

# COVID-19 Vaccine Safety Technical (VaST) Subgroup

## Introduction

Grace M. Lee, MD MPH

VaST Co-Chair

Advisory Committee on Immunization Practices

January 27, 2021



# COVID-19 Vaccine Safety Technical (VaST) Subgroup

## Objectives

- Review, evaluate, and interpret post-authorization/approval COVID-19 vaccine safety data
- Serve as the central hub for technical subject matter expertise from federal agencies conducting post-authorization/approval safety monitoring
- Advise on analyses, interpretation, and data presentation
- Provide updates to the ACIP COVID-19 Vaccines Working Group and the ACIP on COVID-19 vaccine safety

# COVID-19 Vaccine Safety Technical (VaST) Subgroup

- Ensure independence, transparency, and public accountability
- Composition
  - Co-chairs: Grace Lee (ACIP) and Bob Hopkins (NVAC)
  - Members: ACIP and NVAC representation independent expert consultants
  - 2 CDC co-leads
  - 8 ACIP ex officio members (FDA, NIH, OIDP, CMS, HRSA, IHS) and liaisons (VA , DoD)

# VaST Activities

## Pre-authorization

Jun – Oct 2020

- 10 meetings to prepare for vaccine safety surveillance

Nov – mid Dec 2020

- Transition to Vaccine Safety Data Review Group
- 4 meetings to review methods for vaccine safety monitoring and to finalize VaST procedures

## ACIP Recommendations

Dec 12

- ACIP vote for Pfizer/BioNTech

Dec 14

- 1<sup>st</sup> dose administered on in the U.S.

Dec 19

- ACIP vote for Moderna

## Post-authorization

Dec 21

- First call to review safety data, one week after the start of vaccine administration in the U.S.

Dec 21 – present

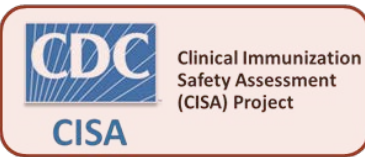
- 6 meetings to date to review post-authorization data



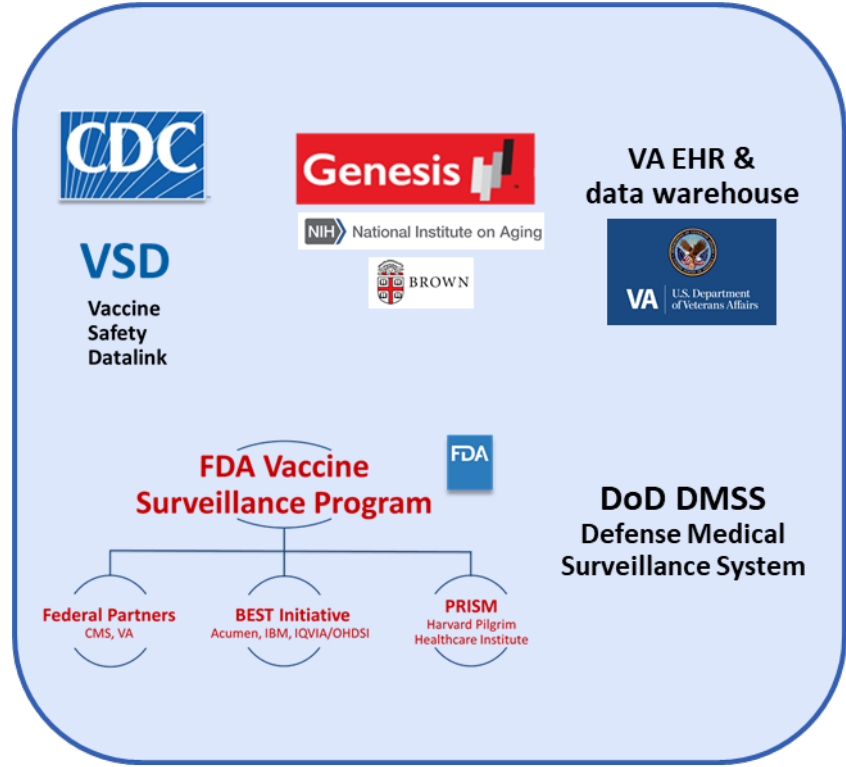
**active  
surveillance**



**passive  
surveillance**



**individual  
case consults**



**active surveillance, passive  
surveillance, case consults**

**large-linked  
database monitoring**

**safety monitoring timeline**

# VaST Procedures

- *Data* - Weekly review of available data on vaccine administration and adverse events of special interest (AESI)
- *Shared learning* - All members, federal partners, and subject matter experts are present for presentation of data
- *Independence* – VaST members discuss findings independently
- *Reports* – Summary and interpretation of aggregate data provided to the ACIP Secretariat on a regular basis

# Outline of Today's Session

- COVID-19 vaccine safety update
- COVID-19 Vaccine Safety Technical (VaST) Subgroup discussion and interpretation

# VaST Members

## Co-Chairs

Grace Lee (ACIP)

Robert Hopkins (NVAC)

## ACIP Members

Beth Bell

Matt Daley

Veronica McNally

Kiepp Talbot

## Expert Consultants

Kathy Edwards

Lisa Jackson

Martin Kulldorff

Laura Riley

Robert Schechter

Patricia Whitley-Williams

## CDC Co-Leads

Lauri Markowitz

Melinda Wharton

## Ex Officio and Liaison Representatives

Tatiana Beresnev (NIH)

Steven Anderson; Karen Farizo; Richard Forshee;  
Narayan Nair; Hui Lee Wong (FDA)

Judith Steinberg (OIDP)

Jeffrey Kelman (CMS)

Matthew Clark (IHS)

Mary Rubin (HRSA)

Fran Cunningham (VA)

Limone Collins (DoD)

## Administrative Support

Susan Hiers

Jared Woo