The National Institute on Aging (NIA) provides the following sample Data Management and Sharing Plan for a hypothetical project that results in the generation of intellectual property. Click here for more sample plans from NIA.

DATA MANAGEMENT AND SHARING PLAN

Element 1: Data Type

A. **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.

This project is estimated to generate: (i) 30 Compound A analog's design, production, characterization, and purification protocols. (ii) in vitro and cell-based assays of Compound A analogs (30 compounds to be tested). (iii) Substance stability and *in vitro* and *in vivo* toxicology (10 compounds, 6 WT mice per dose, 5 doses), (iv) Pharmacokinetics (ADME) (3-4 compounds to be tested, 10 5xFAD mice per dose, 4 doses). (v) Preclinical positron emission tomography (PET) imaging data (2-3 compounds, 15 WT or 5xFAD mice per compound).

B. **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.

The scientific data types mentioned above will be shared with protocols and metadata according to repository requirements so that they can be reproduced by other researchers and/or generate new hypotheses. Types of files that will be generated include, but will not be limited to, *.docs, *.xls, *.pdf, *.cdx, *.mol). Specifically, chemical structures, synthesis workflow, and analytical chemistry will be uploaded as PDF files. Medicinal and analytical chemistry measurements will be processed and shared on spreadsheets and as graphs. For histopathology and immunohistochemistry (IHC) experiments, we will preserve images and process and summarize the data on spreadsheets and graphs. PET imaging will be shared as PET/CT images.

C. **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.

In addition to the subject-level data described above, all the data related to Compound A design, PK/toxicology, assay development, probe chemistry, and in vivo PET imaging, along with related paradigm design and experimental definitions will be included when data are deposited in their respective repositories. For example, quality control measurements and protocols, standard curves, instrument calibration protocols, names of equipment used (to be included in protocols), and list of reagents, including catalog number and provider, especially to reproduce the synthesis of compound A analogs will be shared.

Element 2: 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.

We will generate and use our own codes written on the MATLAB software. These codes will assist with the quantitative data analysis of IHC images. PET/CT images will be processed with the Amide (Sourceforge). Medicinal and analytical chemistry will be processed with EZChrom Elite (OpenLabs). Graphs will be generated with Prism (GraphPad). Chemical structures will be generated with Chemfinder (PerkinElmer). MATLAB, EZChrom Elite, Prism, and Chemfinder are commercially available software. Amide software is available for free.

Element 3: 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.

All preclinical efficacy testing studies will be conducted and reported in compliance with NIH guidance on rigor and reproducibility. Particularly, the preclinical efficacy studies will follow the general ARRIVE guidelines for animal research and the best practice guidelines for AD preclinical efficacy studies.

Element 4: Data Preservation, Access, and Associated Timelines

A. **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).

Compound A analogs design, production, characterization, and purification protocols will be deposited in PubChem (analogs and physicochemical characteristics) and at the AD Knowledge Portal. Data generated from Compound A analogs in vitro and in vivo cell-based assays, PK and toxicology assays, and preclinical PET imaging will be deposited at the AD Knowledge Portal. Codes for the quantitative data analysis of IHC images will be deposited at the AD Knowledge Portal.

B. **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.

The reported data will be findable and identifiable using PMID or DOI identification numbers. The AD Knowledge Portal has its own IDs and metadata to allow for data and projects to be searchable and identifiable. This data DOI will be referenced in the publication to allow the research community easy access to the exact data used in the publication. The PMID or DOI identification numbers will also be posted on the lab website.

C. **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.

The research community will have access to data at publication or at the end of the award, whichever comes first. AD Knowledge portal standard submission deadlines will be taken into consideration to comply with the DMS timeline requirements. Studies will be uploaded to the AD Knowledge Portal prior to publication to include their own digital object identifiers (DOI) to aid in findability. We will include that DOI in the relevant publications. The AD Knowledge Portal will make decisions about how long to preserve the data. This repository has not deleted any deposited data as far as we know.

Element 5: Access, Distribution, or Reuse Considerations

A. **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.

If we have an invention for which we intend to seek patent protection, we may request approval to delay the sharing of scientific data associated with it until a patent is filed and will update this Plan to reflect any approved delays in data sharing beyond expected data sharing timelines. We anticipate that if intellectual property is generated, it would be on the methods of synthesis of Compound A analogs and chemical structures. To maximize data sharing, we will share the physical properties and use of the Compound A analogs, including binding specificity, Kd values, and imaging data without delay.

B. **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).

Scientific data and metadata will be distributed as open access at the AD Knowledge Portal since it is non-human data.

C. **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).
Not applicable since this project involves only preclinical animal models.

Element 6: 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).
Prof. Smith (principal investigator (PI)) will be responsible for all aspects of data management and sharing, including collecting, analyzing, and describing the data. Prof. Smith will monitor adherence to NIH DMS and upload data to the AD Knowledge Portal and other repositories. The PI will validate/curate data once a month.