ACIP COVID-19 Vaccines Work Group

Dr. Beth Bell, Work Group Chair

November 23, 2020
Background

- ACIP responding to ongoing pandemic and accelerated vaccine development through scheduling of additional ACIP meetings

- At the October 30th meeting, ACIP reviewed:
  - Updates from VRBPAC meeting
  - Development program from 2 COVID-19 vaccine manufacturers
  - Updates on vaccine implementation and communication plans
  - Post-authorization safety monitoring
  - Ethical principles and modeling strategies for initial allocation of COVID-19 vaccines
  - Updates to immunity and epidemiology
  - Work Group interpretation of data
  - Policy questions, Evidence to Recommendation Framework and Outcomes
COVID-19 Work Group activities – October 2020

- COVID-19 Vaccine Work Group meets weekly

- Topics covered in November:
  - Ethical principles for allocating initial supplies of COVID-19 vaccine
  - Current evidence for each domain in Evidence to Recommendation Framework
  - Further discussions around initial allocation recommendations
Today’s agenda

- EtR Framework: Public Health Problem, Resource Use and Equity Domains: Dr. Sara Oliver (CDC)
- EtR Framework: Values, Acceptability and Feasibility Domains: Dr. Sara Oliver (CDC)
- Phased Allocation of COVID-19 Vaccines: Dr. Kathleen Dooling (CDC)
Vaccine Update

- Over 200 COVID-19 vaccines currently under development

- Within the United States:
  - Four vaccines in Phase III clinical trials
  - Six vaccines in Phase I/II clinical trials

Phase III Results from Two mRNA Vaccines

- **BNT162b2 vaccine (Pfizer/BioNtech)**
  - Final analysis of **170** cases
    - 162 cases in placebo group
    - 8 cases in vaccine group
  - **95%** effective 7 days post dose 2
  - **94%** effective in adults ≥65 years of age
  - 10 severe cases, 9 in placebo group
  - DSMB: no serious safety concerns
  - EUA submission Friday Nov 20, 2020

- **mRNA-1273 vaccine (Moderna)**
  - Interim analysis of **95** cases
    - 90 cases in placebo group
    - 5 cases in vaccine group
  - **94.5%** effective 2 weeks post dose 2
  - 11 severe cases, all in placebo group
  - DSMB: no serious safety concerns
  - EUA submission soon

*Information from manufacturer press releases*

## COVID-19 vaccines in human clinical trials – United States*

<table>
<thead>
<tr>
<th>Candidate</th>
<th>Manufacturer</th>
<th>Type</th>
<th>Phase</th>
<th>Schedule</th>
<th>Age</th>
<th>Size</th>
<th>Trial #</th>
<th>Recruiting</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNA-1273</td>
<td>Moderna</td>
<td>mRNA</td>
<td>III</td>
<td>2 doses (0, 28d)</td>
<td>≥18 years</td>
<td>30,000 participants</td>
<td>NCT04470427</td>
<td>Enrollment complete</td>
</tr>
<tr>
<td>mRNA-BNT162</td>
<td>Pfizer, Inc./BioNTech</td>
<td>mRNA</td>
<td>III</td>
<td>2 doses (0, 21d)</td>
<td>12-85 years</td>
<td>44,000 participants</td>
<td>NCT04368728</td>
<td>✓</td>
</tr>
<tr>
<td>AZD1222</td>
<td>U of Oxford/AstraZeneca</td>
<td>Viral vector (Non-replicating)</td>
<td>III</td>
<td>2 doses (0, 28d)</td>
<td>≥18 years</td>
<td>40,000 participants</td>
<td>NCT04516746</td>
<td>✓</td>
</tr>
<tr>
<td>Ad26COVS1</td>
<td>Janssen</td>
<td>Viral vector (Non-replicating)</td>
<td>III</td>
<td>1 dose</td>
<td>≥18 years</td>
<td>30,000 participants</td>
<td>NCT04614948</td>
<td>✓</td>
</tr>
<tr>
<td>NVX-CoV2373</td>
<td>Novavax</td>
<td>Protein Subunit</td>
<td>I/II</td>
<td>2 doses (0, 21d)</td>
<td>18-84 years</td>
<td>1400 participants</td>
<td>NCT04368988</td>
<td>Enrollment complete</td>
</tr>
<tr>
<td>--</td>
<td>Sanofi/GSK</td>
<td>Protein Subunit</td>
<td>I/II</td>
<td>1 dose or 2 doses (0, 21d)</td>
<td>≥18 years</td>
<td>440 participants</td>
<td>NCT04537208</td>
<td>✓</td>
</tr>
</tbody>
</table>

*As of Nov 21, 2020

# COVID-19 vaccines in human clinical trials – United States

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<th>Trial #</th>
<th>Recruiting</th>
</tr>
</thead>
<tbody>
<tr>
<td>V591</td>
<td>Merck</td>
<td>Viral Vector (Replicating)</td>
<td>I/II</td>
<td>2 doses (1, 57d)</td>
<td>≥18 years</td>
<td>260 participants</td>
<td>NCT04498247</td>
<td>✓</td>
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<tr>
<td>VXA-CoV2-1</td>
<td>Vaxart</td>
<td>Viral vector (Non-replicating)</td>
<td>I</td>
<td>2 doses (1, 29d) *Oral</td>
<td>18-54 years</td>
<td>48 participants</td>
<td>NCT04563702</td>
<td>✓</td>
</tr>
<tr>
<td>INO-4800</td>
<td>Inovio</td>
<td>DNA plasmid</td>
<td>I</td>
<td>2 doses (0, 4w) *Electroporation</td>
<td>≥18 years</td>
<td>120 participants</td>
<td>NCT04336410</td>
<td>Active, not recruiting</td>
</tr>
<tr>
<td>AV-COVID-19</td>
<td>Aivita</td>
<td>AuDendritic cell</td>
<td>I/II</td>
<td>1 dose</td>
<td>≥18 years</td>
<td>180 participants</td>
<td>NCT04386252</td>
<td>Not yet recruiting</td>
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</table>
COVID-19 vaccines in human clinical trials outside United States – Phase III actively recruiting*

**Inactivated Vaccines**  
4 inactivated vaccines candidates are in Phase I/II

<table>
<thead>
<tr>
<th>Candidate</th>
<th>Manufacturer/Institute</th>
<th>Type</th>
<th>Location</th>
<th>Phase</th>
<th>Trial number</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIBP/Sinopharm</td>
<td>Beijing Institute of Biological Products/Sinopharm</td>
<td>Inactivated</td>
<td>Argentina</td>
<td>Phase III</td>
<td>NCT04560881</td>
</tr>
<tr>
<td>BBIBP-CoRv</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sinovac CoronaVac</td>
<td>Sinovac/Instituto Butantan</td>
<td>Inactivated</td>
<td>Turkey, Brazil, Indonesia</td>
<td>Phase III</td>
<td>NCT04582344; NCT04456595; NCT04508075</td>
</tr>
<tr>
<td>WIBP vaccine</td>
<td>Wuhan Institute of Biological Products/Sinopharm</td>
<td>Inactivated</td>
<td>Morocco</td>
<td>Phase III</td>
<td>ChiCTR2000039000</td>
</tr>
<tr>
<td>WIBP/BIBP/Sinopharm vaccines</td>
<td>Beijing Institute of Biological Products/Wuhan Institute of Biological Products/Sinopharm</td>
<td>Inactivated</td>
<td>UAE, Bahrain, Jordan, Egypt</td>
<td>Phase III</td>
<td>NCT04510207</td>
</tr>
</tbody>
</table>

**Protein Subunit Vaccines**  
11 protein subunit vaccines candidates are in Phase I/II

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<tr>
<th>Candidate</th>
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<th>Type</th>
<th>Location</th>
<th>Phase</th>
<th>Trial number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novavax NVX-CoV2373</td>
<td>Novavax</td>
<td>Protein subunit</td>
<td>UK</td>
<td>Phase III</td>
<td>NCT04583995</td>
</tr>
</tbody>
</table>

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COVID-19 vaccines in human clinical trials outside United States – Phase III actively recruiting*

### Viral Vector Vaccines (non-replicating)

7 non-replicating viral vector vaccines candidates are in Phase I/II

<table>
<thead>
<tr>
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<th>Type</th>
<th>Location</th>
<th>Phase</th>
<th>Trial number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cansino Ad5-nCoV</td>
<td>CanSino Biological Inc/Beijing Institute of Biotechnology</td>
<td>Non-replicating viral vector</td>
<td>Pakistan, Russia</td>
<td>Phase III</td>
<td>NCT04526990; NCT04540419</td>
</tr>
<tr>
<td>Gamaleya Gam-COVID-Vac</td>
<td>Gamaleya Research Institute</td>
<td>Non-replicating viral vector</td>
<td>Belarus, Russia</td>
<td>Phase III</td>
<td>NCT04530396; NCT04564716</td>
</tr>
<tr>
<td>Janssen Ad26.COV2.S</td>
<td>Janssen Pharmaceutical Companies</td>
<td>Non-replicating viral vector</td>
<td>USA, Argentina, Brazil, others</td>
<td>Phase III</td>
<td>NCT04505722</td>
</tr>
<tr>
<td>Oxford ChAdOx1-S</td>
<td>University of Oxford/AstraZeneca</td>
<td>Non-replicating viral vector</td>
<td>UK, Brazil, India, South Africa</td>
<td>Phase II/III</td>
<td>NCT04400838; NCT04536051; CTRI/2020/08/027170</td>
</tr>
</tbody>
</table>

### RNA Vaccines

7 RNA vaccines candidates are in Phase I/II

<table>
<thead>
<tr>
<th>Candidate</th>
<th>Manufacturer/Institute</th>
<th>Type</th>
<th>Location</th>
<th>Phase</th>
<th>Trial number</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioNTech BNT162 (b1/b2)</td>
<td>BioNTech/Fosun Pharma/Pfizer</td>
<td>RNA</td>
<td>USA, Argentina, Brazil, others</td>
<td>Phase II/III</td>
<td>NCT04368728</td>
</tr>
</tbody>
</table>

*As of Nov 21, 2020

Work group members

ACIP members
- Beth Bell (chair)
- Grace Lee
- Jose Romero
- Keipp Talbot

Ex-officio/government members
- FDA: Doran Fink, Rachel Zhang
- NIH: Chris Roberts
- IHS: Thomas Weiser, Jillian Doss-Walker
- DOD: Bryan Schumacher
- CMS: Jeff Kelman
- BARDA: Christine Oshansky
- HHS: David Kim

CDC Co-leads
- Kathleen Dooling
- Sara Oliver

Liaisons
- AAFP: Jonathan Temte
- AAP: Sean O’Leary
- ACOG: Denise Jamieson (primary), Laura Riley (alternate)
- ACP: Jason Goldman
- AGS: Ken Schmader
- AIM: Rob Shechter (primary), Jane Zucker (alternate)
- AMA: Sandra Fryhofer
- ANA: Kendra McMillan (primary), Ruth Francis (alternate)
- APhA: Michael Hogue
- ASTHO: Marcus Plescia
- CSTE: Susan Lett
- IDSA: Jeff Duchin (primary), Carol Baker (alternate)

Liaisons, cont’d
- NACCHO: Matt Zahn (primary), Jeff Duchin (alternate)
- NACI: Matthew Tunis (primary), Linlu Zhao (alternate)
- NFID: Bill Schaffner (primary), Marla Dalton (alternate)
- NMA: Oliver Brooks
- SHEA: Marci Drees

Consultants
- Ed Belongia (safety)
- Matthew Daley (safety)
- Kathy Kinlaw (ethics)
- Dayna Matthew (health equity)
- Kathleen Neuzil (vaccinology)
- Stanley Perlman (microbiology/immunology)
CDC participants

- Doug Campos-Outcalt
- Mary Chamberland
- Thomas Clark
- Amanda Cohn
- Jean Cox-Ganser
- Katie Curran
- Jonathan Duffy
- Anthony Fiore
- Mark Freedman
- Sue Gerber
- Jack Gersten
- Susan Goldstein
- Sam Graitcer
- Lisa Grohskopf
- Rita Helfand
- Terri Hyde
- Tara Jatlaoui
- Cynthia Jorgensen
- Erin Kennedy
- Ram Koppaka
- Jessica MacNeil
- Sarah Mbaeyi
- Nancy McClung
- Lucy McNamara
- Rebecca Morgan
- Titilope Oduyebo
- Christina Ottis
- Anita Patel
- Janell Routh
- Stephanie Schrag
- Tom Shimabukuro
- Natalie Thornburg
- Jennifer Verani
- Megan Wallace
- Cindy Weinbaum
- Yon Yu
- Jane Zucker
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.