

# Update to the mRNA-1273 COVID-19 Vaccine Program

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## Forward-Looking Statements and Disclaimer

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended including, but not limited to, statements concerning the timing, design, objectives and other parameters of the Phase 1, Phase 2 and Phase 3 clinical studies of mRNA-1273. In some cases, forward-looking statements can be identified by terminology such as “will,” “may,” “should,” “could,” “expects,” “intends,” “plans,” “aims,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this presentation are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna’s control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include, among others: preclinical and clinical development is lengthy and uncertain, especially for a new class of medicines such as mRNA, and therefore our preclinical programs or development candidates may be delayed, terminated, or may never advance to or in the clinic; no commercial product using mRNA technology has been approved, and may never be approved; mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines; despite having ongoing interactions with the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) or other regulatory agencies, the FDA, EMA or such other regulatory agencies may not agree with Moderna’s regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted; the fact that the rapid response technology in use by Moderna is still being developed and implemented; the fact that the safety and efficacy of mRNA-1273 has not yet been established; potential adverse impacts due to the global COVID-19 pandemic such as delays in clinical trials, preclinical work, overall operations, regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy; and those risks and uncertainties described under the heading “Risk Factors” in Moderna’s most recent Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC’s website at [www.sec.gov](http://www.sec.gov). Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this presentation in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna’s current expectations and speak only as of the date hereof.

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## Criteria and Scope of the EUA

- The Moderna COVID-19 Vaccine has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA), to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older
- The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of the product, unless the declaration is terminated or the authorization is revoked sooner
- For information on the authorized use of the Moderna COVID-19 Vaccine and mandatory requirements of the EUA, please review the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full EUA Prescribing Information at [<https://www.modernatx.com/covid19vaccine-eua/>]

COVID-19, coronavirus disease 2019.  
Moderna, <https://www.modernatx.com/covid19vaccine-eua/>. Accessed August 27, 2021.

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## Important Safety Information

### Contraindications

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine.

### Warnings and Precautions

- **Management of Acute Allergic Reactions:** Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine. Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>)
- **Myocarditis and Pericarditis:** Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>)
- **Syncope (fainting):** May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting
- **Altered Immunocompetence:** Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine
- **Limitations of Vaccine Effectiveness:** The Moderna COVID-19 Vaccine may not protect all vaccine recipients

### Adverse Reactions

Adverse reactions reported in a clinical trial following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site.

The following adverse reactions have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials:

- Severe allergic reactions, including anaphylaxis
- Myocarditis
- Pericarditis
- Syncope

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

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## Important Safety Information Continued

### Reporting Adverse Events and Vaccine Administration Errors

The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in adults
- Cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS, call [1-800-822-7967](tel:1-800-822-7967). Reports should include the words "Moderna COVID-19 Vaccine EUA" in the description section of the report.

Report to ModernaTX, Inc. by calling [1-866-MODERNA \(1-866-663-3762\)](tel:1-866-MODERNA) or provide a copy of the VAERS form by faxing 1-866-599-1342 or emailing [ModernaPV@modernatx.com](mailto:ModernaPV@modernatx.com).

### Pregnancy and Lactation

Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

### Dosing and Schedule

The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

A third dose of the Moderna COVID-19 Vaccine (0.5 mL) administered at least 1 month following the second dose of this vaccine is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

**Please click for [Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\) and Full EUA Prescribing Information](#) for more information.**

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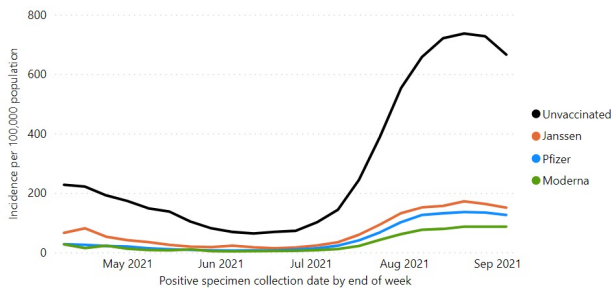
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## Government reports show mRNA-1273's high effectiveness of reducing COVID-19 infection and death



### Rates of COVID-19 Cases by Vaccination Status and Vaccine Product

April 04 - September 04, 2021 (16 U.S. jurisdictions)



In August, unvaccinated persons had:

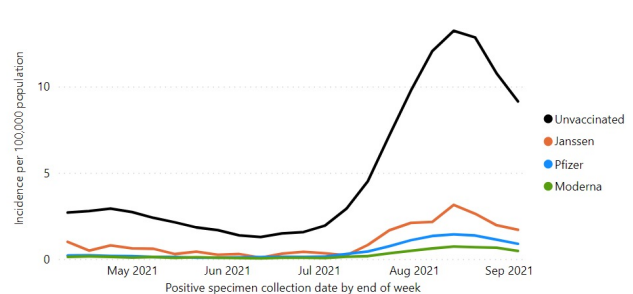
**6.1X**  
Greater Risk of Testing Positive for COVID-19  
compared to fully vaccinated persons

AND

**11.3X**  
Greater Risk of Dying from COVID-19

### Rates of COVID-19 Deaths by Vaccination Status and Vaccine Product

April 04 - September 04, 2021 (15 U.S. jurisdictions)



These are not head-to-head randomized trials designed to compare the vaccines.

<https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status>

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# ACIP Presentation of Myocarditis/Pericarditis Following Primary Vaccination with Moderna COVID-19 Vaccine

## Myocarditis/pericarditis following Moderna

### Myocarditis and Pericarditis

- Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae.<sup>1</sup>
- Highest reporting rate in 18-24yo males (0-7 days post dose 2)= **39 cases/1M doses administered**<sup>2</sup>

<sup>1</sup> Moderna COVID-19 Vaccine Fact Sheet for Health Care Providers (56a.gv)  
<sup>2</sup> VAERS

Dooling AM. CDC COVID-19 Vaccine Task Force. Published October 21, 2021. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/11-COVID-Dooling-508.pdf>. Accessed October 21, 2021.

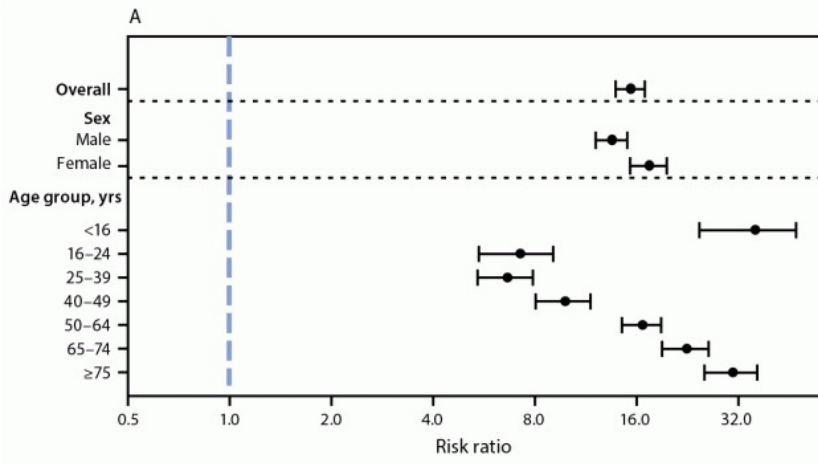
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# COVID-19 is independently associated with an increased risk of myocarditis, compared to those without COVID-19



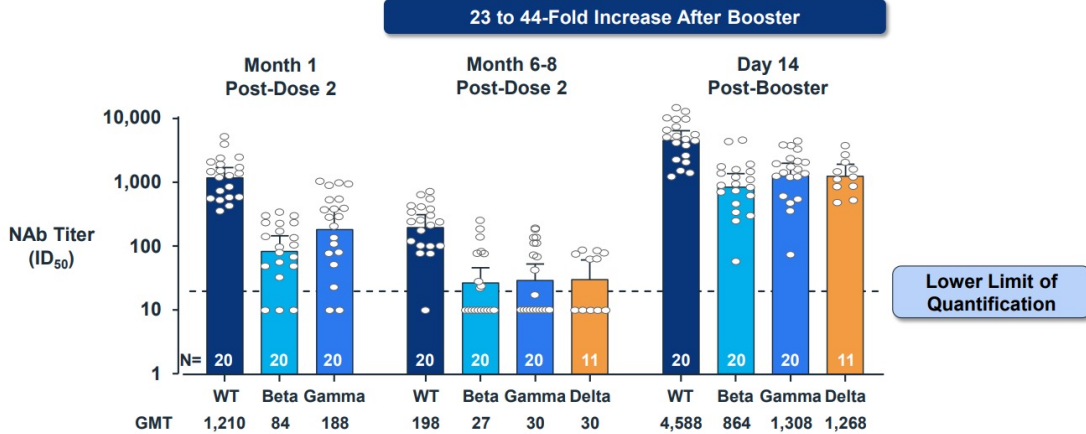
Boehmer TK, Kompaniyets L, Lavery AM, et al. Association Between COVID-19 and Myocarditis Using Hospital-Based Administrative Data — United States, March 2020–January 2021. MMWR Morb Mortal Wkly Rep 2021;70:1228–1232. DOI: <http://dx.doi.org/10.15585/mmwr.mm7035e5>



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## Exploratory Analysis Against Variants of Concern

Study 201B 50 µg booster dose following 100 µg primary series; VSV pseudoneutralization assay



WT, ancestral D614G strain.

Miller J. Vaccines and Related Biological Products Advisory Committee. Published October 14, 2021. <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-14-15-2021-meeting-announcement>. Accessed October 21, 2021. Jviral 22Sept2021 doi: [Sarum Neutralizing Activity of mRNA-1273 Against SARS-CoV-2 Variants \(asm.org\)](https://doi.org/10.1186/s12975-021-00100-0)

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## Vaccine Effectiveness of 50 µg Booster Dose Inferred by Immunobridging to the COVE Study

Study	N	Previous Dose of mRNA-1273		Interval between Dose 2 & Booster Dose
		Dose 1 & 2	Booster Dose	
201B (boost with mRNA-1273)	146	50 µg	50 µg	≥ 6 months
	149	100 µg	50 µg	
301 Immunogenicity Subset	1,055	100 µg (primary series only)	None	-

Miller J. Vaccines and Related Biological Products Advisory Committee. October 14, 2021. <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-14-15-2021-meeting-announcement>. Accessed October 21, 2021

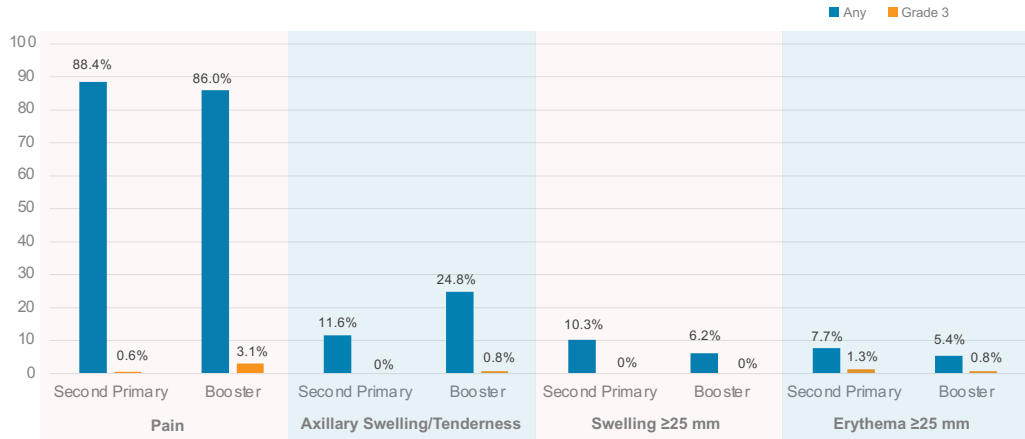
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### Solicited Local Adverse Reactions Starting Within 7 Days\* After the Booster Dose or After the Second Dose of Primary Series in Participants 18-64 Years



\*7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary). Moderna. <https://www.modernatx.com/covid19vaccine-eual> Accessed October 21, 2021.

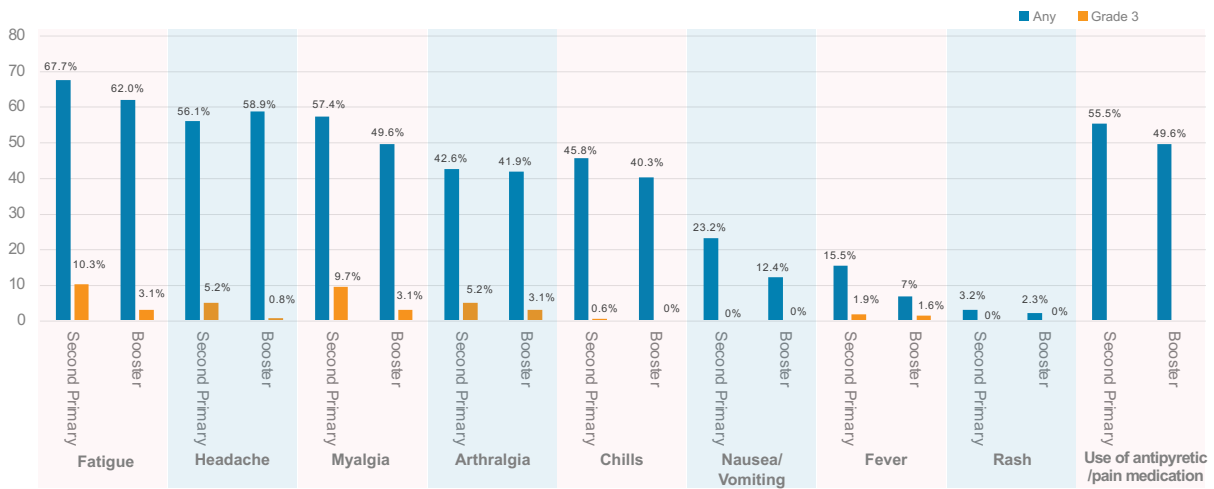
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### Solicited Systemic Adverse Reactions Starting Within 7 Days\* After the Booster Dose or After the Second Dose of Primary Series in Participants 18-64 Years



\*7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary). Moderna. <https://www.modernatx.com/covid19vaccine-eual> Accessed October 21, 2021.

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## Immunogenicity of a Booster Dose Following a Moderna COVID-19 Vaccine Primary Series

- The primary immunogenicity analysis population included 149 booster dose participants in Study 2 and a random subset of 1055 participants from Study 1 who received two doses of Moderna COVID-19 Vaccine

### Neutralizing Antibody Geometric Mean Titers (ID50) Against a Pseudovirus Expressing the SARS-CoV-2 Spike Protein, Per-Protocol Immunogenicity Set<sup>a</sup>

	Study 2 Booster N <sup>b</sup> =149	Study 1 Primary Series N <sup>b</sup> =1053
GMT <sup>c</sup> (95% CI)	1802 (1548-2099)	1027 (968-1089)
GMR (95% CI)	1.8 (1.5, 2.1)	
Met Success Criterion <sup>d</sup>	Lower limit of 95% CI ≥0.67 Criterion: <b>Yes</b> Point Estimate ≥1.0 Criterion: <b>Yes</b>	

<sup>a</sup>Per-Protocol Immunogenicity Set included all subjects who had both baseline (or Study 2 Day 1 for Study 2) and post-vaccination immunogenicity samples, did not have SARS-CoV-2 infection at baseline (or Study 2 Day 1 for Study 2), did not have a major protocol deviation that impacted immune response, and had post-injection immunogenicity assessment at timepoint of primary interest (Day 29 for Study 2 and Day 57 for Study 1). <sup>b</sup>Number of subjects with non-missing data at the corresponding timepoint. <sup>c</sup>Given the lack of randomization in Study 2, the statistical analysis plan pre-specified an analysis of covariance model for estimating the geometric mean titer that adjusts for differences in age groups (<65 years, ≥65 years). <sup>d</sup>Immunobridging is declared if the lower limit of the 2-sided 95% CI for the GMR is >0.67 and the point estimate of the GLSM ratio is ≥1.0.  
Moderna. <https://www.modernatx.com/covid19/vaccine-eval>. Accessed October 21, 2021

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## Safety and Immunogenicity of an mRNA-1273 Booster Injection

P201 study



### Safety

- Rates of AEs with 50-µg booster dose are comparable to those observed post-dose 2 of the primary series
  - Pain at injection site was the most common solicited local AE in both groups
  - Headache, fatigue, and myalgia were the most common systemic AEs in both groups
  - Majority of AEs were mild-to-moderate in severity
- Axillary swelling or tenderness was the only AE reported more frequently after the booster dose

### Immunogenicity

- 50-µg booster dose following 100-µg primary series led to:
  - Higher antibody responses to the ancestral strain (D614G) compared with post-dose 2 in the COVE study (GMR=1.8)
  - 23- to 44-fold increase in neutralizing antibody titers following a booster dose

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AE, adverse event; GMR, geometric mean ratio.  
Miller J. Vaccines and Related Biological Products Advisory Committee, October 14, 2021.  
<https://www.fda.gov/media/153089/download>. Accessed October 21, 2021.

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## Homologous and Heterologous Booster Vaccinations were Well-Tolerated and Immunogenic in Adults<sup>1,2</sup>

Booster vaccination	Group	Primary series vaccine	Interval, weeks	Strategy tested
mRNA-1273 (100 µg)	1	Ad26.COV2.S	≥12	Same strain Heterologous platform
	2	mRNA-1273	≥12	Control- Same strain Same platform
	3	BNT162b2	≥12	Same strain Similar platform
Ad26.COV2.S (5X10 <sup>10</sup> vp)	4	Ad26.COV2.S	≥12	Control- Same strain Same platform
	5	mRNA-1273	≥12	Same strain Heterologous platform
	6	BNT162b2	≥12	Same strain Heterologous platform
BNT162b2 (30 µg)	7	Ad26.COV2.S	≥12	Same strain Heterologous platform
	8	mRNA-1273	≥12	Same strain Similar platform
	9	BNT162b2	≥12	Control- Same strain Same platform

- Mix-and-match boosting strategies were evaluated across 9 groups with a total of 485 participants
  - (mRNA-1273: n=154; AD26.Cov2.S: n=150; BNT162b2: n=153)
- Reactogenicity was comparable to primary vaccination reports
  - Injection site pain, fatigue, headache, and myalgia was reported in >50% of the participants
- mRNA-1273 booster vaccine increased neutralizing activity against D614G pseudovirus (10-76-fold) for all combinations
  - Homologous boost increased neutralizing antibody titers 10-fold
  - Heterologous boost increased titers 32-76-fold

1. Atmar. Advisory Committee on Immunization Practices. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/04-COVID-Atmar-508.pdf> Accessed October 21, 2021. 2. Atmar AL, et al. medRxiv. Published (peer review pending) October 15, 2021. <https://www.medrxiv.org/content/10.1101/2021.10.10.21264927v2.full.pdf> Accessed October 22, 2021.

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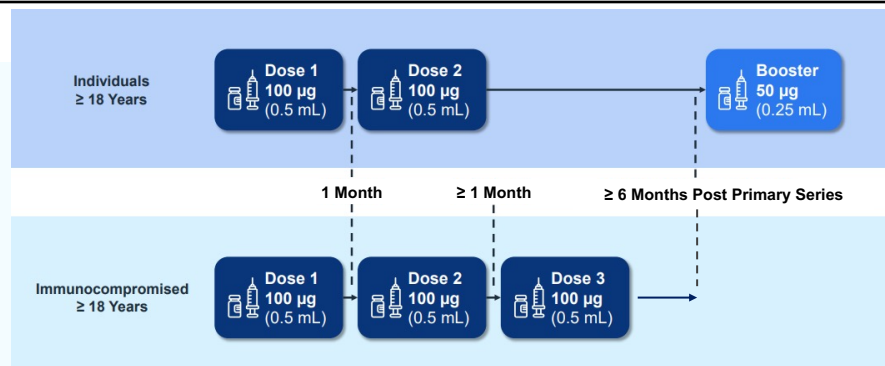
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## mRNA-1273 Vaccination Schedule<sup>1,2</sup>

And Coadministration With Other Vaccines



- Moderna COVID-19 Vaccine may be given with other vaccines, without regard to timing
  - Including simultaneous administration with other vaccines on the same day
- A single Moderna COVID-19 Vaccine booster dose (50 µg; 0.25 mL) may be administered intramuscularly at least 6 months after completing a primary series of the Moderna COVID-19 Vaccine to individuals: ≥65 years, 18 through 64 years of age at high risk of severe COVID-19, or with frequent institutional or occupational exposure to SARS-CoV-2
- A single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) may be administered as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

COVID-19, coronavirus disease 2019. 1. Miller J. Vaccines and Related Biological Products Advisory Committee. October 14, 2021. <https://www.fda.gov/media/153533/Schedule.pdf> Accessed October 21, 2021. 2. Reddy S. CDC COVID-19 Vaccine Task Force. Published October 21, 2021. <https://www.cdc.gov/media/releases/2021/s102121-covid-19-vaccine.html> Accessed October 21, 2021.

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# Moderna HCP Education Resources for Booster Dosing<sup>1,2</sup>

## HCP Education Resource Kit :

- Dosing & Administration PDF
- Vial Dose Tracker
- Billing & Coding Resource
- Fact Sheet & Dear HCP Letter

## EUA Moderna COVID-19 Website Update

- Dear HCP Letter (for download)
- Fact Sheets (for download)
- Fact Sheets language translation
- Booster Detailed Section (Provider & Recipient)
- Dosing & Administration PDF (for download)
- Billing & Coding Resource (for download)
- Updated Booster FAQs sections

See <https://medinfo.modernatx.com/> for more information

The screenshot shows the Moderna COVID-19 Vaccine website interface. At the top, there are navigation links for 'About Our Vaccine', 'Storage & Handling', 'Dosing & Administration', 'For Vaccination Providers', 'For Vaccine Recipients', 'Vaccine Eligibility', and 'FAQs'. Below the navigation, there are three prominent buttons: 'Download EUA Fact Sheet & Full PI for Vaccination Providers', 'Dear HCP Letter for Booster Dosing', and 'Look Up Vaccine Expiration Dates For Vaccination Providers'. A central text block states: 'The Moderna COVID-19 Vaccine has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA), to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older. The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of the product, unless the declaration is terminated or the authorization is revoked sooner.' Below this, there is a 'DOSE TRACKER FOR MODERNA COVID-19 VACCINE' section with tabs for 'EMERGENCY USE AUTHORIZATION', 'WITHDRAWALS', 'DOSE TRACKER FOR MODERNA COVID-19 VACCINE', 'DOSING SCHEDULE', and 'BILLING & ADMINISTRATION'. The 'DOSE TRACKER' tab is active, showing a grid for tracking doses for individuals 18 years and older. To the right, there is a 'Moderna COVID-19 Vaccine Dosing & Administration' section with a 'Dosing Schedule' table and a 'Vial Dose Tracker'.

1. Moderna. <https://www.modernatx.com/covid19vaccine-euaforproviders/>. Accessed October 22, 2021. 2. Moderna. <https://medinfo.modernatx.com/>. Accessed October 22, 2021. Slide 30

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# Upcoming Moderna Webinar

## Conversation on the Moderna COVID-19 Vaccine Booster Dose | Important Information for Healthcare Providers

**National Roundtable Series Registration**

brought to you by MDBriefCase

**November 18 from 3-4pm ET**

Join Moderna and Dr. Jerome Adams, Lauren B. Angelo, and Dr. Jaime E. Fergie for a round table to discuss the EUA for the Moderna COVID-19 Booster Vaccine, the data that informed this approval, and the impact on clinical practice. Moderated by James A. Mansi, Ph.D., Moderna's VP Medical Affairs – Americas.



**Jerome M. Adams**  
MD, MPH



**Lauren B. Angelo**  
PharmD, MBA



**Jaime E. Fergie**  
MD



**James A. Mansi**  
Ph.D.

The Moderna COVID-19 Vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized for emergency use by the FDA, under an EUA, to prevent COVID-19 for use in individuals 18 years of age and older.

COVID-19, Coronavirus Disease 2019; EUA, Emergency Use Authorization. Slide 31

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We've been  
at this for  
ten years.

Our mRNA platform  
is a modern approach  
to medicine.

But it's just the  
beginning.

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