Center for Biologics Evaluation and Research
Office of Biostatistics and Pharmacovigilance

CBER Surveillance Program

COVID-19 Vaccine Safety Surveillance: Low Uptake and Discontinuation of Novavax (NVX-CoV2373) Near Real-Time Monitoring

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Study Team

FDA
Joann F. Gruber, PhD, MSPH Azadeh Shoaibi, PhD, MHS Patricia C. Lloyd, PhD, ScM Sylvia Cho, PhD Hui Lee Wong, PhD Tainya C. Clarke, PhD, MPH, MSc Richard Forshee, PhD Steven A. Anderson, PhD, MPP
Acumen, LLC
Purva Shah, MPH Mao Hu, BS Elizabeth Smith, BS Yoganand Chillarige, MPA

List of Abbreviations

CMS	Centers for Medicare and Medicaid Services
COVID-19	Coronavirus Disease-2019
EUA	Emergency Use Authorization
FFS	Fee-for-Service
FDA	Food and Drug Administration
HCI	HealthCore Inc.
U.S.	United States
VAERS	Vaccine Adverse Event Reporting System

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1 Objective

This addendum updates the United States (U.S.) Food and Drug Administration (FDA) Biologics Effectiveness and Safety (BEST) Initiative Coronavirus Disease-2019 (COVID-19) Vaccine Safety Surveillance Active Monitoring Protocol. The objective of this addendum is to describe the low uptake and discontinuation of near-real time surveillance of Novavax (NVX-CoV2373) COVID-19 vaccine (recombinant, adjuvanted) among the adult population ages 18 years and older.

2 Background

Four monovalent vaccines—Pfizer-BioNTech/Comirnaty (BNT162b2), Moderna/Spikevax (mRNA-1273), Janssen (Ad26.COV2.S), and Novavax (NVX-CoV2373)—are available in the U.S. as primary series and third or booster dose vaccines to protect against serious COVID-19 outcomes based on the original strain of the SARS-CoV-2.[1] On July 13, 2022, the U.S. FDA issued an Emergency Use Authorization (EUA) for Novavax (NVX-CoV2373) COVID-19 vaccine, adjuvanted for individuals ages 18 years and older. FDA has been monitoring vaccine uptake since its authorization.[2]

3 Data Sources

This addendum to the Active Monitoring Protocol discusses NVX-CoV2373 vaccination uptake in CMS with data through December 24, 2022 and three commercial data sources: CVS with data through December 31, 2022; Carelon Research (formerly HCI) with data through January 9, 2023; and Optum with data through January 21, 2023. Commercial insurer claims data have been supplemented with Immunization Information Systems (IIS) data to improve vaccination capture.

4 Novavax (NVX-CoV2373) COVID-19 Vaccine Uptake

Approximately 8,000 doses of NVX-CoV2373 were captured in the data sources in the adult population aged 18 years and older.

5 Discussion

Near real-time surveillance has captured approximately 32 million COVID-19 vaccine doses among those 12–64 years of age and 34 million among those ≥65 years.[3,4] The uptake of NVX-CoV2373 has been very limited and very slow compared to that of BNT162b2, mRNA-1273, and Ad2.COV2.S. To date, our databases have captured approximately 8,000 doses of NVX-CoV2373 among the adult population in the U.S., and the uptake pattern of the vaccine shows that the uptake has plateaued and is not increasing. Due to the very small number of vaccine doses administered and the slow uptake of the NVX-CoV2373 in the U.S. population, it is not feasible to continue monitoring this vaccine in the framework of a near real-time surveillance. Therefore, FDA will discontinue the near real-time surveillance of the NVX-CoV2373. However, FDA will continue to monitor the safety of this vaccine through passive surveillance systems such as the U.S. Vaccine Adverse Event Reporting System (VAERS).

6 References

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