

Christopher K. Giardina, MD, PhD

citizenship: USA & UK
c/m: +1.770.778.6899
email: chrisgiardina@gmail.com
linkedin: linkedin.com/in/chrisgiardina

Education

- The University of North Carolina at Chapel Hill School of Medicine** 2011 – 2022
NIH-Funded Dual-Doctorate Program
M.D. Doctor of Medicine, 2022
Ph.D. Doctor of Philosophy in Biomedical Engineering, 2018
- Emory University Winship Cancer Institute** 2011
Georgia Cancer Coalition's Prostate Cancer Clinical Research Fellowship
- Georgia Institute of Technology** 2006 – 2011
B.S. in Biomedical Engineering, Honors Program, *Highest Honors*

Entrepreneurship, Patents, and Medical Products Launched

- Founder and President, Rhexis Surgical Instruments, Inc.** 2011 – 2017
- Designed, fabricated and tested an ophthalmic device for cataract removal
 - Patent: Giardina CK et al. Apparatus and Diamond blade mechanism for creating an annular incision in soft tissue. US-9700458-B2, Awarded July 11, 2017
- Lead Product Developer of Audiology Tool, Advanced Bionics Corporation, LLC** 2014
- **Designed, tested, and launched** a clinical audiometric tool for assessing post-operative cochlear health

Executive Summary of All Roles as Clinical Researcher, 2006-2023

- **Roles included:** Study oversight, study design, IRB approval, primary/source data collection, processing complex datasets into relevant study metrics, creation and management of databases, statistical analysis of imaging, author of 5 grants, 19 publications, industry quarterly reports, and conference presentations.
- **PI of 4 First-In-Human / Pilot trials using Class II medical devices I invented and fabricated** 2016 – 2022
- **PI of 2 Radiologic studies utilizing a semi-automated computational algorithm I developed** 2019
- **PI of 2 Observational Trials using existing FDA approved Class III medical devices** 2013 – 2018
- **As Non-PI, 20 Interventional and Observational Studies/Trials:**
 - 1 Pharmaceutical Chemotherapy Trial** 2011
 - Prospective RCT of prostate cancer chemotherapy drug adjuvant (Vorinostat)
 - 1 Medical Device Observational Study (Diagnostic Lab Assay, Class III)** 2019
 - Pivotal Study of novel clinical laboratory test for Tuberculosis screening I helped develop
 - 18 Medical Device Interventional Studies/Trials (Cochlear Implants, Class III)** 2013 – 2022
 - Sponsors/Funding Sources included the NIH (NIDCD) and industry sources: **MED-EL Corporation, Cochlear Corporation, and Advanced Bionics Corporation**
 - Investigational trials for **Expanding Indications for Conventional Candidacy**
 - Pediatric populations, auditory nerve genetic subtypes of hereditary deafness, Tinnitus, Meniere's Disease, Unilateral and Asymmetric hearing loss
 - Investigational trials for assessing safety of **new/updated cochlear implant models in pipelines**
 - Electro-acoustic stimulation in unilateral and bilateral deafness
 - Long-Term Safety/Efficacy **Post-Market Surveillance** device trials

As PI of First-in-Human Device Trials with Custom-Fabricated Class II Nerve Monitors

Intervention: 2016 – 2022

- **Designed and Fabricated 4 novel intraoperative cochlear nerve monitors**
- **Devices optimized in rodent pre-clinical trials before advancing to human pilot studies**

Role: PI and Responsible Party of FIH Feasibility Studies

Sponsor: NIDCD F30 Grant (PI: Giardina CK, NIH-F30-DC015168)

Eligibility: Human subjects already receiving surgical cochlear implantation consented or assented

Findings: Intraoperative cochlear signals can predict surgical trauma, device placement and speech outcomes

Regulatory Adherence:

- **FDA Class II, Product Codes GXY/OMC/GWS**
- **IRB determined all devices posed Non-Significant Risk, per FDA 21 CFR 56.111(1)**
- **IDE-Exempt, per FDA 21 CFR 812.2(b)(1)(ii)**
- **Fabricated with steel, platinum, and aluminum alloys, adhering to FDA-2013-D-0350-0001**
- **Reusable and Sterilized with Ethylene-Oxide, adhering to AAMI ANSI ISO 11135:2014**

As PI of Radiologic Studies using of Novel Cochlear Imaging Algorithm

PI of two studies assessing the accuracy and utility of an imaging algorithm I created to estimate cochlear implant positioning from only an XR (compared to CT) 2019

Background of studies: Adults often receive post-operative CT imaging to determine precise cochlear implant positioning as a significant factor in predicting speech outcomes, whereas children only receive low-resolution XR imaging to grossly confirm placement due to CT-related radiation risks. Therefore, clinicians of pediatric patients lacked the ability to accurately device positioning in children.

Study 1: Ensured accuracy, validity, and reliability of imaging algorithm to estimate cochlear implant positioning using XR against blinded gold-standard CT scans of same adult subjects

Study 2: Use of Algorithm with pediatric XR scans to increase accuracy in speech outcome predictions

As Researcher of Pharmaceutical Trial of Chemotherapy with Drug Adjuvant

Prospective RCT assessing prostate cancer recurrence rates and cellular genetic differences among patients receiving standard chemotherapy with Voronstat vs Veronostat plus Genistein 2011

Role: Primary-Source data collection and genetic analyst to identify cellular mechanisms of action

Sponsor: NIH and Emory Cancer Winship Institute Dept of Hematology and Oncology

Findings: Genistein and Voronostat, in combination, lower prostate cancer recurrence via DNA histone acetylation

As Pre-Clinical Researcher of Nerve Regeneration Technologies

Role: Invented novel techniques which contributed to lab-wide preliminary fabrication of neurologically-stimulatory polymers 2006

Sponsor/PI: Laboratory of Yadong Wang, PhD

Findings: Neuro-polymers could induce and direct neuronal regrowth after total/complete axon transection

Impact: Optimized polymers served as foundation for Clinical Trials, Company Formation, and FDA approval

Selected Academic & Professional Honors

- 2022 ▪ **MD Awarded**, University of North Carolina School of Medicine
- 2021 ▪ **Awarded Neurology Highest Honors**, University of North Carolina Neurology Acting Internship
- 2018 ▪ **PhD Awarded**, University of North Carolina Department of Biomedical Engineering
- 2016 ▪ **NIH F30 Fellowship Award**, National Institute of Deafness and Communication Disorders (NIDCD)
- **Poster Award**, American Otological Society (AOS) Spring Meeting
- **Travel Award**, Association for Research in Otolaryngology MidWinter Meeting (ARO)
- 2015 ▪ **NC Impact Award (and Featured Recipient in Newsletter)**, UNC Graduate School

- **Scott Neil Schwirck Fellowship Recipient, UNC School of Medicine**
 - Best Clinical Science Presentation, JGB Research Day 2015, UNC School of Medicine
 - 2nd Place, MIT/Harvard “Hacking Medicine“ Medical Device Design Competition
 - 3rd Place, Duke University’s Triangle Health Medical Device Innovation Challenge
 - Travel Award, Conference on Implantable Auditory Prostheses Conference (CIAP)
- 2014
- Gordon H. DeFries Career Development in Aging Research Award, UNC Institute of Aging
 - **Co-PI, Innovation Pilot Award \$50k Grant**, UNC School of Medicine Center for Innovation
 - Outstanding Poster Award for Scientific Merit, American Academy of Otolaryngology
 - **2nd place, National Cancer Institute (NCI) Business Plan Competition**
- 2013
- Technology Donation Recipient, Texas Instruments University Program
 - Invited Presenter, North Carolina Biotechnology Center Emerging Company Showcase
 - Technology Recipient, Renesas Microcontroller University Donation Program
- 2012
- Inducted into John B. Graham Medical Student Research Society, UNC School of Medicine
- 2011
- **Student Entrepreneur of Atlanta Finalist, TiE Atlanta**
 - Graduated Highest Honors in Georgia Tech’s Biomedical Engineering Program
 - Thesis Accepted (optional submission), Georgia Tech and Emory University School of Medicine
 - 3rd Place, televised pitch-based InventurePrize Competition
- 2010
- Inducted into Tau Beta Pi Engineering Honor Society
 - Senior Design Capstone Winner, Georgia Tech College of Engineering
 - **Georgia Cancer Coalition Carpenter Research Fellowship, Emory University**
 - Co-PI, Congressionally Directed Research Program Prostate Cancer Grant
 - Recipient, Georgia Tech Presidential Undergraduate Research Awards 2010 (William Hunt Lab)
- 2008
- Inducted into Alpha Eta Mu Beta Biomedical Engineering Honor Society
 - Recipient, Georgia Tech Presidential Undergraduate Research Awards 2008 (Yadong Wang Lab)

Publications & Book Chapters

1. Cornaby, C., **Giardina, C. K.**, & Schmitz, J. L. (2022). Repeatability of QuantiFERON-TB gold plus testing utilizing microparticle chemiluminescence. *Journal of Immunological Methods*, 509, 113340.
2. Canfarotta M.D., O’Connell B.P, **Giardina, C.K.**, Buss, E, Brown K.D., Dillon, M.T., Routh, M.A., Pillsbury, H.C., Buchman, C.A., Adunka, O.F., and Fitzpatrick, D.C. (2020). “Relationship Between Electrocochleography, Angular Insertion Depth, and Cochlear Implant Speech Perception Outcomes”, *Ear and Hearing*
3. **Giardina, C.K.**, Canfarotta M.W., Thompson N.J., Fitzpatrick D.C., Hodge S. E., Baker J.A., O’Connell B.P. (2019) “Assessing Cochlear Implant Insertion Angle from an Intraoperative X-ray Using a Rotating 3-D Helical Scala Tympani Model” *Otology & Neurotology*
4. Pappa AK, Hutson KA, Scott WC, Fox KE, Masood MM, **Giardina CK**, Pulver SH, Grana GD, Askew C, and Fitzpatrick KC. (2019) “Hair Cell and Neural Contributions to the Cochlear Summating Potential”. *Journal of Neurophysiology*
5. Fontenot, T. E., **Giardina, C. K.**, Dillon, M. T., Routh, M. A., Teagle, H. F., Park, L. R., ... & Fitzpatrick, D. C. (2019). “Residual cochlear function in adults and children receiving cochlear implants: correlations with speech perception outcomes”. *Ear and hearing*, 40(3), 577-591.
6. **Giardina, C. K.**, Khan, T. E., Pulver, S. H., Adunka, O. F., Buchman, C. A., Brown, K. D., ... & Fitzpatrick, D. C. (2018). Intracochlear Electrocochleography and Hearing Outcomes. *Ear and hearing*.
7. **Giardina, C. K.**, Adunka, O. F., Buchman, C. A., Brown, K. D., & Fitzpatrick, D. C. (2018). Response Changes During Insertion of a Cochlear Implant Using Extracochlear Electrocochleography. *Ear and hearing*.
8. Fontenot, T. E., **Giardina CK**, M. T. Dillon, M. A. Routh, H. F. Teagle, L. R. Park, K. D. Brown, O. F. Adunka, C. A. Buchman, H. C. Pillsbury, and D. C. Fitzpatrick (2018). "Residual Cochlear Function in Adults and Children Receiving Cochlear Implants: Correlations with Speech Perception Outcomes." *Ear and Hearing* (accepted, *Ear and Hearing* 2017)
9. **Giardina, C. K.**, Krause, E. S., Koka, K., & Fitzpatrick, D. C. (2018). Impedance Measures During in vitro Cochlear Implantation Predict Array Positioning. *IEEE Transactions on Biomedical Engineering*, 65(2), 327-335.

10. Fontenot, T. E., **Giardina, C. K.**, & Fitzpatrick, D. C. (2017). A Model-Based Approach for Separating the Cochlear Microphonic from the Auditory Nerve Neurophonic in the Ongoing Response Using Electrocochleography. *Frontiers in neuroscience*, 11, 592.
11. Fontenot, T. E., **Giardina, C. K.**, Teagle, H. F., Park, L. R., Adunka, O. F., Buchman, C. A., ... & Fitzpatrick, D. C. (2017). Clinical role of electrocochleography in children with auditory neuropathy spectrum disorder. *International journal of pediatric otorhinolaryngology*, 99, 120-127.
12. Riggs, W. J., Roche, J. P., **Giardina, C. K.**, Harris, M. S., Bastian, Z. J., Fontenot, T. E., ... & Fitzpatrick, D. C. (2017). Intraoperative electrocochleographic characteristics of auditory neuropathy spectrum disorder in cochlear implant subjects. *Frontiers in neuroscience*, 11, 416.
13. Harris, M. S., Riggs, W. J., **Giardina, C. K.**, O'connell, B. P., Holder, J. T., Dwyer, R. T., ... & Adunka, O. F. (2017). Patterns Seen During Electrode Insertion Using Intracochlear Electrocochleography Obtained Directly Through a Cochlear Implant. *Otology & Neurotology*, 38(10), 1415-1420.
14. Scott WC, **Giardina CK**, Fontenot TE, Pappa AW, Pillsbury HC, Brown KD, and Fitzpatrick DC. "The Compound Action Potential in Cochlear Implant Patients". *Otology & Neurotology*
15. Adunka, OF, **Giardina CK**, Formeister EJ, Choudhury B, Buchman CA, and Fitzpatrick DC. "Round window electrocochleography before and after cochlear implant electrode insertion." *The Laryngoscope* (Sept. 2015).
16. **Giardina CK**, and Adunka OF, "Intra-operative Monitoring". *Otology, Neurotology, and Skull-Base Surgery: A Clinic Reference Guide*. Ed. Brackmann, DE. Print, August 2015.
17. **Giardina CK**, Formeister, EJ, and Adunka, OF. "Cochlear Implants in Single-Sided Deafness." *Current Surgery Reports* 2.12 (2014): 1-11.
18. Phillip CJ, **Giardina CK**, Bilir B, Cutler DJ, Lai YH, Kucuk O, and Moreno CS. "Genistein cooperates with the histone deacetylase inhibitor vorinostat to induce cell death in prostate cancer cells." *BMC Cancer* 12.1 (2012): 145. PMID: 22494660
19. Secasanu VP, **Giardina CK**, and Wang Y. "A novel electrospinning target to improve the yield of uniaxially aligned fibers." *Biotechnology progress* 25.4 (2009): 1169-1175. PMID: 19562742

Selected Oral & Poster Conference Presentations

(OF 25, FULL LIST AVAILABLE UPON REQUEST)

- **Giardina CK**, Fontenot TE, Brown KD, Buchman CA, Adunka OF, Pillsbury HC, and Fitzpatrick DC. "Extracochlear Electrocochleography during Insertion of Cochlear Implants: Intraoperative Responses and Postoperative Hearing Preservation". 2017 Conference on Implantable Auditory Prostheses (CIAP 2017)
 - **Expert Panelist for Intraoperative Monitoring topic**
- **Giardina CK**, Scott WC, Pappa AK, Fontenot TE, Pillsbury HC, Brown KD, and Fitzpatrick DC. "Auditory Neuropathy Spectrum Disorder in Children - Intraoperative Electrocochleography Characteristics" Oral Presentation at the 14th International Conference on Cochlear Implants (CI 2016), May 2016.
 - **Expert Panelist for Pediatric Cochlear Implantation topic**
- **Giardina CK**, Fontenot TE, Pulver SH, Brown KD, Buchman CA, Pillsbury HC, and Fitzpatrick DC. "Intracochlear and Extracochlear Acoustic Responses during Insertion of a Cochlear Implant". Poster Presentation at the American Otological Society (AOS) Combined Otolaryngology Spring Meetings (COSM), 2016
 - **Received American Otologic Society (AOS) Poster Award**
- **Giardina CK**. "Minimizing Trauma and Maximizing Outcomes in Cochlear Implants." Oral presentation at the UNC John B. Graham Annual Research Meeting, Jan 2015
 - **Awarded Best Clinical Science Oral Presentation**
- Formeister EJ, McClellan JH, Merwin WH, **Giardina CK**, Iseli CE, Teagle HF, Buchman CA, Adunka OF, Fitzpatrick DC. "Intraoperative Round Window Electrocochleography and Speech Perception Outcomes in Pediatric Cochlear Implant Recipients." Poster presentation at the American Academy of Otolaryngology-Head and Neck Surgery Annual Meeting (AOS), Orlando, FL, September 2014.
 - **Awarded Outstanding Poster Award for Scientific Merit**
- **Giardina CK** et al. "Novel Surgical Tool for Cataract Surgery Capsulorhexis" Televised Live Pitch competition InventurePrize, September 2011.
 - **Awarded Funding for Company Formation, Patent Fees, and Prototype Development**