Background

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

- At the August 26th meeting, ACIP reviewed:
  - Moderna’s mRNA COVID-19 vaccine clinical development
  - Pfizer/BioNtech’s mRNA COVID-19 vaccine clinical development
  - Overview of post-marketing safety surveillance
  - Epidemiology of individuals at increased risk of severe COVID-19 disease
  - Work Group interpretation
  - Prioritization and Work Group next steps
COVID-19 Work Group activities – September 2020

- COVID-19 Vaccine Work Group meets weekly

- Topics covered in August:
  - Review of published COVID-19 vaccine prioritization and allocation frameworks
  - Qualitative research on a future COVID-19 vaccine
  - Clinical development program for a COVID-19 vaccine, including data from Phase I/II clinical trials and plans for Phase III clinical trials
  - Racial and ethnic disparities in COVID-19 testing, exposure, severity and impact
  - Association between social vulnerability and risk of becoming a COVID-19 hotspot
  - Proposal for Ethics/Equity Framework for COVID-19 vaccine allocation
  - Further discussions regarding COVID-19 vaccine allocation
Today’s agenda

- **Overview of COVID-19 vaccine safety**: Dr. Grace Lee (ACIP)
- **Enhanced vaccine safety surveillance**: Dr. Tom Shimabukuro (CDC)
- **Vaccine implementation**: Dr. Janell Routh (CDC)
- **Disparities in COVID-19 epidemiology**: Dr. Megan Wallace (CDC)
- **Overview of vaccine equity and prioritization frameworks**: Dr. Sara Oliver (CDC)
- **Phase 1 allocation for COVID-19 vaccine: Work Group considerations**: Dr. Kathleen Dooling (CDC)
Considerations for prioritization of COVID-19 vaccines

Today’s session:
- Disparities among COVID-19 disease and proposal for ACIP’s Ethics/Equity Framework
- Review of groups for allocation of initial COVID-19 vaccine

Future sessions:
- Continue to discuss Evidence to Recommendation Framework for COVID-19 vaccines
- Review additional manufacturer data
- Prepare for independent review of safety and efficacy data from Phase III clinical trials
Vaccine Update

- Over 200 COVID-19 vaccines currently under development
- Within the United States:
  - 2 vaccines in Phase III clinical trials, actively enrolling
  - 1 vaccine in Phase III clinical trials, currently on hold
  - 3 vaccines in Phase I/II clinical trials, actively recruiting

- mRNA-1273 vaccine (Moderna)
  - 25,296 participants enrolled as of 9/16/2020
  - 28% of participants enrolled are from “diverse communities”

- BNT162b2 vaccine (Pfizer/BioNtech)
  - 31,928 participants enrolled as of 9/21/2020
  - 26% of participants enrolled have “diverse backgrounds”
  - Proposed expansion to 44,000 participants

Sources:
- https://www.modernatx.com/cove-study
- https://connect.trialscope.com/studies/34986a8ab779-4169-a350-5d929194d428
<table>
<thead>
<tr>
<th>Candidate</th>
<th>Manufacturer</th>
<th>Type</th>
<th>Phase</th>
<th>Trial characteristics</th>
<th>Trial #</th>
<th>Recruiting</th>
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<tbody>
<tr>
<td>mRNA-1273</td>
<td>Moderna TX, Inc.</td>
<td>mRNA</td>
<td>III</td>
<td>2 doses (0, 28d)</td>
<td>NCT04470427</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• IM administration</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>• 18-55, 56+ years</td>
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<tr>
<td>mRNA-BNT162</td>
<td>Pfizer, Inc./BioNTech</td>
<td>mRNA</td>
<td>II/III</td>
<td>Single or 2 doses</td>
<td>NCT04368728</td>
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<td></td>
<td></td>
<td>• 18-85 years</td>
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<td>University of Oxford/AstraZeneca</td>
<td>Viral vector (NR)</td>
<td>III</td>
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<td>NCT04516746</td>
<td>On Hold</td>
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<td>consortium**</td>
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<td></td>
<td>• ≥18 years</td>
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<td>Ad26COV-S1</td>
<td>Janssen Pharmaceutical Companies</td>
<td>Viral vector (NR)</td>
<td>I/II</td>
<td>Single or 2 doses (0,56d)</td>
<td>NCT04436276</td>
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<td>• 18-55, 65+</td>
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<td>--</td>
<td>Sanofi/GSK</td>
<td>Protein Subunit</td>
<td>I/II</td>
<td>Single or 2 doses</td>
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<td>• 18-49, 50+</td>
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<td>NVX-CoV2373</td>
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<td>Protein Subunit</td>
<td>I/II</td>
<td>2 doses (0, 4w)</td>
<td>NCT04368988</td>
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<td>• SC administration/ electroporation</td>
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<td>• ≥18 years</td>
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<td>AV-COVID-19</td>
<td>Aivita</td>
<td>AuDendritic cell</td>
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<td>INO-4800</td>
<td>Inovio Pharmaceuticals, Inc.</td>
<td>DNA plasmid</td>
<td>I</td>
<td>2 doses (0, 4w)</td>
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<td>• SC administration/ electroporation</td>
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<td></td>
<td>• ≥18 years</td>
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*As of September 14, 2020
**Currently on hold in US
# COVID-19 vaccines in human clinical trials outside United States - actively recruiting*  
## Inactivated Vaccines

<table>
<thead>
<tr>
<th>Candidate</th>
<th>Manufacturer</th>
<th>Type</th>
<th>Trial Location</th>
<th>Phase</th>
<th>Trial #</th>
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<tr>
<td>BBIBP-CorV</td>
<td>Beijing Institute of Biological Products/Sinopharm</td>
<td>Inactivated</td>
<td>China, UAE</td>
<td>I/II, III</td>
<td>ChiCTR2000032459, ChiCTR2000034780</td>
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<td>--</td>
<td>Wuhan Institute of Biological Products/Sinopharm</td>
<td>Inactivated</td>
<td>China, UAE</td>
<td>III</td>
<td>ChiCTR2000031809, ChiCTR2000034780</td>
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<td>CoronaVac</td>
<td>Sinovac/Instituto Butantan</td>
<td>Inactivated</td>
<td>Indonesia, Brazil</td>
<td>III</td>
<td>NCT04352608, NCT04383574, NCT04456595</td>
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<tr>
<td>BBV152</td>
<td>Bharat Biotech</td>
<td>Inactivated</td>
<td>India</td>
<td>I/II</td>
<td>CTRI/2020/07/026300, NCT04471519</td>
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<tr>
<td>QazCovid-in</td>
<td>Research Institute for Biological Safety Problems</td>
<td>Inactivated</td>
<td>Kazakhstan</td>
<td>I/II</td>
<td>NCT04530357</td>
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</tbody>
</table>

*Trials outside the United States listed here are limited to those actively recruiting and sorted by vaccine type. Candidates in **bold** are currently approved for emergency/limited use.

*As of September 14, 2020  
Sources:  
- https://milkeninstitute.org/covid-19-tracker  
- https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/  
- https://clinicaltrials.gov/  
COVID-19 vaccines in human clinical trials outside United States - actively recruiting*

Viral Vector Vaccines

<table>
<thead>
<tr>
<th>Candidate</th>
<th>Manufacturer</th>
<th>Type</th>
<th>Trial Location</th>
<th>Phase</th>
<th>Trial #</th>
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<tr>
<td>--</td>
<td>Medicago</td>
<td>VLP</td>
<td>Canada</td>
<td>I</td>
<td>NCT04450004</td>
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<tr>
<td>Oxford ChAdOx1-S</td>
<td>University of Oxford/AstraZeneca</td>
<td>Viral vector (NR)</td>
<td>Brazil, South Africa</td>
<td>III, I/II</td>
<td>NCT04536051, NCT04444674, ISRCTN89951424</td>
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<tr>
<td>aAPC</td>
<td>Shenzhen Geno-Immune Medical Institute</td>
<td>Viral vector</td>
<td>China</td>
<td>I</td>
<td>NCT04299724</td>
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<td>LV-SMENP-DC</td>
<td>Shenzhen Geno-Immune Medical Institute</td>
<td>Viral vector</td>
<td>China</td>
<td>I</td>
<td>NCT04276896</td>
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<tr>
<td>Ad26COVS1</td>
<td>Janssen</td>
<td>Viral Vector (NR)</td>
<td>Belgium, Japan</td>
<td>I/II, I</td>
<td>NCT04436276, NCT04509947</td>
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<td>Gam-COVID-Vac</td>
<td>Gamaleya Research Institute</td>
<td>Viral vector (NR)</td>
<td>Russia</td>
<td>III</td>
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<td>ReiThera GRAd-COV2</td>
<td>ReiThera/Leukocare/Univercells</td>
<td>Viral Vector (NR)</td>
<td>Italy</td>
<td>I</td>
<td>NCT04528641</td>
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<td>Merck V591</td>
<td>Merck</td>
<td>Viral Vector</td>
<td>Belgium</td>
<td>I/II</td>
<td>NCT04498247</td>
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<td>--</td>
<td>Institut Pasteur/ Themis/ University of Pittsburgh CVR/ Merck Sharp &amp; Dohme</td>
<td>Viral vector</td>
<td>France, Belgium</td>
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*As of September 14, 2020

# COVID-19 vaccines in human clinical trials outside United States - actively recruiting*  
Protein Subunit Vaccines

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<th>Type</th>
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<th>Phase</th>
<th>Trial #</th>
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<tr>
<td>NVX-CoV2373</td>
<td>Novavax</td>
<td>Protein subunit</td>
<td>Australia, South Africa</td>
<td>I/II, II</td>
<td>NCT04368988, NCT04533399</td>
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<td>SCB-2019</td>
<td>Clover/GSK/Dynavax</td>
<td>Protein subunit</td>
<td>Australia</td>
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<td>Covax-19</td>
<td>Vaxine</td>
<td>Protein subunit</td>
<td>Australia</td>
<td>I</td>
<td>NCT04453852</td>
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<td>--</td>
<td>University of Queensland/CSL/Seqirus</td>
<td>Protein subunit</td>
<td>Australia</td>
<td>I</td>
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<td>Adimmune AdimirSC-2f</td>
<td>Adimmune Corporation</td>
<td>Protein Subunit</td>
<td>Taiwan</td>
<td>I</td>
<td>NCT04522089</td>
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<td>Covaxx UB-612</td>
<td>Covaxx/University of Nebraska Medical Center</td>
<td>Protein subunit</td>
<td>Taiwan</td>
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*As of September 14, 2020  
COVID-19 vaccines in human clinical trials outside United States - actively recruiting*

<table>
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<tr>
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<th>Manufacturer</th>
<th>Type</th>
<th>Trial Location</th>
<th>Phase</th>
<th>Trial #</th>
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<tr>
<td>CVnCoV</td>
<td>CureVac</td>
<td>mRNA</td>
<td>Belgium, Germany</td>
<td>I/II</td>
<td>NCT04449276, NCT04515147</td>
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<td>BioNTech BNT162</td>
<td>BioNTech/Fosun Pharma/Pfizer (a1/b1/b2/c2)</td>
<td>mRNA</td>
<td>Germany</td>
<td>I/II</td>
<td>NCT04380701</td>
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<td>Arcturus/Duke-NUS</td>
<td>mRNA</td>
<td>Singapore</td>
<td>I/II</td>
<td>NCT04480957</td>
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<td>GX-19</td>
<td>Genexine Consortium</td>
<td>DNA</td>
<td>South Korea</td>
<td>I/II</td>
<td>NCT04445389</td>
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<tr>
<td>--</td>
<td>Osaka University/AnGes</td>
<td>DNA plasmid+adjuvant</td>
<td>Japan</td>
<td>I/II</td>
<td>NCT04463472</td>
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<tr>
<td>Inovio INO-4800</td>
<td>Inovio Pharmaceuticals inc.</td>
<td>DNA</td>
<td>South Korea</td>
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<td>NCT04447781</td>
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<td>DNA plasmid</td>
<td>India</td>
<td>I/II</td>
<td>CTRI/2020/07/026352</td>
</tr>
</tbody>
</table>

*As of September 14, 2020

ACIP: Path to COVID-19 vaccine recommendations

- Currently:
  - Work Group meeting weekly; reviewing Phase I/II data from manufacturers as data are available
  - Designing structure for independent data review that will occur once Phase III data are available

- Once data are available from Phase III Clinical Trials:
  - ACIP Work Group will conduct independent review of safety and efficacy data
    - Evidence to Recommendation (EtR) Framework and GRADE
  - Based on this data review, Work Group will present polity options to full ACIP

- If/when an FDA decision is announced:
  - ACIP will have ‘emergency’ meeting with public comment session
    - Review safety and efficacy data using GRADE/EtR
  - ACIP will vote on recommendations for vaccine, populations for use
    - ACIP recommendations could be more targeted or detailed than FDA “Conditions of Use”

- After an ACIP vote:
  - ACIP submits recommendations to CDC Director
  - If recommendations are accepted, they are published in the MMWR and become official CDC Policy
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: Eric Deussing
- 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
- 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
- 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
For more information, contact CDC
1-800-CDC-INFO (232-4636)

Thank you!

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.