

NIDDK is Seeking Interest  
in Forming Partnership(s) to Extend Efforts to Understand and Prevent  
Drug Induced Liver Injury

NIDDK is committed to investigating the basis and pathobiology of drug and Complementary and Alternative Medicine (CAM) induced liver injury. The purpose of this effort is to identify genetic, metabolic, and other pathways leading to individual susceptibility to rare cases of liver injury resulting from exposure to pharmaceutical therapeutics and/or CAM products. The expected public health benefit to this activity is manifold, but includes providing a basis for patient screening for likely adverse events and resultant prevention of such adverse events, the basis for the development of potential protective strategies and therapeutic agents, and the ability to unlock the mechanisms of liver damage occurring in other settings.

NIDDK recognizes the wide range of scientific resources available within the NIH, other federal agencies, and academia, as well as within industry, and also recognizes that the patient advocacy, philanthropy and professional communities share a commitment to safe and effective drugs without the induction of liver injury and failure. As such, the ability to work in partnership for the synergistic accomplishment of shared aims would hasten the translation of scientific discovery to improvements in the public health.

NIDDK is interested in partners to accomplish the following goals:

- The development of a broadly based prospective effort to identify well-documented cases of drug induced liver injury (DILI) for inclusion in a database and sample repository.
- The development of a repository system for the storage of materials and clinical and research data, which should be robust, accessible, and interoperable with other clinical databases.
- The establishment of centers of expertise with adequate infrastructure dedicated to the identification of cases and the conduct of research in DILI.
- The development of tools, metrics and (internationally agreed upon) standards for the adjudication of cases.
- The distribution of materials and data for research purposes according to defined criteria and appropriate human subjects protections, as well as the establishment and implementation of an appropriate oversight mechanism.
- The broad application of available and emerging technologies to investigation of the basis and process of DILI. This includes genetics/genomics, proteomics, metabolomics, cell biology, immunology, pharmacology approaches, etc.
- The development of new modeling techniques to accommodate clinical and laboratory data and to elucidate underlying mechanisms of injury and repair.
- The development of an authoritative, complete and updated web of knowledge for DILI as well as means to promote high-level scientific information exchange within and across the clinical, translation, and basic research communities and beyond, including scientific communication platforms and meetings.

NIDDK is interested in partners from all sectors, including:

- Other federal agencies, such as the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC)
- European Agency for the Evaluation of Medicinal Products (EMA)
- academic clinicians and scientists
- community clinicians
- industry scientists including pharmaceutical, biotechnology, diagnostics, imaging, and IT sectors
- patient advocacy groups
- professional societies
- philanthropists and foundations
- international partners from all sectors

The NIH mission is to improve the public health through biomedical research. As a Federal agency, NIH must operate under Federal law, regulation and policy. Only activities which conform with the NIH mission as well as NIDDK's interests and priorities will be undertaken. The NIH and NIDDK welcome responses to this request for information and suggestions encompassing a wide range of structures and activities to accomplish the aims represented above.

Potential partners should respond in writing with an approach to meeting the goals identified above within the following requirements:

- Demonstrated ability to work toward a flexible structure that will be compatible with Federal law, regulation and policy.
- Demonstrated ability to organize and govern through consensually agreed-upon structures.
- Demonstrated ability and means for leveraging resources toward realizing the stated activities and goals.
- Demonstrated ability to attract and coordinate scientific and technical experts in DILI to serve in advisory and supportive roles.

Written responses should be submitted to:

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