Resource Summary Report

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NIMH Toxicological Screens of Novel Ligands

RRID:SCR_005631
Type: Tool

Proper Citation

NIMH Toxicological Screens of Novel Ligands (RRID:SCR_005631)

Resource Information

URL: http://www.sri.com/biosciences/nimh/

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Description: The purpose of the NIMH Toxicological Evaluation of Novel Ligands Program is to accelerate the discovery, development, and application of novel ligands for PET, SPECT, and MRI imaging in humans by providing toxicology and safety assessment of promising, target-selective compounds. The program will also provide limited assessment of novel psychoactive agents for clinical research and as potential therapeutics. Toxicology and safety data generated by the program will be used to support an Investigational New Drug (IND) application to the Food and Drug Administration (FDA), or for Radioactive Drug Research Committee (RDRC) evaluation of a compound for human studies. The contract will evaluate toxicity and safety of compounds submitted for testing which may include, but are not limited to, novel chemical entities, structural analogs of compounds with an IND, or analogs of FDA-approved drugs. The services available under this program fall under four general phases: (1) analytical, (2) pharmacokinetics, (3) preliminary safety, and (4) IND-directed toxicity including safety pharmacology. What is available A broad range of tasks are available for assessing the safety and/or pharmacokinetics of each ligand. Specific capabilities available to investigators include: * Validation of the analytical methods for quantitating drug concentrations in dosing solutions, biological fluids, and tissues, as required. Determination of plasma drug levels in animals administered the agent under study, and calculation of pharmacokinetic parameters derived from these data. * Determination of bioavailability of the drug after different routes of administration, including oral, intravenous (i.v.), subcutaneous (s.c.), intramuscular (i.m.), or intraperitoneal (i.p.), as needed. Calculation of the pharmacokinetic parameters from the derived data. * In vitro evaluation of hepatotoxicity in human and animal liver cells. * Preclinical acute toxicity evaluations on lead compounds, evaluating clinical observations, body weights, clinical pathology, histopathology, and plasma drug levels in rodents and non-rodent species. Other toxicology endpoints may be selected if needed. * Subacute and subchronic toxicity

evaluations in rodents and large animal species, evaluating clinical observations, body weights, clinical pathology, and histopathology. * Genotoxicity assessments using a battery of appropriate assays. Since these preclinical studies are needed to demonstrate to the FDA that a candidate medication or imaging agent is understood well enough for designing appropriate clinical treatment regimens, most of the work to be conducted to achieve these objectives must be performed and the resulting data analyzed and reported in strict compliance with the FDA''s GLP regulations for nonclinical laboratory studies (21 CFR 58). These data must be obtained by carefully planned and skillfully executed methods that are specific, accurate, and precise. The applicable portions of the accumulated safety data will be included in documents submitted to the FDA in support of regulatory applications. Who is eligible Academic investigators involved in basic or clinical research relevant to mental health. Research areas are described on the NIMH website.

Abbreviations: Toxicological Evaluation of Novel Ligands

Synonyms: Toxicological Evaluation of Novel Ligands Program, NIMH Toxicological Screens of Novel Ligands Program

Resource Type: production service resource, material analysis service, service resource, analysis service resource

Keywords: ligand, toxicology, pet, spect, mri, imaging, safety

Funding: NIMH

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Ratings and Alerts

No rating or validation information has been found for NIMH Toxicological Screens of Novel Ligands.

No alerts have been found for NIMH Toxicological Screens of Novel Ligands.

Data and Source Information

Source: SciCrunch Registry

Usage and Citation Metrics

We have not found any literature mentions for this resource.