Scientific update on COVID-19

Updated on December 21th 2020
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Question:
- What are the types of vaccines in clinical evaluation?
Vaccine

- **Vaccines aims**: expose the immune system to an antigen that won’t cause disease, provoke an immune response (able to block/kill the virus)

- **Eight types of vaccines**:  
  - virus (inactivated, weakened),  
  - viral vector (replicating, non replicating)  
  - nucleic acid (DNA, RNA)  
  - protein based (protein subunit, virus like particles)
### R&D landscape

WHO lists more than 200 candidates in preclinical development, 48 candidate vaccines in clinical evaluation (November 25th); update available at:

https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

<table>
<thead>
<tr>
<th>VIRUS</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase I/II</th>
<th>Phase II</th>
<th>Phase II/III</th>
<th>Phase III</th>
<th>Licensed</th>
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<tbody>
<tr>
<td>Inactivated</td>
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<td>2</td>
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<table>
<thead>
<tr>
<th>VIRAL VECTOR</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase I/II</th>
<th>Phase II</th>
<th>Phase II/III</th>
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<tr>
<td>Replicating</td>
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<tr>
<td>Non replicating</td>
<td>27</td>
<td>6</td>
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<table>
<thead>
<tr>
<th>NUCLEIC ACID</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase I/II</th>
<th>Phase II</th>
<th>Phase II/III</th>
<th>Phase III</th>
<th>Licensed</th>
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<tbody>
<tr>
<td>DNA</td>
<td>15</td>
<td>2</td>
<td>5</td>
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<tr>
<td>RNA</td>
<td>26</td>
<td>2</td>
<td>2</td>
<td>1</td>
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</tr>
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</table>

<table>
<thead>
<tr>
<th>PROTEIN BASED</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase I/II</th>
<th>Phase II</th>
<th>Phase II/III</th>
<th>Phase III</th>
<th>Licensed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein subunit</td>
<td>63</td>
<td>10</td>
<td>5</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Virus-like Particles</td>
<td>14</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Other/unknown  | 31          | 3       |            |          |              |           |          |

Adapted from LSHTM COVID19 vaccine tracker [https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/](https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/)
# Phase III COVID-19 Vaccines (Nov 26\(^{th}\) 2020)

<table>
<thead>
<tr>
<th>Developer</th>
<th>Vaccine Platform</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioNTech – Pfizer – Fosun Pharma</td>
<td>RNA</td>
<td>BNT162b2*: Lipid nanoparticle-formulated, nucleoside modified mRNA vaccine encoding full-length spike (S) protein</td>
</tr>
<tr>
<td>Moderna – NIAID</td>
<td>RNA</td>
<td>mRNA-1273: Lipid nanoparticle encapsulated, mRNA vaccine encoding pre fusion spike (S) protein</td>
</tr>
<tr>
<td>CureVac</td>
<td>RNA</td>
<td>CVnCoV: Lipid nanoparticle encapsulated, mRNA (non modified) vaccine encoding pre fusion spike (S) protein</td>
</tr>
<tr>
<td>Inovio-IVI</td>
<td>DNA</td>
<td>INO-4800: DNA plasmid vaccine with electroporation</td>
</tr>
<tr>
<td>Osaka University-Takara Bio</td>
<td>DNA</td>
<td>AG0302-COVID19: DNA plasmid vaccine + Adjuvant</td>
</tr>
<tr>
<td>CanSino Biologicals Inc – Beijing Institute of Biotechnology</td>
<td>Non replicating viral vector</td>
<td>Ad5-nCoV: Replication-deficient Ad5 vector containing optimised full-length spike (S) protein</td>
</tr>
<tr>
<td>Gamaleya Research Institute</td>
<td>Non replicating viral vector</td>
<td>Spoutnik V: Recombinant Ad26 (prime) and recombinant Ad5 (boost) viruses expressing the gene for spike (S) protein</td>
</tr>
<tr>
<td>Janssen Pharmaceutical Companies – Beth Israel Deaconness Medical Center</td>
<td>Non replicating viral vector</td>
<td>Ad26COVS1: Recombinant adenovirus vaccine (Ad26) incorporating SARS-CoV-2 full stabilized Spike (S) protein</td>
</tr>
<tr>
<td>University of Oxford – AstraZeneca</td>
<td>Non replicating viral vector</td>
<td>AZD1222: Replication-deficient simian adenovirus (ChAdOx1) vector containing codon-optimised spike (S) protein</td>
</tr>
</tbody>
</table>
# Phase III COVID-19 Vaccines (Nov 26th 2020)

<table>
<thead>
<tr>
<th>Developer</th>
<th>Vaccine Platform</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novavax</td>
<td>Protein subunit</td>
<td>NVX-COV2373: Recombinant nanoparticle vaccine consisting of full-length spike (S) protein, with or without Matrix-M1 adjuvant</td>
</tr>
<tr>
<td>Medicago</td>
<td>Protein subunit</td>
<td>CoVLP: Plant-derived VLP adjuvanted with AS03</td>
</tr>
<tr>
<td>Anhui Zhifei Logcom Biopharmaceutical-Chinese Academy of Sciences</td>
<td>Protein subunit</td>
<td>ZF2001: Adjuvanted recombinant protein (RBD-Dimer) expressed in CHO cells</td>
</tr>
<tr>
<td>Sinovac – Institute Butantan</td>
<td>Inactivated</td>
<td>CoronaVac: β-propiolactone inactivated vaccine administered with aluminium hydroxide adjuvant</td>
</tr>
<tr>
<td>Beijing Institute of Biological Products – Sinophram</td>
<td>Inactivated</td>
<td>BBIBP-CorV: β-propiolactone inactivated vaccine administered with aluminium hydroxide adjuvant</td>
</tr>
<tr>
<td>Wuhan Institute of Biological products–Sinopharm</td>
<td>Inactivated</td>
<td>SARS-CoV-2 Vaccine: β-propiolactone inactivated vaccine adsorbed to 0.5-mg aluminum</td>
</tr>
<tr>
<td>Bharat Biotech-ICMR-National Institute of Virology</td>
<td>Inactivated</td>
<td>COVAXIN: whole-virion inactivated vaccine</td>
</tr>
</tbody>
</table>

- **Approved for limited use**
- **Phase I/II data available (pre-print)**
- **Phase I/II data available (peer reviewed)**
**BioNTech/Pfizer**

**Phase I: NCT04368728**

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Phase I randomized controlled, dose-finding trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age range</td>
<td>18 – 55 or 65 – 85</td>
</tr>
<tr>
<td>Nb of participants</td>
<td>195</td>
</tr>
<tr>
<td>Nb of doses/route</td>
<td>2 (days 1/21)-IM</td>
</tr>
</tbody>
</table>
| Vaccine groups| 10 μg BNT162b2 (S) 18-55y (n = 12)  
               20 μg BNT162b2 (S) 18-55y (n = 12)  
               30 μg BNT162b2 (S) 18-55y (n = 12)  
               10 μg BNT162b2 (S) 65-85y (n = 12)  
               20 μg BNT162b2 (S) 65-85y (n = 12)  
               30 μg BNT162b2 (S) 65-85y (n = 12)  
               +BNT1621b (not used in Phase III) |
| SAE          | None                                              |
| Local AE     | Injection site pain, swelling                     |
| Systemic AE  | Headache, fatigue, chills, muscle pain, fever, joint pain, diarrhoea |

**IMMUNOGENICITY 1/2**

1. **S1 specific binding responses**

**Assay:** Luminex immunoassay  
**Units:** Geometric mean concentration, U/mL (95% CI)

**Antigen-binding IgG and virus-neutralizing responses to vaccination with 10 μg to 30 μg of BNT162b2 boosted by the second dose in both the younger adults and the older adults (lower antigen-binding IgG in elderly group)**
IMMUNOGENICITY 2/2

2. Neutralizing responses

Assay: SARS-CoV-2 virus neutralisation test (mNeonGreen reporter strain), 50% inhibitory dilution

Units: Geometric mean response, ID50 (95% CI)

The 50% neutralizing at the 30-μg dose level on day 28 or day 35 ranged from 1.7 to 4.6 times the GMT of the convalescent serum panel among participants 18 to 55 years of age and from 1.1 to 2.2 times the GMT of the convalescent serum panel among those 65 to 85 years of age.
AZD1222

AstraZeneca-Oxford University  Phase II: NCT04400838

Study Design: Phase II randomised controlled trial

Age range:
1: 18–55; 2: 56–69; 3: ≥70

Nb of participants: 560

Nb of doses/route: 1 (day 0) or 2 (days 0/28) - IM

Vaccine groups:
18–55y: 2 x low dose (n = 50) 18–55y: 2 x std dose (n = 50)
56–69y: 1 x low dose (n = 30) 56–69y: 1 x std dose (n = 30)
≥70y: 1 x low dose (n = 50) ≥70y: 1 x std dose (n = 50)
≥70y: 2 x low dose (n = 50) ≥70y: 2 x std dose (n = 50)

Control group: MenACWY (n = 534)

SAE: 13 serious adverse events have occurred none of which are considered related to either study vaccine as assessed by the investigators (Ph III trial suspended and resumed in Sep 2020 due to 2 cases of tranverse myelitis among participants, found not to be related to vaccination)

Local AE: Tenderness, injection site pain; reported for participants who received 2 doses of vaccine; adverse events were less frequent in older adults (≥56y)

Systemic AE: Fatigue, headache, muscle ache, malaise, feverish, chills, joint pain; reported for participants who received 2 doses of vaccine; adverse events were less frequent in older adults (≥56y)

IMMUNOGENICITY 1/2

1. SARS-CoV-2 IgG response to spike protein

Assay: ELISA
Units: GMT (95% CI)

Total IgGs against the Spike protein were similar in all age groups regardless the dose.

Responses at day 28 decreased with increasing age (low: 18–55 years, median 6439[AU]/mL; 56–69 years, 4553 AU/mL; ≥70 years, 3565 AU/mL. Std: 18–55 years, median 9807 AU/mL; 56–69 years, 5496 AU/mL; ≥70 years, 4156 AU/mL)

Ramasay MN et al. Lancet Nov 2020
IMMUNOGENICITY 2/2

2. Live SARS-CoV-2 microneutralisation assay (MNA$_{80}$)
   
   **Assay:** Microneutralisation test (80% inhibitory dilution) tiation
   
   **Units:** Median titre, ID80 (IQR)

   **Neutralizing antibody responses:** Median titres peaked by day 42 in groups receiving two vaccinations.

   There are no significant differences in normalized titers between age groups at day 42 (low: 18–55 years, median 161; 56–69 years, 143; ≥70 years, 150. Std: 18–55 years, median 193; 56–69 years, 144; and ≥70 years, 161.

3. Induction of T cell responses and increase of IFN-$\gamma$ expression

   IFN-$\gamma$ ELISpot responses against SARS-CoV-2 spike protein peaked 14 days after the prime vaccination.
<table>
<thead>
<tr>
<th>Vaccine &amp; Developer</th>
<th>Phase III regimen</th>
<th>Specific IgG titers (14 - 28 days after 2nd dose) as per Phase I or II published results</th>
<th>NAb titers (14 - 28 days after 2nd dose) as per Phase I or II published results</th>
<th>Publication</th>
</tr>
</thead>
</table>
| BNT162b2 BioNTech – Pfizer – Fosun Pharma | 2 doses (d1 and d22) 30µg/dose | 8147 GMT  
Test: Luminex anti S1 IgG | 163 GMT  
Test: wtVNA50 | Walsh EE et al. NEJM Oct 2020 |
| mRNA-1273 Moderna – NIAID | 2 doses (d1 and d29) 100µg/dose | 782 719 GMT  
Test: ELISA anti S IgG | 654.3 GMT  
Test: PRNT80 | Jackson LA et al. NEJM Jul 2020 |
| Ad5-nCoV CanSino Biologicals Inc –Beijing Institute of Biotechnology | 1 dose  
5x10^10vp | 571.0 GMT  
Test: ELISA anti RBD IgG | 18.3 GMT  
Test: WT virus neutralization | Zhu FC et al. Lancet Jul 2020 |
| SputnikV Gamaleya Research Institute | d1 0,5 mL rAd26  
d21 0,5 mL rAd5 | 14 703 GMT  
Test: ELISA anti RBD IgG | 49.25 GMT  
Test: MNA50 | Logunov DY et al. Lancet Sep 2020 |
| Ad26COVS1 Janssen Pharmaceutical Companies  
Beth Israel Deaconness Medical Center | 1 dose  
1x10^{11} vp | Non published-yet-preprint | | |
| ChAdOx1 nCoV-19 University of Oxford – AstraZeneca | 2 doses (d1 and d29)  
5x10^{10}vp | 639 EU  
Test: ELISA anti S IgG | 136 MT  
Test: MNA80 | Ramasay MN et al. Lancet Nov 2020 |
| NVX COV2373 Novavax | 2 doses (d0 and d28)  
25µg+Matrix M/ dose | 47 521 GMEU  
Test: ELISA anti S IgG | 3305 GMT  
Test: MNA99 | Keech C et al. NEJM Sep 2020 |
| CoronaVac Sinovac – Institut Butantan | 2 doses (d1 and d14) | 1094,3 GMT  
Test: ELISA anti RBD IgG | 27,6 GMT  
Test: Micro cytopathic effect assay | Zhang Y et al. The Lancet Infect Dis Nov 2020 |
| BBIBP-CorV Beijing Inst. Biological Products –Sinopharm | 2 doses (d0 and d21) | Not reported | 219,9 GMT  
Test: MNA50 | Xia S et al. Lancet Infect Dis Oct 2020 |
| SARS-CoV-2 Vaccine Wuhan Inst. Biological products– Sinopharm | 2 doses (d0 and d21) | 215 GMT  
Test: ELISA anti S IgG | 247 GMT  
Test: PRNT50 | Xia S et al. JAMA Sep 2020 |

NOTE: COMPARISONS SHOULD NOT BE MADE AS ASSAYS ARE NOT STANDARDIZED
Efficacy Trial Map (Nov 26th 2020)

Adapted from LSHTM COVID19 vaccine tracker  https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/
First data regarding vaccine efficacy has been made public by the means of press releases by pharmaceutical companies.

### VACCINE EFFICACY DATA

<table>
<thead>
<tr>
<th>Date</th>
<th>Company</th>
<th>Vaccine</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 9th 2020</td>
<td>BioNTech/Pfizer</td>
<td>BNT162b2</td>
<td>1st interim analysis; 28 days after 1st dose 94 confirmed cases of COVID19 • &gt; 90% Efficacy</td>
</tr>
<tr>
<td>November 11th 2020</td>
<td>Gamaleya</td>
<td>Spoutnik V</td>
<td>1st interim analysis; 21 days after 1st dose 20 confirmed cases of COVID19 • &gt; 92% Efficacy</td>
</tr>
<tr>
<td>November 30th 2020</td>
<td>Moderna</td>
<td>mRNA 1273</td>
<td>1st interim analysis; 42 days after 1st dose 95 confirmed cases of COVID19 • 94.5% Efficacy</td>
</tr>
<tr>
<td>November 18th 2020</td>
<td>BioNTech/Pfizer</td>
<td>BNT162b2</td>
<td>Final analysis; 28 days after 1st dose 170 confirmed cases of COVID19 • 95% Efficacy</td>
</tr>
<tr>
<td>November 23rd 2020</td>
<td>AstraZeneca/Oxford</td>
<td>AZD1222</td>
<td>1st interim analysis 14 days after 2nd dose 131 confirmed cases of COVID19 • 90% Efficacy when given as half dose/full dose • 62% Efficacy when given as full dose/full dose • Overall 70% efficacy</td>
</tr>
<tr>
<td>November 24th 2020</td>
<td>Gamaleya</td>
<td>Spoutnik V</td>
<td>2nd interim analysis; 42 days after 1st dose 39 confirmed cases of COVID19 (10 severe) • 95% Efficacy</td>
</tr>
<tr>
<td>November 30th 2020</td>
<td>Moderna</td>
<td>mRNA 1273</td>
<td>Final analysis; 42 days after 1st dose 196 confirmed cases of COVID19 (30 severe) • 94.1% Efficacy</td>
</tr>
</tbody>
</table>
BNT162 b2

- Efficacy data from ongoing double blind, randomized phase III trial across Argentina, Brazil, South Africa and USA (43 548 participants randomized 1:1)
- Two 30 µg doses of BNT162b2 vaccine, 21 days apart
- **Inclusion criteria:** healthy adults or stable chronic medical conditions, including HIV, HBV or HCV aged of 16y or more.
- **Exclusion criteria:** medical history of Covid-19, treatment with immunosuppressive therapy, or diagnosis with an immunocompromising condition
- Primary **efficacy** endpoint: efficacy of BNT162b2 against confirmed Covid-19 with onset at least 7 days after the second dose
- Primary **safety** end points: solicited, specific local or systemic adverse events and use of antipyretic or pain medication within 7 days after the receipt of each dose

**Table 1. Demographic Characteristics of the Participants in the Main Safety Population.**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>BNT162b2: (N=18,866)</th>
<th>Placebo: (N=18,846)</th>
<th>Total: (N=37,712)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex — no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>9,639 (51.1)</td>
<td>9,438 (50.1)</td>
<td>19,075 (50.6)</td>
</tr>
<tr>
<td>Female</td>
<td>9,221 (48.9)</td>
<td>9,419 (49.9)</td>
<td>18,631 (49.4)</td>
</tr>
<tr>
<td>Race or ethnic group — no. (%)†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>15,636 (82.9)</td>
<td>15,630 (82.9)</td>
<td>31,266 (82.9)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>1,729 (9.2)</td>
<td>1,763 (9.4)</td>
<td>3,492 (9.3)</td>
</tr>
<tr>
<td>Asian</td>
<td>801 (4.2)</td>
<td>807 (4.3)</td>
<td>1,608 (4.3)</td>
</tr>
<tr>
<td>Native American or Alaska Native</td>
<td>102 (0.5)</td>
<td>99 (0.5)</td>
<td>201 (0.5)</td>
</tr>
<tr>
<td>Native Hawaiian or other Pacific Islander</td>
<td>50 (0.3)</td>
<td>26 (0.1)</td>
<td>76 (0.2)</td>
</tr>
<tr>
<td>Multiracial</td>
<td>442 (2.4)</td>
<td>406 (2.2)</td>
<td>848 (2.3)</td>
</tr>
<tr>
<td>Not reported</td>
<td>93 (0.5)</td>
<td>115 (0.6)</td>
<td>208 (0.6)</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>5,266 (27.9)</td>
<td>5,277 (28.0)</td>
<td>10,543 (28.0)</td>
</tr>
<tr>
<td>Country — no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Argentina</td>
<td>2,883 (15.1)</td>
<td>2,881 (15.3)</td>
<td>5,764 (15.3)</td>
</tr>
<tr>
<td>Brazil</td>
<td>1,145 (6.1)</td>
<td>1,139 (6.0)</td>
<td>2,284 (6.1)</td>
</tr>
<tr>
<td>South Africa</td>
<td>372 (2.0)</td>
<td>372 (2.0)</td>
<td>744 (2.0)</td>
</tr>
<tr>
<td>United States</td>
<td>14,460 (76.7)</td>
<td>14,454 (76.7)</td>
<td>28,914 (76.7)</td>
</tr>
<tr>
<td>Age group — no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16-55 yr</td>
<td>10,889 (57.7)</td>
<td>10,896 (57.8)</td>
<td>21,785 (57.8)</td>
</tr>
<tr>
<td>&gt;75 yr</td>
<td>7,971 (42.3)</td>
<td>7,959 (42.2)</td>
<td>15,921 (42.2)</td>
</tr>
<tr>
<td>Age at vaccination — yr</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Median</td>
<td>52.0</td>
<td>52.0</td>
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<tr>
<td>Range</td>
<td>16-89</td>
<td>16-91</td>
<td>16-91</td>
</tr>
<tr>
<td>Body mass index:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| ≥30.0: obese  | 6,656 (34.8)          | 6,662 (35.3)         | 13,218 (35.3)     

† Race or ethnic group was reported by the participants.
‡ The body mass index is the weight in kilograms divided by the square of the height in meters.
The BNT162b2 vaccine is reactogenic, but the side effects remain acceptable in all populations studied.

The short-term safety profile of the BNT162b2 vaccine is characterized by mild to moderate pain at the injection site, fatigue, and headache. These manifestations disappear after 24 to 48 hours.

The only grade 3 adverse events with a frequency greater than 2% after the second vaccine administration are fatigue (97/2405 participants; 4.6%) and headache (7/2015; 3.2%).

No grade 4 adverse side effects observed.

Six deaths were reported during the clinical trials, including four in the placebo group, but no relation with vaccination was found.

Limits:
Just 2 month follow up safety data
Data for over 75 is scarce and absent for children, pregnant women or immunocompromised
BNT162 b2

**Efficacy and Safety Data**

**TOTAL OF CASES: 170**
- 8 in the BNT162b2 group/162 in the Control
- 10 severe cases, 9 within the Placebo group

**Vaccine efficacy: 95%**

**Limits:**
Efficacy measured in symptomatic patients
No evidence of an potential effect against viral shedding

Protection occurs as early as the second week after the first vaccine administration, with an increase of protection level up to 95% after the second administration.

Polack FP et al. NEJM Dec 2020
Efficacy data from ongoing blinded, randomized, controlled trials across UK and Brazil

- **COV 002**: Phase II/III study in UK. Two dosage groups:
  - LD/SD: prime $2,2 \times 10^{10}$ vp; boost $5 \times 10^{10}$ vp at 28 days
  - SD/SD: prime $5 \times 10^{10}$ vp; boost $5 \times 10^{10}$ vp at 28 days
- **COV 003**: Phase III study in Brazil. Dosage:
  - SD/SD: prime/boost $3.5–6.5 \times 10^{10}$ vp up to 12 weeks apart (target 4 weeks)

**Inclusion criteria**: healthy adults aged of 18y or more.

- **COV 002**: healthy adults
- **COV 003**: healthy and stable pre-existing health conditions individuals

**Main outcome**: virologically confirmed, symptomatic COVID-19 (positive swab combined with at least one qualifying symptom)

- The interim efficacy is assessed by combining data from COV002 and COV003

Limits:
Immunocompromised volunteers not included in the trial
Elderly participants are low represented
Heterogeneity between trials (concentration and schedule)
Primary Efficacy Analysis: 2 weeks after second dose

- 98 cases in the $SD/SD$ group (2 trials)
  - 27 within the ChAdOx1 nCov19 group
  - 71 within the Control group
- Vaccine Efficacy in $SD/SD$: 62.1%

- 33 cases in the $LD/SD$ group
  - 3 within the ChAdOx1 nCov19 group
  - 33 within the Control group
- Vaccine Efficacy in $LD/SD$: 90%

TOTAL OF CASES: 131
30 in the ChAdOx1 nCov /101 in the Control

Vaccine efficacy: 70.4%

Limits:
Is aggregation of SD/LD and SD/SD data for efficacy analysis possible? (different doses, different vaccination schedules schedules)
Primary Efficacy Analysis at more than 21 days after second dose

TOTAL OF CASES: 192
(only SD/SD group; two trials, different vaccination schedules)
51 in the ChAdOx1 nCov / 141 in the Control
Vaccine efficacy: 64.1%

Limits: No evidence of an potential effect against viral shedding

From 21 days after the first dose: there were ten cases hospitalized for COVID-19, all in the control arm; two were classified as severe COVID-19, including one death
1. What are the types of vaccines in clinical evaluation?

• 48 candidates vaccines are in an ongoing clinical evaluation
• Published Phase I/II data suggests that vaccine candidates on trial are immunogenic and mostly well tolerated in young adults. Data is emerging on elderly, globally keeping the trend described in young adults
• Induced titers of NAb are variable depending on the vaccine candidate. Comparison of Nab titers among candidates should not be made at this stage
• No data on ADE risk on humans nor virus clearance in upper respiratory tract after human vaccination has been published yet
• 12 vaccines are already in Phase III for efficacy evaluation
• Data on vaccine efficacy has first being announced by the means of press releases with results of >94% for BNT162b2, mRNA 1273 and Spoutnik V vaccines. A mean efficacy of 70% has been announced for AZD1222 vaccine.
• AZD1222 and BNT16b2 efficacy data has been recently published confirming these results but leaving caveats regarding sterilization capacity and long term protection
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