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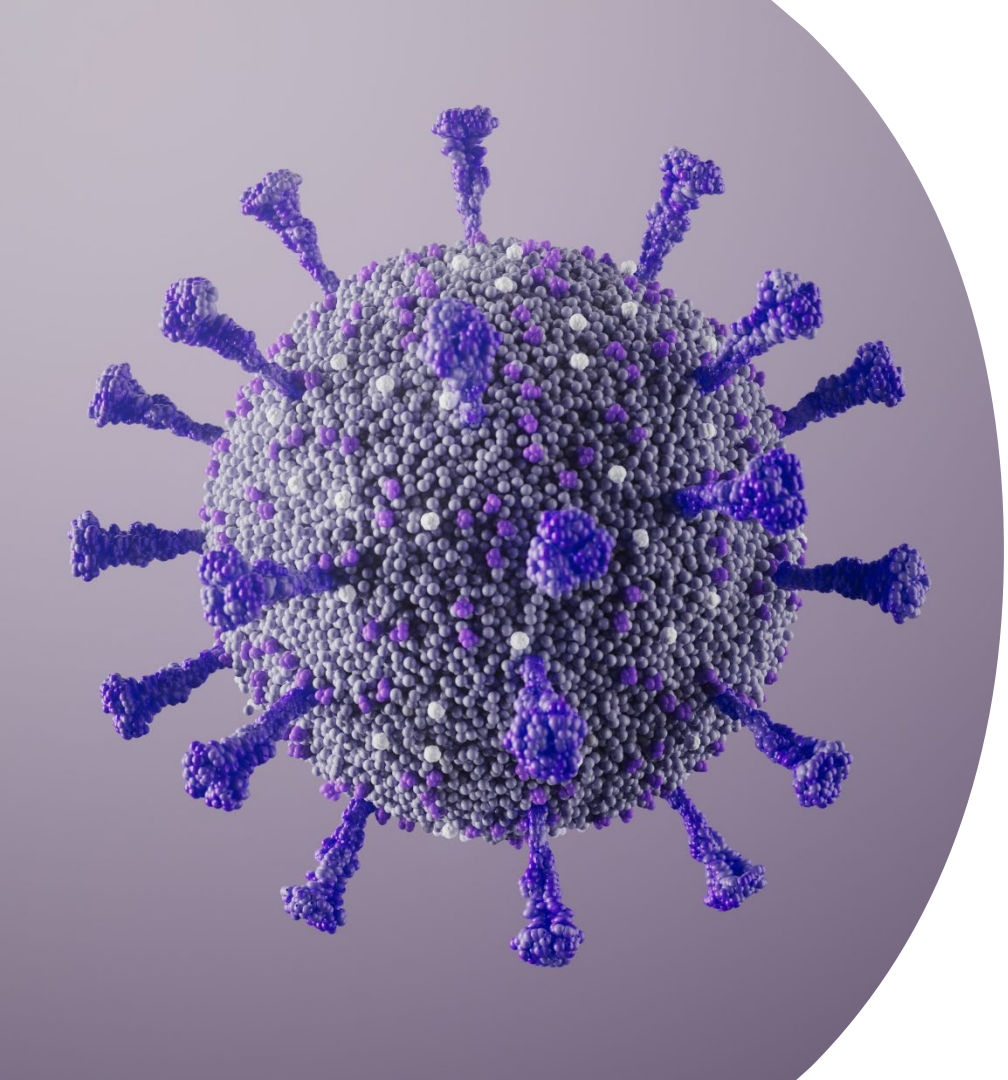

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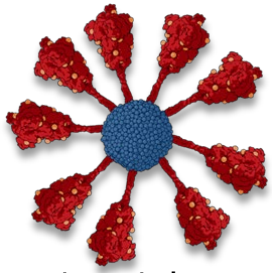
2026-2027
COVID-19 Vaccine Update

Vaccines and Related Biological Products Advisory Committee
May 28, 2026

Tonya Colpitts, PhD
Associate Vice President
Global Project Head, Vaccines

Nuvaxovid™ COVID-19 Vaccine

Nuvaxovid™: Proven Recombinant Technology Platform
Only Protein Non-mRNA Vaccine Licensed in the United States



Recombinant protein nanoparticle

Matrix-M®

Adjuvanted to enhance immunity → larger, broader, more durable response[1,2]

Favorable reactogenicity in large, diverse patient population[3]

Equivalent pivotal efficacy as other approved COVID-19 vaccines[4]

1. Cox MMJ. *Vaccine*. 2012;30(10):1759-1766
2. Stertman L, *et al.* Hum Vaccine Immunother.2023;19(1):2189885
3. Derfalie E. *et al*. Poster P0468 ESCMID 2026
4. Dunkle LM, *et al*. N Engl J Med. 2022;386(6):531-543

XFG Represents the Best Choice for the 2026-27 Vaccine Composition

U.S. COVID Situation

COVID continues to cause severe illness

COVID vaccination rates remain low in older adults

Protein-based vaccine is an important choice for U.S. population due to tolerability and acceptability profile

Current Surveillance

JN.1 lineage accounts for >80% of circulating variants globally

XFG has been prevalent for more than 6 months and remains dominant in the U.S.

BA.3.2 has not become dominant even 18 months after emergence, and less prevalent in older adults

LP.8.1 not circulated in ~ 9 months

Immunogenicity Data

XFG is immunogenic, more effective against current JN.1 lineage variants, and likely boosts BA.3.2 immunity

Recent data indicate BA.3.2 does not cover XFG/JN.1 lineage

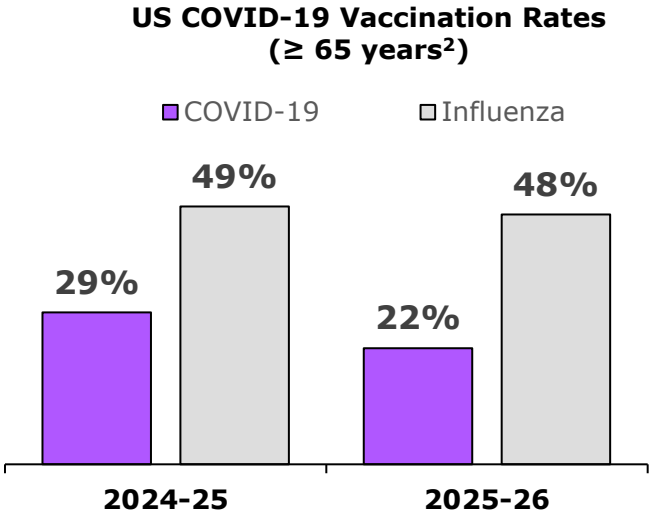
An XFG vaccine would likely provide the best protection for the vulnerable older adult population

COVID Continues to Cause Severe Illness and Deaths, Yet Vaccination Rates are Low

Preliminary 2025-2026 U.S. COVID-19 Burden Estimates[1] (all ages)

CDC estimates* that, from October 1, 2025 through May 2, 2026, there have been:

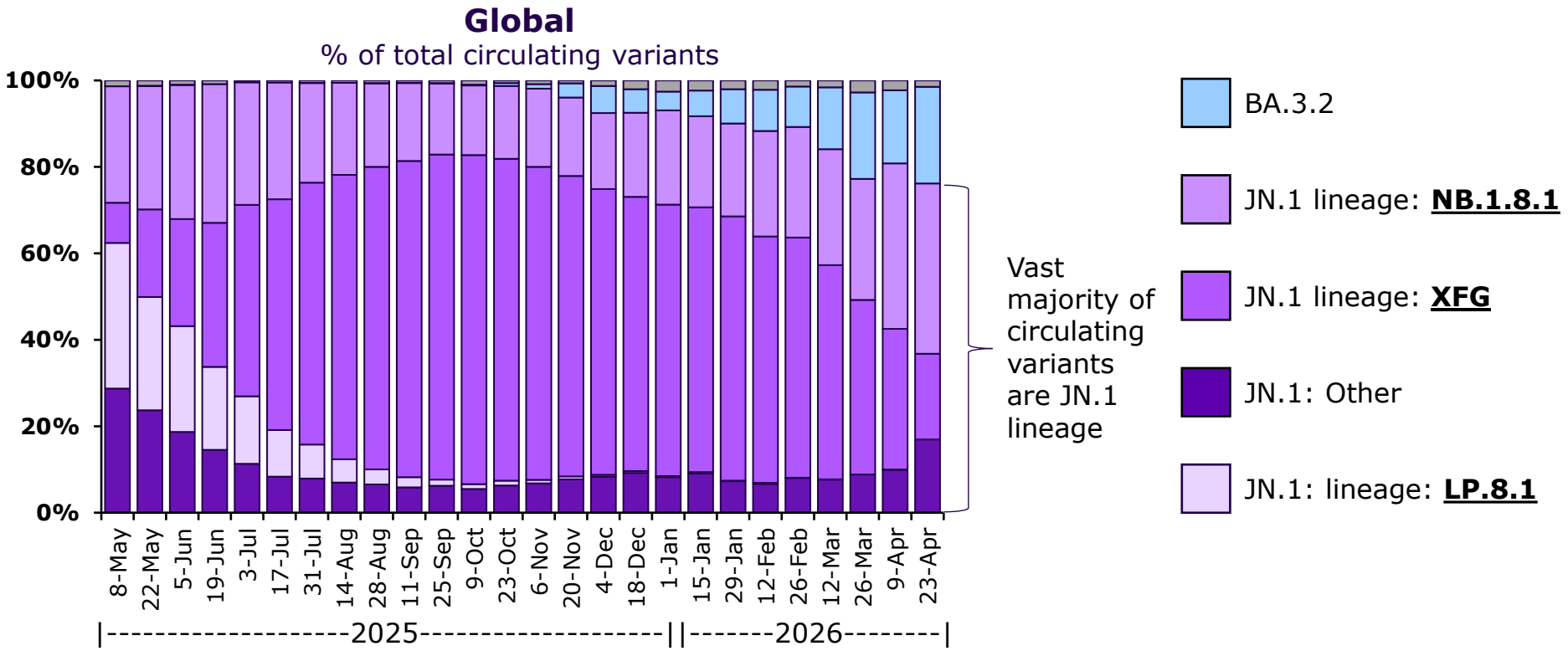
COVID-19 Illnesses	COVID-19 Outpatient	COVID-19 Hospitalization	COVID-19 Deaths
3.8 million- 12.3 million	760,000- 2.3 million	120,000- 250,000	12,000- 41,000



- Sanofi protein-based COVID-19 vaccine has demonstrated low reactogenicity and minimally-disruptive side effects[3]
- This may result in increased future vaccination uptake and satisfaction[3]

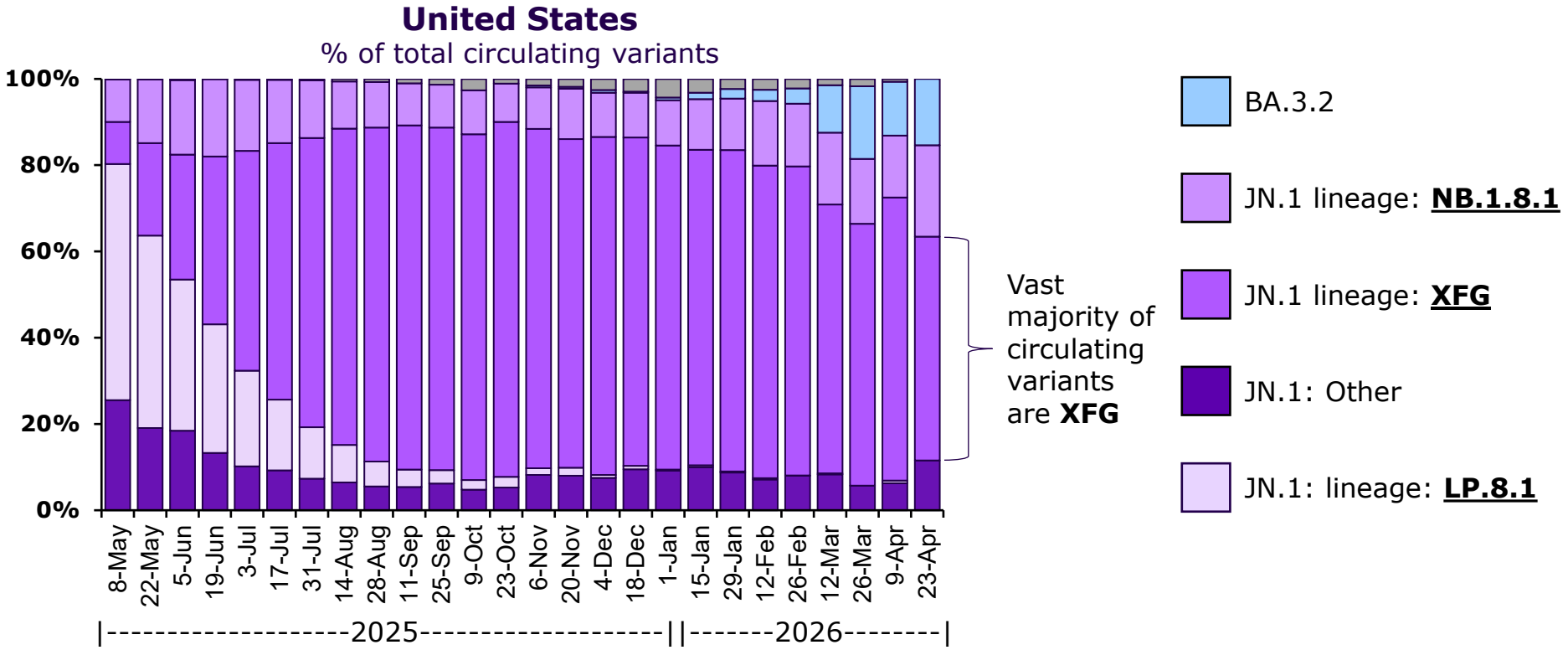
1. Preliminary Estimates of COVID-19 Burden | Covid | CDC
2. COVID-19 Vaccination Coverage, Adults 65 Years and Older, United States | COVIDVaxView | CDC
3. Derfalie E. *et al.* Poster P0468 ESCMID 2026

JN.1 Lineage Variants Remain Dominant Globally



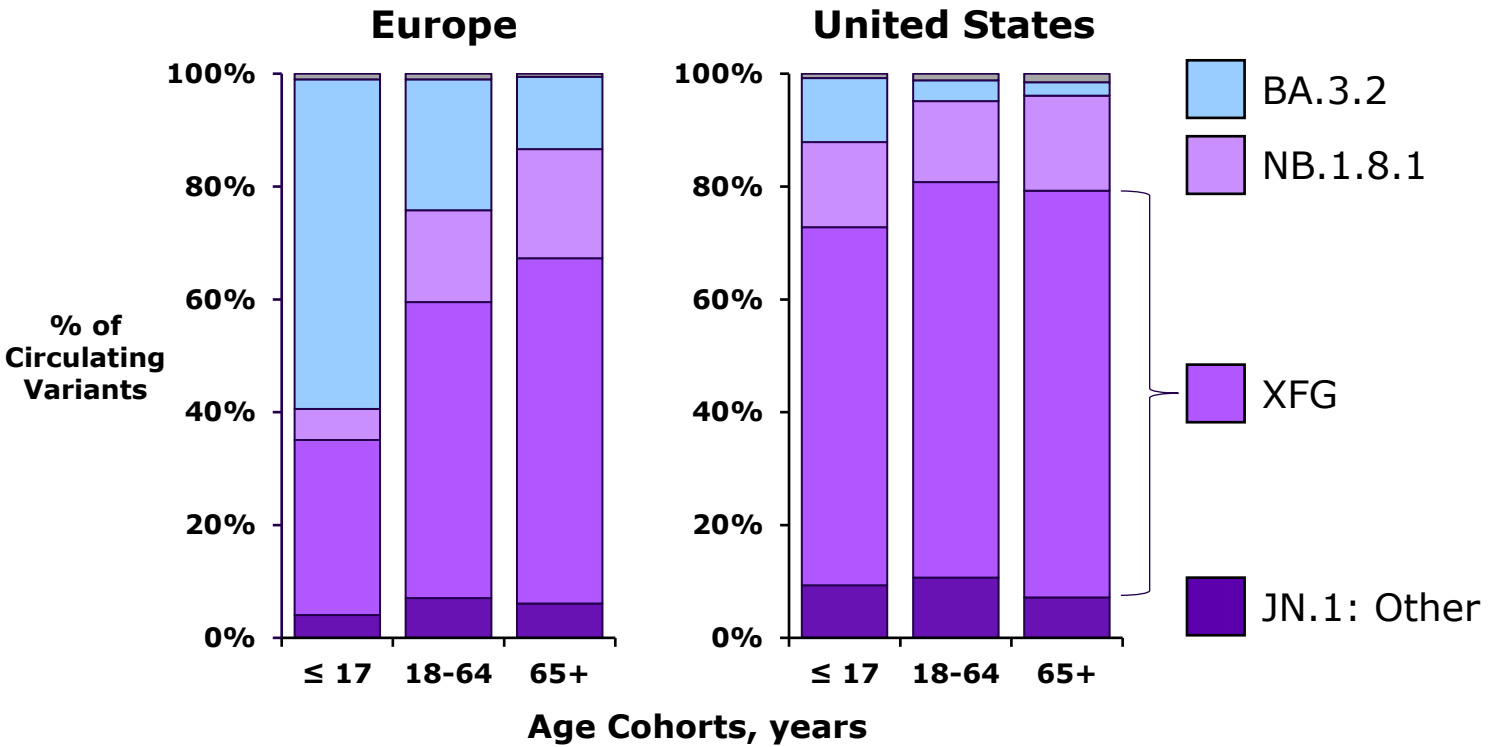
Sanofi analysis of data available in GISAID (Global Initiative on Sharing All Influenza Data) as of May 18, 2026.

U.S. Surveillance Data Demonstrate XFG Variant Remains Dominant



Sanofi analysis of data available in GISAID (Global Initiative on Sharing All Influenza Data) as of May 18, 2026.

XFG is a Critical Concern for Older Adults



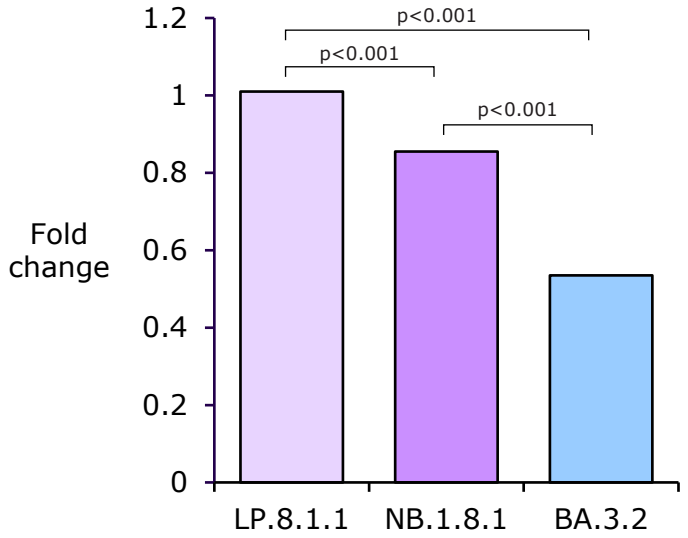
A key consideration for strain selection is protection for the most **vulnerable population of 65+,** where **majority of cases are XFG**

Sanofi analysis of data available in GISAID (Global Initiative on Sharing All Influenza Data) as of January 2026 through May 2026
Europe (N = 2,408); United States (N = 4,464)

No Evidence of Increased Severity of BA.3.2

- Emergence of previous COVID lineages linked to surge in hospitalizations and deaths[1]
- No data linking BA.3.2 with increased disease severity or reduced susceptibility to antivirals[2]
- No increase in hospitalizations despite BA.3.2 rise in Europe[3]
- BA.3.2 showed reduced infectivity compared to JN.1 lineage variants[4]

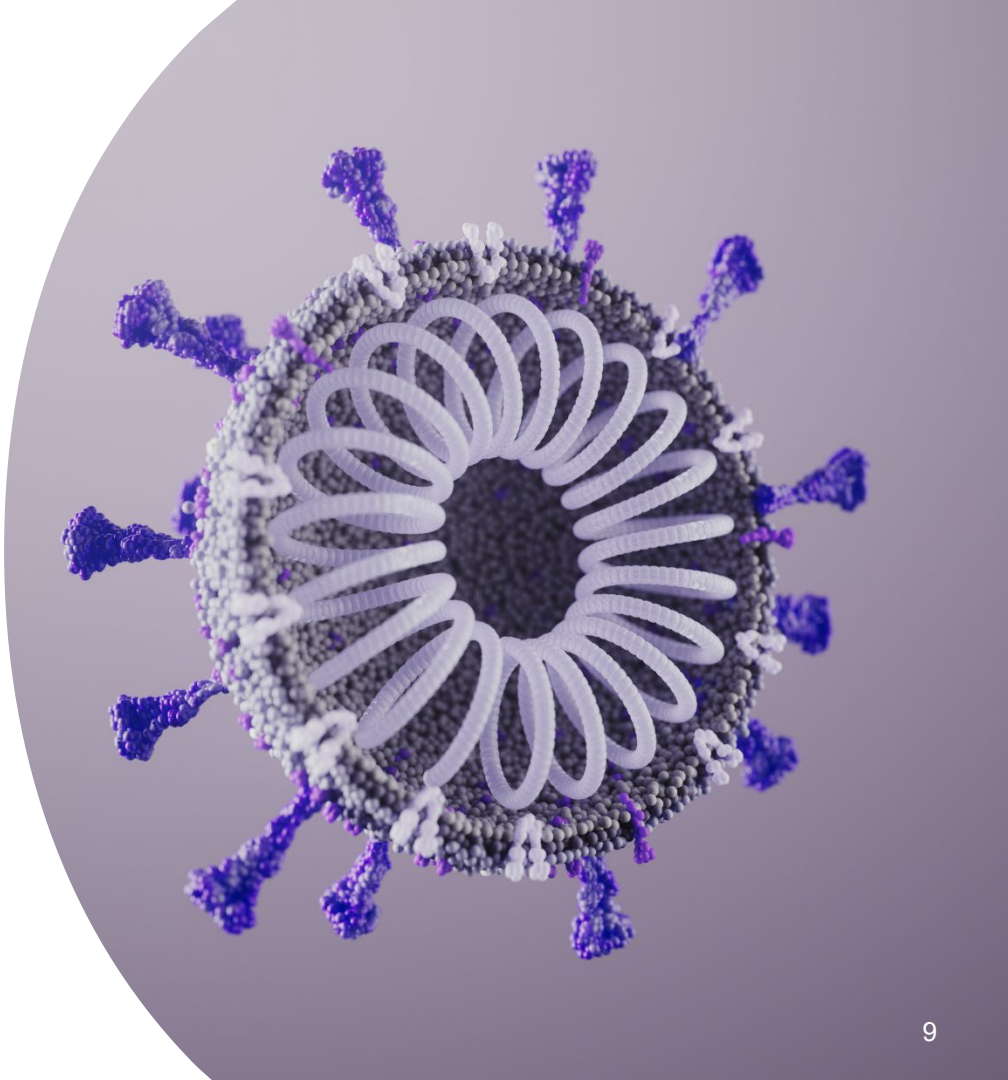
BA.3.2 has low infectivity[4]



1. Lambrou AS, *et al.* MMWR Morb Mortal Wkly Rep. 2022;71(6):206-211
2. Adapted from WHO. WHO TAG-VE Risk Evaluation for SARS-CoV-2 Variant Under Monitoring: BA.3.2. 2025
3. The European Respiratory Virus Surveillance Summary (ERVISS)
4. Guo C, *et al.* The Lancet Infectious Diseases. 2025;25(7):e374-e377

Immunology Data Support

XFG Strain Selection



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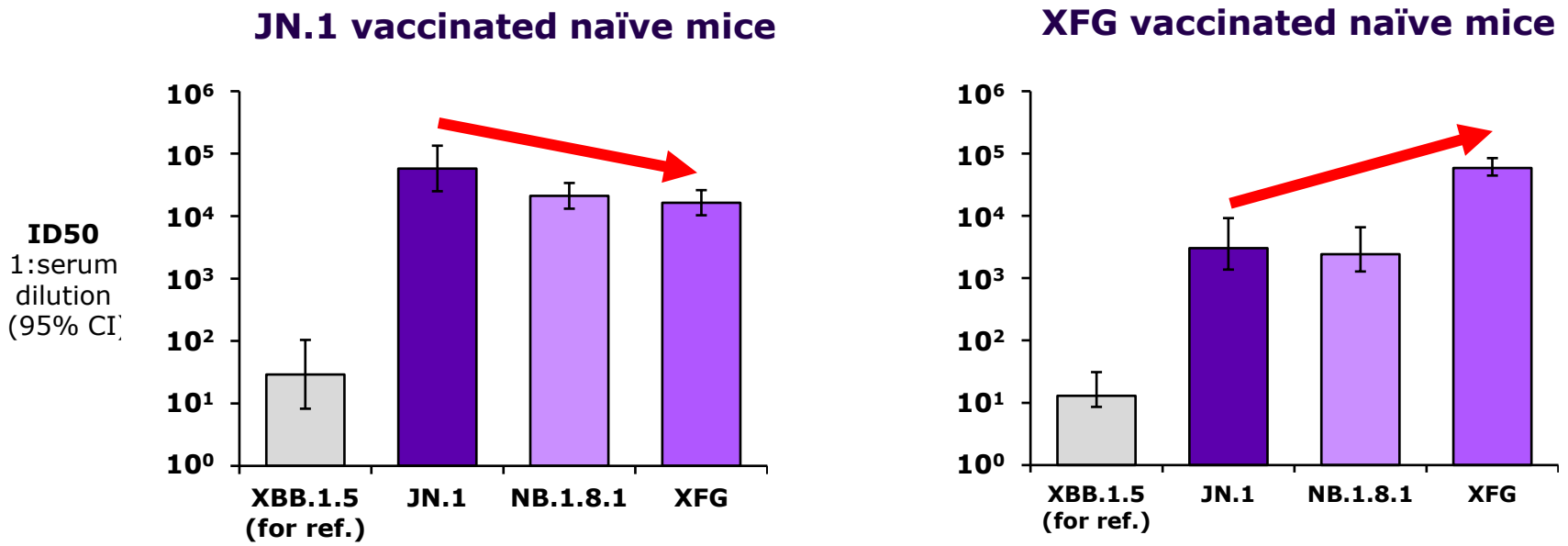
XFG Variant Vaccine Overcomes Immune Escape

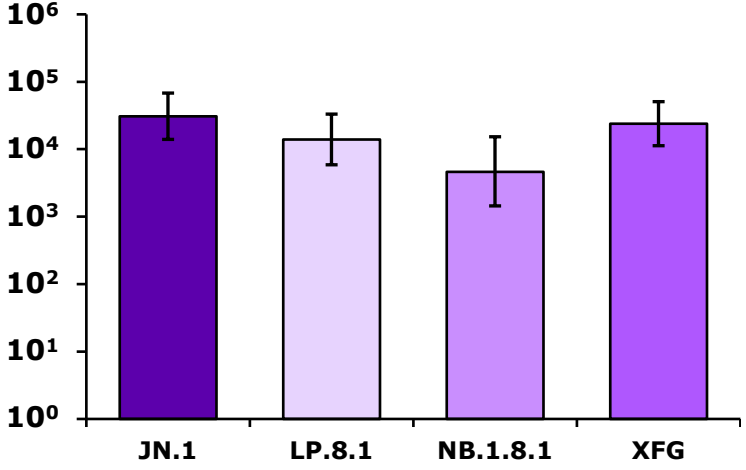


- Reduced neutralization of XFG with JN.1 vaccination indicates evolving immune escape

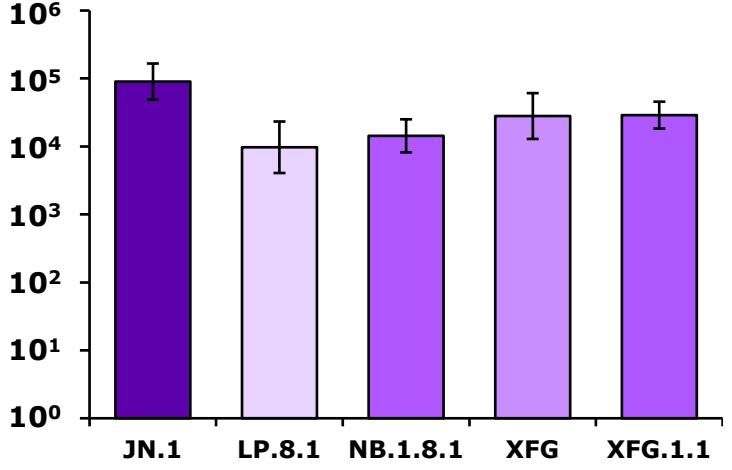
XFG is Immunogenic Across Current JN.1 Strains

ID50
1:serum dilution (95% CI)

Prime: XBB.1.5, JN.1
Boost: XFG



Prime: JN.1, JN.1
Boost: XFG



- Boosting with XFG substantially raises JN.1 lineage titers, including an XFG subvariant
- Data suggest XFG vaccine would cover currently circulating variants

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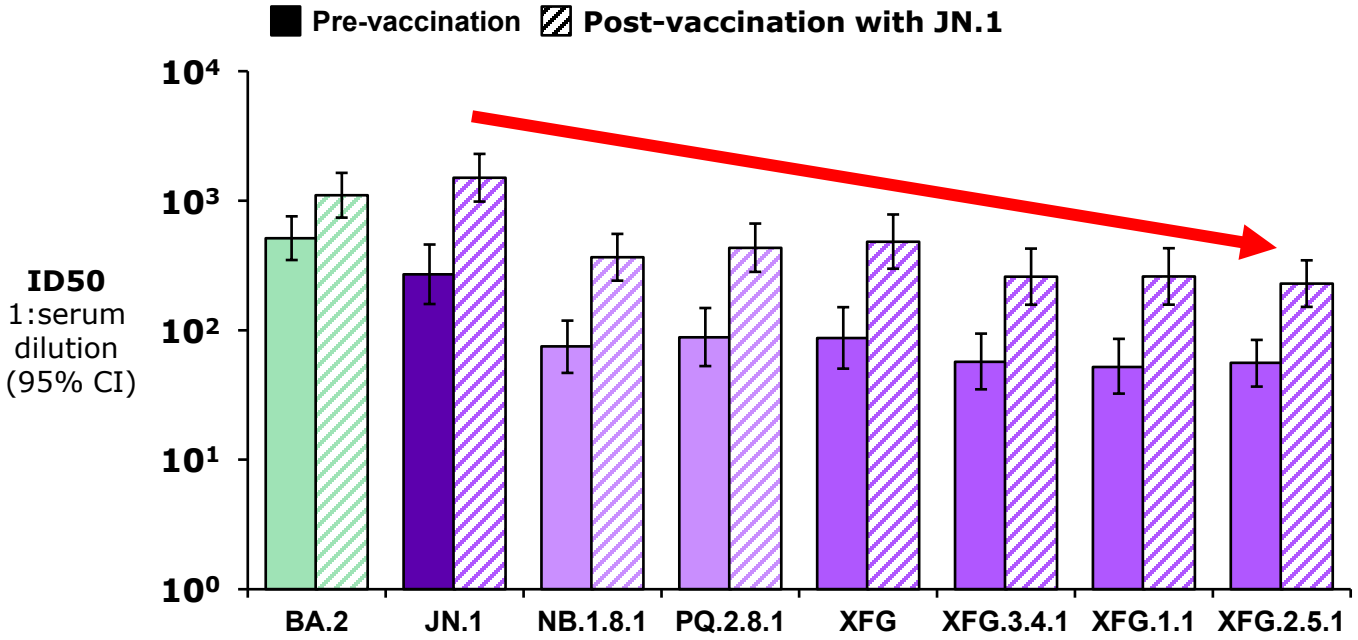
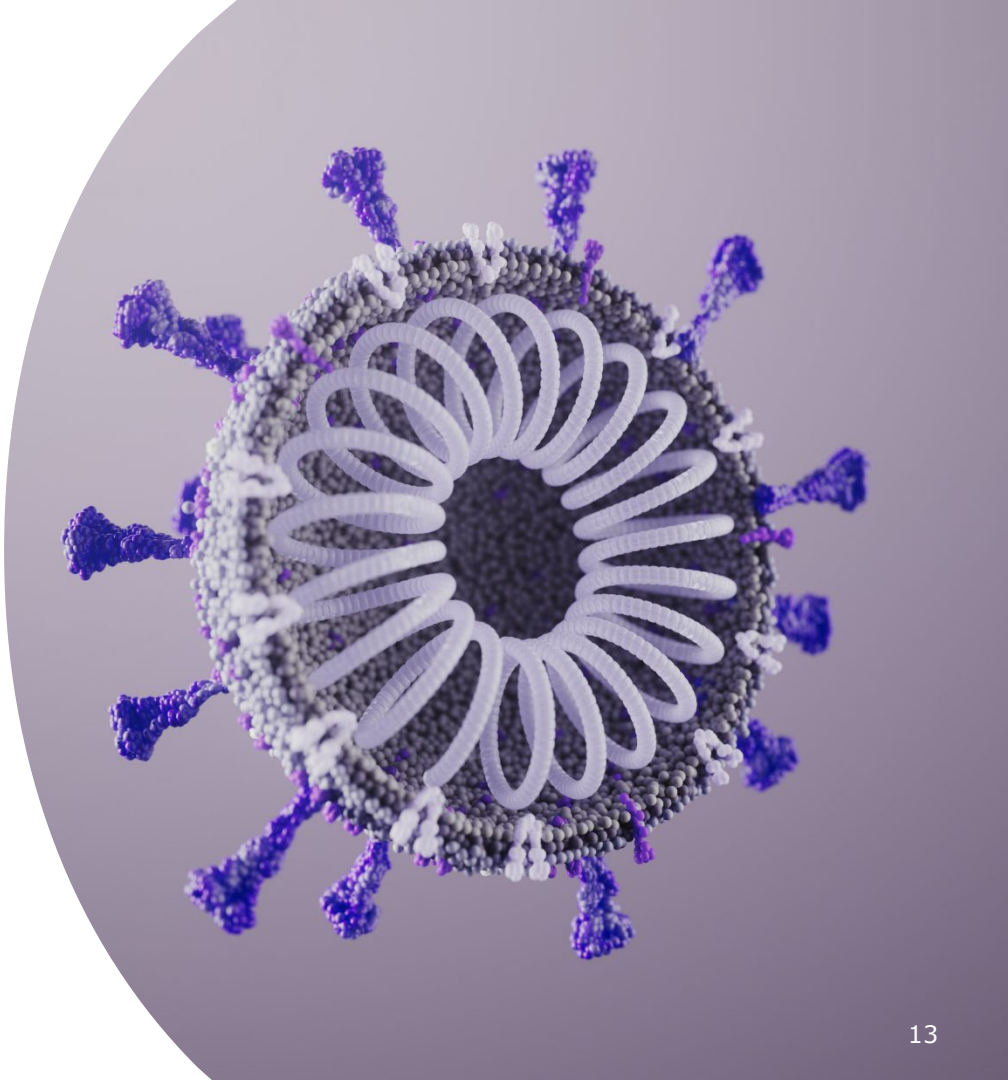
Update to an XFG Vaccine is Supported by Data From Human Sera



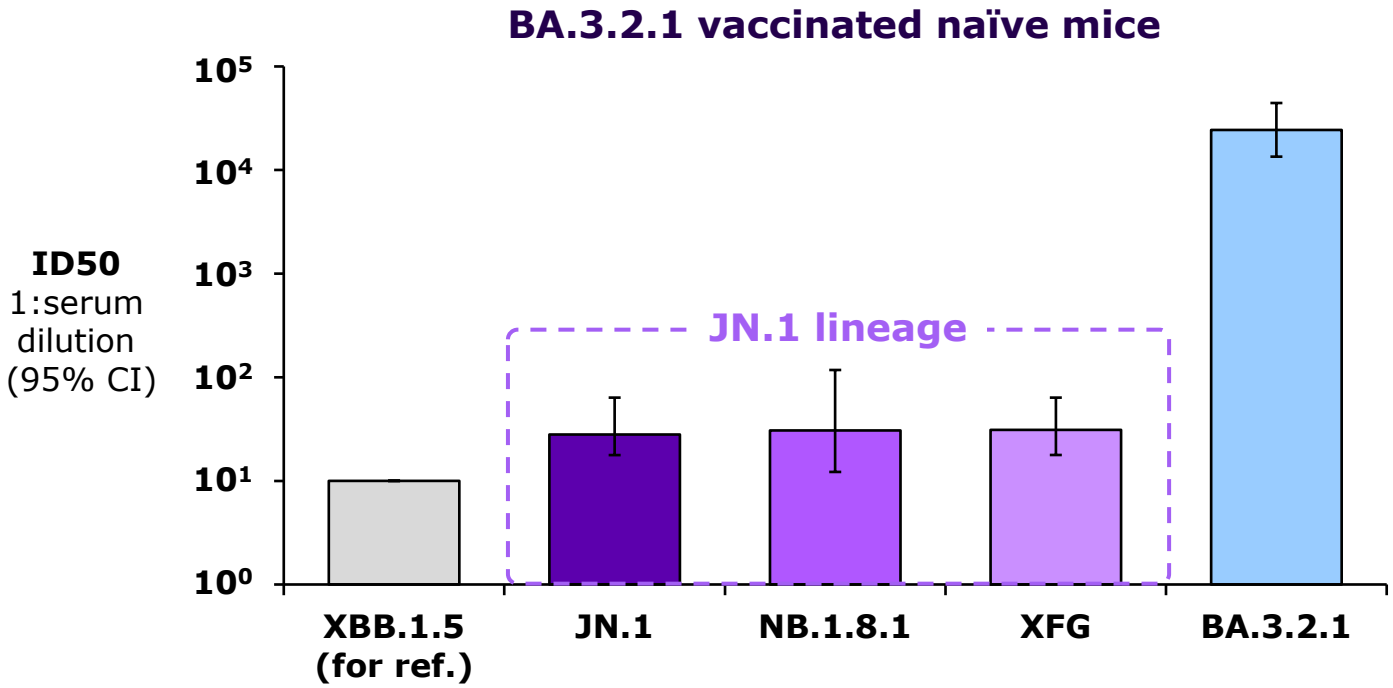
- Immune escape of current variants is also seen in humans
- An XFG vaccine could overcome this immune escape

Annual strain change study with JN.1 (N = 55) conducted in United States, 2025
https://clinicaltrials.gov/study/NCT07079670?term=novavax&viewType=Card&rank=4

Immunology Data
BA.3.2 Variant



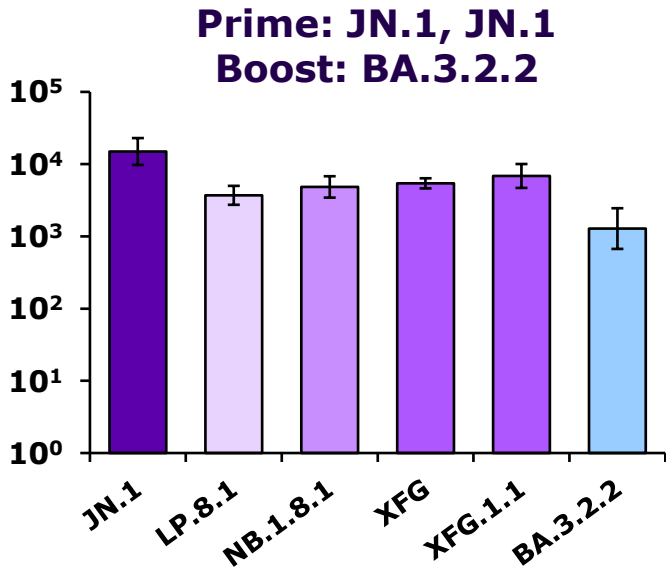
Data Indicate BA.3.2 is Antigenically Distinct

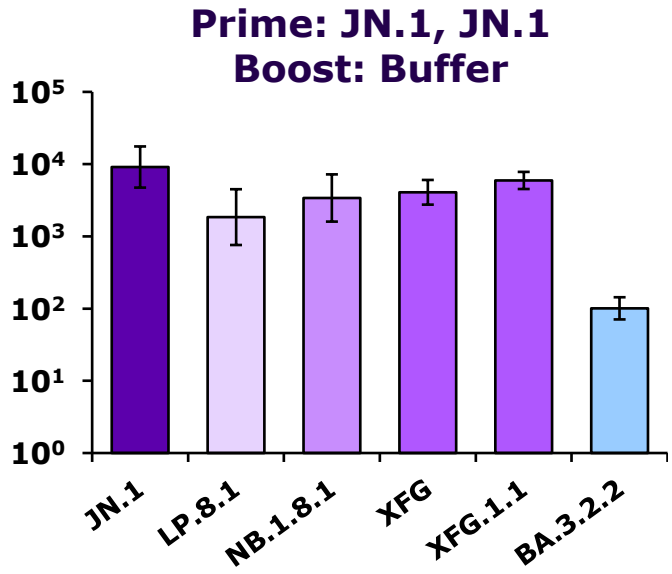


- BA.3.2 is antigenically distinct - minimal cross-reactivity to JN.1

BA.3.2 Vaccination Does Not Raise Antibody Titers Against JN.1 Lineage Variants

ID50
1:serum dilution (95% CI)





- Boosting with BA.3.2.2 has minimal impact on JN.1 lineage titers
- BA.3.2 lineage vaccine would not likely elicit an immune response to protect against JN.1 lineage variants

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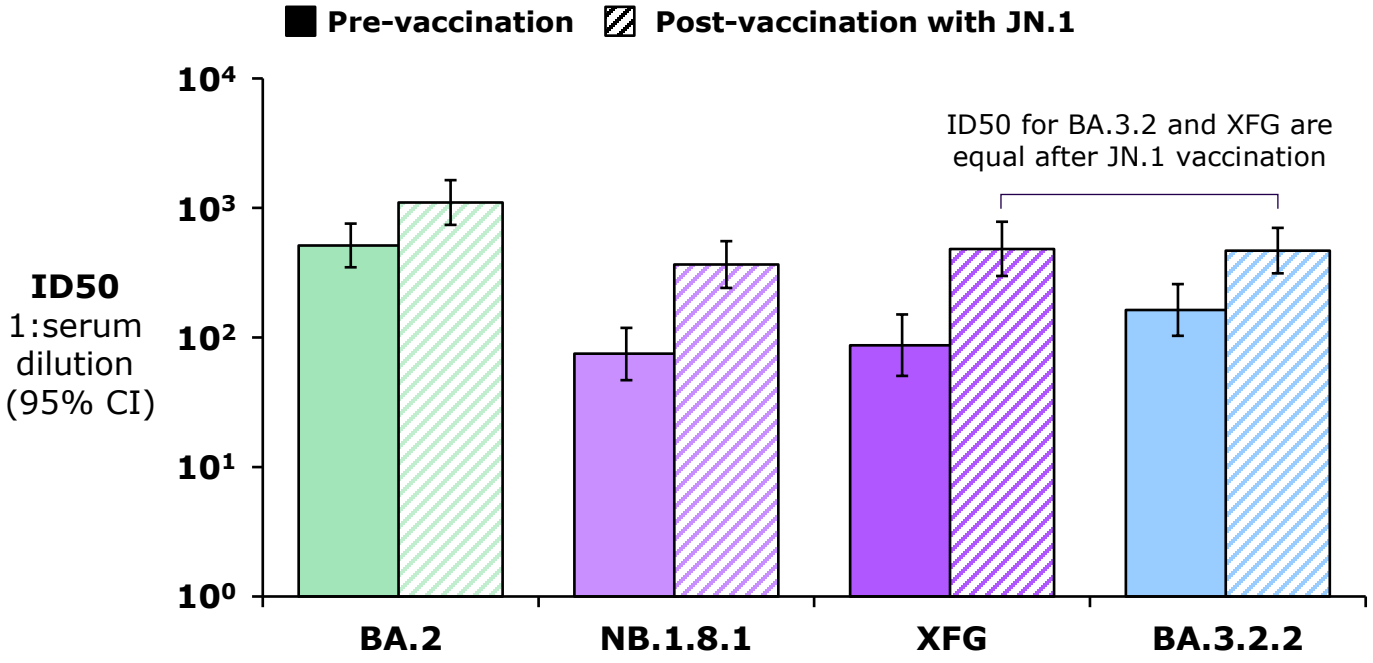
Pre-existing Immunity to BA.3.2 is Boostable with JN.1 Lineage Vaccines



- Pre-vaccination titers to BA.3.2.2 are higher than currently circulating JN.1 variants
- These titers are boostable by JN.1 vaccination
- XFG vaccine expected to protect against BA.3.2

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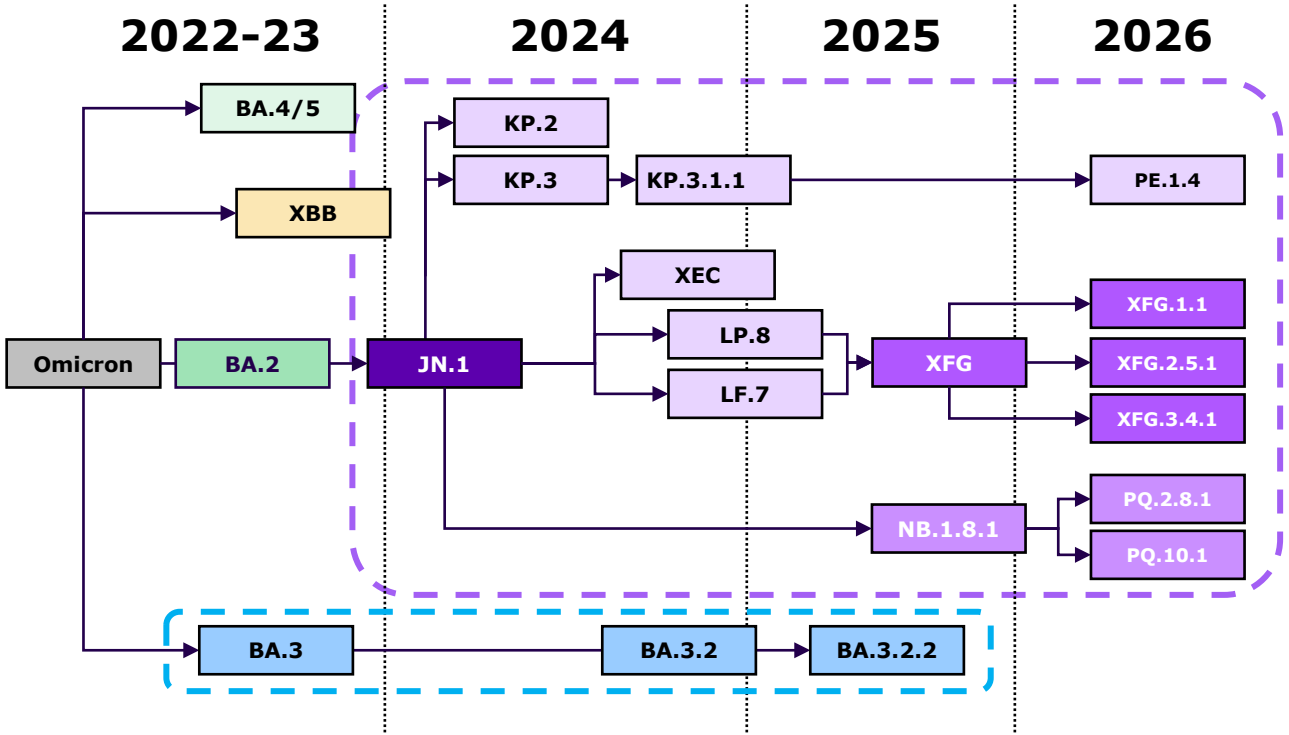
Annual strain change study with JN.1 (N = 55) conducted in United States, 2025
https://clinicaltrials.gov/study/NCT07079670?term=novavax&viewType=Card&rank=4

Future Variants are Likely to Emerge from Currently Circulating and Diversifying Strains



- 80% of circulating variants are JN.1 lineage
- XFG covers currently circulating JN.1 variants
- XFG descendants account for over half of currently circulating variants
- BA.3.2.2 has not evolved in over 12 months

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Evidence supports XFG as the preferred choice for the 2026-27 vaccine composition

Ensuring availability of a **protein-based, non-mRNA** COVID vaccine may help **reduce vaccine hesitancy** and could also **help improve vaccination coverage** rates

XFG variants remain dominant in the US, infect adults of all ages and have given rise to multiple descendent strains which are likely to **continue to circulate** in the 2026-27 season

Even 18 months after emergence, **BA.3.2, has not become dominant** globally, has **not diversified** and is **not associated with severe disease;** notably **LP.8.1 is not circulating**

XFG vaccine is immunogenic, covers a broad panel of currently circulating JN.1 lineage variants, and predicted to **protect vulnerable older adult population**

Sanofi is now manufacturing **XFG protein COVID-19 vaccine** as the single global product for the **2026-27 season**

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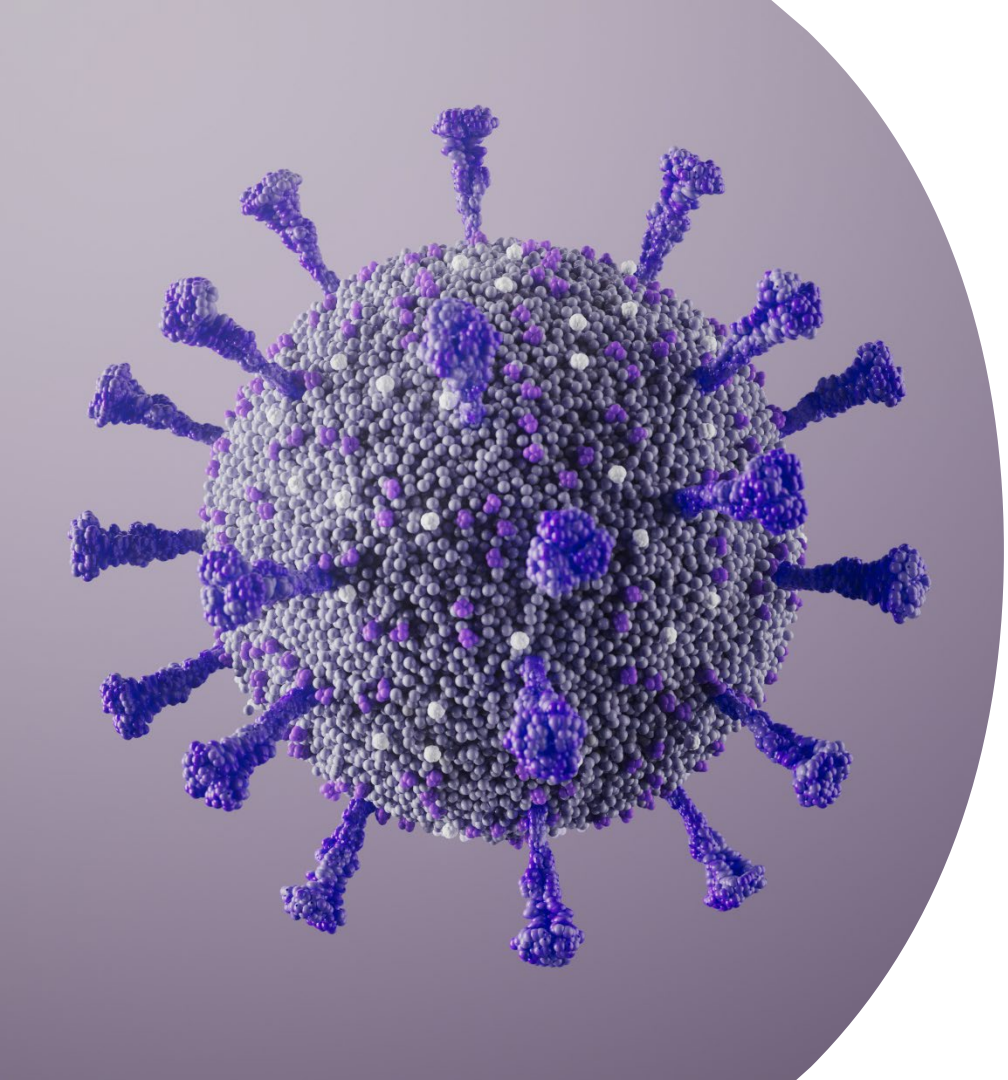

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