



Fifth Global Summit PRECISION DIAGNOSIS AND TREATMENT OF PROSTATE CANCER

September 23-25, 2021 Boston, MA

SUMMIT 2019 RECAP AND PLANS FOR SUMMIT 2021

AdMeTech Foundation's Annual Global Summit and Brain Trust on Precision Diagnosis and Treatment of Prostate Cancer was established 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 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 Summit and related Brain Trust has been 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 diagnosis 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 early detection and treatment (e.g., National Comprehensive Cancer Network, AUA, American College of Radiology, ASTRO, ASCO, 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, Movember Foundation, etc.).

This Annual Summit was also covered by the major media, which is essential for public awareness and consumer demand (e.g., STAT/Boston Globe, Associated Press, National Public Radio, etc.)

The 4th Global Summit and Brain Trust of 2019 and Plans for Summit 2021: Summit 2019 took place on October 3-5, 2019. Building on the success between 2016 and 2018, Summit 2019 had greater participation than past events, with almost 200 attendees (compared to 150 in 2018), representing every key clinical expertise and expanding a cross-disciplinary dialogue. Compared to Summit 2018, the number of sponsors more than doubled (from 14 to 30) and poster presentations increased from 18 to 31. Also, over 40 presentations of the Summit were published by the Ground Rounds of Urology, which has membership of over 12,000 multi-disciplinary genito-urinary experts.

Summit 2019 examined emerging promising innovations and the pathways for their expedited clinical adoption. The scientific program for this event included population-based approach:

- "Smart" screening in asymptomatic general population, including patient selection;
- Diagnostic evaluation of men with abnormal screening or clinical suspicion of PC, to improve risk assessment in order to reduce unnecessary biopsies and improve tissue sampling/targeting;
- In men with localized, recurrent or oligometastatic PC:
 - a) To improve early diagnosis, staging and biologic characterization of lethal prostate cancer, requiring immediate treatment:
 - b) To increase confidence in sub-clinical (indolent) disease, requiring observation strategy (e.g., active surveillance) and related monitoring;
 - c) To improve patient selection for, guidance, local outcomes and monitoring of active surveillance, imageguided, minimally-invasive treatment, whole gland and/or systemic treatment;
- In men with advanced PC, including metastatic castrate resistant disease, to improve diagnosis, biologic characterization and treatment.

Summit 2019 highlighted the following Emerging Important Trends, and the related review and discussion will be expanded in Virtual Summit 2020 and Live Summit 2021:

- 1. 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.
- 2. 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.
- 3. 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.
- 4. In addition to transcriptome, proteome is emerging as the information-dense source for the development of new in vitro and in vivo imaging biomarkers.
- 5. Phenotypical cancer profiling as an emerging tool for prostate cancer characterization.
- 6. "Smart" Screening, including baseline PSA as a critical tool for age-appropriate, individualized risk assessment.
- 7. 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.
- 8. 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.
- 9. 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, 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. Molecular imaging and its role not only in advanced metastatic PC, but also in improved diagnostic assessment prior to and after diagnosis of the localzed PC, in early detection of recurrence, and in the definition and treatment of the oligometastatic disease.
- 10. Image-Targeted, Minimally-Invasive Treatment, emerging as a promising patient care option for localized disease, and build further consensus and design research to define its clinical utility compared to Active Surveillance and Whole-Gland Treatment.
- 11. Further discussion, expert consensus and research is needed to define clinical indications and implementation for adding:
 - a. Genetic cancer profiling to routine pathologic examination of biopsy tissue samples, with the goal to improve patient selection for precision care (e.g., Active Surveillance, Focal Interventions or Immediate Whole Gland Treatment); and
 - b. Genetic cancer profiling to routine pathologic examination of post-surgical tissue specimens, with the goal to optimize treatment planning.
- 12. Evaluation of ImmunoHistoChemistry (IHS)-based molecular tests of other cancers as a model for PC:
- 13. Bioinformatics, Machine Learning and Deep Learning and related tools for multi-factorial, multi-modality, information-intense data analysis; and
- 14. Design and implementation of health-care economic analyses, including cost-benefits of novel diagnostics and therapeutics.

The following additional recommendations have been made for the Summit taking place in 2020 and 2021:

- 1. Due to the COVID-19 pandemic, to hold an Interim Virtual Summit in October of 2020:
- 2. Postpone live in-person Summit until September 23-25, 2021;
- 3. To prepare and submit a Summit 2019 multi-disciplinary overview, including a Consensus Statement, per invitation from *Urology's Editor-in-Chief*;
- 4. To continue work with *Grand Rounds of Urology* to maximize multi-disciplinary audience participation and publish Summit 2021 and all the related presentations and other information;
- 5. To invite organizations leading accreditation, regulatory and reimbursement policies and commercial product development to stimulate discussion on creating a facilitated pathway for clinical adoption of promising diagnostics and therapeutics (modeled after breast cancer and AIDS initiatives);
- 6. To expand Summit 2021 to 3 days to enhance the attendees' participation and discussion at the end of each Scientific Session, in Poster Sessions and Exhibit Tours.