COVID-19 vaccine safety updates: Primary series in children and adolescents ages 5–11 and 12–15 years, and booster doses in adolescents ages 16–24 years

Advisory Committee on Immunization Practices
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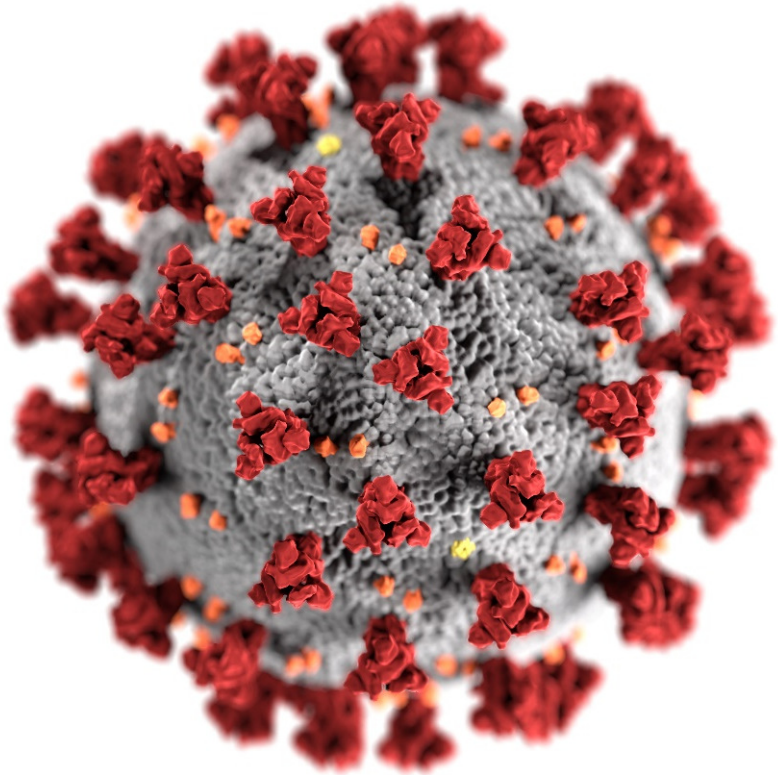

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- Mention of a product or company name is for identification purposes only and does not constitute endorsement by CDC or FDA

Topics

- Reports to VAERS after primary series Pfizer-BioNTech COVID-19 vaccination in children and adolescents ages 5–11 and 12–15 years
- Reports to VAERS after Pfizer-BioNTech COVID-19 booster vaccination in adolescents ages 16–24 years

VAERS is the nation's early warning system for vaccine safety

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

VAERS accepts reports from everyone

Regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event

Key strengths

- Rapidly detects potential safety problems
- Can detect rare adverse events

Key limitations

- Passive surveillance system
- Inconsistent quality and completeness of information
- Reporting biases
- Generally, cannot determine cause and effect

Reports to VAERS after primary series Pfizer-BioNTech COVID-19 vaccination among children and adolescents ages 5–11 and 12–15 years

U.S. reports to VAERS among children and adolescents ages 5–11 and 12–15 years after Pfizer-BioNTech COVID-19 vaccination* (as of Dec 19, 2021)

Age group	Median age	Male n (%)	Female n (%)	Non-serious n (%)	Serious† n (%)	Total reports	Doses admin‡
5–11 years	8 years	1,896 (45)	1,911 (45)	**4,149 (98)**	100 (2)	4,249	8,674,378
12–15 years	13 years	4,946 (47)	5,381 (51)	**9,612 (92)**	846 (8)	10,458	18,707,169

- For both age groups, most reports (≥92%) were non-serious
- Distribution by sex similar

* Among children ages 5–11 years vaccinated during Nov 3–Dec 19, 2021, and among children and adolescents ages 12–15 years vaccinated during May 12–Dec 19, 2021; reports received and processed as of Dec 19, 2021.

† Includes 3 deaths (2 medically complex patients, 1 with influenza) among ages 5–11 years, and 12 deaths with no observable common mechanism among ages 12–15 years.

‡ Doses administered among children ages 5–11 years during Nov 4–Dec 16, 2021, and for children and adolescents ages 12–15 years during May 12–Dec 16, 2021.

Reports to VAERS among children and adolescents ages 5–11 and 12–15 years* after Pfizer-BioNTech COVID-19 vaccination, by race and ethnicity

(as of Dec 19, 2021)

Race and ethnicity	5–11 yrs, n (%)	12–15 yrs, n (%)
Unknown or not reported	1,694 (40)	2,631 (25)
Non-Hispanic White	1,439 (34)	3,973 (38)
Hispanic†	469 (11)	1,429 (14)
Non-Hispanic other	198 (5)	1,136 (11)
Non-Hispanic Black	170 (4)	478 (5)
Non-Hispanic Asian	166 (4)	482 (5)
Non-Hispanic multiracial	84 (2)	199 (2)
Non-Hispanic American Indian/Alaskan Native	22 (1)	112 (1)
Non-Hispanic Native Hawaiian or Other Pacific Islander	Not reported‡	18 (<1)
Total	**4,249**	**10,458**

* Among children ages 5–11 years vaccinated during Nov 3–Dec 19, 2021, and among children and adolescents ages 12–15 years vaccinated during May 12–Dec 19, 2021; reports received and processed as of Dec 19, 2021.

† Includes persons reported as of Hispanic ethnicity, but of unreported or unknown race.

Most frequently reported adverse events to VAERS after Pfizer-BioNTech COVID-19 vaccination, children and adolescents ages 12–15 years* (as of Dec 19, 2021)

Non-serious reports (n=9,612, 92%)

Rank	Adverse event (not mutually exclusive)	n (%)
1	Dizziness	1,512 (16)
2	Syncope	1,057 (11)
3	Headache	888 (9)
4	Product Storage Error	886 (9)
5	Nausea	860 (9)
6	Fever	844 (9)
7	Vomiting	657 (7)
8	Fatigue	640 (7)

Serious reports (n=846, 8%)

Rank	Adverse event (not mutually exclusive)	n (%)
1	Chest Pain	440 (52)
2	Troponin Increased	333 (39)
3	Myocarditis	327 (39)
4	SARS-CoV-2 Test Negative	276 (33)
5	C-Reactive Protein Increased	263 (31)
6	Fever	258 (31)
7	Echocardiogram Normal	249 (29)
8	Headache	221 (26)

- Reflect vaccination error and previously observed adverse events; workup for myocarditis or Multisystem Inflammatory Syndrome in Children (MIS-C)

* Reports among children ages 12–15 years vaccinated May 12–Dec 19, 2021

Most frequently reported adverse events to VAERS following Pfizer-BioNTech COVID-19 vaccination, children ages 5–11 years* (as of Dec 19, 2021)

Non-serious reports (n=4,149, 98%)

Rank	Adverse event (not mutually exclusive)	n (%)
1	No adverse event	1,183 (27)
2	Product preparation issue	925 (21)
3	Incorrect dose administered‡	704 (16)
4	Underdose	326 (7)
5	Vomiting	320 (7)
6	Fever	296 (7)
7	Headache	260 (6)
8	Syncope	256 (6)

Serious reports† (n=100, 2%)

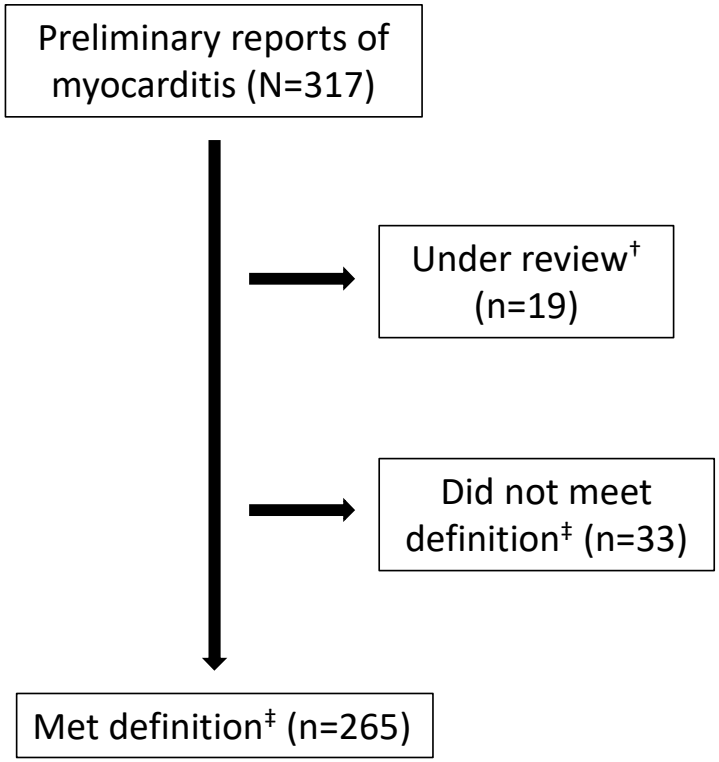
Rank	Adverse event (not mutually exclusive)	n (%)
1	Fever	29 (29)
2	Vomiting	21 (21)
3	Troponin increased	15 (15)
4	Chest pain	12 (12)
5	Echocardiogram normal	12 (12)
6	Blood test	11 (11)
7	C-reactive protein increased	11 (11)
8	SARS-CoV-2 test negative	11 (11)

- Reflect vaccination errors and previously observed adverse events; workup for myocarditis or Multisystem Inflammatory Syndrome in Children (MIS-C)

* Reports among children ages 5–11 years vaccinated Nov 3–Dec 19, 2021.
† No serious reports resulted from the administration of an adult dose in error.
‡ Of reports specifying receipt of an adult dose, few reported a health outcome.

Reports to VAERS of myocarditis after Pfizer-BioNTech COVID-19 vaccination among children and adolescents ages 12–15 years* (as of Dec 19, 2021)

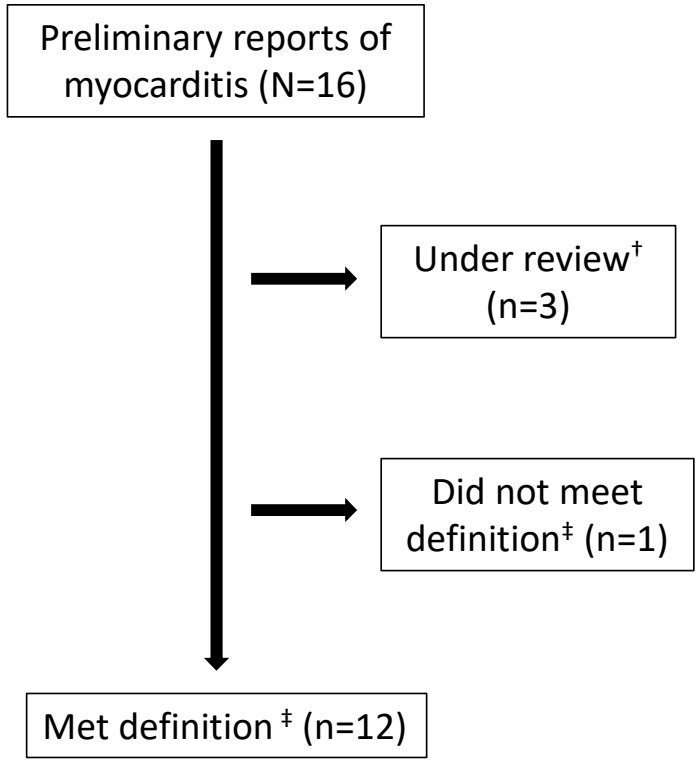
- 265 reports of myocarditis verified to meet case definition
  - Median age: 14 years (IQR: 13–15 years)
  - Median time to onset: 2 days (IQR: 1–3 days)
  - After dose 1 = 41; after dose 2 = 221
  - 238 (90%) males, 27 (10%) females
    - 251 hospitalized patients (241 discharged home)
    - 224 patients with known outcomes
      - 208 (92%) recovered from symptoms at time of report
      - 16 (8%) mostly reported improved, or resolved, symptoms, but ongoing physical restrictions or still under investigation
- Doses administered = 18,707,169§



* Reports of children and adolescents ages 12–15 years vaccinated May 12–Dec 19, 2021
† Awaiting medical records and/or healthcare provider interview; some still processing
‡ Adjudicated after healthcare provider interview and/or medical record review
§ Doses administered among children and adolescents ages 12–15 years May 12–Dec 16, 2021

Reports to VAERS of myocarditis after Pfizer-BioNTech COVID-19 vaccination among children ages 5–11 years* (as of Dec 19, 2021)

- 12 reports of myocarditis verified to meet case definition
  - Median age: 10 years (IQR: 9–11 years)
  - Median time to onset: 2 days (IQR: 2–3 days)
  - After dose 1 = 2; after dose 2 = 9; not reported = 1
  - 8 (67%) males, 4 (33%) females
    - All discharged home
    - 8 recovered from symptoms at time of report
    - 4 still recovering at time of report
    - None reported a vaccination error
- Doses administered = 8,674,378§



* Reports of children ages 5–11 years vaccinated Nov 3–Dec 19, 2021

† Awaiting medical records and/or healthcare provider interview; some still processing

‡ Adjudicated after healthcare provider interview and/or medical record review

§ Doses administered among children ages 5–11 years Nov 4–Dec 16, 2021

Reporting rates of myocarditis (per 1 million doses administered) after Pfizer-BioNTech COVID-19 vaccination, 7-day risk interval*

	Males		Females	
Age group	**Dose 1**	**Dose 2**	**Dose 1**	**Dose 2**
5–11 years	0.0	4.3	Not calculated†	2.0
12–15 years	4.8	45.7	1.0	3.8
16–17 years (included for reference)	6.1	70.2	0.0	7.6

- **37,810,998** total doses 1 and 2 of vaccine administered‡
- Reporting rates exceed background incidence (peach shaded cells) §
  - Males: after dose 1 (ages 12–15 and 16–17 years) and after dose 2 (ages 5–11, 12–15, and 16–17 years)
  - Females: after dose 2 (ages 12–15 and 16–17 years)
  - Reporting rates among males substantially lower among ages 5–11 vs. 12–15 and 16–17 years

* Reports of myocarditis after doses 1 and 2 of Pfizer-BioNTech COVID-19 vaccine during a 7-day risk interval after vaccination (as of Dec 19, 2021); reports verified to meet case definition by healthcare provider interview and/or medical record review.

† Too few reports of females ages 5–11 years to calculate a stable rate.

‡ Children ages 5–11 years vaccinated Nov 3–Dec 19, 2021, children and adolescents ages 12–15 years vaccinated May 12–Dec 19, 2021.

§ An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for the 7-day risk period, this estimated background is 0.2 to 1.9 per 1 million person 7-day risk period.

Summary of VAERS findings — Reports after Pfizer-BioNTech COVID-19 vaccination among children and adolescents ages 5–11 and 12–15 years

- Since authorization, 8.7 million doses of Pfizer-BioNTech COVID-19 vaccine administered to children ages 5–11-years, and 18.7 million doses to children and adolescents ages 12–15-years, in the Unites States
- Regardless of age group, most reports (≥92%) were non-serious
  - Distribution by sex, race, and ethnicity similar between the two age groups
  - Most frequently reported adverse events (AEs) were known and well-characterized AEs associated with Pfizer-BioNTech COVID-19 vaccination, or consistent with vaccination errors or workup for myocarditis or MIS-C
  - Reported myocarditis among children ages 5–11 years:
    - Male predominance and mostly after dose 2, similar to older age groups
    - **Reporting rates for males ages 5–11-years substantially lower than for males ages 12–15 and 16–17-years**
- CDC will continue monitoring COVID-19 vaccine safety among these age groups

Reports to VAERS after Pfizer-BioNTech COVID-19 booster vaccination among persons ages 16–24 years

Reports to VAERS after Pfizer-BioNTech COVID-19 booster vaccination among persons ages 16–24 years * (as of Dec 19, 2021)

Age group	Male n (%)	Female n (%)	Non-serious n (%)	Serious† n (%)	Total reports	Doses administered‡
16–17 years	11 (48)	12 (52)	22 (96)	1 (4)	23	47,040
18–24 years	140 (32)	303 (68)	423 (95)	21 (5)	444	929,842

- Most reports (≥95%) non-serious

* Among adolescents ages 16–17 years who received dose 3 of Pfizer-BioNTech vaccine during Dec 9–Dec 19, 2021, and persons ages 18–24 years who received dose 3 of Pfizer-BioNTech vaccine during Sep 22–Dec 19, 2021; processed and received as of Dec 19, 2021.
† Per federal law, includes reports of hospitalization, prolongation of existing hospitalization, life threatening condition, permanent disability, congenital deformity or birth defect, or death.
‡ Doses administered as of Dec 16, 2021.

Reports to VAERS after Pfizer-BioNTech COVID-19 booster vaccination, ages 16–24 years*, by race and ethnicity

Race and ethnicity	16–17 years n, (%)	18–24 years n, (%)
Non-Hispanic White	<10	181 (41)
Not reported	<10	149 (34)
Hispanic†	<10	55 (12)
Non-Hispanic Asian	<10	29 (7)
Non-Hispanic Black	<10	15 (3)
Non-Hispanic multiracial	<10	10 (2)
Non-Hispanic American Indian/Alaskan Native	<10	<10
Non-Hispanic other	<10	<10
Non-Hispanic Native Hawaiian or other Pacific Islander	<10	<10
Total	**23**	**444**

* Among adolescents ages 16–17 years who received dose 3 of Pfizer-BioNTech vaccine Dec 9–Dec 19, 2021, and persons ages 18–24 years who received dose 3 of Pfizer-BioNTech vaccine Sep 22–Dec 19, 2021; reports processed and received as of Dec 19, 2021.

† Includes persons identified of Hispanic ethnicity of unknown race.

Most frequently reported adverse events to VAERS after Pfizer-BioNTech COVID-19 booster vaccination, ages 16–24 years*

Non-serious reports (n=445, 95%)

Rank	Adverse event (not mutually exclusive)	n (%)
1	Fever	66 (15)
2	Dizziness	61 (14)
3	Pain	59 (13)
4	Chills	54 (12)
5	Headache	53 (12)
6	Fatigue	51 (12)
7	Nausea	47 (11)
8	Pain in extremity	40 (9)

Serious† reports (n=22, 5%)

Rank	Adverse event (not mutually exclusive)	n (%)
1	Chest pain	10 (46)
2	Myocarditis	6 (27)
3	Nausea	6 (27)
4	Fever	6 (27)
5	Troponin increased	6 (27)
6	Palpitations	5 (23)
7	Chest discomfort	4 (18)
8	Blood test	3 (14)

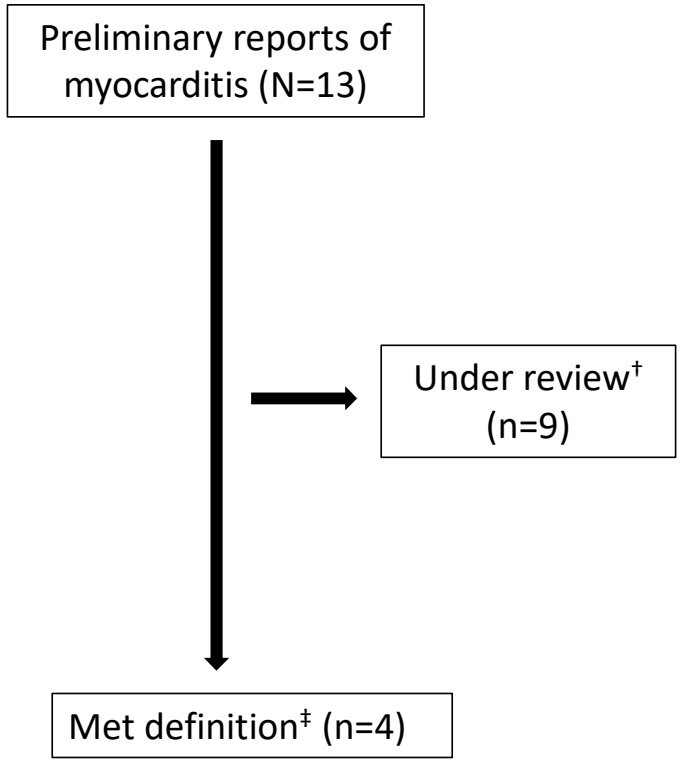
- Reflect previously observed adverse events; workup for myocarditis

* Among adolescents ages 16–17 years who received dose 3 of Pfizer-BioNTech vaccine Dec 9–Dec 19, 2021, and persons ages 18–24 years who received dose 3 of Pfizer-BioNTech vaccine Sep 22–Dec 19, 2021; Reports processed and received as of Dec 19, 2021.

† Per federal law, serious reports include reports of hospitalization, prolongation of existing hospitalization, life threatening condition, permanent disability, congenital deformity or birth defect, or death.

Reports of myocarditis to VAERS after Pfizer-BioNTech COVID-19 booster vaccination among persons ages 16–24 years*

- 13 preliminary reports of myocarditis
  - Median age: 21 years (IQR: 20–22 years)
  - Median time to onset: 1 day (IQR: day of vaccination–1 day)
  - 9 (69%) males, 4 (31%) females
  - 4 reports met case definition
    - 2 reports among ages 16–17 years§
    - 2 reports among ages 18–24 years
    - All reported patients recovered at time of report
- Doses administered = 976,882¶



* Among adolescents ages 16–17 years receiving dose 3 of Pfizer-BioNTech vaccine Dec 9–Dec 19, 2021, and persons ages 18–24 years receiving dose 3 of Pfizer-BioNTech vaccine Sep 22–Dec 19, 2021; reports processed and received as of Dec 19, 2021.

† Awaiting medical records and/or healthcare provider interview; some still processing.

‡ Adjudicated after healthcare provider interview and/or medical record review.

§ One report identified after Dec 19 but vaccinated during Sep 22–Dec 19, 2021.

¶ Doses administered as of Dec 16, 2021.

Summary of VAERS findings after Pfizer-BioNTech COVID-19 booster vaccination, ages 16–24 years

- Since authorization, Pfizer-BioNTech COVID-19 vaccine booster doses have been administered to ~47,000 persons ages 16–17 years and ~930,000 persons ages 18–24 years in the United States
- Most reports (95%) were non-serious (similar to primary series)
  - Most frequently reported AEs were known and well-characterized AEs associated with Pfizer-BioNTech COVID-19 vaccination, or consistent with workup for myocarditis
  - 13 preliminary reports of myocarditis following a booster dose
    - 4 reports met CDC case definition (9 still under review)
      - All 4 reported patients had recovered from symptoms at time of report
    - Characteristics of case reports appear consistent with other reports of myocarditis after dose 1 and dose 2
- CDC will continue to monitor the safety of COVID-19 vaccine booster doses

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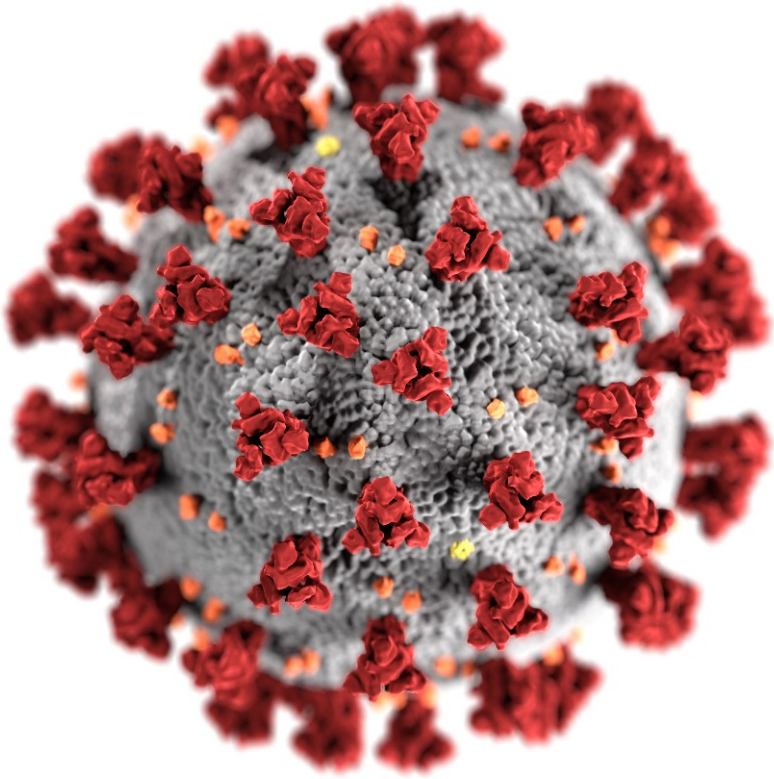
- **Clinical Immunization Safety Assessment Project**
- **COVID-19 Vaccine Task Force Data Monitoring and Reporting Group**
- **FDA/Center for Biologics Evaluation and Research**

Thank you!



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