



The Jacobs Institute (JI) is a non-profit medical device innovation center, strategically located between a state-of-the-art hospital and a world-class university. As such, we can rapidly form the i2R team best suited for your idea, by drawing on the expertise of our physicians, engineers, researchers, inventors, entrepreneurs, and medical device industry partners.

This is not your typical medical innovation center.

We think well outside the box, so your cutting-edge ideas don't wind up on the cutting room floor. Instead, we help your idea get that jump-start it needs, with support from the right people, in the right place, at the right time.

Right People. Right Place. Right Time.

The Jacobs Institute's i2R (Idea to Reality Center) has pulled out all the stops. This *medical device proof-of-concept center* ensures that your life-saving vascular device ideas are quickly designed, prototyped and tested, with constant feedback from the experts and most informed users: physicians.

Next Stop: Reality

Our design process **sparks invention** and re-invention, until we get it right. We've created a **powerhouse** of engineering, product development, research, and clinical expertise under one roof. We carefully evaluate the target problem, prove that the technology will work, and rapidly develop the product.

Our i2R helps you **accelerate** your idea throughout the commercialization process, making your idea a reality.

Guiding the inventor's idea to reality.

Our team will ensure we are solving the right problem in the right way by

- Integrating clinicians and engineers up-front, during vetting and design
- Educating inventors about clinical, technical, and regulatory considerations, to empower them for success
- Performing product testing in the i2R's signature, clinically-relevant 3D-printed models, with immediate feedback from on-site physicians, engineers, and university researchers.

We accelerate product development and commercialization by

- Creating, modifying, and evaluating prototypes all under one roof
- Helping inventors develop the pathway to commercialization that is right for them, whether independently or with industry
- Performing pre-clinical and clinical studies to help inventors prove device safety and efficacy

DEVICE INNOVATION, REFUELED.



Ideation

Early in the process, the i2R handles your idea with care, diligently evaluating it to minimize risk during product development and to stave off failures during verification and testing. Our experts will formulate the device development plan including cost, timelines, and selecting the best team for your idea.

Milestone: Go-to-Market Strategy



Definition & Feasibility

We work to gather and prioritize your **user's needs**, informing design inputs that meet **safety and regulatory requirements**, while optimizing function and performance. We gather design inputs and complete your prototypes, then launch into *core development*. Our team will test your prototypes *in silico* (computational testing), *in vitro* (bench testing), and *in vivo* (animal model) for a comprehensive assessment.

Milestone: Product Development Kick-Off



Design & Development

Here, our i2R team collaborates on **device design** and identifies reliable manufacturing capabilities. Then, the design is frozen while we develop product verification and validation test plans.

Our experts may help you create a start-up at this stage to secure initial external investment, if you have not already done so.

Milestone: Design Freeze



Verification & Validation



Post i2R

Let us put your mind at ease, *performing the necessary testing* to demonstrate reliable manufacturing and insuring that the device meets the regulatory and user requirements.

Our seasoned experts will also assist by **reducing the burden** of submitting the results to relevant regulatory bodies, such as the Food and Drug Administration (FDA) for clearance or approval for sale.

Milestone: Regulatory Submission

Once regulatory agencies approve using the device in patients, most companies **conduct a clinical study** on which to base their marketing efforts and brand positioning relative to competitors. We can assist in coordinating and executing these studies spun out from the i2R.

At this point, your company can **decide which road to take**—whether to license and sell your product to a larger medical device company or continue to commercialize it independently with JI support.