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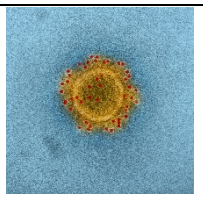
This document is a copy of the APP Submission Form to help you prepare your submission. **You cannot submit this document** in lieu of completing the online submission process.

For additional information, please see the Frequently Asked Questions (FAQs). For all other queries including how to complete a Non-Disclosure Agreement, please contact APPSubmission@nih.gov.

National Institute of Allergy and Infectious Diseases



The Antiviral Program for Pandemics Submission Form

The APP will only accept submissions for virus targeted antiviral candidates that meet program criteria listed on the NIAID webpage. To continue your submission, please complete the Acknolwedgement sections below.

Acknowledgment*

I acknowledge that I have reviewed the **in-scope criteria** and read the **APP Disclaimer** and the **Confidentiality Statement** below.

☐ Yes*

First name Last name	*Today's date*	*Email address*

APP Disclaimer: This submission form is for information and planning purposes only and shall not be construed as a solicitation or funding opportunity; a contract, grant, cooperative agreement, or other transaction; or as an obligation on the part of the Federal Government, the NIH, BARDA, or other partner agencies to provide support for any ideas identified in response to it. The Federal Government will not reimburse or pay for the preparation of any information submitted, or for the Federal Government's use of such information. No basis of claims against the U.S. Government shall arise as a result of a response to this submission form or from the Federal Government's use of such information.

Confidentiality Statement: Submissions to this portal are encouraged to be at a summary level so that they remain non-proprietary and non-confidential. Further, federal employees are bound to protect most types of proprietary information in these submissions (see, for example, Exemption 4 of the Freedom of Information Act at 5 U.S.C. § 552(b)(4) and the law on Disclosure of Confidential Information at 18 U.S. Code § 1905). If further confidentiality is needed, submitters can request a NIAID approved Confidentiality Agreement (CDA) at any time in this process by contacting APPSubmission@nih.gov. Submissions to this portal will be accessed and reviewed by staff at the National Institutes of Health. At NIH's discretion, portal submissions may be shared with partner US Govt. agencies (e.g., BARDA) affiliated with the APP.

Contact information:
For additional information, please refer to the FAQs on the NIAID webpage.

For inquiries regarding your submission including how to obtain a NIAID approved NDA, please contact APPSubmission@nih.gov.

A. SPONSOR AND CONTACT INFORMATION

1. Title (*select one*)

Select One

2. First name*

3. Last name*

4. Location - Country*

5. Phone number (work)*

6. Email address *

7. Affiliated organization*

8. Type of affiliation (select one)*
   a) Government
   b) Academic
   c) Industry
   d) Other (please specify):

B. PROGRAM ELIGIBILITY CRITERIA

1. What type of therapeutic does the candidate represent? (select the single option that best applies)*
   a) Virus targeted antiviral (not including nABs or nnABs)
   b) Neutralizing antibody (nAb) or non-neutralizing antibody (nnAB)
   c) Host-directed therapy
   d) Other (please specify:)

2. What is the candidate's modality? (select the single option that best applies)*
   a) Small molecule
   b) Nucleic acid
   c) Peptide
   d) Antibody-drug conjugate
   e) Biologic
   f) Other (please specify:)

3. What is the candidate's route of administration? (select all options that apply)*
   a) Oral

b) Intranasal
c) Other inhaled
d) Subcutaneous
e) Intramuscular
f) Intravenous
g) Other (please specify:)

4. For this submission, what virus does the candidate target? (select one option. *If multiple options apply, please submit an additional webform for each of the other viral targets.*)*
a) SARS-CoV-2
b) Other viruses of pandemic potential (possible options are listed below)
c) Other virus (please specify:)

Possible options for Other viruses of pandemic potential:
- Arenaviridae - Lassa
- Arenaviridae - Junin
- Phenuiviridae - Rift Valley Fever Virus
- Hantaviridae - Andes
- Hantaviridae - Sin Nombre
- Peribunyaviridae - LaCrosse
- Peribunyaviridae - California encephalitis
- Nairoviridae - Crimean Congo Hemorrhagic Fever
- Coronaviridae – MERS
- Coronaviridae – SARS-CoV-2
- Paramyxoviridae - Nipah
- Paramyxoviridae – Hendra
- Filoviridae - Ebola
- Filoviridae – Marburg
- Togaviridae - Chikungunya
- Togaviridae - EEE
- Togaviridae - VEE
- Togaviridae – WEE
- Flaviviridae – Dengue
- Flaviviridae – Zika
- Flaviviridae – West Nile

5. Do you plan to or have you already submitted additional APP Submission Forms for the same candidate for other viral targets? If so, please indicate select all viral targets below (select all that apply)*
a) Yes (If yes, please specify:)
b) No

6. Is the candidate currently commercially available for another indication? (select one)*
a) Yes
b) No
c) I don't know

7. Did your organization develop this candidate? (select one)*
a) Yes
b) No
c) I don't know

8. Do you or your organization own the IP rights for this candidate? (select one)*
   a) Yes
   b) No (If no, please provide the name of the party that owns the IP rights to this candidate)

   c) I don't know

9. Please provide an overview of any relevant IP considerations.

C. STUDY SUPPORT (Please review APP Disclaimer on the NIAID webpage)

1. What type of support would you be interested in receiving? (select all that apply)*
   a. Preclinical *in vitro* testing support
   b. Preclinical *in vivo* testing support
   c. Clinical PhI support
   d. Other clinical trial support
   e. Other (please specify:)

2. Please provide a concise description of the in-kind support you would be interested in receiving (e.g., research services such as assay development, in vitro assessment, preclinical animal models, therapeutic development services, clinical trial support, manufacturing).*

3. Please provide a concise description of study/studies to be performed.*

   Do you intend to submit additional candidates for support consideration under the APP?*
   a. Yes *(If yes, how many?)*
   b. No
   c. I don't know

4. Have you identified a lead candidate?*
   a. Yes (please specify:)
   b. No
   c. I don't know

5. Please provide a list of all NIAID, NCATS, or BARDA staff you have contacted regarding the candidate(s) over the last 24 months.

6. Please list all previous and/or current support (includes NIH grants,contracts, and intramural collaborations as well as support from other USG Agencies and/or private sources of funding) received for the development of the candidate being submitted to the AV program for consideration.*

If you prefer to provide supporting materials for any of the questions in this section, please attach your supporting materials here. You may only attach PDF documents (File size limitation). You may attach multiple documents simultaneously. Please name the documents as indicated below and provide a cover page describing the attachment.

Supporting materials may address any of the following areas:

(1) Mechanism of action (Document format: Compound name_Mechanism of action data_ YYYY-MM-DD)
(2) Dose response curves for any assay results (Document format: Compound name_Dose response curves_ YYYY-MM-DD)
(3) Published or unpublished results from any safety or efficacy studies (Document format: Compound name_Safety study 1_ YYYY-MM-DD OR Compound name_Efficacy study 2_ YYYY-MM-DD etc.)

D. CANDIDATE – GENERAL INFORMATION

1. Candidate Name/Designation.*

2. Is the candidate an original synthesis? *
   a. Yes
   b. No
   c. I don't know

3. Is the candidate a derivative compound? *
   a. Yes (Please specify:)
   b. No
   c. I don't know

4. Has the candidate been studied for any other indication(s)?*
   a. Yes
   b. No
   c. I don't know

5. List what indication the candidate has been studied for and the current phase of development for each of those indications. You may list multiple indications. *

Indication	**Current phase of development**
	Select One

6. Please provide a concise summary of planned pre-clinical and/or clinical studies.

E. CANDIDATE - MECHANISM OF ACTION

Indicate if data are not available.

1. Do you have data about the candidate's mechanism of action?*
    a. Yes
    b. No or no data available

2. What is the candidate's viral target? (If unknown, indicate N/A)*

3. What is the target's function during the virus' life cycle? (If unknown, indicate N/A)*

4. What is the candidate's detailed mechanism of action?

5. What data is the mechanism of action based on?

6. What data is the expected delivery mechanism based on (e.g., bioavailability, tissue penetration, distribution data)?

F. CANDIDATE – SAFETY & TOXICOLOGY

Indicate if data are not available

1. Safety data is available for (*Select all that apply*)*
    a. Murine model
    b. Rat model
    c. Hamster model
    a. Other small animal model please specify:
    d. Large animal excluding NHP please specify:
    e. NHP
    f. Human
    g. No safety data is available

2. If available, please provide summary of acute toxicity.

3. If available, please provide summary of gene toxicity.

4. If avaliable, please provide summary of safety data.

5. If available, please provide a summary of tolerability data.

6. If available, please provide summary of drug-drug interactions.

7. Summarize additional planned safety and/or toxicology studies (*If applicable*).

G. CANDIDATE – EFFICACY (*IN VITRO*)

Indicate if data are not available. Indicate where studies were performed.

1. Is *in vitro* efficacy data available for the candidate?*
    a. Yes
    b. No or N/A

2. If available, describe results of biochemical screening assay (include IC50 and IC90).

3. If available, describe results of selectivity assay (include comparator data and controls).

4. If available, summarize efficacy data from cellular viral infection assay (include viral source, viral load, cell type, EC50, EC90, CC50).

5. If available, describe results of secondary screening assay (include EC50, EC90, CC50).

6. If available, describe viral end point(s) tested.

7. If available, describe the extent of activity on other viruses tested.

8. If available, summarize additional planned *in vitro* efficacy studies (*If applicable*).

H. CANDIDATE – EFFICACY (*IN VIVO*)

Indicate if data are not available. Indicate where studies were performed.

1. Efficacy data is available for (*Select all that apply*)*
    a. Murine model
    b. Rat model
    c. Hamster model
    d. Other small animal model (please specify:)
    e. Large animal excluding NHP (please specify:)
    f. NHP
    g. Human
    h. No efficacy data is available

2. Describe viral end point(s) tested.

3. Summarize the efficacy for viral target (including viral load, transmission, dose, tissue-specific data, and how it was determined).

4. Describe the extent of activity on other viruses tested.

5. Summarize additional planned efficacy studies (*If applicable*).

I. CANDIDATE – DRUG METABOLISM, PHARMACOKINETICS, PHARMACODYNAMICS

Indicate if data are not available

1. Pharmacokinetics (PK) data is available for (*Select all that apply*) *
    a. Murine model
    b. Rat model
    c. Hamster model
    d. Other small animal model (please specify:)
    e. Large animal excluding NHP (please specify:)

f. NHP
g. Human
h. No PK data is available

2. Provide summary of PK data (*If predicted, indicate data what prediction is based on*).

3. Pharmacodynamics (PD) data is available for (*Select all that apply*)*
   a. Murine model
   b. Rat model
   c. Hamster model
   d. Other small animal model (please specify:)
   e. Large animal excluding NHP (please specify:)
   f. NHP
   g. Human
   h. No PD data is available

4. Provide summary of PD data (*If predicted, indicate data what prediction is based on*)

5. Drug Metabolism (DM) data is available for (*Select all that apply*) *
   a. In vitro
   b. Murine model
   c. Rat model
   d. Hamster model
   e. Other small animal model (please specify:)
   f. Large animal excluding NHP (please specify:)
   g. NHP
   h. Human
   i. No DM data is available

6. Provide summary of DM data (*If predicted, indicate data what prediction is based on*).

7. Provide summary of plasma protein binding.

8. Provide summary of clearance mechanism.

9. Provide summary of solubility.

10. Summarize additional planned DMPK and PD studies (*If applicable*).

J. CANDIDATE – DRUG AVAILABILITY & CMC

Indicate if data are not available

1. Is your compound formulated?*
    a. Yes – Interim
    b. Yes – Final
    c. No
    d. No data is available

2. Please provide formulation data for your drug (including pH, salt conditions, storage).

3. Is drug supply available? *
    a. Yes (please specify:)
    b. No
    c. N/A

4. Is GMP drug supply available? *
    a. Yes (please specify:)
    b. No
    c. N/A

5. Is there sufficient drug supply for planned studies (Preclinical *in vitro*, Preclinical *in vivo*, Clinical PhI, Clinical PhII, etc.)? *
    a. Yes
    b. No
    c. N/A

6. Are you able to scale manufacturing for future clinical studies?*

a. Yes
b. No
c. N/A

7. Are you able to scale GMP manufacturing for commercial use?*
    a. Yes
    b. No
    c. I don't know

8. Please provide stability data for your drug (e.g., temperature data, light data). If data is not available, indicate that data is not available.*

9. Have you identified a matched placebo formulation?*
    a. Yes (Provide biological activity and/or toxicity.)
    b. No
    c. I don't know

10. Has a corresponding placebo or active control been identified for the candidate?*
    a. Yes (please specify:)
    b. No
    c. I don't know

11. Is there sufficient placebo or active control available? *
    a. Yes
    b. No
    c. I don't know