



FRONTIERS
 CLINICAL & TRANSLATIONAL
 SCIENCE INSTITUTE
 AT THE UNIVERSITY OF KANSAS



2024 Institute for Advancing Medical Innovation Trailblazer Award Program

About Frontiers

The Frontiers Clinical and Translational Science Institute (CTSI) 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 **Institute for Advancing Medical Innovation (IAMI) Trailblazer Award** 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.

Awarding Institute	Frontiers: Clinical and Translational Science Institute
Federal Prime Sponsor	National Institutes of Health (NIH) / National Center for Advancing Translational Sciences (NCATS); Award number: UL1 TR002366
Key Dates	<p>Online System Opens & RFA Release: December 1, 2023 Application Deadline: March 1, 2024, 11:59 pm Merit Review Completion: April 2024 Funding Decision Notifications: late-April 2024 NCATS Prior Approval Submission May 15, 2024 - IRB and/or IACUC Final Approval Required: May 7, 2024 Award Letters and Official Announcements: July 2024 Earliest Project Start Date: July 1, 2024, pending Frontiers Notice of Award for 2024-25 fiscal year. <i>*Note: The IAMI Award Program reserves the right to extend submission deadlines to better meet Frontiers' needs; all changes will be communicated in advance.</i></p>
Award Amount	Up to \$25,000 in direct costs can be requested.
Maximum Award Period	July 1, 2024, through June 30, 2025
Number of Awards	Up to 2 awards
Review Criteria	Full applications will be reviewed using NIH-style review process and other stated review criteria.
Contact Information	Carolyn Vivian, IAMI Navigator, cvivian@kumc.edu

Research Focus 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 applications which address the CTSA priority of research into the needs of the rare disease community.

General Application Requirements

- Frontiers CTSI membership is required for submitting applications. [Become a member](#) and learn about member benefits.
- It is expected that research supported by the pilot awards will result in one or more publications in a peer-reviewed journal and will provide critical preliminary data to support extramural grant applications.
- Applications should use Arial 11 font, 0.5-inch margins. Applications must be uploaded as a single PDF. Required naming convention of Application packet: *PILastNameFirstInitial_IAMI*

Applications must be submitted [online here](#).

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 competition 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 Kansas Health System
- University of Missouri-Kansas City
- Kansas City University
- Children's Mercy Kansas City
- St. Luke's Health System
- Kansas State University

Principal Investigators are allowed to apply for more than one funding mechanism but will only be allowed to

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

Volunteer faculty, residents, fellows, or graduate students are generally not eligible to serve as principal investigators. United States citizens, non-citizen nationals, or those who have legal admission as a permanent resident are eligible. However, any questions regarding eligibility should be addressed to individual institutional grants management offices before application submission.

Research Plan should include the following sections and should not exceed six (6) pages. Download the Research Template [here](#).

- a. Specific Aims (1 page)
- b. Research Strategy (5 pages, excluding references)
 - Background
 - Significance
 - Innovation mapped to one of the 4 eligible areas
 - Approach
- c. References (only include crucial references; no page limit, not included in the 6-page limit)

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. Applications should describe projects that will be completed within Frontiers Year funding cycle (ends June 30, 2025). All funding decisions and actual start dates for Trailblazer Awards are contingent on receipt of the NCATS Notice of Award for Year 4. All funds must be spent by June 30, 2025; carryover and extensions are not allowed.

Required Budget forms can be found [here](#).

The following costs are not covered by these awards:

- Non-Frontiers institution staff salaries (with the exception of required consultants, if justified)
- Administrative or office costs (e.g., office supplies, telephone, etc.)
- Meals or hospitality (e.g., food, beverages or alcohol)
- Travel that is not directly related to the conduct of research
- Other items typically supported by Facilities and Administration costs

Indirect costs are allowable with the exception of awards to the University of Kansas Medical Center.

NIH Biographical Sketch: Include for all Key Personnel. Must use the current NIH format. Template, instructions, and samples found [online here](#).

IRB/IACUC Submission: IRB or IACUC application official submission, approval, or IRB determination that the project is 'Not Human Subjects Research' is required before full application submission. **Flexible IRB Review is not allowed.** Note: Inform the IRB this will be a federally funded project.

Applications must be submitted [online here](#).

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.

Merit Review: Applications 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. 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 application. 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 award 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.

Funding Decision and Notice of Award: Funding decisions are anticipated in May 2024. 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 funding is dependent on receipt of the Notice of Award for Frontiers CTSI for the FY24 funding year, which is anticipated by July 01, 2024. Frontiers also reserves the right to withdraw the award for any project that has not received IRB/IACUC approval for human subjects and vertebrate animal research projects by June 1, 2024.

Post Award Requirements for Award Recipients: All awardees and their project teams are required to complete the Frontiers Training Center anti-racism and anti-bias training (or equivalent) within first 6 months of notice of award and include evidence of completion in the mid-term report.

Funded awardees are required to partner with the 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). All recipients of IAMI Awards are required to meet with the Communications Coordinator within four weeks following notification of intent to fund applications. A story will be prepared about your application prior to the issuance of your official Notice of Award. All awardees 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. Awardees will be sent an annual survey for up to 5 years asking about the impact of their work.

It is essential that study outcomes are disseminated – to both the scientific and lay communities; therefore, Frontiers expects that awardees will publish the findings of their research to scientific venues, including peer-reviewed journals, and will disseminate to community groups as appropriate. We will highlight projects at the Frontiers Annual Research Symposium, where you will be required to present. You will receive information about the meeting well in advance for your planning purposes. You may be asked to present your work at additional venues and meetings.

All publications and presentations must acknowledge NIH grant support arising from any research project

that used Frontiers resources. [Learn how to cite Frontiers here.](#)