Updating Labels for Generic Oncology Drugs
March 26, 2019

Keck Center of the National Academies
500 Fifth Street, NW, Room 100
Washington, DC 20001

The National Academies of
SCIENCES • ENGINEERING • MEDICINE
# Updating Labels for Generic Oncology Drugs

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March 26, 2019

Dear Meeting Participants,

It is my pleasure to welcome you to *Updating Labels for Generic Oncology Drugs*, hosted by The National Cancer Policy Forum of the National Academies of Sciences, Engineering, and Medicine, in collaboration with the Academies Forum on Drug Discovery, Development, and Translation. This meeting is in response to a request from the Food and Drug Administration’s Oncology Center of Excellence. Input from the meeting will inform Project Renewal, an FDA initiative with the aim of providing clinicians with the most accurate labeling information in order to inform prescribing decisions.

A number of important, longstanding off-patent cancer drugs have outdated labeling. Such labels may be in older formats, and contain inaccurate information regarding indications, dosing, administration, safety, or use in special populations. This meeting convenes stakeholders with a broad range of expertise to discuss the challenges and opportunities to update generic oncology drugs labels that are inconsistent with the current evidence base and use in clinical practice. The FDA is particularly interested in hearing your perspectives on the evidence to consider when updating cancer drug labeling, as well as what components of labeling should be prioritized.

This meeting will be discussion-based, and participants will be seated in small groups to facilitate these interactions. Over the course of the day, we will be examining what sources of information should be taken into account for labeling updates, the evidentiary standards for labeling updates, and evidence considerations for special populations, such as pediatric oncology.

Enclosed in this briefing book are materials to prepare you for the meeting, including the agenda, discussion questions, and background reading. I look forward to your active involvement and sincerely thank you for taking the time to share your expertise and insights with the Academies.

Sincerely,

Harold L. Moses, M.D.
Chair, Planning Committee
Research Professor of Pharmacology
Professor Emeritus of Cancer Biology
Director Emeritus
Vanderbilt-Ingram Comprehensive Cancer Center

*The National Academies of Sciences • Engineering • Medicine*
Updating Labels for Generic Oncology Drugs

Hosted by the National Cancer Policy Forum
In Collaboration with the Forum on Drug Discovery, Development, and Translation

Keck Center of the National Academies
Room 100
500 Fifth Street, NW
Washington, DC 20001

AGENDA
March 26, 2019

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<tr>
<th>Time</th>
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<tr>
<td>7:30 am</td>
<td>Registration and Breakfast</td>
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| 8:00 am | Welcome and Opening Remarks

Harold L. Moses, Vanderbilt-Ingram Comprehensive Cancer Center
Planning Committee Chair

Richard Pazdur, Food and Drug Administration

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<tr>
<th>8:15 am</th>
<th>Session 1: Background and Overview of the Goals of the Meeting</th>
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<tr>
<td></td>
<td>Moderator: Andy Bindman, University of California, San Francisco</td>
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<td></td>
<td>FDA overview of Project Renewal and regulatory requirements for</td>
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<td>labeling updates (15 mins)</td>
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<td></td>
<td>• Paul Kluetz, Food and Drug Administration</td>
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<td></td>
<td>Evidence review processes for clinical practice guidelines/compendia</td>
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<td>in oncology: lessons learned and how they could inform evidence</td>
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<td>review process for updating labeling (15 mins)</td>
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<td></td>
<td>• Ethan Basch, University of North Carolina, Chapel Hill</td>
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<td></td>
<td>Case examples of how outdated labeling affects clinician prescribing</td>
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<td></td>
<td>and patient care (15 mins)</td>
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<td></td>
<td>• Donald Harvey, Emory University</td>
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<td>Panel Discussion</td>
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<td>Include speakers and</td>
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<td>Lia Gore, University of Colorado &amp; Children’s Hospital Colorado</td>
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<td>Rajeshwari Sridhara, Food and Drug Administration</td>
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<tr>
<td>Time</td>
<td>Session/Activity</td>
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<td>9:15 am</td>
<td><strong>Introduction to Small Group Discussions</strong>&lt;br&gt;Overview of the format and plans for small group discussions&lt;br&gt;Identify moderators/note takers for each table&lt;br&gt;Harold L. Moses, Vanderbilt-Ingram Comprehensive Cancer Center Planning Committee Chair</td>
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<td>9:30 am</td>
<td><strong>Session 2: Sources of Information</strong>&lt;br&gt;<strong>Objectives:</strong>&lt;br&gt;• In small groups, discuss what sources of information could be used to update labels for generic oncology drugs, as well as the challenges and considerations that should be considered when using different information sources (e.g., clinical trials data, meta-analyses, real world evidence).&lt;br&gt;• <strong>Reconvene at 10:30 am</strong> to report out main points for broader discussion.&lt;br&gt;  o S. Gail Eckhardt will moderate the report back discussion.</td>
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<tr>
<td>11:30 am</td>
<td>Lunch</td>
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<td>12:15 pm</td>
<td><strong>Session 3: Evidentiary Standards for Information Sources</strong>&lt;br&gt;<strong>Objectives:</strong>&lt;br&gt;• In small groups, discuss what the evidentiary standards should be for different sources of information discussed in the prior session.&lt;br&gt;• <strong>Reconvene at 1:15 pm</strong> to report out main points for broader discussion.&lt;br&gt;  o Richard L. Schilsky will moderate the report back discussion.</td>
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<tr>
<td>2:15 pm</td>
<td>Break</td>
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<td>2:30 pm</td>
<td><strong>Session 4: Evidence Considerations for Select Populations</strong>&lt;br&gt;<strong>Objectives:</strong>&lt;br&gt;• In small groups, discuss how the strength of evidence and sources of evidence may differ depending on the population being considered (e.g., pediatric populations, patients with comorbidities, those with rare cancers, biomarker-defined population subsets).</td>
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- **Reconvene at 3:30 pm** to report out main points for broader discussion.
  - Katherine Warren will moderate the report back discussion.

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<tr>
<th>Time</th>
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| 4:30 pm | **Session 5: Advancing Progress on Updating Generic Oncology Drug Labeling**  
Moderator: Harold L. Moses, Vanderbilt-Ingram Comprehensive Cancer Center Planning Committee Chair  
**Objectives:**  
- Review key messages from the meeting discussions, including identifying potential next steps, promising areas for future action, and opportunities for collaboration to revise outdated labeling for generic oncology drugs.  
**Panelists (each with 5 minutes for opening remarks, followed by open discussion among the meeting participants)**  
- Andy Bindman, University of California, San Francisco  
- S. Gail Eckhardt, The University of Texas at Austin  
- Susan Halabi, Duke University School of Medicine  
- R. Donald Harvey, Emory University  
- Ishmael Jaiyesimi, William Beaumont Hospital  
- Rebecca Miksad, Flatiron Health  
- Richard L. Schilsky, American Society of Clinical Oncology  
- Steven Sun, Janssen Inc.  
- Josephine M. Torrente, Hyman, Phelps & McNamara, P.C.  
- Katherine Warren, National Cancer Institute  |
| 6:00 pm | **Adjourn** |
Discussion Questions

Questions for Richard Pazdur, Paul Kleutz, and Rajeshwari Sridhara

- Can you please describe FDA’s “Project Renewal”? Which components of a drug label is Project Renewal prioritizing for labeling updates?
- How does the FDA intend to use this meeting’s discussions to inform ongoing work? What would be the most useful outputs of this meeting?
- What is the process to update generic oncology labels within the context of Project Renewal? What regulatory requirements need to be fulfilled? What is the definition of “substantial evidence,” and how does this standard differ from inclusion in a clinical practice guideline or a compendia listing?
- Do FDA expectations regarding the strength of evidence for generic labeling updates differ from label expansions for brand-name drugs? In what ways may the expectations be similar or different?
- Given the current movement within FDA to accelerate new drug review in the context of precision oncology and seamless clinical trial designs, drugs are reaching the market with lesser amounts of data or using endpoints that do not directly reflect clinical benefit, such as high response rate. How does this shift within new drug review fit with FDA’s efforts to improve the information available on generic oncology labels?
  - Would the same approval standards for new molecular entities be applied to updating a generic drug label, particularly if there is little or no opportunity for postmarketing confirmatory studies?
  - Is the FDA willing to consider summary clinical trial results from published literature in support of label updates or would submission of patient-level data be required?
  - What potential does the contribution of real world data, including evidence on off-label use and patient-reported outcomes, pose for supporting a label expansion?
  - Is the FDA interested in ensuring cross-labeling of generic drugs used in combination with new drug approvals?
  - Are there opportunities to promote transparency in the process of updating generic oncology labels?

Session 2: Sources of Information

Objective:
- Discuss what sources of information could be used to update labels (e.g., new indications, dosing, and safety information) for generic oncology drugs, as well as the considerations and challenges associated with these sources of information.
Questions:

● Project Renewal is a public health initiative with the goal to improve labels by enabling clinicians to access important, up-to-date prescribing information. Which sections of a label would workshop attendees prioritize for updating? For example, pharmacology, dosage information, administration, safety, special populations, new indications, etc.

● What data sources can the FDA draw on to update outdated generic oncology labels (e.g., clinical trials, observational clinical data [e.g., electronic health records], administrative claims data, disease registries, adverse event reporting databases, genomic databases [e.g., Project GENIE], expert opinion, patient-reported data)?

● What study designs and evidence review processes could the FDA consider for determining expansions to generic labeling (e.g., clinical practice guidelines, clinical pathways, compendia, individual clinical trials, synthesis of underpowered individual trials, synthesis of heterogeneous designs, observational studies with methods to address confounding such as propensity scores or risk adjustment, natural experiments, cohort studies, case-control, etc)?

● Are different data sources or study designs needed for different types of label updates (indications, dosing, and safety)?

● What are the advantages and disadvantages of different information sources and study designs when considering label updates? Some possibilities include:
  o Alignment between the information that the data source can provide and clinical questions at hand
  o Data quality, transparency, completeness, and relevance (may be out of date due to changes in the standard of care)
  o Data availability, source document traceability, access, and ownership
  o Feasibility/ease of use
  o Generalizability
  o Timeliness of information for updates
  o Funding source for the data
  o Other issues?

● What criteria can be used to assess the quality of data within each of these information sources/study designs? Are there data elements or characteristics that make evidence more or less valuable or useful?
  o For clinical trials, how do sample size, representativeness, study design, and data analysis techniques contribute to their utility for considering label updates?
  o How would the FDA assess evidence from clinical trials conducted outside the United States, especially if study populations differ significantly?
  o In what circumstances would real-world data be appropriate (e.g., as primary evidence—prospective or retrospective? As a control arm? What are the considerations regarding lack of randomization in this context?) Under what circumstances would real world data mitigate uncertainty related to lower levels
of existing evidence for expansion of indications in longstanding off-patent drugs? Is there a benefit to acquiring more contemporary data on use of these older products?

- Is FDA’s current approach for identifying and considering conflicts of interest sufficient for protecting patients from harms given the broadening array of data sources and study designs?

- Are there sources of data that should not be used or considered for updating a label? Would this vary depending on the type of label update (indications, dosing, and safety)?

- Are there opportunities for data sharing or linking data sources to improve the quality, completeness, and generalizability of information to inform labeling updates? Which stakeholders and what actions will be critical for advancing progress in data sharing?

Session 3: Evidentiary Standards for Information Sources

Objective:

- Discuss what the evidentiary standards should be for different sources of information and study designs, as outlined in the prior session. As you discuss the questions below, please keep in mind the regulatory definition of substantial evidence of efficacy:

  “Evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof”

Questions:

- What quality, quantity, and types of evidence would be sufficient for expanding generic labeling? What quality standards should be applied to determine if the data source/study design should be included in a regulatory submission?
  
  - For example, in what circumstances would a phase 2 clinical trial from a single institution be appropriate for updating a generic oncology label?
  
  - In what circumstances would real world data be appropriate?
  
  - How is sufficient follow-up time determined? When is it appropriate to use intermediate endpoints that were not evaluated in the original approval appropriate?
  
  - Would this vary depending on the type of labeling update (e.g., new indication, dosing, safety)?

- FDA typically reviews extensive documentation of trial planning, protocols, conduct, and data handling, as well as detailed patient records in order to confirm that a trial
supporting an effectiveness claim is adequate and well-controlled. Given the variety of data sources under consideration for labeling updates, what other means can the FDA use to ensure the adequacy of the scientific evidence?

- FDA has typically focused on narrow indications based on the studied population, but in the case of off-patent drugs, it may be more feasible to use broader indications. What are some of the issues needing considerations regarding narrow versus broad indications?

- Which information source(s) and study designs should be prioritized in FDA’s review of information to update labeling, especially if multiple data sources or study designs exist (e.g., randomized controlled clinical trials or multiple trials on the same indication > single arm clinical studies with/without real-world control arm > registries, electronic health data, clinical practice guideline, etc)?

- What if there is conflicting information about a potential labeling expansion—which information/data would take precedent?

- What information is critical in the consideration of a labeling expansion or for cross-labeling (e.g., efficacy, effectiveness, safety, pharmacology information)?

- What information describing the benefit/risk ratio of a drug (e.g., magnitude of efficacy, adverse drug reaction) need to be considered for a labeling update? How can benefit/risk be more clearly articulated in labeling updates?

- What lessons can be drawn from evidence evaluations conducted by the compendia or developers of clinical practice guidelines or clinical pathways? When the evidence base is limited, guideline/pathways/compendia developers may rely on expert opinion (see ASCO methodology here) and denote varying levels of evidence. For example, NCCN categories of evidence include:
  - Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
  - Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
  - Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
  - Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

- Could compendia/clinical practice guidelines be used as a starting point to inform FDA evidence review processes? How might requirements for FDA evidence review processes differ from compendia/clinical practice guidelines? What quality standards and endpoints should the FDA accept? Does this depend on the type of label update (e.g., new indication, dosing, safety)?

- Would the FDA consider labeling decisions made by other regulatory bodies, such as the European Medicines Agency, to expand U.S. labeling?
Can evidence from different information sources or study designs be combined to create sufficient justification for updating a label? What are optimal opportunities and methods to combine different data (e.g. quantitative and qualitative)?

**Session 4: Evidentiary Considerations for Select Populations**

**Objective:**
- Discuss how requirements for evidence source and strength may differ for special populations (e.g., pediatric populations, patients with comorbidities or safety concerns (e.g., hepatic function), patients with rare cancers, biomarker-defined population subsets).

**Questions:**
- What evidence should be required to update generic oncology drug labels for pediatric populations?
  - Should evidentiary requirements be different from label updates in adult populations? Should requirements differ by age groups based on physiologic differences (e.g., children under the age of 12 and those 12 and older, or adolescent and young adult populations)?
  - Are there different data needed for assessing labeling updates for pediatric populations? What information would differ?
  - Are there circumstances when evidence from adult populations is sufficient to update a label with a pediatric indication?
- Given the small sample sizes available for study of rare cancers, should evidentiary requirements for label updates be the same as those for more common diseases? What are special data source considerations for small cohorts of rare patients?
- Would the FDA consider labeling decisions made by other regulatory bodies, such as the European Medicines Agency, to expand U.S. labeling, especially in the context of rare cancers?
- How could different information sources be combined to produce a sufficient body of evidence for diseases where there is a dearth of clinical data? What quality standards should be applied to determine which data sources/study designs to combine?
- What are the opportunities and challenges to compile evidence of safety and effectiveness for labeling updates for patients with comorbidities?
- How can labeling changes better protect medically vulnerable populations? What types of evidence should be considered for updating labels for indications and dosing for populations with safety concerns (i.e. hepatic function, etc.)?
- What types of evidence are required for updating generic labels based on biomarker-defined population subsets? What strength of evidence about biomarker performance will need to be met for label expansions of biomarker-defined populations?
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Hyman, Phelps and McNamara, P.C.

Ann Marie Trentacosti, MD
Medical Lead, Labeling Development Team
Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Vikrant Vats, PhD
Director, Clinical Services
Office of Clinical Affairs
Blue Cross Blue Shield Association

Katherine Warren, MD
Senior Investigator
Pediatric Neuro-Oncology
Center for Cancer Research
National Cancer Institute

Janet Wittes, PhD
President
Statistics Collaborative, Inc.

*current as of March 19, 2019
PLANNING COMMITTEE & PARTICIPANT BIOGRAPHIES*

Peter C. Adamson, MD
Children's Oncology Group and the Children's Hospital of Philadelphia

Peter C. Adamson, MD is Chair of the Children's Oncology Group (COG), a National Cancer Institute (NCI) supported international consortium of more than 220 childhood centers that conducts clinical-translational research, including large-scale clinical trials, in children with cancer. Dr. Adamson is Professor of Pediatrics and Pharmacology at the Perelman School of Medicine of the University of Pennsylvania and holds the Alan R. Cohen Endowed Chair in Pediatrics at The Children's Hospital of Philadelphia (CHOP). He is Board Certified in Pediatric Hematology/Oncology and Clinical Pharmacology. Dr. Adamson serves on the National Cancer Advisory Board (NCAB) and has served as a member of the Blue Ribbon Panel for Vice President Biden's National Cancer Moonshot Initiative.

Prior to becoming Chair of the COG in 2011, Dr. Adamson was Director for Clinical and Translational Research at The Children's Hospital of Philadelphia, as well as Chief of the Division of Clinical Pharmacology and Therapeutics. Other past roles include being co-Director of the University of Pennsylvania's - CHOP Clinical Translational Science Award (CTSA), Program Director of the General Clinical Research Center (GCRC) and Principal Investigator of CHOP's Pediatric Pharmacology Research Unit (PPRU). His laboratory research focuses on the clinical pharmacology of new drugs for childhood cancer.

Jeff Allen, PhD
Friends of Cancer Research

Jeff Allen, Ph.D. serves as the President and CEO of Friends of Cancer Research (Friends). During the past 20 years, Friends has been instrumental in the creation and implementation of policies ensuring patients receive the best treatments in the fastest and safest way possible. As a thought leader on many issues related to Food and Drug Administration, regulatory strategy and healthcare policy, he is regularly published in prestigious medical journals and policy publications, and has contributed his expertise to the legislative process on multiple occasions. Recent Friends initiatives include the establishment of the Breakthrough Therapies designation and the development of the Lung Cancer Master Protocol, a unique partnership that will accelerate and optimize clinical trial conduct for new drugs. Dr. Allen received his Ph.D. in cell and molecular biology from Georgetown University, and holds a Bachelors of Science in Biology from Bowling Green State University.

*current as of March 19, 2019
Aylin Altan, PhD  
OptumLabs

Aylin Altan is Senior Vice President of Research at OptumLabs, an open research and innovation collaborative consisting of more than 27 academic, industry, non-profit, and provider partners. Partners in OptumLabs collaborate to conduct clinical, policy, and population health research in the OptumLabs Data Warehouse, which is comprised of linked administrative claims, electronic health records (EHR), consumer and health behavior data, benefit design information, and other assets.

Altan specializes in the use of real world data and evidence in health services research and health economics. At OptumLabs she works with Partners as a consultant and co-investigator, oversees the OptumLabs team of scientists and research analysts, and leads workshops, issues panels, and training sessions both for OptumLabs Partners and at clinical, policy, and industry conferences and meetings. Most recently, Altan served on a July 2018 panel at the National Academies of Sciences, Engineering, and Medicine in Washington, D.C. focused on the use of real world data and evidence for regulatory decisions.

Prior to joining Optum Labs in 2015, Altan led Optum’s North American Health Economics and Outcomes Research organization. In this role, she was responsible for working with Life Sciences companies to develop evidence generation strategies in support of their key assets, with the end goal of publication in the peer-reviewed, clinical and policy literature.

Altan holds an undergraduate degree from Stanford University and a PhD in Health Services Research from the University of Minnesota.

Ethan Basch, MD, MSc  
University of North Carolina, Chapel Hill

Dr. Ethan Basch is a medical oncologist and Professor of Medicine and Public Health at the University of North Carolina, where he is Director of Cancer Outcomes Research. He leads a research program focused on patient-centered care delivery and product development, as well as real world data collection. Dr. Basch is particularly committed to implementing systems for capturing the patient experience during care and clinical trials. He is a member of the Board of Directors of the American Society of Clinical Oncology (ASCO), the Methodology Committee of the Patient-Centered Outcomes Research Institute (PCORI), prior member of the Board of Scientific Advisors of the National Cancer Institute (NCI), and is an Associate Editor at JAMA.
Andy Bindman, MD
University of California, San Francisco

Dr. Andy Bindman is a professor of medicine, epidemiology & biostatistics, and a core faculty member within the Philip R. Lee Institute for Health Policy Studies at the University of California, San Francisco. He is a primary care physician who has practiced and taught clinical medicine at Zuckerberg San Francisco General Hospital over 3 decades while also conducting health services research to improve care within the health care safety net. He has been a leader in translating research into policy through several roles he has played within the federal government. He was a health policy fellow on the staff of the US House Energy and Commerce Committee where he contributed to the drafting of the Affordable Care Act (ACA). He worked for several years to implement the ACA as a senior adviser within the US Department of Health and Human Services and as the Director of the Agency for Healthcare Research and Quality. He currently serves as the co-editor in chief of the journal, Health Services Research. Dr. Bindman was elected to the National Academy of Medicine in 2015.

Leigh M. Boehmer, PharmD, BCOP
Association of Community Cancer Centers

Dr. Leigh Boehmer is the Medical Director, Education for the Association of Community Cancer Centers (ACCC). In this role, he’s responsible for assessing educational needs and designing interventions for multidisciplinary cancer care teams serving patients in the community. He also serves as a liaison with external stakeholders, including patient advocacy organizations, policy experts, and governmental agencies, to advance the objectives of ACCC membership and projects.

An alumnus of the University of Iowa College of Pharmacy, Dr. Boehmer completed PGY1 and PGY2 oncology residencies at The Johns Hopkins Hospital. He has served as an assistant professor in the Department of Clinical Pharmacy at the St. Louis College of Pharmacy in St. Louis, Missouri, and as an inpatient medical oncology clinical pharmacy specialist at Barnes-Jewish Hospital. Prior to his position with ACCC, he served as Oncology Clinical Pharmacy Specialist at Mercy Cancer Center in Mason City, Iowa. In that capacity he served on multiple hospital and system-level committees tasked with oncology clinical standardization and cost savings.
Laurie Beth Burke, MPH
University of Maryland School of Pharmacy

Laurie Burke, MPH, collaborates with medical product development organizations to promote best practices in patient-focused drug development, outcomes research, regulatory strategy, product labeling and advertising. She was a career US Public Health Service officer with the US Food and Drug Administration, Center for Drug Evaluation and Research, where she maintained regulatory policy development and oversight responsibilities related to prescription drug labeling and outcome measurement in clinical trials. She was the lead author of the FDA Patient-Reported Outcomes Guidance published in 2009. She worked extensively on regulatory issues related to the use of clinical outcome assessments to support labeling with the European Medicines Agency, the National Institutes of Health, other US Department of Health and Human Services agencies. She is an Affiliate Associate Professor at the University of Maryland School of Pharmacy. Her academic degrees include a Master of Public Health in Epidemiology from the Uniformed Services University of the Health Sciences and a bachelor of science in pharmacy from the University of Kansas.

Robert W. Carlson, MD
National Comprehensive Cancer Network

Robert W. Carlson, MD, is the Chief Executive Officer at the National Comprehensive Cancer Network (NCCN). He joined NCCN as CEO in January 2013, following an esteemed history of leadership positions within the organization including, most notably, Representative to the NCCN Board of Directors, Chair of the Breast Cancer Guidelines Panel, Member and Founding Chair of the Breast Cancer Risk Reduction Guidelines Panel, and Chair of the Survivorship Guidelines Panel.

Prior to his appointment as CEO at NCCN, Dr. Carlson served as Professor of Medicine in the Division of Oncology and Stanford Medical Informatics at Stanford University Medical Center, as well as Medical Director of inpatient oncology and hematology at Stanford Cancer Institute in California.

Dr. Carlson is a graduate of Stanford University Medical School, and he completed his internship and junior residency in internal medicine at Barnes Hospital Group in St. Louis before returning to Stanford University to complete his senior residency. He earned a Bachelor of Science with distinction from Stanford University, specializing in biological sciences. Dr. Carlson is board certified in Medical Oncology and Internal Medicine.
Barbara Chong, PharmD  
FDA Office of Medical Policy  Immediate Office

Dr. Chong is a Special Assistant for Labeling in the Office of Medical Policy Immediate Office (OMP IO) at the Food and Drug Administration (FDA) where she focuses on policy and guidance development for prescription drug labeling. Prior to her current position, Dr. Chong was a Senior Consumer Safety Officer in the Office of Prescription Drug Promotion (OPDP), formerly the Division of Drug Marketing, Advertising, and Communications (DDMAC) at the FDA. She held various positions during her tenure at OPDP, including policy and guidance development and training & support, in which she was responsible for providing training and leading policy development and special projects. Prior to these positions, she was a DDMAC Team Leader and covered the Cardiovascular & Renal, Reproductive & Urology, Dermatology & Dental, Metabolic & Endocrinology, Special Pathogens & Transplant, and Anti-Infectives & Ophthalmology therapeutic areas. She joined FDA in 2000 as a DDMAC reviewer where she was responsible for reviewing both the professional and consumer-directed promotional materials for the diabetes and urologic drug products. Prior to joining FDA, she was an Assistant Professor at the Medical University of South Carolina, College of Pharmacy in adult internal medicine. Dr. Chong received her Pharm.D. from the University of Maryland School of Pharmacy in Baltimore and her B.S. in Chemistry from the University of Maryland in College Park. She also completed a Geriatric Pharmacy Practice Residency at the Veterans Administration Medical Center in Gainesville, Florida.

Jacqueline Corrigan-Curay, JD, MD  
FDA Office of Medical Policy

Jacqueline Corrigan-Curay, J.D., M.D., serves as Director of CDER’s Office of Medical Policy (OMP). She leads the development, coordination, and implementation of medical policy programs and strategic initiatives. She works collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory review processes. OMP is comprised of the Office of Prescription Drug Promotion (OPDP) and the Office of Medical Policy Initiatives (OMPI). OPDP oversees the regulation of prescription drug promotion and advertising. OMPI provides oversight and direction for new and ongoing policy initiatives in broad-based medical and clinical policy areas.

Prior to joining FDA, she served as supervisory medical officer with the Immediate Office of the Director, National Heart, Lung and Blood Institute (NHLBI), at National Institute of Health’s (NIH) where she focused on developing policies and procedures to enhance the clinical trial enterprise. She also served as the Director of the Office of Biotechnology Activities (OBA), Office of Science Policy at NIH, where she was executive secretary of the NIH Recombinant DNA Advisory Committee. She has held positions as an attending physician with the VA Medical Center, a policy analyst with the Congressional Office of Technology Assessment, and a practicing attorney in Washington, D.C.

*current as of March 19, 2019
Dr. Corrigan-Curay earned her law degree from Harvard Law School, her medical degree from University of Maryland School of Medicine, and a bachelor’s degree in history of science from Harvard/Radcliffe College in Cambridge, MA. She completed her training in internal medicine at Georgetown University Medical Center, where she also served as a clinical assistant professor of medicine. She continues to practice internal medicine part-time at the Veterans Affairs Medical Center in Washington, D.C.

**Thomas Curran, PhD, FRS**

Children’s Research Institute and University of Kansas

Dr. Curran holds the Donald J. Hall Eminent Scholar in Pediatric Research and he serves as the Executive Director and Chief Scientific Officer of the Children’s Research Institute, Children’s Mercy, Kansas City. He is also a Professor of Pediatrics at the University of Missouri-Kansas City School of Medicine and a Professor of Cancer Biology in the University of Kansas School of Medicine. Dr. Curran is responsible for defining the vision and guiding the growth of the Children’s Research Institute into a leading center for pediatric translational research.

He received a bachelor of science degree from Edinburgh University in 1978 and a PhD from University College London, for studies carried out at the Imperial Cancer Research Fund Laboratories, in 1982. He was supported by a Damon-Runyon fellowship during his postdoctoral training at the Salk Institute, San Diego from 1982-84.

From 1984-1995, Dr. Curran worked at the Roche Institute of Molecular Biology ultimately rising to the position of Associate Director. He then founded the Department of Developmental Neurobiology at St. Jude Children’s Research Hospital where he grew the Translational Brain Tumor Program over the period 1995-2006. He served as Deputy Scientific Director of the Children’s Hospital of Philadelphia Research Institute from 2006-2015 and he established the multi-institution Children’s Brain Tumor Tissue Consortium.

Dr. Curran’s research spans the fields of cancer, signal transduction and neurobiology. He discovered and characterized the inducible Fos-Jun oncogenic transcription factor complex and demonstrated its function in diverse signal transduction processes. His lab identified a novel reduction/oxidation mechanism that regulates transcription factor activity. He also identified reelin, the gene responsible for the classic ataxic mouse mutation, reeler, and elucidated its role in the control of neuronal migration in the developing brain. Over the course of the last two decades, he pioneered preclinical analysis of Hedgehog Pathway inhibitors for the treatment of pediatric medulloblastoma and transitioned this work into successful Phase I/II human clinical trials. His work is published in over 290 papers that have been cited more than 50,000 times.

Children’s Mercy Hospital benefits from the breadth and depth of scientific expertise that Dr. Curran brings to the Research Institute. His hands-on experience in conducting translational research, as well as his background in industry, provide a formidable foundation for the task of building a pediatric translational research enterprise.

*current as of March 19, 2019
Dr. Curran was President of the American Association for Cancer Research (AACR) in 2000-2001 and he served on the National Cancer Institute Board of Scientific Advisors from 2000-2005. He has been elected as a fellow of the American Association for the Advancement of Science (1994), the American Society of Microbiology (1994), the Royal Society, London (2005), the National Academy of Medicine (2009), the American Academy of Arts and Sciences (2012) and the Academy of the American Association for Cancer Research (2013). Dr. Curran has received several awards and honors including, the Passano Foundation Young Scientist Award in 1992, the Outstanding Achievement in Cancer Research award from the AACR in 1993, the Golgi Award from the Camillo Golgi Foundation and the Italian Academy of Neurosciences in 1994 and the Fred Epstein Lifetime Achievement Award from the Children's Brain Tumor Foundation in 2015.

The guiding principle of the Children's Research Institute is that we will be led by our patients. They teach us where advances need to be made to improve their health and wellbeing. We believe that children deserve access to the very latest discoveries and technologies and they should have the opportunity to participate in research. The presence of research enhances the environment of clinical care and points the way to future treatments so that one day no parent should ever have to say, “What do we do now?”

**Kristin Davis, JD**
FDA Office of Generic Drug Policy

Kristin Davis is the Deputy Director of the Office of Generic Drug Policy in the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). Prior to this role, Kristin was a Senior Policy Analyst in the Office of Policy within the Office of the Commissioner. Before joining the Office of the Commissioner, she served in various other roles at FDA, including as Associate Director and Acting Director of the Division of Legal and Regulatory Support in the Office of Generic Drug Policy in CDER, as a Senior Regulatory Counsel in the Office of Regulations in the Center for Tobacco Products, and as Deputy Director of the Office of Prescription Drug Promotion in CDER. Before joining FDA, Kristin was an associate with the law firm of Wiley Rein LLP in Washington, D.C. She received her B.S. from the University of Illinois and her J.D. from Harvard Law School.

**S. Gail Eckhardt, MD, FASCO**
University of Texas at Austin

S. Gail Eckhardt, MD is a tenured Professor at the University of Texas at Austin’s Dell Medical School where she is also the inaugural Director of the LIVESTRONG Cancer Institutes, Chair of the Department of Oncology, and Associate Dean of Cancer Programs. She has been a faculty member at the institution since January of 2017. Prior to joining UT Austin, Dr. Eckhardt was at the University of Colorado School of Medicine where she was Division Head of Medical Oncology from 2006-2014; Associate Director for Translational Research at the University of Colorado Comprehensive Cancer Center and Director of the Phase I Program and Fellowship.
Dr. Eckhardt has served on numerous committees/study sections, including the ASCO Molecular Oncology Task Force, the ASCO Board of Directors, the FDA Oncology Drugs Advisory Committee, and the NCI Cancer Centers Study Section. She is a member of the NCI Investigational Drug Steering Committee and serves on 11 External Advisory Boards of NCI designated Cancer Centers and is the lead mentor in ASCO’s Leadership Development Program.

Dr. Eckhardt is the Principal Investigator on grants involving early clinical trials and colorectal cancer research, has conducted numerous phase I and II clinical trials and has published over 200 manuscripts. Her area of interest is in the preclinical and early clinical development of combinations of molecularly targeted compounds, with a laboratory focus on colorectal cancer.

Dr. Eckhardt earned her undergraduate degree in chemistry from Stephen F. Austin State University and her medical degree from the University of Texas Medical Branch in Galveston, TX. She conducted her internship and residency in Internal Medicine at the University of Virginia Medical School followed by a post-doctoral research fellowship in Experimental and Molecular Medicine at Scripps Research Institute, in La Jolla, CA and a fellowship in Medical Oncology at the University of California, San Diego.

Peter G. Ellis, MD
University Pittsburgh Medical Center Hillman Cancer Center

Peter Ellis, MD, is the Deputy Director of Clinical Services, UPMC Hillman Cancer Center, Clinical Professor of Medicine at the University of Pittsburgh School of Medicine, and he also serves as Chief Medical Officer for Via Oncology Pathways. He is a recognized national leader in the efforts to improve the quality and reduce costs of cancer care, and has published numerous abstracts and peer review publications on the topic.

Dr. Ellis has held numerous leadership positions throughout his career, including being a managing partner of Oncology Hematology Association, seven years as national chairman of the Pharmacy and Therapeutics Committee for The US Oncology Network, and 16 years as clinical lead of the UPMC oncology network, which now includes more than 50 sites. He’s served on the board of local and state American Cancer Society, the St. Margaret Foundation, the Allegheny County Medical Society, and American Society of Clinical Oncology’s Clinical Practice Committee.

A Pittsburgh native, Dr. Ellis received his bachelor’s degree from the University of Virginia in Charlottesville, and his medical degree from the University of Pittsburgh. He completed his internal medicine residency at the University of Pennsylvania in Philadelphia, followed by a fellowship in hematology and oncology at Duke University in Durham, NC. Dr. Ellis maintains an active medical oncology practice at UPMC St. Margaret near Pittsburgh.
Lori Ehrlich, MD, PhD
FDA Office of Hematology and Oncology Products

Dr. Lori Ehrlich is a pediatric hematologist/oncologist serving as a clinical reviewer in the FDA’s Division of Hematology Products in the Office of Hematology and Oncology Products, Center for Drug Evaluation and Research (CDER). She joined the FDA in 2014 and reviews benign and malignant hematology drug development with a focus on pediatric drug development. Dr. Ehrlich completed her residency and fellowship training as a pediatric hematologist-oncologist at the Children’s Hospital of Philadelphia. She received her medical degree and doctorate from the University of Pittsburgh School of Medicine. She holds a clinical appointment in benign hematology at Children’s National in Washington, D.C.

William E. Evans, PharmD
St. Jude Children’s Research Hospital

Dr. Evans joined St. Jude Children’s Research Hospital (SJCRH) as a student in 1972, chaired the Pharmaceutical Sciences Department from 1986-2002, served as Scientific Director & EVP from 2002-2004, and as CEO of SJCRH from 2004-2014. He currently holds an Endowed Chair of Pharmacogenomics at SJCRH and is a Professor at the University of Tennessee.

During his decade as CEO, St. Jude was ranked the #1 Children’s Cancer Hospital by USNWR and by Parents Magazine, #1 in the Best Places to Work in Academia by Scientist Magazine, among the Top 100 Best Places to Work by Fortune Magazine, received a perfect score by The Joint Commission and received an “Exceptional” ranking as an NCI Comprehensive Cancer Center.

Evans received his BSc and Pharm.D. degrees from the University of Tennessee HSC (1973, 1974) and spent a sabbatical year (1987-88) at the University of Basel. He has received honorary doctoral degrees from Rhodes College, the Ohio State University and the University of Florida.

For the past 40 years his research has focused on the pharmacodynamics and pharmacogenomics of anticancer agents in children with acute lymphoblastic leukemia, for which he has received three consecutive NIH MERIT Awards from NCI. Evans has authored over 400 scientific publications and has received several national awards for his research, including the 2009 Pediatric Oncology Award from ASCO (with Mary V. Relling of SJCRH), the 2009 Team Science Prize from AACR (shared with SJCRH colleagues), the 2012 Remington Medal from APhA, and the 2013 Oscar B. Hunter Award from ASCPT.

He was elected to the National Academy of Medicine of the US National Academies of Sciences, Engineering, and Medicine in 2002 and the German National Academy of Sciences in 2016.
Evans currently chairs the Scientific Advisory Board of the Princess Maxima Children’s Cancer Center in The Netherlands (2014-present), and has previously served on the Board of Trustees of the University of Tennessee (2014-2018) and the Board of Trustees of Rhodes College (2005-2014).

Christopher R. Friese, PhD, RN, AOCN®, FAAN  
University of Michigan

Christopher Friese is the Elizabeth Tone Hosmer Professor of Nursing at the University of Michigan School of Nursing, where he focuses on measuring and improving the quality of cancer care delivery. He directs the Center for Improving Patient and Population Health. He is also a faculty investigator at the University’s Institute for Healthcare Policy and Innovation, and a core member of the University of Michigan Rogel Cancer Center. He has practiced as a staff nurse at leading cancer centers, including the University of Pennsylvania, Johns Hopkins Hospital, and the Rogel Cancer Center. Friese is a national expert in the analyses of claims data to study care quality and has executed large surveys of ambulatory oncology nurses. The author of over 70 publications, his research findings were among the first to establish a significant relationship between favorable nurse practice environments and lower surgical mortality.

As the first nurse scientist to complete a K99/R00 Pathway to Independence award from the National Institute of Nursing Research, Friese leads an interdisciplinary research program to study the quality of care delivered in understudied ambulatory oncology settings from the perspectives of patients and clinicians. He has led pivotal studies to develop valid and reliable measures of ambulatory nursing work environments. His recent work examines patterns and correlates of hazardous drug exposure in oncology nurses. His research has been funded by the National Cancer Institute, the National Institute for Occupational Safety and Health, the National Institute of Nursing Research, the Agency for Healthcare Research and Quality, the American Cancer Society, and the Robert Wood Johnson Foundation. In 2016, he was selected as Robert Wood Johnson Foundation Health Policy Fellow, where he worked on health policy initiatives in the office of Senator Robert P. Casey, Jr. (Pennsylvania). In 2018, he was appointed by the Comptroller General of the United States to a six-year team on the Patient-Centered Outcomes Research Institute (PCORI) Board of Governors.

Friese received a BSN-PhD from the University of Pennsylvania School of Nursing and completed a 3-year postdoctoral fellowship in Cancer Control and Outcomes at Harvard University/Dana-Farber Cancer Institute. He is a Fellow in the American Academy of Nursing and received the University of Michigan’s Henry Russel Award for Outstanding Junior Faculty. In 2017, he was installed as the inaugural holder of the Elizabeth Tone Hosmer endowed chair at the University of Michigan. He holds a secondary appointment in Health Management and Policy at the School of Public Health.

*current as of March 19, 2019
Lia Gore, MD
University of Colorado and Children’s Hospital Colorado

Lia Gore is a Professor with Tenure at the University of Colorado School of Medicine and Chief of Pediatric Hematology/Oncology/Bone Marrow Transplant and Cellular Therapeutics at Children’s Hospital Colorado. Her research is focused on the development of novel cancer therapeutics with an emphasis on Phase I trials and improving access to clinical trials for children. She has been a Principal Investigator or co-Investigator on more than 200 national and international clinical trials and serves on advisory panels to the Oncology Drug Advisory Committee (ODAC) to the US FDA, the Developmental Therapeutics and Department of Defense Study Sections of the National Institutes of Health, and has advised at the European Medicines Agency. Her interests are in particularly high-risk diseases such as relapsed leukemia, sarcoma, and CNS tumors. She is a founding co-director of the University of Colorado’s NCI designated Comprehensive Cancer Center’s Hematological Malignancies Program, and currently serves as a co-director of the Developmental Therapeutics Program, and on the Executive Committee for Acute Lymphoblastic Leukemia in the Children’s Oncology Group.

Susan Halabi, PhD
Duke University

Susan Halabi, PhD is Professor of Biostatistics and Bioinformatics at Duke University with applied and methodological expertise in the design and analysis of clinical trials in oncology. She has published extensively on prognostic and predictive modelling and on the design and analysis of clinical trials. She has also served as principal investigator on several awards. Dr. Halabi is a member of the National Cancer Institute Genitourinary Committee Steering Committee and a member of the Oncologic Drugs Advisory Committee (ODAC) for the U.S. Food and Drug Administration. She has served and continues to serve on numerous data safety and monitoring boards and study sections for the National Institutes of Health. She is a co-editor of Oncology Clinical Trials: Successful Design, Conduct and Analysis. Dr. Halabi is as an Associate Editor for Clinical Trials, Statistics in Medicine and Diagnostic and Prognostic Research. She is a fellow of the American Statistical Association, the Society of Clinical Trials and the American Society of Clinical Oncology.
R. Donald Harvey, PharmD, BCOP, FCCP, FHOPA
Emory University School of Medicine and Winship Cancer Institute

R. Donald Harvey, PharmD, BCOP, FCCP, FHOPA is Associate Professor of Hematology/Medical Oncology and Pharmacology at the Emory University School of Medicine. Dr. Harvey also serves as director of the Winship Cancer Institute's Phase I Clinical Trials Unit and Section. He has established a clinical pharmacology research program in cancer at Emory with the goal of using pharmacokinetic, pharmacodynamic, and other tools to improve individualization of therapy and clinical outcomes.

Henry (Joe) Henk, PhD
OptumLabs

Henry (Joe) Henk, serves as OptumLabs Vice President of Research/Senior Scientist and co-leads the OptumLabs Cancer Research Collaborative. He serves as the Executive Sponsor or Senior Scientist working with the American Cancer Society, Harvard Pilgrim Health Care Institute, NCI, CDC, and Stand Up To Cancer.

Since joining Optum in 2004, his research has spanned a variety of diseases and treatment areas and has focused on therapy compliance, burden of illness, and cost comparisons, with particular focus on oncology and the use of biologics. Prior to joining OptumLabs, Joe served as Principal Consultant and Head of Optum's Health Economics and Outcomes Research unit. Previously, Joe served as therapeutic lead for Oncology and Biologics, overseeing research, data acquisitions, and study execution in oncology and the use of biologic therapy. In 2011, Joe was selected as an Optum Fellow, and charged with the development and training of others on methods that address specific health economic and outcomes research needs and the efficient/effective use of observational data sets (i.e., “real world” data). Prior to joining Optum, he served eight years as a statistician for a nonprofit research organization and for the Veterans Administration conducting economic evaluations of health care interventions in a variety of clinical areas, including respiratory disease, psychiatry, ophthalmology, neurology, and substance abuse. Joe earned his PhD in population health (with an emphasis in health economics and econometrics) from the University of Wisconsin and a Master’s of Science in applied statistics from the University of Minnesota. Joe specializes in health economics, econometrics, and health outcomes with particular expertise in methods for working with observational data, population health, and health care expenditure.

Currently, he is working with researchers to inform decision making and to advance cancer care and prevention through better access to real world data.
Brenda Huneycutt, PhD, JD, MPH
FasterCures, Milken Institute

Brenda Huneycutt is a director of regulatory innovation at FasterCures, a center of the Milken Institute. Prior to joining FasterCures, Dr. Huneycutt was vice president, regulatory strategy and FDA policy at Avalere Health, advising health-care clients on topics such as patient engagement in drug development, compassionate use/expanded access to investigational products, regulatory exclusivities, the Food and Drug Administration’s orphan drug and expedited programs, and the use of real-world evidence in regulatory decision-making.

Dr. Huneycutt has also practiced as a patent lawyer and started out as a research scientist, primarily studying cell division and cell cycle control in yeast model systems. Dr. Huneycutt is a fellow with the Coalition for Epidemic Preparedness Innovations, working on challenges related to developing vaccines against diseases with epidemic potential. Dr. Huneycutt holds a PhD in molecular biology from the University of Colorado at Boulder, a JD from the George Washington University School of Law, and an MPH from the Johns Hopkins University Bloomberg School of Public Health.

Ishmael Jaiyesimi, DO, MS, FACP
William Beaumont Hospital

Ishmael Jaiyesimi, D.O., M.S., F.A.C.P. is a distinguished hematologist and medical oncologist at Beaumont Hospital in Royal Oak, Michigan. Specializing in Hematology and Oncology medicine, Dr. Jaiyesimi is an active educator certified by the American Board of Internal Medicine, and its subspecialty boards, in Internal Medicine, Medical Oncology, and Hematology. A graduate of the University of Minnesota, College of Pharmacy in Minneapolis with a master’s degree in social and administrative pharmacy, Dr. Jaiyesimi is also a graduate of Western University of Health Sciences in Pomona, California. He completed an internal medicine residency at William Beaumont Hospital in Royal Oak and subsequently completed a fellowship in hematology and oncology at the University of Texas M.D. Anderson Cancer Center in Houston.

Dr. Jaiyesimi is the Chairman of the Department of Medical Oncology and Hematology at Beaumont Hospital in Royal Oak, Michigan. In addition, he is the Director of the Hematology-Oncology Fellowship Program where he has been training internists in the hematology and oncology specialties since 1993. Active in the clinical research of cancer, Dr. Jaiyesimi is a Clinical Associate Professor of Medicine at Wayne State University and a Professor of Medicine and Oncology at the Oakland University William Beaumont School of Medicine. He is a fellow of the American College of Physicians; a member of Cancer Education Committee with the American Society of Clinical Oncology; a member of the American Medical Association; American Society of Hematology; American Osteopathic Association; and Oakland County Medical Society. He is on staff at Beaumont Hospital in Royal Oak and Troy.
Roy A. Jensen, MD
The University of Kansas Cancer Center

Dr. Jensen was appointed the director of the University of Kansas Cancer Center in 2004. As a result of a broad-based university, community and regional effort, The University of Kansas Cancer Center was designated as a cancer center by the National Cancer Institute in July 2012. Dr. Jensen is currently Professor of Pathology and Laboratory Medicine, Professor of Anatomy and Cell Biology, Professor of Cancer Biology, and the William R. Jewell, M.D. Distinguished Kansas Masonic Professor, at the University of Kansas Medical Center. Prior to his appointment at Kansas, Jensen was a member of the Vanderbilt-Ingram Cancer Center and a faculty member in Pathology, Cell Biology, and Cancer Biology for 13 years.

Dr. Jensen graduated from Vanderbilt University School of Medicine in 1984, and remained there to complete a residency in Anatomic Pathology and a Surgical Pathology fellowship with Dr. David Page. Following his clinical training he accepted a postdoctoral fellowship at the National Cancer Institute in the laboratory of Dr. Stuart Aaronson. After joining the faculty at Vanderbilt University, Dr. Jensen’s research interests focused on understanding the function of BRCA1 and BRCA2 and their role in breast neoplasia; and in the characterization of premalignant breast disease at both the morphologic and molecular levels. He currently has over 150 scientific publications and has lectured widely on the clinical and molecular aspects of breast cancer pathology.

Dr. Jensen has served on numerous grant review panels, study sections, and site visit teams for the NIH, the Department of Defense-Breast Cancer Research Program, the Medical Research Council of Canada, the California Breast Cancer Research Program, and the Susan G. Komen Breast Cancer Foundation. Jensen serves on the Science Policy and Governmental Affairs Committees for the American Association for Cancer Research (AACR) and the Federation of American Societies for Experimental Biology. In addition, he is a member of the AACR Pathology Task Force and AACR Publications Committee. He is a member of the Science Policy Working Group of the American Society for Investigative Pathology, and co-chaired the Research Committee for C-Change. In 2013, he was elected to the Board of Directors for the Association of American Cancer Institute's (AACI). Currently, Dr. Jensen serves as the president of AACI. Jensen is chair of NCI’s Subcommittee A and also served on the Director's Working Group for the Board of Scientific Advisors to the National Cancer Institute. Finally, he is the Chair of the University of Oklahoma Stephenson Cancer Center External Advisory Board.
Harvey I. Katzen, MD, F.A.C.P.
George Washington Hospital

Dr. Katzen graduated from Georgetown University with a BS in Biology and earned his medical degree from The George Washington University School of Medicine and Health Sciences. He continued his medical training internship and residency in Internal Medicine at GW, as well as completed a fellowship in Hematology/Oncology.

Dr. Katzen is an oncologist and has served as the Chief of Oncology at both Greater Southeast Community and Southern Maryland Hospital as well as the president of Oncology-Hematology Associates in Maryland.

He currently serves as a Clinical professor of Medicine at George Washington Hospital. He has been recognized as a Top Doctor by US News and World Report and Washingtonian Magazine. He is a member of the American Society of Clinical Oncology, the American Society of Hematology and the Southern Association of Oncology.

Dr. Katzen retired from active practice in 2016. He remains involved in the medical field through various advising and consulting activities. He also advises students who are applying to medical school.

Janice Kim, PharmD
FDA Office of Hematology and Oncology Products

Janice Kim, PharmD, is a regulatory health project manager in the Office of Hematology and Oncology Products – Immediate Office and is a practicing pharmacist. She graduated from the University of Virginia with a Bachelors in biomedical engineering. In addition, she received her Masters degree in biochemistry at Georgetown University before completing her pharmacy degree at the Medical College of Virginia. She completed her ambulatory care residency at a free clinic associated with the Medical College of Virginia. She contributes to the policy development for patient-focused drug development program in the Oncology Center of Excellence at the FDA. Dr. Kim enjoys working with patients and continues to work in the free clinic setting.
Paul Kluetz, MD
FDA Oncology Center of Excellence

Paul Kluetz is a medical oncologist serving as Associate Director within the Oncology Center of Excellence (OCE) at the U.S. FDA. His interests include trial design and endpoints selection to characterize clinical benefit in oncology trials. He has presented at several advisory committee meetings discussing accelerated approval and novel trial designs and endpoints. Recent work includes efforts to advance pragmatic and decentralized trials and explore digitally sourced clinical outcome information from patient reported outcomes (PRO), wearable technologies, and other methods in both the clinical trial and "real-world" settings. In addition to assisting in the implementation of the OCE, he is currently leading a team to develop regulatory science and policy initiatives to advance patient-focused drug development across cancer products at FDA. Dr. Kluetz remains clinically active seeing patients and supervising medical residents at the Georgetown University Hospital.

Iris P. Masucci, PharmD
FDA Office of Medical Policy

Dr. Masucci joined FDA in 1998, and has been focusing on professional labeling and related policy since 2002. In CDER's Office of Medical Policy, she serves as the Office lead on professional labeling policies. She leads Office efforts on the development and implementation of labeling regulations and guidances, working closely with staff from the Office of New Drugs, the Office of Regulatory Policy, and other Offices and Centers as needed.

Lynn M. Matrisian, PhD, MBA
Pancreatic Cancer Action Network

Lynn M. Matrisian, PhD, MBA, is Chief Science Officer at the Pancreatic Cancer Action Network, based in Manhattan Beach, CA and Washington DC. She focuses on understanding and impacting the scientific and medical activities within the pancreatic cancer field to advance the organization's goal to double survival from pancreatic cancer by the year 2020. She has oversight of the organization's research activities, including the Grants Program, Clinical Trial Finder, Patient Registry, Know Your Tumor and Early Detection Initiative, and sits on the Executive Committee of the personalized medicine initiative Precision Promise.

Dr. Matrisian is formerly Professor and the founding Chair of the Department of Cancer Biology at Vanderbilt University. She received her PhD in molecular biology from the University of Arizona and MBA from Vanderbilt University. She is past President of the American Association of Cancer Research, a Fellow of the AACR Academy, and the recipient of the Paget-Ewing
award from the Metastasis Research Society. She served as co-chair of the National Cancer Institute’s Translational Research Working Group and Special Assistant to the Director of the NCI. Research in her laboratory revolved around the molecular mechanisms underlying tumor progression and metastasis, with emphasis on the biology of matrix-degrading proteinases.

**Howard McLeod, PharmD**  
Moffitt Cancer Center

Dr. Howard McLeod is Medical Director of the DeBartolo Family Personalized Medicine Institute at the Moffitt Cancer Center. He is chair of the Department of Individualized Cancer Medicine and a State of Florida Endowed Chair in Cancer Research. He is also a Senior Member of the Division of Population Sciences and Professor at the University of South Florida. Dr McLeod is chair of the NHGRI eMERGE network external scientific panel and a recent member of the FDA committee on Clinical Pharmacology and the NIH Human Genome Advisory Council. Since 2002, Dr McLeod has been vice chair for Pharmacogenomics for the major NCI clinical trials group, overseeing the largest oncology pharmacogenomics portfolio in the world. Dr McLeod is also a 1000 talent scholar of China and a Professor at Central South University in Changsha, China. Howard has published over 530 peer reviewed papers on pharmacogenomics, applied therapeutics, or clinical pharmacology and continues to work to advance individualized medicine.

**Lisa Meier McShane, PhD**  
National Cancer Institute

Lisa Meier McShane, Ph.D., is an Acting Associate Director for the Division of Cancer Treatment and Diagnosis (DCTD), U.S. National Cancer Institute, National Institutes of Health. Dr. McShane heads the Biometric Research Program (BRP) within DCTD. BRP comprises the Biostatistics and Computational and Systems Biology Branches with members including statisticians, bioinformaticians, and computational biologists. Dr. McShane is internationally recognized for her expertise on development of tumor markers for prognosis, therapy selection, and disease monitoring; omics-based predictors for clinical use; and reporting guidelines for health research studies. She holds a Ph.D. in Statistics from Cornell University and is a Fellow of the American Statistical Association. Her statistical research interests include biomarker-driven clinical trial design, analysis of high-dimensional omics data, multiple comparisons methods, surrogate endpoints, measurement error models, and biomarker assay analytical performance assessment. She co-led efforts to develop “Reporting guidelines for tumor marker prognostic studies (REMARK)” and “Criteria for the use of omics-based predictors in clinical trials.” She has coauthored numerous statistical and biomedical papers and the book Statistical Design and Analysis of DNA Microarray Investigations.

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Dr. McShane serves on the Scientific Advisory Board for Science Translational Medicine and the Editorial Board for BMC Medicine. She has served on American Society of Clinical Oncology committees that developed guidelines for HER2 and hormone receptor testing in breast cancer, EGFR mutation testing in lung cancer, and biomarkers in early stage breast cancer. She has served as a member of the Institute of Medicine Committee for Management of the Air Force Health Study Data and Specimens, the Consensus Committee on Management of the Air Force Health Study Data and Specimens-Report to Congress, and the Committee on the State of the Science in Ovarian Cancer Research.

Kelly M. McVearry, PhD, MA, EdM
Hypatia Group, Inc.

Dr. Kelly McVearry, a clinician-scientist and biotechnology investor, has two decades of executive, board-level and PI-level experience in biomedical discovery & commercialization. She speaks frequently about early stage investing in cures, and is a patient advocate for precision medicine in vulnerable populations. She is the managing partner of the Hypatia Group, Inc., a company that invests in emerging medtech and information technologies that bring lifesaving innovation to patients.

Dr. McVearry is the Chairman of the Board of Directors for Lupus Therapeutics (New York, NY), a venture philanthropy fund established by Michael Bloomberg and Woody Johnson (JNJ) to invest in precision medicine strategies for autoimmune disease, with a focus on repositioning approved drugs for lupus patients, and de-risking clinical assets from the pharmaceutical industry, through our 57-site clinical trial network with 200 Clinical investigators. Kelly also serves on the Board of Directors for Life Science Angels (Palo Alto, CA) as Chair of Syndication, and member of the medtech and biopharma investment committees. She has completed terms serving on numerous nonprofit, government and industry boards and executive committees, including the Institute of Medicine Roundtable for Translating Genomic-Based Research for Health (now the National Academies “Genomics Roundtable”). As a biomedical researcher, Dr. McVearry has been a principal investigator and co-investigator for multi-site clinical trials and hypothesis-driven prospective studies of neurodevelopment, fetal exposure to neuroactive drugs, and comparative effectiveness studies in neuropharmacology. In 2010, as Co-Investigator, her clinical cohort study of prenatal exposure to antiepileptic drugs was cited by the FDA as core evidence for relabeling valproate as unsafe for use in women of childbearing age.

Dr. McVearry served as Senior Scientist on the Executive Team of Northrop Grumman Health Information Systems, where she was responsible for long range strategic planning, technology scouting, and serving as Principal Investigator in the Northrop Grumman Futures Lab developing public health data interoperability models for adverse events, proteomics, genomics, and biomedical imaging (US Patent 9,466,024 for Learning health systems and methods). During this tenure, she collaborated with Genomics Roundtable members to develop Genome-Based Diagnostics: Demonstrating Clinical Utility in Oncology (Copyright 2013, National Academies Press) and Sharing Clinical Research Data (Copyright 2013, National Academies Press). She served as the interim product manager for the FDA Clinical Trial Repository, which received a 2014 Merit Award from the NIH National Cancer Institute Director Dr. Harold Varmus, and as lead author for Data Harmonization Architecture for Accelerated Regulatory Review (Integrated Pharma
Informatics & Data Science, Tri-CON 2015). She obtained a doctorate with distinction in Interdisciplinary Neuroscience (Georgetown University), a master’s in Human Development and Cognitive Psychology (Harvard University), and a master’s in Learning Disabilities and Psychoeducational Assessment (American University).

Rebecca Miksad, MD, MPH
Flatiron Health

Rebecca Miksad is senior medical director at Flatiron Health, where she focuses on real-world evidence generation. Rebecca’s academic research has focused on improving cancer treatment decision-making through better characterization of patient outcomes, increasing relevance of clinical trial endpoints and evaluating economic implications of cancer therapy. A nationally recognized clinician and health services researcher, Rebecca publishes in leading medical journals and serves on national clinical and research committees.

Prior to joining Flatiron Health, Rebecca was an assistant professor at Harvard Medical School, a senior scientist at the Institute for Technology Assessment at Massachusetts General Hospital, and the director of gastrointestinal oncology at Beth Israel Deaconess Medical Center (BIDMC). Rebecca earned a BA cum laude in economics from Harvard University and an MD with honors in research from Cornell University. She completed her internal medicine residency training at New York-Presbyterian Hospital and Hematology/Oncology fellowship at BIDMC. With a focus on translating between clinical trial and outcomes research, Rebecca earned a MMS from Harvard Medical School and an MPH from the Harvard School of Public Health in Clinical Effectiveness. She also completed the NCI-funded post-doctoral fellowship in the Dana-Farber/Harvard Cancer Center Program in Cancer Outcomes Research Training (PCORT).

Sally C. Morton, PhD
Virginia Polytechnic Institute and State University

Sally C. Morton, Ph.D., is dean of the College of Science and professor of Statistics at Virginia Tech. She previously served as chair of Biostatistics at the University of Pittsburgh, vice president for Statistics and Epidemiology at RTI International, and head of the RAND Statistics Group. Her methodological research focuses on evidence synthesis, particularly meta-analysis. She is a member of the Agency for Healthcare Research and Quality (AHRQ) National Advisory Council, and has been involved in the AHRQ Evidence-Based Practice Center program since it began. Her research projects span a range of clinical and societal issues including healthcare quality, homelessness, mental health, and substance abuse. Morton served as president of the American Statistical Association (ASA) and
is a Fellow of the ASA and the American Association for the Advancement of Science. She received a PhD in statistics from Stanford University.

**Harold L. Moses, MD**  
Vanderbilt-Ingram Cancer Center

Dr. Moses is the Director Emeritus of the Vanderbilt-Ingram Cancer Center, Research Professor of Pharmacology, Professor of Cancer Biology, Medicine and Pathology, and the founding and current Director of the Frances Williams Preston Laboratories. Moses graduated from Berea College in 1958 and then obtained an M.D. degree from Vanderbilt University School of Medicine in 1962. After residency training in pathology at Vanderbilt and postdoctoral research training at the National Institutes of Health, he spent five years as a faculty member in pathology at Vanderbilt and twelve years at the Mayo Clinic in Rochester, Minnesota, the last six of which were as Chair of the Department of Cell Biology. He returned to Vanderbilt 20 years ago as Professor and Chair of the Department of Cell Biology in the School of Medicine. Twelve years ago he became the Founding Director of the Vanderbilt Cancer Center with a concurrent appointment as the B.F. Byrd, Jr. Professor of Clinical Oncology. He resigned as Chair of the Department of Cell Biology in 1998 to devote more time to the Cancer Center. At the end of 2004, he became Director Emeritus of the Vanderbilt-Ingram Cancer Center and the Hortense B. Ingram Professor of Medical Oncology. In 2013, he became Ingram Professor of Cancer Research.

Dr. Moses was President of AACR (1991-1992), President of the Association of American Cancer Institutes (2003-2005), elected member of the National Academy of Medicine (2003), Founding Chair of the National Cancer Polity Forum (2005-2011), and chair of two IOM/NAM Consensus Committees. He has chaired three NIH study sections and is a Fellow of the AACR Academy and a Fellow of the National Academy of Inventors. He has over 300 peer-reviewed publications.

**Jenny Mosier, JD**  
Michael Mosier Defeat DIPG Foundation

Jenny Mosier is the Executive Director and Co-Founder of Michael Mosier Defeat DIPG Foundation. A lawyer by training, Jenny graduated from the University of Chicago Law School and began her legal career with Covington & Burling LLP from 2003 to 2010, where she focused on litigation and white collar matters. In September 2010, Jenny joined the Office of Attorney General in the Department of Justice, where she advised the Attorney General on litigation, enforcement and policy issues in a range of areas. In Fall 2014, she was serving as Deputy Chief of Staff and
Counselor to Attorney General Eric Holder, when she learned the tragic news that her six-year-old son Michael had a cancerous tumor in his brainstem called diffuse intrinsic pontine glioma (DIPG). After seeing firsthand the desperate need for funding and awareness for DIPG, Jenny turned her professional focus to raising awareness and funds for DIPG to help find a cure for this devastating cancer.

Jenny earned her B.A. from The Johns Hopkins University, with a double major in Psychology and Sociology and a concentration in Social Inequality.

Richard Pazdur, MD
FDA Oncology Center of Excellence

Richard Pazdur, M.D. is the director of the FDA’s Oncology Center of Excellence (OCE), which leverages the combined skills of the FDA’s regulatory scientists and reviewers with expertise in drugs, biologics and devices to expedite the development of novel cancer products. In his role as director of the OCE, Pazdur is responsible for leading the effort to develop and execute an integrated regulatory approach to enhance the cross-center coordination of oncology product clinical review.

Pazdur previously served as the director of the Office of Hematology and Oncology Products (OHOP) in the FDA’s Center for Drug Evaluation and Research and will continue to serve in OHOP as acting director. This Office was formed in 2005 to consolidate the review of drugs and therapeutic biologics for the diagnosis, treatment, and prevention of cancer, as well as the review of drugs and therapeutic biologics for hematologic diseases and for medical imaging. As director of OHOP, Pazdur facilitated coordination of oncology activities across all FDA Centers and ensured an ongoing outreach and collaboration between the FDA, the National Cancer Institute, and other cancer-related organizations within and outside of the government. Pazdur was the director of the Division of Oncology Drug Products from September 1999 to May 2005.

Prior to joining the FDA, Pazdur was professor of medicine at The University of Texas M.D. Anderson Cancer Center in Houston, Texas. Pazdur was on the faculty of the M. D. Anderson Cancer Center from 1988 to 1999. During his tenure at the M. D. Anderson Cancer Center, Pazdur held administrative positions of assistant vice president for academic affairs, associate director of clinical trials administration (Division of Medicine) and director of educational programs (Division of Medicine). Pazdur served on the faculty of Wayne State University, Detroit, Michigan from 1982 to 1988.

Pazdur received his bachelor’s degree from Northwestern University (Evanston, Illinois), his M.D. from Loyola Stritch School of Medicine (Maywood, Illinois), and completed clinical training at Rush-Presbyterian St. Luke’s Medical Center (Chicago, Illinois) and the University of Chicago Hospitals and Clinics. Pazdur has published more than 400 articles, book chapters and abstracts. In 2015, Fortune magazine named Pazdur as one of the 50 World’s Greatest Leaders. The American Association for Cancer Research recognized Pazdur with its Distinguished Public Service Award (2015) and the American Society of Clinical Oncology recognized him with the Service Recognition Award (2009) and the Public Service Award (2013). In 2015, Pazdur also received the Public Service Leadership Award from the National Coalition for Cancer Survivorship and also the Face of Hope Award from the LUNGevity Foundation. Most recently, in 2016, Pazdur was named to Massachusetts General Hospital Cancer Center’s “The One Hundred” list.

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Steven Piantadosi, MD, PhD
Brigham and Women’s Hospital and Alliance for Clinical Trials in Oncology

Dr. Piantadosi received his medical degree from the University of North Carolina, Chapel Hill, followed by a PhD in Biomathematics at the University of Alabama, Birmingham. After six years as Staff Fellow at the National Cancer Institute (NCI), he joined the Department of Oncology at the Johns Hopkins Medical Institutions as Director of Biostatistics. He rose through the ranks as Professor of Oncology, and also in the Departments of Biostatistics and Epidemiology at Johns Hopkins School of Public Health. In 2007, he moved to Cedars-Sinai Medical Center in Los Angeles, where he served as the first Director of the Samuel Oschin Comprehensive Cancer Institute for 10 years.

A leader in the field of clinical trials design and conduct, Dr. Piantadosi is the author of Clinical Trials: A Methodologic Perspective, the definitive textbook on this subject, which is now in its third edition. He is a highly experienced advisor to academia, government and industry, with a broad scope of accomplishment in the cancer clinical research field, including trials testing surgical approaches, optimizing results of bone marrow transplantation, cancer vaccine trials, phase I/II strategies for combining chemotherapy with biologics, design issues in translational research, strategies for accelerating anticancer drug development, and the role of information science in medical research.

In 2018, Dr. Piantadosi joined the Brigham and Women’s Hospital Division of Surgical Oncology as Associate Senior Biostatistician. He also joined the Alliance for Clinical Trials in Oncology Executive Committee as the Associate Group Chair for Strategic Initiatives and Innovation, as well as the Alliance Statistics and Data Management Program.

N.A.M. Atiqur Rahman, PhD
FDA Office of Clinical Pharmacology V

NAM Atiqur Rahman, Ph.D., is the Director of the Division of Clinical Pharmacology V within the Office of Clinical Pharmacology (OCP), OTS, CDER, US Food and Drug Administration (USFDA). The Division includes 30 clinical pharmacology reviewers who are involved in the development, review, approval, and life cycle management of the Hematology/Oncology and Medical Imaging products. Prior to joining FDA in 1991, Dr. Rahman earned his doctorate degree from Washington State University in Pharmacology and Toxicology and completed post-doctoral training at the St-Jude Children’s Research Hospital, Memphis, Tennessee in Molecular Pharmacology and Pharmacogenomics.

Dr. Rahman’s current interest includes immunoncology, dose optimization, and application of modeling and simulation in Oncology product development. Dr. Rahman interest also includes use of pharmacogemonics to

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promote personalized medicine for cancer patients. He supports the review staff that addresses various scientific challenges in drug development and approval, and interacts with pharmaceuticals to promote and facilitate innovation in drug development from Clinical Pharmacology perspectives. Dr. Rahman received over 40 awards at the FDA level awards, published 55 articles in peer review journals and authored 6 book chapters. He has given over 50 presentations in national and international meetings, workshops and symposiums. He is currently a member of American Society of Clinical Oncology.

**Gregory Reaman, MD**  
FAC Cancer Policy Forum  
FACO Oncology Center of Excellence  

Gregory H. Reaman, M.D. is the Associate Director for Oncology Sciences in the Office of Hematology and Oncology Products, OND, CDER and the Associate Director for Pediatric Oncology in the Oncology Center of Excellence. He is Professor of Pediatrics at George Washington University School of Medicine and Health Sciences in Washington, D.C. and a member of the Division of Hematology-Oncology and Executive Director Emeritus of the Center for Cancer and Blood Disorders at the Children’s National Medical Center, which he directed for more than 17 years. He is the Inaugural Chair of the Children’s Oncology Group (COG) having served in this capacity from 2000 through 2010. The COG is comprised of over 200 member institutions, dedicated to clinical, translational, and epidemiology research in childhood cancer. Prior to this, he was the Vice Chair for Scientific Affairs and the Associate Chair for New Agent Studies of the Children’s Cancer Group (CCG) for 10 years and directed the CCG Phase I Consortium. He joined the FDA in 2011 as the Associate Director for Oncology Sciences in the Office of Hematology and Oncology in the Center for Drug Evaluation and Research.

Dr. Reaman serves or has served on several editorial boards; he served as an Associate Editor of Cancer and Leukemia and Lymphoma. He served on the Board of Directors of the American Cancer Society and chaired its Task Force on Children and Cancer and has served on the Board of Directors of the American Society of Clinical Oncology (ASCO) and has served on numerous ASCO committees. He was elected to the Board of the International Society of Pediatric Oncology (SIOP) as treasurer in 2011. He serves on the AACR’s Pediatric Cancer Working Group. His research interests are in the biology and treatment of childhood acute leukemia and new drug development for pediatric cancers. He is the author of more than 350 peer-reviewed manuscripts and 20 book chapters and editor of 5 text books.
Andrew Ryscavage, MA, MBA
Monitor Deloitte

Andrew Ryscavage is a strategy management consultant and former scientist with almost 20 years of experience in innovation, strategy, technology, and organizational development in both biomedical research and business strategy. As a scientist, Andrew conducted extensive life science research at the National Cancer Institute in the Laboratory of Cancer Biology and Genetics. As a strategy practitioner, Andrew leads strategic planning and implementation efforts focusing on innovation and market disruption with biotechnology companies, health systems, non-profits, and various federal agencies including the NIH and FDA.

In addition to his research, Mr. Ryscavage has served as a science diplomat for the Department of State and the National Institutes of Health bridging public policy and life science business strategy. He was an Embassy Science Fellow in Portugal in 2012 where he constructed an economic impact analysis of that country’s life science and health care sector and negotiated agreements between the US and Portugal around health and science collaboration and training.

Wendy R. Sanhai, PhD, MBA
Deloitte

Dr. Wendy R. Sanhai has extensive experience across a broad spectrum of issues in the pharmaceutical, biotech and medical device industries and regulatory science. Over the course of her career, she has held key leadership roles in academia, at federal research and regulatory organizations including the NIH, the Foundation for NIH (FNIH) and the FDA and, most recently, within private industry. Among her many strengths is her ability to identify critical governance, strategic and scientific gaps, and leverage resources to create innovative approaches in support of large-scale, strategic, scientific, and public health initiatives, all directed to patient benefit.

Her experiences include developing strategies for governance, research, business development, as well as the design, implementation, and management of large-scale scientific collaborations at the NIH, FNIH, FDA, academia and industry. She has worked across multiple therapeutic and disease prevention areas as well as in medical product development, addressing specific product development issues, regulatory challenges as well as global health needs.

Dr. Sanhai’s dedication to the advancement of biomedical research and public health began in academia while serving first as Clinical Chemistry Fellow, then scientific researcher, and ultimately a faculty member in the Departments of Pathology and Medical and Research Technology at the University of Maryland, School of Medicine. She left academia in 2001 to join the NIH, Office of Technology Transfer as a Technology Licensing Specialist and Patent Advisor, where she managed a license and intellectual property
portfolio of more than 300 NIH invention families from across 27 Institutes and Centers of the NIH, with special emphasis on the National Cancer Institute. Dr. Sanhai worked extensively with industry, academia, and international organizations on behalf of NIH and FDA, conducting a full range of activities associated with business development including intramural and extramural NIH research, securing appropriate intellectual property protection, and negotiating the transfer of those patent rights to the private sector to promote the research, development, and commercialization of medical products that were patient-focused. Dr. Sanhai joined the FNIH in 2002 as Director of Public-Private Partnerships. In this position, she created, implemented, managed, and evaluated all new and existing programs in clinical research, education, and training. As FNIH’s Chief Scientific Liaison to the NIH, other federal agencies, academia, industry, and non-profit organizations, her program portfolio budget reached $113M, notwithstanding the FNIH’s $200M Grand Challenges in Global Health Initiative.

In 2004, Dr. Sanhai was appointed Senior Scientific Advisor, Office of the Commissioner, FDA, where she led until 2011, the development, implementation, and management of FDA’s Scientific Initiatives and Strategic Partnerships as part of FDA’s public health mission. She served as FDA’s Chief Scientific Member on a number of boards, clinical studies, consortia, and regulatory/scientific committees, leading innovative models of scientific collaborations, governance and collaborative efforts with key stakeholders. Dr. Sanhai was recognized for her outstanding achievements at FDA, receiving the Commissioner’s Leveraging/Collaboration Award in 2005, 2006, and 2008 and two scientific Achievement Awards in 2009 for cross-center clinical collaborations.

Following her 10+ years within the Department of Health and Human Services, Dr. Sanhai joined GlaxoSmithKline (GSK) in 2011 as Senior Director, Regulatory Policy and Advocacy. In this capacity, she was responsible for ensuring that GSK remained current on the continually evolving regulatory environment and, most importantly, retained a leadership role in efforts to adapt to new science/medicine, changes in healthcare policy, and changes in the macro political and economic environment. Dr. Sanhai promoted GSK’s engagement with global regulators, trade organizations and other stakeholders, effectively influencing the global regulatory environment. Dr. Sanhai worked closely with development teams across GSK’s numerous therapeutic areas to develop clinical and regulatory strategies toward efficient product development in the interest of patients. Entering the consulting world in 2014, Dr. Sanhai served as Senior Managing Scientist at Exponent Inc., an international consulting firm with over 90 scientific and engineering disciplines. In 2016 she joined Deloitte Consulting: Federal Strategy and Operations as a Specialist Leader. In this position, Dr. Sanhai combines unparalleled subject matter expertise and business acumen to address the needs of clients in the pharmaceutical, biomedical and medical device fields, and leverages her expertise along with Deloitte’s multidisciplinary teams of strategy and advisory consultants to provide in-depth analysis and strategic solutions to clients.

Dr. Sanhai is a member of the Board of Directors of Medicines for Malaria Ventures (MMV), a leading product development partnership organization with one of the world’s largest antimalarial drug pipelines. She is also an Associate Professor (adjunct) at Duke University School of Medicine, and a Senior Executive Education Fellow and Member of the Advisory Board at the Robert H. Smith School of Business, University of Maryland. Dr. Sanhai received a Ph.D. in clinical biochemistry and structural biology from the School of Medicine, State University of New York at Buffalo, an Executive M.B.A., Smith School of Business, University of Maryland, and a baccalaureate degree in chemistry from the University of Florida, Gainesville.

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Richard L. Schilsky, MD, FACP, FSCT, FASCO
American Society of Clinical Oncology

Dr. Schilsky is the Senior Vice President and Chief Medical Officer (CMO) of ASCO. Formerly the Chief of Hematology/Oncology in the Department of Medicine and Deputy Director of the University of Chicago Comprehensive Cancer Center, he is a highly respected leader in the field of clinical oncology. He specializes in new drug development and treatment of gastrointestinal cancers. Dr. Schilsky is a Past President of ASCO, having served in the role during 2008-2009, and also a Past Chair of one of the National Cancer Institute’s Cooperative Groups, Cancer and Leukemia Group B (CALGB).

Dr. Schilsky’s impressive experience and many accomplishments in both clinical medicine and clinical research reflect his deep passion for cancer medicine. He has spent the majority of his career at the University of Chicago where he joined the faculty in 1984, subsequently rising to the rank of Professor of Medicine and serving in many roles, including Associate Dean for Clinical Research in the Biological Sciences Division and Director of the University of Chicago Cancer Research Center.

From 1995 to 2010, Dr. Schilsky served as chair of the Cancer and Leukemia Group B, a national cooperative clinical research group funded by the National Cancer Institute (NCI). He has extensive experience working with both the NCI and the Food and Drug Administration (FDA) having served as a member and chair of the NCI Board of Scientific Advisors, as a member of the NCI Clinical and Translational Research Committee, and as a member and chair of the Oncologic Drugs Advisory Committee of the FDA. Dr. Schilsky has served on the editorial boards of many cancer journals, including the Journal of Clinical Oncology. He presently serves on the editorial board of the New England Journal of Medicine. Early in his career, he worked in the Clinical Pharmacology Branch of the Division of Cancer Treatment at the NCI and was an Assistant Professor in the Department of Internal Medicine, Division of Hematology and Oncology at the University of Missouri-Columbia School of Medicine. He was also the head of the hematology/medical oncology unit at the Harry S. Truman Veterans’ Administration Hospital in Columbia, Missouri.

Julie Schneider, PhD
FDA Oncology Center of Excellence

Julie Schneider, Ph.D., is Associate Director for Research Strategy and Partnerships at the FDA Oncology Center of Excellence. She previously ran the HHS Entrepreneurs-in-Residence Program within the HHS IDEA Lab and worked in several roles at the National Cancer Institute (NCI) focused on developing new research funding opportunities, including a ~$20 million US-China Program for Biomedical Research Cooperation co-funded by five NIH institutes at the National Natural Science Foundation of China. Julie initially joined the NCI as an AAAS Science and Technology Policy Fellow and

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obtained her doctoral degree in genetics from the University of Oxford and her bachelor’s degree in biology from Yale.

Stacy Shord, PharmD, BCOP, FCCP
FDA Division of Oncology Products II

Dr. Shord is currently Associate Director for Labeling in the Division of Oncology Products II in the U.S. Food and Drug Administration. Dr. Shord received her Doctor in Pharmacy from the University of Maryland at Baltimore in 1997. She then completed a Pharmacy Practice residency at the University of Pittsburgh Medical Center, an Oncology Pharmacy Practice residency at the UNC Hospitals, and a fellowship in Oncology Pharmacotherapy at the School of Pharmacy, University of North Carolina. Dr. Shord joined the faculty at the College of Pharmacy, University of Illinois at Chicago in 2001 as assistant professor where her research focused on drug metabolism in patients with cancer and hematological diseases. She joined the Food and Drug Administration in 2009 and served a primary reviewer and Lead Pharmacologist in the Office of Clinical Pharmacology. Special interests included the clinical development of antibody drug conjugates and epigenome targeted drugs. Dr. Shord participates in the Thoracic Oncology Clinic at the Clinical Center at the National Institutes of Health. Dr. Shord earned her Board Certification in Oncology Pharmacy in 2000. She has authored 45 peer reviewed papers and 11 book chapters. Dr. Shord is a member of the American College of Clinical Pharmacy, American Society of Clinical Oncology and Hematology Oncology Pharmacists Association.

Rajeshwari Sridhara, PhD
FDA Office of Biostatistics

Rajeshwari Sridhara, PhD, is the Division Director of Division of Biometrics V, Office of Biostatistics which supports Office of Hematology Oncology Products at the Center for Drug Evaluation and Research (CDER). She joined the Food and Drug Administration (FDA) in 1999. Dr. Sridhara has contributed in the understanding and addressing the statistical issues that are unique to the oncology disease area such as evaluation and analysis of time to disease progression. Her research interests also include evaluation of surrogate markers and design of clinical trials. She has organized, chaired and given invited presentations at several workshops. She has worked on many regulatory guidance documents across multiple disciplines. She has extensively published in refereed journals and presented at national and international conferences. She is an elected fellow of the American Statistical Association. Prior to joining FDA, Dr. Sridhara was a project statistician for the AIDS vaccine evaluation group at EMMES Corporation, and she was an assistant professor at the University of Maryland Cancer Center.

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Oliver Steck, MSc  
Deloitte & Touche LLP

Oliver Steck is a Principal in Deloitte & Touche's Regulatory & Operational Risk Advisory practice and is leading the Regulatory and Patient Safety Risk Advisory group. He has over 20 years experience as a management consultant in the life science and medical device industry and helped global pharmaceutical and medical device clients to optimize their organizations, conducted and oversaw compliance mitigation programs and managed global programs around regulatory intelligence, drug safety and overall risk and quality management. Oliver lived and worked in Europe, Asia and the Americas.

Mark Stewart, PhD  
Friends of Cancer Research

Mark Stewart serves as a Vice President, Science Policy at Friends of Cancer Research (Friends). Friends is an advocacy organization based in Washington, DC that drives collaboration and has been instrumental in the creation and implementation of policies ensuring patients receive the best treatments in the fastest and safest way possible.

At Friends, Mark leads the development and implementation of the organization’s research and policy agenda as well as overseeing the conduct of research projects to inform ongoing policy discussions. Mark establishes unique partnerships to help develop innovative policy proposals and consensus-driven solutions to address challenges and accelerate cancer drug development. He regularly participates in policy discussions and meetings throughout the year to help catalyze meaningful change for oncology healthcare.

Prior to joining Friends, Mark worked at the National Academies of Sciences, Engineering, and Medicine. At the Academies, he assisted with a congressionally mandated study that resulted in the report titled Ovarian Cancers: Evolving Paradigms in Research and Care. This report identified gaps in ovarian cancer knowledge and care, and established science and policy recommendations to overcome these gaps. Mark also assisted the National Cancer Policy Forum.

Mark has had the honor to serve on several committees and advisory councils, including the Associate Member Council of the American Association for Cancer Research (AACR), Drug Information Association RWE Program Planning Committee, and the Cancer CRG Network Engagement Group. Mark Stewart received his PhD in cancer biology from the University of Alabama at Birmingham and was a recipient of two Federal grants including the NCI’s Ruth L. Kirschstein National Research Service Predoctoral Award.
Steven Sun, PhD
Janssen Research and Development

Dr. Sun is a Senior Scientific Director of Oncology Biostatistics at Janssen Research and Development. He has over 20 years of experience in the pharmaceutical industry with the last 16 years focusing on oncology / hematology therapeutic areas. At Janssen, Dr. Sun has been the statistical leader for multiple major oncology products development and NDA/sNDA/MAA submissions, including the first Breakthrough Designation of oncology therapy IMBRUVICA® for B-cell malignancies and the most recent CD38 monoclonal antibody DARZALEX® for multiple myeloma. He has extensive experience in clinical trial designs and regulatory interactions for drug labeling. He served as a sponsor representative in multiple Oncologic Drugs Advisory Committee (ODAC) meetings. Dr. Sun received a Johnson Medal award for his outstanding leadership in the initial approval of IMBRUVICA®.

Dr. Sun has been the invited speaker for many professional meetings including the FDA/Industry workshop, DIA workshop, Harvard symposium, and Joint Statistical Meetings. He is very active in organizing and chairing professional meetings and has published numerous scientific papers in statistical and medical journals. He got his PhD in statistics from Purdue University and his research interest is in the area of survival analysis and cancer clinical trials.

Marc R. Theoret, MD
FDA Office of Hematology and Oncology Products and Oncology Center of Excellence

Dr. Marc Theoret is a medical oncologist and the Deputy Director (Acting) in the Office of Hematology and Oncology Products (OHOP), CDER, FDA, and the Acting Associate Director of Immuno-Oncology Therapeutics in the Oncology Center of Excellence (OCE), FDA. He received his medical degree from the Penn State College of Medicine, internship and residency training in Internal Medicine at the Beth Israel Deaconess Medical Center in Boston, and fellowship training in Medical Oncology and Hematology at the National Cancer Institute in Bethesda.

In 2009, Dr. Theoret came to FDA and served as primary medical officer in the Division of Biologic Oncology Products and then in the Division of Oncology Products (DOP) 2. He subsequently served as the Clinical Team Leader of the Melanoma-Sarcoma team, DOP2, from 2013 to 2017. In his role as Associate Director, Dr. Theoret is leading initiatives in immuno-oncology product development—regulatory, scientific, and policy efforts. In these roles and now as Acting Deputy Director of OHOP, Dr. Theoret has led reviews of numerous breakthrough therapies, new molecular entities, and novel biologics. His regulatory research interests include evaluation of novel endpoints for development of cancer immunotherapies and novel trial
designs to expedite drug development in oncology. Dr. Theoret remains actively engaged in clinical research at the NCI Genitourinary Malignancies Branch.

Josephine Torrente, JD
Hyman, Phelps & McNamara

Josephine Torrente’s is a partner at Hyman, Phelps & McNamara, P.C., a food and drug law boutique in Washington, DC. Her practice is devoted to bringing promising new drug and biological products, including cell therapies, to market. Ms. Torrente advises clients throughout drug development, from preclinical and Phase 1 matters to complex Phase 3 study design issues, Special Protocol Assessment (SPA) negotiations, and advisory committee preparation. As part of this process, she assists clients in responding to FDA information requests during development and NDA or BLA review with a view toward fully understanding and addressing FDA concerns at the earliest possible time.

Ms. Torrente has provided counsel on issues specific to the drug development of therapies for serious and life threatening diseases (accelerated approval, surrogate endpoints, historical control groups, fast track, breakthrough therapy and orphan drug designation), 505(b)(2) applications (bridging studies and selection of an appropriate listed drug), safety issues (design and timing of large safety studies, including cardiovascular outcomes trials, REMS utility and elements, trade name matters, and abuse-deterrent formulations of prescription opioids), and FDA’s fixed dose combination drug rule. In this context, Ms. Torrente attends drug development meetings at both the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), frequently communicating with various FDA division and office directors.

Ann Marie Trentacosti, MD
FDA Labeling Development Team

Ann Marie Trentacosti is the Medical Lead for the Labeling Development Team (LDT) [Office of New Drugs (OND) Policy staff] in the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). As the LDT medical lead, Dr. Trentacosti participates in CDER labeling policy initiatives to promote consistency in and improve labeling practices, assists in the development and review of the prescribing information, provides oversight of labeling quality, develops labeling resources, and provides labeling review training.
Vikrant Vats, PhD
Blue Cross Blue Shield Association

Vikrant Vats, Ph.D., is a health care professional with long-standing experience in the payer space focusing on pharmacy and medical coverage and policy decisions at a national level. He has performed over 150 evidentiary assessments in that area of pharmaceuticals and devices. Dr. Vats currently serves as Director of Clinical Services in the Office of Clinical Affairs at the Blue Cross Blue Shield Association. In this role, he leads evidence-based assessments of specialty pharmaceuticals and medical technologies that are disseminated to Blue Cross Blue Shield plans for pharmacy and medical benefit coverage decisions.

Prior to his work at the Blue Cross Blue Shield Association, Dr. Vats was an assistant professor at Western University of Health Sciences and a research fellow at the Walgreen’s Health Initiatives. He earned his M.S. and Ph.D. in pharmacology from the All India Institute of Medical Sciences. He additionally completed post-doctoral fellowships at the University of Illinois at Chicago College of Pharmacy and at Walgreens Health Initiatives.

Katherine Warren, MD
National Cancer Institute

Katherine Warren, M.D. is a Senior Investigator at the National Cancer Institute, where she leads the Pediatric Neuro-Oncology Section. Dr. Warren graduated from North Adams State College (now MCLA) with a bachelor’s degree in Medical Technology. After working as a Medical technologist at Massachusetts General Hospital before receiving a medical degree from Tufts Medical School. She completed an internship and residency in Pediatrics at Children’s National Medical Center (Washington, DC) and fellowship training in Pediatric Oncology at the National Cancer Institute.

Dr. Warren has continued at the National Cancer Institute for more than 25 years, leading a pediatric brain tumor program that incorporates pre-clinical, translational and clinical research. Her major focus is developing new therapeutics to improve the outcome and quality of life for children with CNS tumors. The goal of her research is to strengthen the disease-specific rationale and evaluate pharmacokinetics including CNS penetration of drugs in order to optimize clinical trial design and patient outcomes. Dr. Warren has extensive experience in pharmacology, neuro-imaging, and clinical trial design and incorporates each of these into her research. She has led a number of clinical trials, including single institution, multi-institution, national consortium and international trials.

Dr. Warren currently serves as the chair of RAPNO (Response Assessment in Pediatric Neuro-Oncology), a member of the NCI Brain Malignancy Steering Committee, NCI Clinical Trials and Translational Research Advisory Committee Ad hoc Working Group on Glioblastoma, and is a steering committee member for the
Pediatric Brain Tumor Consortium and the DIPG Registry. She has served on numerous national and international scientific committees and advisory boards.

Janet Wittes, PhD
Statistics Collaborative, Inc.

Janet Wittes, PhD is President of Statistics Collaborative, Inc. which she founded in 1990. Previously, she was Chief, Biostatistics Research Branch, National Heart, Lung, & Blood Institute (1983–89). Her 2006 monograph, “Statistical Monitoring of Clinical Trials – A Unified Approach” by Proschan, Lan, and Wittes, deals with sequential trials. Her research has focused on design of randomized clinical trials, capture recapture methods in epidemiology, and sample size recalculation. She has served on a variety of advisory committees and data monitoring committees for government (NHLBI, the VA, NEI, and NCI) and industry. For the FDA, she has been a regular member of the Circulatory Devices Advisory Panel and has served as an ad hoc member of several other panels. Currently, she is a regular member of the Gene Therapy Advisory Committee. She was formerly Editor in Chief of Controlled Clinical Trials (1994-98).
The National Cancer Policy Forum serves as a trusted venue in which experts can identify emerging high-priority policy issues in cancer research and care and work collaboratively to examine those issues through convening activities focused on opportunities for action. The Forum provides a continual focus within the National Academies on cancer, addressing issues in science, clinical medicine, public health, and public policy that are relevant to the goal of reducing the cancer burden, through prevention and by improving the care and outcomes for those diagnosed with cancer. Forum activities inform stakeholders about critical policy issues through published reports and often inform consensus committee studies. The Forum has members with a broad range of expertise in cancer, including patient advocates, clinicians, and basic, translational, and clinical scientists. Members represent patients, federal agencies, academia, professional organizations, nonprofits, and industry.

The Forum has addressed a wide array of topics, including:

- enhancing collaborations to accelerate research and development;
- improving the quality and value of care for patients who have been diagnosed with or are at risk for cancer;
- developing tools and technologies to enhance cancer research and care; and
- examining factors that influence cancer incidence, mortality, and disparities.
Upcoming Workshops

Health Literacy and Communication Strategies in Oncology
July 15-16, 2019

Estimates suggest that more than a third of the U.S. adult population has poor health literacy. Across the cancer care continuum, poor health literacy can make it difficult for individuals to engage in healthy behaviors, navigate the health care system, make informed treatment decisions, and engage in survivorship care.

This workshop will examine opportunities, methods, and strategies to improve the communication of cancer information in a clinic visit, across a health care organization, and among the broader community. Workshop presentations and discussions will address topics such as:

- procedures, policies, programs to assess and address the diverse health literacy needs of patients and their families
- best practices to improve communication with patients and their families about cancer prevention, detection, and treatment
- communication strategies to build public trust and counter inaccurate information about cancer
- opportunities to tailor cancer messaging to meet the needs of diverse populations


Applying Big Data to Address the Social Determinants of Health in Oncology
October 28-29, 2019

The rapidly increasing quantity and quality of big data, platforms for data collection, and innovations in analytic methods have the potential to transform cancer care. Advances in cancer research—across the prevention, treatment, and survivorship continuum—and precision medicine strategies increasingly rely on the collection and interpretation of big data. However, there are concerns that not all individuals and communities may benefit equally from progress that leverages big data.

This workshop will provide a venue for the cancer community to examine the impact of big data on disparities in cancer care and consider opportunities to enhance patient care and population health by addressing the social determinants of health (SDOH). Workshop presentations and discussions will focus on how best to leverage SDOH data in the collection, evaluation, and translation of big data into precision treatments and to reduce bias in capturing and applying big data as research progresses.

Workshop website forthcoming

Related Work: Consensus Study Building on the Work of the Forum

A National Strategy for Cancer Control in the United States

Although many stakeholders in the United States are actively involved in cancer control activities, these efforts are not well-coordinated and to date there has been no national strategy for cancer control. The lack of a national strategy for cancer control can make it difficult to assess progress, coordinate efforts, identify gaps in cancer control planning, and reduce areas of unwarranted duplication. The National Academies launched a new consensus study that will examine existing cancer control efforts in the United States and recommend national strategies to reduce the incidence, morbidity, and mortality from cancer and to improve quality of life for cancer survivors. For more information, please see www.nas.edu/cancercontrol.
Updating Labels for Generic Oncology Drugs
March 26, 2019

This project, sponsored by the Food and Drug Administration, is being conducted under the auspices of the National Cancer Policy Forum, in collaboration with the Forum on Drug Discovery, Development, and Translation. This meeting convenes stakeholders with a broad range of expertise to discuss the challenges and opportunities to update generic oncology drugs labels that are inconsistent with the current evidence base and use in clinical practice. Discussions will examine what sources of information should be taken into account for labeling updates, the evidentiary standards for labeling updates, and evidence considerations for special populations, such as pediatric oncology.

Workshop website:

Developing and Sustaining an Effective and Resilient Oncology Careforce
February 11-12, 2019

Rapid advances in cancer research, new technological innovations, the expanding clinical evidence base, and changing demographics are all transforming the landscape of cancer care. Given these trends, there is a need to ensure the availability of an effective and well-coordinated oncology careforce that can provide high-quality cancer care. This workshop considered opportunities to enhance the delivery of high-quality care to a rapidly increasing number of people with cancer by improving the development and support of the oncology careforce. Workshop presentations and discussion examined strategies to address clinician burnout and better integrate family caregivers on the care team, innovative models of care delivery, as well as opportunities to better leverage technology in oncology care.

Workshop videos and presentation files:

Advancing Progress in the Development of Combination Cancer Therapies with Immune Checkpoint Inhibitors
July 16–17, 2018

Immune checkpoint inhibitors, like those that target PD-1 and PD-L1 proteins, have changed the standard of care for multiple types of cancer and represent a majority share of new cancer drug applications to the FDA. Recently, there has been growing interest in combining checkpoint inhibitors with other therapies to further improve efficacy. Several challenges impede optimal clinical development of combination therapies with checkpoint inhibitors, such as prioritizing combinations for testing, identifying patients who are most likely to benefit, assessing endpoints for safety and clinical benefit, overcoming resistance to therapy, and developing cancer site-agnostic indications. This workshop examined the opportunities to improve the clinical development of combination cancer therapies that include immune checkpoint inhibitors.

Workshop videos and presentation files:

Workshop Series: Improving Cancer Diagnosis and Care
Patient Access to Oncologic Imaging and Pathology Expertise and Technologies
February 12–13, 2018

High-quality cancer diagnosis and care depend on effective collaboration among the members of a patient’s care team, including pathologists and radiologists. This workshop examined strategies to ensure that patients have access to appropriate expertise and technologies in oncologic pathology and imaging to inform their cancer diagnosis, treatment planning, assessment of treatment response, and oncologic surveillance.

Workshop videos and presentation files:

Proceedings: www.nap.edu/catalog/25163

The Clinical Application of Computational Methods in Precision Oncology
October 29–30, 2018

Advances in biomedicine have contributed to the growing use of precision oncology therapies that target specific abnormalities in a patient’s cancer, facilitated in part by the development of large-scale biologic databases, computational methods, and omics technologies that enable molecular characterization of patients’ cancers. This workshop examined the challenges and opportunities to use omics data and methods to develop precision medicine approaches in oncology, as well as to improve the translation of omics technologies in clinical practice.

Workshop videos and presentation files:
WORKSHOP PROCEEDINGS

2019
Advancing Progress in the Development of Combination Cancer Therapies with Immune Checkpoint Inhibitors: Proceedings of a Workshop (In Process)
Improving Cancer Diagnosis and Care: Clinical Application of Computational Methods in Precision Oncology: Proceedings of a Workshop (In Process)
Developing and Sustaining an Effective and Resilient Oncology Careforce: Proceeding of a Workshop (In Process)

2018
Improving Cancer Diagnosis and Care: Patient Access to Oncologic Imaging and Pathology Expertise and Technologies: Proceedings of a Workshop
Establishing Effective Patient Navigation Programs in Oncology: Proceedings of a Workshop
Long-Term Survivorship Care After Cancer Treatment: Proceedings of a Workshop

2017
The Drug Development Paradigm in Oncology: Proceedings of a Workshop
Cancer Care in Low-Resource Areas: Cancer Treatment, Palliative Care, and Survivorship Care: Proceedings of a Workshop
Implementation of Lung Cancer Screening: Proceedings of a Workshop
Incorporating Weight Management and Physical Activity Throughout the Cancer Care Continuum: Proceedings of a Workshop

2016
Policy Issues in the Clinical Development and Use of Immunotherapy for Cancer Treatment: Proceedings of a Workshop
Cancer Care in Low-Resource Areas: Cancer Prevention and Early Detection: Workshop Summary
Appropriate Use of Advanced Technologies for Radiation Therapy and Surgery in Oncology: Workshop Summary

2015
 Comprehensive Cancer Care for Children and Their Families: Summary of a Joint Workshop by the Institute of Medicine and the American Cancer Society
Policy Issues in the Development and Adoption of Biomarkers for Molecularly Targeted Cancer Therapies: Workshop Summary
Assessing and Improving the Interpretation of Breast Images: Workshop Summary
Role of Clinical Studies for Pets with Naturally Occurring Tumors in Translational Cancer Research: Workshop Summary
WORKSHOP PROCEEDINGS

2014

Ensuring Patient Access to Affordable Cancer Drugs: Workshop Summary
Contemporary Issues for Protecting Patients in Cancer Research: Workshop Summary

2013

Identifying and Addressing the Needs of Adolescents and Young Adults with Cancer: Workshop Summary
Implementing a National Cancer Clinical Trials System for the 21st Century: Workshop Summary (2013 and 2011)
Sharing Clinical Research Data: Workshop Summary
Delivering Affordable Cancer Care in the 21st Century: Workshop Summary
Reducing Tobacco-Related Cancer Incidence and Mortality: Workshop Summary

2012

The Role of Obesity in Cancer Survival and Recurrence: Workshop Summary
Informatics Needs and Challenges in Cancer Research: Workshop Summary
Facilitating Collaborations to Develop Combination Investigational Cancer Therapies: Workshop Summary

2011

Patient-Centered Cancer Treatment Planning: Improving the Quality of Oncology Care: Workshop Summary
The National Cancer Policy Summit: Opportunities and Challenges in Cancer Research and Care: Workshop Proceedings
Nanotechnology and Oncology: Workshop Summary

2010

Direct to Consumer Genetic Testing (with the National Research Council): Summary of a Workshop
Extending the Spectrum of Precompetitive Collaboration in Oncology Research: Workshop Summary
A Foundation for Evidence-Driven Practice: A Rapid Learning System for Cancer Care: Workshop Summary
Policy Issues in the Development of Personalized Medicine in Oncology: Workshop Summary

2009

Assessing and Improving Value in Cancer Care: Workshop Summary
Ensuring Quality Cancer Care Through the Oncology Workforce: Sustaining Care in the 21st Century: Workshop Summary
Multi-Center Phase III Clinical Trials and the NCI Cooperative Group Program: Workshop Summary

2008

Implementing Colorectal Cancer Screening: Workshop Summary
Improving the Quality of Cancer Clinical Trials: Workshop Summary

2007

Cancer-Related Genetic Testing and Counseling: Workshop Proceedings
Cancer in Elderly People: Workshop Proceedings
Implementing Cancer Survivorship Care Planning: Workshop Summary

2006

Effect of the HIPAA Privacy Rule on Health Research: Proceedings of a Workshop
Developing Biomarker-Based Tools for Cancer Screening, Diagnosis, and Treatment: Workshop Summary
**RELATED WORK**

**CONSENSUS STUDY REPORTS BUILDING ON NCPF WORK**

Report: nap.edu/catalog/24946

Biomarker Tests for Molecularly Targeted Therapies: Key to Unlocking Precision Medicine (2016)  
Report: nap.edu/catalog/21860

Ovarian Cancers: Evolving Paradigms in Research and Care (2016)  
Report: nap.edu/catalog/21841

Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis (2013)  
Report: nap.edu/catalog/18359

Evolution of Translational Omics: Lessons Learned and the Path Forward (2012)  
Report: nap.edu/catalog/13297

A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program (2010)  
Report: nap.edu/catalog/12879

Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease (2010)  
Report: nap.edu/catalog/12869

Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research (2009)  
Report: nap.edu/catalog/12458

Cancer Biomarkers: The Promises and Challenges of Improving Detection and Treatment (2007)  
Report: nap.edu/read/11892

**INDIVIDUALLY AUTHORED PUBLICATIONS BUILDING ON NCPF WORK**

Independent, individually authored articles* in the literature arising from NCPF workshops—and consensus studies building on the work of NCPF—include:

**2019**


**2018**


**2017**


*access date for all articles: January 31, 2019*
2016


2015


2014


2013


2012


2011


2010


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**Health and Medicine Division Board on Health Care Services**

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ABOUT THE FORUM

The Forum on Drug Discovery, Development, and Translation of the National Academies of Sciences, Engineering, and Medicine was created in 2005 by the Board on Health Sciences Policy to provide a unique platform for dialogue and collaboration among thought leaders and stakeholders in government, academia, industry, foundations, and patient advocacy with an interest in improving the system of drug discovery, development, and translation. The Forum brings together leaders from private sector sponsors of biomedical and clinical research, federal agencies sponsoring and regulating biomedical and clinical research, the academic community, and patients, and in doing so serves to educate the policy community about issues where science and policy intersect. The Forum convenes several times each year to identify, discuss, and act on key problems and strategies in the discovery, development, and translation of drugs. To supplement the perspectives and expertise of its members, the Forum also holds public workshops to engage a wide range of experts, members of the public, and the policy community. The Forum also fosters collaborations among its members and constituencies. The activities of the Forum are determined by its members, focusing on the major themes outlined below.

INNOVATION AND THE DRUG DEVELOPMENT ENTERPRISE

Despite exciting scientific advances, the pathway from basic science to new therapeutics faces challenges on many fronts. New paradigms for discovering and developing drugs are being sought to bridge the ever-widening gap between scientific discoveries and translation of those discoveries into life-changing medications. There is also increasing recognition of the need for new models and methods for drug development and translational science, and “precompetitive collaborations” and other partnerships, including public–private partnerships, are proliferating. The Forum offers a venue to discuss effective collaboration in the drug discovery and development enterprise and also hosts discussions that could help chart a course through the turbulent forces of disruptive innovation in the drug discovery and development “ecosystem.”

Key gaps remain in our knowledge about science, technology, and methods needed to support drug discovery and development. Recent rapid advances in innovative drug development science present opportunity for revolutionary developments of new scientific techniques, therapeutic products, and applications. The Forum provides a venue to focus ongoing attention and visibility to these important drug development needs and facilitates exploration of new approaches across the drug development lifecycle. The Forum has held workshops that have contributed to the defining and establishment of regulatory science and have helped inform aspects of drug regulatory evaluation.

CLINICAL TRIALS AND CLINICAL PRODUCT DEVELOPMENT

Clinical research is the critical link between bench and bedside in developing new therapeutics. Significant infrastructural, cultural, and regulatory impediments challenge efforts to integrate clinical trials into the health care delivery system. Collaborative, cross-sector approaches can help articulate and address these key challenges and foster systemic responses. The Forum has convened a multiyear initiative to examine the state of clinical trials in the United States, identify areas of strength and weakness in our current clinical trial enterprise, and consider transformative strategies for enhancing the ways in which clinical trials are organized and conducted. In addition to sponsoring multiple symposia and workshops, under this initiative, the Forum is fostering innovative, collaborative efforts to facilitate needed change in areas such as improvement of clinical trial site performance.

INFRASTRUCTURE AND WORKFORCE FOR DRUG DISCOVERY, DEVELOPMENT, AND TRANSLATION

Considerable opportunities remain for enhancement and improvement of the infrastructure that supports the drug development enterprise. That infrastructure, which includes the organizational structure, framework, systems, and resources that facilitate the conduct of biomedical science for drug development, faces significant challenges. The science of drug discovery and development, and its translation into clinical practice, is cross-cutting and multidisciplinary. Career paths can be opaque or lack incentives such as recognition, career advancement, or financial security. The Forum has considered workforce needs as foundational to the advancement of drug discovery, development, and translation. It has convened workshops examining these issues, including consideration of strategies for developing a discipline of innovative regulatory science through the development of a robust workforce. The Forum will also host an initiative that will address needs for a workforce across the translational science lifecycle.

The National Academies of
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Forum on Drug Discovery, Development, and Translation

Robert Califf (Co-Chair)
Duke University and
Verily Life Sciences

Gregory Simon (Co-Chair)
Kaiser Permanente Washington Health Research Institute and
University of Washington

Christopher Austin
National Center for Advancing Translational Sciences, NIH

Linda Brady
National Institute of Mental Health, NIH

Tanisha Carino
FasterCures, Milken Institute

Barry Coller
The Rockefeller University

Thomas Curran
Children’s Mercy, Kansas City

Richard Davey
National Institute of Allergy and Infectious Diseases, NIH

James Doroshow
National Cancer Institute, NIH

Jeffrey Drazen
New England Journal of Medicine

Steven Galson
Amgen Inc.

Carlos Garner
Eli Lilly and Company

Julie Gerberding
Merck & Co., Inc.

Deborah Hung
Harvard Medical School

Jeff Hurd
AstraZeneca

Lynn Hudson
Critical Path Institute

S. Claiborne (Clay) Johnston
University of Texas, Austin

Freda Lewis-Hall
Pfizer Inc.

Ross McKinney
Association of American Medical Colleges

Joseph Menetski
Foundation for the NIH

Bernard Munos
InnoThink Center for Research in Biomedical Innovation

Kelly Rose
Burroughs Wellcome Fund

Michael Severino
Abbvie, Inc.

Anantha Shekhar
Indiana University School of Medicine

Ellen Sigal
Friends of Cancer Research

Lana Skirboll
Sanofi

Amir Tamiz
National Institute of Neurological Disorders and Stroke, NIH

Pamela Tenaerts
Clinical Trials Transformation Initiative

John Wagner
Takeda Pharmaceuticals

Joanne Waldstreicher
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Carrie Wolinetz
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Alastair Wood
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Janet Woodcock
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