BUILDING BRIDGES *through* GENOMIC MEDICINE

EVENT SUMMARY

March 26–27, 2021
Hosted virtually via
The Jackson Laboratory
Courses and Conferences platform

Maine Cancer Genomics Initiative (MCGI) Forum

PRESENTED BY THE JACKSON LABORATORY
WITH THE SUPPORT OF THE HAROLD ALFOND® FOUNDATION

Building Bridges *through* Genomic Medicine

MAINE CANCER GENOMICS INITIATIVE (MCGI) FORUM

MARCH 26–27, 2021

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The Jackson Laboratory

Leading the search for tomorrow's cures

Welcome to the fourth 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 more than 90% 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.

At the end of September 2020, MCGI completed its first study protocol, which focused on the experiences of patients and clinicians in the integration of genomic panel tumor testing into the cancer care journey. A total of 1,637 patients were enrolled and results for more than a fourth of those patients were reviewed in MCGI Genomic Tumor Boards. The number of patients referred to clinical trials, or for whom drug access was secured, has substantially increased as well.

As MCGI moves into its second phase, we will focus on making precision oncology even more actionable for cancer patients, focusing on treatment options and new digital technologies. We will continue to implement MCGI on a 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. This next phase of MCGI aims to increase oncology genomic tumor testing accessibility, interpretability and actionability. Accessibility will be supported by both accepting patients into the study who have had a genomic oncology panel test from any clinical testing provider, as well as offering subsidized testing via The Jackson Laboratory ActionSeq Plus™ 2.0 panel for eligible participants. 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 becoming 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 are pleased to have hosted an exciting virtual Forum and look forward to the continued growth of MCGI in Northern New England.

The Maine Cancer Genomics Initiative

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 observational 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 participants, testing costs will be subsidized for analyses performed in the 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.

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 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.

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
207-288-6000


The Jackson Laboratory

JAX ActionSeq™ Plus 2.0 Assay

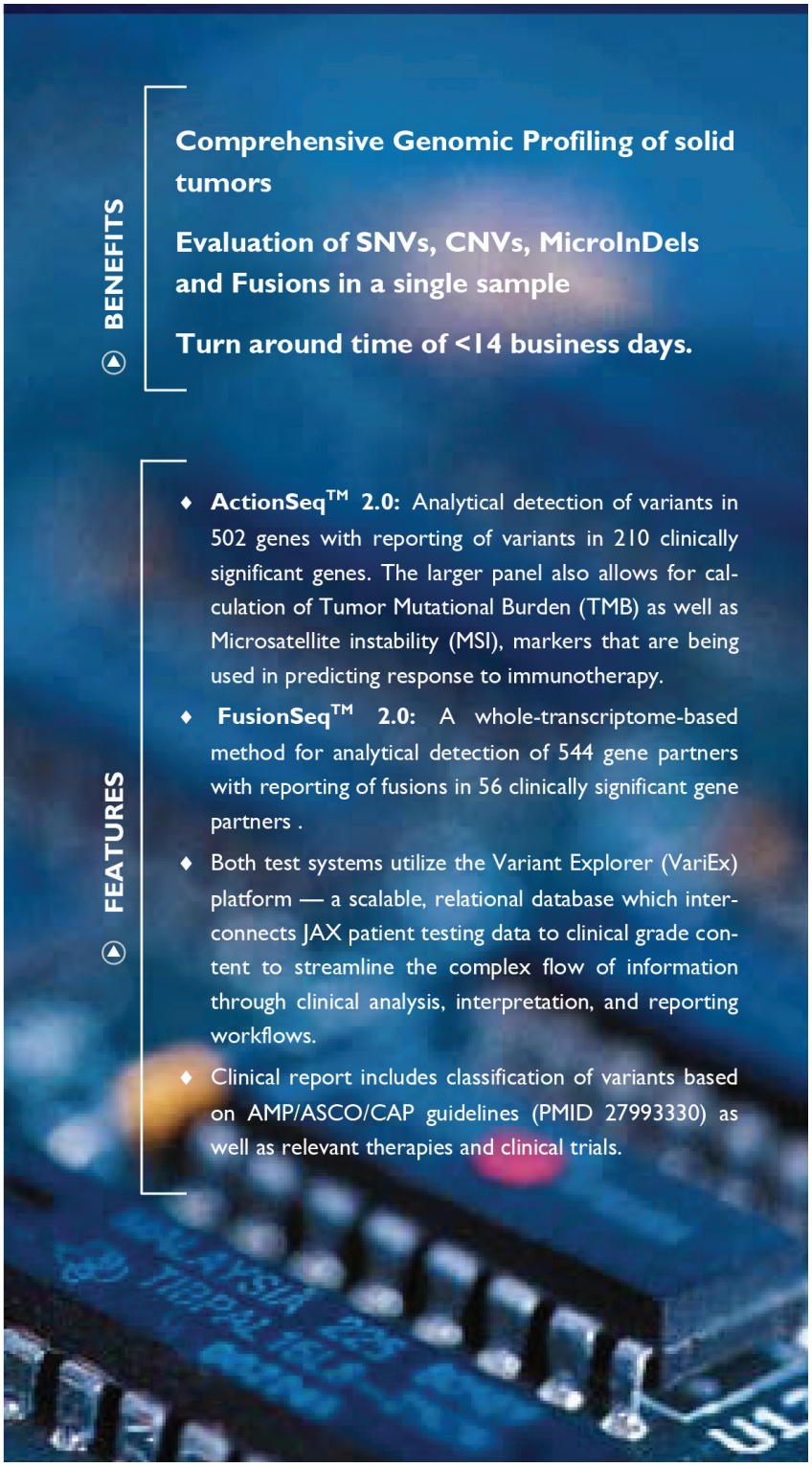
MOLECULAR PROFILING

Profiling of Tumors

Molecular profiling of tumors is performed to identify mutations that accumulate in cancer cells, in particular driver mutations that can serve as treatment targets. Mutations identified in tumors usually include single nucleotide variants (SNVs), deletions and duplications. Fusion genes were originally associated with hematologic cancers; however, more than 300 gene fusions have been identified in almost every kind of solid tumor (sarcomas, carcinomas and tumors of the central nervous system). Identifying and characterizing the mutations in tumors therefore can have both diagnostic and therapeutic applications. The advent of Next-Generation sequencing has enabled high-throughput, low cost, accurate molecular profiling across many tumor types.

JAX ACTIONSEQ™ PLUS

The JAX ActionSeq™ Plus 2.0 test reports on 210 cancer related genes and 56 genes known to form fusions associated with solid tumors; analyzed using next-generation sequencing. The larger DNA panel of 501 genes allows for calculation of TMB and MSI, markers that are being used currently in predicting response to immunotherapy. All identified variants are assessed for clinical relevance, based on associations in the biomedical literature with response or resistance to FDA-approved targeted therapies. Evidence of association between genomic variants and potential response to therapy or availability of clinical trials is curated from the peer-reviewed literature, publically available databases, and The Jackson Laboratory Clinical Knowledgebase (CKB).



BENEFITS

Comprehensive Genomic Profiling of solid tumors

Evaluation of SNVs, CNVs, MicroInDels and Fusions in a single sample

Turn around time of <14 business days.

FEATURES

- **ActionSeq™ 2.0:** Analytical detection of variants in 502 genes with reporting of variants in 210 clinically significant genes. The larger panel also allows for calculation of Tumor Mutational Burden (TMB) as well as Microsatellite instability (MSI), markers that are being used in predicting response to immunotherapy.
- **FusionSeq™ 2.0:** A whole-transcriptome-based method for analytical detection of 544 gene partners with reporting of fusions in 56 clinically significant gene partners .
- Both test systems utilize the Variant Explorer (VariEx) platform — a scalable, relational database which interconnects JAX patient testing data to clinical grade content to streamline the complex flow of information through clinical analysis, interpretation, and reporting workflows.
- Clinical report includes classification of variants based on AMP/ASCO/CAP guidelines (PMID 27993330) as well as relevant therapies and clinical trials.

JAX-ACTIONSEQ™ 2.0

210 Genes Reported (SNPs, CNVs and microInDels)

ABL1, ABL2, AKT1, AKT2, AKT3, ALK, APC, AR, ARAF, ARID1A, ARID1B, ARID2, ATM, ATR, ATRX, AURKA, AURKB, AURKC, AXIN1, AXL, BAP1, BARD1, BCL2, BIRC2, BIRC3, BIRC5, BLM, BRAF, BRCA1, BRCA2, BRD4, BRIP1, CBL, CCND1, CCND2, CCND3, CCNE1, CD274, CDH1, CDK12, CDK4, CDK6, CDK8, CDKN1A, CDKN1B, CDKN2A, CDKN2C, CHEK1, CHEK2, CREBBP, CRKL, CRTC1, CRTC2, CSF1R, CTNNB1, DDR2, EGFR, EP300, EPHA2, EPHB4, ERBB2, ERBB3, ERBB4, ERCC2, ERCC3, ESR1, EZH2, FAM175A, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCL, FANCM, FBXW7, FGF19, FGF3, FGFR1, FGFR2, FGFR3, FGFR4, FH, FLCN, FLT1, FLT3, FLT4, GEN1, GLI1, GLI2, GLI3, GNA11, GNAQ, GNAS, HDAC2, HGF, HRAS, ID1, IDH1, IDH2, IGF1R, IRS2, JAK1, JAK2, JAK3, JUN, KDM4C, KDM6A, KDR, KEAP1, KIT, KRAS, LMO1, LRP1B, MAP2K1, MAP2K2, MAPK1, MCL1, MDM2, MDM4, MEN1, MET, MLH1, MLH3, MLL2, MLL3, MRE11, MRE11A, MSH2, MSH3, MSH6, MST1R, MTOR, MUTYH, MYC, MYCL, MYCL1, MYCN, NBN, NCOA3, NF1, NF2, NFE2L2, NOTCH1, NOTCH2, NOTCH3, NRAS, NTRK1, NTRK2, NTRK3, PAK1, PALB2, PBRM1, PDGFA, PDGFRA, PDGFRB, PDPK1, PIK3CA, PIK3CB, PIK3CD, PIK3CG, PIK3R1, PIK3R2, PIM1, PMS1, PMS2, POLB, PPM1D, PRDM1, PTCH1, PTEN, PTPN11, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD52, RAD54L, RB1, RET, RHEB, RICTOR, RNF43, ROS1, RPA1, SDH, SLX4, SMAD4, SMARB1, SMARC1, SMARCA4, SMARCB1, SMO, SRC, STAT3, STAT5A, STAT5B, STK11, SYK, TGFBR2, TNK2, TP53, TSC1, TSC2, VHL, WRN, XRCC2, XRCC3, YAP1, YES1

JAX FUSIONSEQ™ 2.0

56 Genes Reported (Fusions)

ABL1, ALK, ATF1, AXL, BCL2, BCL6, BCR, BRAF, BRCA1, BRCA2, CBFB, CD74, CRAF, EGFR, EIF3E, ELM4, EML4, ERG, ESR1, ETV4, EWSR1, FGFR1, FGFR2, FGFR3, FGFR4, FIP1L1, FLI1, HER2, KMT2A, MAST1, MET, MYC, MYH11, NFKB2, NOTCH1, NRG1, NTRK1, NTRK2, NTRK3, PAX8, PDGFRA, PDGFRB, PML, PPARG, PRSPO3, PTPRK, QKI, RAF1, RARA, RET, ROS1, RSPO2, RSPO3, RUNX1, TERT, TMPRSS2

ASSAY SPECIFICATIONS

Specimen Requirements

- Formalin-fixed, paraffin-embedded (FFPE) material only (includes pleural effusions and small core biopsies).
- One representative hematoxylin and eosin (H&E) stained slide and 10 adjacent unstained 5 um sections on uncoated, unbaked slides. We also accept tumor blocks.
- Any solid tumor, primary or metastatic tissue with ≥30% neoplastic content. The area of highest tumor cell content should be a minimum of 3 x 3 mm.

ASSAY DETAILS

Assay	Nucleic Acid	Input	Mean Target Coverage	Variants identified
ActionSeq™ 2.0	DNA	50ng	≥500x	SNVs, CNVs microInDels
FusionSeq™ 2.0	RNA	50ng	N/A	Fusions

Specimen Requirements

ActionSeq™ 2.0 Plus with PD-L1

If the patient received targeted therapy, post-therapy specimen should be used, if available.
Use the most recent specimen if available.

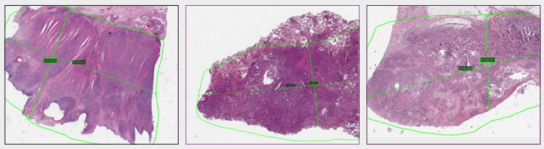
Sample Size:

- 13 unstained slides (positively charged and unbaked at 5 microns) and 1 original H&E slide (not recut) — Preferred
- 1 block and 1 original H&E (not recut)

Sample Area Size:

Optimal is 25mm² Minimal 9mm²
Smaller samples will require additional material to extract for DNA and RNA

Neoplastic Content Percentage: 30% minimum



Area of tumor cell content should be a minimum of 3x3mm or 5,000 cells and be comprised of at least 30% cancer cells.

Acceptable Specimens:

Free specimens including needle core biopsies, FNAs, effusion materials
Unacceptable FFPE specimens include specimens fixed/processed in alternative fixatives (e.g., alcohol or heavy metal fixatives), decalcified specimens, and frozen specimens.

Shipping Instructions:

All specimens should be shipped priority overnight in appropriate packaging container per relevant shipping conditions and comply with relevant shipping criteria (e.g., DOT and/or IATA). Shipments should be planned so that they arrive to JAX Monday-Friday only.

Please label all specimens with at least two identifiers corresponding to the patient or specimen information and ensure that the completed requisition form is included in the shipment.

Any specimens not meeting the above criteria will be processed at the discretion of the Clinical Laboratory Director. All samples are subject to additional downstream QC requirements. Please contact the laboratory for additional questions regarding acceptable specimens.

https://www.jax.org/clincial-genomics

Shipping Address

Clinical Genomics Laboratory
The Jackson Laboratory for Genomic Medicine
10 Discovery Drive
Farmington, CT 06032

Contact JAX

Phone # 860-837-2320
Fax # 860-837-2380
Email: CGL_CS@jax.org

Please use this email for service related questions only. Due to the sensitive nature of PHI do not submit the requisition via email.

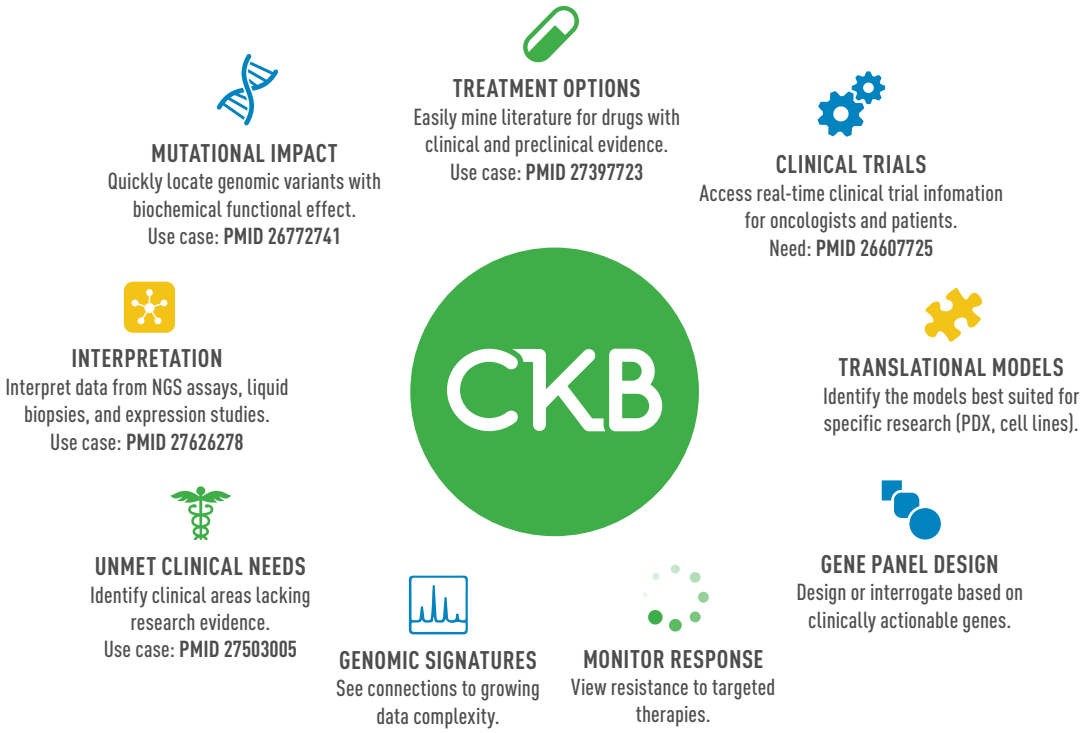
Clinical Knowledgebase (CKB)

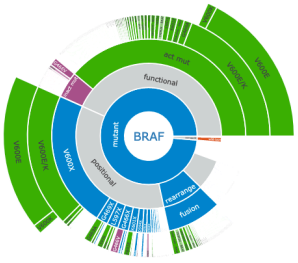
A platform for the sharing of highly curated cancer genomic knowledge to foster translational and clinical advancements

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.

Genomic Testing Nomenclature

Genomic test results using DNA extracted from tumor tissue frequently demonstrate a complex molecular signature that is different from that of normal tissue for any given patient. Test results provide a synopsis of the genomic variants that have been identified and categorized by potential actionability with regard to treatment options.

This resource provides some explanation of commonly used terminology included in test reports.

Types of genomic alterations/changes reported

Somatic or acquired variants arise in cancers and alter the normal sequence pattern of DNA. They occur when cells are damaged during replication, by viruses, or by exposure to carcinogens, such as tobacco smoke or radiation.

TABLE 1. TYPES OF GENOMIC VARIANTS/ALTERATIONS

ALTERATION	TYPE OF VARIANT	DESCRIPTION	EXAMPLE
POINT MUTATION	Single nucleotide variant (SNV) or nucleotide change	Substitution, deletion, duplication, insertion, or a combination	BRAF V600E (substitution)
AMPLIFICATION	Copy number variant (CNV)	Change in the number of copies of a cancer-related gene	ERBB2 Amplification
FUSION	Structural rearrangement	May include chromosome translocations, deletions, duplication, or inversions	EML4-ALK recurrent inversion mutation in non-small cell lung cancer

For more information

Sequence Variant Nomenclature: recommendations for the description of sequence variants. Nomenclature authorized by Human Genome Variation Society (HGVS), Human Variome Project (HVP), and the HUman Genome Organization (HUGO). (http://varnomen.hgvs.org/)

Types of Molecular Tumor Testing: description of different types of genomic variants/alterations and testing methodology. (https://www.mycancergenome.org/content/page/molecular-testing/)

Reporting the impact of genomic variants

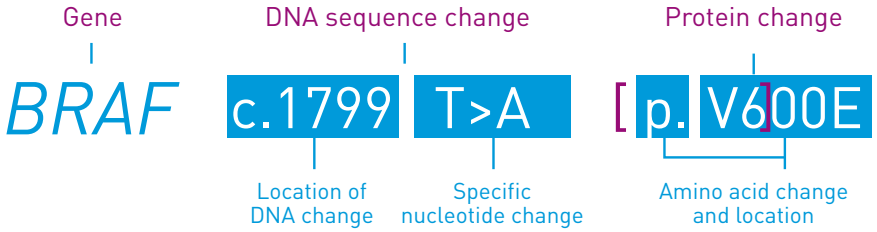
Variants may or may not have an impact on the function of the gene. Genomic variations that do impact function may be activating, resulting in a gain of function of the protein, or inactivating, resulting in a loss of function.[1] The significance of the change depends on the location of the variant, the type of genetic aberration, and the normal function of the protein.

Genomic variants are classified into three general categories:

- **Benign or likely benign:** variants do not have any functional consequences and are often seen commonly in the general population. You may also see these referred to as "polymorphisms."
- **Pathogenic or likely pathogenic:** variants impact the function of the gene in some way. Most accurately, these are referred to as "variants that impact function." More commonly, these may be referred to as "mutations."
- **Variants of unknown significance or VUS** are changes in the gene for which the impact is unknown. This may be because they are rare and there is not enough data available to be conclusive about their functional impact. Over time, VUS are likely to be re-classified as benign or pathogenic as more data are amassed.

Genomic Marker Notations and Abbreviations

The combination of numbers and letters provides a variant's location, type of aberration and protein change.



"c." prefix denotes standard variant nomenclature based on coding DNA reference sequences
"p." prefix denotes standard variant nomenclature based on protein-level amino acid sequences

References

1. Li MM, Datto M, Duncavage EJ, Kulkarni S, Lindeman NI, Roy S, et al. Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer: A Joint Consensus Recommendation of the Association for Molecular Pathology, American Society of Clinical Oncology, and College of American Pathologists. J Mol Diagn. 2017;19(1):4-23.

Updated 2/5/2020

Agenda

Friday, March 26, 2021

12:30 PM–1:15 PM **Welcome Remarks and MCGI Program Update** **0.75 CME, 0.75 CNE, 0.75 CGC CEU**
Jens Rueter, M.D. | Medical Director, MCGI | The Jackson Laboratory

Leah Graham, Ph.D. | Associate Director, MCGI | The Jackson Laboratory

1:15 PM–1:45 PM **MCGI Q&A** **0.25 CME, 0.25 CNE, 0.25 CGC CEU**
Jens Rueter, M.D. | Medical Director, MCGI | The Jackson Laboratory

Leah Graham, Ph.D. | Associate Director, MCGI | The Jackson Laboratory

Session 1: Impact of Precision Oncology on Patient Outcomes 1.5 CME, 1.5 CNE, 1.42 CGC CEU

2:40 PM **Session 1: Introductory Remarks***
Jens Rueter, M.D. | Medical Director, MCGI | The Jackson Laboratory

2:45 PM–3:15 PM **Checkpoint Blockade Therapy: Focusing on Combinations to Improve Outcomes***
Jedd Wolchok, M.D., Ph.D., F.A.S.C.O. | Chief of Immuno-Oncology Service
Memorial Sloan Kettering Cancer Center

3:15 PM–3:40 PM **BRCA 1/2 and Beyond: Risk Prediction to Targeted Therapies***
Susan Domchek, M.D. | Executive Director, Basser Center for BRCA | Penn Medicine

4:00 PM–4:30 PM **Panel Discussion: Impact of Precision Oncology on Patient Outcomes***
Moderator: Jens Rueter, M.D. | Medical Director, MCGI | The Jackson Laboratory

Session 2: Precision Oncology Programs and Clinical Trials 2.0 CME, 2.0 CNE, 1.92 CGC CEU

4:40 PM **Session 2: Introductory Remarks***
Jens Rueter, M.D. | Medical Director, MCGI | The Jackson Laboratory

4:45 PM–5:15 PM **Precision Oncology at Moffitt Cancer Center***
Christine Walko, Pharm.D., F.C.C.P., B.C.O.P. | Associate Member | Moffitt Cancer Center

5:15 PM–5:42 PM **Precision Health: Implementation, Value, and Scope***
Lincoln Nadauld, M.D., Ph.D. | Vice President, Chief of Precision Health and Academics
Intermountain Healthcare

5:45 PM–6:15 PM **The TAPUR Study: Learning From Precision Medicine in Practice***
Richard Schilsky, M.D., Ph.D., F.A.C.P., F.S.C.T., F.A.S.C.O. | Senior VP and Chief Medical Officer
American Society of Clinical Oncology

6:30 PM–7:00 PM **Panel Discussion: Precision Oncology Programs and Clinical Trials**
Moderator: Jens Rueter, M.D. | Medical Director, MCGI | The Jackson Laboratory

Saturday, March 27, 2021

Session 3: Precision Oncology in Pediatrics 1.5 CME, 1.25 CNE, 1.17 CGC CEU

7:55 AM **Session 3: Introductory Remarks***
Jens Rueter, M.D. | Medical Director, MCGI | The Jackson Laboratory

8:00 AM–8:22 AM **Precision Therapeutics for Childhood Cancer: Successes and Challenges***
Steven Dubois, M.D., M.S. | Director, Experimental Therapeutics | Dana-Farber Cancer Institute

8:30 AM–8:48 AM **Using Molecular Diagnostics to Support Pediatric Cancer Patients***
Alanna Church, M.Sc., M.D., F.R.C.P.C. | Associate Director, LaMPP | Boston Children's Hospital

9:00 AM–9:30 AM **Panel Discussion: Precision Oncology in Pediatrics**
Moderator: Ching Lau, M.D., Ph.D. | Professor and Medical Director at Connecticut Children's Hospital
The Jackson Laboratory

Session 4: How to Test – Tissue-based vs. Liquid Biopsies 1.5 CME, 1.5 CNE, 1.35 CGC CEU

9:40 AM — **Session 4: Introductory Remarks***
Jens Rueter, M.D. | Medical Director, MCGI | The Jackson Laboratory

9:45 AM–10:12 AM — **Current and Future Clinical Applications of Liquid Biopsies***
Milan Radovich, Ph.D. | Associate Professor and Co-Director | IU Health Precision Genomics Program
Indiana University School of Medicine

10:15 AM–10:40 AM — **Precision Oncology Tumor Testing***
Nikoletta Sidiropoulos, M.D. | Associate Professor, Pathology and Laboratory Medicine
University of Vermont Medical Center

11:00 AM–11:30 AM — **Panel Discussion: How to Test – Tissue-based vs. Liquid Biopsies ***
Moderator: Emily Edelman, M.S., C.G.C. | Assistant Director, Clinical Education | The Jackson Laboratory

MCGI Community Discussions

12:00 PM–12:45 PM — **All discussions run concurrently and are intended for attendees who are active within the MCGI network**

Remote Study Activities and New EDC for MCGI 2.0
Petra Helbig, C.C.R.P. | Clinical Research Manager, MCGI | The Jackson Laboratory

Lory Guerrette, B.S. | Clinical Research Assistant, MCGI | The Jackson Laboratory

Genomic Tumor Boards
Melissa Rockwood, M.S. | Genomic Tumor Board Coordinator, MCGI | The Jackson Laboratory

Jennifer Bourne, M.S. | Program Manager, MCGI | The Jackson Laboratory

Navigating a Patient Through Precision Oncology
Erin Bradshaw | Chief of Mission Delivery | Patient Advocate Foundation

JAX Clinical Knowledgebase
Cara Statz, Ph.D. | Clinical Analyst, Clinical Analytics and Curation | The Jackson Laboratory

Sara Patterson, Ph.D. | Clinical Analyst, Clinical Analytics and Curation | The Jackson Laboratory

Genetic Counselors Connect 0.75 CGC CEU
Kunal Sanghavi, M.S., C.G.C. | Program Manager, Genetic Counseling | The Jackson Laboratory

Emily Edelman, M.S., C.G.C. | Assistant Director, Clinical Education | The Jackson Laboratory

MCGI 2.0 Needs – Community Listening Session
Kate Reed, M.P.H., Sc.M., C.G.C. | Director, Clinical Educatio | The Jackson Laboratory

Leah Graham, Ph.D. | Associate Director, MCGI | The Jackson Laboratory

Session 5: NeuroOncology 1.5 CME, 1.25 CNE, 1.25 CGC CEU

1:40 PM — **Session 5: Introductory Remarks***
Jens Rueter, M.D. | Medical Director, MCGI | The Jackson Laboratory

1:45 PM–2:10 PM — **Clinical Impact of Molecular Neuro-Oncology***
Floris Barthel, M.D. | Postdoctoral Associate | The Jackson Laboratory

2:15 PM–2:38 PM — **Brain Immunology and Immunotherapy in Brain Tumors***
David Ashley, M.B.B.S. (Hons.), F.R.A.C.P., Ph.D. | Neuro and Pediatric Oncologist | Duke Cancer Center

3:00 PM–3:30 PM — **Panel Discussion: NeuroOncology**
Moderator: Roel Verhaak, Ph.D. | Professor and Associate Director of Computational Biology
The Jackson Laboratory

* Presentation Recording Available on Canvas Learning Platform as Enduring Continuing Education Content Through April 18, 2021

Forum Presentation Summaries

MCGI Welcome Session

Following a hiatus in 2020 caused by the emergence of the COVID-19 pandemic, the Maine Cancer Genomics Initiative Forum convened once again, albeit virtually, on March 26, 2021. More than 300 oncologists, nurses, genetic counselors, researchers and others from across the U.S. and 22 other countries took part.

The Forum took place at a time of transition for MCGI, as its successful original five-year study protocol has concluded but an exciting new research project — MCGI 2.0 — is set to be rolled out. With funding again provided by the Alfond Foundation, MCGI 2.0 will expand the program to further benefit Maine cancer patients over the next five years. MCGI has also become a coordinating center for the national Target Agent and Profiling Utilization Registry (TAPUR™) Study and has enrolled its first patient.

The Forum began with a presentation by MCGI Associate Director Leah Graham, Ph.D., on the history of MCGI. Originally developed to create an end-to-end solution for community genomic cancer medicine throughout Maine, MCGI's clinician network now comprises 100% of Maine's oncologists and oncology practices across five health care systems and one private practice. The oncologists are provided with decision and treatment strategy support based on genomic test reports and contribute to MCGI's research findings. More than 1,600 patients were enrolled between July 2017 and December 2020, and more than 400 cases have been discussed by the genomic tumor boards convened by MCGI.

Medical Director Jens Reuter, M.D., expanded upon Graham's talk to discuss how MCGI has fared during the pandemic and its current status. Interestingly, converting to an entirely virtual format has increased both attendance at and the number of cases discussed by the genomic tumor boards. A majority of participating oncologists have presented at least one patient at a tumor board, and those patients are more likely to start on a genome-informed therapy than those not discussed. Over the past five years, MCGI has also gathered data indicating that physician "genomic confidence" has increased from initial baseline, and that today's patients have high expectations and positive attitudes towards genomic testing. MCGI has rich data sets available, including genomic data, test reports, treatment and survival data, sequence data, and more, that are already being used for multiple novel research projects.

MCGI 2.0 officially started on October 1, 2020, and the new protocol is at the Internal Review Board now. Dr. Reuter is hoping to start enrolling patients again soon, with expanded access to testing, enhanced genomic tumor boards, increased access to therapies and a more comprehensive genomic care model across the patient journey. The TAPUR™ trial, a basket trial of FDA-approved drugs in off-label indications, will also expand patient access to precision therapies. Moving forward, MCGI is enrolling enough patients to answer important questions still outstanding about genomic-based cancer care, such as what is the financial toxicity for patients? How well is physician-patient communication going? And, of greatest importance, what are the patient outcomes?

Session 1: Impact of Precision Oncology on Patient Outcomes

Jedd Wolchok, M.D., Ph.D., F.A.S.C.O. Chief of Immuno-Oncology Service, Memorial Sloan Kettering Cancer Center

Checkpoint Blockade Therapy: Focusing on Combinations to Improve Outcomes

Immune checkpoint blockade therapy emerged from James Allison's Nobel Prize-winning research into CTLA-4 inhibition. Clinically, the CTLA-4 inhibitor Ipilimumab has provided some profound successes, including long-term survival for some metastatic melanoma patients who previously would have had no options. But low response rates and sometimes severe immune toxicities have driven efforts to further improve immunotherapies, including the development of PD-1 inhibitors that target a different immune checkpoint pathway, based on Nobel Prize-winning science from Tasuku Honjo. Trials using combination strategies that inhibit both pathways — e.g., Ipilimumab

Day 1 Recap *March 26, 2021*

plus Nivolumab (a PD-1 blockade) — are showing higher response rates and better five-year survival rates than either therapy alone. High tumor mutational burden indicates a better probability of response to immunotherapies, but a better genomic understanding of why some patients remain non-responsive will be needed to further improve response rates. Also, tumor glycolysis has been shown as a barrier to anti-tumor immunity, so glycolysis inhibitors also have the potential to improve immunotherapy efficacy.

Susan Domchek, M.D. Executive Director, Basser Center for BRCA, Penn Medicine

BRCA 1/2 and Beyond: Risk Prediction to Targeted Therapies

Germline testing for BRCA 1/2 mutations has served as a prototype for individualized cancer care. Risks for BRCA carriers can be reduced with prophylactic surgery, but better targeted therapies remain essential. Recently, poly ADP ribose polymerase (PARP) inhibitors, which disrupt cells' ability to repair DNA, have been explored as treatments for cancers with DNA repair defects, including those with BRCA 1 and 2 mutations. Trials comparing the PARP inhibitor Olaparib versus standard chemotherapy for BRCA+ metastatic breast cancer showed that Olaparib improved progression-free survival and quality of life. Combination therapies including PARP inhibitors are also being assessed, though they have yet to receive FDA approval. Other BRCA 1/ 2 tumor types, including pancreatic and prostate cancer, also respond to PARP inhibitors, and multiple studies with Olaparib have indicated benefits for pancreatic cancer patients versus placebo and physician's choice treatments. Finally, investigations into other germline mutations have shown variability in response to PARP inhibition. For example, PALB2 mutation carriers benefited significantly, whereas CHEK2 carriers did not.

Panel Q&A

The panel discussion focused on issues related to biomarkers that might guide therapy. For example, whether PDL1 expression should be checked in melanoma before immunotherapy or homologous recombination deficiency for PARP inhibitor treatment. The panelists also discussed the potential for combining immunotherapy with PARP inhibition, future directions for the field and how these relatively new therapies can be better applied to cancer therapy.

Session 2: Precision oncology programs and TAPUR

Christine Walko, Pharm.D., F.C.C.P., B.C.O.P.
Associate Member, Department of Individualized Cancer Management, Moffitt Cancer Center

Targeting the tumor genome

We can now do the molecular profiling needed in cancer cells, and quite a few targeted drugs are available. The list of genome-guided therapies approved by the FDA is growing quickly, including multi-kinase and kinase family inhibitors. Mutation selective inhibitors are emerging now, and while still primarily investigational, they are more specific still, providing reduced off-target toxicity and increased target selectivity. With more precision, however, comes smaller patient populations, and clinical trials have needed to evolve. Early in the process, the SHIVA trial, a randomized, controlled phase 2 trial conducted at sites in France, showed no change in median progression free survival between targeted and control therapies. The lessons learned from the trial — ensuring the genetic alteration a true predictive biomarker, learning which combinations may impede therapy efficacy and so on — are being applied to design current and future ones more effectively. At Moffitt Cancer Center, the personalized medicine clinical service was launched in 2013, and they have developed a full tumor genome analysis workflow, with weekly sequencing panels and monthly clinical genomics action committee meetings for more in-depth case discussions. They have close to 10,000 cases in their database and have addressed many of the barriers — administrative support, EMR challenges, funding — to effective implementation of precision oncology.

EVENT SUMMARY

Day 1 Recap *March 26, 2021*

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

Precision Health: Implementation, Value and Scope

Intermountain Healthcare has a simple mission statement: Helping people live the healthiest lives possible. They're looking to achieve their mission through applying precision medicine in their clinical services and using it to guide and implement patient care strategies where possible. In oncology, Intermountain is using genomic analysis to identify causal variants and apply precision treatment. In addition to specific case benefits, Intermountain undertook a study that showed a patient cohort treated using precision medicine practices lived longer and lowered costs by more than 20% when compared with a cohort treated using standard of care. Moving forward, Intermountain's health insurance arm, Selecthealth, is covering genomic testing, with a goal of having 100% of patients with advanced cancers receiving a full genomic profiling. They also launched the Heredigene study across all cancers and found that 15% of cancer patients are positive for a known germline pathogenic cancer variant, indicating that early detection can improve patient outcomes and lower costs. Finally, Intermountain is embarking on a population-wide genome sequencing initiative, with the goal of sequencing 500,000 subjects over the next five years. Preliminary data from the first 10,000 participants has found that 2.1% carry highly pathogenic genetic variants.

Richard Schilsky, M.D., Ph.D., F.A.C.P., F.S.C.T., F.A.S.C.O. Senior VP and Chief Medical Officer, American Society of Clinical Oncology

The TAPUR™ Study: Learning from precision medicine in practice

Dr. Schilsky is leading the Target Agent and Profiling Utilization Registry Study, a national study run by the American Society of Clinical Oncology. The primary goal of TAPUR™ is to learn from the real-world practice of prescribing targeted therapies to patients with advanced cancer whose tumors harbor known targetable mutations. It's a basket trial, in which patients are enrolled if they match with a drug or drug combination being assessed in TAPUR™. The primary endpoint is disease control rate, with other data including overall survival, progression-free survival, time on treatment and high grade/serious adverse events. The overall administration of the trial aims at pragmatism, with broad eligibility and physician discretion in many areas, but there are specific inclusion/exclusion and response criteria as well as mandatory evaluations and data submissions. As of late January 2021, more than 2,000 patients had been enrolled at 124 participating sites in 24 states, and they are looking to continue to expand the number of study sites. There are also international TAPUR™-inspired studies in the Netherlands, Canada, Korea, Australia and Denmark, with some data sharing with TAPUR™ already initiated.

Panel Q&A

The panelists were asked about how targeted therapies can be applied across different population groups, and they discussed some of the challenges that still exist regarding different responses in different ethnicities. They also spoke on the process of patient education and consent, particularly when implementing a large, population-wide sequencing program. Finally, they weighed in on where clinical trials are going in the future and how the data collected can be applied for the most patient benefit.

Day 2 Recap *March 27, 2021*

Session 3: Precision Oncology in Pediatrics

Introduction

Only at the beginning of 2020 did MCGI start to enroll pediatric patients. It has now enrolled seven patients total, a small number but pediatric cancer incidence is only about one-tenth of adult rates. None of the patients were able to be enrolled into a clinical trial, so there is obviously much more work to be done.

The NCI children's oncology group pediatric has launched a MATCH trial and is looking to screen 200 to 300 pediatric patients a year who can then receive a targeted drug. The trial is being offered at about 200 sites in the U.S. at this time.

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

Precision Therapeutics for Childhood Cancer: Successes and Challenges

The framework for precision oncology is to profile the individual patient's cancer to find an actionable target and treat the patient with a drug against the target. But that hasn't been easy for pediatric cancers. A recent success story is Larotrectinib, a selective pan-tropomyosin receptor kinase (TRK) inhibitor that received FDA approval only three-and-a-half years after the first in-child trial launched. TRK fusions are seen in a diverse range of pediatric tumors, including gliomas, nephromas, sarcomas and more, many of which are not amenable to standard-of-care treatment, including surgical resection. Children with TRK fusion tumors had a high response rate to Larotrectinib, while children without TRK fusion did not respond. Several factors contributed to Larotrectinib's quick approval, but the paradigm is hard to replicate for both biological (rarity and heterogeneity of pediatric tumors) and systemic reasons (uneven access, regulatory hurdles). Only six out of the 117 non-hormonal drugs approved by the FDA from 1997 to 2017 had initial approvals that included children, and the rates of industry sponsorship for pediatric cancer clinical trials remain lower than those for non-oncology trials. The RACE act, a component of the FDA reauthorization act of 2017, may help with the situation, as it allows the FDA to mandate pediatric evaluation of oncology agents with potential relevance to pediatric malignancies.

Alanna Church, M.Sc., M.D., F.R.C.P.C. Associate Director, LaMPP, Boston Children's Hospital

Using Molecular Diagnostics to Support Pediatric Cancer Patients

Pediatric cancers provide significant opportunities as well as significant challenges for molecular diagnoses. The pediatric cancer genome is different than adult counterparts, as there is a greater likelihood of germline predisposition, and each tumor is rare. Pediatric cancers usually arise from a sudden event, such as a fusion, not the gradual accumulation of genomic alterations that underlie most adult carcinomas. To increase insight and make pediatric cancer data more useable, Dana Farber Cancer Institute has implemented the Profile project, a research platform for sequencing cancer tissues from patients, including pediatric patients, across the health care system. At the same time, Dana-Farber is participating in the GAIN and LEAP consortia, collaborating with sites across the United States to pool pediatric cancer data. The work is providing important insights, and 63% of patients in GAIN had one or more diagnostically relevant genetic alterations identified by sequencing. At the same time, a lot of patients are enrolled in a lot of different studies — sequencing, clinical trials, etc. — and tissue samples can be tiny, so tissue allocation can be difficult. Reimbursement issues have also presented challenges for clinicians and patient families.

Panel Q & A

Moderator: Ching Lau, M.D., Ph.D. Professor and Medical Director at Connecticut Children's Hospital, The Jackson Laboratory

How can opportunities for new pediatric drugs be expanded without being tied to shared targets with adult drugs? The panelists addressed this difficult issue, as well as possible new diagnostic platforms and the prospects for implementing liquid biopsies for pediatric patients. Given the difficulty of doing serial biopsies in pediatric patients, serial blood draws would provide advantages, but issues with accuracy and reimbursement remain. Finally, the panelists discussed how NCI and other organizations can help clinicians better meet the needs of pediatric cancer patients.

Day 2 Recap *March 27, 2021*

Session 4: How to Test—Tissue-based versus liquid biopsies

Milan Radovich, Ph.D. Associate Professor Co-Director, Indiana University Health Precision Genomics Program, Indiana University School of Medicine

Current and Future Clinical Applications of Liquid Biopsies

All cells secrete DNA into blood, including tumor cells. The overwhelming majority of DNA in plasma is normal, but it's possible to detect circulating tumor DNA (ctDNA) with genome sequencing technology, for what is known as a liquid biopsy. Tissue biopsy is the current standard, but it can be painful and invasive, it's not always feasible or safe because of the location of the tumor, and it provides only a single snapshot of the disease state. Liquid biopsies are quick, relatively noninvasive and painless, provide real-time monitoring, and have the potential to sample from multiple foci of disease. On the other hand, they are still prone to lack of specificity and error, and different studies have reached different conclusions regarding their discordance with tissue biopsies. One confounder can be clonal hematopoiesis of indeterminant potential (CHIP), somatic mutations in blood cells that can introduce false positive reporting of ctDNA variants not associated with the cancer of interest in liquid biopsy assays. As a result, in its current state, liquid biopsy is best applied as a complementary technology, not a replacement for tissue biopsies. At this time, it is particularly useful for residual disease detection, finding variants in cancer predisposition genes in the germline and for molecular profiling of metastatic disease.

Nikoletta Sidiropoulos, M.D.
Associate Professor, Pathology and Laboratory Medicine, University of Vermont Medical Center

Precision Oncology Tumor Testing

The University of Vermont Medical Center opened a Genomic Medicine laboratory in 2017 to provide precision oncology testing as a service and to look at the value of going "beyond the test" to support and enhance clinical workflows. A vital component of the service is early identification of key stakeholders and ongoing engagement, as well as realistically defined and communicated test performance expectations. The clinical sequencing workflow itself, from sample to sequence, is pretty straightforward but needs to be well integrated with the clinical reporting function. In addition, Dr. Sidiropolous addressed the gap that exists between molecular biology and clinical relevance and expertise, which mandates careful assay development and investment in medical interpretation. She cited the example of MET Exon 14 skipping mutations in non-small cell lung cancer, which are diverse and may be outside of the sequences targeted for sequencing. Accurate detection requires additional assays and close coordination that merges molecular biology with clinical expertise. Overall, effective genomic testing requires engaged "champions" for the service as well as effective education across surgery, pathology, allied health professionals, informatics and the patient population itself.

Panel Q&A

Moderator: Emily Edelman, M.S., C.G.C. Assistant Director, Clinical Education, The Jackson Laboratory

The panelists expanded upon the topic of when and how to use liquid biopsies in concert with tissue biopsies if possible, the sources of discordance between the two and how discordant results can be resolved. They also discussed the importance of physician knowledge when ordering molecular assays, and the responsibility of the laboratory to both help guide the clinician and be transparent about the data produced. Finally, they emphasized the importance of a collaborative effort by the larger team for results interpretation.

Community discussions

Over the lunch hour, attendees active within the MCGI network were able to participate in one of six breakout discussion sessions. In addition to a community listening session regarding MCGI 2.0 moving forward, there were informational sessions on the JAX Clinical Knowledgebase, the genomic tumor boards and helping patients navigate precision oncology. There was also a session for the genetic counselor community and one on remote-study activities and electronic data capture for MCGI 2.0.

Day 2 Recap *March 27, 2021*

Session 5: Neuro-Oncology

Introduction

Brain tumors are strongly represented in MCGI, with the vast majority being glioblastoma multiforme, a highly lethal cancer. The participation indicates a high level of interest in sequencing for brain tumors, perhaps because of the poor patient prognosis. Thus far 78 brain tumor patients have participated in MCGI, and eight patients went on genome-informed therapy — just over 10%. Most courses of therapy were under three months, however, so it's important to consider how useful genomic information is in this context.

Floris Barthel, M.D. Postdoctoral Associate, The Jackson Laboratory

Clinical Impact of Molecular Neuro-Oncology

Gliomas are derived from glial cells — astrocytes and oligodendrocytes — and are the most common malignant brain tumor. Brain tumors were traditionally classified based on histologic appearance, but studies have found a 25 – 50% rate of diagnostic discordance between pathologists. The last decade has seen the establishment of consortia to inform molecular approaches to central nervous system tumor taxonomy, substantially increasing the use of biomarkers or methylation over traditional histopathology. But the fact remains that gliomas of all subtypes invariably relapse following treatment. The Glioma Longitudinal AnalySiS Consortium was established to identify common features of recurrence and determine if treatment exerts selective pressures on glioma genomes. Research has found that certain features — hypermutation, CDKN2A deletions, aneuploidy — are important in tumor recurrence. Standard treatments include Temozolomide, an alkylating agent, and hypermutation was found in all subtypes of treated patients. Also, radiotherapy treatment is associated with a significant increase in small DNA deletions as well as large inversions and deletions, which may hit key tumor suppressor genes. The findings provide early indications of the mechanisms driving tumor recurrence following treatment.

David Ashley, M.B.B.S. (Hons.), F.R.A.C.P., Ph.D. Neuro and Pediatric Oncologist, Duke Cancer Center

Brain Immunology and Immunotherapy in Brain Tumors

Primary malignant brain tumors occur at a rate of 3.4 cases per 100,000 lives, and glioblastoma is the most malignant, invasive and difficult-to-treat brain cancer. The standard of care includes surgical resection, radiation and Temozolomide (TMZ), but unfortunately the five-year survival rates are still measured in single digits and the median survival is only about 15 months for first-line therapy. Immunotherapies provide a new therapeutic strategy that is currently being investigated. Challenges include the relatively low tumor mutational burden (TMB) in glioblastomas, which often indicate a barrier to immune therapies but don't tell the whole story. Also important is the presence of T-cell response as indicated by gene expression profile signatures. Further research indicated that a very low tumor mutational burden (TMB) is a feature of a subset of recurrent glioblastomas that, counter-intuitively, are more responsive to immunotherapy. Subsets of recurrent glioblastoma patients have also responded to PVSRIPO virotherapy approaches, but success rates are lower in those with TMZ-associated hypermutation following first-line treatment. Patients with a very low TMB have an inflamed tumor microenvironment in recurrent but not initially diagnosed glioblastoma, and research is ongoing into whether this may contribute to their better response to therapy.

Panel Q&A

Moderator: Roel Verhaak, Ph.D. Professor and Associate Director of Computational Biology, The Jackson Laboratory

The panelists revisited how very low tumor mutational burden and hypomethylation, while still being studied, may help stratify patient and guide therapies in recurrent tumors. They also discussed the mutations introduced by TMZ treatment and radiotherapy can affect recurrent disease and addressed whether TMZ should even be used given that hypermutation is associated with poor survival. They also answered questions about the effects of radiotherapy, how it might be combined with synthetic cell lethality, and whether it can generate neoantigens for immunotherapy.

Forum Presenters and Moderators

David Ashley, M.B.B.S. (Hons.), F.R.A.C.P., Ph.D.

Professor Ashley's career in cancer research dates more than two decades. He is credentialed in both pediatric and adult neuro-oncology practice, and this has been the focus of his efforts in translational research and leadership at Duke University. His peer-reviewed publication record is diverse and includes laboratory-based cancer research, clinical trials, as well as public-health and psycho-oncology research. His primary research focus is on the immunology, epigenetics, and genetics of brain tumors. His achievements in research have led to change in practice in the care of both children and adults with brain tumors. Ashley is highly regarded for his work, as evidenced by numerous awards and invitations to plenary sessions and symposia of international standing. He has been the principal investigator of a number of important national and international studies both clinical and pre-clinical. He is recognized as a senior figure and opinion leader in academic medicine nationally and internationally.

Floris Barthel, M.D.

Floris Barthel graduated from the VU University Medical Center in Amsterdam, The Netherlands with an MD degree in 2014. He subsequently joined the laboratory of Dr. Roel Verhaak at the MD Anderson Cancer Center in Houston, Texas for a postdoctoral fellowship. He has since relocated to The Jackson Laboratory for Genomic Medicine in Farmington, Connecticut where he continues his postdoctoral studies. He is broadly interested in the evolutionary tumor genomics of adult gliomas.

Alanna Church, M.Sc., M.D., F.R.C.P.C.

Dr. Church is a board-certified Pediatric Pathologist and Molecular Genetic Pathologist. She is the Associate Director of the Laboratory for Molecular Pediatric Pathology (LaMPP) at Boston Children's Hospital, and an Instructor at Harvard Medical School. She has participated in several high-impact studies using molecular profiling to support the care of children with cancer, including the iCat study, Profile study, and the ongoing multi-institutional GAIN consortium study.

Susan M. Domchek, M.D.

Susan M. Domchek, MD is the Basser Professor in Oncology at the Perelman School of Medicine of the University of Pennsylvania. She serves as Executive Director of the Basser Center for BRCA at the Abramson Cancer Center and Director of the Mariann and Robert MacDonald Cancer Risk Evaluation Program. Her work focuses on the genetic evaluation and medical management of individuals with inherited risk factors for cancer. Dr. Domchek is particularly interested in developing new cancer therapies, such as PARP inhibitors, for breast cancer due to genetic risk factors. An elected member of the National Academy of Medicine, the American Society of Clinical Investigation, and the Association of American Physicians, Dr. Domchek is also a member of the American Society of Clinical Oncology for which she has served on a number of committees. A significant contributor to the oncology literature, she has authored/co-authored more than 350 articles appearing in scholarly journals including the New England Journal of Medicine, the Journal of the American Medical Association and the Journal of Clinical Oncology. Dr. Domchek also serves on a number of editorial review boards, including the Journal of Clinical Oncology, as well as on the Scientific Advisory Board for the Breast Cancer Research Foundation.

Steven G. DuBois, M.D., M.S.

Dr. DuBois completed medical school and pediatric 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.

Dr. 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.

Dr. 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., C.G.C.

Emily is the Associate Director for Clinical Education at The Jackson Laboratory. She is a board-certified genetic counselor whose work focuses on genetics education for health professionals. At The Jackson Laboratory, she collaborates with healthcare providers to incorporate genetics and genomics into clinical practice through diverse education programs, including initiatives in family health history, obstetrics, and oncology. Emily received her undergraduate degree from Mary Washington College followed by her Master's degree in Genetic Counseling at Virginia Commonwealth University. Emily is a past Board Member of the National Society of Genetic Counselors.

Leah C. Graham, Ph.D.

Leah Graham, Ph.D., joined the Maine Cancer Genomics Initiative in January 2021. Previously, Dr. 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 School of Biomedical Sciences at Tufts University School of Medicine in April 2017. Dr. 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.

Ching Lau, M.D., Ph.D.

Ching Lau is the Martin J Gavin Endowed Chair and Division Head of Hematology-Oncology at Connecticut Children's, and Professor at JAX 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 neurooncology, solid tumors, and osteosarcoma.

Forum Presenters and Moderators

Lincoln D. Nadauld, M.D., Ph.D.

Lincoln Nadauld 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. Dr. 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. Dr. 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.

Milan Radovich, Ph.D.

Dr. Milan Radovich, PhD, is an Associate Professor at the Indiana University School of Medicine (IUSM) and Vice President for Oncology Genomics at Indiana University Health (IUH). He is also Co-Director of the IU Health Precision Genomics Program, a clinical program dedicated to the integration of cutting-edge genomics for the care of metastatic cancer patients.

As an NCI-funded investigator, his research expertise focuses on the use of genomics in translational oncology. In particular, his research concentrates on the use of genomics in clinical studies, genomically-informed drug combinations, circulating biomarkers of cancer detection, and creating novel bioinformatic pipelines for cancer genome analyses. His laboratory has long standing-expertise in the research of triple-negative breast cancer, thymic malignancies, and cancer precision medicine.

As IUH Vice President for Oncology Genomics and Co-Director of the IU Health Precision Genomics Program, he co-leads a clinical service line that uses genomics to guide therapy for cancer patients. This program has sequenced over 5,000 patients to date. With five clinics across the State of Indiana, the program provides access to cutting-edge genomic-based cancer care for patients.

Dr. Radovich is passionate about providing the best care to patients through precision medicine. He actively engages with patient advocacy, philanthropic groups, and mentoring to bring genomics research to patients. He is also actively involved in national precision medicine research as the ORIEN network scientific committee co-chair, a member of the Big Ten Cancer Research Consortium Basket Trials Working Group, and also served in the NCI Cancer Genome Atlas (TCGA). When he is not in the cancer center or in the lab, he enjoys spending time with his family. As a native Chicagoan and Purdue graduate, he also enjoys cheering on the Bears and Boilermakers.

Jens Rueter, M.D.

Dr. Rueter is the Medical Director for the MCGI. He joined JAX for this position in August 2016. Dr. Rueter came to JAX from Eastern Maine Medical Center Cancer Care in Brewer, Maine, where he was the 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, Dr. Rueter has 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.

Richard L. Schilsky, M.D., F.A.C.P., F.S.C.T., F.A.S.C.O.

Dr. Schilsky is the Executive Vice President and Chief Medical Officer (CMO) of ASCO. Formerly the Chief of Hematology/Oncology in the Department of Medicine and Deputy Director of the University of Chicago Comprehensive Cancer Center, he is a highly respected leader in the field of clinical oncology. He specializes in new drug development and treatment of gastrointestinal cancers. Dr. Schilsky is a Past President of ASCO, having served in the role during 2008-2009, and also a Past Chair of one of the National Cancer Institute's Cooperative Groups, Cancer and Leukemia Group B (CALGB). Dr. Schilsky's impressive experience and many accomplishments in both clinical medicine and clinical research reflect his deep passion for cancer medicine. He has spent the majority of his career at the University of Chicago where he joined the faculty in 1984, subsequently rising to the rank of Professor of Medicine and serving in many roles, including Associate Dean for Clinical Research in the Biological Sciences Division and Director of the University of Chicago Cancer Research Center. From 1995 to 2010, Dr. Schilsky served as chair of the Cancer and Leukemia Group B, a national cooperative clinical research group funded by the National Cancer Institute (NCI). He has extensive experience working with both the NCI and the Food and Drug Administration (FDA) having served as a member and chair of the NCI Board of Scientific Advisors, as a member of the NCI Clinical and Translational Research Committee, and as a member and chair of the Oncologic Drugs Advisory Committee of the FDA. Presently, he serves as a member of the board of directors of Friends of Cancer Research and of the Reagan-Udall Foundation for the FDA. Dr. Schilsky has served on the editorial boards of many cancer journals, including the Journal of Clinical Oncology. He presently serves on the editorial board of the New England Journal of Medicine. Dr. Schilsky is the author of nearly 400 original research articles, reviews and commentaries. Early in his career, he worked in the Clinical Pharmacology Branch of the Division of Cancer Treatment at the NCI and was an Assistant Professor in the Department of Internal Medicine, Division of Hematology and Oncology at the University of Missouri-Columbia School of Medicine. He was also the head of the hematology/medical oncology unit at the Harry S. Truman Veterans' Administration Hospital in Columbia, Missouri.

Nikoletta Sidiropoulos, M.D.

Dr. Nikoletta Sidiropoulos is an Associate Professor of Pathology and Laboratory Medicine at the Larner College of Medicine and the Inaugural Medical Director of the Genomic Medicine Program at the UVM Medical Center. Dr. Sidiropoulos received her medical degree from the University of Connecticut School of Medicine graduating with the award in "Excellence in Medical Studies". She completed her residency in Anatomic and Clinical Pathology at Dartmouth Hitchcock Medical Center and subsequently completed fellowships in cytopathology and molecular genetic pathology. She also is a diplomate of the American Board of Pathology and American Board of Preventative Medicine in Clinical Informatics. Her areas of expertise include molecular genetic pathology with subspecialty interests in oncology and quality improvement.

Roel Verhaak, Ph.D.

Roel Verhaak, PhD., is a Professor and Associate Director of The Jackson Laboratory for Genomic Medicine in Farmington, CT. The Verhaak lab studies glioma using genomic characterization and computational analyses, work that has helped redefine the way glioma in adult patients is classified. More recent efforts are focused on tumor evolution, which the lab is investigating using longitudinal tumor sequencing, single-cell sequencing, and via comparative oncology approaches. Roel Verhaak is a recipient of the AAAS Wachtel Award, the Agilent Early Career Professor Award, and the Peter Steck Memorial Award. He is a co-founder of Boundless Bio, a biotech company developing therapies against cancers containing extrachromosomal DNA amplifications.

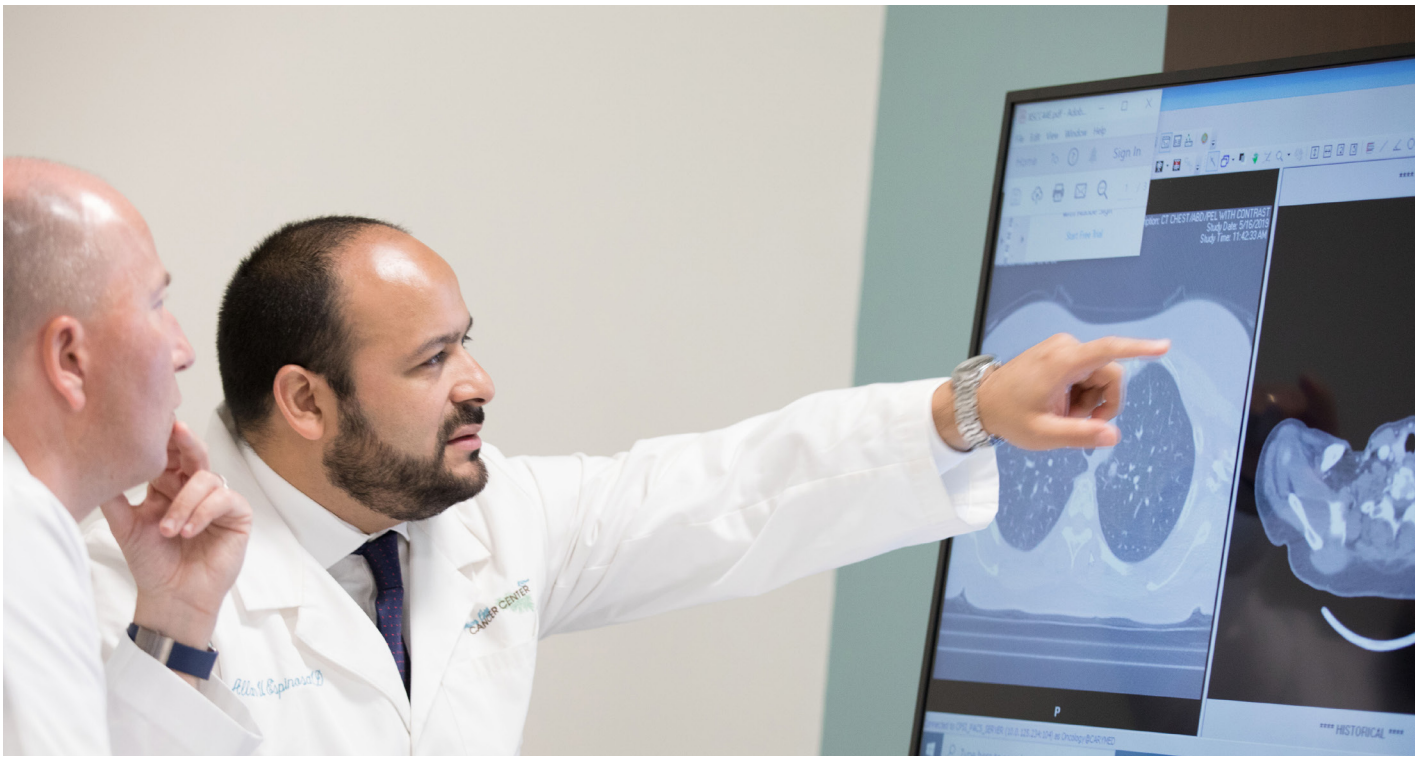
Forum Presenters and Moderators

Christine Walko., Pharm.D., F.C.C.P., B.C.O.P.

Dr. Walko 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. Dr. Walko is now an Associate Member in the Department of Individualized Cancer Management at Moffitt Cancer Center, 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.

Jedd D. Wolchok, M.D., Ph.D., F.A.S.C.O.

Jedd Wolchok is Chief of the Immuno-Oncology Service and holds The Lloyd J. Old Chair in Clinical Investigation at Memorial Sloan Kettering Cancer Center, Associate Director of the Ludwig Center for Cancer Immunotherapy and Director of the Parker Institute for Cancer Immunotherapy at MSK. Dr. Wolchok is a clinician-scientist exploring innovative immunotherapeutic strategies in laboratory models, and a principal investigator in numerous pivotal clinical trials. He specializes in the treatment of melanoma. The focus of his translational research laboratory is to investigate innovative means to modulate the immune response to cancer as well as to better understand the mechanistic basis for sensitivity and resistance to currently available immunotherapies.



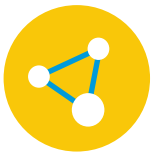
The Maine Path to the Genomic Tumor Board

Test result received by treating clinician

You, the treating clinician, would like to discuss a genomic test result for a MCGI patient with peer, national medical oncology experts and local clinical trial experts to discuss potential treatment options.

Preparation for the discussion

Share the patient's MCGI number with the MCGI Genomic Tumor Board (GTB) team to add the case to an existing GTB session at your or another practice.



GTB session — Connecting

An Outlook calendar invitation with connection information is sent to you and all participating clinicians in the MCGI network. As previously agreed upon, a MCGI team representative may come in-person to your practice to moderate the session or assist with AV set up.

GTB session — Discussion

As the treating clinician, you provide a recent clinical history for the patient(s) being discussed and why you felt a review through the MCGI GTB could be helpful. The testing laboratory then reviews the genomic test result findings followed by variant interpretation and clinical trials options by a precision oncology expert. A nationally recognized medical oncology expert will share their opinion on the case, followed by open discussion for all medical professionals on the call.

GTB session — Follow-up

After the GTB session, the MCGI GTB team sends meeting minutes to session attendees. You may choose to use these minutes as part of next step efforts in patient treatment, as appropriate to the individual patient's situation.

Want to learn more?

The MCGI GTB team applies annually to be able to offer AMA PRA Category 1 Credit(s)™ for participation in the annual GTB session series. Visit our website or reach out to us at mcgi@jax.org for more information and to be added to the GTB sessions invitation list.

Therapy Navigation

At some point in a patient's care the treating physician may decide that an off-label or investigational agent is worth pursuing. This creates a need for the practice to navigate the processes to help get the treatment to the patient.

Seeking treatment with an investigational agent outside of a clinical trial or "off-label" use of an approved drug:

- Even with the recent trend towards accelerated market approval, new treatments often do not make it to market fast enough to help patients with a serious disease or life-threatening condition like cancer.
- Fortunately, several pathways exist to make investigational or off-label products available to use in clinical practice outside of a clinical trial or if not covered by insurance.

To be considered for any of these pathways, patients must meet all of the following basic conditions per the judgement of the physician:

- The patient has a serious disease or condition, or the patient's life is immediately threatened by the disease or condition.
- There can be no comparable or satisfactory alternative therapy to treat the disease or condition.
- The patient has already tried all approved treatment options.
- The patient is unable to participate in a clinical trial due to ineligibility or feasibility issues (access to a trial site, lack of ongoing clinical trials).

1: Expanded Access

Expanded access, sometimes called "compassionate use," is a potential pathway for a patient to gain access to an investigational medical product (drug, biologic or medical device) for treatment outside of a clinical trial.

Expanded access for cancer drugs may be appropriate when the following apply (in addition to the basic conditions listed above):

- Potential patient benefit justifies the potential risks of treatment.
- Providing the investigational drug will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.

Other key points

The purpose of expanded access is not evaluation of the drug, but rather to provide treatment with an investigational drug outside of a clinical trial. Expanded access will NOT provide investigational drugs for treatments outside of the intended label criteria. An expanded access application requires FDA, IRB and manufacturer involvement and approval.

2: Right to Try

The Right to Try law is another way for patients to potentially gain access to an investigational drug for treatment outside of clinical trials. In addition to the basic conditions listed above, the patient must provide written informed consent regarding the use of the eligible investigational drug.

An eligible investigational drug is an investigational drug:

- For which a Phase 1 clinical trial has been completed.
- That has not been approved or licensed by the FDA for any use.
- That is the subject of a new drug application pending FDA decision or is the subject of an active investigational new drug application being studied in a clinical trial.
- For which active development or production is ongoing, and that has not been discontinued by the manufacturer or placed on clinical hold by the FDA.

While both these pathways enable patients to ask for investigational therapies that have not been approved for any indication, manufacturers have the right to refuse to provide the drug to requesting patients.

"Off-Label" use of an approved drug

The emerging field of genomic testing can result in the identification of a cancer drug (not approved for the patient's condition) that could show an effect based on an identified genomic mutation in a patient's tumor. After viable approved treatments have been exhausted, the care team might decide to use a drug in an off-label application.

First, insurance authorization for the anticipated off-label use is sought. The application and appeals process (in case of denial) requires the provision of documentation of efficacy, which consists of provider notes, Genomic Tumor Board notes, or other evidence-based documentation. If insurance authorization cannot be obtained, the care team can apply directly on behalf of the patient to get the drug(s) free of charge or with a minimal co-pay through the Manufacturer's Access Program.

Managing the negotiations for payment for off-label use can put a tremendous strain on patient and provider resources. Depending on the health system, different models exist for oncology providers in Maine. Some provider clinics have designated departments while others task individual care team members with obtaining prior authorization or other forms of coverage for such treatments. The process can involve cross-functional team member involvement ranging from pharmacists to navigators to clinicians to nursing staff. A significant amount of time is spent on identifying resources (Manufacturer Access Programs and Foundation funds), obtaining required documentation, managing and renewing approved applications, as well as managing the shipment of drugs. Additional time is spent aligning the process if several staff members are involved.

Recent interviews with professionals involved in the application and management process for securing off-label drugs for oncology patients identified the following key areas for improvement:

- Provide ready-to-use, standardized, evidence-based documentation for the most commonly used off-label drugs and most commonly identified mutations to reduce the number of insurance denials up front.
- Create a designated position to manage the process for all patients to increase effectiveness and reduce burden.

1. https://www.fda.gov/news-events/public-health-focus/expanded-access

2 https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try

Certified Continuing Education Activities

Maine Cancer Genomics Initiative (MCGI)

The 2021 MCGI Forum will provide educational content in a live and synchronous broadcast during sessions on Friday, March 26 and Saturday, March 27. Some content from the live dates will be available in enduring format via the Canvas learning system through mid-April.

These sessions will focus on many facets of precision oncology, including impact on patient outcomes; programs and clinical trials; pediatric precision oncology; precision oncology testing methodologies; and neuro-oncology. Sessions will feature a series of pre-recorded 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 2021 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 medicine in clinical care;
2. Assess the use of precision medicine in clinical practice by appraising its benefits and limitations; and
3. Identify and address barriers to effective implementation of genomics-based patient treatment options as interpreted from results of cancer somatic testing within the setting of community oncology practices.

ABIM CME MOC ACCREDITED

PART 2 MOC
THE AMERICAN BOARD of PEDIATRICS

Target Audience: Physicians

These sessions will offer up to 8.75 AMA PRA Category 1 Credits™ for live attendance and 6.25 AMA PRA Category 1 Credits™ for asynchronous attendance. 4.5 American Board of Internal Medicine (ABIM) Medical Knowledge Points and 0.75 American Board of Pediatrics (ABP) MOC Part 2 points are offered for either live or asynchronous attendance.

CME is intended for physician attendees, primarily Maine clinicians practicing oncology and involved in cancer patient care and/or cancer research. MOC is intended for physicians who are certified by the American Board of Internal Medicine (ABIM) or the American Board of Pediatrics (ABP).

Claiming CME Credit

In order to claim CME credit, attendees must: 1) log in to the Canvas learning platform to document attendance at sessions; 2) complete the post-assessment quiz with a score of 80% or higher; and 3) complete the evaluation in the Canvas 'assignments' section. Attendees can access content through the Canvas learning system and complete these requirements until Sunday, April 18, 2021. A CME documentation certificate is provided to participants via email after the electronic evaluation results are received.

Claiming MOC points

In order to claim MOC points, attendees must: 1) complete the requirements to claim CME credit above; 2) complete the post-assessment quiz for the relevant specialty with a score of 80% or higher; and 3) complete the specialty-specific MOC participant form. Attendees can access content through the Canvas learning system and complete these requirements until Sunday, April 18, 2021. MOC documentation is submitted to the appropriate board on behalf of the attendee once requirements to claim credit are satisfied.

AMA Designation Statement: The Maine Medical Education Trust designates this live activity for a maximum of 8.75 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.

ABIM Recognition Statement: Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 4.5 Medical Knowledge MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

ABP MOC Recognition Statement: Successful completion of this CME activity, which includes participation in the evaluation component, enables the learner to earn up to 0.75 MOC points in the American Board of Pediatrics' (ABP) Maintenance of Certification (MOC) program. It is the CME activity provider's responsibility to submit learner completion information to ACCME for the purpose of granting ABP MOC credit.

Genetic Counselor CEUs

The National Society of Genetic Counselors (NSGC) has authorized The Jackson Laboratory to offer up to 0.91 CEUs or 9.10 Category 1 contact hours for the activity Maine Cancer Genomics Initiative Annual Forum 2021. 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 9.1 contact hours or 0.91 CEUs 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 GC CEU Credit

In order to claim credit, attendees must: 1) log in to the Canvas learning platform to document attendance at sessions; 2) complete the post-assessment quiz with a score of 80% or higher; and 3) complete the evaluation in the Canvas 'assignments' section. Attendees can access content through the Canvas learning system and complete these requirements until Sunday, April 18, 2021.

Certified Continuing Education Activities

Nursing Contact Hours

Learning Outcomes for Nurses

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 8.5 contact hours upon the completion of this activity. Please see the agenda to review which presentations carry nursing contact hours. You are not required to complete all sessions to earn CEUs and you may earn partial credit. You may choose to attend/view only some sessions. You will only be awarded CEUs for those sessions for which you complete in full, including the module quiz and evaluation.

Learning Outcomes

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

- Recognize precision oncology programs, clinical trials and the advantages and limitations of their impact on patient outcomes.
- Identify sub-specialty specific concerns for precision oncology patients in Pediatrics and NeuroOncology.
- Recognize the difference between tissue-based and liquid biopsy testing methods for tumor testing.

Claiming Nursing Contact Hours

In order to claim credit, attendees must: 1) attend at least 1 session of the multi-session activity; and 2) complete and submit evaluation form(s) for attended activities. Attendees can access content through the Canvas learning system and complete these requirements until Sunday, April 18, 2021.

Approval Statement: This continuing nursing education activity was approved to the Northeast Multi-State Division (NE-MSD), 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 of the American Nurses Association.

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 in the continuing education sections on the Canvas learning platform.

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 more than 2,300 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

Leslie Bradford, M.D.

Dr. Bradford is a native of Maine and a practicing gynecologic oncologist at Maine Medical Center/Maine Medical Partners. She completed her medical school training at the University of Vermont College of Medicine followed by a residency in obstetrics and gynecology at the University of Wisconsin Hospital & Clinics in Madison, WI. She returned to New England to complete her fellowship in gynecologic oncologic at Massachusetts General Hospital, with a research focus on the PI3K pathway, targeted therapies and xenograft models in endometrial cancer. She then joined the faculty at the University of Massachusetts. There, her research focused on HPV vaccination and cervical cancer screening in low-income countries, collaborating with investigators in Cameroon to launch large-scale cervical cancer screening programs using novel HPV detection technology. She now serves as the Director of Research in gynecologic oncology at Maine Medical Center/Maine Medical Partners and is an Associate Professor at Tufts University School of Medicine. In addition to overseeing the gynecologic oncology clinical trials program, she is a co-PI on the institution's NCORP grant, serves on the NCI Gynecologic Cancer Steering Committee Ovarian Cancer Task Force and is an active mentor for resident and medical student education and research. She has a strong interest in rare tumors, developmental therapeutics, and minimally invasive surgery.

Philip L. Brooks, M.D.

Dr. Brooks practices at Northern Light Cancer Care and oversees their clinics at the Mt. Desert Island Hospital, the Maine Coast Memorial Hospital and the Blue Hill 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. Dr. 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.

Dr. 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. Dr. 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.

Dr. 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. Dr. Christman received his M.D. from Temple University School of Medicine, where he also served his residency and held a fellowship position.

Elizabeth (Betsy) Connelly, D.O.

Dr. Connelly practices medical oncology and hematology at Waldo County General Hospital and Pen Bay Medical Center. She is board certified in medical oncology, hematology and internal medicine. Dr. Connelly is a member in the American Society of Clinical Oncology and is on active staff at Waldo County and Pen Bay Medical Center. She received her D.O. from Texas College of Osteopathic Medicine followed by a residency at Akron General Medical Center in internal medicine and a fellowship with the Cleveland Clinic Foundation in medical oncology/hematology.

Nicholette Erickson, M.D.

Dr. 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.

Clinical Steering Committee Bios

Peter Georges, M.D

Dr. Georges practices oncology at York Hospital in Southern Maine. He holds board certification in internal medicine, hematology and medical oncology. Dr. 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.

Dr. Ridhi Gupta is a Medical Oncologist and Hematologist who 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.

Roger Inhorn is the Medical Director of Oncology at Maine Medical Partners. 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. Dr. 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 was the Chief of Oncology at Mercy Hospital for 14 years prior to joining Maine Medical Partners. He has a special interest in breast cancer and GI oncology.

Rachit Kumar, M.D.

Dr. 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. His interests include targeted therapies and immunotherapy.

Christine Lu-Emerson, M.D.

Dr. Lu-Emerson is a board-certified neuro-oncologist at Maine Medical Center. Her experience includes the development and conduction of 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. Dr 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.

Mayur K. Movalia, M.D.

Dr. 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. Dr. Movalia 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., F.A.C.M.G.

Dr. 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. Dr. 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. Dr. 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.

Dr. Remick is Physician Leader of Oncology at Maine Medical Center Cancer Institute and Maine Health, where he specializes in internal medicine and oncology. He is board certified in internal medicine with a sub-specialty of oncology. Dr. Remick received his M.D. from New York Medical College followed by a residency at Johns Hopkins Baltimore City Hospital and fellowship at University of Wisconsin Hospitals & Clinics. In August 2019, Drs. Remick, Christopher Darus 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.

Dr. Rubin practices oncology at SMHC Cancer Care Center and is Medical Director. He is board certified in hematology and medical oncology. Dr. 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.

Dr. Sinclair practices oncology at Northern Light Cancer Care. She is board certified in internal medicine and medical oncology. Her interests include breast cancer, clinical research and general oncology. Dr. 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.

Dr. 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. Dr. 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.

Vatche 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. He has an interest in molecularly targeted therapies, clinical research, education and thoracic/head and neck cancers.

Christian Thomas, M.D.

Dr. 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. Dr. 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.

THANK YOU FOR ATTENDING!

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Abdullagi Abdulrahman
Hassan Abushukair
Adeseye Adeyiga
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Lordstrong Akano
Rabab Al Deabel
Noor AL-Hamid
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"WE'RE GOING TO BEAT THIS."

—Betty Walls