

COVID-19 Vaccine Safety Technical (VaST) Subgroup

Introduction

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VaST Co-Chair

Advisory Committee on Immunization Practices

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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

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ACIP Recommendations

Dec 12

- ACIP vote for Pfizer/BioNTech

Dec 14

- 1st dose administered on in the U.S.

Dec 19

- ACIP vote for Moderna

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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

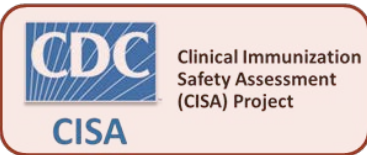
- 6 meetings to date to review post-authorization data



**active
surveillance**



**passive
surveillance**



**individual
case consults**

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

**large-linked
database monitoring**

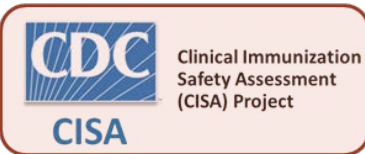
safety monitoring timeline



active
surveillance

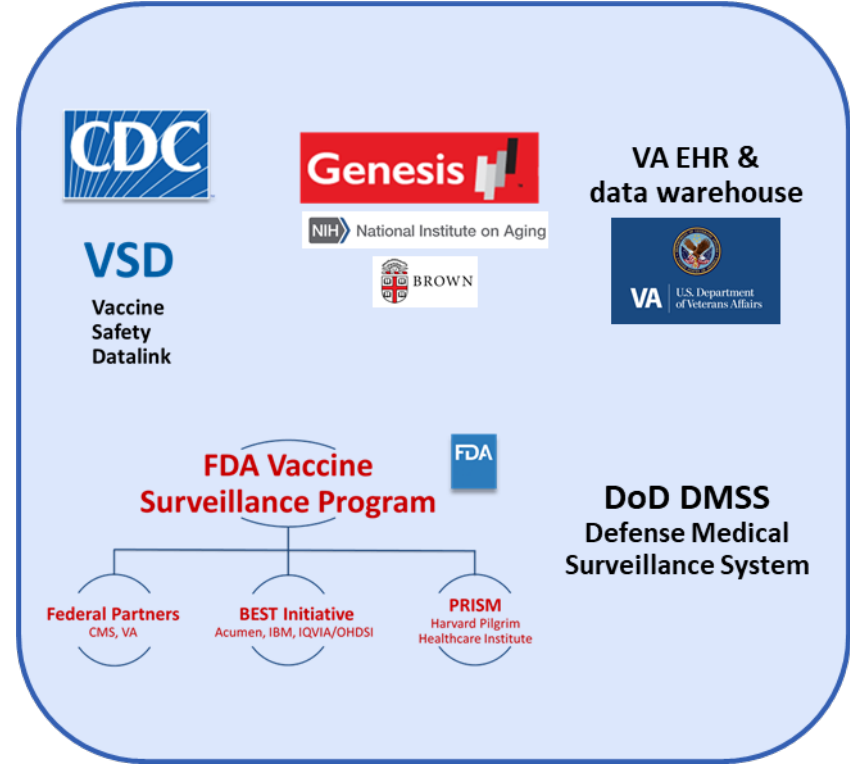


passive
surveillance



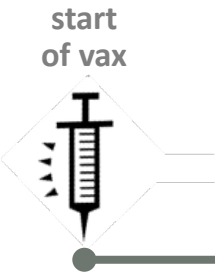
individual
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active surveillance, passive
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large-linked
database monitoring

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