COVID-19 Conversations

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COVID19Conversations.org
#COVID19Conversations
COVID-19 Vaccine Distribution and Administration

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## 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>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) &lt;br&gt; - IM administration &lt;br&gt; - 18-55, 56+ years</td>
<td>NCT04470427</td>
<td>Enrollment complete</td>
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<tr>
<td>mRNA-BNT162</td>
<td>Pfizer, Inc./BioNTech</td>
<td>mRNA</td>
<td>II/III</td>
<td>- 2 doses (0, 21d) &lt;br&gt; - IM administration &lt;br&gt; - 18-85 years</td>
<td>NCT04368728</td>
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<tr>
<td>AZD1222</td>
<td>University of Oxford/AstraZeneca consortium**</td>
<td>Viral vector (NR)</td>
<td>III</td>
<td>- 2 doses (0, 28d) &lt;br&gt; - IM administration &lt;br&gt; - ≥18 years</td>
<td>NCT04516746</td>
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<tr>
<td>Ad26COV1</td>
<td>Janssen Pharmaceutical Companies</td>
<td>Viral vector (NR)</td>
<td>III</td>
<td>- 1 dose &lt;br&gt; - IM administration &lt;br&gt; - 18-55, 65+ years</td>
<td>NCT04436276</td>
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<tr>
<td>--</td>
<td>Sanofi/GSK</td>
<td>Protein Subunit</td>
<td>I/II</td>
<td>- Single or 2 doses &lt;br&gt; - IM administration &lt;br&gt; - 18-49, 50+</td>
<td>NCT04537208</td>
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<tr>
<td>NVX-CoV2373</td>
<td>Novavax</td>
<td>Protein Subunit</td>
<td>I/II</td>
<td>- 2 doses (0, 21d) &lt;br&gt; - IM administration &lt;br&gt; - 18-84</td>
<td>NCT04368988</td>
<td>Enrollment complete</td>
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<tr>
<td>V591</td>
<td>Merck</td>
<td>Viral Vector</td>
<td>I/II</td>
<td>- 2 doses (1, 57d) &lt;br&gt; - IM administration &lt;br&gt; - 18-55</td>
<td>NCT04498247</td>
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</tbody>
</table>

*As of October 27, 2020  
**Currently on hold in US  
Overarching objectives for COVID-19 vaccination program

Ensure safety and effectiveness of COVID-19 vaccines

Reduce mortality, morbidity, and incidence of COVID-19 disease

Help minimize disruption to society and economy, including maintaining healthcare capacity

Ensure equity in vaccine allocation and distribution
ACIP Pathway to Recommendation

1. Should COVID-19 vaccine ‘A’ be recommended?
2. Evidence to Recommendation Framework GRADE
3. To whom should early allocation of COVID-19 vaccine ‘A’ be recommended?
4. Scientific Evidence Ethical Principles Implementation

FDA approval
- Licensure
- Emergency use Authorization
- Expanded Access
Possible groups for Phase 1 vaccination

From prior ACIP Discussions:

**Phase 1a:**
- HCP

**Phase 1b:**
- Essential Workers
- High Risk Medical Conditions
- Adults ≥ 65 years old
Distribution will adjust as volume of vaccine doses increases

**Limited Doses Available**
- Constrained supply
- Highly targeted administration required to achieve coverage in priority populations

**Large Number of Doses Available**
- Likely sufficient supply to meet demand
- Supply increases access
- Broad administration network required, including surge capacity

**Continued Vaccination, Shift to Routine Strategy**
- Likely excess supply
- Broad administration network for increased access

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**Example populations**

- **HCPs** First responders
- **People with high-risk conditions** Older adults, including those living in long-term care facilities
- **Non-healthcare critical workers** People in congregate settings All other older adults
- **Young adults** Other critical workers
- **All others in the US who did not have access in previous phases**

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Illustrative scenario for planning purposes; will be adapted based on clinical/manufacturing information on all OWS candidates & vaccine prioritization

Illustrative example populations; final prioritization to be decided by ACIP
Vaccine Safety Monitoring

- The Vaccine Safety Datalink (VSD), Clinical Immunization Safety Assessment (CISA) Project, and other planned projects are key components of COVID-19 vaccine safety monitoring and adverse event assessment.

- VAERS is the U.S. frontline vaccine safety monitoring system.
  - VAERS traditionally has provided the initial data on the safety profile of new vaccines when they are introduced for use in the population.
  - Healthcare providers (HCPs) can play an important role in identifying and reporting potential AEs to VAERS: **HCPs are partners in safety monitoring**.

- **V-safe** is a new smartphone-based active surveillance program.
  - HCPs can play an important role in helping CDC enroll patients in **v-safe** at the time of vaccination: **HCPs are partners in safety monitoring**.
1. Text message check-in or email from CDC (daily 1st week post-vaccination and weekly thereafter until 6 weeks post-vaccination)

Vaccine recipient completes web survey

2. Clinically important event(s) reported
   - Missed work
   - Unable to do normal daily activities
   - Received medical care

VAERS call center

3. A VAERS customer service representative conducts active telephone follow-up on a clinically important event and completes a VAERS report if appropriate