NVX-CoV2373 Patient Characteristics in Germany: Real-World Retrospective Database Study Shows Most Vaccine Recipients Were Among the High-Risk Category

RWD103
Contact: Lucie Kutikova
lkutikova@Novavax.com

Atif Adam[1], Kawitha Helme[2], Milou Brand[1], Jack Brewster[1], Sarah Seager[1], James Brash[1], Lucie Kutikova[2*], Karel Kostev[1], Jörg Schelling[3]

[1]IQVIA, East Sussex, United Kingdom, [2]Novavax Europe, Zurich, Switzerland, [3]Munich University Hospital, Munich, Germany

BACKGROUND

- Emergence of immune-evasive variants of SARS-CoV-2 necessitates ongoing vaccination[1]
- Results from the phase 3 PREVENT-19 trial demonstrated that the protein subunit vaccine, NVX-CoV2373, which contains the Matrix-M™ adjuvant (Novavax, Inc., MD, USA) was 90.4% effective in preventing COVID-19 infection and 100% effective in preventing moderate-to-severe COVID-19[2-4]
  - Durable protection was seen across primary and booster vaccinations in people aged 12 to 95 years
- In Germany, NVX-CoV2373 has been available since March 2022 for immunization to prevent COVID-19 in those ≥12 years of age[5], and is recommended by the Standing Committee on Vaccination (STIKO) as an alternative to mRNA vaccines[6]
- This retrospective, observational, database study is one of the first studies to evaluate NVX-CoV2373 use in a real-world setting

METHODS

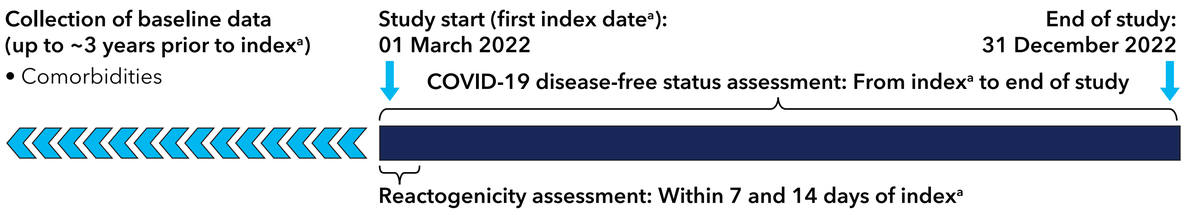
Study Objective

- To describe the characteristics of NVX-CoV2373 recipients in Germany and assess vaccine reactogenicity and protection from COVID-19 disease

Study Design

- Data were sourced from the IQVIA™ German Disease Analyzer, a general practitioner database converted to Observational Medical Outcomes Partnership Common Data Model
- Eligible participants were 12 years of age or older (as per the NVX-CoV2373 indication)[5] and received an NVX-CoV2373 primary series or booster dose in Germany (**Figure 1**)

Figure 1. Study Design



[a]Date of NVX-CoV2373 vaccination (as second dose of primary series or as a booster dose).

Assessments

- Assessment of participant characteristics included a stratification of those defined as high risk for severe COVID-19, based on STIKO recommendations:[7]
  - Age ≥60 years
  - Age ≥18 years with underlying comorbidities causing an increased risk of severe COVID-19
  - Frailty/residence in care facility
- Doctor's visit or sick leave note due to reactogenicity-related symptom(s)
  - Assessed within 7 and 14 days post–index date
  - Consisted of fatigue, malaise, muscle pain, joint pain, nausea/vomiting, and headache
- COVID-19 disease-free status following NVX-CoV2373 vaccination was assessed through the end of the study period
  - Kaplan-Meier plots were generated to estimate COVID-19 diagnosis-free status after vaccination

RESULTS

Participant Characteristics

- 597 participants received NVX-CoV2373 as a primary series (58.5%) or booster dose (41.5%) between March and December 2022 (**Table 1**)
  - Overall, mean (SD) age was 57.9 years (18.6), and most participants (81%) were vaccinated by a general practitioner

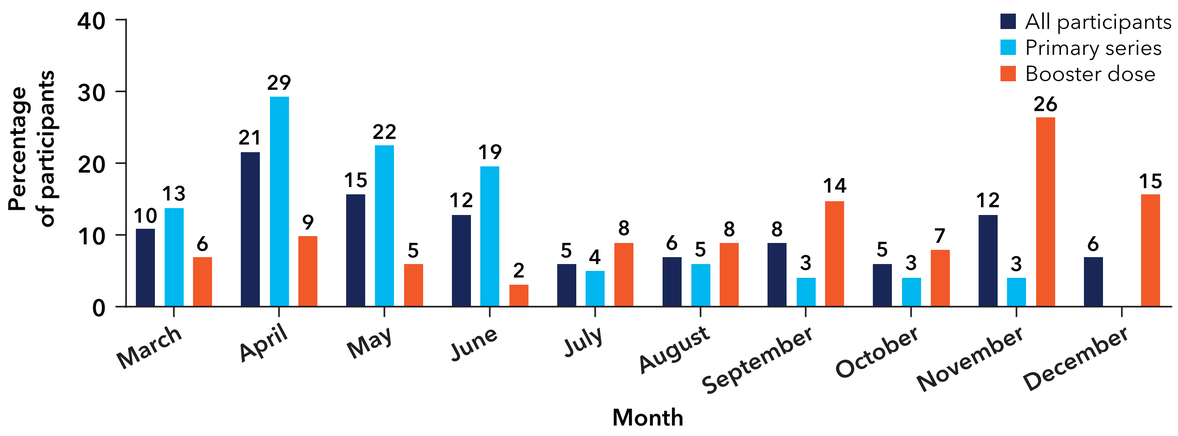
Table 1. Participant Demographics and Baseline Characteristics

Parameter	All participants (n = 597)	Primary series (n = 349)	Booster dose (n = 248)
Age, mean (SD) years	57.9 (18.6)	50.9 (16.7)	67.8 (16.5)
Female, n	323 (54%)	202 (58%)	121 (49%)
Median follow-up, days (IQR)	207 (156)	240 (60)	94 (79)
Treating physician specialty, n General practitioner Other	 485 (81%) 112 (19%)	 282 (81%) 67 (19%)	 203 (82%) 45 (18%)
Geographical region, n East West	 337 (56%) 260 (44%)	 135 (39%) 214 (61%)	 202 (81%) 46 (19%)
STIKO high-risk group factor[a], n Age ≥60 years Age ≥18 years, with comorbidity Frailty[b]	404 (68%) 274 317 20	202 (58%) 102 156 <5	202 (81%) 172 161 <20

[a]Participants may have been characterized with >1 STIKO high-risk group factor. [b]Frailty was defined as having a prior diagnosis of dementia, Alzheimer's disease, and/or Parkinson's disease.
Abbreviations: IQR, interquartile range; STIKO, Standing Committee on Vaccination; SD, standard deviation.

- Vaccine uptake was rapid upon NVX-CoV2373 availability (**Figure 2**)
  - 83% of participants in the primary series group were vaccinated within 4 months of availabilty
  - 62% of participants who received a booster dose did so in September through December 2022

Figure 2. NVX-CoV2373 Vaccine Uptake by Month in 2022



- The majority (68%) of participants had a STIKO high-risk factor; participants often had multiple STIKO high-risk factors (≥1 factor, 53%; ≥2 factors, 30%; ≥3 factors, 17%) (**Table 2**)
  - The most common baseline comorbidities among vaccine recipients were chronic neurological diseases (36%) and intestinal diseases (21%)
  - Participants with a chronic respiratory, cardiovascular, or metabolic disease each encompassed 10–11% of the total population; of those with a metabolic disease, the majority (65%) had diabetes
  - Distribution of comorbidities by whether participants received a primary series or booster NVX-CoV2373 vaccination were similar to each other and the total population

RESULTS, CONT.

- A similar trend in comorbidities was observed among the STIKO subgroups, the overall STIKO population, and all study participants

Table 2. Comorbidities Among Participants

Baseline risk factor[a]	All participants, n (%) [n = 597]	Primary series, n (%) [n = 349]	Booster dose, n (%) [n = 248]	STIKO high risk, n (%) [n = 404]
≥1 STIKO risk factors	318 (53)	157 (45)	161 (65)	317 (78)
≥2 STIKO risk factors	179 (30)	81 (23)	98 (40)	179 (44)
≥3 STIKO risk factors	102 (17)	46 (13)	56 (23)	102 (25)
Chronic neurological diseases	217 (36)	100 (29)	117 (47)	217 (54)
Chronic intestinal diseases	126 (21)	67 (29)	59 (24)	125 (31)
Metabolic diseases (including obesity and diabetes mellitus)	58 (10)	33 (9)	25 (10)	58 (14)
Chronic cardiovascular diseases	64 (11)	22 (6)	42 (17)	64 (16)
Chronic diseases of the respiratory system	65 (11)	32 (9)	33 (13)	65 (16)
Diabetes	38 (6)	22 (6)	16 (6)	38 (9)
Psychiatric disorders	32 (5)	21 (6)	11 (4)	32 (8)
Cancers	32 (5)	8 (2)	24 (10)	32 (8)
Chronic kidney disease	21 (4)	8 (2)	13 (5)	21 (5)
Dementia or intellectual disability	14 (2)	<5 (NA)	<15 (NA)	14 (3%)
Chronic liver disease (including cirrhosis)	6 (1)	<5 (NA)	<5 (NA)	6 (1)
Autoimmune disease (including rheumatological diseases)	<5 (NA)	<5 (NA)	<5 (NA)	<5 (NA)
Congenital/acquired immunodeficiency or immunosuppression[b]	<5 (NA)	<5 (NA)	–	<5 (NA)

[a]No participants were identified to have Down Syndrome. [b]Includes HIV infection, condition post organ transplantation with immunosuppressive agents.
Abbreviations: NA, not available; STIKO, Standing Committee on Vaccination.

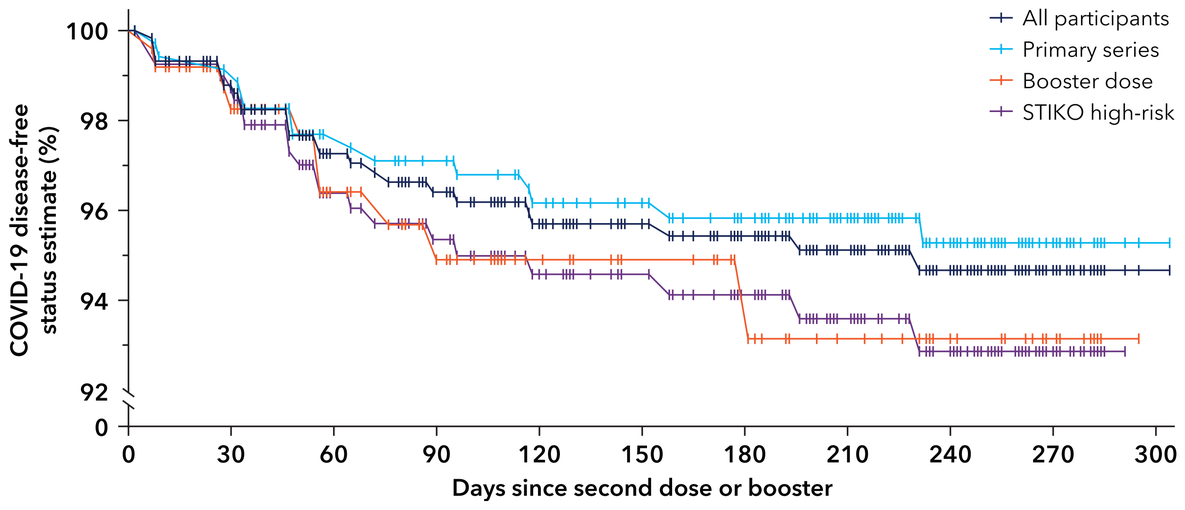
Reactogenicity

- Reactogenicity events were observed in ≤1% of participants, regardless of the time interval post vaccination (short interval: 7 days; longer interval: 14 days)
- Respectively, 5 and 6 participants visited a doctor within 7 and 14 days of receiving NVX-CoV2373
- There were no sick leave notes associated with NVX-CoV2373

COVID-19 Disease-Free Status

- 95% (95% CI, 93-95) of participants were estimated to be COVID-19 disease-free after vaccination with NVX-CoV2373, with a maximum follow-up of 10 months (median ~7 months)
- Disease-free status was consistent among participants who received NVX-CoV2373 as a primary series or booster, and for those with a STIKO high-risk factor (**Figure 3**)

Figure 3. COVID-19 Disease-Free Status Over Time



Limitations

- As this is a retrospective database analysis, not all information may be recorded
- Data are limited to the outpatient setting; therefore, those participants who were hospitalized or without a doctor's visit might not be captured in the reactogenicity or COVID-19 disease-free status outcomes
- Due to the nature of the data and the nonrandomized study population, there is possibility of selection bias in assessing the outcomes

CONCLUSIONS

- NVX-CoV2373 was used successfully in all participants, including the high-risk, older population
- Given the rapid uptake upon introduction of NVX-CoV2373, a broader vaccine choice for a non-mRNA option may be needed
- Negligible reactogenicity events were observed, with no sick leave notes associated with NVX-CoV2373
- Robust protection, with a 95% disease-free estimate, confirms strong clinical trial results

References
1. Carabelli AM, et al. *Nature Reviews Microbiology* 2023; 21:162–177. **2.** Dunkle LM, et al. *N Engl J Med* 2022; 386:531-543. DOI: 10.1056/NEJMoa2116185. **3.** Heath PT, et al. *N Engl J Med* 2021; 385:1172-1183. DOI: 10.1056/NEJMoa2107659. **4.** Áñez G, et al. *JAMA Netw Open*. 2023;6(4):e239135. DOI: 10.1001/jamanetworkopen.2023.9135. **5.** Nuvaxovid [summary of product characteristics]. Novavax CZ, Jevany, Czechia. Accessed 25 September, 2023. https://www.ema.europa.eu/en/documents/product-information/nuvaxovid-epar-product-information_en.pdf. **6.** NVXIR: https://ir.novavax.com/press-releases/German-Health-Authority-Expands-Recommendation-for-Use-of-Novavax-COVID-19-Vaccine-as-a-Booster. **7.** Statement of the STIKO on the decision on the implementation of the COVID-19 vaccination into the regular recommendations of the STIKO 2023. Accessed 25 September, 2023. https://www.rki.de/EN/Content/infections/Vaccination/recommandations/implementation_covid-19_vaccination.pdf?__blob=publicationFile.

Acknowledgements
This work was supported by Novavax Europe. Medical writing and editing support were provided by Rebecca Harris, PhD, Kelly Cameron, PhD, and Ebenezer M. Awuah-Yeboah of Ashfield MedComms (New York, USA), an Inizio company.

Disclosures/Conflicts of Interest:
KH and LK are employees of Novavax Europe and may hold stock. AA, MB, JB, SS, and KK are employees of IQVIA. JS is a consultant/speaker for Bavarian Nordic, BioNTech, GlaskoSmithKline, Janseen, Merck, Sharp & Dohme, Moderna, Novavax, Pfizer, Sanofi, Seqirus, Takeda, and Viatris.

*Presenting author