



# Update: v-safe after vaccination health checker

**Advisory Committee on Immunization Practices (ACIP) meeting**

**April 19, 2023**

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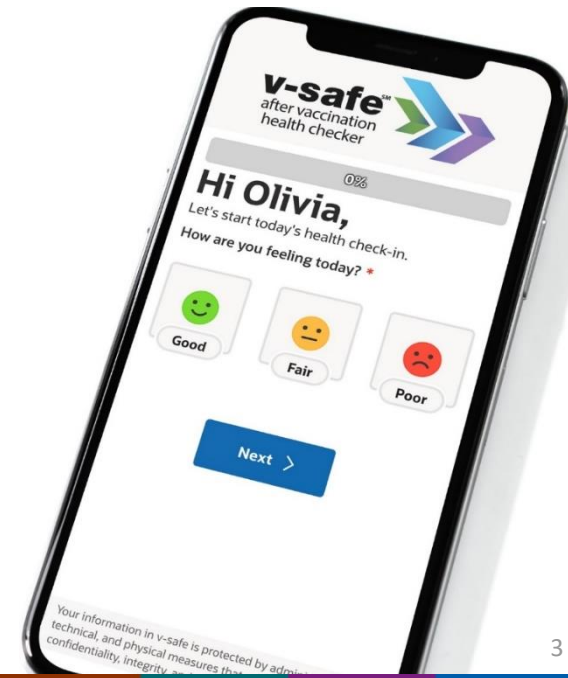
Centers for Disease Control and Prevention (CDC)

# Topics

- Overview of v-safe
- Contributions of v-safe to the COVID-19 response
- Historical and current participation in v-safe
- Planning for the wind-down of the current system and development of next version of v-safe
- Continued safety monitoring of COVID-19 vaccines

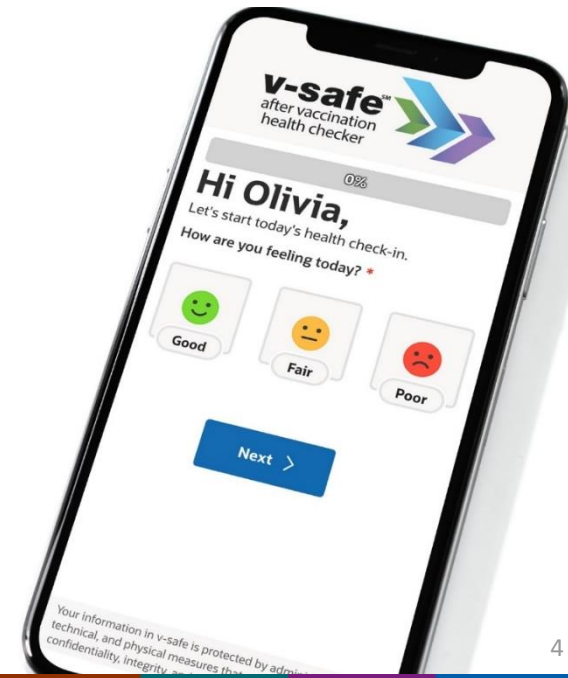
# Overview of v-safe for COVID-19 vaccines

- Implemented December 2020
- Designed to collect near-real time data by direct outreach to COVID-19 vaccine recipients
  - Initially conceived to rapidly collect basic safety data (local and systemic reactogenicity, health impacts) at the onset of the COVID-19 vaccination program to provide early data while other systems, such as VAERS and the Vaccine Safety Datalink, were accruing data
  - Identified vaccinated pregnant persons for possible enrollment in the COVID-19 Vaccine Pregnancy Registry
  - Was useful in rapidly collecting early safety data when authorizations and recommendations expanded to other age and risk groups (e.g., additional doses for immunocompromised persons)
  - Was quickly adapted to capture simultaneous administration of other non-COVID vaccines (e.g., flu vaccine)
- Designed, built, and supported in collaboration with Oracle Health Services under a donation agreement with HHS



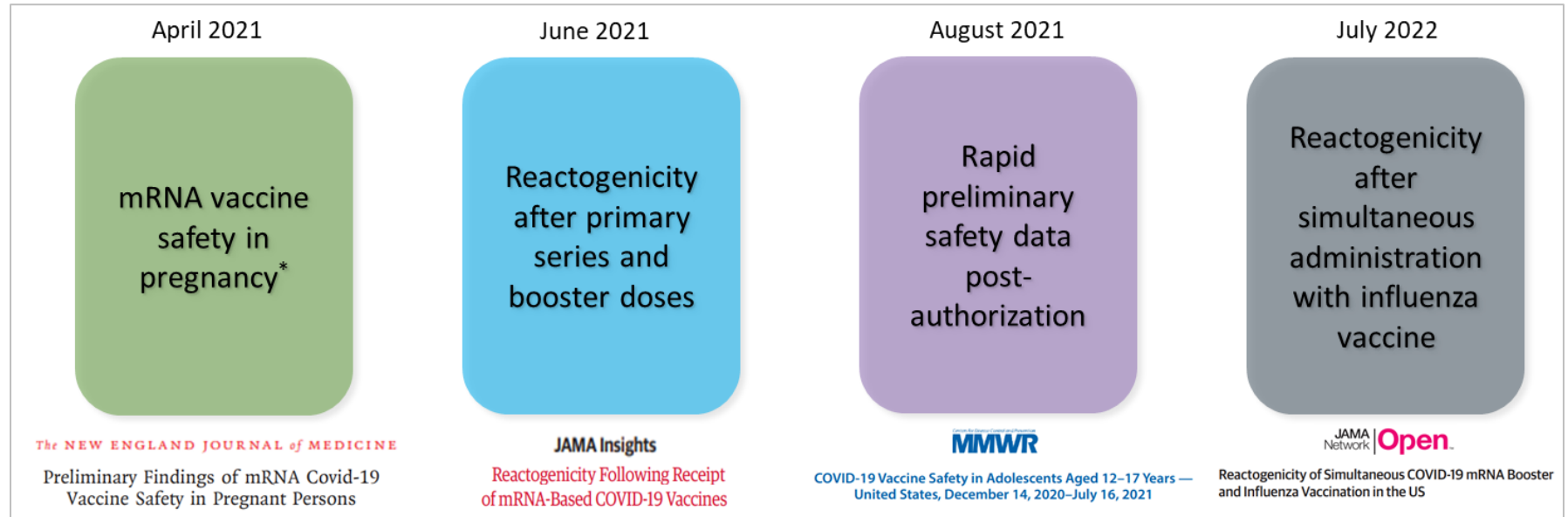
# Overview of v-safe for COVID-19 vaccines (continued)

- Enrollment by self-registration on smartphone with any dependents added to guardian's account
- Survey completion prompted by text message reminders for "health check-ins"
- Call follow-up to all participants who report a medically attended event
- Robust participation in its first year
  - 9.3 million participants / 131 million health surveys completed
- Total participation to date
  - 10.1 million participants / 151 million health surveys completed



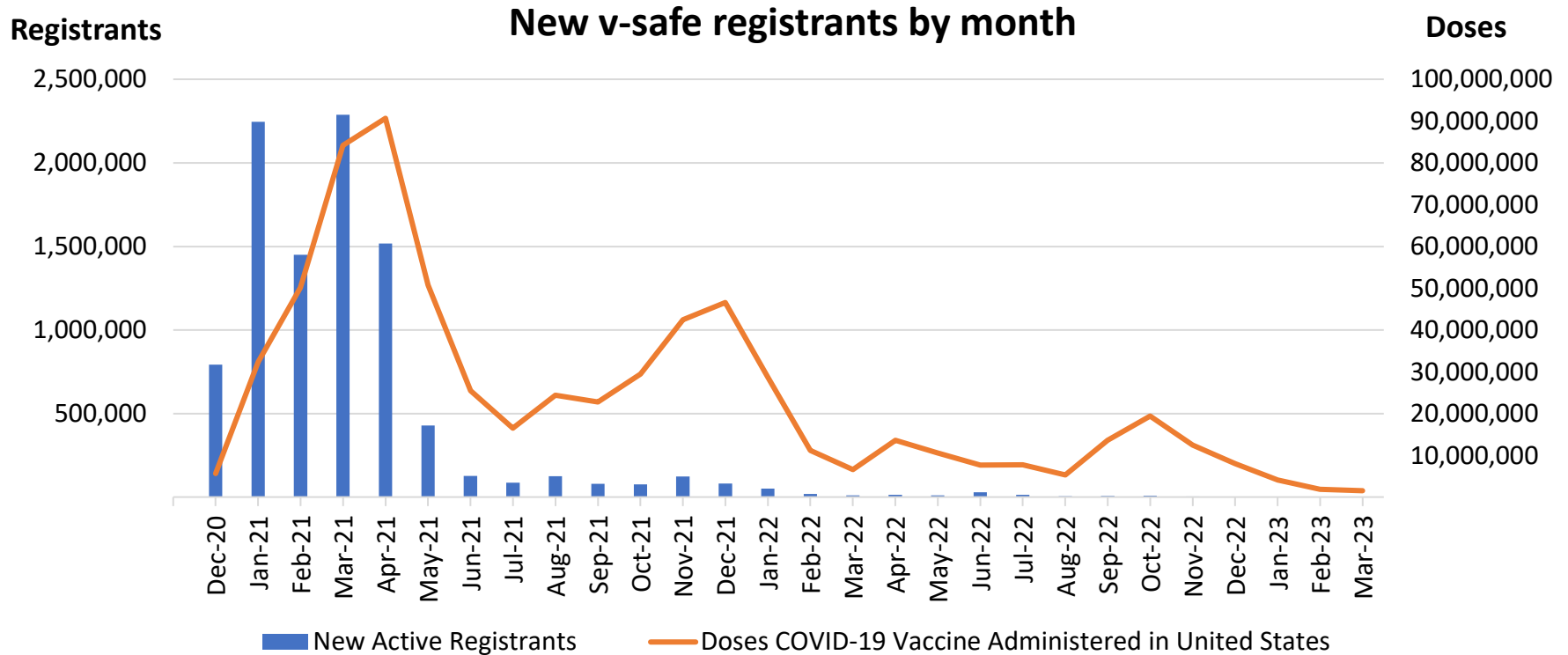
# Key contributions of v-safe to COVID-19 vaccine safety

- V-safe has been particularly effective in characterizing the basic safety of COVID-19 vaccines during early vaccine introduction and following new authorizations and recommendations
- V-safe successfully accomplished its mission and worked as intended



\*V-safe identifies pregnant people for enrollment in [Vaccine Pregnancy Registry | CDC](#)

# Participation in v-safe for COVID-19 vaccines



Active registrants defined as those completing at least one survey by April 9, 2023

Doses COVID-19 vaccine administered sourced from COVID Data Tracker

## Next steps for v-safe

- Timing for final registration and completing surveys will be announced soon
- Follow up will continue on reports of medically attended health events
- Next generation v-safe is under development
  - Plans to collect data on new vaccines
  - Will allow greater flexibility for surveys and use CDC IT infrastructure
  - Designed to permit longer-term support for collecting data rapidly from a large number of vaccine recipients

# CDC vaccine safety monitoring for COVID-19 vaccines

- Safety monitoring and assessment of COVID-19 vaccines will continue in:
  - Vaccine Adverse Events Reporting System (VAERS)  
[VAERS | Vaccine Safety | CDC, Vaccine Adverse Event Reporting System \(VAERS\) \(hhs.gov\)](#)
  - Vaccine Safety Datalink (VSD)  
[Vaccine Safety Datalink \(VSD\) | VSD | Monitoring | Ensuring Safety | Vaccine Safety | CDC](#)
  - Clinical Immunization Safety Assessment (CISA) Project  
[Clinical Immunization Safety Assessment \(CISA\) Project | CISA | Monitoring | Ensuring Safety | Vaccine Safety | CDC](#)



# CDC vaccine safety monitoring

- Strong, complementary systems are in place—both new and established

VAERS



VSD



CISA Project



v-safe



**Full list of U.S. COVID-19 vaccine safety monitoring systems**

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>

Vaccine Adverse Event Reporting System (VAERS), Vaccine Safety Datalink (VSD), Clinical Immunization Safety Assessment (CISA)

# Acknowledgements

- CDC Immunization Safety Office
  - V-safe Team
- COVID-19 Vaccine Task Force Data Monitoring and Reporting Group
- CDC NCEZID and DHQP Communications Teams
- Oracle Health Services
- Participants in v-safe



For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Photo credit: James Gathany  
(<https://phil.cdc.gov/Details.aspx?pid=8876>)

