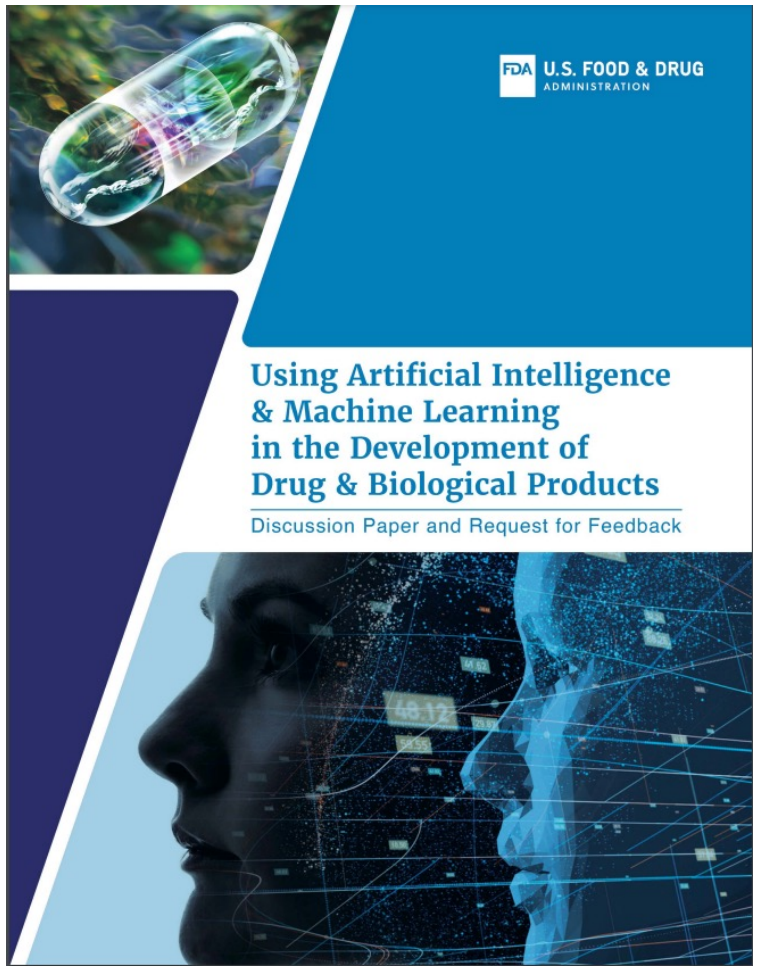
The Alliance for Digital Pathology

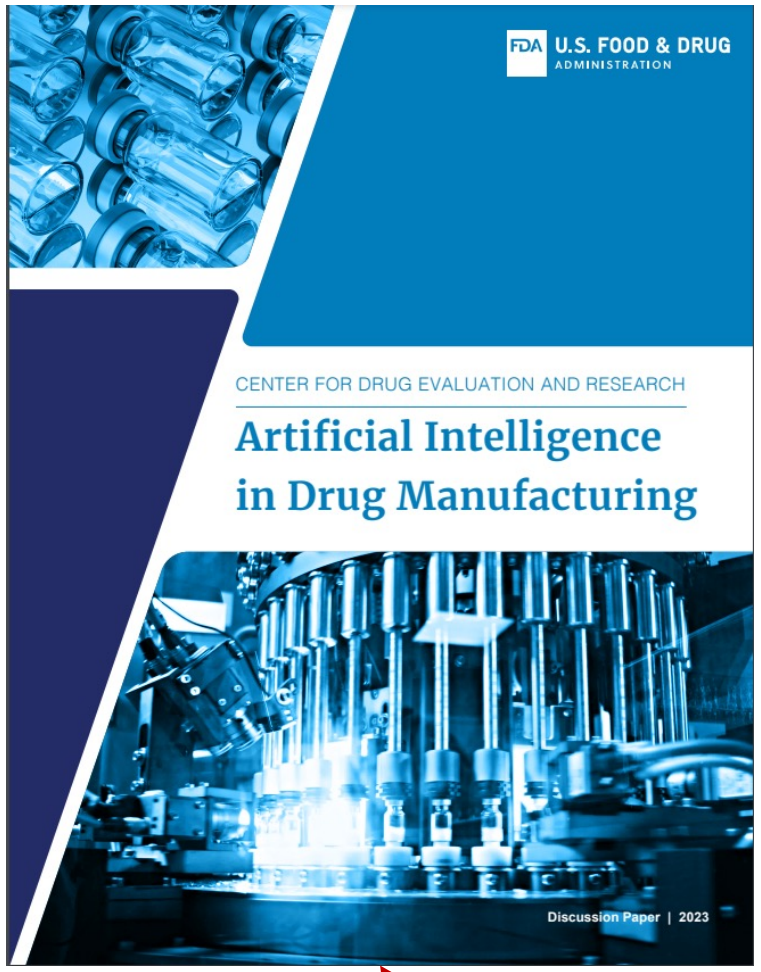
FDA

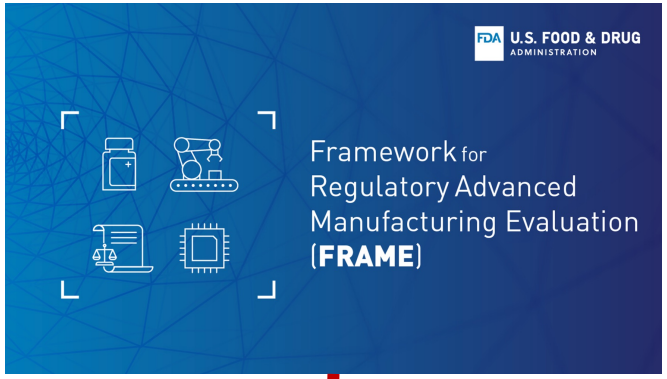
FDA

- DHCoE
  - Cybersecurity update (link)
    - Video: Tips for Health Care Facilities (link)
  - The Veterans Cardiac Health and AI Model Predictions (V-CHAMPS) Challenge (link)
- CDER's Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) Initiative (link)
- Oncology Center of Excellence: Project Optimus (link)
- Action Plan for Rare Neurodegenerative Diseases including Amyotrophic Lateral Sclerosis (download. pdf)
- Draft Guidance
  - Acute Radiation Syndrome: Developing Drugs for Prevention and Treatment (download .pdf)
- News:
  - CDRH What's New in Regulatory Science (download .pdf)
  - FDA Releases Two Discussion Papers to Spur Conversation about Artificial Intelligence and Machine Learning in Drug Development and Manufacturing (link)
  - FDA Takes Additional Steps to Advance Decentralized Clinical Trials (link)
  - FDA's International Collaboration on Food Safety is a Top Priority (link)
- 5/9/23 SAMSHA and CDER letter on buprenorphine (download .pdf)
- FDA CBER OTAT Town Hall: Clinical Development of Gene Therapy Products for Rare Diseases (download .pdf)
- Medical Devices
  - Supply and Shortages of Medical Devices: Frequently Asked Questions (link)
  - List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools) (link)
- Events:
  - June 5-9 Regulatory Education for Industry (REdI) Annual Conference 2023 (link)

FDA Releases Two Discussion Papers to Spur Conversation about Artificial Intelligence and Machine Learning in Drug Development and Manufacturing





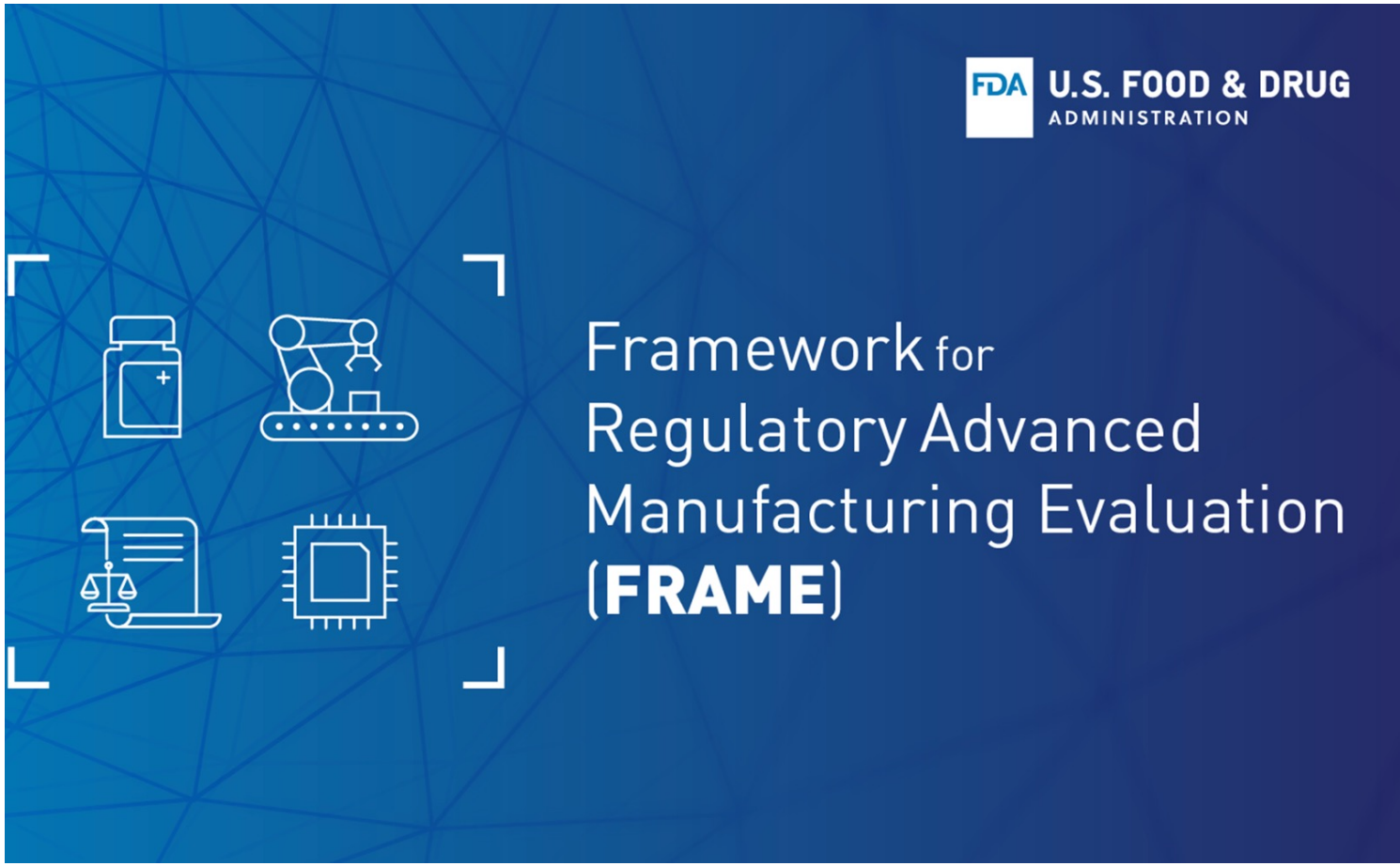


Center for Drug Evaluation and Research | CDER

FRAME Priorities

FRAME focuses on four key priorities to develop a regulatory framework for advanced manufacturing technologies:

1. **Seek and Analyze Input** to ensure CDER's understanding of advanced manufacturing technologies is thorough and its analysis of the regulatory framework is science- and risk-based.
    - CDER plans to solicit stakeholder feedback by releasing discussion papers and holding a public workshop on regulatory areas of consideration for advanced manufacturing technologies.
2. **Address Risks** to ensure regulations and policy are compatible with future advanced manufacturing technologies.
    - Through FRAME, CDER is evaluating our existing risk-based regulatory framework as it applies to these technologies to enable timely adoption of advanced manufacturing technologies
3. **Clarify Expectations** for stakeholders implementing advanced manufacturing.
    - As a result of FRAME, CDER may issue new or updated guidance to explain the current thinking on a regulatory issue.
4. **Harmonize** to ensure global regulatory practice is clear to stakeholders implementing advanced manufacturing.
    - The FRAME initiative is aligned with FDA's efforts to work through the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) to develop international guidelines related to advanced manufacturing technologies, such as continuous manufacturing, the subject of a new ICH Q13 guideline.

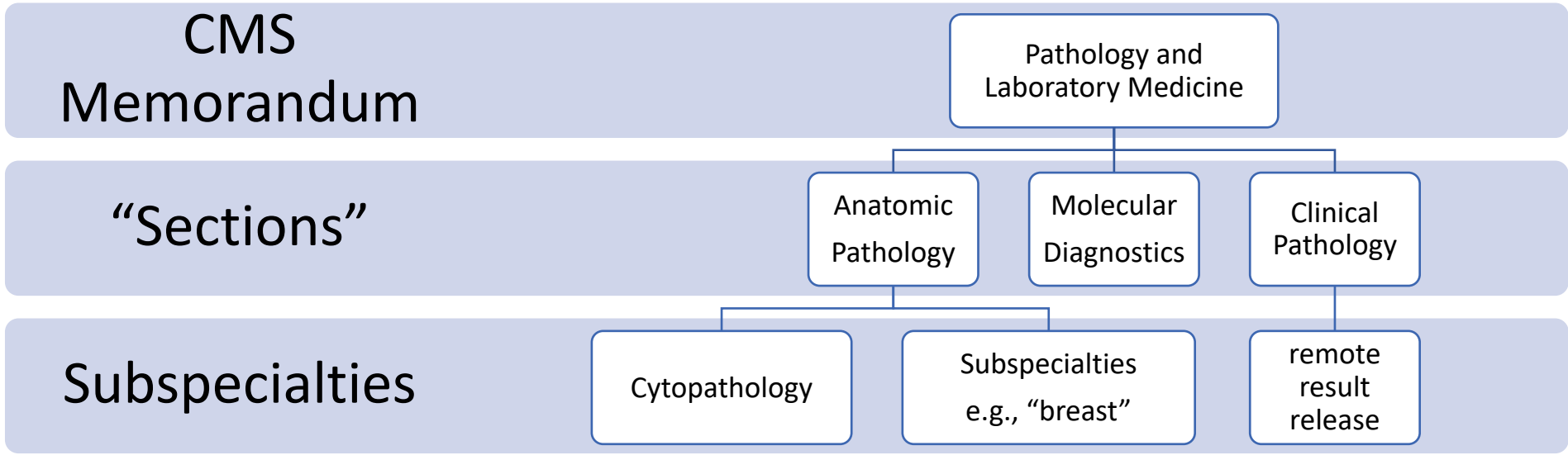


Medical Devices

- May 12, 2023, Update: The FDA has updated multiple FAQs to reflect the end of the COVID-19 public health emergency (PHE) and added three new FAQs
- List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)
  - Group labeling table

Regulatory Update CMS – May 11th

Scope



Function

signing out cases remotely	reviewing cases remotely	using digital pathology	using digital pathology remotely
• "key out results obtained at CLIA lab" <**VPN example**>	• "taking slides home, reviewing using a microscope in home office" <**home screening**>	• "using WSI in a CLIA laboratory" <**primary review**>	• "having a WSI process in CLIA laboratory. Primary review at an off-site location" <**primary remote review**>

Regulatory Update CMS – May 11th

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-23-15-CLIA

DATE: May 11, 2023

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Post-Public Health Emergency (PHE) Guidance

Memorandum Summary

- **CMS only has authority to require reporting of SARS-CoV-2 test results until the end of the Federal PHE declaration. As a result, the CLIA requirement for laboratories to report SARS-CoV-2 test results will expire with the termination of the PHE.**
- **CMS is clarifying the post-PHE status of the temporary exercise of enforcement discretion and other flexibilities CMS utilized during the COVID-19 PHE.**

Background

CMS has been committed to taking critical steps to ensure America's clinical laboratories could respond to the threat of COVID-19 to ensure patient health and safety. The intent of the CLIA program is to ensure that laboratory test results provided to individuals and their health care providers are accurate and reliable. During the Public Health Emergency (PHE) posed by COVID-19, there was an urgent need to expand laboratory capacity. In response, CMS exercised enforcement discretion and used other flexibilities to address this critical need.

During the PHE, CMS did not enforce certain CLIA regulations, provided that laboratories followed the specific parameters outlined in CLIA PHE guidance. CMS also relaxed or changed policies and procedures to provide more flexibility within the CLIA regulations and highlighted flexibilities that already existed.

The exercise of some of these enforcement discretions and broad flexibilities will be terminated by the end of the PHE, as they were intended to address the acute and extraordinary circumstances of a rapidly evolving pandemic and not replace existing requirements.

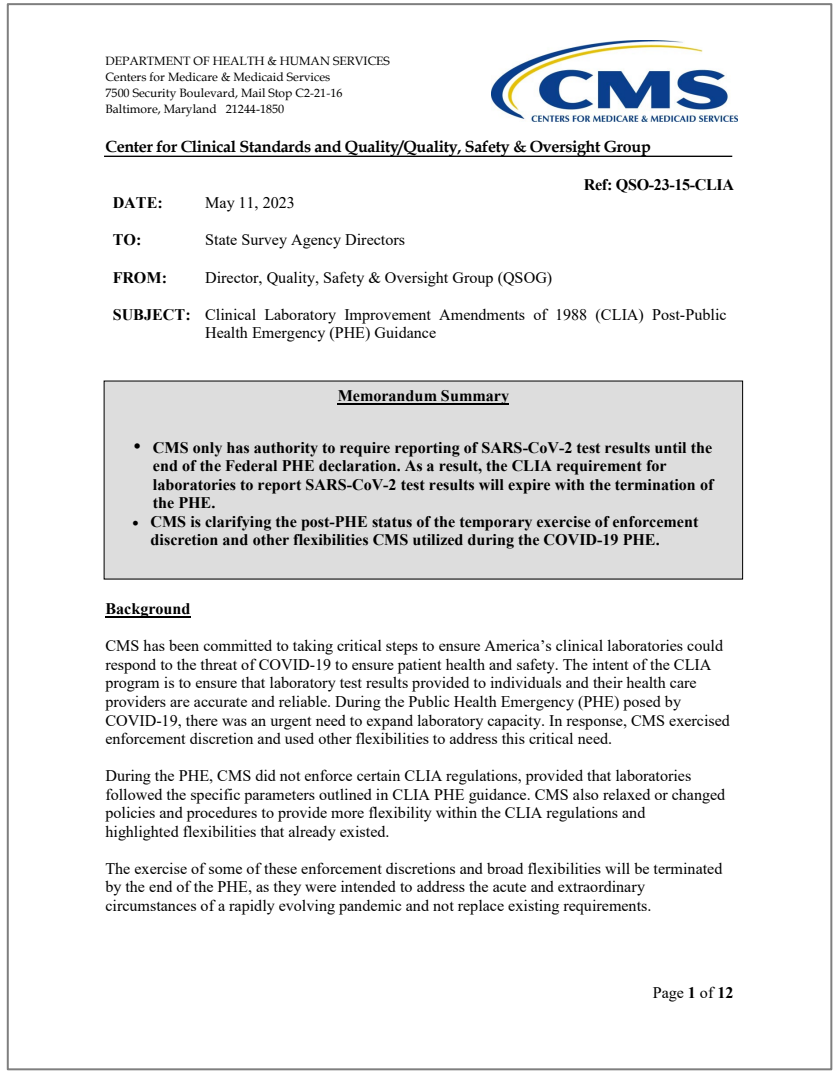
To ensure the accuracy, reliability and timeliness of laboratory results, CMS will continue to exercise enforcement discretion to permit pathologists and other laboratory personnel to review digital laboratory data, digital results and digital images ("digital materials") remotely, without obtaining a separate CLIA certificate for the remote testing site, provided that the designated primary site or home base has such a certificate (using the address of the primary site) and the

[1] https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf

work being performed at the remote testing site falls within the specialties/subspecialties under the primary site's certificate. A private residence may be a remote testing site. We consider digital data, results and images accessed by VPN or other secure method to be an extension of the laboratory that does not require a microscope or other laboratory equipment. Therefore, the remote review of these materials does not require equipment that is essential to being a separate laboratory, while maintaining the accuracy, reliability, and timeliness of laboratory results.

However, when slides are reviewed remotely, a microscope and other laboratory equipment is necessary to perform the testing. The necessity of such equipment is a hallmark of a separate laboratory and, without heightened oversight, increases the potential for inaccurate laboratory results. In addition, physically transferring slides from one site to another constitutes a referral to another laboratory and involves increased risk of error. Therefore, after the PHE has terminated, CMS will not continue to exercise its enforcement discretion for the review of physical slides.

Regulatory Update CMS – May 11th



DEPARTMENT OF HEALTH & HUMAN SERVICES
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CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

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Page **1** of **12**

Laboratories that choose to allow staff to remotely review digital laboratory data, digital results and digital images may do so only if the following criteria are met:

- The primary, home site, laboratory has a current, unrevoked or unsuspended certificate of waiver, registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory (42 C.F.R. § 493.3(a)(1))
- The primary laboratory complies with other applicable Federal laws, including HIPAA.
- The laboratory director of the primary site CLIA number is responsible for all testing performed under its CLIA certificate, including testing and reporting performed remotely.
- Survey findings will be cited under the primary laboratory's CLIA certificate. Enforcement actions, if taken, will affect the primary laboratory's CLIA certificate.
- The primary laboratory's test reports must indicate the remote site location where the testing is performed. The laboratory may use a coding system rather than the remote site address, e.g., personnel residence, on the final report. This coding system must be available upon request.
- The primary laboratory must be certified in the specialties and/or subspecialties of the work performed at the remote site.
- The primary laboratory must provide CMS a list of all staff working remotely, upon request.
- The primary location is responsible for retaining all documentation, including testing performed by staff working remotely.
- The individual performing remote review must be on the primary laboratory's Form CMS-209, Laboratory Personnel Report (CLIA).

PIcc23 => annual meeting focus

8:30 am - Breakout session 1: Remote work, PCCP, Statistics, Open Topic

8:30 am	Breakout session 1: Remote work, PCCP, Statistics, Open Topic Remote Work Leaders: Mike Isaacs, Matt Leavitt, Monica de Baca, and Joe Sirintrapun PCCP Leaders: Emre Gulturk, Kevin Schap Statistics Leaders: Brandon Gallas, Kim Blenman, and Gina Giannini Open Topic Leaders: Jeni Caldera
9:15 am	Create Summary Slides
10:00 am	Break, networking, rotate

LEGISLATIVE UPDATES

APRIL 06, 2023

Executive Order on Modernizing Regulatory Review

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to modernize the regulatory process to advance policies that promote the public interest and address national priorities, it is hereby ordered as follows:

Section 1. Improving the Effectiveness of the Regulatory Review Process. (a) This order supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866 of September 30, 1993 (Regulatory Planning and Review), and Executive Order 13563 of January 18, 2011 (Improving Regulation and Regulatory Review). Any provisions of those orders not amended in this order shall remain in effect. This order also further implements the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review).

EU

- April 26: **Commission proposes pharmaceuticals reform for more accessible, affordable and innovative medicines**
- May 11: AI Act: a step closer to the first rules on Artificial Intelligence
  - World's first (legislative) rules on AI

Next steps

Before negotiations with the Council on the final form of the law can begin, this draft negotiating mandate needs to be endorsed by the whole Parliament, with the vote expected during the 12-15 June session.

European Parliament

Committee on the Internal Market and Consumer Protection
Committee on Civil Liberties, Justice and Home Affairs

16/5/2023

KMB/DA/AS

Version: 1.1

DRAFT Compromise Amendments

on the Draft Report

Proposal for a regulation of the European Parliament and of the Council on harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts

(COM(2021)0206 – C9 0146/2021 – 2021/0106(COD))

Rapporteurs:
Brando Benifei & Ioan-Dragoş Tudorache

(Joint committee procedure – Rule 58 of the Rules of Procedure)

Regulating AI

- 5/16 – CEO of ChatGPT proposed the formation of an agency, whether U.S. or global, to license the most powerful AI systems
  - Provides the power to take the license away

"It's the fear of these (super-powerful) systems and our lack of understanding of them that is making everyone have a collective freak-out," said Suresh Venkatasubramanian, a Brown University computer scientist who was assistant director for science and justice at the White House Office of Science and Technology Policy. "This fear, which is very unfounded, is a distraction from all the concerns we're dealing with right now."

OpenAI has expressed those existential concerns since its inception. Co-founded by Altman in 2015 with backing from tech billionaire Elon Musk, the startup has evolved from a nonprofit research lab with a safety-focused mission into a business. Its other popular AI products include the image-maker DALL-E. Microsoft has invested billions of dollars into the startup and has integrated its technology into its own products, including its search engine Bing.

Altman is also planning to embark on a worldwide tour this month to national capitals and major cities across six continents to talk about the technology with policymakers and the public. On the eve of his Senate testimony, he dined with dozens of U.S. lawmakers, several of whom told CNBC they were impressed by his comments.

Also testifying were IBM's chief privacy and trust officer, Christina Montgomery, and Gary Marcus, a professor emeritus at New York University who was among a group of AI experts who called on OpenAI and other tech firms to pause their development of more powerful AI models

THE ASSOCIATED PRESS

Genetics in Medicine Open (2023) 1, 100806

ELSEVIER

Genetics in Medicine OPEN
An Official Journal of the ACMG

www.journals.elsevier.com/genetics-in-medicine-open

ARTICLE

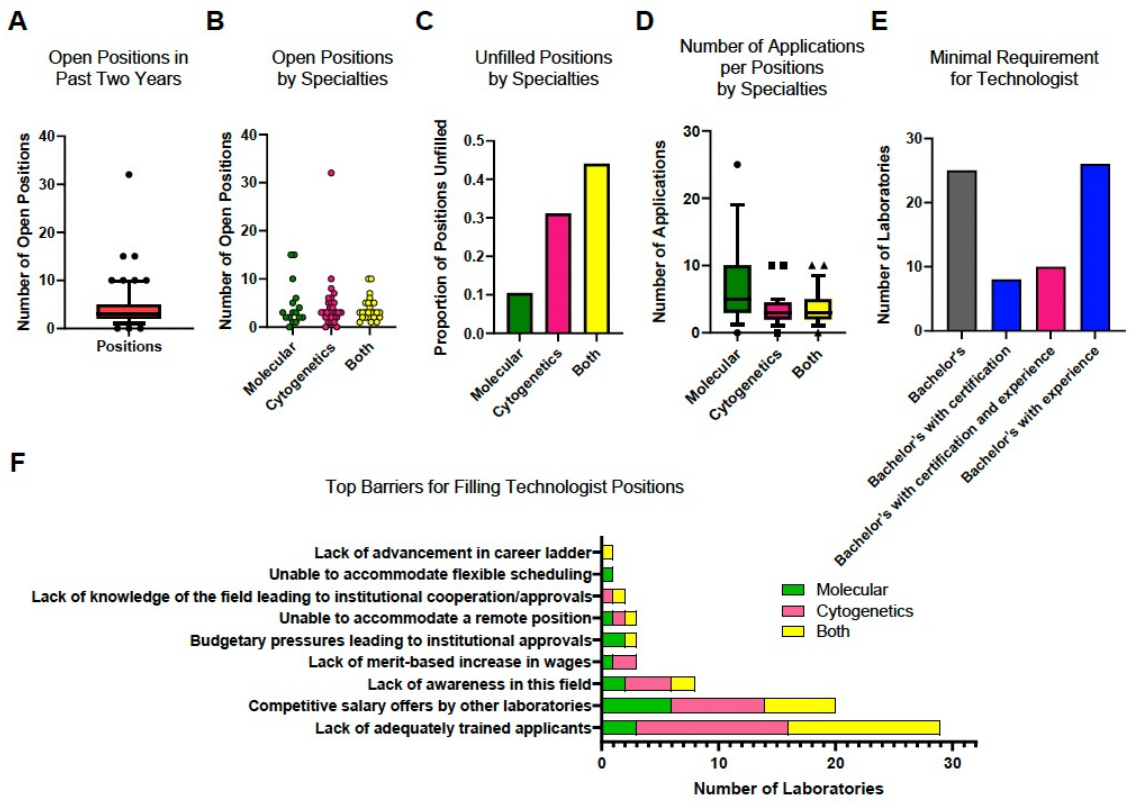
Exploring current challenges in the technologist workforce of clinical genomics laboratories

Yassmine Akkari[1,2], Sheila Dobin[3], Robert G. Best[4], Marco L. Leung[1,2,5,*]

[1]*The Steve and Cindy Rasmussen Institute for Genomic Medicine, Nationwide Children's Hospital, Colu*
[2]*Department of Pathology, The Ohio State University College of Medicine, Columbus, OH;* [3]*Department*
Baylor Scott & White Health – Temple Medical Center, Temple, TX; [4]*The University of South Carolina Sc*
Greenville, SC; [5]*Department of Pediatrics, The Ohio State University College of Medicine, Columbus, O*

ARTICLE INFO

ABSTRACT



SALSA Support Letter

Sincerely,

AdvaMedDx
ADVION (Formerly the National Association for the Support of Long Term Care (NASL))
American Academy of Family Physicians
American Association for Clinical Chemistry
American Association of Bioanalysts
American Clinical Laboratory Association
American Medical Association
American Medical Technologists
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
American Society for Microbiology
Association for Molecular Pathology
Association of Pathology Chairs
California Clinical Laboratory Association
College of American Pathologists
Medical Group Management Association (MGMA)
National Independent Laboratory Association
New York State Clinical Laboratory Association
Point of Care Testing Association

MPHLW Coalition Workforce Letter

The Honorable Richard Hudson
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Anna G. Eshoo
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Sanders, Ranking Member Cassidy, and Representatives Hudson and Eshoo:

We, the undersigned organizations, represent medical and public health laboratory workforce and healthcare organizations in the United States. This letter is in response to the Committee's recent work examining the healthcare workforce shortages across our nation and in response to Congress' ongoing efforts to reauthorize the Pandemic and All-Hazards Preparedness Act. The laboratory workforce organizations that are part of our coalition represent approximately 350,000 essential laboratory professionals and pathologists responsible for patient care and public health.

We urge the Committee to include the medical and public health laboratory workforce as a primary consideration in all policy solutions related to addressing healthcare workforce shortages. Prior to the onset of COVID-19, the pathology and laboratory medicine workforce was suffering from staffing shortages. COVID has significantly worsened these problems. Currently, most medical and public health laboratories suffer from significant personnel shortages, and many are operating at or near crisis-mode. Staffing shortages now have the potential to undermine the ability of these laboratories to provide timely test results, which is imperative to both the public health and patient access to quality care. These shortages are the result of high educational costs, lack of familiarity with laboratory medicine as a career option, declines in the number of training programs and students trained, and high levels of workload, stress, and burnout.

Currently, the Health Resource and Services Administration administers a number of programs designed to support the healthcare workforce. These programs, in the form of grants to training programs, scholarship and fellowship programs, and loan repayment programs, are generally reserved for a subset of health professionals, such as physicians, nurses, and dentists. Laboratory professionals, and in particular entry-level laboratory professionals, are unable to benefit from these programs. To better address the workforce shortages affecting the medical and public health laboratory workforce, **we urge Congress to include medical and public health laboratory professionals in all federal workforce programs and to consider how addressing visa issues could help the laboratory and pathology workforce.**

Sincerely,

American Association for Clinical Chemistry
American Association of Pathologists' Assistants
American Clinical Laboratory Association
American Medical Technologists
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
American Society for Clinical Pathology Board of Certification
American Society for Microbiology
American Society of Cytopathology
American Society of Hematology
America's Blood Centers
Association for Molecular Pathology (AMP)
Association for the Advancement of Blood and Biotherapies
Association of Genetic Technologists
Association of Pathology Chairs
Association of Public Health Laboratories
College of American Pathologists
COLA Inc.
Infectious Diseases Society of America
National Association of Medical Examiners (NAME)
National Society for Histotechnology
Philippine Association of Medical Technologists-USA, Inc.
Project Sant Fe Foundation
The Joint Commission

SMPPA Support Letter

May 3, 2023

The Honorable Raul Ruiz, MD
United States House of Representatives
2342 Rayburn House Office Building
Washington, DC 20515

The Honorable Larry Bucshon, MD
United States House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

The Honorable Ami Bera, MD
United States House of Representatives
172 Cannon House Office Building
Washington, DC 20515

The Honorable Mariannette Miller-Meeks, MD
United States House of Representatives
1034 Longworth House Office Building
Washington, DC 20515

Dear Representatives Ruiz, Bucshon, Bera and Miller-Meeks:

On behalf of the undersigned physician and non-physician organizations, representing more than one million clinicians and the patients they serve, thank you for introducing H.R. 2474, the Strengthening Medicare for Patients and Providers Act. The legislation applies a permanent inflation-based update to the Medicare Physician Fee Schedule (MPFS) conversion factor, which will provide much-needed stability to the Medicare payment system as our members contend with an increasingly challenging environment providing Medicare beneficiaries with access to timely and quality care.

Congress has taken action to mitigate some of the recent MPFS cuts on a temporary basis, however, reimbursement continues to decline. According to an American Medical Association analysis of Medicare Trustees data, when adjusted for inflation, Medicare payments to clinicians have declined by 26% from 2001-2022[1]. The failure of the MPFS to keep pace with the true cost of providing care

American Medical Group Association
erican Medical Rehabilitation Providers Association
erican Occupational Therapy Association
erican Optometric Association
erican Orthopaedic Foot & Ankle Society
erican Osteopathic Association
erican Physical Therapy Association
erican Podiatric Medical Association
erican Psychiatric Association
erican Psychological Association Services
erican Rhinologic Society
erican Society for Dermatologic Surgery Association
erican Society for Gastrointestinal Endoscopy
erican Society for Radiation Oncology
erican Society for Surgery of the Hand Professional Organization
erican Society of Anesthesiologists
erican Society of Breast Surgeons
erican Society of Cataract and Refractive Surgery
erican Society of Colon & Rectal Surgeons
erican Society of Diagnostic and Interventional Nephrology
erican Society of General Surgeons
erican Society of Hand Therapists
erican Society of Neuroradiology
erican Society of Nuclear Cardiology
erican Society of Plastic Surgeons
erican Society of Retina Specialists
erican Society of Transplant Surgeons
erican Speech-Language-Hearing Association
erican Urogynecologic Society
erican Urological Association
ociation for Clinical Oncology
ociation for Quality Imaging
ociation of Black Cardiologists
ociation of Diabetes Care & Education Specialists
ociation of Freestanding Radiation Oncology Centers
ociation of Pathology Chairs
ociation of Women in Rheumatology
dioVascular Coalition
Clinical Social Work Association
Coalition of State Rheumatology Organizations
College of American Pathologists
Congress of Neurological Surgeons

Academy of Neurologic Physical Therapy
Academy of Nutrition and Dietetics
Academy of Orthopaedic Physical Therapy
ADVION (Formerly the National Association for the Support of Long Term Care (NASL))
Alliance for Physical Therapy Quality and Innovation
Alliance for Recovery Care
Alliance of Specialty Medicine
Alliance of Wound Care Stakeholders
Ambulatory Surgery Center Association
American Academy of Allergy, Asthma & Immunology
American Academy of Audiology
American Academy of Dermatology Association
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Family Physicians
American Academy of Hospice and Palliative Medicine
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Otolaryngology-Head and Neck Surgery
American Academy of Physical Medicine and Rehabilitation
American Association of Hip & Knee Surgeons
American Association of Neurological Surgeons
American Association of Nurse Anesthesiology
American Association of Oral and Maxillofacial Surgeons
American Association of Orthopaedic Surgeons
American Chiropractic Association
American College of Allergy, Asthma and Immunology
American College of Cardiology
American College of Emergency Physicians
American College of Foot and Ankle Surgeons
American College of Gastroenterology
American College of Mohs Surgery
American College of Obstetricians and Gynecologists
American College of Osteopathic Family Physicians
American College of Osteopathic Internists
American College of Physicians
American College of Radiation Oncology
American College of Radiology
American College of Rheumatology
American College of Surgeons
American Gastroenterological Association
American Health Care Association
American Medical Association

Dialysis Vascular Access Coalition
Digestive Health Physicians Association
Emergency Department Practice Management Association
Heart Failure Society of America
Infectious Diseases Society of America
Infusion Providers Alliance
Large Urology Group Practice Association
Medical Group Management Association
National Association of Rehab Providers & Agencies
National Association of Spine Specialists
National Center for Assisted Living
Outpatient Endovascular and Interventional Society
Private Practice Section of the American Physical Therapy Association
Radiology Business Management Association
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons
United Specialists for Patient Access
US Oncology Network

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

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https://mdic.org/

Join us at PIcc23!

Industry, FDA, and other thought leaders will be convening for this exciting 2-day meeting to discuss the impact of regulatory and legislative developments on digital pathology and AI tools in diagnostics!

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Time	Session Title	Speakers
8:00 am	Check-in/Breakfast	
8:30 am	Welcome (MDIC and PIcc)	Andy Fish & Joe Lennerz
Session 1: Updates from Organizations and Initiatives related to DP/AI		
9:00 am	Digital Pathology Association (DPA) and DPA Foundation: Current scope of the work of the DPA and Foundation	Esther Abels
9:10 am	College of American Pathology (CAP): Pathology Innovation and Data Science	Doc deBaca
9:20 am	Association for Pathology Informatics (API) : Pathology Informatics – A Field or a New Practice?	Ji-Yeon Kim
9:30 am	American Clinical Laboratory Association (ACLA) Updates	Susan Van Meter & Adam Borden
9:40 am	Association of Directors of Anatomic and Surgical Pathology (ADASP) Updates	Alex Kalof
9:50 am	Panel Discussion for Session 1	Moderated by TBD
10:20 am	Coffee Break + Networking	
10:30 am	FDA Talk 1: DHCoE Overview and Updates	Troy Tazbaz (Invited)
Session 2: From Regulatory Science to Patients		
11:30 am	Friends of Cancer research (FOCR): Advancing Regulatory Science	Mark Stewart
11:40 am	Alva10	Hannah Mamuszka
11:50 pm	CorePlus: Pathologist Perspective: Journey to Digital Pathology Practice and Benefits of AI	Mariano de Socarraz
12:00 pm	NIH	Mickey Williams
12:10 pm	APPIA	Joshua Greenlee
12:20 pm	Panel Discussion	Moderated by Brittany Mckelvey
12:50 pm	Lunch	All attendees
1:45pm	Key Note: Thomas Fuchs	Moderated by Joe Lennerz
Session 3: Research in the FDA: an overview		Moderated by Ed Margerrison (Invited)
2:30 pm	FDA Talk 2: Regulatory science projects in OSEL's digital pathology program	Brandon Gallas
3:00 pm	FDA Talk 3: DIDSR AI/ML research program and gaps	Alexej Gossmann
3:30 pm	Coffee Break + Networking	
Session 4: Breakout session topics		
3:35 pm	Remote work	Mike Isaacs Matthew Leavitt Doc de Baca Joe Sirintrapun
3:40 pm	PCCP	Emre Gulturk Kevin Schap
3:45 pm	Statistics	Kim Blenman Gina Giannini Brandon Gallas
3:50 pm	Open topic	Moderated by Joe Lennerz & Jeni Caldera
4:00 pm	Discussion and Open Topic Selection	Moderated by Joe Lennerz
5:00 pm	Adjourn	
5:30 pm	Networking Dinner	

Time	Session Title	Speakers
8:00 am	Check-in/Breakfast	Joe Lennerz
8:30 am	Breakout session 1: Remote work, PCCP, Statistics, Open Topic	Remote Work: Mike Isaacs Matthew Leavitt Doc de Baca Joe Sirintrapun PCCP: Emre Gulturk Kevin Schap Statistics: Kim Blenman Gina Giannini Brandon Gallas Open Topic: Joe Lennerz Jeni Caldera Confirmed (all)
9:15 am	Create Summary Slides	All Attendees
10:00 am	Break, networking, rotate	All Attendees
10:30 am	5 minute presentations (for all 4 topics)	Session leads
10:50 am	Vote	All Attendees
11:00 am	Breakout session 2: Remote work, PCCP, Statistics, Open Topic	Remote Work: Mike Isaacs Matthew Leavitt Doc de Baca Joe Sirintrapun PCCP: Emre Gulturk Kevin Schap Statistics: Kim Blenman Gina Giannini Brandon Gallas Open Topic: Joe Lennerz Jeni Caldera Confirmed (all)
11:45 am	Create Summary Slides	All Attendees
12:00 pm	Break, networking, rotate	All Attendees
12:30 pm	5 minute presentations (for all 4 topics)	Session leads
12:50 pm	Vote	All Attendees
1:00 pm	Lunch	All Attendees
2:00 pm	Breakout session 3: Chosen topics 1 and 2	All Attendees
2:45 pm	Create Summary Slides	All Attendees
3:00 pm	Break, networking, rotate	All Attendees
3:15 pm	5 minute presentations (for topics 1 and 2)	Session leads
3:25 pm	Vote	All Attendees
3:30 pm	Discussion and next steps	All Attendees
4:00 pm	Adjourn and Thank you	Jithesh Veetil & Joe Lennerz

MDIC Updates

- Science of Patient Input (SPI) Survey on Digital Health Technologies and Patient Input
- https://mdic.tech/3nM9Yu1

MDIC Updates

- Case for Quality: Make CAPA Cool White Paper
- https://mdic.org/resource/make-capa-cool-white-paper/

MDIC Updates

Call for Volunteers! MDIC Digital Health Software Vertical

- The MDIC Digital Health Software Vertical is looking for software experts with experience in deploying software in various formats like: embedded in medical device/diagnostics, mobile apps, and desktop apps, among others. We also seek more regulatory experts who have experience with Class III software submissions to participate in these activities. Selected volunteers work with abrader group to develop an MDIC framework
- For more information, please contact: Jithesh Veetil jveetil@mdic.org or Taylor Matheny TMetheny@mdic.org

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM
Align. Achieve. Accelerate.

MDIC Updates

<u>Seeking Subject Matter Expert volunteers to support Science of Patient Input Post-Market Patient Engagement Working Groups</u>

- MDIC's Science of Patient Input (SPI) initiative invites experts to contribute to the scoping and initial landscaping in three focus areas within post-market patient engagement.
  - Focus areas include: Real World Evidence in Post-Market, Product Safety Communications, and/ or Patient Benefit/ Risk Assessments

MDIC
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MDIC Updates

Leadership Engagement Culture Initiative

- The Leadership Engagement program implores leaders to focus on company performance with quality and safety as pillars. Presented as an essential toolbox with personalized messaging and training to organizational leaders, the program is looking for leaders to transform their organizational culture by applying this novel, practical approach.

- Interested? Contact cfqcc@mdic.org to get involved with Case for Quality initiatives.

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Diversity & Inclusion

"Watson's narrative contains an absurd presumption. It implies that Franklin, the skilled chemist, could not understand her own data."

Setting the agenda in research

Comment

What Watson and Crick really took from Franklin

Matthew Cobb & Nathaniel Comfort

Rosalind Franklin was no victim in the discovery of DNA's structure. An overlooked letter and an unpublished news article, both from 1953, show that she was an equal contributor.

Chemist Rosalind Franklin independently grasped how DNA's structure could specify proteins.

James Watson and Francis Crick are two of the twentieth century's most renowned scientists. The seminal paper from the pair at the University of Cambridge, UK, detailing the discovery of the DNA double helix, was published as part of a trio in *Nature* 70 years ago this week[1–3]. They are also widely believed to have hit on the structure only after stealing data from Rosalind Franklin, a physical chemist working at King's College London.

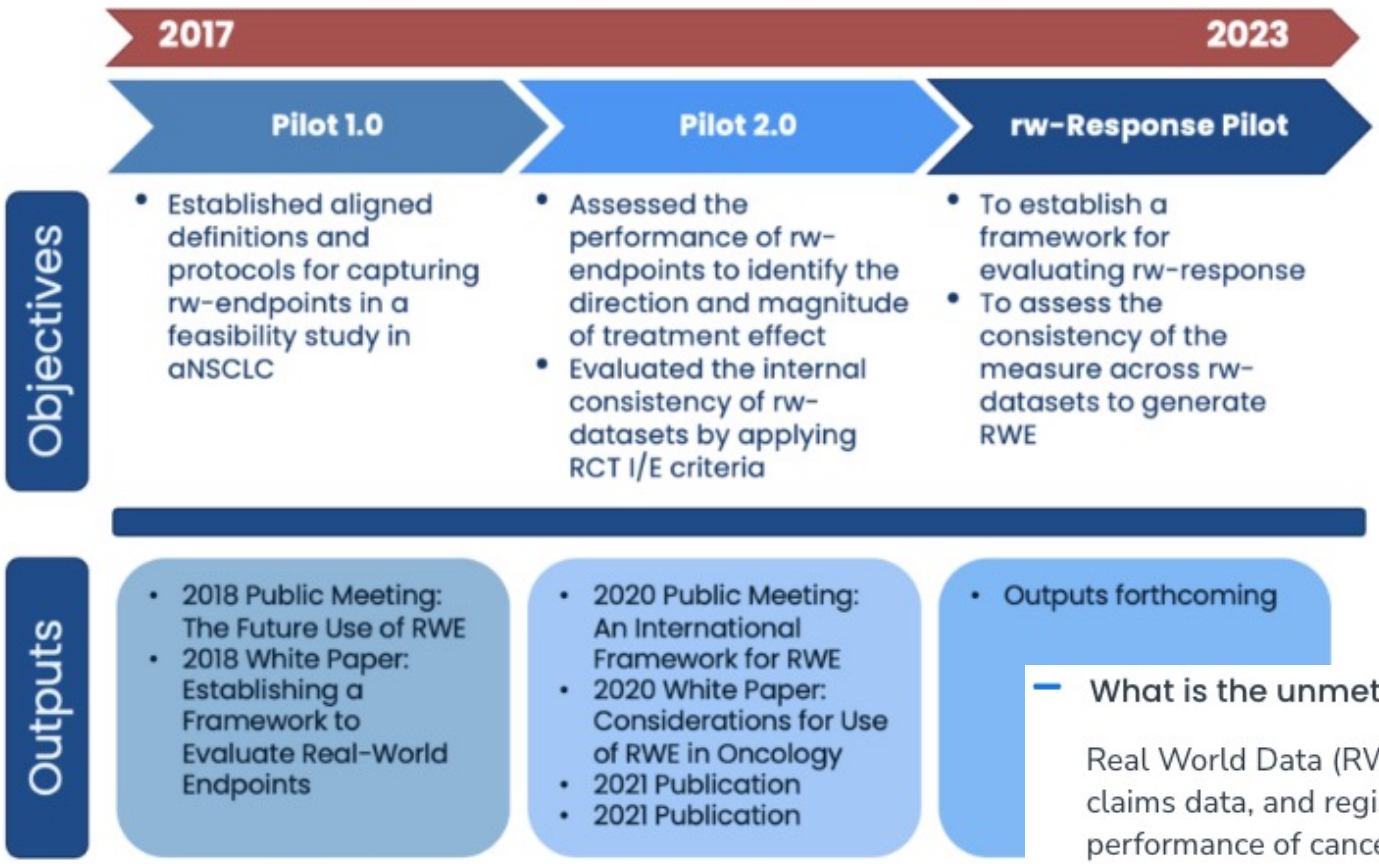
Lore has it that the decisive insight for the double helix came when Watson was shown an X-ray image of DNA taken by Franklin — without her permission or knowledge. Known as Photograph 51, this image is treated as the philosopher's stone of molecular biology, the key to the 'secret of life' (not to mention a Nobel prize). In this telling, Franklin, who died of ovarian cancer in 1958 at just 37, is portrayed as a brilliant scientist, but one who was ultimately unable

Patient advocacy

Real-World Evidence Portfolio

FRIENDS of CANCER RESEARCH

RWE Portfolio Timeline



What is the unmet need and why does it matter?

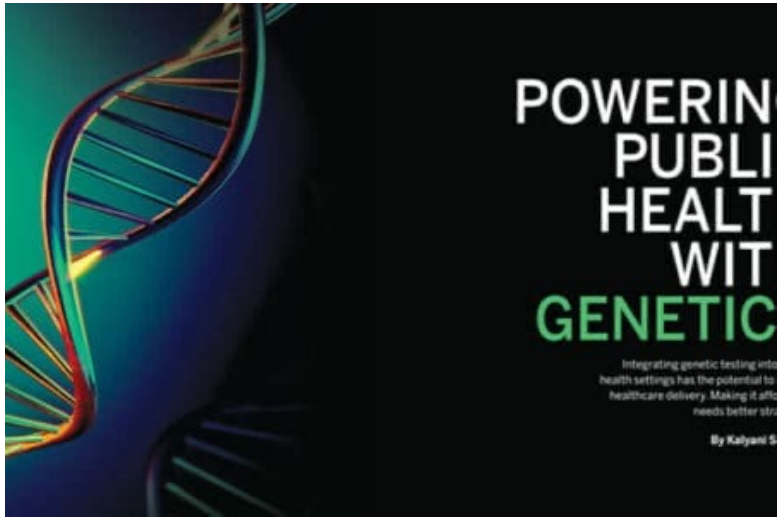
Real World Data (RWD) is patient data routinely collected in electronic health records (EHRs), claims data, and registries that can provide valuable information about the real-world performance of cancer therapies and diagnostics. Unlike in traditional clinical trial settings where data are collected at pre-established timepoints and reported uniformly for trial participants, there is typically a lot of variation in the way RWD are reported within and across sources. Inconsistent definitions and data missingness in RWD present challenges to using these data sources to investigate treatment effectiveness, such as how the therapy impacts survival or can be used in certain patient populations. Strategies and methodologies for mitigating these factors and aligning RWD are needed to fully realize the potential of RWD.

Resources

Articles

Why Advances in Imaging Will Revolutionize the Way We Detect and Treat Disease
-MedCityNews

Fake scientific papers are alarmingly common
-Science



Powering public health with genetics
-Express Healthcare

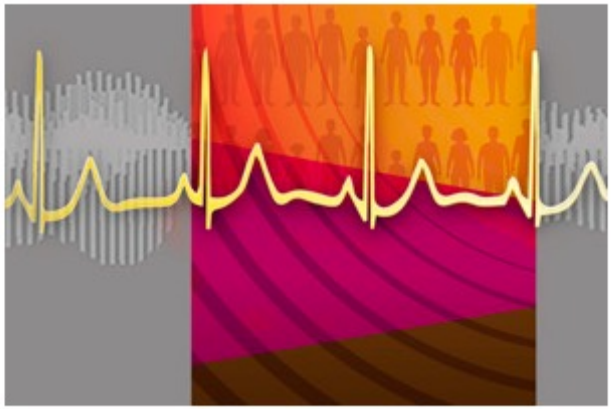
Listen: Intention to Treat from NEJM

Is Medicine Ready for AI?

Supplement to the N Engl J Med 2023; 388:e49

In this episode of "Intention to Treat," Maia Hightower and Isaac Kohane join host Rachel Gotbaum to explore the promise and hazards of artificial-intelligence and machine-learning tools for both clinical and administrative uses in medicine.

Related article Sign Up for NEJM Podcasts



00:02 29:11

Find more…

Resources

- Article: Why Advances in Imaging Will Revolutionize the Way We Detect and Treat Disease (link)
- Article: Fake scientific papers are alarmingly common (link)
- Cochrane UK - Guide to writing abstracts for systematic reviews (download .pdf)
- Public Health Strategy 2022 (download .pdf)
- Article: Powering public health with genetics (link)
- Façade of Evidence: How Medicare's Coverage with Evidence Development Paradigm Rations Care and Exacerbates Inequity (download .pdf)
- ISO 15189:2022 Medical laboratories — Requirements for quality and competence (link)
- Podcast from NEJM: INTENTION TO TREAT - Is Medicine Ready for AI? (link)
- AAMC: Physician Specialty Data Report (link)
- MEthods for LOcalization of Different types of breast lesions (EUBREAST 4) (link)

EUBREAST NETWORK

iBRA NET

Intergroup Study EUBREAST – iBRA-NET

- KarenAI - "Your personal Karen that fights for you" (link) (example)

KarenAI

Publications

- Fernandez-Martinez et al.
- Prognostic and Predictive Value of Immune-Related Gene Expression Signatures vs Tumor-Infiltrating Lymphocytes in Early-Stage ERBB2/HER2-Positive Breast Cancer A Correlative Analysis of the CALGB 40601 and PAMELA Trials

JAMA Oncology | Original Investigation

Prognostic and Predictive Value of Immune-Related Gene Expression Signatures vs Tumor-Infiltrating Lymphocytes in Early-Stage ERBB2/HER2-Positive Breast Cancer
A Correlative Analysis of the CALGB 40601 and PAMELA Trials

Aranzazu Fernandez-Martinez, MD, PhD; Tomás Pascual, MD; Baljit Singh, MD; Paolo Nuciforo, MD, PhD; Naim U. Rashid, PhD; Karla V. Ballman, PhD; Jordan D. Campbell, PhD; Katherine A. Hoadley, PhD; Patricia A. Spears, BS; Laia Pare, PhD; Fara Brasó-Maristany, PhD; Nuria Chic, MD; Ian Krop, MD, PhD; Ann Partridge, MD; Javier Cortés, MD, PhD; Antonio Llombart-Cussac, MD, PhD; Aleix Prat, MD, PhD; Charles M. Perou, PhD; Lisa A. Carey, MD

Supplemental content

IMPORTANCE Both tumor-infiltrating lymphocytes (TILs) assessment and immune-related gene expression signatures by RNA profiling predict higher pathologic complete response (pCR) and improved event-free survival (EFS) in patients with early-stage ERBB2/HER2-positive breast cancer. However, whether these 2 measures of immune activation provide similar or additive prognostic value is not known.

OBJECTIVE To examine the prognostic ability of TILs and immune-related gene expression signatures, alone and in combination, to predict pCR and EFS in patients with early-stage ERBB2/HER2-positive breast cancer treated in 2 clinical trials.

DESIGN, SETTING, AND PARTICIPANTS In this prognostic study, a correlative analysis was performed on the Cancer and Leukemia Group B (CALGB) 40601 trial and the PAMELA trial. In the CALGB 40601 trial, 305 patients were randomly assigned to weekly paclitaxel with trastuzumab, lapatinib, or both for 16 weeks. The primary end point was pCR, with a secondary end point of EFS. In the PAMELA trial, 151 patients received neoadjuvant treatment with trastuzumab and lapatinib for 18 weeks. The primary end point was the ability of the HER2-enriched subtype to predict pCR. The studies were conducted from October 2013 to November 2015 (PAMELA) and from December 2008 to February 2012 (CALGB 40601). Data analyses were performed from June 1, 2020, to January 1, 2022.

MAIN OUTCOMES AND MEASURES Immune-related gene expression profiling by RNA sequencing and TILs were assessed on 230 CALGB 40601 trial pretreatment tumors and 138 PAMELA trial pretreatment tumors. The association of these biomarkers with pCR (CALGB 40601 and PAMELA) and EFS (CALGB 40601) was studied by logistic regression and Cox analyses.

RESULTS The median age of the patients was 50 years (IQR, 42-50 years), and 305 (100%) were women. Of 202 immune signatures tested, 166 (82.2%) were significantly correlated with TILs. In both trials combined, TILs were significantly associated with pCR (odds ratio, 1.01; 95% CI, 1.01-1.02; $P = .02$). In addition to TILs, 36 immune signatures were significantly associated with higher pCR rates. Seven of these signatures outperformed TILs for predicting pCR, 6 of which were B-cell related. In a multivariable Cox model adjusted for clinicopathologic factors, including PAM50 intrinsic tumor subtype, the immunoglobulin G signature, but not TILs, was independently associated with EFS (immunoglobulin G signature–adjusted hazard ratio, 0.63; 95% CI, 0.42-0.93; $P = .02$; TIL-adjusted hazard ratio,

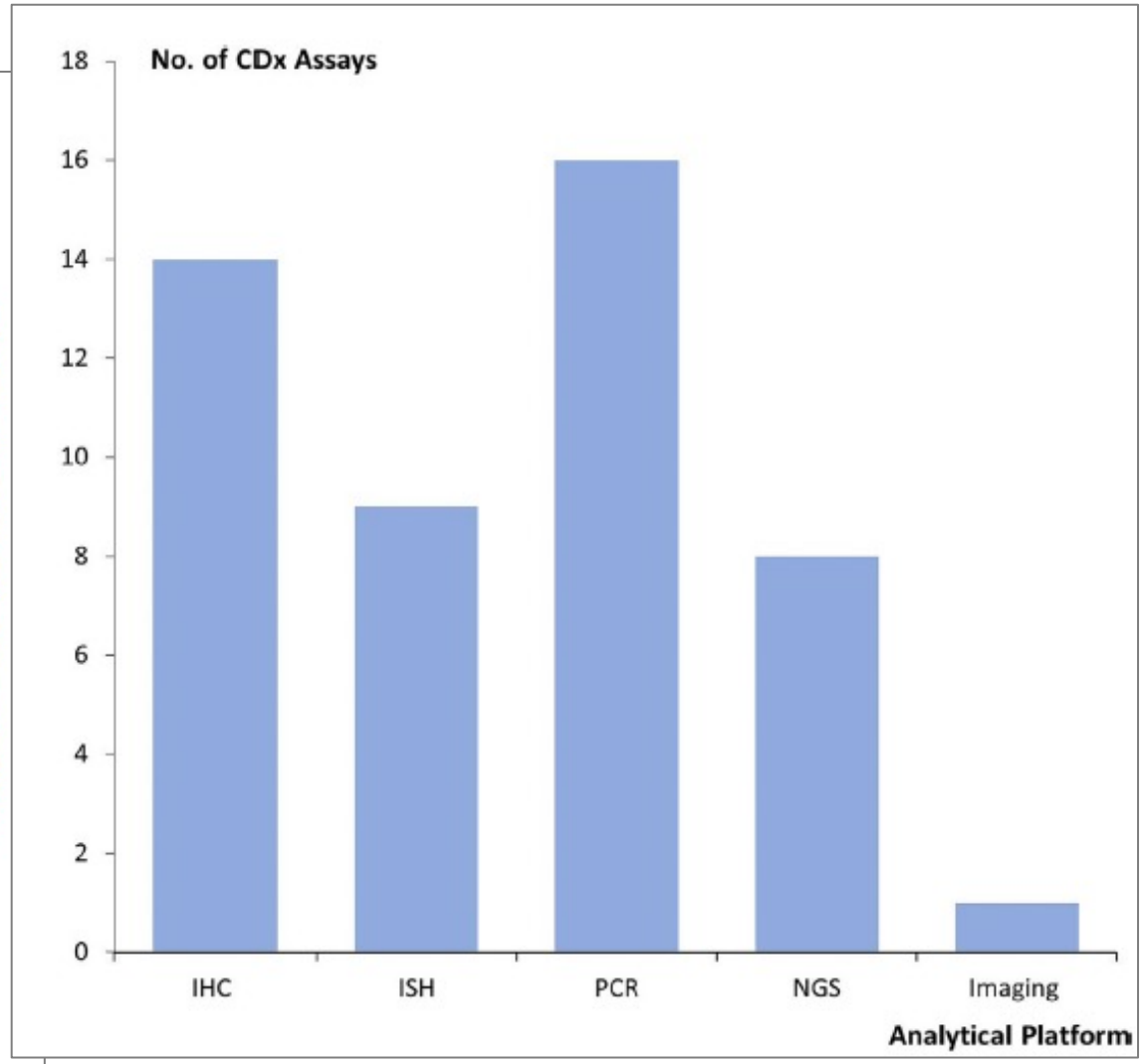
Jorgensen 2023

Companion and complementary diagnostics as tools of precision medicine

Jan Trøst Jørgensen, Dx-Rx Institute, Fredensborg, Denmark,

Abstract

Companion diagnostics (CDx) is an important element in the realization of precision medicine. The FDA defines a CDx assay as an in vitro diagnostic device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. Most CDx assays have been developed prospectively using the drug-diagnostic codevelopment model, in which the assay is developed in parallel to the drug. However, a CDx assay is not only important during clinical development, but just as important as a treatment decision tool when the drug is regulatory approved and routinely used in the clinic. Owing to the central role of the CDx assay in the treatment of individual patients, regulators have imposed strict requirements on assay quality. Before a CDx assay can be used in the clinic, careful analytical and clinical validation must be performed to document the accuracy, reproducibility, and clinical performance.



Bychkov et al.,

Virchows Archiv
https://doi.org/10.1007/s00428-023-03547-0

BRIEF REPORT

Integrating cytology into routine digital pathology workflow: a 5-year journey

Andrey Bychkov[1] · Akira Yoshikawa[1] · Jijgee Munkhdelger[1] · Takashi Hori[1] · Junya Fukuoka[1,2]

Received: 22 January 2023 / Revised: 13 March 2023 / Accepted: 20 April 2023

Abstract
Despite recent advances in digital imaging, the adoption of digital cytology is challenging due to technical limitati
study describes our 5-year institutional experience with the implementation of digital cytology. The routine cytolo
flow included conventional two-step screening by cytotechnologists, followed by sign out by pathologists. We in
sign out of cytologic cases using a microscopic digital imaging platform operated by cytotechnologists, which all
remote review of slides by cytopathologists via video streaming. We also provided cytologic correlation to support th

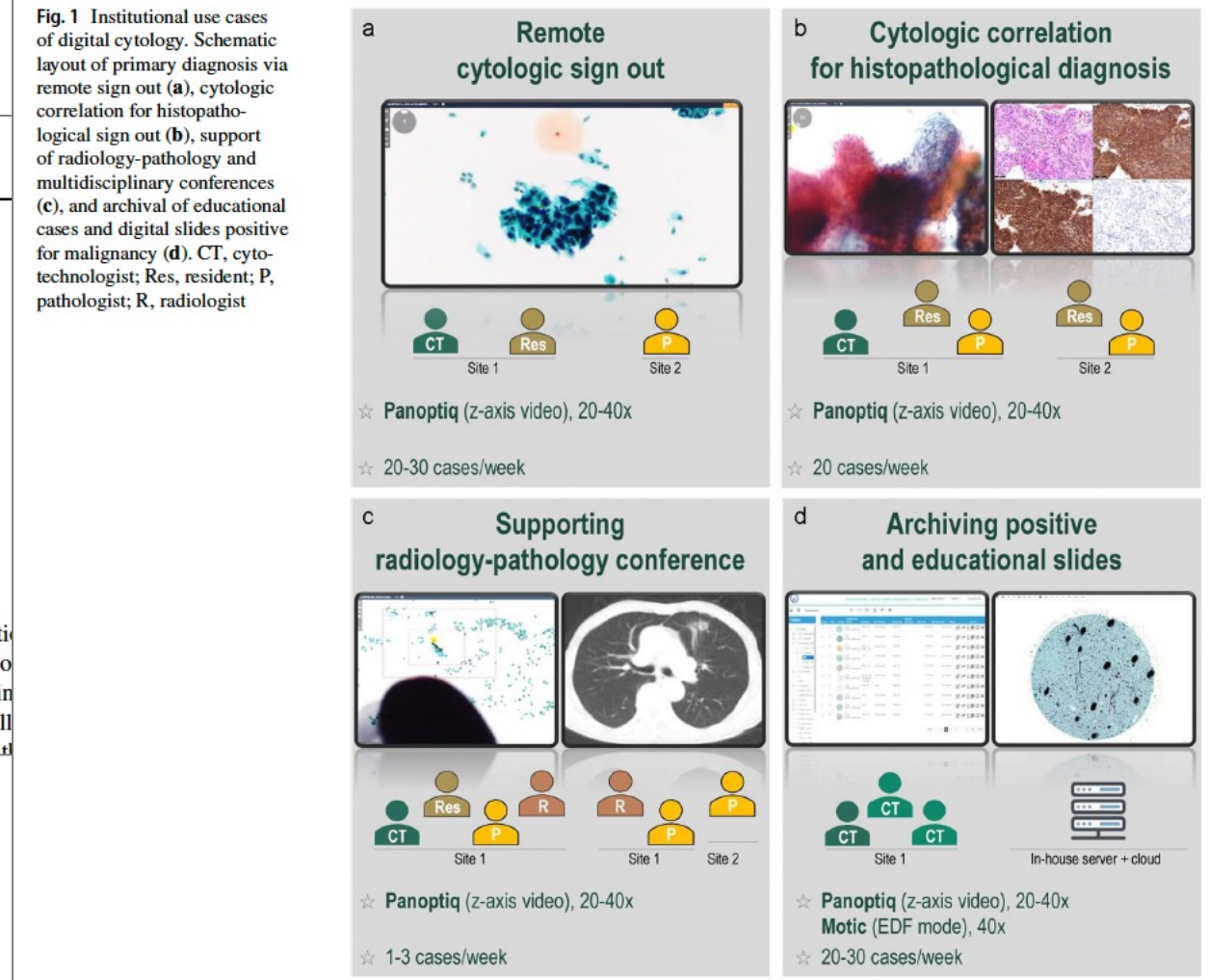


Fig. 1 Institutional use cases of digital cytology. Schematic layout of primary diagnosis via remote sign out (**a**), cytologic correlation for histopathological sign out (**b**), support of radiology-pathology and multidisciplinary conferences (**c**), and archival of educational cases and digital slides positive for malignancy (**d**). CT, cytotechnologist; Res, resident; P, pathologist; R, radiologist

Harada et al.,

nature reviews clinical oncology

Review article

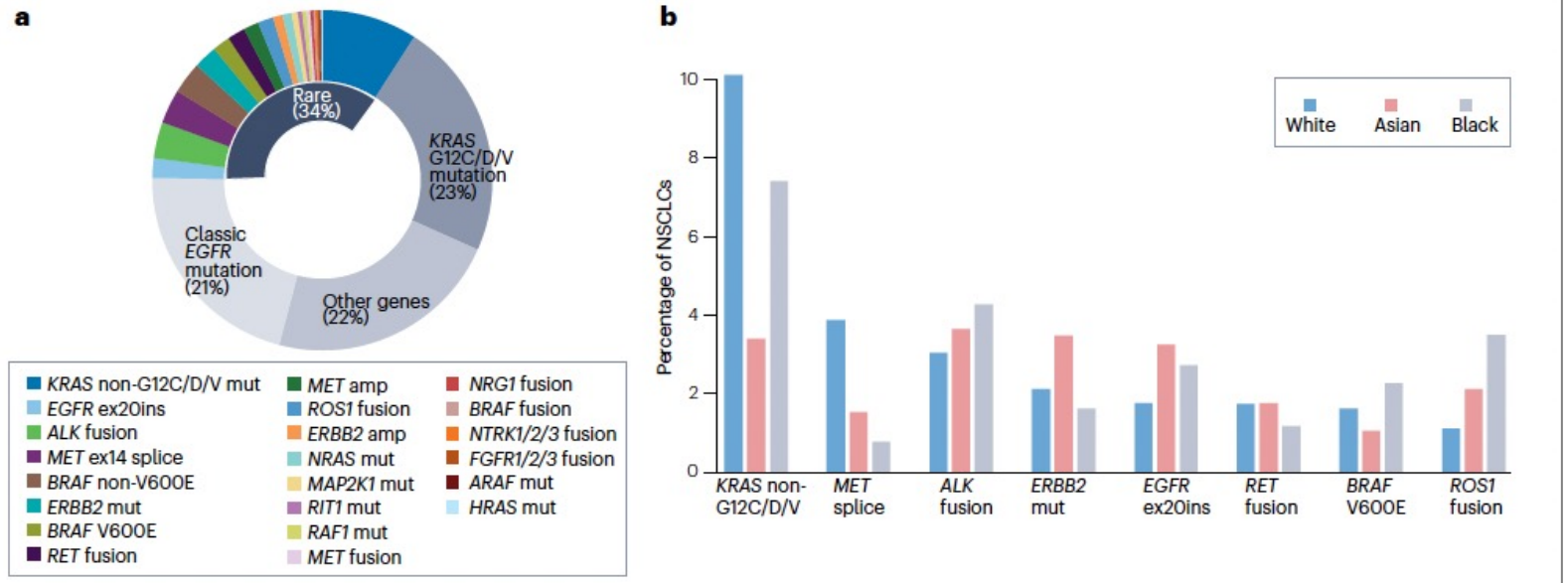
Rare molecular subtypes of lung cancer

Guilherme Harada[1,5], Soo-Ryum Yang[2,5], Emiliano Cocco[3,6] & Alexander Drilon[1,4,6]

Abstract

Sections

Review article



Find more…

Publications

- Akkari et al. Exploring current challenges in the technologist workforce of clinical genomics laboratories (download .pdf)

  #cytogenetics #education #technologists #genetics #workforce

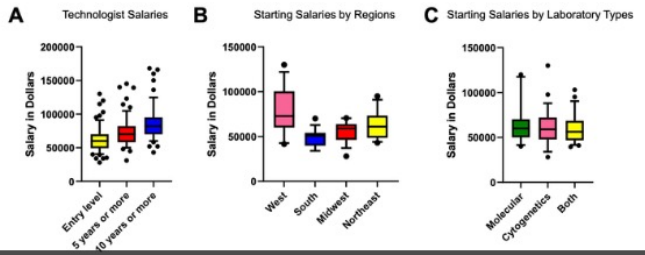
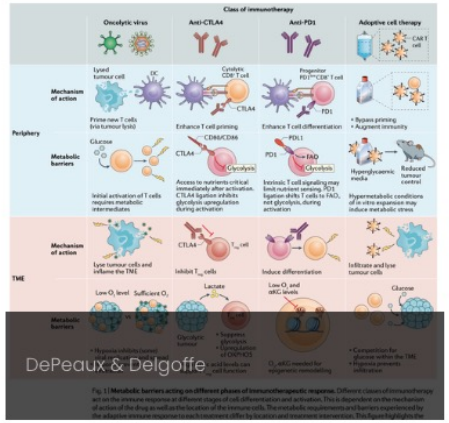


Figure 2 Salaries for technologists. (A) In this cohort, the average salaries for technologists at entry level, 5 years of experience, and 10 years of experience were $61,647, $73,950, and $86,929, respectively. (B) When stratified by regions, West had the highest salary on average for entry level ($78,691), compared with Northwest ($63,268), Midwest ($55,425), and South ($49,124). (C) Laboratory specialties did not have significant differences in starting salaries (*P*-value = .7642, Welch's analysis of variance test).

Akkari et al.



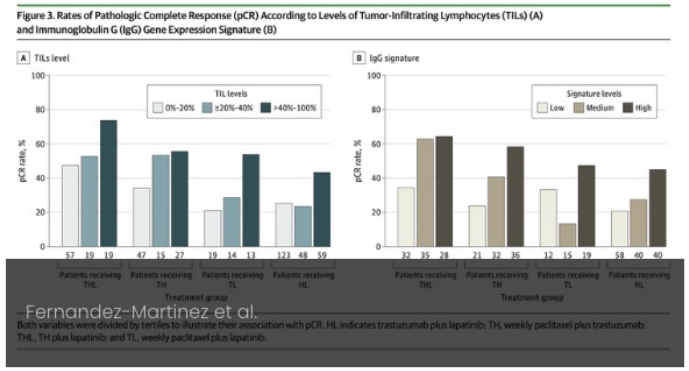
DePeaux & Delgoffe

- Kristin DePeaux & Greg M. Delgoffe. Metabolic barriers to cancer immunotherapy (download .pdf)

  #memory #metabolism #PD1 #tumor #hypoxia

- Fernandez-Martinez et al. Prognostic and Predictive Value of Immune-Related Gene Expression Signatures vs Tumor-Infiltrating Lymphocytes in Early-Stage ERBB2/HER2-Positive Breast Cancer A Correlative Analysis of the CALGB 40601 and PAMELA Trials (download .pdf)

  #gene expression #cancer #tumor #EFS #TIL #lapatinib



Fernandez-Martinez et al.

- Gold et al. Perspectives of Rare Disease Experts on Newborn Genome Sequencing (download .pdf)

  #rare disease #mucopolysaccharidosis #NBSeq #OTC

- Huang et al. The oral microbiome in autoimmune diseases: friend or foe? (download .pdf)

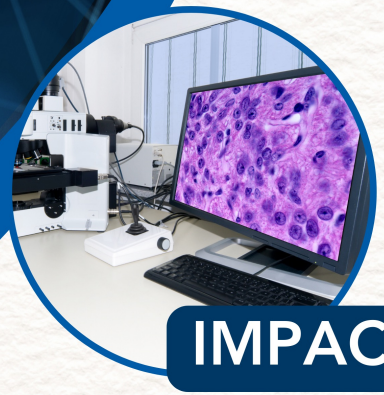
  #autoimmune #P. gingivalis #pathogenesis #translocation #dysbiosis

- George M. Ibrahim & Michael D. Taylor. How thought itself can drive tumour growth (download .pdf)

  #neurons #brain cancer #tumor #tumorigenesis

Next meeting is in-person

PICC23: UNLOCKING THE POTENTIAL OF DIGITAL PATHOLOGY AND AI THROUGH REGULATORY SCIENCE



IMPACT

SYNERGIZE

MEET

27-28 JUNE

Networking Dinner Included!

Le Méridien Arlington | 1121 19th St N, Arlington, VA 22209

Join us for the Pathology Innovation Collaborative Community Annual Meeting. The theme for PIcc23 is "Meet. Synergize. Impact: Unlocking the Potential of Digital Pathology and Artificial Intelligence (AI) through Regulatory Science.

Why you should attend:

- Network with domain experts with keen interest in moving regulatory science forward through in-person interactive working sessions
- The most comprehensive overview from a multistakeholder organization on digital pathology and AI
- Opportunities to share your unique point of view with the entire community
- Synergize to large scale project(s) to create practically relevant regulatory science tools and templates

During PIcc23, thought-leaders, regulators and pioneers in digital pathology will network and discuss:

- Advances in digital pathology and AI applications
- How these advances create new incentives to tackle the next big hurdle, to broadly implement digital pathology and AI/machine learning (ML)
- Impact of regulatory and legislative developments digital pathology and AI tools in diagnostics due to the end of covid pandemic public health emergency
- And more

Visit mdic.tech/PICCMeeting for more information


Pathology Innovation
Collaborative Community
MAY UPDATES MEETING
Wednesday
May 31 at 3:00-4:00 PM ET
PIcc2023
Steering committee series: Final Wednesday of every month

Your personal Karen that fights for you

KarenAi

Your personal Karen that fights for you

Location of Complaint

What was the issue you encountered?

Complaint

Respond like a Karen