REQUEST FOR APPLICATIONS (RFA)

mdPACE Program

Purpose:

The mdPACE Program (the "Program") is a three year initiative funded jointly by TEDCO and a Federal Department of Commerce EDA i6 Grant. It is designed to address the problem of too few experienced medical device entrepreneurs in the Region by bringing together a team of medical device professionals who can lead multiple commercialization efforts in parallel using an efficient and proven commercialization process – the Stage Gate Development Process – to train the next generation of medical device entrepreneurs and to leverage the other assets in the Region to form 5 – 7 new medical device companies each year. Upon completing the 18 month Program, these companies ("Project Companies") will be better positioned to attract investment, hire employees, and generate revenues. Applications will be accepted on a rolling basis and those that represent the best fit with the goals of the Program will receive the highest consideration.

The mdPACE Program will create a virtual Commercialization Center: Projects will be located in geographically different places, including in many of the region's incubators. Medical device professionals will meet monthly at TEDCO's offices to provide updates on the status of their projects and to engage in stage-gate meetings (i.e., go-no/go decision points). The founders of company projects will also be asked to attend these meetings to present updates on their progress.

Program Overview:

The overall purpose of the Program is to increase the number of medical device start-up companies in the Region – especially those based on technologies developed at local research institutions – to train future medical device professionals by giving them an opportunity to work along seasoned professionals on commercialization projects, and to refine a model for commercialization that can be duplicated in other regions or for other industry verticals such as diagnostics and therapeutics. Ultimately, the goal is to make the Region a nationally recognized hub for medical device innovation and commercialization.

The Program is similar to a business accelerator in that start-up medical device companies will be selected from an applicant pool, accepted into the Program, and graduate from the Program after 18 months. The Program will differ from most business accelerators in two critical ways. First, the founders of the accepted Project Companies will receive the active, continual guidance of a team of experienced Medical Device Professionals while the company is in the Program; second, the Stage-Gate Process used by the Program may result in the rejection of up

to half of the companies based on the outcomes of that process. Typically, business accelerators provide mentors rather than executives and they generally do not have a mechanism for rejecting companies as part of the process.

The Program will rely primarily, but not exclusively, on the universities and hospitals for sources of novel medical device technologies. As previously described, the universities alone generate approximately 60 new medical device technologies each year. Others are developed by physicians, engineers, and entrepreneurs. All would be eligible to apply for the Program.

By leveraging (i) the innovations in medical devices emerging from the Central Maryland/Baltimore/Washington Metropolitan region's prominent medical and engineering schools including the University of Maryland and Johns Hopkins University and (ii) the region's significant entrepreneurial support infrastructure, the Program will help significantly increase the number of successful medical device companies in Maryland.

Eligibility:

The prospective Program team will have formed a corporate entity, will be coachable and will have secured some funding, either dilutable or non-dilutable.

Target technologies with a clear 510(k) regulatory pathway and the following characteristics will be eligible to participate in the Program. Note that criteria may be modified in years 2 and 3.

- Material IP with real competitive roadblocks.
- Either an existing reimbursement code or a clean, quantifiable revenue model.
- A predicate device (i.e. no De Novo applications).
- No requirement for a PMA.
- No requirement for human trials.

Additional selection preferences may include the following.

- Quadrant 4 on cost/value continuum (i.e. low cost, high value).
- Large market (i.e. >$500M) or represent a threat to an existing product line.

Applying to the mdPACE Program:

The applicant will submit an application consisting of a maximum 5 pages with one inch margins and 12 point Calibri font in PDF format to the Program Manager that clearly contains the following information:

- General Company description.
    - The name of the full legal entity submitting the application.
    - Web address.

  - Date Business was founded and date of fiscal year end.
  - Target Industry and NAICS Code.
  - Complete business address to be used for all communications concerning the application and contact information for applicant's point person.
  - Brief biographical sketches of key team members.
- Economic Development Baseline Information (unless otherwise indicated, provide information either for the most recently competed calendar quarter or at the close of the most recently completed calendar quarter).
  - Total number of paid full-time employees (quarter close).
  - Total number of paid part-time employees (quarter close).
  - Total number of unpaid full-time employees (quarter close).
  - Total number of unpaid part-time employees (quarter close).
  - Total number of paid hours worked (total quarter).
  - Total number of unpaid hours worked (total quarter).
  - Median compensation (salary + incentive) of paid employees (total quarter).
  - Approximate amount of capital raised over life of business. Separate by type (loans, loan guarantees, grants, SBIR, private investment, etc.).
  - Gross commercial sales for the most recently completed fiscal year.
  - Gross commercial sales for the life of the business.
  - Total number of patent applications currently in process (provide patent application number(s)).
  - Total number of patents held by the applicant (provide patent numbers(s)).
  - Technology Readiness Level (see TRL Chart for description).
- Statement confirming the applicant's willingness to enter into a $50,000 deferred success fee payment agreement that is contingent upon the participant 1) completing the mdPACE Program and filing a 510(k) application, 2) receiving FDA clearance, 3) achieving either a liquidity event or an outside investment at a pre-money valuation of at least $5,000,000.
- If applicable, identification of current or completed TEDCO funding program (i.e. TCF or MII) in which either the Company or founders have participated, the status of funded project, and the name of TEDCO portfolio manager.
- Narrative describing the applicant's technology, including any clinical validation.
- Narrative describing the source of the technology and, if applicable, the status of license negotiations with the owner of the technology.
- Narrative describing the applicant's alignment with Program eligibility requirements as outlined above. Address each point of the eligibility requirements and be sure to describe any work done to validate the FDA pathway.
- Any other information required by TEDCO from time-to-time to expeditiously process the application.

Application Review:

Once a Program application has been submitted, TEDCO will begin its review process.

Compliance Review:

The Program Manager will initially review all applications to ensure that they meet the basic requirements indicated by this RFA. Those not meeting the specified requirements will be rejected without further review and the applicant will be so notified.

Review Committee:

A Review Committee comprised of TEDCO staff and external members of the medical device community will review and discuss all the Program applications. After reviewing all of the applications, the Review Committee will make a decision whether or not to recommend each specific application for inclusion in the Program. Decisions will be based upon the extent to which the applicant has demonstrated the following:

- Alignment between the proposed technology and Program eligibility requirements.
- Control of underlying intellectual property.
- Validation of clinical need.
- Validation of 501(k) pathway.
- Validation of reimbursement strategy.
- Applicants that include all of the requested information and present that information in an organized, convincing way will be considered more favorably.

A qualitative assessment of the strength of the proposed technology and the likelihood of its success, and the ability and commitment of the team to create that success will also be conducted.

An in-person presentation and/or Q&A session may be required as part of the adjudication process.

For those applications that are not recommended for funding, the Program Manager will summarize the Review Committee's concerns with the application and provide that summary to the applicant. The final decision for inclusion in the Program is made by TEDCO's president.

The Award Process

In the event that an applicant is selected for inclusion in the Program, a notice of selection will be sent to the applicant via e-mail. The applicant is then expected to confirm its acceptance of the selection, also via e-mail, at which time a TEDCO Program Agreement will be created. When the Agreement is fully executed, TEDCO will assign a Program Lead and schedule a kick-off meeting prior to the beginning of the Program. In the event that an application is rejected, TEDCO will so notify the applicant.

Reports:

The successful applicant will be required to submit periodic reports, as follows:

Financial Reports: For a period of five (5) years following completion of Company's participation in the Program, Company shall provide TEDCO with quarterly financial statements, which include an Income Statement, Balance Sheet, and Cash Flows Statement. The financial statements for the first quarter of each calendar year shall include complete State and federal income and payroll tax returns.

Milestone Reports: During the term of Company's participation in the Program, Company shall submit milestone reports describing its accomplishments related to the proposed specific aims and the achievement of any designated project milestones. These reports shall be emailed to the Program Manager. A final milestone report shall be due within 90 days of completion of the Program. The report will describe the company's accomplishments related to the proposed specific aims, the achievement of any designated project milestones, any intellectual property created or improved during the project, any licensing or other commercialization activities related to the project, and company's employment data (Full-time equivalents and total payroll) at the completion of the project.

Annual Economic Development Reports: For a period of five (5) years following completion of Company's participation in the Program, Company shall provide to TEDCO an Annual Economic Development Report. The report will include State and federal income and payroll tax returns, an employee census reflecting the current number of full-time equivalent employees who are Maryland residents, and such other information which TEDCO may reasonably request from time to time.

Program Manager Information:

Inquiries regarding the Incubator Assistance Program should be directed to:

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