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BIONTECH

2026-2027 COVID-19 Vaccine Formula: Pfizer/BioNTech Supportive Data

Vaccines and Related Biological Products Advisory Committee

May 28, 2026

Presentation Outline



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Global Medical Affairs,
Vaccines, Pfizer Inc.

Vaccine Adaptation Framework

SARS-CoV-2 Lineage Epidemiology

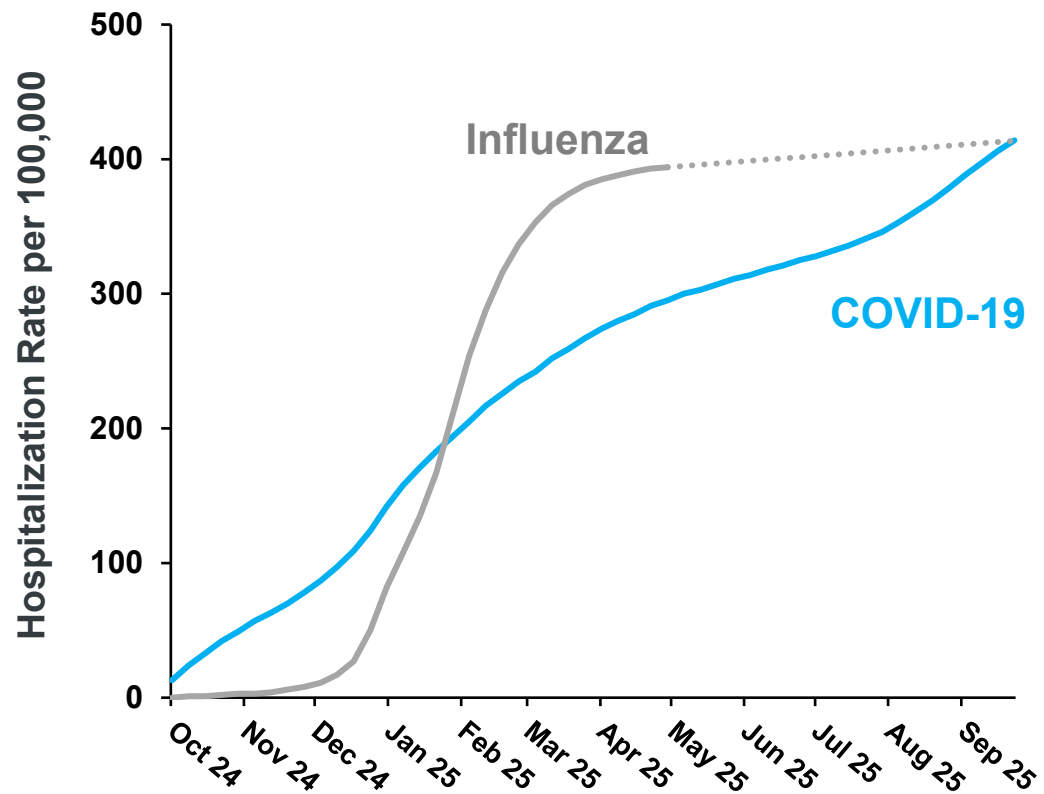
LP.8.1 Vaccine Effectiveness

LP.8.1 Vaccine Clinical Immunogenicity

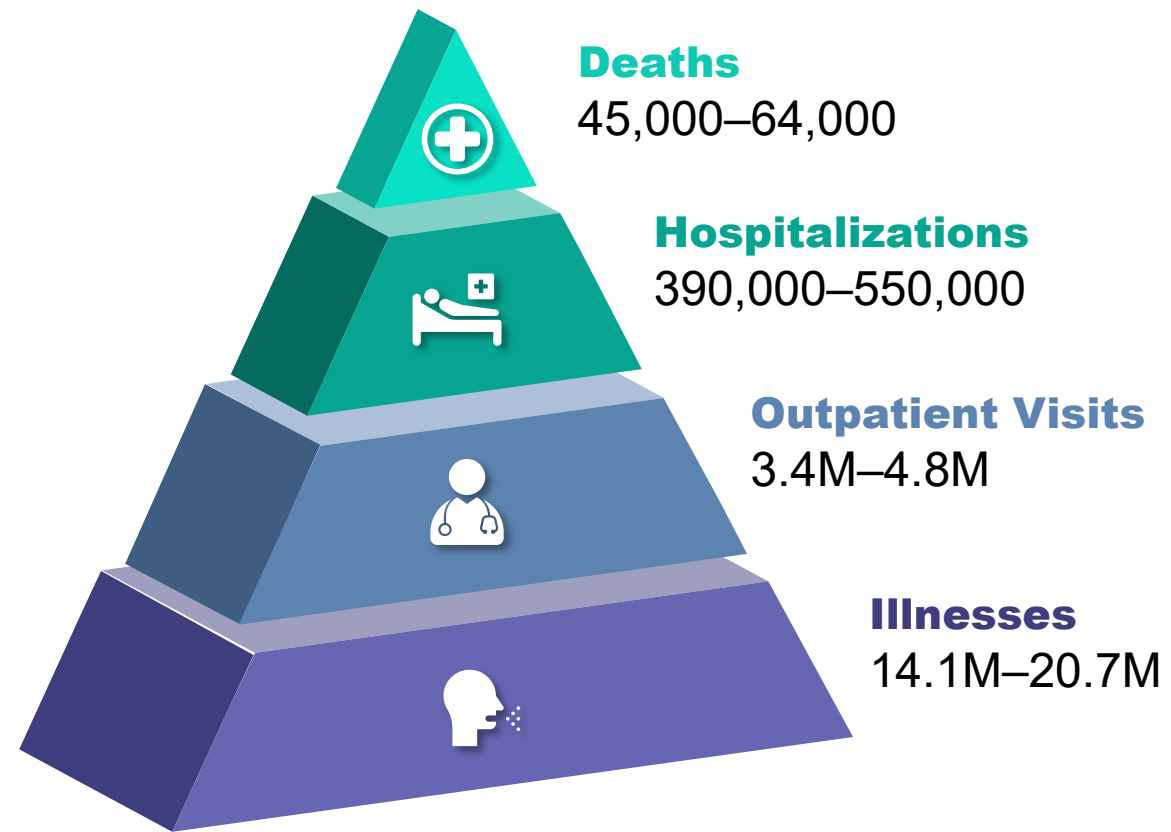
**Preclinical Immunogenicity of
Candidate Vaccines**

COVID-19 Occurs Throughout Year in US; Severe Burden in Older Adults Similar to Influenza

Cumulative Hospitalization Rates^{1*}
(≥65 years, Oct 2024–Sep 2025)



US COVID-19 Burden Estimates²
(All ages, Oct 2024–Sep 2025)



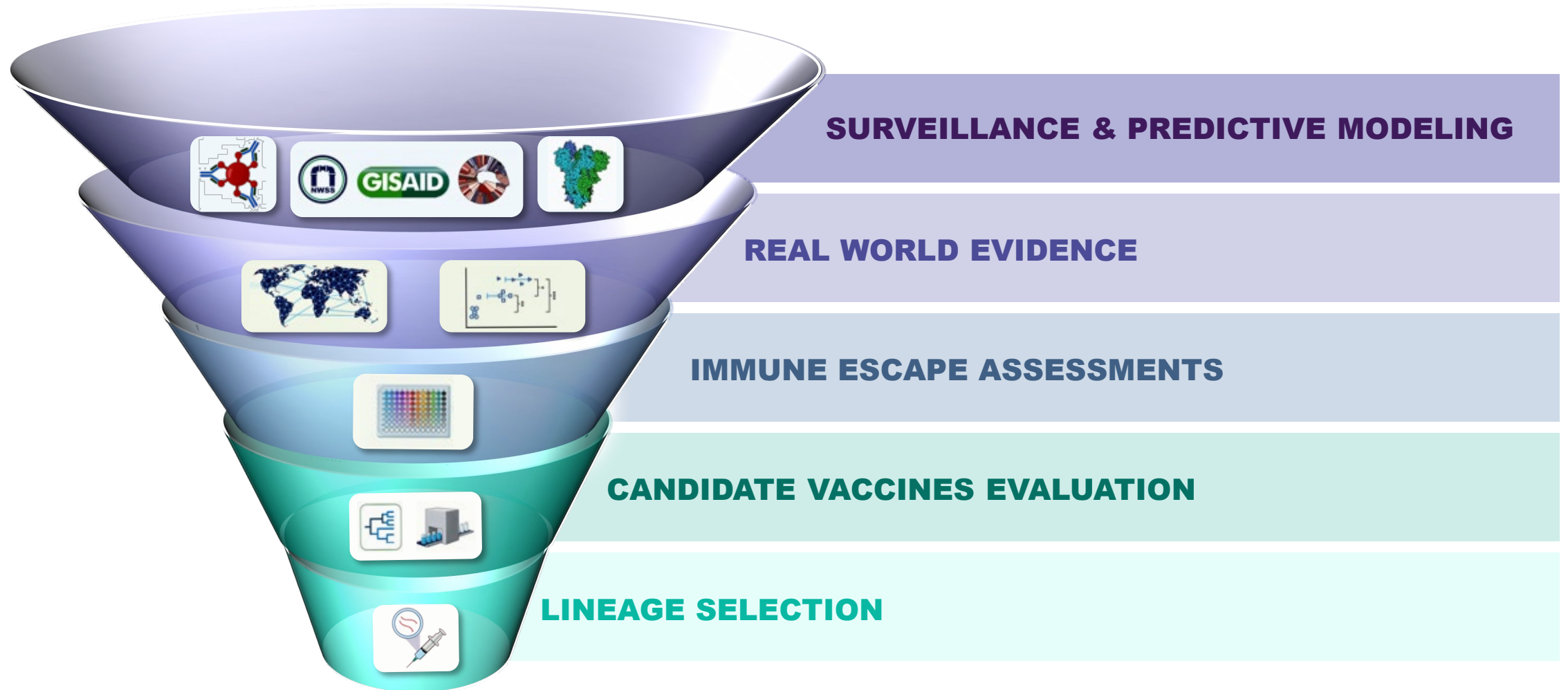
RESP-NET. <https://www.cdc.gov/resp-net/dashboard/index.html>. Accessed May 6, 2026.

Preliminary Estimates of COVID-19 Burden. <https://www.cdc.gov/covid/php/surveillance/burden-estimates.html>. Accessed May 6, 2026.

* Dotted gray line for influenza represents estimated influenza hospitalization rate during May 3 - September 27, 2025 assuming a similar trend in burden as reported for the period May 5 through September 28, 2024.

M, million; RESP-NET, Respiratory Virus Hospitalization Surveillance Network; US, United States.

Multi-Layered and Resilient Evidence Platform Informs Vaccine Formula Composition



COVID-19 Vaccination in the US from September 2023- August 2024 was estimated by the CDC to prevent approximately 107,000 hospitalizations, 18,000 ICU admissions and 6,700 deaths.

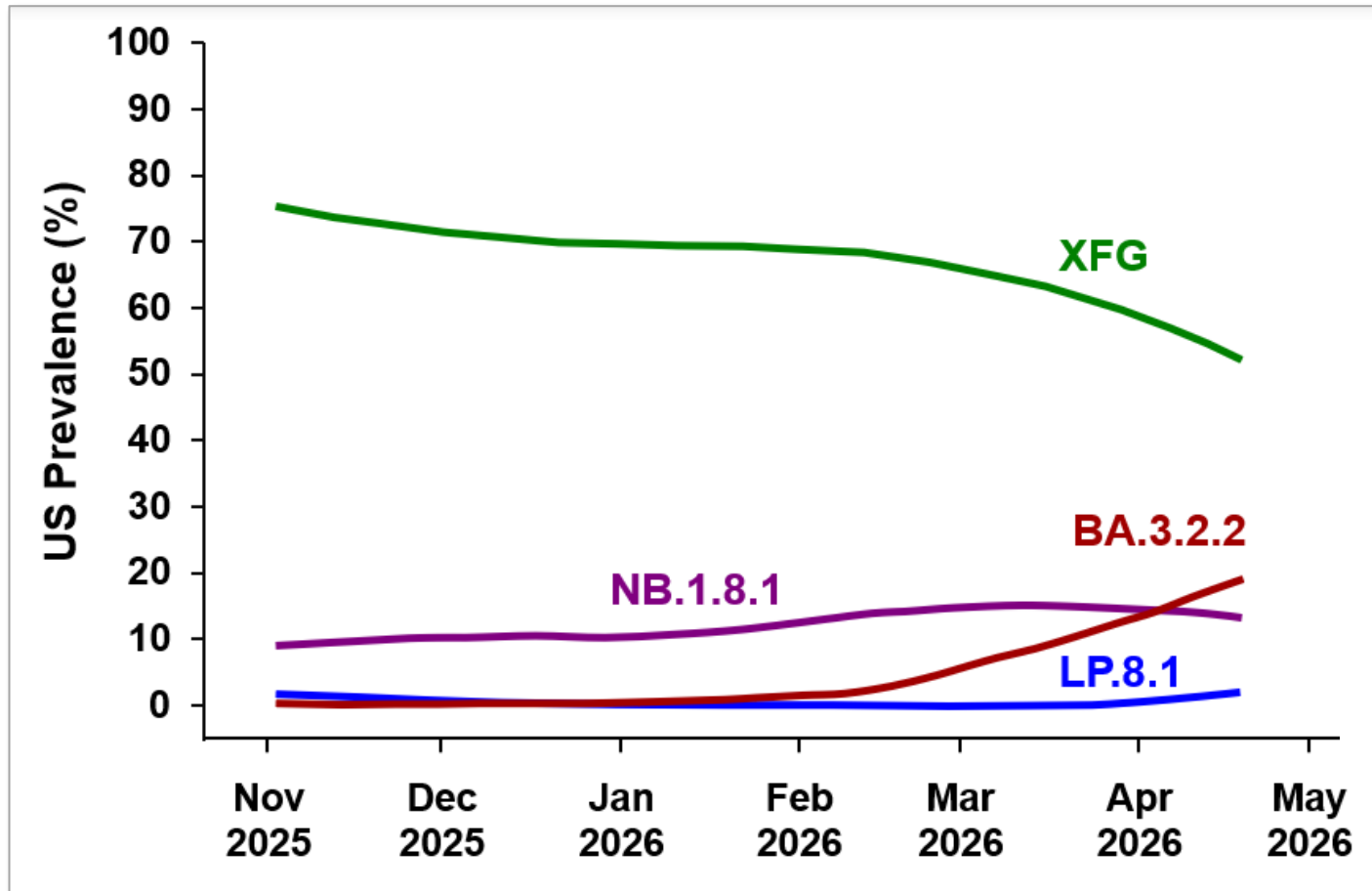
(Wiegand et al. Vaccine. 2024. DOI: 10.1016/j.vaccine.2025.126808)

CDC, Centers for Disease Control and Prevention; GISAID, Global Initiative on Sharing All Influenza Data; ICU, Intensive Care Unit.

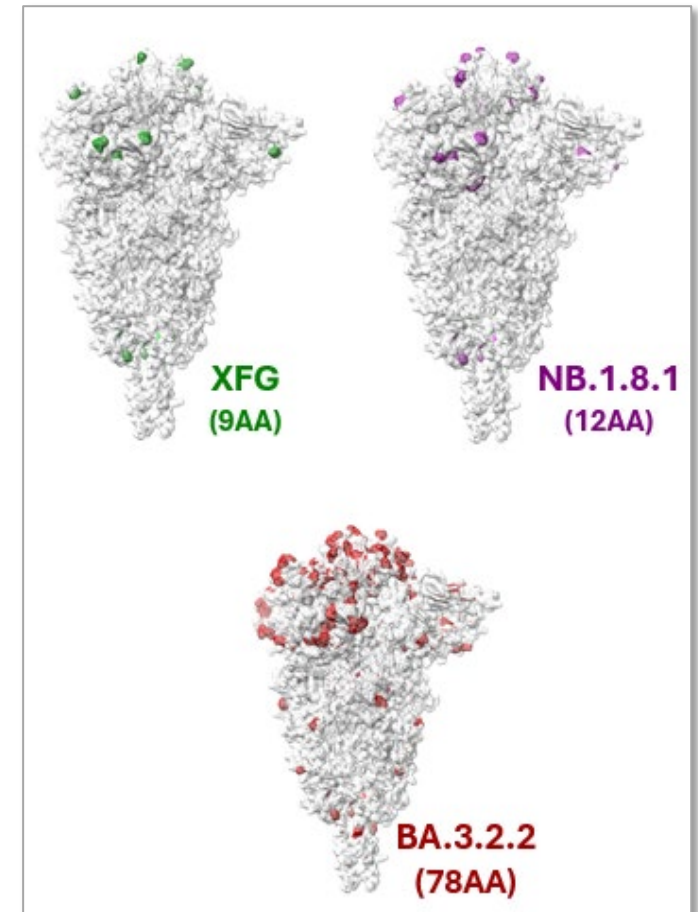
SARS-CoV-2 Lineage Epidemiology

JN.1 Sublineages Currently Predominant in US, with BA.3.2.2 Prevalence Rising

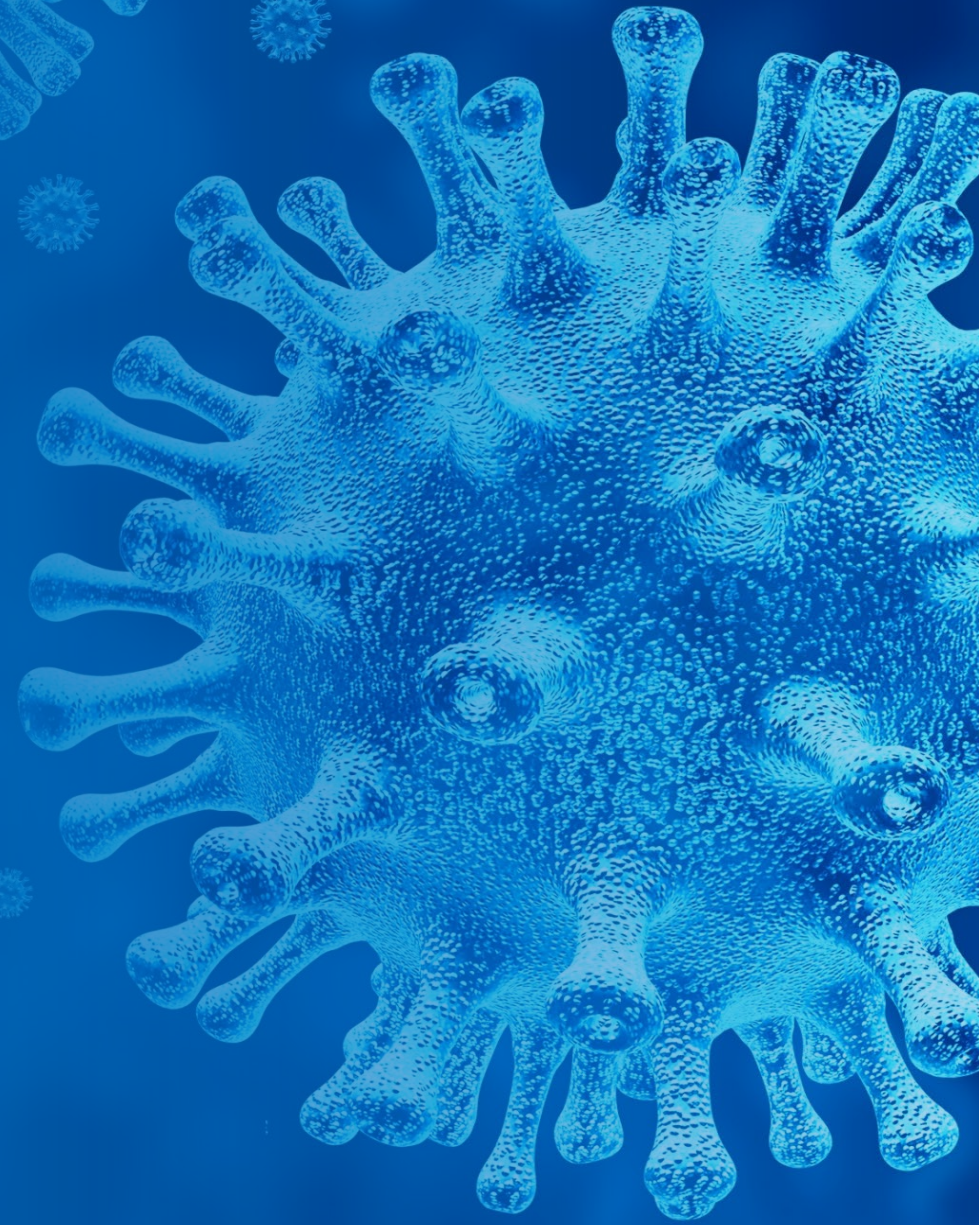
US Prevalence of Major SARS-CoV-2 Lineages



Spike Amino Acid (AA) Differences Relative to LP.8.1



LP.8.1 Vaccine Effectiveness



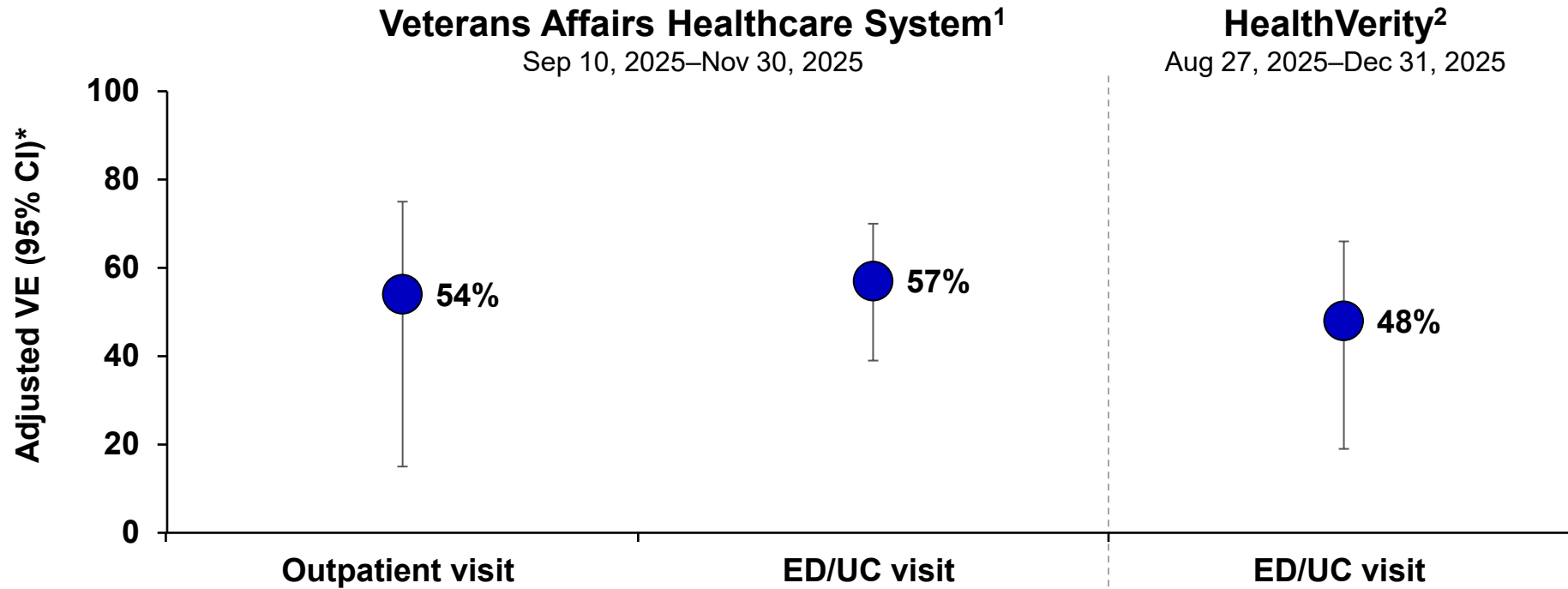
Real-World Evidence Consistently Validates BNT162b2 Vaccine Performance

- >500 studies report on BNT162b2 effectiveness in real-world¹
- Real-world data from diverse populations, against multiple endpoints¹⁻¹¹
- Effectiveness estimates trend with preclinical data and clinical immunogenicity studies¹²⁻¹³
- Consistent protection against circulating lineages year-to-year²⁻¹¹

	2020-2022	2022-2023	2023-2024	2024-2025	2025-2026
Vaccine Formula	Original	Original + Omicron BA.4/5	Omicron XBB.1.5	Omicron KP.2	Omicron LP.8.1
Effectiveness Against Hospitalization in US²⁻¹¹	32–97%	34–76%	32–74%	35–68%	

1. IVAC. <https://view-hub.org/vaccine/covid>. Accessed May 14, 2026. 2. Tartof et al. 2022. DOI: 10.1016/j.lana.2022.100198 3. Tartof et al. 2023. DOI: 10.1016/S2213-2600(22)00354-X 4. Tartof et al. 2023. DOI: 10.1016/S2213-2600(23)00306-5 5. Tartof et al. 2024. DOI: 10.1093/ofid/ofae370 6. Caffrey et al. 2024. DOI:10.1038/s41467-024-53842-w 7. Tartof et al. 2024. DOI: 10.1001/jamainternmed.2024.1640 8. Appaneal et al. 2025. DOI: 10.1038/s41467-025-59344-7 9. Andersen et al. 2025 DOI: 10.1016/j.vaccine.2025.126881 10. Andersen et al. 2025. DOI: 10.1016/j.vaccine.2025.127534 11. Tartof et al. 2026. DOI: 10.1093/ofid/ofag019 12. Diya et al. 2025. DOI: 10.1016/j.vaccine.2025.126869 13. Chen et al. 2025. DOI: 10.1038/s41467-025-65896-5

LP.8.1 Vaccine Effective Against Non-Severe Disease During JN.1 Sublineage Dominance



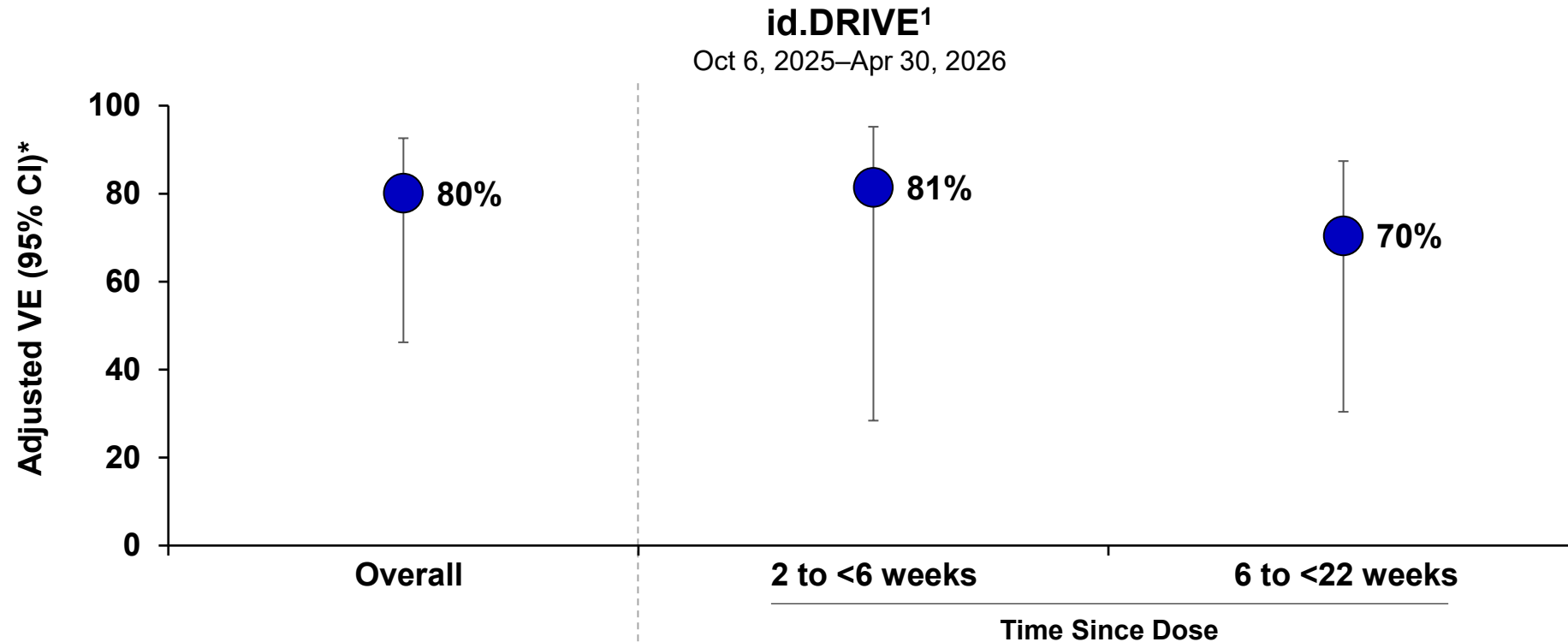
Design	Test-negative case-control		Population cohort
Population	≥18y with ARI diagnosis and SARS-CoV-2 PCR or RAT test in the US (nationwide)		≥65y in the US (CA, LA)
VE (95% CI)*	54% (15 to 75)	57% (39 to 70)	48% (19 to 66)
Median (IQR) days since dose	24d (16 to 37)	32d (21 to 42)	75d (52 to 94)
Median (IQR) age	66y (52 to 76)		72y (68 to 78)
Number of cases (%)	3,696 (10.7%)		1,651 (0.12%)

*Compared to no receipt of any 2025–2026 COVID-19 vaccine.

1. Appaneal et al. 2026. In Press (Nat Commun). 2. Pfizer data on file.

ARI, acute respiratory infection; CA, California; CI, confidence interval; d, days; ED/UC, emergency department/urgent care; IQR, interquartile range; LA, Louisiana; PCR, polymerase chain reaction; RAT, rapid antigen test; US, United States; VE, vaccine effectiveness; y, years.

LP.8.1 Vaccine Effective Against Severe Disease During JN.1 Sublineage Dominance



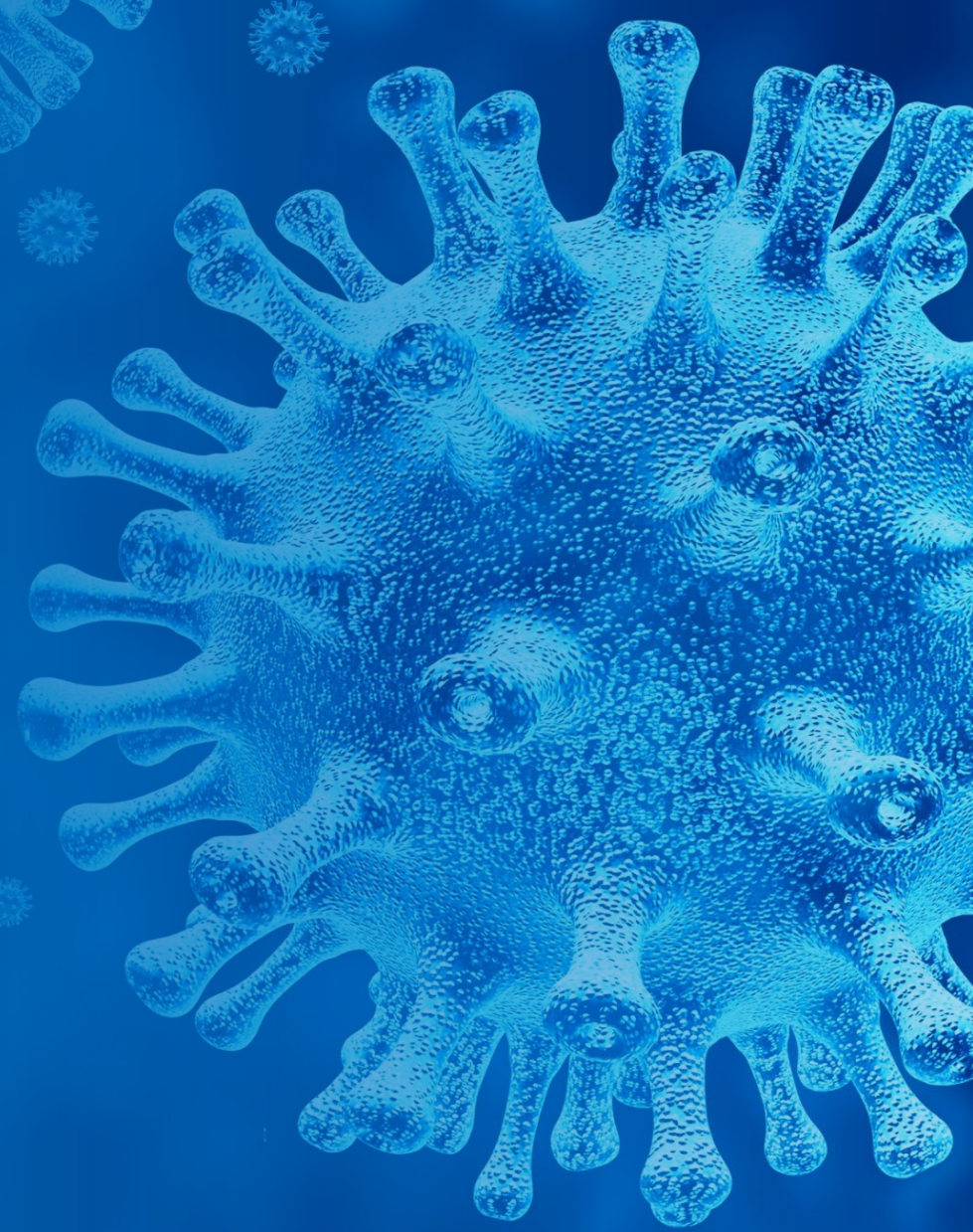
Design	Test-negative case-control		
Population	≥18y with SARI diagnosis and SARS-CoV-2 PCR test, Spain		
VE (95% CI)*	80% (46 to 93)	81% (28 to 95)	70% (30 to 87)
Median (IQR) days since dose	44d (28 to 63)	27d (20 to 33)	63d (52 to 76)
Median (IQR) age	79y (67 to 87)		
Number of cases (%)	101 (20%)	93 (22%)	96 (22%)

* Compared to no receipt of any 2025–2026 COVID-19 vaccine.

1. Pfizer data on file. >55% of COVID-19 cases occurred by end of October 2025. Vaccine effectiveness measured against COVID-19 hospitalization.

CI, confidence interval; d, days; IQR, interquartile range; PCR, polymerase chain reaction; SARI, severe acute respiratory infection; VE, vaccine effectiveness; y, years.

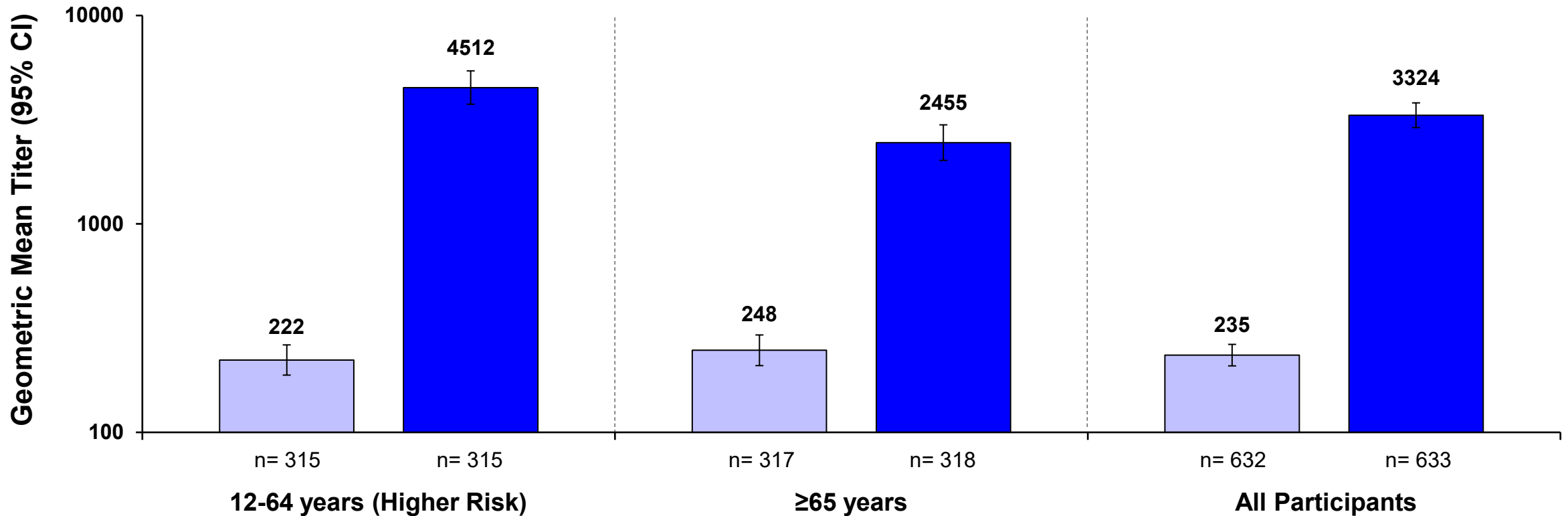
LP.8.1 Vaccine Clinical Immunogenicity



LP.8.1 Vaccine Induces Robust Clinical Immune Responses in At-Risk Populations

□ Pre-vax (LP.8.1) ■ 1MPD (LP.8.1)

GMFR (95% CI)	15.1 (12.6, 18.0)	7.7 (6.4, 9.2)	10.7 (9.4, 12.2)
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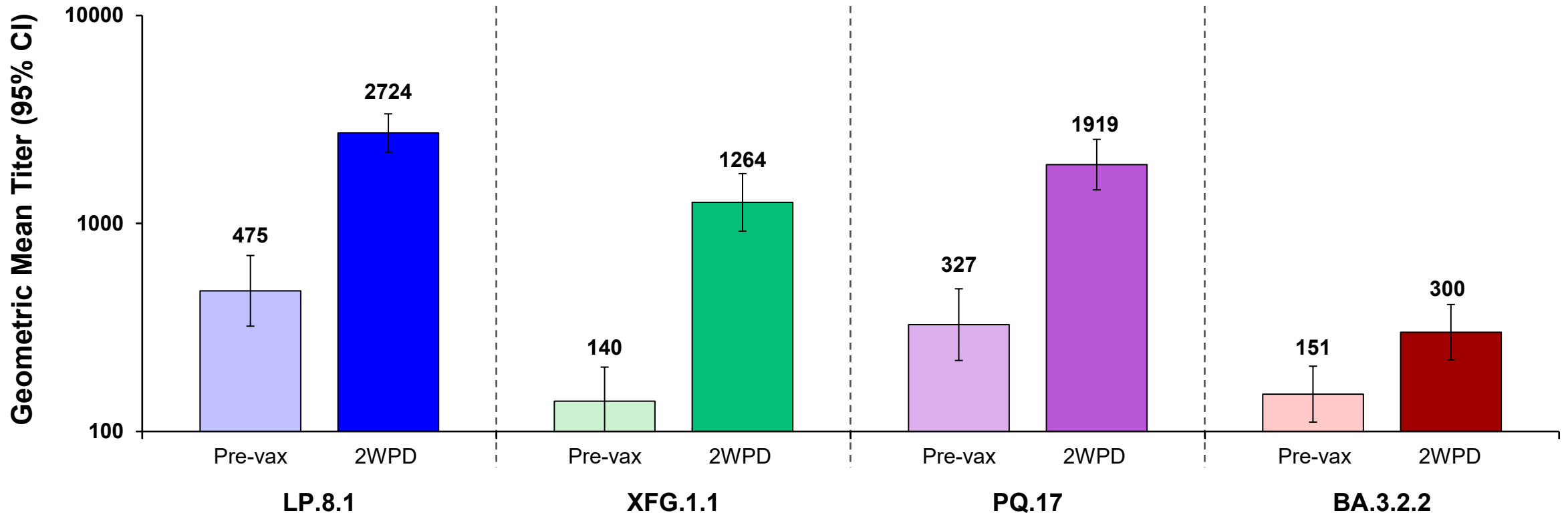


LP.8.1-adapted vaccine 30 µg (C4591076 Cohort 2) administered 07-27 October 2025.
 C4591076 Cohort 2 included participants who did not receive any COVID-19 vaccine in prior 5 months and vaccine-naïve individuals.
 Geometric Mean Titer measured by validated authentic virus neutralization assay.
 CI, Confidence interval; GMFR, Geometric Mean Neutralizing Titer Fold Rise; Pre-vax, Pre vaccination; 1MPD, 1 month post vaccination.

LP.8.1 Vaccine Elicits Broad JN.1 Lineage Clinical Immune Response; Diminished Against BA.3.2.2

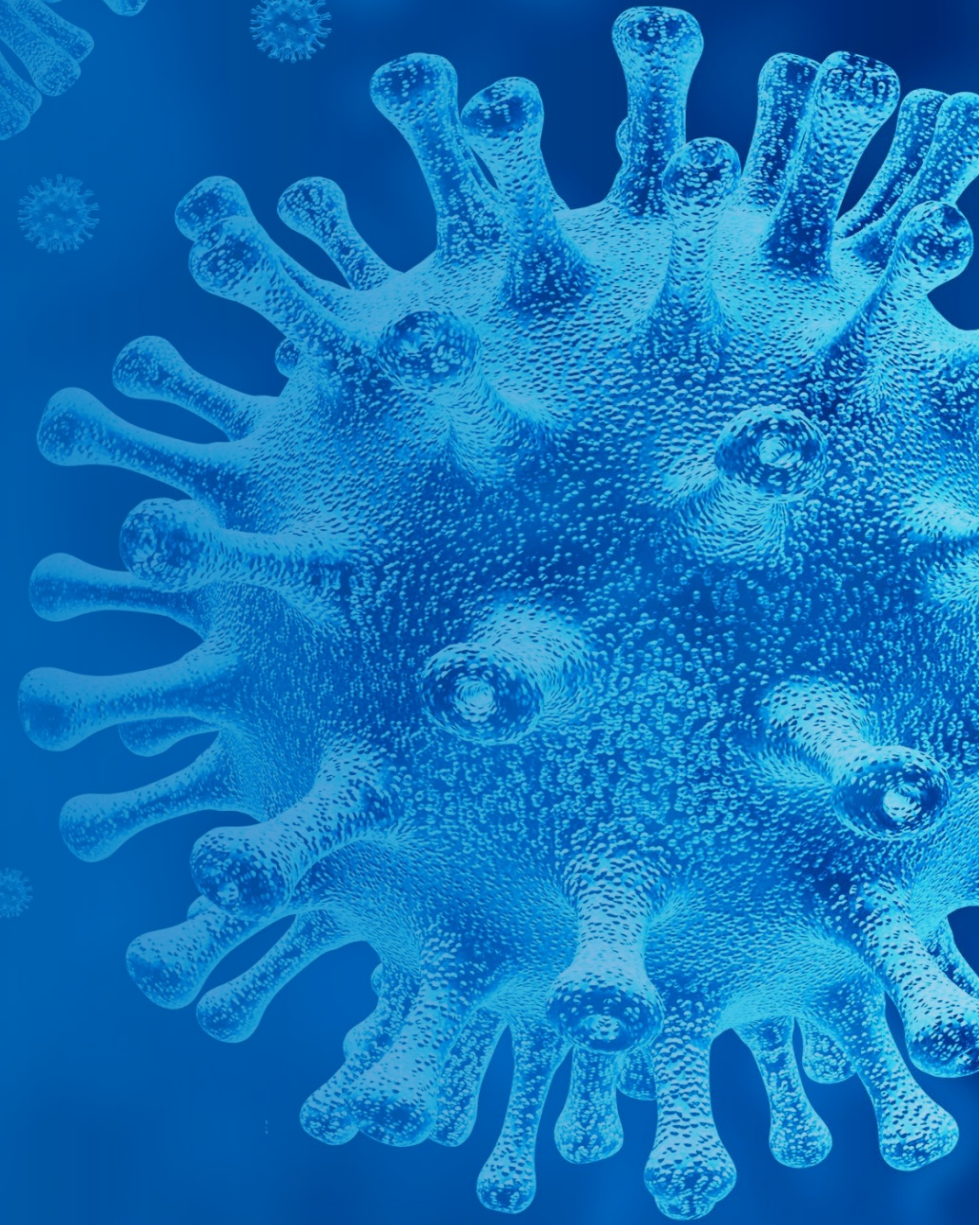
≥18 Years (n=79)

GMFR (95% CI)	5.4 (4.1, 7.3)	7.8 (6.0, 10.1)	5.4 (4.2, 7.0)	1.9 (1.6, 2.2)
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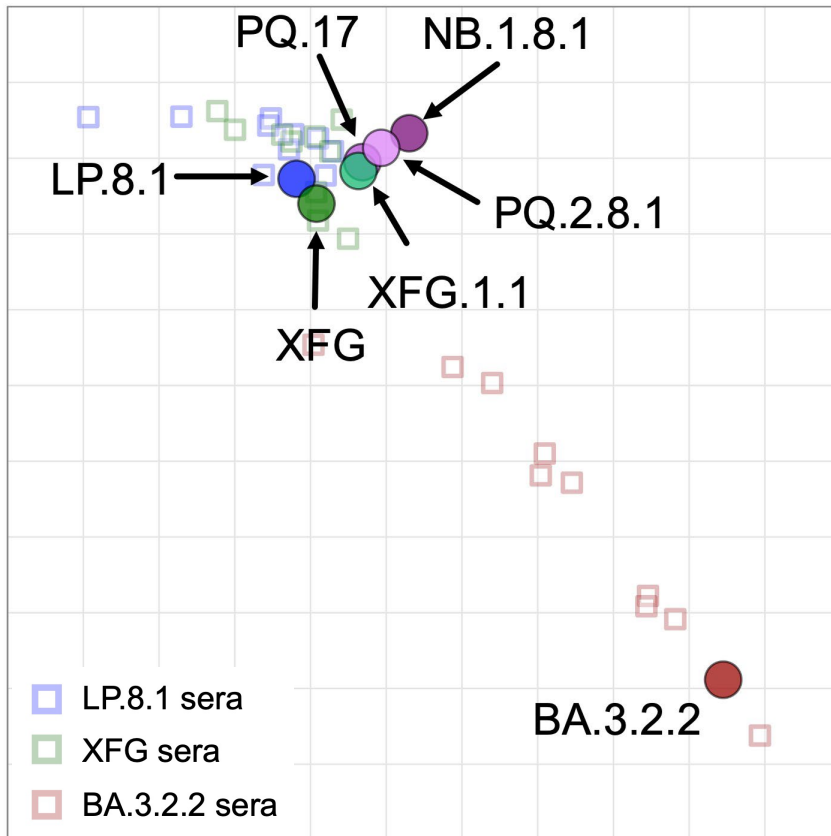


LP.8.1-adapted vaccine 30 µg (C4591076 Cohort 1) administered 08-09 July 2025
 Cohort 1 included participants who had received KP.2 vaccine > 6 months with no subsequent Covid-19 vaccine prior enrollment
 Geometric Mean Titer measured by qualified pseudovirus neutralization assay.
 CI, Confidence interval; GMFR, Geometric Mean Neutralizing Titer Fold Rise; Pre-vax, Pre vaccination; 2WPD, 2 weeks post vaccination.

Preclinical Immunogenicity of Candidate Vaccines

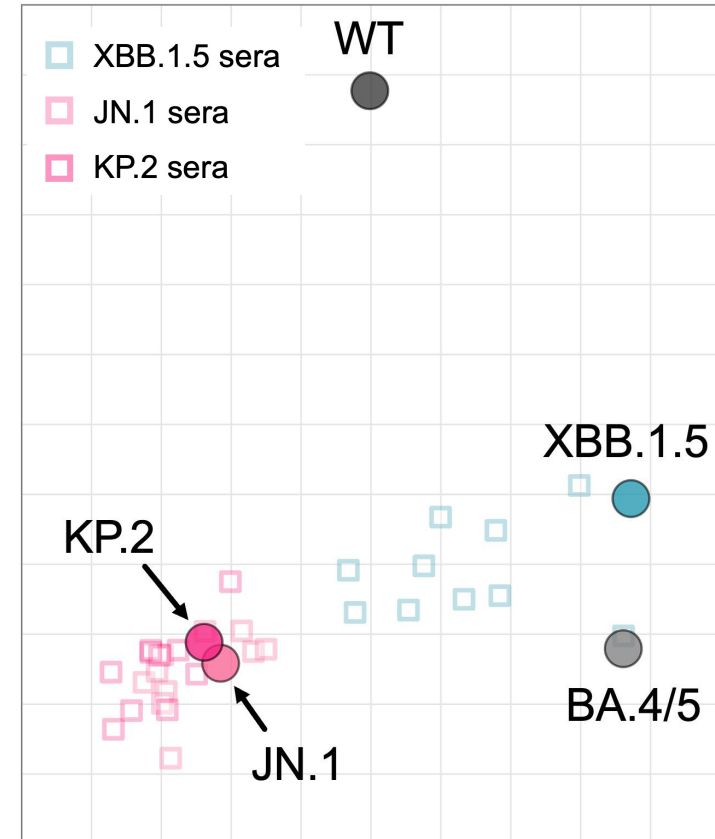


Antigenic Distance of LP.8.1 to BA.3.2.2 is Greater than from XBB.1.5 to KP.2



Antigenic distance

LP.8.1 $\xrightarrow{8.6 \text{ AU}}$ BA.3.2.2



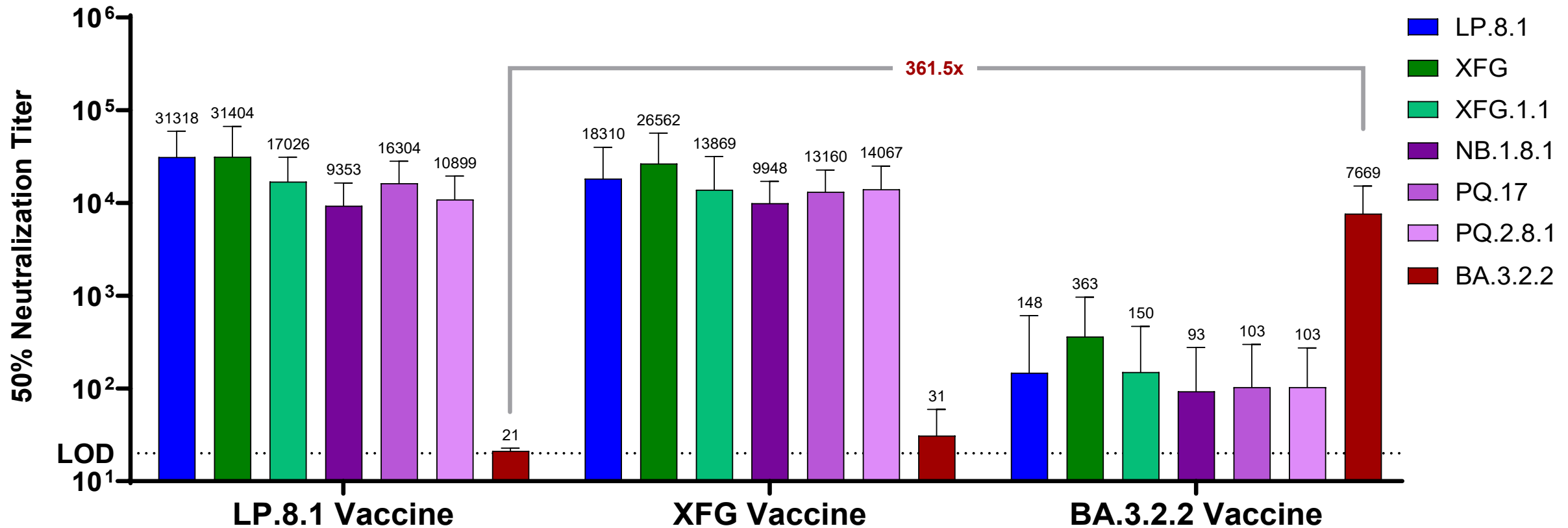
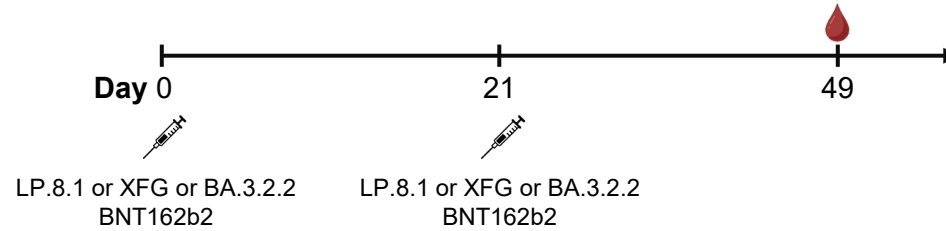
XBB.1.5 $\xrightarrow{6.2 \text{ AU}}$ KP.2

Each box in antigenic map represents 1 antigenic unit (AU) = 2-fold difference in neutralization titer

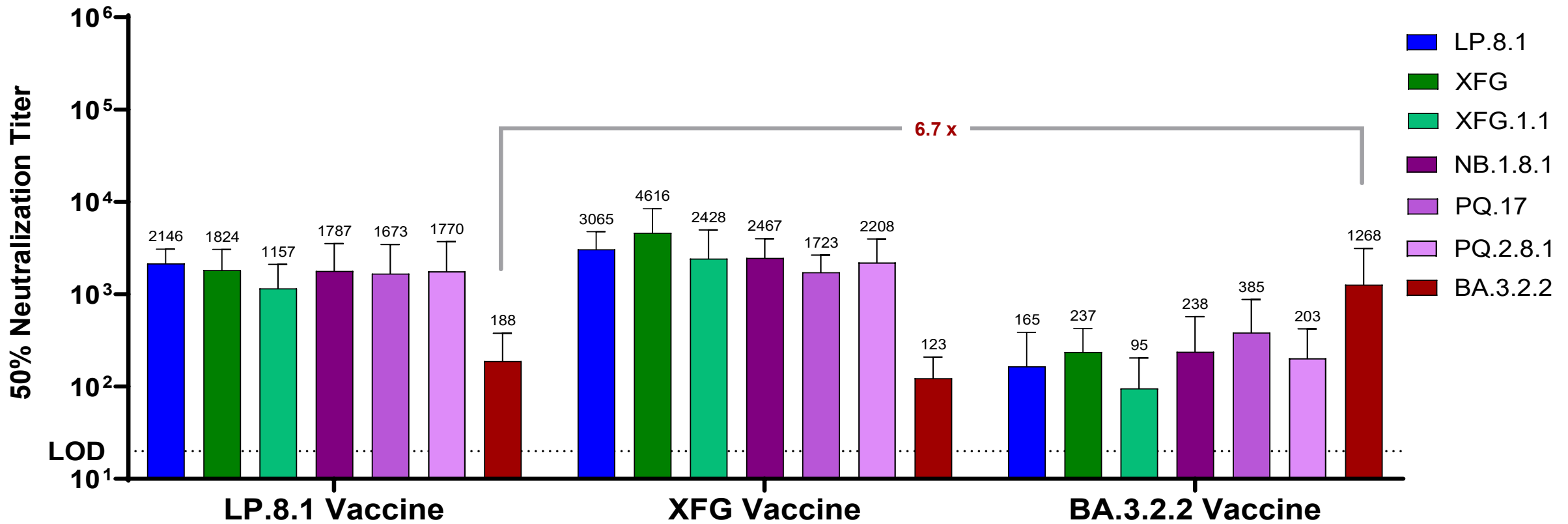
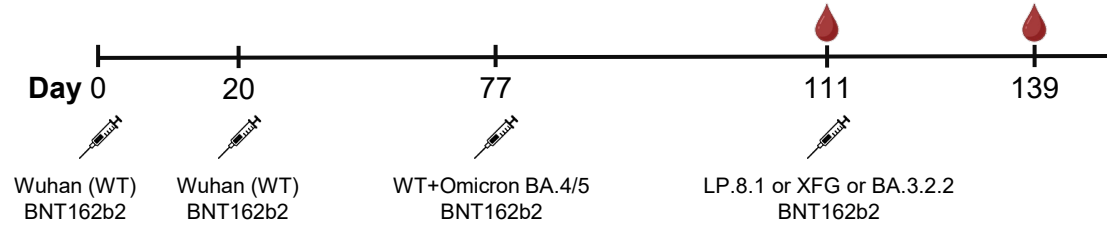
Antigenic map generated in Racmacs package in R using 2000 optimizations, with the minimum column basis parameter set to "none."

Generated from pseudovirus neutralization titers elicited by LP.8.1-, XFG- and BA.3.2.2-adapted vaccines (left) and XBB1.5-, JN.1- and KP.2-adapted vaccines administered as primary series to naïve mice.

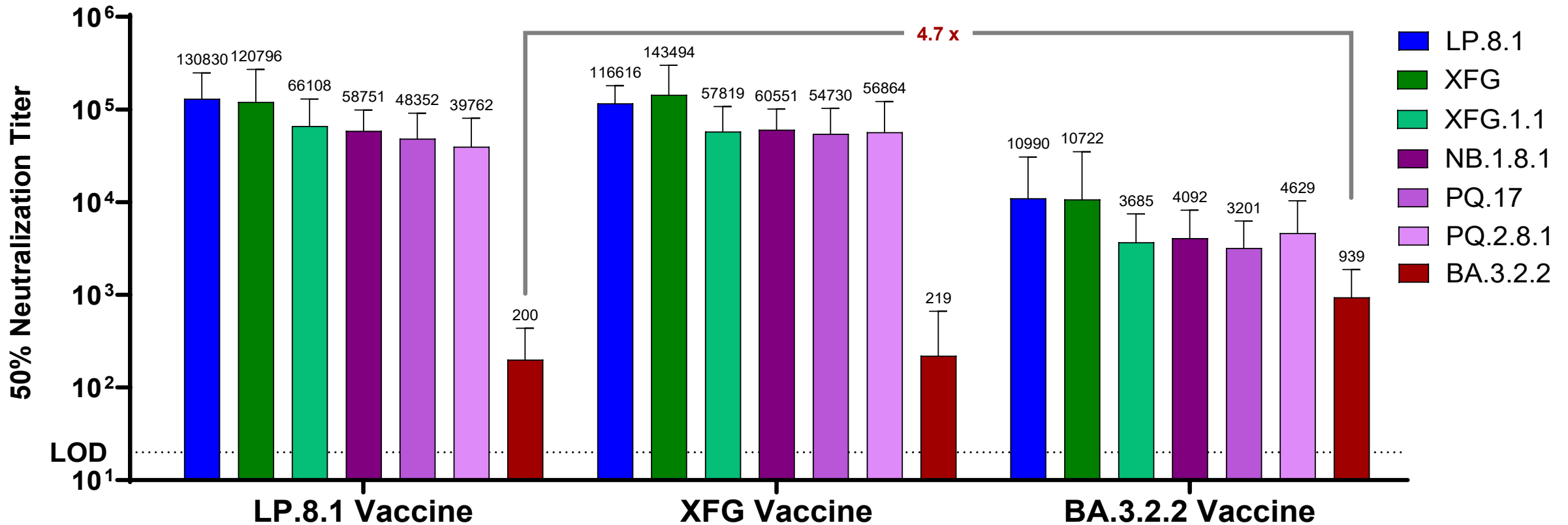
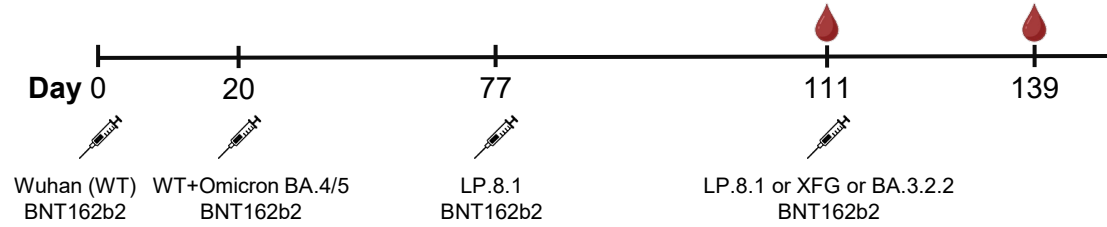
LP.8.1 and XFG Vaccines Elicit Similar Neutralizing Responses in Naïve Mice; Diminished Against BA.3.2.2



LP.8.1 and XFG Vaccines Elicit Similar Patterns of Neutralizing Responses in Vaccine-Experienced Mice



Trends in Neutralizing Responses Consistent in Alternate Vaccine-Experienced Model



Summary

Integrated Evidence from 2025-2026 Supports Continued Benefit of Lineage-Adapted Vaccine Formulas

- **COVID-19 disease burden remains substantial across a range of milder and more severe clinical outcomes**
- **LP.8.1 vaccine maintained effectiveness during period of XFG predominance, as anticipated by breadth of neutralization in clinical and nonclinical studies**
- **LP.8.1 and XFG vaccines exhibited similar patterns of elicited immunity in nonclinical models, with limited coverage of antigenically distinct BA.3.2.2**
- **Pfizer/BioNTech is prepared to supply 2026-2027 vaccine formula per FDA recommendation and upon approval**



2026-2027 COVID-19 Vaccine Formula: Pfizer/BioNTech Supportive Data

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