This document is a preview of the MucInn Proposal Abstract template. Please use the application link on the VITAL MucInn Page to access the most up-to-date version for your submission.

MucInn – Pre-submission package and Abstract template
(Please delete all italicized text prior to submission)

General Instructions

The Pre-proposal application submission (referred to as the "Abstract") is intended to provide sufficient information for MucInn to assess the relevance, feasibility, maturity, potential impact, and translational potential of the proposed technology.

Note: The Abstract is not intended to be a full technical proposal. The Abstract shall be limited to 4 pages.

The Abstract must address the technical requirements described in the MucInn solicitation in sufficient detail to permit a technical review in accordance with the responsiveness requirements and evaluation factors. Applicants are strongly encouraged to use pictures and graphics to succinctly represent proposed ideas, organization, etc.

In addition, the submission should include:

- ***Cover page*** *(not included in page count)*
- ***Quad chart*** *(limited to* ***1 Page only*** *and not included in the page count)*

Pages in excess of the 4-page limit will not be considered. Applicants are advised that the number of pages should be commensurate with the degree of complexity of the proposed effort.

Please make note of the following formatting requirements:

- *12-point font (or larger), single-spaced, single-sided, 8.5 by 11 inches*
- *Smaller type may be used in figures and tables, but must be 8-point font (or larger)*
- *Margins on all sides (top, bottom, left, and right) should be at least 0.75-inch*
- *Submit files in Microsoft Word or Adobe Acrobat (PDF, portable and searchable document format) format. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames shall contain the appropriate filename extension (.docx, .pdf). Filenames should not contain special characters. iOS users must ensure the entire filename and path are free of spaces and special characters. Movie and sound file attachments or other additional files will not be accepted.*

To ensure Abstracts receive proper consideration, ***the format described above is mandatory****. If there are any items which are not applicable to a specific Abstract, include the section topic in the Abstract with a short explanation as to why it is not applicable.*

[A.] Cover page (not included in page count): Should include the following information.

[Title of Abstract]

[Name of Applicant]
[Address of Applicant]
[Phone Number and Email Address of Applicant]

[Administrative Point of Contact]
[Phone Number and Email Address of Administrative Point of Contact]

[B.] Components of the Abstract (Total 4 Pages): Should include the following information.

1) Executive Summary (*250 words max.*)
2) Technical Proposal

    Technical challenges of mucosal vaccines addressed:

    ☐ Mucosal penetration/delivery
    ☐ Mucosal clearance, poor uptake, tolerance/residence time
    ☐ Robust and durable mucosal and systemic immunity

a) Proposed influenza vaccine application and approach
  i) Type(s) of influenza antigen and adjuvant(s) to be used in this proposal
  ii) Details of formulation engineering and/or delivery system.
  iii) Ability of the proposed approach to be extended to other respiratory pathogens
b) Scientific rationale, preliminary evidence and feasibility:
  i) Applicants should provide available preliminary data or other supporting evidence demonstrating the feasibility of the proposed approach. Evidence may include vaccine-specific data and/or data generated using other therapeutic applications as well as data from relevant publications.
  ii) Applicants should indicate if prior development and evaluation efforts have generated supportive data, including (but not limited to):
    (1) Preliminary experimental data
    (2) Published data
    (3) Relevant non-vaccine data
    (4) Prior data from animal models
    (5) In vitro/ex vivo/NAM/MPS data, if any, demonstrating effective biological performance and/or immunogenicity
    (6) Antigen/adjuvant co-delivery or vaccine formulation or mucosal vaccine delivery data
    (7) Manufacturing feasibility data
  iii) If the technology has not previously been evaluated in influenza vaccine candidates, the applicant should describe how the technology would be adapted/incorporated into a mucosal influenza vaccine and how the proposed strategy would improve vaccine performance.
  iv) Applicants should explain the relevance of existing data to the proposed activities under the MucInn program.

3) Development approach and plan
a) Indicate specific aims that will demonstrate the ability of the product/technology to address the objectives of MucInn.
  i) Mucosal penetration and/or residence time
  ii) Antigen uptake/presentation
  iii) Antigen-adjuvant co-delivery, if applicable
  iv) Mucosal immune activation

v) *Expected sIgA, TRM/BRM, systemic and cellular responses*
vi) *Animal study design*

4) Estimated Budget and Period of Performance
   a) *Provide a rough order of magnitude (ROM) cost estimate and any relevant assumptions for the proposed work.*
   b) *Propose a Period of Performance (PoP) in months and describe the overall timeline and milestones with their associated costs.*
   c) *Indicate whether cost sharing is proposed and, if so, the percentage (%) of cost share.*

5) Team capabilities and proposed collaborators
   a) *Describe any current or potential partnerships or collaborations (clinical, industry, etc.) that may be beneficial to the application, and the monetary value (in USD), if applicable, of these partnerships. Briefly describe the purpose of the collaboration and role of the partner.*

[C.] Components of the Quad chart (1 Page only): Should include the following information. *A picture or graphic that illustrates the research or concept (e.g., data figures, molecule illustrations, or processes) is acceptable.*

QUAD Chart Template

Your quad chart must contain the following information and be positioned in a landscape view. Any quad chart submitted that exceeds the one-page limit will not be read or evaluated.

<table>
<tr><td colspan="2">PROJECT TITLE:
POC: Name, email, phone Company Name & Address</td></tr>
<tr><td>

- **Technology:**
  [Briefly describe the technology]

- Influenza antigen:
- Adjuvant(s):
- Key MucInn barrier addressed:
- Route: ☐ IN ☐ IH ☐ Oral/sublingual ☐ Other
- Development stage: ☐ Early ☐ Preclinical ☐ Advanced
- Preliminary evidence: ☐ Yes ☐ No
  Evidence Type: ☐ In vitro/ex vivo ☐ NAM/MPS ☐ Animal ☐Vaccine ☐ Other
- Key delivery attributes: ☐ Mucoadhesion ☐Mucus penetration
  ☐ Controlled/extended release ☐ Antigen protection/stabilization
  ☐ Targeted uptake ☐ Antigen/adjuvant co-delivery ☐ Other:
- Formulation type: ☐ Nanoparticle ☐ Microparticle ☐ Liposome ☐ Hydrogel
  ☐ Emulsion ☐ Dry powder ☐ Thin films/oral capsules ☐ Other:

</td><td rowspan="2">Scientific rationale and strategic/translational impact:</td></tr>
<tr><td>Development strategy</td></tr>
</table>

	Proposed Funding, Period of Performance (POP), Teaming: *For funding requested, indicate whether cost sharing is included (highly desirable)* **Year 1:** **Year 2:** **Cost sharing:** ☐ Yes ☐ No Indicate %: **POP:** **Team + partners:**