

STAGE	GENERAL ACTIVITIES	TIME AND FUNDING
<div>Stage 1</div> <div>Assessment</div> <div>1</div>	<p>Institutions form an assessment team comprised of two staff members and two professionals from industry:</p> <ol style="list-style-type: none">1. Program Leader (institution assignment)2. Tech Transfer Representative (institution assignment)3. Design for Manufacture Expert (industry volunteer)4. Clinical Expert (clinician volunteer) <p>This team would look at projects for potential development and the barriers they may present (methods, time, ownership, etc.). This team can select projects that have the greatest promise for business, regional or global impact and direct them toward a most fitting development pathway for for-profit ownership, open-source, or a hybrid model.</p> <p>Stage Goal: Produce actionable decisions on moving forward with ideas in one of three directions: Monetary Benefit; Hybrid, Humanitarian Global and Monetary Benefit; Humanitarian Global Benefit Only. Decisions to make some projects open source may be made at this point if neither monetary or philanthropic investment is found.</p>	<p>Quarterly activity funded by institutional resources. There may be different assessment teams for different types of technology, or guest experts present during the assessment process.</p>
<div>Stage 2</div> <div>Assignment</div> <div>2</div>	<p>Once the institution has decided what products have the highest probability for success to move to the next step, the assessment team would assign a development team, consisting of a product-specific, clinical champion and project manager as well as an institutional liaison (who may be the same person as the assessment team Program Leader). The development team would be paid professionals, contracted to generate a development plan and budget. At this point the assessment team would decide if the project were moved forward to seeking investment or not. Projects which are not funded may be made open-source at this stage.</p> <p>If the plan is to move forward, the two teams would work together on a funding initiative. This may include grants by philanthropic organizations and NGOs, who may demand that the project be made open-source, or it may focus on potential private industry partners interested in manufacturing-distribution partners.</p> <p>Stage Goal: to create a team that has all the components of the large companies using a group of smaller more nimble design, manufacture, and distribution companies.</p>	<p>60-90 day-process. limited institutional, or grant funding needed to support activity. Partnerships would be sought out with specific intent for deployment in mind.</p>
<div>Stage 3</div> <div>Development</div> <div>3</div>	<p>Once partially funded, typically based on a staged function plan, the program would follow the design plan path set up initially to take the product through the stages of DFM development, reassessing and acquiring additional funding as needed at the set milestones. The funders may be medtech firms or NGOs, emphasizing different value for the project. Once the design is tested and the design documents necessary for regulatory filing are complete, the program would transfer all the materials to the planned manufacturer of record. If a decision is made not to continue funding the product may be open-sourced to obtain goodwill for the research institution.</p> <p>Stage Goal: Complete development through testing (not including regulatory submissions).</p>	<p>1–3-year process, large financial support needed through grant or private funding</p>
<div>Stage 4</div> <div>Production</div> <div>4</div>	<p>Manufacturer of record would file the regulatory documents and deal with any question or design changes needed from a regulatory perspective. They would implement a quality management system (QMS) around production and complete the design files. Finally, they would begin production based on the terms agreed to as part of the initial agreements.</p> <p>Stage Goal: Move information into the hands of those who can manufacture or distribute the product via licensing, open-source or some variation of the two.</p>	<p>~1-year process, financial support provided by manufacturer of record</p>