



If your company won (1st-3rd place) an Innovation Challenge since RESI JPM 2018, or were a finalist at RESI NYC 2018, you do not qualify to participate in the Innovation Challenge at RESI JPM 2019. 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 resi@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:	

*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 Digital Health company, please fill out form II-D

*Is your company an SBIR/STTR grant recipient?

If yes, which institute?

*Are you a tech hub member?

If yes, which tech hub?

II-A. Therapeutics-Specific Survey Questions

Your Company/Technology Description - elevator pitch (80-120 words)

The description here will be used for our RESI program guide and other marketing material if you are selected as one of the finalists.

***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 Vivo (animal) Activity
- ☐ Acceptable Safety/Tox Profile
- ☐ IND Enabling Safety/Tox
- ☐ Phase 1 Safety Demonstrated
- ☐ Phase 2 Proof of Concept Achieved

***Regulatory pathway (Select one)**

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

Your Company/Technology Description - elevator pitch (80-120 words)

The description here will be used for our RESI program guide and other marketing material if you are selected as one of the finalists.

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 one)**

510k Pathway Exempt

510k Required

Premarket Approval Application (PMA) will be required

Humanitarian Device Exemption Process (rare diseases)

II-C. Medtech Diagnostics-Specific Survey Questions

Your Company/Technology Description - elevator pitch (80-120 words)

The description here will be used for our RESI program guide and other marketing material if you are selected as one of the finalists.

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 one)**

510k Pathway Exempt

510k Required

Premarket Approval Application (PMA) will be required

Humanitarian Device Exemption Process (rare diseases)

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

Your Company/Technology Description - elevator pitch (80-120 words)

The description here will be used for our RESI program guide and other marketing material if you are selected as one of the finalists.

***Digital health subsector (select all that apply)**

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

***Regulatory pathway (Select one)**

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

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)

*** 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)

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

***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 One)**

Patent disclosures at university

Patent applications filed

Key patent(s) issued

Broad IP position established

***CEO profile (Select One)**

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)**

- ☐ CEO
- ☐ 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
- ☐ Founder Funded
- ☐ Angel
- ☐ Seed
- ☐ Series A
- ☐ Series B
- ☐ Series C or later

***Capital raised to date (in millions \$USD)**

Please include non-dilutive funding that the company itself received (SBIR/STTR) but **do NOT include** academic/university research grants that were used for technology development

***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 resi@lifesciencenation.com

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