April 1–2, 2022

2022 MCGI Forum

Building Bridges Through Genomic Medicine

EVENT SUMMARY

Hosted by The Jackson Laboratory in person
at the Samoset Resort in Rockport, ME and virtually

The Jackson Laboratory

Building Bridges through Genomic Medicine

MAINE CANCER GENOMICS INITIATIVE (MCGI) FORUM

APRIL 1–2, 2022

HOSTED IN PERSON AND VIRTUALLY BY

THE JACKSON LABORATORY

The Jackson Laboratory

Welcome to the fifth Maine Cancer Genomics Initiative (MCGI) Forum: Building Bridges Through Genomic Medicine. Together, we have created a network of oncology practices covering the entire State of Maine, the first of its kind in the country. This network is supported by a majority of Maine medical oncologists. It is governed by a clinical steering committee under the guidance of an external panel of clinical oncology genomics experts from nine of the leading NCI-designated cancer centers around the country.

In October 2021, MCGI moved into its second phase focused on genomic tumor testing accessibility, interpretability and actionability. To that end, our team will focus on making precision oncology even more actionable for cancer patients, focusing on treatment options and new digital technologies. We have launched the MCGI 2.0 study protocol with a goal to enroll 3,200 patients over the next five years, while working closely with the community to increase options for local clinical trial participation for cancer patients. Accessibility will be supported by accepting patients into the study who have had a genomic oncology panel test from any clinical testing provider, including testing via JAX SOMASEQ™ test.

Our Genomic Tumor Board sessions will support and advance interpretability, as treating clinicians gather to discuss their patients' test results with a broad panel of experts. We have begun to expand actionability by adding a dedicated Genomic Navigator to the MCGI team. In addition, we are the Northern New England Coordinating Center for the American Society of Clinical Oncology (ASCO) Targeted Agent and Profiling Utilization Registry (TAPUR™) study, making this important clinical study available locally for cancer patients.

As our initiative grows, we remain committed to delivering on the promise of precision oncology in both established partnerships and new relationships with clinicians in the community oncology setting.

Thank you once again for your participation and ongoing support. We look forward to an exciting Forum and continued growth of MCGI in Northern New England.

The Maine Cancer Genomics Initiative

With The Jackson Laboratory's expertise in genomic sequencing, bioinformatics, cancer analytics and drug curation; the participation of professionals from Maine oncology and pathology practices; and financial support from The Harold Alfond® Foundation, MCGI continues its efforts to bring world-class cancer care to Maine patients.

The Maine Cancer Genomics Initiative (MCGI) is a program of The Jackson Laboratory enabled through continued financial support from The Harold Alfond® Foundation, as part of their landmark 2020 $500M gift to Maine institutions, leveraging the strengths of key medical and bioscience research institutions in Maine. MCGI has created an alliance focused on helping patients and clinicians across the state and region to achieve better outcomes through precision cancer diagnostics and treatment.

Approximately 9,000 new cancer cases occur in Maine each year. Oncologists and other health care providers often struggle to identify optimal therapies for many of these patients using conventional diagnostic methods and clinical guidelines. However, the combination of genetic mutations in a tumor — its molecular signature — may be much more indicative of the appropriate treatment.

In addition, a rapidly evolving body of knowledge about genomics in cancer demonstrates significant promise for treatment of many types of cancer.

The mission of MCGI is to enable widespread access to clinical cancer genomic tests for the Maine oncology community and to increase the understanding of cancer genomics by Maine oncology clinicians. Specifically, MCGI has three major goals:

1. Support precision oncology accessibility: The second MCGI study will enroll up to 3,200 patients and their respective oncology clinicians in Maine. A key aim of this study is to observe the ease with which patients and their clinicians gain access to somatic cancer genomic tests and clinical reports. For eligible Maine cancer patients, assistance with testing costs is available for analyses performed in the JAX CLIA-certified/CAP-accredited Clinical Genomics Laboratory.

2. Support precision oncology interpretability: The MCGI program will offer Genomic Tumor Boards to participating clinicians and deliver other educational programs in cancer genomics and precision medicine. These educational offerings will include an oncology clinician curriculum consisting of educational modules in convenient learning formats.

3. Support precision oncology actionability: MCGI will continue to build its research network for "community genomic medicine" by leveraging the collaborative state-wide research network of cancer providers and institutions to bring additional clinical trials to the region and enable participation of rural practices in Maine in this network.

The Harold Alfond® Foundation

Founded in 1950, The Harold Alfond® Foundation furthers the philanthropic legacy of Harold Alfond, the founder of Dexter Shoe Company and a longtime supporter of Maine communities in which he and his family worked and resided. Harold Alfond awarded matching challenge grants to organizations to build community partnerships and to inspire and leverage additional giving by others. He ensured that his philanthropy would live on by committing nearly all of his wealth to the Foundation, which continues to support charitable causes in the State of Maine.

Consistent with Harold Alfond's own giving pattern and philanthropic principles, the Foundation favors education, health care, youth development, and other selected charitable causes. The Foundation applies Harold Alfond's business approach to funding decisions, his belief in teamwork, and his love of competition by continuing to award matching challenge grants to projects that meet a demonstrable need, are entrepreneurial, promote teamwork, have measurable performance outcomes, are financially viable, and have quality management and board leadership.

The Jackson Laboratory

The Jackson Laboratory (JAX) is making a new future of human health and personalized medicine possible — using an individual's unique genomic makeup to predict, treat and even prevent disease.

Our mission is bold: **to discover precise genomic solutions for disease and empower the global biomedical community in the shared quest to improve human health**.

Founded in 1929, JAX is an independent, 501(c)3 nonprofit biomedical research institution that seeks to decipher the biological and genomic causes of human disease. With over 90 years' experience, a staff of over 3,000 and locations across the US, China, and Japan, JAX is well positioned to advance its mission.

Our research breakthroughs have helped form the foundation of modern medicine. Organ and bone marrow transplants, stem cell therapies, and in vitro fertilization all have a foundation in JAX research.

Today, JAX is integrating mouse genetics and human genomics to decipher the genetic and molecular causes of human health and disease.

JAX uniquely amplifies the efforts of the global biomedical research community. We develop and share our research, innovative tools and solutions, ever expanding data resources, more than 11,000 specialized mouse models and services, and a comprehensive suite of educational programs to empower basic scientific research and speed drug discovery across the globe.

www.jax.org
600 Main Street, Bar Harbor, ME 04609
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The Jackson Laboratory

Agenda

Friday, April 1, 2022

10:00 a.m. — **On-Site Arrival and Forum Check-In**

11:00 a.m. – 12:00 p.m. — **Buffet Lunch**

12:00 p.m. – 12:20 p.m. — **Welcome Remarks and MCGI Program Update — Eligible for CME, CNE, and CGC CEUs**
Jens Rueter, M.D. | Medical Director, MCGI | The Jackson Laboratory

12:20 p.m. – 12:45 p.m. — **Initial Insights into Attitudes, Perspectives and Outcomes of MCGI Patient and Physician Participants — Eligible for CME, CNE, and CGC CEUs**
Eric Anderson, Ph.D. | Faculty Scientist | Maine Medical Center Research Institute

12:45 p.m. – 1:00 p.m. — **Q&A**

1:00 p.m. – 1:30 p.m. — **Break**

Session 1 — **Navigating the Precision Oncology Pathway**
Session Chair: Lindsey Kelley, M.P.H., M.S., CGC | Genomic Navigator, MCGI | The Jackson Laboratory

1:30 p.m. – 2:20 p.m. — **Identifying Hereditary Risks through Genomic Tumor Testing — Eligible for CME, CNE, and CGC CEUs**
Moderators: Emily Edelman, M.S., CGC | Director, Clinical Education | The Jackson Laboratory
Kate Reed, M.P.H., Sc.M., CGC | Director, Precision Oncology Education, Clinical Education Program | The Jackson Laboratory
Gregory Omerza, Ph.D. | Manager, Clinical Data Analysis & Reporting | The Jackson Laboratory
Stephanie Sharp, M.S., CGC | Genetic Counselor, Cancer Risk and Prevention Clinic | Maine Medical Center
Christine Walko, Pharm.D., BCOP, FCCP | Associate Member, Individualized Cancer Management | Moffitt Cancer Center

2:20 p.m. – 2:30 p.m. — **Break**

2:30 p.m. – 2:50 p.m. — **The Oncology Patient's Journey and Patient Advocate Foundation — Eligible for CME, CNE, and CGC CEUs**
Erin Bradshaw | Chief of Mission Delivery | Patient Advocate Foundation

2:50 p.m. – 3:25 p.m. — **FDA Oncology Center of Excellence's *Project Facilitate*: An Overview of the Oncology Expanded Access Program — Eligible for CME, CNE, and CGC CEUs**
Ramya Antony, F.N.P., M.S.N., B.S.N., M.S. | Clinical Analyst | FDA Project Facilitate

3:25 p.m. – 4:00 p.m. — **An Oncologist's Guide to the Mysteries of Prior Authorization — Eligible for CME, CNE, and CGC CEUs**
Andrew Norden, M.D., M.P.H., M.B.A. | Chief Medical Officer | OncoHealth Boston

4:00 p.m. – 4:30 p.m. — **Panel Discussion: Navigating the Precision Oncology Pathway — Eligible for CME, CNE, and CGC CEUs**
Moderator: Lindsey Kelley, M.P.H., M.S., CGC | Genomic Navigator, MCGI | The Jackson Laboratory
Ramya Antony, F.N.P., M.S.N., B.S.N., M.S. | Clinical Analyst | FDA Project Facilitate
Erin Bradshaw | Chief of Mission Delivery | Patient Advocate Foundation
Andrew Norden, M.D., M.P.H., M.B.A. | Chief Medical Officer | OncoHealth Boston

4:30 p.m. – 5:00 p.m. **Break – Hotel Check-In**

Session 2 **Genomic Tumor Board Panel Discussions**
Session Chair: Jens Rueter, M.D. | Medical Director, MCGI | The Jackson Laboratory

5:00 p.m. – 6:00 p.m. **GTB Case Panel Discussion 1: Adult Cases — Eligible for CME, CNE, and CGC CEUs**
Moderator: Jens Rueter, M.D. | Medical Director, MCGI | The Jackson Laboratory
Jessica Cary, M.S., R.N., CGC | Genetic Counselor | New England Cancer Specialists
Jill Kolesar, Pharm.D., M.S. | Professor, Pharmacy and Medicine | University of Kentucky
Lincoln Nadauld, M.D., Ph.D. | Vice President, Chief of Precision Health and Academics | Intermountain Healthcare
David Thomas, FRACP, Ph.D. | Head, Genomic Cancer Medicine | Garvan Institute of Medical Research
Christine Walko, Pharm.D., BCOP, FCCP | Associate Member, Individualized Cancer Management | Moffitt Cancer Center

6:05 p.m. – 6:55 p.m. **GTB Case Panel Discussion 2: Pediatric Cases — Eligible for CME, CNE, and CGC CEUs**
Moderator: Ching Lau, M.D., Ph.D. | Professor | The Jackson Laboratory
Alanna Church, M.Sc., M.D., FRCPC | Associate Director, LaMPP | Boston Children's Hospital
Steven DuBois, M.D., M.S. | Director, Experimental Therapeutics | Dana-Farber Cancer Institute

7:00 p.m. – 7:15 p.m. **Keynote Address: MCGI 2030**
Edison T. Liu, M.D. | Professor and President Emeritus | The Jackson Laboratory

7:15 p.m. – 8:30 p.m. **Dinner**

8:30 p.m. **Open Q&A in the Pub**
Jens Rueter, M.D. | Medical Director, MCGI | The Jackson Laboratory

Saturday, April 2, 2022

7:00 a.m. – 8:00 p.m. **Breakfast Bar**

Session 3 **NGS in Myeloid Malignancies**
Session Chair: Leah Graham, Ph.D. | Associate Director, MCGI | The Jackson Laboratory

8:00 a.m. – 8:40 a.m. **Uncoding Genetic Complexity of Myeloid Malignancies — Eligible for CME, CNE, and CGC CEUs**
Coleman Lindsley, M.D., Ph.D. | Assistant Professor, Medicine | Harvard Medical School

8:45 a.m. – 9:30 a.m. **Identifying Pathways and Treatment for Myeloid Malignancies — Eligible for CME, CNE, and CGC CEUs**
Jennifer Trowbridge, Ph.D. | Associate Professor | The Jackson Laboratory

9:30 a.m. – 10:00 a.m. **Panel Discussion: NGS in Myeloid Malignancies — Eligible for CME, CNE, and CGC CEUs**
Coleman Lindsley, M.D., Ph.D. | Assistant Professor, Medicine | Harvard Medical School
Jennifer Trowbridge, Ph.D. | Associate Professor | The Jackson Laboratory

10:00 a.m. – 10:10 a.m. **Break**

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Session 4 — New Diagnostic Technologies

Session Chair: Edison T. Liu, M.D. | Professor and President Emeritus | The Jackson Laboratory

10:10 a.m. – 11:00 a.m. — **Big Data and Wearable Approaches for Managing Health and Q&A**
— Eligible for CME, CNE, and CGC CEUs
Michael Snyder, Ph.D. | Professor and Chair, Genetics | Stanford Medicine

11:00 a.m. – 11:45 a.m. — **Improving Early Detection for Ovarian Cancer: The MiDe Study and Q&A**
— Eligible for CME, CNE, and CGC CEUs
Dipanjan Chowdhury, Ph.D. | Chief, Division of Radiation and Genomic Stability | Dana-Farber Cancer Institute

Lunch and Roundtable Discussions

12:00 p.m. – 12:45 p.m.

Continuing Education Programs
Emily Edelman, M.S., CGC | Director, Clinical Education Program | The Jackson Laboratory
Gregory Omerza, Ph.D. | Manager, Clinical Data Analysis & Reporting | The Jackson Laboratory

Dempsey Center
Maureen Higgins | Community Engagement Coordinator | Dempsey Center

Genetic Counselors Connect
Lindsey Kelley, M.P.H., M.S., CGC | Genomic Navigator, MCGI | The Jackson Laboratory
Kunal Sanghavi, M.S., M.B.B.S., CGC | Program Manager, Genetic Counseling | The Jackson Laboratory

Genomic Tumor Boards
Jennifer Bourne, M.S. | Program Manager, MCGI | The Jackson Laboratory
Susan Halverson, B.A. | Genomic Tumor Board Coordinator | The Jackson Laboratory

JAX Clinical Knowledgebase
Sara Patterson, Ph.D. | Associate Director, Clinical Genomics Informatics Products | The Jackson Laboratory
Cara Statz, Ph.D. | Senior Clinical Analyst, JAX Clinical Knowledgebase (CKB) | The Jackson Laboratory

MCGI 2.0 Study Activities
Lory Gaitor, CCRC | Clinical Research Coordinator, MCGI | The Jackson Laboratory
Petra Helbig, CCRP | Clinical Research Manager, MCGI | The Jackson Laboratory

Session 5 — Emerging Therapeutic Approaches

Session Chair: Jens Rueter, M.D. | Medical Director, MCGI | The Jackson Laboratory

1:15 p.m. – 1:40 p.m. — **mRNA-Based Therapeutics in Oncology — Eligible for CME, CNE, and CGC CEUs**
Khanh Do, M.D. | Director, Oncology Clinical Development | Moderna

1:45 p.m. – 2:30 p.m. — **Current and Upcoming Developments in CAR-T Therapy — Eligible for CME, CNE, and CGC CEUs**
Matthew Frigault, M.D. | Assistant Professor | Harvard Medical School

2:30 p.m. – 2:50 p.m. — **Panel Discussion: Emerging Therapeutic Approaches — Eligible for CME, CNE, and CGC CEUs**
Khanh Do, M.D. | Director, Oncology Clinical Development | Moderna
Matthew Frigault, M.D. | Assistant Professor | Harvard Medical School

Session 6 — **Precision Oncology Trials**
Session Chair: Jens Rueter, M.D. | Medical Director, MCGI | The Jackson Laboratory

2:50 p.m. – 3:20 p.m. — **NCI-MATCH: Updated Results — Eligible for CME**
Peter O'Dwyer, M.D. | Professor, Medicine | Penn Medicine

3:25 p.m. – 4:00 p.m. — **The ASCO TAPUR Study: Recent Findings and Future Directions — Eligible for CME, CNE, and CGC CEUs**
Richard Schilsky, M.D., FACP, FSCT, FASCO | Senior VP and Chief Medical Officer Emeritus | ASCO

Session 7 — **Precision Oncology — Where Do We Go from Here**
Session Chair: Jens Rueter, M.D. | Medical Director, MCGI | The Jackson Laboratory

4:00 p.m. – 5:00 p.m. — **Panel Discussion — Eligible for CME, CNE, and CGC CEUs**
Kim Blackwell, M.D. | Chief Medical Officer | Tempus
Jill Kolesar, Pharm.D., M.S., FCCP, BCPS | Professor, Pharmacy and Medicine | University of Kentucky
Andrew Norden, M.D., M.P.H., M.B.A. | Chief Medical Officer | OncoHealth Boston
Peter J. O'Dwyer, M.D. | Professor, Medicine | Penn Medicine
Richard Schilsky, M.D., FACP, FSCT, FASCO | Senior VP and Chief Medical Officer Emeritus | ASCO
Sarah Sinclair, D.O. | Director, Clinical Research | Northern Light Cancer Care
Christian Thomas, M.D., FASCO | Director, Clinical Research | New England Cancer Specialists
David Thomas, FRACP, Ph.D. | Head, Genomic Cancer Medicine | Garvan Institute of Medical Research
Christine Walko, Pharm.D., BCOP, FCCP | Associate Member, Individualized Cancer Management | Moffitt Cancer Center

5:00 p.m. — **Adjourned**

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Forum Sessions

MCGI Progress Summary

The Maine Cancer Genomics Initiative (MCGI) was initiated in 2016 and successfully assembled a network of oncology clinicians from all major practices across the state of Maine. The MCGI 1.0 study closed to patient enrollment in 2020. The Initiative has become the coordinating center for the TAPUR™ trial, launched the MCGI 2.0 study and is pursuing additional opportunities to improve the landscape of Maine's rural oncology care.

Dr. Jens Rueter, chief medical officer, The Jackson Laboratory, and medical director, MCGI, will speak about the initiative's achievements, current activities and future plans.

The Maine Medical Center Research Institute (MMCRI) conducts and supports a broad spectrum of research from basic laboratory-based studies through translational implementation efforts. As part of the institute, the Center for Outcomes Research and Evaluation (CORE) maintains a strong focus on health services and behavioral research and seeks to evaluate and improve new technologies and health care delivery programs. This research includes patient-centered outcomes and community engaged approaches to improving health care. MCGI has partnered with the MMCRI CORE team for the design of data collection instruments and analysis of observational and clinical outcomes for study participants.

Dr. Anderson, faculty scientist on the MMCRI CORE team, will speak about the testing and clinical outcomes of the MCGI 1.0 study.

Session 1: Navigating the Precision Oncology Pathway

The precision oncology pathway is not just about finding a targeted precision oncology treatment at the right time. It is also about navigating the crossroads of clinical findings, financial realities, drug access and insurance approval. Session 1 will start with a panel discussion on the intersection of hereditary cancer risk and somatic tumor testing, an increasingly relevant feature of new genomic tumor tests followed by high profile speakers addressing various and diverse aspect of the journey associated with precision oncology.

Panel: Identifying Hereditary Risks Through Genomic Tumor Testing

Genomic tumor testing performed for treatment decision-making may also identify variants associated with hereditary cancer risk to the patient and relatives. Knowing when a hereditary (germline) variant is present can be helpful in identifying targeted treatments, informing about future cancer susceptibility, and identifying when close relatives might be at risk. However, interpreting possible hereditary or germline risks based on genomic tumor testing can be challenging. Interpretation depends on the type of testing performed, the patient's cancer diagnosis and family history, the specific genes and variants identified on the tumor report, and other molecular findings such as microsatellite instability (MSI) and variant allele fraction (VAF). The goal of this session is to help clinicians interpret genomic tumor test results to determine when a patient should be further evaluated for hereditary risk. The panel will be moderated by Emily Edelman, M.S., CGC, who will be joined by a multidisciplinary panel of clinical and laboratory experts to discuss challenging case studies highlighting factors relevant for the interpretation of tumor results for hereditary risks.

A series of short presentations will follow:
Ramya Antony, F.N.P., M.S.N., B.S.N., M.S., will share information about the FDA's *Project Facilitate*, which lessens regulatory barriers to accessing drugs in the investigational new drug (IND) stage for targeted treatment of individual patients. Often overlooked when talking about advances in cancer treatment, financial toxicity is a major factor in a patient's journey. **Erin Bradshaw** from the Patient Advocate Foundation (PAF) will describe how PAF assists patients in understanding the many complexities of the financial aspects of their care and how they can connect with financial safety nets.

Making the right decision in cancer care goes beyond just which drug is right for a specific genomic variant. **Andrew Norden, M.D., M.P.H., M.B.A.**, will provide a detailed look at the complexity of clinical, financial and access factors through the lens of utilization management.

The session will close with another panel discussion which will feature Antony, Bradshaw and Norden, and **Jens Rueter, M.D.**, who will moderate.

Session 2: Genomic Tumor Board Panel Discussions

The purpose of each Genomic Tumor Board (GTB) is for oncology clinicians to discuss and analyze genomic tumor tests with pathology and genomic experts in order to design treatment plans for each patient. GTBs offered within the MCGI provide a community engaged approach to examining each patient's tumor mutational profile.

Each GTB begins with a presentation of the patient's clinical background and the outcomes of different treatment regimens prescribed over time. Results from tumor and liquid biopsy genomic testing including immunotherapy markers, germline testing, and variants of clinical and unknown significance are then presented by a genomic laboratory expert. Additionally, the frequency of mutations altered in the patient's tumor is compared to solid tumors from larger datasets. Potential therapy approaches and clinical trials are then discussed followed by a summary of the case and treatment options.

While pediatric and adult GTBs share similar formats, pediatric GTBs are approached differently as there are fewer targeted therapies available for children with cancer. Pediatric cancers exhibit a high prevalence of difficult-to-target mutations, including transcription factors and epigenetic regulators.[1]

The adult diagnoses GTB panel will feature the expertise of **Jessica Cary, M.S., CGC; Jill Kolesar, Pharm.D., M.S., FCCP, BCPS; Lincoln Nadauld, M.D., Ph.D.; Christine Walko, Pharm.D., BCOP, FCCP; and David Thomas, M.B.B.S., Ph.D.** The pediatric diagnoses GTB panel will feature the expertise of **Alanna Church, M.Sc., M.D., FRCPC**; and **Steven DuBois, M.D., M.S.; and Ching Lau, M.D., Ph.D.**, who will moderate the discussion.

1. Cancer Discov . 2021 Mar;11(3):545-559. doi: 10.1158/2159-8290.CD-20-0779. Epub 2020 Dec 4.

Keynote Address: MCGI 2030: The future of community precision medicine

Ed Liu, M.D.

The field of precision oncology is rapidly advancing and the MCGI has become a leader in the challenging task of disseminating and implementing precision oncology in rural communities. While the goal for the next 5 years is clear — increasing treatment options for cancer patients through clinical trials access and genomic navigation as well as through implementation of novel technologies — the quick lifecycle of technologies and approaches will provide many opportunities for additional programs and initiatives moving forward.

Based on decades of experience in translational and clinical oncology research as well as experience in epidemiology and public health, Edison Liu, M.D., Professor and President Emeritus at JAX is the MCGI's original conceptual thought leader. In his keynote address, Liu will provide an outlook into the future of the MCGI and provide some thought-provoking ideas with respect to the future of the dissemination of precision oncology in a rural state like Maine.

Session 3: Next Generation Sequencing in Myeloid Malignancies

Session 3 will focus on Next Generation Sequencing (NGS) of myeloid malignancies. Myeloid malignancies are caused by the abnormal differentiation or excessive proliferation of HSCs (hematopoietic stem cells) or myeloid progenitor cells. Aging has been tied to dysregulation and functional decline of the immune response and especially hematopoietic systems.[1] In addition to advanced age, evidence supports the

Forum Sessions

influence of environmental factors on the development of hematopoietic premalignancies. While myeloid malignancies are considered rare forms of cancer, the associated five-year survival rates are concerningly low.

The laboratory of **Coleman Lindsley, M.D., Ph.D.**, utilizes mouse and cell line models to dissect the mechanistic basis of genetic cooperation during myeloid disease progression, with a specific focus on mutations that cause epigenetic alterations.[2] The research focuses on the biology and treatment of myeloid malignancies. Lindsley has used detailed genetic analyses of large cohorts of patients with myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) to define genetic pathways of disease ontogeny and to identify mutations that predict overall survival after chemotherapy and stem cell transplantation. Lindsley will summarize current understanding of the development and maintenance of HSCs and the alterations that cause myeloid malignancies.

The laboratory of **Jennifer Trowbridge, Ph.D.**, studies the interplay between intrinsic and extrinsic mechanisms of HSCs and how these interactions make identifying ideal therapeutic targets challenging but not impossible. Trowbridge's research aims to reveal epigenetic patterns and processes that are uniquely deregulated during aging and/or transformation, which can be used to identify novel biomarkers of disease and targets for development of therapeutics for these rare malignancies. She will discuss the impact of her findings in the context of myeloid malignancies and aging. **Leah Graham, Ph.D.** will moderate the session 3 panel discussion.

1. Trowbridge JJ, Starczynowski DT. Innate immune pathways and inflammation in hematopoietic aging, clonal hematopoiesis, and MDS. *J Exp Med*. 2021;218(7):e20201544. doi:10.1084/jem.20201544 **2.** Coleman Lindsley, MD, PhD - DF/HCC. (2015, June 8). Retrieved January 7, 2022, from https://www.dfhcc.harvard.edu/insider/member-detail/member/coleman-lindsley-md-phd

Session 4: New Diagnostic Technologies

Advances in new technologies are wide-ranging. Session 4 will cover both detection and health monitoring approaches in data generation through wearable devices and early cancer detection through microRNA analysis in the blood.

A prominent member in the field of functional genomics and proteomics, **Michael Snyder, Ph.D.**, is involved with the Encyclopedia of DNA Elements (ENCODE) project. ENCODE hopes to develop a comprehensive map of functional elements in the human genome, specifically biochemical regions associated with gene regulation.[1] ENCODE provides public access to valuable data and resources which the scientific community utilizes when posed with unique genomic variations and how they've been treated in the past. ENCODE is a source of big data that is constantly expanding and evolving with new biological discoveries through research and addition of unique ailments.[2]

Snyder will discuss his analyses of data generated through wearable devices. With the widespread use of wearable devices like the Apple Watch, WHOOP band and Fitbit, there are copious datasets that have the potential to be used for disease detection and monitoring.

The laboratory of **Dipanjan Chowdhury, Ph.D.**, at Dana-Farber researches how cells recognize and repair DNA damage.[3] Chowdhury and his team have utilized different genetic, biochemical and proteomic approaches to increase the scientific community's understanding of different causes and treatments of cancer. As the principal investigator of the microRNA Detection study, Chowdhury focuses on ovarian cancer, striving to develop a blood test to detect it in the early stages of development. Ovarian cancer is the seventh most common cancer to affect women worldwide and is often not detected until stage III or IV. Chowdhury will discuss how utilizing microRNAs may one day aid clinicians in earlier disease detection and improve survival rates of women with ovarian cancer.

1. The ENCODE Project Consortium., Snyder, M.P., Gingeras, T.R. *et al*. Perspectives on ENCODE. Nature **583**, 693–698 (2020). https://doi.org/10.1038/s41586-020-2449-8 **2.** The ENCODE Project Consortium., Snyder, M.P., Gingeras, T.R. *et al*. Perspectives on ENCODE. Nature **583**, 693–698 (2020). https://doi.org/10.1038/s41586-020-2449-8 **3.** *Chowdhury lab - radiation and genome stability*. Chowdhury Lab - Radiation and Genome Stability. (n.d.). Retrieved January 13, 2022, from https://chowdhurylab.dana-farber.org/ **4.** *Chowdhury lab - radiation and genome stability*. Chowdhury Lab-Radiation and Genome Stability. (n.d.). Retrieved January 13, 2022, from https://chowdhurylab.dana-farber.org/ **5.** Momenimovahed, Z., Tiznobaik, A., Taheri, S., & Salehiniya, H. (2019). Ovarian cancer in the world: epidemiology and risk factors. *International journal of women's health*, 11, 287–299. https:doi.org/10.2147/IJWH.S197604

Session 5: Emerging Therapeutic Approaches

The focus of Session 5 will be newer therapies in precision oncology: CAR-T therapy and mRNA cancer vaccines.

Chimeric Antigen Receptor T-cell (CAR-T) therapy modifies a patient's T cells with the addition of a chimeric antigen receptor to boost the immune system. It is used to treat certain blood cancers and other types of cancers.[1]

Khanh Do, M.D. is the Director of Clinical Development at Moderna Therapeutics, where she works on the development of mRNA-based therapeutics for oncology treatment.

Do's research focuses on developmental strategies for enhancing the T-cell effector response by reversing the adaptive immune response through the manipulation of cytokine signals, enhancing the antigenic response, and bolstering the immune system's surveillance of tumors by co-stimulating tumor cells. mRNA-based oncological therapies train the patient's immune system to target specific proteins found on the surface of the tumor cells. Prior to joining Moderna, Do's research focused on the immune modulating activity of the CHK1 inhibitor prexasertib and anti-PD-L1 antibody LY3300054 in patients with high-grade serous ovarian cancer and other solid tumors.[3] Do will present Moderna's most recent work on advancing mRNA-based vaccines into the clinic.

The research of **Matthew Frigault, M.D.**, focuses on translating new cellular therapy products for clinical applications while further understanding the immunological mechanisms of efficacy, toxicity and resistance. He has studied the use of genetically modified CAR T-cells as immunotherapy in cancer patients in the Maus Lab at Massachusetts General Hospital, and developed CAR-T therapy to treat CD19+ B cell malignancies.[2] Frigault will summarize his research and discuss how CAR-T therapy is advancing the field of precision oncology.

1. *NCI Dictionary of Cancer terms*. National Cancer Institute. (n.d.). Retrieved January 10, 2022, from https://www.cancer.gov/publications/dictionaries/cancer-terms/def/car-t-cell-therapy
2. Frigault, M. J., & Maus, M. V. (2020). State of the art in CAR T cell therapy for CD19+ B cell malignancies. *The Journal of clinical investigation*, 130(4), 1586–1594. https://doi.org/10.1172/JCI129208 **3.** Do KT, Manuszak C, Thrash E, Giobbie-Hurder A, Hu J, Kelland S, Powers A, de Jonge A, Shapiro GI, Severgnini M. Immune modulating activity of the CHK1 inhibitor prexasertib and anti-PD-L1 antibody LY3300054 in patients with high-grade serous ovarian cancer and other solid tumors. Cancer Immunol Immunother. 2021 Oct;70(10):2991-3000. doi: 10.1007/s00262-021-02910-x. Epub 2021 Mar 20. PMID: 33745032.

Session 6: Precision Oncology Trials

Session 6 will focus on clinical trials in oncology research. In recent years, basket clinical trials have become an important part of oncology research. Basket trials, such as those discussed in this session, sort patients into study arms based on genetic changes in their tumors rather than by cancer diagnosis. Peter O'Dwyer, M.D., co-chair of the National Cancer Institute's Molecular Analysis for Therapy Choice trial (NCI-MATCH) and Richard Schilsky, M.D., FASCO, FSCT, FACP, principal investigator of the American Society of Clinical Oncology's (ASCO) Targeted Agent and Profiling Utilization Registry (TAPUR™) study will discuss the impact of these clinical trials and how knowledge gained from them is advancing precision oncology.

Basket Trials and MATCH: Advancing Precision Oncology

The National Cancer Institute Molecular Analysis for Therapy Choice (NCI-MATCH) Trial, also known as MATCH, is a clinical trial for precision medicine cancer treatments. The trial is coordinated by ECOG-ACRIN, with the participation of all Cooperative Groups, and as such is open at over 1,300 sites across the US. Trial participants receive unique treatment regimens based on somatic genetic mutations discovered with Next-Generation Sequencing of tumor tissue. A total of 39 distinct treatment arms have been developed, each for specific genomic abnormalities. MATCH aims to learn how effective it is to treat cancer with these specific genetic changes, regardless of the type of cancer.

The structure of the trial is such that each arm (each drug-mutation pair) is a separate study, planned to accrue 35 or more patients, with a primary Phase II endpoint of tumor response. The drug treatments in MATCH are credentialed for their activity against the molecular target and show

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responses in at least one tumor type with that abnormality. Patients with an advanced solid tumor, myeloma, or lymphoma that has progressed beyond standard treatment or have a rare cancer with no standard treatment may be eligible to participate in MATCH. When MATCH began in 2015, researchers set a goal for at least 25% of enrolled patients to have uncommon or rare cancers. This goal has been exceeded and approximately 60% of enrolled patients have cancers not including rectal, colon, breast, prostate, or non-small cell lung cancer. To enroll in a MATCH treatment arm, patients must be under the care of an oncologist at a participating MATCH site in the U.S. or Puerto Rico.

As one of the first major clinical trials to match patients with treatments based upon specific genetic changes and not their cancer type, NCI-MATCH is and continues to be a ground-breaking, novel study for treating advanced, rare cancers with greater precision. MATCH has proved that treating cancer based upon particular genetic abnormalities is feasible across cancer centers and community sites. In addition, a substantial number of correlative studies of the tissues obtained in the trial are in progress. As the trial draws to a close, it will be replaced by three distinct Precision Medicine trials that will be discussed.

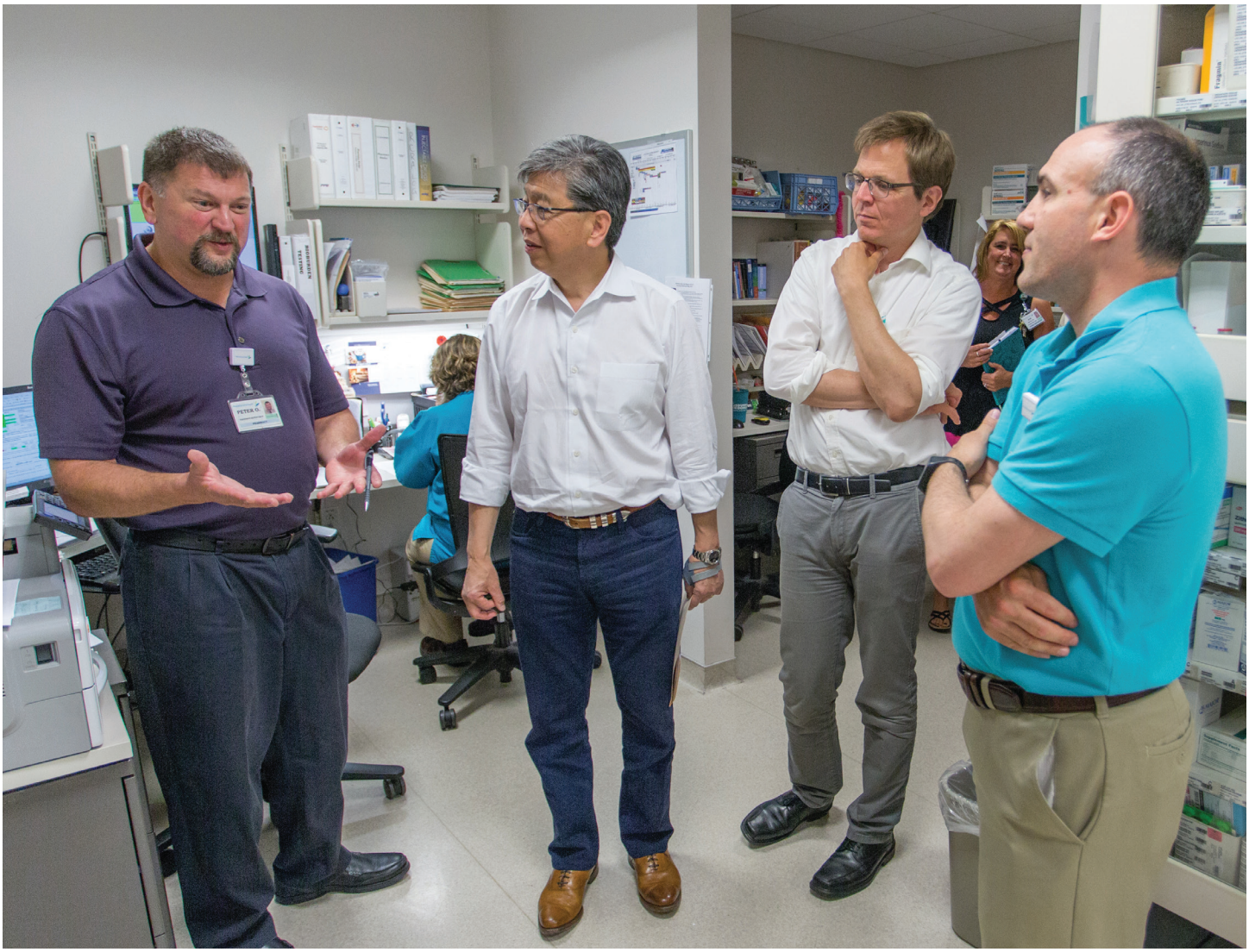
The ASCO TAPUR™ Study: Recent Findings and Future Directions

The Targeted Agent and Profiling Utilization Registry (TAPUR™) study is a prospective, single arm, phase II, multi-center, multi-basket pragmatic precision medicine trial that aims to detect signals of activity of commercially available targeted anti-cancer agents used outside of their approved indications in patients with advanced solid tumors that harbor a pre-specified genomic target. Eligible patients are at least 12 years of age, have advanced solid tumors, no standard treatment options, ECOG PS 0-2 and acceptable organ function. Tumor genomic testing is performed in CLIA-certified, CAP-accredited (or NY State-accredited) laboratories selected by the clinical sites. Drugs available in the TAPUR™ study target 85-90 pre-specified genomic alterations. If at least one such alteration is identified in the patient's tumor and the patient meets both general and drug-specific inclusion and exclusion criteria, the patient may be enrolled on the study. If a match to a pre-specified genomic alteration is not identified or multiple potential matches are found, the treating physician may send the case to the TAPUR™ Molecular Tumor Board for review. Once enrolled, patients are treated according to the FDA-approved dose and schedule and are evaluated at weeks 8 and 16 and then every 12 weeks thereafter if they continue study drug treatment. The primary endpoint of TAPUR™ is disease control, defined as complete or partial objective response or stable disease of at least 16 weeks duration (SD16+) per RECIST v.1.1. Progression-free survival (PFS), overall survival (OS) and high-grade adverse events are also collected. TAPUR™ assesses drug efficacy in histology-specific cohorts of patients defined by tumor type, genomic alteration and treatment and uses a Simon's 2-stage design with a null hypothesis of disease control rate of 15% or less and an alternative hypothesis of disease control rate of at least 35%. Ten patients are enrolled in Stage I. If at least two patients have objective response or SD of at least 16 weeks duration, the cohort is expanded to a total of 28 patients. If seven or more patients of 28 are observed to have objective response or SD16+, the null hypothesis is rejected, and the treatment is declared to have a signal of activity.

TAPUR™ launched in March 2016 and, to date, has enrolled more than 2,300 participants. The study is currently enrolling at 186 sites in 27 states and 16 treatments are available at no charge to patients. All publicly disclosed results can be found at www.asco.org/research-data/tapur-study/study-results.

TAPUR™ was designed in 2015 at a time when comprehensive genomic profiling for cancer was expanding across the U.S. Genomic alterations that were potentially actionable with commercially available drugs were observed in the tumors of 20-40% of patients, but the drugs were often not accessible to patients due to lack of insurance coverage for their off-label use. Even if a patient could

receive treatment, no mechanism existed to capture patient outcomes and learn about the efficacy of the treatment. Thus, ASCO launched the TAPUR™ study to address these issues. Collaborating pharmaceutical companies provide drugs at no cost to patients to solve the access problem and TAPUR™ collects, analyzes, and reports routinely obtained clinical data to inform the oncology community about the efficacy and toxicity of the treatments employed. ASCO hopes that the information developed by the TAPUR™ study will be useful to patients, physicians, guideline developers, payers, and the broader oncology community in informing clinical decisions and future research directions.



Presenters, Panelists and Moderators

Eric Anderson
Ph.D.

Eric Anderson, Ph.D. is a faculty scientist at the Center for Outcome Research and Evaluation at the Maine Medical Center Research Institute. He completed a Ph.D. in experimental psychology at Northeastern University with a focus on affective science. His current research explores how psychological factors influence medical decision making and access to care, particularly for rural, disadvantaged patients.

Ramya Antony
F.N.P., M.S.N., B.S.N., M.S.

Ramya Antony, F.N.P., M.S.N., B.S.N., M.S., is a Clinical Analyst at the FDA. Currently, she is one of the team members that manages the Oncology Center of Excellence Project Facilitate, a single point of contact call and information center to help oncology health care providers or regulatory professionals submit an Expanded Access Request. Antony started her nursing career at the National Institutes of Health on the surgical oncology floor. After that, she transitioned to become a research nurse for the Developmental Therapeutics Clinic at the National Cancer Institute. During this time, she received her MSN-FNP certification from George Washington University. For three years, she worked as a primary care Nurse Practitioner in a clinic in DC. She returned to oncology in 2018 when she was a nurse practitioner for the Neuro-Oncology Branch at NCI. She then transitioned to the FDA in her current role in August 2020.

Kimberly Blackwell
M.D.

Kimberly Blackwell, M.D., currently serves as Chief Medical Officer and Senior Vice President, Oncology Clinical Development, at Tempus Labs. In this role, she oversees precision medicine initiatives to improve cancer care and guide therapeutic drug development and discovery. Prior to joining Tempus, she was VP of Early Phase Oncology and Immunology-oncology at Eli Lilly and Company, where she worked on early-stage cancer therapeutics. During her time at Lilly, she was named as one of "Twenty extraordinary women in biopharma R&D who worked their way to the top" by *Endpoints News*. For 18 years, Blackwell was a faculty member at the Duke University Cancer Institute. While at Duke, she served as the principal or co-principal investigator for over 50 cancer clinical trials, co-founded the radiotherapeutics company-Cereius, and co-directed the Woman's Cancer Program and Precision Medicine Initiative. As one of the nation's leading breast cancer researchers, she played a role in developing therapies that represent revolutionary non-chemotherapy-based approaches for treating cancer. This work led to Blackwell's inclusion in *TIME Magazine's* 100 Most Influential People in the World for 2013, recognizing her accomplishments contributing to the development of lapatinib and T-DM1 for the treatment of HER2+ breast cancer. She holds a BA degree in Bioethics from Duke University and a MD degree from Mayo Clinic Medical School.

Erin Bradshaw

Erin Bradshaw is the Chief of Mission Delivery for the Patient Advocate Foundation (PAF). Working directly with the CEO and President, Operations, it is her duty to provide leadership to PAF's case management, and patient education and empowerment divisions to ensure the achievement of the organization's philosophy, mission as well as goals and objectives.

Since joining PAF in 1998, Bradshaw served as Case Manager, Quality Assurance Officer and Chief of External Communications, where she worked to educate and empower catastrophically ill individuals.

Bradshaw has served as a founding member and Senior Editor of PAF's publication committee and she researched, wrote, and provided editorial management for the production of scholastic materials designed to enhance the patient's knowledgebase. For example, she assisted with the production of *The Coverage Access Guide*: a compendium of topics that span a patient's full insurance journey from initial plan selection to usage and benefits; *National Financial Resource Directory*: an online search tool and advocate booklet specifically designed for those patients seeking resources to address their financial burdens.

Jessica Cary

M.S., R.N., CGC

Jessica Cary, M.S., R.N., CGC, is board-certified in genetic counseling (CGC) and nursing. She worked in prenatal, pediatric, and lab-based genetic counseling before joining New England Cancer Specialists in 2010. She specializes as a hereditary cancer genetic counselor. She is a graduate of Brandeis University's Master of Science in Genetic Counseling program and University of Vermont's Bachelor of Science in Nursing program.

Alanna Church

M.Sc., M.D., FRCPC

Alanna Church, M.Sc., M.D., FRCPC, is a board-certified Pediatric Pathologist and Molecular Genetic Pathologist, with a clinical and research focus on the genetics of pediatric solid tumors. She is the Associate Director of the Laboratory for Molecular Pediatric Pathology (LaMPP) at Boston Children's Hospital, and an Assistant Professor at Harvard Medical School. She participates in several high-impact studies using molecular profiling to support the care of children with cancer, including the Profile study, the multi-institutional GAIN consortium study, and the Broad's NIH-funded Count Me In project.

Dipanjan Chowdhury

Ph.D.

Dipanjan Chowdhury, Ph.D., is the Chief of the Division of Radiation and Genomic Stability at Dana-Farber and Co-Director of the new Center for BRCA and Related Genes (CBRG). He received his Ph.D. in Molecular Biology from Brandeis University, and did his post-doctoral fellowship training at Harvard Medical School. His recent awards include the Outstanding Achievement Award in 2021 from the Society of Asian American Scientists in Cancer Research, and The Brigham and Women's Physicians Organization Pillar Award in 2019 for his research leadership. Chowdhury is currently leading an exciting new protocol called "The MiDe Study" which uses a novel blood test aimed at early detection for ovarian cancer.

Presenters, Panelists and Moderators

Khanh Do
M.D.

Khanh Do, M.D., received her M.D. from George Washington University (GWU) in 2006, followed by a residency in Internal Medicine at GWU, and a fellowship in Hematology/Oncology at the National Cancer Institute, National Institutes of Health. She was an Assistant Professor of Medicine at Harvard School of Medicine in 2016 and served as the Clinical Director for the Early Drug Development Center, Dana-Farber Cancer Institute from 2015-2020. She now serves as the Director for Oncology Clinical Development at Moderna in Cambridge Massachusetts.

Steven DuBois
M.D., M.S.

Steven DuBois, M.D., M.S., completed medical school and pediatrics training at the University of California, San Francisco (UCSF). He completed pediatric oncology training at Dana-Farber / Boston Children's Hospital and obtained a Master of Science in Epidemiology from the Harvard School of Public Health. He is currently an Associate Professor of Pediatrics at Harvard Medical School. He is the Director of Experimental Therapeutics at Dana-Farber / Boston Children's Cancer and Blood Disorders Center where he leads a program designed to bring new targeted therapies to children with cancer. DuBois leads an active clinical and translational research program focused on patients with advanced neuroblastoma and Ewing sarcoma. He conducts clinical trials of novel targeted agents relevant to these diseases, including national phase 1, 2, and 3 clinical trials. He also studies new biomarkers that improve our understanding of the biology of pediatric solid tumors and of the pharmacodynamic effects of targeted therapies. DuBois has served on a number of national committees, including the Children's Oncology Group (COG) Neuroblastoma Steering Committee, COG Bone Tumor Committee, the American Society of Clinical Oncology (ASCO) Scientific Program Committee, and the US FDA Pediatric Oncology Drugs Advisory Committee (ODAC).

Emily Edelman
M.S., CGC

Emily Edelman, M.S., CGC, is a board-certified genetic counselor whose work focuses on genetics education for health professionals. She has over 15 years of experience in adult genetics, healthcare provider education, and program implementation and evaluation. At The Jackson Laboratory, as the Director of Clinical Education, she collaborates with healthcare providers to incorporate genetics and genomics into clinical practice through diverse education programs, including initiatives in oncology and precision medicine. Edelman is a past Board member of the National Society of Genetic Counselors.

Matthew Frigault
M.D.

Matthew Frigault, M.D., is a bone marrow transplant and cellular therapy physician with extensive preclinical, clinical and translational research experience involving the use of immune effector cell therapy for hematologic and solid tumor malignancies. His work has focused on high-risk patient populations, rare tumor subtypes and immunomodulatory approaches for toxicity mitigation and augmentation of T cell function. Frigault is an Assistant Professor at Harvard Medical School and the Clinical Director of the Cellular Immunotherapy Program at Massachusetts General Hospital.

Leah Graham
Ph.D.

Leah Graham, Ph.D., joined the Maine Cancer Genomics Initiative in January 2021. Previously, Graham was the manager of Government Affairs for The Jackson Laboratory (JAX), where she focused on managing public policy issues in the state of Maine, at local, state and federal levels. Other responsibilities included community relations and supervising special projects. She brought a wealth of scientific knowledge to Government Affairs, having received her Ph.D. in Genetics from the School of Biomedical Sciences at Tufts University School of Medicine in April 2017. Graham's research background is in environmental and genetic contributions to age-related cognitive impairment and Alzheimer's disease, and she has produced a number of primary research articles, including first author publications. Her dissertation work was funded partially through an F31 Predoctoral Individual National Research Service Grant Award from the National Institute on Aging. She is currently the Board Chair of the Maine Council on Aging.

Lindsey Kelley
M.P.H., M.S., CGC

Lindsey Kelley, M.P.H., M.S., CGC, joined the MCGI team in April 2021 as the Genomic Navigator. Prior to joining MCGI, Kelley worked as a Genetic Counselor in clinical oncology at Maine Medical Center. Additionally, she has worked as a Program Manager for injury and violence prevention for the state of Connecticut Department of Public Health, and in clinical research at the University of Connecticut Health Center analyzing substance use interventions. She brings a wealth of knowledge about genetic testing, program management, and research to the new role of Genomic Navigator, where she will provide patient navigation and facilitate access to genomic testing throughout Maine. Her education includes a B.A. in Mathematics and Statistics from Smith College, a M.P.H. from the University of Connecticut, and a M.S. in Genetic Counseling from Baypath University.

Jill Kolesar
Pharm.D., M.S., FCCP, BCPS

Jill Kolesar, Pharm.D., M.S., FCCP, BCPS, is a University Research Professor of Pharmacy and Medicine at the University of Kentucky and holds administrative positions at the Markey Cancer Center as the Director of the Precision Medicine Center, Co-Chair of the Molecular Tumor Board, and the Co-Leader of the Translational Oncology Program. She is a member of the Graduate Faculty in the College of Pharmacy, a member of the Markey Cancer Center and holds a joint appointment in the Division of Gynecologic Oncology in the College of Medicine.

Kolesar contributes substantial and sustained professional service to both the National Cancer Institute (NCI) and several pharmacy organizations. Serving on both the Early Phase and Cancer Prevention Central IRBs (CIRBs), multiple NCI study sections, and the Cancer Therapy and Evaluation Program (CTEP) Pharmacology task force and the Investigational Drug Steering Committee. Kolesar is a board-certified Pharmacotherapy Specialist and is a past President of the American College of Clinical Pharmacy (ACCP).

Kolesar's research focuses on the drug development of anticancer agents with an emphasis on targeted therapies and biomarkers. She has authored more than 300 abstracts, research articles, and book chapters, and as a principal investigator she has received more than $5 million in research funding from the NCI, American Cancer Society and other sources.

Presenters, Panelists and Moderators

Ching Lau
M.D., Ph.D

Ching Lau, M.D., Ph.D., is the Martin J Gavin Endowed Chair and Scientific Director of the Center for Cancer and Blood Disorders at Connecticut Children's, Professor at The Jackson Laboratory where he specializes in pediatric brain and bone tumor research, and Head of the Division of Pediatric Hematology-Oncology in the Department of Pediatrics at the UConn School of Medicine. His clinical interests include neuro-oncology, solid tumors, and osteosarcoma.

Coleman Lindsley
M.D., Ph.D.

Coleman Lindsley, M.D., Ph.D., is an Assistant Professor of Medicine at Harvard Medical School and of Medical Oncology at the Dana-Farber Cancer Institute and a member of the Dana-Farber/Harvard Cancer. Lindsley's research is focused on the biology and treatment of myeloid malignancies. He has used detailed genetic analysis of large cohorts of patients with myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) to define genetic pathways of disease ontogeny and to identify mutations that predict overall survival after chemotherapy and stem cell transplantation. The Lindsley lab utilizes mouse and cell line models to dissect the mechanistic basis of genetic cooperation during myeloid disease progression, with a specific focus on mutations that cause epigenetic alterations. Next generation sequencing (NGS) has vastly increased our understanding of the biology of myeloid malignancies including MDS and AML.

Edison T. Liu
M.D.

Edison Liu, M.D. is Professor and President Emeritus of The Jackson Laboratory (JAX). Between 2012–2022, he was president and CEO of JAX as well as the Director of the NCI designated JAX Cancer Center. Previously, he was the founding executive director of the Genome Institute of Singapore and held other positions including the president of the Human Genome Organization (HUGO), the scientific director of the National Cancer Institute's Division of Clinical Sciences in Bethesda, Md., and faculty member at the University of North Carolina at Chapel Hill, where he was the director of the UNC Lineberger Comprehensive Cancer Center's Specialized Program of Research Excellence in Breast Cancer; the director of the Laboratory of Molecular Epidemiology; and the Chief of Medical Genetics. Liu is an international expert in cancer biology, systems genomics, human genetics, molecular epidemiology and translational medicine. He has authored over 320 scientific papers and reviews and co-authored two books. He obtained his B.S. in chemistry and psychology, as well as his M.D., at Stanford University. He received his residency and fellowship training at Washington University, St. Louis, and Stanford, and post-doctoral training in molecular oncology at the University of California at San Francisco. Throughout his career Liu has received numerous awards, including the AACR Rosenthal Award and the Brinker International Award, both for breast cancer research; and the Chen Award for Distinguished Academic Achievement in Human Genetics. He is an elected member to the American Society of Clinical Investigation, foreign member of the European Molecular Biology Organization, and a Fellow of the American Association for the Advancement of Science (AAAS). Liu also holds honorary degrees from Queen's University (UK), University of Southern Maine, and Colby College (Maine).

Lincoln Nadauld
M.D., Ph.D.

Lincoln Nadauld, M.D., Ph.D., founded the Intermountain Precision Genomics program with a vision of finding solutions to improve health and disease through genomics and precision medicine without increasing costs. With his vision in mind, he oversees the clinical implementation of precision genomics across Intermountain's 24 hospitals and 160 physician clinics. Nadauld serves as Intermountain Healthcare's Chief Academic Officer. In addition, he facilitates genomic research to better understand the human genome. Nadauld conceived of and is leading the recently announced Heredigene, Population Study — a collaborative effort with deCODE Genetics in Iceland to collect and perform whole-genome sequencing on 500,000 participants in the Intermountain system. Nadauld's work in founding Intermountain Precision Genomics was recognized with the Utah Governor's 32nd Annual Science Medal for Industry, which is the highest civilian award to be bestowed by the state of Utah and honors significant contributions to science and technology. Nadauld also received the 2020 C2 Catalyst for Precision Medicine award, honoring those who improve personalized treatment for cancer patients. He is married with five children and enjoys attending their many activities and events, as well as water sports, fishing and other athletic pursuits.

Andrew Norden
M.D., M.P.H., M.B.A.

Andrew Norden, M.D., M.P.H., M.B.A., is the Chief Medical Officer at OncoHealth, where he leads the company's clinical and innovation strategy teams.

An accomplished neuro-oncologist, Norden previously served as Chief Medical Officer of COTA, an oncology company focused on the curation and use of real-world data and evidence for cancer care and research. Before COTA, Norden served as lead physician for oncology and genomics at IBM Watson Health and held several positions at the Dana-Farber Cancer Institute, including Associate Chief Medical Officer and Medical Director of Satellites and Network Affiliates.

OncoHealth is a leading digital health company dedicated to helping health plans, employers, providers, patients and life science researchers navigate the physical, mental and financial complexities of cancer through technology enabled services and real-world data analytics. Supporting more than 7 million people in the US and Puerto Rico, OncoHealth offers digital solutions for treatment review, real-world evidence, and virtual care across all cancer types.

Peter J. O'Dwyer
M.D.

Peter J. O'Dwyer, M.D., is a medical oncologist who specializes in GI cancers and Developmental Therapeutics and is Professor of Medicine at the University of Pennsylvania. O'Dwyer also serves as the co-chair of the ECOG-ACRIN (Eastern Cooperative Oncology Group — American College of Radiology Imaging Network) Cancer Research Group, where he has served as co-chair of NCI-MATCH (National Cancer Institute-Molecular Analysis for Therapy Choice), one of the first major precision medicine cancer treatment clinical trials.

Presenters, Panelists and Moderators

Gregory Omerza
Ph.D., M.B.(ASCP)

Gregory Omerza,, Ph.D., M.B. (ASCP), is a Clinical Genomic Scientist at The Jackson Laboratory for Genomic Medicine. Omerza joined JAX in September of 2018 from Thomas Jefferson Hospital in Philadelphia, where he was the Manager of the Genomic & Molecular Pathology Laboratory. He brought with him over two years of experience in molecular oncology and infectious disease testing in addition to 5 years of signaling pathway research. As Manager of the Genomic & Molecular Pathology Laboratory, Omerza has been involved in the validation, testing, and reporting of molecular oncology tests using various sequencing technologies including next generation sequencing. Omerza holds a Ph.D. in Cell and Developmental Biology from Thomas Jefferson University in which he investigated the non-canonical activation of a MAPK.

Kate Reed
M.P.H., Sc.M., CGC

Kate Reed, M.P.H., Sc.M., CGC, directs the precision oncology education efforts in the Clinical Education Program at The Jackson Laboratory. The team focuses on developing and implementing education to facilitate the integration of genetics and genomics into clinical practice. Reed has over a decade of experience in clinical genetics, healthcare provider education, and program development and implementation. She is a board-certified genetic counselor and has previously practiced clinically in a variety of settings, including general genetics, cancer, and neurology.

Jens Rueter
M.D.

Jens Rueter, M.D. is the Chief Medical Officer of The Jackson Laboratory and Medical Director for MCGI. Rueter came to JAX from Eastern Maine Medical Center Cancer Care (EMMC) in Brewer, Maine, where he was Medical Director for EMMC's Translational Oncology Program and the EMMC Biobank. He has been a hematologist/oncologist at EMMC Cancer Care since 2010, and a member of the JAX adjunct faculty since 2012. Prior to joining JAX, Rueter collaborated with several JAX investigators and technicians on developing new approaches to treating cancers while advancing translational research at EMMC. After graduating from medical school in Berlin, Germany, Rueter completed his residency in internal medicine at Tulane University and fellowship training in hematology/oncology at the University of Pennsylvania.

Stephanie Sharp
M.S., CGC

Stephanie Sharp, M.S., CGC, is a certified genetic counselor who provides cancer genetic counseling services at the Maine Medical Center Cancer Risk and Prevention Clinic and the Harold Alfond Center for Cancer Care. Sharp obtained her Master of Science in Genetic Counseling from the University of Michigan in 2018 and her Bachelor of Arts in Psychology from McGill University in 2016. In addition to her clinical role, Sharp also serves as a clinical coordinator for the MaineHealth Cancer Genetics ECHO Project, a collaboration with The Jackson Laboratory Clinical Education team that aims to improve access tocancer genetic services for underserved populations throughout the state of Maine and parts of New Hampshire.

Sarah Sinclair
D.O.

Sarah Sinclair, D.O., is the Director of the Clinical Research program and a hematologist/oncologist at Northern Light Cancer Care. She is board certified in Hematology and Oncology. Her interests include breast cancer, clinical research and genomic medicine. Sinclair received her D.O. from University of New England College of Osteopathic Medicine followed by a residency at University of Connecticut School of Medicine in internal medicine, and a fellowship with the National Cancer Institute in hematology/oncology.

Richard Schilsky
M.D., FACP, FSCT, FASCO

Richard Schilsky, M.D., FACP, FSCT, FASCO, is professor emeritus at the University of Chicago having recently retired from his position of Executive Vice President and Chief Medical Officer (CMO) of ASCO. Schilsky is also a Past President of ASCO, having served in the role during 2008-2009, and former Board member of Conquer Cancer, the ASCO Foundation. Before joining ASCO in 2013, Schilsky spent the majority of his career at the University of Chicago where he joined the faculty in 1984. Over the next nearly 30 years, Schilsky served in many leadership roles including as Director of the University of Chicago Cancer Research Center, Associate Dean for Clinical Research in the Biological Sciences Division and as the Chief of the Hematology/Oncology section in the Department of Medicine.

From 1995 to 2010, Schilsky served as chair of the Cancer and Leukemia Group B, a national cooperative clinical research group funded by the National Cancer Institute (NCI), now part of the Alliance for Clinical Trials in Oncology. 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. Presently, he serves as a member of the board of directors of Friends of Cancer Research, of the Reagan-Udall Foundation for the FDA and of the European Organization for Research and Treatment of Cancer (EORTC) and is Chairman of the WIN Consortium, a global translational research network. 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*. Dr. Schilsky is the author of more than 400 original research articles, reviews and commentaries.

Michael Snyder
Ph.D.

Michael Snyder, Ph.D. is the Stanford Ascherman Professor and Chair of Genetics and the Director of the Center of Genomics and Personalized Medicine. Snyder received his Ph.D. training at the California Institute of Technology and carried out postdoctoral training at Stanford University. He is a leader in the field of functional genomics and multiomics, and one of the major participants of the ENCODE project. His laboratory study was the first to perform a large-scale functional genomics project in any organism and has developed many technologies in genomics and proteomics. These including the development of proteome chips, high resolution tiling arrays for the entire human genome, methods for global mapping of transcription factor (TF) binding sites (ChIP-chip now replaced by ChIP-seq), paired end sequencing for mapping of structural variation in eukaryotes, de novo genome sequencing of genomes using high throughput technologies and RNA-Seq. These technologies have been used for characterizing genomes, proteomes and regulatory networks. Seminal findings from the Snyder laboratory include the discovery

Presenters, Panelists and Moderators

that much more of the human genome is transcribed and contains regulatory information than was previously appreciated (e.g. lncRNAs and TF binding sites), and a high diversity of transcription factor binding occurs both between and within species. He launched the field of personalized medicine by combining different state-of–the-art "omics" technologies to perform the first longitudinal detailed integrative personal omics profile (iPOP) of a person, and his laboratory pioneered the use of wearables technologies (smart watches and continuous glucose monitoring) for precision health. He is a cofounder of many biotechnology companies, including Personalis, SensOmics, Qbio, January, Protos, Oralome, Mirvie and Filtricine.

Christian Thomas
M.D., FASCO

Christian Thomas, M.D., FASCO, joined New England Cancer Specialists as a physician and the Director of Clinical Research in 2012. His clinical focus is on thoracic cancers (lung cancer, esophageal cancer) as well as GU cancers (prostate, testicular, bladder and kidney cancers). He also serves as an advisor to the American Society of Clinical Oncology, the Northern New England Clinical Oncology Society and CMS/Medicare. Thomas completed his medical school training in Frankfurt, Germany and an internal medicine residency and hematology/ oncology fellowship at Columbia University in New York City.

David Thomas
FRACP, Ph.D., M.B.B.S.

David Thomas, FRACP, Ph.D., is Head of the Genomic Cancer Medicine Laboratory at the Garvan Institute of Medical Research, and Chief Executive Officer of Omico. He is a NHMRC L3 Investigator and medical oncologist whose focus is on the application of genomic technologies to the understanding and management of cancer. Thomas founded the Australasian Sarcoma Study Group, a national research organization, and established Australia's leading adolescent and young adult cancer unit at the Peter MacCallum Cancer Centre. Thomas leads the International Sarcoma Kindred Study, now recruiting from 23 centers in 7 countries, and led the first international study of denosumab in Giant Cell Tumor of bone, leading to FDA and TGA approval. He has over 150 research publications, including lead or senior author papers in Science, Cancer Cell, Molecular Cell, Journal of Clinical Investigation, Lancet Oncology, JAMA Oncology, and Journal of Clinical Oncology. Since moving to NSW, he has established the Australian Genomic Cancer Medicine Centre, a national precision medicine program for patients with rare and early onset cancers. In 2018, he was President of the Connective Tissue Oncology Society, the peak international body in his field.

Jennifer Trowbridge
Ph.D.

Jennifer Trowbridge, Ph.D. is an Associate Professor at The Jackson Laboratory where she started her independent laboratory in 2012. She received her Ph.D. from the University of Western Ontario and trained as a postdoctoral fellow with Dr. Stuart Orkin at the Dana-Farber Cancer Institute. Trowbridge is a Scholar of the Leukemia and Lymphoma Society and is a past recipient of the Janet Rowley Award from the International Society for Experimental Hematology, a V Foundation V Scholar award, Ellison Medical Foundation New Scholar Award in Aging, and American Society of Hematology Scholar Award. Her research interests span hematopoiesis, stem cell biology, aging and cancer biology.

Christine Walko
Pharm.D., BCOP, FCCP

Christine Walko, Pharm.D., BCOP, FCCP, graduated with her Pharm.D. degree from Duquesne University in Pittsburgh, Pennsylvania, and completed a pharmacy practice residency at the Medical College of Virginia/VCU in Richmond, Virginia, and a hematology/oncology specialty residency at the University of North Carolina (UNC). She stayed at UNC to complete a 2-year academic oncology fellowship focused on drug metabolism and translational research before taking an Assistant Professor position at UNC in the Division of Pharmacotherapy and Experimental Therapeutics. Walko is now an Associate Member in the Department of Individualized Cancer Management at Moffitt Cancer Center, Program Leader for Precision Medicine, an Attending on the Personalized Medicine Clinical Service and Co-Chair of the Clinical Genomic Action Committee, which serves as Moffitt' s Molecular Tumor Board (MTB). She is also a member of the ASCO TAPUR™ trial MTB. Her research focus is on optimizing drug therapy using pharmacogenomics and pharmacokinetics to personalize intravenous and oral anticancer therapy for patients with cancer.

About Patient Advocate Foundation (PAF)

About Patient Advocate Foundation (PAF)

Patient Advocate Foundation's (PAF) is a national 501(c)3 non-profit organization which provides case management services and financial aid to Americans with chronic, life-threatening and debilitating illnesses.

Chief of Mission Delivery Role

Erin Bradshaw is the Chief of Mission Delivery providing strategic and visionary executive operational leadership to deliver effective, compassionate case management interventions. With 23 years of experience with PAF she is passionate about improving patients' lives around the nation.

Interest that relates to MCGI

Like the Maine Cancer Genomics Initiative, PAF believes every patient should have equal access to precision medicine, innovative clinical trials and target therapies. Unfortunately, effective use of, and access to precision oncology care is still highly dependent on health care coverage, patient and provider education, and patient geographic location and socioeconomic status.

PAF strives to quantify and qualify the experience of vulnerable, underserved people of all kinds while increasing the types of assistance and programs we offer to improve the lives of those battling serious illness right now. We seek to amplify their voices, their experiences, their concerns and their priorities. High-quality health care is not just about treatment; it's about a care plan that considers challenges to daily life — transportation, housing, food security, employment, childcare and self-care. We know that too many people are trying to figure out how to pay for testing, medications, hospital bills and lab tests while keeping the lights on and putting food on the table. We envision a future in which a care team surrounds each patient and responds to these concerns in a comprehensive and effective way, which is what our case management and financial support programs are designed to do.

Relevance to cancer patients

Offering a free service, our case managers help bridge the gap between what happens in the clinical setting and the practical; assistance for overturning health insurance denials, assessing barriers, finding critical safety net programs and support, preserve financial stability, and curtail distressing medical debt that otherwise harms health outcomes.

Services include helping to:

- navigate insurance denials preventing coverage of tests or identified treatment, clinical trials or second opinions;
- navigate through the reimbursement system, including initial interpretation of the patient's benefit language, with an emphasis on evaluating reimbursement for the test itself;
- provide screening and assistance for patients seeking access to investigational therapies under compassionate use; and
- help in covering costs associated with the ancillary treatment related fees.

Patient Advocate Foundation
https://patientadvocate.org | (800) 532-5274

Personalized Medicine CareLine
https://personalizedmedicine.pafcareline.org

FDA Oncology Center of Excellence's Project Facilitate

An Overview of the Oncology Expanded Access Program

Oncology Center of Excellence Project Facilitate is a single point of contact call and information center created to help oncology healthcare providers or regulatory professionals submit an Expanded Access Request (also referred to as: Compassionate Use, Emergency IND, Single-Patient IND, or Pre-Approval) for an individual patient with cancer through FDA's Expanded Access Program.

FDA's Expanded Access Program allows patients with life-threatening diseases or conditions such as cancer try investigational medical products (drug, biologic, or medical device) when no satisfactory therapies are available and there is no opportunity for the patient to enroll in a clinical trial.

Investigational medical products have not yet been approved by the FDA and the FDA has not found these products to be safe and effective for their specific use. The investigational medical products may, or may not, be effective in the treatment of the condition, and use of the product may cause serious side effects that were not expected.

The request process can be complex to navigate, particularly for oncologists who don't have experience working with clinical trials or these types of requests. To make a request, a member of the patient's healthcare team will approach the pharmaceutical company to ask for its agreement that it will provide the medical product. The company has the right to approve or disapprove the physician's request.

The FDA Expanded Access Program allows a vast majority of these requests to proceed, and Project Facilitate is here to guide oncology healthcare providers through the process.

Dempsey Center

Maureen from the Dempsey center will anchor an open house lunch table at the Samoset on Sat 4/2.

The Dempsey Center was founded by Patrick Dempsey in 2008 as a way to give back to the community where his mother, Amanda, first received cancer treatment. Their experiences led Patrick to set out on a mission to make life better for people impacted by cancer. Through support groups, complementary therapies, workshops, classes, and counseling, the Dempsey Center is able to provide a wide range of services for cancer patients, survivors, care partners, and family members…all at no cost.

Currently, the Dempsey Center provides services at their offices in Lewiston and South Portland, Maine and virtually to anywhere via Dempsey Connects. In 2022, the Dempsey Center plans to open Clayton's House, a hospitality home located in Portland, Maine's picturesque East End. Here, patients who have to travel 30+ miles for treatment will be able to find solace and a home away from home at no cost.

Maureen Higgins
M.S.W.

Maureen Higgins, M.S.W. is the Community Engagement Coordinator with the Dempsey Center. She has worked as an oncology social worker since 1990 in both in-patient and out-patient settings. Higgins joined the Dempsey Center in 2009, providing cancer prevention, risk reduction and early detection education to groups in the community. Currently she provides outreach to our healthcare partners. She is an active member in the Maine Cancer Impact Network and the Association of Maine Cancer Support Centers.

Clinical Knowledgebase (CKB)

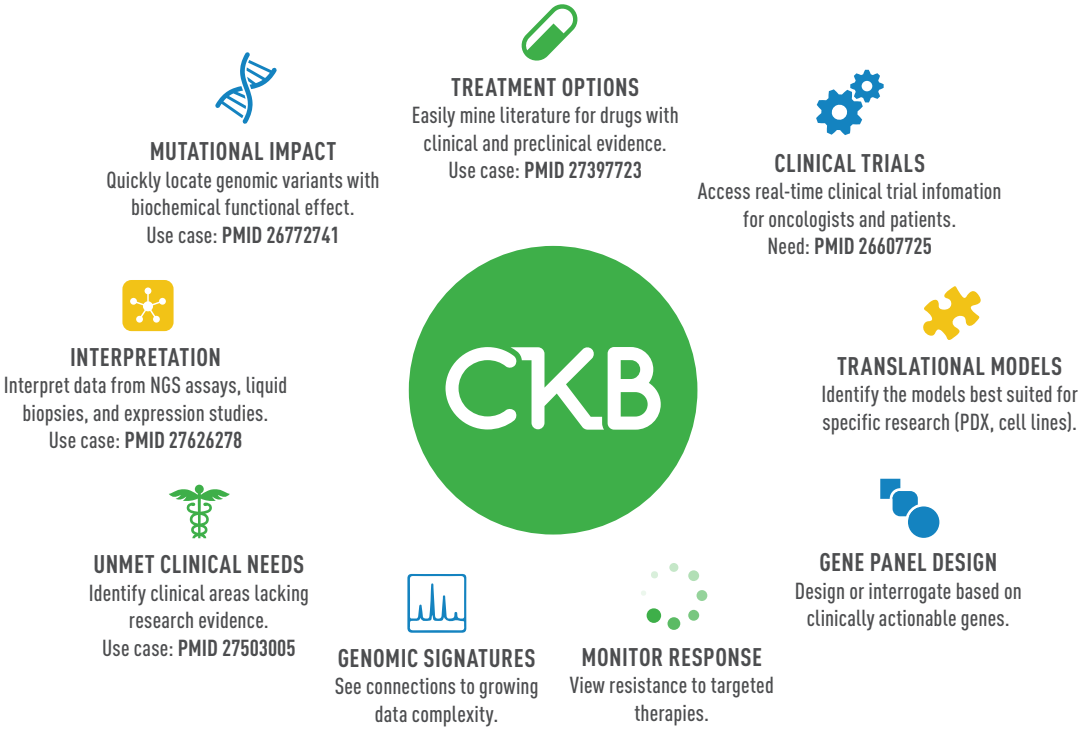
A platform for the sharing of highly curated cancer genomic knowledge to foster translational and clinical advancements

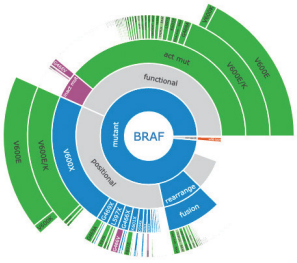
Deciding on the best treatment for a patient when the tumor includes multiple genomic variants is not always straightforward. The Jackson Laboratory's Clinical Knowledgebase (CKB) is a valuable tool that can be used to interpret genomic variants, and allows rapid identification and ranking of therapeutic evidence in the context of one or more variants.

CKB is updated daily and includes data related to FDA-approvals, approved companion diagnostics, professional guidelines and clinical and preclinical studies.

For more information about CKB and its offerings, visit ckbhome.jax.org.

To request a demo, contact ckbsupport@jax.org.





CKB BOOST™ subscribers can navigate gene variant relationships through our patent-pending technology for visual rendering.

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Opening Remarks

Jens Rueter, M.D., Chief Medical Officer, The Jackson Laboratory; Medical Director, MCGI

Eric Anderson, Ph.D., Faculty Scientist, Maine Medical Center Research Institute

Welcoming the nearly 100 in-person attendees to the 2022 Maine Cancer Genomics Initiative (MCGI) Forum, Jens Rueter, M.D., noted the Forum's long-awaited return to the Samoset Resort. After the COVID-19 pandemic led to the cancellation of the Forum in 2020 and a fully virtual meeting in 2021, the 2022 meeting was hybrid, with some presenters and attendees in person and others remote.

Rueter presented an overview of MCGI 1.0 (2016–2020) and, following a new round of Harold Alfond® Foundation funding, MCGI 2.0 and its future plans. MCGI 1.0 was successfully implemented in all oncology practices throughout Maine, providing Maine cancer patients with access to genomic tests at no costs, genomic tumor board input for actionable results, education and more. In addition to the tumor testing, the program collected data on patient and clinician attitudes, perceptions and knowledge regarding the testing and analysis process. It also assessed patient outcomes and how they were affected by the testing and tumor board guidance. In all, 1,637 patients were enrolled in the program before enrollment stopped in December 2020.

MCGI 2.0 will build on the foundation in place, expanding the network and access to testing and enhancing the genomic tumor board's activities. A key new development is patient access to therapies in Maine through compassionate use and expanded access programs, as well as through clinical trials, including participation in the national The Targeted Agent and Profiling Utilization Registry (TAPUR™) and National Cancer Institute – Molecular Analysis for Therapy Choice (MATCH) trial programs, both of which were the subjects of presentations at the Forum. According to Rueter, MCGI 2.0 will provide patients and providers with "navigation of genomic care across the patient journey."

Eric Anderson, Ph.D., presented his findings from the survey and interview data collected from MCGI 1.0 patients and clinicians. The project sought to assess participant knowledge of, expectations for, and attitudes about genomic testing and targeted therapies. The results indicate that patients, 71% of whom completed the surveys, have positive attitudes towards them and expect them to improve outcomes despite having low knowledge of what genomic tumor testing entails. While encouraging, the data underscores the importance of managing patient expectations. And physicians, while also positive about genomic testing, were concerned about patient access to genome-informed therapies.

Out of 1,603 patients enrolled, 1,294 patients have had test results returned to date, with 1,012 containing an actionable variant but no genome-matched treatment available and 215 with actionable findings plus a genome-matched treatment indicated. The patients with genome-matched treatments have slightly higher preliminary survival rates than those with actionable variants but no matched treatments, but there are many caveats remaining. The next steps include longitudinal studies to follow patients for longer time frames, investigations of treatment access disparities, more interviews with physicians, and continuing physician education.

Session 1 Panel: Identifying Hereditary Risks through Genomic Tumor testing

Gregory Omerza, Ph.D., Manager, Clinical Data Analysis & Reporting, The Jackson Laboratory

Stephanie Sharp, M.S., CGC, Genetic Counselor, Cancer Risk and Prevention Clinic, Maine Medical Center

Christine Walko, Pharm.D., BCOP, FCCP, Associate Member, Individualized Cancer Management, Moffitt Cancer Center

Moderators

Emily Edelman, M.S., CGC, Director, Clinical Education, The Jackson Laboratory

Kate Reed, M.P.H., Sc.M., CGC, Director, Precision Oncology Education, Clinical Education Program, The Jackson Laboratory

A panel of experts presented two sample cases that demonstrate the importance of considering additional germline testing after genomic tumor testing. Knowing when a variant is present in the germline can be useful for providing access to certain treatments, management of future cancer risk, and informing relatives of a possible need for them to learn more about their own risks. The benefits and limitations of parallel germline blood testing and somatic tumor testing in their ability to detect germline variants were discussed. In the first case presented, a small intestine adenocarcinoma in a 61-year-old patient who had recurrent colon cancer when younger, germline mutations were not found on the somatic and germline panel. The history indicated the possibility of Lynch syndrome, however, so a comprehensive germline test was performed that did indeed detect a germline mutation, which guided therapy strategy as well as reveal the importance of genetic counseling for family members. The other case, a 62-year-old with pancreatic adenocarcinoma, presented with a BRCA2 loss of function mutation detected via liquid biopsy and confirmed germline in subsequent testing. Again, the finding had important implications for patient management and family counseling.

The Oncology Patient's Journey and Patient Advocate Foundation

Erin Bradshaw, Chief of Mission Delivery, Patient Advocate Foundation (PAF)

The Patient Advocate Foundation (PAF) provides case management and financial aid to Americans with serious disease and assisted more than 190,000 patients in 2020 alone. Patients need support to navigate the patient treatment journey and the financial hardships it can bring. They have many roadblocks along the way, including but not limited to insurance access, medical debt, employment protections, emotional distress and cost of living impacts. PAF works to ensure access and affordability, helping with transportation and other logistical needs as well as working to avoid financial toxicity in the context of medical care. Financial stress is a significant barrier to achieving clinical goals, and it needs to be addressed for patients to receive the best care. Overall PAF seeks to be what Bradshaw called a "precision charity," providing the right help to the right patient at the right time through reducing financial burden, helping patients with obtaining the appropriate insurance, and linking them with available social and charity programs.

FDA Oncology Center of Excellence's Project Facilitate: An Overview of the Oncology Expanded Access Program

Ramya Antony, F.N.P., M.S.N., B.S.N., M.S., Clinical Analyst, FDA Project Facilitate

Ramya Antony presented common misconceptions about the FDA's Oncology Expanded Access program, and its actual processes and performance. Expanded access is the use of an investigational (not previously FDA approved) medical product to treat a patient with a serious disease with no alternative therapies, the third line for access behind approved drugs and clinical trials. Like clinical trials, where the primary intent is research, expanded access necessitates the weighing of potential patient risks and benefits. Human subject protection is a critical component of the program, which mandates informed consent and IRB approval for non-emergency applications.

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The recently implemented Project Facilitate provides a single point of contact call and information center to assist with Expanded Access requests for individual cancer patients. Its mission is to address any barriers involved with Expanded Access requests and help both patients and oncology health care providers stay informed and efficiently navigate the request process.

An Oncologist's Guide to the Mysteries of Prior Authorization

Andrew Norden, M.D., M.P.H., M.B.A, Chief Medical Officer, OncoHealth

Oncology, as well as U.S. health care in general, faces significant challenges with unsustainable cost growth and variations in care plans that are not necessarily rooted in evidence. For oncology alone, costs are forecast to increase 34% from 2015 to 2030, reaching more than $245B by 2030. Though not well-loved, prior authorization seeks to address these issues within the existing health care system. OncoHealth is completely oncology focused and provides a web-based prior authorization portal for prior authorization requests. Norden discussed how prior authorization organizations decide to approve or deny a particular treatment regime while also noting that it's a highly regulated process. Indeed, for off-label coverage, OncoHealth has a team that keeps up to date with medical literature evidence, but Medicare manuals spell out which journals meet quality metrics for supporting the use of a drug. When prior authorization criteria are not met, there are alternatives, including clinical trials and compassionate use provisions from manufacturers.

Panel Discussion: Navigating the Precision Oncology Pathway

A lively question and answer session with the Session 1 presenters expanded upon the information presented in the talks. Of particular interest were further details about accessing the Project Facilitate system and navigating the process, particularly in regard to IRB resources, and how patients can most readily be connected with the Patient Advocate Foundation. Prior authorization generated considerable discussion, particularly given that it is a process that can take a lot of time. Also, the Medicare "gray area" of NCCN 2b-level evidence for prior approval has led to ambiguity in coverage by payers. Some are willing to support 2b-level evidence, others are not, and it can feel arbitrary and difficult to deal with. What would be a better situation? Have Medicare negotiate at a national level. But with things as they are, prior authorization is an important tool in the system.

Genomic Tumor Board Case Panel Discussions: Adult Cases

Jessica Cary, M.S., R.N., CGC, Genetic Counselor, New England Cancer Specialists

Jill Kolesar, Pharm.D., M.S., Professor, Pharmacy and Medicine, University of Kentucky

Lincoln Nadauld, M.D., Ph.D., Vice President, Chief of Precision Health and Academics, Intermountain Healthcare

David Thomas, FRACP, Ph.D., Head, Genomic Cancer Medicine, Garvan Institute of Medical Research

Christine Walko, Pharm.D., BCOP, FCCP, Associate Member, Individualized Cancer Management, Moffitt Cancer Center

Moderator

Jens Rueter, M.D., Chief Medical Officer, The Jackson Laboratory; Medical Director, MCGI

A cornerstone of MCGI is the Genomic Tumor Board series which leverages a team of experts that convenes regularly to review patient test results with the practicing oncologist, identify possible actionable genomic variants and discuss treatment options based on the findings. MCGI Forum attendees were able to learn about what happens during GTB sessions, as tumor board members discussed real patient cases, the insights provided from the genomic test results, and the challenges that can arise from the analyses.

The adult cases discussed by the panel provided examples of several of the issues that can come into play. For example, the first patient had genomic results from a liquid biopsy, leading to discussions about the pros and cons of liquid biopsies and how they may complement tissue biopsies, particularly as a less invasive way to monitor treatment response over time. Also, the patient had three potentially druggable targets identified, so how should that be approached? Combination therapies are an option, but they can be risky, especially if not extensively studied, or drug recommendations can be tiered based on available evidence for clinical benefit. The second case featured loss of function mutations with high allele frequency in two DNA damage repair genes, indicating that they were possibly in the germline but also affecting the therapeutic strategy. The panelists also discussed how genomic test results affect whether to recommend the use of traditional therapies such as radiation. At this time, oncologists still need to treat known cancers based on standard therapies and regimens, so if radiation is indicated, it should be used even in the presence of DNA damage repair gene abnormalities.

Genomic Tumor Board Case Panel Discussion: Pediatric Cases

Alanna Church, M.Sc., M.D., FRCPC, Associate Director, Laboratory for Molecular Pediatric Pathology, Boston Children's Hospital

Steven DuBois, M.D., M.S., Director, Experimental Therapeutics, Dana-Farber Cancer Institute

Moderator

Ching Lau, M.D., Ph.D., Professor, The Jackson Laboratory

Relative to adult cancers, pediatric cancers often present additional challenges and considerations for GTB analysis and treatment decisions. They are often driven by germline variants and can be very rare, with little or no diagnostic or therapy guidance provided in the literature. Also, aggressive treatments may be indicated to slow or stop cancer progression, but they may also affect healthy growth and development for the child, providing an additional risk factor to take into account.

The pediatric cases presented highlighted these issues. The first patient, a 16-year-old female, had two separate brain tumors that turned out to be quite different in origin and type. Initial pathology indicated that they were different, and a comprehensive solid tumor panel revealed that the first tumor was an IDH1-driven oligodendroglioma, while the subsequent one was a BCR-NTRK2 fusion driven anaplastic astrocytoma. The finding emphasizes that one cannot assume that tumors arise from the same origin, and the presence of two different drivers can obviously affect therapy decision-making. Also, two different primary tumors occurring before the age of 18 argues for a cancer risk assessment. The patient previously had a germline cancer risk panel done that provided no additional insight, but it was years prior and another could be helpful. The second patient, a 10-year-old female, was diagnosed with a low-grade glioma (grade 1 pilocytic astrocytoma). The gene panel revealed a ZC3H7A-ALK fusion/chromosomal rearrangement, a potential oncogenic driver but one that is usually associated with high-grade gliomas, making therapy decision-making difficult. The case was therefore sent for a whole genome methylation array, and it didn't match any methylation class, indicating that it likely represented a novel rare entity.

Keynote Address: Maine Cancer Genomics Initiative in 2030

Edison Liu, M.D., Professor and President Emeritus, The Jackson Laboratory

In his evening keynote address, Edison Liu reflected on the origins of MCGI and how he sees it — and oncology in general — progressing in the near future. He emphasized the importance of technology dissemination to drive cancer patient benefit and noted that MCGI has succeeded in closing the gaps in oncology practice between rural and urban environments in Maine. But can it move forward to establish Maine as an innovator to reduce disparities in rural cancer care? Access to technology and therapeutic progress is essential for this, as genomic testing becomes fundamental in oncology, and medicine in general. Virtual platforms

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will provide the power to deliver not just medical care but also innovative expertise, such as that provided by GTBs, and decentralize clinical trials. He envisions MCGI in 2030 as being a complete precision oncology platform, providing the genomic education needed to keep up with the continuous technology changes as well as the infrastructure for delivering the best care. That includes online GTBs, clinical trial networks, web-based TeleOncology and state-based precision medicine navigation expertise. There has been a 32% drop in cancer mortality over the past two decades, and it is still falling at a constant rate. His vision is to maintain the linear path to 50%, 75% and ultimately 100% over the coming decades, with MCGI serving as a model for disseminating the technology and expertise needed to achieve it.

Session 3: NGS in Myeloid Malignancies

Uncoding Genetic Complexity of Myeloid Malignancies

Coleman Lindsley, M.D., Ph.D., Assistant Professor, Medicine, Harvard Medical School

How does a normal hematopoietic stem cell transform into a malignant leukemic cell? A single mutation can provide a competitive advantage, leading to clonal expansion but not necessarily to detectable dysfunction or subsequent transformation. Additional mutations may confer further clonal advantages, however, and lead to myeloid disease, including myeloid dysplastic syndrome (MDS) and acute myeloid leukemia (AML). Primary MDS patients usually have multiple driver mutations in a variety of molecular systems, while treatment-related MDS (i.e. MDS after prior cytotoxic chemotherapy), which is associated with worse outcomes, are largely driven by mutations in two genes, *TP53* and *PPM1D*. In the primary disease pathway, mutations are "stitched together" over time, driving parallel processes of genetic evolution. While the process presents fundamental challenges for clinical intervention, research is revealing a regulatory logic of MDS/AML genetics that provides opportunities for therapeutic target discovery. Some mutations tend to arise early and define disease initiation, while others are found to occur later in the process and are associated with leukemic transformation. These assessments of clonal architecture and evolution are the basis of ongoing inquiry.

Identifying Pathways and Treatment for Myeloid Malignancies

Jennifer Trowbridge, Ph.D., Associate Professor, The Jackson Laboratory

Clonal hematopoiesis (CH) is a natural consequence of aging, but 0.5%-1% progress to malignancy each year. Trowbridge investigates the variables underlying progression versus non-progression, with the goal of determining how to detect and prevent the process before the development of AML. She is using mice to model a gene frequently mutated in adult AML, DNMT3A, and found that hematopoietic stem cells with DNMT3A mutations have a selective growth advantage versus wild type. The cells did not progress to AML, however, so she investigated other gene mutations that frequently co-occur. Using an inducible knock-in mouse model, she showed that sequential mutations, first in DNMT3A and then in NPM1, together progressed to myeloid leukemia. Environmental factors also contribute, and the aging bone marrow microenvironment accelerates transformation. Early findings implicated increased inflammatory signaling associated with TNFα and knocking out the TNF receptor 1 (TNFR1) reduces DNMT3A mutant selective advantages. The TNFR1 pathway therefore provides an intriguing target for AML prevention.

Panel Discussion: NGS in Myeloid Malignancies

In the panel discussion, the panelists considered the difficulty involved with preventing MDS, an asymptomatic, low-risk condition, from transitioning to high-risk AML. It's a tough nut to crack, because MDS can be indolent for years, and how would you create a clinical trial for otherwise

healthy people that carries immune suppression risks? A retrospective study could likely be done into less toxic anti-inflammatories such as aspirin, looking back to see if people on anti-inflammatories for other disease have CH mutations. We also need to get better at predicting risk factors for CH—there are obvious pro-inflammatory molecules to look for, but they're likely to be the tip of the iceberg. Finally, narrowing the gap between the basic research being done and actual practice will take more programmatic, interdisciplinary approaches that involve all parts of the pipeline, including those who don't currently communicate with each other. If translational science becomes more patient-focused, it can be more pragmatic much of the time.

Session 4: New Diagnostic Technologies

Big Data and Wearable Approaches for Managing Health

Michael Snyder, Ph.D., Professor and Chair, Genetics, Stanford Medicine

A visit to a doctor's office provides clinical data, but it's a snapshot of a patient's state at only one hour out of what might be a year or two. Snyder has been researching the benefits of constant data acquisition through technologies such as wearable devices, a process he calls longitudinal personal 'omic profiling. He now has tracked 109 individuals that began the study healthy for up to eight and a half years, starting with genome sequencing and building personal baselines — individually stable but variable between people — based on billions of measurements. During the study, 49 of the participants have had major health discoveries before physical symptoms manifested, including cardiovascular disease, metabolic disease, infectious disease and cancers. Moving forward Snyder is studying environmental effects, such as seasonal changes, and aging profiles within the study cohort. There is already a large population of wearables users, including 50 million Americans with smart watches, and such profiling is likely to become more feasible and scalable as prices drop. The value of personal baselining was further emphasized by a study demonstrating early COVID detection before symptom onset. A Q&A session focused largely on some of the challenges and barriers involved, such as the potential psycho-social impacts of constant monitoring, incorporating data into current EHR systems, addressing health care delivery disparities and the hurdles for obtaining FDA approvals for diagnostic applications.

Improving Early Detection for Ovarian Cancer: The MiDe Study

Dipanjan Chowdhury, Ph.D., Chief, Division of Radiation and Genomic Stability, Dana-Farber Cancer Institute

More than 140,000 women die from ovarian cancer annually, almost 13,000 in the U.S. alone. Early detection greatly increases survival rates, but there is no FDA-approved biomarker for ovarian cancer and most women don't enter treatment until they're at stage 3 or 4. Research into microRNAs (miRNAs) is providing promising insights, however. miRNAs don't code for proteins but influence gene expression, and they play important roles in cancer and therapy response. They are found in blood and are easy to isolate, are more stable than proteins or DNA, and can be rapidly analyzed, so they have potential to serve as biomarkers. But can serum miRNAs actually detect cancer? Preliminary studies have shown they can, with 92% sensitivity and three-fold fewer false positives than other methods. Chowdhury is working with Aspira, a women's health company, to further develop testing protocols. In the Q&A session, Chowdhury clarified that miRNA signatures look like they're related to DNA repair but are not specific to BRCA mutations, so they may apply to other high-risk carriers in the future. Also, the researchers are investigating whether the miRNA profiles can also pinpoint other BRCA+ cancers, such as breast and pancreatic cancers. At this point it's not known how different BRCA mutations can affect miRNA patterns, or what the differences are between BRCA 1 and BRCA 2.

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Session 5: Emerging Therapeutic Approaches

mRNA-Based Therapeutics in Oncology

Khanh Do, M.D., Director, Oncology Clinical Development, Moderna

The speed of development and clinical success of mRNA-based COVID-19 vaccines rightfully vastly increased awareness of mRNA therapeutic technologies. While the pivot to COVID was impressively fast, however, vaccination using mRNAs is not a novel concept. The first preclinical study of an mRNA vaccine was launched a decade ago and a personalized cancer vaccine entered Phase 1 clinical trials in 2017. An initial challenge was presented by the fragility of single-stranded mRNA, so the COVID vaccines use a lipid nanoparticle technology to stabilize the mRNAs and deliver them into cells. The mRNAs themselves can also be optimized to increase translation into proteins within cells and activating more effective immune responses. Effective personalized cancer vaccines appear to need to produce cytokine-directed signal enhancement beyond just neoantigen stimulation and to work in concert with checkpoint blockades. Research into optimizing mRNA-based cancer vaccines is ongoing, and while an experimental vaccine, mRNA-4157, had a low response percentage in a phase 1 study, it did elicit durable responses in some patients.

Current and Upcoming Developments to CAR-T Therapy

Matthew Frigault, M.D., Assistant Professor, Harvard Medical School

There has been a huge increase in clinical trials using chimeric antigen receptor T-cell (CAR-T) therapies in recent years, with 1,059 active in January 2022. There are FDA-approved CAR products targeted to lymphoma and melanoma now commercially available. Patient response rates are generally good (around 50%), with durable survival. So far, they have been used as third-line therapies, but could they be more effective if employed sooner? Also, could they be effective when used outside of their currently approved indications? Frigault discussed work looking to expand CAR-T applications, such as a phase 1 trial for multiple myeloma with an engineered synthetic protein binding domain that has seen some level of response in 100% of patients. Solid tumors can be more of a challenge because of heterogeneity and immunosuppressive microenvironments, but early data for a combination therapy with a PD-1 inhibitor is very promising. Finally, a lot of effort is being applied to lowering cytokine release storm toxicities, which can be life threatening. Anakinra is a promising candidate, at least for the potential to minimize steroid use in response.

Panel Discussion: Emerging Therapeutic Approaches

The presentations on emerging individualized therapies sparked a discussion on how they affect treatment access and the patient journey. CAR-T therapies in particular are a relatively extended process, including a long hospital stay, toxicity and regulatory considerations, and considerable expense, so expanding access to community settings is an ongoing challenge. The panelists also discussed the need to better predict patient responses to the therapies, with the insight that mRNA vaccine response can mirror the response to checkpoint blockade therapies. COVID vaccine strategies may apply to mRNA cancer vaccines as well, such as increasing efficacy with booster doses, but the data isn't yet mature enough to make that determination. For CAR-T, the effect of age on efficacy is not yet known for quality outcomes, but increased age may also increase side effect risks. Better, more durable responses have been seen in pediatric patients, but everyone does have a chance for a good response regardless of age.

Session 8: Precision Oncology Trials

NCI-MATCH: Updated Results

Peter J. O'Dwyer, M.D., Professor of Medicine, University of Pennsylvania

NCI-MATCH is a disease agnostic basket trial established to explore genomics-based targeted cancer treatment as a signal-seeking trial to identify promising treatments directed to specific tumor mutations. When opened in 2015 the goal was to have 3,000 patients, but enrollment exceeded expectations, and screening of about 6,000 patients was completed by July 2017, almost two years ahead of schedule. Treatment design centered on a biopsy before starting treatment, and the core genetics assay developed and used for the initial screened patients covered 143 genes. Eventually 39 different treatment arms were formed, with a target accrual of 35 patients each. Following the conclusion of the screening portion, an outside "designated laboratory" consortium was set up to complete accrual to the remaining arms. A total of 686 patients (18%) were assigned to treatment based on core screening, but 500 more were subsequently assigned through the outside lab consortium. The results from 26 arms with available data show that five were positive, meaning that they exceeded the 16% response rate sought. So, while genomic aberrations underlie most cancers and some positive results, there has been limited success in fully translating cancer genomics to patient benefit. There are a number of possible reasons for this: maybe the available drugs simply aren't good enough, they are applied too late, they need to be administered in combination, co-occurring mutations may confer therapy resistance and more. To further explore the issue, successor trials are in development, including ComboMATCH (combination therapy testing) and iMATCH (immunotherapy guidance).

The ASCO TAPUR Study: Recent Findings and Future Directions

Richard Schilsky, M.D., FACP, FSCT, FASCO, Senior VP and Chief Medical Officer Emeritus, ASCO

The goal of the ASCO TAPUR trial is to learn from real-world practice of prescribing targeted therapies off label to patients with advanced cancers whose tumor harbors a targetable genomic variant. Nine companies are participating in the study, with several providing multiple drugs. Most of the cohorts are still open and enrolling patients based on matching criteria, not pre-assigned treatment arms. The endpoints include disease control rate measured as objective response rate, overall survival, and others. TAPUR was set up to be a pragmatic trial with broad eligibility criteria and allowing for considerable physician discretion. It does have firmly established genomic matching rules and reporting mandates, however. As of February 8, 2022, 3,462 participants have been registered at 186 locations in 26 states, and 2,340 participants have been matched to and have received a drug. TAPUR is looking to have more than 200 sites established by the end of the year. Of the cohorts reporting, 11 have reported positive outcomes, including some therapies that are now FDA approved for their cohort indication but weren't when TAPUR began. There are also eight negative cohorts reported, which is also important, as the results will help steer clinicians away from ineffective therapies. ASCO plans to continue the study for as long as it provides useful information, and there are some new drugs in the pipeline and some matching rules that may be refined. There are also TAPUR-inspired international studies ongoing, some of which are sharing data and increasing the potential for insights across studies.

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Precision Oncology — Where Do We Go from Here?

Panel Discussion

Jill Kolesar, Pharm.D., M.S., FCCP, BCPS, Professor, Pharmacy and Medicine, University of Kentucky

Andrew Norden, M.D., M.P.H., M.B.A., Chief Medical Officer, OncoHealth

Peter J. O'Dwyer, M.D., Professor, Medicine, Penn Medicine

Richard Schilsky, M.D., FACP, FSCT, FASCO, Senior VP and Chief Medical Officer Emeritus, ASCO

Sarah Sinclair, D.O., Director, Clinical Research, Northern Light Cancer Care

David Thomas, FRACP, Ph.D., Head, Genomic Cancer Medicine, Garvan Institute of Medical Research

Christian Thomas, M.D., FASCO, Director, Clinical Research, New England Cancer Specialists

Christine Walko, Pharm.D., BCOP, FCCP, Associate Member, Individualized Cancer Management, Moffitt Cancer Center

Moderator

Jens Rueter, M.D., Chief Medical Officer, The Jackson Laboratory; Medical Director, MCGI

The panelists each explored a different aspect of precision oncology and how to address various challenges that still exist.

Leading off the presentations, Schilsky was asked about the pragmatic design of TAPUR. He emphasized that pragmatic trials attempt to replicate real-world practice as closely as possible. It's important to have broad eligibility criteria, allow for physicians to be able to use their own discretion in many areas, make patient response data easy to collect, and try to avoid mandating unnecessary data collection (e.g., low grade adverse events) or excessive auditing and monitoring. Maybe because of that, it was successful in enabling a high percentage of patients to participate. It has to be simple for patients to participate and simple for sites to meet requirements.

O'Dwyer commented that MATCH has more stringent restrictions than TAPUR, but the studies are very complementary. Moving forward, NCI will be using findings from the first MATCH study to inform the comboMATCH follow up, such as the low hit rate with single agents. For comboMATCH, the team had to revisit the criteria for construction of the different study arms and go further than it did for MATCH regarding drug choices and targets: drugs must show activity in PDX or specifically engineered mouse models to be chosen. Also, for comboMATCH they will have tissue type agnostic plus tissue type specific arms.

Walko presented her thoughts on how to integrate novel technology and novel biomarkers into practice. It's important to balance excitement about the new options available, such as immunotherapies, with the need for evidence-based medicine. Education amplifies the impact of research, but at the same time recommendations based on molecular data are only as good as the data that's out there. Those in oncology need good data to prove that the treatments work. Still, there is a lot to be excited about, such as the potential for innovative therapies like CAR-T to be delivered outside of big medical centers.

Sinclair spoke on the barriers she sees in delivering precision oncology to a rural, underserved patient population. She noted the difficulty many patients have in simply accessing care in a timely manner, which magnifies the challenges involved with enrolling them in clinical trials. At Northern Light, the research nurses provide vital physician support regarding available trials and screening patients for them. Also, a program like MCGI is very important for data interpretation and treatment decisions, which really can't be done on one's own. With that support, it's important to initiate testing ASAP and not after multiple lines of treatments have been tried.

Kolesar also considered how to overcome the challenges that come with rural populations and large disparity issues based on her experiences in Kentucky. There, the patient population wasn't benefiting from advances outside of major

medical centers, and community practices had little knowledge of or value for personalized therapies. They started a molecular tumor board to support decision making, and the data show a large patient benefit for genomic testing and board analysis. Her group is now addressing the lack of access and has been very successful after hiring a genomics navigator to handle logistics. Some clinics went from 0% to 100% sequencing rates very quickly.

Christian Thomas is part of a private practice in a more suburban part of Maine, but recently he encountered similar challenges to those reported by Sinclair and Kolesar. The broader statistics show that only 50% of eligible patients receive genomic testing, and a few years ago he found it was a similar rate in his clinic. He had to figure out how to access the testing, interpret the results and translate their implications for the patient, overcome financial barriers, deal with testing turnaround time and so on. He has found MCGI extremely important for physician education, but also for getting people to work in concert, such as in the GTBs. Norden addressed patient access issues from a prior authorization perspective. It is difficult trying to figure out what is the best thing to do for a given patient, but people should keep in mind that a short time ago we were having debates about doing any NGS panel testing at all because of insurance barriers, so there has been progress. Off-label therapy use, based on preclinical evidence, presents a difficult situation for an insurance company, and Medicare's clear guidance on what constitutes adequate clinical evidence guides a lot of decisions. Peer-to-peer calls between doctors and insurers or prior authorization organizations are worthwhile for building understanding.

David Thomas is based in Australia, which has a different funding ecosystem from that in the U.S. Providing all cancer patients with genomic screening and targeted treatment requires that the process and delivery is affordable and sustainable in the long term. Systems don't like uncertainty, and while research is needed to develop changes, it has to be thought of in the context of increasing health care costs. One huge change over the past 30 years has been a patient's chance of response in a phase 1 trial, which has risen from 5% to 31%. We need to rethink how clinical trials fit into the treatment landscape and increase access to them. Finally, health should be considered wealth, not a cost to society.

A participant asked what social determinants of health affected patient outcomes in the MATCH trial? O'Dwyer noted that it was an area of great interest, as it is well known that environmental effects determine standard of care outcomes, such as from chemotherapy, in ways that are independent of race, age, etc. So how does genomics come into play? Teasing out economic or environmental circumstances of patients is a goal, but there are a lot of challenges involved. The U.K. biobank is a phenomenal resource in this regard, with 500,000 individuals with genomic testing of germline DNA, plus data on diet, income and clinical histories. We should be aiming for this type of analysis, but we're not there yet in the U.S.

Rueter summarized the messages and the conclusions from the Forum. Simply put, communication and collaboration are key. The community needs to work together to implement new efforts, continue to design and implement pragmatic clinical trials, learn from outcomes, and keep redesigning things to improve targeted therapy. The advances need to be brought to the community, not just to academic medical centers. There should be a shorter dissemination gap for new and emerging treatments and diagnoses, and evidence-based treatments provided for patients that cannot participate in clinical trials. Decision support tools like tumor boards will remain very important for improving outcomes and impacting patient care, and there must be ongoing efforts to educate physicians and patients. The key components are all interlinked, from screening to diagnosis to somatic mutation analysis to clinical delivery.

Certified Continuing Education

Maine Cancer Genomics Initiative (MCGI)

The 2022 MCGI Forum will provide educational content in a live and synchronous broadcast during sessions on Friday, April 1 and Saturday, April 2.

Some content from the live dates will be available in enduring format through the end of April.

These sessions will focus on several facets of precision oncology: navigating the patient journey, myeloid malignancies, new technologies and clinical trials.

Sessions will feature a series of presentations by leaders in the field and live interactive panel discussions with Forum attendees.

Overview

While somatic cancer panel tests are available to oncologists, many questions remain on how to best integrate them into clinical practice. Among these questions are when to incorporate genomic testing during the course of a patient's care to achieve maximum benefit and whether repeated testing can serve to track cancer evolution and refine treatment regimens. Addressing these questions ultimately depends on clinicians' ability to understand the genomic information provided in test reports and to efficiently extract and evaluate actionable results. The Maine Cancer Genomics Initiative (MCGI) aims to overcome these barriers. The 2022 MCGI Forum provides an educational opportunity for Maine oncology clinicians with the objectives outlined below.

Learning Objectives

After attendance participants should be able to:

1. Recognize the application of precision oncology programs, clinical trials and new diagnostic and therapeutic technologies in patient care.
2. Identify advantages and limitations of new diagnostic technologies and emerging therapeutic approaches and their impacts on patient outcomes.
3. Recognize the direction of precision oncology and future advancements in patient-centered care.

Target Audience: Physicians

These sessions will offer up to 12.75 AMA PRA Category 1 Credits™ for live attendance and 11.5 AMA PRA Category 1 Credits™ for asynchronous attendance.

CME is intended for physician attendees, primarily Maine clinicians practicing oncology and involved in cancer patient care and/or cancer research.

Claiming CME Credit

In order to claim CME credit, in person attendees must sign in on-site each day at the event check in desk. Attendees must log on to the enduring content platform using the name and contact information they want on their CME certificate. All attendees, both in person and virtual, must complete the event evaluation online. Attendees can access the online content through Friday April 29, 2022. A CME documentation certificate is provided to participants via email after the electronic evaluation results are received.

AMA Designation Statement: The Maine Medical Education Trust designates this live activity for a maximum of 12.75 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

CCMEA Accreditation Statement: Maine Medical Education Trust is accredited by the Maine Medical Association's Committee on Continuing Medical Education and Accreditation to provide continuing medical education (CME) to practicing physicians.

MMET Joint-Provider Statement: This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the Maine Medical Education Trust and The Jackson Laboratory. The Maine Medical Education Trust is accredited by the Maine Medical Association Committee on Continuing Medical Education and Accreditation to provide continuing medical education for physicians.

Genetic Counselor CEUs

The National Society of Genetic Counselors (NSGC) has authorized The Jackson Laboratory to offer up to 0.995 Category 1 contact hours (0.995 credits) for the activity Maine Cancer Genomics Initiative Annual Forum 2022. The American Board of Genetic Counseling (ABGC) will accept CEUs earned at this program for the purposes of genetic counselor certification and recertification.

Genetic Counselors can earn up to 0.995 Category 1 contact hours (0.995 credits) for this event. Please see the agenda to review which presentations carry Genetic Counselor CEUs. Attendees are not required to complete all sessions to earn CEUs and may earn partial credit by choosing to attend/view only some sessions. CEUs will be awarded for those sessions that are completed in full, including the module quiz and evaluation.

Claiming CGC CEU Credit

In order to claim CCG CEUs, in person attendees must sign in on-site each day at the event check in desk. Attendees must log on to the enduring content platform using the name and contact information they want on their CEU certificate. All attendees, both in person and virtual, must complete the event evaluation online. Attendees can access the online content through Friday April 29, 2022.

Nursing Contact Hours

Nursing Continuous Professional Development

This activity is designed to meet the educational needs of registered nurses (RNs), RNs in Oncology, and clinical research associates. Nurses are eligible for a maximum of 10 contact hours upon the completion of this activity. Please see the agenda to review which presentations carry nursing continuing professional development. You are not required to complete all sessions to earn nursing continuous professional development and you may earn partial credit. You may choose to attend/view only some sessions. You will only be awarded nursing continuous professional development for those sessions for which you complete the event evaluation in full.

Learning Outcomes

After participation in this training, the nurse will be able to:

1. Recognize the application of precision oncology programs, clinical trials and new diagnostic and therapeutic technologies in patient care.
2. Identify advantages and limitations of new diagnostic technologies and emerging therapeutic approaches and their impacts on patient outcomes.
3. Recognize the direction of precision oncology and future advancements in patient-centered care.

Claiming Nursing Continuous Professional Development

In order to claim credit, in person attendees must attend at least one session of the multi-session activity, and sign in on-site each day at the event check in desk. All attendees must log on to the enduring content platform using the name and contact information they want on their CME certificate and complete the event evaluation online. Attendees can access the online content through Friday April 29, 2022.

Approval Statement: This nursing continuing professional development activity was approved by the Northeast Multi-state Division (NE-MSD)Educational Unit, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation. The Maine, New Hampshire, New York, Rhode Island, and Vermont Nurses Associations are members of the Northeast Multi-State Division Education Unit of the American Nurses Association.

To claim nursing continuing professional development please go to https://thejacksonlaboratory.qualtrics.com/jfe/form/SV_8j45jsV0Q5yA5b8 to complete the evaluation survey.

Alternatively, scan the QR code below to be taken to the continuing education survey.

Certified Continuing Education

Conflicts of Interest (COI)

Planning Committee, presenters, faculty, authors, and content reviewers have disclosed conflicts of interest where they exist. Detailed information and the mechanisms by which COI is addressed can be found on the 2022 MCGI Forum website.

MCGI Forum Support

There is no commercial support for the MCGI Forum or its educational activities. The Maine Cancer Genomics Initiative is a program of The Jackson Laboratory (JAX) funded through a generous grant by the Harold Alfond® Foundation.

The Jackson Laboratory is an independent, nonprofit biomedical research institution with over 3,000 employees. Headquartered in Bar Harbor, Maine, it has a National Cancer Institute-designated Cancer Center, a genomic medicine institute in Farmington, Conn., and facilities in Ellsworth and Augusta, Maine, in Sacramento, Calif., and in Beijing and Shanghai, China. Its mission is to discover precise genomic solutions for disease and empower the global biomedical community in the shared quest to improve human health.

Founded in 1950, Harold Alfond® Foundation furthers the philanthropic legacy of Harold Alfond, the founder of Dexter Shoe Company and a longtime supporter of Maine communities in which he and his family worked and resided. Harold Alfond awarded matching challenge grants to organizations to build community partnerships and to inspire and leverage additional giving by others.

He ensured his philanthropy would live on by committing nearly all of his wealth to the foundation, which continues to support charitable causes in the State of Maine.

Americans with Disabilities Act (ADA)

Services for the disabled: If special arrangements are required for an individual with a disability to attend this course, please contact JAX's Jennifer Bourne at (207) 288-6113 or jennifer.bourne@jax.org.

For more information, please contact us at mcgi@jax.org.

Clinical Steering Committee Bios

Philip L. Brooks
M.D.

Brooks practices at Northern Light Cancer Care and oversees their clinics at the Mt. Desert Island Hospital and the Maine Coast Memorial Hospital. He is board certified in internal medicine, hematology and medical oncology caring for patients in all areas of medical oncology, hematologic oncology and benign hematology. He received his M.D. from the University of Pennsylvania School of Medicine before completing his medical residency at the University of Pennsylvania-Presbyterian Medical Center. He completed a three-year fellowship in hematology/oncology at Dartmouth-Hitchcock Medical Center. Brooks spent time in China as Senior Vice President of Medical Affairs and Chief of Oncology Development for United Family Healthcare.

Catherine Chodkiewicz
M.D.

Chodkiewicz practices oncology at Northern Light Cancer Care. Her experience includes work in the development of clinical protocols, and she has served as the PI on a number of clinical trials sponsored by major academic centers and pharmaceutical companies. Chodkiewicz completed her medical school training as well as an internship and residency at Bobigny School of Medicine, University of Paris XIII followed by an internal medicine residency at Graduate Hospital, University of Pennsylvania and a clinical fellowship in medical oncology and hematology with Kaplan Comprehensive Cancer Center at New York Medical Center.

Robert Christman
M.D.

Christman is the Maine Medical Center (MMC) Pathology Department Chief and Medical Director of MMC Hematology, NorDx Flow Cytometry and Molecular Pathology Laboratories. He holds board certification from the American Board of Pathology in anatomic pathology, clinical pathology and hematology. Christman received his M.D. from Temple University School of Medicine, where he also served his residency and held a fellowship position.

Nicholette Erickson
M.D.

Erickson practices at Hematology-Oncology Associates in Lewiston, Maine. She is board certified in hematology and medical oncology. She received her M.D. from Medical College of Virginia followed by a residency in internal medicine and a fellowship with the University of Virginia Health Sciences Center in hematology-oncology.

Peter Georges
M.D.

Georges practices oncology at York Hospital in Southern Maine. He holds board certification in internal medicine, hematology and medical oncology. Georges received his M.D. from Georges University School of Medicine in Grenada, West Indies followed by an internship and residency at University of Massachusetts. He completed his fellowship in hematology/oncology at M.D. Anderson Cooper Cancer Center, Cooper Medical School of Rowan University.

Ridhi Gupta
M.D.

Gupta is a medical oncologist and hematologist of joined MaineGeneral Medical Center in July 2018 after completing her Blood and Marrow Transplant fellowship at Stanford University in Palo Alto, Calif. Prior to that she trained in Hematology and Medical Oncology at the Medical University of South Carolina, Charleston. Her research interests include the role of immunotherapy in solid and blood cancers as well as the role of bone marrow transplant and cellular therapy in the treatment of blood cancers. She has presented her research at many national meetings.

Roger C. Inhorn
M.D., Ph.D.

Inhorn is the Associate Medical Director of Coastal Healthcare Alliance Oncology. A native Madisonian, he studied mathematics and molecular biology at the University of Wisconsin. He is a graduate of the M.D./Ph.D. program at Washington University Medical School. He completed his internal medicine residency at Brigham and Women's Hospital followed by a medical oncology fellowship at the Dana-Farber Cancer Institute. Inhorn practiced in St. Louis for seven years, where he was associate director of hematology/oncology at St. John's Mercy Medical Center, prior to relocating to Maine. He has a long history of caring for Maine's cancer patients having served as the Chief of Oncology at Mercy Hospital for over a decade and as Medical Director at Maine Medical Partners prior to joining Coastal Healthcare Alliance. He has a special interest in breast cancer and GI oncology.

Rachit Kumar
M.D.

Kumar is a medical oncologist and hematologist who sees patients at the Harold Alfond Center for Cancer Care and the Alfond Center for Health in Augusta, Maine. A member of MaineGeneral Medical Center's active staff, he joined the cancer staff in July 2017 after completing a hematology/oncology fellowship at Georgetown University/MedStar Washington Hospital Center in Washington, D.C. He received his medical degree from Maulana Azad Medical College, New Delhi, India and then did his internal medicine residency and chief residency at Georgetown University/MedStar Washington Hospital Center. Kumar's interests include targeted therapies and immunotherapy.

Christine Lu-Emerson
M.D.

Lu-Emerson is a board-certified neuro-oncologist at Maine Medical Center. Her experience includes the developing and conducting phase 2/3 trials for brain tumor patients, with current research focus on the mortality and morbidity associated with brain tumors and associated treatments. She has also been involved in investigator-initiated studies including the study of neurocognitive decline in glioma patients. Lu-Emerson received her M.D. from New York University School of Medicine, followed by a residency at University of Washington in Seattle and a Fellowship in the Neurooncology program at Massachusetts General Hospital/Dana-Farber Cancer Institute/Brigham and Women's Hospital in Boston, Mass.

Clinical Steering Committee Bios

Mayur K. Movalia
M.D.

Movalia is a pathologist with Dahl-Chase Pathology Associates in Bangor, Maine. He holds board certifications from the American Board of Pathology in anatomic and clinical pathology and hematopathology. He received his M.D. from Flinders University School of Medicine followed by an internship in internal medicine and a pathology residency at University of Hawaii, as well as a hematopathology fellowship at Hartford Hospital.

Karen Rasmussen
Ph.D., FACMG

Rasmussen is Director of Molecular Genetics at Spectrum Medical Group. She has extensive experience in clinical molecular genetics: development and interpretation of molecular genetic assays, including next-generation sequencing and gene expression profiling. Rasmussen has provided cancer genetic counseling in the community oncology setting. She also has experience in tumor tissue banking for research and has worked in cancer molecular genetic research, primarily identifying mutational or gene expression profiles of tumors for prognosis or prediction of response to therapy. Rasmussen received her Ph.D. from University of New Hampshire followed by a fellowship in clinical molecular genetics at the University of North Carolina School of Medicine.

Scot Remick
M.D.

Remick is Chief of Oncology at Maine Medical Center and the MaineHealth Cancer Care Network, where he specializes in internal medicine and oncology. He is board certified in internal medicine with a sub-specialty of oncology. Remick received his M.D. from New York Medical College followed by a residency at Johns Hopkins Hospital, and fellowship at University of Wisconsin. In August 2019, Drs. Remick, Leslie Bradford, and Peter Rubin were awarded a six-year, $5.1M grant from NCI to join the NCI Community Oncology Research Program (NCORP) network, further extending NCI research opportunities across the entire cancer care continuum to patients and providers in Maine.

Peter Rubin
M.D.

Rubin practices oncology at SMHC Cancer Care Center and serves as Medical Director. He is board certified in hematology and medical oncology. Rubin received his M.D. from University of Calgary followed by residencies at University of Calgary, University of Western Ontario and University of Western Ontario-Schulich School of Medicine & Dentistry. He also held a fellowship at Duke University Medical Center.

Sarah Sinclair
D.O.

Sinclair is the Director of the Clinical Research program and a hematologist/oncologist at Northern Light Cancer Care. She is board certified in Hematology and Oncology. Her interests include breast cancer, clinical research and genomic medicine. Sinclair received her D.O. from University of New England College of Osteopathic Medicine followed by a residency at University of Connecticut School of Medicine in internal medicine, and a fellowship with the National Cancer Institute in hematology/oncology.

Marek Skacel
M.D.

Skacel is a Pathologist at Dahl-Chase Pathology Associates in Bangor, Maine. He holds board certifications from the American Board of Pathology in anatomic and clinical pathology and hematopathology. He takes a special interest in the areas of gastrointestinal pathology, genitourinary pathology, soft tissue pathology, hematopathology and molecular pathology. Skacel received his M.D. followed by an internship at Palacky University in Olomouc, Czech Republic. Subsequently he completed residency in anatomic and clinical pathology at The Cleveland Clinic Foundation followed by fellowships in gastrointestinal, genitourinary & soft tissue pathology, molecular pathology research, hematopathology and surgical pathology.

Vatche Tchekmedyian
M.D.

Tchekmedyian is a medical oncologist at MaineHealth Cancer Care. He studied anthropology at New York University before pursuing his medical education at the David Geffen School of Medicine at UCLA. He completed internal medicine residency and chief residency at Brigham and Women's Hospital in Boston, Mass. He then pursued oncology fellowship training at Memorial Sloan Kettering Cancer Center in New York City where he received subspecialty training in malignancies of the head and neck. In 2019, he was awarded an ASCO Young Investigator Award supporting a clinical trial in thyroid cancer. Tchekmedyian has an interest in molecularly targeted therapies, clinical research, education and thoracic/head and neck cancers.

Christian Thomas
M.D., FASCO

Thomas joined New England Cancer Specialists as a physician and the Director of Clinical Research in 2012. His clinical focus is on thoracic cancers (lung cancer, esophageal cancer) as well as GU cancers (prostate, testicular, bladder and kidney cancers). He also serves as an advisor to the American Society of Clinical Oncology, the Northern New England Clinical Oncology Society and CMS/Medicare. Thomas completed his medical school training in Frankfurt, Germany and an internal medicine residency and hematology/ oncology fellowship at Columbia University in New York City.

Forum Attendees

THANK YOU FOR ATTENDING!

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