

## EXECUTIVE SUMMARY

**PROJECT TITLE:** South Carolina Medical Device Alliance

**FUNDING SOURCE:** Economic Development Administration Regional Innovation Strategies i6 Challenge

**FEDERAL FUNDING:** \$749,994

**NON-FEDERAL FUNDING:** \$1,064,852

**TOTAL PROJECT FUNDING:** \$1,814,846

### SUMMARY:

South Carolina Research Authority (SCRA) will create the South Carolina Medical Device Alliance (MDA) to invent, advance, and bring products to market. This multi-stakeholder partnership, comprised of Clemson University (CU), Medical University of South Carolina (MUSC), and industry leaders, will form a regional innovation cluster to grow the economic impact of this sector through job creation and startup formation, as well as to attract international businesses to establish a presence in South Carolina. Working within this framework, the MDA will advance technologies to market by designing solutions, determining initial commercial feasibility, de-risking innovations with multidisciplinary teams, and launching startups that have been rigorously evaluated by seasoned industry experts.

SCRA's capabilities in managing collaborations, coupled with its state-wide focus on fueling the innovation economy, provide the foundation to execute the MDA. Through CU's Bioengineering and MBAe programs, MUSC's clinical capabilities, and SCRA's industry advisors, the state has substantial expertise and intellectual assets in the field that, once coordinated by the MDA, will lead to tremendous opportunity for economic impact. Leveraging South Carolina's existing expertise, infrastructure, and funding, the MDA will facilitate and accelerate the commercialization of medical technologies, build entrepreneurial capabilities among students, faculty and clinicians, and foster startup formation in the sector.

### KEY PERSONNEL:

**Christine Dixon Thiesing**, MBA, is Director of Academic Programs at SCRA. Ms. Dixon Thiesing coordinates translational research across South Carolina's institutions of higher learning, brings industry insight to inform the direction of academic research and enhances funding opportunities for research fields of strategic interest to the state. Prior to SCRA, her career was split between holding business development and finance roles in life science academic startups and educating and supporting academic entrepreneurs. She co-founded CuRE Innovations, an advanced dental materials company, and sits on the boards of Southeastern Medical Device Association, SCBIO, and KIYATEC, Inc. Ms. Dixon Thiesing will oversee execution of the scope of work, coordinate with co-applicants, and be accountable for deliverables.

**John DesJardins**, Ph.D., is the Hambright Leadership associate professor in Bioengineering at CU and the director of the Frank H. Stelling and C. Dayton Riddle Orthopaedic Education and Research Laboratory at CUBEInC. His research interests are in the areas of biomechanics, tribology, engineering education, and implant design. He is active in professional organizations including BMES, ASEE, VentureWell, ORS, NIH, and NSF. Dr. DesJardins directs the bioengineering senior capstone design program, leads a bioengineering study abroad program in bioethics to Spain each summer, and directs the NIH funded CU-MUSC summer needs-finding experience for bioengineering students called DeFINE. He is active in the areas of undergraduate leadership, innovation, and entrepreneurship education. Dr. DesJardins will coordinate the engineering efforts among faculty, students, and entrepreneurs.

**Michael J. Yost**, Ph.D., is Professor of Surgery and Vice Chairman of Surgery for Research at MUSC. He worked for 15 years in industry as a research and process engineering manager. In this role, he made extensive use of his biomaterials knowledge to develop new processes and products for several companies, where he managed projects up to \$6 million and a staff of 20 people. Since coming to academia in 2000, Dr. Yost has invented many regenerative medicine technologies including cell stretching bioreactors, collagen tube technology of both the straight curved and branched collagen scaffolds. He has over 80 scientific publications and has been continuously funded for over 18 years. Dr. Yost will coordinate clinical engagement and ensure clinical perspectives are pervasive throughout the development process.

## SCOPE OF WORK

### **PHASE I: DESIGN PRELIMINARY SOLUTIONS & IDENTIFY COMMERCIALY VIABLE PROJECTS.**

CU and MUSC have an existing unique partnership in its senior design program, which engages clinical innovators with engineering students to identify, develop, and solve critical clinical problems and advance those solutions to become commercial products. *Checkpoint A:* Prior to public disclosure, the first phase of the MDA will bring industry insight to the initial stages of medical device development. Beginning with the 2018-2019 program, CU's existing IAB will identify the top commercially-viable senior design program projects. The top projects will then be disclosed to their respective TTO's, where preliminary technology evaluations will be performed to determine patentability and commercial opportunity. The early IAB input and preliminary TTO evaluation will better enable the TTOs at CU and MUSC to justify investing in patent filings prior to public disclosure, protecting the ability to file for patent protection world-wide. The TTOs and SCRA will identify the top faculty innovations from across the state to also feed into Phase II.

### **PHASE II: DEVELOP PRODUCT PROFILES AND DETERMINE INITIAL FEASIBILITY.**

SCRA will lead the effort to develop product profiles for the top technologies resulting from Phase I. The profiles will include a regulatory assessment, comprehensive market and competitive analysis, production assessment/cost of goods analysis, patent landscape, and reimbursement assessment. *Checkpoint B:* The product profiles will be provided to the MDCAP as the background information necessary to determine the next steps of development for each project. The MDCAP also will evaluate each project based on an established, multi-faceted rubric for the potential commercial value and make recommendations regarding which projects should advance to Phase III.

### **PHASE III: DE-RISK INNOVATIONS WITH MULTIDISCIPLINARY TEAMS.**

CU will hire a Professor of Practice (PoP) with extensive industry experience in medical device development who will curate and lead multidisciplinary teams consisting of masters-level bioengineering students, business students, and law students, along with clinical subject matter experts. The teams will de-risk the medical devices to address the needs identified by the IAB and MDCAP. This phase will include funding of fellowships in entrepreneurship for bioengineering graduate students. The student teams will also conduct market research by convening focus groups in coordination with clinicians at MUSC and other clinical partner institutions. *Checkpoint C:* After one year, the students will present their findings to the MDCAP for re-evaluation and determination of the next steps.

### **PHASE IV: IMPLEMENT TRANSLATION/MATURATION.**

The MDCAP, in conjunction with the PoP, will determine which of four paths a project will take in this phase:

- 1) Optimally, projects will be adequately de-risked to serve as the basis of a startup company and attract follow-on funding. Funding from the i6 will be deployed to hire an EIR to provide a strong foundation for the startup and increase the potential for successful translation into the marketplace;
- 2) Some projects may require additional de-risking. In such cases, the project will revert to Phase III for an additional year of development;
- 3) Some projects will be best suited to an out-licensing model by the relevant TTO upon completion of Phase III;
- 4) A portion of projects will have encountered an insurmountable issue, resulting in termination.

At the end of the Performance Period, South Carolina will have a sustainable mechanism to produce entrepreneurial jobs in the medical device field and expand the entrepreneurial capacity of the state. This will serve as an outlet for previously unmined clinical needs to have a significant and enduring economic impact for the state.

**SCRA welcomes additional industry engagement. If you have industry-based medical device development expertise and are interested in participating in one of the advisory panels, please contact Christine Dixon Thiesing at [Christine.thiesing@scra.org](mailto:Christine.thiesing@scra.org).**