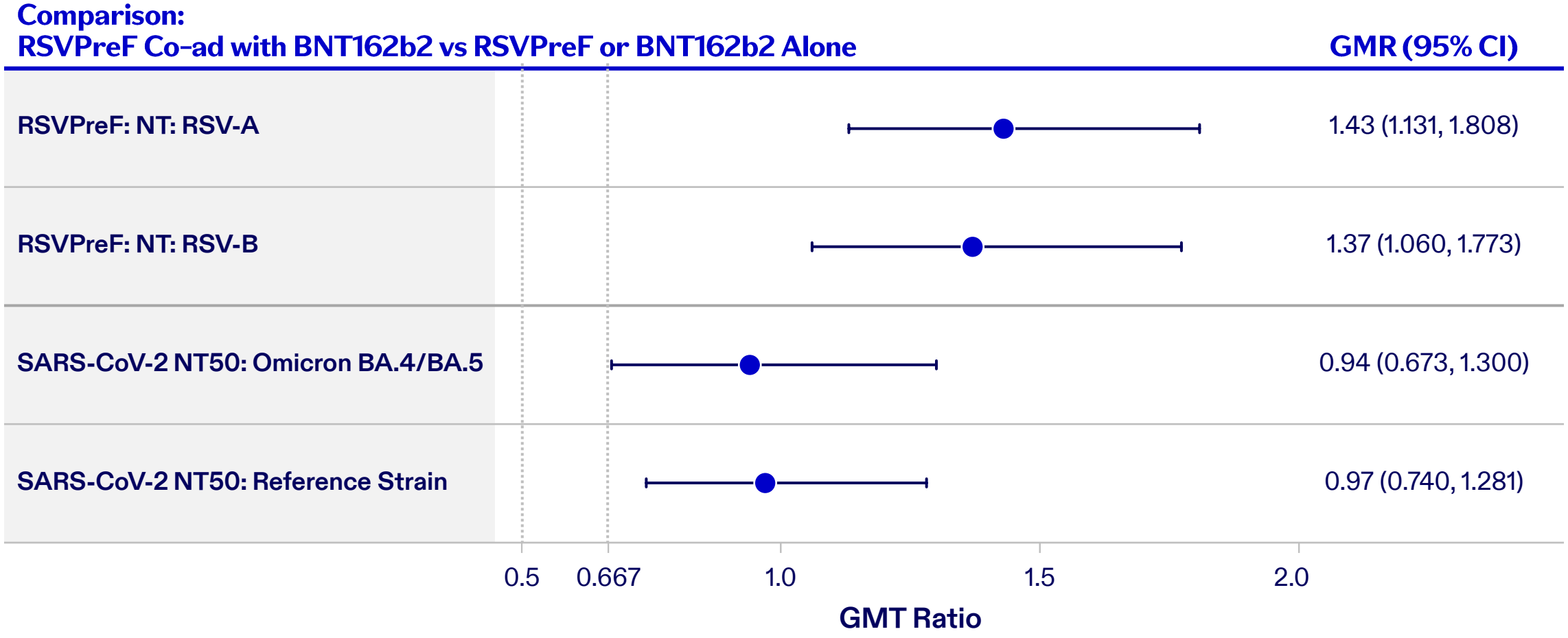
Clinicaltrials.gov NCT05886777

Demographics and Baseline Characteristics

	COVID (N=150)	RSV (N=152)	QIV (N=149)	RSV + COVID (N=157)	RSV + COVID + QIV (N=158)
Sex	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Female	80 (53.3)	80 (52.6)	79 (53.0)	94 (59.9)	83 (52.5)
Race					
White	131 (87.3)	140 (92.1)	135 (90.6)	139 (88.5)	138 (87.3)
Black or African American	13 (8.7)	10 (6.6)	9 (6.0)	14 (8.9)	13 (8.2)
American Indian or Alaska Native	1 (0.7)	0	1 (0.7)	0	1 (0.6)
Asian	2 (1.3)	1 (0.7)	3 (2.0)	3 (1.9)	5 (3.2)
Other	3 (2)	1 (0.7)	1 (0.7)	1 (0.6)	1 (0.6)
Ethnicity					
Hispanic/Latino	10 (6.7)	17 (11.2)	12 (8.1)	18 (11.5)	15 (9.5)
Age at Vaccination (Years)					
Median (min, max)	70 (65, 87)	71 (65, 85)	71 (65, 87)	70 (65, 87)	71 (65, 90)

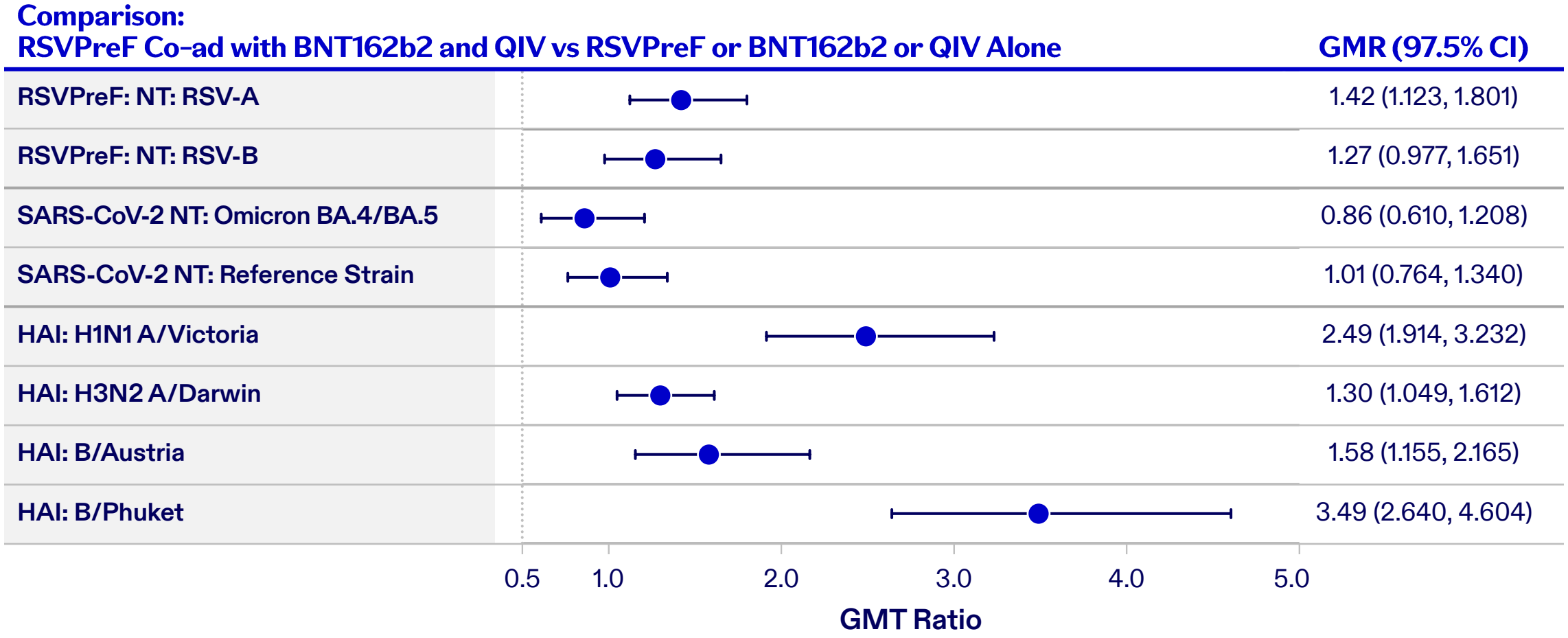
Race Other: Native Hawaiian or other Pacific Islander, Multiracial, or Not reported

Co-administered Bivalent BNT162b2 COVID-19 & RSVpreF Met 1.5-Fold Non-inferiority for All Four Antigens



Abbreviations: GMR = geometric mean ratio; NTS0 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Co-administered Bivalent RSVpreF, BNT162b2 COVID-19, & QIV Met Protocol-specified Non-inferiority Criteria



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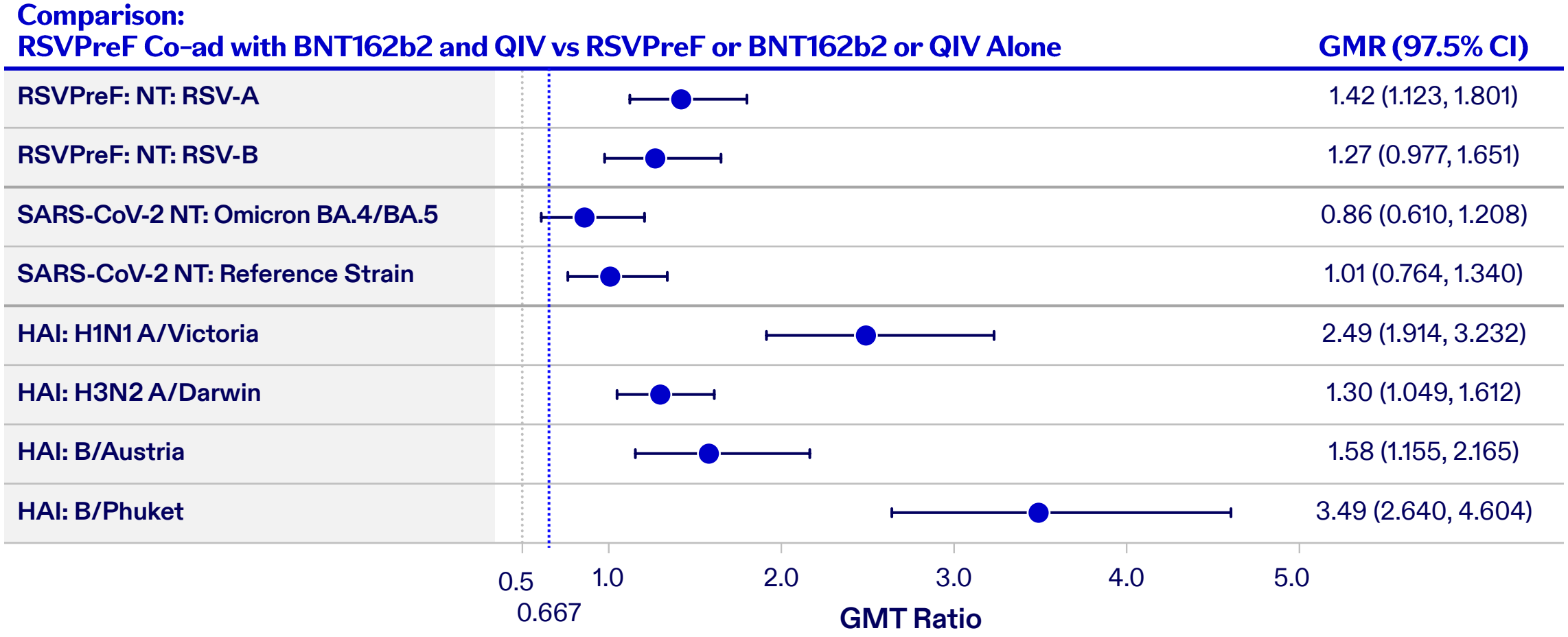

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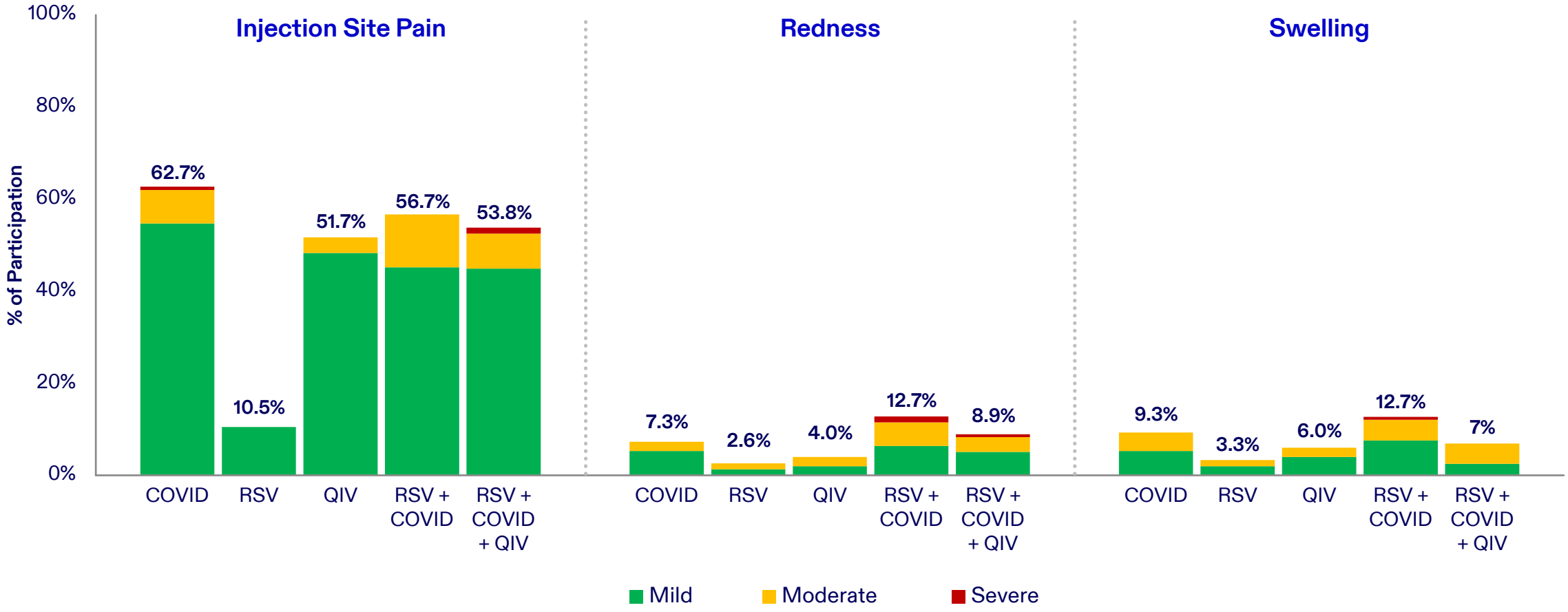
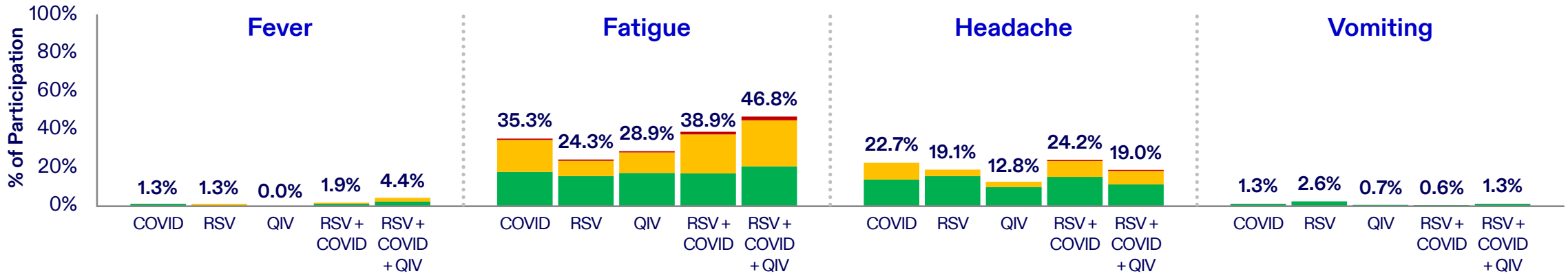
Local Reactions in Co-Ad Groups Mostly Mild or Moderate, Similar to Stand-Alone

Vaccine as Administered



Systemic Events in Co-Ad groups Within 7 Days After Vaccination Were Mostly Mild to Moderate, Similar to Stand-Alone

Vaccine as Administered



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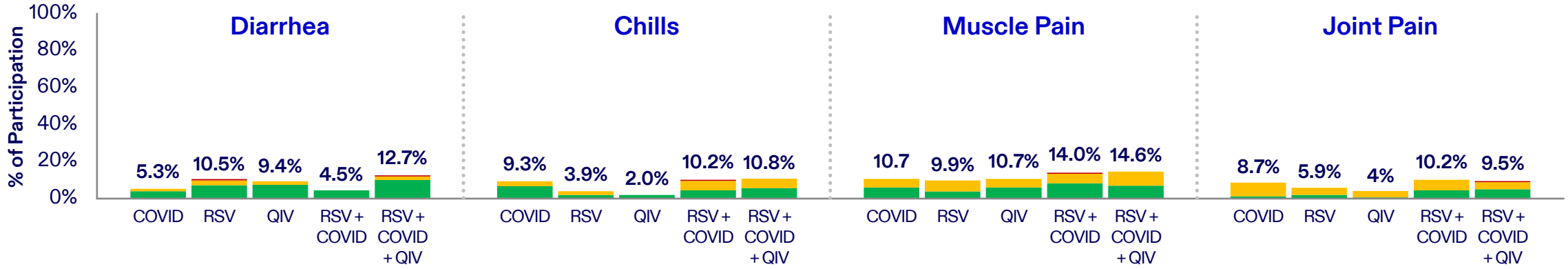

Adverse Events Similar When Administered Alone or Concomitantly

Adverse Event Category	COVID (N=150)	RSV (N=152)	QIV (N=149)	RSV + COVID (N=157)	RSV + COVID + QIV (N=158)
From Vaccination Through 1-Month Follow-Up Visit					
Any Event	12 (8)	11 (7.2)	12 (8.1)	14 (8.9)	14 (8.9)
Related	1 (0.7)	1 (0.7)	2 (1.3)	4 (2.5)	4 (2.5)
Immediate	0	0	0	0	1 (0.6)
Severe	1 (0.7)	0	0	0	1 (0.6)
From Vaccination Throughout the Study					
SAE	4 (2.7)	2 (1.3)	2 (1.3)	1 (0.6)	3 (1.9)
AE Leading to Death	0	0	0	0	0
AE of Special Interest	9 (6)	2 (1.3)	3 (2)	5 (3.2)	4 (2.5)

AE: Adverse Event, AESI: Adverse Event of Special Interest (COVID-19, positive SARS-CoV-2 test, Guillain-Barré Syndrome, Acute polyneuropathy without an underlying etiology, Atrial fibrillation, Preterm delivery, Hypertensive disorder of pregnancy), SAE: Serious Adverse Event, NDCMC: Newly Diagnosed Chronic Medical Condition.

Adverse Events Similar When Administered Alone or Concomitantly

Adverse Event Category	COVID (N=150)	RSV (N=152)	QIV (N=149)	RSV + COVID (N=157)	RSV + COVID + QIV (N=158)
From Vaccination Through 1-Month Follow-Up Visit					
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Related	**1 (0.7)**	**1 (0.7)**	**2 (1.3)**	**4 (2.5)**	**4 (2.5)**
Immediate	0	0	0	0	1 (0.6)
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Severe	**1 (0.7)**	**0**	**0**	**0**	**1 (0.6)**
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Summary

- Co-administration is common; safety and immunogenicity data supports ACIP co-administration guidelines regarding RSVpreF with COVID and/or with Influenza Vaccines.
- Safety and immunogenicity was demonstrated for a single dose of RSVpreF in IC and HR adults
- Ongoing Clinical Trials and Post-Licensure Studies continue to provide meaningful data to assess the safety, effectiveness, and benefit/risk of the product. There have been no new safety concerns identified in the post-licensure period to date.

Thank You

Pfizer