



## AMP 2018 Committee and Subdivision Annual Reports

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Solid Tumors Subdivision Chair	Roger D. Klein, MD, JD
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

## AMP Awards Committee Annual Report, 2018

### COMMITTEE MEMBERS:

Chair	Victoria M. Pratt, PhD
Member	Helen Fernandes, PhD
Member	Margaret L. Gulley, MD
Member	David R. Hillyard, MD
Member	Ted E. Schutzbank, PhD

### PURPOSE SUMMARY:

The Awards Committee consists of 5 members (4 appointed) who oversee the nomination and selection of the recipient of the Award for Excellence in Molecular Diagnostics, the Jeffrey A. Kant Leadership Award, and, if determined applicable, the recipient(s) of the Meritorious Service Award(s). The Committee evaluates the current awards, addresses the need for new awards, and conducts the formal nomination process for potential award recipients.

The President-Elect serves as the Chair of the Awards Committee. The remaining 4 committee members are appointed by the Board and serve rotating two-year terms. The annual selection of 2 incoming committee members is conducted by the committee and the candidates' names are brought forward for Board approval and appointment.

### Timeline for AMP Awards

The Awards Committee coordinated the timing of the AMP recognition awards as follows:

November through February: Nominations from the Board, Committees, and Membership

March: Review and selection by Awards Committee

April through May: Notification of recipients

May through September: Assess need for new recognition awards, if any

### Award Recipients

- 2018 Jeffrey A. Kant Leadership Award: Roger D. Klein, MD, JD
- 2018 Meritorious Service Award: Kevin C. Halling, MD, PhD
- 2020 Award for Excellence in Molecular Diagnostics: To be announced

## AMP Clinical Practice Committee Annual Report, 2018

### COMMITTEE MEMBERS:

Chair	Antonia R. Sepulveda, MD PhD
Genetics Subdivision Representative	Jess F. Peterson, MD
Genetics Subdivision Representative	Josh Deignan, PhD
Hematopathology Subdivision Representative	Keyur P. Patel, MD PhD
Hematopathology Subdivision Representative	Noah A. Brown, MD
Infectious Diseases Subdivision Representative	Susan Butler-Wu, PhD
Infectious Diseases Subdivision Representative	Kenneth L. Muldrew, MD
Informatics Subdivision Representative	Mark Boguski, MD PhD
Informatics Subdivision Representative	Justin Zook, PhD
Solid Tumors Subdivision Representative	Kandelaria Rumilla, MD
Solid Tumors Subdivision Representative	Pranil Chandra, DO
Junior Member	Alex Greninger, MD PhD
Junior Member	Megan Wachsmann, MD

### PURPOSE SUMMARY:

The Clinical Practice Committee (CPC) is comprised of AMP members with expertise in one or more of the molecular specialties: infectious diseases, hematopathology, solid tumors, genetics and informatics. Its purpose is to address the challenges of clinical laboratories and, therefore, improve the service we provide. Separate working groups plan, organize and coordinate efforts such as practice guidelines, sample exchanges, reporting surveys, validation and quality control measures, and advocate for policies that will advance the practice of high quality clinical molecular pathology services.

### Publications

- **January 2018:** *Standards and Guidelines for Validating Next-Generation Sequencing Bioinformatics Pipelines: A Joint Consensus Recommendation of the Association for Molecular Pathology and the College of American Pathologists.* Led by Somak Roy and Alexis Carter with Christopher Coldren, Arivarasan Karunamurthy, Nefize Sertac Kip, Eric Klee, Stephen Lincoln, Annette Leon, Mrudula Pullambhatla, Robyn Temple-Smolkin, Karl Voelkerding and Chen Wang, *The Journal of Molecular Diagnostics.* (<https://doi.org/10.1016/j.jmoldx.2017.11.003>)
- **February 2018:** *Recommendations for Clinical CYP2C19 Genotyping Allele Selection: A Report of the Association for Molecular Pathology.* Led by Victoria Pratt with Andria del Tredici, Houda Hachad, Yuan Ji, Lisa Kalman, Stuart Scott and Karen Weck, *The Journal of Molecular Diagnostics.* (<https://doi.org/10.1016/j.jmoldx.2018.01.011>)
- **March 2018:** *Updated Molecular Testing Guideline for the Selection of Lung Cancer Patients for Treatment With Targeted Tyrosine Kinase Inhibitors: Guideline From the College of American Pathologists, the International Association for the Study of Lung Cancer, and the Association for Molecular Pathology.* Led by Neal I. Lindeman with Philip T. Cagle, Dara L. Aisner, Maria E. Arcila, Mary Beth Beasley, Eric H. Bernicker, Carol Colasacco, Sanja Dacic, Fred R. Hirsch, Keith Kerr, David J. Kwiatkowski, Marc Ladanyi, Jan A. Nowak, Lynette Sholl, Robyn Temple-Smolkin,

Benjamin Solomon, Lesley H. Souter, Erik Thunnissen, Ming S. Tsao, Christina B. Ventura, Murry W. Wynes and Yasushi Yatabe. Simultaneously published in *The Journal of Molecular Diagnostics* (<https://doi.org/10.1016/j.jmoldx.2017.11.004>), *American Journal of Clinical Pathology* and *Journal of Thoracic Oncology*.

- *Clinical Significance of DNA Variants in Chronic Myeloid Neoplasms (CMNs): A Report of the Association for Molecular Pathology*. Led by Rebecca McClure, Mark Ewalt, Jennifer Crow, Robyn L. Temple-Smolkin, Mrudula Pullambhatla, Rachel Sargent, and Annette S. Kim, *The Journal of Molecular Diagnostics*. (<https://doi.org/10.1016/j.jmoldx.2018.07.002>)

### **Clinical Practice Guidelines, Working Groups, and Task Forces**

- *Recommendations for Clinical CYP2C9 Genotyping Allele Selection: A Report of the Association for Molecular Pathology*. AMP-led working group chaired by Victoria Pratt, Larisa Cavallari, Lisa Kalman, Andria Del Tredici, Houda Hachad, Yuan Ji, Stuart Scott, Ann Moyer (CAP representative), Karen Weck and Michelle Whirl-Carrillo. Manuscript submitted to *The Journal of Molecular Diagnostics*.
- **In development:** *AMP Recommendations for Laboratory Detection and Interpretation of Intragenic (Exonic Level) Deletions/Duplications*. Chaired by Madhuri Hegde with Elaine Lyon, Carolyn Sue Richards and Birgit Funke.
- **In development:** *Variant Interpretation Test Across Labs (VITAL)*. Chaired by Elaine Lyon with Madhuri Hegde, Julie Gastier-Foster, Carolyn Sue Richards, Sherri Bale and Glenn Palomaki. Project supported by an unrestricted educational grant from QIAGEN, Inc.
- **In development:** *AMP Guidance for Non-standard or Emerging Applications: Liquid Biopsy*. Chaired by Christina Lockwood with Laetitia Borsu, Christopher Gocke, Milena Cankovic, Kandelaria Rumilla, Meera Hameed, Jason Merker (CAP representative), Geoffrey Oxnard (ASCO representative), Jacquelyn Reuther and Antonia Sepulveda.
- **In development:** *AMP Guidance/Standards for NGS Germline Variant Confirmation*. Chaired by Kristy Crooks with Linda Jo Bone Jeng, Avni Santani, Diana Mandelker, Steve Lincoln, Ryan Schmidt and Kelly Hagman (NSGC representative).
- **In development:** *AMP NGS utility for assessment of T/B-cell clonality*. Chaired by David Viswanatha with Keyur Patel, Maria Arcila, Timothy Greiner, David Wu, Frank Kuo (SH representative), Joseph Khoury and Habibe Kurt.
- **In development:** *AMP report on New Frontiers in Infectious Diseases Multiplex Testing*. Chaired by Michael Lewinski with Susan Butler-Wu, Kevin Alby, Jennifer Dien Bard, Alex Greninger, Esther Babady (PASCV representative), Duane Newton (ASM representative), Kimberly Hanson (IDSA representative) and Samia Naccache.

- **In development:** *AMP Guidance/Standards for Tumor Mutational Burden Testing by Molecular Methods*. Chaired by Larissa Furtado with Jeffrey Gregg, Benjamin Kipp, Jonathan Nowak, Susan Hsiao, Antonia Sepulveda, Daniel Dolderer, Jeremy Segal, Lauren Ritterhouse and Ahmet Zehir.
- **In development:** *AMP report on Implementation of AMP/ASCO/CAP Reporting and Interpretation of Somatic Sequence Variants Recommendations in Clinical Practice*. Chaired by Marilyn Li and Marina Nikiforova with Somak Roy, Cindy Vnencak-Jones and Scott Turner.
- **In development:** *Appropriate Collection and Handling of Thoracic Specimens for Laboratory Testing*. The College of American Pathologists (CAP) in collaboration with the American College of Chest Physicians (CHEST), Association for Molecular Pathology (AMP), American Society for Cytopathology (ASC), American Thoracic Society (ATS), Pulmonary Pathology Society (PPS), Papanicolaou Society of Cytopathology (PSC), Society of Interventional Radiology (SIR), and Society for Thoracic Radiology (STR). AMP Expert Panelist and Steering Committee member Jan Nowak; AMP Expert Panelist Dara Aisner.
- **In development:** *Diagnostic Testing for Diffuse Gliomas*. The College of American Pathologists in Collaboration with Association of Neuropathologists (AANP), American Society of Clinical Oncology (ASCO), Association for Molecular Pathology (AMP), Society for Neuro-Oncology (SNO), AMP Expert Panelists Peter Canoll and Dolores Lopez-Terrada.
- **In development:** *Checkpoint Inhibitor Testing in Body Sites Other Than Lung*. The College of American Pathologists in Collaboration with the American Society of Clinical Oncology (ASCO) and Association for Molecular Pathology (AMP). AMP Expert Panelist Antonia Sepulveda.

#### **Representatives to Other Organizations**

- CAP Molecular Oncology Committee, Daniel Farkas
- ACMG Interpretation of Sequence Variants Update workgroup, Scott Turner
- NIST Genome in a Bottle Steering Committee, Monica Basehore
- ACMG Incidental Findings in Inherited Diseases Update Workgroup, Carolyn Sue Richards
- CAP/AMP/ASCO Roundtable, Marina Nikiforova
- ACMG ClinGen Somatic Cancer Clinical Domain Workgroup, Marilyn Li
- CAP/ASCP /ASCO HER2 Testing in Gastroesophageal Adenocarcinoma Guideline project, Advisory Panelist, William Sukov
- ASCO-CAP Liquid Biopsies White paper project, Christina Lockwood
- CAP NGS Test Validation/Metrics manuscripts Working group, Marina Nikiforova
- FNIH Biomarkers Consortium Steering Committee for Inflammation and Immunity, Maria Bettinotti
- FNIH Biomarkers Consortium Steering Committee for Metabolic Diseases, Ming Rong
- FNIH Biomarkers Consortium Steering Committee for Cancer, Snehal Patel
- American Society of Cytopathology, Sinchita Roy-Chowdhuri
- American Society for Microbiology (ASM) Next Generation Sequencing Coalition, Benjamin Pinsky
- CAP Personalized Healthcare Committee Incidental Findings in the Context of Tumor Genomic Evaluations Project Workgroup, Pranil Chandra

- CAP Cytopathology Committee/Personalized Healthcare Committee Pre-analytics for Precision Medicine Cytology Preparations for Molecular Testing Project Team, Nikoletta Sidiropoulos and Jane Gibson
- Medical Device Innovation Consortium (MDIC) Somatic Reference Samples working group, Feras Hantash
- CAP Genomic Medicine Resource Committee, Ryan Schmidt
- Clinical Laboratory Standards Institute (CLSI) Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine, 2nd Edition (MM09) Working Group, Avni Santani

#### **Additional Accomplishments**

- AMP hosted a Reference Materials Forum prior to the 2018 Annual Meeting on Tuesday, October 30, 2018 with representatives from CDC, NIST, and NCI.
- Multiple CPC and Scientific Subdivision members hosting or presenting in AMP Webinar events.
- CPC members actively brainstormed and launched five new projects in 2018. Several additional project ideas are awaiting to be launched in the near future.
- The AMP Test Directory continues to be populated with additional labs and tests.
- Multiple early career AMP members working on CPC working groups as Junior members.

*Congratulations on a job well done!*

#### **Requests from the CPC:**

- We encourage all AMP members to alert the Board or appropriate committees when laboratory guidelines or recommendations are opened for public comment.
- We encourage AMP members to actively contribute to calls for information from the CPC.
- Suggestions from AMP members for new CPC initiatives are always welcome! Visit [http://amp.org/committees/clinical\\_practice/](http://amp.org/committees/clinical_practice/) for more details.

## AMP Economic Affairs Committee Annual Report, 2018

### COMMITTEE MEMBERS:

Chair	Samuel K. Caughron, MD
Vice Chair, New Codes & Pricing	Anthony N. Sireci, MD, MS
Vice Chair, Coverage	Pranil Chandra, DO
Member	Dara L. Aisner, MD, PhD
Member	Aaron D. Bossler, MD, PhD
Member ( <i>Ex Officio</i> – President)	Kojo Elenitoba-Johnson, MD
Member	Andrea Ferreira-Gonzalez, PhD
Member	Stephanie Hallam, PhD
Member	Mathew Hiemenz, MD
Member	Lloyd Hutchinson, PhD
Member	Loren Joseph, MD
Member ( <i>Ex Officio</i> – PRC Chair)	Jordan Laser, MD
Member	Elaine Lyon, PhD
Member	Jay L. Patel, MD
Member ( <i>Ex Officio</i> – President-Elect)	Victoria Pratt, PhD
Member	Richard Press, MD, PhD
Member	Aparna Rajadhyaksha, MD
Member	Ester Stein, MBA
Member	Katherine Tynan, PhD
Junior Member	Oana C. Rosca, MD
Committee Advisor	Jan A. Nowak, MD, PhD

### PURPOSE SUMMARY:

The Economic Affairs Committee (EAC) addresses, advises, and educates the AMP Board of Directors, membership, payors, legislators, and the public on economic issues of importance to the field of molecular pathology; prepares documents of importance to the Centers for Medicare & Medicaid Services (CMS); and develops and advocates for sound economic policies that promote the availability to patients of high quality molecular pathology services. The Committee's scope encompasses short and long-term issues associated with the coding for molecular procedures, utilization of and coverage for molecular pathology, the determination of test pricing, and the potential economic impact of public policy decisions on molecular pathology practice. The Committee interacts with the American Medical Association and other interested organizations in order to achieve common goals.

### 2018 ACTIVITIES:

CMS, who has oversight of Medicare, has increasingly either denied coverage or reduced payment for many medically necessary molecular pathology tests. The increasing restrictions create a challenging environment for clinical practice and for innovators to translate new genomic discoveries into clinical applications. AMP continues to work with the broader professional community to address policy challenges and opportunities, and engage and inform payors aiming to achieve rightful reimbursements for appropriate patient care services.

#### **National Coverage Determination for NGS for Advanced Cancer for Medicare Beneficiaries**

In late November 2017, CMS released a proposed National Coverage Determination (NCD) for next generation sequencing (NGS) for advanced cancer. The proposed policy had the potential to restrict laboratories' ability to obtain Medicare coverage for NGS-based tests for oncology. After working with stakeholders to receive a comment period deadline extension, the EAC worked diligently to assess the content of the NCD and develop a comprehensive response. Additionally, EAC educated AMP members, relevant stakeholders, and organizations

on this policy and urged them to comment. CMS received over 315 comments, with the majority of the comments expressing concern and seeking clarification from CMS on the proposed policy.

The final policy released by CMS in March was significantly different than the proposed policy. The coverage indications for patients and the laboratories performing NGS based tests were expanded to include more patients; and, patients may now receive an NGS test more than once when certain conditions are met. Coverage for NGS-based tests were expanded to include FDA cleared and approved tests, rather than only FDA approved, with a companion diagnostic indication. Moreover, the coverage with evidence development and non-coverage portions of the proposed policy were removed. A new section was added that allows Medicare Administrative Contractors (MACs) to determine coverage of other NGS-based tests for cancer when the test is performed in a CLIA-certified laboratory. The EAC continues to monitor implementation of this policy to ensure that patient access to NGS tests continues and that MACs continue to develop LCDs for appropriate NGS testing for advanced cancer patients.

### **Protecting Access to Medicare Act (PAMA)**

Under the Protecting Access to Medicare Act (PAMA), laboratories are required to report HCPCS laboratory codes, associated private payor rates, and volume data if they have more than \$12,500 in Medicare revenues from laboratory services on the Clinical Laboratory Fee Schedule (CLFS) and receive more than 50% of their Medicare revenues from laboratory and physician services during a collection period. Additionally, under PAMA, CMS is required to establish a coding system for laboratories or manufacturers that want to specifically identify their test (such as Clinical Diagnostic Laboratory Tests or Advanced Diagnostic Laboratory Tests). To fulfill this requirement, AMA generated the Proprietary Laboratory Assay (PLA) codes. In 2018, this new set of codes continues to undergo incorporation into the CMS pricing exercise and Medicare coverage policies. The PLA codes have experienced some hurdles during these processes, which has led to a handful of unexpected problems. To assist laboratories with their PLA codes, AMP is working with both CMS and AMA to help address these problems and to propose solutions moving forward.

Established by PAMA, the Advisory Panel on Clinical Diagnostic Tests (The Panel) advises CMS on various issues under PAMA including payment rates for new tests, including whether to use the “crosswalk” or “gapfill” methodology for initial price determination; application of market rates for established tests; and evaluation and designation of tests as “advanced laboratory diagnostic tests” as defined by the Act. Several AMP members are members of The Panel, with **Drs. Aaron Bossler** and **Pranil Chandra** nominated by AMP to serve.

In 2018, a joint EAC and PRC task force of volunteers was convened to monitor the effect of PAMA on clinical laboratories and to continue to develop AMP policy recommendations and possible solutions. CMS solicited stakeholder feedback in an attempt to better understand applicable laboratories’ experiences during the first reporting period under PAMA, including the data reporting, data collection, and other compliance requirements. In our comments to the agency, AMP welcomed the opportunity to work with the agency to ensure that PAMA is implemented successfully and accurately represents the market rates paid for laboratory tests. However, AMP expressed to CMS significant concerns about the process used and rates set from the first reporting period, which have resulted in inaccurate, inequitable and, in some instances, frankly absurd pricing, and encouraged CMS to revisit the reporting requirements and process, as well as address data integrity concerns. Additionally, AMP continues to discuss solution options with other professional organizations.

### **Clinical Lab Fee Schedule for Calendar Year 2019**

During the summer, AMP provided written and oral comments to CMS on the Calendar Year 2019 Clinical Lab Fee Schedule (CY2019 CLFS). **Dr. Anthony Sireci** represented AMP at the annual CLFS meeting at CMS on June 25, 2018. He presented crosswalk recommendations for the new 2019 CLFS molecular pathology procedures, genomic sequencing procedures (GSPs), and microbiology procedures. There were over 45 molecular procedures on which AMP provided crosswalk recommendations.



In June 2018, CMS released CY2019 Preliminary Gapfill Determinations for a number of codes. AMP expressed concern that the preliminary national limitation amounts (NLAs) did not accurately reflect the value of these procedures. AMP provided information to CMS on the work and resources to perform these procedures and urged CMS to seriously consider the comments provided by AMP and other stakeholders during the preliminary determination comment period as undervaluation of these services threatens patient access to care.

In late September, CMS released the CY2019 CLFS Preliminary Determinations for the new and reconsidered services. AMP appreciates that many of the preliminary CMS determinations align with AMP and other laboratory organizations' recommendations. However, we are concerned that some of the preliminary recommendations provided by CMS differ vastly from both Advisory Panel recommendations and stakeholder input and, in many cases, do not represent the best options for crosswalks. AMP provided detailed comments to CMS on the preliminary determinations in mid-October. Pricing determinations will be finalized in later this year.

### **Educational Initiatives**

Healthcare economics is a complex ecosystem comprised of players in the provider space (doctors, patients, professional societies), healthcare leaders, government agencies and payors in the private sector. Navigating this space can be very difficult but is vital for molecular professionals, particularly laboratory directors, to understand. In 2017, a workgroup formed within the EAC, led by **Drs. Dara Aisner and Anthony Sireci**, to develop a manuscript that builds off of previous efforts by the EAC to educate others on molecular diagnostic coding, coverage, and reimbursement process, procedures, and policies. We anticipate that the manuscript will be submitted for publication by the end of 2018.

Additionally, the EAC New Codes Committee held a live webinar that explained the history of CPT® coding, how to apply for either a CPT® or a PLA code and the role of AMP in this process. The webinar, titled "the ABCs of CPT® Coding," was moderated by Training and Education Chair, **Dr. Cecilia Yeung**, and presented by three EAC members, **Drs. Aaron Bossler, Victoria Pratt, and Anthony Sireci**. The webinar was very well attended. A written tutorial based on the information provided during the webinar is available in the Advocacy section of AMP's website. In addition, the webinar is available at [educate.amp.org](http://educate.amp.org).

### **Medicare Administrative Contractors' (MACs) Local Coverage Determinations (LCDs)**

AMP continues to advocate with CMS regarding coverage policy actions taken by Medicare Administrative Contractors (MACs). Thus far in 2018, AMP has provided responses to various MACs for over 15 draft local coverage determinations (LCDs). Many of the coverage policies released contained substantial problems, either denying or narrowing coverage for important molecular pathology procedures. Currently, AMP is in the process of drafting comments to additional draft LCDs which will be submitted to the MACs in late November. Monitoring emerging policies continued to be a major focus of the committee and was led by **Dr. Pranil Chandra**. AMP and the College of American Pathologists (CAP) collaborated to draft joint responses. The EAC is very thankful to the AMP members who volunteered their time and subject matter expertise to assist in responding to the diverse coverage policy issues.

### **Capitol Hill and Agency Activity**

Throughout 2018, AMP met with numerous offices on Capitol Hill regarding concerns about Medicare coverage and pricing, including majority and minority staff of Senate Finance and House Ways and Means Committees. Additionally, AMP met with CMS representatives from both the pricing and coverage groups about concerns regarding the national coverage determination on NGS, pricing process for PLA codes, and gapfill pricing transparency.

### **CPT Codes**

The EAC New Codes and Pricing Subcommittee, led by **Dr. Anthony Sireci**, advises and reviews new CPT code applications submitted to the Pathology Coding Caucus (PCC) and the Molecular Pathology Advisory Group (MPAG). Throughout the year, the Subcommittee also submits new CPT code change proposals to AMA. In 2018, AMP submitted one CPT code change application. The subcommittee also provided input to CMS' National

Correct Coding Initiative (NCCI) to help ensure national correct coding methodologies of procedure to procedure (PTP) and medically unlikely edits (MUEs) for molecular procedures.

#### **Outside Organization Involvement**

- **Dr. Jan Nowak** serves on the CPT Editorial Panel
- **Drs. Victoria Pratt, Jan Nowak, Aaron Bossler** serve on the AMA Proprietary Laboratory Analyses Technical Advisory Group (PLA-TAG)
- **Dr. Aaron Bossler** serves on the PCC, with **Dr. Anthony Sireci** serving as the technical advisor.
- The AMA Molecular Pathology Advisory Group (MPAG) includes AMP members **Drs. Aaron Bossler, Roger Klein, Elaine Lyon, and Victoria Pratt.**

## AMP Finance Committee Annual Report, 2018

### COMMITTEE MEMBERS:

Chair	Daniel E. Sabath, MD, PhD
President	Kojo S. J. Elenitoba-Johnson, MD
President-Elect	Victoria M. Pratt, PhD
Past President	Federico A. Monzon, MD
Member	Sharathkumar Bhagavathi, MD
Member	Gail H. Vance, MD
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

The Finance Committee oversees AMP's financial affairs, including reviewing quarterly revenue & expense reports and recommending to the Board for approval an annual operating budget and the investment policy for the Association's assets.

## AMP International Affairs Committee Annual Report, 2018

### COMMITTEE MEMBERS:

Chair and Membership Affairs Liaison (Middle East)	Rami Mahfouz, MD
Member (Africa)	Adewunmi Oluseye Adeoye, MD
Member and Professional Relations Liaison (Europe)	David E. Barton, PhD
Member (East Asia)	Yoon-La Choi, MD, PhD
Member (Latin America)	Renata A. Coudry, MD, PhD
Member and India Affiliate Liaison (South Asia)	Bibhu R. Das, PhD
Member (Australia)	Andrew P. Fellowes, PhD
Member and Korea Affiliate Liaison (East Asia)	Chang-Ho Jeon, MD, PhD
Member (Southeast Asia)	Lynette Lin Ean Oon, MD
Member and Training & Educ Liaison (Latin America)	Roberta Sitnik, PhD
Member and Hong Kong Affiliate Liaison (East Asia)	Lei Po (Chris) Wong, PhD
Member (Africa)	Denis Francis York, PhD
German Affiliate Coordinator	Silke Lassman, PhD
Italy Affiliate Coordinator	Massimiliano (Max) M. Corsi Romanelli, MD, PhD
Advisor	Helen Fernandes, PhD
Advisor	Jin-Yeong Han, MD, PhD

### PURPOSE SUMMARY:

The International Affairs Committee (IAC):

- Enhances AMP as an international organization
- Promotes AMP's vision and mission internationally
- Facilitates international presence and participation in AMP groups and programs
- Expands excellence in education and advocacy on behalf of patients, clinicians, and lab professionals to an international audience
- Enables the interaction of scientists and molecular pathologists in the various parts of the world

### 2018 ACTIVITIES:

- AMP Europe 2018 meeting was held on April 30- May 2, 2018 in Rotterdam, The Netherlands
- AMP 2018 Annual Meeting Events:
  - Molecular Tumor Boards luncheon
- Selected International Trainee Travel Awardees from Brazil, Germany and India.
- Awarded International Membership Grants to 4 scientists from India.
- Welcomed first Institutional Affiliate member, the American University of Beirut Medical Center.
- AMP speakers supported at international (non-U.S.) conferences:
  - Jacqueline Payton, MD, PhD at the 2018 Annual Meeting of Korean Society for Genetic Diagnostics, Seoul, Korea. Organizing Committee AMP Member: Chang-Ho Jeon, MD, PhD.
  - Charles Hill, MD and Laura Tafe, MD at the International Academy of Pathology, Arab Division, XXXII Congress, Dead Sea, Jordan. Organizing Committee AMP Member: Rami Mahfouz
- Created an "Establishing a Molecular Laboratory – Best Practices Around the Globe" Pocket Card. Will be debuted at the AMP Global 2019 in Hong Kong.

## AMP Membership Affairs Committee Report, 2018

### COMMITTEE MEMBERS:

Chair	Ron M. Przygodzki, MD
Member	Betsy A. Bove, PhD
Member	Yi Ding, MD, PhD
Member	Midhat S. Farooqi, MD, PhD
Member	Katherine Geiersbach, MD
Member	Lisa M. Haley, MS
Member	Giovanni Insuasti-Beltran, MD
Member	Cynthia L. Jackson, PhD
Member	Wanda Reygaert, PhD
Member	Angshumoy Roy, MD, PhD
Member	Yaolin Zhou, MD
International Affairs Liaison	Rami Mahfouz, MD

### PURPOSE SUMMARY:

The AMP Membership Affairs Committee (MAC) provides recommendations to Board and assistance to other committees regarding matters of membership and professional development. The committee plays an important role in helping AMP respond to the needs of its members and in facilitating the development of leaders in the field of molecular pathology.

### Responsibilities

- Assesses and makes recommendations that will enhance the professional development of AMP members and the benefits of AMP membership
- Provides regular and timely notification to members about opportunities for special projects within or outside of standing committees and subdivisions
- Facilitates leadership development for AMP through various initiatives such as the *ad hoc* and junior member volunteer process
- Receives requests from Chairs or Board for *ad hoc* members to work on projects and manages the volunteer application process
- Surveys member volunteers annually regarding their volunteer service experiences
- Surveys the membership periodically regarding how well their membership in AMP is meeting their needs and how well AMP is serving the needs of the profession
- Conducts a member recruitment and retention program

### 2018 ACTIVITIES:

- Disseminated and assessed responses to the biennial Member Satisfaction Survey
- Selected the winners of the Technologist Travel Awards and Diversity Assistance Grant for 2018
- Planned and hosted the brand new Speed Networking Events at the 2018 Annual Meeting & Expo
- Planned and hosted the New Member & First Timer Lunch at the 2018 Annual Meeting & Expo
- **Shepherded the largest growth in membership in the last 5 years**

## AMP Nominating Committee Annual Report, 2018

### COMMITTEE MEMBERS:

Chair	Federico A. Monzon, MD
Genetics Subdivision Representative	Carolyn Sue Richards, PhD
Genetics Subdivision Representative	Bert Gold, PhD
Hematopathology Subdivision Representative	Rachel L. Sargent, MD
Hematopathology Subdivision Representative	David Viswanatha, MD
Infectious Diseases Subdivision Representative	Jim Dunn, PhD
Infectious Diseases Subdivision Representative	Amanda Harrington, PhD
Informatics Subdivision Representative	Brian Hanson Shirts, MD, PhD
Informatics Subdivision Representative	Carlos J. Suarez, MD
Solid Tumors Subdivision Representative	John Thorson, MD, PhD
Solid Tumors Subdivision Representative	Shelby Melton, MD
President	Kojo S. J. Elenitoba-Johnson, MD
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

### PURPOSE SUMMARY:

The AMP Nominating Committee is composed of the Past President (Chair) and two representatives from each subdivision. The chair and subdivision representatives are responsible for recruiting qualified AMP members to run for elected offices. A ballot is compiled and made available for voting by all current Regular AMP members. Voting for elected offices takes place during the month of May each year.

### 2018 ACTIVITIES:

The Nominating Committee nominated Officers and Committee Representatives for the 2018 annual elections.

## AMP Professional Relations Committee Annual Report, 2018

### COMMITTEE MEMBERS:

Chair	Jordan Laser, MD
Member	Linnea M. Baudhuin, PhD
Member ( <i>Ex officio</i> – EAC Chair)	Samuel Caughron, MD
Member ( <i>Ex officio</i> – President)	Kojo Elenitoba-Johnson, MD
Member	Rajyasree Emmadi, MD
Member	Jill Hagenkord, MD
Member	Robert F. Klees, PhD
Member	Roger Klein, MD, JD
Member	Eric Q. Konnick, MD
Member	Elaine Lyon, PhD
Member	Shelby Melton, MD
Member	Jill Murrell, PhD
Member	George J. Netto, MD
Member	Nirali M. Patel, MD
Member ( <i>Ex officio</i> – President-Elect)	Victoria M. Pratt, PhD
Member	David Viswanatha, MD
Member	Barbara Zehnbauer, PhD
Junior Member	Amy Lo, MD
Junior Member	Jason Rosenbaum, MD
International Affairs Committee Liaison	David E. Barton, PhD
AMP Rep. to FASEB Science Policy Committee ( <i>Ex Officio</i> )	Betsy A. Bove, PhD

### PURPOSE SUMMARY:

The AMP Professional Relations Committee (PRC) is the primary liaison between AMP and other organizations for public policy issues other than reimbursement, which is the purview of the Economic Affairs Committee. Major responsibilities of the Committee include:

1. Communicating and coordinating activities with the appropriate government offices, coalitions, trade associations, and patient and professional organizations to inform policy discussions that have an impact on the practice of molecular pathology;
2. Developing AMP positions on emerging issues affecting molecular pathology;
3. Interacting with a wide variety of entities, including other professional associations, Congress and U.S. Federal Agencies such as FDA, CDC, DHHS;
4. Advocating for policy changes in legislation and regulation that will advance the practice of molecular pathology.

The committee membership includes individuals employed in a variety of medical, scientific, institutional and commercial capacities.

### 2018 ACTIVITIES:

The PRC continues to monitor the activities of, and in some cases work with, federal agencies and panels such as FDA and CMS as well as policy committees such as the Roundtable on Genomics and Precision Health at the National Academies of Sciences, Engineering, and Medicine. After extensive discussion, the committee drafts AMP's policy positions and comments to federal agencies and members of Congress. AMP's government relations consultants, Jennifer Leib, Megan Anderson Brooks, and Lindsey Trischler of CRD Associates, keep the Committee informed of all policy and legislative activity, assist in drafting policy positions, provide advice

regarding advocacy strategies, and guide AMP's presence on Capitol Hill. Jennifer Leib, Megan Anderson Brooks, AMP Senior Director of Public Policy and Advocacy, Tara Burke, AMP Public Policy Fellow, Sarah Thibault-Sennett and when possible, Committee or other AMP members meet with congressional staff to educate them about issues relevant to molecular pathology, to offer AMP's expertise, and to advocate for AMP members' interests. (Note: As a 501c3 tax-exempt organization, AMP is prohibited from participating in any partisan activities and may not have a Political Action Committee (PAC). In addition, its direct and grassroots lobbying activities are limited per IRC 501h.)

### **Oversight of Laboratory Developed Testing Procedures (LDPs)**

A major advocacy issue of 2018 continued to be regulatory oversight of laboratory developed testing procedures (LDPs), also known as laboratory developed tests (LDTs). Since FDA announced their decision not to finalize their draft guidance for LDPs, conversations about LDP oversight have shifted to Congress. AMP remains actively engaged with legislators on Capitol Hill. AMP maintains that updating the Clinical Laboratory Improvement Amendments (CLIA) oversight will preserve a flexible system that fosters innovation and is also the most streamlined, cost-effective approach to addressing clinical and analytic validity and establishing enhanced transparency.

LDP advocacy efforts in 2018 involved communicating concern about a draft bill, released by Reps. Bucshon and DeGette in 2017, entitled "Diagnostic Accuracy and Innovation Act (DAIA)." DAIA proposes a single regulatory pathway oversight for both IVDs and LDPs under an entirely new center at FDA. While AMP provided detailed comments to the bill on this draft bill in 2017, there was increasing concern from AMP and other aligned stakeholders that bill conversations related to LDP oversight did not involve all relevant groups. To address this concern, AMP led a sign-on letter effort. The letter was signed by over 15 major organizations, laboratories, and academic medical centers stakeholders and was sent to relevant staffers on the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor and Pensions. The letter expressed concerns regarding the draft legislation, the lack of stakeholder input during the development process, and states that updates to LDP oversight should be made primarily through updates to CLIA. Following the delivery of this letter, AMP and the stakeholders who signed the letter held multiple Hill meetings with members of the House E&C committee to disseminate and discuss the concerns expressed within the letter.

In August, the FDA released a technical assessment (TA) of the DAIA draft legislation that consisted of an alternative regulatory framework that differed substantially from that proposed in DAIA. AMP submitted comments expressing concerns and seeking clarification on a number of provisions within the TA. AMP also participated in a closed-door stakeholder meeting where FDA explained the regulatory proposal within their TA and answered questions.

### **Patient Advocacy Group Engagement**

Since 2016, AMP has held "Lunch and Learn" events with patient groups, with the objective of identifying and establishing relationships with relevant patient groups in oncology, inherited conditions, and infectious diseases. AMP aims to understand the goals and needs of the patient groups, identify ways we can work together, and effectively communicate that patient care is central to AMP members' practice. The events have been incredibly well-received with both the representatives from patient groups and AMP members excited by the things that were discussed.

In March, AMP held a Washington, D.C.-based lunch and learn hosted by **Drs. Jordan Laser** and **Vicky Pratt** with a focus on the current molecular diagnostic policy landscape. The next lunch and learn will take place at the Annual Meeting and a third event in Washington, D.C. is in the works for later in 2018 to discuss coverage and reimbursement issues affecting molecular diagnostics. The goals of these events are for the patient groups to gain a better understanding of why molecular pathology needs to be better incorporated into standard of care, the hurdles to achieving that, and how they can partner with AMP to make this a reality. Additionally, AMP is able to identify ways that they can engage and strengthen working relationships with the patient community in



order to create the bidirectional conversation that will result in professional practice that reflects patients' needs. The PRC is continuing these efforts and plans to continue this program in 2019.

### **National Coverage Determination for NGS for Advanced Cancer for Medicare Beneficiaries**

The PRC assisted the Economic Affairs Committee (EAC) in developing comments to CMS on the National Coverage Determination for NGS for Advanced Cancer for Medicare Beneficiaries. The proposed coverage determination required FDA approval for national coverage of next generation sequencing oncology services and thus had serious implications not only for Medicare coverage but also oversight of these types of LDPs. The final policy released by CMS in March was significantly different than the proposed policy. Coverage for NGS-based tests were expanded to include FDA cleared and approved tests, rather than only FDA approved, with a companion diagnostic indication. A new section was added that allows Medicare Administrative Contractors (MACs) to determine coverage of other NGS-based tests for cancer when the test is performed in a CLIA-certified laboratory.

### **Clinical Laboratory Improvement Amendments**

In March, AMP responded to a request for information from CMS regarding revisions to personnel regulations, proficiency testing referral, histocompatibility regulations and fee regulations under the CLIA. In addition to providing specific feedback on each section of the RFI, AMP commended CMS on their efforts to explore updating CLIA to better reflect current knowledge, changes in the academic context, and advancements in laboratory testing.

### **Investigational IVDs used in Clinical Investigations of Therapeutic Products**

AMP provided comments to FDA on a draft guidance for investigational IVDs used in clinical investigations of therapeutic products. AMP appreciates the goal of FDA to provide stakeholders, including institutional review boards (IRBs), with more information in making determinations as to whether an IVD is investigational. However within the letter, AMP expressed concern that the guidance document provided unclear information regarding when molecular laboratory tests are subject to the FDA's Investigational Device Exemption (IDE). In AMP's letter, recommendations were provided to aid in refining the guidance document to assist clinical investigators working to improve patient care.

### **Capitol Hill**

AMP continues to nurture existing and grow new relationships on Capitol Hill. Throughout 2018, AMP met with over 35 offices on Capitol Hill regarding oversight and regulation of LDPs. Specifically, AMP met with staff for Senate HELP and the offices of 13 other Senators. AMP also met with staff working for the House Energy and Commerce Committee and the House Ways and Means Committee, in addition to the offices of 15 Representatives.

### **Collaborations**

AMP continues to participate in a variety of policy discussions with other professional societies, laboratory groups, as well as coalition groups such as the Personalized Medicine Coalition (AMP representatives **Drs. Shelby Melton, Roger Klein, and Amy Lo**), National Academies of Sciences, Engineering, and Medicine Roundtable on Genomics and Precision Health (AMP representative **Dr. Vicky Pratt**), Federation of American Societies for Experimental Biology (FASEB) (AMP representative **Dr. Betsy Bove**), and the Cancer Leadership Council.

## AMP Program Committee Annual Report, 2018

### COMMITTEE MEMBERS:

Chair	Lynne V. Abruzzo, MD, PhD
Chair-Elect	Neal Lindeman, MD
Genetics Representative	Linda Jo Bone Jeng, MD, PhD
Genetics Representative	Elaine B. Spector, PhD
Hematopathology Representative	Eric J. Duncavage, MD
Hematopathology Representative	Y. Lynn Wang, MD, PhD
Infectious Diseases Representative	Belinda Yen-Lieberman, PhD
Infectious Diseases Representative	Jennifer Dien Bard, PhD
Informatics Representative	Somak Roy, MD
Informatics Representative	Matthew Lebo, PhD
Solid Tumors Representative	Lynette Marie Sholl, MD
Solid Tumors Representative	Christina Lockwood, PhD
Technical Topics Representative	Lynne Whetsell, BS
Technical Topics Representative	Fernanda Sabato, MS

### PURPOSE SUMMARY:

The Program Committee is responsible for overall planning and organization of the AMP Annual Meeting, including sessions and abstracts/posters. In addition, the Committee selects the winners of the Technologist Poster Awards.

### 2018 ACTIVITIES:

Programming the 2018 Annual Meeting & Expo, "Precision Medicine Starts Here" from November 1-3, 2018 at the Henry B. Gonzalez, Convention Center in San Antonio, TX.

## AMP Publication & Communication Annual Report, 2018

### COMMITTEE MEMBERS:

Chair	Paul G. Rothberg, PhD
<i>JMD</i> Editor-in-Chief	Barbara A. Zehnbauer, PhD
Test Directory Editor	Alexis Carter, MD
Test Directory Co-Editor	Nefize Sertac Kip, MD PhD
Test Directory Co-Editor	Annette Leon Meredith, PhD
Web Editor	Mary C. Lowery-Nordberg, PhD
Member	Dahui Qin, MD, PhD
Member	Mohamadou Sene, BS, MB(ASCP)
Member	Shalini Verma, MD
Member	Shaochun Bai, PhD
<i>JMD</i> Managing Editor	Emily Essex
<i>JMD</i> Scientific Editor	Chhavi Chauhan, PhD

**PURPOSE SUMMARY:** The Publication and Communication Committee is comprised of appointed volunteers from the AMP membership. The task of the Committee is to review and monitor all AMP “publications,” whether print or electronic. The committee communicates via monthly conference calls.

### 2018 ACTIVITIES:

- Solicited and reviewed submissions for the AMP/CAP TODAY Case Report Program
- Supported kickoff of AMP’s redesigned “AMPlifications” monthly newsletter
- Continued support and feedback for Test Directory Editors and *Journal of Molecular Diagnostics* editorial team
- Discussed compliance efforts for new General Data Protection Regulation (GDPR) in Europe
- Identified representative for FASEB Bio Advances Editorial Board

## AMP Strategic Opportunities Committee Annual Report, 2018

### COMMITTEE MEMBERS:

Chair	Victoria M. Pratt, PhD
Member	Michael Hadjisavas, PhD
Member	Annette S. Kim, MD, PhD
Member	Roger D. Klein, MD, JD
Member	Ester Stein, BS, MBA
Member	Karl V. Voelkerding, MD
President	Kojo S. J. Elenitoba-Johnson, MD
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

### PURPOSE SUMMARY:

The Strategic Opportunities Committee assesses the opportunities and challenges in the molecular pathology profession and other environments external to the organization that affect AMP interests.

### 2018 ACTIVITIES:

The Strategic Opportunities Committee carries out the activities listed below and provides relevant reports and recommendations to the Board of Directors:

- Assessing trends and activities in the broad environment external to AMP, *i.e.*, "Horizon Scanning"
- Identifying and assessing external threats that could prevent AMP from attaining its goals
- Identifying and assessing external opportunities that can help AMP attain its goals
- Identifying organizations for potential relationships that can help AMP attain its goals

## AMP Training & Education Committee Annual Report, 2018

### COMMITTEE MEMBERS:

Chair	Cecilia C. S. Yeung, MD
Genetics Subdivision Representative	Kristy R. Crooks, PhD
Genetics Subdivision Representative	Yasmine Akkari, PhD
Hematopathology Subdivision Representative	Mark D. Ewalt, MD
Hematopathology Subdivision Representative	Rashmi S. Goswami, MD, PhD
Infectious Diseases Subdivision Representative	Sophie S. Arbefeville, MD
Infectious Diseases Subdivision Representative	Preeti Pancholi, PhD
Informatics Subdivision Representative	Joshua F. Coleman, MD
Informatics Subdivision Representative	Sabah Kadri, PhD
Solid Tumors Subdivision Representative	Anna Yemelyanova, MD
Solid Tumors Subdivision Representative	Susan J. Hsiao, MD
Junior Member	Jeffrey Gagan, MD, PhD
Junior Member	Brittany Coffman, MD
Medical Technologist Member	Barbara Anderson, BS, MS
Medical Technologist Member	Mara Williams, MS
Membership Affairs Committee Liaison	Cynthia Jackson, PhD
International Affairs Committee Liaison	Roberta Sitnik, PhD

### PURPOSE SUMMARY:

The Training and Education (T&E) Committee is comprised of representatives from each of AMP's subdivisions: genetics, hematopathology, infectious diseases, informatics and solid tumors as well as technologist representatives, junior members, and liaisons from the International Affairs and Membership Affairs Committees (IAC and MAC). It oversees important issues such as education and certification in molecular pathology and mentoring of trainees, as well as developing educational programs for different audiences.

### Educational Programs

- ***Molecular Pathology Outreach Course (MPOC 2018)***: The T&E Committee organized an annual outreach course held just prior to annual meeting on October 31, 2018, which was geared to individuals with little experience in molecular diagnostics. This year the course was entitled "*AMPlicons: A Practical Molecular Toolkit and Case Studies*." The course included an overview of pre-analytic considerations in molecular pathology, followed by case studies presented by T&E members that illustrated a wide range of molecular diagnostic applications.
- ***Early Bird Sessions at the Annual Meeting & Expo - Case Studies presented by Trainees or Technologists***: The T&E Committee hosted an opportunity for fellows, residents, postdocs, graduate students, or technologists who attended the AMP 2018 Annual Meeting & Expo to present an interesting and/or challenging case study during an Early Bird Session. Trainee/technologist presenters in 2018 were:

Case Studies in Genetics and Informatics	Case Study: Utilization of Mate-Pair Sequencing to Aid in the Diagnosis of a Patient with a De Novo Balanced Translocation	Nicole Boczek, PhD	Mayo Clinic, Rochester, MN
	Case Study: Identification of a Novel Likely Pathogenic PIK3R1 Variant by Targeted Next-generation Sequencing Analysis in a Patient with Overgrowth Syndrome and Lymphatic Malformation	Christopher Suci, MD, MS	Washington University School of Medicine, St. Louis, MO
	Case Study: Sex Check: Verifying Patient Sex Based on Off-panel SNPs on the X Chromosome	Jennifer Bynum, MD	Johns Hopkins University, Baltimore, MD
	Case Study: A Discrepancy Between the Human Reference Genome (GRCh37) and Transcriptome (RefSeq) Results in the Incorrect Annotation of a Clinically-relevant Sequence Variant in RECQL4	Lisa Lansdon, PhD	Children's Mercy Hospital, Kansas City, MO
Case Studies in Solid Tumors	Case Study: Circulating Tumor DNA (ctDNA) Detection in CSF in a Patient with Metastatic Melanoma to the CNS	Andres Moon, MD	University of Washington, Seattle, WA
	Case Study: An Unusual Driver Mutation in a Lung Adenocarcinoma	Erik Nohr, MD	Stanford Healthcare, Palo Alto, CA
	Case Study: LMNA/NTRK1 Fusion in a Paravertebral Soft Tissue Mass	Yulei Shen, MD, PhD	Baylor College of Medicine, Houston, TX
	Case Study: Recurrent Glioblastoma with Primary and Secondary Features in a Patient with a Deficiency of Mismatch Repair	Martin Powers, MD	University of California, San Diego CA

Case Studies in Hematopathology	Case Study: Identification of a rare germline POT1 mutation by targeted next-generation sequencing of a splenic marginal zone lymphoma	Audrey Jajosky, MD, PhD	University Hospitals Cleveland Medical Center, Cleveland, OH
	Case Study: Identification of Acute Leukemia Risk Mutations in a Child with Severe Congenital Neutropenia	Jennifer Yoest, MD	Washington University School of Medicine, St. Louis, MO
	Case Study: Whole Genome Sequencing Identifies Cryptic High-risk Cytogenetic Findings in a Patient with Acute Myeloid Leukemia	Michael Alberti, MD, PhD	Washington University School of Medicine, St. Louis, MO
	Case Study: A Case of Myeloid Neoplasm with Germline Predisposition: Connecting the Clinical, Laboratory, Morphology and Molecular Dots	Fatima Z. Jelloul, MD	MD Anderson Cancer Center, Houston, TX

- **Webcasts and Recorded Online Content (ROCs):**

Date	Title	Speaker/T&E Moderator	NOTES
<b>Major Initiative: Advancing Patient Care in NSCLC: Breaking Down Barriers</b>			
May 29	<b>NSCLC Guidelines:</b> Molecular Testing Guideline for Selection of Lung Cancer Patients - Revision	Neal Lindeman / Anna Yemelyanova	
June 20	<b>NSCLC Guidelines:</b> Best Practices in NSCLC Small Specimen Collection for Clinicians	Eric Bernicker / Christopher Gilbert	
Aug 16	<b>NSCLC Guidelines:</b> Best Practices in Small Specimen Management for Laboratory Professionals	Dara Aisner / Sinchita Roy-Chowdhuri	
October 9	<b>NSCLC Guidelines:</b> Liquid Biopsies – Promises and Pitfalls	Lynette Sholl / Christina Lockwood	
December 13	<b>NSCLC Guidelines:</b> Best Practices in Test Ordering	Sinchita Roy-Chowdhuri and Christopher R. Gilbert /	
<b>Major Initiative: Tumor Mutational Burden: Challenges and Opportunities for Improving Cancer Patient Care</b>			
June 27	<b>Tumor Mutational Burden:</b> Clinical and Diagnostic Utilization in Oncology	Lauren Ritterhouse / Susan Hsiao	
August 28	<b>Tumor Mutational Burden:</b> Best Practices to Address Clinical and Technical Challenges	Jonathan Nowak / Jeremy Segal	
September 26	<b>Tumor Mutational Burden:</b> Result Reporting and Application to Improve Patient Care	Ahmet Zehir / Jonathan Nowak	
<b>Webinar Series: 2016 World Health Organization (WHO) Updates in Hematologic Malignancies</b>			
January 18	WHO Revisions: Nodal Peripheral T-cell Lymphomas	Stefano Pileri / Jennifer Dunlap	ROC: WHO Guideline Series
January 22	WHO Revisions: Update on the 2016 WHO Classification of Acute Leukemias	Dan Arber / Mark Ewalt	ROC: WHO Guideline Series
February 2	WHO Revisions: B-Lymphoid Neoplasms (and how practice is changing)	Eric Hsi /Mark Ewalt	ROC: WHO Guideline Series
February 15	WHO Revisions: Myelodysplastic Syndromes and Myelodysplastic/Myeloproliferative Neoplasms	Robert Hasserjan / Jennifer Dunlap	ROC: WHO Guideline Series
March 1	WHO Revisions: Myeloproliferative Neoplasms	Tracy George /Mark Ewalt	ROC: WHO Guideline Series
January 26	AMP/ASCO/CAP Standards and Guidelines of Somatic Variant Interpretation and Reporting	Marilyn Li /Antonia Sepulveda	ROC: CPC Guideline
March 21	AMP Pharmacogenomics Working Group Presents: Recommendations for Clinical CYP2C19 Genotyping Allele Selection	Karen Weck /Joshua Deignan	ROC: CPC Guideline
April 20	Standards and Guidelines for Validating Next Generation Sequencing Bioinformatics Pipelines: A Joint Recommendation of the Association for Molecular Pathology and College of American Pathologists	Alexis Carter and Somak Roy / Justin Zook	CPC Guideline
April 25	Practical Considerations for the Validation of Next-Generation Sequencing-Based Oncology Panels	Larry Jennings / Antonia Sepulveda	CPC Guideline
July 17	Global ROCs: Complexities in the Analysis and Interpretation of NGS Data for Inherited Disorders	Avni Santani / Kristy Crooks	
July 19	Clinical Significance of DNA Variants in Chronic Myeloid Neoplasms (CMNs)	Annette Kim / Todd Kelley	CPC Guideline
September 18	The ABCs of CPT® Coding	Aaron Bossler, Vicky Prat and Anthony Sireci / Cecilia Yeung	EAC Collaboration
ROC	Lab Management Series: Feel like QC and IQCP are affecting your IQ?	Ana Maria Cardenas	
ROC	Lab Management Series: Reporting Results of Molecular Pathology Laboratory Tests	Peggy Gulley	
ROC	Lab Management Series: Scientific Aspects of Test Development in the Molecular Pathology Lab	Peggy Gulley	

## Education Initiatives

- **Continuing Education credits (SAMs, CME, and CMLE):** AMP offers Continuing Education credits for many of its educational activities. Accredited activities include the MGP Review Course (live and online), the MPOC, the 2018 Annual Meeting & Expo, and Recorded Online Content (ROC) lectures.
- **AMP Online:** The T&E Committee and staff spent significant time designing and developing educational materials for populating the online learning platform at [educate.amp.org](http://educate.amp.org). Selected online educational offerings are complimentary for AMP members. Current content includes the a 3-webinar series on Tumor Mutational Burden, a 5-webinar series on NSCLC, the online MGP Review Course, the Molecular Diagnostic Toolkit and Practical Applications, 2017 Annual Meeting highlights, Global Congress highlights, and AMP Europe 2018 Highlights .
- **Target Audience Groups (TAGs):** The T&E committee established TAGs within the T&E Committee dedicated to the development of new educational materials to extend the positive influence and educational mission of AMP to meet the needs of molecular professionals and non-molecular audiences. The following TAGs were created: Trainees, Technologists, Oncologists, Primary Care Physicians, and the lay (non-medical) public.
- **Pocket Cards:** The T&E Committee designed “Molecular in my Pocket” reference cards with topics from the Infectious Diseases, Hematopathology, Solid Tumors, and Genetics subdivisions. These cards were created to target trainees and, more recently, oncologists/clinician audiences were targeted with oncology pocket cards on Myeloproliferative Neoplasms, Molecular Biomarkers of Colorectal Cancer, Molecular Biomarkers of Thyroid Cancer, and Interpretation of Genomic Assays. These are available online, but hard copies are also distributed at the MGP Review Course, the USCAP annual meeting, and AMP Central.
- **FISE Question Bank:** Done in collaboration with the MGP-PD Council, the exam questions were written by MGP faculty from many MGP-Fellowship institutions and cover a range of topics. The T&E Committee screens all questions. For each examination, a total of 45 questions randomly populated from a question bank of approximately 200 questions is given, yielding a different test each time. AMP staff provides non-attributed results to participating institutions at the beginning of the fellowship year (in October) and at the end of the year (in May/June).
- **Course Bundles/AMP Certificate Programs:**
  - **WHO updates:** A content series on the WHO guidelines using existing LMS content augmented with materials dictated by content-directors Jennifer Dunlap and Mark Ewalt.
  - **Course bundles:**
    - Circulating tumor DNA testing – advances, challenges, and applications
    - Infectious Disease: From Emerging Pathogens to Emerging Paradigms
    - Laboratory Management Online Curriculum

## Trainee Activities (Residents, Fellows, and Students)

- **AMP 2018 Annual Meeting & Expo**
  - Trainee and Technologists Luncheon and Book Drawing: The T&E junior and technologist members organized table discussion topics between junior and senior faculty members at the 2018 Training & Education Luncheon. Donated textbooks from AMP member authors were given away during the Trainee Luncheon.



## **Technologist Activities**

- Technologist Career presentation at the Annual Meeting's Innovation Stage
- Technologist mixer at AMP Central during the Annual Meeting
- Ongoing planning of the development and coordination of resources for technologists

## **Awards**

- Young Investigator Awards – 35 poster candidates
- Technologist Poster Awards – 20 poster candidates
- International Trainee Travel Award (Supported by the Jeffrey A. Kant – AMP Education Fund) – Three recipients (from Brazil, Germany and India).

## **Molecular Genetic Pathology Fellowship Program Directors (MGP PD) Working Group**

The MGP Program Directors (MGP PD) Council consists of Shuko Harada (Chair), Allison Cushman-Vokoun (Chair-Elect), and Dolores Lopez-Terrada (Past-Chair). The MGP PD Council facilitates the discussions of the MGP Program Directors Working Group and responds to the ABP and ACGME on matters related to MGP Fellowship programs. The Council worked with the T&E Committee to launch an in-service practice exam question bank for MGP Fellows.

## **Curriculum Development Task Forces**

- ***Genomics Education for Primary Care Residents:*** This Task Force is led by Laura Tafe. Their task is to develop a modified basic genomics curriculum for primary care residents, *i.e.*, internal medicine, family practice, pediatrics to be submitted to a primary care-type journal. Other working group members are Yasmine Akkari, Maria Arcila, Devon Chabot-Richards and Anthony Snow.
- ***MGP Fellow Training and Curriculum in Genomics Task Force:*** The Task Force is headed by co-leaders Jason Rosenbaum and Mark Ewalt and includes working group members Kristy Crooks, Jeff Gagan and David Wu. The manuscript is in the final stages of outlining a suggested molecular pathology and genomics curriculum for fellows. Upon completion, the manuscript will be submitted to *JMD*. Additional authors are: Anna Berry, Alanna Church, Linda Jeng, Roger Klein, Mahesh Mansukhani, Federico Monzon, John Pfeifer, Hanna Rennert, Iris Schrijver, Laura Tafe, Vivianna Van Deerlin and David Wu.

## **Co-Sponsorships, Companion Meetings, and/or Collaborations**

- **Joint AMP – Society for Hematopathology Webinar Series on the 2016 WHO Updates in Molecular Testing**
- ***United States and Canadian Academy of Pathology (USCAP) 2018***

The AMP 2018 Companion Society Symposium, “*Lessons Learned in Molecular Pathology*”, was co-moderated by Cecilia Yeung and Yaolin Zhou:

- *Image Analysis and Biomarker Evaluation: Linking Digital Pathology*, Andrew Evans, MD, PhD
- *High-Throughput Cancer Genomics as a Disruptive Technology*, Fei Dong, MD
- *Synergism Between Liquid Biopsy Testing and Pathology*, Christina Lockwood, PhD

An AMP Short Course, *AMPLICONS: Basic Tools and Emerging Fronts in Molecular* was co-presented by Annette Kim, MD, PhD and Cecilia Yeung, MD.

An AMP-USCAP co-sponsored Special Course, *Molecular Diagnostic and Genomic Applications in Cancer: A Primer for the Pathologist*, was co-directed by George Netto, MD, and Karen Kaul, MD, PhD

- **American Society for Clinical Pathology (ASCP)**
  - **ASCP 2018 AMP Workshop: October 2-5 in Baltimore, MD:** *Molecular Diagnostics Primer- Basic Principles* and *Molecular Diagnostics Primer- Advanced Topics* were presented by Mark Ewalt and Jason Rosenbaum.
  
- **College of American Pathologists (CAP)**
  - **CAP 2018 Course Presentations: October 20-24 in Chicago, IL**
    - *The WHO and Beyond: The Myeloproliferative Neoplasms* was presented by Mark Ewalt and Cecilia Yeung.
    - *CAP-IASLC-AMP Molecular Testing Guidelines for Selection of Lung Cancer Patients—Revision* was presented by Neal Lindeman
  
- **Regional/Local Conferences**
  - **Beaumont Symposium: September 13-14 in Troy, MI.**  
Organizer: Bobby Boyanton.
  
- **Cambridge Health Institute (CHI) Conferences**
  - **Molecular Medicine Tri-Conference, February 11-16, 2018, San Francisco, CA**
    - **Short Courses:**
      - **NGS Assay Selection, Validation and Compliance:** Maria E. Arcila, Eric Duncavage, Birgit Funke.
      - **Clinical Informatics: Returning Results from Big Data:** N. Sertac Kip, Mark Routbort, and Stephen E. Lincoln
    - **Keynote Session**
      - **New Clinical Practice Guidelines for NGS-Guided Oncology:** Maria E. Arcila, Somak Roy, and Marina N. Nikiforova.
  - **Next Generation Dx Summit, August 20-24, 2018, Washington, DC**
    - **Plenary Keynote Session Panel: Global Dx Insights: Policy and Prediction for Diagnostics:** Vicki Pratt, panelist
    - **AMP Co-organized Plenary Session: Technology Panel: Disruptive Technologies in Lab Medicine** Moderator: Gregory J. Tsongalis
  - **Biomarkers & Immuno-Oncology World Congress, June 11-13, 2018 | Boston, MA**
    - **Precision Oncology: Practical Strategies for Genomic Test Implementation with Case Vignettes:** Christina Lockwood
  
- **ASCO-CAP-AMP Molecular Oncology Tumor Boards**

The Molecular Oncology Tumor Boards are a series of monthly user-driven discussions designed to help cancer care providers with the interpretation and understanding of tumor molecular profiling tests and studies: <http://university.asco.org/motb>. AMP collaborates with the American Society for Clinical Oncology (ASCO) and the College of American Pathologists (CAP).

  - AMP Representatives: Maria Arcila and Christopher Watt.

## AMP Subdivision Leadership Annual Report, 2018

### SUBDIVISION LEADERSHIP

	Genetics	Hematopathology	Infectious Diseases	Informatics	Solid Tumors
<b>Chair</b>	Birgit Funke	Annette Kim	David Hillyard	Alexis Carter	Roger Klein
<b>Clinical Practice Committee</b>	Jess Peterson	Keyur Patel	Susan Butler-Wu	Mark Boguski	Kandelaria Rumilla
	Joshua Deignan	Noah Brown	Kenneth Muldrew	Justin Zook	Pranil Chandra
<b>Nominating Committee</b>	Carolyn Sue Richards	Rachel Sargent	James Dunn	Brian Shirts	John Thorson
	Bert Gold	David Viswanatha	Amanda Harrington	Carlos Jose Suarez	Shelby Melton
<b>Program Committee</b>	Linda Jo Bone Jeng	Eric Duncavage	Belinda Yen-Lieberman	Somak Roy	Lynette Sholl
	Elaine Spector	Lynn Wang	Jennifer Dien Bard	Matthew Lebo	Christina Lockwood
<b>Training &amp; Education Committee</b>	Kristy Crooks	Mark Ewalt	Sophie Arbefeville	Joshua Coleman	Anna Yemelyanova
	Yasmine Akkari	Rashmi Goswami	Preeti Pancholi	Sabah Kadri	Susan Hsiao

#### PURPOSE SUMMARY:

The Subdivision Leadership consists of a Chair and Representatives to the Clinical Practice, Nominating, Program, and Training & Education Committees. Subdivision Chairs are responsible for the successful operation and development of the subdivision that they lead.

Each Subdivision Leadership group meets quarterly and functions in an AMP advisory panel of discipline-specific subject matter experts convened to address issues of importance to their Subdivision. They carry out their subdivision leadership responsibilities by:

- Identifying and ascertaining the needs of the Subdivision membership and of the discipline itself
- Discovering, vetting, and recommending projects to the Clinical Practice Committee, Training and Education Committee, or other relevant committee
- Providing input and suggestions regarding content for the Annual Meeting and other educational events
- Assisting to identify and recommend future AMP volunteers and leaders

#### 2018 ACTIVITIES

**Genetics** - Addressed contemporary genetics topics as they relate to the clinical molecular diagnostics laboratory, including variant interpretation, variant confirmation methods and newborn genomic sequencing.

**Hematopathology** - Addressed topics in molecular hematopathology, including advances in translational research related to genomics and mutations in hematologic malignancies, resistance to targeted therapies, next-generation sequencing and immunology.

#### **Infectious Diseases**

Addressed infectious disease topics relevant to the clinical molecular diagnostics laboratory, including next-generation sequencing, microbiome, immunotherapy and emerging molecular infectious disease testing platforms. Hosted additional special sessions on meningitis/ encephalitis syndromic testing and genomic

susceptibility testing. Developed and hosted ID Town Hall at the AMP 2018 Annual Meeting to engage AMP ID Subdivision members regarding challenges and opportunities for the infectious diseases community and explore how AMP might best address them.

**Informatics** - Addressed topics related to clinical applications and development of validation guidelines for next-generation sequencing bioinformatics pipelines for somatic variants and other developments in clinical molecular informatics pertaining to the use of artificial intelligence.

**Solid Tumors** - Addressed topics related to clinical applications and development of next-generation sequencing validation guidelines for somatic variants, genomic tumor diversity, liquid biopsies and other evidence-based clinical practice guidelines projects.

Subdivision members provided invaluable assistance to the Economic Affairs Committee on drafting comments to proposed LCDs for molecular pathology procedures and genomic sequence analysis panels in the treatment of hematolymphoid diseases. The responses were submitted jointly with the College of American Pathologists (CAP). The ID Subdivision members also assisted with providing recommendations to CMS for new and reconsidered CPT codes pertaining to infectious diseases.

Members of the Subdivision Leadership participated in the “Get involved with AMP” event at the Annual Meeting to engage with their respective Subdivision members and inform them of AMP’s initiatives and projects in their interest areas.

**Requests from the Subdivision Leadership**

- We encourage all AMP members to alert their Subdivision Chair or Representatives for current or emerging specific needs that AMP should consider and address.
- We encourage AMP members to actively contribute to requests for information from their respective Subdivision Leadership.