Piedmont Triad Regenerative Medicine Engine (PTRME) Ecosystem Building Grant Call 2024
The RegenMed Development Organization (ReMDO) is excited to announce a funding opportunity intended to help grow our regional ecosystem for regenerative medicine in partnership with the newly formed National Science Foundation (NSF) PTRME.

What is the PTRME?
The Wake Forest Institute for Regenerative Medicine (WFIRM) is the recipient of an inaugural NSF Engines Program award. The NSF-PTRME is an initiative to build a regional innovation ecosystem to accelerate the translation of regenerative medicine use-inspired research to commercialization, thus stimulating economic growth, workforce development, and job creation. The PTRME partnership consists of more than 80 regional stakeholders, including industry, academia, government, and not-for profit entities.

Ecosystem Building in North Carolina
ReMDO is a 501(c)3 non-profit organization with the mission to accelerate discovery and translation of regenerative medicine therapies. It is part of a thriving regenerative medicine landscape across the Piedmont region of North Carolina called the Regenerative Medicine Hub (RegenMed Hub) that is joining forces with the PTRME to develop a comprehensive ecosystem to accelerate the manufacturing and commercialization of regenerative medicine products within our region. This ecosystem is intended to become an integrated solution provider for regenerative medicine, where companies have access to specialized technologies and expertise, a trained workforce, and capital investment opportunities through a vast network of stakeholders in the regenerative medicine space.

To further advance the regional footprint in regenerative medicine, the PTRME and ReMDO are issuing a call for proposals from entities seeking to advance regenerative medicine related technologies that are planned for commercialization, where significant progress towards transition of the product to the marketplace can be accomplished within 15 months with funding of up to $500,000. An ideal product would be a regionally manufactured regenerative medicine-based product or enabling technology. It is important to understand that the core mission of the PTRME is to grow the Piedmont Triad Regenerative Medicine regional industry and increase our inclusive workforce, and applications should clearly indicate how PTRME investments into your group will advance these goals. Companies will be prioritized for funding that have a physical presence in the PTRME region of service or have a demonstrated commitment to creating a physical presence within the region during the period of award. Entities not within our region of service may apply but must provide a clear rationale for how their efforts will provide a measurable benefit to the PTRME region of service. Partnerships and teaming with others, such as commercial, academic and non-profit entities, are allowed.

Grant Objectives: The field of regenerative medicine is poised to explode over the coming decade, with many products nearing the finish-line. ReMDO and the PTRME recognize the hardships associated with securing capital necessary for product transition, including navigation of regulatory pathways, development of commercial prototypes and manufacturing processes, and creation of business plans and marketing strategies. These activities would generally occur during Technology Readiness Levels 4 and above. This grant call is primarily intended to accelerate the transition of products to the marketplace that will accomplish the following objectives:

1. Grow the regenerative medicine industry within the PTRME region of service.
2. Create job opportunities for the growing PTRME regional regenerative medicine workforce.

3. Magnify the impact of PTRME investments through leveraged funds.
4. Ensure broadening participation and inclusivity within the emerging field of regenerative medicine.
5. Create a positive impact across the broader National regenerative medicine landscape.
6. Create a significant economic impact within the PTRME region of service.

Example Technologies: This Ecosystem Building Grant will prioritize funding of technologies with a clear pathway to commercialization but are facing hurdles that additional capital could help clear. Any biomaterial, cell or tissue based regenerative medicine product would be eligible for funding. Additionally, the PTRME will consider products that drive the development or aid in the manufacturing of other regenerative medicine commercial products. These ancillary technologies are crucial for advancing the field of regenerative medicine by providing the tools and processes necessary to develop and manufacture regenerative medicine products. The examples below represent technologies the PTRME sees as providing an extended benefit across the regional industry. These are only examples and should not be viewed as focus areas that will be granted special consideration in funding.

1. 3D Bioprinters:
    - 3D bioprinting allows for the creation of complex tissue structures by precisely depositing layers of living cells and biomaterials. Other manufacturing strategies could also be supported.
    - Bioink Scaffolds tailored to a specific patient's need, promoting tissue self-organization.
2. Gene Editing for Cell Therapies and Tissue Engineered Constructs:
    - Technologies that address genetic disorders and diseases.
3. De-Cell/Re-Cell Approach / Organ and Tissue Banking Technologies:
    - Address the need for biomimetic cell scaffolds in tissue engineering.
    - Cell scaffolds derived from decellularized tissues.
    - Organ, tissue and cell banking technologies could be proposed.
4. Injectable Hydrogels and cells for Tissue Repair:
    - Minimally invasive biomaterials, cells or combinations of both for restoring tissue function.
    - Injectable hydrogels designed to be delivered into compromised tissue to promote endogenous regeneration; these could be loaded with cells, growth factors, or other therapeutic factors.
5. Cell Processing:
    - Devices that automate the isolation of a desired cell type.
    - Devices that capture exosomes, small vesicles secreted by cells that can carry proteins, lipids, and genetic material, that may be used therapeutically.
6. Transport/Shipping/Logistics:
    - Products used for maintaining viability and quality of regenerative medicine products during transport from a centralized manufacturing facility to point of care.
7. Bioreactors:
    - Bioreactors provide a controlled environment for conditioning cells and tissues.
    - May provide control over conditions such as oxygen levels, nutrient availability, and provide mechanical stimulation to enhance tissue maturation and functionality.
8. Advanced Imaging and Diagnostic Tools:
    - Live cell imaging techniques enable real-time monitoring of cell behavior and tissue development, providing valuable qualitative data.

- High-Resolution MRI and CT scans that allow for detailed visualization of tissues and organs, aiding in the assessment of regenerative therapies.

9. Analytical Methods that use or facilitate regenerative medicine strategies. standards, development, or other therapeutics:
    - Genomics, proteomics, metabolomics and artificial intelligence technologies that provide comprehensive profiles of living regenerative medicine products.
    - Tissue and body-on-a-chip technologies that can be used as diagnostics, testing, or for determining therapeutics.
    - In-line analytics and sensors that continuously monitor and provide feedback on the biomanufacturing of tissue regenerative medicine products.

Grant Terms:
Financial – This grant is a non-dilutive, non-equity grant and ReMDO PTRME does not seek any financial return on the grant awards.
Reporting – All grant recipients will be required to submit a quarterly report detailing use of funds, project progress, upcoming challenges, and risks.
Disbursement of Funds – Funds will be disbursed in equal quarterly increments unless grant recipients provide a special funding request outlining their budget needs and plan.
Geographic Location – The preference is for grant recipients to have a physical presence in the Piedmont Triad region of North Carolina at least for the duration of the grant, with a minimum of one full time employee authorized to work collaboratively as a member of the PTRME ecosystem.
Eligibility – This grant call is open to:

- Entities that have a physical presence in the PTRME region of service, or can demonstrate a commitment to creating a physical presence in the PTRME region of service during the period of award, or can demonstrate evidence that successful commercialization of their product will directly impact the regenerative medicine field within the PTRME region of service.

Funding Details –

- Maximum funding per project in direct and indirect costs: $500,000
- Maximum duration of funding of 15 months
- Company cost-match: Preferable, although a specific level of cost share is not required.
- Funding scope: personnel, equipment, materials, and other direct costs.

Proposal Submission: Interested applicants should submit a comprehensive proposal as a single PDF document (1" margins, Times New Roman 12 pt font single spaced) including the following sections with page limits as indicated:
10-page limit:
Project title, principal investigator(s), and contact information.
Abstract – Include a brief summary of the project.
Commercial Profile – Please briefly describe your entity. This should include a general overview of existing product lines and annual sales (if any), number of current employees, and how long the entity has been in existence. Include a short description of the market segments targeted by the technology being commercialized, competitive landscape, and significant hurdles to commercialization that will be addressed by awarded funds. Please include an overview of existing or planned protection of intellectual property associated with the technology to be commercialized.

Background and Significance – Context, problem statement, and relevance.
Objectives – Clear and measurable objectives of the project.
Approach and Methods – Detailed description of the proposed activities leading to commercialization and how the requested funding, in combination with company matching funds if included, will accelerate the transition of the technology to the marketplace by overcoming a clear obstacle to commercialization and advance the TRL level within the 15-month period of award. The application should include a brief strategy for broadening participation through mechanisms such as engagement with PTRME workforce development programs.
Work Plan –Timeline and milestones for the project.
Expected Outcomes – Potential impact the project is intended to have on the Ecosystem for regenerative medicine within the PTRME regional of service, as well as the broader National regenerative medicine industry (see grant objectives above).
2 page limit:
Budget – Detailed budget and justification for funds requested. Please also include matching investments, if any, that potentiate the impact of PTRME funding.
Additional pages as needed for the following:
Qualifications – CVs of the principal investigator(s) and key team members. (please limit to no more than 2 pages per PI and/or key team member).
Collaboration(s) – Description of collaborative efforts with associated letters demonstrating commitment of third parties.

Evaluation Criteria:
Intellectual Merit.
- Technical approach
- Creativity and innovation
- Organization of plan

Feasibility.
- Budget and matching funds
- Qualifications of team
- Adequate resources available to complete plan

Impacts.
- Economic impact on region
- Potential to create jobs within the region
- Benefit to society

Commercialization
- Sound commercialization plan
- Broadening participation plan
- Regulatory considerations

Submission Deadline:
- Proposals must be submitted by September 3, 2024.
- Proposal awards announced October15, 2024.
- Project start: December 1, 2024.

Submission Instructions: Proposals should be submitted electronically to our landing page https://regenmedengine.com/2024-ecosystem-building-grant-call/ by the specified deadline above. Late submissions will not be considered. For questions contact us at wfirmoraf@wakehealth.edu