

# Anna M Galea, PhD

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## SUMMARY:

Proven leader and medical device innovator with >20 years' experience turning unmet needs to fully realized technologies, developing solid strategy, and guiding diverse teams of engineers, scientists, and clinicians, through device concept and development to launch.

- Inventor on **42 patents**, 26 issued
- Authored **23 journal articles and technical abstracts**
- Awarded **66 US grants and contracts**
- Technical lead in **>\$50M direct projects**
- Partnered with **>30 clinical and academic collaborators** across multiple projects
- Presented at numerous **technical conferences**, as well as to advisory boards and to non-scientific audiences

## PROFESSIONAL EXPERIENCE:

### Lung Biotechnology PBC / United Therapeutics

#### Sr Director & Chief Scientist

2016-present

United Therapeutics bought the Total Artificial Lung technology I developed starting at Foster Miller and brought me in to take it to clinical trials in Lung Biotechnology, a wholly owned subsidiary.

- Achieved milestones on time and in budget every year
- Grew the project from a 3-person team to a multi-disciplinary and geographically diverse team
  - Biomedical, mechanical, electrical and software engineers, scientists, doctors, regulatory and QA/QC personnel
  - 18 local FTEs, 80+ person team located across 6 states and 3 countries
- Guided the basic and applied artificial lung research and product development efforts, developed high-level concepts, communicated product requirements and design ideas, reviewed designs, set milestones, and supervised employees and project progress
- Provided written and oral communication to the project team as well as executive leadership and Advisory Board at the parent company United Therapeutics
- Served as technical reviewer for due diligence activities

### Craniosense LLC

#### Chief Technology Officer

2015-2016

Craniosense spun out from Vivonics to focus on completing clinical trials of a non-invasive intracranial pressure monitor I invented.

- Founding CTO
- Prepared and presented business case to funding sources
- Developed the concepts, oversaw the product designs, and finalized the initial algorithms
- Designed, prepared, recruited, and ran human subjects trials of the initial prototypes

## Vivonics Inc

**Chief Innovation Officer**

**2015-2016**

**Principal Engineer**

**2012-2014**

Vivonics spun out from Infoscitex to continue development of medical devices from concept to clinical trials.

- Responsible for overall company vision, including securing new market entries
- Directed oversight on all device development, including lung technologies (acquired by United Therapeutics), vestibular stimulation technologies (acquired by vMocion) and intracranial pressure monitoring (spun out as Craniosense)
- Identified market opportunities and developed responsive technology concepts
- Prepared development plans including financial trade-offs and engineering program plans
- Secured development funding, most often through grants or government contracts
- Led the development team to bring the device from concept to launch
- Prepared regulatory filings, ran animal or clinical trials as appropriate

## Infoscitex Corp

**Director of Technology, Biomedical Director, Principal Engineer**

**2005-2012**

Infoscitex (IST) was the successor-in-interest of Foster-Miller after acquisition. IST grew from ~20 people to ~200 people, and was acquired by a large defense contractor during my tenure.

- Besides technical efforts, also headed the Technology Development Team, the PhD-level scientists and engineers who were the technical leads across the entire company

## Foster-Miller Corp

**Project Engineer**

**2004-2005**

Foster-Miller was a ~500 person firm with leading technologies in robotics and materials.

- Responsible for leading the growth of biomedical capabilities and offerings

## EDUCATION:

|      |      |                         |                       |                              |
|------|------|-------------------------|-----------------------|------------------------------|
| 2003 | PhD  | Biomedical Engineering  | Harvard University    | Tactile Imaging              |
| 2002 | MS   | Quantitative Physiology | Harvard University    | Classes at Harvard Medical   |
| 1999 | MS   | Electrical Engineering  | MIT                   | Navigation for AUVs          |
| 1997 | BASc | Biomedical Engineering  | University of Toronto | Stereolithography with glass |

## Technical Skills:

|                             |                          |                            |
|-----------------------------|--------------------------|----------------------------|
| Medical Devices             | Research and Development | Design Control             |
| Preclinical Trial Execution | Grant Applications       | Clinical Trial Development |
| Regulatory, FDA             | Noninvasive Technology   | Image Processing           |
| Algorithm Generation        | Budget Planning          | Mechanical Design          |

## Soft Skills:

|               |                    |                        |
|---------------|--------------------|------------------------|
| Team Building | Strategic Planning | Mentoring              |
| Communication | Product Design     | Appropriate delegation |

Eligible to work in US, Canada and EU.

Fluent in English, Italian, French

**Select technologies developed:**

| <b>Technology</b>   | Electronics | Software | Algorithms | Mechanical | Materials | Fluidics | Non-FDA | Dsg Manf |
|---|-------------|----------|------------|------------|-----------|----------|---------|----------|
| <b>Noninvasive Imaging:</b>   |             |          |            |            |           |          |         |          |
| Automated ocular artery imaging   | ●           | ●        | ●          | ●          |           |          |         |          |
| Noninvasive Intracranial Pressure Monitor                                     | ●           | ●        | ●          |            |           |          |         | ●        |
| Tactile imaging for breast cancer screening                                   | ●           | ●        | ●          | ●          |           |          |         | ●        |
| <b>Wearable Monitoring:</b>   |             |          |            |            |           |          |         |          |
| 3-axis sensing for pressure and shear   | ●           | ●        | ●          |            | ●         |          |         |          |
| Electronic textiles for shear sensing   | ●           | ●        | ●          |            | ●         |          | ●       |          |
| Physiological monitoring using wearable sensors and neural network processing | ●           | ●        | ●          |            |           |          | ●       |          |
| Large array wearable sensing for noninvasive nonionizing catheter guidance    | ●           | ●        | ●          |            | ●         |          |         |          |
| Wearable gait analysis  | ●           | ●        | ●          | ●          |           |          | ●       |          |
| <b>Organ support:</b>   |             |          |            |            |           |          |         |          |
| Compact hollow fiber membrane array   |             |          |            | ●          | ●         | ●        |         | ●        |
| Nanofiltration for dialysis   |             |          |            |            | ●         | ●        |         |          |
| Vestibular stimulation for motion sickness mitigation                         | ●           |          | ●          | ●          | ●         |          |         |          |
| Artificial lung   | ●           | ●        | ●          | ●          | ●         | ●        |         | ●        |
| <b>Orthopedic:</b>  |             |          |            |            |           |          |         |          |
| Composite spinal disc   |             |          |            | ●          | ●         | ●        |         |          |
| Deformable composite material for orthopedics & prosthetics                   |             |          |            | ●          | ●         |          |         | ●        |
| Minimally invasive deployable cage for spinal fusion                          |             |          |            | ●          | ●         |          |         | ●        |
| Robotics for rehabilitation   | ●           | ●        | ●          | ●          |           |          |         |          |
| Minimally invasive surgical tools   |             |          |            | ●          |           |          |         |          |
| Sensors and cooling systems for diabetic neuropathy                           | ●           | ●        |            | ●          | ●         | ●        |         |          |
| <b>Electronics and software:</b>  |             |          |            |            |           |          |         |          |
| Interactive route planning software to minimize combat risk                   |             | ●        | ●          |            |           |          | ●       |          |
| Biomimetic orientation tracking   | ●           |          | ●          | ●          | ●         | ●        | ●       |          |
| Bone conduction hearing protection  | ●           |          |            | ●          | ●         |          | ●       |          |
| Multi-modal cognitive assessment system                                       | ●           | ●        | ●          | ●          |           |          |         |          |
| Physiological feedback for Anti-G Straining Maneuver training                 | ●           | ●        | ●          |            |           |          | ●       | ●        |
| <b>Training Systems:</b>  |             |          |            |            |           |          |         |          |
| Vestibular display for enhanced flight simulation                             | ●           | ●        | ●          |            |           |          | ●       | ●        |
| Medical Training Simulators for surgery and trauma training                   | ●           | ●        | ●          |            |           |          | ●       | ●        |
| Pneumatic tactile display   | ●           | ●        |            |            | ●         | ●        | ●       |          |
| Glove-mounted sensor array for flight training                                | ●           | ●        |            |            | ●         |          | ●       |          |
| <b>Transcatheter devices:</b>   |             |          |            |            |           |          |         |          |
| Transcatheter deployable Pulmonary Artery Resistor                            |             |          |            | ●          | ●         |          |         |          |
| Reversible stent lock for indwelling catheters                                |             |          |            | ●          | ●         | ●        |         | ●        |
| Deployable intracranial sensor array  | ●           |          |            | ●          | ●         |          |         |          |
| <b>Other:</b>   |             |          |            |            |           |          |         |          |
| Passive casualty warming system   |             |          |            | ●          | ●         |          |         | ●        |
| Navigation for autonomous underwater vehicle                                  |             |          | ●          |            |           | ●        | ●       | ●        |

## Select Peer Reviewed Publications and Presentations:

- Kaneelil, P. R., Pahlavan, A. A., Kipyegon, K., LeRoy, K., Stengel, K., Warner, S., Galea A. M., Stone, H. A. (2019). Two-phase flow instability at a channel outlet. APS, G34-007.
- Galea, A., Louis, E., LeRoy, K., O'Toole, S., "NonInvasive IntraCranial Pressure Assessment using a Compact, Portable Monitor", Poster Presentation at Military Health System Research Symposium (MHSRS) 2014, Ft. Lauderdale, Florida.
- Galea AM, Klem E, Duong M, Leroy K, O'Toole S. PATIENT: Physical Anatomical Trainer Instrumented for Education and Non-Subjective Testing. *Studies in health technology and informatics*. 2014; 196:121-7.
- Sohn K, Lv W, Lee K, Galea A, Hirschman G, Barrett C, Cohen RJ, Armoundas AA. A method to noninvasively identify cardiac bioelectrical sources. *Pacing and clinical electrophysiology : PACE*. 2014; 37(8):1038-50.
- Cevette MJ, Pradhan GN, Cocco D, Crowell MD, Galea AM, Bartlett J, Stepanek J. Electrogastrographic and autonomic responses during oculovestibular recoupling in flight simulation. *Aviation, space, and environmental medicine*. 2014; 85(1):15-24.
- Sohn K, Lv W, Lee K, Galea AM, Hirschman GB, Hayward AM, Cohen RJ, Armoundas AA. The single equivalent moving dipole model does not require spatial anatomical information to determine cardiac sources of activation. *IEEE journal of biomedical and health informatics*. 2014; 18(1):222-30.
- Lee K, Lv W, Ter-Ovanesyan E, Barley ME, Voysey GE, Galea AM, Hirschman GB, Leroy K, Marini RP, Barrett C, Armoundas AA, Cohen RJ. Cardiac ablation catheter guidance by means of a single equivalent moving dipole inverse algorithm. *Pacing and clinical electrophysiology : PACE*. 2013; 36(7):811-22.
- Hirschman, G., LeRoy, K., Galea, A., LaBrecque, B., De, S., Wen, J., Saunders, G., Birkett, D., Nepomanyshy, D., "THEO: Tactile and Haptic Enhanced Open Surgery Simulator" Poster Presentation at Military Health System Research Symposium (MHSRS) 2012 Ft. Lauderdale, Florida.
- Cevette MJ, Stepanek J, Cocco D, Galea AM, Pradhan GN, Wagner LS, Oakley SR, Smith BE, Zapala DA, Brookler KH. Oculo-vestibular recoupling using galvanic vestibular stimulation to mitigate simulator sickness. *Aviation, space, and environmental medicine*. 2012; 83(6):549-55.
- Cevette MJ, Cocco D, Pradhan GN, Galea AM, Wagner LS, Oakley SR, Smith BE, Zapala DA, Brookler KH, Stepanek J. The effect of galvanic vestibular stimulation on distortion product otoacoustic emissions. *Journal of vestibular research: equilibrium & orientation*. 2012; 22(1):17-25.
- Cevette MJ, Stepanek J, Galea AM, Oakley S, Wagner L, Smith BE, Zapala D, Cocco D, Brookler K, Pradhan G. Galvanic vestibular stimulation mitigates motion sickness. 38th NES Meeting and European Society for Clinical Evaluation of Balance Disorders Meeting; 2011 September; Nancy, France. c 00 .
- Barley ME, Choppy KJ, Galea AM, Armoundas AA, Rosbury TS, Hirschman GB, Cohen RJ. Validation of a novel catheter guiding method for the ablative therapy of ventricular tachycardia in a phantom model. *IEEE transactions on bio-medical engineering*. 2009; 56(3):907-10.
- Cevette MJ, Stepanek J, Galea AM, Brey RH, Chase R, Davis L, Wester M, Sydlowski S, Shallop J, McPherson JH. Galvanic vestibular stimulation-induced disruption of performance during computerized dynamic posturography. *Journal of the American Academy of Audiology*. 2009;

Nanne, E., Choppy, K., Galea, A., Leonard, E., “Membraneless Dialysis: Importance of Secondary Separators” presented at the American Society for Artificial Internal Organs 52nd Annual Conference, June 8-10, 2006, Chicago.

Barley, ME, Armoundas, AA, Choppy, KJ, Galea, AM, Hirschman, GB, Cohen, RJ, “Demonstration of a Novel Catheter Guiding Method for the Ablative Therapy of Ventricular Tachycardia”, Computers in Cardiology 2006;33:613–616

Nanne EE, Choppy KJ, Galea AM, Leonard EF. Secondary separators for long-term dialysis. ASAIO transactions / American Society for Artificial Internal Organs. 2006 March; 52(2):73A.

Galea AM, Nagarajan H, Kasturi S, Punwani SK. Injury mitigation in locomotive crashes. ACIM. 2004; :1-8.

Galea AM, Howe RD. Liver Parameter Estimation from Tactile Scanning. Lecture Notes in Computer Science. 2004; 3078:59-66.

Kerdok AE, Cotin SM, Ottensmeyer MP, Galea AM, Howe RD, Dawson SL. Truth cube: establishing physical standards for soft tissue simulation. Medical image analysis. 2003; 7(3):283-91.

Galea AM, Howe RD. Mammography Registered Tactile Imaging. IS4TM. 2003; 2673:183-193.

Galea AM, Howe RD. Tissue Stiffness from Tactile Imaging. IEEE Eng. In Med. and Bio. Soc.; 2002 October; Houston, TX, USA. c 00 .

Galea AM, Dennerlein JT. Schlager Fencing Biomechanics: Determinates of Impact Force American Society of Biomechanics. 2000;

Galea AM. Various methods for obtaining the optimal path for a glider vehicle in shallow water and high currents. Unmanned Untethered Submersible Technology. 1999 August; :150-161.

#### Patents:

| Country               | Patent No./ Serial No. | Title   | Inventors  | Issued/Filed |
|-----------------------|------------------------|---|--|--------------|
| <b>Issued Patents</b> |                        |   |  |              |
| US                    | 10,568,634             | Transcatheter Device and Minimally Invasive Method for Constricting and Adjusting Blood Flow Through a Vessel | Goldie, BaBrecque, Galea, Klem, Doyle, Cohen, Robinson             | 2/25/2020    |
| US                    | 10,456,045 B2          | System and Method for Determining a Measure of the Resistance of Peripheral Vasculature                       | Galea, Stepanek  | 10/29/2019   |
| Australia             | 2017238038 B2          | System and Method for Suppressing Vestibular Activity of a Human Subject                                      | Galea, Cevette, Pradhan, Stepanek, Cocco, Oakley, Scheibler, Bogle | 8/22/2019    |
| PCT                   | WO 2019/108890 A1      | A System and Method for Measuring and Controlling Foot Temperature  | Cohen, Hirschman, Galea, Hsiang-wei,                               | 6/6/2019     |

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|--------|-----------------|--|--|------------|
|        |                 |  | Yavuz, Amas, Ersen                                     |            |
| US     | 10,264,986      | Non-Invasive Intracranial Pressure Monitoring System and Method Thereof  | Galea  | 4/23/2019  |
| US     | 10,207,101      | System and Method for Suppressing Vestibular Activity of a Human Subject   | Galea, Cevette, Stepanek                               | 2/19/2019  |
| US     | 10,137,004 B2   | Insertion Tools and Methods for Minimally Invasive Spinal Fusion Cage  | Galea, Klem, LaBrecque                                 | 11/27/2018 |
| US     | 9,895,070       | Non-Invasive Intracranial Pressure Monitoring System   | Galea  | 2/20/2018  |
| US     | 10,264,986      | Non-invasive intracranial pressure monitoring system and method thereof  | Galea  | 12/28/2017 |
| US     | 9,826,913       | Non-Invasive Intracranial Pressure Monitoring System And Method Thereof  | Galea  | 11/28/2017 |
| US     | 9,579,442       | An Array Of Hollow Fibers And A System And Method Of Manufacturing Same  | Galea, LeRoy, Vitale                                   | 2/28/2017  |
| US     | 9,564,059       | Galvanic Vestibular Stimulation System and Method of Use for Simulation, Directional Cueing, and Alleviating Motion-Related Sickness | Cevette, Stepanek, Galea                               | 2/7/2017   |
| US     | 10,568,634      | Transcatheter device and minimally invasive method for constricting and adjusting blood flow through a blood vessel                  | Goldie, LaBrecque, Galea, Klem, Doyle, Cohen, Robinson | 1/31/2017  |
| Europe | EP 2 403 585 B1 | Galvanic Vestibular Stimulation System and Method of Use for Simulation, Directional Cueing, and Alleviating Motion-Related Sickness | Cevette, Stepanek, Galea                               | 12/28/2016 |
| Japan  | 6,032,894       | Galvanic Vestibular Stimulation System and Method of Use for Simulation, Directional Cueing, and Alleviating Motion-Related Sickness | Cevette, Stepanek, Galea                               | 11/4/2016  |
| US     | 13/506,473      | Active Prosthetic Socket   | Galea, LeRoy, Truong                                   | 2/9/2016   |
| US     | 8,574,309       | Two-Stage System and Method for Oxygenating and Removing Carbon Dioxide from a Physiological Fluid                                   | Galea, Hirschman, Truong, Vitale                       | 11/5/2015  |
| US     | 9,071,894       | Hearing Protection System  | Galea, Louis, LeRoy                                    | 6/30/2015  |
| US     | 9,034,083       | Array of Hollow Fibers and a System and Method of Manufacturing Same   | Galea, LeRoy, Vitale                                   | 5/19/2015  |
| US     | 8,953,154       | Orientation Tracking System and Method   | Galea, LeRoy, Hirschman                                | 2/10/2015  |
| US     | 8,876,743       | Conformable Material, Prosthetic Socket, and Method of Manufacturing Same  | Galea, LeRoy, Player                                   | 11/4/2014  |

|                        |                   |  |  |            |
|------------------------|-------------------|--|--|------------|
| Australia              | 2010221761        | Galvanic Vestibular Stimulation System and Method of Use for Simulation, Directional Cueing, and Alleviating Motion-Related Sickness | Cevette, Stepanek, Galea   | 8/7/2014   |
| US                     | 8,718,796         | Galvanic Vestibular Stimulation System and Method of Use for Simulation, Directional Cueing, and Alleviating Motion-Related Sickness | Cevette, Stepanek, Galea   | 5/6/2014   |
| US                     | 10,456,045        | System and method for determining a measure of the resistance of peripheral vasculature  | Anna M. Galea, Jan Stepanek, Gaurav N. Pradhan                             | 7/25/2013  |
| US                     | 8,361,133         | Patient Warming Applique   | Cushman, Kovar, Mulligan, Babin, Galea, Slade, Hirschman                   | 1/29/2013  |
| US                     | 7,905,920         | Support System for Intervertebral Fusion   | Galea  | 3/15/2011  |
| <b>Pending Patents</b> |                   |  |  |            |
| US                     | 20,190,151,645    | System and Method for Suppressing Vestibular Activity of A Human Subject   | Galea, Cevette, Pradhan, Stepanek, Cocco, Oakley Holbert, Scheibler, Bogle | 1/17/2019  |
| US                     | 20,190,159,546    | System and Method for Measuring and Controlling Foot Temperature   | Cohen, Hirschman, Galea, Ma, Yavuz, Adams, Ersen                           | 11/30/2018 |
| US                     | 20,200,368,420    | Systems and Methods for Exchanging Small Molecules with Fluid  | Galea, Johnson, Parse  | 5/22/2020  |
| US                     | US20160007921A1   | Head-Mounted Neurological Assessment System  | Galea, Cevette, Bogle, Brookler  | 7/9/2015   |
| EP                     | 13823903.3        | System and Method for Determining a Measure of the Resistance of Peripheral Vasculature  | Galea, Stepanek  | 1/6/2015   |
| PCT                    | PCT/US2014/040680 | Non-Invasive Intracranial Pressure Monitoring System   | Galea  | 6/3/2014   |
| US                     | 14/153,727        | Galvanic Vestibular Stimulation System and Method of Use for Simulation, Directional Cueing, and Alleviating Motion-Related Sickness | Cevette, Stepanek, Galea   | 1/13/2014  |
| PCT                    | PCT/US2013/052197 | System and Method for Determining a Measure of the Resistance of Peripheral Vasculature  | Galea, Stepanek  | 7/25/2013  |
| US                     | US20160174858A1   | Non-Invasive Intracranial Pressure Monitoring System   | Galea  | 7/11/2013  |
| US                     | US20160192849A1   | Non-Invasive Intracranial Pressure Monitoring System   | Galea  | 7/11/2013  |
| EP                     | 11858232.9        | Two-Stage System and Method for Oxygenating and Removing Carbon Dioxide from a Physiological Fluid                                   | Galea, Hirschman, Truong, Vitale   | 2/10/2011  |
| PCT                    | PCT/US2011/000236 | Two-Stage System and Method for Oxygenating and Removing Carbon Dioxide from a Physiological Fluid                                   | Galea, Hirschman, Truong, Vitale   | 2/10/2011  |