Maine Cancer Genomics Initiative (MCGI) Forum

Building Bridges through Genomic Medicine

April 6 – 8, 2018
Samoset Resort, Rockport, Maine

Presented by The Jackson Laboratory with the support of the Harold Alfond® Foundation
Welcome to the second Maine Cancer Genomics Initiative (MCGI) Forum: Building Bridges Through Genomic Medicine. We are so pleased to see all the faces in this room — together, we’ve made tremendous progress over the last year.

We have:

• Created a unique, Maine-centric oncology network focused on improved care through genomic technology adoption
• Designed and approved an innovative study protocol that allows us to collect important data and measure results including patient outcomes and longitudinal clinician knowledge
• Opened the study at almost every single oncology practice in the state of Maine — a major accomplishment
• Enrolled more than 150 patients with more than 80 percent of Maine medical oncologists and oncology nurse practitioners on board already
• Run nearly 20 Genomic Tumor Boards.

And, as we’ll learn during this year’s forum, we’re just getting started.

We have an exciting day of learning planned. We’re going to hear about similar precision medicine programs and their application in clinical practice; we will discuss how MCGI can benefit your own practice and improve cancer care in Maine; and we’ll share successes and challenges as a community.

Some of you may know that The Jackson Laboratory (JAX) has been part of the Maine community since 1929. As an NCI-designated basic science cancer center, traditionally our contributions have been focused in the lab. This is part of what makes MCGI such an exciting program. We are grateful for the chance to work directly with all Maine oncology practices and the Maine Medical Center Research Institute (MMCRI) to improve access and outcomes for Mainers with cancer. With your support and your dedication, we can change the game for our neighbors and friends touched by cancer. We can apply the rapidly developing field of precision medicine to accelerate its application in Maine, and, together, we can help our communities gain better outcomes after cancer diagnoses.

Thank you for your trust, support and dedicated partnership in this novel, state-wide, community precision medicine initiative. We look forward to continuing our work with you to bring new technologies to clinical practice and define new clinical pathways.

Best regards,

Jens Rueter, M.D., Medical Director, MCGI | The Jackson Laboratory
Andrey Antov, Ph.D., M.B.A., Program Director, MCGI | The Jackson Laboratory

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The Maine Cancer Genomics Initiative

The Maine Cancer Genomics Initiative (MCGI), enabled through generous financial support from The Harold Alfond® Foundation, leverages the strengths of key medical and bioscience research institutions in Maine to create an alliance focused on precision cancer diagnostics and treatment.

Approximately 9,000 new cancer cases occur each year in Maine. Oncologists and other healthcare providers often struggle with identifying 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 increasing body of knowledge about genomics in cancer demonstrates significant promise for treatment of cancer of all types.

The mission of the 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, the MCGI has four major goals. They are:

- To provide up to 1800 patients and their respective oncology clinicians in Maine with access to somatic cancer genomic tests and clinical reports from the CLIA-certified/CAP-accredited Clinical Genomics Laboratory.
- To advance the field of clinical genomics by increasing knowledge about the adoption and use of these tests in the Maine community oncology setting.
- To deliver educational programs in cancer genomics and precision medicine consisting of online educational modules and MCGI-organized and supported genomic tumor boards to Maine oncology clinicians.
- To build a research network for “Community Genomic Medicine” by establishing a collaborative Maine-wide research network of cancer providers and institutions and a mechanism to 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 healthcare professionals from Maine oncology and pathology practices, and financial support from The Harold Alfond® Foundation, MCGI continues the effort 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, healthcare, 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.
We discover precise genomic solutions for disease and empower the global biomedical community in our shared quest to improve human health.

At The Jackson Laboratory (JAX), we apply passion, innovation and ever-increasing precision to make this mission a reality. We are accelerating disruptive scientific breakthroughs tailored to the needs of individual patients and closing in on the genetic and molecular causes of disease. We also educate current and future scientists and empower the global biomedical community by providing critical resources, data, tools and services.

Founded in 1929, The Jackson Laboratory is an independent, nonprofit biomedical research institution with nearly 2,000 employees who are passionate about our mission: to discover precise genomic solutions for disease and empower the global biomedical community in the shared quest to improve human health.

JAX conducts mammalian genetics research and raises research mice in Bar Harbor, Maine; it has a new genomic medicine research laboratory in Farmington, Conn. which enables the Laboratory to translate its fundamental science into the clinic. And, it conducts contract research and raises research mice at its laboratory in Sacramento, California. The Laboratory is a National Cancer Institute-designated Basic Cancer Center and also has initiated a cancer research laboratory in Seoul, Korea.

The Jackson Laboratory has more than 60 principal investigators who come together from diverse backgrounds and areas of expertise to advance mammalian genetics and human genomics research in aging, behavioral disorders, bioinformatics, cancer, complex traits, developmental disorders, diabetes and obesity, eye research, genetics and genomics, immune disorders, infectious diseases, neurodegenerative and neuromuscular diseases, reproductive disorders, resource development and skin disease.

From high school summer programs to graduate and postdoctoral training to conferences that further the education of practicing scientists, physicians and professionals, The Jackson Laboratory advances science and improves health through our commitment to education.

JAX® Mice, Clinical & Research Services at The Jackson Laboratory is a global resource for developing, distributing and analyzing innovative models of human disease. It offers an array of model creation, husbandry and diagnostic and analytic services ranging from custom breeding and strain preservation to drug efficacy studies and genome sequencing, all focused on empowering basic scientific research and drug discovery.
The April 2018 forum will focus on:

- Discussions on the integration of cancer genomics testing in clinical care
- Updates on the MCGI Study and Initiative
- Building a collaborative network of oncology healthcare providers to facilitate the growth of genomic medicine initiatives

Friday, April 6, 2018

3:00 P.M.  Arrival and Check-in Begins
4:00 P.M.  Steering Committee Meeting — members only
5:00 P.M.  Reception
6:00 P.M.  DINNERN AND KEYNOTE

Introductions and Acknowledgments
Jens Rueter, M.D. | The Jackson Laboratory

Opening Address
U.S. Senator Susan Collins | Welcoming Video Message

7:30 P.M.  Break
8:00 P.M.  Informal Q&A

Edison T. Liu, M.D. | The Jackson Laboratory
Chuck Hewett, Ph.D. | The Jackson Laboratory
Jens Rueter, M.D. | The Jackson Laboratory
Andrey Antov, Ph.D., M.B.A. | The Jackson Laboratory

Saturday April 7, 2018

7:30 A.M.  Breakfast

8:20 A.M.  OPENING REMARKS
Jens Rueter, M.D. | The Jackson Laboratory
Andrey Antov, Ph.D., M.B.A. | The Jackson Laboratory

SESSION 1:
The Promise of Precision Medicine
3.0 CME, 1.5pt MK MOC, 1.5pt PA MOC

8:30 A.M.  Update on the MCGI Study and Initiative
Jens Rueter, M.D. | The Jackson Laboratory
Andrey Antov, Ph.D., M.B.A. | The Jackson Laboratory

9:00 A.M.  Identifying Features that Predict Outcome from Cancer Sequencing Data
Jeff Chuang, Ph.D. | The Jackson Laboratory

9:30 A.M.  New Genomic Signatures in Triple Negative Breast Cancer
Edison T. Liu, M.D. | The Jackson Laboratory

10:15 A.M.  Break

10:30 A.M.  Breakout Session: Communicating with Patients About Cancer Somatic Testing
Paul Han, M.D. | Maine Medical Center Research Institute

Break out rooms:
Penobscot Bay, Owl’s Head, Spruce Head

12:00 P.M.  Lunch

SESSION 2:
Experiences in Implementing Precision Medicine
3.5 CME, 3.5pt PA MOC

1:00 P.M.  Integration of Genomics into Clinical Pathways
Andrew Hertler, M.D., F.A.C.P. | New Century Health

2:00 P.M.  Implementation of the Precision Medicine Program at InterMountain Health
Lincoln Nadauld, Ph.D., M.D. | InterMountain Health

3:00 P.M.  Breakout Session: Implementing Cancer Somatic Testing in Community Oncology Practice
Paul Han, M.D. | Maine Medical Center Research Institute

Break out rooms:
Penobscot Bay, Owl’s Head, Spruce Head

4:30 P.M.  Break
5:00 P.M.  Reception
6:00 P.M.  Dinner
7:30 P.M.  Cash Bar — JAX team available for Q&A

Sunday April 8, 2018

8:00 A.M.  Breakfast
8:45 A.M.  Networking and Free Time
10:30 A.M.  Hotel Check-out
11:00 A.M.  FORUM ADJOURNED
Certified CME Educational Activities

MAINE CANCER GENOMICS INITIATIVE (MCGI)

Overview
While somatic cancer panel tests are available clinically to oncologists, many questions remain on how to best integrate them into clinical practice. Major questions include 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 the clinician’s ability to understand the genomic information being provided by tests and to efficiently extract and evaluate actionable results. The lack of education in the theory and application of cancer genetics from most clinical training programs remains a principal barrier to widespread adoption of cancer genomic testing. The Maine Cancer Genomics Initiative (MCGI) aims to overcome these barriers. The MCGI Genomic Tumor Board session series functions as an initial educational opportunity for Maine oncology clinicians with the objectives outlined below.

Learning Objectives
After attendance participants should be able to:
• Recognize the application of Precision Medicine in clinical care
• Assess the use of Precision Medicine in practice; appraise the benefits and limitations of Precision Medicine for an individual patient case.
• Effectively communicate benefits and limitations of cancer somatic tests to patients.
• Identify and address barriers to effective implementation of cancer somatic testing into oncology practice in community settings.

Target Audience
Maine clinicians practicing oncology, involved in cancer patient care and/or cancer research.

Claiming CME Credit
After the Forum an electronic evaluation is sent to participants who signed the in-person hard copy sheet.

Accreditation and Joint Sponsorship
The 2018 MCGI Forum sessions are a certified Continuing Medical Education Activity sponsored by the Maine Medical Education Trust.

AMA Designation Statement: The Maine Medical Education Trust designates this live activity for a maximum of 6.5 AMA PRA Category 1 Credit(s)™ TM. Physicians should only claim credit commensurate with the extent of their participation in the activity.

CCMCE Accreditation Statement: Maine Medical Education Trust is accredited by the Maine Medical Association’s Committee on Continuing Medical Education and Accreditation through the partnership of Maine Medical Education Trust and The Jackson Laboratory. The Maine Medical Education Trust is accredited by the Maine Medical Association to provide CME activities for physicians.

Joint Sponsorship: This activity has been planned and implemented in accordance with the Essentials and Standard of the Maine Medical Associate Committee on Continuing Medical Education and Accreditation through the partnership of Maine Medical Education Trust and The Jackson Laboratory. The Maine Medical Education Trust is accredited by the Maine Medical Association to provide CME activities 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 1.5 Medical Knowledge MOC points and 5.0 Practice Assessment 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.

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

The Jackson Laboratory (www.jax.org) is an independent, nonprofit biomedical research institution with more than 1,800 employees. Headquartered in Bar Harbor, Maine, it has a National Cancer Institute-designated Cancer Center, a facility in Sacramento, Calif., and a genomic medicine institute in Farmington, Conn. 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.

American 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.
Forum Presenters
MAINE CANCER GENOMICS INITIATIVE (MCGI)

Andrey Antov, Ph.D., M.B.A.
Dr. Antov is the Program Director for MCGI. His healthcare professional experience includes basic research, medical device contracting and pharmaceutical. He has held a number of different roles from administration to consulting. Andrey holds a Ph.D. in immunobiology and a M.B.A. in marketing and strategy from Yale University as well as a M.Sc. in biochemistry and a M.Sc. in ecology from The Sofia University in Bulgaria.

Paul Han, M.D., M.A., M.P.H.
Dr. Han leads activities related to decision support and outcomes assessment for MCGI.

Andrew Hertler, M.D., F.A.C.P.
Dr. Hertler is the Chief Medical Officer of New Century Health, is responsible for the advancement of the company’s clinical quality initiatives, value-based strategies and utilization management policies and operations. A board certified oncologist who left clinical practice in 2014, he is a nationally recognized leader in oncology clinical practice. Dr. Hertler is a member of several American Society of Clinical Oncology committees, including the Clinical Practice, Quality of Care and Payment Reform Committees.

Prior to joining the New Century Health in 2014, Dr. Hertler was the Administrative Medical Director for Physician Practices at Maine General Medical Center and the Medical Director of the Harold Alfond Center for Cancer Care in Augusta, ME. He is a past president of the Northern New England Clinical Oncology Society. Earlier in his career, Dr. Hertler was Assistant Professor of Medicine in Hematology/Oncology at the Louisiana State University Medical School.

Edison T. Liu, M.D.
Dr. Liu is president and CEO of The Jackson Laboratory. Previously, he was the founding executive director of the Genome Institute of Singapore (2001–2011), and was the president of the Human Genome Organization (HUGO) from 2007 to 2013. Between 1997 and 2001, he was the scientific director of the National Cancer Institute’s Division of Clinical Sciences in Bethesda, MD, where he was in charge of the intramural clinical translational science programs. From 1987 to 1996, Dr. Liu was a faculty member at the University of North Carolina at Chapel Hill, where he was the director of the UNC Lineberger Comprehensive Cancer Center’s Specialized Program of Research Excellence in Breast Cancer, the director of the Laboratory of Molecular Epidemiology at UNC School of Public Health, chief of Medical Genetics, and the chair of the Correlative Science Committee of the national clinical trials group, CALGB. Dr. Liu is an international expert in cancer biology, genomics, human genetics, molecular epidemiology, and translational medicine. Dr. Liu’s own scientific research has focused on the functional genomics of human cancers, particularly breast cancer, uncovering new oncoproteins, and deciphering on a genomic scale the dynamics of gene regulation that modulate cancer biology. He has authored over 350 scientific papers and reviews, and co-authored two books. He obtained his B.S. in chemistry and psychology, and his M.D., at Stanford University. He served his internship and residency at Washington University’s Barnes Hospital in St. Louis, followed by an oncology fellowship at Stanford. From 1982 to 1987 he was at the University of California, San Francisco, at the G.W. Hooper Foundation.

Lincoln Nadauld, M.D., Ph.D.
Lincoln Nadauld, Ph.D. M.D. is the Executive Director of Precision Medicine and Precision Genomics at InterMountain Healthcare, an integrated healthcare system located in the Intermountain West. Dr. Nadauld oversees the clinical implementation of genomic cancer medicine across InterMountain Healthcare’s 22 hospitals and 180 physician clinics.

Dr. Nadauld completed his undergraduate education at Brigham Young University and went on to complete combined M.D./Ph.D. and clinical training at the University of Utah. He completed additional clinical training in Medical Oncology at Stanford University School of Medicine, where he also completed a postdoctoral fellowship in solid tumor genomics. While at Stanford, Dr. Nadauld received the prestigious Young Investigator Award from the American Society of Clinical Oncology, and a Career Development Award from the National Cancer Institute. He remains on the research faculty at Stanford University School of Medicine, where he is currently a board-certified medical oncologist at the Stanford University School of Medicine focusing on cancer genomics and personalized cancer medicine.

His work has been published extensively in journals such as Nature Medicine, Journal of Clinical Oncology, and Genome Medicine. He also serves on the Board of Directors of the Gastric Cancer Foundation and regularly reviews grant applications on behalf of the Department of Defense.

In 2016, Dr. Nadauld participated in the Precision Medicine Initiative Summit and round tables at the White House with former President Barack Obama. He also attended former Vice President Joe Biden’s Cancer Moonshot Summit, where the Oncology Precision Network (OPhEN), spearheaded by Dr. Nadauld, was mentioned among the Vice President’s remarks. OPhEN is a consortium of healthcare partners working to advance data-sharing in precision medicine, including genomic information and outcomes.

Jens Rueter, M.D.
Dr. Rueter is the Medical Director for MCGI. Dr. Rueter came to The Jackson Laboratory (JAX) in 2016 from Eastern Maine Medical Center Cancer Care, where he was the medical director for Eastern Maine Medical Center’s (EMMC) 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 collaborated with several JAX investigators and technologists 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.
CKB Capabilities

Promises of precision oncology have enabled progress in patient care, but with this comes the challenge of an overwhelming amount of data burying the proverbial needle in a haystack. Identifying the needle, or a potential therapeutic target, from the haystack of genomic data using traditional literature searches can be a tedious process. A knowledgebase, such as the JAX Clinical Knowledgebase (JAX-CKB), strives to structure the available literature into a format that is easy to navigate, while maintaining the integrity of the data. The JAX-CKB is an integrated knowledgebase that contains data on genomic variants, targeted therapies, clinical trials and evidence of therapeutic efficacy in oncology. These data are curated from the published literature into the JAX-CKB on a daily basis by a team of Ph.D. scientists, to ensure the most up-to-date content possible. On top of this database sits a searchable publicly accessible interface that enables easy searching on genes, variants, therapies and tumor types, as well as advanced searching for therapeutic evidence and clinical trials. In this way, the JAX-CKB can impact healthcare in real time. A user, such as an oncologist, has access to information at their fingertips that can aid in therapeutic decision making.

The JAX-CKB makes meaningful connections between genomic variants, therapeutic efficacy, and tumor type, and supports easy retrieval of information based on those connections. For example, a given genomic variant can be connected to a therapy and response in the context of a specific tumor type, supported by manually curated efficacy evidence annotation. A user searching on a specific gene variant will find an interpretation of that variant, if available, and will also be able to navigate to the related evidence data in the JAX-CKB. This allows the user to access the functional significance of a variant, and may provide some insight into potential therapeutic options. The JAX-CKB can function as an initial portal for somatic variant interpretation, and can complement the more extensive interpretation support provided in the setting of a genomic tumor board.

The JAX-CKB has over 20,000 users to date, spanning 107 countries, and continues to inform patient cancer care while contributing to development of technology and methodology to advance the field of oncology precision medicine. Key commercial collaborators are aiding sustainability of the JAX-CKB by leveraging machine-learning capabilities. Additionally, third-party software platforms have integrated the JAX-CKB to enable easy and scalable access for use in informing cancer patient care. The unique position of JAX, with world-renowned principal investigators, will continue to power the depth and quality of CKB, enabling the latest knowledge to flow from the front lines of cancer research to the clinician and patient.

**CLINICAL KNOWLEDGEBASE (CKB)**

**Basic Search**
- Explore by Gene
- Explore by Variant
- Explore by DrugClass
- Explore by Indication

**Advanced Search**
- Clinical Trial Search
- Evidence Search

**CKB OPEN ACCESS**
ckb.jax.org
### Overview of Gene and Variant Interpretation

All ActionSeq Plus reports contain gene and variant summaries based on interpretive findings. Gene descriptions cover fundamental clinical genetic information such as the encoded protein and its primary function, disease mechanism, common variant types, common tumors associated with aberrant forms of the gene and a brief overview of the therapeutic landscape. Similarly, variant descriptions include information such as the impacted protein domain, molecular function, pathogenic mechanism and tumors known to harbor the specific aberration (Figure 1). Evidence supporting the role of these genetic findings in cancer are collected from peer-reviewed literature, public databases and a variety of computational tools to assess clinical significance. Due to the rapid pace of oncology research, comprehensive re-assessment of variants is conducted on a six-month cycle to ensure the most accurate and current information is provided in a clinical report.

#### Gene Level

<table>
<thead>
<tr>
<th>Molecular</th>
<th>Variant Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gene function and role</td>
<td>Mechanism of oncology</td>
</tr>
<tr>
<td>Gene function and role</td>
<td>Mechanism of oncology</td>
</tr>
</tbody>
</table>

#### Variant Level

<table>
<thead>
<tr>
<th>Molecular</th>
<th>Variant Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanism of oncology</td>
<td>Known mechanism of action</td>
</tr>
<tr>
<td>Type of mutation as well as where it is located in the genome</td>
<td>Known cancer associations</td>
</tr>
</tbody>
</table>

### Overview of Clinical Interpretation

All ActionSeq Plus reports contain summaries for the targeted drugs included based on interpretive findings. Both approved and investigational drug descriptions cover fundamental pharmaceutical information such as the USAN generic name, brand name, drug class and mechanism of action in addition to an overview of the current approval status and prescribing indications. Additionally, www.fda.gov is reviewed and targeted clinical trials that potentially provide therapeutic avenues for the patient based on their genomic profile and pathology report are also included. Evidence supporting the role of these therapeutic findings in cancer are collected from www.fda.gov, NCCN clinical practice guidelines, peer-reviewed literature, public databases and JAX-CKB. Based on this information, variants with molecular classifications are clinically classified according to the joint AMP/ASCO/CAP variant interpretation guidelines.

### Figure 1: Stratification of evidence in variant classification

- Tier I: Strong clinical significance
- Tier II: Potential clinical significance
- Tier III: Unknown clinical significance
- Tier IV: Benign variants

### Figure 2: Examples of Tier I/II classification

- **Therapeutic**
  - BRAF V600E, T. melanoma
- **Prognostic**
  - BRAF V600E, T. melanoma
- **Diagnostic**
  - LOH mut in bile, T. CAP

### Overview of the types of evidence and their contribution to the different variant classes.

Preclinical can enrich support for a variant or justify class upgrade, but will not alone reach Tier II. FDA drug for patient/tumor profile is default Tier I. Tier IV variants (not displayed) are benign/likely benign and not included on the final report.

### Legend

- **V**: variant
- **T**: tumor type
- **Rx**: Drug
- **Dx**: disease
- **+**: increase
- **-**: decrease

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**References**


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**Team**

Andrew Hesse, M.S., M.B. (ASCP), clinical data analytics & reporting manager

Matthew Prego, clinical genomic analyst

Greg Lewis, Pharm.D., R.Ph., clinical genomic scientist

Bridgette Sisson, clinical genomic analyst

Pavalan Selvam, M.B.B.S., clinical genomic scientist
Overview of Analysis & Reporting Quality Processes

Quality Control (QC) and chain of custody are the hallmarks of clinically accredited laboratories such as the CLIA/CAP-accredited genomic testing lab at JAX. For Analysis & Reporting (A&R), we have taken a Quality by Design (QbD) approach integrating four primary QC steps with dynamic dataflow that affords us the flexibility to adapt to the case-by-case complexity of genomic testing in oncology. Patient data entering A&R has unique de-identified sample IDs generated by the LIMS system that are used to establish traceability from start to finish, tracking who worked on the samples, when they were worked on, the client and the assays performed. Samples are initially assessed for overall performance metrics and experimental controls, followed by review of the requisition, pathology report or other test result findings, which can fine-tune the relevance of clinical trials as well as the evidence for variants and therapies. Parameters such as hormone receptor status, previously identified genetic mutations, or other laboratory results that narrow focus of the somatic test results facilitates removal of non-eligible trials, inclusion/exclusion of known resistance mechanisms and higher specificity evidence to support a treatment recommendation will be recorded after the discussion for each case is reviewed. A&F Director Jens Rueter, M.D. Our genomic tumor board advisors have extensive experience in using clinical genomic test results to guide patient treatment. The conclusion of each meeting, minutes for the session detailing the discussion and potential treatment options are distributed to attendees.

Requisition and Pathology Report Review

Over the past few months, A&R CLIA briefs have touched on the quality control processes, variant classification system, as well as the molecular and clinical variant interpretation methods used to transform DNA sequencing data into the clinical test reports issued to physicians (figure 1). Another important component of this process is initial review of the medical history information gathered from the requisition, pathology report and other test result findings, which can fine-tune the relevance of clinical trials as well as the evidence for variants and therapies. Parameters such as hormone receptor status, previously identified genetic mutations, or other laboratory results that narrow focus of the somatic test results facilitates removal of non-eligible trials, inclusion/exclusion of known resistance mechanisms and higher specificity evidence to support a treatment recommendation will be recorded after the discussion for each case is reviewed. A&F Director Jens Rueter, M.D. Our genomic tumor board advisors have extensive experience in using clinical genomic test results to guide patient treatment. The conclusion of each meeting, minutes for the session detailing the discussion and potential treatment options are distributed to attendees.

The MCGI Genomic Tumor Board Sessions

The MCGI Genomic Tumor Board (MCGI GTB) sessions are a series of meetings coordinated as part of the Maine Cancer Genomics Initiative. During a genomic tumor board meeting, report results from clinical genomic tumor testing are discussed with a panel of expert external advisors, oncologists and pathologists from the MCGI network — clinical trial and genomic testing experts. The goal of the sessions is to provide interpretation support for treating clinicians and to allow the assembled community of M.D.s to discuss potential treatment options for the patient. MCGI GTB addresses a barrier to wider adoption of cancer genomic testing in clinical care — the interpretation of clinical genomic test results. The report includes a significant amount of curated data to give a clinician the highest amount of information to aid in treatment decisions. However, the process of interpreting this information and translating it into clinical care can be time consuming. The MCGI GTB is designed to facilitate this process. Clinicians attending the MCGI genomic tumor board sessions benefit from the input of a number of experts in the field in a discussion moderated by MCGI Medical Director Jens Rueter, M.D. Our genomic tumor board advisors have extensive experience in using clinical genomic tumor testing results to guide patient treatment. The conclusion of each meeting, minutes for the session detailing the discussion and potential treatment options are distributed to attendees.

GTB Session Format

Meeting attendance is offered in person at select MCGI study sites on a rotating basis and sessions are open virtually via conference call and presentation content sharing. Interested clinicians can attend in person at a study site, by teleconference or video-teleconference, allowing providers from across the State of Maine to access this educational activity without need for travel. Genomic Tumor Board Sessions, to date, have attracted a large number of participants from across the Maine Oncology Community. AMA PRA Category 1 Credits™ are offered for participation in GTB sessions. Reach out to us at mcki@jax.org for more information and to be added to the invitation list.

Genomic Tumor Board
20 Maine Cancer Genomics Initiative (MCGI) Forum

**Steering Committee**

**MAINE CANCER GENOMICS INITIATIVE (MCGI)**

- **Philip L. Brooks, M.D.**
  - Dr. Brooks practices at Maine Medical Center (MMC) and oversees their clinic at the Mt. Desert Island Medical Center. He is board certified in internal medicine, hematology, and medical oncology. Dr. Brooks received his M.D. from Temple University School of Medicine before completing his medical residency at Pennsylvania-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.

- **Robert Christian, M.D.**
  - Dr. Christian is the Maine Medical Center (MMC) Pathology Department Chief and Medical Director of MMC hematology.
  - Dr. Christian received his M.D. from the University of Connecticut School of Medicine. He holds board certifications in clinical molecular pathology, anatomic pathology, and clinical pathology.
  - He is board certified in internal medicine, hematology, and medical oncology.
  - Dr. Christian received his M.D. from the University of Connecticut School of Medicine. He holds board certifications in clinical molecular pathology, anatomic pathology, and surgical pathology.

- **Elizabeth (Betsy) Connelly, M.D.**
  - 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 of the American Society of Clinical Oncology and is on active staff at Waldo County and Pen Bay Medical Center. She received her M.D. from Texas College of Osteopathic Medicine followed by a residency at MCGI, and a fellowship with the Cleveland Clinic Foundation in medical oncology/hematology.

- **Christopher Darus, M.D.**
  - Dr. Darus practices gynecologic oncology at Maine Medical Center. He holds board certification from the American Board of Obstetrics and Gynecology and specializes in gynecologic oncology. Dr. Darus received his M.D. from Wright State University School of Medicine, followed by a residency at University of Colorado Health Sciences Center and a fellowship at University of Virginia Medical Center.

- **Nichollette Erickson, M.D.**
  - Dr. Erickson practices Hematology-Oncology Associates in Lewiston, ME. She is board certified in Hematology and Medical Oncology. She received her M.D. from Medical College of Virginia followed by a residency in Internal Medicine and a fellowship with the University of Virginia Health Sciences Center in Hematology-Oncology.

- **Peter Georges, M.D.**
  - 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 the University of the West Indies. He then completed an internship in the medical school followed by a residency in Internal Medicine at University of Medicine and Dentistry in Camden, NJ. He then completed a fellowship in medical oncology at the University of Pennsylvania Medical Center.

- **Roger C. Inhorn, M.D., Ph.D.**
  - Dr. Inhorn is the Chief of Oncology at Mercy Hospital in Portland, Maine. 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 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 to assume this position. He has a special interest in breast cancer and clinical trials.

- **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. 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, DC. He received his medical degree from Maulana Azad Medical College, New Delhi, India and then did his internal medicine residency and chief residency at the University of Medicine and Dentistry of South Carolina before completing his fellowship in medical oncology at Georgetown University/MedStar Washington Hospital Center. His interests include targeted therapies and immunotherapy.

- **Mayur K. Movalia, M.D.**
  - Dr. Movalia is a Pathologist with Dahl Chaos Pathology Associates in Bangor, ME. He holds board certifications in pathology and nuclear medicine. He has served on the Maine Board of Pathology in anatomic and clinical pathology and hematology.

- **Antoine Harb, M.D.**
  - Dr. Harb practices oncology at Eastern Maine Medical Center (EMMC) and is affiliated with Blue Hill Memorial Hospital. He is board certified in hematology, internal medicine, and medical oncology. Dr. Harb received his M.D. from Saint Joseph University, where he also served his residency in internal medicine. Later Dr. Harb did an additional residency at University of Buffalo followed by a fellowship in hematology/oncology at UM DMC (University of Medicine and Dentistry of New Jersey)-Cooper Medical Center.

- **G. Richard Polkinghorn, M.D.**
  - Dr. Polkinghorn is a practicing oncologist at Maine Medical Center and Mid Coast Medical Center for 14 years prior to coming to Maine General Medical Center. His professional interests include breast cancer and lung cancer involving novel and targeted therapies. Dr. Polkinghorn received his M.D. from Case Western Reserve University followed by an internship and residency in internal medicine at UCLA Medical Center in Los Angeles, CA, and a fellowship in medical oncology at Harvard Medical School in Boston, MA. He has a special interest in breast cancer and clinical trials.

- **Nadia Rajack, M.D.**
  - Dr. Rajack is the Medical Director at the Jefferson Cary Cancer Center. She takes a special interest in quality improvement initiatives with the goal of delivering high-quality care. She is a rural oncology practice setting, Dr. Rajack received her undergraduate B.B.S. degree from the University of the West Indies. She went on to pursue postgraduate training at SUNY Downstate Health Science Center in Brooklyn, NY. She completed the American Society of Clinical Oncology fellowship at Mount Sinai Medical Center in New York City. Dr. Rajack is board certified in internal medicine, hematology, and medical oncology.

- **Karen Rasmussen, Ph.D.**
  - Dr. Rasmussen is a Director of Molecular Genetics at Spectrum Medical Group. She has experience in clinical molecular research and interpretation of molecular genetic assays, including next-generation sequencing and gene expression profiling. Dr. Rasmussen has provided 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 mutations 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.

- **Mark Skacel, Ph.D.**
  - Dr. Skacel is a Pathologist at Dahl-Chase Pathology Associates in Bangor, ME. He holds board certifications from the American Board of Pathology in anatomic and clinical pathology and hemopathology. He takes a special interest in the areas of gastrointestinal pathology, genitourinary pathology, soft tissue pathology, hemopathology, and molecular pathology. Dr. Skacel received his M.D. followed by an internship at Paley Hospital 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, hemopathology, and surgical pathology.

- **Christian Thomas, M.D.**
  - Dr. Thomas joined New England Cancer Specialists as a physician and the Director of Clinical Research in 2015. His clinical focus is on thoracic cancers (lung cancer, esophageal cancer) as well as GU cancers (prostate, bladder, kidney cancers). He also serves as an advisor to the American Society of Clinical Oncology and the Northern New England Clinical Oncology Society and CMS/Medicare. Dr. Thomas completed his medical training at University of California in Los Angeles, CA, and a fellowship in medical oncology at the University of California in Santa Monica. Dr. Thomas is board certified in internal medicine/hematology and oncology.

- **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 California followed by residencies at University of California, 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 Eastern Maine Medical Center & 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.

- **Scott 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 subspecialty 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.

- **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. 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, DC. He received his medical degree from Maulana Azad Medical College, New Delhi, India and then did his internal medicine residency and chief residency at the University of Medicine and Dentistry of South Carolina before completing his fellowship in medical oncology at Georgetown University/MedStar Washington Hospital Center. His interests include targeted therapies and immunotherapy.

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MCGI Timeline

160 enrolled & >80 tested patients
16 GTBs run
58/78 oncologists participating
13/16 oncology sites open

1st Genomic Tumor Board (GTB) run
Aug ’17
1st Patient registered
Jul ’17
1st Practice opened for the study
Jun ’17
1st Oncologist enrolled
Jun ’17
Study Protocol approved by IRB
May ’17
MCGI Forum - all oncology practices participated and MCGI office open
Feb ’17
MCGI Office staffed
Jan ’17
Community-based Clinical Steering Committee formed
Oct ’16

1st Patient registered
Jul ’17
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Oct ’16

MCGI Network

16
HOSPITAL-BASED PRACTICES
AFFILIATED WITH 2 HEALTHCARE SYSTEMS

1
PRIVATE PRACTICE

78
ONCOLOGISTS

~9000
NEW CANCER PATIENTS PER YEAR

*numbers as of March 2018
“Leading the Search for Tomorrow’s Cures”
— THE JACKSON LABORATORY

“Don’t Tell Me, Show Me”
— HAROLD ALFOND