

Frontiers Institute for Advancing Medical Innovation Trailblazer Award

Funding Opportunity Title	Frontiers Institute for Advancing Medical Innovation (IAMI) Trailblazer Award
Awarding Organization	Frontiers: University of Kansas Clinical and Translational Science Institute
Federal Prime Sponsor	National Institutes of Health (NIH) / National Center for Advancing Translational Sciences (NCATS)
Federal Award Number	UL1 TR002366
Purpose	IAMI Trailblazer Awards support four targeted areas of clinical and translational research: Experimental Therapeutic trials, Drug and Medical Device Development, Biomarker Discovery and Validation, Entrepreneurship activities consistent with IAMI's mission.
Eligibility	Faculty investigators from all Frontiers partner institutions are eligible to apply: The University of Kansas Medical Center (Kansas City, Wichita and Salina campuses), the University of Kansas, Kansas State University (Manhattan and Olathe campuses), the University of Missouri-Kansas City, Kansas City University of Medicine and Biosciences, Children's Mercy Kansas City, and St. Luke's Health System.
Process	Applicants are encouraged to consult with Frontiers leadership to ensure maximal use of Frontiers resources in developing and executing of their projects.
Funding	Maximum award: \$25,000
Project Duration	July 1, 2021 through June 30, 2022

Key Dates	
RFA Posted Date	February 26, 2021
Letter of Intent Due Date	March 5, 2021
Invite Applicants to Prepare and Submit Full Trailblazer Proposals	March 8, 2021
Application Due Date (IRB/IACUC Applications Due)	April 2, 2021
Decision Notifications to Applicants	April 15, 2021
Prior Approval materials submitted to Frontiers (Pending IRB/IACUC Review)	May 1, 2021
Prior Approval Materials Sent to NCATS	May 8, 2021
Funding Received/Project Start (Pending NCATS Approval)	July 1, 2021

A goal of Frontiers' funding agency, the National Center for Advancing Translational Sciences, is "to get more treatments to more patients more quickly". The Frontiers IAMI Trailblazer Award addresses this goal by providing funds to help investigators carry out early-stage, feasibility studies to identify drug, diagnostic, and medical device product development opportunities. Data generated from successful studies will be disseminated in impactful publications and support successful extramural funding applications.

Eligibility

Frontiers IAMI Trailblazer Awards support multidisciplinary translational research projects that address all diseases, and include academic disciplines such as chemistry, molecular biology, medicine, pharmacy, allied health professions, nursing, veterinary medicine, and other areas that impact clinical and translational science.

Faculty investigators from all Frontiers partner institutions are invited to apply. Applications should describe projects that will be completed within Frontiers Year 5 funding cycle (ends June 30, 2022). All funding decisions and actual start dates for Trailblazer Awards are contingent upon receipt of the NCATS Notice of Award for Year 5 funding.

IAMI Trailblazer Application Areas of Eligibility:

- Experimental Therapeutics Trials
Eligible research activities include: a) clinical validation of a drug target; b) clinical pharmacology (e.g., drug metabolism, bioanalysis, pharmacokinetics, pharmacodynamics, pharmacogenomics, allometric scaling); c) clinical proof of concept of a novel therapeutic or a repurposed FDA-approved or abandoned drug. Eligible awardees must have demonstrated proof of principle in validated in vitro and/or in vivo preclinical models.
- Drug and Medical Device Development
Eligible research activity includes high throughput screening; generation and optimization of small molecule lead candidates; discovery of macromolecule therapeutics; synthesis of sufficient quantities of active pharmaceutical ingredient required for animal testing; conduct of preclinical safety, pharmacokinetic and proof of principle studies in validated animal models of disease; formulation development (including analytical chemistry support); as well as creation of prototype medical devices as well as necessary device testing.
- Biomarker Discovery and Validation
Eligible research activities include biospecimen collection; patient registry development; genetic, genomic, proteomic and metabolomic analysis of patient specimens, and analysis of patient specimens using established and investigational methods to discover and validate biomarkers of drug activity.
- Entrepreneurship Activities Consistent with IAMI's Mission
Eligible research activities defining the investment thesis for potential product development opportunities, including unmet medical need, proposed solution, market, competitive landscape, patent position and strategy, summary of existing data, product development and regulatory planning, marketing and licensing strategy, as well as support for obtaining key opinion leader input.

Application Requirements

Letter of Intent: A letter of intent, not to exceed 1 page, must be submitted which briefly outlines the product development opportunity and addresses the categories below:

1. indicate which area of eligibility (listed above) to which the product development opportunity belongs
2. describe whether the product development opportunity represents new intellectual property or repurposes existing medical innovation technologies for a new therapeutic application
3. indicate the disease area(s) and relevant population(s) the proposed product is intended to treat
4. whether the potential product has relevance to treat disorders across the lifespan
5. list of collaborating investigators if applicable

After review of Letter of Intent, selected applicants will immediately be notified, invited to submit full proposals and provided a link to the application materials.

Full Proposals: Selected applicants must upload application materials as a single PDF.

1. **Trailblazer Application Form:** Proposals should include the following sections: background, significance, specific aims that map to one of the four eligible areas, and innovation/benefit. Applications should not exceed 5 pages.
2. **Budget:** Applicants may request up to \$25,000; lesser amounts are acceptable and encouraged especially if the Frontiers IAMI Trailblazer Award can be used to match or leverage additional resources. Budget may NOT be used for PI salary.

All funds must be spent by June 30, 2022; no carry-over is allowed. IRB/IACUC documentation, if relevant, is required before funds can be released. Accordingly, projects that have applicable IRB/ IACUC-approval are encouraged; projects ready to submit for approval are allowed.

Indirect/Facilities and Administration costs are not allowed for Frontiers Trailblazer Awards.

3. **NIH Biographical Sketch:** Include for all key personnel, use the current NIH format.
4. **IACUC/IRB Submission:** If applicable to project, indicate date of IACUC or IRB submission. Relevant documents must be submitted prior to application deadline.

Required naming convention of Application packet: *PILastNameFirstInitial_IAMI*

Instructions on combining documents into a single PDF may be found [here](#).

Additional Application Guidance

Notice of Proprietary Information: Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the full application. Applications containing information that constitutes trade secrets, that is financial or commercial, or that is confidential or privileged, should identify the pages that contain this information by marking those paragraphs or lines with an asterisk (*) at the beginning of the paragraph. Applications proposing novel drug, diagnostic, or medical device technologies invented by Frontiers investigators, repurposing an existing technology for a new therapeutic application based on data generated by Frontiers investigators, the proposed product is designed to address the unmet needs of patients with rare diseases, whether the innovation is applicable across the lifespan, and a well-described multidisciplinary, multi-organizational team will be considered strengths.

Awardees

Funded awardees are required to partner with the Frontiers IAMI Navigator, who will provide project management support, including the development and execution of project plans, submission of materials to Frontiers for review and approval by NCATS (if required), as well as preparation and submission of mid-term and final progress reports. They are also required to provide details of all published manuscripts, meeting abstracts, and grant applications that result from data obtained from Trailblazer awards.

Review Process

Letters of Intent will be used to identify applicants invited to prepare and submit full proposals. Full proposals will be reviewed by a peer review team comprised of drug, diagnostic, and medical device development experts. Funding recommendations will be reviewed and approved by Frontiers leadership, after which time, applicants will be notified.

Contact for Additional Information

Frontiers Administrative Office, frontiers-info@kumc.edu or 913-588-6290.

Jen Baker, Administrative Director, at jbaker16@kumc.edu or 913-588-0976.

Carolyn Vivian, Frontiers IAMI Navigator, at cvivian@kumc.edu or 913-945-8445