

Frontiers Institute for Advancing Medical Innovation Trailblazer Award

About Frontiers

The Frontiers Clinical and Translational Science Institute at the University of Kansas is a regional initiative involving academic institutions, healthcare systems, and community organizations that address the clinical and translational research needs of Kansas and western Missouri. Frontiers supports high quality clinical and translational science innovation in research methods and training and career development of investigators committed to improving health and achieving health equity across the lifespan, with a focus on underserved and excluded populations. The goal of Frontiers' funding agency, the National Center for Advancing Translational Sciences, is "to get more treatments to more patients more quickly".

The **Institute for Advancing Medical Innovation Trailblazer Pilot Program** provides grant funding and other support for clinical and translational research across a broad range of scientific disciplines. The objective of this pilot program is to support new and innovative ideas that will lead to externally funded awards. The Frontiers IAMI Trailblazer Award addresses this goal by providing funds to help investigators carry out early-stage project development of novel drugs, devices, and diagnostics. The overall intent is to acquire research results that are disseminated in impactful publications, support successful extramural funding applications, and yield products to be entered into our product development pipeline.

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	Applications are invited from faculty investigators from all Frontiers partner institutions: The University of Kansas Medical Center (Kansas City, Wichita and Salina campuses), the University of Kansas, the 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 their projects.
Funding	Maximum award: \$25,000

Project Duration	July 1, 2022 through June 30, 2023
Key Dates	Letter of Interest (LOI) Deadline: March 21, 2022 LOI Status Notification: March 30, 2022 Full Application Deadline: April 15, 2022 Merit Review Completion: April 25, 2022 NCATS Prior Approval Process: April-May 2022 Award Announcement: May 1, 2022 Earliest Project Start Date: July 1, 2022 pending Frontiers Notice of Award for 2022-23 funding year.
Award Amount	Up to \$25,000 in direct costs can be requested. Indirect costs are not covered by the pilot awards.
Maximum Award Period	12 calendar months.
Review criteria	Invited full proposals will be reviewed using NIH-style review process and other stated review criteria.

Eligibility

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

This is open to principal investigators who are eligible to receive federal funding and employed by any Frontiers partner institution:

- University of Kansas Medical Center (all campuses)
- University of Kansas
- University of Missouri-Kansas City
- Kansas City University
- Children's Mercy Kansas City
- St. Luke's Health System
- Kansas State University

Applicants may serve as PI on only one application but may be included as collaborators on any number of applications.

Applications are invited from multidisciplinary teams comprised of faculty investigators from Frontiers partner institutions.

Applications should describe projects that will be completed within Frontiers Year 1 funding cycle (ends June 30, 2023). All funding decisions and actual start dates for Trailblazer Awards are contingent on receipt of the NCATS Notice of Award for Year 1..

Eligible Areas

- 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: a) biospecimen collection; b) patient registry development; c) genetic, genomic, proteomic and metabolomic analysis of patient specimens, and d) 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.

While not required, special consideration will be given to proposals which address the CTSA priority of research into the needs of the rare disease community.

Application Requirements

Letter of Intent Requirements and Review

Letters of Intent should be sent directly to the Frontiers IAMI Navigator at cvian@kumc.edu

Applicants should engage their institutional pre-award grant management office prior to submission of a Letter of Intent to ensure all institutional criteria are met.

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 be invited to submit full proposals and provided a link to the application materials.

Applicants who do not advance to the full application stage will be notified via email. No score or written critique/comments will be provided to the applicants.

Full Proposals: Applications must be uploaded as a single PDF.

Required naming convention of Application packet: *PILastNameFirstInitial_IAMI*

Proposals should use Arial 11 font, 0.5-inch margins, single space format,

1. **Research Plan:** should include the following sections and should not exceed 6 pages.
 - a. Specific Aims (1 page)
 - b. Research Strategy (5 pages, excluding references)
 - i. Background
 - ii. Significance
 - iii. Innovation mapped to one of the 4 eligible areas
 - iv. Approach
 - c. References (only include crucial references; no page limit, not included in the 6-page limit)
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, 2023; 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:** Necessary IRB or IACUC applications (or approval) are required prior to submission of the full application. The official IRB or IACUC correspondence of submission and/or approval should be uploaded as one pdf document. Applications for projects that do not require an IRB or IACUC protocol should provide supporting documentation.

The following costs are not covered by these awards:

- a. Salaries for personnel at Non-Frontiers institutions (with the exception of required consultants, if justified)
- b. Administrative or office costs (e.g., office supplies, telephone, etc.)
- c. Meals or hospitality (e.g., food, beverages, or alcohol)
- d. Travel that is not directly related to the conduct of research
- e. Other items typically supported by Facilities and Administration costs
- f. Facilities and Administration costs. These awards are direct costs only

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. Selection will be confirmed by a leadership group that represents all the institutional partners of Frontiers.

Full Proposal Review

Applications will be reviewed and scored using NIH review criteria by at least three reviewers. Applicants will receive a summary statement describing strengths and weaknesses of the proposal. The review criteria described below will be considered in the review process.

- **Significance**

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

- **Investigator**

Is the PI well suited to the project? If early-stage investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? Does the team include appropriate involvement of community members?

- **Innovation**

To what extent are innovative methods evident, such as experimental approaches to identify best practices in translational research; workforce education and training; and stakeholder outreach?

- **Potential of pilot to result in future funding and publication**

Is there evidence that successful completion of the pilot will competitively position the PI for an NIH award? For an impactful publication?

- **Overall Impact**

Overall Impact is the synthesis/integration of the review criteria as well as the relevance of the budget (and budget justification) for the project to exert a sustained, powerful influence on the research field(s) involved.

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.

Funding Decision and Notice of Award

Applicants will be notified regarding the outcome of review. Successful applications will be submitted to the NCATS for prior approval, which must be received before release of funds and any public announcements. Release of pilot project funding is also dependent on receipt of the Notice of Award for Frontiers CTSI for the FY23 funding year, which is anticipated by July 01, 2022.

Post Award Requirement for Award Recipients

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.

All recipients of Frontiers Pilot Awards are required to provide mid-term and final progress reports. Details of all published manuscripts, meeting abstracts, and grant applications that result from data obtained from pilot grants should be included in the reports. Report templates will be provided.

Contact for Additional Information

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