Coronavirus Disease 2019 Vaccine Tracker (Lexi-Drugs)

Candidate SARS-CoV-2 Vaccines in Advanced Clinical Trials: Key Aspects

Compiled by John D. Grabenstein, RPh, PhD | All dates are estimates. All Days are based on first vaccination at Day 0.

Vaccine Sponsor [with Major Partners]	Univ. of Oxford (Jenner Institute) with AstraZeneca	ModernaTX USA	BioNTech with Pfizer	Johnson & Johnson (Janssen Vaccines & Prevention)	Novavax	Sanofi Pasteur with GlaxoSmithKline	CureVac	CanSino Biologics with Academy of Military Medical Sciences	Sinopharm (China National Biotec Group) (Beijing IBP, Wuhan IBP)	Sinovac Biotech Co.
Headquarters	Oxford, England; Cambridge, England, Gothenburg, Sweden	Cambridge, Massachusetts	Mainz, Germany; New York, New York	New Brunswick, New Jersey (Leiden, Netherlands)	Gaithersburg, Maryland	Lyon, France; Brentford, England	Tübingen, Germany	Tianjin, China; Beijing, China	Beijing, China; Wuhan, China	Beijing, China
Product Designator	ChAdOx1 or AZD1222	mRNA-1273	BNT162b2, tozinameran, *Comirnaty*	Ad26.COV2.S, JNJ-78436735	NVX-CoV2373	TBA	CVnCoV	Ad5-nCoV, *Convidecia*	BBIBP-CorV	CoronaVac
Vaccine Type	Adenovirus 63 vector	mRNA	mRNA	Adenovirus 26 vector	Subunit protein	Subunit protein	mRNA	Adenovirus 5 vector	Inactivated whole virus	Inactivated whole virus
Product Features	Chimpanzee adenovirus type 63 vector	Within lipid nanoparticle dispersion	Within lipid nanoparticle dispersion	Human adenovirus type 26 vector	Adjuvanted with Matrix-M	Adjuvanted with AS03 or AF03	Adjuvanted with AS03	Human adenovirus type 5 vector	Adjuvanted with aluminum hydroxide	Adjuvanted with aluminum hydroxide
Production Medium (origin)	HEK-293A (human embryo)	Cell free (synthetic)	Cell free (synthetic)	PER.C6 (human embryo)	Baculovirus/Sf9 (insect)	Baculovirus/Sf9 (insect)	Cell free (synthetic)	HEK-293 (human embryo)	Vero cells (monkey)	Vero cells (monkey)
Route	IM	IM	IM	IM	IM	IM	IM	IM	IM	IM
CPT Code		91301	91300							
CVX Code		207	208							
NDC Code		80777-0273-10	59267-1000-01							
Dosing Regimen	Single dose or Weeks 0 + 4-12	Days 0 + 28	Days 0 + 21	Single dose or Days 0 + 56	Days 0 + 21	Days 0 + 21	Days 0 + 28	Single dose or Days 0 + 56	Days 0 + 14 or Days 0 + 21	Days 0 + 14 or Days 0 + 28
Expected Dose	$5x10^{10}$ viral particles in 0.5 mL	100 mcg in 0.5 mL	30 mcg/0.3 mL (after dilution)	$5x10^{10}$ viral particles in 0.5 mL	5 mcg protein plus 50 mcg Matrix-M in 0.5 mL	5 or 15 mcg, TBD	6 or 8 mcg, TBD	$5x10^{10}$ or $1x10^{11}$ viral particles	4 mcg	3 mcg
Expected Packaging	Solution, 8- or 10-dose vial, preservative free	Frozen liquid. 10-dose vial, preservative-free	Frozen liquid. 5-dose vial, preservative-free. Dilute 0.45 mL of concentrate with 1.8 mL NaCl 0.9% to yield 30 mcg/0.3 mL	Liquid, 5-dose vial, preservative-free	Liquid, 10-dose vial, preservative-free	TBA	TBA	TBA	TBA	TBA
Expected Storage & Handling Conditions	Refrigerate unopened vial @ 2°C to 8°C for up to 6 months, protecting from light. After first use, use within 6 hours, storing @ 2°C to 25°C	Ship @ -20°C. Refrigerate @ 2°C to 8°C NMT 30 days. Room temp NMT 12 hours after thaw.	Ship and store @ -70°C. Refrigerate @ 2°C to 8°C NMT 5 days. After diluting, use within 6 hours	Long-term storage @ -20°C up to 2 years. Refrigerate @ 2°C to 8°C up to 3 months. Use within 6 hours	Refrigerate @ 2°C to 8°C	Refrigerate @ 2°C to 8°C. Before injection, mix antigen with adjuvant	>3 months @ 2°C to 8°C. Room temp 24 hours	Refrigerate @ 2°C to 8°C	Refrigerate @ 2°C to 8°C	Refrigerate @ 2°C to 8°C
Clinical Trial Status	Phase 3	Phase 3	Phase 3	Phase 3	Phase 3	Phase 1	Phase 2	Phase 3	Phase 3	Phase 3
Date Data Sufficient for EUA	2021 Apr?	issued 18 Dec 20	issued 11 Dec 20	2021 Feb?	2021 Jan?	2021 May?	2021 Mar?	2020 Jun - China: military uses	2020 Jul - China: workers and families	2020 Jul - China: workers and families
Goal Date to File for Licensure	2021 Apr?	2020 Dec	2020 Dec	2021 Mar?	2021 Feb?	2021 Mar?	2021 Mar?	PRC 2021 Jan?	PRC 2021 Jan?	PRC 2021 Jan?
US Gov't Contracts, 2020-21 (doses)	300 million	200 million plus options	200 million	100 million	100 million	100 million	none	none	none	none
Clinicaltrials.gov Numbers	NCT04324606, NCT04400838, NCT04444674, NCT04516746, NCT04536051, NCT04536051, NCT04540393	NCT04283461, NCT04405076, NCT04470427, NCT04649151	NCT04368728, NCT04380701, NCT04523571, NCT04537949	NCT04436276, NCT04505722, NCT04509947	NCT04368988, NCT04533399	NCT04537208	NCT04449276, NCT04515147	NCT04313127, NCT04341389, NCT04398147, NCT04526990, NCT04540419, NCT04552366	NCT04510207	NCT04352608, NCT04383574, NCT04456595, NCT04508075, NCT04551547
Ages Studied to Date (y)	18 to 55, 5 to 12	≥18	12 to 55, 56 to 85	18 to 59, ≥60	18 to 59	≥18	≥18	≥18	18 to 59, 60 to 80	≥18
Evidence in Non-Human Primates	Graham 2020; van Doremalen 2020	Corbett 2020	Sahin 2020; Vogel 2020	Mercado 2020; Yu 2020	Guebre-Xabier 2020; Tian 2020				Wang 2020	Gao 2020
Evidence in Humans	Folegatti 2020; Ramasamy 2020, Voysey 2020	Jackson 2020; Anderson 2020; Widge 2020; Baden 2020	Mulligan 2020; Walsh 2020; Polack 2020	Sadoff 2020	Keech 2020		Kremsner 2020	Zhu 2020a, Zhu 2020b	Xia 2020 a, Xia 2020 b	Zhang 2020
Analogous Licensed Vaccines	No other adenovirus type-63 based vaccine	No other licensed mRNA vaccine	No other licensed mRNA vaccine	Adenovirus type-26 EU-registered Ebola vaccine component *Zabdeno* (Janssen, JNJ)	Influenza hemagglutinin vaccine (*FluBlok* , Sanofi), with NVX-CoV2373 adding an adjuvant	Influenza hemagglutinin vaccine (*FluBlok* , Sanofi), with this candidate adding an adjuvant	No other licensed mRNA vaccine	No other adenovirus type-5 based vaccine	Inactivated hepatitis A, poliovirus, rabies vaccines	Inactivated hepatitis A, poliovirus, rabies vaccines

Abbreviations & Acronyms: EUA (Emergency Use Authorization); IBP (Institute of Biological Products); mRNA (messenger ribonucleic acid); NMT (not more than); Sf9 (*Spodoptera frugiperda*); TBA (to be announced); TBD (to be determined)

Last updated: 1/4/2021

CLINICAL TRIALS:

https://clinicaltrials.gov/ct2/show/NCT04324606

https://clinicaltrials.gov/ct2/show/NCT04400838

https://clinicaltrials.gov/ct2/show/NCT04444674

https://clinicaltrials.gov/ct2/show/NCT04516746

https://clinicaltrials.gov/ct2/show/NCT04283461

https://clinicaltrials.gov/ct2/show/NCT04405076

https://clinicaltrials.gov/ct2/show/NCT04470427

https://clinicaltrials.gov/ct2/show/NCT04368728

https://clinicaltrials.gov/ct2/show/NCT04380701

https://clinicaltrials.gov/ct2/show/NCT04523571

https://clinicaltrials.gov/ct2/show/NCT04436276

https://clinicaltrials.gov/ct2/show/NCT04505722

https://clinicaltrials.gov/ct2/show/NCT04509947

https://clinicaltrials.gov/ct2/show/NCT04368988

https://clinicaltrials.gov/ct2/show/NCT04449276

https://clinicaltrials.gov/ct2/show/NCT04515147

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RESOURCE DOCUMENTS:

Biomedical Advanced Research & Development Authority (BARDA): Award list: https://medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx

Coalition for Epidemic Preparedness Innovations (CEPI): https://cepi.net/news/

Food & Drug Administration, Emergency Use Authorizations (EUA): https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Food & Drug Administration, Fast Track & Similar Designations: https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review

SARS-CoV-2 Vaccines: Evidence from Human Immunogenicity Studies

Compiled by John D. Grabenstein, RPh, PhD | All Days based on first vaccination at Day 0.

Table describes results with doses carried forward into phase 3 efficacy trials. Other available data noted.

Vaccine Sponsor (with Major Partners)	Univ. of Oxford (Jenner Institute) with AstraZeneca	ModernaTX USA	BioNTech with Pfizer	Johnson & Johnson (Janssen Vaccines)	Novavax	Sanofi Pasteur with GlaxoSmithKline	CureVac	CanSino Biologics with Academy of Military Medical Sciences	Sinopharm (China National Biotec Group) (Beijing IBP, Wuhan IBP)	Sinovac Biotech Co.
Product Designator	ChAdOx1 or AZD1222	mRNA-1273	BNT162b2, tozinameran, *Comirnaty*	Ad26.COV2.S, JNJ-78436735	NVX-CoV2373	TBA	CVnCoV	Ad5-nCoV, *Convidecia*	BBIBP-CorV	CoronaVac
Vaccine Type	Adenovirus 63 vector	mRNA	mRNA	Adenovirus 26 vector	Subunit protein	Subunit protein	mRNA	Adenovirus 5 vector	Inactivated whole	Inactivated whole
Product Features	Chimpanzee adenovirus type 63 vector	Within lipid nanoparticle dispersion	Within lipid nanoparticle dispersion	Human adenovirus type 26 vector	Adjuvanted with Matrix-M	Adjuvanted with AS03 or AF03	Adjuvanted with AS03	Human adenovirus type 5 vector	Adjuvanted with aluminum hydroxide	Adjuvanted with aluminum hydroxide
PHASE 3: Clinicaltrials.gov #	NCT04400838, EudraCT # 2020-001228-32	NCT04470427, "COVE"	NCT04368728							
Volunteers	N=11,636	N=30,351	N=43,998							
Dosing Regimen	2.5 x 10^{10} + 5 x 10^{10} vp or 2 doses 5 x 10^{10} vp, Days 0 + 28	100 mcg per 0.5 mL, Days 0 + 28	30 mcg per 0.3 mL, Days 0 + 21							
Age Cohorts (y)	≥18	18 to 64, ≥65 with or without risk factors	16 to 55, 56 to 85							
Control Arm(s)	Meningococcal ACWY vaccine	NaCl 0.9%	NaCl 0.9%							
Source Document	Voysey 2020	VRBPAC documents, Baden 2020	VRBPAC documents, Polack 2020							
Interim and Primary Analyses	131 and 150 cases, identified ≥14 days after Dose 2	95 and 196 cases, identified ≥14 days after Dose 2	94 and 170 cases, identified ≥7 days after Dose 2							
Protective Efficacy	90% with 2.5/5 (half/full) regimen; 62% with 5/5 (full/full) regimen, 70% overall	94.1%, based on 196 cases (185 control, 11 vaccine)	95%, based on 170 cases (162 control, 8 vaccine)						Reportedly 79% to 86% effective	Reportedly 91% effective in Turkish trial
Distribution of Disease Severity	0 hospitalizations or severe cases in vaccine group, 6 in control group	100% protection against severe disease (30 control, 0 vaccine)	1 case in vaccine group, 9 in control group							
Principal Safety Findings	No serious safety events related to vaccine have been confirmed	Common AEs: injection-site pain (92%), fatigue (69%), headache (63%), muscle pain (60%), joint pain (45%), chills (43%). Grade 3: Fatigue 9.7%, muscle ache 8.9%, joint pain 5.2%, headache 4.5%, pain 4.1%	Injection site (84%), fatigue (63%), headache (55%), myalgia (38%), chills (32%), arthralgia (24%), fever (14%). Grade 3: Fatigue 3.8%, headache 2.0%							
PHASE 1/2: Publication lead author	Folegatti 2020, Ramasamy 2020, Voysey 2020	Jackson 2020 (18 to 55); Anderson 2020 (≥56)	Walsh 2020; Sahin 2020 Dec	Sadoff 2020	Keech 2020	*not yet reported*	Kremsner 2020	Zhu 2020a, Zhu 2020b	Xia 2020 Aug 13, Xia 2020 Oct 15	Zhang 2020
Vaccinee Cohort 1: age range (y), n	Folegatti: 18 to 55, n=533	Jackson: 18 to 55, n=15	18 to 55, n=12	18 to 55, n=402	18 to 59, n=29		18 to 59, n=28	≥18, n=253	Xia-Oct: 18 to 59, n=56	18 to 59, n=120
1. Vaccine Dosage, Regimen	5x10^{10} vp, single dose	100 mcg, Days 0 + 28	30 mcg, Days 0 + 21	5x10^{10} or 1x10^{11} vp, single dose or Day 0 + 56	5 mcg spike + 50 mcg adjuvant, Days 0 + 21		12 mcg, Days 0 + 28	1x10^{11} vp, single dose	5 mcg, Days 0 + 21	3 mcg, Days 0 + 28
1. Neutralizing antibody responses: Onset (A). Assay (B), Peak	Onset by Day 28 (moderate at Day 14). MNA: 51 at Day 28, detected in 91% (n=35) rising further to Day 42. PRNT: 218 at Day 28, detected in 100% (n=35). MarburgVN: 62% at Day 56 (n=37)	Onset by Day 35 (moderate at Days 14 and 28). PsVNA: 344 (peak Day 42), detected in 100% at Day 35. PRNT: 654 at Day 42, detected in 100% at Day 42	Onset by Day 28 (modest at Day 21). VNT: 361 at Day 28, detected in 100%	Onset by Day 28. wtVNA: 214 (low dose) or 243 (high dose), detected in 92% at Day 28. Response to dose 2 pending	Most respond by Day 21 (earliest measurement), all by Day 35. MNA: Peak 3906 at Day 35, detected in 100%		Onset by Day 35, VNT >4-fold 64%, and 100% at Day 43	Onset by Day 28. NA-LV: 19.5 at Day 28, detected in 43%. NA-PV: 61 at Day 28, detected in 85%. Prior Ad5 immunity reduced nAb response ~2-fold	Onset by Day 35. PRNT: 247 at Day 35, detected in 98%	94% respond by Day 56 (only day tested). MCEA: 23.8 at Day 56
1. Relative to convalescent serum pool (C)	Pool n=142, pseudoneutralization, Figure 5, vaccinees similar to pool at Day 35 or 52. Pool n=5, Marburg VN, Figure 4, less than pool	Pool n=41. PsVNA: 109. PRNT: 158. Figure 2b: Dose 1--similar, Dose 2 (Day 56) vaccinees exceeded pool	Pool n=38. VNT: 94. Figure 4: Vaccinees 3.8-fold higher than pool	Pool n not described. wtVNA: 899 (NSS)	Pool n=29. MNA: 983. Figure 3B: Vaccinees 4-fold higher than pool		Pool n=67. MNA: 113.	Not assessed	Not compared to convalescent serum	Pool not described. MCEA: 164. Vaccinees 2.5- to 6.8-fold lower than pool
1. T-cell response	100% responded, peak Day 14, n=43. No mention of CD8	100% responded, Th1 biased (TNFα > IL2 > IFNγ >> IL4, IL13). Low-level CD8 response post second 100-mcg dose	92% expanded CD8 cells. Th1 CD4 response, most producing IFNγ	CD4+ response in 80% at Day 14. Robust CD8 response, yet Th1 bias. Response to dose 2 pending	Most responded, Th1 biased (TNFα > IL2 > IFNγ >> IL5, IL13)		Not studied	IFNγ in 90% at Day 28. Not influenced by ad-5 status. No mention of CD8	No differences from controls for Th1, Th2 or Th17	Positive for IFNγ spot-forming cells
Vaccinee Cohort 2: age range (y), n	Ramasamy: 18 to 55 (n=100), 56-69 (n=120, ≥70 (n=200)	Anderson: 56 to 70, n=10, ≥71, n=10	65 to 85, n=12	≥65, n=394. Data on first 15 (65 to 88) reported here	18 to 59, n=28			≥18, n=129	18 to 59, n=42	18 to 59, n=120
2. Vaccine Dosage, Regimen	5x10^{10} vp, Days 0 + 28	100 mcg, Days 0 + 28	30 mcg, Days 0 + 21	5x10^{10} or 1x10^{11} vp, single dose or Day 0 + 56	25 mcg spike + 50 mcg adjuvant, Days 0 + 21			5x10^{10} vp, single dose	5 mcg, Days 0 + 14	3 mcg, Days 0 + 14
2. Neutralizing antibody responses: Onset (A). Assay (B), Peak	Onset by Day 28 (moderate at Day 14), higher with boost. MNA: peak at Day 42; 144 to 193; detected in >99%	Onset by Day 35 (moderate at Days 14 and 28). PsVNA: 402 or 317 (peak at Day 56), detected in 100%. Two other assay results similar	Onset by Day 28 (modest at Day 21). VNT: 149 at Day 28, detected in 100%	Onset by Day 28. wtVNA: 1967 (low dose, n=50) or 127 (high dose, n=50), detected in 100% and 83% at Day 28. Response to dose 2 pending	Most respond by day 21 (earliest measurement). MNA: 3305 at Day 35, detected in 100%			Onset by Day 28. NA-LV: 18.3 at Day 28, detected in 35%. NA-PV: 55 at Day 28, detected in 83%. Prior Ad5 immunity reduced nAb response ~2-fold	Onset by Day 28. PRNT: 121, detected in 98%	92% respond by Day 28. MCEA: 27.6 at Day 28
2. Relative to convalescent serum pool (C)	Not assessed in this study	Pool n=41. Figure 2b: above median titer at Day 56	Pool n=38. VNT: 94. Figure 4: Vaccinees 1.6-fold higher than pool	Pool n not described. wtVNA: 899 (NSS)	Pool n=29. MNA: 983. Figure 3B: Vaccinees 3.4-fold higher than pool			Not assessed	Not compared to convalescent serum	Pool not described. MCEA: 164. Vaccinees 2.5- to 6.8-fold lower than pool
2. T-cell response	100% responded, peak Day 14, little response to boost. Those 56-69 y/o had higher responses than younger and older volunteers. No mention of CD8	100% responded, Th1 biased response across all age groups	Results pending	CD4+ response in 83% at Day 14. Robust CD8 response, yet Th1 bias. Response to dose 2 pending	Most responded, Th1 biased (TNFα > IL2 > IFNγ >> IL5, IL13). No mention of CD8			IFNγ in 88% at Day 28. Not influenced by ad-5 status. No mention of CD8	No differences from controls for Th1, Th2 or Th17 (CD4, CD8, NK, B, TNFα, IFNγ, IL2, IL4, IL5, IL6)	Positive for IFNγ spot-forming cells
3. Other cohorts described in papers, but omitted here	None	Jackson: 25 mcg (n-15), 250 mcg (n=15). Anderson 25 mcg (n=20)	See Mulligan 2020 for BNT162b1	None	25 mcg spike alone twice (n=25): 25 mcg spike + 50 mcg adjuvant, Day 0 only (n=25)		2 mcg (n=47), 4 mcg (n=48), 6 mcg (n=48), 8 mcg (45)	None	Xia-Aug: 2.5, 5, 10 mcg, Days 0+28+56. Xia-Oct: 2,4 8 mcg. Days 0=14 or 21 or 28	6 mcg, either Days 0 + 14 or Days 0 + 28
Total n reported, all vaccinated study arms	543	55	72 with BNT162b2, others with BNT162b1	402+15=417	100		216	382	Xia-Aug 240. Xia-Oct 640	480
Most common injection-site symptoms	Tenderness, pain, warmth	Any ~100%; pain, swelling, redness	Pain, swelling, redness	Any: 27% to 58%; pain	Any ~90%; tenderness, pain		Pain, itching, swelling	Pain, itch, induration, swelling, redness	Pain, itching, swelling	Pain
Most common systemic adverse events	Fatigue, headache, muscle ache, chills, feverishness	Any: 65% w/dose 1, 100% w/dose 2; fatigue, headache, joint ache, chills, muscle ache	Fatigue, headache, chills, muscle pain, fever, joint pain	Any: 36% to 64%; fatigue, headache, myalgia, fever (5% grade 3) among 18 to 55 y/o	Any ~60%; headache, fatigue, muscle pain, malaise, joint pain, nausea		Headache, fatigue, myalgia, chills, fever, arthralgia, nausea, diarrhea	Fatigue, fever, headache, muscle pain, joint pain, appetite impaired	Fever, nausea, fatigue, headache	Fatigue, fever
SAEs in these trials related to vaccine	None	None	None	One - fever (hospitalized)	None		None	None	None	None

Abbreviations: Ad5 (adenovirus type 5); AlOH3 (aluminum hydroxide); MCEA (modified cytopathic effect assay); MNA (microneutralization assay); NA (neutralizing activity); nAb (neutralizing antibody); NA-LV (neutralizing antibody against live SARS-CoV-2 virus); NA-PV (neutralizing antibody against pseudovirus); PRNT (plaque-reduction neutralization test); PsVNT (pseudotyped single-round virus neutralization assay); SAE (serious adverse event); TBA (to be announced); VNT (virus neutralization titer); VN (virus neutralization); vp (viral particles); wt (wild-type)

Notes:

A - Onset defined as significant rise in neutralizing in all or most vaccine recipients. Comparison limited by few and inconsistent data points.

B - Major differences in assay methods between studies. Do not directly compare values between studies.

C - Each pool of convalescent plasma differs in size, donor age, disease severity, time since disease onset, and other factors.

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Applies to

Coronavirus Vaccine; COVID-19; COVID-19 Vaccine Tracker; COVID19; COVID19 Vaccine Tracker; SARS-CoV-2 Vaccine

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