Discussion on the Next Steps

dr. Herman Kosasih, Ph.D

UPCOMING EVENTS

- Grant proposal writing training session (online) - The 4th week of June 2023
- Grant proposal writing workshop session (face-to-face) - The 4th week of July 2023
- R01 grant submission time limit – The 1st week of August 2023

NEXT STEPS

- Hospitals Identify the potential ideas from researchers
- Hospital encourage selected researchers to submit the research concept plan (based on INA-CRC template) to INA-CRC via ina-registry@kemkes.go.id (Deadline May 17, 2023, at 23.59)
- INA-CRC announce the selected participants *for Grant proposal writing training session (online)* via email on May 22, 2023.
- Selected participants will discuss with INA-CRC/INA-RESPOND/NIH team via email/zoom.

Funding Opportunity Examples

Funding Source	Grant Name	Link
SAEMF Foundation	Emerging Infectious Disease and Preparedness Grant	https://www.saem.org/about-saem/academies-interest-groups-affiliates2/saem-foundation/apply-for-a-grant/what-we-fund/
NIH	International Research in Infectious Diseases (R01 Clinical Trial Not Allowed)	https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-023.html
Wellcome Trust	Wellcome Discovery Awards, Wellcome Early-Career Awards, & Wellcome Career Development Awards	https://wellcome.org/grant-funding/
ESCMID	Individual Research Grant, Study Group Research Grant, and Study Group Collaboration Grant	https://www.escmid.org/membership-organisation/escmid-research-grants
Merck	Healthcare Speed Grant	https://www.merckgroup.com/en/research/
Pfizer	Pfizer's Competitive Grants Program	https://www.pfizer.com/about/programs-policies/grants/
UK Research and Innovation	A lot of grant opportunities	https://www.ukri.org/opportunity/
LPDP Kemenkeu	Riset Inovatif Produktif (RISPRO)	https://risprolpdp.kemenkeu.go.id/information-corner

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Institute of Allergy and Infectious Diseases (NIAID)
Funding Opportunity Title	International Research in Infectious Diseases (R01 Clinical Trial Not Allowed)
Activity Code	R01 Research Project Grant
Funding Opportunity Announcement (FOA) Number	RFA-AI-23-023

Topics of interest for this program cover **a broad range of infectious diseases** research topics.
Amount: **Up to $125,000 in direct costs per year for a maximum of 5 years**
Submission date July 02 – August 02, 2023 (due by 5:00 PM local time of applicant organization)**.**
Letter of intent 30 days prior to the application due date (not mandatory).

International Research in Infectious Diseases (IRID)
https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-023.html

https://grants.nih.gov/grants/how-to-apply-application-guide.html

MSD

Investigator Studies Program (MISP)

To advance science and improve patient care by supporting, through the provision of drug/vaccine and/or total/partial funding, high-quality research that is initiated, designed, implemented and sponsored by external investigators. Results will be generated and properly disseminated in peer-reviewed publications.

- The Company Investigator Studies Program is **open to all academic and community-based physicians and researchers worldwide** who are interested in conducting their own research.
- **Support is provided based on the scientific merit of the proposal** as well as whether it is in **alignment with the published areas of interest.**
- Submission of a proposal does not imply or guarantee approval. All proposals will be reviewed based on research merit criteria. **Financial and/or product support is contingent upon full execution by both parties of the research agreement.**

https://engagezone.msd.com/misp.php

This site is intended for US investigators only. Investigators outside of the US interested in submitting research proposals to the Investigator Studies Program should contact their **local MSD office.**

Support Material

iEnvision-Visiontracker Site
Applicant Guide
Instructions: Correlative Data Entry

Clinical Protocol Template
Clinical Interventional Budget Template
Clinical Non-Interventional Budget Template

The current MISP areas supported are:

- Anesthesia
- Cardiovascular
- Immunology
- Infectious Disease
- Non-Alcoholic SteatoHepatitis
- Neuroscience
- Oncology
- Patient Engagement, Diversity and Health Literacy
- Respiratory
- SARS CoV-2/COVID-19 TREATMENT
- Vaccines

Section #2- Core Protocol	
2.1 Objectives & Hypotheses	*2.1 List the objectives.* *The objectives must clearly define and specifically state what the study is intended to accomplish.* *One to two secondary objectives may be stated. They should be in the order of priority. The higher priority secondary objectives should have corresponding secondary hypotheses associated with them.* *2.1.1 List the clinical hypotheses.* *All hypotheses should be in the order of priority. If the study is estimation study, no hypotheses is needed.*
2.2 Background & Rationale, Significance of Selected Topic & Preliminary Data	*A brief presentation should be made of the reasons for conducting the clinical study based on current knowledge of the product and /or disease state so that the study is presented in the proper perspective. Include the rationale for conducting the study and selecting the dose(s). Selected literature references critical to the study design, dosage selection, or rationale for the study should be cited, as appropriate. Studies using marketed products must cite the currently approved package circular for the product(s) (for the appropriate country) and the package circular may be included as an appendix.*
2.3 Study Design	*This section is a concise overview of the study design stating the type of experimental design (observational or interventional; randomized block, crossover, etc). The procedures must be clear and concise. A description of the specific patient population to be studied should be stated. Both inclusion and exclusion criteria should be listed and should be consistent with the current product label.* *If the study is intended to be observational then the protocol needs to state this and the expectations are different since most observational studies are database studies, retrospective, aggregate studies as opposed to open label studies for efficacy and safety.*
2.4 Diversity & Inclusion	*Please explain how the study would support diversity in access to enrollment and inclusion of people of varying age, race, ethnicity, and gender reflecting the patient population that is affected by the disease/condition being studied.*
2.5 Study Flowchart	*A study flow chart is highly recommended. It should display all clinical and laboratory measurements and the time periods (e.g., hours, days, weeks) at which data are to be collected.*
2.6 Study Procedures	*This section is a detailed explanation of the design. The use of subheadings, lists, tables, or outlines are recommended. In protocols that specify a screening or washout period, indicate that once a patient signs a consent form, a unique number (screening or baseline number) should be assigned for identification purposes.*
2.7 Study Duration	Estimate the length of time (e.g., number of days, weeks, months) required to recruit patients and complete the study.
2.8 Statistical Analysis and Sample Size Justification	*State who will be responsible for analyzing the study data (Investigator, contract CRO, etc.).* • *Variables/Time Points of Interest* • *Statistical Methods* • *Multiplicity* • *Power/Sample Size*
2.9 Specific Drug Supply Requirements	*The following should be indicated in the study protocol or provided by the investigator:* *Include whether the drug supplies will be purchased locally as marketed product or if open label or blinded supplies will be required by MSD.* *Note: At conclusion of the study or upon drug expiration, the MSD Scientific Leadership & Research Manager will be responsible for issuing a Drug Disposition Letter to the investigator for US based studies.* *For US and non-US studies, the investigator will be responsible for the destruction of the supplies at the study center pursuant to the ICH/GCP Guidelines, local regulations and the investigator's institutional policies. Clinical supplies must be received by a designated person at the study site, handled and stored safely and properly, and kept in a secured location to which only the investigator and designated assistants have access. Clinical supplies are dispensed in accordance with the protocol. The investigator is responsible for keeping accurate records of the clinical supplies, the amount dispensed to and returned by the patients, and the disposition at the end of the study.*
2.10 Adverse Experience Reporting	*The study agreement outlines the requirement for adverse experience reporting. For clinical protocols, specific adverse experience reporting requirements must be identified in the protocol if the Model Study Agreement is not used (in general, this would apply to non-US. studies whose local requirements may prohibit the use of the agreement).*
2.11 Itemized Study Budget	*A preliminary study budget must be provided with the initial proposal submitted to give guidance to the MISP Review Committee as to the expected study costs. A refined itemized budget detailing the costs associated with the study should be provided with the final protocol or included in the study agreement as Exhibit B.*
2.12 References	*All literature references cited in the protocol should be listed accordingly in the reference section.*
2.13 Publication Plan	*Generally, a publication plan is discussed between the investigator and MSD /MSD during time when the protocol is under development. Details of the publication and the obligations to MSD are outlined in the study agreement.* *The following should be considered for the publication plan:* • *What are your publication plans? How many manuscripts do you anticipate?* • *Include projected target date for manuscript submission and name of the journal* • *Do you anticipate abstracts? How many?* • *What scientific meetings would you consider presenting the study results?*

MSD - Respiratory Syncytial Virus (RSV) – Effective Nov 2022

Pediatrics

- **Immunity:**
  - Studies, including modeling, that address timing of RSV neutralizing mAb administration.
  - Studies that advance the understanding of immune responses including correlates of immune protection.
- **Virology:**
  - Studies evaluating RSV A and RSV B epidemiology, burden of illness and strain sequence heterogeneity.
  - Studies evaluating resistance to RSV monoclonal antibodies and vaccines.
- **Epidemiology:**
  - Sensitivity and specificity of case definitions for RSV-infection.
  - Understanding of bacterial co-infection.
  - Primary data collection evaluating the population-based incidence.
  - Risk factors for recurrent wheezing/reactive airway.
  - Loss of work hours for parents/guardians and emotional stress.
  - The proportion of medically attended bronchiolitis and RSV infection that is accompanied by acute otitis media (AOM).
  - Compare the percentage of respiratory specimens positive for RSV with the incidence of medically attended RSV in tropical and temperate regions.
  - Understanding the reservoirs of RSV (as there is no animal host).
  - Changes in the seasonality and impact of non-RSV respiratory viruses.

Adults

Immunity:

- Studies that advance the understanding of immune response including correlates of immune protection in the elderly.
- Studies that advance the understanding of how alterations of an established RSV immune response.
- Incidence of RSV infections and hospitalizations in elderly adults residing in assisted living facilities in the US and ex-US.
- Impact of protection of infants on disease in adults.

Pediatrics and Adults

- Inter-relationships between RSV and common respiratory viruses.
- Studies that advance the understanding of bacterial co-infection and antimicrobial consumption.
- Studies that advance the understanding of immune responses including correlates of immune protection.

Critical Activities and Timelines:

Deadline Dates/Activity	1st Review Cycle
Protocol Submission with Detailed Budget	May 8, 2023
Final Comments to Investigator	August 7, 2023

https://engagezone.msd.com/RespSynVir.php

MSD - Dengue – Effective Feb 2023

Focus Area 1: Epidemiology

- The burden of dengue infection and disease in specific sub-populations.
- The burden of dengue infection and disease in under-studied regions of the world (e.g., Africa, South and Central Asia, etc).
- Demographic changes in the epidemiology of dengue infection and disease in endemic countries.
- Impact of large dengue outbreaks or peak dengue cases on the healthcare system (e.g., hospital occupancy, dengue severity compared to non-outbreak periods, lengths of stay for dengue and non-dengue patients, outcomes for dengue and non-dengue patients, postponement of elective surgeries and appointments and amount of revenue lost *vs.* deferred as a result).
  - ➢ The burden of dengue infection in pregnancy: maternal and fetal outcome
  - ➢ Post-acute, persistent, or long-term dengue sequelae in endemic countries.

Focus Area 2: Modeling

Development of mathematical models related to the **epidemiology of dengue infection and public health impact of interventions:**

- ➢ Cost-effectiveness of dengue vaccination vs. the cost of managing dengue disease (outpatient, inpatient, and severe) in endemic countries.
- ➢ Understand the impact (e.g., cost-effectiveness, sustainability) of vector control strategies on dengue infection and disease in endemic regions alone or in conjunction with vaccination.
- ➢ Modeling to predict changes in the future incidence of autochthonous dengue infection in non-endemic regions

Focus Area 3: Vaccination Confidence

- Qualitative and quantitative studies to describe barriers to dengue vaccine acceptance and uptake in dengue endemic regions.
- Pilot studies to evaluate interventions that reduce dengue vaccination hesitancy and increase acceptance in dengue endemic regions.

https://engagezone.msd.com/Dengue.php

Critical Activities and Timelines:

Deadline Dates/Activity	Review Cycle
Full Protocol Submission with Detailed Budget	June 12, 2023
Target Final Comments to Investigators	August 10, 2023

MSD - Pulmonary Hypertension – Effective Apr 2023

The following areas are of interest to the Investigator Studies Program Committee:

Disease state

- Molecular mechanisms and novel genetic factors involved in the progression of disease.
- Link between surrogate clinical endpoints and long-term outcomes: multicomponent improvement (MCI) endpoint 'validation' or association with clinical outcomes.
- Phenotyping (Clinical including hemodynamics, imaging, &/or diagnostic or clinical biomarkers; +/- AI/ML) and/or clinical course of different groups of PH patients (All 5 WHO groups).

Product related

- Characterization of pulmonary vascular remodeling/reverse remodeling +/- effect of sotatercept.
- Impact of activin signaling inhibition on pulmonary vasculature and/or right ventricle +/- Imaging and/or physiologic changes with sotatercept.
- Effect of sotatercept in select subgroups / disease severity / background therapies.

https://engagezone.msd.com/Pulmonary%20Hypertension.php

Critical Activities and Timelines:

Activity	1st Review Cycle	2nd Review Cycle	3rd Review Cycle	4th Review Cycle	5th Review Cycle
Protocol Submission / Detailed Budget Deadline	March 13, 2023	May 15, 2023	July 10, 2023	September 11, 2023	November 6, 2023

Overview

Pembrolizumab Funding Review Cycle
Clinical trials and preclinical studies (efficacy primary endpoints) with funding or funding & drug support.

Pembrolizumab Quarterly Drug Only Review Cycle
Clinical trials (efficacy primary endpoints) with "drug only" support.

Belzutifan Drug & Funding Review Cycle
Clinical trials and preclinical studies (efficacy primary endpoints) with funding & drug support or “drug only” support.

Nemtabrutinib Drug & Funding Review Cycle
Clinical trials and preclinical studies (efficacy primary endpoints) with funding & drug support or “drug only” support.

Pembrolizumab Oncology Translational Studies Program (OTSP)
Translational studies (translational primary endpoints)

Olaparib and Selumetinib Proposals
Due to the recent partnership with AstraZeneca, MSD will now be jointly evaluating Externally Sponsored Research (ESR) proposals with olaparib and selumetinib

Pembrolizumab Quarterly Drug Only Review Cycle

Critical Activities and Timelines:
Review of drug only proposals will be handled on a quarterly basis according to the below schedule.

Submission Deadline	Expected decision
June 30, 2023	August 31, 2023
September 30, 2023	November 30, 2023
December 31, 2023	February 29, 2024

Department of Health and Human Services

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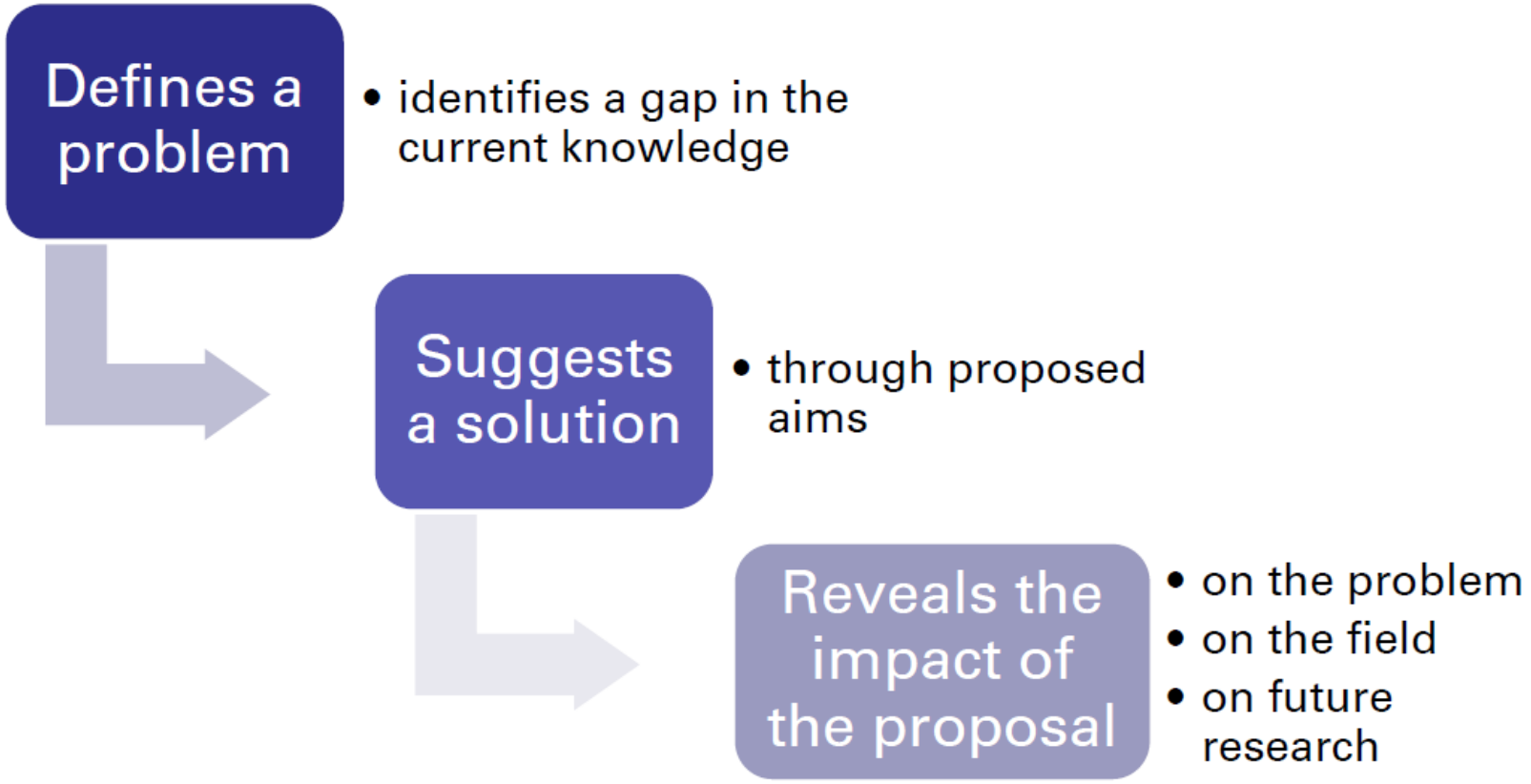
Letter of intent 30 days prior to the application due date.

https://grants.nih.gov/grants/how-to-apply-application-guide.html

Specific Aims in Grant Proposal



SMART:

- Specific
- Measurable
- Achievable
- Relevant
- Time-based

Fardal, 2004

<u>Considerations for writing aims</u>

- ✓ Must be explicit
- ✓ Derived from study hypothesis
- ✓ Based on literatures review

R01 Grant Awardee-Project title

Hair Extensions: Using Hair Levels to Interpret Adherence, Effectiveness and Pharmacokinetics with Real-World Oral PrEP, the Vaginal Ring, and Injectables

PI : Monica Gandhi, MD, MPH (2017)

Problem/ Gap

Lessons of the PrEP (pre-exposure prophylaxis) clinical trials - **that adherence is critical to effectiveness, that pharmacologic adherence measures are more reliable than self-report** – **must be applied to the next phase of HIV prevention research**.

Suggest Solutions – through SMART AIMS!

We hypothesize that **hair concentrations**, coupled with shorter-term measures, in large studies of PrEP **(both oral and the dapivirine vaginal ring)** will allow us **to better predict effectiveness and assess patterns of adherence to these agents among key subgroups in Africa.** We further hypothesize that examining **both hair and plasma metrics** for **long-acting injectable cabotegravir (CAB)** will provide insight for **real-world pharmacokinetic monitoring**.

AIM 1:

To evaluate **concentrations of PrEP drugs in hair and plasma as biomarkers of adherence and predictors of effectiveness** in a large community cluster randomized trial.

AIM 2:

To investigate **the use of hair levels as a long-term measure** of dapivirine exposure in the open- label trial of **the dapivirine vaginal ring.**

AIM 3:

To examine **the utility of hair levels for pharmacokinetic monitoring** of long-acting injectablecabotegravir in a diverse population.

https://www.niaid.nih.gov/grants-contracts/sample-applications

Sample Applications & More

Several NIAID investigators have graciously agreed to share their exceptional applications and summary statements as samples to help the research community. Below the list of applications, you'll also find example forms, sharing plans, letters, emails, and more. Find more guidance at NIAID's Apply for a Grant.

Find sample applications and summary statements below by type:

- Research grants. R01, R03, R15, R21, and R21/R33
- Small business grants. R41, R42, R43, and R44
- Training and career awards. K01, K08, and F31
- Extramural Associate Research Development Award. G11
- Cooperative agreements. U01

Find additional resources in the NIAID and NIH Sample Forms, Plans, Letters, Emails, and More section.

FURTHER INFORMATION & COMMUNICATION

- Today Zoom meeting can be accessed via Youtube https://www.youtube.com/watch?v=TgtF_2Mj1Wo .
- Training materials, including research concept plan, will be shared via https://ina-respond.net/
- Considering WhatsApp group for further communication.