



Please fill out this form as completely as possible. Note: There is no fee to apply. Please send additional materials such as your pitch deck and executive summary to FIRSTCOAST@lifesciencenation.com for us to review along with your application to the Innovation Challenge.

I. Company Information

*Your Name:	
*Your Email:	
*Company Name:	
*Job Title:	
*Address:	
Address2:	
*City:	
*State/Province:	
*Zip/Other Postal Code:	
*Country:	
*Phone:	
*Website:	
*Industry:	

* Is your company an SBIR/STTR grant recipient?

Yes

No

If yes, which institute:

* What events will you attend during the First Coast Healthtech Week? (select all that apply)

Day 1, Sept. 5: Healthcare Innovators Gathering

Day 2, Sept. 6: RESI Global Partnering Conference

Day 3, Sept. 7: Entrepreneurs Academy - Workshop Series

***Please Choose your Company Type**

If you are a Therapeutics company, please fill out form II-A

If you are a Medical Devices company, please fill out form II-B

If you are a Diagnostics company, please fill out form II-C

If you are a Healthcare IT company, please fill out form II-D

II-A. Therapeutics-Specific Survey Questions

Company description/elevator pitch (80-120 words)

Descriptive summary of technology (20 words max)

***Drug/technology type (Select all that apply)**

- Small Molecule
- Protein/Peptide Biologic
- Cell-based Therapy
- Ab
- Nucleic Acid (e.g. RNA)
- Gene Therapy Approach
- Ab-Drug Conjugate
- Therapeutic Vaccine
- Drug Delivery
- Technology Platform
- Regenerative Medicine

***Program Stage (Select One)**

- Discovery (candidate seeking)
- Preclinical Development (Pre-IND Studies)
- Phase 1
- Phase 2
- Phase 3
- On the Market

***Technical Validation achieved to date (Select all that apply)**

- Target Engagement Demonstrated
- Preclinical Development (pre-IND studies)
- In Vitro (animal) Activity
- Acceptable Safety/Tox Profile
- IND Enabling Safety/Tox
- Phase 1 Safety Demonstrated
- Phase 2 Proof of Concept Achieved

***Regulatory pathway (Select all that apply)**

- Standard FDA Approval Process
- Generic Drug Approval
- Drug for Rare/Orphan Disease
- Fast Track Approval Possible/Granted
- Priority Review Voucher Possible

II-B. Medtech Devices-Specific Survey Questions

Company description/elevator pitch (80-120 words)

Descriptive summary of technology (20 words max)

Subsector (Select all that apply)

- Implantable Devices
- Patient Monitoring Device
- Imaging Hardware, Tracers, etc
- Delivery Devices
- Biomaterials, Coatings
- Single Use Devices (disposable)
- Reusable Instrumentation
- Infection Control
- In Vitro Diagnostics
- Companion Diagnostics (theranostics)
- Patient Aids
- Wound Care
- Portable Device

*Regulatory pathway (Select all that apply)

- 510k Pathway for Market Approval
- 510k Required
- Premarket Approval Application (PMA) will be required
- Humanitarian Device Exemption Process (rare diseases)

II-C. Medtech Diagnostics-Specific Survey Questions

Company description/elevator pitch (80-120 words)

Descriptive summary of technology (20 words max)

Subsector (Select all that apply)

- Implantable Devices
- Patient Monitoring Device
- Imaging Hardware, Tracers, etc
- Delivery Devices
- Biomaterials, Coatings
- Single Use Devices (disposable)
- Reusable Instrumentation
- Infection Control
- In Vitro Diagnostics
- Companion Diagnostics (theranostics)
- Patient Aids
- Wound Care
- Portable Device

***Regulatory pathway (Select all that apply)**

- 510k Pathway for Market Approval
- 510k Required
- Premarket Approval Application (PMA) will be required
- Humanitarian Device Exemption Process (rare diseases)

II-D. Healthcare IT/Digital Health -Specific Survey Questions

Company description/elevator pitch (80-120 words)

Descriptive summary of technology (20 words max)

***Digital health subsector (select one)**

- Consumer Health Self-Management
- Wearables and Biosensing
- Care Coordination
- Electronic Health (EHR) and Medical (EMR) Records
- Telemedicine and Virtual Care
- Payer Administration
- Analytics and Big Data (Including Pt Records)
- Population Health
- Non-Regulated Consumer Health Product
- Other

*** Market traction (Select One)**

- Free Pilot
- Paid Pilot
- Post-Pilot Sales
- Successful Crowd Funding
- Sustained Sales

III. General Questions for All Industry Sectors

***Technology Overview:** Briefly describe the technology you are developing. Be sure to describe its ultimate utility and be sure to highlight any new science that enables its development. If Digital Health is your focus, please describe the gap/unmet stakeholder need that will be addressed by your product and how it will be accomplished. (500 words max)

***Is your product Iterative (next-gen, incremental improvement, etc.), Breakthrough (new drug target, new use, etc.), or Transformational (novel technology)? (Select One)**

Iterative (next-gen, incremental improvement, etc.)

Breakthrough (new drug target, new use, etc.)

Transformational (novel technology)

*** Technical Validation Achieved to Date: Biotech / Medtech:** Describe any data confirming that your technology achieves its intended purpose. (e.g., performance in animal models, device/test performance, platform technology validation, clinical proof-of-concept, etc.) **Digital Health:** Describe the progress you have achieved to date in gaining market traction with your product. (500 words max)

***Have you completed a competitive analysis? (Select One)**

Yes

No

***Please provide a list of your competitors. How is your technology differentiated from each competitor?**

***Can you currently provide data to support your differentiation? If not, what is your time horizon to generate this data? (Select One)**

Currently Have Data

0-6 Months

7-12 Months

13-18 Months

18+ Months

***Company Milestones: Describe key milestones that have been achieved and the projected timeline to the next inflection point for your company. (500 words max)**

***What is the estimated cost to achieve commercialization? Please provide estimated costs to reach each milestone.**

***Achieving Market Entry: Briefly describe how your therapeutic, device, technology or digital health product will distinguish itself from current and anticipated competitors in your market segment. How novel is your technology? What, if any, new stakeholder groups are you targeting? (500 words)**

***What is the expected market size upon approval? Please provide both monetary value and disease prevalence. (500 words)**

***Alliances & Collaborations: Biotech / Medtech: Highlight any strategic alliances you have established that will enable development, validation, regulatory approval, production or marketing of your technology. Digital Health: Highlight any manufacturing partners engaged, any flagship customer(s) obtained or distribution agreements you have entered into. (500 words)**

***Please list any valued 3rd party relationships (CRO, Vendors, Distribution Partners, etc.), or n/a if not applicable. Are these relationships regional or global players? (500 words)**

***IP status (Select all that apply)**

- Patent disclosures at university
- Patent applications filed
- Key patent(s) issued
- Broad IP position established

***What university, if any, did you obtain your Tech Transfer License from? (500 words)**

***Is there a royalty associated with your license? (Select One)**

- Yes
- No

***Do you have global patent protection? If not, what regions are excluded? (500 words)**

***CEO profile (Select all that apply)**

- Technical Expert Founder/Academic Entrepreneur
- Management Experience Leading Multiple Companies
- Successfully Obtained Non-dilutive Funding
- Successfully Obtained Investment Capital
- Serial Entrepreneur with Significant Business Experience

***Management team in place (Select all that apply)**

- Virtual (CEO only)
- CSO/CTO
- CFO
- Business Development support
- SAB Established
- Experienced external advisors

***Please list Management Team (Title + Relevant Experience)**

***Please list Advisory Board (Title + Relevant Experience)**

***Company financing to date (Select all that apply)**

- SBIR/STTR
- Angel
- Seed
- Series A
- Series B
- Series C or later

***Are you currently fundraising? (Select One)**

- Actively looking for investment capital
- Not at Present Time
- Will be Raising Funds Within 6 Months
- Will be Raising Funds Within 1 Year

***If actively fundraising, what stage of financing are you raising? (Select One)**

None/ Not Applicable

Angel

Seed

Series A

Series B or Later

What amount (in millions \$USD) are you hoping to raise?

Thank you for applying to the Innovation Challenge.

If you have any questions, please contact FIRSTCOAST@lifesciencenation.com

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