BEEHIVE
Booster Epidemiological Evaluation of Health, Illness and Vaccine Efficacy

Statistical Analysis Plan

Study title: Booster Epidemiological Evaluation of Health, Illness and Vaccine Efficacy (BEEHIVE) Study

Protocol Version Date: October 11, 2023

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LIST OF ABBREVIATIONS

ANOVA	Analysis of Variance
BMI	Body Mass Index
CDC	Centers for Disease Control and Prevention
CI	Confidence Interval
CLI	COVID Like Illness
COVID-19	SARS-CoV-2 Coronavirus Disease 2019
GMR	Geometric Mean Ratio
GMT	Geometric Mean Titer
HI	Haemagglutination Inhibition
mITT	Modified Intent-to-treat Population
MN	Microneutralization
NAI	Neuraminidase Antibody Mediated Inhibition
NVX	Novavax
PBMC	Peripheral Blood Mononuclear Cell
PH	Proportional Hazards
PPP	Per Protocol Population
RAT	Rapid Antigen Test
RNA	Ribonucleic Acid
RT-PCR	Reverse Transcription Polymerase Chain Reaction
VE	Vaccine Efficacy
rVE	Relative Vaccine Efficacy
SAP	Statistical Analysis Plan

1. STUDY OBJECTIVES AND ENDPOINTS

1.1 Study Objectives

1. Compare the VE between adult participants who receive a single dose of Novavax (NVX) (2023-2024 formula) vaccinate or Pfizer mRNA (2023-2024 formula) vaccinate and a group of non-randomized participants who are recommended to be vaccinated by CDC/ACIP but decline the 2023-2024 updated vaccine to prevent CLI-associated SARS-CoV-2 infection, confirmed by COVID-19 rapid antigen test (RAT).
2. Determine the relative vaccine efficacy (rVE) of a single dose of Novavax (NVX) (2023-2024 formula) vaccine and a single dose of the Pfizer mRNA (2023-2024 formula) vaccine to prevent CLI-associated SARS-CoV-2 infection, confirmed by COVID-19 RAT, to confirm non-inferiority for NVX.

Secondary Objectives

1. Evaluate the effect of prior number of doses of COVID-19 vaccination during the preceding 3 years on the relative efficacy of a single dose of NVX.
2. Assess the vaccine efficacy against asymptomatic or any (asymptomatic or symptomatic) RAT-confirmed SARS-CoV-2 infections.
3. Examine the individual, occupational, and environmental predictors of SARS-CoV-2 infection and compare these predictors between asymptomatic infection versus symptomatic COVID-19 illness.
4. Describe the clinical characteristics and outcomes associated with COVID-19[2].
    a. Determine the duration and severity of illness and examine the socio-demographic and health characteristics associated with prolonged or severe illness.
    b. Determine the impact of COVID-19 on indicators of functioning, including missed work, ability to complete normal work and home activities, and working while ill.
    c. Determine the proportion of COVID-19 illnesses that are medically attended and examine the factors associated with seeking medical care and treatment.
5. Compare illness characteristics and duration with primary vs. re-infection with SARS-CoV-2.
6. Examine if VE is modified by socio-demographic characteristics, occupation, health status, or other risk factors.
7. Examine if booster modifies illness severity and duration among participants with breakthrough infection despite vaccination.
8. Assess the incidence of post-COVID conditions (PCC) and factors associated with PCC symptoms.

9. Determine if PCC symptoms differ among boosted participants and participants who decline the booster.
10. Determine if PCC symptoms are modified by vaccination status prior to infection.
11. Characterize the knowledge, attitudes, and practices (KAPs) of participants related to new COVID-19 2023 variant vaccines and examine the associations between KAP and subsequent vaccination behaviors (including vaccine refusal, hesitancy, or incomplete adherence to vaccination recommendations).

1.2 Study Endpoints

1.2.1 Primary Endpoint

Time from enrollment in the study or start of active surveillance, whichever is later, to CLI-associated SARS-CoV-2 infection, confirmed by COVID-19 rapid antigen test (RAT).

2. STUDY DESIGN

This randomized, three arm, active comparator trial will compare the clinical efficacy of NVX 2023-2024 updated vaccine (Arm 1) with a single dose of the Pfizer mRNA 2023-2024 updated vaccine (Arm 2) as well as non-recipients comparison group (Arm 3). The study hypotheses are 1) to compare vaccine efficacy (VE) between participants who receive either the NVX 2023-2024 updated vaccine (Arm 1) or Pfizer mRNA 2023-2024 updated vaccine (Arm 2) with the non-recipient participants who are recommended to be vaccinated based on CDC, state or organizational guidelines but decline the 2023-2024 updated vaccine and 2) to determine the relative vaccine efficacy (relative VE) of the NVX 2023-2024 updated vaccine and Pfizer mRNA 2023-2024 updated vaccine and the in preventing SARS-CoV-2 infection to confirm non-inferiority for NVX.

3. RANDOMIZATION AND BLINDING

3.1 Method of Group Assignment and Randomization

Randomization to vaccine type for the group of participants who elect to receive a booster vaccine will be stratified by age group (18-49 years and 50+ years) and sex. If participants do not report a sex, they will be stratified in the male category. Randomization will be done after completing the Pre-vaccination Questionnaire (Appendix K) that confirms that the participant is able to receive study vaccine on the same day. Participants will be randomized within each age and sex stratum in a 1:1 treatment ratio to receive either NVX or mRNA. The stratified randomization list will be generated before enrollment starts using a computerized random-number generator to select randomly permuted group blocks of size 6 with 3 of each vaccine type in each block. The next available sequential randomization slot number within the

appropriate stratified age and sex group will be assigned to each enrolled participant at the time of randomization.

3.2 Blinding

Because participants will elect whether they receive a booster vaccine or decline a booster vaccine, all participants will be aware of their group assignment. However, those participants in the booster group as well as study investigators will be blinded to study arm assignments within the booster group. A limited number of study staff handling and administering the vaccines will be aware of vaccine assignment and will be trained not to divulge vaccine assignment information to the investigator team. Study staff administering vaccine will not be involved with study surveillance to avoid involvement with measurement of study outcomes. The study will provide electronic documentation confirming that participants received one of the study vaccines (without indicating which vaccine) with date of vaccine administration (Appendix M: Documentation of Vaccine Administration). The electronic documentation of vaccine administration will be password protected to maintain blinding. At the completion of the trial, a designated group of investigators may be unblinded to the vaccine assignment groups to conduct analyses to address objectives related to vaccine efficacy.

3.3 Emergency Unblinding

Unblinding of vaccine assignment for a participant may be necessary due to a medical emergency or other significant medical event. Study participation will be discontinued for participants whose vaccine has been unblinded.

If unblinding is required:

- Only the Principal Investigator or delegated co-investigator or sub-investigator will make the decision to unblind the vaccine assignment.
- Only the affected participant will be unblinded.
- The study pharmacist(s)/designee at the study site will provide the unblinded vaccine assignment to the investigator.

The investigator will notify the sponsor designee as soon as possible after unblinding the participant.

4. SAMPLE SIZE AND POWER CONSIDERATIONS

4.1 Sample Size for Primary Objectives

Power and sample size are examined for both primary objectives to 1) compare VE between vaccinated arms (both NVX and mRNA) and the non-vaccinated comparison arm with a 2-sided alpha=0.05 superiority test and 2) determine non-inferiority of NVX 2023-2024 formula vaccine variant compared to a single dose of Pfizer mRNA 2023-2024 updated vaccine with a 1-sided alpha=0.05

confidence interval. The rate of CLI-associated SARS-CoV-2 infection, confirmed by COVID-19 rapid antigen test (RAT) in those not vaccinated with the 2023-2024 formulation is expected to be 80 per 100,000 person-days. We expect those choosing not to vaccinate in Fall 2023 to Spring 2024 to be a mix of unvaccinated and fully vaccinated but not boosted individuals, but to be conservative we will assume this group is solely comprised of fully vaccinated individuals. Using publicly available data on the historic case rates in Utah for COVID-19 from the week of October 2, 2022 to the week of May 21, 2023[3] [CITE https://coronavirus-dashboard.utah.gov/risk.html], the average rate of cases in those fully vaccinated in Fall 2022-Spring 2023 is 56.63 per 100,000 person-days for those fully vaccinated. From a survey conducted in spring of 2022, it has previously been reported that of those testing for COVID-19 44.2% report testing at a lab or clinic and 25.7% reported testing at a drive-thru clinic[4]. Therefore, using at-home test kits to identify cases, we expect rates to be 43.1% higher (1/(0.257+0.442)) than what is shown on Utah's dashboard. This under-reporting adjustment to Utah's observed rates from last fall leads to a conservative estimate for the rate of CLI-associated SARS-CoV-2 infection, confirmed by COVID-19 rapid antigen test (RAT), in those not vaccinated with the 2023-2024 formulation to be 80 per 100,000 person-days. Using the same logic applied to the reports for those with a bivalent booster last fall, after adjusting for under-reporting, we estimate the infection rate to be 68 per 100,000 person-days in those vaccinated in Fall 2023 to Spring 2024.

For the superiority test of the first primary objective, on which the sample size is based, the null hypothesis that vaccine efficacy, or VE, of the 2023-2024 formula compared to no vaccination in Fall 2023-Spring 2024 is 0 is tested against the alternative that the VE is not equal to 0. That is, H_0: VE = 0 is tested against H_a: VE $\neq$ 0. VE is calculated as 1- hazard ratio, HR, comparing those receiving the 2023-2024 formulation (either NVX or Pfizer) to those choosing not to be vaccinated in Fall 23 to Spring 24, times 100 or 100*(1-HR). HR will be estimated using Cox proportional hazards models with α=0.05. Table 1 provides the required sample size to yield 80% power to detect VE of 40%, 50%, and 60% or higher, assuming an attrition rate of 15% or less. We plan that the NVX and Pfizer arms will each have twice as many participants as the arm of those choosing no Fall 2023 to Spring 2024 vaccination, a ratio of 4:1. Calculations were made in PASS using the Multi-Arm Tests for Treatment and Control Survival Curves using Cox's Proportional Hazards Model[5]. In 24 weeks of follow-up, the rate of 80 cases per 100,000 person-days equates to an event probability of 13.44%. This probability corresponds to a hazard rate of 0.14433. With a total of 1500 participants enrolled (1200 with 2023-2024 formulation and 300 without Fall 2023 to Spring 2024 vaccination), we have 80% power to detect a VE of 50% or more, even if we see 15% attrition. With 1500 enrolled and an observed VE of 50%, we anticipate there will be approximately 124 RAT confirmed symptomatic COVID-19 cases in total (41 in the not

vaccinated arm and 84 in the vaccinated arm) with no attrition, and 106 with 15% attrition.

Table 1. Relationship between Vaccine Efficacy and Sample Size, assuming a 4:1 ratio vaccinated with 2023-2024 formulation to not vaccinated in Fall 2023-Spring 2024 and 15% rate of attrition.	
Lowest Detectable VE comparing between non-vaccinated and vaccinated (NVX and Pfizer combined) arms	**Sample size for 80% power**
40%	2,378
50%	1,460
60%	960

For the non-inferiority test in the second primary objective, the null hypothesis that the NVX vaccine of 2023-2024 formulation is inferior to the Pfizer vaccine of the 2023-2024 formulation is tested against the alternative that NVX is non-inferior. That is, H_0: $rVE < 0 + \delta$ is tested against H_a: $rVE \geq 0 + \delta$, where δ is the "interval of equivalence", the range in which the effectiveness of the two vaccines would be considered clinically equivalent. Relative VE, or rVE, is calculated as 1- hazard ratio, HR, comparing those receiving the NVX 2023-2024 formulation to those receiving the Pfizer 2023-2024 formulation, times 100, or 100*(1-HR). We believe an interval of -50% would be clinically acceptable. For example, if Pfizer reduces the hazard of infection by half, reducing the hazard by 25% (VE of 25%) would correspond to an rVE of -50%. Similarly if Pfizer shows 80% VE compared to the non-vaccinated, a NVX VE of 70% would correspond to an rVE of -50%. For the power calculations for the second primary objective, the significance level is $\alpha=0.05$.

Table 2 gives the power for testing the non-inferiority hypothesis with a sample of 600 enrolled patients per arm with an equivalence interval of -50%, with observed rVE ranging from -20 to 20 and observed rates of CLI-associated SARS-CoV-2 infection, confirmed by COVID-19 rapid antigen test (RAT) in the Pfizer arm ranging from 60 to 90 per 100,000 person-days. Additionally, an attrition rate of 15% from 600 is assumed. The power decreases as the observed case-rate in the Pfizer arm decreases or as the observed rVE decreases. Calculations were made in PASS 2023 using Non-Inferiority Tests for Vaccine Efficacy using the Hazard Ratio (Cox's Proportional Hazards Model). If we assume an infection rate of 60 per 100,000 person-days in the Pfizer vaccinated arm we have 81.12% power to determine non-inferioirty of NVX for observed rVEs of 10 or greater.

Table 2. Power assuming 600 at enrollment for each group (NVX and Pfizer) accounting for 15% attrition for non-inferiority of NVX vs. Pfizer 2023-2024 formulations and a non-inferiority limit of -50 rVE.

Assumed rate of COVID-19 infection in 100,000 person days for Pfizer 2023-2024 formulation arm	Possible Observed Relative VE						
	20	10	5	0	-5	-10	-20
50	86.88	74.60	67.13	59.16	51.02	43.03	28.63
60	91.71	81.12	74.00	65.94	57.33	48.57	32.20
70	94.84	86.12	79.58	71.75	62.97	53.70	35.66
80	96.84	89.88	84.08	76.70	67.98	58.41	38.98
90	98.08	92.68	87.66	80.86	72.41	62.72	42.16

With a planned sample size of 600 per arm and 15% attrition, if the observed rate of infection in the Pfizer 2023-2024 updated vaccine formulation arm differs from 60 per 100,000 person-days, 600 participants in each arm assures 80% power to claim non-inferiority for observed rVE greater than 10, sometimes less than 10, as outlined in the table above. The grey cells in the table indicate which scenarios will have 80% power with 600 participants.

5. DETERMINATION OF PROTOCOL DEVIATIONS

A list of protocol deviations include but are not limited to:

- Subject randomized and did not satisfy entry criteria
- Subject received the wrong treatment or incorrect dose
- Key study procedures missed or performed out of window

Number and percentage of subjects with a major protocol deviation by type of deviation and vaccine group will be reported.

6. ANALYSIS POPULATIONS

6.1 Modified Intent-to-Treat Population

All participants who are randomized, received a study vaccine, and participated in study surveillance by responding to at least one surveillance contact during the SARS-CoV-2 circulation period (active surveillance) will be included in the modified intent-to-treat (mITT) population for the primary objectives. The mITT population will be the primary population for efficacy analyses and participants are analyzed according to their randomized treatment. For participants who were identified as not receiving a booster

(comparison group) they will be analyzed in that group under the mITT population, even if they subsequently do get a vaccine during the study period.

6.2 Per Protocol Population

The per protocol population will include participants who met eligibility criteria, received study vaccine per protocol, participated in study surveillance by responding to at least one surveillance contact during the SARS-CoV-2 circulation period (active surveillance), and did not receive another SARS-CoV-2 vaccine outside of the study during the study period. If participants were in the non-vaccinated comparison group but subsequently received a vaccination, they will be censored at that point.

7. GENERAL ISSUES FOR STATISTICAL ANALYSIS

7.1 Adjustment for Covariates

Cox proportional hazard models will have vaccine group as the main effect. For the primary objectives age, prior COVID-19 vaccination in the preceding 3 years and week will be adjusted for (time-varying covariate). Prior COVID-19 vaccination will be categorized (1 prior vaccine (2 course vaccination), 2 prior vaccines (initial vaccination and 1 booster), 3 prior vaccines and ≥4 prior vaccines), if there are less than 30 people in a category, then we will collapse down (e.g. ≥3 instead of 3 and ≥4) until we have stable estimates.

Other baseline characteristics will be included as covariates if there are significant imbalances between vaccine groups and kept in the model if they adjust the hazard ratio by ≥5%. If there is evidence that the proportional hazard assumption is not met, weekly SARS-CoV-2 circulation will be added as a covariate or will be investigated for stratifying the baseline hazard. Covariates will not be used in subgroup models, where they are the event of interest. Season will not be included in models of SARS-CoV-2 type and subtype if they only occur in one season. If an analysis has <10 events, an unadjusted model only will be calculated.

7.2 Handling of Dropouts, Missing Data

The analyses will be done without adjustments for missing values. Subjects who withdraw or are lost to follow up will be censored at the last time of surveillance. Primary analysis will be analyzed on the mITT population and any missing swabs will be considered missing completely at random. A sensitivity analysis will repeat the primary efficacy analysis on the PP population.

7.3 Multiple Comparisons and Multiplicity

Primary efficacy and relative efficacy are assessed by only one endpoint and will not be adjusted for multiplicity.

7.4 Subgroups

Subgroup analysis will be performed with the subgroup as a categorical variable and tested for interaction with vaccination.

The efficacy analyses will be performed for the following subgroups as feasible:

Time since last immune challenge (prior vaccine or infection) as a category of >1 year, 6 months-1 year, 3 to 6 months and age category (18-49 and 50+)

7.5 Derived and Computed Variables

Demographics

Age, if not already provided, will be calculated in years using the following formula: Age (years) = (Date of Visit 1 – Date of Birth + 1) / 365.25, round to smallest integer

Body Mass Index (BMI, kg/m^2) will be calculated using the following formula:

BMI = Weight (kg) / Height2 (m^2)

Efficacy

Time at Risk

- Beginning of time at risk starts with the first active surveillance contact
- End of time at risk is illness onset with rapid test confirmed SARS-Co-v2 virus infection or the last submitted response to study surveillance.
    - Illness onset is defined for participants with an illness as the earlier of the first positive swab collection (excluding false positives) and the date of reported symptom start.
- Duration of time at risk in days is defined as: End of time at risk – beginning of time at risk + 1.
- We will assess the need to statistically adjust for time since last infection or time since last vaccination as 2 separate potential covariates

7.6 Analysis Software

All analyses will be performed using SAS® Software version 9.4 or higher or R version 4.1.2 or higher.

7.7 Data Transformation

None

8. STATISTICAL ANALYSIS

8.1 General Principles

Superiority confidence intervals (CIs) will be two-sided with a 95% confidence level, and superiority hypothesis tests will be evaluated at two-sided significance level of 0.05. Non-inferiority hypothesis tests will be evaluated with a one-sided 95% confidence interval. Descriptive summaries for interval scale variables will include number of participants with evaluable information, mean and standard errors. Descriptive summaries for categorical scale variables will include number of participants with evaluable information and percentage based on number of participants with evaluable information.

The choice of statistical test will be guided by the objective and the type of measurement: Pearson's chi-square test for comparing distributions of categorical measures (Fisher's exact test where cell counts do not support Pearson), 2-sample t-test for comparing two means of interval scale measures, analysis of variance for comparing >2 means of interval scale measurements or two means with a covariate, Cox proportional hazard regression for comparing distributions of time to event, logistic regression for comparing rates of categorical measures, and Poisson regression for comparing rates of events.

8.2. Demographics and Other Baseline Characteristics

Location, age group, sex, self-reported race and ethnicity, occupation, preexisting medical conditions, SARS-CoV-2 vaccine history during prior seasons (as feasible), and frequency of mask-use while in close proximity of others during the SARS-CoV-2 circulation period will be summarized overall and by vaccine group. All demographics and baseline characteristics will use the mITT population.

8.3. Efficacy Analysis

8.3.1 Primary Objective Analysis

The primary analysis for VE will be a superiority test comparing vaccine efficacy (VE) between participants who receive either the NVX 2023-2024 updated vaccine (Arm 1) or Pfizer mRNA 2023-2024 updated vaccine (Arm 2) with the participants who are recommended to be vaccinated based on CDC, state or organizational guidelines but decline the 2023-2024 updated vaccine. Cox proportional hazards models will use the Andersen and Gill counting method[6] with participants able to contribute time at risk for each day of follow-up. Vaccine efficacy is defined as 100% × (1−HR) calculated using the Cox proportional hazards regression with vaccine group as a main effect, adjusting for age group.

$$h(t) = h_0(t)\exp(\beta V + b_i Z_i)$$

where t is the time at risk, β is the effect of vaccine group of interest (different for VE and rVE objectives) and b_i is the effect of covariates indicated by Z_i. The HR for VE or rVE is then defined as exp(β).

For the VE objective, Cox proportional hazard models will have randomized vaccine group versus the non-randomized arm as the main effect. For both primary objectives age, prior COVID-19 vaccination in the past 4 years and week will be adjusted for (time-varying covariate). Prior COVID-19 vaccination will be categorized (1 prior vaccine (2 course vaccination), 2 prior vaccines (initial vaccination and 1 booster), 3 prior vaccines and ≥4 prior vaccines), if there are less than 30 people in a category, then we will collapse down (e.g. ≥3 instead of 3 and ≥4) until we have stable estimates. Other baseline characteristics will be included as covariates if there are significant imbalances between vaccine groups and kept in the model if they adjust the hazard ratio by ≥5. If an analysis has <10 events, an unadjusted model only will be calculated.

If models for a single month do not meet the proportional hazard assumption, the Andersen and Gill counting method will be used to allow for weekly circulation as a covariate. If a model still does not meet the assumption the proportional hazards assumption after the inclusion of weekly circulation as a covariate, the Prentice, Williams, and Peterson total time model[7] will be used with season as a strata and circulation as a covariate, allowing for circulation to vary. Participants who do not experience a SARS-CoV-2 case prior to the discontinuation of the study will be right censored at their last response to weekly surveillance contacts.

The relative vaccine efficacy against SARS-CoV-2 illness for NVX boosted participants versus mRNA boosted participants will be calculated with the mITT population using time at risk with the following null and alternative hypotheses for the objective comparing NVX vs mRNA:

H_0: rVE < -50 and H_a: rVE≥ -50

Here rVE is estimated with the same analytic approach described for the VE, however the Cox proportional hazard models will have NVX arm versus the Pfizer arm as the main effect. The primary objective will be achieved if the lower limit of the one-sided 95% confidence interval of rVE estimate exceeds -50 between NVX and Pfizer mRNA vaccine groups, adjusting for potential confounders or differences in baseline groups.

8.3.2 Secondary Objective Analyses

Incidence of SARS-CoV-2 will be calculated using Poisson regression with vaccine group as a main effect, and study month as covariates and log person weeks as an offset. Person weeks is defined as the time at risk (in days) divided by seven and rounded up. If assumptions for Poisson regression do not hold, zero-inflated Poisson and Negative Binomial models will be considered instead.

Proportional hazard or logistic regression analyses will be used to assess hazard ratio or relative risk and associated 95% confidence intervals for secondary endpoints such as individual, occupational, and environmental predictors of SARS-CoV-2 infection and of asymptomatic infection versus symptomatic COVID-19 illness. The choice to use PH or logistic model will depend on the specific secondary outcome being identified. If PH models are used, time-varying covariates will be used as available. Multivariable models will be adjusted for potential confounders.

8.3.3 Sensitivity analysis

In addition to the above specified primary analysis, the following analyses will be conducted as sensitivity analyses:

- The primary efficacy analysis will be repeated using the per protocol population.
- The primary efficacy analysis will be repeated using mITT population who complete ≥20% of surveillance each season.

9. SAFETY ANALYSES

Since all study vaccines are licensed for use in participants meeting the eligibility criteria and safety and tolerability of each vaccine have been established in prior studies, data on reactogenicity events will be solicited in a separate reactogencity substudy. This substudy has separate protocol and statistical analysis plan (SAP) documents (Refer to Appendix S2 and the Post-Vaccination Substudy Protocol).

10. REFERENCES

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