2025 Institute for Advancing Medical Innovation Trailblazer Award Program

About Frontiers

The Frontiers Clinical and Translational Science Institute (Frontiers) 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 science 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	Online System Opens & RFA Release: December 4, 2024 Application Deadline: March 3, 2025, 11:59 pm Merit Review Completion: April 4, 2025 Funding Decision Notifications: late-April 2025 NCATS Prior Approval Submission May 15, 2025 – IRB and/or IACUC Final Approval Required: May 7, 2025 Award Letters and Official Announcements: July 2025 (anticipated) Earliest Project Start Date: July 1, 2025, pending Frontiers Notice of Award for 2025-26 fiscal year. **Note: The IAMI Award Program reserves the right to extend submission deadlines to better meet Frontiers' needs; all changes will be communicated in advance.*
Award Amount	Up to $25,000 can be requested.
Maximum Award Period	July 1, 2025, through June 30, 2026. All funds must be spent by June 30, 2026 – carry over and no-cost extensions are not allowed.
Number of Awards	Up to 2 awards
Review Criteria	Invited full applications will be reviewed using the new NIH-Simplified Peer Review Framework and other stated review criteria.
Contact Information	Carolyn Vivian, IAMI Navigator, cvivian@kumc.edu

Translational Science Requirement
Pilot projects are ***required*** to focus on translational science, i.e., understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research. ***Applicants will be required to address at least one of the principles but should include any principles that are relevant.***

Translational research focuses on advancing a step of the translational process for a specific target/disease, translational science seeks to develop, demonstrate, and disseminate generalizable innovations and strategies to improve the process of translational research.

Translational science projects seek to ***1. identify and understand barriers that delay progress or limit the quality, impact, or equity of translational research*** (e.g., clinical trial recruitment, data interoperability, implementation, etc.), and ***2. develop innovative solutions*** (e.g., methods, best practices, tools, technologies) to overcome these barriers. Addressing critical barriers will allow subsequent translational research to accelerate the time from discovery to improved human health. The innovative solutions will have broad applicability to multiple research projects, increasing capacity and efficiency.

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 for the rare disease community.

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 (PIs) at any partner institution who are eligible to receive investigator-initiated federal funding at their respective institutions.

- Children's Mercy Kansas City
- Kansas City University

- Kansas State University
- University of Kansas
- University of Kansas Health System
- University of Kansas Medical Center (all campuses)
- University of Missouri-Kansas City
- Saint Luke's

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). See Review Criteria below for additional details.
   - Importance of the Research (Significance, Innovation)
   - Rigor and Feasibility (Approach, Rigor and Feasibility)
   - Expertise and Resources (Investigator, Environment)

a. References (only include crucial references; no page limit, not included in the 5-page limit)

Budget: Applicants may request up to $25,000. All funds must be spent by June 30, 2026 – carry over and no-cost extensions are not allowed. **Contact Jen Whitaker,** jwhitaker5@kumc.edu, for institutional guidance regarding indirects. 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, 2026). All funding decisions and actual start dates for Trailblazer Awards are contingent on receipt of the NCATS Notice of Award for Year 4.

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

NIH Biographical Sketch: Include for all Key Personnel. Template, instructions, and samples found here.

IRB or IACUC Submission and/or Approval: Official documentation of IRB or IACUC application submission, approval, or IRB/Human Research Protection Program 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 application. Applications containing information that constitutes trade secrets, that is financial or commercial, or that is confidential or privileged should identify the content by

marking those paragraphs or lines with an asterisk (*). All reviewers sign a Confidentiality Agreement.

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 the new NIH Simplified Peer Review Framework as described below. Applicants will receive a summary statement describing strengths and weaknesses of the application in the late spring/early summer of 2025.

Factor 1: Importance of the Research (Significance, Innovation), scored 1-9

Significance

- Evaluate the importance of the proposed research in the context of current scientific challenges and opportunities, either for advancing knowledge within the field, or more broadly. Assess whether the application addresses an important gap in knowledge in the field, would solve a critical problem, or create a valuable conceptual or technical advance.
- Evaluate the rationale for undertaking the study, the rigor of the scientific background for the work (e.g., prior literature and/or preliminary data) and whether the scientific background justifies the proposed study.

Innovation

- Evaluate the extent to which innovation influences the importance of undertaking the proposed research. Note that while technical or conceptual innovation can influence the importance of the proposed research, a project that is not applying novel concepts or approaches may be of critical importance for the field.
- Evaluate whether the proposed work applies novel concepts, methods or technologies or uses existing concepts, methods, technologies in novel ways, to enhance the overall impact of the project.

Factor 2: Rigor and Feasibility (Approach), scored 1-9

Approach

- Evaluate the scientific quality of the proposed work. Evaluate the likelihood that compelling, reproducible findings will result (rigor) and assess whether the proposed studies can be done well and within the timeframes proposed (feasibility).

Rigor

- Evaluate the potential to produce unbiased, reproducible, robust data.
- Evaluate the rigor of experimental design and whether appropriate controls are in place.
- Evaluate whether the sample size is sufficient and well-justified.
- Assess the quality of the plans for analysis, interpretation, and reporting of results.
- Evaluate whether the investigators presented adequate plans to address relevant biological variables, such as sex or age, in the design, analysis, and reporting.
- For applications involving human subjects or vertebrate animals, also evaluate:
- the rigor of the intervention or study manipulation (if applicable to the study design).
  - Whether outcome variables are justified.
  - Whether the results will be generalizable or, in the case of a rare disease/special group, relevant to the particular subgroup.
  - Whether the sample is appropriate and sufficiently diverse to address the proposed question(s).
- For applications involving human subjects, including clinical trials, assess the adequacy of inclusion plans as appropriate for the scientific goals of the research. Considerations of appropriateness may include disease/condition/behavior incidence, prevalence, or population burden, population representation, and/or current state of the science.

Feasibility

- Evaluate whether the proposed approach is sound and achievable, including plans to address problems or new challenges that emerge in the work. For proposed studies in which feasibility may be less certain, evaluate whether the uncertainty is balanced by the potential for major advances.
- For applications involving human subjects, including clinical trials, evaluate the adequacy and feasibility of the plan to recruit and retain an appropriately diverse population of participants. Additionally, evaluate the likelihood of successfully achieving the proposed enrollment based on age, racial, ethnic, and sex/gender categories.
- For clinical trial applications, evaluate whether the study timeline and milestones are feasible.

Factor 3: Expertise and Resources (Investigator, Environment), to be evaluated as either sufficient for the proposed research or not (in which case reviewers must provide an explanation)
Investigator(s)

- Evaluate whether the investigator(s) have demonstrated background, training, and expertise, as appropriate for their career stage, to conduct the proposed work. For Multiple Principal Investigator (MPI) applications, assess the quality of the leadership plan to facilitate coordination and collaboration.

Environment

- Evaluate whether the institutional resources are appropriate to ensure the successful execution of the proposed work**.**

Overall Impact, scored 1-9
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.

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 and an impactful publication.

Funding Selections and Notice of Award: Selections for Intent to Fund are anticipated in April 2025. Selected applications will be submitted to the NCATS for Prior Approval, when applicable. NCATS approval must be received before release of funds and any public announcements. Release of funding is also dependent on receipt of the Notice of Award for Frontiers Y4 funding year, which is anticipated in July 2025.

Post Award Requirements
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). Clinical trials are required to be registered prior to official approval from NCATS.

Meeting
All recipients of pilot awards are required to meet with the Communications Coordinator within four weeks following notification of Intent to Fund. A story will be prepared about awards prior to the issuance of official Notice of Awards.

Dissemination: Presentations and Publications
Awardees will be required to present their awarded projects to Frontiers Advisory Groups during the funding year and at the completion of the project. Find additional information about the Advisory Groups here.

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. Details of all published manuscripts, meeting abstracts, and grant awards that result from data obtained from pilot grants should be included in the mid-year and end of year progress reports and annual surveys. 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 also disseminate findings to participants and community groups as appropriate. Frontiers will highlight projects at the Annual Research Symposium, where awardees will be required to present.

All publications and presentations must acknowledge NIH grant support arising from any research project that used Frontiers resources. Learn how to cite Frontiers here.

Find Additional Resources and Frequently Asked Questions here.