

Sixth Global Summit
PRECISION DIAGNOSIS AND TREATMENT OF PROSTATE CANCER

SAVE THE DATES
SEPTEMBER 22-24, 2022

Creating the Future of Patient Care

GLOBAL SUMMIT AND BRAIN TRUST ON PRECISION DIAGNOSIS AND TREATMENT OF PROSTATE CANCER:

Overview, Background and Current Plans

(Updated March 23, 2023)

I. Annual Global Summit and Brain Trust on Precision Diagnosis and Treatment for Prostate Cancer (PC) and their Impact (2016-2022); and

II. Recap and Highlights of the Summit 2022 and Planning for the 7th Global Summit Scheduled for September 21-23, 2023, Boston

[AdMeTech Foundation's Annual Global Summit and Brain Trust on Precision Diagnosis for PC took place starting in September 2016](#) and brought together – for the first time - the key international opinion leaders of every clinical subspecialty involved in patient care to bridge the gap between in-vivo imaging, in-vitro diagnostics (liquid and tissue biomarkers) and novel therapeutics.

This program has become seminal in shaping the state of the art and future vision for precision care by:

- 1) Educating the key healthcare stakeholders;
- 2) Creating and supporting a sustained cross-disciplinary dialogue and consensus on the best emerging clinical practices and research priorities; and
- 3) Expediting clinical adoption of promising novel diagnostics and therapeutics.

Our public Summit has been integrated with a private Brain Trust and recognized as one of the most influential educational and strategic efforts in prostate cancer for stimulating development and implementation of a comprehensive, multimodality approach to diagnostic patient evaluation and its integration with precision treatment.

In addition to stimulating new groundbreaking ideas and collaborations, this program has had extensive participation from the members of the professional and non-profit organizations playing a central role in:

- 1) Developing clinical guidelines for patient care (e.g., National Comprehensive Cancer Network, AUA, American College of Radiology, ASTRO, ASCO, European Association of Urology, AUA, etc.); and
- 2) Creating national and global scientific strategy and related infrastructure (e.g., VP Joe Biden's 1.8 billion Cancer Moonshot Program, National Cancer Institute, Prostate Cancer Foundation, Movember Foundation, etc.).

Brain Trust on Precision Diagnostics and Therapeutics, established following the First Summit, was convened in February and May 2017, October 2017, August 2018, October 2019, October 2020, September 2021 and September 2022. This program included the key leaders of national and international programs in precision biomarkers, imaging and therapeutics from academia, industry, government and non-profit organizations.

Our Brain Trust participants are the key pioneers and opinion leaders of multiple clinical disciplines (radiology, urology, radiation oncology, pathology and medical oncology), including, but not limited to:

1. Dr. Gerald Andriole, University of Washington, St. Louis;
2. Drs. Wassim Abida, Sigrid Carlsson, Amita Dave, Hedvig Hricak, Steve Larson, Michael Morris, Howard Scher, Andrew Vickers and Michael Zelefsky, Memorial Sloan Kettering Cancer Center;

3. Drs. Jelle Barentsz and Jurgen Futterer, Nijmegen/Radboud University, The Netherlands;
4. Drs. Matthew Cooperberg, Mack Roach, Thomas Hope, Antonio Westphalen and Susan Noworolski, UCSF;
5. Dr. David Crawford, University of California, San Diego;
6. Drs. Angelo DeMarzo, Martin Pomper, Daniel Song and Steven Rowe of Johns Hopkins;
7. Drs. Masoom Haider, Sanjeet Ghai and Laurence Klotz, University of Toronto, Canada;
8. Drs. Ashesh Jani, David Schuster, Christopher Filson and Mehrdad Alemozaffar, Emory University;
9. Drs. Adam Kibel, Clare Tempany, Marc Garnick, Christopher Sweeney, Jason Efstathiou, Adam Feldman, Heather Jacene and Quoc Dean Trinh, Harvard Medical School;
10. Drs. Richard Babayan, Mark Katz and Jennifer Rider, Boston University;
11. Dr. Eric Klein of Cleveland Clinic;
12. Drs. Neil Bander, James Hu, David Margolis and David Nanus of Cornell Weill/Columbia;
13. Dr. Peter Nelson, Washington University;
14. Drs. Daniel Petrylak, Preston Sprenkle and Jeffrey Weinreb, Yale;
15. Drs. Alan Pollack, Sanoj Punnen and Radka Stoyanova, University of Miami;
16. Dr. Peter Albers (Germany) and Dr. Arnulf Stenzl (Germany) – European Association of Urology;
17. Dr. Thomas Wheeler, Baylor College of Medicine.
18. Dr. Wolfgang Weber, Technical University of Munich, Germany;
19. Drs. Paul Boutros, Robert Reiter and Steven Raman, UCLA;
20. Dr. Ethan Halpern, Jefferson University;
21. Dr. Liang Wang, Beijing Friendship Hospital, China
22. Dr. Mitchell Sokoloff, University of Massachusetts;
23. Drs. Sadhna Verma, University of Cincinnati;
24. Dr. Aytakin Oto, University of Chicago;
25. Dr. Philip Koo, Banner MD Anderson Cancer Center;
26. Drs. Peter Choyke, Peter Pinto and Baris Turkbey, National Cancer Institute;
27. Drs. Edward Schaeffer and Adam Murphy, Northwestern University;
28. Dr. Kelvin Moses, Vanderbilt University Medical Center.

- 2) Drs. Kibel, Moses, Nelson, Roach, Schaeffer, Sprenkle, Vickers and others are members of the National Cancer Comprehensive Network's (NCCN) Panels on Prostate Cancer Detection and Treatment, developing the cutting-edge clinical guidelines for patient care;
- 3) Drs. Choyke, Pinto, Siddiqui, Turkbey, and Summit Chair Dr. Faina Shtern of the AdMeTech Foundation participate in the US VP Joseph Biden's \$1.8 Billion Cancer Moonshot Program, developing national strategy for cancer research and related infrastructure; and
- 4) Dr. Mark Buzza, former Director of Global Biomedical Research Programs for Movember Foundation (headquartered in Australia) led international scientific strategy, with specific interest in advanced PC.

The goal of the Brain Trust is to review the current and emerging data in imaging, fluid-based molecular diagnostics, tissue-based genomics, radiogenomics and proteomics, drug development and novel approaches to treatment and observation strategies, and reach consensus on the best emerging clinical practices and priority needs in research, medical education, clinical training and public awareness². Our primary goal is to outline clinical, research and educational priorities, including statistically powered pilot studies on clinical role of radiogenomics in patient selection for appropriate care (observation strategy, image-targeted minimally invasive, whole gland or systemic treatment).

[Annual Global Summit](#) has emerged as the seminal scientific and educational event in recognizing integrated diagnostics, such as radiogenomics and multiomics, as the future of PC care. The program of these events, which took place in each year since 2016, was structured to review recent clinical advances and related scientific data in radiomics (quantitative imaging) and molecular diagnostics (including genomics) and their integration into radiogenomics that has been making a transformational impact on patient selection for, design and monitoring of clinical interventions (e.g., biopsy and management strategy). This event has played a central role in shifting the emerging field of radiogenomics from the scientific fringe to the central role in the discussions on the current state of the art and future vision for precision care. More recently, we have seen the emerging value of broader "multiomics"- including proteomics, advanced pathology (e.g., immunohistochemistry), and other anatomic, histologic and biologic tools. Summit 2023 will have the first panel dedicated to multiomics.

Virtual 6th Global Summit of 2022 and Plans for 7th Virtual Summit 2023: Summit 2022 took place on September 22-24, 2022. Building on the success between 2016 and 2021, Summit 2022 had over 200 registrants, representing every key clinical expertise and expanding a cross-disciplinary dialogue.

Over 50 presentations and top three winning abstracts have been published by Grand Rounds in Urology (GRU), reaching over 15,000 multi-disciplinary genito-urinary experts (primarily urologists, radiation and medical oncologists). Together with AdMeTech Foundation, focusing on imaging experts, more than 21,000 physicians have been reached. Urology Today covered Summit 2022 extensively, reaching over 35,000 physicians globally.

Summit 2022 review and highlights were requested to be presented to the National Cancer Institute in November 2022 and the Annual International Prostate Cancer Update in January 2023.

Pre-Summit 2022 press release was picked up by major news media, reaching well over 100 million people globally.

The Summit 2022 was held virtually, and the participants provided the following feedback:

- 1) High quality of speakers, scientific exchange and discussions and their role in stimulating new ideas and strategic directions;
- 2) Multiple networking opportunities between participants, including speakers and sponsors during private events (e.g., special events, including private digital rooms), resulting in new strategic partnerships and alliances;
- 3) Highly engaged audience – multiple questions from general attendees to speakers during public scientific sessions;
- 4) Our Summit's cross-disciplinary clinical and scientific dialogue among academic and industry leaders and related consensus on the best emerging clinical practices and research priorities has been effectively maintained - if not enhanced – in a virtual setting;
- 5) Several faculty members were excited about the quality of the presentations and discussions - and expressed enthusiasm about increasing participation in the Summit in their regions, particularly in Central and South America, Middle East, Africa and Asia in 2023. Consequently, we established an International Organizing Committee in early 2023;
- 5) High exposure of the presentations (including sponsored speakers) -
 - a) To the key opinion leaders, leading multiple national and international professional organizations, during the event; and
 - b) To the network of over 21,000 physicians after the event via the AdMeTech and GRU newsletters.

Summit 2022 examined emerging promising innovations and the pathways for their expedited clinical validation and adoption. The [Summit Program](#) had the following scientific sessions and panels:

Session 1 was dedicated to men prior to diagnosis of prostate cancer, including:

- 1) “Smart” screening in asymptomatic general population, when principal investigators of each major and active clinical trial presented emerging data on PSA screening and its integration with imaging (particularly MRI) and liquid biomarkers; and
- 2) Diagnostic evaluation of men with abnormal screening or clinical suspicion of PC, to improve risk assessment to reduce unnecessary biopsies and improve tissue sampling.

Session 2 was focused on men with localized PC (including initial or recurrent disease). This session showcased emerging advances in diagnostics (e.g., liquid and tissue genetic markers, MRI and molecular imaging), with the following goals:

- 1) To improve early diagnosis, staging and biologic characterization of aggressive prostate cancer (including non-metastatic disease), requiring immediate treatment;
- 2) To increase confidence in sub-clinical (indolent) disease, requiring observation strategy (e.g., active surveillance) and related monitoring; and
- 3) To review the emerging role of image-targeted, minimally invasive treatment vs. active surveillance and whole gland treatment.

Session 3 was dedicated to men with advanced PC, including oligometastatic disease and systemic metastases caused by castrate-sensitive and castrate-resistant disease. This session highlighted emerging advances in diagnosis, biologic characterization and treatment, including MRI, molecular imaging and theranostics as the game changers for precision care.

Session 4 reviewed the state of the art and future directions in image-guided, minimally invasive focal treatment, including patient selection, target definition, monitoring and local outcomes.

This session highlighted the next critical step in transitioning this treatment modality from experimental stage to standard care: Multi-center study for a definitive clinical evaluation. Consequently, AdMeTech Foundation established an [International Working Group in Focal Treatment](#) to develop strategy for expedited clinical validation and large-scale implementation of this technology. This Working Group will focus on the role of diagnostic tools such as MRI and molecular imaging on developing new approaches to the assessment of the short-term patient outcomes, which are essential for reducing duration of the clinical studies. The current main outcome used for such studies (mortality) requires at least 15 years of clinical follow up.

Panel on Health Disparities examined the emerging data on the role of the environment, genetics and access to care, including screening, precision diagnostics and therapeutics.

Panel on Bioinformatics, Machine and Deep Learning, Artificial Intelligence highlighted the importance of these technologies for every aspect of patient care and related research.

The following recommendations have been made for Summit 2023:

1. To hold the 7th Annual Summit as a virtual event to maintain and enhance global participation;
2. To establish [International Organizing Committee](#) to expand global participation in the Summit even further. This will include, but will not be limited, to the participation of the World Association of the Radiopharmaceutical and Molecular Therapy, Middle Eastern Prostate Cancer Consortium, and World Federation of Nuclear Medicine and Biology.
3. To continue and expand the Panels on Health Disparities and Bioinformatics.
4. To prepare and submit a Summit 2023 multi-disciplinary overview, including a Consensus Statement, per invitation from *Urology's Editor-in-Chief*; and
5. To maintain and expand participation of the organizations leading research funding (e.g., National Cancer Institute, Prostate Cancer Foundation), accreditation, regulatory and reimbursement policies and/or commercial product development to stimulate discussion on creating a facilitated pathways for clinical validation and adoption of promising diagnostics and therapeutics.

Summit 2022 highlighted the following Emerging Important Trends, and the related review and discussion will be expanded in the Virtual Summit 2023:

1. "Smart" Screening, including baseline PSA as a critical tool for age-appropriate, individualized risk assessment.
2. Multiple promising in vitro novel liquid and tissue biomarkers and in vivo imaging tools have emerged recently for improved prediction and early diagnosis of clinically significant PC that require further research.
3. Increased utilization of liquid biomarkers (e.g., phi, 4K Score, EPI, germline testing, etc.) based on clinical validation and/or consensus - and their integration (including the appropriate sequencing) with imaging for improved selection of patients for biopsy and improved tissue sampling for both standard histology and genetic tissue profiling.
4. Several areas of advanced imaging, including their standardization and evaluation of clinical utility of single imaging tools and multi-modality image fusion:
 - a. Real-time, high resolution and contrast-enhanced Ultrasound, emerging as a promising tool for early detection of PC;
 - b. Multi-parametric MRI, which is currently widely used before and after diagnosis of PC; and
 - c. Rapid evolution of molecular imaging and its emerging role in localized and advanced metastatic PC. Summit 2022 highlighted recent promising data on the role of molecular imaging in improved diagnostic assessment prior to and after diagnosis of the localized PC, as well as in early detection of recurrence, and in the definition of the oligometastatic disease vs. systemic metastases for treatment planning.
5. While standard histology has been the primary tool for patient assessment, emerging data indicate the importance of biologic information (e.g., liquid biomarkers, in vivo imaging, genetic tissue profiling) for diagnostic evaluation, prediction of clinical course and clinical outcomes, treatment planning and monitoring.
6. Radiogenomics as a specific example of the integrated, multi-modality, comprehensive approach to precision diagnosis and its impact on precision care, including patient selection for the appropriate clinical interventions for localized, recurrent and advanced PC.
7. Rapidly expanding discovery of new genetic and molecular targets for both early and advanced PC, which are critical for further development and integration of in vitro diagnostics with dedicated drugs for novel in vivo imaging and therapeutics.

8. In addition to transcriptome, proteome is emerging as the information-dense source for the development of new in vitro and in vivo imaging biomarkers.
9. Phenotypical cancer profiling as an emerging tool for prostate cancer characterization.
10. Image-Guided, Minimally Invasive Focal Treatment is emerging as a promising albeit experimental patient care option for localized disease. However, further consensus and research is needed to define its clinical utility compared to Active Surveillance and Whole-Gland Treatment. In particular, the importance of the phase 3, randomized clinical trial was pointed out for expedited clinical evaluation and implementation of this technology.
11. Further discussion, expert consensus and research is needed to define clinical indications and large-scale implementation of genetic cancer profiling on the biopsy and post-surgical tissue samples for optimizing prediction of progression and long-term outcomes. This biologic tool appears to be particularly relevant to low-risk, large-volume and intermediate-risk, small-volume PC.
12. Evaluation of advanced histopathology, including staining for molecular, genetic, immunohistochemical and other markers.
13. The importance of the access to high quality care for eliminating health disparities in Black men.
14. Bioinformatics, Machine Learning and Deep Learning and related tools for multi-factorial, multi-modality, information-intense data analysis, including predictive modeling (e.g., nomograms); and
15. Design and implementation of health-care economic analyses, including cost-benefits of novel diagnostics and therapeutics.

Impact on Clinical Community, National and International Scientific Strategy (2016-2022)

The First Global Summit and related "Brain Trust" meetings were instrumental in shifting integrated, multi-modality approach to PC Diagnosis and its impact on patient management strategies from the fringe to the center of strategic planning for medical education and research, both nationally and internationally. As a direct result of this event, our outstanding faculty members ensured that US Vice President Joe Biden's \$1.8B Cancer Moonshot Program prioritized prostate cancer in general and precision oncology specifically, including radiogenomics. This program invited AdMeTech to take part in a strategic planning for national research agenda and related infrastructure, starting in early 2017.

The subsequent events between 2017 and 2022 exceeded everyone's expectations even further. These events brought into a sharp focus the groundbreaking potential of the emerging field of multiomics, including radiogenomics, for patient care:

- 1) Several Summit presentations on imaging were featured in the 39th International Prostate Cancer Update (IPCU) in January 2019, and its many participants identified imaging as the most promising emerging clinical and research area. This tradition continues, when Summit 2022 overview will be presented at the IPCU 2023;
- 2) Summit Overview (presented by Dr. Shtern of AdMeTech at IPCU 2019) was published online by Grand Rounds of Urology (3). This video was requested by Whitney Tilton, Medical Director at VuMedi (YouTube for Physicians). VuMedi is an online community with over 220,000 registered physicians;
- 3) Members of the National Comprehensive Cancer Network's Panels on Detection and Treatment of PC have been and will continue to be involved extensively in the Annual Summit; and
- 4) Participants of the VP Biden's Cancer Moonshot Program have been and will continue to take part in the Summit;
- 5) National Cancer Institute's Quantitative Imaging Network invited an overview of Summit 2022 and is currently considering to develop a panel for Summit 2023; and
- 6) National Cancer Institute's Clinical Imaging Trial Branch took part in Summit 2021 and Summit 2022, and is currently taking part in considering to establish a multi-disciplinary working group for the development of a clinical trial design for a definitive clinical trial in image-guided focal treatment.

Impact on Public Awareness/Opinion/Consumer Demand: Annual Summit has been covered by the major media, including but not limited to, Boston Globe/STAT medical news, National Public Radio, Boston Business Journal, and Associated Press. This coverage has had a groundbreaking impact on public awareness of novel diagnostic tools and their transformational impact on the current state of patient care and reducing concerns about PSA screening, including unnecessary procedures.

AdMeTech Foundation is a 501c3 non-profit organization, which has established the Manogram[®] Project and provides international leadership in creating a new standard of care for prostate cancer, including precision screening, diagnosis, and treatment. To fulfill on this mission, the Manogram[®] Project has been designing, developing, managing, and implementing groundbreaking programs in research, education, awareness, advocacy and improve access to high-quality care (www.admetech.org).