COVID-19 Vaccine Updates

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DISCLAIMER

The information presented today is based on CDC's recent guidance and MAY change.

February 22, 2022


FDA
U.S Food and Drug Administration

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Pfizer Pediatric (6 months - 4 years) COVID-19 Vaccine

- February 1, 2022, at the request of the U.S. Food and Drug Administration (FDA), Pfizer initiated a rolling submission for Emergency Use Authorization (EUA) of their COVID-19 vaccine in children 6 months through 4 years of age.[1]
- February 11, 2022, the FDA postponed its advisory committee meeting scheduled for Feb. 15th to discuss the authorization of Pfizer COVID-19 vaccine for children 6 months through 4 years of age.[2]
  - As part of its rolling submission, Pfizer recently notified the FDA of additional findings from its ongoing clinical trial.
  - Based on the FDA's preliminary assessment, and to allow more time to evaluate additional data, the FDA believes additional information regarding the ongoing evaluation of a third dose should be considered as part of our decision-making for potential authorization.
  - The FDA stated that an update on timing for the advisory committee meeting will be provided once they receive additional data on a third dose in this age group and have an opportunity to complete an updated evaluation.

1. https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-initiate-rolling-submission-emergency
2. Coronavirus (COVID-19) Update: FDA Postpones Advisory Committee Meeting to Discuss Request for Authorization of Pfizer-BioNTech COVID-19 Vaccine for Children 6 Months Through 4 Years of Age | FDA

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Moderna COVID-19 Vaccine

- On January 31, 2022, the FDA approved a second COVID-19 vaccine, the Moderna COVID-19 vaccine. The approved vaccine will be marketed as Spikevax for the prevention of COVID-19 in individuals 18 years and older.[1]
- Pending the FDA's decision on the age expansion in adolescents 12-17 years of age submitted in June 2021.[2]
- Moderna COVID-19 vaccine is authorized for 12 years and older in multiple countries outside the United States including UK, Canada, and Australia.
- Most recently, Australia authorized the vaccine in children 6 through 11 years of age.[3]

1. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine
2. https://investors.modernatx.com/news/news-details/2021/Moderna-Files-for-Emergency-Use-Authorization-for-its-COVID-19-Vaccine-in-Adolescents-in-the-United-States-06-10-2021/default.aspx
3. https://investors.modernatx.com/news/news-details/2022/Therapeutic-Goods-Administration-of-Australia-Authorizes-Modernas-Covid-19-Vaccine-in-Children-6-11-Years/default.aspx

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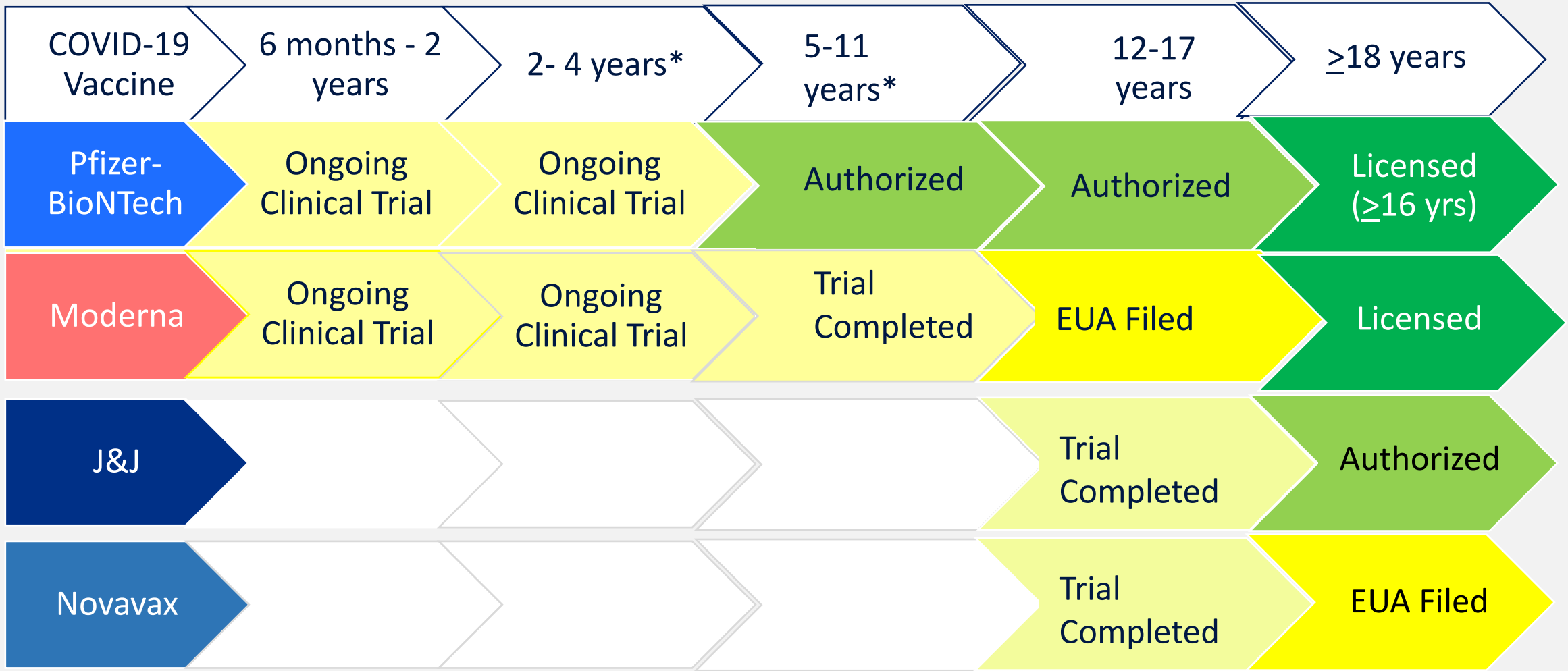
Novavax COVID-19 Vaccine

- On January 31, 2022, Novavax submitted a request to the FDA for EUA for its COVID-19 vaccine (NVX-CoV273) for individuals 18 years and older.[1]
  - 2-dose series given 21 days apart
- To date, NVX-CoV2373 has received authorization from multiple regulatory authorities globally, including European Commission, UK, Canada, Australia, and emergency use listing from the World Health Organization.
- The Company has announced positive results of the vaccine in adolescents ages 12 through 17 and plans to submit the data to global regulatory agencies.[2]

1. https://ir.novavax.com/2022-01-31-Novavax-Submits-Request-to-the-U-S-FDA-for-Emergency-Use-Authorization-of-COVID-19-Vaccine

2. https://ir.novavax.com/2022-02-10-Novavax-Announces-Positive-Results-of-COVID-19-Vaccine-in-Pediatric-Population-of-PREVENT-19-Phase-3-Clinical-Trial

Summary of COVID-19 Vaccines Approvals/Authorization by Age Groups by the FDA



*Moderna age groups: 2- 5 years & 6-11 years of age

As of 2/21/2022

Omicron Variant & COVID-19 Vaccines

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Omicron Variant & COVID-19 Vaccines

- Vaccine effectiveness against symptomatic disease with the Omicron variant is significantly lower than compared with the Delta variant. However, protection against hospitalization remains high, particularly after a booster dose.

Table 2. Hazard ratios and vaccine effectiveness against hospitalisation (all vaccine brands combined). OR = odds ratio, HR = hazards ratio, VE = vaccine effectiveness

Dose	Interval after dose (weeks)	OR v symptomatic disease	HR vs hospitalisation	VE vs hospitalisation
1	4+	0.74 (0.72-0.76)	0.57 (0.38-0.85)	58% (37-72)
2	2 to 24	0.81 (0.8-0.82)	0.45 (0.36-0.56)	64% (54-71)
2	25+	0.94 (0.92-0.95)	0.6 (0.49-0.74)	44% (30-54)
3	2 to 4	0.32 (0.31-0.33)	0.26 (0.19-0.35)	92% (89-94)
3	5 to 9	0.42 (0.41-0.43)	0.29 (0.23-0.37)	88% (84-91)
3	10+	0.5 (0.49-0.51)	0.34 (0.26-0.44)	83% (78-87)

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1050236/technical-briefing-34-14-january-2022.pdf

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Omicron Variant & COVID-19 Vaccines

- Moderna has initiated a study of Omicron-specific booster candidate (mRNA-1273.529) as a single booster dose in ≥18 yrs.[1]
  - Cohort 1: Previously received the two-dose primary series of mRNA-1273 with the second dose being at least six months ago
  - Cohort 2: previously received the two-dose primary series and a 50mcg booster dose of mRNA-1273 with the booster dose being at least three months ago
  - Additionally, Moderna is evaluating the inclusion of mRNA-1273.529 in its multivalent booster program.

- Pfizer has initiated a study to evaluate an Omicron-based vaccine candidate in individuals ages 18 through 55 years.[2]
  - Cohort 1: Received two doses of the current Pfizer COVID-19 vaccine 90-180 days prior to enrollment; in the study, participants will receive one or two doses of the Omicron-based vaccine
  - Cohort 2: Received three doses of the current Pfizer-BioNTech COVID-19 vaccine 90-180 days prior to enrollment; in the study, participants will receive one dose of the current Pfizer- COVID-19 vaccine or the Omicron-based vaccine
  - Cohort 3: Vaccine-naïve participants will receive three doses of the Omicron-based vaccine

1. https://investors.modernatx.com/news/news-details/2022/Moderna-Announces-First-Participant-Dosed-in-Phase-2-Study-of-Omicron-Specific-Booster-Candidate-and-Publication-of-Data-on-Booster-Durability-Against-Omicron-Variant/default.aspx
2. https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-initiate-study-evaluate-omicron-based

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Omicron Variant & COVID-19 Vaccines

- FDA took multiple actions to expand use of Pfizer COVID-19 Vaccine.[1]
  - Expand the use of a single booster dose to include use in individuals 12 through 15 years of age.
  - Shorten the time between the completion of primary vaccination of the Pfizer COVID-19 vaccine and a booster dose to at least five months.
  - Allow for a third primary series dose for certain immunocompromised children 5 through 11 years of age.
- FDA amended the EUA for the Moderna COVID-19 Vaccine to shorten the time between the completion of a primary series of the vaccine and a booster dose to at least five months for individuals 18 years of age and older.[2]

1. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-multiple-actions-expand-use-pfizer-biontech-covid-19-vaccine
2. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-shortens-interval-booster-dose-moderna-covid-19-vaccine-five-months

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COVID-19 Vaccination Recommendations

February 14, 2022

	Primary Series (General Population)		Booster Dose
	Dose 1	**Dose 2**	**Single Booster Dose [b]**
Pfizer (5-11 years) (orange cap)	0.2 mL *After dilution*	0.2 mL[a] @ 21 days after dose 1	**NO** booster dose
Pfizer (≥12 years) (purple → gray cap)	0.3 mL *(Gray cap does not require diluent)*	0.3 mL @ 21 days after dose 1	0.3 mL **≥ 5 Months** after dose 2
Moderna (≥18 years)	0.5 mL	0.5 mL @ 28 Days after dose 1	0.25 mL **≥ 5 Months** after dose 2
J&J's Janssen (≥18 years) [c]	0.5 mL	N/A	0.5 mL **≥ 2 Months** after dose 1

a: Dose based on age at the time of the vaccination
b: Booster doses may be mix and match for individuals ≥18 yrs, mRNA vaccines are preferred : Booster dose may be mix-and-match vaccine
c: mRNA COVID-19 vaccines are preferred over the J&J COVID-19 vaccine

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COVID-19 Vaccination Recommendations

February 14, 2022

	Primary Series (Moderate or Severe Immunocompromised Individuals)			Booster Dose
	Dose 1	**Dose 2**	**Dose 3 (Additional Dose)**	**Single Booster Dose[b]**
Pfizer (5-11 years) (orange cap)	0.2 mL *After dilution*	0.2 mL[a] @ 21 days after dose 1	**0.2 mL[a] at least 28 days after dose 2**	**NO** booster dose
Pfizer (≥12 years) (purple → gray cap)	0.3 mL *(Gray cap does not require diluent)*	0.3 mL @ 21 days after dose 1	0.3 mL at least 28 days after dose 2	0.3 mL **≥ 3 Months** after dose 3
Moderna (≥18 years)	0.5 mL	0.5 mL @ 28 Days after dose 1	0.5 mL at least 28 days after dose 2	0.25 mL **≥ 3 Months** after dose 3
J&J's Janssen (≥18 years)[c]	0.5 mL	**Pfizer or Moderna COVID-19 vaccine @ 28 Days after dose 1**	N/A	0.5 mL **≥ 2 Months** after dose 2

a: Dose based on age at the time of the vaccination
b: Booster doses may be mix and match for individuals ≥18 yrs, mRNA vaccines are preferred : Booster dose may be mix-and-match vaccine
c: mRNA COVID-19 vaccines are preferred over the J&J COVID-19 vaccine

TEXAS Health and Human Services | Texas Department of State Health Services

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Thank you!

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