



National Institute of
Allergy and
Infectious Diseases

Preclinical & Clinical Services

for Antiviral Program for
Pandemics (APP) Projects

For more information contact
APPSubmission@mail.nih.gov

Date Created
11.22.2022








About NIAID's Antiviral Program for Pandemics

The Antiviral Program for Pandemics (APP) provides free access to preclinical services (PCS) through a suite of service contracts to support the development of therapeutics, vaccines, and diagnostics. APP seeks to bring together the biomedical research community across the public and private sector to advance the development of novel targeted therapies and compress the timelines from onset of pandemic to treatment.

APP Targets Viruses Aligned to NIAID's Pandemic Preparedness Plan

APP is different from other NIH funding opportunities because it uses special appropriations from the Department of Health and Human Services (HHS) to drive the delivery of novel treatments for viral families of pandemic potential that would benefit from additional investment. Antivirals of interest are new chemical entities and small biotherapeutics (excluding mAbs) that directly block viral targets. Of particular interest is the discovery and development of drug candidates with suitable safety profiles and route-of-administration (e.g., oral, intranasal, etc.) for broad use in the outpatient setting to reduce viral burden in early stages of infection.

PRIORITY VIRUSES FOR APP

 Coronaviridae – MERS, SARS-CoV-2, SARS-CoV	 Flaviviridae – Dengue, Zika, West Nile
 Bunyavirales – Lassa, Junin, Rift Valley Fever, Andes, Sin Nombre, La Crosse, California Encephalitis, Crimean-Congo Hemorrhagic Fever	 Paramyxoviridae – Nipah, Hendra
 Filoviridae – Ebola, Marburg	 Picornaviridae – EV-D68, EV-A71
	 Togaviridae – Chikungunya, EEE, VEE, WEE

APP Offers Services Across the Spectrum of Therapeutics Discovery and Development

APP provides preclinical and clinical services for antiviral assessment, synthesis and manufacturing, nonclinical therapeutics profiling, and early clinical trials. APP will evaluate, prioritize, and advance antiviral candidates to de-risk early-stage development and guide candidates along development paths.



Antiviral Assessment



Synthesis & Manufacturing



Non-clinical Profiling



Early Clinical Trials

NIAID establishes contracts with service providers and covers expenses for the requested studies. Results are returned to the requestor for use in advancing their product development efforts. Data provided to support requests and requirements are commensurate with the complexity/cost of the request, e.g., more data must be provided to support a clinical trial request than an in vitro assay.

For more details, please contact NIAID's Antiviral Program for Pandemics at APPSubmission@mail.nih.gov.



Antiviral Assessment

- In vitro Antiviral Testing including cytopathic effect, plaque assay, virus yield reduction and/or replicon assays. NIAID can engage contractors to develop and standardize reproducible in vitro assays
- In vivo Antiviral Testing of candidates in a wide range of standardized or new rodent infection models. Supportive MTD and pharmacokinetics (PK) studies are also available to inform study design



Non-clinical Profiling

- A full suite of assays is available to support therapeutic product development at all stages, from lead identification to IND-enabling studies
- Typical assays include in vitro ADMET profiling, screening PK, bioanalytical method development and qualification, non-GLP and GLP PK/bioavailability, and non-GLP and GLP safety and toxicology



Synthesis & Manufacturing

- NIAID holds service contracts supporting synthesis of small molecules and products containing recombinant proteins, peptides, and nucleic acids
- Services include synthesis of advanced intermediates, building blocks, or final targets; chemical process optimization; pilot and GMP manufacturing; assay development and product release testing



Early Clinical Trial Support

- Support for first-in-human, single-ascending or multiple-ascending dose, and Phase I studies in Healthy Volunteers
- Assistance with design, development, and conduct of clinical trials to generate safety and PK and/or pharmacodynamics (PD) for candidate therapeutics
- Requires signed Clinical Trial Agreement

Please contact NIAID's Antiviral Program for Pandemics at APPSubmission@mail.nih.gov for additional details. Learn more at <https://www.niaid.nih.gov/research/antivirals>.

How to Access APP Preclinical and Clinical Resources

APP preclinical and clinical services (PCS) are free and can be requested by investigators in academia, nonprofit organizations, industry, or government across the United States or worldwide. You need not be a grantee of NIAID or another NIH Institute or Center. Confidentiality and Intellectual Property are protected under a Nonclinical Evaluation Agreement (NCEA) to cover all PCS requests.

How it Works – One Simple Step!

Submit proposals to test or develop antiviral candidates in the discovery phase through early clinical trials that target SARS-CoV-2 and other viruses of pandemic potential using the APP Antiviral Candidate Submission Form.

Available at:

<https://www.niaid.nih.gov/research/submit-antiviral-candidates>

Contact Us for More Information

Please contact NIAID staff at e-mail below for specific details since available models change periodically. Additional viral pathogens beyond those listed in this APP document are also available for assessing broader spectrum for candidates.

Interested in Antiviral PCS? Email APPSubmission@mail.nih.gov

Viral pathogens typically available through NIAID for in vitro and animal model testing

Viral Order/ Family	Viral Pathogen	In vitro	Animal Model*
Bunyavirales	Andes virus	✓	Hamster (SGH)
	Crimean-Congo Hemorrhagic Fever virus	✓	
	Heartland virus	✓	Mouse
	Junin virus	✓	Guinea Pig (Hartley)
	La Crosse virus	✓	
	Lassa Fever virus (incl GP-adapted)	✓	Guinea Pig (Hartley)
	Lymphocytic Choriomeningitis virus	✓	Mouse
	Maporal virus	✓	
	Oropouche virus	✓	Mouse
	Pichinde virus	✓	
	Punta Toro virus	✓	
	Rift Valley Fever virus	✓	Mouse (AG129, Balb/c, C57BL/6, CD-1), Hamster (SGH)
	Severe Fever Thrombocytopenia Syndrome virus	✓	Mouse
	Tacaribe virus	✓	Mouse (AG129)
Coronaviridae	Alpha Human Coronavirus 229E	✓	
	Alpha Human Coronavirus NL63	✓	
	Beta Human Coronavirus OC43	✓	
	MERS Coronavirus	✓	Mouse (BALB/c, hDPP4 Tg, Ces1c-/-), Hamster (SGH)
	SARS-CoV	✓	Mouse (BALB/c, hACE2 Tg, Ces1c-/-), Hamster (SGH)
	SARS-CoV-2 (WA-1 and variants)	✓	Mouse (BALB/c, hACE2 Tg, Ces1c-/-), Hamster (SGH)
Filoviridae	Ebola virus (incl GP-adapted)	✓	Guinea Pig (Hartley)
	Marburg virus (incl GP-adapted)	✓	Guinea Pig (Hartley)
Flaviviridae	Dengue virus	✓	Mouse (AG129)
	Japanese Encephalitis virus	✓	Mouse (C57BL/6), Hamster (SGH)
	Powassan virus	✓	Mouse
	Usutu virus	✓	Mouse
	West Nile virus	✓	Mouse (C57BL/6), Hamster (SGH)
	Yellow Fever virus	✓	Hamster (SGH)
	Zika virus	✓	Mouse (AG129)
Paramyxoviridae	Measles virus	✓	
	Nipah virus	✓	Hamster (SGH)
	Parainfluenza virus	✓	Cotton Rat
	Respiratory Syncytial virus (Pneumoviridae)	✓	Cotton Rat
Picornaviridae	Coxsackie virus B3	✓	Mouse
	Echovirus 11	✓	
	Echovirus 30	✓	
	Enterovirus-68 (EV68)	✓	Mouse (AG129)
	Enterovirus-71 (EV71)	✓	Mouse (AG129)
	Human Rhinovirus	✓	
	Polio virus	✓	Mouse
Togaviridae	Chikungunya virus	✓	Mouse (DBA/1J, C57L/6), Hamster (SGH)
	Eastern Equine Encephalitis virus	✓	Mouse (AG129, Balb/c, C57B/7), Hamster (SGH)
	Mayaro virus	✓	Mouse (C57BL/6), Hamster (SGH)
	Venezuelan Equine Encephalitis virus	✓	Mouse (C57BL/6, Balb/c)
	Western Equine Encephalitis virus	✓	Mouse (C57BL/6, Balb/c)

*Note that some animal models use a modified or adapted form of the virus. Please inquire for more details, as needed.