Vaccines and Related Biological Products Advisory Committee September 17, 2021 Meeting Presentation

Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

BNT162b2 [COMIRNATY® (COVID-19 Vaccine, mRNA)] Booster (Third) Dose

Vaccines and Related Biological Products Advisory Committee

September 17, 2021

Donna Boyce, MS

Senior Vice President
Global Regulatory Affairs
Pfizer Inc

Presentation Agenda

Introduction

Donna Boyce, MS
Senior Vice President
Global Regulatory Affairs
Pfizer Inc

Public Health Need for the Booster Dose

Clinical Development Program

- Neutralization Results from Phase 1
- Phase 3 Immunogenicity and Safety data
- Pharmacovigilance plans
- Real World Evidence
- Benefit Risk Conclusion

William C. Gruber, MD, FAAP, FIDSA,FPIDS
Senior Vice President
Vaccine Clinical Research and Development
Pfizer Inc

Conclusion

Donna Boyce, MS
Senior Vice President
Global Regulatory Affairs
Pfizer Inc

Introduction

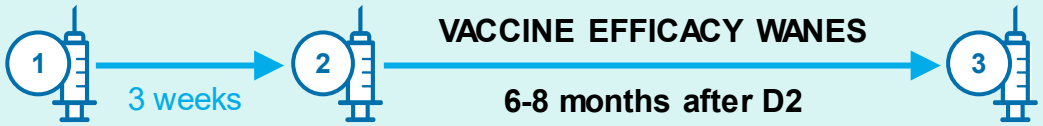
DEC 2020/ May 2021	**BNT162b2 [COMIRNATY (COVID-19 Vaccine, mRNA)] available for prevention of COVID-19 disease**	• **Emergency Use Authorization (EUA):** - Individuals ≥16 years of age - ≥12 years of age in May 2021
Feb/May 2021	**Booster Dose Evaluation**	• **FDA guidance describes criteria for booster doses** • **Phase 1 and 3 safety and immunogenicity substudy conducted**
23 AUG 2021	**US FDA approval**	• **For prevention of COVID-19 disease in individuals ≥16 years old** • **Currently administered intramuscularly (IM) as two 30-µg doses (0.3 mL each) three weeks apart**
27 AUG 2021	**Submitted supplemental Biologics License Application (sBLA)**	• **Seek approval of a single booster dose of BNT162b2** - Individuals ≥16 years of age - Administered intramuscularly at least 6 months after the primary series

Duration of protection is currently unknown, however, Real World and Clinical trial evidence shows that initial vaccine efficacy wanes over time

FDA guidance Feb 2021 available at https://www.fda.gov/media/146173/download

Data to Support Public Health Need for Booster

Data from Israel and the United States suggest vaccine protection against COVID-19 infection wanes approximately 6 to 8 months following the second dose



Data Source	Type	Result
Kaiser Permanente Southern California (KPSC)	Retrospective Cohort Study	• Reduction in VE is likely due to waning effectiveness rather than to Delta escaping vaccine protection
FDA requested analysis	Post-hoc	• Waning effectiveness over time
C4591001 substudy	RCT	• A booster dose of BNT162b2 has an acceptable safety profile and elicits robust immune responses
Israeli booster vaccination program	RWE	• Reactogenicity profile similar or better to that seen after the second primary series dose • Restores high levels of protection against COVID-19 outcomes

Safety and Immunogenicity Data Meet FDA Criteria for Booster Dose ≥16 Years of Age

Substudy of C4591001 pivotal study in ≥ 18 to 55 years of age with booster dose of BNT162b2 administered ~6 months after Dose 2 complies with FDA Guidance for Industry and met prespecified endpoints

Phase 1

- Resulted in acceptable safety profile
- Elicited robust immune responses against the wild-type (reference strain), Beta and Delta variants of concern support effectiveness to be inferred against Delta variant

Phase 3

- Safety profile similar or better than dose 2
- Elicited immune responses against wild-type non-inferior to responses observed post dose 2
- Met protocol pre-specified immunobridging success criteria for GMTs and seroresponse rates

In accordance with FDA guidance, safety and effectiveness of the booster dose demonstrated in ≥18 to 55 years of age can be extrapolated to 16 and 17 years of age and to 55 years of age and older

Benefit-Risk of Booster Dose is Favorable

- The demonstrated safety and effectiveness of a third dose of BNT162b2 support adding a single booster dose to the vaccination schedule
- Global RWE demonstrate that the reduction in VE is likely due to waning effectiveness and Israeli data supports that a booster dose can restore high levels of protection with an acceptable safety profile
- Pfizer/BNT is requesting licensure of a single booster dose of BNT162b2 administered intramuscularly at least 6 months after the primary series in individuals ≥16 years of age

BNT=BioNTech

William C. Gruber, MD

Senior Vice President
Vaccine Clinical Research and Development
Pfizer Inc

Public Health Need

BNT162b2 Vaccine is Highly Protective Against COVID-19 but Duration of Protection Wanes Over Time

- **Data from the pivotal Phase 3 clinical study (C4591001) showed that 2 doses of BNT162b2 vaccine administered 3 weeks apart confers protection against both symptomatic and severe COVID-19**
- **Duration of protection of BNT162b2 is currently unknown**
- **An analysis of efficacy up to six months after Dose 2 shows that initial vaccine efficacy slightly wanes over time in the pre-Delta period**
  - 96.2% from 7 days after Dose 2 to <2 months after Dose 2
  - To 90.1% from ≥2 months to <4 months after Dose 2
  - To 83.7 % for ≥4 months up to ~6 months after Dose 2

Thomas SJ, Moreira ED, Kitchin N, et al. Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine. medRxiv 2021:2021.07.28.21261159.

Waning of Immunity has Been Observed Across the World Coinciding with Penetration of Delta Variant

- **Delta variant became widespread globally in June and July of 2021**
- **Reports describing reduced effectiveness of BNT162b2 (and other COVID-19 vaccines) against SARS-CoV-2 infections caused by Delta have surfaced from Israel[a,b], the United States[c,d,e], and Qatar[f]**
- **Recently in Israel[g]: Reduction in VE has been observed against hospitalization and severe infection after a two-dose BNT162b2 primary series**
- **VE studies to date have not adequately differentiated the impact of Delta from potential waning immunity on recent reductions of vaccine effectiveness**
- **In collaboration with Kaiser Permanente Southern California, Pfizer evaluated overall and variant-specific real-world effectiveness of BNT162b2 against SARS-CoV-2 infections and COVID-19-related hospitalizations by time since vaccination[e]**

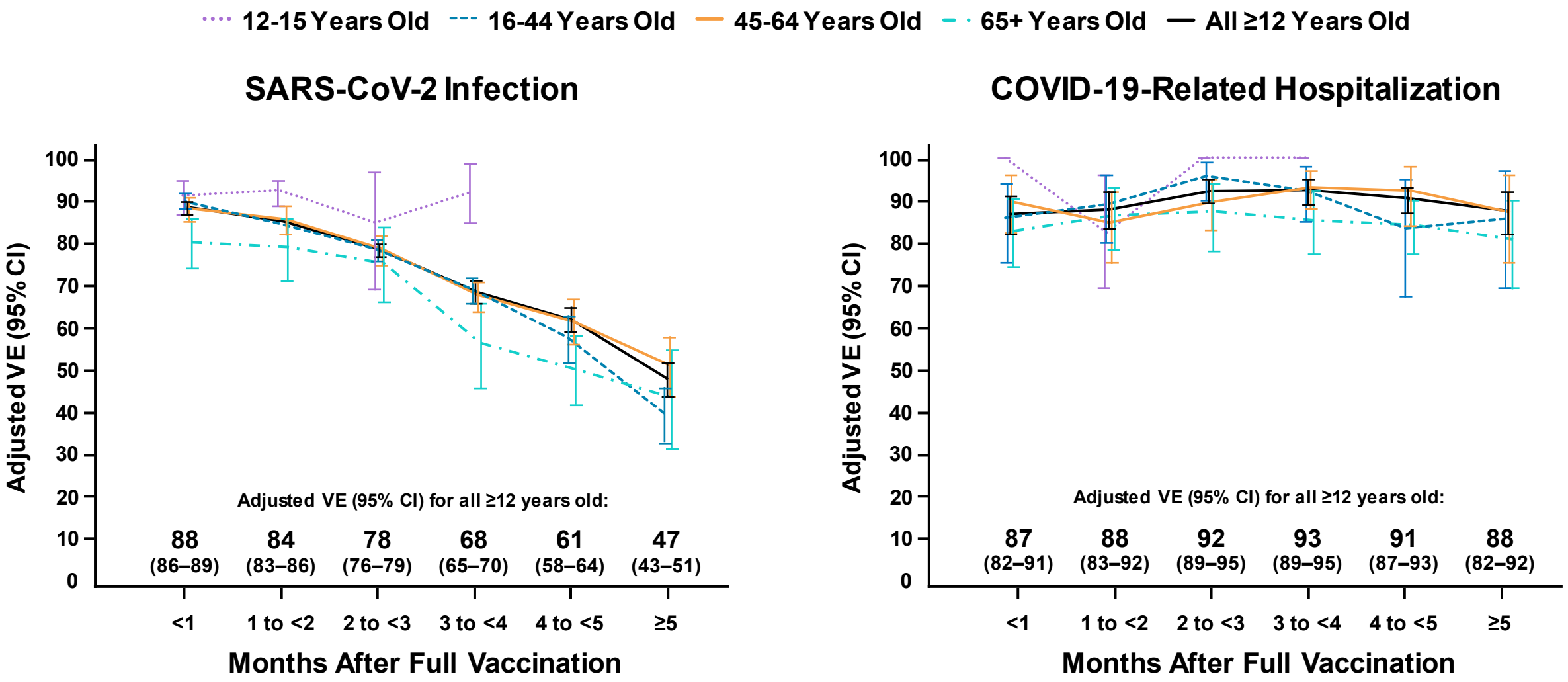
a. Israel Ministry of Health. Presented at Israel Ministry of Health COVID-19 Vaccines Campaign Effectiveness Committee Meeting on 20-JUL-2021. 2021.
b. Goldberg Y, et al. medRxiv 2021.08.24.
c. Nanduri SA, Pilishvili T, Derado G, et al. National Healthcare Safety Network, March 1–August 1, 2021. 2021;70 Early Release.
d. Rosenberg ES, Holtgrave DR, Dorabawila V, et al. MMWR Morb Mortal Wkly Rep Aug 18, 2021;70 - Early Release.
e. Tartof SY, et al. Available at SSRN: https://dx.doi.org/10.2139/ssrn.3909743
f. Tang P, Hasan MR, Chemaitelly H, et al. medRxiv 2021:2021.08.11.21261885.
g. Israel Ministry of Health. COVID-19 Weekly Data Update, 11-AUG-2021. 2021.

Methods of the KPSC BNT162b2 VE Study

Study Parameter	Description
Setting	• Kaiser Permanente Southern California (KPSC) • ~3.4 million members ≥12 years of age with ≥1-year prior membership
Study period	• *Full study period:* Dec 14, 2020 – Aug 8, 2021 • *Whole Genome Sequencing on all samples:* Mar 4, 2021 – Jul 21, 2021
Design	• Cohort approach using Cox models (estimation of hazards ratios [HR])
Outcomes	• (1) SARS-CoV-2 infection[a] • (2) COVID-19-related hospitalization[b]
Vaccine status	• Fully vaccinated with BNT162b2 (2 doses with ≥7 days after second dose) • Unvaccinated (never received any COVID-19 vaccine)

a. SARS-CoV-2 infection defined as any positive PCR test, regardless of symptoms.
b. COVID-19-related hospitalization defined as a PCR positive test 14 days before to 3 days after hospital admission
Tartof SY, et al. Six-Month Effectiveness of BNT162B2 mRNA COVID-19 Vaccine in a Large US Integrated Health System: A Retrospective Cohort Study. Available at SSRN: https://dx.doi.org/10.2139/ssrn.3909743

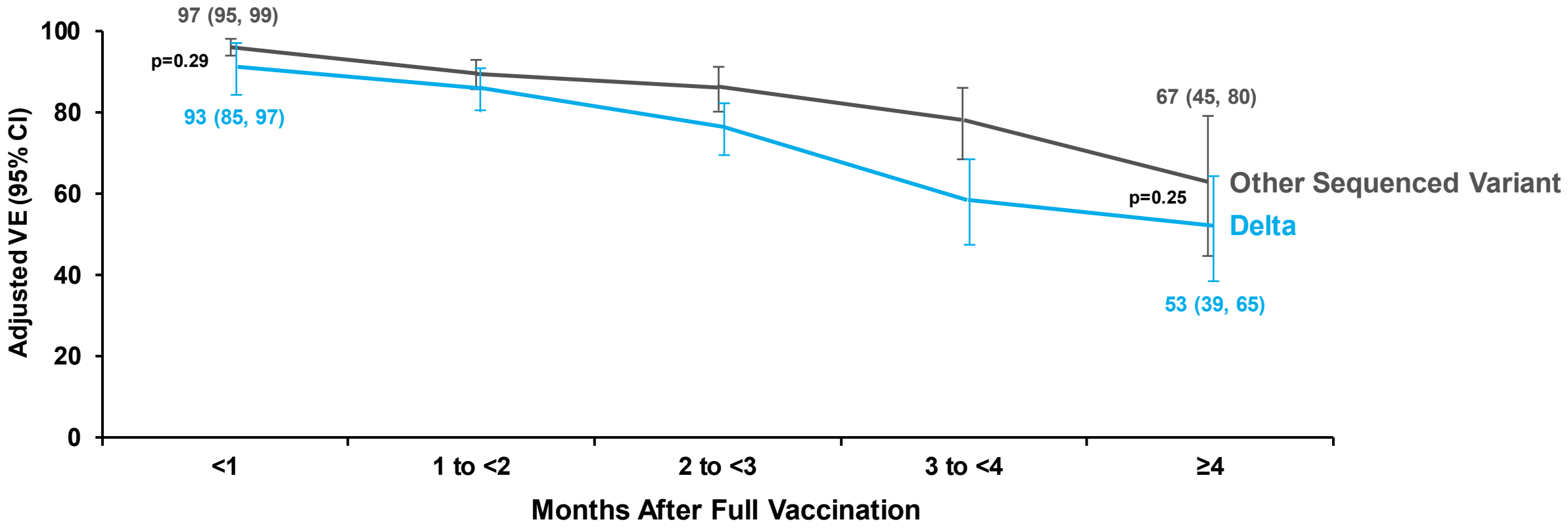
In All Age Groups, Vaccine Effectiveness Wanes Over Time Against Infections but Not Against Hospitalizations



Tartof SY, et al. Six-Month Effectiveness of BNT162B2 mRNA COVID-19 Vaccine in a Large US Integrated Health System: A Retrospective Cohort Study. Available at SSRN: https://dx.doi.org/10.2139/ssrn.3909743

Vaccine Effectiveness Wanes Over Time Irrespective of the Variant of Concern

Adjusted VE Against SARS-CoV-2 Infections, KPSC Members ≥12 Years of Age

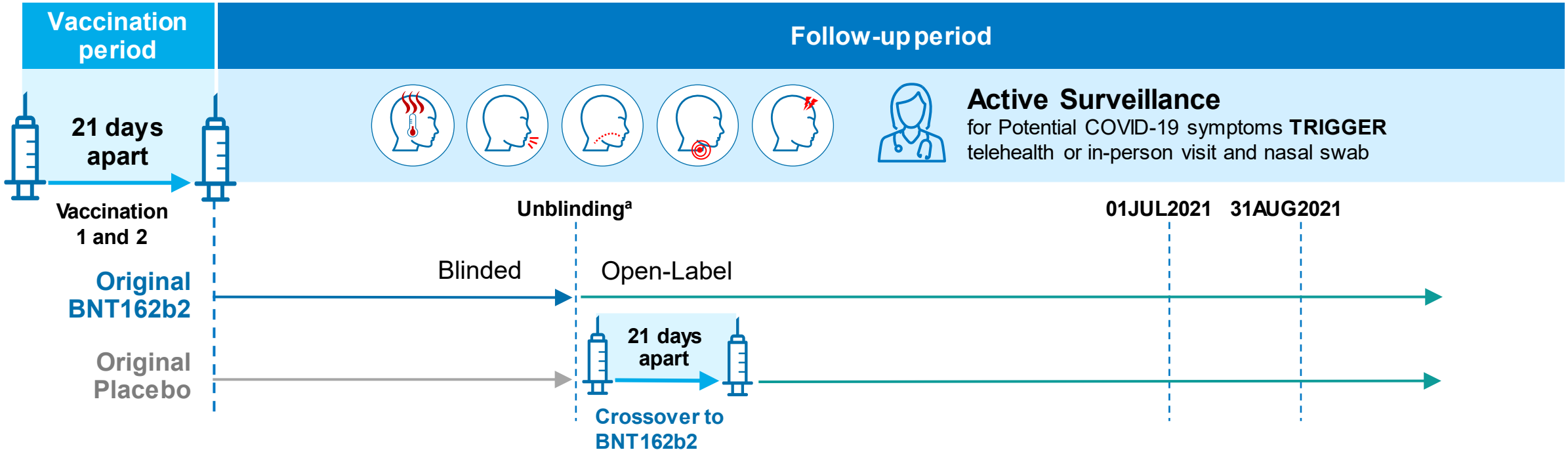


Note: no statistically significant difference in rate of decline between Delta and other sequenced variants (p=0.30)

a. Whole genome sequencing was performed on all PCR+ samples collected Mar 4, 2021 – Jul 21, 2021.

Tartof SY, et al. Six-Month Effectiveness of BNT162B2 mRNA COVID-19 Vaccine in a Large US Integrated Health System: A Retrospective Cohort Study. Available at SSRN: https://dx.doi.org/10.2139/ssrn.3909743.

Delta Variant Surveillance (01JUL2021 Through 31AUG2021) Reveals Waning Protection Between 5 and 10 Months After 2 Doses of BNT162b2



Mean time from Dose 2 to July 1 is 4.7 months for the crossover group and 9.8 months for the original group

Relative vaccine efficacy (later compared to early vaccination): 26.3% (95% CI: 7.4%, 41.4%)

- If protection against COVID-19 falls below 70% at 5 months after vaccination, efficacy would be expected to be below 60% at 10 months

Difference in incidence rates: -18.6 cases/1000 person-years of follow-up

- Magnitude of risk reduction highlights the public health importance of time since immunization

a. Unblinding and placebo crossover started after EUA approval date, date varies by participant

FDA Requested Analysis of COVID-19

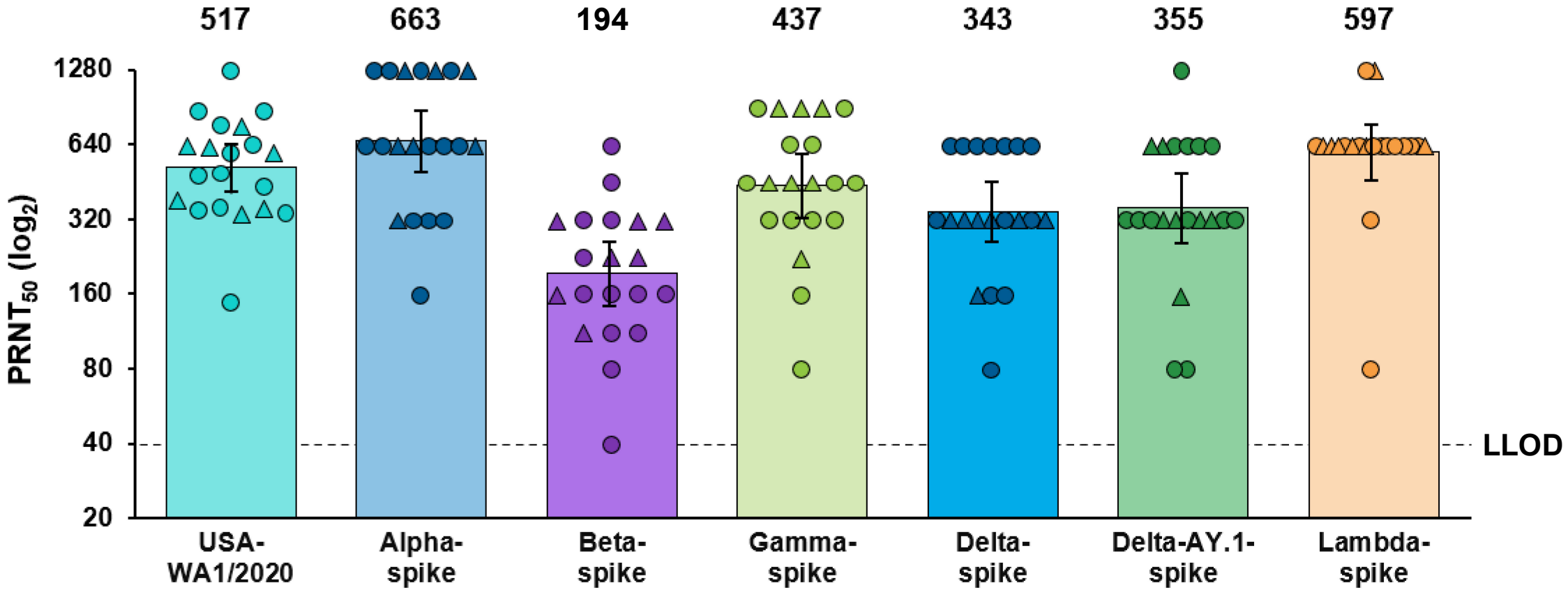
Public Health Need for a Booster: Conclusions

- Israel and the United States RWE suggest that VE against COVID-19 infection wanes approximately 6 to 8 months following the second dose when the delta variant is predominant
- A retrospective KPSC study suggests that VE reductions are primarily due to waning vaccine induced immunity rather than due to Delta escaping vaccine protection
- Waning vaccine effectiveness is further supported by the recent FDA requested post-hoc analysis of breakthrough cases in the C4591001 pivotal Phase 3 clinical study
- While waning VE against hospitalization was not observed in the US, this should be carefully monitored as data from Israel suggest that reduced effectiveness against severe disease could eventually follow reductions in VE against SARS-CoV-2 infections

Overview of Clinical Program

BNT162b2-elicited Sera Effectively Neutralize a Broad Range of SARS-CoV-2 Spike Variants After 2 Doses

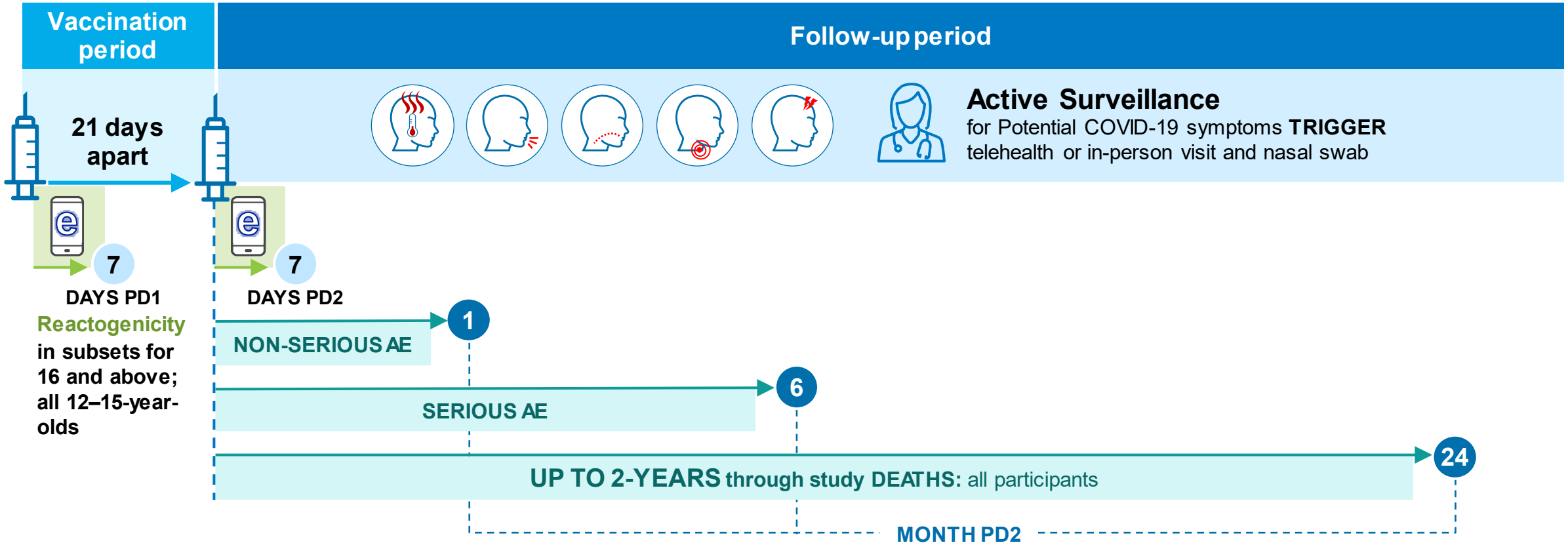
Viruses are isogenic, recombinant SARS-CoV-2 strains, with variant spike coding sequences on a common, USA-WA1/2020 genetic background



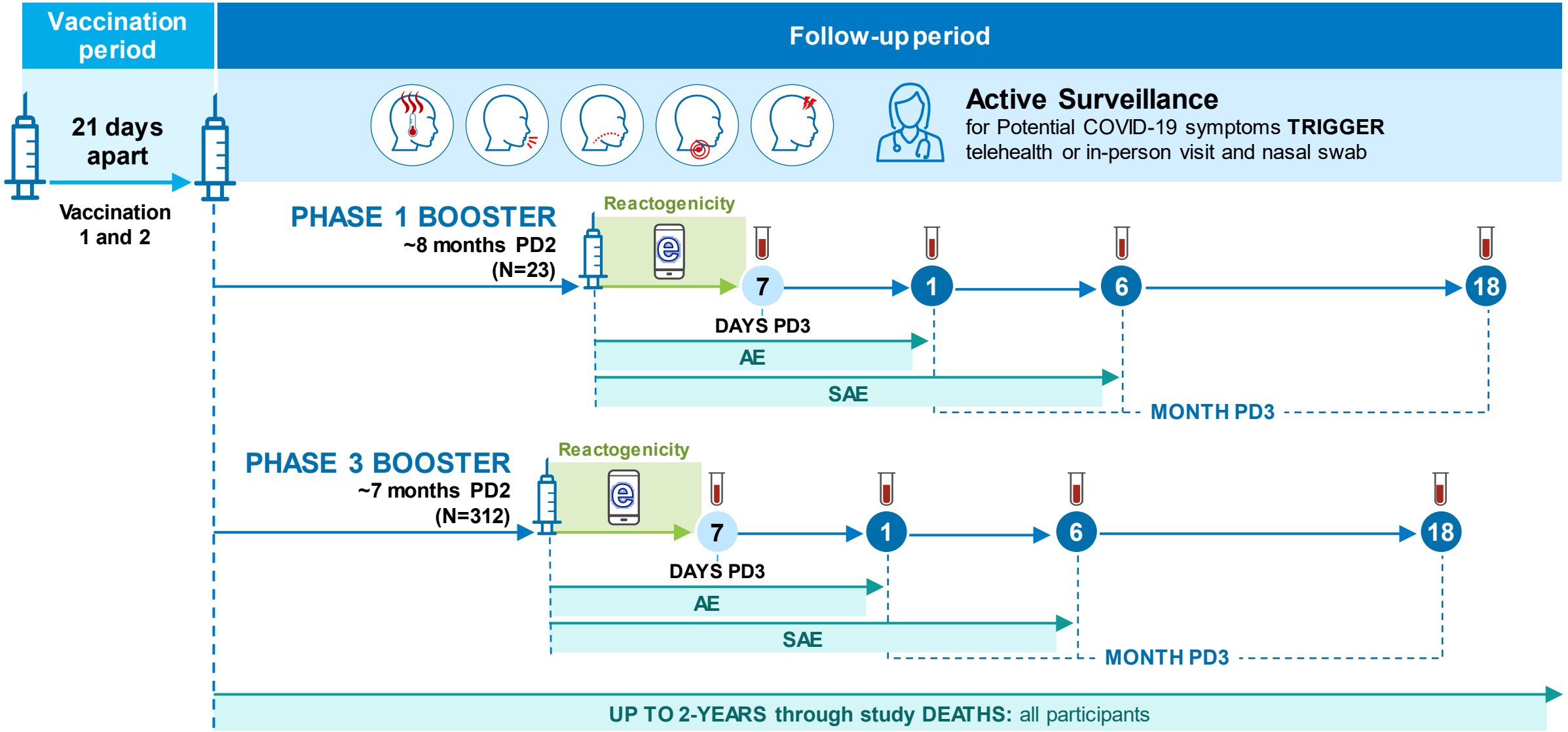
Circles: 2 weeks PD2
Triangles: 4 weeks PD2

Data from Liu et al., 2021, Nature DOI: ; L10.1038/s41586-021-03693-y; Liu et al., 2021 NEJM, DOI: 10.1056/NEJMc2102017; Delta-AY.1, Lambda data submitted for publication

Original Pivotal Study Design (C4591001) – Started 27 July, 2020

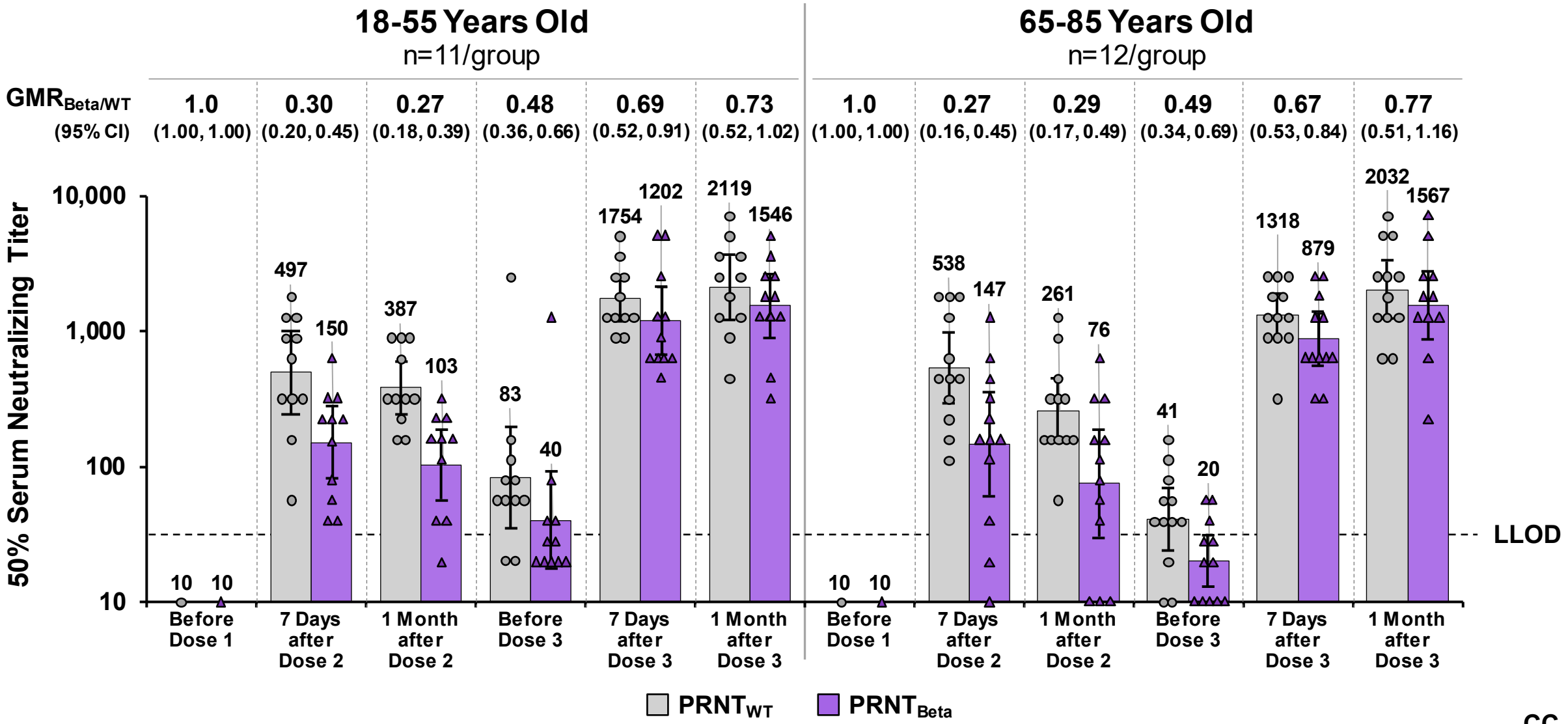


3rd Dose Evaluated in Both Phase 1 and Phase 3 Participants from Original Pivotal Trial



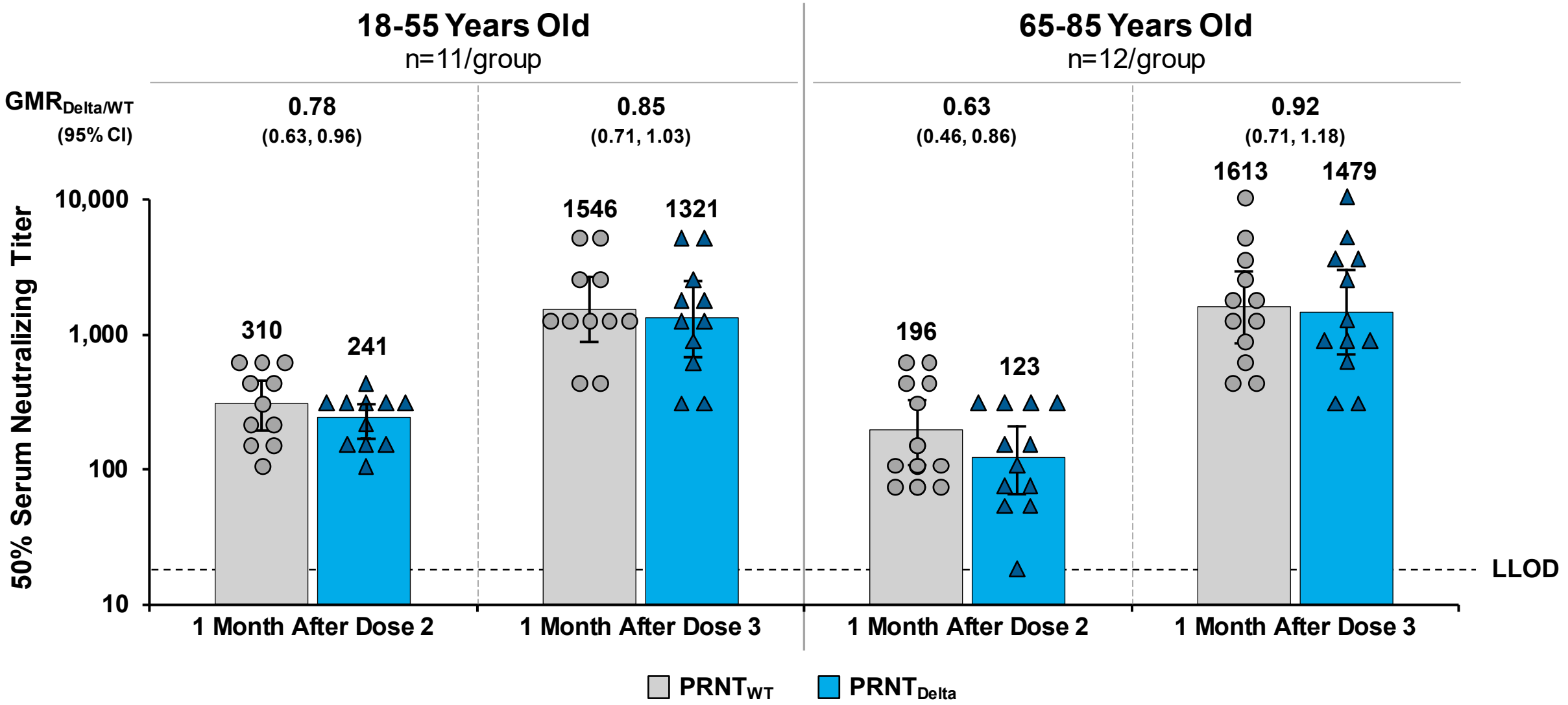
Summary of Data for BNT162b2 Booster (3rd Dose) Administered in C4591001: Phase 1

Post-dose 3 BNT162b2 GMTs Indicate a Substantial Boost and Reduced Gap Between WT and Beta Neutralization



Submitted for publication.

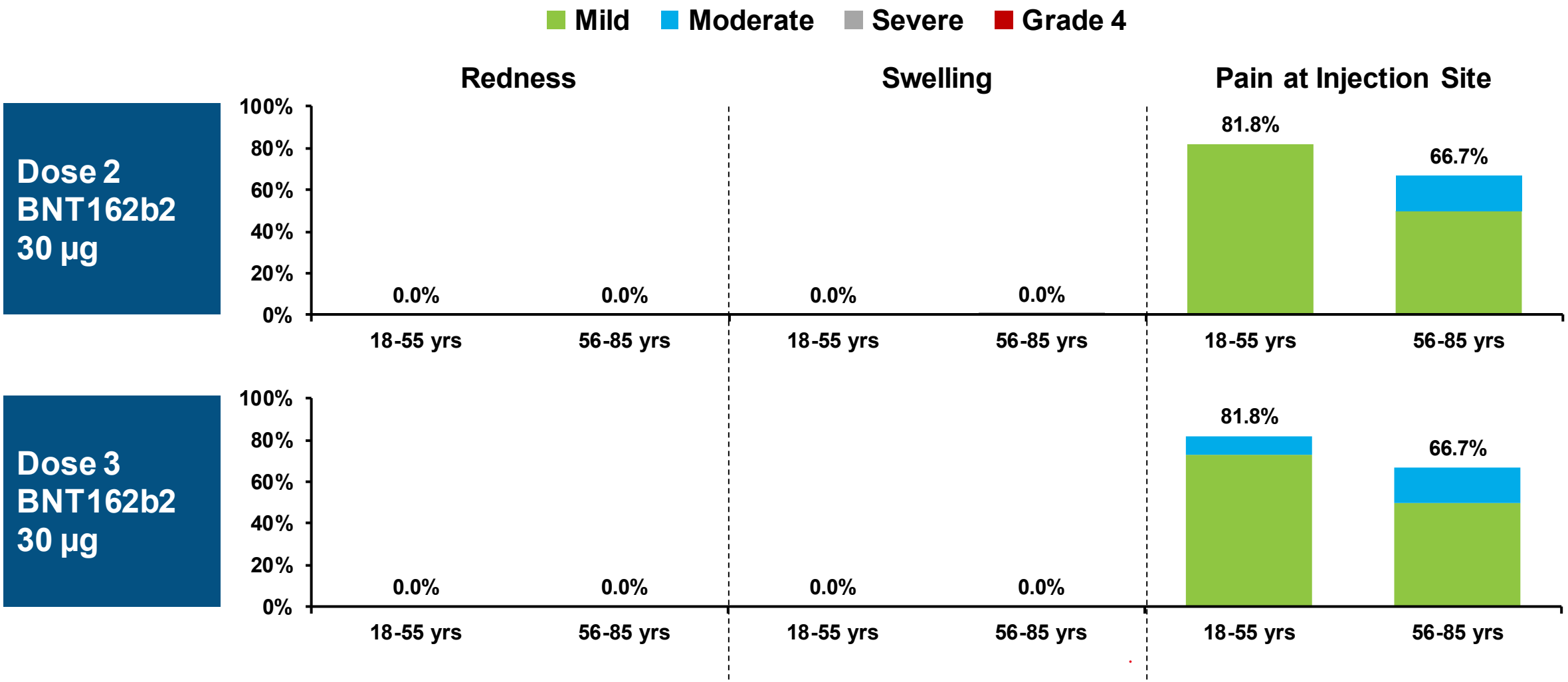
Post-dose 3 BNT162b2 GMTs Indicate a Substantial Boost to the Delta Variant Similar to Wild Type



Submitted for publication.

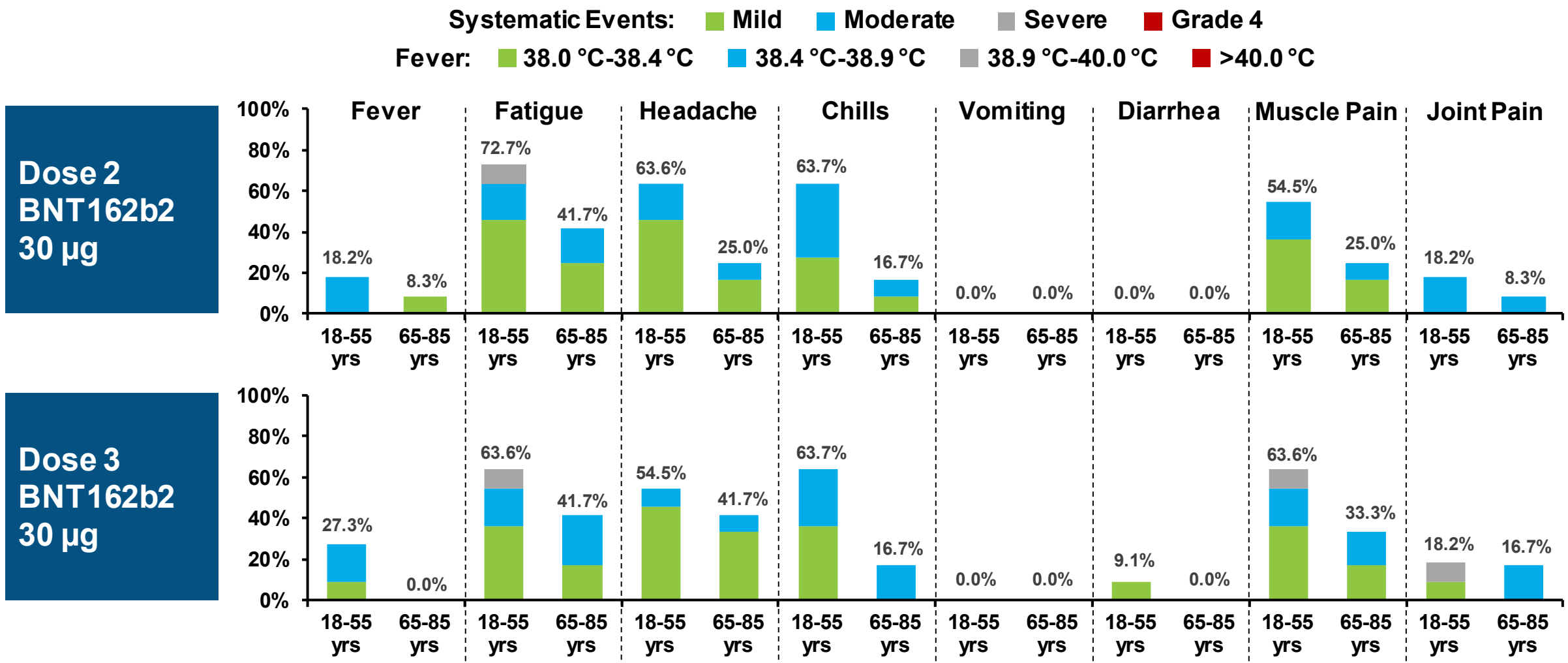
CC-23

Local Reactions by Maximum Severity within 7 Days of 3rd Dose Similar to Post-dose 2



Redness and swelling severity definition: Mild = >2-5 cm, Moderate = >5-10 cm; Severe = >10 cm; Grade 4 = necrosis
Pain at injection site severity definition: Mild = no interference; Moderate = some interference; Severe = prevents daily activity; Grade 4 = ER visit or hospitalization
N=11 for 18-55 years, N=12 for 65-85 years
Submitted for publication

Systemic Events by Maximum Severity within 7 Days of 3rd Dose Similar to Post-dose 2



Fatigue, headache, chills, muscle pain, joint pain severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
Vomiting severity definition: Mild=1-2 time in 24h; Moderate=>2 times in 24h; Severe=Requires IV hydration; Grade 4=ER visit or hospitalization
Diarrhea severity definition: Mild=2-3 times in 24h; Moderate=4-5 times in 24h; Severe=6 or more times in 24h; Grade 4=ER visit or hospitalization
N=11 for 18-55 years, N=12 for 65-85 years
Submitted for publication.

Summary of Data for BNT162b2 Booster (3rd Dose) Administered in C4591001: Phase 3

Basis for Extrapolation of Phase 3 3rd Dose Data to 16-17 and >55 Year Olds

- **Immunogenicity***
  - "Studies....may be conducted in a single age group (e.g., adults 18-55 years of age), with extrapolation of results to other age groups for which the prototype vaccine has been authorized....".
- **Safety**
  - 16-17 year olds** – based upon post-dose 2 data:
    - Reactogenicity would be expected to be similar to 18-55 year olds
  - >55 year olds:
    - Local reactions and systemic events in participants >55 years after dose 2 were lower than those in younger adults.
    - This predicts lower reactions after the third dose in >55 year olds based on the lower reactogenicity profile seen after the third dose compared to the second dose in 18-55 year olds

*Food and Drug Administration (FDA). Emergency Use Authorization for Vaccines to Prevent COVID-19. Guidance for Industry. May 2021
**Pediatric Research Equity Act of 2007.
PREA FDA guidance September 2005 available at https://www.fda.gov/media/72274/download

FDA Immunogenicity Criteria For Booster Dose

- **The booster study must be adequately powered to demonstrate that the immune responses induced by the booster dose (serum neutralizing titers against SARS-CoV-2, as measured by seroresponse rates and GMTs), are statistically non-inferior compared to those elicited by the vaccine in the primary series**
- **The success criteria include demonstration of non-inferiority margins of -10% for seroresponse rates and 1.5 fold for GMTs**
- **Based on consultations with CBER, these criteria are also considered sufficient to support licensure of a booster following full approval of the primary series**

FDA guidance May 2021: https://www.fda.gov/media/142749/download

Subjects Receiving 3rd Dose were Representative of US 18-55 Year Olds in Parent Study

		SAFETY POPULATION
		BNT162b2 N=306
Sex, n (%)	Male	140 (45.8)
	Female	166 (54.2)
Race, n (%)	White	249 (81.4)
	Black or African American	28 (9.2)
	American Indian or Alaska Native	2 (0.7)
	Asian	16 (5.2)
	Native Hawaiian or other Pacific Islander	1 (0.3)
	Multiracial	4 (1.3)
	Not reported	6 (2.0)
Ethnicity, n (%)	Hispanic/Latino	85 (27.8)
	Non-Hispanic/non-Latino	219 (71.6)
	Not reported	2 (0.7)
Comorbidity[a]	Present	174 (56.9)
Age at booster vaccination (years)	Mean (SD)	41.3 (9.44)
	Min, Max	(19,55)
Time from Dose 2 to booster dose (months)	Mean (SD)	6.8 (0.56)
	Min, Max	(4.8. 8.0)

a. One or more Charlson comorbidity index, hypertension or obese

Immunogenicity

Geometric Mean Ratio of Neutralization Titers Non-inferiority Criterion (Post-dose 3 vs. Post-dose 2) was Met, with Titers ~3-fold Higher

		Booster Evaluable Immunogenicity Population			
		1 Month Post Booster (Dose 3)	1 Month After Dose 2	1M Post Booster/1M PD2[a]	
Assay	N	GMT (95% CI)	GMT (95% CI)	GMR (97.5% CI)	Met NI (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)	210	2476.4 (2210.1, 2774.9)	753.7 (658.2, 863.1)	3.29 (2.76, 3.91)	Yes

a. Noninferiority is declared if the lower bound of the 97.5% confidence interval is > 0.67 and the point estimate of the GMR is ≥0.8
NT50 = 50% neutralizing titers (Booster Evaluable Immunogenicity Population)

Noninferiority of Booster Dose Demonstrated Based on Proportion of Subjects with a Seroresponse

Seroresponse is defined as achieving a ≥4-fold rise from baseline (before Dose 1)

		Booster Evaluable Immunogenicity Population		
		1 Month Post Booster (Dose 3)	1 Month After Dose 2	1M Post Booster - 1M PD2[a]
Assay	N	n (%) (95% CI)	n (%) (95% CI)	% (97.5% CI)
SARS-CoV-2 neutralization assay - NT50 (titer)	198	197 (99.5) (97.2, 100.0)	194 (98.0) (94.9, 99.4)	1.5 (-0.7, 3.7)

a. Noninferiority is declared if the lower bound of the 2-sided 97.5% confidence interval for the percentage difference is greater than -10
If the baseline measurement is below the LLOQ, a postvaccination assay result ≥4 × LLOQ is considered a seroresponse

Noninferiority Also Confirmed Based on FDA-defined Alternative Analysis

FDA requested post-hoc analysis: Alternative definition – comparison of pre-booster versus post-booster response

		Booster Evaluable Immunogenicity Population		
		1 Month Post Booster (Dose 3)	1 Month After Dose 2	1M Post Booster - 1M PD2[a]
Assay	N	n (%) (95% CI)	n (%) (95% CI)	% (95% CI)
SARS-CoV-2 neutralization assay - NT50 (titer)	179	168 (93.9) (89.3, 96.9)	175 (97.8) (94.4, 99.4)	-3.9 (-8.2, 0.4)

a. Noninferiority is declared if the lower bound of the 2-sided 97.5% confidence interval for the percentage difference is greater than -10
If the baseline measurement is below the LLOQ, a postvaccination assay result ≥4 × LLOQ is considered a seroresponse

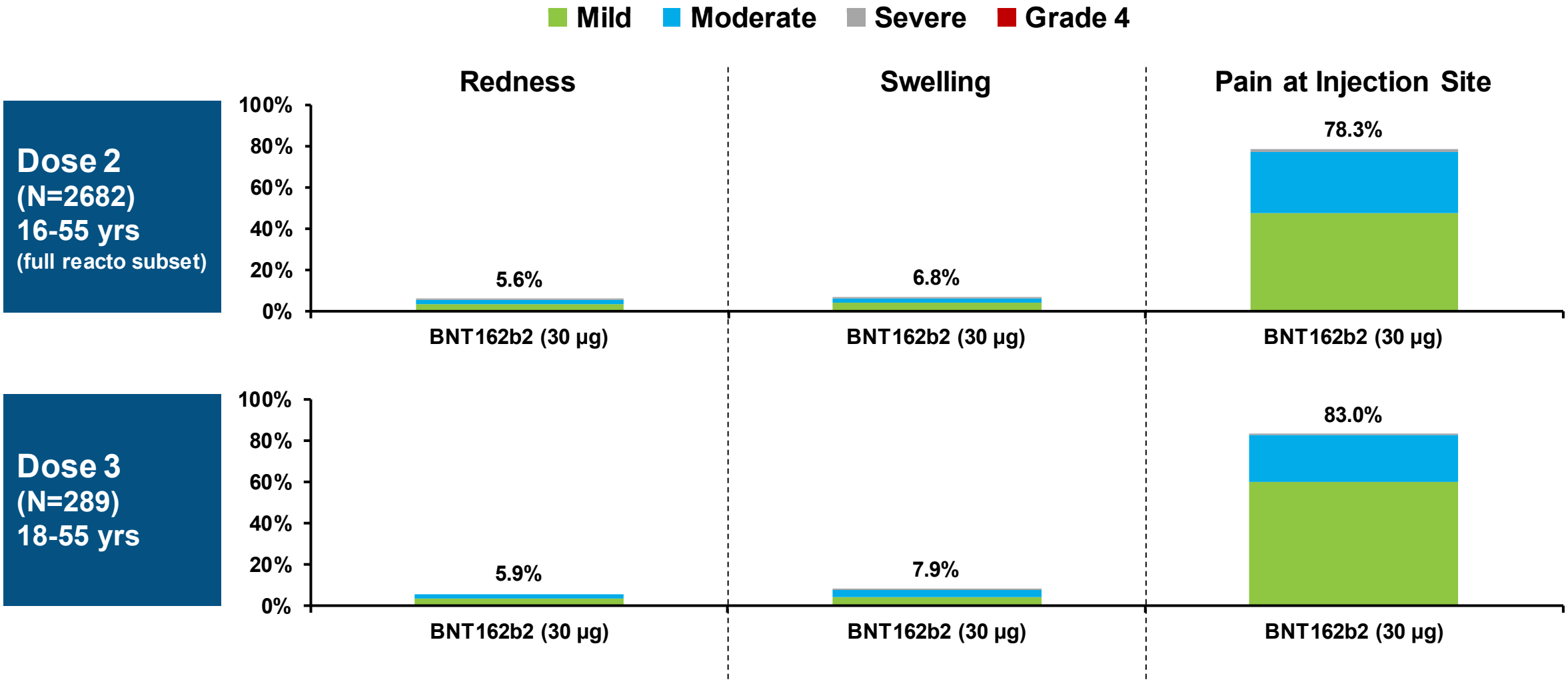
Safety

Follow-up Time for Booster Dose

		BNT162b2 (30µg) Booster (3rd) Dose N=306
Total exposure from booster vaccination to cutoff date (months)	Mean (SD)	2.7 (0.15)
	Median	2.6
	Min, Max	(1.1, 2.8)
Total exposure from Dose 2 to cutoff date (months)	Mean (SD)	9.4 (0.57)
	Median	9.5
	Min, Max	(7.5, 10.8)

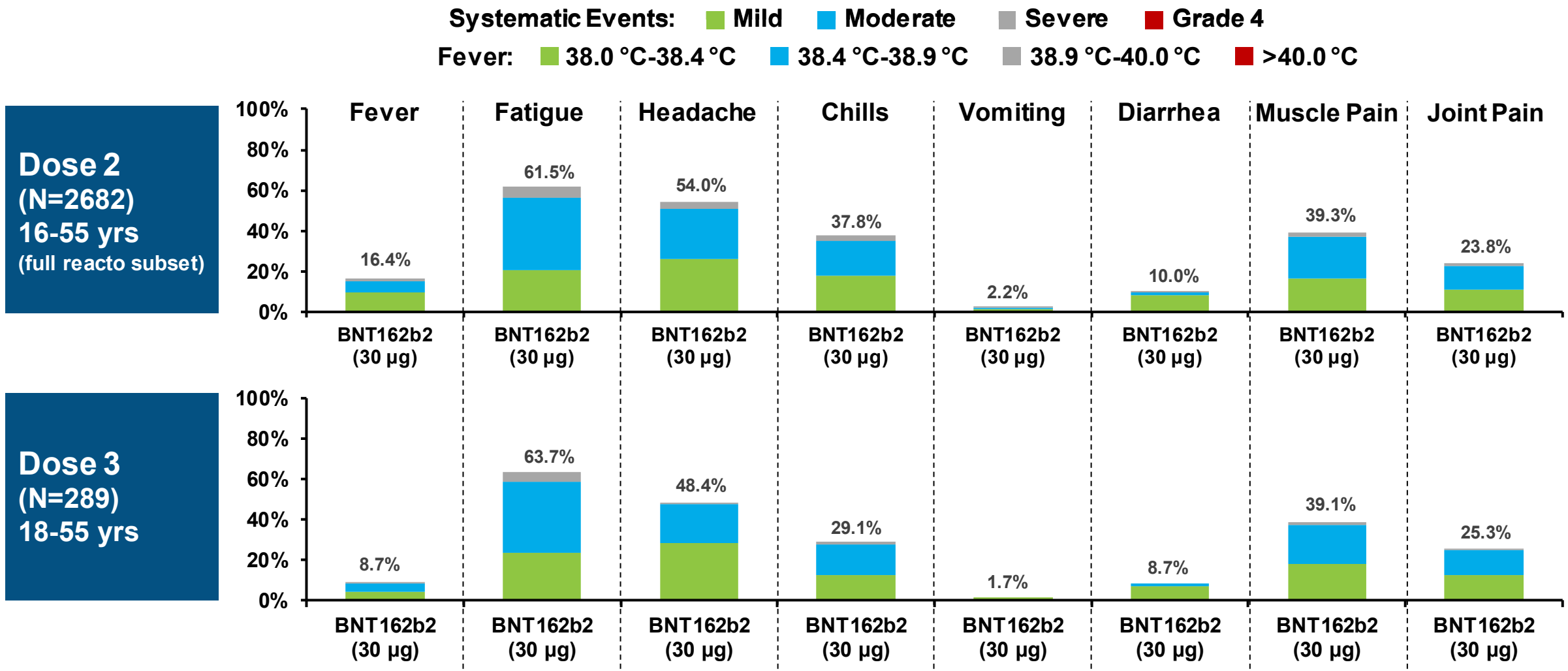
Data cutoff date 17Jun2021

Local Reactions Comparable to Those Seen After Dose 2



Redness and swelling severity definition: Mild= >2-5 cm, Moderate= >5-10 cm; Severe= >10 cm; Grade 4= necrosis
Pain at injection site severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization

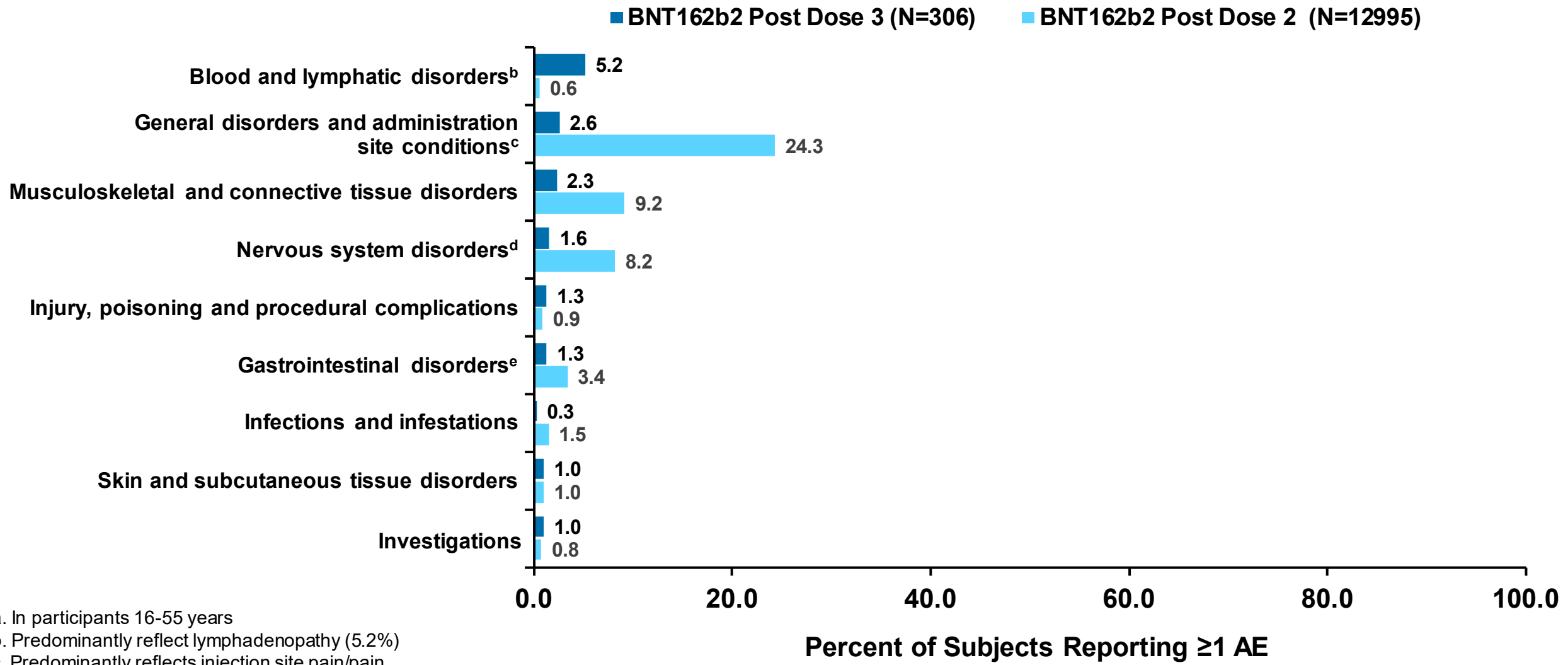
Systemic Events by Maximum Severity within 7 Days of 3rd Dose Similar to Post-dose 2 in Parent Study



Fatigue, headache, chills, muscle pain, joint pain severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
Vomiting severity definition: Mild=1-2 time in 24h; Moderate=>2 times in 24h; Severe=Requires IV hydration; Grade 4=ER visit or hospitalization
Diarrhea severity definition: Mild=2-3 times in 24h; Moderate=4-5 times in 24h; Severe=6 or more times in 24h; Grade 4=ER visit or hospitalization

Adverse Events by System Organ Class ≥1% 1 Month Post 3rd Dose Overall Less than Those Post-dose 2 in Parent Study[a]

Safety Population



a. In participants 16-55 years
b. Predominantly reflect lymphadenopathy (5.2%)
c. Predominantly reflects injection site pain/pain
d. Predominantly reflects headache
e. Predominantly reflects nausea

One Serious Adverse Event Through Median 2.6 Months Follow-up, Assessed as Unrelated to Vaccination

	BNT162b2 (30 µg) N=306 n (%)
Any event	**1 (0.3)**
Acute myocardial infarction	**1 (0.3)**

Ongoing and Active Pharmacovigilance and Pharmacoepidemiology

Pharmacovigilance

- Expanded intake capability with web-based AE portal
- Active follow-up of safety reports
- Frequent signal detection and evaluation
- Post-approval safety monitoring
- Continued pharmacovigilance for adverse events of special interest including anaphylaxis and myocarditis

Proactive Risk minimization

- Labeling & Educational Materials
- Real-time product quality monitoring (cold-chain)

Pharmacoepidemiology Studies

- Extended follow up (for high-severity low-incidence events in large populations)
- Safety surveillance studies (including analysis of booster dose and myocarditis)
- Vaccine effectiveness
- Event background rate (contextualization)

Collaborate with Vaccine Safety Stakeholders

- Interface with CDC (VAERS, V-SAFE, VSD, CISA) to optimize pharmacovigilance activities
- Collaborate with international groups to ensure consistent approach to PV

Real World Safety and Effectiveness of a Booster Dose

Israel has Shown that a Booster Roll-out Campaign Can be Implemented Safely

- As a result of emerging evidence of waning immunity and increasing rates of infection and hospitalization following the introduction of the Delta variant, the Israel Ministry of Health launched a BNT162b2 booster (third dose) program covering the entire vaccine-eligible population five months after the second dose
- As of today, around 2.7 million people have received a third dose of BNT162b2, including most of the elderly population
- To date no new safety concerns have been identified and rates of reported adverse events are lower post third dose compared to those observed post dose 1 and 2

Israel Ministry of Health data on file.

In Israel, a 3rd Booster Dose Restored High Levels of Effectiveness for Both Infections and Severe COVID-19

- **Fold reduction in risk of developing SARS-CoV-2 outcomes after three doses of BNT162b2 (vs. 2 doses only) among adults ≥60 years of age who were fully vaccinated before March 1, 2021: Israel nationwide MoH data Jul 30, 2021 – Aug 22, 2021**

BNT162b2 Doses	Confirmed Infection % (95% CI)	Severe COVID-19 % (95% CI)
2 doses only[a]	ref	ref
3 doses[b]	11.4-fold (10.0, 12.9)	15.5-fold (10.5, 22.8)

These fold reductions translate to roughly 95% effectiveness after a booster against infections and severe disease in the Delta era

a. Fully vaccinated before March 1, 2021, thus ≥5 months since receipt of the second dose.
b. ≥12 days from the third dose.
Estimates with 95%CIs from a Poisson regression model adjusted for age, sex, sector, and calendar day.
Bar-On et al. BNT162b2 vaccine booster dose protection: A nationwide study from Israel. *medRxiv* 2021. doi: https://doi.org/10.1101/2021.08.27.21262679

Benefit-Risk Conclusions

Benefit-Risk Summary

- BNT162b2 demonstrated high efficacy (>90%) against COVID-19 and safety in the pivotal clinical trial after a 2-dose primary series
- Reductions in real-world VE against COVID-19 are observed over time, especially coinciding with the Delta period, based primarily on waning immunity and not on escape
- While VE against severe disease and hospitalization remains high in most populations in the US, data from Israel predicts this may not be sustained
- Clinical safety and effectiveness data meet the FDA licensure requirements
- Real-world data from Israel suggest a booster dose vaccination campaign can be implemented safely and can restore high levels of immune response and protection

Donna Boyce, MS

Senior Vice President
Global Regulatory Affairs
Pfizer Inc

Proposed Revisions to the Dosing Schedule

Current Dosing Regimen

COMIRNATY administered intramuscularly as a primary series

2 doses
(0.3 mL each)
3 weeks apart

Proposed Additional Dosing Regimen

A single booster dose may be administered intramuscularly

1 dose
(0.3 mL)
at least 6 months after the primary series

Clear and Compelling Data Support a Booster (Third) Dose of BNT162b2

- Well-tolerated and elicits a strong booster response against wild type and variants
- Vaccine's benefits outweigh risks based on well-designed Phase 3 clinical trial
- Real World Evidence supports Benefit and Safety
- Plans for active follow-up for safety

Acknowledgments

- **Pfizer and BioNTech wish to thank:**
  - Sites, investigators, CRO, our partners and their staff
  - The clinical trial participants and their families
  - FDA guidance to assess this urgent medical need

BNT162b2 [COMIRNATY® (COVID-19 Vaccine, mRNA)] Booster (Third) Dose

Vaccines and Related Biological Products Advisory Committee

September 17, 2021

CC-50