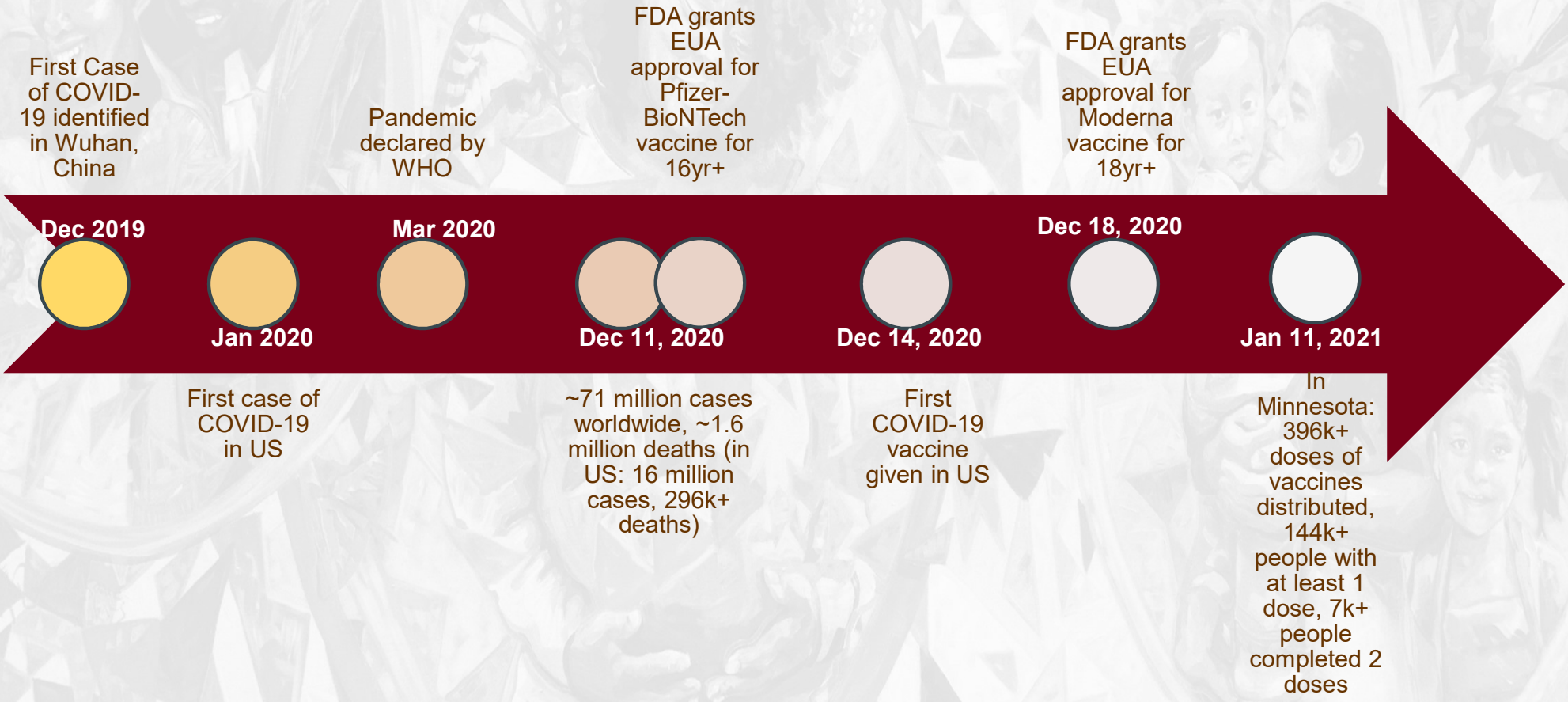
COVID-19 Vaccines Authorized for Emergency Use by FDA

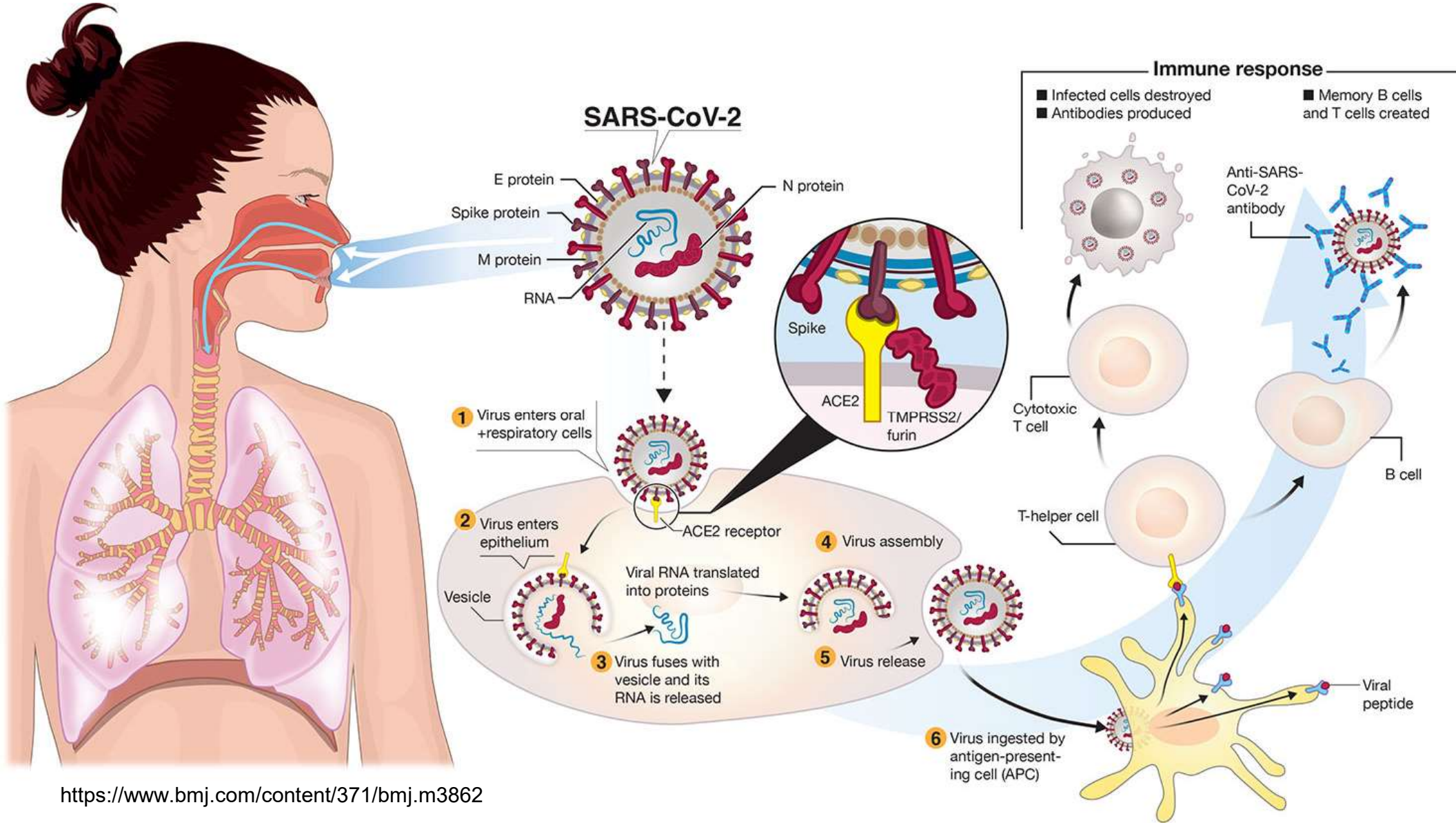
Presenter: Kim Tran, PharmD
Panelist: Emily Evan, PharmD

Learning Objectives

1. Explain mechanism behind mRNA vaccine induced immune response
2. Interpret results from recent vaccine trials leading to Emergency Use Authorization (EUA)
3. Describe similarities and differences between COVID-19 vaccines approved under EUA
4. Discuss administration recommendations and safety monitoring

A Brief Review

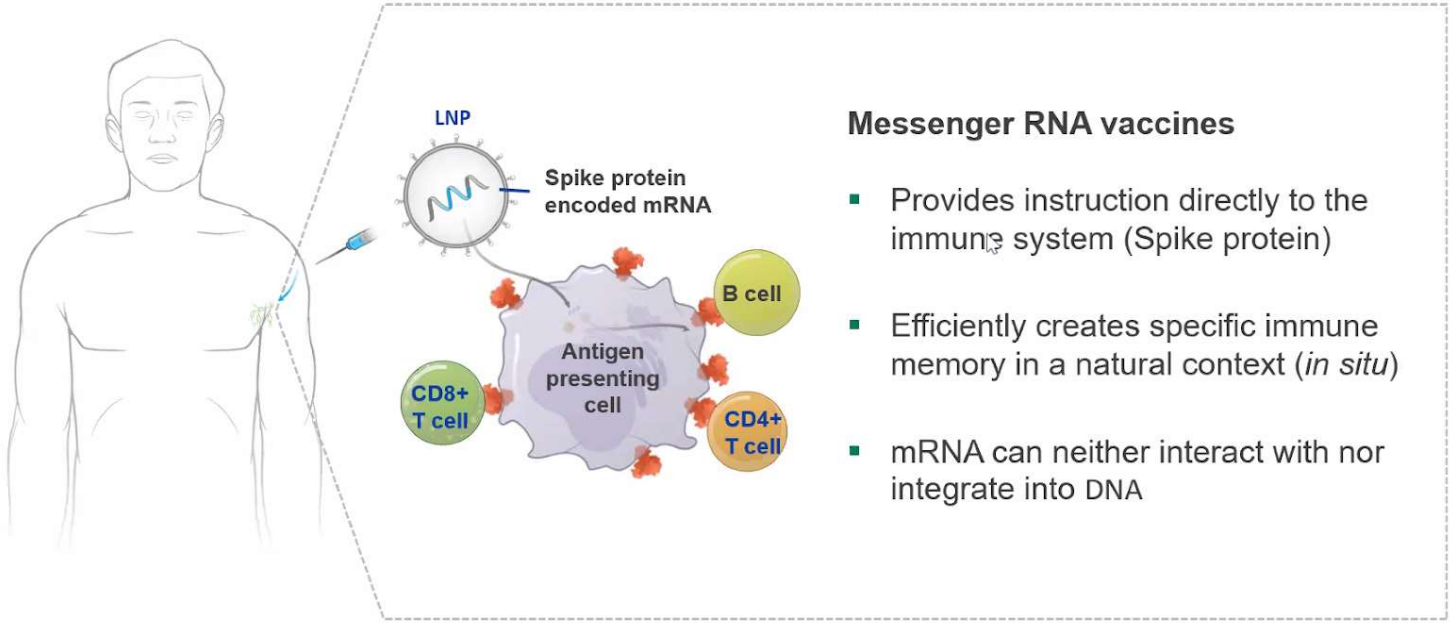




https://www.bmj.com/content/371/bmj.m3862

mRNA COVID-19 Vaccine

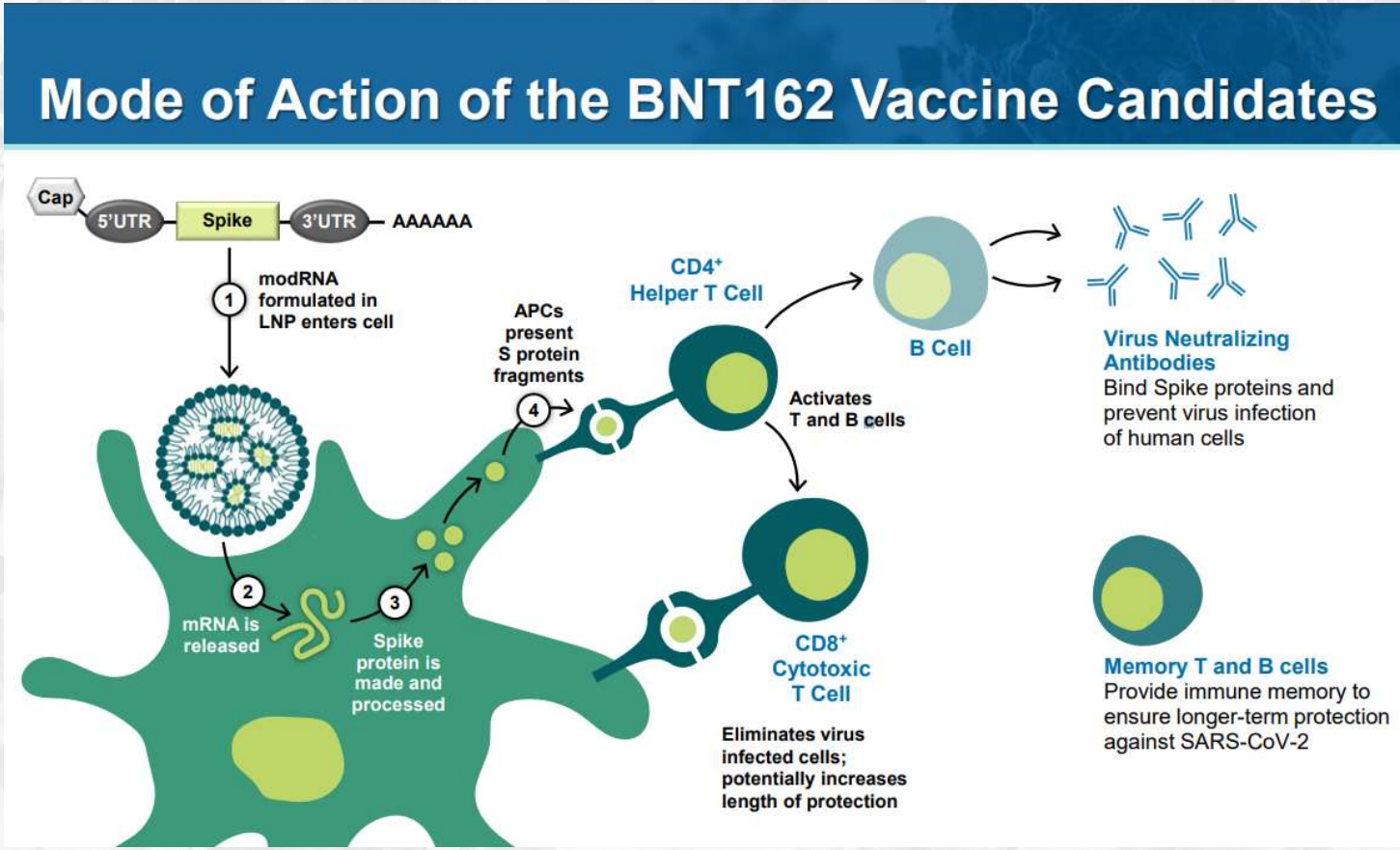
- mRNA vaccines take advantage of the process that cells use to make proteins in order to trigger an immune response



Source: https://www.fda.gov/media/144583/download

mRNA Inherent Safety Features:

1. Does not self-replicate
2. Does not enter nucleus or integrate into DNA
3. Manufacturing process is cell-free and contains no human or animal products, preservatives, or adjuvants
4. mRNA and LNP degraded in ~1 day

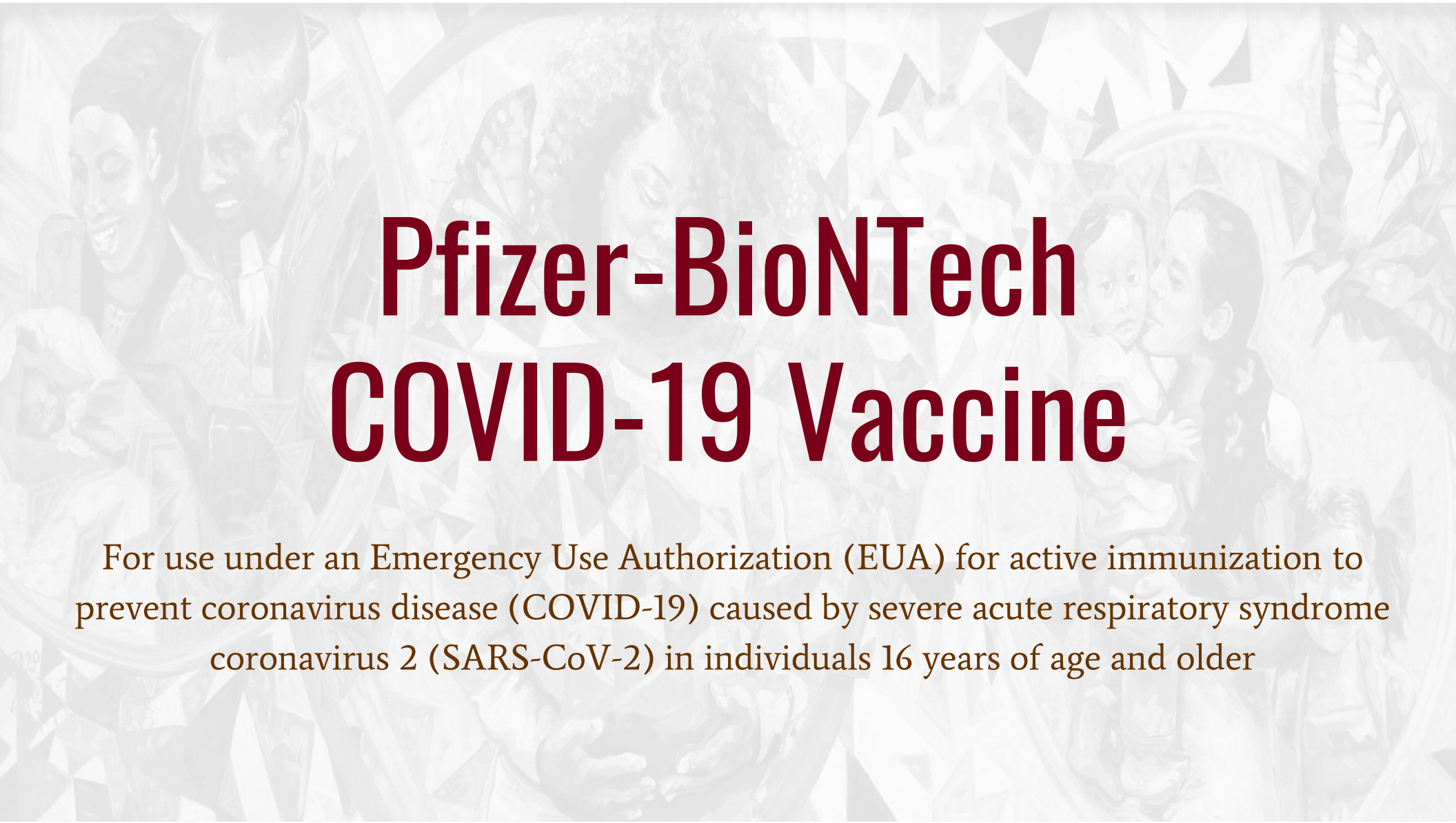


https://www.fda.gov/media/144325/download

What is an Emergency Use Authorization (EUA)?

- An EUA is a process to facilitate the availability and use of:
  1. A new treatment or test
  2. An existing treatment or test for a new indication
- In effect for as long as the public health emergency lasts
- Goal: provide access to medical products that may potentially be used when there are no adequate, approved, and available options.

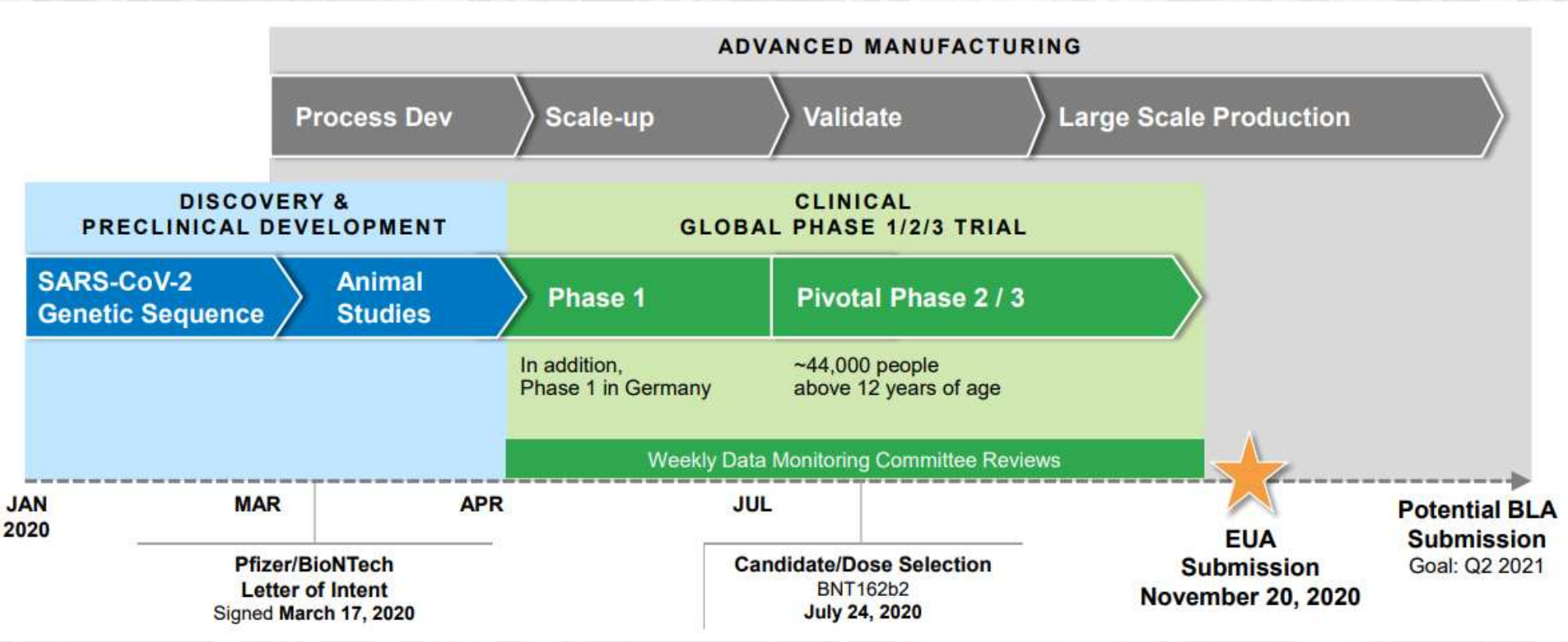
Emergency Use Authorization (EUA)	FDA Approval
Approval based on the "best available evidence"	Approval based on "substantial evidence" that the drug is effective for its intended use
Balance the potential risks and benefits of the products based on the data currently available.	The benefits of the drug outweigh its risks when used according to the product's approved labeling.
Can be revised or revoked by the FDA at any time as evaluation of data continues and patient needs during the public health emergency.	Can be revised or revoked by the FDA for safety or effectiveness reasons



Pfizer-BioNTech COVID-19 Vaccine

For use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older

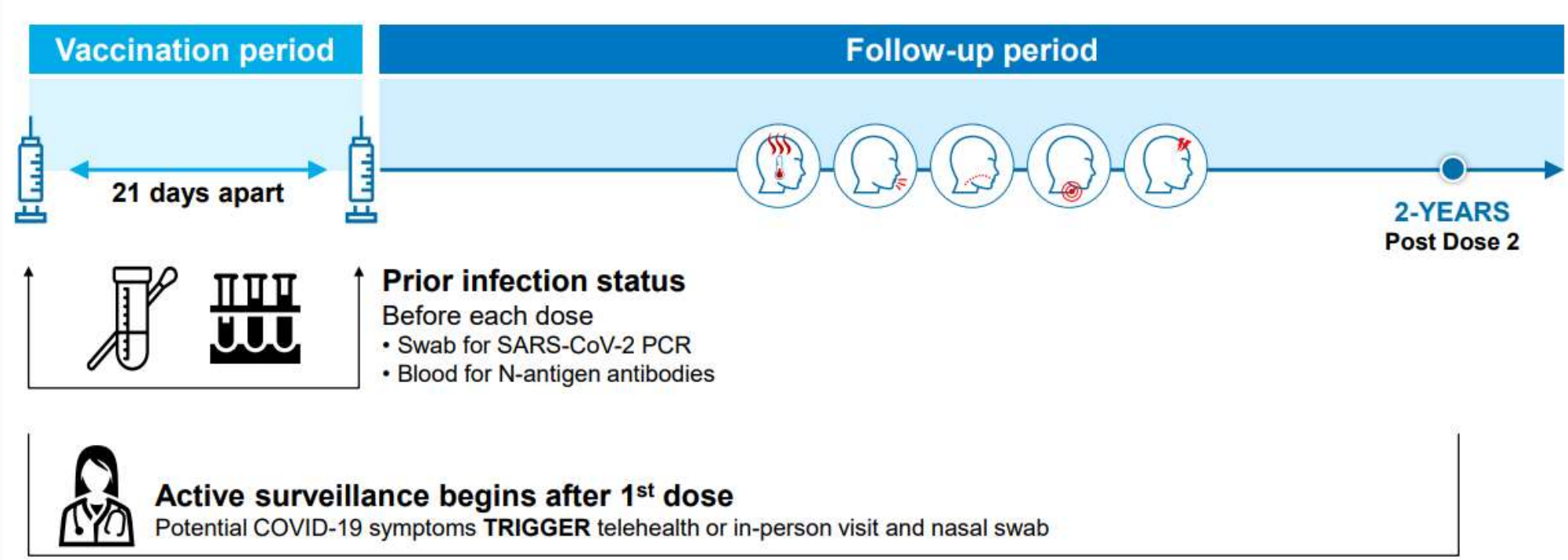
Production Timeline



https://www.fda.gov/media/144325/download

Trial Design	Phase 2/3 randomized (1:1), double-blinded and saline placebo-controlled, multi-center, multi-national study to evaluate safety, immunogenicity and efficacy of COVID-19 vaccine - US, Argentina, Brazil, Germany, South Africa, Turkey
Participants	43,448 participants (21720 vaccine, 21728 placebo)
Primary Endpoints	1. Incidence of COVID-19 among participants without evidence of SARS-CoV-2 infection before or during the 2-dose vaccination regimen 2. Incidence of COVID-19 among participants with and without evidence of SARS-CoV-2 infection before or during the 2-dose vaccination regimen
Inclusion	1. Aged ≥12 years 2. Willing and able to comply with study procedures and lifestyle considerations 3. Healthy determined by medical history, physical examination (if required), and clinical judgement of investigator (pre-existing stable disease included: HIV, HCV, HBV) 4. At high risk of acquiring COVID-19 5. Signed informed consent
Exclusion	1. medical/psych condition that may risk study participation (ie. SI, lab abnormalities) 2. History of severe adverse reactions associated with a vaccine 3. Receipt of medications intended to prevent COVID-19 4. Previous diagnosis of COVID-19 5. Immunocompromised 6. Women who are pregnant or breastfeeding 7. Other prior/concomitant therapy: another coronavirus vaccine, immunosuppressive therapy, blood/plasma product or immunoglobulin in past 60 days 8. Prior/concurrent clinical studies: within 28 days prior to study, other studies involving lipid nanoparticles 9. Investigator, site staff, or Pfizer/BioNTech employees and their family members

Efficacy Analysis



https://www.fda.gov/media/144325/download

Efficacy Analysis

Table 5: Demographics (population for the primary efficacy endpoint)[a]

	Pfizer-BioNTech COVID-19 Vaccine (N=18,242) n (%)	Placebo (N=18,379) n (%)
Sex		
Male	9318 (51.1)	9225 (50.2)
Female	8924 (48.9)	9154 (49.8)
Age (years)		
Mean (SD)	50.6 (15.70)	50.4 (15.81)
Median	52.0	52.0
Min, max	(12, 89)	(12, 91)
Age group		
≥12 through 15 years	46 (0.3)	42 (0.2)
≥16 through 17 years	66 (0.4)	68 (0.4)
≥16 through 64 years	14,216 (77.9)	14,299 (77.8)
≥65 through 74 years	3176 (17.4)	3226 (17.6)
≥75 years	804 (4.4)	812 (4.4)
Race		
White	15,110 (82.8)	15,301 (83.3)
Black or African American	1617 (8.9)	1617 (8.8)
American Indian or Alaska Native	118 (0.6)	106 (0.6)
Asian	815 (4.5)	810 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)
Other[b]	534 (2.9)	516 (2.8)
Ethnicity		
Hispanic or Latino	4886 (26.8)	4857 (26.4)
Not Hispanic or Latino	13,253 (72.7)	13,412 (73.0)
Not reported	103 (0.6)	110 (0.6)
Comorbidities[c]		
Yes	8432 (46.2)	8450 (46.0)
No	9810 (53.8)	9929 (54.0)

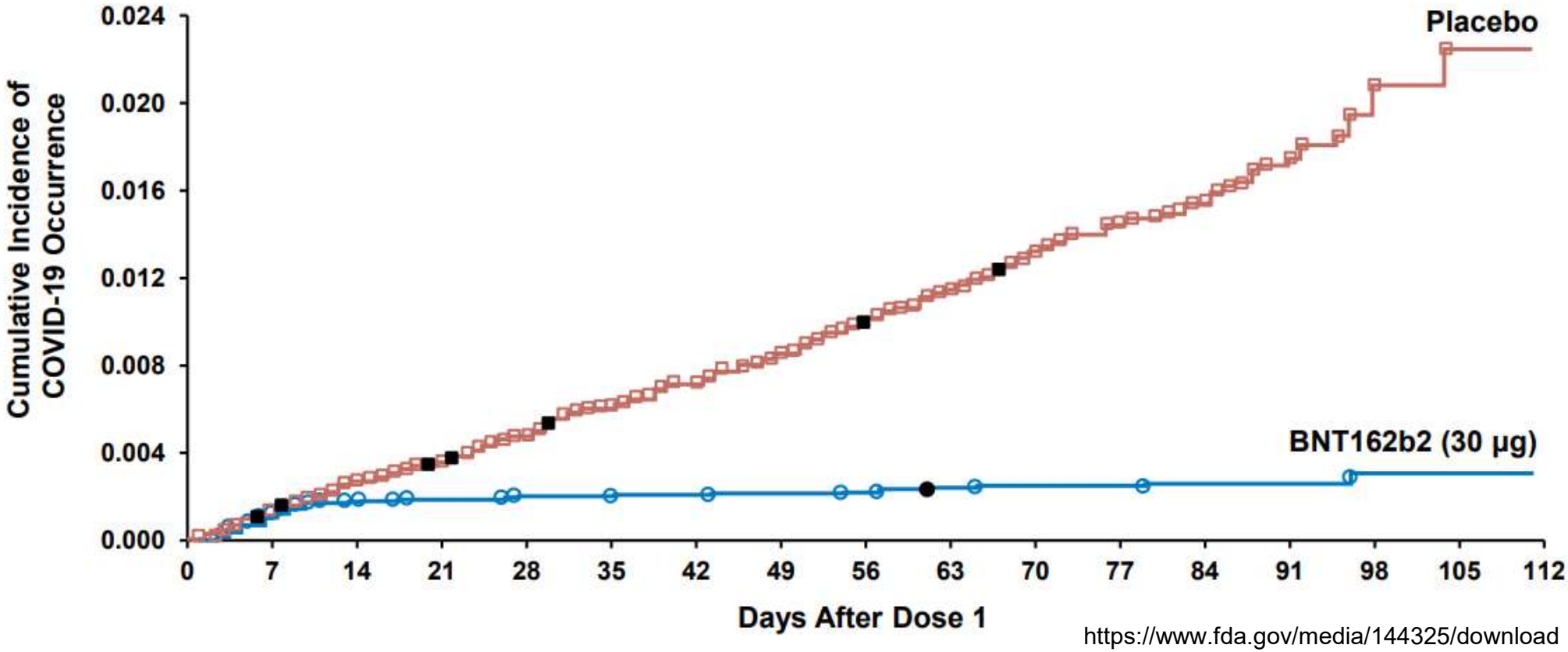
Efficacy Analysis

Table 6: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*			
Subgroup	Pfizer-BioNTech COVID-19 Vaccine N[a]=18,198 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=18,325 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)
All subjects[e]	8 2.214 (17,411)	162 2.222 (17,511)	95.0 (90.3, 97.6)[f]
16 to 64 years	7 1.706 (13,549)	143 1.710 (13,618)	95.1 (89.6, 98.1)[g]
65 years and older	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9)[g]
First COVID-19 occurrence from 7 days after Dose 2 in participants with or without evidence of prior SARS-CoV-2 infection			
Subgroup	Pfizer-BioNTech COVID-19 Vaccine N[a]=19,965 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=20,172 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)
All subjects[e]	9 2.332 (18,559)	169 2.345 (18,708)	94.6 (89.9, 97.3)[f]
16 to 64 years	8 1.802 (14,501)	150 1.814 (14,627)	94.6 (89.1, 97.7)[g]
65 years and older	1 0.530 (4044)	19 0.532 (4067)	94.7 (66.8, 99.9)[g]

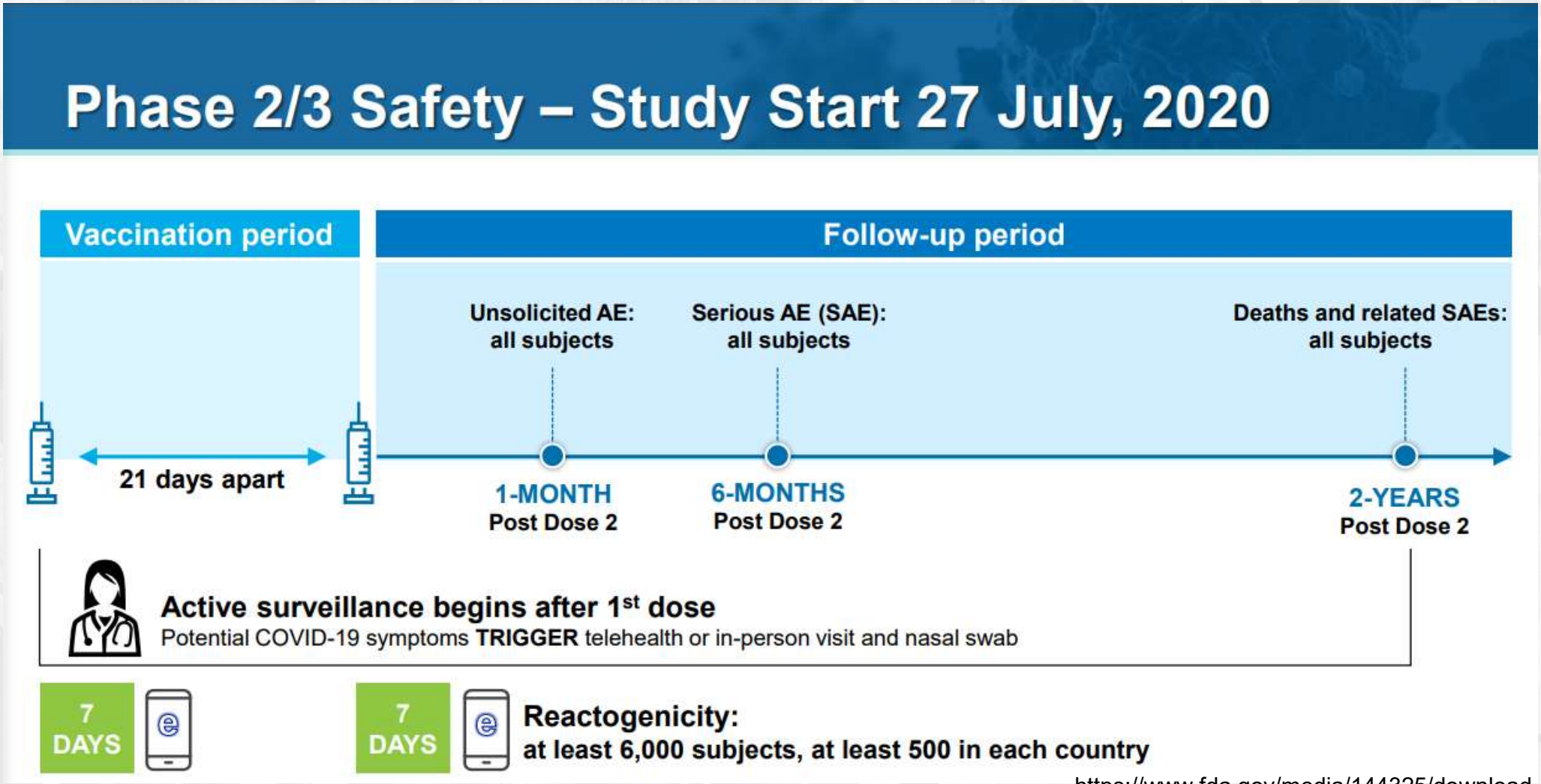
Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

Cumulative Incidence of COVID-19 After Dose 1



https://www.fda.gov/media/144325/download

Safety Analysis

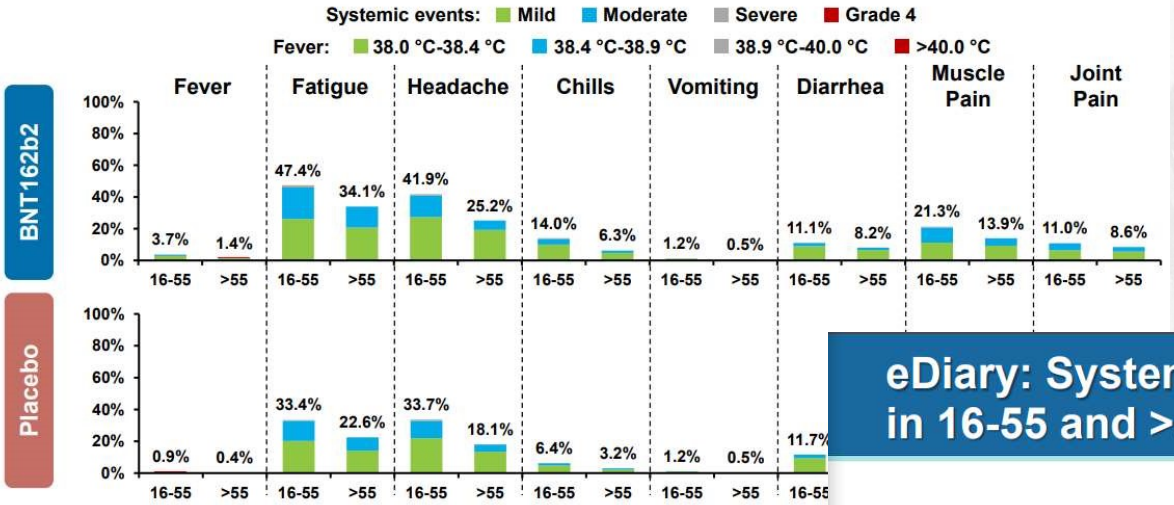


https://www.fda.gov/media/144325/download

Safety Analysis

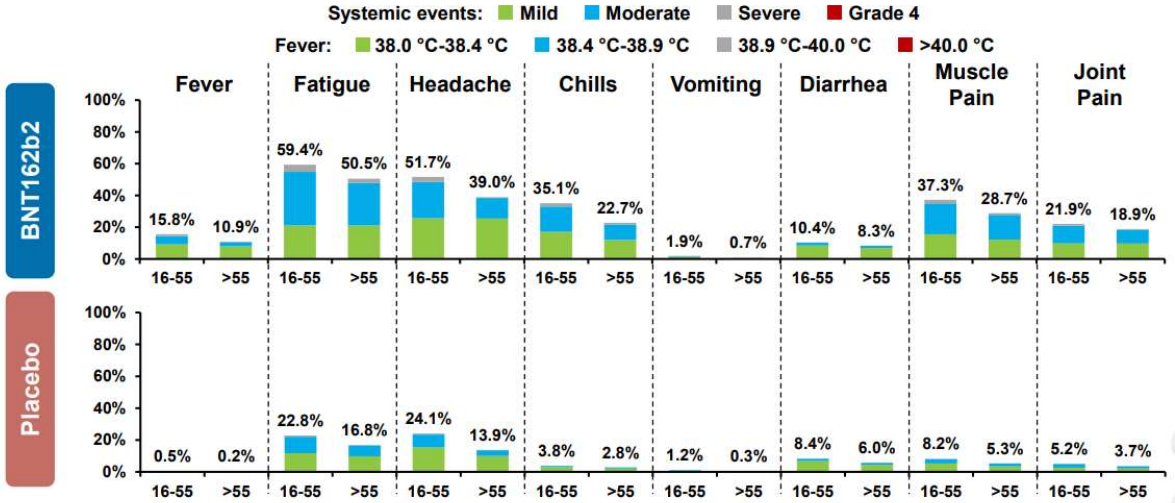
- Safety data from 2 months of follow up after second dose
- Most common:
  - Injection site reaction (84.1%)
  - Fatigue (62.9%)
  - Headache (55.1%)
  - Muscle pain (38.3%)
  - Chills (31.9%)
  - Joint pain (23.6%)
  - Fever (14.2%)
  - Severe reactions (0.0% to 4.6%) – ie. Lymphadenopathy, Bell's palsy (but no more than expected in general population)

eDiary: Systemic Events Within 7 Days From Dose 1 in 16-55 and >55 Year Olds (N=8,183)



tigue, headache, chills, muscle pain, joint pain severity definition: Mild=no interference; Moderate=some interference; Severe=prevei
miting severity definition: Mild=1-2 time in 24h; Moderate=>2times in 24h; Severe=Requires IV hydration; Grade 4=ER visit or hospit
arrhea 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 hos
se 1: 16-55 yrs N=4589; >55 yrs N=3594 Dose 2: 16-55 yrs N=4201 >55 yrs N=3306

eDiary: Systemic Events Within 7 Days From Dose 2 in 16-55 and >55 Year Olds (N=8,183)

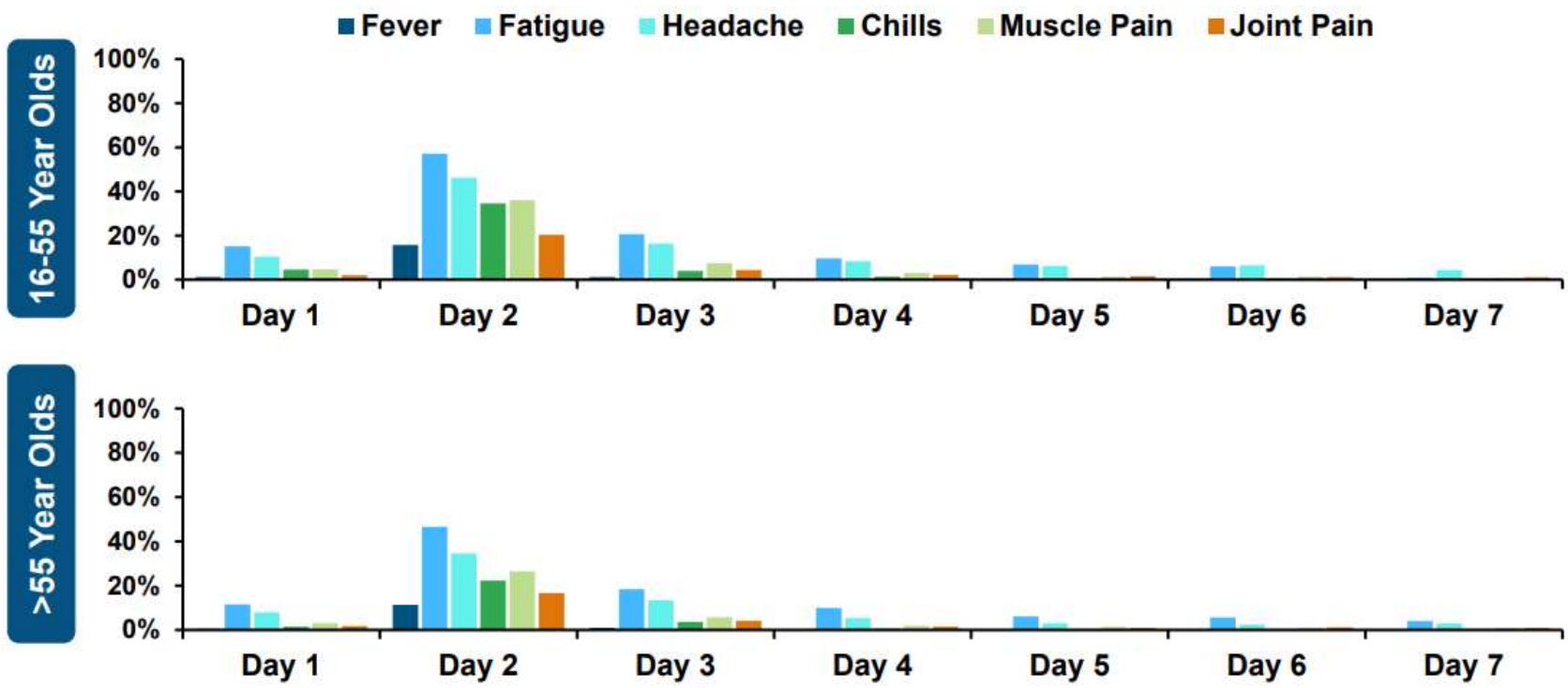


Fatigue, headache, chills, muscle pain, joint pain severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
Vomiting severity definition: Mild=1-2 time in 24h; Moderate=>2times in 24h; Severe=Requires IV hydration; Grade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

https://www.fda.gov/media/144325/download

Safety Analysis

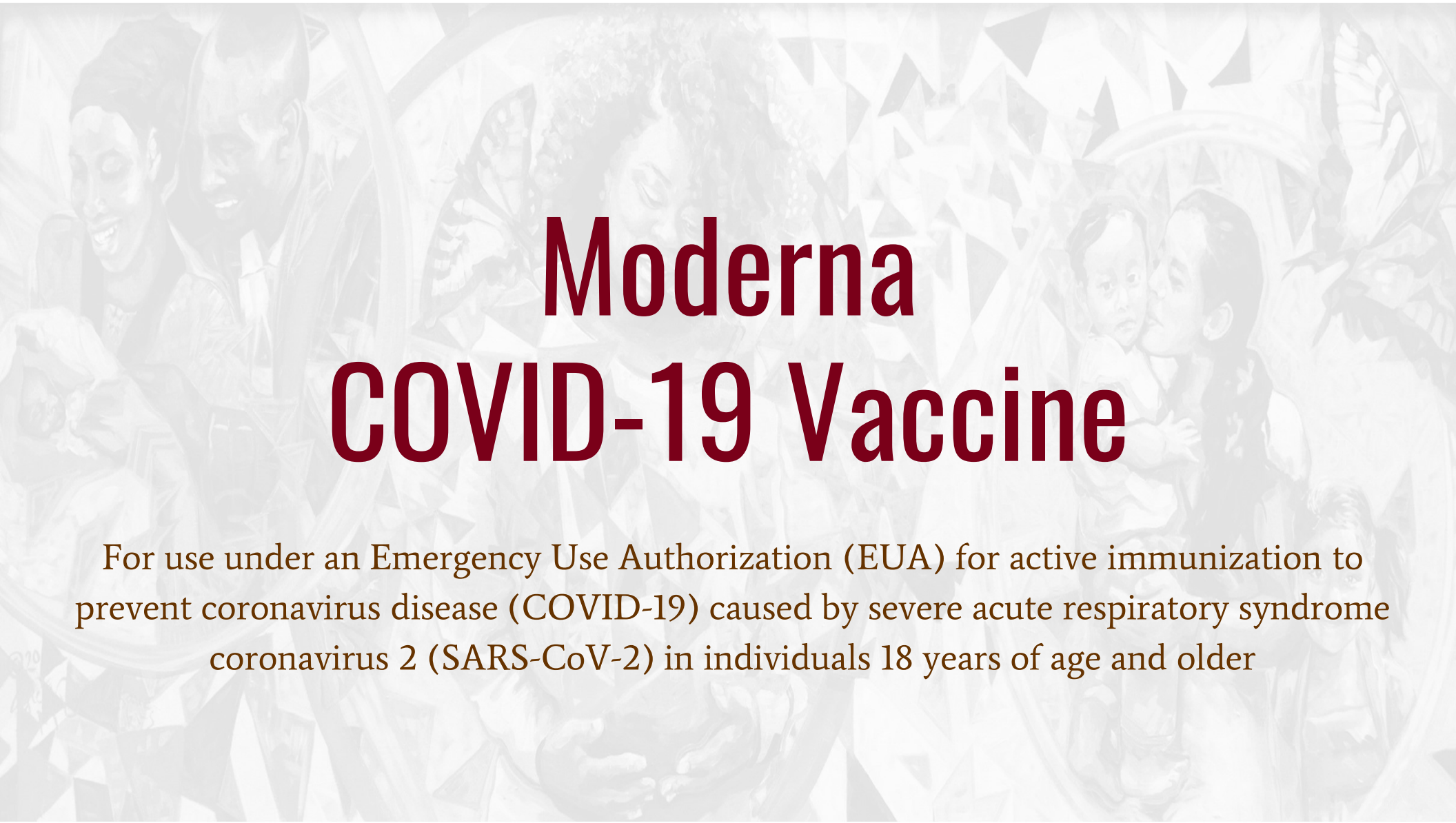
eDiary: Systemic Events Each Day From Dose 2 in 16-55 and >55 Year Olds (N=8,183) BNT162b2



https://www.fda.gov/media/144325/download

Pfizer-BioNTech Post EUA Approval

- Offer vaccinations to participants ≥16 years of age who originally received placebo
  - participants will be unblinded upon request and will receive the vaccine as part of the study
  - Continue to follow up for a total of 24 months
- Continue studies to assess:
  - continued safety monitoring
  - use in pregnancy and lactation
  - use in immunocompromised
  - use in pediatric patients less than 16 years of age
  - need for booster dose
  - co-administration with influenza vaccine
  - refrigeration temperature storage



Moderna COVID-19 Vaccine

For use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older

Trial Design	Phase 3 randomized (1:1), double-blinded, placebo-controlled, multi-center, multi-center trial of mRNA-1273 to evaluate the efficacy, safety, and immunogenicity - 99 sites in the US
Participants	30,351 participants (15181 vaccine, 15170 placebo) - 24,907 (82.1%) participants considered at occupational risk for acquiring SARS-CoV-2 infection
Primary Endpoints	Efficacy of the vaccine to prevent protocol-defined COVID-19 occurring at least 14 days after the second dose in participants with negative SARS-CoV-2 status at baseline • Symptoms of COVID-19 experienced by participants during post-vaccination follow-up prompted an unscheduled illness visit and nasopharyngeal (NP) swab • protocol defined COVID-19 defined as: 1. At least TWO of the following systemic symptoms: Fever (≥38ºC), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s), or 2. At least ONE of the following respiratory signs/ symptoms: cough, shortness of breath or difficulty breathing, OR clinical or radiographical evidence of pneumonia; and 3. NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR
Inclusion	1. Aged ≥18 years 2. Willing and able to comply with study procedures and lifestyle considerations 3. Healthy adult or adults with pre-existing medical conditions who are in stable condition not requiring significant change in therapy or hospitalization 4. At high risk of acquiring COVID-19 5. Signed informed consent
Exclusion	1. Acutely ill or febrile 72 hours prior to or at screening 2. Pregnant or breastfeeding 3. Known history of SARS-CoV-2 infection 4. Prior administration of an investigational coronavirus vaccine 5. History of anaphylaxis or significant adverse reaction after receipt of a vaccine 6. Has participated in another clinical study or received another vaccine within 28 days prior to first dose 7. Immunocompromised 8. Investigator, site staff, or Pfizer/BioNTech employees and their family members

Study 301: Representation of Participants with Risk Factors

Full Analysis Set

	mRNA-1273 N=15,181		Placebo N=15,170		
	n	%	n	%	
Age and health risk for severe COVID-19					
≥ 18 to < 65 without comorbid conditions	8,888	**59%**	8,886	**59%**	
≥ 18 to < 65 with comorbid conditions	2,530	**17%**	2,535	**17%**	
		42%			**42%**
≥ 65 with and without comorbid conditions	3,749	**25%**	3,749	**25%**	

Comorbid conditions included chronic lung disease or moderate to severe asthma, significant cardiac disease, severe obesity, diabetes, liver disease, stable HIV infection

https://www.fda.gov/media/144585/download

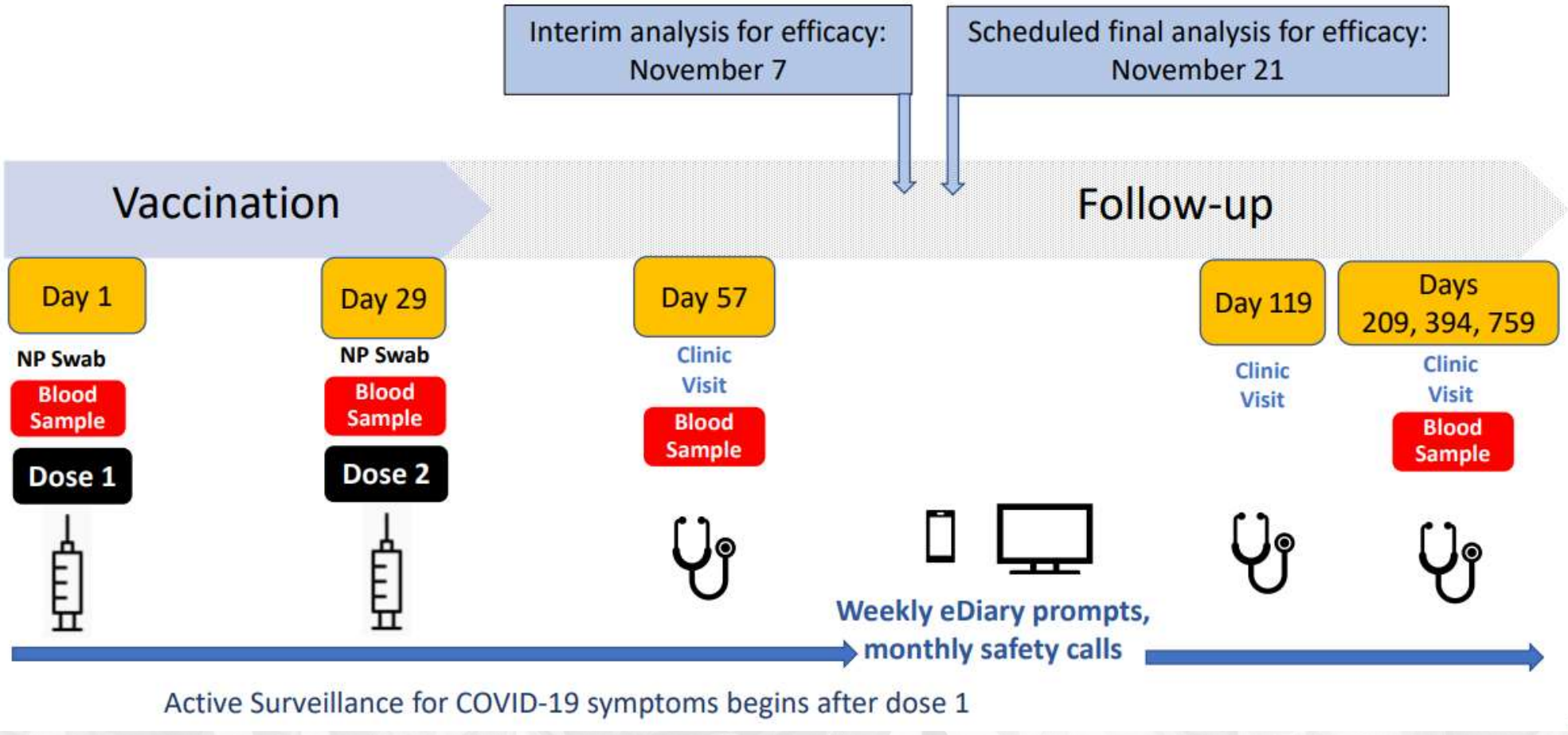
Study 301: Participants with Occupational Risk Factors Under Consideration for Priority Vaccination

Full Analysis Set – Primary Efficacy Analysis

	mRNA-1273 N=15,181		Placebo N=15,170	
	n	%	n	%
Healthcare workers	3,790	25%	3,831	25%
Educators and students	1,543	10%	1,552	10%
Pastoral, social, or public health workers	533	4%	503	3%
Transportation and delivery services	482	3%	473	3%
Personal care and in-home services	469	3%	469	3%
Manufacturing and production operations	425	3%	421	3%
Emergency response	302	2%	297	2%
Warehouse shipping and fulfillment centers	191	1%	175	1%
Border protection and military personnel	69	0.5%	68	0.4%

https://www.fda.gov/media/144585/download

Study 301 Timeline



https://www.fda.gov/media/144585/download

Table 6. Demographic Characteristics[a], Per-Protocol Set

Characteristic	Vaccine Group (N=13934) n (%)	Placebo Group (N=13883) n (%)	Total (N=27817) n (%)
Sex			
Female	6661 (47.8)	6514 (46.9)	13175 (47.4)
Male	7273 (52.2)	7369 (53.1)	14642 (52.6)
Age (years)			
Mean (SD)	51.6 (15.45)	51.5 (15.55)	51.6 (15.50)
Median	53.0	52.0	53.0
Min, max	18, 95	18, 95	18, 95
Age- subgroups (years)			
18 to <65	10407 (74.7)	10384 (74.8)	20791 (74.7)
65 and older	3527 (25.3)	3499 (25.2)	7026 (25.3)
Race			
American Indian or Alaska Native	107 (0.8)	110 (0.8)	217 (0.8)
Asian	616 (4.4)	684 (4.9)	1300 (4.7)
Black or African American	1369 (9.8)	1338 (9.6)	2707 (9.7)
Native Hawaiian or Other Pacific Islander	33 (0.2)	30 (0.2)	63 (0.2)
White	11078 (79.5)	11005 (79.3)	22083 (79.4)
Other	298 (2.1)	293 (2.1)	591 (2.1)
Ethnicity			
Hispanic or Latino	2783 (20.0)	2769 (19.9)	5552 (20.0)
Not Hispanic or Latino	11073 (79.4)	10967 (79.0)	22040 (79.2)
Race and Ethnicity			
Non-Hispanic white	8858 (63.6)	8755 (63.1)	17613 (63.3)
Communities of color	5054 (36.3)	5102 (36.7)	10156 (36.5)
Occupational Risk*	11397 (81.8)	11408 (82.2)	22805 (82.0)
Healthcare worker	3541 (25.4)	3531 (25.4)	7072 (25.4)
High Risk Condition**			
No high risk condition	11820 (77.9)	11788 (77.7)	23608 (77.8)
One high risk condition present	3116 (22.4)	3075 (22.1)	6191 (22.3)
Two or more high risk conditions present	561 (4.0)	554 (4.0)	1115 (4.0)
Age and Health Risk for Severe COVID-19***			
18 to <65 years and not at risk	8309 (59.6)	8323 (60.0)	16632 (59.8)
18 to <65 years and at risk	2098 (15.1)	2061 (14.8)	4159 (15.0)
≥65 years	3527 (25.3)	3499 (25.2)	7026 (25.3)

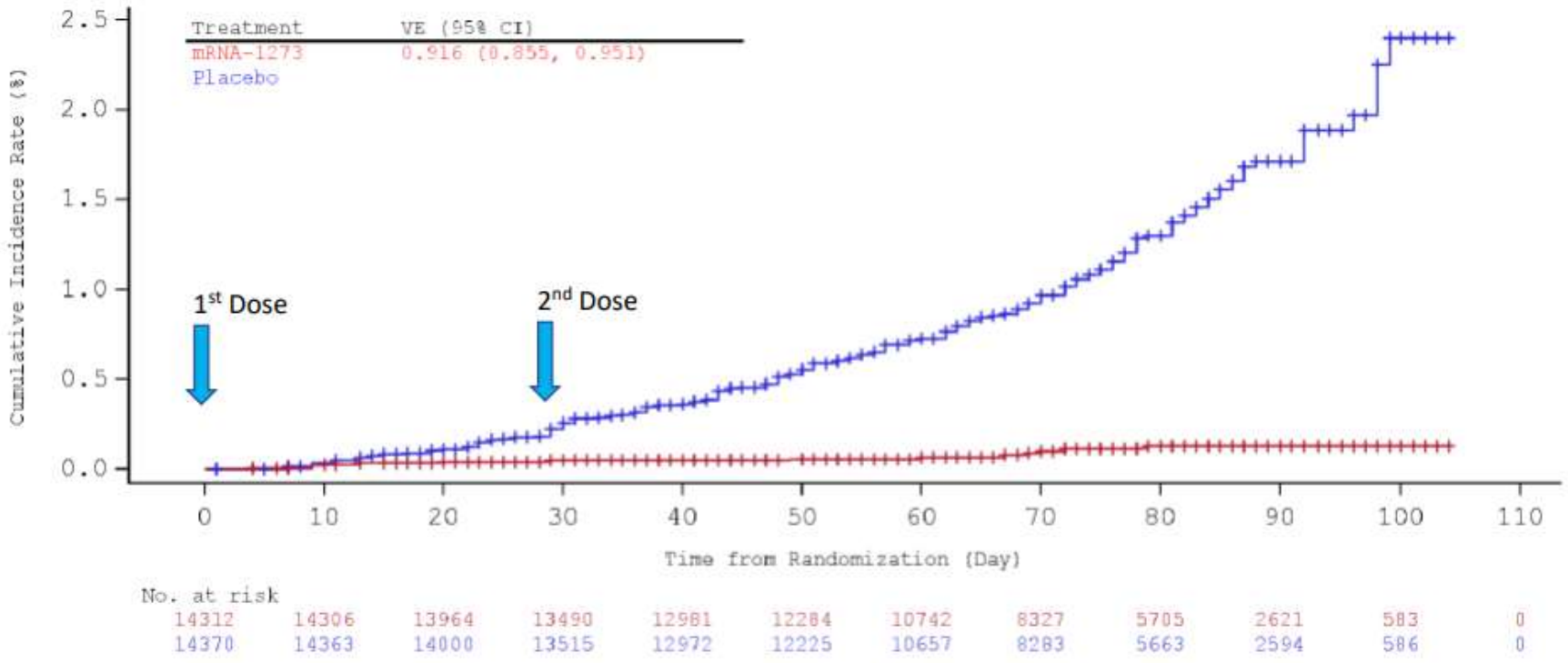
Table 17. Final Scheduled Efficacy Analysis, Primary Endpoint, COVID-19 Starting 14 Days After the Second Dose per Adjudication Committee Assessments, Per-Protocol Set

Primary Endpoint: COVID-19 (per adjudication committee assessment)	Vaccine Group N=13934 Cases n (%) (Incidence Rate per 1,000 person-years)*	Placebo Group N=13883 Cases n (%) (Incidence Rate per 1,000 person-years)*	Vaccine Efficacy (VE) % (95% CI)**	Met Predefined Success Criterion***
All participants	11 (<0.1) 3.328	185 (1.3) 56.510	94.1% (89.3%, 96.8%)	Yes
18 to <65 years[1]	7/10551 (<0.1) 2.875	156/10521 (1.5) 64.625	95.6%; (90.6%, 97.9%)	NA
65 years and older[2]	4/3583 (0.1); 4.595	29/3552 (0.8); 33.728	86.4%; (61.4%, 95.5%)	NA

Table 18. Secondary Efficacy Analysis, Severe COVID-19 Starting 14 Days After the Second Dose per Adjudication Committee Assessments, Per-Protocol Set

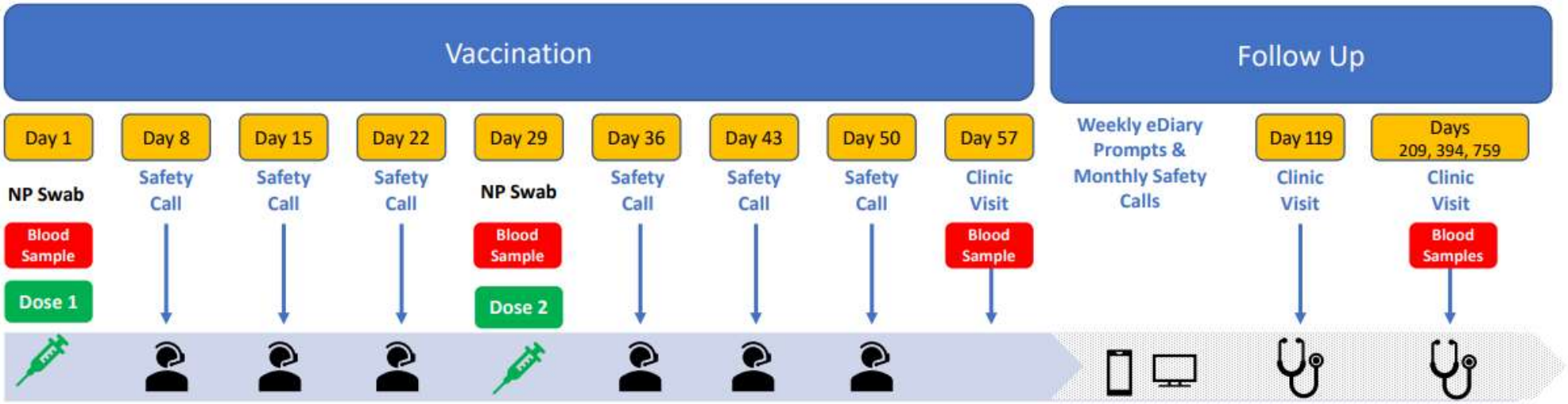
Severe Cases 14 Days After Dose 2 Based on Adjudication Committee Assessments	Vaccine Group N=13934 Cases n (%) (Incidence rate per 1,000 person-years)	Placebo Group N=13883 Cases n (%) (Incidence rate per 1,000 person-years)	Vaccine Efficacy (VE) % (95% CI)*
All participants	0	30 (0.2) 9.138	100%

Cumulative Incidence Curve of COVID-19 Starting After Randomization—mITT Set



https://www.fda.gov/media/144585/download

Safety Analysis



COVID-19 active surveillance throughout the study
Daily telemedicine visits for participants with COVID-19
eDiary captures solicited local and systemic adverse reactions in all participants for 7 days after each dose
SAEs and MAAEs captured through the study

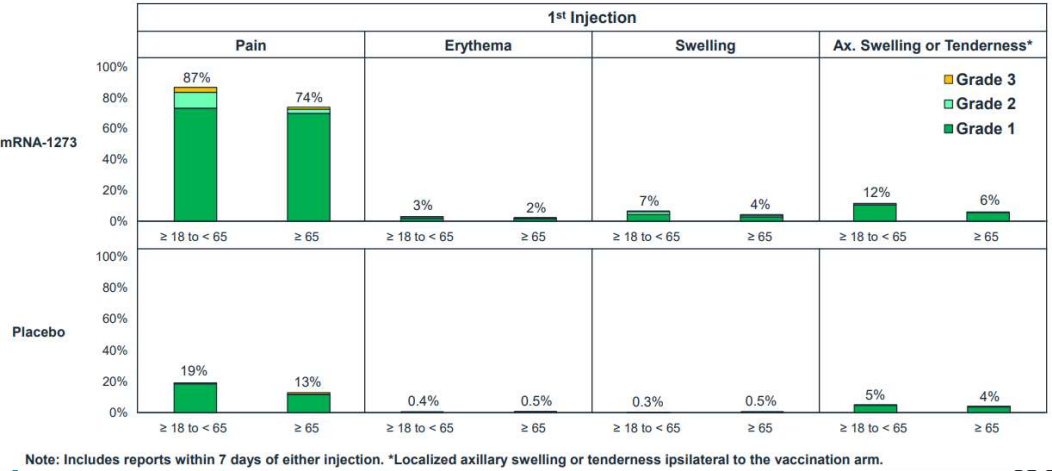
https://www.fda.gov/media/144585/download

Safety Analysis

- Median of 9 weeks of follow up after second dose
- Most common:
  - injection site pain (91.6%)
  - fatigue (68.5%)
  - headache (63.0%)
  - muscle pain (59.6%)
  - joint pain (44.8%)
  - chills (43.4%)
  - fever (14.8%)
  - severe adverse reactions 0.2% to 9.7%
    - lymphadenopathy in 173 participants (1.1%) in vaccine group and 95 participants (0.63%) in placebo (duration 1-2 days)
    - Bell's palsy in 3 vaccine recipients and 1 placebo recipient - occurring 22-32 days post vaccination

Study 301: Most Solicited Local Adverse Reactions Were Mild-to-Moderate (1st Injection)

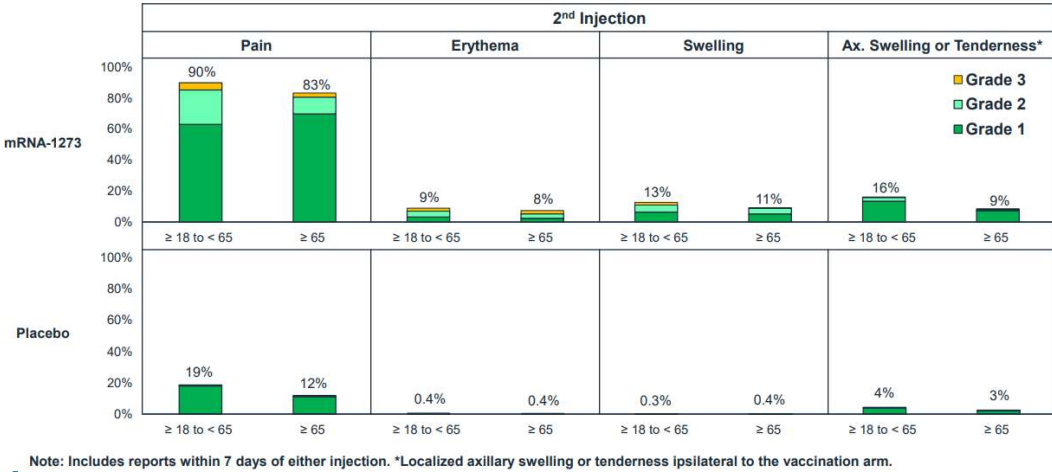
Safety Set, 9-Week Median Follow-up



Note: Includes reports within 7 days of either injection. *Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

Study 301: Most Solicited Local Adverse Reactions Were Mild-to-Moderate (2nd Injection)

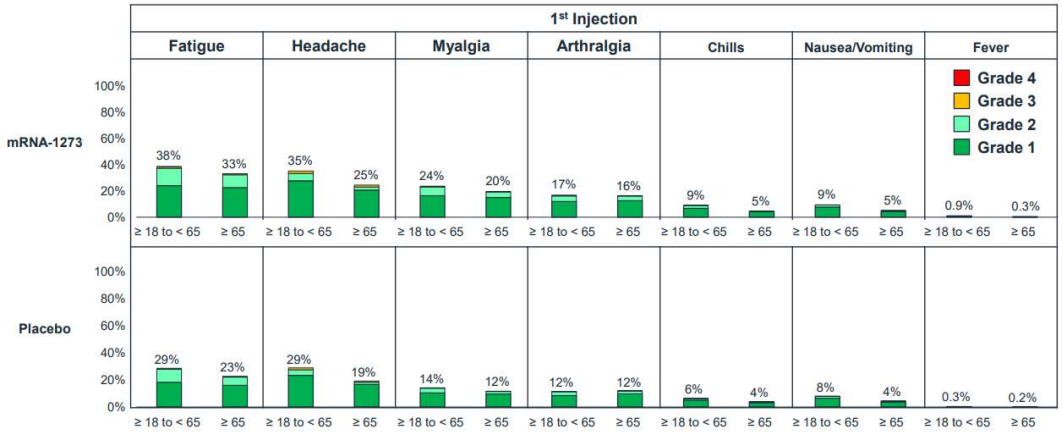
Safety Set, 9-Week Median Follow-up



Note: Includes reports within 7 days of either injection. *Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

Study 301: Most Solicited Systemic Adverse Reactions Were Mild-to-Moderate (1st Injection)

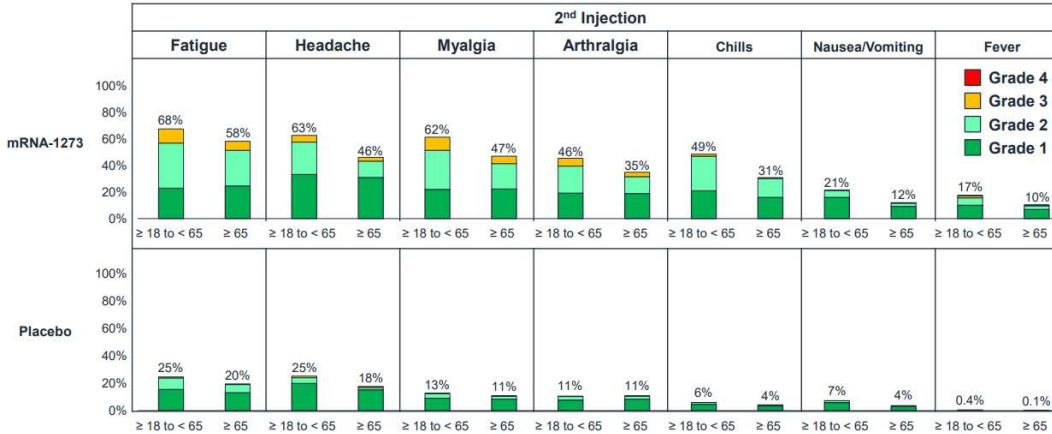
Safety Set, 9-Week Median Follow-up



Note: Solicited Systemic ARs include reports within 7 days of either injection

Study 301: Most Solicited Systemic Adverse Reactions Were Mild-to-Moderate (2nd Injection)

Safety Set, 9-Week Median Follow-up



Note: Solicited Systemic ARs include reports within 7 days of either injection

https://www.fda.gov/media/144585/download

Moderna Post EUA Approval

- Since many study participants are in the priority group to receive vaccine, expecting many will be unblinded. Will amend the protocol to reconsent those individuals to remain in the trial and receive vaccine.
- Goal to complete 24 months of follow up.
- Continue studies to assess:
  - long term safety
  - use in pediatric population
  - use in pregnancy/lactation
  - use in immunosuppression
  - concomitant administration with non-COVID vaccines

Pfizer-BioNTech & Moderna Summary

- Both studies met FDA requirement for participant numbers (30k+) and initial follow up duration (2 months after dose #2)
- Efficacy: 94%-95% when given both doses as directed
- Common side effects: injection site pain, fatigue, headache, muscle pain
- Ongoing study for:
  - Children
  - Pregnant/lactating women
  - Immunocompromised
  - Long term safety and efficacy (e.g. booster dose needed?)

General Vaccine Information*

	Pfizer-BioNTech	Moderna
Age indication	16+ years	18+ years
Dose & Route	0.3mL; intramuscular	0.5mL; intramuscular
Schedule	Two dose series: 0, 21 days	Two dose series: 0, 28 days
Presentation/Preparation	MDV (5 doses/vial) Must thaw prior to use/reconstitution Reconstitution: yes, with 1.8mL of 0.9% sodium chloride	MDV (10 doses/vial) Must thaw prior to use Reconstitution: none
Storage & Handling	**Ultra-cold freezer** (-80°C to -6 0°C/-112°F to -76°F): up to 6 months. **Thermal shipper**: (-90°C to -6 0°C /-130°F to -76°F): up to 30 days from delivery, if replenished with dry ice upon receipt and every five days. **Refrigerator**: (2 to 8°C/36°F to 46°F): up to 120 hours (five days). If not used, discard. **Room temperature**: Thawed vials must be reconstituted within two hours. Once reconstituted, must use within six hours (discard unused vaccine).	**Freezer**: -25°C to -15°C (-13°F to 5°F): up to 6 months **Refrigerator**: 2°C to 8°C (36°F to 46°F): up to 30 days **Room temperature**: up to 12 hours (unpunctured). Once punctured, must use within six hours (discard unused vaccine).
Notes	Preservative-free Vial stoppers not made of natural rubber latex	Preservative-free Vial stoppers not made of natural rubber latex

*Refer to EUA Fact Sheet for specific information and preparation steps

General Vaccine Information

Pfizer-BioNTech and Moderna COVID-19 Vaccines

- COVID-19 vaccines are not interchangeable with one another
  - Complete two dose series with the same product
- COVID-19 vaccine should be administered alone with a minimum interval of 14 days before or after administration with any other vaccines

Recipient Considerations	Ok to receive COVID-19 Vaccine?
History of SARS-CoV-2 infection	Yes
Current SARS-CoV-2 infection	Yes – but defer until recovery from acute illness and criteria met to discontinue isolation
Previously received passive antibody therapy for COVID-19	Yes – but defer for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses
Known SARS-CoV-2 exposure (i.e., community/outpatient setting, congregate setting)	Yes – consider waiting until after quarantine period

Vaccination of Special Populations

Pfizer-BioNTech and Moderna COVID-19 Vaccines

Recipient Considerations	Ok to receive COVID-19 Vaccine?
Underlying medical conditions	Yes – if no contraindications
Immunocompromised	Yes – if no contraindications. Counsel on: 1. Unknown vaccine safety and efficacy profiles 2. Potential for reduced immune response 3. Need to continue to follow all current public health guidance
Pregnant	Per guidance from the American College of Obstetricians and Gynecologists, if a woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine and is pregnant, she may choose to be vaccinated. A discussion with her healthcare provider can help her make an informed decision. Considerations for vaccination: • level of COVID-19 community transmission • personal risk of contracting COVID-19 (occupation or other activities) • risk of COVID-19 to her and to fetus • efficacy of vaccine • known side effects of vaccine • lack of data about vaccine in pregnancy
Breastfeeding/lactating	Per guidance from the American College of Obstetricians and Gynecologists, If a woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine and is breastfeeding/lactating, she may choose to be vaccinated.

Contraindications & Precautions to mRNA COVID-19 Vaccination

Pfizer-BioNTech and Moderna COVID-19 Vaccines

Contraindication:

- Known history of a severe allergic reaction (e.g., anaphylaxis) to a previous dose of an mRNA COVID-19 vaccine or to any of its components

Precaution:

- Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components
  - Should avoid additional doses of either mRNA vaccine unless evaluated by an allergist-immunologist and it is determined safe to receive (e.g., under observation, in medical setting)
- Any immediate allergic reaction to any other vaccine or injectable therapy (i.e., IM, IV, SQ vaccines or therapies not related to a component of mRNA COVID-19 vaccine)
- Immunocompromised persons, those receiving immunosuppressant therapy, may have a diminished immune response to the vaccine

Ingredients included in mRNA COVID-19 Vaccines

Description	Pfizer-BioNTech	Moderna
mRNA	nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N,Nditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	cholesterol	cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1- diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts, sugars, buffers	potassium chloride	Tromethamine
	monobasic potassium phosphate	Tromethamine hydrochloride
	sodium chloride	Acetic acid
	dibasic sodium phosphate dihydrate	Sodium acetate
	sucrose	sucrose

What is NOT in the vaccines

- NO pork
- NO gelatin
- NO fetal cells
- NO microchip
- NO live/attenuated/inactivated virus
- NO egg
- NO preservative
- NO adjuvant

Distinguishing allergic reactions from other types of reactions

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
Timing after vaccination	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring day after vaccination)
Signs and symptoms			
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
Cutaneous	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema or swelling at injection site; lymphadenopathy in same arm as vaccination
Neurologic	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache
Respiratory	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; if accompanied by anxiety, may have an elevated respiratory rate	n/a
Cardiovascular	Hypotension, tachycardia	Variable; may have hypotension or bradycardia during syncopal event	n/a
Gastrointestinal	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea may occur
Musculoskeletal	n/a	n/a	Myalgia, arthralgia
Vaccine recommendations			
Receive 2nd dose of mRNA COVID-19	**No**	**Yes**	**Yes**

Algorithm for the triage of persons presenting for mRNA COVID-19 vaccine

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	**CONDITIONS** • Immunocompromising conditions • Pregnancy • Lactation **ACTIONS** • Additional information provided* • 15 minute observation period	**CONDITIONS** • Moderate/severe acute illness **ACTIONS** • Risk assessment • Potential deferral of vaccination • 15 minute observation period if vaccinated	**CONDITIONS** • None **ACTIONS** • N/A
ALLERGIES	**ALLERGIES** • History of food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies • History of allergy to oral medications (including the oral equivalent of an injectable medication) • Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis) • Family history of anaphylaxis • Any other history of anaphylaxis that is not related to a vaccine or injectable therapy **ACTIONS** • 30 minute observation period: Persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause • 15 minute observation period: Persons with allergic reaction, but not anaphylaxis	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including Pfizer-BioNTech vaccine) • History of severe allergic reaction (e.g., anaphylaxis) to an injectable therapy **ACTIONS:** • Risk assessment • Potential deferral of vaccination • 30 minute observation period if vaccinated	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech vaccine **ACTIONS** • Do not vaccinate

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html

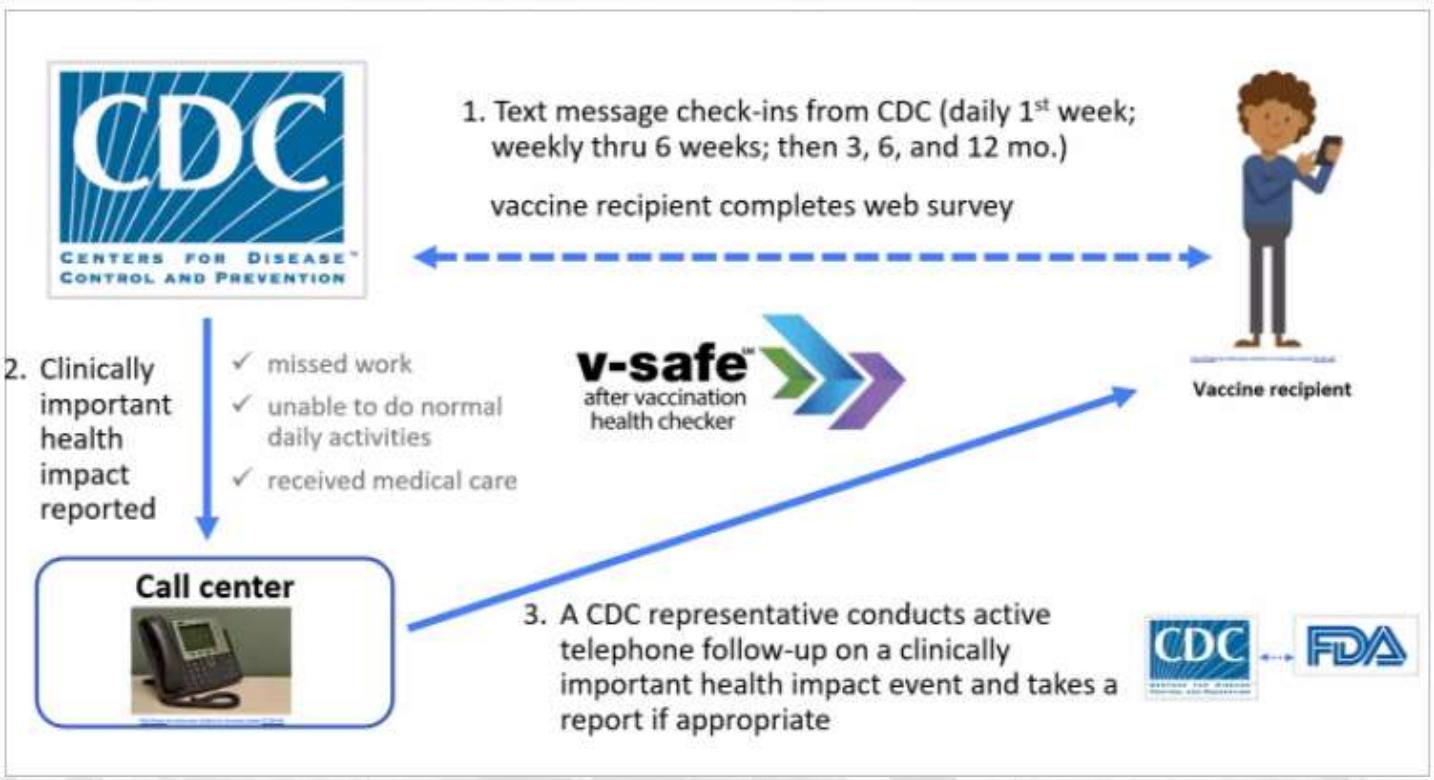
Neither Contraindication nor Precaution to mRNA COVID-19 Vaccine

- History of allergic reactions not related to vaccines, injectable therapies, components of mRNA COVID-19 vaccines, or polysorbates, including:
  - Food
  - Pet dander
  - Venom
  - Environment
  - Oral medications
  - Latex
  - Eggs
  - Gelatin

Safety Monitoring Post Vaccination

v-safe℠ after vaccination health checker

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov



Patient Counseling for Vaccination

BEFORE Vaccination

- Counsel on the expected local and systemic post-vaccination symptoms
- Complete the series even if they develop post-vaccination symptoms (that are not contraindications)

AFTER Vaccination

- Protection from vaccine is not immediate – will take 1-2 weeks after second dose to be considered fully vaccinated
- No vaccine is 100% effective – continue to follow public health guidance to protect themselves
- May take antipyretic or analgesic for treatment of post-vaccination symptoms
  - Routine prophylaxis to prevent these symptoms is not recommended at this time due to lack of information on impact on vaccine-induced antibody response

Resources for healthcare providers with questions regarding COVID-19 vaccines:

- MDH: health.covid.vaccine@state.mn.us or call 651-201-5414, Monday-Friday, 8:00 am – 4:30 pm
- CDC: 1-800-232-4636 (800-CDC-INFO) Coronavirus Disease 2019 Questions open 24 hours, 7 days a week, including holidays, CDC INFO | CDC
- Pfizer BioNTech: website: https://www.cvdvaccine-us.com/ 1-800-438-1985 https://www.pfizermedicalinformation.com/en-us/pfizer-biontech-covid-19-vaccine
- Moderna: website: www.modernatx.com 1-866-moderna (1-866-663-3762)

FDA vaccine information:

- https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
- https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement

Thank You for attending

Questions?