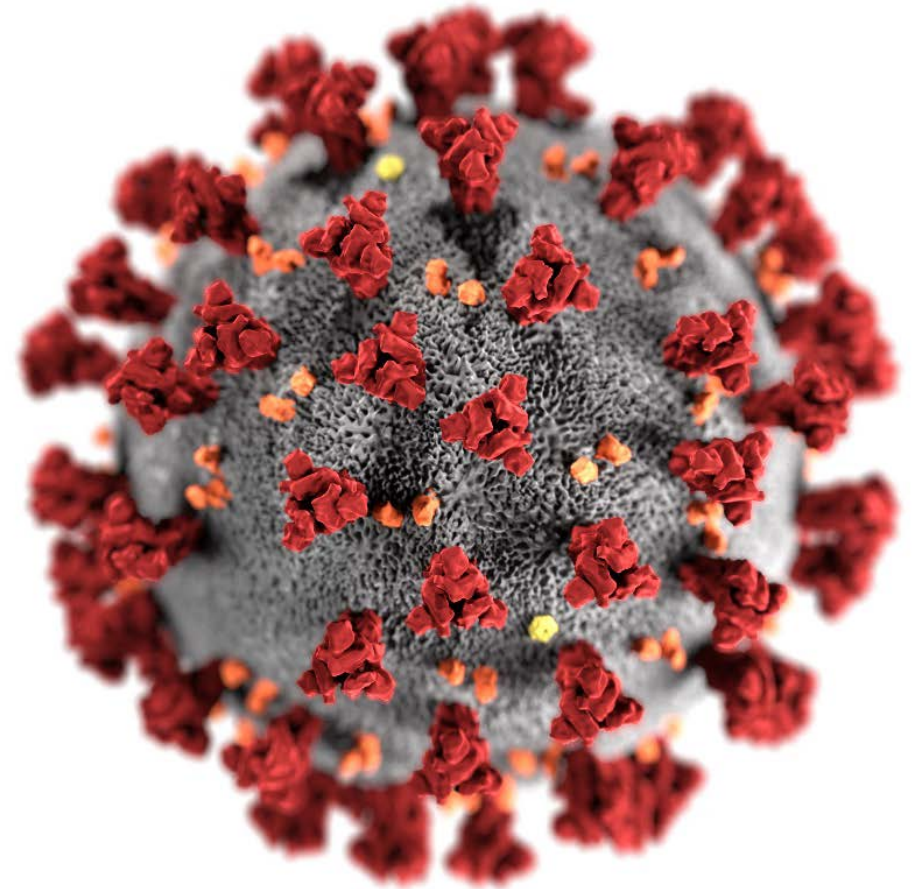


# ACIP COVID-19 Vaccines Work Group

**Dr. Beth Bell, Work Group Chair**

**September 22, 2020**



# Background

- ACIP responding to ongoing pandemic and accelerated vaccine development through scheduling of monthly emergency ACIP meetings
- At the August 26<sup>th</sup> 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:** ??
- **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

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

Candidate	Manufacturer	Type	Phase	Trial characteristics	Trial #	Recruiting
mRNA-1273	Moderna TX, Inc.	mRNA	III	<ul style="list-style-type: none"> <li>• 2 doses (0, 28d)</li> <li>• IM administration</li> <li>• 18-55, 56+ years</li> </ul>	NCT04470427	✓
mRNA-BNT162	Pfizer, Inc./BioNTech	mRNA	II/III	<ul style="list-style-type: none"> <li>• Single or 2 doses</li> <li>• IM administration</li> <li>• 18-85 years</li> </ul>	NCT04368728	✓
AZD1222	University of Oxford/AstraZeneca consortium**	Viral vector (NR)	III	<ul style="list-style-type: none"> <li>• 2 doses (0, 28d)</li> <li>• IM administration</li> <li>• ≥18 years</li> </ul>	NCT04516746	On Hold
Ad26COVS1	Janssen Pharmaceutical Companies	Viral vector (NR)	I/II	<ul style="list-style-type: none"> <li>• 2 doses (0,56d)</li> <li>• IM administration</li> <li>• 18-55, 65+</li> </ul>	NCT04436276	✓
--	Sanofi/GSK	Protein Subunit	I/II	<ul style="list-style-type: none"> <li>• Single or 2 doses</li> <li>• 18-49, 50+</li> </ul>	NCT04537208	✓
NVX-CoV2373	Novavax	Protein Subunit	I/II		NCT04368988	✓
AV-COVID-19	Aivita	AuDendritic cell	I/II		NCT04386252	
INO-4800	Inovio Pharmaceuticals, Inc.	DNA plasmid	I	<ul style="list-style-type: none"> <li>• 2 doses (0, 4w)</li> <li>• SC administration/ electroporation</li> <li>• ≥18 years</li> </ul>	NCT04336410	

\*As of September 14, 2020

\*\*Currently on hold in US

Sources: <https://milkeninstitute.org/covid-19-tracker>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; [https://vaccineshinyapps.io/ncov\\_vaccine\\_landscape/](https://vaccineshinyapps.io/ncov_vaccine_landscape/); <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>



# COVID-19 vaccines in human clinical trials outside United States - actively recruiting\*

## Inactivated Vaccines

Candidate	Manufacturer	Type	Trial Location	Phase	Trial #
<b>BBIBP-CorV</b>	<b>Beijing Institute of Biological Products/Sinopharm</b>	<b>Inactivated</b>	<b>China, UAE</b>	<b>I/II, III</b>	<b>ChiCTR2000032459 ChiCTR2000034780</b>
--	<b>Wuhan Institute of Biological Products/Sinopharm</b>	<b>Inactivated</b>	<b>China, UAE</b>	<b>III</b>	<b>ChiCTR2000031809 ChiCTR2000034780</b>
<b>CoronaVac</b>	<b>Sinovac/Instituto Butantan</b>	<b>Inactivated</b>	<b>Indonesia, Brazil</b>	<b>III</b>	<b>NCT04352608, NCT04383574, NCT04456595</b>
--	<b>Inst. of Med. Biology/Chinese Acad. Med. Sciences</b>	<b>Inactivated</b>	<b>China</b>	<b>I/II</b>	<b>NCT04412538, NCT04470609</b>
<b>BBV152</b>	<b>Bharat Biotech</b>	<b>Inactivated</b>	<b>India</b>	<b>I/II</b>	<b>CTRI/2020/07/026300, NCT04471519</b>
<b>QazCovid-in</b>	<b>Research Institute for Biological Safety Problems</b>	<b>Inactivated</b>	<b>Kazakhstan</b>	<b>I/II</b>	<b>NCT04530357</b>

*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://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; [https://vaccines.shinyapps.io/ncov\\_vaccine\\_landscape/](https://vaccines.shinyapps.io/ncov_vaccine_landscape/); <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>





# COVID-19 vaccines in human clinical trials outside United States - actively recruiting\*

## Viral Vector Vaccines

Candidate	Manufacturer	Type	Trial Location	Phase	Trial #
--	Medicago	VLP	Canada	I	NCT04450004
Oxford ChAdOx1-S	University of Oxford/AstraZeneca	Viral vector (NR)	Brazil, South Africa	III, I/II	NCT04536051, NCT04444674, ISRCTN89951424
aAPC	Shenzhen Geno-Immune Medical Institute	Viral vector	China	I	NCT04299724
LV-SMENP-DC	Shenzhen Geno-Immune Medical Institute	Viral vector	China	I	NCT04276896
Ad26COVS1	Janssen	Viral Vector (NR)	Belgium, Japan	I/II, I	NCT04436276, NCT04509947
<b>Gam-COVID-Vac</b>	<b>Gamaleya Research Institute</b>	<b>Viral vector (NR)</b>	<b>Russia</b>	<b>III</b>	<b>NCT04437875, NCT04436471</b>
ReiThera GRAd-COV2	ReiThera/Leukocare/Univercells	Viral Vector (NR)	Italy	I	NCT04528641
Merck V591	Merck	Viral Vector	Belgium	I/II	NCT04498247
--	Institut Pasteur/ Themis/ University of Pittsburgh CVR/ Merck Sharp & Dohme	Viral vector	France, Belgium	I	NCT04497298

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Sources: <https://milkeninstitute.org/covid-19-tracker>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; [https://vaccineshinyapps.io/ncov\\_vaccine\\_landscape/](https://vaccineshinyapps.io/ncov_vaccine_landscape/); <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>



# COVID-19 vaccines in human clinical trials outside United States - actively recruiting\*

## Protein Subunit Vaccines

Candidate	Manufacturer	Type	Trial Location	Phase	Trial #
NVX-CoV2373	Novavax	Protein subunit	Australia, South Africa	I/II, II	NCT04368988, NCT04533399
SCB-2019	Clover/GSK/Dynavax	Protein subunit	Australia	I	NCT04405908
Covax-19	Vaxine	Protein subunit	Australia	I	NCT04453852
--	University of Queensland/CSL/Seqirus	Protein subunit	Australia	I	NCT04495933; ACTRN12620000674932
Adimmune AdimrSC-2f	Adimmune Corporation	Protein Subunit	Taiwan	I	NCT04522089
Covaxx UB-612	Covaxx/University of Nebraska Medical Center	Protein subunit	Taiwan	I	NCT04545749

\*As of September 14, 2020

Sources: <https://milkeninstitute.org/covid-19-tracker>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; [https://vaccines.shinyapps.io/ncov\\_vaccine\\_landscape/](https://vaccines.shinyapps.io/ncov_vaccine_landscape/); <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>



# COVID-19 vaccines in human clinical trials outside United States - actively recruiting\* mRNA/DNA vaccines

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

\*As of September 14, 2020

Sources: <https://milkeninstitute.org/covid-19-tracker>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; [https://vaccines.shinyapps.io/ncov\\_vaccine\\_landscape/](https://vaccines.shinyapps.io/ncov_vaccine_landscape/); <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>



# 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 policy 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

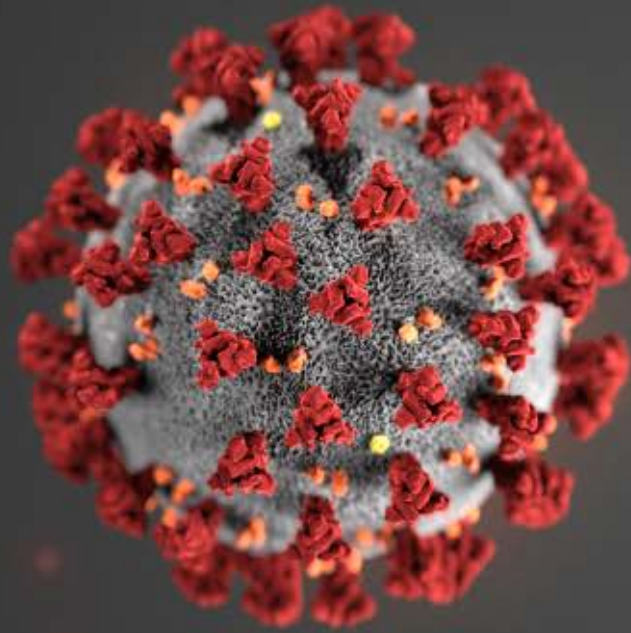
- NACCHO: Matt Zahn (primary), Jeff Duchin (alternate)
- NACI: Matthew Tunis (primary), Linlu Zhao (alternate)
- NFID: Bill Schaffner (primary), Marla Dalton (alternate)
- NMA: Oliver Brooks
- SHEA: Marci Drees

## 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)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

# 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.

