

ABSTRACT

The NIH-RAID (Rapid Access to Interventional Development) Pilot Program provides Translational Research Core Services as a part of the Re-engineering the Clinical Research Enterprise initiative of the NIH Roadmap. Promising ideas for novel therapeutic interventions may encounter roadblocks in bench-to-bedside testing. While translation is sometimes facilitated by public-private partnerships, high-risk ideas or therapies for uncommon disorders frequently do not attract private sector investment. Where private sector capacity is limited or not available, public resources can bridge the gap between discovery and clinical testing so that more efficient translation of promising discoveries may take place. The NIH-RAID Pilot Program is intended to reduce some of the common barriers between laboratory discoveries and clinical trials for new therapies. Projects in both the early and late stages of pre-clinical development are suitable for NIH-RAID applications. The NIH Pilot will accept requests for access to certain critical resources needed for the development of new small molecule therapeutic agents, natural products, and the preclinical testing of biologic materials. A brief listing of available services includes synthesis in bulk of small molecules, oligonucleotides, and peptides, development of analytical methods, isolation and purification of natural sources, pharmacokinetic/ADME studies including bioanalytical method development, development of suitable formulations, manufacture of drug supplies, Range-finding and IND-directed toxicology, Product development planning and advice in IND preparation, and later-stage preclinical development of monoclonal antibodies, recombinant proteins, and gene therapy agents.

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