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 and health disparities 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 an *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 to support the completion of project milestones and tasks as defined in a Project Funding Agreement. In addition to receiving proof-of-concept funding, an 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	Friday, April 12 th
Workshop 1: Unmet Need	Thursday, May 2 nd (12:00pm MT)
Workshop 2: Market Potential	Tuesday, May 7 th (12:00pm MT)
Workshop 3: Intellectual Property & Technology Transfer	Monday, May 13 th (12:00pm MT)
Workshop 4: Developing a RMT-REACH workplan	Thursday, May 23 rd (12:00pm MT)
First Draft of Application for Internal Review Due (optional)	Monday, May 20 th (5:00pm MT)
Feedback on Submitted First Draft Applications	Tuesday, May 28 th
Workshop 5: Pitch Practice	Wednesday, May 29 th (12:00pm MT)
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 RTGC	Friday, June 28 th
Earliest Decision	Early August
Funding and Support Allocated	September 1st

Office Hours

Beginning Thursday, April 18th, we will be running a series of office hours **every Thursday and Friday from 12:00pm – 1:00pm MT / 11:00am – 12:00pm PT**. This series will run through Friday, May 31st. Office hours will be held via Zoom and provide applicants the opportunity to connect with project managers and ask any questions they may have while preparing their application. Note that any innovator may attend office hours during the time period so conversations may not be private. ***We will <u>NOT</u> have office hours on Thursday, May 2nd or Thursday, May 23rd to accommodate the workshops scheduled on those dates (see above). This will not affect the Friday office hours scheduled during those weeks. **

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RMT-REACH 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 up to \$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.
	RMT-REACH funds CANNOT be used for clinical trials. Please review this <u>guide</u> to determine if your proposed study is a NIH-defined clinical trial. Matching funds can be utilized for clinical trials. Please email us at <u>rmtreach@umontana.edu</u> if your proposal includes clinical trial activity.
	F&A is allowable.
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 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 non-academic 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

	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)	

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

Content and Form of Application Submission

- 1. Letter of Intent (details are in Appendix A)
 - DUE March 29, 2024 (5:00pm MT) 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).
- DUE May 31, 2024 (5:00pm MT) 2. RMT-REACH Application (details are in Appendix B)
 - Applications are submitted for review through the RMT-REACH UpdateTracker Application Portal at https://redcapedc.rti.org/seed/surveys/?s=nDevjGW9NdzWfMFw. 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 (mtreach@umontana.edu).
- 3. Project Pitch (details are in Appendix C)

Week of June 10th, 2024

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 an 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 & Innovations Manager, RMT-REACH, <u>caroline.mclean@mso.umt.edu</u> Leidy Wagener, Operations Manager, RMT-REACH, <u>leidy.wagener@mso.umt.edu</u>

Appendices

Appendix A: RMT-REACH Letter of Intent Questions



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

Applicant Information:

Contact Inform	ation	
	First Name	
	Last Name	
Principal	Institution	
Investigator	Position/Title	
	Telephone	
	Email Address	
	First Name	
Altowarto	Last Name	
Alternate Contact	Title	
Contact	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

APPLICATION PORTAL

Proposal Format and Instructions:

Please complete the required sections below to submit a proposal.

Supporting documents required for full proposals include the completed budget template and justification, biosketches for key personnel in NIH's required format, institutional contact information and authorization, and the compliance form.

Contact Information			
Project Title			
	First Name		
	Last Name		
Principal Investigator(s)	Position/Title		
	Telephone		
	Email Address		
	Institution		
	First Name		
	Last Name		
Alternate Contact	Title		
	Telephone		
	Email Address		
Has the PI ever licensed a technolo	gy?		Y/N
Has the PI ever started a company?)		Y/N
Has the PI ever applied for a patent	:?		Y/N
Has the PI ever applied for a trader	nark?		Y/N
Has the PI ever applied for a copyri	ght?		Y/N
Technology Characteristics			
Technology type (Select one from I	ist)		
Biologic Drug	Health Information Technology	0,	
Diagnostic	Research Tool	Therapeutic Device	
How many years have you been de	veloping this technology?	year(s)	
Please identify ALL NIH Institutions	and Centers that have relev	ance to your technology (Select all th	at apply from list):
National Cancer Institute (NCI)		National Institute of Environmental Hea	. ,
National Eye Institute (NEI)		National Institute of General Medical S	. ,
National Heart, Lung, and Blood Institu		National Institute of Mental Health (NI National Institute on Minority Health a	,
National Human Genome Research Institute (NHGRI) National Institute on Aging (NIA)		(NIMHD)	nu rieaitii Dispanties
National Institute on Alcohol Abuse and	d Alcoholism (NIAAA)	National Institute of Neurological Disor	ders and Stroke (NINDS)
National Institute of Allergy and Infecti	ous Diseases (NIAID)	National Institute of Nursing Research (NINR)	
National Institute of Arthritis and Muse	culoskeletal and Skin Diseases	National Library of Medicine (NLM)	
(NIAMS)		NIH Clinical Center (CC)	-1
National Institute of Biomedical Imagin National Institute of Child Health and F		Center for Information Technology (CI Center for Scientific Review (CSR))
National Institute on Deafness and Oth	1 ()	Fogarty International Center (FIC)	
(NIDCD)		National Center for Advancing Translat	ional Sciences (NCATS)
National Institute of Dental and Cranio	· · ·	National Center for Complementary an	d Integrative Health
National Institute of Diabetes and Dige	stive and Kidney Diseases	(NCCIH)	
(NIDDK) National Institute on Drug Abuse (NIDA	A)		
Hational Institute on Drug Abuse (MDA	Y		

Project Description			
Disease area (Select all that a	pply from list)		
Aging	Gastroenterology	Neurology	Regenerative Medicine
Analgesia	Heart	No disease or organ indication	Sepsis
Anesthesiology	Hepatology	(platform technology)	Sleep
Antimicrobial Products	HIV/AIDS	Obesity	Speech Pathology
Autism	Immunology	Ophthalmology	Spine
Blood	Infection control	Orthopedics	Sports Medicine
Bone disease	Maternal Health	Pain	Substance Use Disorders/Dr
Cancer	Medical	Palliative Care	Abuse
Cardiovascular Health	Countermeasures	Pediatrics	Surgery
Dentistry	Medical Imaging	Pharmacology	Toxicology
Dermatology	Mental Health	Physical Medicine	Urology
Diabetes	Metabolic Disorder	Pulmonary	Wound healing
ENT Health	Nephrology		-
unding History for This Proje	ect		
s this application a resubmiss	sion?	Y/N	
las this technology received f	federal funding support prior to		
his submission? If yes, which			
f NIH provide grant number	(i.e. R01HL123456) then select		
he NIH Institute or Center fro			
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Reimbursement: If applicable, describe the (250 word maximum)	likely reimbursement or payment approach for this te	chnology.	
Risks: Discuss notable risks for this project (addresses them. (250 word maximum)	(e.g., technical, market, regulatory) and provide a brief	mitigation plan that	
	ghlight relevant technical expertise, any relevant trans he roles anticipated for each team member. (500 word		
expected commercialization activities (e.g.,	orkplan for this project, including (1) technical develop securing follow-on funding, developing a start-up com milestones, go/no-go criteria for each milestone, and p (1,000 word maximum)	pany plan), and (3) a	
Gantt chart: Upload a Gantt chart with mile	stones, timelines, and dependencies. (PDF Upload)		
References: List any publications.			
Appendix A: Compliance Form		I	
Financial Overlap: Financial overlap is active or pending funding and must be resolved prior to award.	g for the same scope of work and/or budgetary item,	Y/N	
materials derived from humans) A human Institution Review Board (IRB) app	ve or retrospective use of private identifiable data or roval letter must be received before funds will be er should include the protocol title, approval date, the or federal wide assurance number.	Y/N	
Animal Use: (includes the use of live animals An Animal Care and Use Committee (IACUC)	s in research, teaching or testing) approval letter must be received before funds will be Ild include the protocol title, approval date, the	Y/N	
Amondia (continued)			
Appendix (continued).	Budget justification	Budget justification	
Appendix (continued). Appendix B:	Biosketch(es)		
Appendix B:	Budget pages (by milestone)		

Y/N

Y/N

Y/N

Has the technology been licensed?

Has this technology been discussed with the relevant technology transfer office?

Has a disclosure been filed with the relevant technology transfer office?

Save & Return Later Option: Please note, once an application is started in the portal, you can choose to save your progress by selecting the "Save & Return Later" button at the bottom of the webpage. If you choose to do so, a hyperlink unique to your application will be emailed to you. You can share this link with other members of your team to work on the application together within the portal. Anyone with access to this link will be able to make changes. The RMT-REACH team has very limited administrative control in the application portal and cannot provide timely support. Any reports of errors will be escalated to the administrative team at the NIH. Please allow adequate time before the deadline to submit the application.

Appendix C: 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)

• 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.
- o Patents filed
- Signed contracts with partners, if any. Customers if any.

Market Size (30 seconds)

- How large is the addressable market?
- How is the market segmented?
- Go to Market plan (30 seconds)
 - Who are the decision makers and influencers within your prospect customer?
 - 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)

- 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
- How will spending the money advance commercialization?

Close