The National Breast Cancer Coalition
2023 Advocate Leadership Summit

May 6-8, 2023
Lobby Day: May 9, 2023
Park Hyatt Hotel, Washington, DC

BOLD ADVOCATES

FORGING A PATH to End Breast Cancer

When	Where
May 6 – May 8, 2023 Lobby Day May 9, 2023	Park Hyatt 1201 24th St NW, Washington, DC 20037
Summit Hours	
Saturday: *Pre-conference Project LEAD Grad session - 12:30 pm – 2:15 pm* **Saturday**: 2:45 pm – 7:00 pm **Sunday:** 8:00 am – 6:15 pm **Monday:** 9:00 am – 6:00 pm	

Confirmed Topics and Speakers

Project LEAD® Workshop Topic

- **Biomarkers -Testing in Breast Cancer**
  Breast cancer molecular markers, such as HER2, estrogen receptor, and progesterone receptor, are used in a clinical setting to select treatments for patients. Because they act as major drivers of breast cancer, they have been successful therapeutic targets. Dr. Press will discuss key issues around current biomarkers and tests available to help guide treatment decisions. Special focus will be given to critical issues surrounding HER2 testing in the new era of HER2-low breast cancer.
    - **Michael Press, MD, PhD** Professor of Pathology, Harold E. Lee Chair in Breast Cancer Research, Director of Breast Cancer Analysis Lab, Keck School of Medicine, University of Southern California

Plenaries

- **Artemis Plenary**
  Hear from members of the Artemis Project on the current status of the preventive breast cancer vaccine phase 1 clinical trial, and key activities of the metastasis prevention project.
    - **Cyrus Ghajar, PhD**, Director, Laboratory for the Study of Metastatic Microenvironments, Fred Hutchinson Cancer Research Center
    - **Keith Knutson, PhD**, Professor of Immunology, Mayo Clinic; Director, Mayo Clinic Cancer Center's Cancer Immunology and Immunotherapy Program
    - **Alana Welm, PhD,** Professor of Oncological Sciences, University of Utah; Investigator, Huntsman Cancer Institute (HCI); Co-Leader, Cell Response and Regulation Program, HCI

- **Health Care Costs and Value In Cancer Treatment**
  Since 2010, dozens of new cancer drugs have received U.S. FDA approval at a median cost of well over $150,000 a year, and yet little information exists on whether or not many of these drugs improve endpoints that matter to patients (i.e., how long or well a person with cancer lives). Since the accelerated approval in 2021 of the drug aducanumab for Alzheimer's disease, there has been heated debate about the accelerated approval program and the value (to patients) of the drugs that reach the market through this path. This panel discussion will explore

what opportunities exist for reforming the FDA and current efforts to control drug costs, promote innovation, and ensure access to effective treatment for all patients.

- **Anna Kaltenboeck, MA, MBA**, Principal, ATI Advisory
- **Lewis Grossman, JD, PhD,** Professor, Washington College of Law, American University
- **Laura McWright, JD, MSW**, Deputy Director, Seamless Care Models Group, Center for Medicare and Medicaid Innovation, Centers for Medicare & Medicaid Services
- **Reshma Ramachandran MD, MPP, MHS**, Assistant Professor of Medicine, Collaboration for Regulatory Rigor, Integrity, and Transparency, Yale University

Workshops

- **Ancestry, Gene Expression, and Disparities in Breast Cancer**
  Recent studies have indicated that racial disparity in breast cancer outcomes between patients of African compared to those of Caucasian ancestry may be due in part to biological factors including differences in gene expression patterns of tumor cells as well as differences in the local tumor microenvironment. Dr. Davis will take a deep dive into research seeking to unravel the multifocal contributions to cancer risk, disparities in clinical oncology outcomes and link this information back to genetic ancestry, particularly Sub-Saharan West African Ancestry.
  - **Melissa Davis, PhD**, Scientific Director, International Center for the Study of Breast Cancer Subtypes, Surgery, Weill Cornell Medicine

- **ctDNA – Current and Future Uses**
  This session will do a deep dive into the current uses of circulating tumor DNA (e.g., response to treatment and/or drug resistance marker) and future uses (e.g., early detection and drug development, surrogate endpoint in clinical trials, etc.) as well as limitations and areas for improvement.
  - **Heather A. Parsons**, **MD, MPH**, Dana Farber Cancer Institute

- **History of the FDA and the Birth of Accelerated Approval**
  Over the last several decades, a number of regulatory changes have been implemented within the U.S. Food and Drug Administration (FDA) in an effort to help speed the release of new and innovative therapies to patients in need. This session will explore varied perspectives on FDA regulatory changes, what these changes were intended to accomplish, and whether the current approval mechanisms are promoting the development of drugs that benefit patients.
  - **Lewis Grossman, JD**, Professor, Washington College of Law, American University

- **History of the Treatment of Breast Cancer**
  This session would explore changes in the treatment of breast cancer over time including the costs, mechanisms, and effectiveness of the treatments, as well as the clinical trial designs and endpoints.
  - **Ian F. Tannock CM, MD, PhD, DSc**, Emeritus Professor of Medical Oncology, Princess Margaret Cancer Centre & University of Toronto, Chair of the Board of the Optimal Cancer Care Alliance

- **How Big is the Problem of Uninformative Clinical Trials in Oncology?**
  Individuals who enroll in clinical trials do so with the belief that their participation will help to advance medical science. Yet, many trials are not designed, conducted, and reported in ways that meet this objective. These are considered to be “uninformative” clinical trials. This is a violation of research ethics and a breach of trust. Advocates will learn about the extent of this problem, how to spot it, and what can be done to prevent it.
  - **Nora Hutchinson, MDCM, MPhil**, Multi-Regional Clinical Trials Center, Brigham and Women’s Hospital and Harvard

- **NBCC Breast Cancer Models Project: Why Can We Cure Cancer in Mice but Not In Humans?**
  Participants will take part in an expert-led discussion about the broad array of models (in vitro, in vivo, in silico) used in breast cancer research, including a discussion of their benefits and limitations. Participants will also hear about a new set of resources developed for research advocates.
    - **Senthil Muthuswamy, PhD**, Senior Investigator, Laboratory of Cancer Biology and Genetics, NCI/CCR

Topics in Development

Plenaries

- **Issues in the Clinical Trials Enterprise**
  This plenary panel will include a discussion on the broad spectrum of issues that currently plague the cancer clinical trial enterprise. From issues related to diversity, equity, and inclusion to ethical issues in clinical trial reporting, design, and informativeness, this discussion will help to identify key leverage points for change and how NBCC advocacy can support efforts to improve the current system.
    - **Monique Gary, DO, MSc, FACS**, Medical Director of the Grand View Health/Penn Cancer Network cancer program (confirmed)
    - Speakers: TBD

- **Political Plenary**
    - Speakers: TBD

Workshops

- **The Future of Antibody Drug Conjugates**
  Over the last decade, a number of antibody-drug conjugates (ADCs) have been developed to treat cancer. The idea behind ADCs is to deliver high doses of a chemotherapeutic agent selectively to cancer cells while minimizing toxicity to healthy cells. ADCs have continued to evolve especially in the treatment of breast cancer with FDA approvals of two new ADCs: sacituzumab govitecan and trastuzumab deruxtecan. Advocates will hear more about how these drugs work and what the future of “smart” chemotherapy looks like.
    - Speaker: TBD

- **Strategies for Building Your Local Advocacy Network**

- **Working With the New Congress**