Update on Novavax NanoFlu™ vaccine and COVID-19-NanoFlu Combination Vaccine development

Vivek Shinde, MD, MPH, VP Clinical Development

October 20, 2021
Overview

NanoFlu Vaccine Development
NVX-CoV2373 Vaccine Development
COVID-NanoFlu™ Combination Vaccine Development
NanoFlu (qNIV) Vaccine Development
# Gaps in current seasonal influenza vaccine technologies

NanoFlu was developed to addresses major gaps in vaccine performance.

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>Gaps to be Addressed</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antigenic drift</td>
<td>Immunosenescence</td>
</tr>
<tr>
<td></td>
<td>Antibodies</td>
<td>T-cells</td>
</tr>
<tr>
<td>Standard Inactivated(^{1,2,3,4,5})</td>
<td>❌</td>
<td>❌</td>
</tr>
<tr>
<td>High-dose inactivated(^{1,3,4,5})</td>
<td>❌</td>
<td>✓</td>
</tr>
<tr>
<td>MF-59 Adjuvanted(^{4,5,6,7})</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Cell-derived inactivated(^{5,8})</td>
<td>❌</td>
<td>❌</td>
</tr>
<tr>
<td>Recombinant(^{2,3,4})</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>NanoFlu(^{9,10})</strong> [recombinant + adjuvanted]</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

- NanoFlu induces **BOTH** broadly cross-reactive antibodies **AND** potent polyfunctional CD4+ T-cell responses; **AND** avoids egg-adaptive antigenic changes.

The NanoFlu vaccine:
The hemagglutinin nanoparticle antigen and Matrix-M™ adjuvant

Recombinant hemagglutinin (HA) nanoparticles
- Produced in a Baculovirus/Sf9 insect cell system
- Expressed as recombinant, full-length, wild-type, uncleaved HA0 that assembles into homotrimers
- Purified homotrimers form higher order nanoparticle structures of 20-40 nm with PS-80
- Manufactured in a rapid, high-yield, high purity process

Potent saponin-based Matrix-M adjuvant
- Purified fractions extracted as saponins from the bark of Quillaja saponaria Molina
- Formulated with cholesterol and phospholipid, forming cage-like particles
- Characterized by mechanisms of action that include:
  - Enhancement of antigen delivery to draining lymph nodes
  - Enhancement of activated T cell, B cell, and APC populations in draining lymph nodes
  - Induction of functional, and broadly cross-reactive antibodies (e.g. influenza)
  - Enhancement in peak and durability of antibody responses (e.g. RSV)
  - Induction of polyfunctional T cells, including CD4+ (e.g. Ebola, influenza), and CD8+ (e.g. Ebola)
- Antigen sparing in the context of novel antigens: pandemic influenza and Ebola antigens
Matrix-M™ Adjuvant Production Process

Saponins, from the Quillaja saponaria tree, help generate a robust immune response

1. Trees are pruned and bark is harvested
   Saponins are found in the tree’s bark. Bark is harvested sustainably, without felling the whole tree.

2. Bark is processed
   Bark extract is processed into Fraction-A and Fraction-C, then freeze-dried (lyophilized). These powders contain “raw” saponin molecules.

3. Liquid formulation prepared
   Fraction-A and Fraction-C, as liquids, are formulated with phospholipids and cholesterol, producing distinctive nanostructures.

4. Matrix-M™ adjuvant formation
   Matrix-A and Matrix-C components are mixed to form Matrix-M™ adjuvant.

5. Final vaccine
   Matrix-M™ adjuvant is mixed with the vaccine antigen to form the final vaccine product.
Phase 1: NanoFlu (tNIV) induced higher *wild-type* HAI antibody responses (GMFRs) vs. Fluzone-High Dose (IIV3-HD) against 5 generations of antigenically drifted A(H3N2) strains.

**Improved Titers against Influenza Drift Variants**

with a Nanoparticle Vaccine

Shinde, et al. NEJM 378 (2018); 24
DOI: 10.1056/NEJMc1803554

**Phase 1 design:**

330 US adults aged ≥60 years
Randomized 1:1:1
- tNIV: 15µg each HA (45µg total) + 50µg Matrix-M, or
- tNIV: 60µg each HA (180µg total) + 50µg Matrix-M, or
- Fluzone High Dose: 60µg each HA (180µg total)

**Objectives/endpoints:**

- Day 21 wild-type HAI antibody responses against homologous and drift strains
- Safety profile through 1 year

**Geometric Mean Fold Titer Rise (95% CI)**

<table>
<thead>
<tr>
<th>Group</th>
<th>A/Victoria H3N2</th>
<th>A/Texas H3N2</th>
<th>A/Switzerland H3N2</th>
<th>A/Hong Kong H3N2</th>
<th>A/Singapore H3N2</th>
</tr>
</thead>
<tbody>
<tr>
<td>45µg NanoFlu</td>
<td>2.3 (0.99-5.2)</td>
<td>2.3 (1.4-3.9)</td>
<td>2.5 (1.1-5.6)</td>
<td>2.7 (1.1-7.3)</td>
<td>2.1 (0.92-4.9)</td>
</tr>
<tr>
<td>180µg NanoFlu</td>
<td>2.3 (0.99-5.2)</td>
<td>2.3 (1.4-3.9)</td>
<td>2.5 (1.1-5.6)</td>
<td>2.7 (1.1-7.3)</td>
<td>2.1 (0.92-4.9)</td>
</tr>
<tr>
<td>IIV3-HD</td>
<td>2.2 (0.99-5.2)</td>
<td>2.2 (1.4-3.9)</td>
<td>2.2 (1.1-5.6)</td>
<td>2.2 (1.1-7.3)</td>
<td>2.2 (0.92-4.9)</td>
</tr>
</tbody>
</table>

| Ratio of Day 21 GMTs | 38% | p=0.0056 | 28% | p=0.036 | 54% | p=0.0065 | 47% | p=0.0056 | 64% | p=0.0009 |

A(H3N2) clades/subclades concurrently circulating in North America
Phase 1: egg-adapted reagents may give a misleading result

Microneutralization antibody responses (GMFRs) against egg-adapted vs. wild-type A/Singapore A/H3N2 virus

Ratio of Day 21 GMTs
61% ↑ p=0.0002

NanoFlu induced improved neutralization responses against wild-type vs. egg-adapted A/Singapore H3N2 viruses underscoring the problem of egg-adaptive mutations

Neutralization antibody responses against wild-type circulating viruses are the most clinically relevant
Phase 2: High-level summary

Primary endpoint met:
  • Demonstration of an “adjuvant effect”, i.e. Matrix-M adjuvant resulted in significant enhancement of immune responses when compared to unadjuvanted formulation.

Higher wild-type HAI antibody responses against homologous A/H3N2 and drifted A/H3N2 strains as compared to Fluzone HD.

Similar wild-type HAI antibody responses against homologous and drifted strains as compared to Flublok.

Strong induction of polyfunctional CD4+ T cell responses, which were higher than both Fluzone HD and Flublok.

NanoFlu was well-tolerated, with acceptable safety profile.
Phase 3: a non-inferiority immunogenicity trial

Aims and design

**Aims**

- **Demonstrate immunologic non-inferiority** to licensed influenza vaccine (Fluzone Quadrivalent) on 4 homologous strains
- Establish pivotal clinical trial dataset to support filing of BLA via accelerated approval path

**Design**

- **2650** adults ≥65 years of age, across 19 US sites
- Randomized to 1:1 to either NanoFlu or Fluzone Quadrivalent
- Stratified by receipt of *prior year* seasonal influenza vaccine
- Single dose of test vaccine on Day 0

---

**Table: Day 0 Trial Treatment Injection**

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Vaccine</th>
<th>HA Dose per Strain, µg (H1N1/H3N2/BV/BY)</th>
<th>Matrix-M1 Adjuvant Dose, µg</th>
<th>Formulation</th>
<th>Subjects Per Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>NanoFlu (qNIV)</td>
<td>60, 60, 60, 60</td>
<td>75</td>
<td>Co-form</td>
<td>1325</td>
</tr>
<tr>
<td>B</td>
<td>Fluzone Quad [standard dose]</td>
<td>15, 15, 15, 15</td>
<td>N/A</td>
<td>N/A</td>
<td>1325</td>
</tr>
<tr>
<td><strong>Total Trial Subjects</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>2650</strong></td>
</tr>
</tbody>
</table>
### Phase 3 top-line safety data through Day 365

**NanoFlu well tolerated**

<table>
<thead>
<tr>
<th>Event Type</th>
<th>NanoFlu</th>
<th>Fluzeone Quad (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>1333</td>
<td>1319</td>
</tr>
<tr>
<td>Any treatment emergent adverse event (TEAE)</td>
<td>783 (58.7)</td>
<td>697 (52.8)</td>
</tr>
<tr>
<td>Any Solicited TEAE</td>
<td>551 (41.3)</td>
<td>420 (31.8)</td>
</tr>
<tr>
<td>Local solicited</td>
<td>372 (27.9)</td>
<td>243 (18.4)</td>
</tr>
<tr>
<td>Severe local solicited</td>
<td>8 (0.6)</td>
<td>2 (0.2)</td>
</tr>
<tr>
<td>Systemic Solicited</td>
<td>369 (27.7)</td>
<td>292 (22.1)</td>
</tr>
<tr>
<td>Severe systemic solicited</td>
<td>15 (1.1)</td>
<td>11 (0.8)</td>
</tr>
<tr>
<td>Unsolicited TEAE</td>
<td>469 (35.2)</td>
<td>466 (35.3)</td>
</tr>
<tr>
<td>Severe unsolicited</td>
<td>75 (5.6)</td>
<td>59 (4.5)</td>
</tr>
<tr>
<td>Severe &amp; related unsolicited</td>
<td>10 (0.8)</td>
<td>2 (0.2)</td>
</tr>
<tr>
<td>Medically-attended unsolicited</td>
<td>353 (26.5)</td>
<td>354 (26.8)</td>
</tr>
<tr>
<td>Serious adverse events (SAEs)*</td>
<td>81 (6.1)</td>
<td>78 (5.9)</td>
</tr>
</tbody>
</table>

*No SAEs in either treatment group were assessed by study investigators as related to vaccine at either timepoint.

Shinde et al. Lancet ID. 2021; DOI: https://doi.org/10.1016/S1473-3099(21)00192-4
Phase 3 HAI testing plan

Substantial A/H3N2 strain diversity and scope of HAI testing

Purple – vaccine strains
Purple with box – current N and S hemisphere strains
Red dot – drifted strains to be tested in Phase 3
Phase 3 immunogenicity: homologous strains

Day 28 egg-based or wild-type HAI GMTs and GMT ratios (NanoFlu / Fluzone)

<table>
<thead>
<tr>
<th>Assay</th>
<th>Strain</th>
<th>NanoFlu D28 GMT</th>
<th>Fluzone Quad D28 GMT</th>
<th>(NanoFlu / Fluzone)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAI: EGG</td>
<td>A/Brisbane/02/2018 (H1N1) pdm09 (Homologous)</td>
<td>49.3</td>
<td>45.0</td>
<td>1.09</td>
<td>(1.03, 1.15)</td>
</tr>
<tr>
<td></td>
<td>A/Kansas/14/2017 (H3N2) (Homologous)</td>
<td>151.5</td>
<td>126.8</td>
<td>1.19</td>
<td>(1.11, 1.27)</td>
</tr>
<tr>
<td></td>
<td>B/Maryland/15/2016 (Vic) (Homologous)</td>
<td>110.7</td>
<td>106.3</td>
<td>1.03</td>
<td>(0.99, 1.07)</td>
</tr>
<tr>
<td></td>
<td>B/Phuket/3073/2013 (Yam) (Homologous)</td>
<td>168.5</td>
<td>133.9</td>
<td>1.23</td>
<td>(1.16, 1.29)</td>
</tr>
<tr>
<td>HAI: WT</td>
<td>A/Brisbane/02/2018 (H1N1) pdm09 (Homologous)</td>
<td>76.6</td>
<td>62.7</td>
<td>1.24</td>
<td>(1.17, 1.32)</td>
</tr>
<tr>
<td></td>
<td>A/Kansas/14/2017 (H3N2) (Homologous)</td>
<td>153.6</td>
<td>90.7</td>
<td>1.66</td>
<td>(1.53, 1.79)</td>
</tr>
<tr>
<td></td>
<td>B/Maryland/15/2016 (Vic) (Homologous)</td>
<td>62.8</td>
<td>47.2</td>
<td>1.32</td>
<td>(1.26, 1.39)</td>
</tr>
<tr>
<td></td>
<td>B/Phuket/3073/2013 (Yam) (Homologous)</td>
<td>118.3</td>
<td>78.4</td>
<td>1.47</td>
<td>(1.40, 1.55)</td>
</tr>
</tbody>
</table>

• GMT ratio success criteria met for non-inferiority
• NanoFlu: 3—23% better using egg-based HAI
• NanoFlu: 24—66% better using wild-type HAI

Shinde et al. Lancet ID. 2021; DOI: https://doi.org/10.1016/S1473-3099(21)00192-4
Phase 3 immunogenicity: drifted A/H3N2 and B-Victoria strains

Day 28 wild-type HAI GMTs and GMT ratios (NanoFlu / Fluzone)

<table>
<thead>
<tr>
<th>Assay</th>
<th>Strain</th>
<th>NanoFlu D28 GMT</th>
<th>Fluzone Quad D28 GMT</th>
<th>D28 GMT Ratio (NanoFlu / Fluzone)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAI: WT</td>
<td>A/Brisbane/02/2018 (H1N1) pdm09 (Homologous)</td>
<td>76.6</td>
<td>62.7</td>
<td>1.24</td>
<td>(1.17, 1.32)</td>
</tr>
<tr>
<td></td>
<td>A/Kansas/14/2017 (H3N2) (Homologous)</td>
<td>153.6</td>
<td>90.7</td>
<td>1.66</td>
<td>(1.53, 1.79)</td>
</tr>
<tr>
<td></td>
<td>B/Maryland/15/2016 (Homologous)</td>
<td>62.8</td>
<td>47.2</td>
<td>1.32</td>
<td>(1.26, 1.39)</td>
</tr>
<tr>
<td></td>
<td>B/Phuket/3073/2013 (Homologous)</td>
<td>118.3</td>
<td>78.4</td>
<td>1.47</td>
<td>(1.40, 1.55)</td>
</tr>
<tr>
<td></td>
<td>A/California (“Drifted” H3N2; Clade 3C2a1b-131K)</td>
<td>115.0</td>
<td>80.6</td>
<td>1.41</td>
<td>(1.33, 1.50)</td>
</tr>
<tr>
<td></td>
<td>A/Cardiff (“Drifted” H3N2; Clade 3C2a1b-135N)</td>
<td>63.9</td>
<td>45.4</td>
<td>1.34</td>
<td>(1.27, 1.43)</td>
</tr>
<tr>
<td></td>
<td>A/Netherlands (“Drifted” H3N2; Clade 3C3a)</td>
<td>102.3</td>
<td>74.7</td>
<td>1.38</td>
<td>(1.30, 1.46)</td>
</tr>
<tr>
<td></td>
<td>A/So. Aus. (“Drifted” H3N2; Clade 3C2a1b-131K)</td>
<td>98.1</td>
<td>70.4</td>
<td>1.36</td>
<td>(1.28, 1.44)</td>
</tr>
<tr>
<td></td>
<td>A/Idaho (“Drifted” H3N2– Clade 3C3a)</td>
<td>202.5</td>
<td>136.8</td>
<td>1.46</td>
<td>(1.37, 1.56)</td>
</tr>
<tr>
<td></td>
<td>A/Tokyo (“Drifted” H3N2– Clade 3C2a2)</td>
<td>78.0</td>
<td>54.5</td>
<td>1.39</td>
<td>(1.31, 1.48)</td>
</tr>
<tr>
<td></td>
<td>B/Washington (“Drifted B-Victoria”)</td>
<td>88.2</td>
<td>71.4</td>
<td>1.23</td>
<td>(1.18, 1.28)</td>
</tr>
</tbody>
</table>

NanoFlu: 34—46% better on drifted H3N2s using wild-type HAI and 23% better on drifted B-Victoria strain

Shinde et al. Lancet ID. 2021; DOI: https://doi.org/10.1016/S1473-3099(21)00192-4
Phase 3 CMI:

RCD of Day 0 and 7 counts of double cytokine+ effector CD4+ T cells against A/Kansas (H3N2)

- NanoFlu substantially right shifted distribution ("cleans out basement")
- Virtually all NanoFlu subjects became “CMI responders,” including those with low baseline
- Similar pattern of CMI responses seen against B/Maryland (B-Vic)

Shinde et al. Lancet ID. 2021; DOI: https://doi.org/10.1016/S1473-3099(21)00192-4
NanoFlu induced substantially higher fold-rises of IFN-γ+ CD4+ T cells as compared to Fluzone HD, Flublok, or FLUAD based on comparable literature estimates [Cowling, 2019].

Cowling 2019; DOI: 10.1093/cid/ciz103
Primary endpoint met:

- Demonstrated immunologic non-inferiority to Fluzone Quad in terms of hemagglutination inhibition (HAI) antibody responses (assayed with egg-derived virus reagents) against all four vaccine homologous strains (per CBER criteria).

Statistically significant higher HAI antibody responses (assayed with wild-type reagents) compared to Fluzone Quadrivalent:

- 24—66% improved Day 28 GMTs against homologous strains
- 34—46% improved Day 28 GMTs against drifted A/H3N2 strains
- 11.4—20.4% increased Day 28 seroconversion rate against homologous strains
- 14.1—18.8% increased Day 28 seroconversion rate against drifted H3N2 strains

Wild-type neutralizing antibody responses as a confirmatory functional antibody assay corroborated previously observed broadly cross-reactive wild-type HAI antibody responses, including against both drifted A/H3N2 and drifted B viruses.

Substantially improved polyfunctional CD4+ T-cell responses across both Total and Effector CD4+ T cells subsets, with persistence one year later

- Unlike Fluzone Quad, virtually all NanoFlu subjects became “CMI responders”, including, most notably, those with low baseline CMI
- Substantially greater induction of CMI than what has been reported for other “enhanced” influenza vaccines in older adults

NanoFlu was well-tolerated with acceptable long term safety profile comparable to Fluzone Quadrivalent
NVX-CoV2373 Vaccine Development
NVX-CoV2373 Vaccine Design

1. SARS-CoV-2 Spike gene inserted into insect virus
   - The full-length, stabilized Spike gene is engineered into baculovirus.

2. Sf9 cells infected
   - Recombinant baculovirus infects S. frugiperda (Sf9) in the moth cell expression system.

3. Spike gene enters Sf9 cell nucleus
   - Spike DNA is transcribed.

4. Sf9 cells produce Spike
   - Spike proteins are expressed in their native trimer conformation.

5. Nanoparticle formation
   - Spike protein trimers are harvested. Vaccine nanoparticles assemble as rS protein trimers arrange around a Polysorbate 80 (PS80) core.

6. Final vaccine
   - Vaccine nanoparticles are mixed with Matrix-M™ adjuvant to create ready-to-use NVX-CoV2373 vaccine.
## PREVENT-19 Pivotal Phase 3 Trial Summary

### Participants Enrolled
- **29,960** participants enrolled

### Sites
- **119** sites
  - **113** in U.S.
  - **6** in Mexico

### Adult Crossover
- Completed

---

### Consistent, High Efficacy Among Circulating Variants

<table>
<thead>
<tr>
<th>Efficacy Metric</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall efficacy</td>
<td>90.4%</td>
</tr>
<tr>
<td>Protection against moderate and severe disease</td>
<td>100%</td>
</tr>
<tr>
<td>Efficacy in high-risk populations</td>
<td>91.0%</td>
</tr>
<tr>
<td>Efficacy against variants NOT considered VoI/VoC</td>
<td>100%</td>
</tr>
<tr>
<td>Efficacy against VoI/VoC</td>
<td>92.6%</td>
</tr>
</tbody>
</table>

### Reasserted Favorable Safety Profile

- Vaccine generally well-tolerated with favorable reactogenicity profile
- Serious and severe adverse events were low in number and balanced between vaccine and placebo groups

---

Dunkle et al. 2021; doi: https://doi.org/10.1101/2021.10.05.21264567
# UK Phase 3 Trial Summary

<table>
<thead>
<tr>
<th>Participants Enrolled</th>
<th>Adult Crossover Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>15,203</td>
<td>Completed</td>
</tr>
</tbody>
</table>

**Primary Efficacy Endpoint Achieved**

- **90%** Overall efficacy
- **96%** Efficacy against original COVID-19
- **86%** Efficacy against Alpha (B.1.1.7) variant (first described in UK)
- **89%** Efficacy in participants ≥ 65 years of age
- **91%** Efficacy in participants with high-risk medical comorbidities

**Demonstrated Favorable Safety Profile**

- Safety events were infrequent and balanced between vaccine and placebo groups
- **When co-administered with influenza:**
  - Generally well-tolerated
  - Immune responses and vaccine efficacy preserved

Heath et al. 2021; DOI: 10.1056/NEJMo2107659
COVID-NanoFlu (qNIV/CoV2373) Combination Vaccine Development
Rationale for development of a COVID-NanoFlu Combination Vaccine

• Recurrent boosters of a SARS-CoV-2 vaccine may be needed in future with:
  • Ongoing potential for emergence of variants escaping natural/vaccine immunity
  • Continued SARS-CoV-2 circulation for the foreseeable future, potentially in a seasonally recurrent pattern
  • Waning of neutralizing antibody responses in 6 to 12 months following vaccination or infection

• Ongoing need for annual seasonal influenza vaccination:
  • Despite little to no influenza during COVID-19 pandemic in 2020, influenza transmission likely to rebound in 2021 and beyond with reopening of society
  • Continued urgent public health need to develop more effective seasonal influenza vaccine

• Development of a combination vaccine anticipates future need to annually immunize against both SARS-CoV-2 and influenza virus in advance of the winter transmission season
  • Address two major public health problems with one vaccine solution
COVID-NanoFlu™ Combination Vaccine Design

1. Genes inserted into insect virus
   SARS-CoV-2 Spike and four Influenza Hemagglutinin (HA1, HA3, HAB1, HAB2) genes are engineered into baculovirus for independent expression.

2. Sf9 cells infected
   Reombinant baculovirus infects moth cells in S. frugiperda (Sf9) expression system.

3. DNA enters Sf9 cell nucleus
   Spike and HA DNA is transcribed

4. Sf9 cells produce proteins
   Proteins are each expressed in their native conformation

5. Nanoparticle formation
   Proteins are harvested. Vaccine nanoparticles assemble as proteins arrange around a Polysorbate 80 (PS80) core.

6. Final vaccine
   Spike and HA vaccine nanoparticles are mixed with Matrix-M™ adjuvant to create the ready-to-use vaccine.
COVID-NanoFlu Combination Vaccine Development

May 2021
Announced positive preclinical data*

June 2021
Announced data from co-administration sub-study**

September 2021
Initiated phase 1/2 clinical trial of COVID-NanoFlu Combination Vaccine

Preclinical Development

- Hemagglutination inhibition (HAI) and ACE2 titers were comparable between individual and component vaccines (hamster and ferrets)
- Maintained clinical and virologic protection against experimental challenge with SARS-CoV-2 (hamster model)
- Induced antibodies against SARS-CoV-2 neutralizing epitopes common between USA-WA1 (original strain) and Beta (B.1.351) variant

Clinical Proof of Concept

- UK Phase 3 co-administration sub-study completed
- Demonstrated viability of simultaneous COVID-19 and influenza vaccination

Clinical Development

- Phase 1/2 trial in Australia initiated and fully enrolled
  - Safety, immunogenicity, and dose finding
  - ~640 adults 50-70 years of age

*Massare et al. 2021; DOI: 10.1101/2021.05.05.442782
**Toback et al. 2021; DOI: 10.1101/2021.06.09.21258556
NanoFlu™ - COVID Combination Vaccine Trial

The study will evaluate dose ranges for both Spike and Hemagglutinin antigens, using a Design of Experiments (DoE) approach with 14 treatment groups.

Key antibody and cell-mediated immunity responses will be used to select one or more doses to advance into further development.

Control Groups

NanoFlu Only

NVX-CoV2373 Only

Participants are administered the reference formulation of a single vaccine, at the dose level evaluated in previous Phase 3 trials.