RMT-REACH Research Funding Announcement — 2024 Pilot Award



Overview

The <u>Rocky Mountain Research Evaluation & Commercialization Hub</u> (RMT-REACH) is a National Institutes of Health (NIH)-funded program created to accelerate commercialization of health innovations in **academic institutions across Montana, Alaska, Idaho, and Wyoming** and develop products that address unmet medical needs across the United States.

This 2024 Pilot Cohort Research Funding Announcement (RFA) seeks proposals that will support the translational advancement of promising health innovations. The program supports proof-of-concept and go-to-market strategy activities through milestone-driven funding. Supported innovations may span the spectrum of health outcomes, including therapeutics, preventatives, diagnostics, devices, methods, or research tools that move the needle forward on unmet patient and public health needs. **RMT-REACH intends to fund 4 pilot projects with up to \$50,000 each** in this application cycle. Awarded teams will be eligible to apply for an additional \$50,000 through the *RMT-REACH Drive Award* RFA, anticipated to be released in Winter 2024. Successful completion of a *RMT-REACH Pilot Award* is required to apply for the *RMT-REACH Drive Award*.

Successful applications will explain how the intended product addresses an unmet medical need, the product's market potential, and include a sound product validation workplan. Projects must be completed within 6-12 months with the ultimate goal of follow-on funding through SBIR/STTR or venture mechanisms in startup companies. Applications should focus on explaining how the RMT-REACH funds would improve your chances of success in translating your innovation into clinical practice.

Proposals will be evaluated for both scientific merit and product development potential, with emphasis on the following criteria:

- Translational potential
- Unmet need (high disease burden/health disparities) and clinical impact
- Research/Development status and planning

Successful RMT-REACH awardees will receive funding based on stage-gated milestone development tasks defined in a Project Funding Agreement. In addition to receiving proof-of-concept funding, a RMT-REACH Project Manager will be assigned to support the recruitment of domain experts for development and advise on strategies to make products widely accessible. Awardees will also have access to an array

of experts ranging from regulatory strategy, intellectual property, market analysis, and follow-on, non-dilutive grant development.

Even if a project does not receive an award, principal investigators (PIs) of reviewed proposals will gain key insights from industry and technology experts through the RMT-REACH External Review Board (ERB). PIs may also receive independent verification of product concept, reimbursement strategy, and IP development from the National REACH Technology Guidance Committee (RTGC), which is composed of members from the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Center for Medicare and Medicaid Services (CMS), third party payers, and the United States Patent and Trade Office (USPTO).

Key Dates

Activities	Dates
Launch Intro Webinar / Release RFP	Friday, March 1st
Letter of Intent Due	Friday, March 29th (5:00pm MT)
Invitation to submit full application & Book a Call	Friday, April 12 th
Workshop 1: Unmet Need & Office Hours	Week of April 29 th
Workshop 2: Market Potential & Office Hours	Week of May 6 th
Workshop 3: Intellectual Property & Technology Transfer & Office Hours	Week of May 13 th
Workshop 4: Developing a RMT-REACH workplan & Office Hours	Week of May 20 th
First Draft of Application for Internal Review Due (optional)	Monday, May 20 th (5:00pm MT)
Feedback on Submitted First Draft Applications	Monday, May 27 th
Workshop 5: Pitch Practice & Office Hours	Week of May 27 th
RMT-REACH Final Application Due	Friday, May 31st (5:00pm MT)
RMT-REACH Project Pitch	Week of June 10 th
RMT-REACH ERB-EC Finalize Scores	Friday June 21 st
Selected applications submitted to NIH TGC	Friday, June 28 th
Earliest Decision	Early August
Funding and Support Allocated	September 1 st

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RMT-RFACH Award Process Overview

Award Information

Funds Available & Structure of Support

The number of awards is contingent upon the submission of a sufficient number of meritorious applications. RMT-REACH supported projects provide value-added and managed services including administrative and regulatory support, recruitment, and participation of domain experts. The national review from the NIH RTGC provides independent due diligence, typically required for seeking private funding.

Award Budget

Projects are scoped in an on-boarding process where key milestones and associated budget items are defined by the team and RMT-REACH personnel. All funded milestones and activities will be vetted as necessary and essential by the RMT-REACH project team to ensure that projects are in the best position to prepare for follow-on funding. RMT-REACH supports no more than \$50,000 in direct costs based on clearly written milestones associated with the objective to reach a meaningful exit. Budgets are linked to actionable activities anchored on achieving milestones.

RMT-REACH awards are for product commercialization. All salaries and outsourced work must be directly aligned with key milestone deliverables.

RMT-REACH funds can be used for internal commercialization work, outsourced expertise, and contract work.

All funding is for direct costs only.

Award Project Period

Projects are expected to be completed within 6-12 months. During this project span, teams will participate in weekly calls to finalize the project agreement documents (the PAD process), and then monthly update calls during the course of the project. After completion from RMT-REACH, teams agree to respond to future requests from RMT-REACH for information regarding their project status, follow-on funding received, and any startup company information (date of startup, employees hired, etc.) to support RMT-REACH obligations for NIH program evaluation.

Eligibility

- 1. This funding opportunity is open to faculty, staff, postdoctoral researchers, graduate students, and undergraduate students.
 - a. Students and postdoctoral researchers must identify a faculty sponsor.
- 2. Eligible Investigators are affiliated with an academic institution in Alaska, Idaho, Montana, or Wyoming.
- 3. Collaborators from external institutions are eligible to apply with an Eligible Investigator.
- 4. The project's intellectual property must be owned by or otherwise assigned to an academic institution in Alaska, Idaho, Montana, or Wyoming.
- 5. The project's innovations must be at pre-company or licensing stage.

Application and Submission Information

The submission deadline for the 2024 Pilot Cycle is as follows:

	Letter of Intent (LOI)	First Application Draft (Optional)	Full Application	Earliest start date
2024 Pilot	March 29, 2024	May 20, 2024	May 31, 2024	September 2024
Award Cycle	(5:00 PM MT)	(5:00 PM MT)	(5:00 PM MT)	

Content and Form of Application Submission

- 1. Letter of Intent (details are in Appendix A)
- **DUE March 29, 2024 (5:00pm MT)**
- a. Letters of Intent are submitted for review through the RMT-REACH LOI portal at https://www.umt.edu/rmt-reach/funding-opportunities.php. We will not accept applications via email. If, at any time, you experience difficulty with the database, please contact the RMT-REACH team as soon as possible (rmtreach@umontana.edu).
- 2. RMT-REACH Application (details are in Appendix B) DUE May 31, 2024 (5:00pm MT)
 - a. Applications are submitted for review through the RMT-REACH UpdateTracker Application Portal at https://www.umt.edu/rmt-reach/funding-opportunities.php.
 We will not accept applications via email. If, at any time, you experience difficulty with the database, please contact the RMT-REACH team as soon as possible (rmtreach@umontana.edu).
- 3. Project Pitch (details are in Appendix D)

Week of June 10th, 2024

a. Use the provided Pitch Template as a guide for preparing your presentation. Teams will have 10 minutes to pitch their projects, followed by 20 minutes of discussion and Q&A.

Application Review Information

RMT-REACH applicants will pitch their proposals to an integrated review committee including the RMT-REACH Executive Committee and External Review Board (ERB), comprised of industry and technology-experts. Selected RMT-REACH proposals will be sent to the NIH RTGC for review and input. Both the RMT-REACH external review group's comments and the comments from the RTGC will be considered by the RMT-REACH Executive Committee, who will make the final determination for RMT-REACH funding. The input from the RTGC is not scored, but comments provide the applicant with preliminary due diligence done by the highest authorities for the proposed development plans.

Award Administration Information

If an award is issued, you will receive a letter containing details of next steps. The first step will be to schedule a Kickoff Milestone Meeting with a RMT-REACH Project Manager to discuss the award process and to finalize the budget, milestones, and activities. Funds will be administered through the <u>L.S. Skaggs Institute for Health Innovation</u> at the University of Montana and project management will be administered through RMT-REACH.

RMT-REACH Program Contacts

Caroline McLean, Projects & Technologies Manager, RMT-REACH, caroline.mclean@mso.umt.edu Leidy Wagener, Operations Manager, RMT-REACH, leidy.wagener@mso.umt.edu

Appendices

Appendix A: RMT-REACH Letter of Intent Questions



Full instructions and the LOI portal are available at: https://www.umt.edu/rmt-reach/funding-opportunities.php

Applicant Information:

Contact Informa	ation	
	First Name	
	Last Name	
Principal Investigator	Institution	
	Position/Title	
	Telephone	
	Email Address	
Alternate Contact	Last Name	
	First Name	
	Title	
	Telephone	
	Email	
Project Title		

Instructions:

Please answer the following questions. (Word limit for each answer = 300 characters with spaces)

- 1. Identify the Project Team members, including their institutional affiliation (if different than PI), expertise, project roles, and how long they have been a part of the project to date?
- 2. Explain your technology and how it will address an unmet human health need, particularly related to high disease burden or health disparities?
- 3. How strong is the available evidence supporting a proof-of-product concept showing that the proposed product is safe, effective, and feasible?
- 4. To what extent does the proposed project address a critical step or milestone needed to advance a research discovery toward commercial development?

If you have any trouble accessing the form or questions about this process, please contact: rmtreach@umontana.edu.

Appendix B: RMT-REACH Project Application

Proposal Format and Guidelines:

Full instructions and the application portal are available at: https://www.umt.edu/rmt-reach/funding-opportunities.php

Contact Information		
	First Name	
	Last Name	
Principal Investigator	Institution	
Timelpar investigator	Position/Title	
	Telephone	
	Email Address	
	Last Name	
	First Name	
Alternate Contact	Title	
	Telephone	
	Email	
Project Description		
Project Title		
Technology type		Select one from list
Disease area		Select all that apply from list
Is this application a resubmission?		Y/N
Funding History for This Project		
Federal funding support (if yes, what agency)		
If NIH, provide grant number (i.e. R01HL123456)		
Abstract: Place we wide a 200 word suprement that describes the unwest read results to the place and teams		

Abstract: Please provide a 300-word summary that describes the unmet need, market potential, technology, and team proposed for this project.

300 word maximum.

Background: Describe the unmet need your technology will address and the current standard of care. The description could also include disease burden, incidence, prevalence, cost to the health system and society, and other pertinent background information.

500 word maximum.

Technology: Explain your technology and how it will address the unmet need and impact the standard of care. This should include a description of the technology's current level of maturity and a description of any evidence that has been generated to support its efficacy.

500 word maximum.

Market: Describe the market size for your technology, including who the customer is (i.e., direct to consumer, patient, provider, payer) and how that market will be captured (e.g., provide a solution where none exists, augment current technology for better outcomes, displace existing standard of care). Discuss any notable barriers to entry into the market.

500 word maximum.

Competition: Characterize competitors in this market. What is the value proposition for your technology?

500 word maximum.

Intellectual Property: Who currently owns this IP? Briefly explain your plans to protect any intellectual property.		
250 word maximum		
Has a disclosure been filed with the relevant technology transfer office?	Y/N	
Has a provisional patent been filed?	Y/N	
Has a full patent been filed?	Y/N	
Has a copyright been filed?	Y/N	
Has a trademark been filed?	Y/N	
Has the technology been licensed?	Y/N	

Regulatory: If applicable, describe the likely regulatory pathway and any predicate (if identified) for your technology.

250 word maximum.

Reimbursement: If applicable, describe the likely reimbursement or payment approach for this technology.

250 word maximum.

Risks: Discuss notable risks for this project (e.g., technical, market, regulatory) and provide a brief mitigation plan that addresses them.

250 word maximum.

Team: Briefly describe the project team. Highlight relevant technical expertise, any relevant translational or entrepreneurial expertise or interest, and the roles anticipated for each team member.

500 word maximum.

Project Plan: Provide an overview of the workplan for this project, including (1) technical development activities, (2) expected commercialization activities (e.g., securing follow-on funding, developing a start-up company plan), and (3) any expected regulatory activities. Identify key milestones, go/no-go criteria for each milestone, and pivot points for technical and commercialization activities.

1,000 Words

Gantt chart: Upload a Gantt chart with milestones, timelines, and dependencies.

Excel upload.

References: List any publications.

- I. Appendix
 - a. Compliance Form (Appendix C)
 - b. Budget Justification
 - c. Biosketches
 - d. Budget pages (by milestone; Excel template provided)
 - e. Other

Appendix C: Compliance Form

For questions about this form, please contact us at $\underline{\mathsf{rmtreach@umontana.edu}}.$

1)	Principal Investigator:
2)	Project Title:
3)	Institution: (a compliance form must be completed for each performance site)
4)	Financial Overlap: Yes No
	Financial overlap is active or pending funding for the same scope of work and/or budgetary item, and must be resolved prior to award.
5)	Human Subject Use: Yes No (includes the prospective or retrospective use of private identifiable data or materials derived from humans)
	A human Institution Review Board (IRB) approval letter must be received before funds will be released to awardees. The IRB approval letter should include the protocol title, approval date, the protocol number, and the multiple project or federal wide assurance number.
6)	Animal Use: Yes No (includes the use of live animals in research, teaching or testing)
	An Animal Care and Use Committee (IACUC) approval letter must be received before funds will be released to awardees. The IACUC letter should include the protocol title, approval date, the protoco number, and the animal welfare assurance number.

Appendix D: Pitch Practice

The following topics should be covered in your presentation although the order and time spent on each is at your discretion. Prepare for a 10-minute pitch with 20 minutes of discussion and Q&A.

Three slides will be allowed for your presentation: an introduction slide to the product and team, a slide discussing the technology you are developing, and a slide discussing the market potential for the technology. In your presentation, please incorporate feedback and questions you received from the RMT-REACH External Review Board on your Letter of Intent.

Suggested Pitch Structure:

Introduction & Team (15-45 seconds)

o In a few sentences, explain your technology/innovation and introduce your team.

The Problem (30 seconds – 1 minute)

- Describe the qualitative and quantitative view of the problem. Using a story or scenario is helpful.
- Describe any disruption in market that might provide an opening for your technology
 The Solution (1-2 minutes)
- Describe the product or service you envision.

Benefits (1-2 minutes)

• Describe the benefits of the solution and how it addresses the problem/opportunity you have presented.

Traction (60-90 seconds)

- Do you have a prototype? Completed solution? Describe where the technology is in its development.
- Patents filed
- Signed contracts with partners, if any. Customers if any.

Market Size (30 seconds)

- o How large is the addressable market?
- O How is the market segmented?

Go to Market plan (30 seconds)

- o Who are the decision makers and influencers within your prospect customer?
- o How will you reach them?

Competition (30-60 seconds)

- Describe direct and indirect competition
- Highlight your differential advantage

Need for and Use of Innovation Funding (30 seconds)

- o What still needs to be done after this funding to get to license or to market?
- o Discuss key milestones that funding will be used for
- o How will spending the money advance commercialization?

Close