

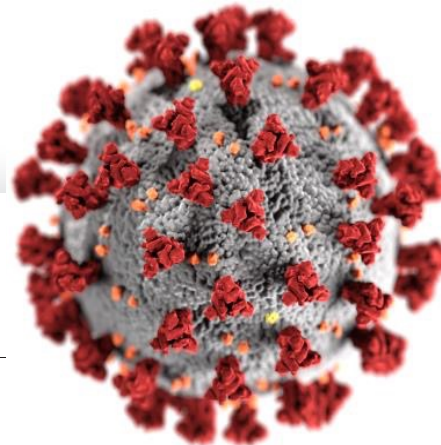
COVID-19 VACCINE SAFETY

June 17, 2021

Presenting To

Healthy Arizona Worksite Program | Phoenix AZ

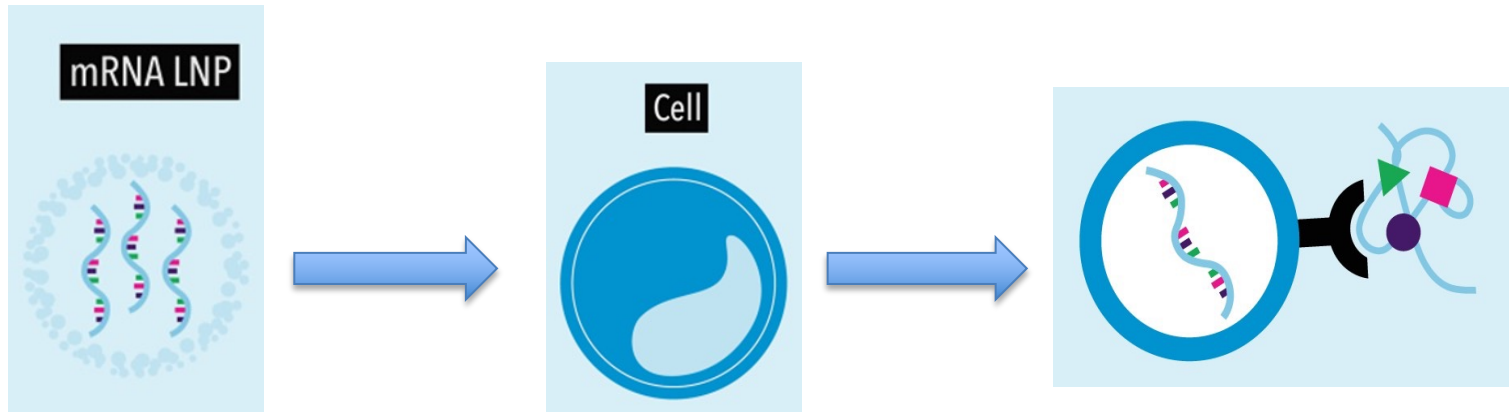
Karen Lewis, M.D. | AIPO Medical Director



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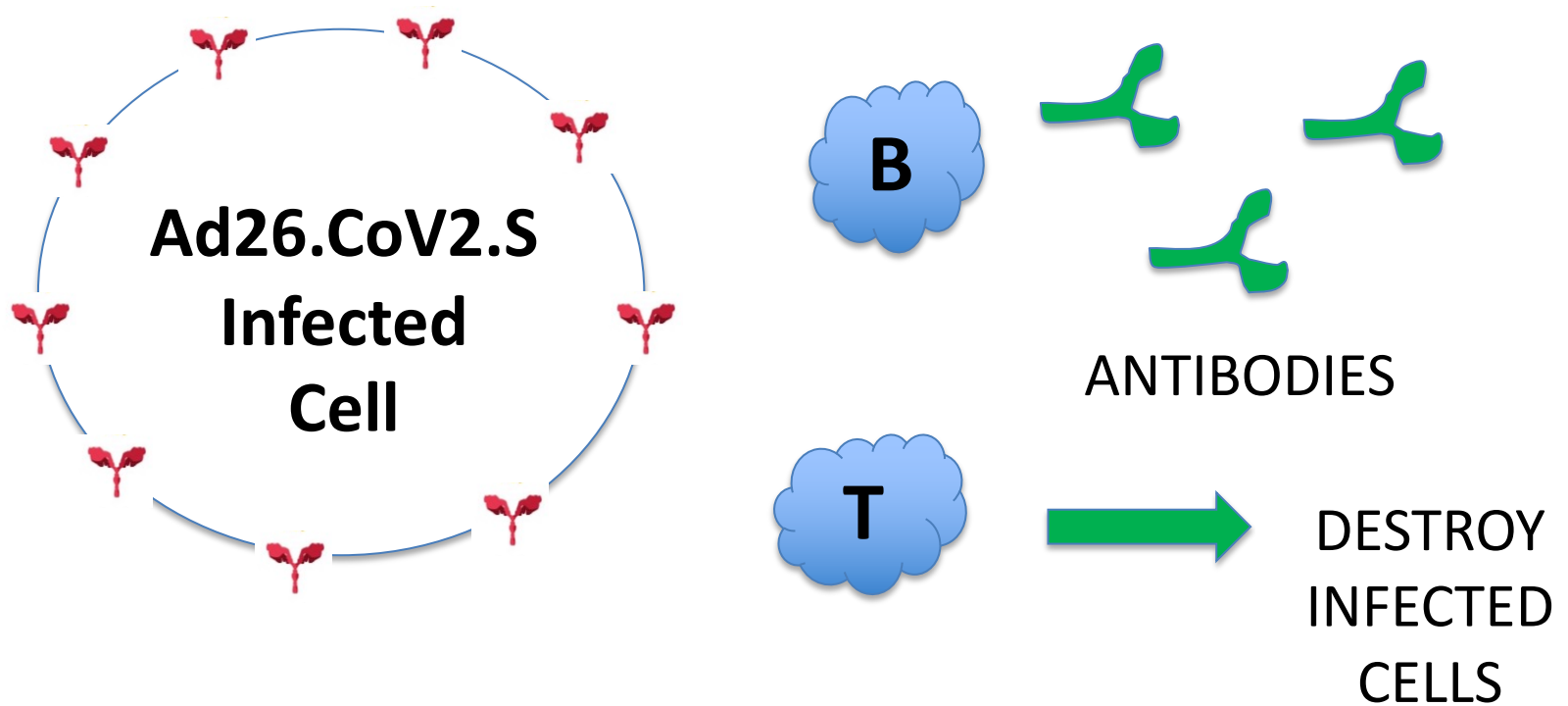
Pfizer and Moderna mRNA Vaccines



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Non-replicating Viral Vector



Reasons for the rapid development of COVID-19 vaccines



TECHNOLOGY



RESOURCES



COLLABORATION

FDA
EUA

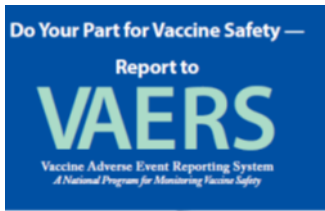
REGULATORY
APPROVAL



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Ongoing Safety Monitoring



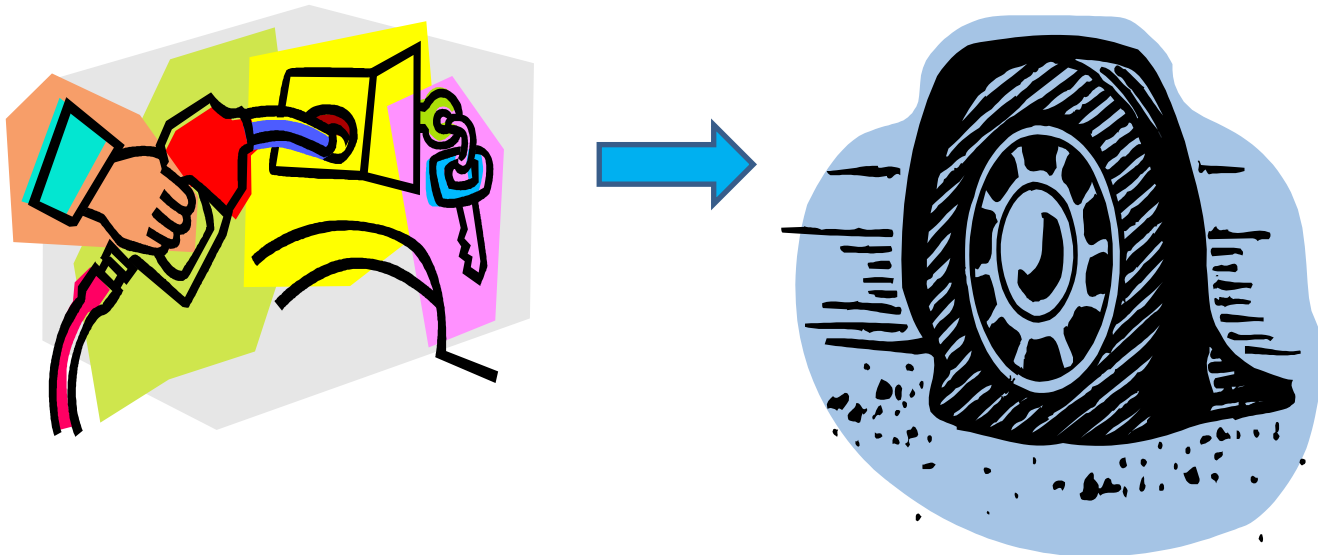
VACCINE ADVERSE EVENTS REPORTING SYSTEM



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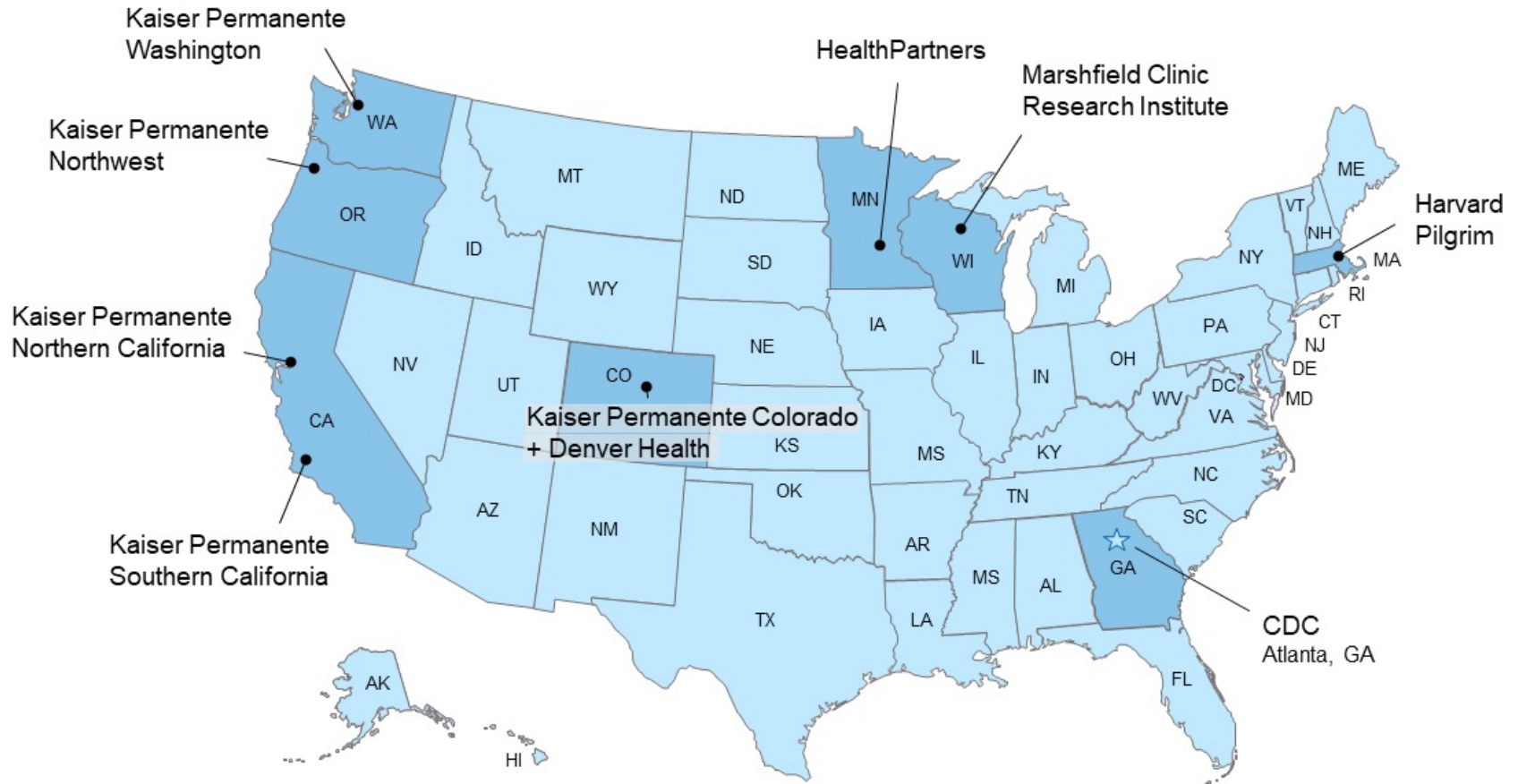
Temporal occurrence does not prove cause and effect



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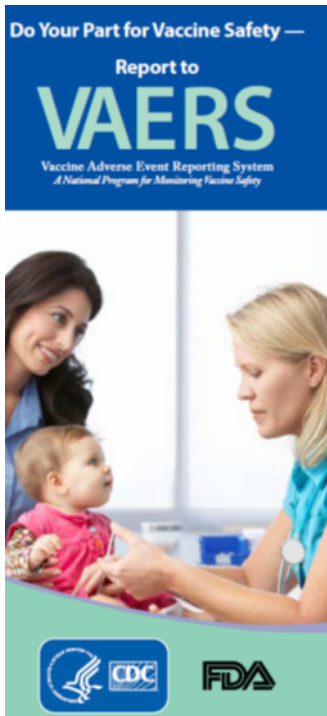
Vaccine Safety Datalink Sites



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Ongoing Safety Monitoring



Vaccine
Safety
Datalink



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mRNA COVID-19 Vaccines:

Pfizer-BioNTech

Moderna

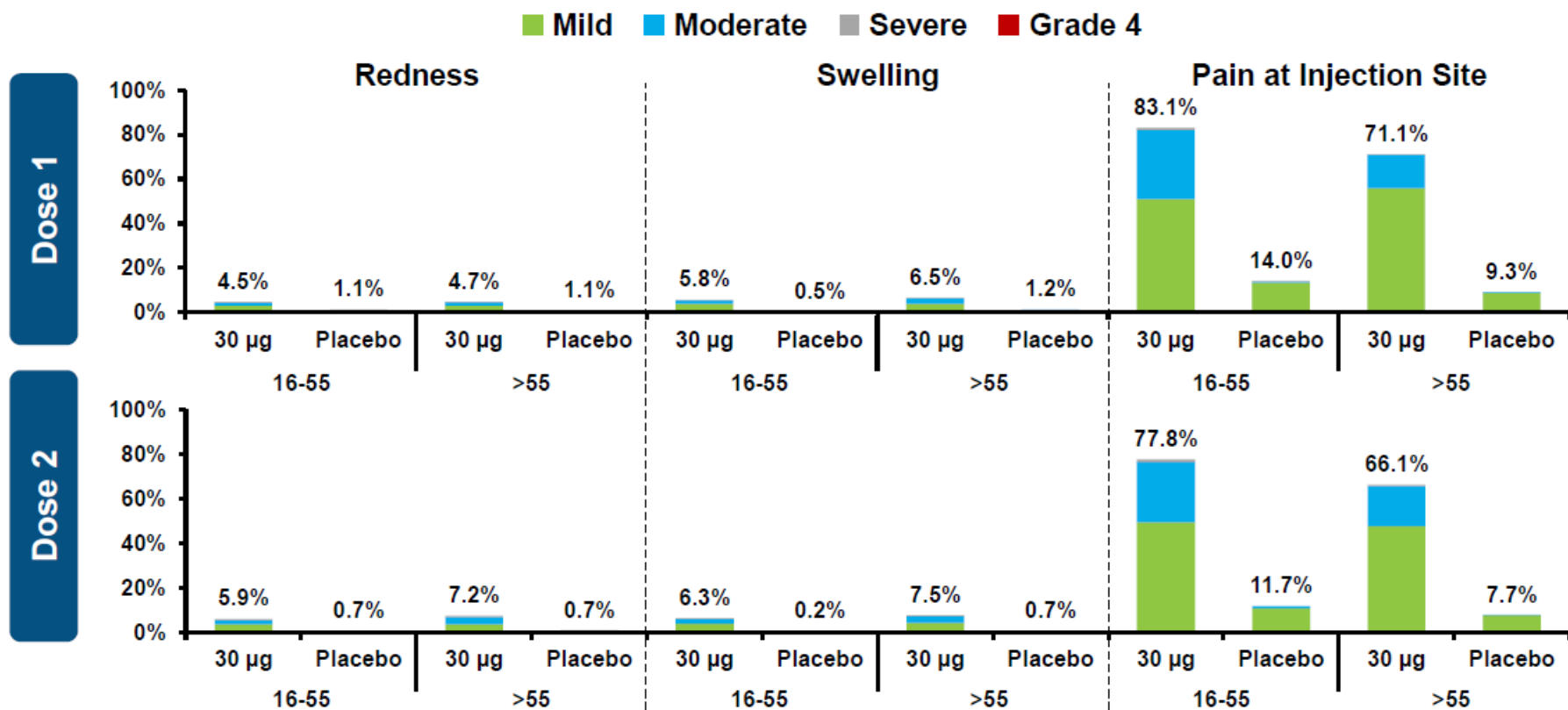


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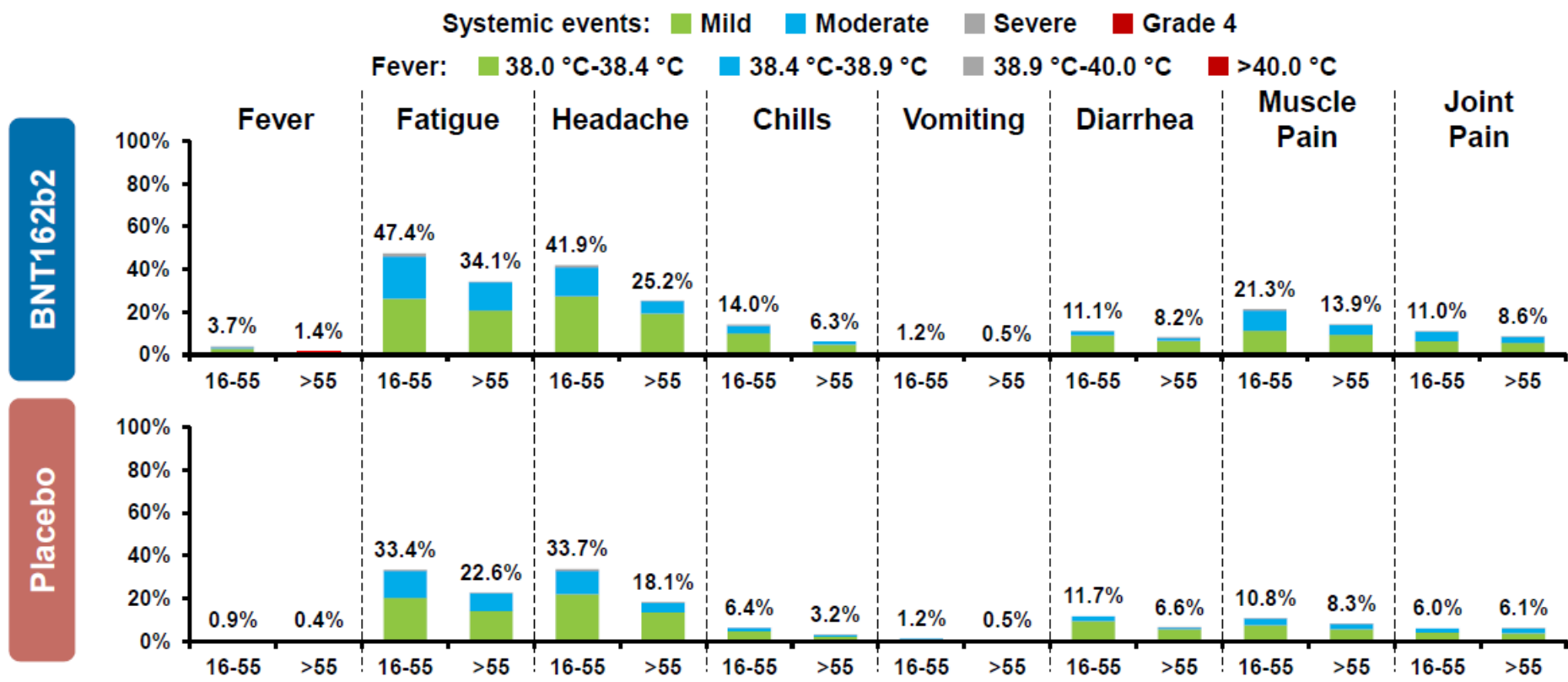
Pfizer-BioNTech Vaccine Safety

eDiary: Local Events Within 7 Days From Dose 1 and 2 in 16-55 and >55 Year Olds (N=8,183)



Pfizer-BioNTech Vaccine Safety

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



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Gruber. ACIP. 12/11/2021

Anaphylaxis Events After mRNA COVID-19 Vaccines

	Pfizer/BioNTech	Moderna
Doses administered	9,943,247	7,581,429
Anaphylaxis	50	21
Rate per doses administered	5.0 per million	2.8 per million

Reporting period: December 14, 2020-January 18, 2021



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Shimabukuro, ACIP, 1/27/2021

Observation period following vaccination

- History of immediate allergic reaction (any severity) to a vaccine or injectable therapy
- Contraindication to a different type of COVID-19 vaccine
- History of anaphylaxis (due to any cause)

All other persons



30 minutes



15 minutes



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Myocarditis/Pericarditis

- European Medical Agency requested Pfizer and Moderna data in 5/2021
- CDC: US numbers have not been more than historic background
- Ongoing investigations



Janssen COVID-19 Vaccine

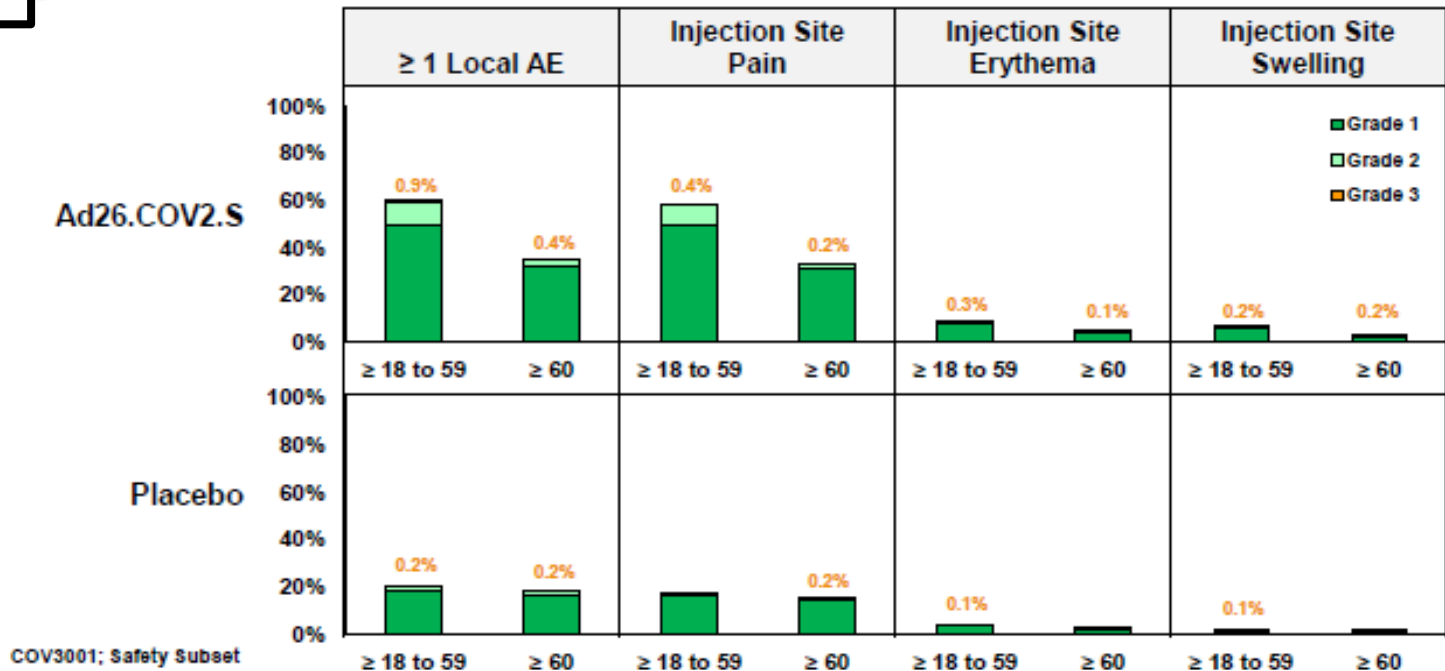


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**Janssen
COVID-19
Vaccine**

**Local Adverse Events, Nearly All Grade 1 and 2
in Severity, All Events Resolved 2-3 Days After Injection**



Douguih, ACIP, February 28, 2021

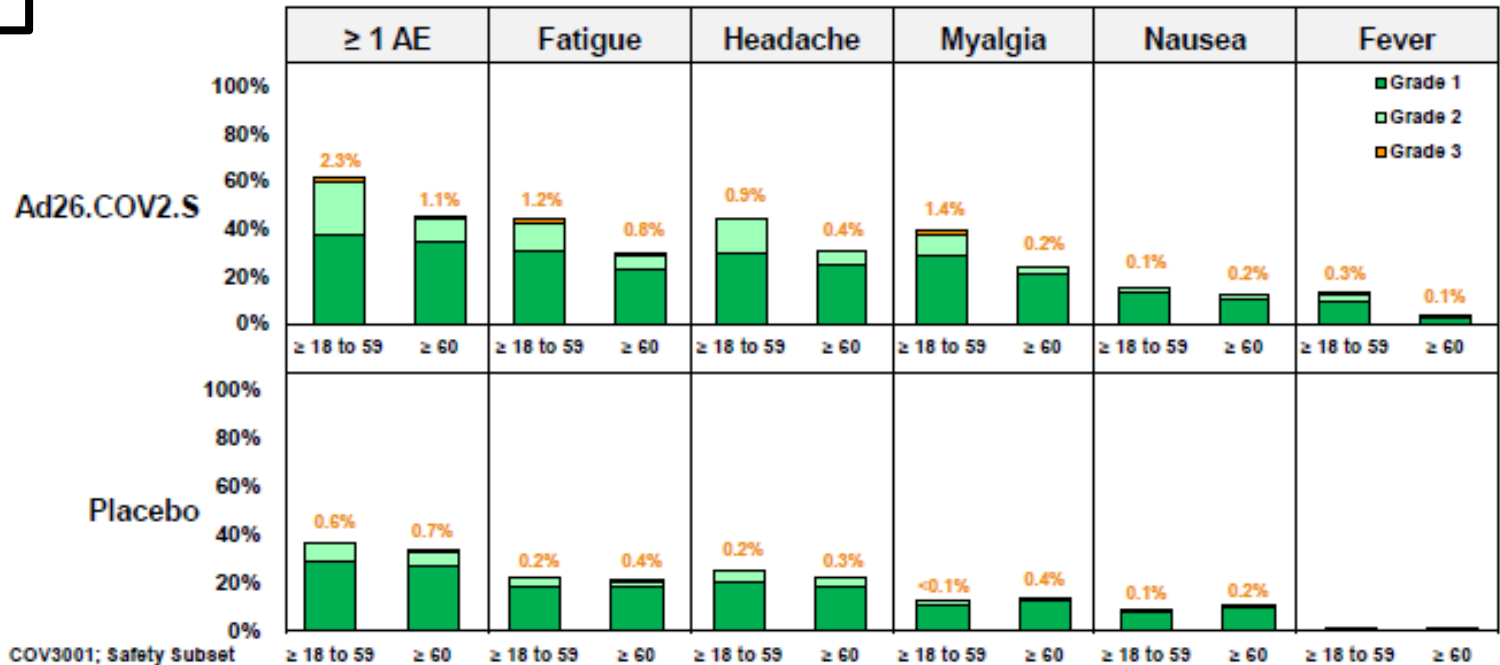


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**Janssen
COVID-19
Vaccine**

Systemic Adverse Events Transient with Median Duration of 1-2 Days



Douguih, ACIP February 28, 2021



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Cranial Venous Sinus Thrombosis after COVID-19 Vaccines

- Rare occurrence with AstraZeneca vaccine
- Janssen COVID-19 vaccine
 - After 6.86 million doses → 6 cases
 - Rate of 0.87 per million doses



Cerebral venous sinus anatomy

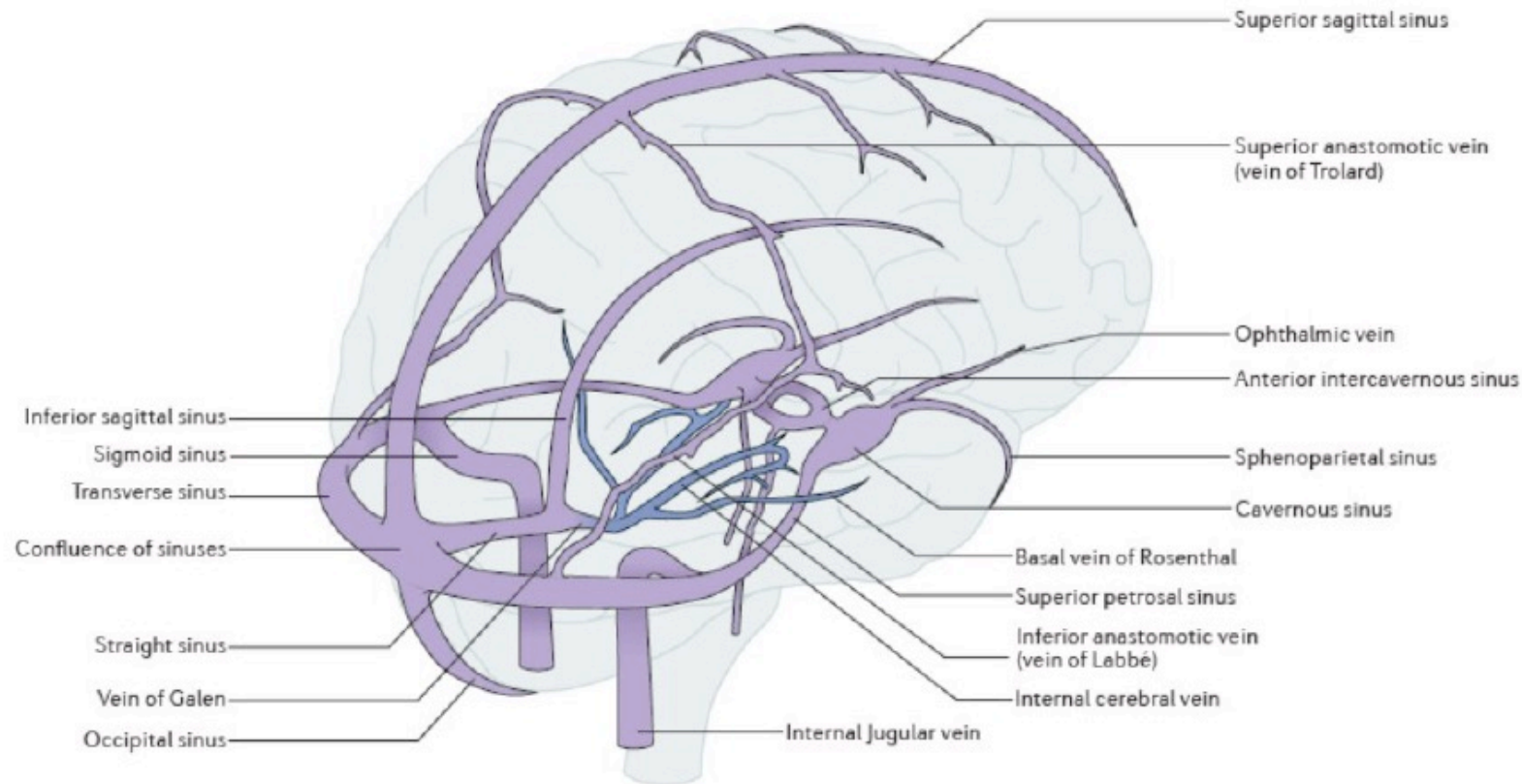


Figure 1 | **Anatomy of the cerebral venous system.** Diagram showing the main components of the cerebral venous system. Blue vessels represent the deep venous system.

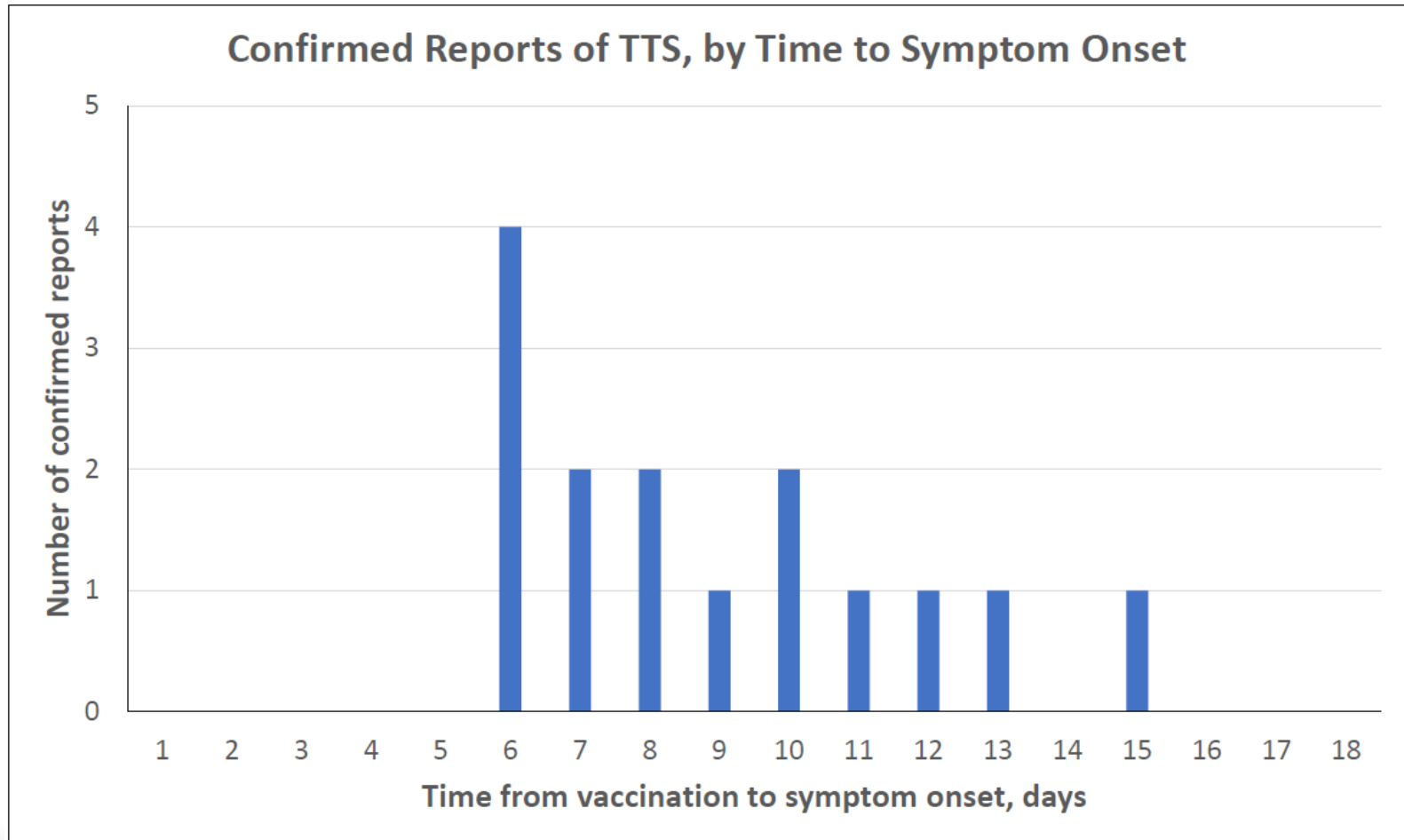


Thrombotic Thrombocytopenic Syndrome (TTS)

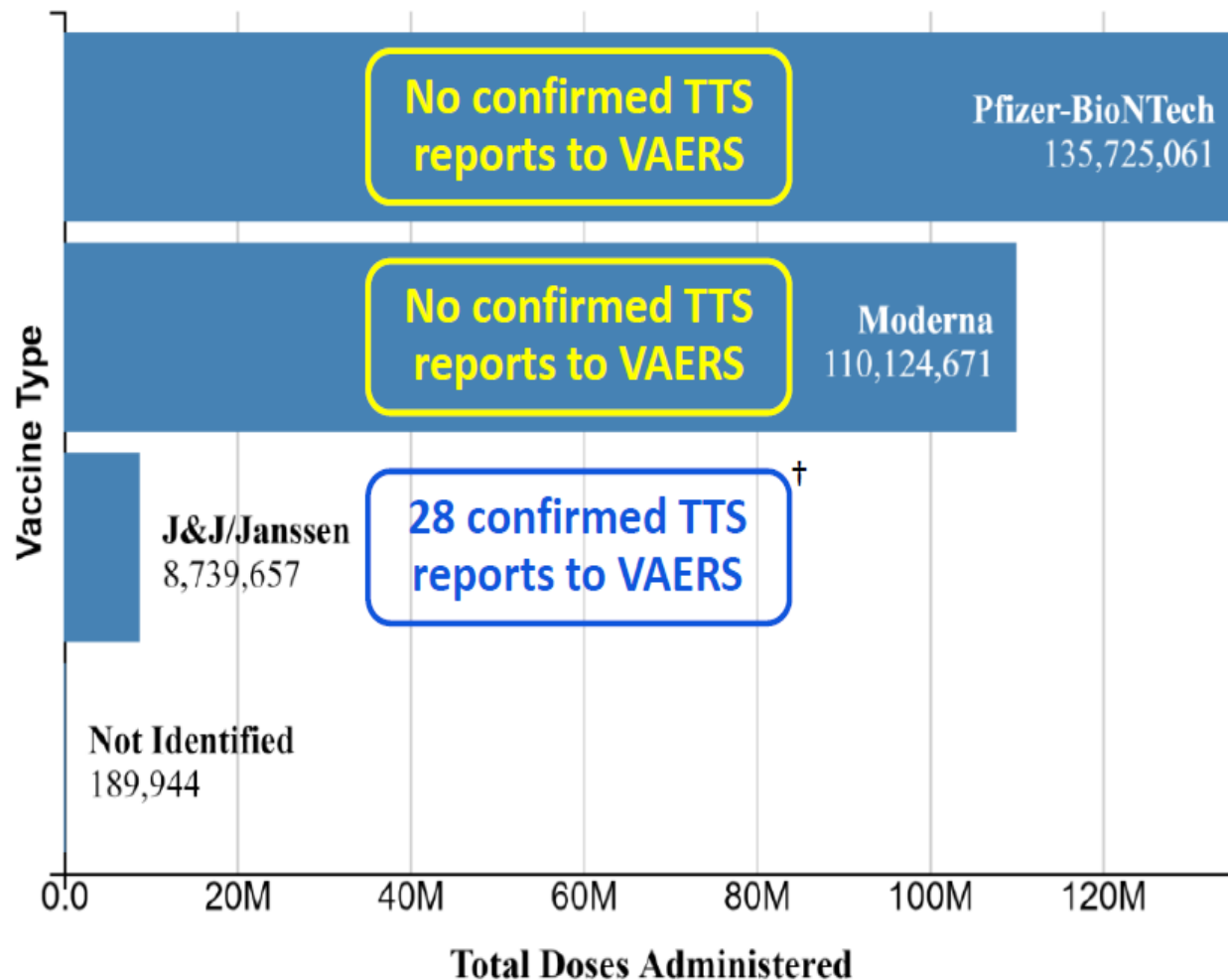
- Blood clots with low platelets
 - Rare locations
 - Cranial veins; intra-abdominal
 - Common locations
 - Deep vein thrombosis; pulmonary emboli



TTS from Vaccine to Symptom Onset



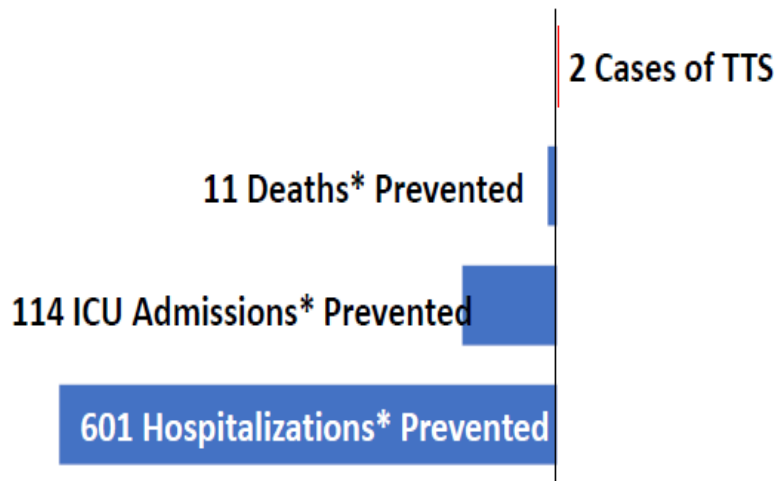
U.S. COVID-19 vaccine administration by product type and TTS reports to VAERS (as of May 7, 2021)*



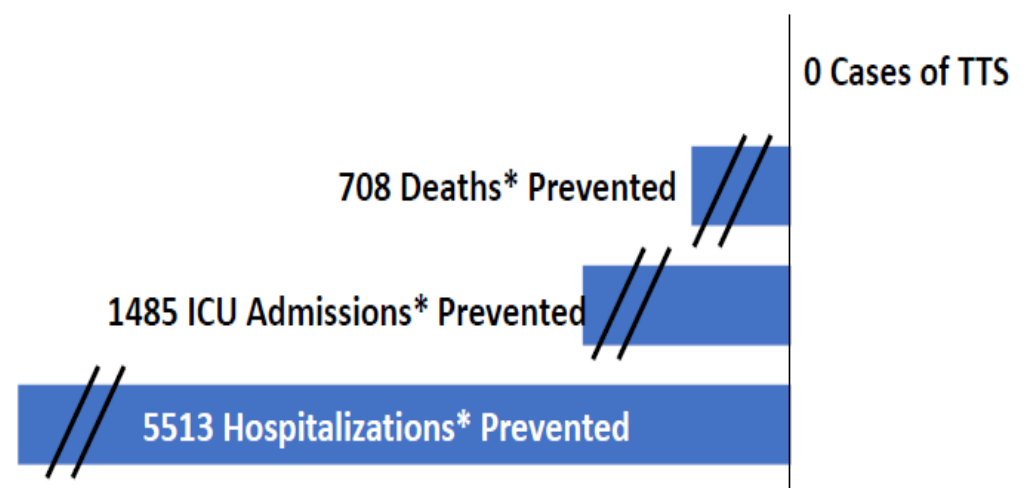
Risks and benefits males, by age group

For every **1 million** doses of vaccine given with current US exposure risk¹

Males 18-49[†]



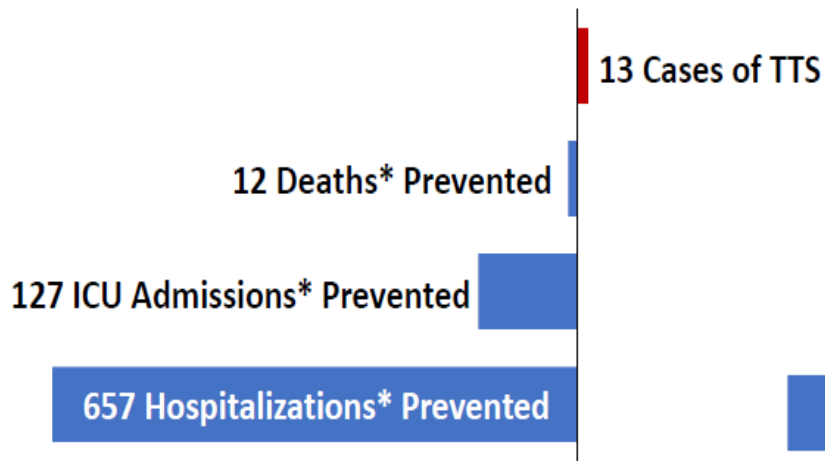
Males 50+



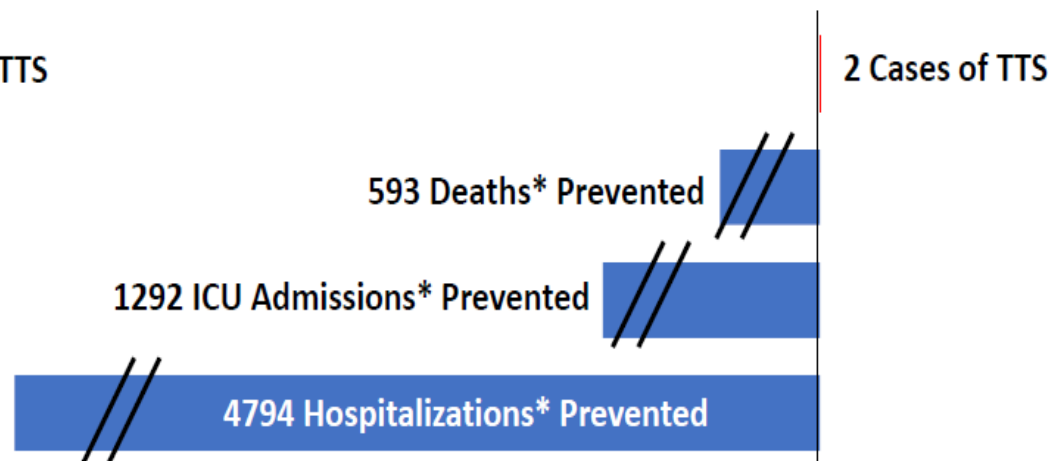
Risks and benefits females, by age group

For every **1 million** doses of vaccine given with current US exposure risk¹

Females 18-49



Females 50+



Known side effects from COVID-19 vaccines

Local

- Pain
- Swelling
- Redness

Systemic

- Fever
- Chills
- Headache
- Tiredness
- Muscle aches
- Joint aches

Rare

- Anaphylaxis
(mRNA)
- TTS
(Janssen)



Symptoms After COVID-19 Vaccine That Are NOT Due to the Vaccine

- Cough
- Shortness of breath
- Runny nose
- Sore throat
- Loss of taste or smell



COVID-19 Infection Is Not Safe

- Arizona
 - Deaths: 17,715
 - Cases: 885,042
- WHO reports
 - Deaths: 3,744,408
 - Cases: 173,674,509
- United States
 - Deaths: 595,625
 - Cases: 33,224,075

As of June 9, 2021



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Disease is bad.

Vaccines are good.



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THANK YOU

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www.azhealth.gov



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