

Plan Overview

A Data Management Plan created using DMPTool

Title: A natural peptide antibacterial to treat bacterial vaginosis

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Template: NIH-GEN DMSP (2023)

Project abstract:

Bacterial vaginosis is a condition associated with numerous disease and adverse health outcomes in women, fetus, and newborns. The prevalence of bacterial vaginosis in women of child-bearing age in the US is approximately 30% with recurrence rates near 45%. Here, we will develop and test new therapeutics combining antibacterial peptides with beneficial vaginal probiotics with the long-term goal of preventing and/or treating the symptoms and health complications associated with bacterial vaginosis.

Start date: 11-30-2023

End date: 11-29-2024

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A natural peptide antibacterial to treat bacterial vaginosis

Data Type

Types and amount of scientific data expected to be generated in the project: *Summarize the types and estimated amount of scientific data expected to be generated in the project.*

Describe data in general terms that address the **type and amount/size of scientific data** expected to be collected and used in the project (e.g., 256-channel EEG data and fMRI images from ~50 research participants). Descriptions may indicate the data modality (e.g., imaging, genomic, mobile, survey), level of aggregation (e.g., individual, aggregated, summarized), and/or the degree of data processing that has occurred (i.e., how raw or processed the data will be)

This project will produce _____ [*Data type, e.g., imaging, sequencing, experimental measurements*] data generated/obtained from _____ [*Data modality, e.g., instrument, method, survey, experiment, data source*]. Data will be collected from ____ [*number*] of research participants/specimens/experiments, generating ____ [*number*] datasets totaling approximately ____ [*amount of data*] in size. The following data files will be used or produced in the course of the project: _____ [*list input data files, intermediate files, and final, post-processed files*]. Raw data will be transformed by ____ [*analysis, method*], and the subsequent processed dataset used for statistical analysis. To protect research participant identities, _____ [*e.g., individual, aggregated, summarized*] data will be made available for sharing.

Scientific data that will be preserved and shared, and the rationale for doing so: *Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.*

Question not answered.

Metadata, other relevant data, and associated documentation: Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

Question not answered.

Related Tools, Software and/or Code

State whether **specialized tools, software, and/or code** are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.

Pharmacokinetic (PK) - drug concentration over time and pharmacodynamic (PD) data - bacterial counts reported as colony forming units (CFU) will be made available in **csv format** and will not require the use of specialized tools to be accessed or manipulated.

Standards

State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist

Data will be stored in **common and open formats**, such as **csv** for our **in vivo study data**. Information needed to make use of this data [e.g., *the meaning of variable names used as column headers, information about missing data if any*] along with **references to the sources** of those standardized names and **metadata items** will be included wherever applicable.

Data Preservation, Access, and Associated Timelines

Repository where scientific data and metadata will be archived: Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived; see [Selecting a Data Repository](#)

All datasets that can be shared will be deposited in Dataverse.

How scientific data will be findable and identifiable: Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.

A_Natural_Peptide_Antibacterial provides searchable study-level metadata for dataset discovery. The repository will assign DOIs as persistent identifiers, and there is a preservation plan to ensure long-term access. Data will be discoverable online through standard web search of the study-level metadata as well as the persistent pointer from the DOI to the dataset.

When and how long the scientific data will be made available: Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.

All scientific data generated from this project will be made available as soon as possible, and no later than the time of publication. The duration of preservation and sharing of the data will be a minimum of 10 years after the funding period.

Access, Distribution, or Reuse Considerations

Factors affecting subsequent access, distribution, or reuse of scientific data: NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing. See [Frequently Asked Questions](#) for examples of justifiable reasons for limiting sharing of data.

There are no anticipated factors or limitations that will affect the access, distribution or reuse of the scientific data generated by the proposal.

Whether access to scientific data will be controlled: State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).

Controlled access will not be used. The data that is shared will be shared by unrestricted download.

Protections for privacy, rights, and confidentiality of human research participants:

If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).

Oversight of Data Management and Sharing

Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).

Contact PI, Dr. Laurie Comstock, ORCID: 0000-0002-9298-9973, will be responsible for the day-to-day oversight of lab/team data management activities and data sharing. Broader issues of DMS Plan compliance oversight and reporting will be handled by the PI and Co-PI team as part of general campuses stewardship, reporting, and compliance processes.

Planned Research Outputs

Dataset - "A_Natural_Peptide_Antimicrobial_PK_PD"

Time course pharmacokinetic data for drug concentrations over 7 days and pharmacodynamic data about impact of treatment on bacterial inoculum (colony forming units, cfu).

Planned research output details

Title	Type	Anticipated release date	Initial access level	Intended repository(ies)	Anticipated file size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
A_Natural_Peptide_Antimicrobial_PK_PD	Dataset	Unspecified	Open	None specified	5 MB	None specified	None specified	No	No