

TRND

therapeutics for rare and neglected diseases

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The National Institutes of Health (NIH) **Therapeutics for Rare and Neglected Diseases (TRND)** program is a new Congressionally mandated program that performs preclinical and early clinical development of new drugs for rare and neglected diseases, and develops new technologies and paradigms to improve the efficiency of therapeutic development for these diseases. The operational model of TRND is collaboration between intramural NIH drug development scientists and partners having promising leads and disease/target knowledge but lacking the expertise or resources to develop these projects into clinical stage programs attractive to biopharmaceutical or other suitable organizations. TRND is establishing collaborations with researchers in the public and private sectors to together “de-risk” Rare and Neglected disease drug development projects by accomplishing lead optimization through an FDA Investigational New Drug (IND) application and, when needed, proof-of-concept human studies.

TRND collaborative projects will be initiated at any stage during preclinical development. Projects of interest will be at one of the following stages:

- lead optimization including clear structure-activity relationships (SAR) in at least two structurally distinct chemical series or well defined biological lead, reproducible activity in primary and orthogonal assays, efficacy in an accepted animal model (or when not available, cellular model) of the disease, and initial indications of favorable Absorption, Distribution, Metabolism, and Excretion (ADME) properties
- high-quality New Molecular Entity (NME) lead(s) with clear efficacy, good DMPK properties and initial non-GLP safety studies demonstrating absence of gross toxicities
- NME clinical candidates with incomplete IND-enabling PK/PD/toxicology/formulation studies
- a drug previously approved for another indication by FDA with efficacy in an animal (or when not available, cellular) model of a rare or neglected disease, making it a candidate for repurposing but in need of formulation, dose-finding, disease-specific toxicology, or other studies to allow clinical testing to commence.

The TRND program will partner with academic laboratories, not-for-profit organizations, and for-profit companies. Foreign organizations may also apply. Applications are made through the online grants management website ProposalCentral. Submitted research proposals will be reviewed for scientific merit and technical feasibility, as well as program balance and availability of resources. Successful applicants will collaborate with TRND to create and implement a therapeutic development project plan. Note this is not a grant or contract program.

To apply to the TRND program, please visit the TRND webpage at <http://trnd.nih.gov>

The application deadline for the first cycle of the program is **December 6th, 2010**.