Pathology Innovation Collaborative Community

PIcc

The Alliance for Digital Pathology

A collaborative community with FDA participation

Steering Committee Meeting | August 2022

Digital Pathology CPT codes

New Category III CPT Codes for Digital Pathology

Category III CPT Code	Short Description	Use in conjunction with Category I CPT Code
0751T	Digitization of glass slides for level II, surgical pathology	88302
0752T	Digitization of glass slides for level III, surgical pathology	88304
0753T	Digitization of glass slides for level IV, surgical pathology	88305
0754T	Digitization of glass slides for level V, surgical pathology	88307
0755T	Digitization of glass slide for level VI, surgical pathology	88309
0756T	Digitization of glass slides for special stain, group I	88312
0757T	Digitization of glass slides for special stain, group II	88313
0758T	Digitization of glass slides for special stain, frozen tissue block	88314
0759T	Digitization of glass slides for special stain, enzyme constituents	88319
0760T	Digitization of microscope slides for immunohistochemistry, initial stain	88342
0761T	Digitization of glass slides for immunohistochemistry, each additional stain	88341
0762T	Digitization of glass slides for immunohistochemistry, each multiplex stain	88344
0763T	Digitization of glass slides for morphometric analysis, tumor IHC	88360

Source: American Medical Association

- Category III codes = tracking
- Clinical Utilization can help facilitate Medicare in establishing national reimbursement rates.
- New codes.
- Estimated to be ~3-5% of the global rates for existing codes
- Could be ~$2-4
- Prepare Systems to Report
- Go-live is January 1, 2023

FDA

Re-classification of Skin Lesion Analyzers

FDA Executive Summary
General Issues Panel Meeting
on Skin Lesion Analyzers

Prepared for the Meeting of the
General and Plastic Surgery Devices
Advisory Panel

July 28, 2022

FDA CDRH
General and Plastic Surgery Devices
Advisory Committee Meeting

July 28-29, 2022

*****Virtual*****

As required by section 513(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food and Drug Administration (FDA) is convening the General and Plastic Surgery Devices Advisory Panel (the Panel) for the purposes of obtaining recommendations about the reclassification of skin lesion analyzers (SLAs) and to discuss appropriate controls necessary to mitigate the risks to health and assure the safety and effectiveness of these devices.

FDA is holding this panel meeting to obtain input on the risks and benefits of SLAs for external use. The Panel will be asked to recommend to FDA whether SLAs should be down classified from Class III into Class II (subject to General and Special Controls). The Panel will be asked to discuss the types of evidence (including clinical evidence) that would be helpful to support certain indications as well as appropriate special controls necessary to mitigate the risks to health and assure the safety and effectiveness of these devices

FDA Modernization in Action 2022

Importantly, in September 2021, the FDA completed a strategic reorganization to form the Office of Digital Transformation (ODT). Reporting directly to the FDA Commissioner, ODT directs and coordinates enterprise strategic planning, policy, and resource management to ensure that IT, data, and cybersecurity investments and activities provide maximum value to FDA. ODT brings together the Offices of Information Management and Technology (OIMT); Data, Analytics, and Research (ODAR); and Information Security (OIS), to provide high quality, secure, and efficient IT and

The FDA Modernization Framework

TMAP

The Technology Modernization Action Plan (TMAP) outlined agency-wide technology modernization, including computer hardware, software, data, and analytics

TECHNOLOGY INFRASTRUCTURE

Modernizing the FDA's technical infrastructure, with a focus on cloud computing, data interfaces, and cybersecurity

TECHNOLOGY PRODUCTS

Enhancing the FDA's capabilities to develop solutions using standardized technology products to support its regulatory mission

STAKEHOLDER COLLABORATION

Communicating and collaborating with stakeholders to drive technological progress that is interoperable across the IT enterprise and delivers value to consumers and patients

DMAP

The Data Modernization Action Plan (DMAP) proposed a framework and actionable recommendations for the FDA's data strategy

HIGH-VALUE DRIVER PROJECTS

Identifying and executing high-value, scalable driver projects for individual centers and for the agency

DATA PRACTICES

Developing consistent and repeatable data practices across the agency

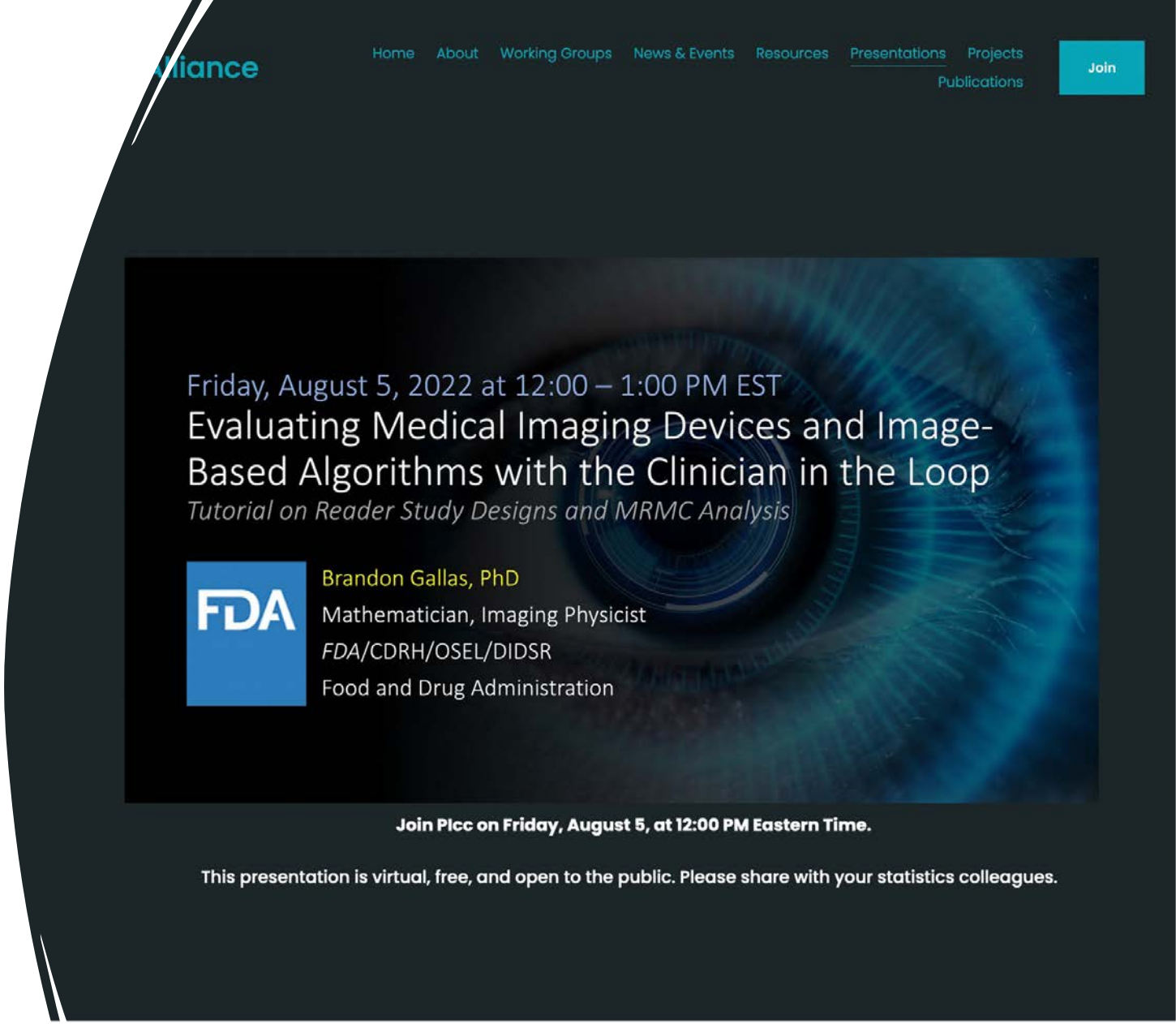
TALENT NETWORK

Creating and sustaining a strong talent network combining internal strengths with key external partnerships

Dr. Gallas (FDA) Lecture

- https://pathologyinnovationcc.org/presentations/aug-2022-reader-study-designs-and-mrmc-analysis

- August 5th
- online now
- Multi-Reader Multi-Case Resource

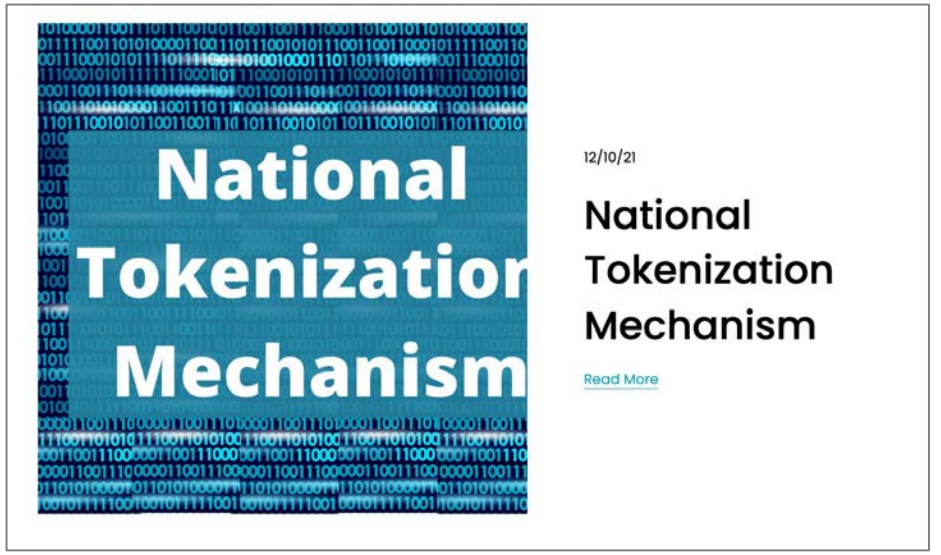


Watch the recording of the presentation here:

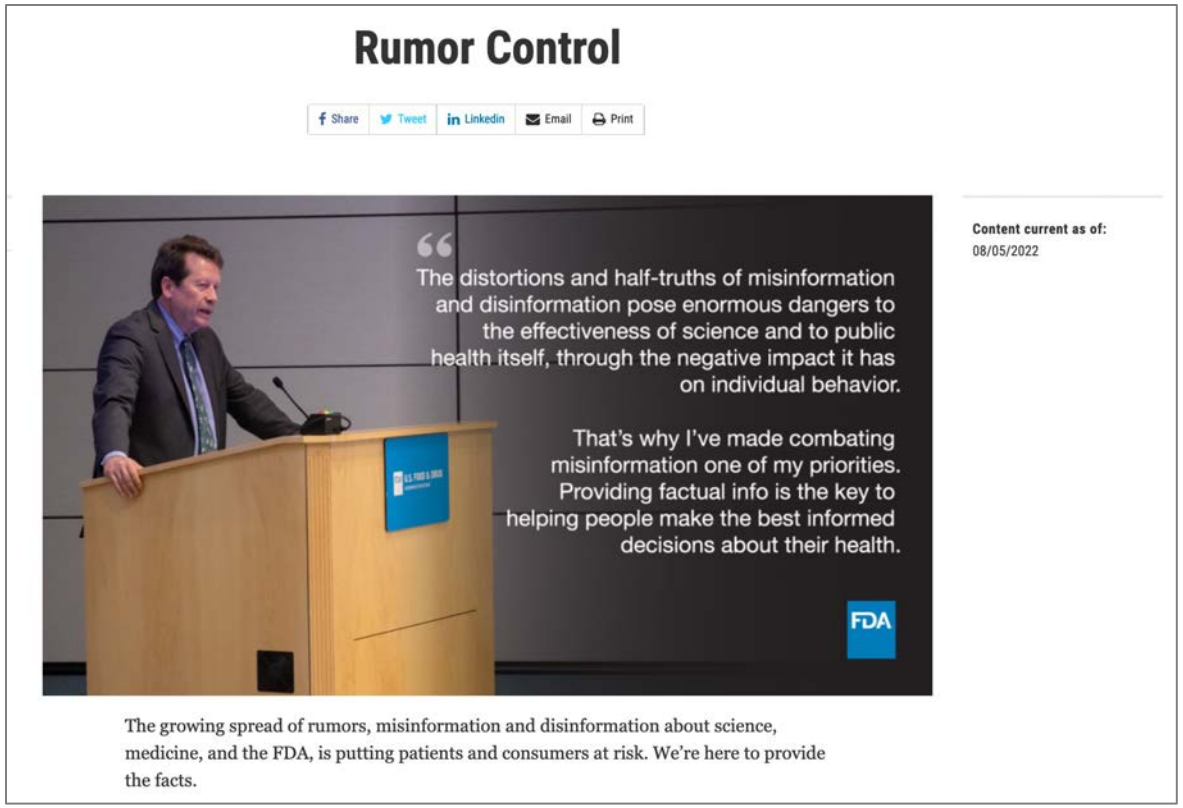
FDA: OGPS

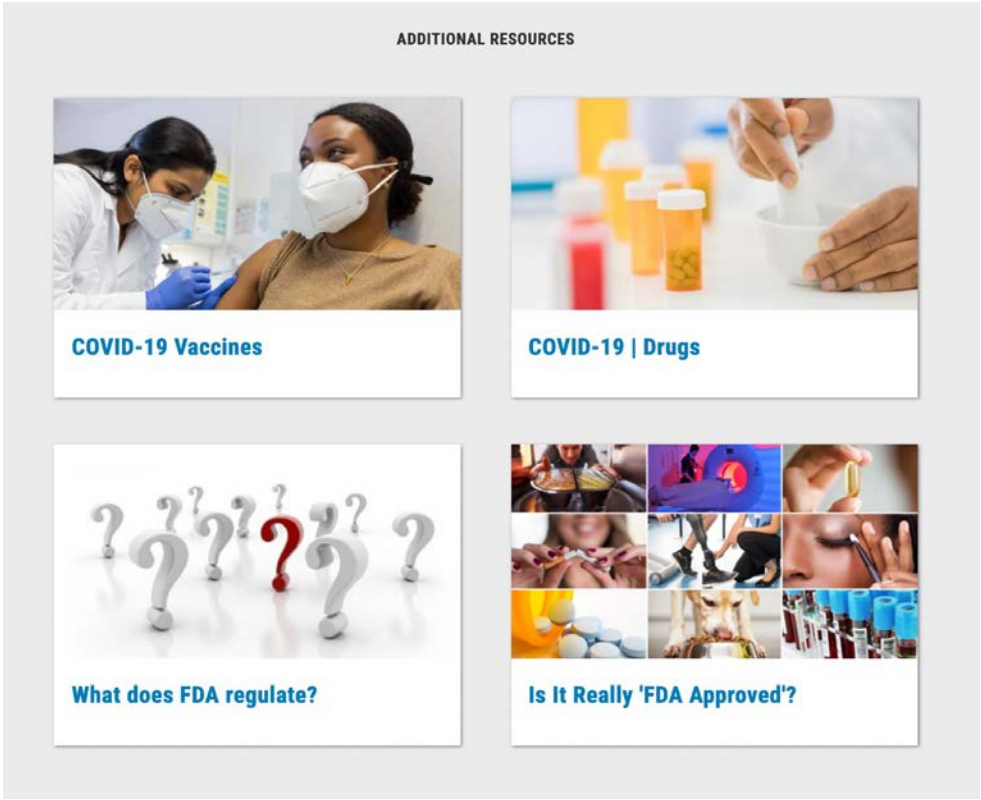
Three sub-offices:

- The Office of Global Operations (**OGO**), which includes our foreign posts,
- The Office of Global Diplomacy and Partnerships (**OGDP**),
  and
- The Office of Trade, Mutual Recognition, and International Arrangements (**OTMRIA**).



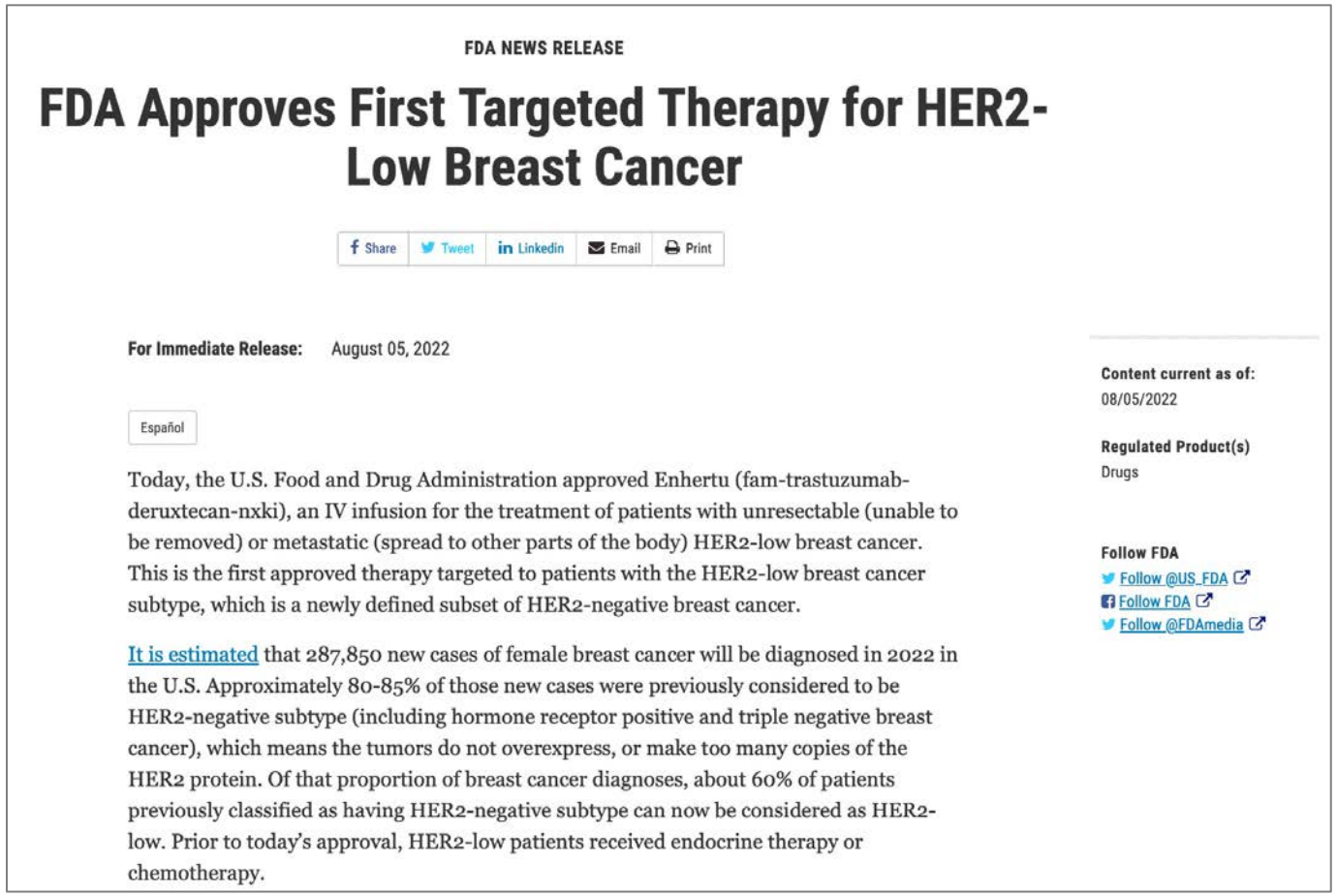
FDA: Rumor control





https://www.fda.gov/news-events/rumor-control

FDA approval => project “HER2-Low Project”



FDA NEWS RELEASE

FDA Approves First Targeted Therapy for HER2-Low Breast Cancer

Share | Tweet | LinkedIn | Email | Print

For Immediate Release: August 05, 2022

Español

Today, the U.S. Food and Drug Administration approved Enhertu (fam-trastuzumab-deruxtecan-nxki), an IV infusion for the treatment of patients with unresectable (unable to be removed) or metastatic (spread to other parts of the body) HER2-low breast cancer. This is the first approved therapy targeted to patients with the HER2-low breast cancer subtype, which is a newly defined subset of HER2-negative breast cancer.

It is estimated that 287,850 new cases of female breast cancer will be diagnosed in 2022 in the U.S. Approximately 80-85% of those new cases were previously considered to be HER2-negative subtype (including hormone receptor positive and triple negative breast cancer), which means the tumors do not overexpress, or make too many copies of the HER2 protein. Of that proportion of breast cancer diagnoses, about 60% of patients previously classified as having HER2-negative subtype can now be considered as HER2-low. Prior to today's approval, HER2-low patients received endocrine therapy or chemotherapy.

Content current as of:
08/05/2022

Regulated Product(s)
Drugs

Follow FDA
Follow @US_FDA
Follow FDA
Follow @FDAmedia

Biomarker Testing Health Insurers Will Be Required To Cover Cancer Testing In RI

Gov. Dan McKee's signed

Insurers will have to cover biomarker testing, beginning in 2024

Rhode Island

(b) Every individual or group health insurance contract, or every individual or group hospital or medical expense insurance policy, plan, or group policy delivered, issued for delivery, or renewed in this state on or after January 1, 2024, shall provide coverage for the services of biomarker testing in accordance with each health insurer's respective principles and mechanisms of reimbursement, credentialing, and contracting. Biomarker testing must be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition to guide treatment decisions, when the test provides clinical utility as demonstrated by medical and scientific evidence, including, but not limited to:

(1) Labeled indications for an FDA-approved or -cleared test or indicated tests for an FDA-approved drug;

(2) Centers for Medicare Services ("CMS") National Coverage Determinations or Medicare Administrative Contractor ("MAC") Local Coverage Determinations; or

(3) Nationally recognized clinical practice guidelines and consensus statements.

(c) Coverage as defined in subsection (b) of this section shall be provided in a manner that limits disruptions in care including the need for multiple biopsies or biospecimen samples.

2022 -- S 2201 SUBSTITUTE A

LC004362/SUB A/3

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2022

AN ACT

RELATING TO INSURANCE -- ACCIDENT AND SICKNESS INSURANCE POLICIES -- BIOMARKER TESTING COVERAGE

Introduced By: Senators Goodwin, McCaffrey, Coyne, Miller, Pearson, Gallo, and Ruggerio

Date Introduced: February 08, 2022

Referred To: Senate Health & Human Services

What will this act enable?

(b) Every individual or group health insurance contract, or every individual or group hospital or medical expense insurance policy, plan, or group policy delivered, issued for delivery, or renewed in this state on or after January 1, 2024, shall provide coverage for the services of biomarker testing in accordance with each health insurer's respective principles and mechanisms of reimbursement, credentialing, and contracting. Biomarker testing must be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition to guide treatment decisions, when the test provides clinical utility as demonstrated by medical and scientific evidence, including, but not limited to:

(1) Labeled indications for an FDA-approved or -cleared test or indicated tests for an FDA-approved drug;

(2) Centers for Medicare Services ("CMS") National Coverage Determinations or Medicare Administrative Contractor ("MAC") Local Coverage Determinations; or

(3) Nationally recognized clinical practice guidelines and consensus statements.

(c) Coverage as defined in subsection (b) of this section shall be provided in a manner that limits disruptions in care including the need for multiple biopsies or biospecimen samples.

When and how will this act go into effect?

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

RELATING TO INSURANCE -- ACCIDENT AND SICKNESS INSURANCE POLICIES -- BIOMARKER TESTING COVERAGE

***

This act would require health insurers, nonprofit hospital service corporations, nonprofit medical service corporations and health maintenance organizations to issue policies that provide coverage for biomarker testing, on or after January 1, 2024.

This act would take effect upon passage.

========
LC004362/SUB A/3
========

Rhode Island Genetic Counselor Licensing *GENETIC* COUNSELORS LICENSING ACT

7/25/2022

Rep. McEntee and Sen. Sosnowski's genetic counselors legislation ceremonially signed into law

STATE HOUSE – Legislation (2022-H 6643A, 2022-S 2205A) sponsored by Rep. Carol Hagan McEntee and Sen. V. Susan Sosnowski to establish a licensing process for genetic counselors within the Department of Health was ceremonially signed into law by the governor today.

Currently in Rhode Island, there is no legal standard to determine who can represent themselves as genetic counselors.

The legislation would ensure minimum standards for genetic counselors in the areas of academic training, certification, clinical experience and the delivery of high-quality genetic counseling services.

"If a patient is concerned or frightened about a potential genetic illness, it is imperative that the genetic counselors utilized by the patient are qualified to deliver the care that is needed. These patients are put into vulnerable positions and their health, safety and wellbeing needs to be protected through the proper licensing and regulation of genetic counselors in Rhode Island," said Representative McEntee (D-Dist. 33, South Kingstown, Narragansett).

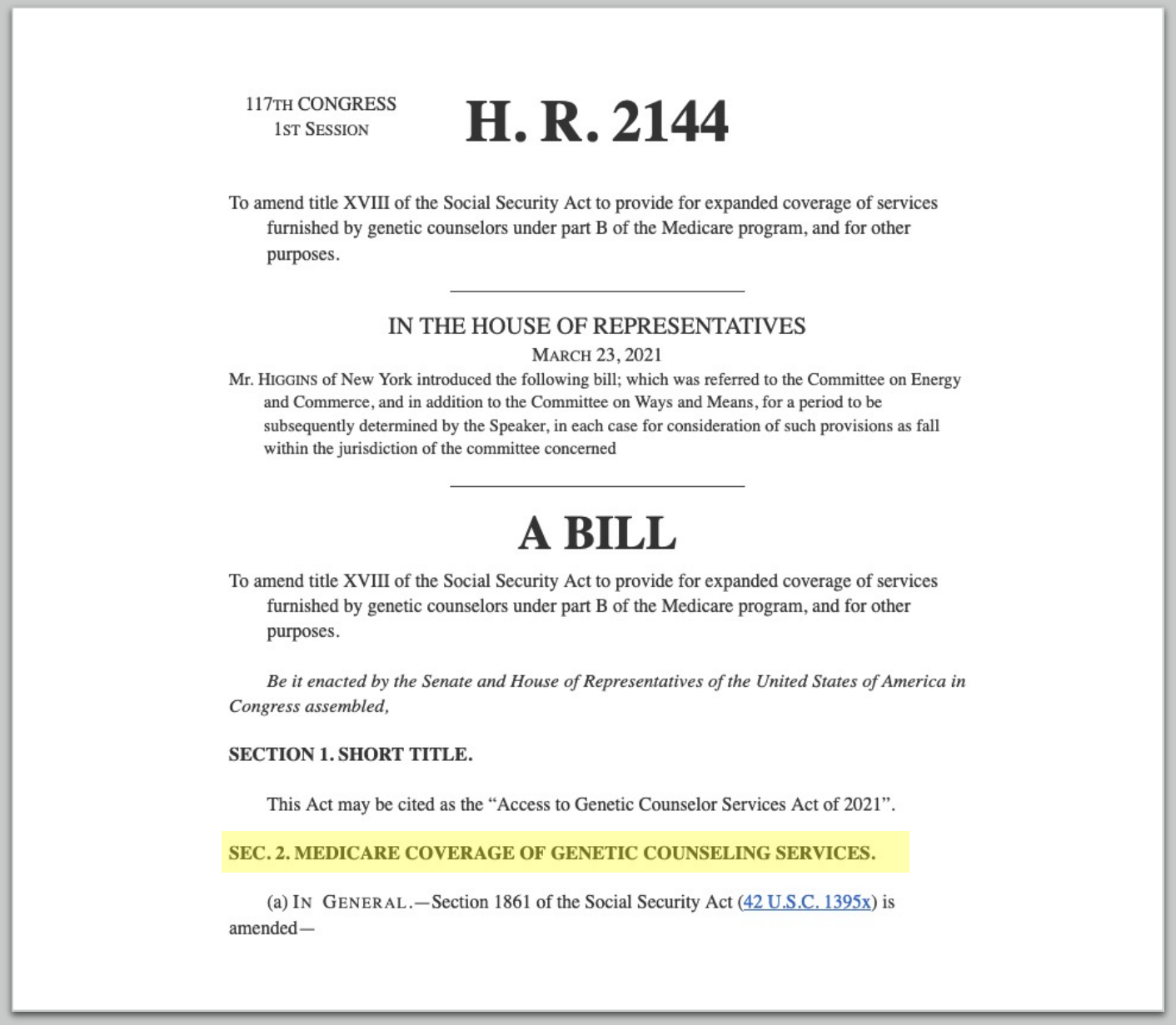
"This bill is about protecting our state's patients when utilizing genetic counselors while also controlling health-care costs through the ordering of correct tests, the prevention of unnecessary testing and proper interpretation of genetic tests. These patients are experiencing significant anxiety and stress and the legislation will ensure they are treated properly and safely," said Senator Sosnowski (D-Dist. 37, South Kingstown, New Shoreham).

Genetic Counselor (GC)
…national level…

- GCs are licensed but Licensure is not recognized
- Access to Genetic Services Act

NSGC

- CMS to recognized GC as independent providers
- Coalition of supporters (>350 organizations)
- Bipartisan support
- End of the year Medicare package ??
- 96040 (CPT)



117TH CONGRESS
1ST SESSION

H. R. 2144

To amend title XVIII of the Social Security Act to provide for expanded coverage of services furnished by genetic counselors under part B of the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 23, 2021

Mr. HIGGINS of New York introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to provide for expanded coverage of services furnished by genetic counselors under part B of the Medicare program, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Access to Genetic Counselor Services Act of 2021".

SEC. 2. MEDICARE COVERAGE OF GENETIC COUNSELING SERVICES.

(a) IN GENERAL.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended—

Biden Cancer Moonshot Relaunch Will "End Cancer as We Know It"

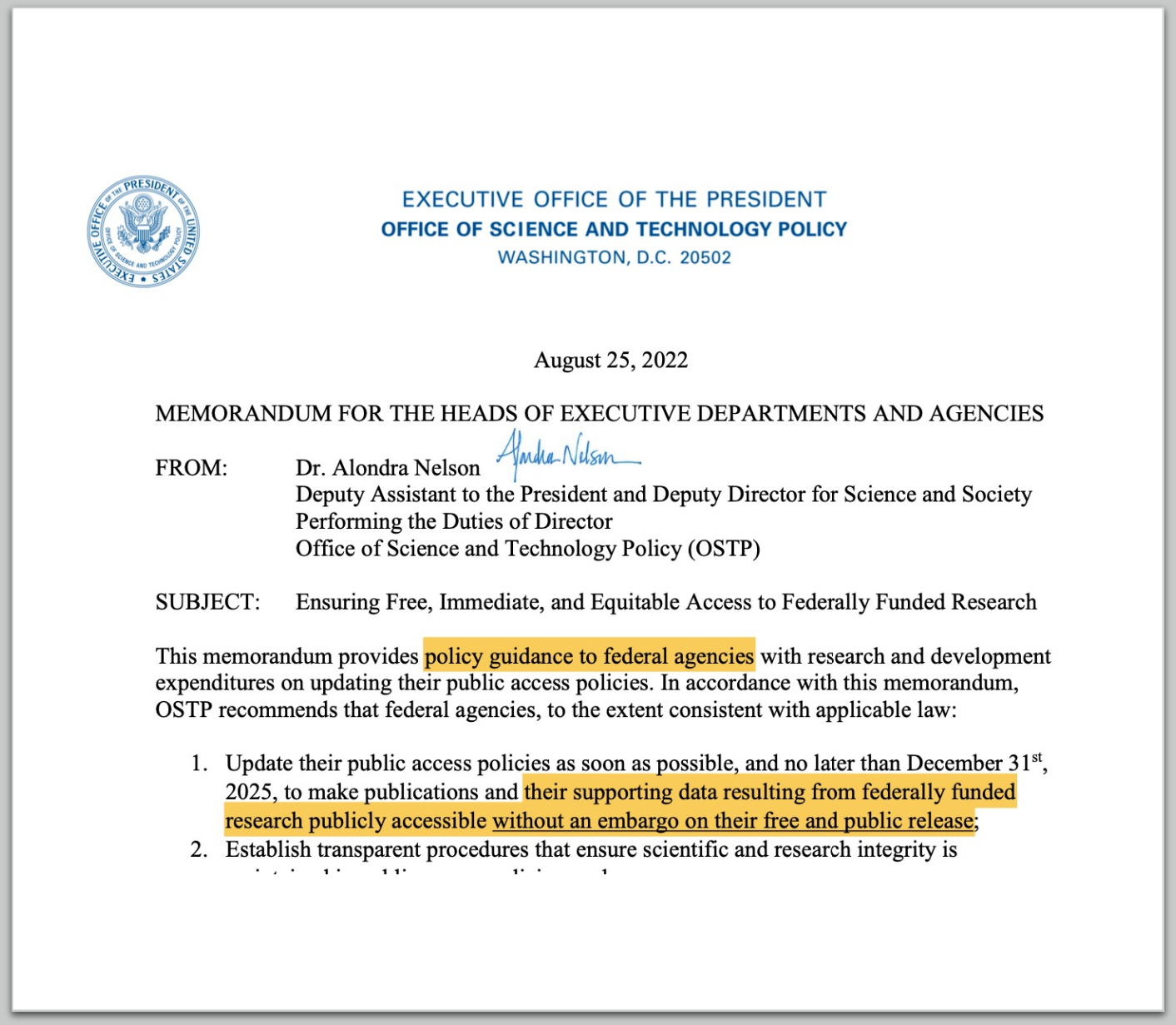
July 21, 2022 by Alec Stone MA, MPA, ONS Government Affairs Director

https://voice.ons.org/advocacy/biden-cancer-moonshot-relaunch-will-end-cancer-as-we-know-it

Executive, Office of the President

- From Dr. Alondra Nelson (Deputy Assistant to the President)
- Memorandum for the Heads of Executive Departments and Agencies

- Support increased public access
- “data resulting from federally funded research… publicly accessible without an embargo on their free and public release”
- Peer Reviewed Scholarly Publications



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20502

August 25, 2022

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: Dr. Alondra Nelson
Deputy Assistant to the President and Deputy Director for Science and Society
Performing the Duties of Director
Office of Science and Technology Policy (OSTP)

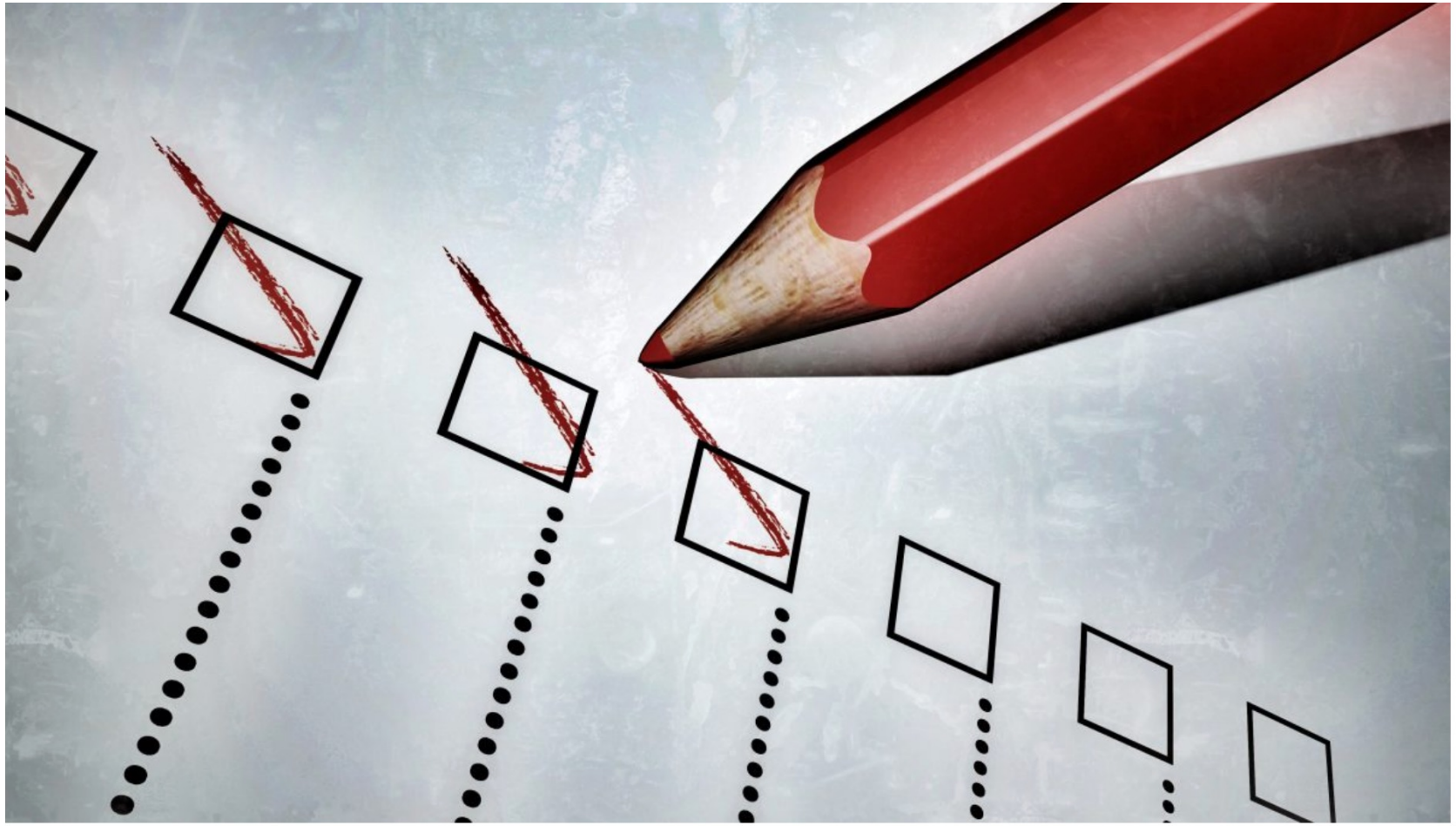
SUBJECT: Ensuring Free, Immediate, and Equitable Access to Federally Funded Research

This memorandum provides policy guidance to federal agencies with research and development expenditures on updating their public access policies. In accordance with this memorandum, OSTP recommends that federal agencies, to the extent consistent with applicable law:

1. Update their public access policies as soon as possible, and no later than December 31st, 2025, to make publications and their supporting data resulting from federally funded research publicly accessible without an embargo on their free and public release;
2. Establish transparent procedures that ensure scientific and research integrity is

Peer review

https://www.theepochtimes.com/the-new-peer-review-why-unbiased-science-is-now-often-misleading_4685781.html?utm_source=ref_share&utm_campaign=copy&rs=SHRQNXXX



(JNT Visual/Shutterstock*)

PREMIUM HEALTH VIEWPOINTS

The New Peer Review: Why 'Unbiased' Science Is Now Often Misleading

BY JENNIFER MARGULIS AND JOE WANG TIME AUGUST 24, 2022 PRINT

SHARE 151 Friends Read Free Copy

12 Comments Hide Comments

Policies and Regulations

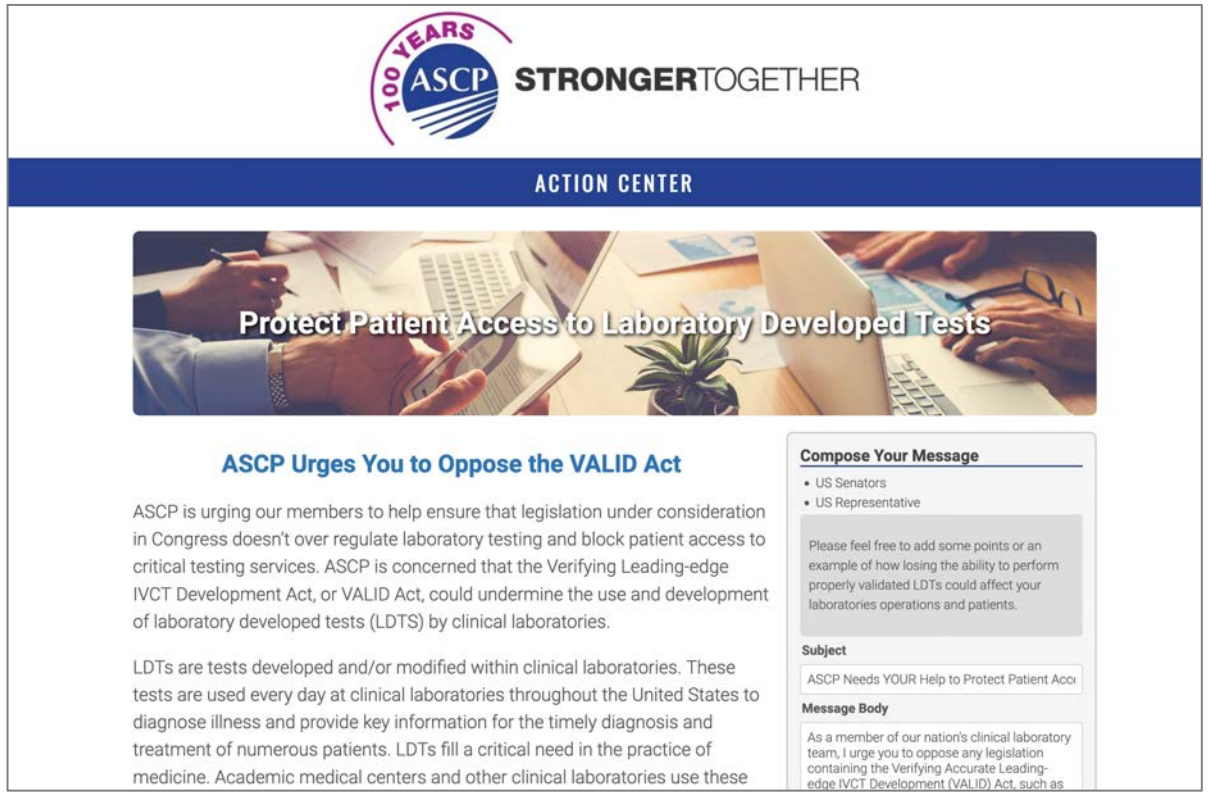
Legislative updates

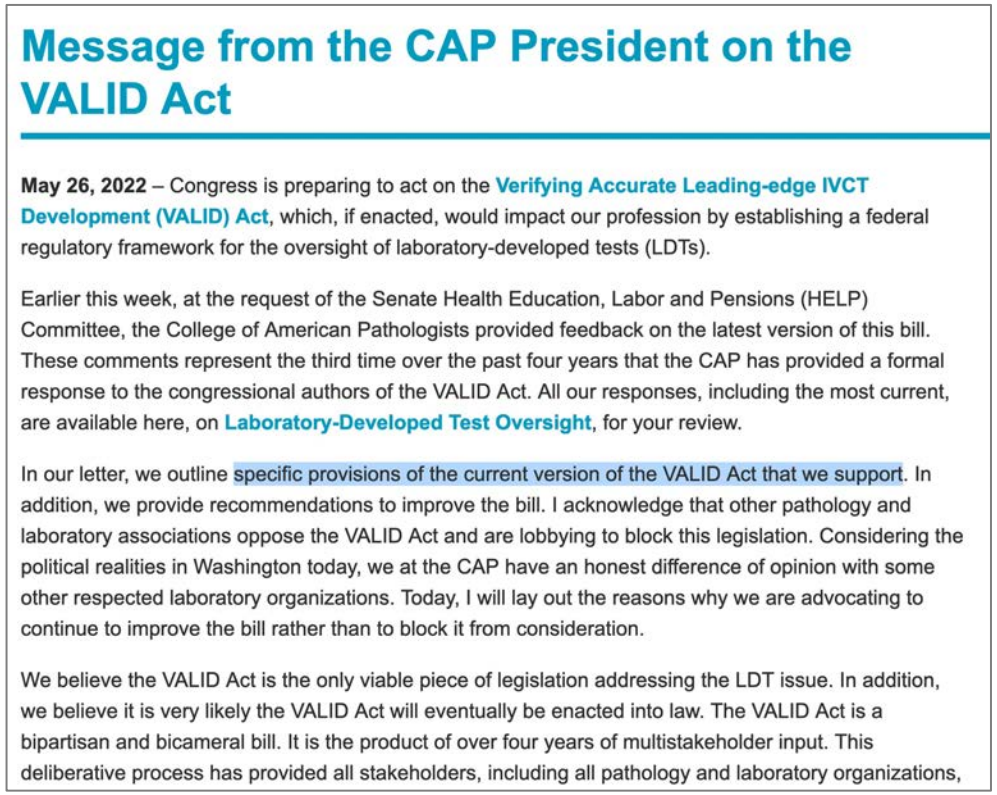
- **A. VALID/FDASLA/MDUFA**
  - Currently most societies wait to hear what might happen...
  - With Congress in recess, things are relatively quiet,
  - Staffers are probably working behind the scenes on reconciliation.
  - The week **after Labor Day** a mad scramble will begin to get MDUFA over the finish line (with or without VALID)
  - FDA has indicated they'll need to start sending out furlough warnings if FDASLA [pewtrusts.org] doesn't pass by the end of September
  - The FDA probably has enough funding until November/December = that sets the timeline

- **B. SALSA**
  - The SALSA Act is trying to get co-sponsors = that's the bill to permanently fix PAMA calculations. (ACLA letter on the topic attached)
  - https://www.cap.org/advocacy/laboratory-oversight-and-regulation/protecting-access-to-medicare-act-for-laboratorie

- **C. CMS proposed CLIA changes**
  - The proposed CMS CLIA changes **would allow people with nursing degrees to perform moderate and high complexity testing** (proposal attached).
  - Groups like ASCP [ascp.org] and AACC (letter attached) are up in arms about that.

VALID Act





https://www.healthaffairs.org/do/10.1377/forefront.20220622.414686/

SALSA

https://www.bigmarker.com/lighthouse-lab-services/How-the-SALSA-Act-Would-Fix-Clinical-Lab-Repricing

ACLA
AMERICAN CLINICAL LABORATORY ASSOCIATION

ACLA Urges Congress to Enact SALSA

Set a Sustainable Path for Patient Access to Laboratory Services, and Keep Our Clinical Lab Infrastructure Healthy

Summary Points

- Prior to the COVID-19 pandemic, Medicare reimbursement for clinical laboratory services had been set on an unsustainable path of multi-year, double-digit cuts.
- The cuts are a result of flawed implementation of the *Protecting Access to Medicare Act of 2014 (PAMA)* which only used the lowest private market rates to set Medicare rates.
- The bipartisan *Saving Access to Laboratory Services Act* (SALSA) would reform PAMA by collecting accurate and representative data from all laboratory market segments that serve Medicare beneficiaries, setting a sustainable path forward.

ACLA urges Congress to enact SALSA to reform PAMA, protecting patient access to laboratory services.

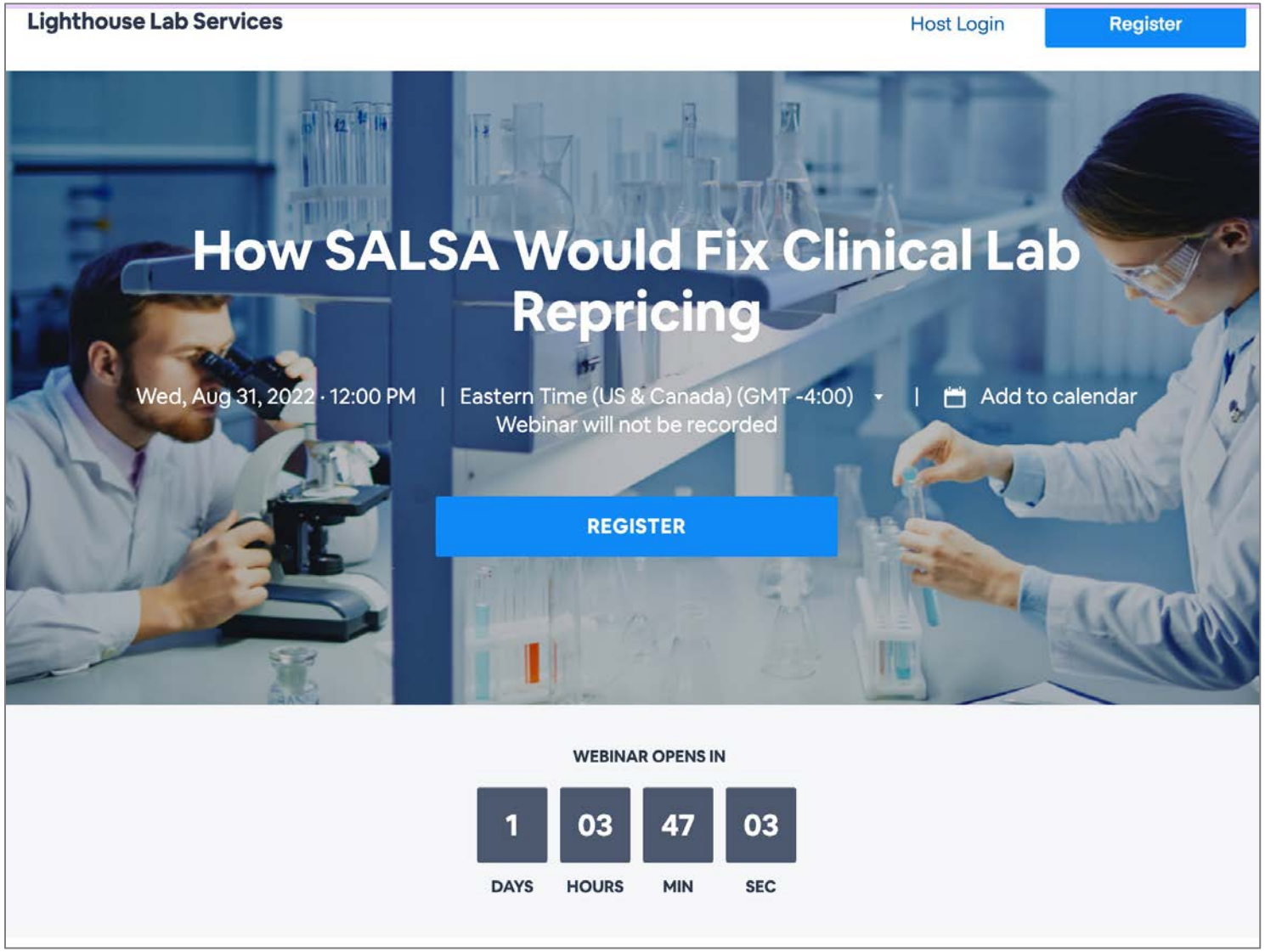
Background

In 2014, Congress passed PAMA to reform the Medicare Clinical Laboratory Fee Schedule (CLFS) to a single national fee schedule based on private payor rates for clinical laboratory services. Congress intended for the collection of private market data from all types of laboratories, including hospital outreach laboratories, independent laboratories, and physician office laboratories. Unfortunately, the first round of data collection failed to collect data from large, significant segments of the market.

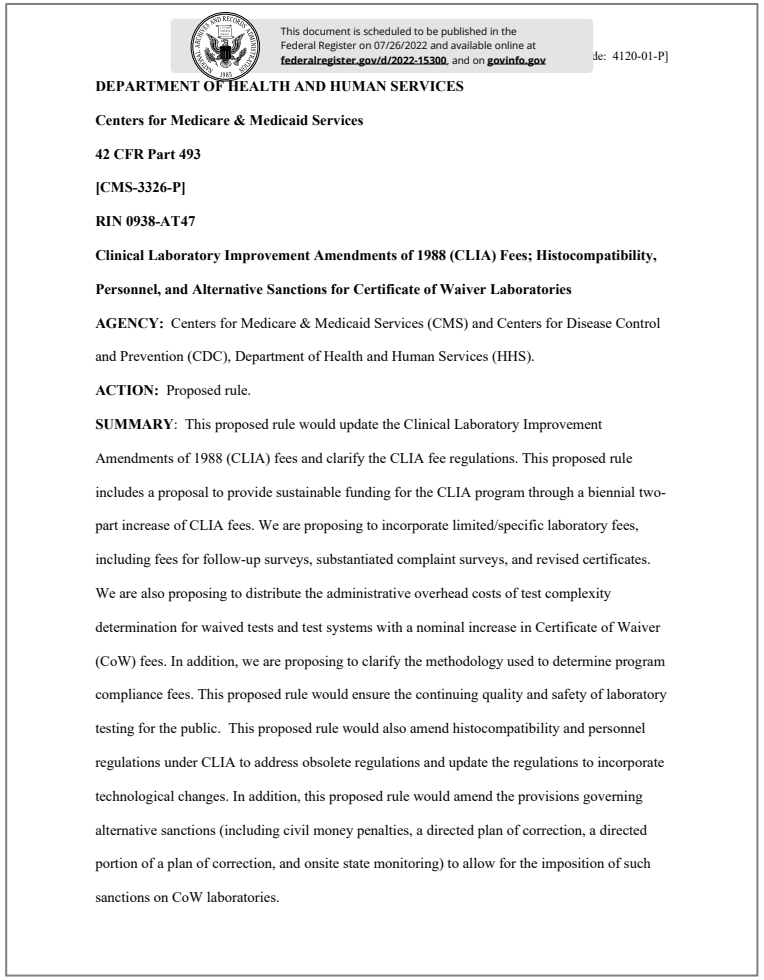
The result was three years of 10 percent annual cuts for the majority of the fee schedule in 2018-2020, with more cuts scheduled. These cuts amounted to **nearly $4 billion in cuts from laboratories** providing the most commonly ordered test services for Medicare beneficiaries. Congress, on a bipartisan basis, has now intervened **three times** to "press the breaks" on PAMA, beginning with the enactment of the *Laboratory Access for Beneficiaries (LAB) Act* in 2019, followed by the *Coronavirus Aid, Relief, and Economic Security (CARES) Act* in 2020 and the *Protecting Medicare and American Farmers from Sequester Cuts Act* in 2021. However, cuts of up to 15 percent are only delayed and are scheduled to resume January 1, 2023.

The COVID-19 pandemic has demonstrated the clear need for patient access to timely, accurate and reliable clinical laboratory testing for the diagnosis, monitoring, and screening for all diseases. The impact of these cuts will include roadblocks to investments to meet unmet clinical needs and necessary research to improve care across diseases and health conditions, including cancer. Further, these cuts could make it far more challenging for the clinical laboratory community to invest in testing capacity and infrastructure to meet the health care needs of the country, especially in medically underserved communities and during a time when many patients are resuming routine care.

The PAMA cuts, and the resulting risks to patients, are a direct contradiction to the national goals of bolstering public health to bring the United States out of the pandemic, preparing for the future, and to expand and improve the quality of care available to patients.



CLIA Memorandum



This document is scheduled to be published in the Federal Register on 07/26/2022 and available online at federalregister.gov/d/2022-15300, and on govinfo.gov

de: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 493

[CMS-3326-P]

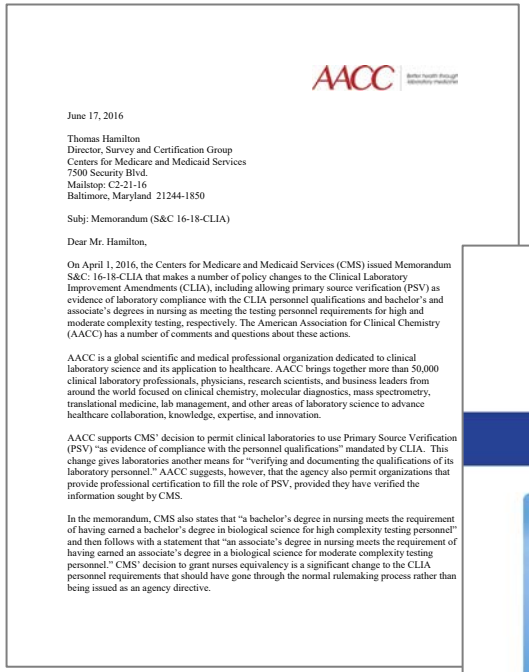
RIN 0938-AT47

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories

AGENCY: Centers for Medicare & Medicaid Services (CMS) and Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the Clinical Laboratory Improvement Amendments of 1988 (CLIA) fees and clarify the CLIA fee regulations. This proposed rule includes a proposal to provide sustainable funding for the CLIA program through a biennial two-part increase of CLIA fees. We are proposing to incorporate limited/specific laboratory fees, including fees for follow-up surveys, substantiated complaint surveys, and revised certificates. We are also proposing to distribute the administrative overhead costs of test complexity determination for waived tests and test systems with a nominal increase in Certificate of Waiver (CoW) fees. In addition, we are proposing to clarify the methodology used to determine program compliance fees. This proposed rule would ensure the continuing quality and safety of laboratory testing for the public. This proposed rule would also amend histocompatibility and personnel regulations under CLIA to address obsolete regulations and update the regulations to incorporate technological changes. In addition, this proposed rule would amend the provisions governing alternative sanctions (including civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite state monitoring) to allow for the imposition of such sanctions on CoW laboratories.



AACC

June 17, 2016

Thomas Hamilton
Director, Survey and Certification Group
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Mailstop: C2-21-16
Baltimore, Maryland 21244-1850

Subj: Memorandum (S&C 16-18-CLIA)

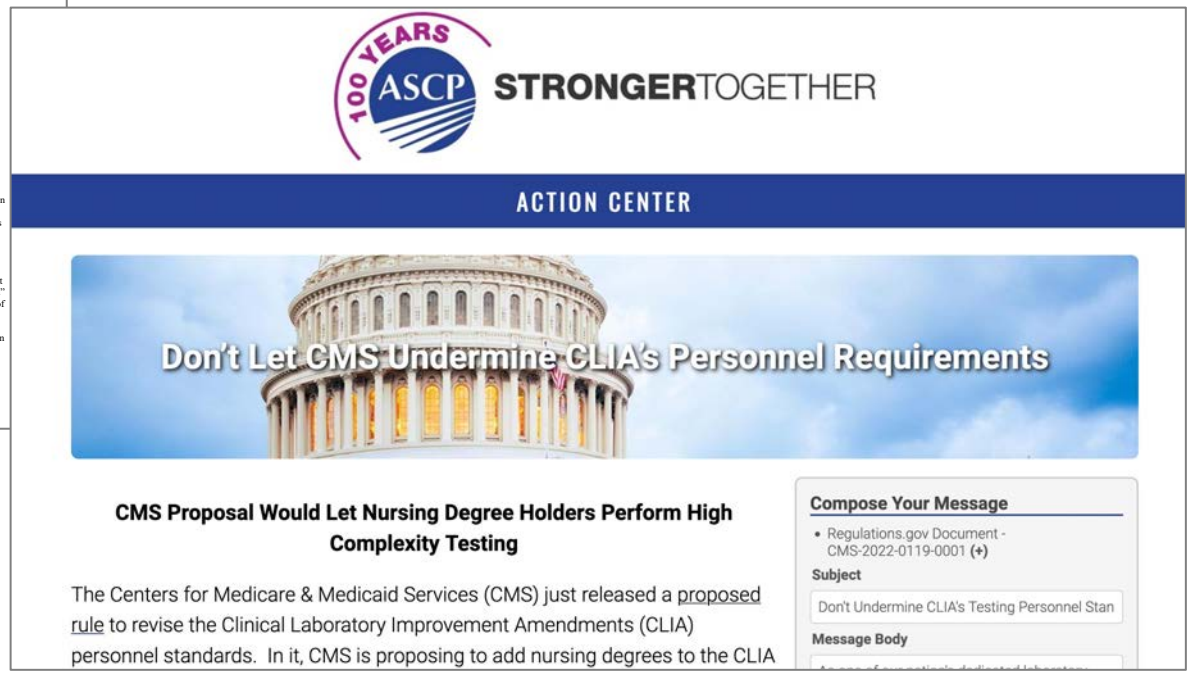
Dear Mr. Hamilton,

On April 1, 2016, the Centers for Medicare and Medicaid Services (CMS) issued Memorandum S&C: 16-18-CLIA that makes a number of policy changes to the Clinical Laboratory Improvement Amendments (CLIA), including allowing primary source verification (PSV) as evidence of laboratory compliance with the CLIA personnel qualifications and bachelor's and associate's degrees in nursing as meeting the testing personnel requirements for high and moderate complexity testing, respectively. The American Association for Clinical Chemistry (AACC) has a number of comments and questions about these actions.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

AACC supports CMS' decision to permit clinical laboratories to use Primary Source Verification (PSV) "as evidence of compliance with the personnel qualifications" mandated by CLIA. This change gives laboratories another means for "verifying and documenting the qualifications of its laboratory personnel." AACC suggests, however, that the agency also permit organizations that provide professional certification to fill the role of PSV, provided they have verified the information sought by CMS.

In the memorandum, CMS also states that "a bachelor's degree in nursing meets the requirement of having earned a bachelor's degree in biological science for high complexity testing personnel" and then follows with a statement that "an associate's degree in nursing meets the requirement of having earned an associate's degree in a biological science for moderate complexity testing personnel." CMS' decision to grant nurses equivalency is a significant change to the CLIA personnel requirements that should have gone through the normal rulemaking process rather than being issued as an agency directive.



100 YEARS ASCP STRONGERTOGETHER

ACTION CENTER

Don't Let CMS Undermine CLIA's Personnel Requirements

CMS Proposal Would Let Nursing Degree Holders Perform High Complexity Testing

The Centers for Medicare & Medicaid Services (CMS) just released a proposed rule to revise the Clinical Laboratory Improvement Amendments (CLIA) personnel standards. In it, CMS is proposing to add nursing degrees to the CLIA

Compose Your Message

- Regulations.gov Document - CMS-2022-0119-0001 (+)

Subject

Don't Undermine CLIA's Testing Personnel Stan

Message Body

One aspect:
Enable Nursing Degree to substitute for former Requirements for moderate. And high-complexity testing.

Pro: Lack of qualified personnel

Con: Undermines CLIA's Testing Personnel Standards

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

Search mdic.org

About | Membership | Initiatives | News | Meetings & Events | Resource Library

MDIC Updates

https://mdic.org/

Noor Falah, MS

- Project Manager for Cybersecurity at MDIC and PIcc
- Bench research- Effect of Neuropeptide Y on development of Ewing sarcoma
- Clinical research- Early Identification of Maternal CV Risk
- Georgetown University- MS, 2021
- George Mason University-BS, 2020
- Fun fact- avid baker

Upcoming Events

- Successfully Navigating the USPTO and FDA Seminar
  - September 8th
  - Virtual
- Cybersecurity Summit
  - September 12th
  - Virtual and in-person- JW Marriott Washington DC: 331 Pennsylvania Avenue NW, Washington, District of Columbia, 20004
- Annual Public Forum
  - September 13th
  - JW Marriott- Washington DC: 331 Pennsylvania Avenue NW, Washington, District of Columbia, 20004

How to register

To register for the Successfully Navigating the USPTO and FDA Seminar, please visit: https://www.eventbrite.com/e/successfully-navigating-the-uspto-and-fda-tickets-396126975447

To register for the Cybersecurity Summit, please visit: https://www.eventbrite.com/e/mdic-medtech-cybersecurity-summit-tickets-396587573107

To register for the Annual Public Forum, please visit: https://www.eventbrite.com/e/mdic-annual-public-forum-2022-tickets-356705494737

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

5G Communication in Healthcare: Background, Landscape, and Use Cases

- Hosted on August 8th
- A webinar focused on an overall description of 5G communication technology, the role 5G plays in the healthcare landscape, and examples of 5G-enabled healthcare applications including medical extended reality (MXR), robotics, mobile units, and remote care.
- Recording can be found at: https://www.youtube.com/watch?v=9CeoiF7BWew

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

DIGITAL PATHOLOGY ASSOCIATION

DPA

search

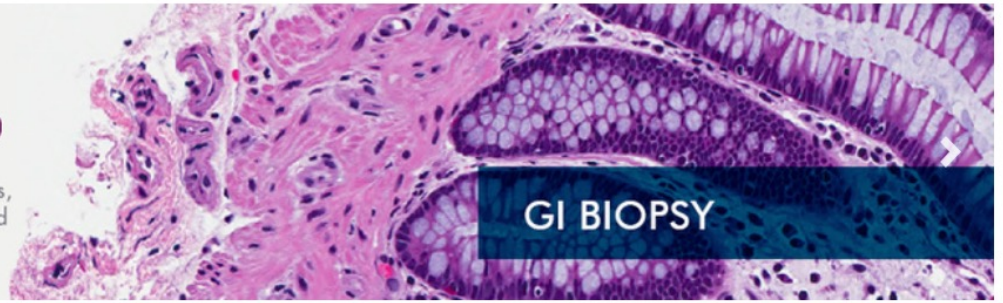
MEMBER LOGIN | NON-MEMBER LOGIN | JOIN TODAY

ABOUT | MEMBERSHIP | COLLABORATE | PATHOLOGY VISIONS | DAPA | BLOG

PODCAST | PUBLICATIONS | EVENTS | OTHER RESOURCES | FOUNDATION

WHAT IS THE DIGITAL PATHOLOGY ASSOCIATION?

The DPA is a nonprofit organization comprised of pathologists, scientists, technologists and industry representatives dedicated to advancing the field of digital pathology.



PATHOLOGY VISIONS

THE LENS OF INNOVATION

OCTOBER 16-18 | MGM GRAND | LAS VEGAS, NV

#PathVisions22

NEWS

AMA Announces New Add-On Digital Pathology Codes

Aug 03, 2022

AMA Addition of Add-on Codes Associated with Digital Pathology Procedures (Tab #44)

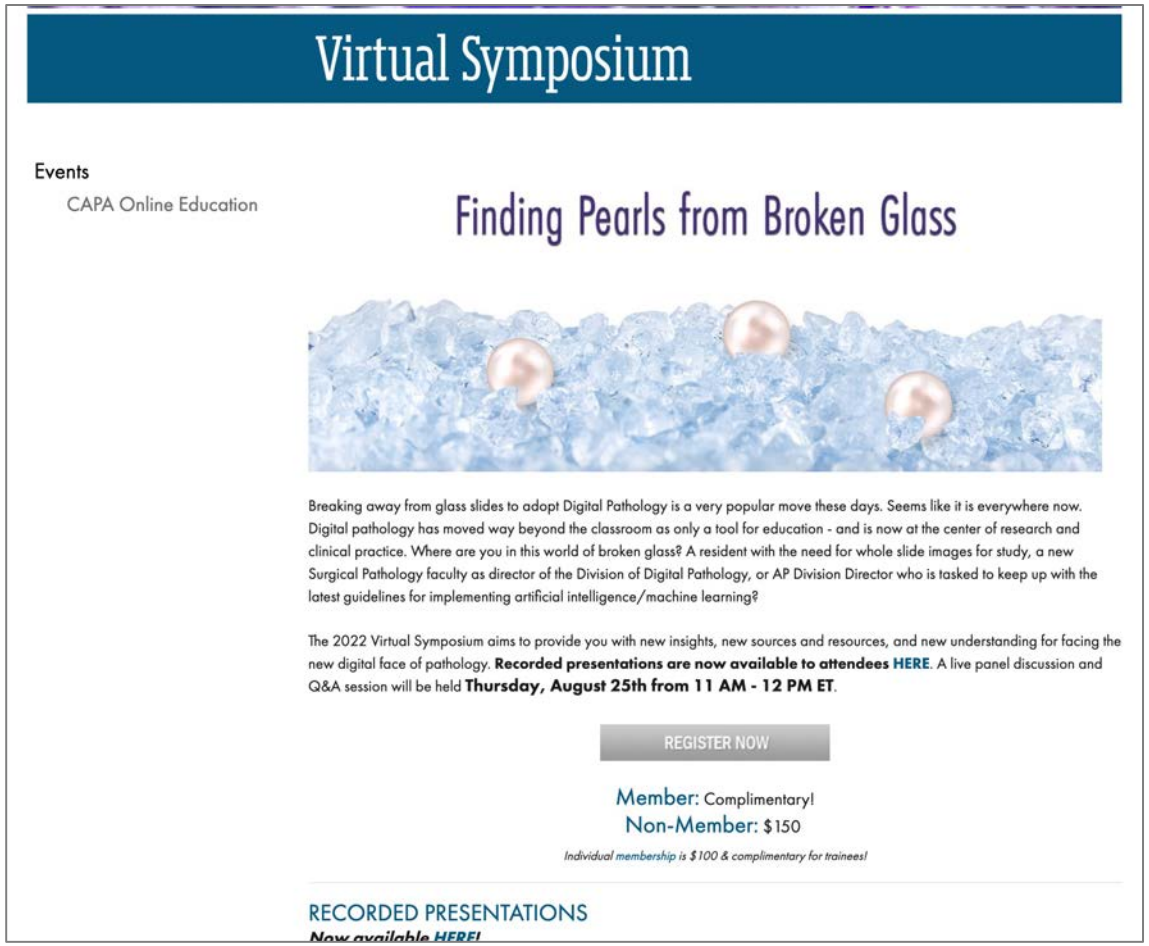
Jun 22, 2022

Webinar: Can AI Grand-Challenges inform Regulatory Science in Anatomic Pathology?

Feb 24, 2022

DIGITAL PATHOLOGY ASSOCIATION

- https://digitalpathologyassociation.org/virtual-symposium
- Dr. Adam Booth
- Dr. Marilyn Bui + Dr. Raj Singh
- Dr. Patricia Raciti
- Dr. Eric Glassy



Virtual Symposium

Events

CAPA Online Education

Finding Pearls from Broken Glass

Breaking away from glass slides to adopt Digital Pathology is a very popular move these days. Seems like it is everywhere now. Digital pathology has moved way beyond the classroom as only a tool for education - and is now at the center of research and clinical practice. Where are you in this world of broken glass? A resident with the need for whole slide images for study, a new Surgical Pathology faculty as director of the Division of Digital Pathology, or AP Division Director who is tasked to keep up with the latest guidelines for implementing artificial intelligence/machine learning?

The 2022 Virtual Symposium aims to provide you with new insights, new sources and resources, and new understanding for facing the new digital face of pathology. **Recorded presentations are now available to attendees HERE**. A live panel discussion and Q&A session will be held **Thursday, August 25th from 11 AM - 12 PM ET**.

REGISTER NOW

Member: Complimentary!
Non-Member: $150

Individual membership is $100 & complimentary for trainees!

RECORDED PRESENTATIONS

Adam Booth, MD
Northwestern University Feinberg School of Medicine
Adam L. Booth, MD is an Assistant Professor of Pathology at Northwestern Feinberg
his anatomic and clinical pathology residency at the University of Texas Medical Bra
fellowship in gastrointestinal, liver, and pancreatobiliary pathology at Beth Israel De
School in Boston, MA. His research interests include serrated polyps of the colon, esc
transplant lymphoproliferative disorders, and the role of social media in medical edu
the College of American Pathologists, United States and Canadian Academy of Path

Marilyn Bui, MD, PhD
Moffitt Cancer Center
Dr. Marilyn Bui is a Senior Member and Professor of Pathology, Scientific Director
Cytopathology Fellowship at the Moffitt Cancer Center in Tampa, FL. Her expertise
biomarker testing, and digital pathology/AI. She combines research, education, an
Bui has received 3 patents in digital pathology and cancer diagnostics. She is the st
has published over 200 articles, 24 book chapters and 3 books. Dr. Bui is an aware
frequently lectured both nationally and internationally, including keynote presentations. She is the editorial board m
experience includes but not limited to the President of the Digital Pathology Association (2019), the Chair of the Publ
CAP Today (2018-2021), and the Chair of the Digital and Computational Pathology committee of the College of An

Eric F. Glassy, MD
Affiliated Pathologists Medical Group
Dr. Glassy is a community pathologist in Southern California and medical director a
Center in San Pedro. He is a member of Affiliated Pathologists Medical Group, a 40
15 hospitals and laboratories in California, Portland, and Phoenix. He has been inv
and is past president of the Digital Pathology Association. He edited and illustrated
software programs for pathology reporting, outreach, and practice management. He holds a green belt in Six Sigm
Pathology as well as a governor of the College of American Pathologists. Dr. Glassy received his medical degree fr
did his pathology residency and hematopathology fellowship at Harbor-UCLA Medical Center.

Tobi Ozoya, MD
University of South Florida Morsani College of Medicine
Tobi Ozoya is a senior resident in pathology at the University of South Florida, Tamp
and is passionate about leveraging relationships and technology to advance popul
residency, he participated in transformational projects at different levels of society t
believes that pathologists should be central players in exploring artificial intelligence
population laboratory data is delivered. As a Digital Anatomic Pathology Association Awardee, he has forged new
opportunities. He is being mentored by leaders in the field of digital pathology, participated in DAPA education con
cases and an advocate for the work DPA is doing.

Patricia Raciti, MD
Paige
Dr. Raciti is a Board certified, practicing general pathologist as well as Medical Dire
has been a part of the team since its founding in 2018. After graduating from Harva
she trained at Columbia University Medical Center in Anatomic and Clinical Patholo
Surgical Pathology at Memorial Sloan Kettering Cancer Center, Hematopathology
Dermatopathology at Montefiore Medical Center. She is a member of the Digital &
the Digital Pathology Resource Guide Working Group. Her interest and expertise are in developing, testing and stud
pathology, as well as contributing to the development of an AI-native digital pathology solutions. She is passionate
development process to optimize the efficacy, utility and safety of these emerging, novel solutions.

Rajendra Singh, MD
Summit Health
Dr. Singh is the co-founder of PathPresenter, an online digital platform that has 425
multiple academic departments, private pathology groups and organizations in the
(https://pathpresenter.ai/) Dr. Singh has served on various committees both at No
as well as national societies such as the ASDP, AAD, DPA and CAP. Dr.Singh is the
Mt. Sinai School of Medicine for 5 consecutive years. He has served as the Chair o

DIGITAL PATHOLOGY ASSOCIATION

- https://digitalpathologyassociation.org/digital-anatomic-pathology-academy

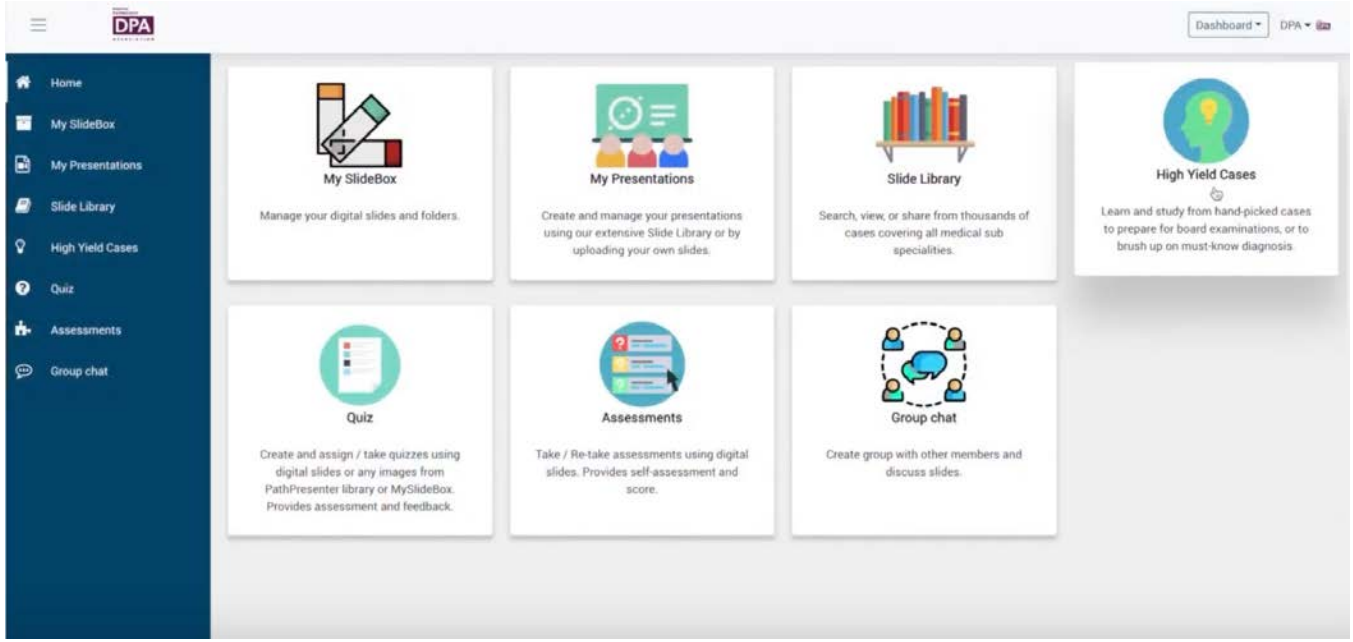
Digital Anatomic Pathology Academy (DAPA)

WSI educational platform provided by the DPA for its members

- Cloud-based platform which provides annotated digital slides with diagnosis and relevant information of morphology and ancillary testing

- Accessible from anywhere, on any device, without downloading any software

https://www.youtube.com/watch?v=IZ7vV7WVpGw



WHO/IARC

International Agency for Research on Cancer

World Health Organization

- https://www.iarc.who.int/vacancy/it-database-and-web-developer-req-2207536/
- https://www.iarc.who.int/vacancy/scientist-exposure-req-2207524/
- https://www.iarc.who.int/vacancy/scientist-epidemiology-req-2207525/
- https://www.iarc.who.int/vacancy/scientist-toxicology-req-2207533/
- https://www.iarc.who.int/vacancy/scientist-toxicology-req-2207526/
- https://careers.who.int/careersection/ex/jobdetail.ftl?job=2207525

IT Database and Web Developer

Branch/Service: Evidence Synthesis and Classification Branch (ESC)

Requisition Number: REQ-2207536

Grade: LY5

Contractual Arrangement: Fixed-term appointment

First Published: 10 August 2022

Closing Date: 31 August 2022

MORE INFORMATION (access for IARC/WHO staff members)

MORE INFORMATION (access for external candidates)

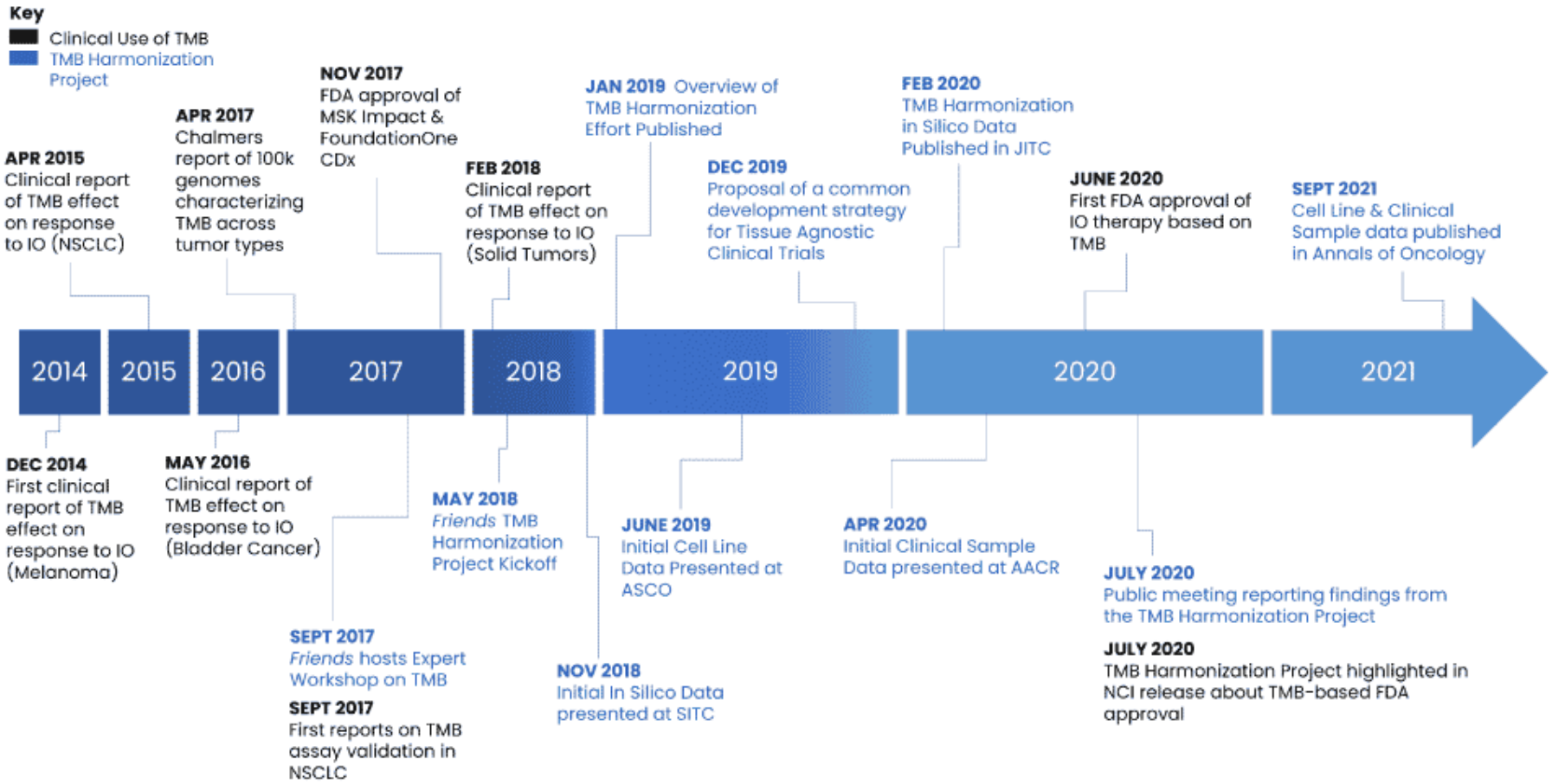
Regulatory Affairs Professionals Society (RAPS)

RAPS honors 11 distinguished professionals and one advocacy group with 2022 awards

RAPS Announcements RAPS' Latest | 17 August 2022 | By Ryan Connors

- The **Patient-Centered Health Award** recognizes organizations or individuals for significantly advancing patient-centered policy, product development or regulatory decision-making. The recipient of this year's honor is:
  - Friends of Cancer Research

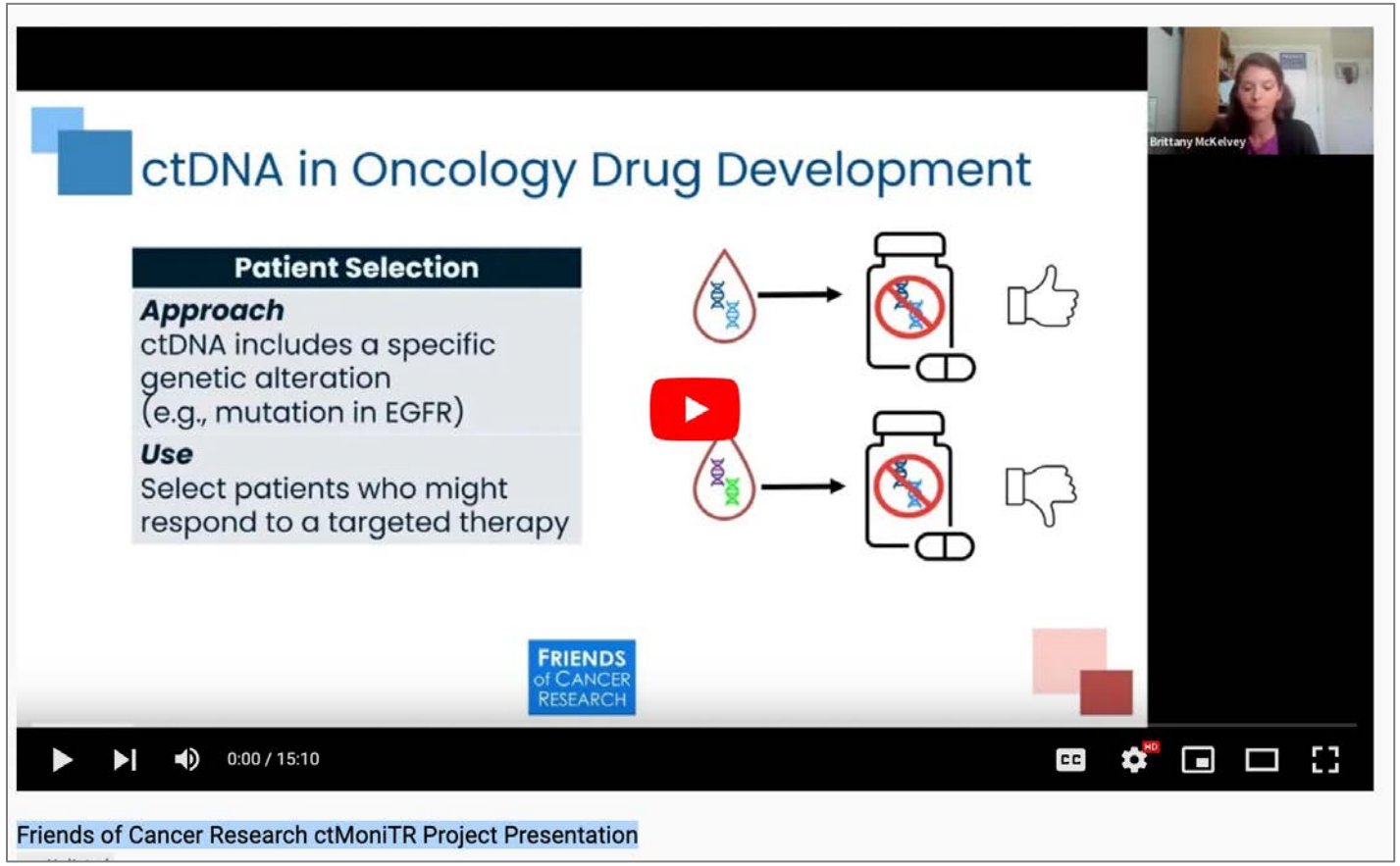
Friend of Cancer Research https://friendsofcancerresearch.org/tmb/



ctDNA

Friends of Cancer Research ctMoniTR Project Presentation

- https://www.youtube.com/watch?v=-QCyAn023vM



Collection

Liquid biopsies

Submission status
Open

Submission deadline
30 September 2022

The diagnosis and treatment of cancer presents a physical and mental burden to the patient, often involving diagnostic biopsies and surgeries or chemotherapeutic approaches with severe side-effects. Advances which enable early detection of cancer and close monitoring of the disease course without invasive procedures, and which can underpin a tailored approach to treatment, can therefore make a big difference to the quality of life of patients. Liquid biopsies can be used to access tumour cells and tumour DNA circulating in the blood. Monitoring these species can provide a minimally invasive and repeatable means to detect cancer, or gain information about its response to treatment. — show all

Submit manuscript

Editors

Julie E. Lang, Dario Marchetti & Catherine Alix-Panabières

Barriers to adopting digital pathology in developing economies and mitigation strategy

By Rohitashva Agrawal | Aug 04, 2022

- https://www.the-yuan.com/363/Barriers-to-adopting-digital-pathology-in-developing-economies-and-mitigation-strategy.html

Diversity & Inclusion

Human Rights Campaign

Human Rights Foundation

https://www.hrc.org/resources/workplace

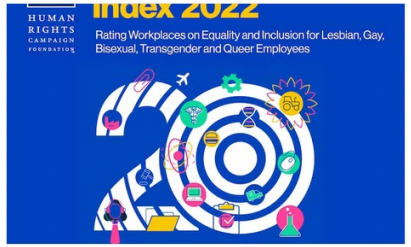
HRC works to provide employers the resources they need to improve and promote fairness in the workplace.

HUMAN RIGHTS CAMPAIGN FOUNDATION™

Talking About Pronouns in the Workplace

Community

Poverty generally refers to a lack of basic necessities, resources and income, though its exact definition is often widely debated and measured in a variety of ways. A common way...



WORKPLACE

2023 CEI Criteria Evolution: Toolkit and FAQ

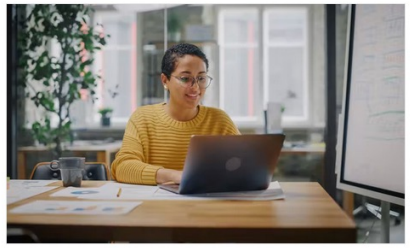
The Human Rights Campaign Foundation is excited to share the upcoming changes to the CEI, and, moreover, grateful for the opportunity to raise the bar for LGBTQ+ inclusive workplaces.

This...

WORKPLACE

The Wage Gap Among LGBTQ+ Workers in the United States

In an HRC Foundation analysis of nearly 7,000 full-time LGBTQ+ workers, median earnings were about $900 weekly, about 90% of the $1,001 median weekly wage a typical worker earns in...



WORKPLACE

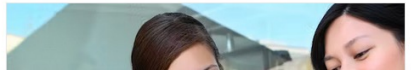
The LGBTQ+ Women's Wage Gap in the United States

Last Updated 6/12/22

PUBLICATIONS, STATE & LOCAL POLICY, WORKPLACE

MEI 2021: See Your Cities' Scores

HRC's Municipal Equality Index (MEI) demonstrates the ways that many cities can — and do — support the LGBTQ+ people who live and work there, even where states and the...



WORKPLACE, GLOBAL

HRC Equidad AR and BR: Global Workplace

Article: 5 Specifications That The FDA's Diversity Plan Needs To Include

- In April 2022, the FDA made available for public comment its *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials*
- https://www.regulations.gov/docket/FDA-2021-D-0789

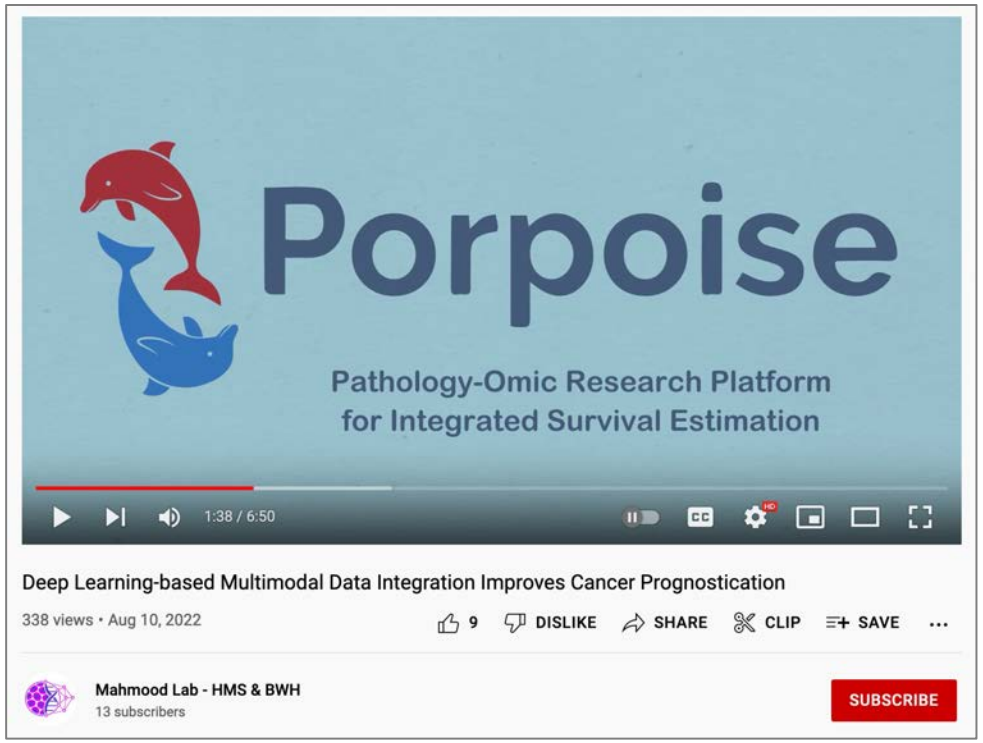
1. **Implement A Community Engagement Plan**
2. **Be More Inclusive With Your Eligibility Criteria**
3. **Provide Resources For Patients To Address/Overcome Barriers To Trial Adherence**
4. **Include Sites In Diverse Areas**
5. **Take On Accountability For Diversity Plan Adherence**

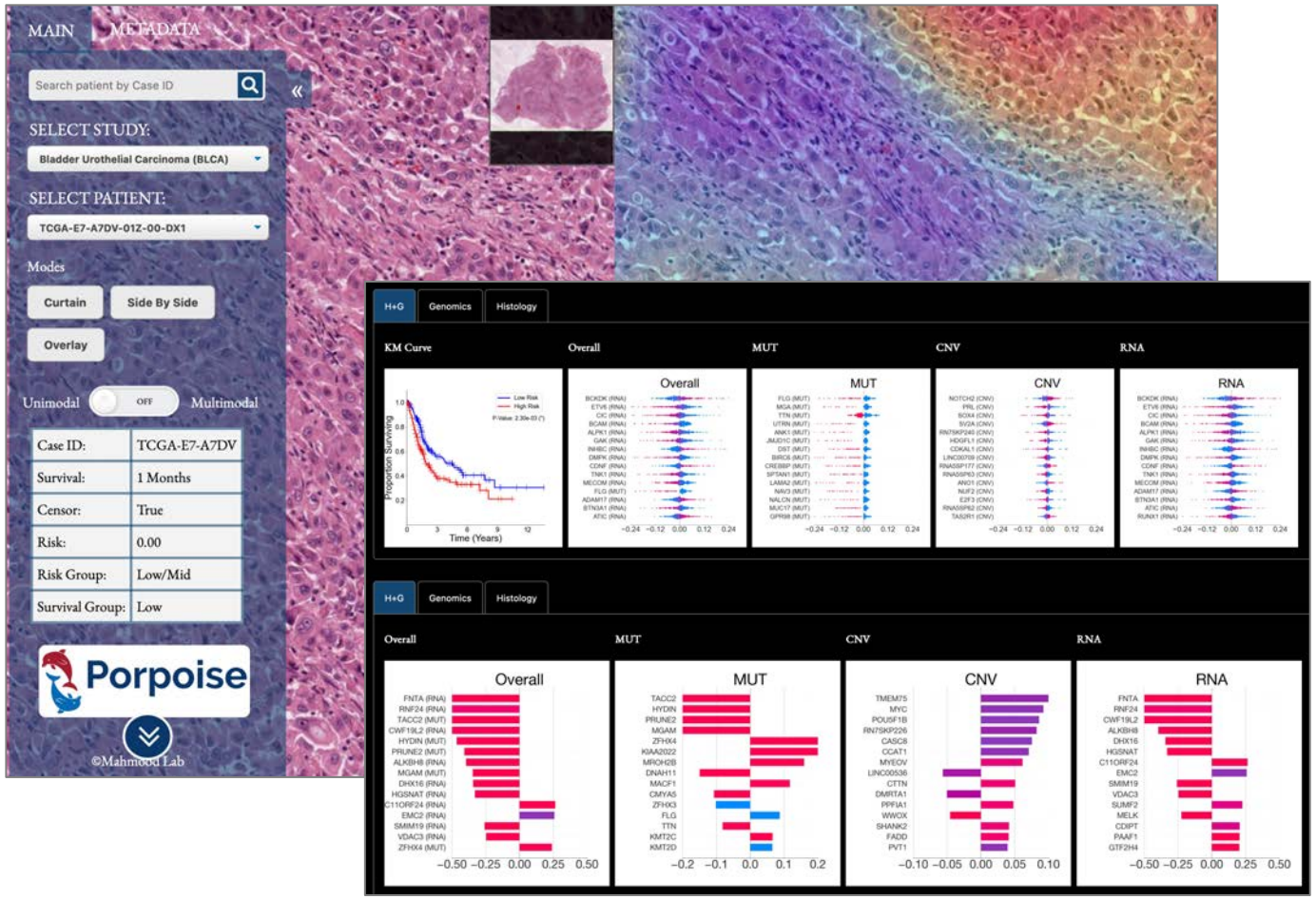
Maimah Karmo is the founder and CEO of the Tigerlily Foundation and is also a 16-year survivor of breast cancer.

Link to article: https://www.clinicalleader.com/doc/specifications-that-the-fda-s-diversity-plan-needs-to-include-0001

Resources

Pathology-Omic Research Platform for Integrated Survival Estimation





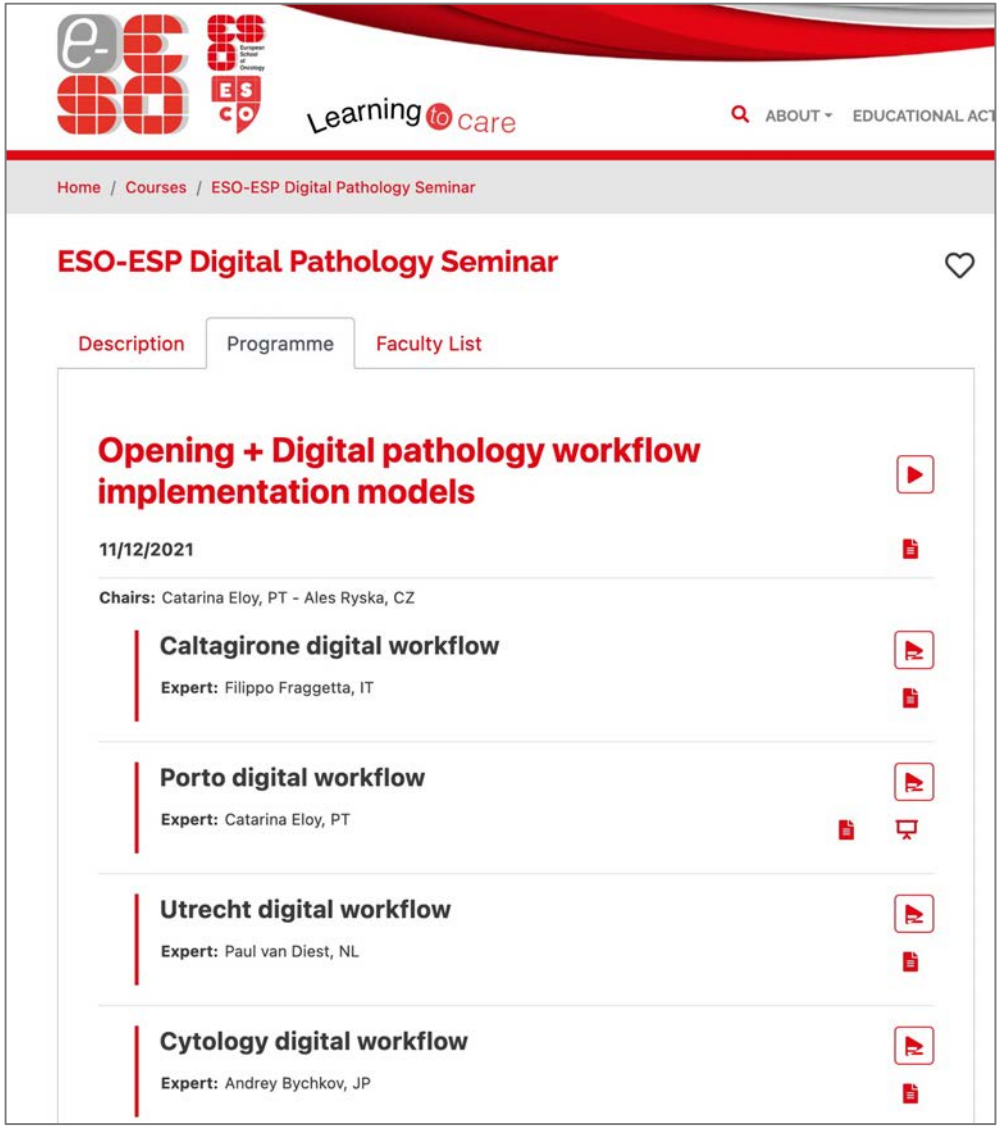
http://pancancer.mahmoodlab.org/

https://www.youtube.com/watch?v=NnAaeGYUi_U

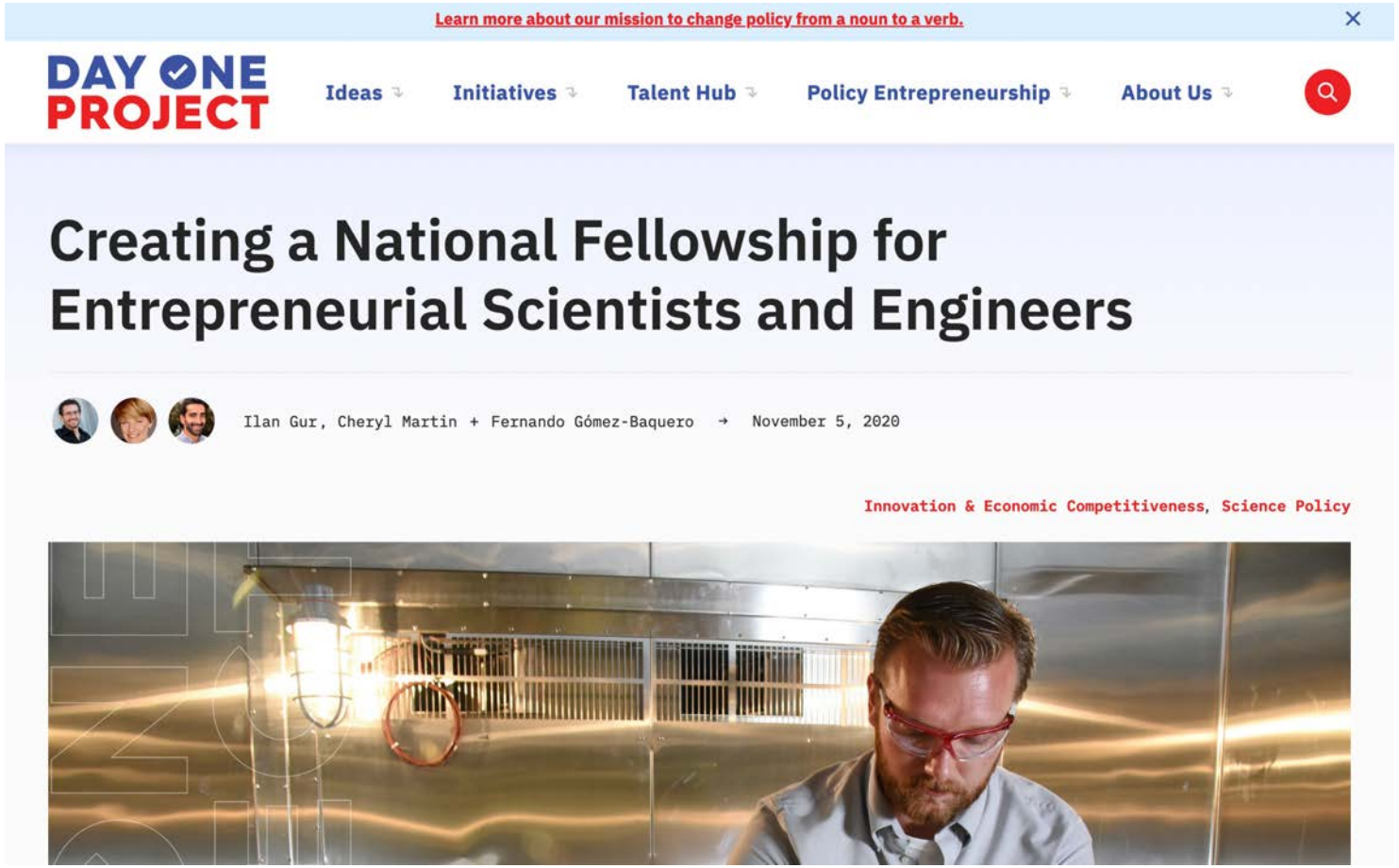
ESO-EDP Digital Pathology Seminar

- The ESO-ESP Digital Pathology Seminar is an event devoted to physicians, specifically to pathologists and oncologists, focusing on the digital transformation of the pathology laboratories and consequent benefits. Here, examples of digital workflow implementation will be demonstrated, as well as the potentialities of image analysis tools in the setting of biomarkers and, broadly, in cancer models.

- https://www.e-eso.net/courses/21DPA#eso-desc



National Fellowship

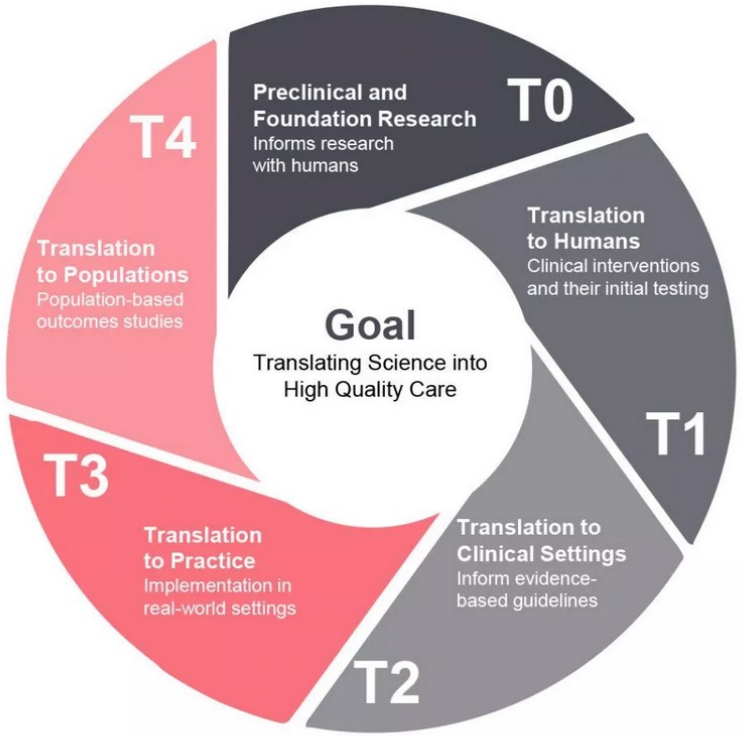


https://www.dayoneproject.org/ideas/creating-a-national-fellowship-for-entrepreneurial-scientists-and-engineers/

FutureBridge Article

Challenges and Drivers of Translational Research

EXHIBIT 3: Translation Research Goals & different models



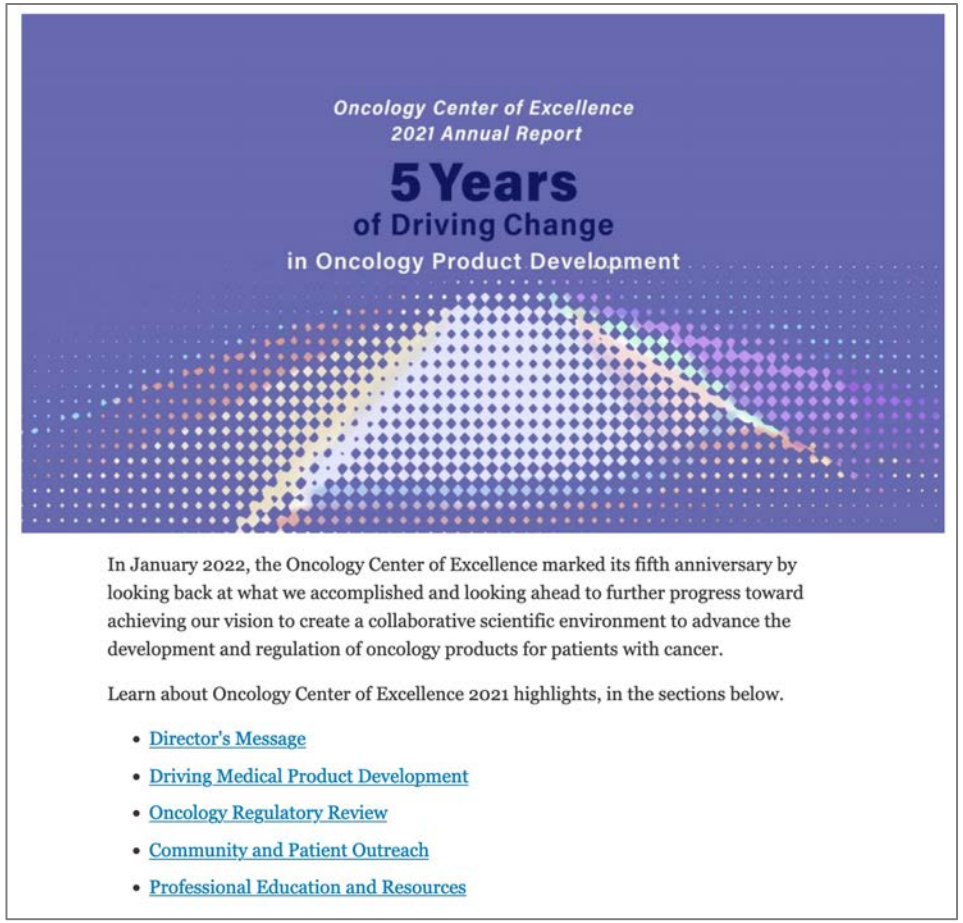
Source: CPEC

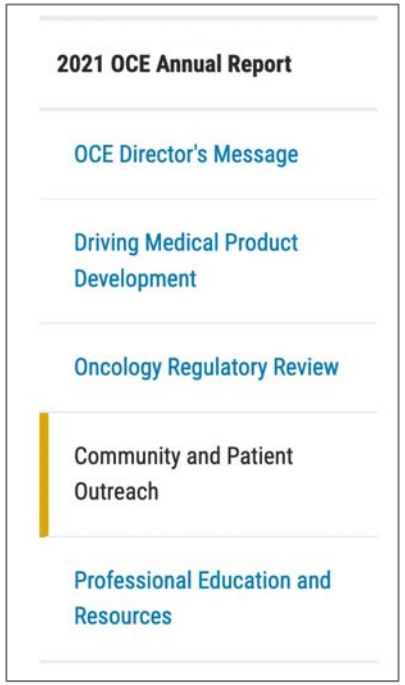
https://www.futurebridge.com/industry/perspectives-life-sciences/challenges-and-drivers-of-translational-research/

Broad Institute: rare variant resource

- Genebass summarizes a genetic analysis of nearly 400,000 people in the UK Biobank and could help researchers identify new therapeutic targets.
- https://www.broadinstitute.org/news/new-online-resource-helps-connect-rare-genetic-variants-human-health-and-disease

FDA
Oncology Center of Excellence – 2021 Annual Report





https://www.fda.gov/about-fda/oncology-center-excellence/2021-oce-annual-report

FDA: Project Socrates

- Episode 1: FDA's role in Oncology Product Development
- Episode 2: Oncology Trial Design Considerations
- Episode 3: Statistical Considerations in Designing Cancer Clinical Trials
- Episode 4: Investigational New Drug Applications

https://www.fda.gov/about-fda/oncology-center-excellence/project-socrates

Guidebook

In order to use this Guidebook effectively, the following areas must be agreed upon by institution and country leadership prior to LIS selection:

1. Defining success
2. Defining standards
3. Adopting a standard set of procedures
4. Defining sustainability for the country/laboratory.

Book feature

The empowered Woman's Guide to Better Health

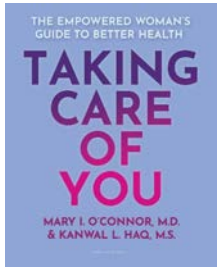
Mary I. O'Connor, MD is an orthopedic surgeon, health equity leader

Kanwal L Haq, MS is a medical anthropologist, community organizer, and non-profit consultant

MAYO CLINIC | Mayo Clinic Press

Contact: Jacqui Daniels
McCartin | Daniels PR
702-450-6464 / JDaniels6464@gmail.com

A practical and extensive resource guide for women who want to understand and take charge of their own health and healthcare, presented in short, focused, easy-to-read chapters.



TAKING CARE OF YOU

THE EMPOWERED WOMAN'S GUIDE TO BETTER HEALTH

by Mary I. O'Connor, M.D. & Kanwal L. Haq, M.S.

Women do not always receive the same healthcare as men. In fact, for too long medicine has not recognized that numerous health conditions such as heart disease, mental health, stroke, stress, and more, impact women differently than men. Orthopedic surgeon Mary I. O'Connor and medical anthropologist Kanwal L. Haq want to change that by empowering women with knowledge about the current landscape of women's health, and how to be actively engaged with their healthcare team.

In a groundbreaking publication, **TAKING CARE OF YOU*: The Empowered Woman's Guide to Better Health* (Mayo Clinic Press/Trade paperback $40.00/October 4, 2022)**, O'Connor and Haq have enlisted 111 leading women physicians and health experts from all across the country to create a practical resource guide for women to improve their health and obtain better healthcare.

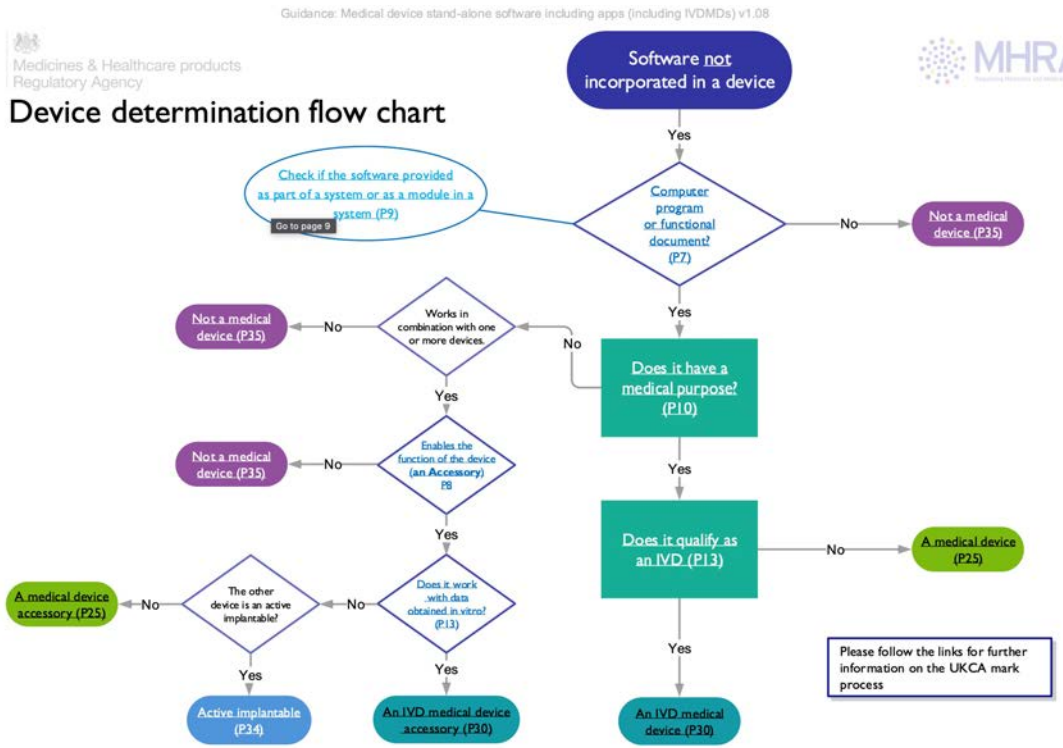
TAKING CARE OF YOU is refreshingly supportive and jargon-free, with colorful illustrations to help the reader better understand what can often be dense medical information. Its unique approach includes three main sections:

Medicines & Healthcare products Regulatory Agency

Guidance:

Medical device stand-alone software

42-page interactive .pdf



Publications

Organ specific

original reports

Overall Survival and Biomarker Analysis of Neoadjuvant Nivolumab Plus Chemotherapy in Operable Stage IIIA Non–Small-Cell Lung Cancer (NADIM phase II trial)

Mariano Provencio, MD, PhD[1]; Roberto Serna-Blasco, MSc[1]; Ernest Nadal, MD[2]; Amelia Insa, MD[3]; M. Rosario García-Campelo, MD[4]; Joaquín Casal Rubio, MD[5]; Manuel Dómine, MD[6]; Margarita Majem, MD[7]; Delvys Rodríguez-Abreu, MD[8]; Alex Martínez-Martí, MD[9]; Javier De Castro Carpeño, MD[10]; Manuel Cobo, MD[11]; Guillermo López Vivanco, MD[12]; Edel Del Barco, MD[13]; Reyes Bernabé Caro, MD[14]; Nuria Viñolas, MD[15]; Isidoro Barneto Aranda, MD[16]; Santiago Viteri, MD[17]; Eva Pereira, MSc[18]; Ana Royuela, PhD[1]; Virginia Calvo, MD[1]; Javier Martín-López, MD[1]; Francisco García-García, PhD[19]; Marta Casarrubios, MSc[1]; Fernando Franco, MD[1]; Estela Sánchez-Herrero, MSc[1,20]; Bartomeu Massuti, MD[21]; Alberto Cruz-Bermúdez, PhD[1]; and Atocha Romero, PhD[1]

Clinicopathologic characteristics and outcomes for patients with *KRAS* G12D-mutant non-small cell lung cancer

Authors: Alissa J. Cooper[1], Alona Muzikansky[1], Jochen Lennerz[1], Farhaana Narinesingh[1], Mari Mino-Kenudson[1], Yin P. Hung[1], Zofia Piotrowska[1], Ibiayi Dagogo-Jack[1], Lecia V. Sequist[1], Justin F. Gainor[1], Jessica J. Lin[1], Rebecca S. Heist[1]

Institutional Affiliations:

1. Massachusetts General Hospital/Harvard Medical School, 55 Fruit St, Boston, MA, 02114, USA

USCAP www.nature.com/modpathol

ARTICLE

Check for updates

Activating *IGF1R* hotspot non-frameshift insertions define a novel, potentially targetable molecular subtype of adenoid cystic carcinoma

Matthew Margolis[1,3]✉, Tyler Janovitz[1,3], Jason Laird[1,3], Douglas A. Mata[1], Meagan Montesion[1], Jessica K. Lee[1], Russell W. Madison[1], Alexa B. Schrock[1], Hanna Tukachinsky[1], Justin M. Allen[1], Rachel Erlich[1], Matthew C. Hiemenz[1], Richard S. P. Huang[1], Julia Elvin[1], Jo-Anne Vergilio[1], Douglas I. Lin[1], Jeffrey Ross[1,2], Geoffrey Oxnard[1] and Brennan Decker[1,3]

British Journal of Cancer www.nature.com/bjc

ARTICLE OPEN

Check for updates

Molecular Diagnostics

Integrative tumour mutation burden with CD39 and PD-L1 for the prediction of response to PD-L1 blockade and adjuvant chemotherapy in muscle-invasive bladder cancer patients

Chunnan Liu[1,8], Zhaopei Liu[1,8], Kaifeng Jin[2,8], Han Zeng[3,8], Fei Shao[4], Yuan Chang[1], Yiwei Wang[5], Le Xu[6], Zewei Wang[3]✉, Yu Zhu[1]✉ and Weijuan Zhang[7]✉

CANCER IMMUNOLOGY RESEARCH | RESEARCH ARTICLE

Tumor MHC Class I Expression Associates with Intralesional IL2 Response in Melanoma

Maryam Pourmaleki[1,2], Caitlin J. Jones[3], Charlotte E. Ariyan[4], Zheng Zeng[3], Mono Pirun[3], Daniel A. Navarrete[1], Yanyun Li[5], Mianlei Zhang[5], Subhiksha Nandakumar[6], Carl Campos[1], Saad Nadeem[7], David S. Klimstra[5], Claire F. Temple-Oberle[8,9], Thomas Brenn[10], Evan J. Lipson[11], Kara M. Schenk[11], Julie E. Stein[12], Janis M. Taube[11,12,13], Michael G. White[14], Raymond Traweek[14], Jennifer A. Wargo[14,15], John M. Kirkwood[16], Billel Gasmi[17,18], Stephanie L. Goff[17], Alex D. Corwin[19], Elizabeth McDonough[19], Fiona Ginty[19], Margaret K. Callahan[20,21,22], Andrea Schietinger[23,24], Nicholas D. Socci[3,6], Ingo K. Mellinghoff[1,25,26], and Travis J. Hollmann[5,22]

NSCLC *Without* Driver Guidance

ASCO special articles

Therapy for Stage IV Non–Small-Cell Lung Cancer Without Driver Alterations: ASCO Living Guideline

Navneet Singh, MD, DM[1]; Sarah Temin, MSPH[2]; Sherman Baker Jr, MD[3]; Elizabeth Blanchard, MD[4]; Julie R. Brahmer, MD[5]; Paul Celano, MD[6]; Narjust Duma, MD[7]; Peter M. Ellis, MD, PhD[8]; Ivy B. Elkins, MBA[9]; Rami Y. Haddad, MD[10]; Paul J. Hesketh, MD[11]; Dharamvir Jain, MD[12]; David H. Johnson, MD[13]; Natasha B. Leighl, MD[14]; Hirva Mamdani, MD[15]; Gregory Masters, MD[16]; Pamela R. Moffitt[17]; Tanyanika Phillips, MD[18]; Gregory J. Riely, MD, PhD[19]; Andrew G. Robinson, MD[20]; Rafael Rosell, MD[21]; Joan H. Schiller, MD[22]; Bryan J. Schneider, MD[23]; David R. Spigel, MD[24]; and Ishmael A. Jaiyesimi, MD, MS[25]

CSER Consortium

Genetics in Medicine (2022) 24, 1108–1119

ELSEVIER

Genetics in Medicine

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

ARTICLE

Integration of stakeholder engagement from development to dissemination in genomic medicine research: Approaches and outcomes from the CSER Consortium

ARTICLE INFO

Article history:
Received 24 September 2021
Received in revised form
7 January 2022
Accepted 13 January 2022
Available online 25 February 2022

Keywords:
Clinical research
Genetic medicine
Genomics
Stakeholders
Stakeholder engagement

ABSTRACT

Purpose: There is a critical need for genomic medicine research that reflects and benefits socioeconomically and ancestrally diverse populations. However, disparities in research populations persist, highlighting that traditional study designs and materials may be insufficient or inaccessible to all groups. New approaches can be gained through collaborations with patient/community stakeholders. Although some benefits of stakeholder engagement are recognized, routine incorporation into the design and implementation of genomics research has yet to be realized.

Methods: The National Institutes of Health–funded Clinical Sequencing Evidence-Generating Research (CSER) consortium required stakeholder engagement as a dedicated project component. Each CSER project planned and carried out stakeholder engagement activities with differing goals and expected outcomes. Examples were curated from each project to highlight engagement strategies and outcomes throughout the research lifecycle from development through dissemination.

Results: Projects tailored strategies to individual study needs, logistical constraints, and other challenges. Lessons learned include starting early with engagement efforts across project stakeholder groups and planned flexibility to enable adaptations throughout the project lifecycle.

Conclusion: Each CSER project used more than 1 approach to engage with relevant stakeholders, resulting in numerous adaptations and tremendous value added throughout the full research lifecycle. Incorporation of community stakeholder insight improves the outcomes and relevance of genomic medicine research.

Explainable Artificial Intelligence (XAI): Concepts, Taxonomies, Opportunities and Challenges toward Responsible AI

Alejandro Barredo Arrieta[a], Natalia Díaz-Rodríguez[b], Javier Del Ser[a,c,d], Adrien Bennetot[b,e,f], Siham Tabik[g], Alberto Barbado[h], Salvador Garcia[g], Sergio Gil-Lopez[a], Daniel Molina[g], Richard Benjamins[h], Raja Chatila[f], and Francisco Herrera[g]

[a]*TECNALIA, 48160 Derio, Spain*
[b]*ENSTA, Institute Polytechnique Paris and INRIA Flowers Team, Palaiseau, France*
[c]*University of the Basque Country (UPV/EHU), 48013 Bilbao, Spain*
[d]*Basque Center for Applied Mathematics (BCAM), 48009 Bilbao, Bizkaia, Spain*
[e]*Segula Technologies, Parc d'activité de Pissaloup, Trappes, France*
[f]*Institut des Systèmes Intelligents et de Robotique, Sorbonne Universitè, France*
[g]*DaSCI Andalusian Institute of Data Science and Computational Intelligence, University of Granada, 18071 Granada, Spain*
[h]*Telefonica, 28050 Madrid, Spain*

Montesinos-López et al. BMC Genomics (2021) 22:19
https://doi.org/10.1186/s12864-020-07319-x

BMC Genomics

REVIEW Open Access

A review of deep learning applications for genomic selection

Osval Antonio Montesinos-López[1], Abelardo Montesinos-López[2*], Paulino Pérez-Rodríguez[3], José Alberto Barrón-López[4], Johannes W. R. Martini[5], Silvia Berenice Fajardo-Flores[1], Laura S. Gaytan-Lugo[6], Pedro C. Santana-Mancilla[1] and José Crossa[3,5*]

British Journal of Cancer www.nature.com/bjc

PERSPECTIVE

Cellular and Molecular Biology

High-dimensional role of AI and machine learning in cancer research

Enrico Capobianco[1✉]

USCAP www.nature.com/modpathol

ARTICLE OPEN

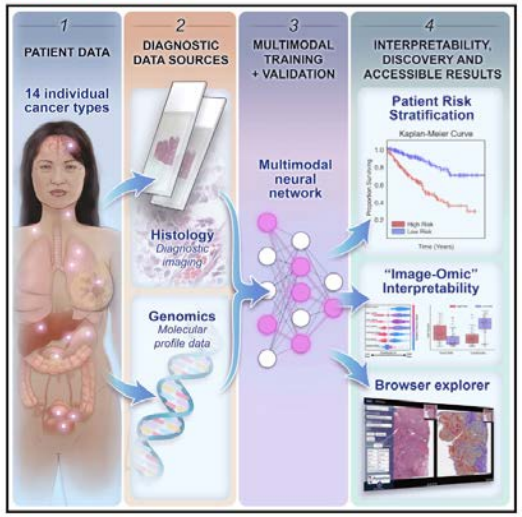
Integrating artificial intelligence in pathology: a qualitative interview study of users' experiences and expectations

Johanneke Drogt[1✉], Megan Milota[1], Shoko Vos[2], Annelien Bredenoord[1] and Karin Jongsma[1]

Cancer Cell Article

Pan-cancer integrative histology-genomic analysis via multimodal deep learning

Graphical abstract



Authors

Richard J. Chen, Ming Y. Lu, Drew F.K. Williamson, ..., Mane Williams, Bumjin Joo, Faisal Mahmood

Correspondence

faisalmahmood@bwh.harvard.edu

In brief

Chen et al. present a pan-cancer analysis that uses deep learning to integrate whole-slide pathology images and molecular features to predict cancer prognosis, with multimodal interpretability used to elucidate morphologic and molecular correlates of prognosis.

communications medicine

ARTICLE

https://doi.org/10.1038/s43856-022-00138-z OPEN

A user-friendly tool for cloud-based whole slide image segmentation with examples from renal histopathology

Brendon Lutnick[1], David Manthey[2], Jan U. Becker[3], Brandon Ginley[1], Katharina Moos[3], Jonathan E. Zuckerman[4], Luis Rodrigues[5], Alexander J. Gallan[6], Laura Barisoni[7], Charles E. Alpers[8], Xiaoxin X. Wang[9], Komuraiah Myakala[9], Bryce A. Jones[10], Moshe Levi[9], Jeffrey B. Kopp[11], Teruhiko Yoshida[11], Jarcy Zee[12], Seung Seok Han[13], Sanjay Jain[14], Avi Z. Rosenberg[15], Kuang Yu. Jen[16], Pinaki Sarder[1✉] & the Kidney Precision Medicine Project*

npj | digital medicine

www.nature.com/npjdigitalmed

ARTICLE OPEN

Check for updates

Unleashing the potential of digital pathology data by training computer-aided diagnosis models without human annotations

Niccolò Marini[1,2✉], Stefano Marchesin[3], Sebastian Otálora[1,2], Marek Wodzinski[1,4], Alessandro Caputo[5,6], Mart van Rijthoven[7], Witali Aswolinskiy[7], John-Melle Bokhorst[7], Damian Podareanu[8], Edyta Petters[9], Svetla Boytcheva[10,11], Genziana Buttafuoco[6], Simona Vatrano[6], Filippo Fraggetta[6,12], Jeroen van der Laak[7,13], Maristella Agosti[3], Francesco Ciompi[7], Gianmaria Silvello[3], Henning Muller[1,14] and Manfredo Atzori[1,15]

scientific reports

OPEN

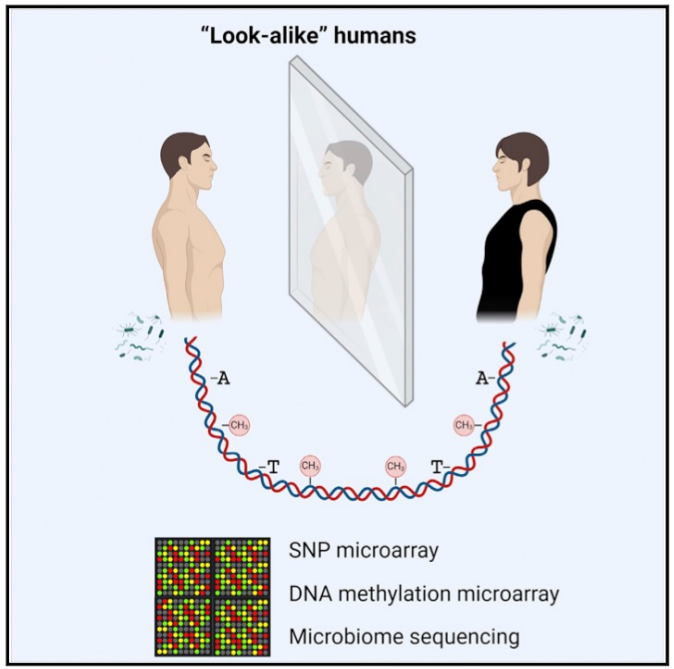
Multimodal deep learning models for the prediction of pathologic response to neoadjuvant chemotherapy in breast cancer

Sunghoon Joo[1,4,5], Eun Sook Ko[2,5], Soonhwan Kwon[1], Eunjoo Jeon[1], Hyungsik Jung[1], Ji-Yeon Kim[3], Myung Jin Chung & Young-Hyuck Im[2,3]✉

Cell Reports

Look-alike humans identified by facial recognition algorithms show genetic similarities

Graphical abstract



Authors

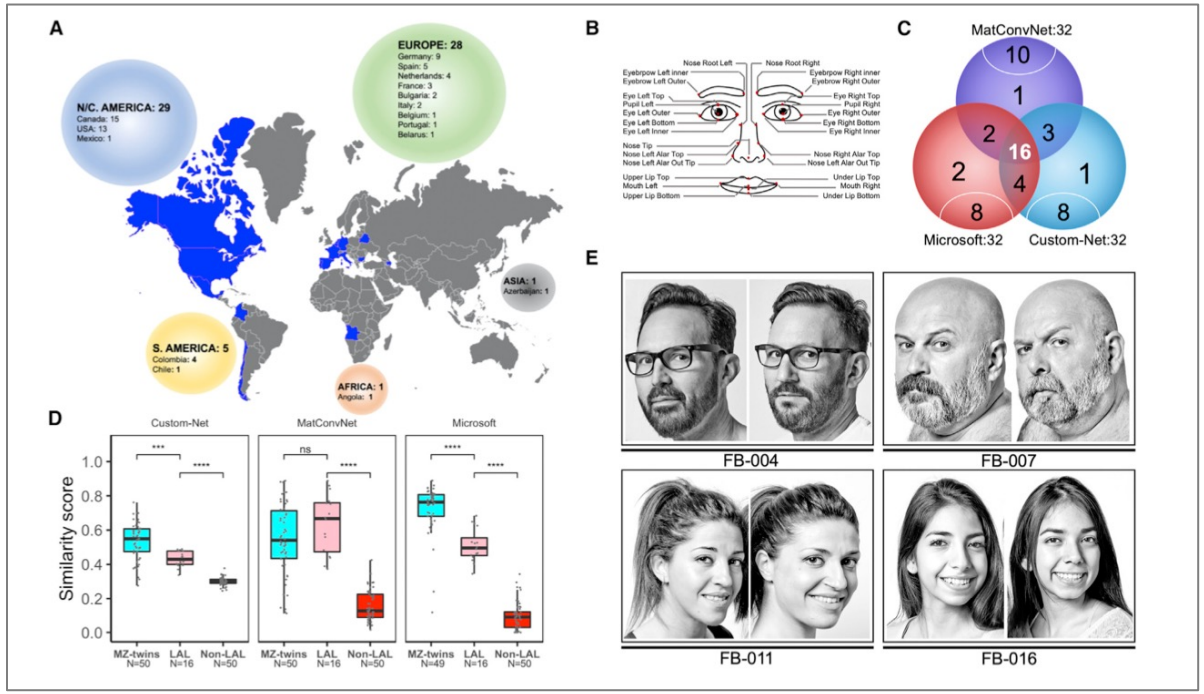
Ricky S. Joshi, Maria Rigau, Carlos A. García-Prieto, ..., Xavier Binefa, Alfonso Valencia, Manel Esteller

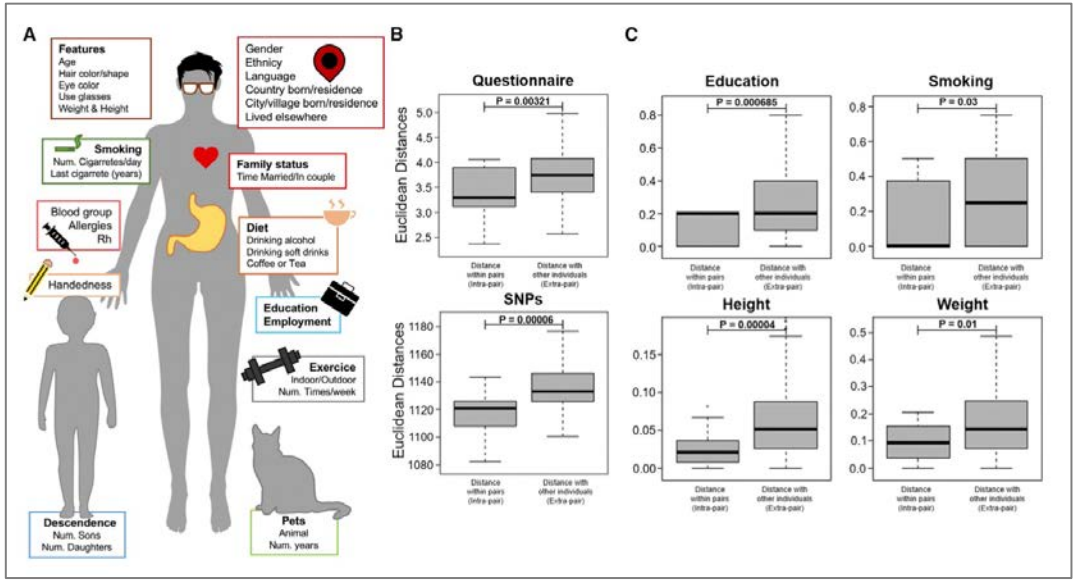
Correspondence

mesteller@carrerasresearch.org

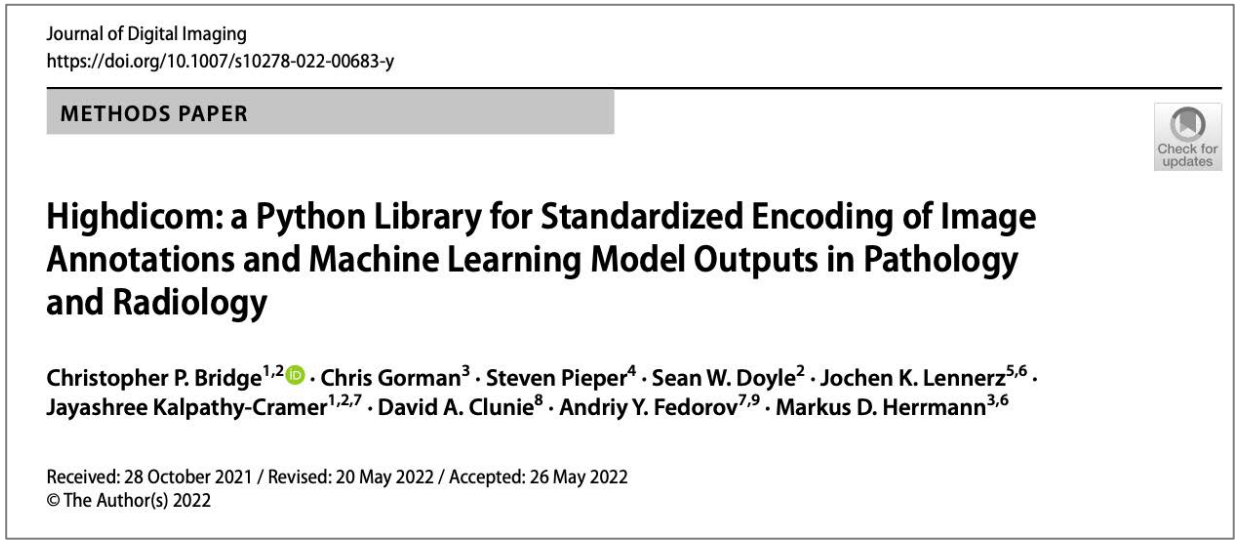
In brief

We recognize each other by relying on our face uniqueness. However, there are humans with uncanny resemblance. Joshi et al. reported that look-alike pairs identified by facial recognition algorithms share genotypes but not DNA methylomes and microbiomes. The identified SNPs also provide a readout of other anthropomorphic and behavioral characteristics.





ct-DNA (see project)
Standards + Payors Group



Journal of Digital Imaging
https://doi.org/10.1007/s10278-022-00683-y

METHODS PAPER

Check for updates

Highdicom: a Python Library for Standardized Encoding of Image Annotations and Machine Learning Model Outputs in Pathology and Radiology

Christopher P. Bridge[1,2] · Chris Gorman[3] · Steven Pieper[4] · Sean W. Doyle[2] · Jochen K. Lennerz[5,6] · Jayashree Kalpathy-Cramer[1,2,7] · David A. Clunie[8] · Andriy Y. Fedorov[7,9] · Markus D. Herrmann[3,6]

Received: 28 October 2021 / Revised: 20 May 2022 / Accepted: 26 May 2022

VIEWPOINT

From Scientific Discovery to Covered Treatments
Understanding the Payer Perspective as a Keystone to Achieving High-Value Care

The mission of the National Institutes of Health (NIH) is ment and Coverage Advisory Committee to review and con-

Events

Missed the Next Generation Dx Summit this Year?

PURCHASE ON-DEMAND

Missed this year's event? Access content across all of this year's programs on-demand. At your convenience, access archived presentations for on-demand learning from anywhere, at any time.

Conference Programs

MON AUG 22 & TUES AM, AUG 23

Enabling Point-of-Care Diagnostics

TUES PM, AUG 23 & WED, AUG 24

Advanced Diagnostics for Infectious Disease

Digital Diagnostic Summit 9/21-9/23

WED 21

4-6 PM	Registration in St Regis Lobby
6-8 PM	VIP Reception with speakers and sponsors - ***invite only***
6:30 PM	Champagne Sabering hosted by St Regis, all guests invited

THURS 22

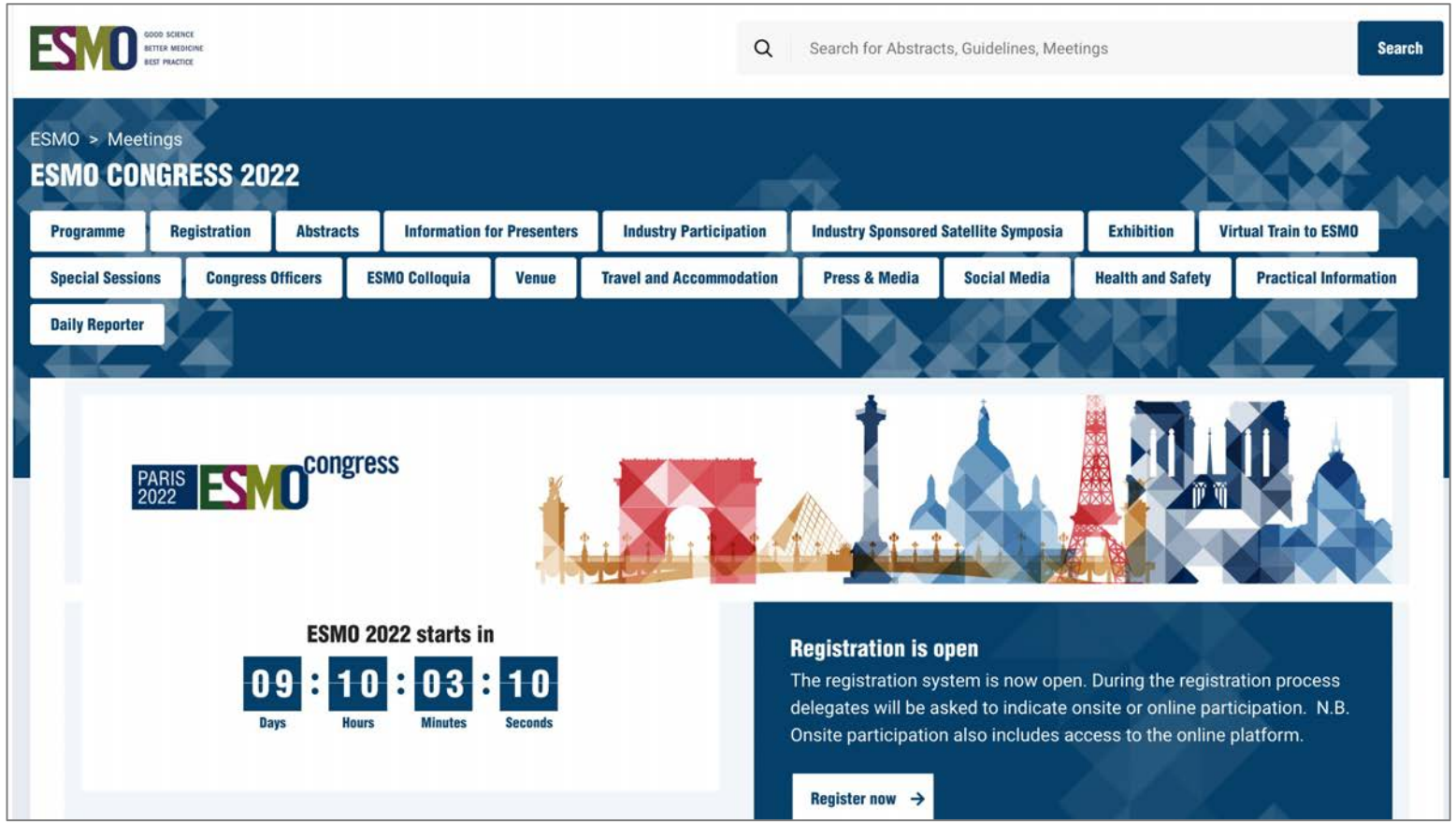
7:30-8 AM	Breakfast
8 AM	Welcome & Keynote intro | **John Wirthlin**
8:15-9 AM	How Innovation is Shaping the Future of Healthcare, Global | **Michael Leavitt, Keynote**
9-9:45 AM	Leveraging AI for Advancing Precision Medicine | **Martin Stumpe PhD**
9:45-10:15 AM	Advances and Opportunities for AI in Digital Pathology | **Verily Speaker TBA**
10:15-10:45 AM	Break
10:45-11:30 AM	Genetic and Genomic Opportunities for Pathology | **Myriad Speaker TBA**
11:30-12:30 PM	AI and the Future of Patient Care Panel | **Moderator: Matt Leavitt MD with Howard Korman MD, Verily, Tempus, AstraZeneca, & Adam Cole MD**
1:00-6:30 PM	Grab & Go Lunch | Excursions
6:30-7:30 PM	Dinner at the RIME restaurant
7:30-9 PM	Dessert & Fireside Chat | Digital Pathology in The Real World - The Puts and Takes Pathologist Panel, moderated by **Joseph Anderson MD**

FRI 23

7:30-8 AM	Breakfast
8-8:30 AM	DDX: The Link Between Digital Pathology and the Patient | **Matt Leavitt MD**
8:30-9:15 AM	How Digital Pathology can Differentiate Your Practice and Help You Thrive - How I Did it, and You Can Too | **Adam Cole MD**
9:15-9:45 AM	FDA Oversight of AI in Digital Pathology, Can I Use This? | **Ralph Hall JD**
9:45-10:30 AM	Real World Experience with Diagnostic AI | **Hillel Kahane MD**
10:30-11:15 AM	Future of Digital Pathology & Closing Remarks | **Open Pathology**
11:30 AM	Checkout

ESMO, Paris – 9/9/2022-9/13/2022

- https://www.esmo.org/meetings/esmo-congress-2022



JSDP – 8/26/2022- 8/28/2022

- **Annual Meeting of Japanese Society of Digital Pathology**
- https://jsdp2022.com/en/index.html

OHSY - 10/27/2022. OSU Digital Pathology Workshop

Podcast

- Sanjay Mukhopadhyay
- https://insidethelab.buzzsprout.com/1230539/10686342-s2ep18-evolution-of-anatomic-and-clinical-pathology-in-the-last-century

Tian Yu 8/10/2022

Future Trends in Spatial Biology; the Pathologist

The use of spatial biology in laboratory medicine is on the rise – but what does the future hold?

1. Automation
2. Resolution
3. Multi-omics and multiplex
4. Artificial Intelligence
5. Sample quality
6. Standardized diagnostic biomarkers

Link: https://thepathologist.com/diagnostics/future-trends-in-spatial-biology