

## **WE-REACH Application Intake, Review, and Approval Process**

The following information is intended to help set expectations as you proceed through the WE-REACH application process.

The charter for WE-REACH is to make technologies more clinically viable by providing regulatory, product development, reimbursement, intellectual property, and market analysis support. Successful applicants should already have a proven concept satisfying a clinical need established through a robust customer discovery process. WE-REACH funding is NOT a research grant. While some process or product refinement may be funded, your application should focus on explaining how these funds would improve your chances of success in delivering your product or therapy to clinical practice.

### **Process**

All applications are reviewed by our External Review Group (ERG). Questions raised in the course of review will be forwarded to PI's to be addressed in live pitches to the ERG. Following pitches, the ERG will settle on final scores for each project. ERG comments and scores are compiled and summarized by WE-REACH Technology Development staff. Applications scoring 5 or worse are triaged from the current WE-REACH funding round. Generally, triaged teams are those that are too early in concept evolution or have not yet identified their mechanism of action.

For the projects not triaged out, the WE-REACH Program Administrator submits the review summary, ERG comments and scores, and full applications to NIH for review by relevant NIH branches, FDA, USPTO, CMS, and Kaiser Permanente. (NIH may triage applications it deems to be inappropriate.) This incredibly valuable feedback is collected and shared with project teams to guide their future planning.

Following national review, the Program Administrator receives, compiles, and disseminates NIH partner comments and scores to our Executive Leadership Group (ELG).

ELG reviews compiled ERG and NIH summaries, comments, and scores for each application and selects projects by vote for advancement to the project agreement phase. Projects must have a quorum majority affirmative vote to advance. At this point, applying teams are notified of their application status, and all ERG and national review comments and scores are shared.

Note that due to NIH funding restrictions, applicants should not have already licensed their technology from the university, and they may be disqualified if a commercial entity already exists.

### *External Reviewer Selection*

- Reviewers are selected by WE-REACH Technology Development staff.
- All reviewers have a signed CDA on file with CoMotion.
- Reviewers have domain expertise in the field of projects reviewed.
- Reviewers may not review an application with which they have a conflict of interest.

### *Review Process Steps*

1. Enough reviewers are selected so that each application is reviewed by at least 3 reviewers with a background related to the technology reviewed.
2. Applications are sent to reviewers (ERG) for evaluation, commentary, and scoring.
3. Reviewers submit all comments and scores to WE-REACH Program Administrator for compilation.
4. Reviewer discussion meeting is hosted by Technology Development staff. For each application, comments and scores are presented by each reviewer to the larger ERG body. Discussion of each application is moderated by Technology Development staff. After discussion, scores are submitted for each application by all ERG members. (ELG may silently observe application review meeting. Applicants are not present.)
5. Reviewer comments and questions are compiled and sent to applicants by Program Administrator.
6. Technology Development staff host application pitch/defense presentation to ERG at which applicants are encouraged to address questions raised in ERG review. ELG and other invited reviewers may observe and ask questions.
7. Presentation minutes are compiled by Program Administrator and reviewed by WE-REACH staff.
8. Application summary is written for each application by Technology Development staff.
9. Program Administrator submits summaries, ERG commentary, and final ERG scoring for each application.
10. NIH orchestrates further review by relevant NIH branches, FDA, USPTO, CMS, and Kaiser-Permanente. Note that prior to review, NIH may triage applications it deems to be inappropriate.
11. Program Administrator receives national reviewer commentary and scoring, which is then presented to ELG for deliberation along with compiled ERG review findings.
12. Projects are ranked by ELG vote, and the top teams are selected as funding allows.
13. With approval from the WE-REACH Executive Committee and Steering Committee, ELG selected teams advance to discussions with the WE-REACH team to develop a stage-gated Project Agreement Plan for funding.
14. Finally, all teams will receive a letter indicating the review outcome along with all comments and scores from the ERG and national reviewers.

### **Guidance to WE-REACH Applicants**

When compiling your application, follow the instructions in the WE-REACH RFP carefully. In addition to submitting a Project Description and Project Plan, each grant applicant seeking WE-REACH grant funding is asked to provide information on the Regulatory Path and Commercialization Plan for their impactful product. This document provides some guidance for applicants to consider.

#### **Regulatory Path**

Here we ask you to describe the expected regulatory pathway for the technology and identify which FDA division will regulate the technology. Describe foreseeable regulatory risks or accelerated programs that could impact the technology development. Comment on the clinical indications for use and trials considerations and how those might impact the regulatory approach. Please also include information on technologies that are currently in development.

To define the regulatory path, we recommend looking into the available information on predicate devices and systems to consider the regulatory path they have taken. This information can be obtained by searching [clinicaltrials.gov](https://clinicaltrials.gov) for relevant clinical trials, [FDA Guidance Documents](#) on the type of product being developed and its indication, [FDA Drug and Approvals](#) database, FDA [Device Classification](#) database, FDA [510\(k\) Clearances](#) history, and FDA [Premarket Approval](#) database. You may also want to schedule a session with the [DDAC](#) for guidance.

#### **Sample Regulatory Path Description from a Successful WE-REACH Device Application**

The first Negative Pressure Wound Therapy (NPWT) device/system (KCI VAC) received FDA approval in 1997. Since that time, NPWT has been used extensively for treating open injuries and other wounds, showing great efficacy in accelerating healing and reducing edema and infection risk. Unfortunately, there is no simple or effective NPWT

treatment for injuries of the hand. The Peer-Reviewed Orthopaedic Research Program (PRORP) Clinical Trial Award under the Congressionally Directed Medical Research Program has funded an Early Feasibility Study (EFS) of the [technology name]. Our team is awaiting FDA guidance (teleconference March 2020) for investigational device exemption (IDE) requirements before the start of the EFS study. We expect to pursue a 510(k) pathway as a Class II device.

#### Sample Regulatory Path Description from a Successful WE-REACH Drug Application

Based on publicly available clinical trial information for the FDA approval of antibodies to treat Crohn's Disease (CD) and ulcerative colitis (UC), as well as the ongoing development of PTG-200 for CD (a competitor product), we have an coarse-grained idea of how to approach a regulatory path with our technology. We would greatly benefit from access to and guidance from experts in drug regulation through the WE-REACH program. If nonclinical studies show comparable or better efficacy than the competitor PTG-200, we will likely proceed with a standard non-commercial, treatment IND (21 CFR 312.34 and 312.35) to pursue a phase 1 clinical trial in healthy adults and subsequent phase 2 and 3 trials in adults with moderately to severely active CD or UC as a first-line therapy. Based on advice from physicians and regulators, we may choose to pursue second-line therapy if biologic-naive patients are too difficult to recruit. We hope to gather advice on critical IND-enabling nonclinical studies through WE-REACH.

#### **Commercialization Plan**

Here we ask what are the next steps in technology and/or business development for this technology after WE-REACH and the plan for funding these activities? Identify and size the markets addressable with the technology. Identify how much funding is needed to get the technology to a viable 'exit' or inflection point for commercial investment. What is the likely commercialization strategy for the envisioned product? What are the perceived barriers to commercialization?

For the commercialization plan, we recommend that you focus on clarifying the (i) most important parts of the development plan that the WE-REACH funding can support, (ii) provide insight into the intellectual property (IP) management plan or patent strategy, and (iii) outline a specific set of early stage Start Up – Spin Out financing objectives.

To specify the commercialization plan, we recommend looking into the trajectory of financing of small companies in your field. At the end of the day, every successful commercialization path is unique and varied. Several paths can be taken, with one common theme, that is raising the capital needed to progress a project through each major stage of development. We recommend building a simple cash flow based expected net present value (eNPV) model for your project as this will help to better define the target product profile and the needed capital to bring a new product to market and commercialize it (examples of eNPVs and spreadsheet templates can be provided upon request).

Because of the protracted length of drug development cycles, we recognize that biotechnology companies are initially focused on the earliest stages of drug development. The Start Up phase generally involves getting your founding team together, incorporating the company, raising a seed round of convertible note financing (loan that will convert to stock upon a larger qualified financing), writing non-dilutive SBIR grant applications to support research and development, and hiring lawyers to reach a licensing deal (option or agreement) with the University to enable exclusive commercial development of the drug asset that you are inventing / developing. The Spin Out phase occurs when the company and its University partners has solidified a clinical development plan including all pre-clinical manufacturing, safety, metabolism, pharmacokinetics / dynamics studies, Phase I clinical trial plan, needed to file an investigational new drug application (IND) with the FDA.

The drug Spin Out will likely need to raise a Series A venture capital financing in order to finance the remaining pre-IND work and Phase I clinical trial. At this point the Spin Out is likely pursuing many financing opportunities including (i) non-dilutive grant funding (Phase 2 SBIR), (ii) strategic Pharmaceutical company partnership for development, (iii) Series B or cross-over financing, (iv) or an Initial Public Offering. These next rounds of financing will support Phase 2 and or Phase 3 development work.

### Sample Commercial Description from a Successful WE-REACH Device Application

*Market Size:* According to Ootes et al [2012]) an estimated total of 3,468,996 upper extremity injuries were seen in emergency rooms in 2009. This corresponds to an incidence of 1,130 upper extremity injuries per 100,000 persons per year, and per de Putter et al [2012] the total cost for care and lost productivity approaches \$1 Billion annually. A marketing analysis done by our UW Coulter Award advisors indicated that burn, crush, and laceration injuries account for an addressable market of approximately 185,000 upper extremity injuries per year. Any of these open hand wounds could be indicated for use of the [technology name]. A prototype of the [technology name] brought strong interest from hand surgeons at the 2016 American Society of Surgery of the Hand annual meeting (Austin, TX).

*Reimbursement:* Several potential predicate devices exist (FDA Premarket Submission Numbers K050261, K032310, K053627, K092992, K132936, K082211, K110078) and have resulted in CPT codes (97605, 97606, 97607, 97608) that can be used with the [technology name].

*Competitive Landscape:* NPWT therapy accounted for 12.2 % of global wound care devices and was valued at \$1.9 Billion in 2018 [BRC]. The market landscape for portable medical equipment products (PMEP) is deceiving at first glance. Most of the PMEPs market share is directed towards hearing aids and insulin management. In 2014, the market for "Wound Care" PMEPs was more accurately ~13%. Kinetic Concepts Inc. (Acelyty) 6.7% and Smith & Nephew 6.2% having the greatest market share for wound care management devices valued at \$2.9 billion [Dewan]. Wound care dressing manufacturers rely on foam, with only three silicone products available, and one of which silicone product that can use NPWT (see Fig. 3).

The "Wound Care Management Market" combines elements of both device and dressing. NPWT is applied by a device through a dressing, making them distinctly interlinked. Smith & Nephew and Molnlycke (Fig. 4) have the strongest market shares in synthetic wound dressings [Elder], however the [technology name] is unlike most synthetic dressings, it is "synthetic dressing" that is compatible with a NPWT device (part of the PMEP market). The synthetic dressing market focuses on flat surfaces for market share, leaving complex geometries like the hand an untapped market. Integra (Integra Lifesciences Corp) produces a silicone acellular dermal regeneration template that can be used on single digits, but does not use NPWT [Azzeena].

*Commercialization:* We have begun discussions with [company name] regarding licensing and they have expressed interest, though they wish to see the project further de-risked. Alternatively, we are prepared to engage contract manufacturers and distribute through our existing company, [company name]. We plan for FDA approval by mid- to late 2020, with our DoD-funded clinical trials to follow. Commercialization of the device depends on progress in these areas (regulatory; clinical performance) and is our long-term goal.

### Sample Commercial Description from a Successful WE-REACH Drug Application

WE-REACH funding will help establish pharmacokinetic and pharmacodynamic behavior of our leads in rodents. With these data, as well as additional market and regulatory path advice from WE-REACH, we will be better positioned to seek additional funding. If the proposed PK/PD rodent studies meet the defined metrics of success, we plan to spin out a company within the next year that will license this technology through CoMotion in conjunction with the filing of provisional patent applications (PCT) protecting intellectual property (IP). This new company will seek non-dilutive funding from a number of disease-related foundations and also the NIH in the form of SBIR grant applications. Based on the track record of spin outs from the IPD's Translational Investigator Program (e.g. PvP Biologics, Icosavax, Neoleukin Therapeutics), we expect to finance the first year of operations with a seed round of \$3-5M as a convertible note from our local network of biotechnology investors. Funds will be used to build a management team, license UW IP, and plan the IND-enabling and Phase I clinical trial in advance of a Series A financing. Further venture capital fundraising will coincide with key milestones of planning and execution including the effort to secure non-dilutive grant funding.