

Subject Case Report Forms

CoVPN3004-01_Version_2.0_PROD_EC_22JUN2021 - ALL FORMS

Signature Prompt: I certify that I have ensured the accuracy and completeness of the data reported in the Case Report Forms.

CoVPN3004-01_Version_2.0_PROD_EC_22JUN2021: ALL FORMS

Form: Participant Identifier

Generated On: 28 Jun 2021 23:28:20

Participant ID:

NOW

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Form: Informed Consent

Generated On: 28 Jun 2021 23:28:20

Informed consent type Parental/Guardian

Self

Witness

Informed consent date _____

If parental/guardian or witness consent was selected above, did the
minor participant give assent? Yes

No

Date of assent _____

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Form: Inclusion Exclusion Criteria

Generated On: 28 Jun 2021 23:28:20

Has the participant screened for the study before? Yes
No

If yes, record the first Rave PTID assigned: _____

Screening date _____

Did the participant meet all eligibility criteria? Yes
No

Eligibility status Eligible and enrolled
Eligible/Not enrolled
Ineligible
Incomplete screening

Date participant was found "Eligible/Not Enrolled", "Ineligible," or "Incomplete Screening" _____

- Select reason(s) why participant is ineligible.
- I1. Enrolled in the parent study
 - I2. Less than 18 years and > or = 12 years of age at time of enrollment
 - I3. Ability and willingness to give informed consent/assent prior to study enrollment and comply with the study procedures
 - I4. Received two doses of study product
 - I5. Providing surveillance data on COVID-19 symptoms as described in the parent protocol
 - I6. Access to a cell phone with ability to download and use the MG Scanner™ Application
 - I7. Active email address
 - E1. Any condition that would, in the opinion of the investigator, place the participant at an unacceptable risk of injury or render him/her unable to comply with the study requirements

If eligible, but participant declined enrollment, specify reason: _____

Was the participant enrolled in the study? Yes
No

Date of enrollment (maximum 7 days between Screening and Enrollment is allowed) _____

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Form: Contact Information

Generated On: 28 Jun 2021 23:28:20

Novavax main study ID (ABXXX-XXXX)

Enter Novavax main study ID exactly as it appears in the main study. For example, US123-1234 (country, site-participant number).

| | |
|---------------|-----------------------|
| Date of birth | _____ |
| Age | _____ Fixed Unit: yrs |

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Form: Adverse Event Y/N

Generated On: 28 Jun 2021 23:28:20

Has the participant experienced an adverse event during the study?

Yes

No

If "Yes", update the Adverse Event log.

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Form: Adverse Event

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Date AE reported to site _____

Adverse event (AE) _____

Onset date _____

At which visit was this adverse event first reported? Screening/Enrollment
Study Termination
Interim Visit

If "Interim visit", specify interim visit code. _____

Is the AE still ongoing? Yes
No

If "No", outcome date _____

Severity grade Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Grade 5 (Death)

Other actions

Mark "None" or all that apply.

None _____

Medication(s)

Therapeutic procedure/surgery

Diagnostic procedure

Other

If "Other", specify (max. 200 characters): _____

Status/Outcome Recovered/Resolved
Recovering/Resolving
If "Severity/Frequency increased" is selected, report as a new adverse event. Recovered/Resolved with sequelae
Not recovered/Not resolved
Fatal
Severity/Frequency increased

If status or outcome is "Severity/Frequency increased", select adverse event. _____

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Form: Adverse Event

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Is this a serious adverse event according to ICH/GCP or protocol guidelines? Yes
No

If "No", go to "Has or will this AE be reported as an SAE/EAE?".

If "Yes", check all that apply.

- Results in death
- Is life-threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above

Has or will this AE be reported as a SAE/EAE? Yes
No

If "Yes", provide SAE/EAE number below.

If "No", go to "Was this AE a worsening of a baseline medical condition?".

SAE/EAE number _____

Begin number with 4-digit year, followed by 6-digit SAE/EAE number (no dashes or spaces). _____

SAE/EAE onset date _____

Comments (max. 450 characters): _____

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Form: Study Termination

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Date of study exit _____

Primary reason for completion/discontinuation

Scheduled exit visit/end of study

Death

Participant is unwilling or unable to comply with required study procedures

Lost to follow-up

Investigator decision

Early study closure

Protocol deviation

Adverse event

Pregnancy

Withdrawal of consent by participant

Study terminated by sponsor

Other, specify

If "Other", specify (max. 200 characters): _____

If "Death", enter date of death. _____

If "Adverse event", select applicable adverse event. _____

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Form: Call Y/N

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Has there been a phone contact with the participant or participant's
parent/guardian?

Yes

No

If "Yes", update the Call log.

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Form: Call Log

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Call date _____

Call time _____

Type of call Inbound

Outbound

Summary of interaction _____

Additional actions None

Staff to contact lab team

Asked participant to contact

healthcare provider

Referral to study PI

Other

If "Other", specify: _____

Resolution Resolved

Unresolved

Name of staff member _____

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Form: Interim Visit

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Interim visit date _____

Interim visit code _____

Did the participant exit/terminate the study at this visit? Yes
No

If "Yes", please complete the Study Termination CRF.

Were any new adverse events (AEs) reported at this visit? Yes

If "Yes", please complete the Adverse Event Log. No

Have any protocol deviations been reported at this visit? Yes

If "Yes", please complete the Protocol Deviations Log. No

Reason for interim visit _____

AE report or follow-up

Other

If "Other", specify: _____