Focused Ultrasound and Cancer Immunotherapy Workshop

1–2 September 2021

Virtual Meeting

Sponsored by

Focused Ultrasound Foundation

Cancer Research Institute

Welcome Letter

Focused Ultrasound and Cancer Immunotherapy Workshop
September 1-2, 2021

Dear Colleagues,

Welcome to the Focused Ultrasound Foundation and Cancer Research Institute's fourth workshop on focused ultrasound and cancer immunotherapy. This invitational event is being held to share and assess the progress made since the previous workshops and to ensure that we continue along the optimal path towards clinically relevant combination therapies.

A primary goal of this workshop (and previous workshops) is to bring together all critical stakeholders – researchers, clinicians, industry, government, and others – in an environment that encourages the free dissemination of information and ideas. We have a diverse group of participants with wide-ranging expertise, and we hope that you will take advantage of this opportunity to form relationships that will complement your own research interests and to think of how we can best utilize the group's combined knowledge and talents in order to continue advancing this field.

Our ultimate mission is to reduce the time it takes for focused ultrasound and immunotherapy combination treatment(s) to reach clinical adoption. This workshop is another step towards accomplishing this goal, with your help, by critically evaluating the current body of evidence, assessing the value of ongoing work, and creating a roadmap of projects that will address any remaining gaps and "burning questions." There will be several presentations available to view before the meeting to orient us to the current state of the field, and the bulk of the meeting itself will include moderated open discussion to encourage the active engagement of all participants as we develop our roadmap forward.

The primary objectives of the workshop are to:

1. Develop a one to two-year action plan of projects that address the "burning questions" for the field and can potentially be supported by the Focused Ultrasound Foundation and/or Cancer Research Institute.
2. Produce a white paper documenting the discussion and results of the meeting.
3. Create a collaborative environment to facilitate the achievement of our goals as rapidly as possible.

Thank you for joining us and for helping us to achieve our mission of saving more lives by fueling research in promising applications of focused ultrasound and cancer immunotherapy. We trust that you will take advantage of the collaborative opportunity that this meeting affords, and we know that we will be able accomplish our goals with your help.

Sincerely,

Jessica Foley, PhD
Chief Scientific Officer
Focused Ultrasound Foundation

Jill O'Donnell-Tormey, PhD
Chief Executive Officer and
Director of Scientific Affairs
Cancer Research Institute

Focused Ultrasound Foundation

The Technology

Focused ultrasound is an early-stage, disruptive, noninvasive therapeutic technology that has the potential to improve the lives of millions of patients with a variety of serious medical disorders by providing an alternative or complement to surgery, radiation therapy, drug delivery, and cancer immunotherapy.

This game-changing technology has the potential to increase the quality and longevity of life and decrease the cost of care for countless patients by transforming the treatment of a range of conditions including tumors of the brain, breast, prostate, liver, and pancreas; Parkinson's and Alzheimer's disease and epilepsy; depression and obsessive-compulsive disorder; arthritis and hypertension. With further technological development, laboratory research and clinical trials, focused ultrasound could be as revolutionary to therapy as magnetic resonance (MR) scanning has been to diagnosis.

Focused ultrasound treats tissue with multiple intersecting beams of high-frequency sound focused accurately on targets deep in the body without damaging surrounding structures, much like beams of light can be focused on a point with a magnifying glass. At the focal point where the beams of light converge, the ultrasound energy induces a variety of biological effects including destroying tissue, delivering drugs in high concentrations, enhancing radiation therapy, and stimulating the immune response. The multiple biological effects create the possibility to treat a wide range of disorders. MR or ultrasound imaging is used to identify the targets and guide and control the treatment in real time.

The Problem

Unfortunately, it can take decades for a new therapeutic technology like focused ultrasound to become mainstream. Every year we shave off that process could reduce death, disability, and suffering for countless people.

The Focused Ultrasound Foundation

The Foundation is a unique medical research, education and advocacy organization created as the catalyst to accelerate the development and adoption of focused ultrasound. The Foundation is a tax-exempt 501(c)(3) corporation started in 2006. To achieve its goals, the Foundation utilizes an approach that is entrepreneurial, high-impact, high performance, market-driven, and results oriented.

We advance the field by leveraging opportunities and overcoming barriers, thereby shortening the time from laboratory research to widespread patient treatment as a standard of care.

Major Initiatives include:

- Influencing the direction of the field, identifying priorities, and defining areas of clinical benefit
- Fostering collaboration and stimulating innovation
- Providing resources, both financial and human capital
- Creating knowledge by organizing, conducting, and funding research
- Aggregating and sharing knowledge through our website, newsletter, social media, webinars, and open-source publications
- Overcoming barriers, including regulatory and reimbursement challenges
- Cultivating the next generation of clinicians and scientists by supporting internships and fellowships
- Convening the community through meetings, symposia, and workshops
- Increasing awareness through events and media outreach

Cancer Research Institute

The Cancer Research Institute (CRI) is the world's leading nonprofit organization dedicated exclusively to harnessing the immune system's power to conquer all cancers. CRI awards research grants and fellowships to support scientists at leading universities and clinics around the world.

This important work has led to a promising new class of cancer treatments called cancer immunotherapy. These treatments can mobilize, strengthen, and sustain the immune system's natural ability to destroy cancer cells, wherever they are in the body.

CRI's funding decisions are guided by a Scientific Advisory Council composed of renowned immunologists and tumor immunologists, including Nobel Prize winners and members of the National Academy of Sciences. CRI also offers educational programming on cancer immunotherapy for patients, caregivers, and healthcare professionals.

To learn more about CRI's laboratory, translational, and clinical research programs, go to www.cancerresearch.org/grants-programs.

Detailed Agenda

On-Demand Presentations:

On-Demand - beginning August 27th
Introduction
Introduction to Focused Ultrasound Foundation *Jessica Foley, Chief Scientific Officer, Focused Ultrasound Foundation*
Introduction to Cancer Research Institute *Jill O'Donnell-Tormey, CEO and Director of Scientific Affairs, Cancer Research Institute*
Introduction to Parker Institute for Cancer Immunotherapy *Theresa LaVallee, VP Translational Med. & Reg. Affairs, Parker Institute for Cancer Immunotherapy*
Immune Effects by FUS Modality
Treatment Reporting Guidelines *Gail ter Haar, Team Leader, Institute of Cancer Research*
Turning Up the Heat: Using Non-thermal Histotripsy to Shift the Immunosuppressive Tumor Microenvironment from "Cold" to "Hot", Augmenting Systemic Anti-Tumor Immune System Activation *I. Coy Allen, Associate Professor, Virginia Polytechnic Institute and State University*
FUS & Immunotherapy *Kathy Ferrara, Professor, Stanford University School of Medicine*
Hyperthermia and Cancer Immunity: Some Brief Comments with Implications for Focused Ultrasound *Elizabeth Repasky, Professor, Roswell Park Cancer Institute*
Immunological Effects of Boiling Histotripsy Tumor Ablation *Tatiana Khokhlova, Associate Professor, University of Washington*
Low Intensity Focused Ultrasound's Effect on the Immune Response *Petros Mouratidis, Research Scientist, Institute of Cancer Research*
Immune Response to BBB/BTB Opening with Focused Ultrasound *Richard Price, Professor, University of Virginia*
Overview of radio therapy's effect on the immune response *Chandan Guha, Professor & Vice Chairman, Montefiore Medical Center*
Immune Effects by Tumor Type
Overview of the conclusions from the GBM consortium *Pavlos Anastasiadis, University of Maryland School of Medicine*
Focused Ultrasound and Cancer Immunotherapy
June 2021 Fireside chat on Focused Ultrasound and Cancer Immunotherapy *Jessica Foley, Chief Scientific Officer, Focused Ultrasound Foundation* *Jill O'Donnell-Tormey, CEO and Director of Scientific Affairs, Cancer Research Institute* *Theresa LaVallee, VP Translational Med. & Reg. Affairs, Parker Institute for Cancer Immunotherapy*

Detailed Agenda

September 1, 2021:

Time	Discussion Topics
Welcome	
10:00 AM	Welcome from Focused Ultrasound Foundation and Cancer Research Institute *Jessica Foley, Chief Scientific Officer, Focused Ultrasound Foundation* *Jill O'Donnell-Tormey, CEO and Director of Scientific Affairs, Cancer Research Institute*
Immune Effects by FUS Modality	
10:10 AM	Presentation: Focused Ultrasound Cancer Therapies: Brief Overview of Different FUS Modalities *Eli Vlaisavljevich, Assistant Professor, Virginia Tech*
10:20 AM	Moderated Open Discussion: Immune Effects by FUS Modality & Roadmap • What are the immune effects of thermal vs. mechanical modalities? Can these effects be modulated (partial ablation, etc.)? Are these findings consistent across tumor types? • How does the immune response to FUS compare to other modalities (radiation, etc.)? How might FUS synergize with other modalities? • Is there a rationale for combining different FUS modalities? At what point do combination therapies (multiple modalities) lose translational potential? • What projects/knowledge gaps are critical for moving forward? *All Participants- moderated by: Kelsie Timbie*
11:15 AM	**5-minute break**

Detailed Agenda

September 1, 2021- continued:

Immune Effects by Tumor Types	
11:20 AM	Moderated Open Discussion: Immune Effects by Tumor Types & Roadmap • What do we know about the responses of different tumor types to FUS? • Brain v. periphery: are there different components of the response to FUS? • What can we sort the responses in terms of "cold" v. "hot" tumors? • What can/should be compared across tumor types & studies? What are the constrains to these comparisons? (Immune guidelines, leveraging 'core labs'… to be developed also on day 2) • Should we set-up more consortium projects (brain, pancreas)? For what tumors? • What constitutes a translationally relevant study - to ensure that preclinical findings occur outside of the typical model organisms • What projects are critical for moving forward? *All Participants- moderated by: Frédéric Padilla*
12:05 PM	**30-minute break**
Clinical Disease Targets	
12:35 PM	Focused Ultrasound Immune Impact in Liver Tumors *Joan Vidal-Jove, Director, Comprehensive Tumor Center Barcelona*
12:45 PM	Presentation: HIFU for Pancreatic Cancer: Challenges and Future Directions *Srikanth Reddy, Consultant Surgeon, Churchill Hospital* *Keaton Jones, NIHR Academic Clinical Lecturer, University of Oxford*
12:55 PM	Presentation: A Clinical Trial of Focused Ultrasound with Low-Dose Gemcitabine to Augment Immune Control of Early-Stage Breast Cancer *Patrick Dillon, Medical Oncologist, University of Virginia Health System*
1:05 PM	Presentation: Potential of Focused Ultrasound as an Immunotherapy Tool for Treatment of Melanoma *Lynn Dengel, Assistant Professor, University of Virginia Health System*

Detailed Agenda

September 1, 2021- continued:

Clinical Disease Targets continued	
1:15 PM	Presentation: FUS and Immunotherapy for Glioblastoma *Michael Lim, Professor and Chair, Stanford University School of Medicine*
1:25 PM	Q&A on Trial Design *Theresa LaVallee, VP, Parker Institute for Cancer Immunotherapy*
1:40 PM	**5-minute break**
1:45 PM	Moderated Open Discussion: Clinical Disease Targets & Roadmap • What clinical disease targets are ideal for focused ultrasound plus immunotherapy combinations? • What do we know about the role of different "modes" of FUS clinically? • What are strategies to consider for FUS treatment of the tumor – e.g., treating entire tumor, treating primary tumor vs metastasis? • What elements of trial design are critical to include in all FUS – IO clinical trials? • What projects are critical for moving forward? • What role for FUS: tumor debulking vs. immune modulation vs. drug delivery? enhance response rate to IO in partially sensitive cancers? Transform "cold" into "hot" tumors? Enhance immunotherapy delivery? *All Participants- moderated by: Jessica Foley*
2:30 PM	**End of Day 1**

Detailed Agenda

September 2, 2021

Time	Discussion Topics
Welcome	
10:00 AM	Day Two Welcome *Kelsie Timbie, Scientific Programs Manager, Veterinary Program Director, Focused Ultrasound Foundation*
Optimization of FUS for Immunomodulation	
10:05 AM	Moderated Open Discussion: Optimization of FUS for Immunomodulation & Roadmap • How should we envision the role of FUS in immune-oncology – as a drug adjuvant, replacement, or delivery system; an immune primer; a debulking method? Does this vary by mechanism or tumor type? • Does the timing of FUS treatment depend on mechanism? How so? • At what point do combination therapies (FUS + drug) lose translational potential? • Based on the existing data regarding FUS-induced immune response, what are the most logical drug targets for combination therapy? How does this vary by mechanism or tumor type? • What projects/knowledge gaps are critical for moving forward? *All Participants- moderated by: Kelsie Timbie*
10:50 AM	**5-minute break**
10:55 AM	Presentation: Engineering Remotely Controllable CAR T Cells for Cancer Immunotherapy *Peter Wang, Professor, University of California, San Diego*

Detailed Agenda

September 2, 2021- continued:

Optimization of FUS for Immunomodulation continued	
11:05 AM	Moderated Open Discussion: Role for FUS in Therapeutic Delivery • What immunotherapies have emerged as the strongest candidates for delivery with FUS? • What are the chief 'delivery' challenges posed by different tumor types (e.g., stroma, BBB, sparsity of immune cells, etc.) and where can the known FUS MOAs plug in to help potentiate therapeutic delivery in these settings? • What are the key experimental/technical parameters that need to be systematically assessed in an effort to improve or optimize FUS therapeutic delivery? • Which animal models are most appropriate for studying questions related to FUS therapeutic delivery? How do the considerations change for different classes of immunotherapy / adjuvant? • What are the outstanding challenges with novel immunotherapies (e.g., CAR T, gene therapy) that FUS can help to address? • What endpoints or monitoring strategies should we be using to evaluate the effectiveness of FUS in aiding therapeutic delivery? Pre-clinical? Clinical? • What projects / knowledge gaps need to be fulfilled to move the field forward? *All Participants- moderated by: Natasha Sheybani*
Metrics to Predict Clinical Success	
11:35 AM	Presentation: Guidelines for Immune Analysis of Focused Ultrasound Treatment *Frédéric Padilla, Dir of Applied Physics, Focused Ultrasound Foundation*
11:50 AM	Presentation: Introduction to Imaging Applications in Immuno-Oncology *Natasha Sheybani, Post-doctoral Fellow, Stanford University* *Senior Scientist, Focused Ultrasound Foundation*

Detailed Agenda

September 2, 2021- continued:

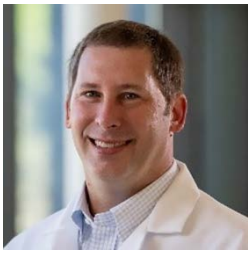
Metrics to Predict Clinical Success continued	
12:00 PM	Presentation: Multi-Omic Biomarker Analysis for Tumor and Immune Learnings in Clinical Studies *Theresa LaVallee, VP, Parker Institute for Cancer Immunotherapy*
12:10 PM	**30-minute break**
12:40 AM	Moderated Open Discussion: Metrics to Predict Clinical Success & Roadmap • What should be endpoints for FUS / IO clinical trials? • What can we learn, biomarkers/toolkits…, from other ablative treatment modalities? • What metrics can be used to predict clinical success (T cell ratios, etc.)? is it tumor type-dependent? • What role for FUS: enhance response rate to IO in partially sensitive cancers? Transform "cold" into "hot" tumors? • What timing for immune monitoring in FUS studies? • Do we need biopsies in all cases, or can blood samples reliably predict response? • What is the role of imaging for immune monitoring in FUS studies? • What projects are critical for moving forward? *All Participants- moderated by: Frédéric Padilla*
1:10 PM	Moderated Open Discussion: Knowledge Gaps, Funding Gaps, Other Gaps & Pharma Partnerships, Wish List *All Participants- moderated by: Jessica Foley*
2:10 PM	Wrap Up & Next Steps *All Participants- moderated by: Jessica Foley*
2:30 PM	**End of Day 2**

Workshop Attendees

as of Friday, 27 August 2021

Gosse Adema, PhD
Full Professor
Radiotherapy & OncoImmunology (ROI) laboratory, Dept. of Radiation Oncology, RadboudUMC, Nijmegen, Netherlands
gosse.adema@radboudumc.nl

Gosse J. Adema, PhD (13-11-1962, Dutch), holds the chair in Molecular Immunology at the Radiotherapy & OncoImmunology lab (ROI), Department of Radiation Oncology, RadboudUMC, in Nijmegen. He discovered the melanocyte differentiation antigen Gp100 and uncovered its recognition by the immune system. Gosse Adema received the Eijkman Winkler Medal of the University of Utrecht (2004), the VICI award (2006) and the Radboud University Educational Price (2011). He has written > 10 patents, supervised >25 Ph.D. students, has > 200 scientific publications and holds member of the (advisory) board positions of Scientific Councils within Europe.



Irving Coy Allen, MD
Associate Professor
Virginia Tech, Blacksburg, VA, USA
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Dr. Irving Allen is an immunologist and expert in preclinical animal modeling. We routinely participate in transdisciplinary collaborations with clinicians, veterinarians, engineers, and researchers to assist in the translation of novel ideas and concepts into viable treatment strategies targeting a diverse range of immune system disorders and cancer. Our team is especially interested in novel cancer treatment modalities that can impact the tumor microenvironment and augment the anti-tumor immune response. This includes studies with focal tumor ablation modalities, such as histotripsy and HIFU, where the benefits appear to extend well beyond the ablation zone.

Joseph Amaral, MD
Vice President, Medical and Clinical Affairs
HistoSonics, Ann Arbor, MI, USA
joseph.amaral@histosonics.com

Dr. Joe Amaral currently serves as the Vice President of Medical and Clinical Affairs for HistoSonics. Dr. Amaral has more than 35 years of significant clinical and executive leadership in the healthcare space, and prior to his role with HistoSonics, was the Global Vice President of Surgical Innovation at Johnson & Johnson. Dr. Amaral's other notable accomplishments include serving as President and CEO of Rhode Island Hospital, serving as the Chairman of the Department of Surgery at Brown University School of Medicine, and was an inventor and co-developer of significant medical technology and companies, among others.

Pavlos Anastasiadis, PhD
Research Associate
University of Maryland School of Medicine, Baltimore, MD, USA
panast@som.umaryland.edu

Pavlos Anastasiadis received his Ph.D. in Molecular Bioengineering from the University of Hawaii at Manoa. Before his graduate studies, he trained as a Fellow of the German Research Foundation, the Max-Planck Foundation, and the Fraunhofer Foundation. In 2016, he joined the University of Maryland School of Medicine as a Postdoctoral Fellow. In 2017 he was appointed to the NIH T32 Training Grant in Cancer Biology and in 2021 he was promoted to Research Associate in Neurosurgery. His current research studies are exploring the use of focused ultrasound for drug delivery, immunotherapy, and liquid biopsy in the setting of infiltrating gliomas.

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Thomas Andreae, PhD
FUS Ambassador, Europe
Focused Ultrasound Foundation, Charlottesville, VA, USA
tandreae@fusfoundation.org

Thomas Andreae, PhD, joined the Foundation in May 2019 after a long track record in the medical technology industry. As a focused ultrasound ambassador in Europe, Thomas is promoting the clinical impact of focused ultrasound and the high potential it has in many clinical areas. He acts as a liaison between the Foundation and the European focused ultrasound community by identifying new opportunities for scientists, clinicians, patients, and industry. He fosters collaboration to advance clinical applications from experimental and clinical trials to clinical routine. He received his PhD in physics from the Ludwig Maximilian University of Munich in 1993.

Costas Arvanitis, PhD
Assistant Professor
Georgia Institute of Technology, Atlanta, GA, USA
costas.arvanitis@gatech.edu

Dr Arvanitis is a joint Assistant Professor at the Woodruff School of Mechanical Engineering and the Coulter Department of Biomedical Engineering at Georgia Institute of Technology and Emory University. Dr Arvanitis research program is focused on ultrasound biophysics and bioengineering and its overarching goal is the discovery and translation to the clinics of novel therapeutic interventions against human disease. His lab is particularly active in the field of brain research, where they investigate ultrasound meditated mass transport and drug delivery in the brain and develop computational tools to support the more rational design of focused-ultrasound-based treatment of brain cancer.

Matthew Bucknor, MD
Radiologist
UCSF, San Francisco, CA, USA
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Matthew Bucknor, MD is an Associate Professor in the Musculoskeletal Imaging section of the Department of Radiology and Biomedical Imaging at the University of California, San Francisco (UCSF) where he serves as Director of Focused Ultrasound. At UCSF he has used focused ultrasound technology to perform more than 80 clinical procedures with a focus on musculoskeletal tumors. Dr. Bucknor's research program involves both basic and translational studies aimed at better understanding the impact of technical parameters of focused ultrasound. He is particularly interested in developing focused ultrasound techniques to augment clinical response of cancer treatments such as immunotherapy.

Kim Bullock, PhD
Director, Protocol Development
University of Virginia/Cancer Center OCR, Charlottesville, VA, USA
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Dr. Bullock received her Ph.D. in Immunology from Thomas Jefferson University in 1998. She went on to complete her post-doctoral training in clinical trial design and clinical trial protocol development at the University of Virginia (UVA) and joined the faculty at UVA in 1999 as Director of Protocol Development. Dr. Bullock oversees the design and development of investigator-initiated clinical trials for the UVA Cancer Center. She also oversees the regulatory submissions (IND/IDE) for the clinical research program. Dr. Bullock has been an author on more than 30 clinical trial protocols and has co-authored manuscripts reporting clinical trial outcomes.

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as of Friday, 27 August 2021

Timothy Bullock, PhD
Associate Professor
University of Virginia School of Medicine, Charlottesville, VA, USA
tb5v@virginia.edu

Tim Bullock is a tumor immunologist whose primary research focus is understanding how TNF-superfamily members can be leveraged to promote anti-tumor immunity. In the context of Focused Ultrasound, he has been working to understand the innate and adaptive immune responses that are elicited, both in pre-clinical models and clinical trials, primarily be thermal ablation. For GBM, he has worked with Dr Richard Price to develop microbubble-based mechanical damage and delivery systems that are designed to promote intracranial immunity.

Jennifer Carroll
Dual Resident (Veterinary Medical Oncology)
Virginia Tech, Blacksburg, VA, USA
jenccarroll@vt.edu

My name is Jennifer Carroll and I recently completed my residency in Veterinary Medical Oncology at Virginia Tech. I am currently working on my PhD which is focused on studying the immune response to minimally invasive ablative techniques for canine liver cancer.

Anna Christou, BA
Post-baccalaureate fellow
National Institutes of Health, Bethesda, MD, USA
christoua2@nih.gov

Anna Christou graduated in May 2021 from Columbia University with a BA in Biological Sciences. She is now completing a post-baccalaureate fellowship at the National Institutes of Health Center for Interventional Oncology, where she completed research over two summers. She is involved in projects about combining immunotherapies and ablation techniques.

Clifford S. Cho, MD
Professor
University of Michigan Medical School, Ann Arbor, MI, USA
cliffcho@med.umich.edu

Dr. Cho is a liver/pancreas cancer surgeon at the University of Michigan. He is also PI of a cancer immunotherapy laboratory that is exploring the immunostimulatory effects and immunotherapeutic implications of histotripsy focused ultrasound ablation.

Abigail Collins, Meng
DPhil Student
University of Oxford, Oxford, United Kingdom
abigail.collins@eng.ox.ac.uk

Abigail is researching the immunomodulatory effects of focused ultrasound induced cavitation, nucleated by solid protein-based nanoparticles.

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Marion Cortet, MD PhD
Breast Surgeon
INSERM LabTAU, Lyon, France
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As a gynecologist and surgeon, I treat patients with breast cancer in Lyon University Hospital. I am also researcher in the Laboratory for therapeutic application of ultrasound. My research field is about therapeutic use of ultrasound for breast cancer treatment.

Constantin Coussios FREng
Professor
University of Oxford, Oxford, United Kingdom
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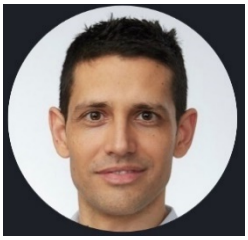
Professor Constantin Coussios is the Director of the Oxford Institute of Biomedical Engineering. He received his BA, MEng and PhD in Engineering from the University of Cambridge and was elected to the first statutory chair in Biomedical Engineering at the University of Oxford in 2011, with special responsibility for drug delivery and therapeutic devices. In 2017, he received the Silver Medal of the UK's Royal Academy of Engineering for his contributions to organ preservation and ultrasound-enhanced drug delivery. In 2019, he was elected a Fellow of the Royal Academy of Engineering.



Mor Dayan
Senior Director, Product Management | Neuro
Insightec, Tirat Carmel, Israel
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Mor has been with Insightec for the last 12 years in different R&D, Program and Product Management positions. Now leading the Upstream (strategic) Marketing and Product Management for the company.

John de Groot, MD
Professor and Director, Clinical Research
Department of Neuro-Oncology
The University of Texas MD Anderson Cancer Center, Houston, TX, USA
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Dr. de Groot a neuro-oncologist with clinical and translational research experience in the fields of glioma angiogenesis, molecularly targeted therapy, and immunotherapy. He has been the PI of 44 clinical trials, and collaborator on another 78 studies. He has experience leading multiple biomarker-driven clinical trials, including neo-adjuvant studies of various immunotherapeutic agents. He has been a peer reviewer for 23 scientific journals. He is a grant reviewer for numerous international foundations, government agencies, and currently serve as an ad hoc reviewer for NCI Transition Career Development Award (K22) and NIH Academic Industry Partnership (AIP) study sections.

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Jaydira Del Rivero, MD
Physician Scientist
National Cancer Institute, Bethesda, MD, USA
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Dr. Del Rivero is a Physician Scientist in the Developmental Therapeutics Branch. She is the Principal Investigator of the Natural History Study for Neuroendocrine Neoplasm and Adrenocortical Cancer to provide the basis of further development of therapeutic interventions, prevention/screening guidelines, endpoints for future clinical trials, and patient reported outcome measures. Dr. Del Rivero's current efforts is the development of novel treatment approaches and targeted therapies for endocrine malignancies such as advanced gastroenteropancreatic neuroendocrine tumors, adrenocortical cancer and pheochromocytoma/paraganglioma.

Lynn T. Dengel, MD, MSc
Assistant Professor
University of Virginia, Charlottesville, VA, USA
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Dr. Lynn Dengel is a board-certified and fellowship-trained surgical oncologist. She completed general surgery residency at the University of Virginia followed by a fellowship at Memorial Sloan Kettering Cancer Center in New York. She has authored and co-authored several articles in leading peer-reviewed publications, including the Annals of Surgical Oncology, Journal of Clinical Oncology, and Annals of Surgery. Dr. Dengel serves as the Principal Investigator for the clinical trial AM003 Focused Ultrasound Ablation and PD-1 Antibody Blockade in Advanced Solid Tumors, currently open to enrollment at the University of Virginia.

Nick Dervisis, DVM, PhD, DACVIM (Oncology)
Associate Professor of Oncology
Virginia Tech, Blacksburg, VA, USA
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Nick Dervisis earned a Doctor of Veterinary Medicine degree from the School of Veterinary Medicine at Aristotle's University in Thessaloniki, Greece, and a doctorate in comparative medicine and integrative biology at Michigan State University. He completed his residency in Medical Oncology at Michigan State University, where he stayed as a research associate and faculty until 2012. He then moved to Virginia Tech to start the Oncology Service and research program, at the Department of Small Animal Clinical Sciences. His research focuses on the tumor microenvironment and immune system response to tumor ablation.

Parth Anil Desai
Clinical Fellow
NIH, Bethesda, MD, USA
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Clinical fellow working in field of small cell lung cancer interested in targeting liver specific metastases in SCLC, which are a clinical challenge to current therapeutics.

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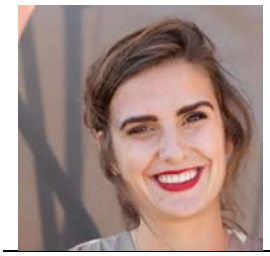

Mirjam de Visser, MD
PhD Candidate
University Medical Center Utrecht, Utrecht, Netherlands
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Dr. de Visser is a PhD Candidate at the Medical Imaging & Oncology division, focusing primarily on MR-HIFU applications.

Patrick Dillon, MD
Medical Oncologist
University of Virginia, Charlottesville, VA, USA
pmd5b@hscmail.mcc.virginia.edu

Dr. Dillion is a medical oncologist and treats all stages of breast cancer in the clinic. He is a focused ultrasound researcher and clinical user.

Daniel Markus Düx
Doctor
Stanford University, Stanford, CA, USA
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Medical school in Göttingen and Rostock, Germany until December 2018. Surgery Residency in Wiesbaden, Germany until December 2020. Now Research Internship in Stanford University until February 2022.

Victor Engelhard, PhD
Professor of Microbiology, Immunology, and Cancer Biology
University of Virginia School of Medicine, Charlottesville, VA, USA
vhe@virginia.edu

Victor Engelhard is Harrison Distinguished Teaching Professor of Microbiology, Immunology and Cancer Biology. His laboratory work has been concerned with processing and presentation of antigens by CD8 T lymphocytes, particularly antigens displayed by tumors, and the role of vascular endothelium and tertiary lymphoid structures in regulating homing and organization of immune cells in tumors. He has been Section Editor for Journal of Immunology, Advisory Editor for Journal of Experimental Medicine, Associate Editor for Immunity, and a Faculty of 1000 Immunology Section member. His has published 210 peer-reviewed and invited publications and has been recognized as an ISI Highly Cited Researcher.

Avinash Eranki
Assistant Professor
Indian Institute of Technology Hyderabad, Telangana, India
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Avinash Eranki has prior experience working on therapeutic ultrasound in both preclinical and clinical areas. He currently is the PI of the Medical Ultrasound Research Laboratory (MURL), that is dedicated to developing novel therapeutic ultrasound techniques for clinical applications.

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Katherine Ferrara, PhD
Professor
Stanford University, Stanford, CA, USA
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Dr. Ferrara is Professor of Radiology and Division Chief of the Molecular Imaging Program at Stanford University. She previously served as the founding chair of the Department of Biomedical Engineering at UC Davis. Dr. Ferrara is a member of the National Academy of Engineering and a fellow of the American Association for the Advancement of Science, Institute of Electrical and Electronic Engineers, Biomedical Engineering Society, Acoustical Society of America, World Molecular Imaging Society and American Institute of Medical and Biological Engineering. Her publications include 300 manuscripts in the area of image-guided drug and gene delivery.

Jessica Foley, PhD
Chief Science Officer
Focused Ultrasound Foundation, Washington, DC, USA
jfoley@fusfoundation.org

Jessica Foley, PhD is the Chief Scientific Officer for the Focused Ultrasound Foundation, whose mission is to accelerate the development and adoption of focused ultrasound, a breakthrough noninvasive therapeutic medical technology. Dr. Foley guides strategy, development, and implementation of scientific and research programs for the Foundation, and aligns these with business operations, communications, and development activities. She leads alliance-building efforts with external stakeholders including governmental policymakers, regulatory agencies, and disease-specific foundations whose interests are complementary to those of the Foundation. She is a representative and advocate for the Foundation and the focused ultrasound community among a wide variety of stakeholders. Prior to the Foundation she spent several years in the medical device industry (Insightec, Medtronic) and was a 2011-2012 AAAS Science and Technology Policy Fellow at the National Science Foundation. She holds a BSE in Biomedical Engineering from Duke University and a PhD in Bioengineering from the University of Washington.

Joseph Frank, MD
Senior Investigator
Frank Laboratory, NIH, Bethesda, MD, USA
jfrnak@nih.gov

Dr. Frank is a board-certified medical oncologist and tenured scientist at NIH whose research focus is directed towards improving cellular therapies in treatment of malignancy and regenerative medicine. His current interest is in investigating the ability of therapeutic ultrasound to initiate proteomic, transcriptomic, and cellular changes in the tumor immune microenvironment that can result influence innate and adoptive immune cellular response in tumors. We are applying therapeutic ultrasound to enhance cellular therapies in the treatment of diseases.

Awndre Elijah Gamache, PhD
Postdoctoral Fellow
University of Virginia, Charlottesville, VA, USA
aeg2c@virginia.edu

I am a postdoctoral researcher in Dr. Timothy Bullock's lab at the University of Virginia. We are passionate about integrating immunotherapy and focused ultrasound therapy to treat pancreatic cancer.

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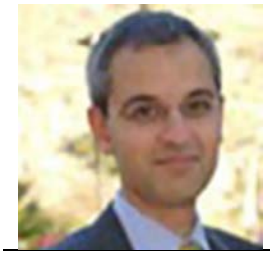
Bjoern Geroldi, MD
Head of Fundamental Research
Theraclion, France
bjoern.gerold@theraclion.com

Dr. Geroldi develops high intensity focused ultrasound devices for the medical applications of the future. 10 years of experience in the field and my degrees in biomedical engineering and a PhD in medical physics allow me to investigate and design medical devices starting from fundamental physics, creating the hardware up to the clinical validation. I use numerical simulations in conjunction with in-vitro, ex-vivo and in-vivo experimental experience to develop the newest therapeutic ultrasound applications.



Pejman Ghanouni, MD, PhD
Associate Professor of Radiology
Stanford University, Stanford, CA, USA
ghanouni@stanford.edu

My expertise is in MR guided focused ultrasound therapies, including for the treatment of movement disorders, bone and soft tissue tumors, prostate cancer and uterine fibroids.

David Goertz
Senior Scientist
Sunnybrook Research Institute, Toronto, ON, Canada
goertz@sri.utoronto.ca

David Goertz is a Senior Scientist with the focused ultrasound group at the Sunnybrook Research Institute and Associate Professor in the Department of Medical Biophysics at the University of Toronto. He has a primary research interest in the use of FUS to potentiate the effects of anticancer agents such as chemotherapy and immunotherapy. In particular he has a focus on the development and control of cavitation-based methods to elicit therapeutically relevant bioeffects for cancer therapy.

Heather Gorby, PhD
Medical Writer
Gorby Consulting LLC, Washington, DC, USA
heather@gorbyconsulting.com

Dr. Gorby received her PhD from Stony Brook University followed by a postdoctoral fellowship at the National Institutes of Health, National Institute of Mental Health (NIH/NIMH) before pursuing medical writing full-time. She also worked as a medical writer (contract) for the National Institutes of Health, National Cancer Institute (NIH/NCI) for three years. As a medical writer she has written a variety of documents including clinical trial manuscripts, literature reviews, continuing medical education, and meeting summaries and white papers.

Holger Gruell, PhD
Professor
University Hospital of Cologne and University of Cologne, Cologne, Germany
holger.gruell@uk-koeln.de

Holger Gruell is professor at the department of Radiology at the University Hospital of Cologne as well as professor of Physical Chemistry at the University of Cologne. Currently he is responsible for the MR-HIFU research and its clinical translation at the University Hospital. His research is covering HIFU-induced drug delivery, hyperthermia, ablation as well as histotripsy with application in oncology but also bone treatment. Of special interest are the applications of HIFU for treatment of sarcomas and pancreatic cancer.

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Chandan Guha, PhD
Professor & Vice Chairman
Montefiore Medical Center, Bronx, NY, USA
cguha@montefiore.org

Dr. Guha has the expertise, leadership, training, expertise, and motivation necessary to successfully carry out the proposed research project. My research includes neuropsychological changes associated with addiction. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications.

Joe Guy
Research Specialist
University of Michigan, Ann Arbor, MI, USA
jlguy@med.umich.edu

I am a researcher in the laboratory of Clifford Cho at the University of Michigan. We work closely with Zhen Xu and her lab at U of M to develop therapeutic approaches for the treatment of various cancers, combining histotripsy and various immunotherapies.

Adriana Haimovitz-Friedman, PhD
Radiation Biologist
Memorial Sloan Kettering Cancer Center, New York, NY, USA
haimovia@mskcc.org

Dr. Haimovitz-Friedman studies the effects of radiation on both normal tissues and different tumor models focusing on tumor microenvironment and development of radiosensitizers. We are focusing on signal transduction pathways activated by radiation and their modulation to increase cell death within tumors while protecting the normal adjacent tissue. Recently, my Lab is working on radiation-induced innate immune responses in different mouse models +/- immune checkpoint blockade. Specialties: Basis and translational research; Endothelial cell apoptosis; Involvement of sphingolipids signaling apoptotic pathways in tumor cells.

Alayna Hay, PhD
Postdoctoral Research Associate
Virginia Tech Animal Cancer Care and Research Center, Blacksburg, VA, USA
anw5137@vt.edu

Dr. Hay is a postdoctoral research associate at the Virginia Tech Animal Cancer Care and Research Center. Currently, my research focuses on investigating the immune response associated with histotripsy treatment of primary bone tumors in canine osteosarcoma patients.

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Amy B Heimberger, MD, FAANS
Director of the MBTI
Northwestern University, Evanston, IL, USA
amy.heimberger@northwestern.edu

Amy B Heimberger, MD, FAANS, is the Jean Malnati Miller Professor of Neurological Surgery, Vice-Chair for Research in the Department of Neurological Surgery at Northwestern University and Scientific Director of The Malnati Brain Tumor Institute at the Robert H. Lurie Comprehensive Cancer Center. Her research program focuses on immune therapeutic strategies for patients with Central Nervous System (CNS) malignancies and she studies tumor-mediated mechanisms of immune suppression. She has been intricately involved in a wide variety of bench-to-bedside immune therapeutics, including those that were developed in her laboratory and arising from her own patents.

Joanna Hester, MD
University Research Lecturer
University of Oxford, Oxford, United Kingdom
joanna.hester@nds.ox.ac.uk

Joanna is a University Research Lecturer at the University of Oxford and jointly leads the Transplantation Research and Immunology Group at the Nuffield Department of Surgical Sciences. Her research interests span immune effects of therapeutic and experimental drug delivery devices, basic and cancer immunology as well as clinical trials. She is collaborating with Oxford's High Intensity Focused Ultrasound team on HIFU cancer clinical trials and Institute of Biomedical Engineering on preclinical projects.

Ryan Hubbard
PhD Student
University of Michigan, Ann Arbor, MI, USA
ryanhub@umich.edu

Mr. Hubbard is a PhD student in the histotripsy group at the University of Michigan and is researching histotripsy induced immune stimulation.

Kullervo Hynynen, PhD
Temerty Chair in Focused Ultrasound Research
Sunnybrook Research Institute, Toronto, ON, Canada
khynynen@sri.utoronto.ca

Dr. Hynynen's research has focused on studying the effects of ultrasound beams on tissue and their utilization in therapy. He is investigating the use of focused ultrasound for noninvasive surgery, vascular surgery, targeted drug delivery and gene therapy. He has developed theoretical models to help understand treatment parameters and to allow optimization of treatment devices. He has conducted in vivo experiments to investigate the various biological end points that can be induced by controlling the sonication parameters. His research on ultrasound transducers has been used to design and develop new phased array applicators and better ways to deliver therapy.

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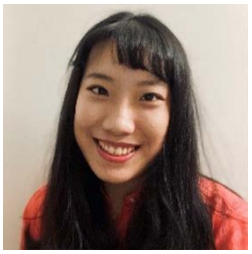
Keaton Jones
Clinical Lecturer
University of Oxford, Oxford, England
keaton.jones@nds.ox.ac.uk

Keaton Jones is a Resident in Hepatobiliary and Pancreatic Surgery at Oxford University Hospitals. He is also a Clinical Lecturer at the University of Oxford where his research focuses on characterizing the immune response to targeted therapies for pancreatic cancer.



Olive Jung
MD/PhD Candidate
NIH, Bethesda, MD, USA
olive.jung@nih.gov

NIH-Oxford Scholar, pre-doctoral fellow at National Institutes of Health, DPhil candidate at University of Oxford.

Hilary Keeley
Executive Director
The Sontag Foundation, Ponte Vedra Beach, FL, USA
hkeeley@sontagfoundation.org

As the Executive Director of The Sontag Foundation, Hilary oversees the development and execution of the strategic objectives of the Foundation. Hilary joined The Sontag Foundation from The Nemours Foundation where she served as Chief Legal Officer. Prior to this role, she served in various capacities within the United States Department of Health and Human Services including, Acting Chief of Staff of the Indian Health Service, a $6 billion integrated healthcare system, and as a Senior Attorney in the Public Health Division of the Office of the General Counsel.

Tatiana Khokhlova, PhD
Associate Professor
University of Washington, Seattle, WA, USA
tdk7@uw.edu

Dr. Tatiana Khokhlova is an Associate Professor of Research at the Department of Medicine, University of Washington. Her research interests lie in physics of ultrasound wave propagation and the associated bioeffects, primarily in therapeutic applications of focused ultrasound. Dr. Khokhlova's most recent work was targeted at the development of methods of soft tissue erosion and permeabilization by ultrasound-induced bubbles in the context of pancreas cancer and the investigation of the resulting systemic effects. She obtained her PhD degree in physics from M.V. Lomonosov Moscow State University in Moscow, Russia, followed by post-doctoral training at Applied Physics Lab, University of Washington.

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Cyril Lafon, PhD
Research Scientist
INSERM, Paris, France
cyril.lafon@inserm.fr

Cyril Lafon earned his Ph.D. degree in Biomedical Engineering from University Claude Bernard of Lyon, France, in 1999. After developing interstitial HIFU probes during his Ph.D. study in INSERM, he joined the University of Washington to work on ultrasound induced hemostasis and the development of tissue mimicking phantoms for HIFU. He was recruited by INSERM in 2002 as research scientist and became the director of LabTAU, INSERM Unit 1032 in 2016. His research interests focus on development of ultrasonic therapeutic devices for thermal ablation or drug delivery. Dr Lafon is the current President of the ISTU.

Theresa LaVallee, PhD
VP Translational Medicine & Regulatory Affairs
Parker Institute for Cancer Immunotherapy, San Francisco, CA, USA
tlavallee@parkerici.org

Theresa LaVallee has more than 20 years of industry experience with a broad knowledge and proven success in end-to-end discovery and development of drugs and diagnostics in the therapeutic areas of oncology and inflammation. Theresa is Vice President, Translational Medicine and Regulatory Affairs at the Parker Institute for Cancer Immunotherapy. She is author or co-author of more than 50 publications and abstracts with a focus on Translational Medicine approaches in clinical development. She received her Ph.D. degree from University of California, Los Angeles and her B.A. degree from the University of California, Santa Barbara.

Barbara Lavery
Chief Program Officer
Alliance for Cancer Gene Therapy, Stamford, CT, USA
blavery@acgtfoundation.org

Finding and funding life-changing opportunities to cure cancer, Ms. Lavery is guided by an inspired sense of appreciation for innovation. "Cell and gene therapies embrace an entirely new paradigm," says Ms. Lavery whose years of experiences with non-profit and for-profit organizations, government agencies, and academic institutions helped build her framework of knowledge in life sciences. "Since its inception, Alliance for Cancer Gene Therapy has led the way in recognizing and advancing revolutionary new ideas that really matter." As chief program officer, Ms. Lavery is responsible for programmatic initiatives, including leadership of the Academic Research Program and the Biotechnology Investment Program.

Suzanne LeBlang, MD
Director of Clinical Relationships
Focused Ultrasound Foundation, Boca Raton, FL, USA
sleblang@fusfoundation.org

With her prior clinical experience as a neuroradiologist and having performed hundreds of focused ultrasound procedures since 2004, Suzanne LeBlang, MD, now represents the Focused Ultrasound Foundation by interacting with various researchers, clinicians, and manufacturers to foster collaborations. She interfaces with the medical community at various meetings to update the Foundation staff. In coordination with the communications team, she helps increase awareness through oral presentations and articles. She also assists the Chairman and the development team with building relationships with individuals, other foundations, and non-profits. She has published papers and delivered numerous scientific talks in the field of focused ultrasound.

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Michael Lim
Professor
Stanford University School of Medicine, Stanford, CA, USA
mklim@stanford.edu

Dr. Michael Lim is a Professor and Chair of Neurosurgery at Stanford University. Dr. Lim's surgical interest is in both benign and malignant brain tumors. Dr. Lim's primary research interest is developing immune-based therapies against brain tumors. His research laboratory is focused on understanding the mechanisms of immune evasion by primary brain tumors. Findings from his laboratory are directed towards translation to novel therapies against brain tumors. In addition to running a laboratory, he currently serves as the principal investigator of several large brain tumor immunotherapy clinical trials based on findings from his laboratory.

Herbert Kim Lyerly, MD
Professor
Duke University, Durham, NC, USA
kim.lyerly@duke.edu

Dr. Lyerly is the George Barth Geller Professor of Cancer Research, Professor of Surgery, Pathology and Immunology, and former Director of the Comprehensive Cancer Center at Duke University in North Carolina. Dr. Lyerly is internationally recognized expert in cancer therapy and immunotherapy and has published over 300 scientific articles and book chapters, and has edited 10 textbooks on surgery, cancer immunotherapy, and cancer therapies. He has co-founded biotechnology companies Argos, Replicate and SONOKINE, as serves as a member of the Board of Directors for Oncosec. He was appointed by President George Bush to serve on the National Cancer Advisory Board.

Subha Maruvada, MD
Acoustics Research Engineer
U.S. Food and Drug Administration, Silver Spring, MD, USA
subha.maruvada@fda.hhs.gov

Dr. Maruvada is the lead for the Therapeutic Ultrasound Program in the Division of Applied Mechanics which is a part of the Office of Science and Engineering Laboratories. Her current areas of research are pre-clinical characterization of high-intensity therapeutic ultrasound (HITU) devices, characterization of tissue-mimicking materials for HITU applications, HITU-induced bioeffects, and comparison of acoustics measurements to modeling results. Dr. Maruvada is active in scientific and standards organizations. She serves as Working Group Convener, primary liaison, and technical expert on several working groups within IEC TC 87. She is the current Vice President Elect of the Acoustical Society of America.

Nathan McDannold, PhD
Professor
Brigham and Women's Hospital, Boston, MA, USA
njm@bwh.harvard.edu

Dr. McDannold is a Physicist in Radiology Department at Brigham and Women's Hospital and the Director of the Focused Ultrasound Laboratory. His work has been primarily concerned with the development and implementation of targeted drug delivery, ablation, and other focused ultrasound therapies, and methods to guide and monitor these therapies. He has also worked on clinical implementation of focused ultrasound.

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Reliza McGinnis, BS
Graduate Student
University of Michigan, Ann Arbor, MI, USA
remcginn@umich.edu

2nd year PhD student interested in studying the effects of Histotripsy focused ultrasound therapy on the tumor microenvironment and optimizing treatment parameters for maximizing the observed immune response.

Tim Meakem, MD
Chief Medical Officer
Focused Ultrasound Foundation, Charlottesville, VA, USA
tmeakem@fusfoundation.org

Tim Meakem, MD, joined the Foundation in 2016 as Chief Medical Officer. He helps cultivate relationships with key physicians and health system leaders as well as oversees the growing number of research projects the Foundation is supporting at leading academic research institutions around the world. Prior to joining the Foundation, Tim was also the CEO of a contract research organization and then the CMO of a medical device company.

Chrit Moonen, PhD
Professor
University Medical Center Utrecht, Utrecht, Netherlands
C.Moonen@umcutrecht.nl

Chrit Moonen did his PhD in biophysics at Wageningen, a postdoc at the Univ Oxford. He was Visiting Scientist at Univ Davis, became head of the NIH In Vivo NMR Research Center from 1987-1996, and director of the laboratory "Molecular and Functional Imaging" at Bordeaux until 2011. He is currently professor at Utrecht, the Netherlands. He was President of the ISMRM (2006), the SMI (2009), and ESMI (2016). He received the European Magnetic Resonance Award (2000) and the Fry Award of the International Society for Therapeutic Ultrasound (2019).

Petros Mouratidis, PhD
Research Scientist
The Institute of Cancer Research, London, United Kingdom
petros.mouratidis@icr.ac.uk

Petros received his PhD in cancer cell biology from St. George's Hospital Medical School University of London, where he investigated the cytotoxic effects of small molecules including thalidomide and vitamin analogues in pancreatic cancer. In 2013 he was recruited in the group of Prof Gail ter Haar to work on the biological effects of focused ultrasound on cancer. He investigated the activation of apoptosis and autophagy and has demonstrated that hyperthermia synergises with HSP90 inhibition to kill colon cancer cells. Petros's most recent focus has been the investigation of the immunological effects of focused ultrasound in pancreatic cancer.

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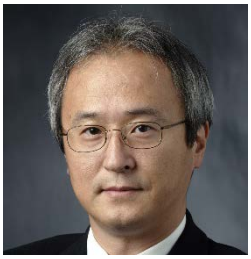
Jill ODonnell-Tormey, PhD
CEO and Director of Scientific Affairs
Cancer Research Institute, New York, NY, USA
jtormey@canceresearch.org

Dr. Jill O'Donnell-Tormey is the CEO and Director of Scientific Affairs at the Cancer Research Institute (CRI), a global nonprofit organization whose mission is to save more lives by fueling the discovery and development of powerful immunotherapies for all types of cancer. Prior to joining CRI, she was a postdoctoral fellow in the laboratory of cellular physiology and immunology at The Rockefeller University and a research associate in the Department of Medicine at Cornell University Medical College. She received a B.S. in chemistry, summa cum laude, from Fairleigh Dickinson University, and a Ph.D. in cell biology from the SUNY Downstate.



Takuya Osada, MD, PhD
Associate Professor of Surgery
Duke University, Durham, NC, USA
takuya.osada@duke.edu

Dr. Osada has extensive research experience in cancer immunology/immunotherapy and local therapy. Dr.Osada's recent study focuses on induction of systemic antitumor immunity by local therapies, including mechanical High Intensity Focused Ultrasound therapy, Hsp90-targeted photodynamic therapy (PDT) and intratumoral IL-12 gene therapy. His studies demonstrated the induction of potent local/systemic antitumor immunity by these local therapies, and enhanced antitumor efficacy against distant tumors when combined with immune checkpoint inhibitors. Currently, Dr. Osada and his colleagues are conducting a clinical trial of Hsp90-targeting photosensitizer for breast and prostate cancers at Duke University, planning to test PDT in the near future.

Frédéric Padilla, PhD
Director of Applied Physics Research
Focused Ultrasound Foundation, Charlottesville, VA, USA
fpadilla@fusfoundation.org

Frédéric Padilla, PhD, was trained as a physicist and an electrical engineer. He joined the FUS Foundation in 2017, first as a Merkin Fellow, and is now its Director for Applied Physics Research. Previously, he was a faculty at the French National Center for Scientific Research (CNRS). Frederic is a Fulbright Fellow. His research agenda currently mainly focuses on the activation of anti-cancer immune response by combination of therapeutic ultrasound and immunotherapies, in various preclinical tumor models including pancreas and breast. He is also involved in a clinical trial on immune monitoring in patients following FUS thermal ablation of prostate cancer.

Lauren Powlovich, MD
Associate Chief Medical Officer
Focused Ultrasound Foundation, Charlottesville, VA, USA
lpowlovich@fusfoundation.org

Lauren Powlovich, MD, joined the Foundation in March 2019 and serves as Associate Chief Medical Officer. Since joining the Foundation, she has become a passionate advocate of Focused Ultrasound technology. Her role includes outreach, education, and oversight of specific research initiatives within the Foundation, including pain, pediatrics, sonodynamic therapy and lung cancer. Lauren previously worked at the University of Virginia as a resident Anesthesiologist. She graduated from the University of Vermont with a BA in Biology and later received her MD from the Larner College of Medicine at The University of Vermont.

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Richard J. Price, PhD
Professor Biomedical Engineering
University of Virginia, Charlottesville, VA, USA
rprice@virginia.edu

Richard J. Price, PhD, is the Lawrence R. Quarles Endowed Chair Professor of Biomedical Engineering at the University of Virginia (UVa). He is also Research Director of the UVa Focused Ultrasound Center. Dr. Price studies how focused ultrasound can synergize with immunotherapies. His research supports UVa clinical trials for multiple cancer indications (NCT04796220, NCT03237572 and NCT04116320). He has received the Andrew J. Lockhart Memorial Award from the FUS Foundation and the Jorge Heller Award from the Controlled Release Society. He is a Fellow of AIMBE and the Controlled Release Society, and he serves on the ISTU Board of Directors.

Ashish Ranjan, BVSc, PhD
Professor and Director
Oklahoma State University, Stillwater, OK, USA
ashish.ranjan@okstate.edu

Dr. Ranjan is an Endowed Professor in the College of Veterinary Medicine at Oklahoma State University (OSU). He also serves as the Director of the Institute for Translational and Emerging Research in Advance Comparative Therapy (INTERACT). INTERACT leads one-health research at OSU. He was professionally trained at Virginia Tech and the National Institutes of Health (NIH) on nanomedicines and their application in combination with focused ultrasound (FUS) for therapy of solid tumors and infectious diseases. His lab is focused on developing FUS based chemo-immunotherapy approaches mainly against melanoma and head and neck cancer and is running several veterinary clinical trials.

Srikanth Reddy MBBS FRCS (Gen Surg) PhD
Consultant Hepatopancreaticobiliary and Transplant Surgeon
Oxford University, Oxford, United Kingdom
srikanth.reddy@ouh.nhs.uk

Srikanth Reddy was appointed as Consultant Hepatopancreaticobiliary and Transplant Surgeon at Oxford in 2010. He trained in Oxford and Birmingham in General, Hepatopancreaticobiliary and Transplant Surgery. He did three years of research in Oxford and obtained a PhD in normothermic perfusion for organ preservation in liver transplantation. He is lead for Clinical Governance in the Transplant Division, where his role is to ensure safe clinical practice. His research interests include strategies to reduce ischaemia reperfusion injury in liver, pancreas, and kidneys.

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Elizabeth Repasky, PhD
Professor, Department of Immunology
Roswell Park Comprehensive Cancer Institute
Elizabeth.Repasky@RoswellPark.org

Dr. Elizabeth Repasky is a Distinguished Member of Roswell Park Comprehensive Cancer Center, and Professor of Oncology, the William Huebsch Professor of Immunology, and Program Leader for the Cell Stress and Biophysical Therapies Program. She is originally from Western Pennsylvania, graduating from Seton Hill University with a BA in Biology. She received her PhD from SUNY Buffalo and did a postdoctoral fellowship in cell biology at the California Institute of Technology. Dr. Repasky's research program focuses on exploration of stress and its physiological and immunological consequences so that we can better understand how to manipulate stress to improve the efficacy of cancer therapies, including radiation, chemotherapies, and immunotherapies. A major passion for her has been her research in the area of thermal stress, and the impact of thermoregulation on the on the anti-tumor immune response. This interest has led her to new research projects in the lab focusing on understanding why patients with cancer often "feel cold" despite having a normal core body temperature and the impact of thermal stress on metabolism and anti-tumor immunity. Dr. Repasky is a 2015 awardee of the J. Eugene Robinson Award from the Society for Thermal Medicine (STM) and the STM 2018 William C Dewey Award. She is a Section Editor for the International Journal of Hyperthermia and an Associate Editor for the Journal of Immunology. During her career, she has authored or co-authored over 200 research publications and has received longstanding support from the NIH. Training and mentorship have been very important to her during her career, and she has served as major advisor to 24 PhD students and 12 Postdoctoral Fellows, nearly all of whom have gone on to become successful members of the research, academia, or bio-tech communities.

Jocelyne Rivera, BS
PhD trainee
National Institutes of Health
jocelyne.rivera@nih.gov

My name is Jocelyne Rivera. I graduated Summa Cum Laude from University of Arizona BS in Biomedical Engineering in May 2021. Furthermore, I applied for and was selected as a PhD trainee in the NIH Oxford-Cambridge Scholars Program. As a NIH-Oxford Scholar, I intend to accelerate the development of accessible diagnostics, treatments, and cures for the most devastating diseases facing humanity.

Jia-Ling Ruan, PhD
Postdoc
University of Oxford, Oxford, United Kingdom
jia-ling.ruan@oncology.ox.ac.uk

Jia-Ling Ruan is a postdoctoral researcher at the Department of Oncology, and also a junior research fellow at the Kellogg College, University of Oxford. As a bioengineer, she is interested in tackling human diseases using bioengineering approaches. Her research in Oxford focuses on optimising cancer radiotherapy by smart drug delivery and modelling radiation-induced damage by organoids and tissue engineering.

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Naren T Sanghvi, MSEE
Chief Scientific Officer
Sonablate Corporation, Charlotte, NC, USA
narensanghvi@sonablate.com

Mr. Naren Sanghvi is Chief Scientific Officer for Sonablate Corp. (AKA - SonaCare Medical and Focus Surgery, Inc.) He is a developer of the Sonablate HIFU system used for the treatment of BPH and prostate cancer in over 49 countries. Mr. Sanghvi is a recipient of Fry Award (ISTU-2018) and Visionary Award (FUF-2018). He has published over 150 papers and holds over 30 patents in the field of medical ultrasound.

John Schiller
NIH Distinguished Investigator
National Cancer Institute, National Institutes of Health, Bethesda, MD, USA
schillej@mail.com

In his 35 years at the NCI, Dr. Schiller has studied various aspects of papillomavirus molecular biology, immunology, and epidemiology. The laboratory co-directed by Dr. Schiller led in the discovery, characterization, and clinical testing of virus-like particle (VLP) vaccines to prevent the HPV infections that cause cervical and other cancers. His current interests include developing tumor-tropic HPV VLP/drug conjugates whose tumoricidal potential is activated locally by light or ultrasound. In collaboration with Aura BioSciences, he developed HPV VLP/infrared dye conjugates for treatment of solid tumors that have successfully completed phase II clinical trials targeting ocular melanoma.

Natasha D. Sheybani, PhD
Postdoctoral Fellow, Senior Scientist
Stanford University, Focused Ultrasound Foundation, Stanford, CA, USA
sheybani@stanford.edu

Natasha Sheybani, PhD, is a Postdoctoral Research Fellow in Oncology, Radiology, and Biomedical Data Science at Stanford University focusing on applications of radiomics/radio genomics for precision immuno-oncology. Dr. Sheybani received her BS (2015) and PhD (2020) in Biomedical Engineering from Virginia Commonwealth University and University of Virginia, respectively. Her dissertation explored immuno-oncology applications of FUS, specifically in glioblastoma and breast cancer. Dr. Sheybani was previously supported by the NSF GRFP and Wagner Fellowship, and currently holds the NCI F99/K00 Award. As Senior Scientist at the FUS Foundation, she supports research programs in glioblastoma and immuno-oncology and directs the gene therapy program.

Kritika Singh
PhD Student
University of Oxford, Oxford, United Kingdom
kritika.singh@magd.ox.ac.uk

Kritika Singh is a DPhil student jointly between the National Cancer Institute at the NIH and the University of Oxford. She is mentored by Dr. John Schiller (NCI), Dr. Eleanor Stride (Oxford), Dr. Udo Oppermann (Oxford), and Dr. Ralph Mazitschek (Harvard) and funded through the Rhodes Trust and the NIH Oxford-Cambridge Scholars Program. Her work focuses on developing therapies that can be widely adapted in high- and low-resource settings. After her DPhil, Kritika plans to go to medical school in the US and pursue a career at the intersection of biomedical research, clinical practice, and health policy.

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Karijn Suijkerbuijk
Medical Oncologist
UMC Utrecht, Utrecht, Netherlands
K.Suijkerbuijk@umcutrecht.nl

Karijn Suijkerbuijk is associate professor and medical oncologist with expertise in immunotherapy and melanoma treatment at the UMC Utrecht Cancer Center. As a clinician, she treats advanced melanoma patients and coordinates melanoma care within the UMC Utrecht and surrounding hospitals. She is clinical coordinator of the immunotherapy network within the UMC Utrecht. Dr Suijkerbuijk is scientific chair of the Dutch Melanoma Treatment Registry (DMTR) that prospectively registers clinical data from all advanced melanoma patients in the Netherlands. She is project leader of multiple multicenter clinical and translational immunotherapy projects and has authored numerous high-impact publications in this field.

Naoko Takebe
Associate Chief, DTC
NCI, NIH, Bethesda, MD, USA
Takeben@mail.nih.gov

I specialize in experimental therapeutics in oncology.

Gail ter Haar
Team Leader
The Institute of Cancer Research, London, United Kingdom
supadhaya@cancerresearch.org

Medical physicist specializing in therapeutic ultrasound, at both pre-clinical and clinical levels.

Kelsie Timbie, PhD
Program Director
Focused Ultrasound Foundation, Charlottesville, VA, USA
ktimbie@fusfoundation.org

Kelsie Timbie, PhD joined the Foundation in 2015. As the Scientific Programs Manager, she is responsible for developing and guiding research projects that address critical unmet needs. As the Director of the Veterinary Program, she is responsible for guiding and developing the scope of the program. She is also involved in managing the research portfolios of the Cancer Immunotherapy and Brain Programs here at the Foundation, as her extensive research experience in brain and cancer applications for focused ultrasound provides her with particular insight in these areas.

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Caitlin Tydings, MD
Research Associate
Children's National Hospital, Washington, DC, USA
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Dr. Tydings is a recent graduate of her pediatric hematology/oncology fellowship, and her research interests include the development of novel therapeutics and combined therapies for both benign and malignant pediatric solid tumors. Dr. Tydings' primary research is in the development of novel applications for magnetic resonance-guided high intensity focused ultrasound (MR-HIFU) and defining evaluations for treatment effects for patients treated with MR-HIFU. In her role as Research Associate, she will continue focusing on the development of MR-HIFU ablation and mechanical histotripsy as an immune modulator and enhancer in combination with immune check point inhibitors in pediatric cancer models.

Samik Upadhaya, PhD
Assistant Director of Scientific Affairs
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Samik Upadhaya, Ph.D., is the assistant director of scientific affairs at the Cancer Research Institute. Together with the Anna-Maria Kellen Clinical Accelerator team, he leads the program's scientific diligence efforts, including analyses of emerging trends and challenges in the global cancer immunotherapy landscape. He assists in the team's collaborative ventures, clinical trial design, drug development plan, and maintenance of immuno-oncology landscape databases. He is also involved in all of CRI's research programs, and closely follows the research done by CRI grantees, evaluating their potential contributions to the field as a whole.

Joan Vidal-Jove, MD, PhD
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Joan Vidal-Jove is a surgical and interventional oncologist of the Comprehensive Tumor Center Barcelona and the Institute Khuab for Interventional Oncology. In 2010, he learns the fundamentals of the Ablation of Tumors by Focused Ultrasound and leads the first oncological FUS-HIFU Unit of his country. Since then, he has performed more than 200 oncological cases with Focused Ultrasound and lead clinical research, with special attention to pancreatic and liver tumors. He was the PI of the First in Human Study of Histotripsy in Liver Tumors where he has researched the abscopal immune effect.

Eli Vlaisavljevich, PhD
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Dr. Vlaisavljevich is an Assistant Professor of Biomedical Engineering and Mechanics at Virginia Polytechnic Institute and State University. His research interests include focused ultrasound, non-invasive tissue ablation (HIFU, histotripsy), cavitation physics, nanoparticle-mediated histotripsy (NMH), biomaterials, tissue regeneration, cancer, non-invasive neuromodulation, and clinical translation. Prior to joining Virginia Tech, Dr. Vlaisavljevich conducted his graduate degrees in the Histotripsy Lab at the University of Michigan (2010-2015) and then spent two years working at HistoSonics (2015-2017) on the development of histotripsy for the treatment of liver cancer. More information about Dr. Vlaisavljevich's research group can be found at https://ultrasound-lab.beam.vt.edu/.

Workshop Attendees

as of Friday, 27 August 2021

Suhe Wang, MD, PhD
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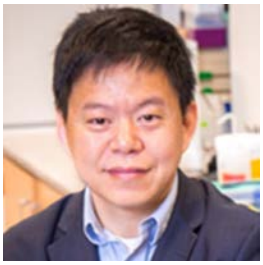
Su He Wang obtained her MD and PhD from Fujian Medical University and the University of Strathclyde, respectively. Dr. Wang completed her post-doctoral training at London King's College School of Medicine, and University of Michigan. Currently Dr. Wang works as an associate professor at the University of Michigan Medical School. Her main research interest is the application of Nanomedicine to vaccine and cancer immunotherapy. Her research has been widely published and supported by DOD, NIH, and US Thyroid Research Council.



Peter Yingxiao Wang, PhD
Professor
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Dr. Wang obtained his bachelor's and master's degrees in Mechanics and Fluid Mechanics from Peking University, P.R. China, in 1992 and 1996, respectively. He received his Ph.D. degree in Bioengineering from the University of California, San Diego (UCSD) in 2002 and continued his postdoctoral work under Professors Shu Chien and Roger Y. Tsien. He is a professor in Bioengineering at UCSD and a fellow of American Institute of Medical and Biological Engineering (AIMBE). Dr. Wang is the recipient of the Wallace H. Coulter Early Career Award, the National Science Foundation CAREER Award, and National Institutes of Health Independent Scientist Award.

Emily C. Whipple, PhD, MBA
Director of Strategic Initiatives
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Emily Whipple joined the Foundation as Director of Strategic Initiatives in 2018. She has over thirteen years of operations, project management, and customer relationship experience in an entrepreneurial environment from early-stage venture funding through acquisition. Prior to joining the Foundation, Emily served as the Vice President of Business Development and Operations for AMPEL BioSolutions. At the Focused Ultrasound Foundation, she works to help develop and implement projects and programs that support the mission of the Foundation to promote the advancement and adoption of focused ultrasound. She holds a BS degree in Molecular Biology from Cornell University as well as an MS and PhD in Biochemistry, Molecular Biology, and Genetics from the University of Virginia. She also holds an MBA from the Darden Graduate School of Business Administration.

Emily White, MD
Director of Operations, Managing Director of FUS Partners
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Emily White, MD joined FUSF in 2016 as Director of Operations. Prior, Dr. White was a private consultant working in operations and business development in healthcare and medical start-ups. Her background includes general surgery, leadership positions in technical start-up companies with federal clients, non-profit executive management, and grant writing. She holds a BA from Smith College, certification for Community Conflict Resolution from Loyola Law School, and is a University of Virginia School of Medicine graduate. In 2018, Emily expanded her role, becoming Managing Director of FUS Partners, which helps the FUS industry's commercialization efforts.

Workshop Attendees

as of Friday, 27 August 2021

Bradford J. Wood, MD
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Dr. Wood is the founding Director of the NIH Center for Interventional Oncology, which translates technologies and paradigms for first-in-human treatments for cancer and cultivates interventional radiology applications within a multi-disciplinary framework, to apply biomedical engineering to meet real-life unmet clinical needs. His team's achievements include helping to pioneer several technologies from concept to bench to patient, and was first-in-human; for the following device/drug combinations: prostate cancer MRI/TRUS fusion biopsy and ablation, image-able iodinated drug eluting beads for chemoembolization of liver tumors, kidney cancer ablation, adrenal cancer ablation, heat-deployed nanoparticle chemotherapy with thermal ablation for liver cancer, electromagnetic tracking for fusion of ultrasound to CT, MR, and PET, and fusion for biopsy and ablation.

Tejaswi Worlikar, MS, MSE
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Tejaswi Worlikar is currently a Ph.D. Candidate in the Department of Biomedical Engineering at the University of Michigan, Ann Arbor, MI. She received the M.S.E. degree in Electrical Engineering: Systems and M.S. degree in Biomedical Engineering from the University of Michigan in 2014. Her current research interests include developing therapeutic ultrasound for tumor ablation, immunomodulation, and image processing.

Cheng-Chia Wu, MD, PhD
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Dr. Wu is a pediatric radiation oncologist with an interest in drug delivery for pediatric brain tumors. We are interested it combining radiation therapy with focused ultrasound and drug delivery to improve outcomes. We are also examining the immune modulatory effects of radiation and focused ultrasound on the tumor microenvironment.

Feng Wu, MD, PhD
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Professor Feng Wu began his research career in HIFU therapy in 1988. He developed his own clinical prototype HIFU device in China, with his work largely dedicated to clinical trials for treating patients with solid tumors. In 2002, he moved to UK to establish the first HIFU Unit for clinical trials in Oxford University Hospitals. He is currently working as HIFU Consultant at Oxford University Hospitals and Senior Clinical Scientist at University of Oxford. He has published more than 200 articles in peer-reviewed journals and received William and Francis Fry Award in 2013 for his outstanding contributions to therapeutic ultrasound.

Workshop Attendees

as of Friday, 27 August 2021

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Zhen Xu is a Professor of Biomedical Engineering at the University of Michigan. Her research focuses on ultrasound therapy, and she is a pioneer in developing histotripsy. She received the IEEE UFFC Outstanding Paper Award in 2006, Federic Lizzi Early Career Award from The International Society of Therapeutic Ultrasound (ISTU) in 2015, the Fellow of American Institute of Medicine and Bioengineering in 2019, and The Lockhart Memorial Prize for Cancer Research in 2020. She is an associate editor for IEEE Transactions on UFFC and Frontiers in Bioengineering and Biotechnology, VP of IEEE Ultrasonics, and an elected board member of ISTU.

Sin Yuin Yeo, PhD
Clinical Product Expert/Clinical Scientist
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Dr. Sin Yuin Yeo has a background in Biomedical Engineering and has more than 10 years of experience in MR-HIFU translation research and supporting clinical MR-HIFU treatments, such as uterine fibroids, bone metastases, osteoid osteoma, and desmoid tumors. She has experience working in both industry and academia, and is driving multidisciplinary research involving the department of radiology, orthopedics, gynecology, radiation oncology, immunology and experimental medicine. Her current work focuses on preclinical and clinical assessment of MR-HIFU for palliation of osteoarthritis pain and pancreatic cancer treatment.

Eyal Zadicario, PhD
COO & GM
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Chief Operating Officer for INSIGHTEC with over 20 years in development of Focused Ultrasound technology.

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Guiding Questions

Immune Effects by FUS Modality

- What are the immune effects of thermal vs. mechanical modalities? Can these effects be modulated (partial ablation, etc.)? Are these findings consistent across tumor types?
- How does the immune response to FUS compare to other modalities (radiation, etc.)? How might FUS synergize with other modalities?
- Is there a rationale for combining different FUS modalities? At what point do combination therapies (multiple modalities) lose translational potential?
- What projects/knowledge gaps are critical for moving forward?

Immune Effects by Tumor Types

- What do we know about the responses of different tumor types to FUS?
- Brain v. periphery: are there different components of the response to FUS?
- What can we sort the responses in terms of "cold" v. "hot" tumors?
- What can/should be compared across tumor types & studies? What are the constrains to these comparisons? (Immune guidelines, leveraging 'core labs'… to be developed also on day 2)
- Should we set-up more consortium projects (brain, pancreas)? For what tumors?
- What constitutes a translationally relevant study - to ensure that preclinical findings occur outside of the typical model organisms
- What projects are critical for moving forward?

Clinical Disease Targets

- What clinical disease targets are ideal for focused ultrasound plus immunotherapy combinations?
- What do we know about the role of different "modes" of FUS clinically?
- What are strategies to consider for FUS treatment of the tumor – e.g., treating entire tumor, treating primary tumor vs metastasis?
- What elements of trial design are critical to include in all FUS – IO clinical trials?
- What projects are critical for moving forward?
- What role for FUS: tumor debulking vs. immune modulation vs. drug delivery? enhance response rate to IO in partially sensitive cancers? Transform "cold" into "hot" tumors? Enhance immunotherapy delivery? …

Guiding Questions

Optimizing FUS for Immunomodulation

- How should we envision the role of FUS in immune-oncology – as a drug adjuvant, replacement, or delivery system; an immune primer; a debulking method? Does this vary by mechanism or tumor type?
- Does the timing of FUS treatment depend on mechanism? How so?
- At what point do combination therapies (FUS + drug) lose translational potential?
- Based on the existing data regarding FUS-induced immune response, what are the most logical drug targets for combination therapy? How does this vary by mechanism or tumor type?
- What projects/knowledge gaps are critical for moving forward?

Role for FUS in Therapeutic Delivery

- What immunotherapies have emerged as the strongest candidates for delivery with FUS?
- What are the chief 'delivery' challenges posed by different tumor types (e.g., stroma, BBB, sparsity of immune cells, etc.) and where can the known FUS MOAs plug in to help potentiate therapeutic delivery in these settings?
- What are the key experimental/technical parameters that need to be systematically assessed in an effort to improve or optimize FUS therapeutic delivery?
- Which animal models are most appropriate for studying questions related to FUS therapeutic delivery? How do the considerations change for different classes of immunotherapy / adjuvant?
- What are the outstanding challenges with novel immunotherapies (e.g., CAR T, gene therapy) that FUS can help to address?
- What endpoints or monitoring strategies should we be using to evaluate the effectiveness of FUS in aiding therapeutic delivery? Pre-clinical? Clinical?
- What projects / knowledge gaps need to be fulfilled to move the field forward?

Metrics to Predict Clinical Success

- What should be endpoints for FUS / IO clinical trials?
- What can we learn, biomarkers/toolkits…, from other ablative treatment modalities?
- What metrics can be used to predict clinical success (T cell ratios, etc.)? is it tumor type-dependent?
- What role for FUS: enhance response rate to IO in partially sensitive cancers? Transform "cold" into "hot" tumors?
- What timing for immune monitoring in FUS studies?
- Do we need biopsies in all cases, or can blood samples reliably predict response?
- What is the role of imaging for immune monitoring in FUS studies?
- What projects are critical for moving forward?

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