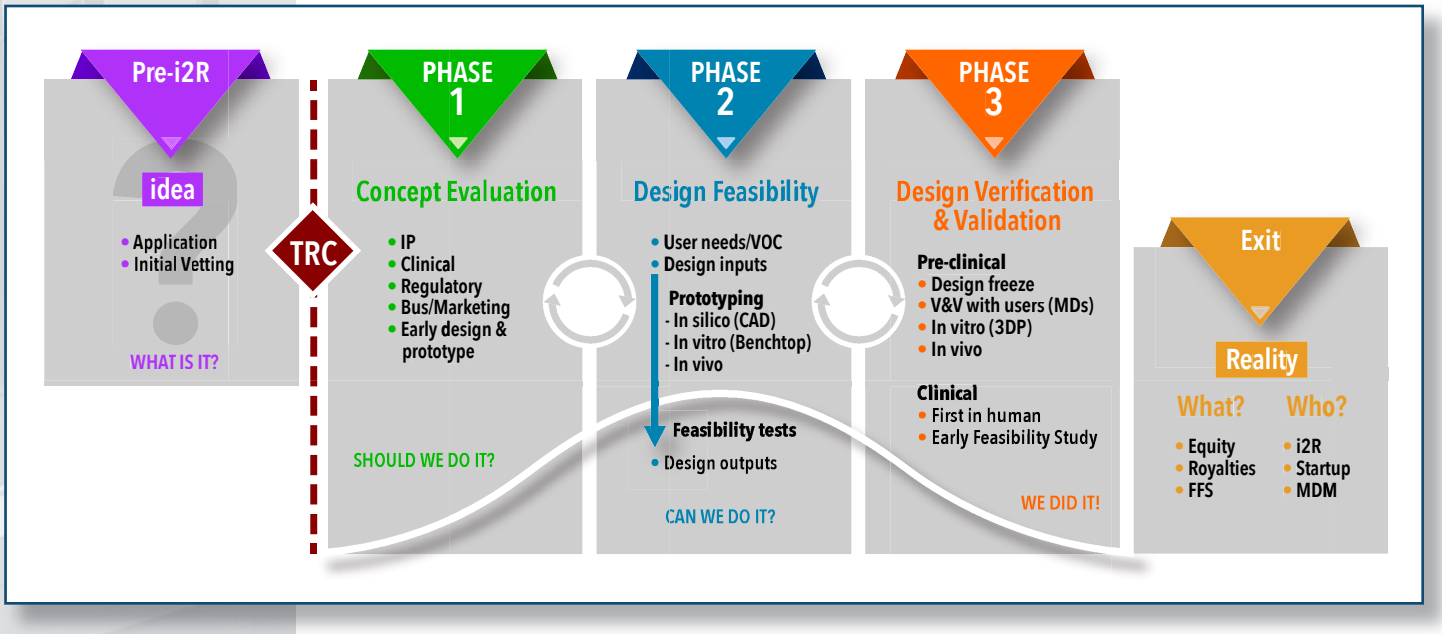
i2R: Idea to Reality Center

JACOBS INSTITUTE

The Jacobs Institute (JI) is a non-profit medical innovation center based in Buffalo, New York, whose mission is to create the next generation of medical devices to treat vascular disease. It achieves this through a multidisciplinary approach to everything the JI does: innovation & product development, training & experiential learning, and education & leadership programs. The JI is strategically positioned between Kaleida Health's Gates Vascular Institute (GVI) and the University at Buffalo's Clinical and Translational Research Center (CTRC), in a building designed to unite physicians, inventors, engineers, researchers, and the medical device industry through purposeful collisions.

Too often, inventors' ideas for new medical devices are never realized, due to their lack of time, technical skills, trusted partners, and money. The JI created the i2R, or idea to Reality Center, as a medical device proof of concept center to address this issue. The i2R ensures that life-saving vascular device ideas are quickly designed, prototyped, and tested until clinical validation is achieved. It is the smartest, fastest, most cost-effective way to actualize an endovascular device idea. Upon reaching proof of concept, the device can move out of the JI and on to the next stage in the commercialization continuum. The i2R device development process involves three iterative phases following initial device vetting as described below.

The Three Phases of the i2R's Device Development Process



Pre-i2R (idea)

Inventors with an idea for a new medical device enter the i2R following initial vetting by the Technical Review Committee (TRC). The TRC is composed of a mix of experts who assess each device idea in terms of user acceptance, product risk, patentability, regulatory path, market trends, product reimbursement, and competition. If the TRC is satisfied that the idea deserves further exploration, it sends it to the i2R where the inventor is helped through three iterative phases by the i2R's combination of engineers, scientists and physicians. The inventor pays no upfront costs, but does agree to provide the i2R with some form of equity and/or portion of the device's future royalty stream.

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Phase 1 – Concept Evaluation
In the first phase of the i2R process, the idea is evaluated from a variety of perspectives in order to minimize product risk during product development and to prevent unexpected failures during design verification and validation testing. Evaluation activities include:

- Intellectual property searches to assess an ideas patentability
- Market studies to assess market need
- Clinical regulatory studies to assess the pathway through the FDA
- Reimbursement evaluation thorough an economic value assessment

Phase 2 - Design Feasibility
In the second phase, user needs are collected and prioritized and then used to identify design inputs that capture all functional, performance, safety, and regulatory requirements. Once the design inputs are defined and prototypes are produced, core development begins during which device prototypes are tested:

- ***In silico.*** Computational testing assesses such things as sheer stress, structural integrity and material behavior under different scenarios.
- ***In vitro.*** Device testing equipment is used to test and analyze qualitative and quantitative feedback from hands-on user based assessments
- ***In vivo.*** Following appropriate protocol design and approval, the device can be evaluated in a suitable animal model. This test usually leads to design modifications and final development prior to design freeze.

Phase 3 – Design Verification & Validation
The third phase involves the preclinical and clinical stages of device development. In the preclinical part of this phase, the design of the device is frozen and validation of the device's intended use is undertaken with end users (physicians) and in 3D printed vascular models and animals. Further testing in models and in animals under Good Laboratory Practice (GLP) standards and biocompatibility is achieved leading to our i2R exit stage which is Proof of Concept.

Exit – Commercialization Strategy (Reality)
Once proof of concept is achieved, the JI will implement the commercialization exit strategy that was developed concurrently with the device development process. i2R projects will either transfer into a newco or license and/or sell the technology directly to a commercialization or industry partner.

i2R Customers
Individual inventors are not the only entities to work with the i2R. Start-up companies and industry partners can enter at any phase depending on their stage of device development. For example, if they already have functional prototypes, they may come in Phase 2 for physician input and testing or they may enter after device freeze in Phase 3 for later stage testing and consultation with physicians. JI's reimbursement is dependent on the scope of work performed and value created. We are focused on being agile and flexible based on the i2R engagement terms ranging from equity ownership, royalties on sales, and/or fee for service.

For additional information, please contact Mike Springer: mspringer@jacobsinstitute.com