COVID-19 Clinical Update

Nov. 25, 2020

COVID-19 Vaccines: Current State of Development and OptumRx Perspective

- *This COVID-19 Vaccine Perspective Update is designed to provide insights into developments around COVID-19 vaccine clinical data, FDA review, allocation, distribution and reimbursement.*
- *The COVID-19 vaccine landscape remains highly dynamic and fluid, with new information and new data emerging almost daily. As such, it is important to note that the information provided here summarizes the most up-to-date information at our disposal at the point in which this document was issued. The information contained within is subject to change as new information is brought forth. Any projections/assumptions contained here are based upon current market conditions and data available within the public domain.*
- *OptumRx provides this information for discussion purposes only. The information is intended for the private use of OptumRx clients and affiliated consultants, is confidential, and must not be distributed to any third party or reproduced, in whole or part, without express written permission from OptumRx.*
- *We hope that you find this information of value, and we welcome your feedback and any additional questions you may have.*
- *We will update this document and share with you as new information emerges.*

Background

OptumRx continues to closely monitor developments regarding COVID-19 vaccines to inform plan sponsors of available clinical efficacy and safety data, manufacturing and distribution considerations, as well as state and federal coverage mandates. This is an update to the OptumRx Perspective on COVID-19 vaccines that was previously published in September (found here).

Multiple vaccines are in late stage clinical development in the U.S. and globally. One product has filed with the Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) and others are expected to follow in November or early December. This Clinical Update provides a summary of considerations as plan sponsors prepare for roll-out of a COVID-19 vaccine.

Two m-RNA vaccines from Pfizer and Moderna likely to be first to market

Two different vaccines that use messenger RNA technology targeting the COVID-19 virus spike protein are the leading candidates to reach the U.S. market first, likely through FDA EUA designation rather than full FDA approval via a biological license application (BLA). Both manufacturers have publicly released the findings from interim analysis of their pivotal phase 3 efficacy studies, and the results indicate efficacy (approximately 95%) that supersedes the threshold of 50% efficacy established by the FDA in a Guidance for Industry as the benchmark for potential approval decisions.

BNT162b2 by Pfizer / BioNTech

On Nov. 9, 2020, Pfizer issued a press release describing the first interim analysis of the phase 3, placebo-controlled trial of BNT162b2 indicating that the vaccine was 90% effective at preventing COVID-19. Shortly thereafter on Nov. 18, 2020, Pfizer announced the results of the final efficacy analysis indicating that BNT162b2 had an efficacy of 95% ($P<0.0001$) in individuals without prior COVID-19 infection. The final efficacy analysis was conducted when the number of confirmed symptomatic COVID-19 cases reached a predetermined threshold of 170 individuals. At the time of analysis, 43,661 individuals had enrolled in the trial, with 41,135 having received both doses of the vaccine (94%). Of the 170 COVID cases, 162 occurred in the placebo group vs only 8 in the vaccinated group. Similarly, 10 severe cases of COVID-19 were reported, with nine in the placebo group vs. one in the vaccinated group.

Pfizer reports that efficacy was consistent across age, gender, race, and ethnicity demographics and that the enrolled population had 30% of participants from racially- and ethnically-diverse backgrounds and 45% were 56 – 85 years of age. The efficacy in adults over 65 years of age was 94%. The study did not include individuals younger than 18 years old. Regarding safety and tolerability, severe (Grade 3) events included fatigue (3.8%) and headache (2%).

FDA approval timing
Pfizer has submitted an application for BNT162b2 to the FDA for Emergency Use Authorization and the FDA has scheduled an Advisory Committee meeting for Dec. 10, 2020 to review the data in a public forum.

mRNA-1273 by Moderna

On Nov. 16, 2020, Moderna issued a press release describing the first interim analysis of the phase 3, placebo-controlled trial (COVE) of mRNA-1273 and reported that the vaccine was 94.5% (P<0.0001) effective at preventing COVID-19. This first efficacy analysis was conducted after the number of confirmed symptomatic COVID-19 cases reached a predetermined threshold of 95 individuals. The final efficacy analysis will be conducted when the number of COVID-19 cases reaches 151. The Phase 3 trial enrolled 30,000 adults in the U.S., and the trial is being conducted in collaboration with the National Institutes of Allergy and Infectious Diseases (NIAID). Of the 95 COVID-19 cases, 90 occurred in the placebo group vs. only five in the vaccinated group. A total of 11 severe cases of COVID-19 were reported and all occurred in the placebo group; none occurred in the vaccinated group.

Moderna reports that the COVE trial enrolled 11,000 participants from communities of color (37% of the trial population), and 23% of participants were over the age of 65 years. Additionally, 42% of individuals in the trial were considered high risk for COVID-19 infection. The COVE trial did not include individuals younger than 18 years of age. The majority of adverse events were mild to moderate in severity; severe (Grade 3) events after the first dose included injection site pain (2.7%), and after the second dose included fatigue (9.7%), muscle pain (8.9%), joint pain (5.2%), headache (4.5%), pain (4.1%) and redness at the injection site (2.0%).

FDA approval timing
Moderna expects to file with the FDA for Emergency Use Authorization after the final efficacy analysis is conducted and when a median of 2 months of follow-up has been conducted. These are expected to be achieved within a few weeks.

Distribution and storage

If approved, the Pfizer vaccine will be distributed by Pfizer itself without a wholesaler, due to the cold chain shipping and storage requirements necessary to preserve the vaccine, which requires extreme cold temperatures. Pfizer and BioNTech have developed specially designed, temperature-controlled thermal shippers utilizing dry ice to maintain temperature conditions of -70°C ±10°C. They can be used as temporary storage units for 15 days by refilling with dry ice. Each shipper contains a GPS-enabled thermal sensor to track the location and temperature of each vaccine shipment across their pre-set routes leveraging Pfizer's broad distribution network.

Moderna, on the other hand, reports that their vaccine, mRNA-1273, remains stable at -20° C (-4°F) for up to six months, at refrigerated conditions 2° to 8°C (36° to 46°F) for up to 30 days, and at room temperature for up to 12 hours. The stability at refrigerated conditions allows for storage at most pharmacies, hospitals, or physicians' offices. If approved, Moderna plans to distribute the vaccines via McKesson, the wholesaler contracted through Operation Warp Speed.

If approved, Pfizer has stated they will be able to provide 40 million doses of BNT162b2 by the end of 2020. The U.S. government has an agreement for 100 million doses of Pfizer's vaccine with an option to purchase 500 million more. Similarly, Moderna has an agreement with the U.S. government to supply 100 million doses of mRNA-1273, with 20 million doses available by the end of 2020. With over 300 million individuals in the U.S., and each vaccine requiring two doses, such a limited initial supply will need to be prioritized until the manufacturing capabilities can ramp up to meet the demand of the entire population (See Coverage Options section below).

Review of vaccines

FDA review and approval

The United States Food and Drug Administration (FDA) is responsible for review and approval of vaccines and has a division specifically tasked for this purpose: The Office of Vaccines Research and Review (OVRR).

The FDA is expected to convene a meeting of the Vaccine and Related Products Advisory Committee (VRBPAC) prior to any FDA action to approve or issue an EUA for a COVID-19 vaccine. VRBPAC is one of the many advisory committees at FDA, and is composed of independent experts in the fields of vaccine safety and infectious disease. A public meeting was held on Oct. 22, 2020, to discuss the general matter of the development, authorization, and/or licensure of vaccines indicated to prevent COVID-19. The FDA has subsequently reaffirmed that it will convene a VRBPAC prior to issuing an approval decision on any COVID-19 vaccine for EUA and has scheduled a meeting for Dec. 10, 2020 to publicly discuss the data supporting Pfizer's vaccine. It is very likely that the FDA could issue an EUA approval decision soon after the VRPBAC meeting.

CDC's Advisory Committee on Immunization Practices (ACIP)

The Centers for Disease Control and Prevention (CDC) is making COVID-19 vaccination recommendations based on input from the Advisory Committee on Immunization Practices (ACIP). ACIP is a federal advisory committee made of up of medical and public health experts who develop recommendations on the use of vaccines in the U.S. public. During the pandemic, ACIP has been meeting regularly to discuss the progress of vaccine development and discuss key issues related to vaccine distribution. ACIP has stated that if the FDA approves a vaccine for COVID-19, it will convene an emergency meeting to review the available data for the approved vaccine. ACIP will then vote on whether to recommend the vaccine, who should receive it, and prioritization if supply is limited.

Coverage options

To receive/administer COVID-19 vaccine, constituent products, and ancillary supplies, vaccination provider facilities/organizations must enroll in the federal COVID-19 Vaccination Program coordinated through their jurisdiction's immunization program. Enrolled COVID-19 vaccination providers must be credentialed/licensed in the jurisdiction where vaccination takes place, and sign and agree to the conditions in the *CDC COVID-19 Vaccination Program Provider Agreement.*

COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. CMS and the Departments of Labor and the Treasury is requiring that all health plans and issuers cover administration of the vaccine, at no cost-share and no deductible, within 15 days after the date that the United States Preventive Services Task Force (USPSTF) or ACIP makes a recommendation relating to a qualifying coronavirus preventive service. Medicare administration fees shall be paid under Medicare Part B and have been set at $16.94 for the first dose, and $28.39 for the second dose, for those vaccines with divided doses, and $28.39 for single dose vaccines. CMS is hoping there would be alignment to the CMS rates by State Medicaid and commercial plans. Additionally, the CARES Act created a federal fund to provide the vaccine

free of charge to people who do not have health insurance. State Medicaid agencies are anticipated to provide details on administration requirements shortly.

The U.S. Department of Health and Human Services (HHS) is also partnering with pharmacies to increase access to COVID-19 vaccine once a vaccine is authorized or approved and recommended for use in the United States. With more than 86% of people living within five miles of a community pharmacy, pharmacies have unique reach and ability to provide access to COVID-19 vaccine and support broad vaccination efforts. Ultra-cold storage requirements of the mRNA vaccines may hinder widespread availability at pharmacies.

The CDC is making COVID-19 vaccine allocation recommendations based upon input from ACIP, which is holding regular meetings to discuss the key criteria for prioritizing who should receive COVID-19 vaccines if the supply is limited. Although ACIP has not issued final recommendations, the groups under consideration for early vaccination include the following:

- **Group 1a:** Health care personnel, and long-term care facility residents
- **Group 1b:** Essential workers and critical industries
- **Group 1c:** Adults with high-risk medical conditions, and adults age 65 years and older

Once the first phase of vaccinations has occurred, additional groups will be prioritized and the ACIP continues to gather input from other professional organizations, including the National Academies of Sciences, Engineering, and Medicine, and the public to inform their recommendations.

OptumRx continues to monitor all federal and state guidance, and work is in progress for standard benefit set-ups to enable coverage via the pharmacy benefit that plans may opt-in to, as soon as vaccines become available. We will also monitor USPSTF and ACIP guidelines and should COVID -19 vaccines be added as required preventive vaccinations, the vaccine(s) will be added to our ACA Preventive Medication lists.

OptumRx perspective

While multiple COVID-19 vaccines are being tested, FDA clearance will be determined by efficacy and safety data that is still being generated. Early results have been released, and plan sponsors should expect that one or more COVID-19 vaccines will become available under EUA from the FDA by the end of 2020 or early 2021, with potential full FDA approval by mid-2021.

Initial supply will be limited, and access prioritized for high-risk individuals, such as health care workers, with expansion to other individuals when supply increases. The federal government will oversee the distribution of COVID-19 vaccines and will coordinate with state and local jurisdictions.

Providers will receive vaccine through the federally-contracted distributor, or directly from the vaccine manufacturer. COVID-19 vaccine will be provided in a similar manner to other preventive vaccines, with administration of the vaccine primarily through physicians' offices and pharmacies, and reimbursement typically under the medical benefit. However, like other preventive vaccines, coverage under the pharmacy benefit will be an option for plan sponsors, and OptumRx stands ready to support claims adjudication and reimbursement via network pharmacies should sponsors wish to include coverage under the pharmacy benefit, or where required legislatively.

Pipeline vaccine candidates for COVID-19 in the U.S.

Six vaccine candidates have the greatest potential to reach the U.S. marketplace within the next 12 months (see table below). Viability, and potential availability, of these candidates are heavily dependent on the results of phase 3 clinical trials which are underway. Data supporting the efficacy, safety, stability, and storage of these vaccines are continuously accruing and new information is expected to be released as the evidence continues to evolve into 2021 and beyond.

Product and Manufacturer Route	Method and Storage	Phase of development	# Doses (Schedule)	Other Details	Earliest Potential US Availability
BNT162b2 **Pfizer/BioNTech** IM	**mRNA vaccine** **Storage requirements:** **Freeze:** Ship and store up to 6 months at -70 to -80° C **Refrigerate:** Up to 5 days at 2 – 8° C **Room temperature:** 2 hours	**Phase 2/3** began July 27, 2020, will enroll 44,000 healthy volunteers, includes patients 12 years and older (in global arm). Nov. 9, 2020, 43,538 enrolled, 30% diverse	2 (0, 21 days)	**Fast Track status** Deal with U.S. for 100 million doses (with option for 500 million more) at $20/dose ($40 for 2 dose regimen). Has received $1.95 billion in funding from U.S. Vowed 40 million doses by year-end. Nov. 16, 2020: Interim results show 95% efficacy ($p < 0.0001$) at day 28. Expected to distribute directly to vaccination sites (not through wholesaler); multi-dose vial with 3 doses per vial; each box is packed with dry ice to retain -94° C temperature for 10 days; ~300 doses in each box.	Late 4Q2020 EUA filed Nov. 20, 2020
mRNA-1273 **Moderna/NIAID** IM	**mRNA vaccine** **Storage requirements:** **Freeze:** Ship and store up to 6 months at -20° C **Refrigerate:** Up to 30 days at 2-8°C **Room temperature:** 12 hours	**Phase 1 –** fully enrolled **Phase 2 –** fully enrolled **Phase 3** (COVE) fully enrolled (N=30,000)	2 (0, 28 days)	**Fast Track status** Phase 1 interim data shows antibody titers are in the upper level seen with convalescent plasma 57 days after dose #2. Similar results observed in 3 age groups (18 – 55; 56 – 70, 71+ years). mRNA-1273 induced consistently high levels of pseudovirus neutralization antibody titers in all participants in the 56-70 (n=10) and 71+ (n=10) age cohorts. Nov. 18, 2020: Final efficacy analysis shows 94.5% efficacy ($p < 0.0001$) two weeks after second dose. Pricing between $50 - $60 per course; has received $1 billion in funding from U.S. Has signed $1.5 billion deal with U.S. government to supply 100 million doses; will supply about 20 million doses by year-end. Expects to be distributed in 10-dose vials with no preservative.	Late 4Q2020 EUA filing Possible By late Nov./Dec.

COVID-19 Vaccines: Current State of Development and OptumRx Perspective

NVX-CoV2373 **Novavax** IM	Protein sub-unit vaccine focused on spike protein **Storage requirements:** Liquid formulation in vials, stable at 2 - 8° C	**Phase 1/2; Phase 3** to start end of November with 30,000 individuals	2 (0, 21 days)	**Fast Track status** Has received $1.6 billion in funding from U.S. Expects to produce 100 million doses by late 2020. Plans 2 billion doses by mid-2021. Phase 1/2 results: 131 Australian participants (18-59 years) received 2 doses (given 21 days apart) of NVX-CoV2373 with or without adjuvant or placebo. The addition of adjuvant resulted in enhanced immune responses, was antigen dose–sparing, and induced a T helper 1 (Th1) response. The two-dose 5-µg adjuvanted regimen produced greater geometric mean responses than convalescent serum.	Early 2021
Ad26.COV2.S (JNJ-78436735) **Janssen Pharmaceuticals (J&J)** IM	Viral vector vaccine **Storage requirements:** 2 - 8° C (stable for 3 months) 20° C (stable for 2 years) After first-use, 2 - 8° C (stable for 6 hrs)	**Phase 1/2** began in July; **Phase 3** (ENSEMBLE 1) began in September – expects data year end of 2020, enrolling 60,000 individuals, U.S. and ex-U.S. **Phase 3** (ENSEMBLE 2) began in November, enrolling 30,000 individuals U.S. and ex-U.S.	1 (N/A) 2 (0, 57 days)	Has received $480 million in funding from U.S. for phase 3 trial. U.S. agreed to pay $1 billion for 100 million doses if the vaccine is approved. Aiming to produce 1 billion doses in 2021. Phase 2/3 results (from UK): 560 volunteers, similar immunogenicity was seen in 18–55 years, 56–69 years, and ≥70 years. Older adults tolerated the vaccine better. Oct. 13, 2020: J&J has paused their vaccine (Ad26.COV2.S) trial of 60,000 participants due to an unexplained illness in a study participant. Oct. 23, 2020, received approval to resume the trial in U.S. 5 doses per vial for EUA; 10 vials/carton; 48 cartons per shipper case.	Potential EUA 1Q2021
AZD1222 (or ChAdOx1 nCoV-19) **AstraZeneca** IM	Viral vector vaccine **Storage requirements:** Unknown 6 months at 2 - 8° C	**Phase 2/3, Phase 3** started in 3Q2020 in 40,000 individuals.	2 (0, 28-42 days)	Has received $1.2 billion in funding from U.S. Sept. 8, 2020: AstraZeneca voluntarily paused the trial of AZD-1222 after a trial participant in the U.K. was diagnosed with transverse myelitis. On Sept. 12, 2020 the trial was restarted in the UK. Oct. 23, 2020, received approval to resume in U.S. Nov. 23, 2020: Interim analysis shows 70% efficacy across multiple cohorts and regimens. One regimen consisting of one half-strength dose followed by one full-	Potential EUA early 2021

				strength dose one month apart showed 90% efficacy in a cohort of 2,741 individuals. Older adults had antibody and T-cell responses for at least 56 days similar to younger adults.	
Coronavirus vaccine **Sanofi/GSK** IM	Protein-based vaccine (recombinant viral protein plus an adjuvant) **Storage requirements:** 2 - 8° C	Phase 1/2 – results expected Dec. 2020; Phase 3 to start by end of 2020	2 (unknown)	Has received $2.1 billion in funding from the U.S. for vaccine development and clinical trials; and for manufacturing and delivery of 100 million doses and an option for 500 million more. Sanofi/GSK aim to be able to produce 1 billion doses in 2021. Vaccine uses similar technology to Sanofi's vaccine for seasonal influenza.	Late 2021

References

1. World Health Organization. Draft landscape of COVID-19 candidate vaccines. August 25, 2020. https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines Accessed September 8, 2020.
2. Callaway E. The race for coronavirus vaccines. *Nature*. 2020;580:576-577
3. US Food and Drug Administration. Development and Licensure of Vaccines to Prevent COVID-10: Guidance for Industry. June 2020. https://www.fda.gov/media/139638/download. Accessed August 7, 2020.
4. BioMedTracker.com. Accessed August 7, 2020.
5. Janssen Pharmaceuticals. Vaccine Technology. August 7, 2020. https://www.janssen.com/infectious-diseases-and-vaccines/vaccine-technology. Accessed August 7, 2020.
6. Immunization Action Coalition. States Authorizing Pharmacists to Vaccinate. https://www.immunize.org/laws/pharm.asp. Accessed August 7, 2020.
7. Oliver S. COVID-19 vaccines: Work Group Interpretations. . Slide Presentation. ACIP-COVID-19 Vaccines Work Group. August 26, 2020. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-08/COVID-07-Oliver.pdf Accessed August 26, 2020.
8. mRNA-1273 Clinical Development Program. Moderna presentation to ACIP. August 26, 2020.
9. Moderna COVID-19 vaccine appears to work as well in older adults in early study. August 26, 2020. https://www.reuters.com/article/us-health-coronavirus-cdc-moderna/moderna-covid-19-vaccine-appears-to-work-as-well-in-older-adults-in-early-study-idUSKBN25M1Y0?utm_source=STAT+Newsletters&utm_campaign=9ed634f75d-RO_COPY_04&utm_medium=email&utm_term=0_8cab1d7961-9ed634f75d-151970389 Accessed August 27, 2020.
10. Novavax. NVX-CoV2373 COVID-19 vaccine candidate phase 1/2 , part 1, clinical trial results. August 4, 2020. https://novavax.com/download/files/2020.08.06-NVXCoV2373Phase1ClinicalResults.pdf Accessed August 27, 2020.
11. Dooling K. COVID-19 vaccine prioritization: Work Group considerations. Slide presentation. ACIP-COVID-19 Vaccines Work Group. August 2, 2020. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-08/COVID-08-Dooling.pdf Accessed August 27, 2020.
12. Personal Communication. Pfizer, Inc. August 27, 2020.
13. American Society of Health-system Pharmacists (ASHP). Issue Brief: CARES Act and COVID-19 Diagnostic Testing and Immunization. https://www.ashp.org/Advocacy-and-Issues/Key-Issues/Other-Issues/GRD-Issue-Brief-CARES-Act?loginreturnUrl=SSOCheckOnly#
14. H.R.748 – 116th Congress (2019-2020) Public Law 116–136. March 27, 2020. Coronavirus Aid, Relief, and Economic Security Act or the CARES Act https://www.congress.gov/116/plaws/publ136/PLAW-116publ136.pdf. Accessed August 27, 2020.
15. Center for Medicare & Medicaid Services. Information related to coronavirus disease 2019 – COVID-19. May, 22, 2020..
16. Phase 3 clinical testing in the US of AstraZeneca COVID-19 vaccine candidate begins. August 31, 2020. https://www.nih.gov/news-events/news-releases/phase-3-clinical-testing-us-astrazeneca-covid-19-vaccine-candidate-begins. Accessed September 4, 2020.Covid-19 vaccine won't come with copays, US health official says. The Wall Street Journal. August 13, 2020. https://www.wsj.com/articles/covid-19-vaccines-will-not-come-with-copays-u-s-health-official-says-11597360354. Accessed September 4, 2020.
17. AstraZeneca pauses COVID-19 vaccine trial amid safety concern. September 8, 2020. https://beta.firstwordpharma.com/story/5101813. Accessed September 9, 2020.
18. COVID-19 vaccine sponsors' pledge to wait for phase III helps US FDA. Pink Sheet. September 9, 2020. https://pink.pharmaintelligence.informa.com/PS142871/COVID19-Vaccine-Sponsors-Pledge-To-Wait-For-Phase-III-Helps-US-FDA. Accessed September 9, 2020.
19. Biopharma leaders unite to stand with science. September 8, 2020. https://www.pfizer.com/news/press-release/press-release-detail/biopharma-leaders-unite-stand-science. Accessed September 9, 2020.
20. U.S. Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee October 22, 2020 Meeting Announcement. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-

and-related-biological-products-advisory-committee-october-22-2020-meeting-announcement#event-information. Accessed September 10, 2020.
21. National Academies of Sciences, Engineering, Medicine. A framework for equitable allocation of vaccine for the novel coronavirus. https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus. Accessed September 10, 2020.
22. U.S. Department of Health and Human Services. Guidance for licensed pharmacists and pharmacy interns regarding COVID-19 vaccines and immunity under the PREP Act. September 3, 2020. https://www.hhs.gov/sites/default/files/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf. Accessed September 10, 2020,
23. Fink D. Update form the Vaccines and Related Biologics Products Advisory Committee (VRBPAC) meeting of October 22, 2020. Slide Presentation. ACIP-COVID-19 Vaccines Work Group. October 30, 2020. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-10/COVID-Fink.pdf Accessed November 13, 2020.
24. Pfizer And BioNTech Conclude Phase 3 Study Of Covid-19 Vaccine Candidate, Meeting All Primary Efficacy Endpoints. November 18, 2020. https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine
25. Moderna's COVID-19 Vaccine Candidate Meets its Primary Efficacy Endpoint in the First Interim Analysis of the Phase 3 COVE Study. November 16, 2020. https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy
26. Coronavirus (COVID-19) Update: FDA Announces Advisory Committee Meeting to Discuss COVID-19 Vaccine Candidate. November 20, 2020. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-announces-advisory-committee-meeting-discuss-covid-19-vaccine?source=content_type%3Areact%7Cfirst_level_url%3Anews%7Csection%3Amain_content%7Cbutton%3Abody_link
27. Moderna Announces Longer Shelf Life for its COVID-19 Vaccine Candidate at Refrigerated Temperatures November 16, 2020. https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-longer-shelf-life-its-covid-19-vaccine
28. Centers for Disease Control and Prevention. How CDC Is Making COVID-19 Vaccine Recommendations. November 20, 2020. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html
29. AZD1222 vaccine met primary efficacy endpoint in preventing COVID-19. November 23, 2020. https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2020/azd1222hlr.html
30. Centers for Disease Control and Prevention. Frequently asked questions about COVID-19 vaccination. November 13, 2020. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html
31. Phased allocation of COVID-19 vaccines. Dooling K. Presentation to the ACIP COVID-19 Vaccines Work Group. November 23, 2020. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-11/COVID-04-Dooling.pdf
32. The National Academies of Sciences, Engineering, and Medicine. Framework for equitable allocation of COVID-19 vaccine. 2020. https://www.nap.edu/catalog/25917/framework-for-equitable-allocation-of-covid-19-vaccine#resources

OPTUM