Plcc Alliance

Home About Working Groups News & Events Resources Presentations Projects Publications

Join

Pathology Innovation Collaborative Community

Plcc

The Alliance for Digital Pathology

A collaborative community with FDA participation

Steering Committee Meeting

July 2023

https://pathologyinnovationcc.org/picc23-annual-meeting

CLICK HERE TO VIEW THE MEETING SUMMARY

Join us in-person in the Washington DC metro area on Jun 27-28, 2023 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."

Register here

Why you should attend:

- Network with domain experts with keen interest in moving regulatory science forward through in-person interactive working sessions

PIcc23 took place on June 27&28 in Arlington, VA

Thank you to all attendees, presenters, our sponsors, and MDIC

PIcc23 Recap

PIcc23 occurred on June 27 and 28. A productive and collaborative meeting that brought together members to help advance PIcc and different initiatives.
Thank you to everyone that joined us!

Click here for a recap of the event

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MEDICAL DEVICE INNOVATION CONSORTIUM
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Join at **menti.com** use code **6455 6367**

Mentimeter

Please rank the topics you believe can effectively synergize towards one large-scale regulatory science project.

GO TO
menti.com
ENTER THE CODE
6455 6367
0

30

Real World Data Collection

Key elements, next steps, timeline

- Understanding of what RWD vs RWE is
  - RWD is clinical data – what is generated day to day. This is then **harmonized** (from different locations)/cleaned when you have an intended use to become evidence
- Standards-based data formats, minimum requirements.
- Standardized language and lab reporting is needed and a tangible RS tool
- Least burden to prepare the data

Pros for Patient, Clinical, R&D, and regulatory

- Helpful for the transition of EUA to 510k
- Established best practices – later define statistics behind this
- Could using an exiting LDT within the regular, routine pathologist's workflow be a way to expedite gathering RWD? Does the vendor have the right to use this data? "Triangle" between lab, Vendor, and FDA
- Registries

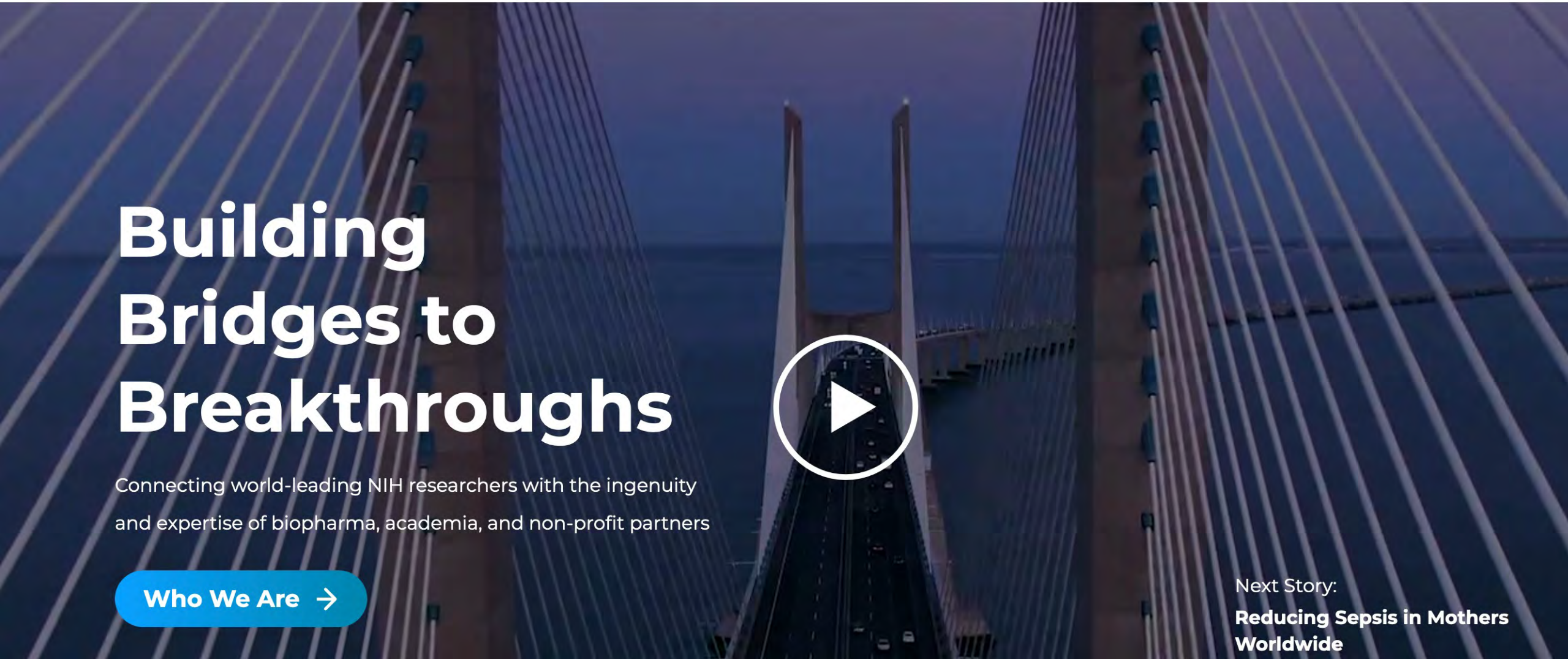
- Define terms and characteristics around data set types (training, testing, tuning)
- Checklist or position paper with FDA around these terms
- Example of what data set should look like under each term

Concerns for patients, clinical, R&D, and regulatory

- Is presented data true and accurate?
- Will the RWD gathering process via FDA for approval be so long that the technology is no longer applicable?
- Post-market surveillance issues? Quality assurance/control monitoring

Implications and efforts

- Understand current definitions within PCCP guidance
- Data variability needed will be specific to the question being asked
- These are recommendations
- Collecting data is active work, to be done by humans
- Early adopting labs using LDTs are the generators for much of this RWD



Building Bridges to Breakthroughs

Connecting world-leading NIH researchers with the ingenuity and expertise of biopharma, academia, and non-profit partners

Who We Are →

Next Story:
Reducing Sepsis in Mothers Worldwide

FNIH

- Initial meeting
- Tue 7/18/2023

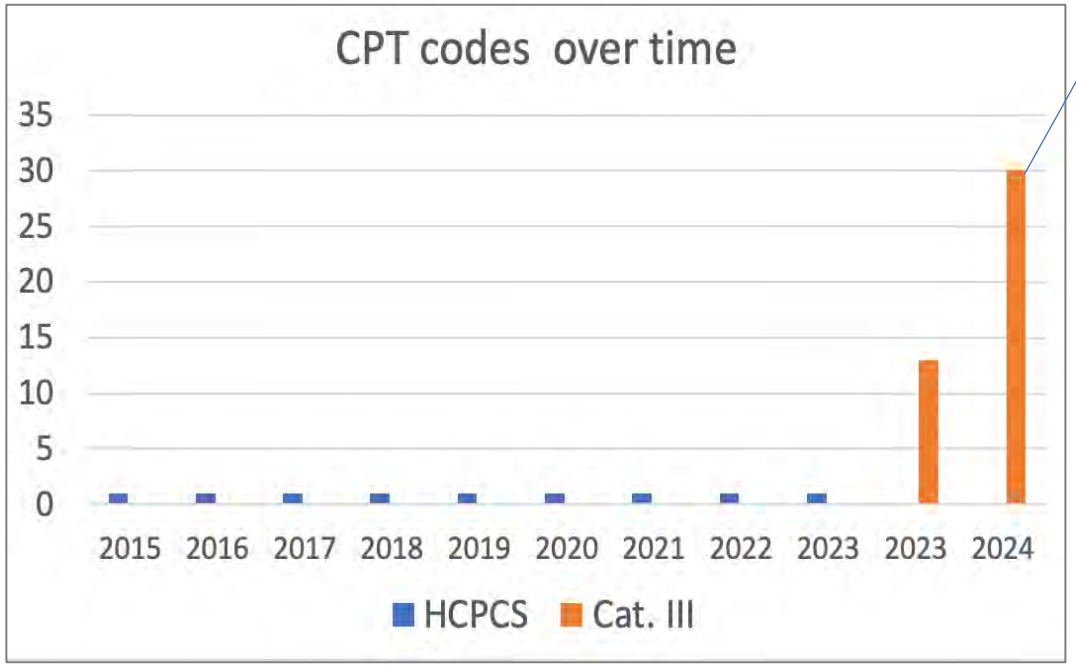
- connection
- Opportunities for collaboration

- Dedicated meeting
- Project overview; looking for collaborators

Digital Pathology

- Coding update
- CLFS – new PLA codes
- Remote work

The evolution of digital pathology codes



DP CPT	Year	CPT	Description
0827T	2024	88104	Cytopathology, fluids, wa
0828T	2024	88106	Cytopathology, fluids, wa with interpretation
0829T	2024	88108	Cytopathology, concentr

DP CPT	Year	CPT	Description
0842T	2024	88332	Intraoperative consultation, ea
0843T	2024	88333	Intraoperative consultation, cy

For all major use cases including

- Routine histology (2023)
- Immunohistochemistry (2023)
- Cytopathology (2024)
- Intraoperative Consultations (2024)
- Smears/bone marrows (2024)
- FISH and IF (2024)

Currently Category III codes

- not used for CMS billing
- established for volume tracking with new technologies
- must be used when performing the procedure

Questions, please e-mail:
Joe Lennerz or Stephen Black-Schaffer

CLFS 2024 => new PLA codes

				Algorithmic Analyses		determining the risk of distant metastases, and prostate cancerspecific mortality, includes predictive algorithm to androgen deprivationtherapy response, if appropriate	2.Crosswalk to 0220U: 6 3. Gapfill: 1 4. Abstain: 1
9	80	X084U	NEW	Multianalyte Assays with Algorithmic Analyses	MAAA-DP	X084U: Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (ALK, BRAF, EGFR, ERBB2, MET, NTRK1-3, RET, ROS1), and KRAS G12C and PD-L1, if performed, formalin-fixed paraffin-embedded (FFPE) tissue, reported as positive or negative for each biomarker [**REVISED by CPT 6-12-2023]	1. Crosswalk to 0220U: 9 2. Gapfill: 0 3. Abstain: 0
10	84	X088U	NEW	Multianalyte Assays with Algorithmic Analyses: Immunology	MAAA-DP	X088U: Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score [**REVISED by CPT 6-12-2023]	1. Crosswalk to 0220U: 9 2. Gapfill: 0 3. Abstain: 0
11	72	X076U	NEW	Multianalyte Assays with	MAAA	Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4-carboxyphenyl] porphyrin [TCPP], CD206, CD66b,	1. Crosswalk to 0021U: 8 2. Gapfill: 1

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, M.D., M.P.H.
Acting Commissioner

MEGAN E. BALDWIN
Acting Executive Deputy Commissioner

May 12, 2023

In accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Post-Public Health Emergency (PHE) Guidance issued May 11, 2023, the New York State (NYS) Clinical Laboratory Evaluation Program (CLEP) will likewise allow pathologists and other laboratory personnel to review digital results and digital images remotely, under the conditions described below. The examination of physical slides requiring the use of a microscope or any examination that requires laboratory equipment other than a computer and VPN connection may not be performed at a location that does not hold a New York State clinical laboratory permit with the appropriate permit category.

Remote examination, review, and results reporting policy conditions:

- The primary laboratory location must hold New York State (NYS) clinical laboratory permit (permit) to include the permit category(ies) relevant to the testing being offered.
- The laboratory director of the primary laboratory location is responsible for all testing performed, including tasks performed remotely.
- The primary laboratory location must maintain all documentation for testing performed, including remote work.
- Persons performing remote tasks must be bona fide employees of the primary laboratory location holding the NYS permit.
- Remote tasks are performed in accordance with policies and procedures approved by the laboratory director.
- The test report must include the location where the testing (i.e., examination or analysis) was performed. Remote sites operating under the primary laboratory location's permit may be indicated using a coding system rather than the remote site address.
- The primary laboratory location must maintain a list of all personnel performing remote work, to include name, tasks qualified to perform, and the address of the remote location including any code being used to identify the location on test reports. This list must be made available to the Department upon request.
- The personnel performing remote work must be included on the Department's facility personnel form (fpf).
- Transmission of patient data is maintained over a secure VPN or equivalent level of security.
- Confidentiality of data is maintained at all times and the primary laboratory location and all remote sites comply with applicable federal laws, including HIPAA.

Any questions related to this policy can be directed to clepcomp@health.ny.gov.

FDA

FDA NEWS RELEASE

FDA Launches Pilot Program to Help Reduce Risks Associated with Using Laboratory Developed Tests to Identify Cancer Biomarkers

Pilot Geared Toward Sponsors of Certain Oncology Drug Products Used with Certain In Vitro Diagnostic Tests to Identify Patients for Certain Cancer Treatments

More Press Announcements

For Immediate Release: June 20, 2023

Today, the U.S. Food and Drug Administration announced a new voluntary pilot program for certain oncology drug products used with certain corresponding in vitro diagnostic tests to help clinicians select appropriate cancer treatments for patients.

"We believe this guidance and the launch of the pilot program are important steps towards addressing safety risks posed by the use of poorly performing laboratory developed tests," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "The pilot aims to help by making transparent performance recommendations for diagnostic tests used to select certain oncology drug treatments."

Under current FDA policy, an in vitro companion diagnostic test is one that provides information essential for the safe and effective use of a corresponding treatment. In oncology, for example, specific tests may be used to identify patients, such as those with a particular genetic mutation, who may or may not benefit from certain cancer treatments.

Content current as of:
06/20/2023

Regulated Product(s)
Drugs
Medical Devices

Related Information

- Guidance: Oncology Drug Products Used with Certain In Vitro Diagnostic Tests
- Oncology Center of Excellence Guidance Documents
- Companion Diagnostics
- Oncology Drug Products Used with Certain In Vitro Diagnostics Pilot Program | CDRH

###

https://www.fda.gov/news-events/press-announcements/fda-launches-pilot-program-help-reduce-risks-associated-using-laboratory-developed-tests-identify

- LDT discussion

STUDY DATA
TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

This Document is incorporated by reference into the following Guidance Document(s):

Guidance for Industry *Providing Regulatory Submissions in Electronic Format – Standardized Study Data*

For questions regarding this technical specifications document, contact CBER at cber-edata@fda.hhs.gov or CDER at cder-edata@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)
Center for Drug Evaluation and Research (CDER)

May 2023

FDA U.S. FOOD & DRUG ADMINISTRATION

Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products

Discussion Paper and Request for Feedback

FDA U.S. FOOD & DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Office of Surveillance and Epidemiology 2022 Annual Report

Detecting, Assessing, Preventing, and Managing Risks

FDA U.S. FOOD & DRUG ADMINISTRATION

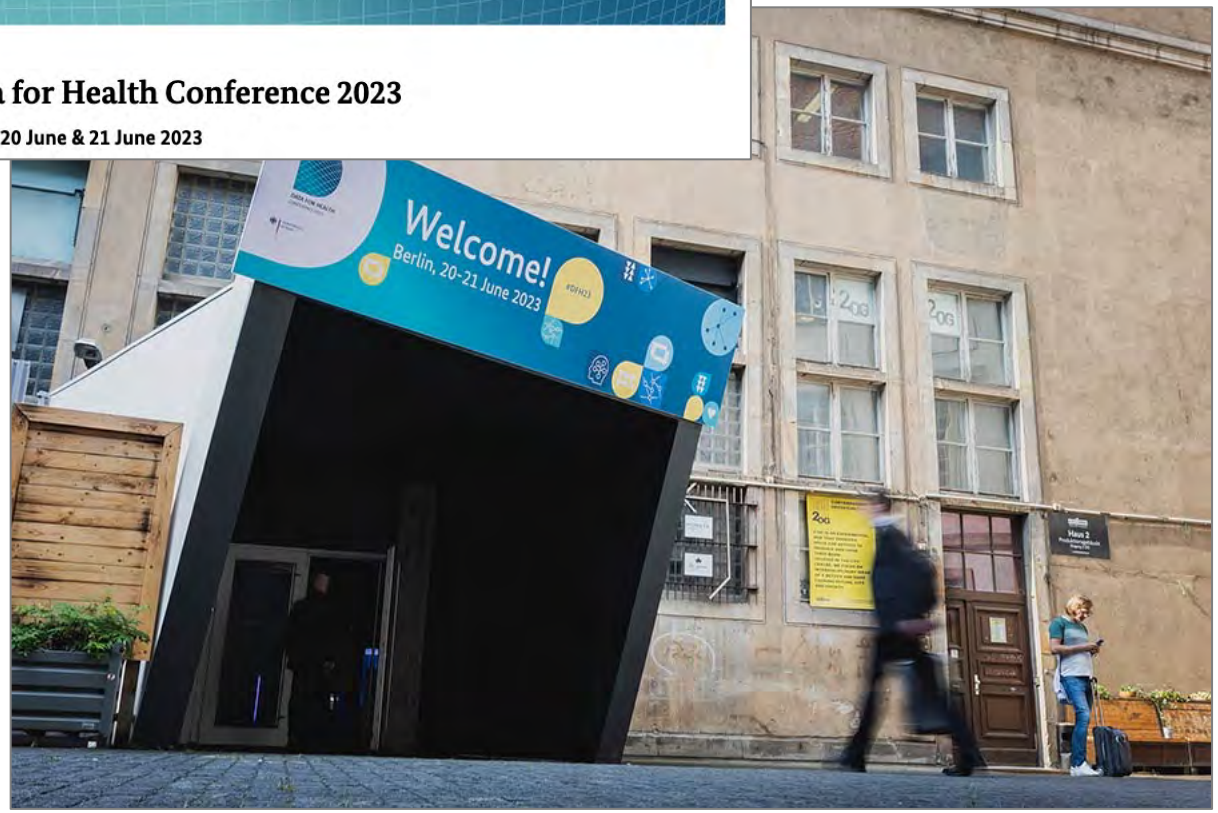
Accelerating Rare disease Cures (ARC) Program

YEAR ONE: Anniversary Update

Driving Innovation through Collaboration and Engagement with Rare Disease Stakeholders

LEGISLATIVE UPDATES

PIcc activities in the Data for Health Space

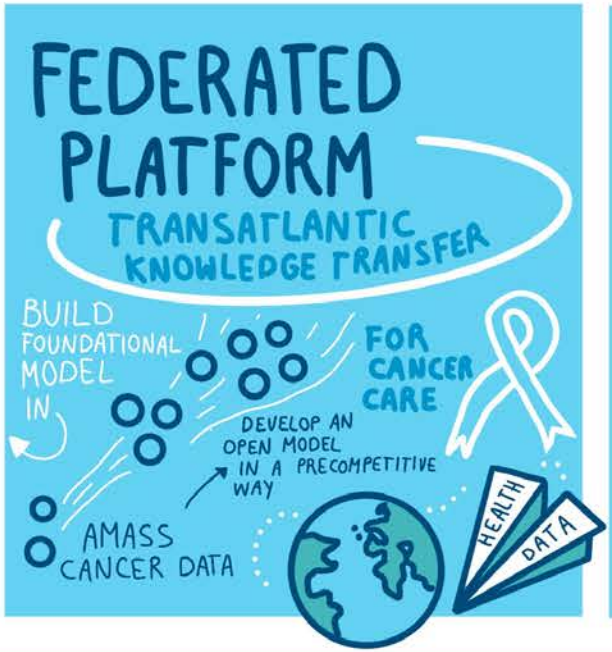


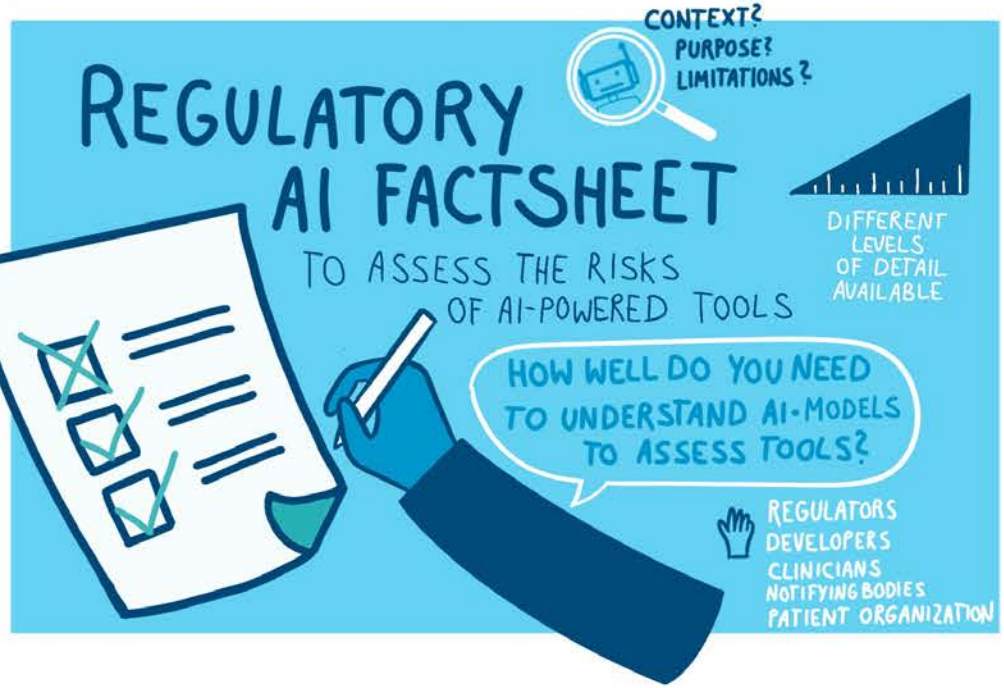

DATA FOR HEALTH
CONFERENCE 2023
#DFH23
Opening keynote

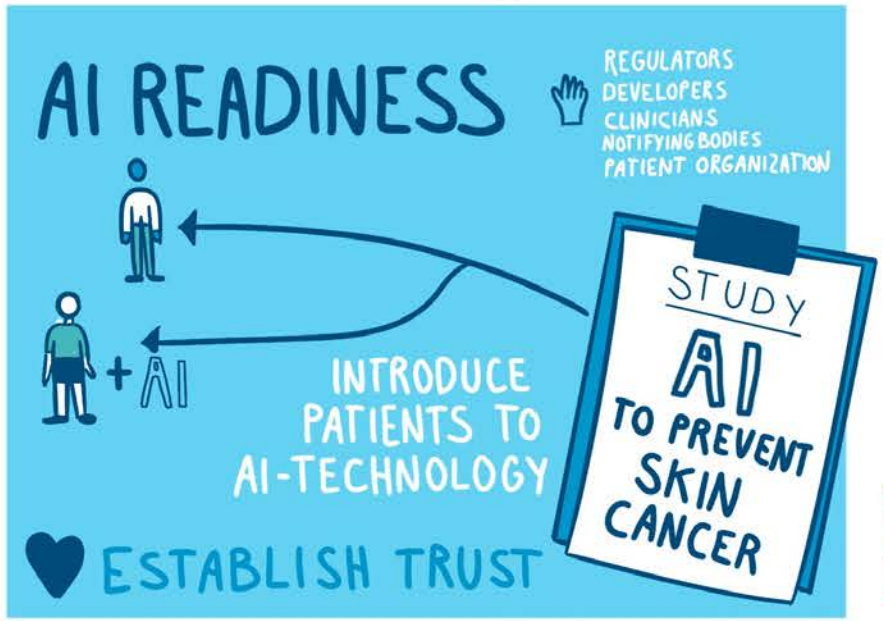
DATA FOR HEALTH
CONFERENCE 2023

Regulatory Science for AI

Overcoming regulatory barriers for the use of AI

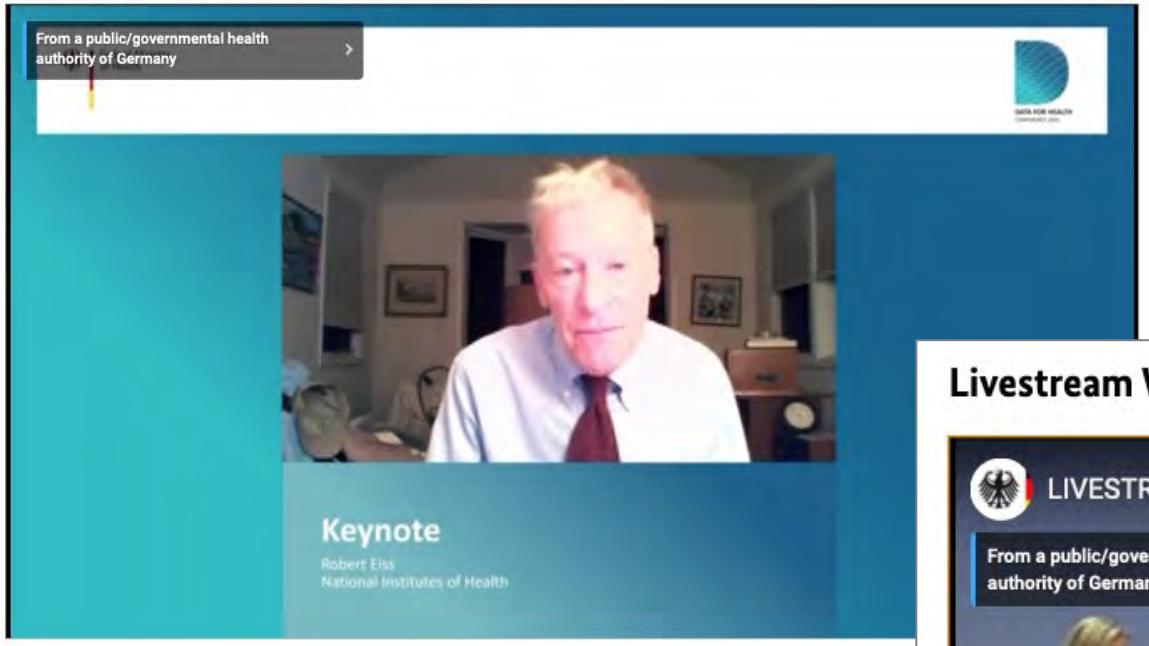




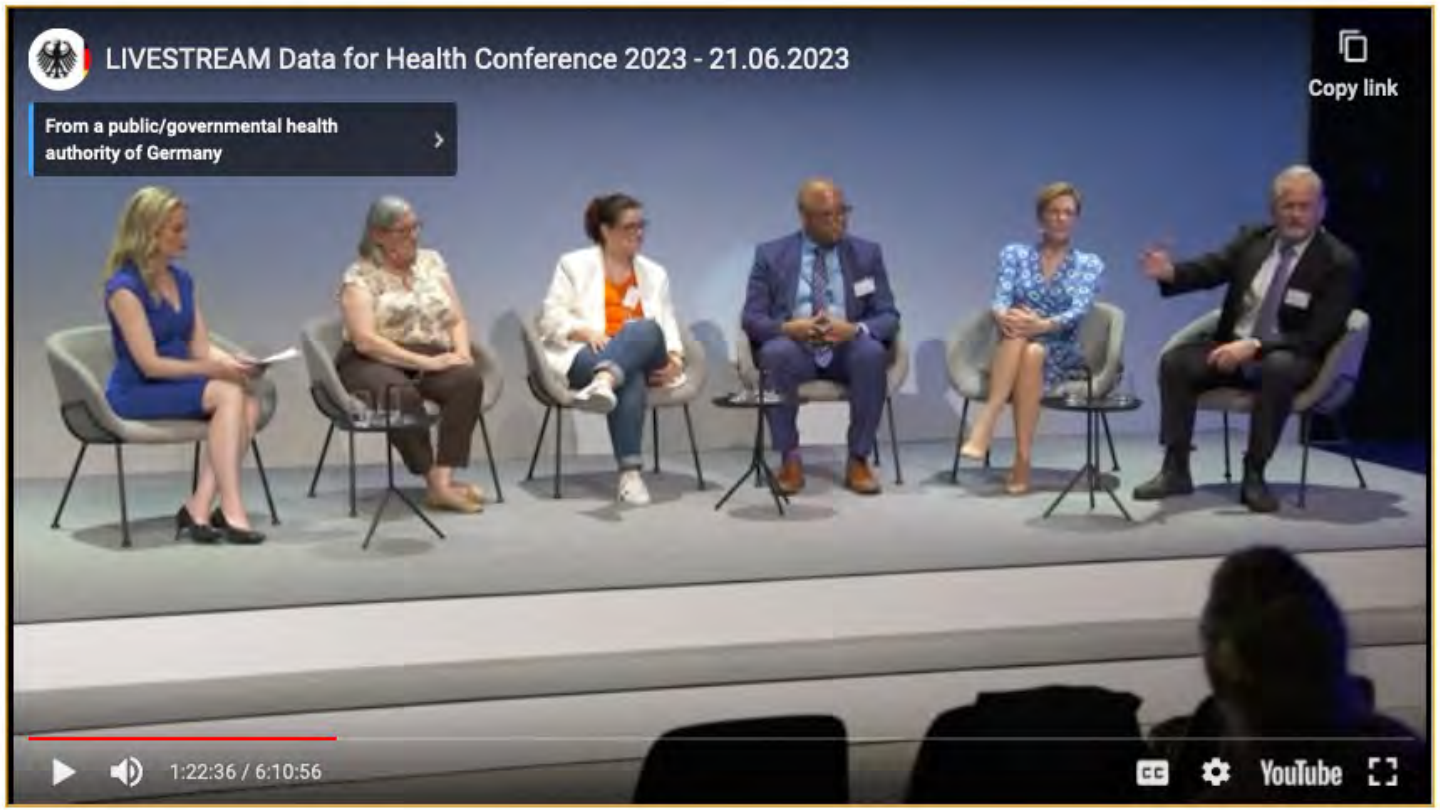


GRAPHIC RECORDING: MANUEL RECKER.DE

Livestream Wednesday, June 21st, 2023



Livestream Wednesday, June 21st, 2023

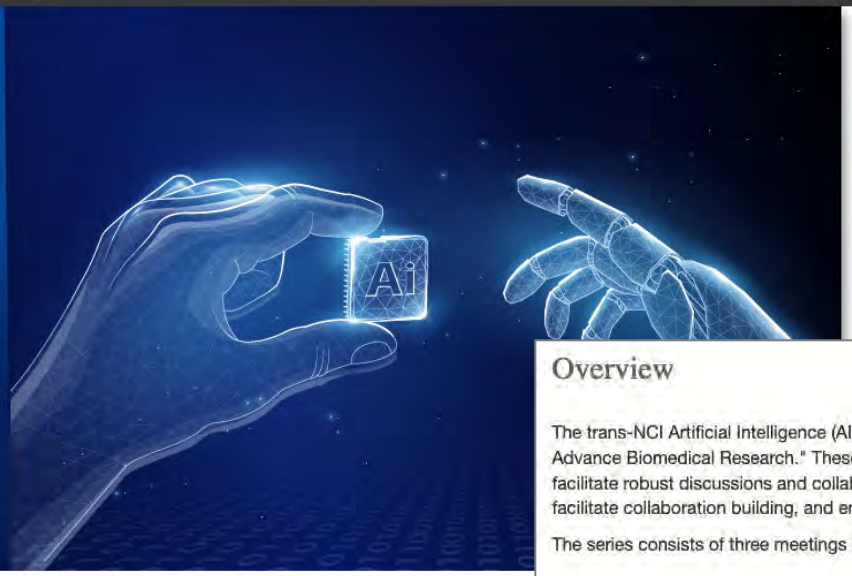


NIH NATIONAL CANCER INSTITUTE

OVERVIEW AGENDA REGISTRATION SPEAKER BIOS

United States - European Union:

Artificial Intelligence Engagement Seminar Series



Overview

The trans-NCI Artificial Intelligence (AI) Working Group is proud to announce a series of meetings focused on discussing "Equitable and Engaged AI to Advance Biomedical Research." These meetings will bring together diverse subject matter experts from both the United States and the European Union to facilitate robust discussions and collaborative efforts in the field of equitable and engaged AI. The objective of these meetings is to maximize interactivity, facilitate collaboration building, and encourage open sharing of information and novel ideas.

The series consists of three meetings each exploring various AI topics relevant to cancer research, with a specific focus on the following areas:

July 25th from 9am -12pm EDT
Meeting 1- **Privacy Preserving AI**: This session centers around AI techniques (e.g., federated learning) and ethical considerations that aim to safeguard and uphold the privacy of participants' data.

July 26th from 9am -12pm EDT
Meeting 2- **Community/Patient Engaged AI for Biomedical Research**: This session showcases technologies and tools that foster patient engagement in cancer research. It builds upon the well-established tradition of community-based participatory research in the U.S. and the EU, while incorporating the latest advancements in explainable AI.

July 28th from 9am -12pm EDT
Meeting 3 - **Ethical AI and the Inclusion of Underserved Communities**: This session aims to explore the ethical use of AI and foster the inclusion of underserved communities. It builds upon the principles of explainable AI, trust in AI, and technical strategies to address challenges associated with limited data sets and data annotation.

NCI Planning Committee

Jennifer Couch, Ph.D.
Sylvia Gayle, Ph.D.
Freddie Pruitt, Ph.D.

HARVARD T.H. CHAN | SCHOOL OF PUBLIC HEALTH
India Research Center

Follow-up

- Data for Health Workshop
- September 2023
- Boston, MA
- Four tracks –
  - **Workshop 1** "Striking the Perfect Balance: Navigating Privacy Issues at the State Level”
  - **Workshop 2** "Bridging the Atlantic Divide: Crafting a Transatlantic Consent Form for Data Exchange"
  - **Workshop 3** "United in Health Data: Exploring a Federated Administrative Approach for Transatlantic Exchange”
  - **Workshop 4** "Data from Within: Advancing Healthcare through Brain-Computer Interface Insights"

GDPR vs. HIPAA

Privacy shield 1.0 => ended
March 2022 = EC => final stages

On **July 10th** the European Commission adopted its adequacy decision for the EU-US Data Privacy Framework.

On the basis of the **adequacy decision**, personal data can flow freely from the EU to companies in the United States that participate in the Data Privacy Framework.

Health data (more complicated)

EUROPEAN
COMMISSION

Brussels, 10.7.2023
C(2023) 4745 final

COMMISSION IMPLEMENTING DECISION

of 10.7.2023

pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council on the adequate level of protection of personal data under the EU-US Data Privacy Framework

(Text with EEA relevance)

Note: An adequacy decision is **one of the tools provided under GDPR to transfer personal data from the EU to third countries**. In theory, it should give EU residents the certainty that if their data is exported to the US, it will be processed with the same level of protection as within the EU.

MDIC Updates

https://mdic.org/

Join us at MXR2023!

Join MDIC, FDA, and top industry leaders in this exciting two-day regulatory science conference convening leaders in augmented and virtual reality! Learn about technological advances, current medical applications, drivers of innovation and adoption, and recent regulatory advances in the field of MXR.

Click here for registeration and poster submissions

Contact MXR@mdic.org for Exhibition/Sponsorship opportunities

Early Bird Registration ends: August 31, 2023

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Join us at APF!

The APF theme is Insight. Innovation. Impact. This once-a-year event will bring together industry experts, patient advocates, regulators, and other community innovators to transform the future of medical technology and diagnostics. Topics to be discussed include health equity, cybersecurity, real-world evidence, and more.

Click here to register

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Learn How to Apply for $300,000 USD in Funding for Your Advanced Manufacturing Project!

MDIC recently demonstrated how to submit a successful application for the chance to earn $300,000 USD and project support to manufacture an innovative medical device through the Advanced Manufacturing Clearing House initiative.

Experts Steve Zera, Senior Program Manager, AMCH and Prakash Patwardhan, Program Director, CFQ Advanced Manufacturing, illustrated the application process including explaining the submission criteria and eligibility requirements.

Do you have an innovative idea and want to be eligible for funding? If so, view the video below for instructions and insight into completing the application. If you're ready, select the application button and get started. Good luck!

View Video

Start Application

Advanced Manufacturing Clearing House (AMCH)

MDIC's AMCH has funding for you to apply for!
To learn more, click here

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Professional Societies

COLLEGE of AMERICAN PATHOLOGISTS

CAP Logo

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Home > Advocacy

Advocacy

Our advocacy update is your source for the latest news. Read the current update.

Home > Advocacy > Payments for Pathology Services > 2023 Digital Pathology Codes

2023 Digital Pathology Codes

The College of American Pathologists (CAP) worked with the American Medical Association (AMA) CPT Editorial Panel to establish **13 new digital pathology add-on codes**. The new codes are intended to capture and report additional clinical staff work and service requirements associated with digitizing glass microscope slides for primary diagnosis. Digitization of glass microscope slides enables remote examination by the pathologist and/or in conjunction with the use of artificial intelligence (AI) algorithms. As a result of **CAP advocacy**, the new codes will help pathologists, pathology practices, and laboratories providing digital pathology digitization procedures appropriately report these services. The new digital pathology codes will be effective January 1, 2023.

The AMA CPT also added a new heading in the Category III section with CPT instructions and guidelines to define digital pathology digitization procedures. For more information on the digital pathology codes **watch the Final 2023 Medicare Payment Regulations webinar** or **download the slides**.

CPT Category III *codes 0751T-0763T may be reported in addition to the appropriate Category I service code when the digitization procedure of glass microscope slides is performed and reported in conjunction with the Category I code for the primary service as noted in the below table.*

CPT Code	Long Descriptor
+0751T	Digitization of glass microscope slides for level II, surgical pathology, gross and microscopic examination (List separately in addition to code for primary procedure) ►(Use 0751T in conjunction with 88302)◄
+0752T	Digitization of glass microscope slides for level III, surgical pathology, gross and microscopic examination (List separately in addition to code for primary procedure) ►(Use 0752T in conjunction with 88304)◄
+0753T	Digitization of glass microscope slides for level IV, surgical pathology, gross and microscopic examination (List separately in addition to code for primary procedure)

DIGITAL PATHOLOGY
DPA
ASSOCIATION

search

MEMBER LOGIN

NON-ME

ABOUT MEMBERSHIP COLLABORATE PATHOLOGY VISIONS

PODCAST PUBLICATIONS EVENTS

WHY ATTEND PV?

CME & CE

TRAVEL AWARD RECIP

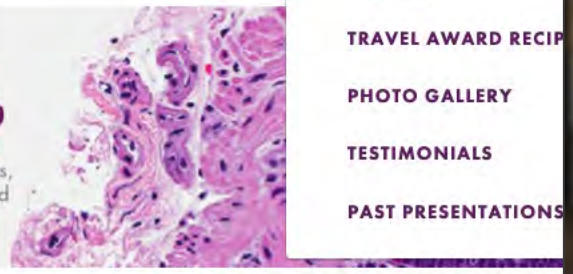
PHOTO GALLERY

TESTIMONIALS

PAST PRESENTATIONS

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

SAVE THE DATE OCTOBER 29-31

HYATT REGENCY ORLANDO | ORLANDO, FL

#PathVisions23

NEWS

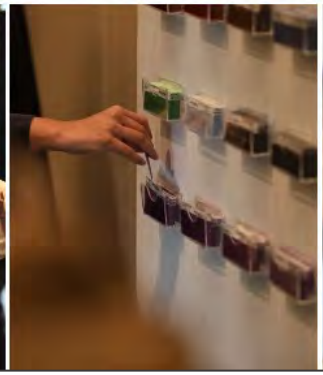
AMA Announces Codes

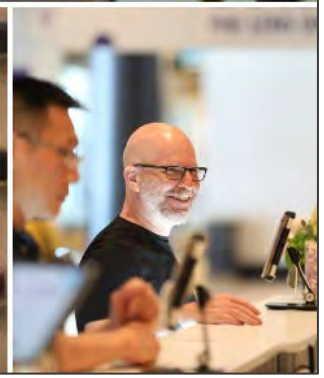
AMA Addition of Digital Pathology

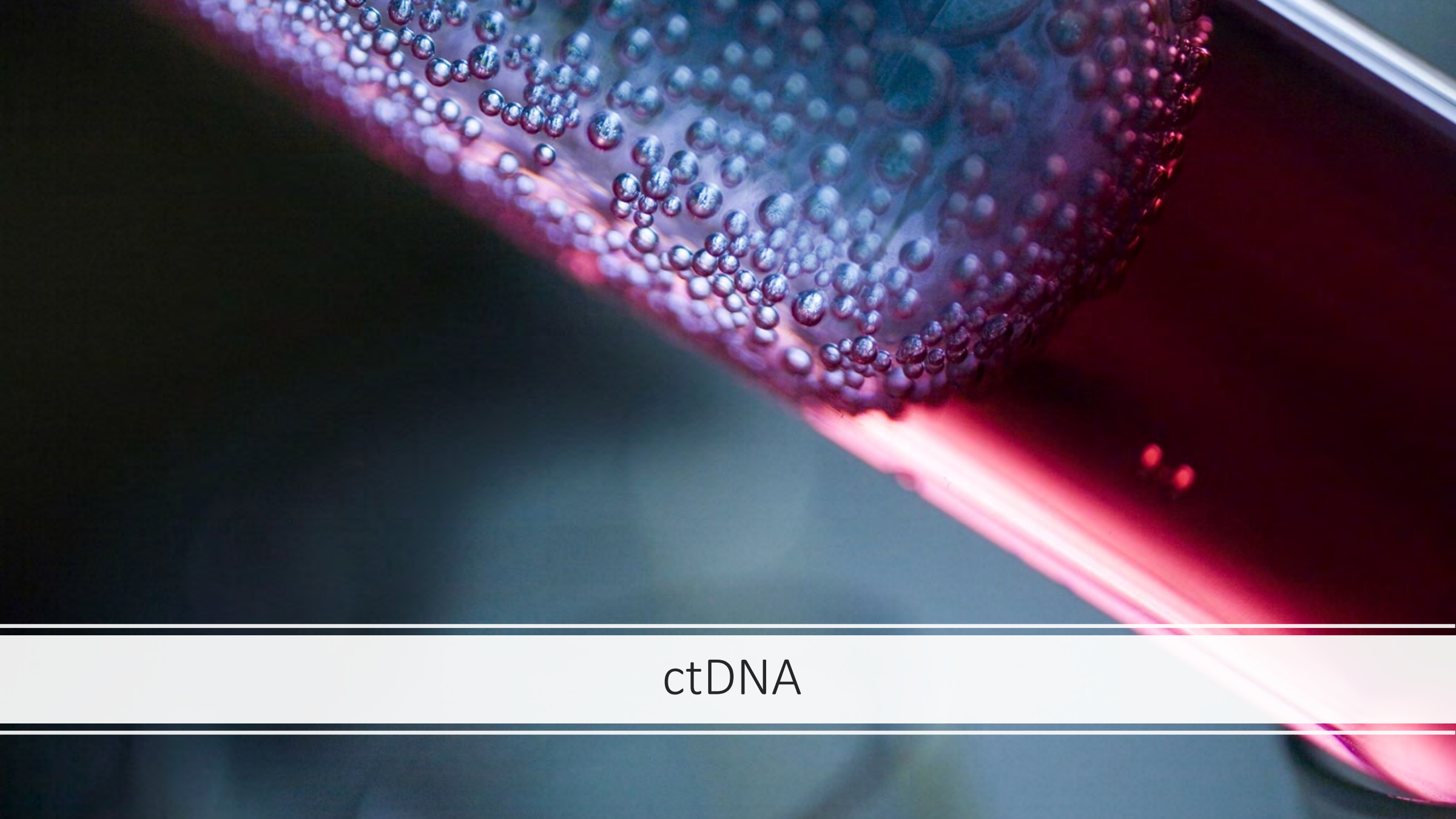
Webinar: Can AI Regulatory Scien

Digital Pathology Association
6,506 followers
1w •

We're getting all checked in and kicking off #PathVisions22. It's so good to see everyone again!







ctDNA

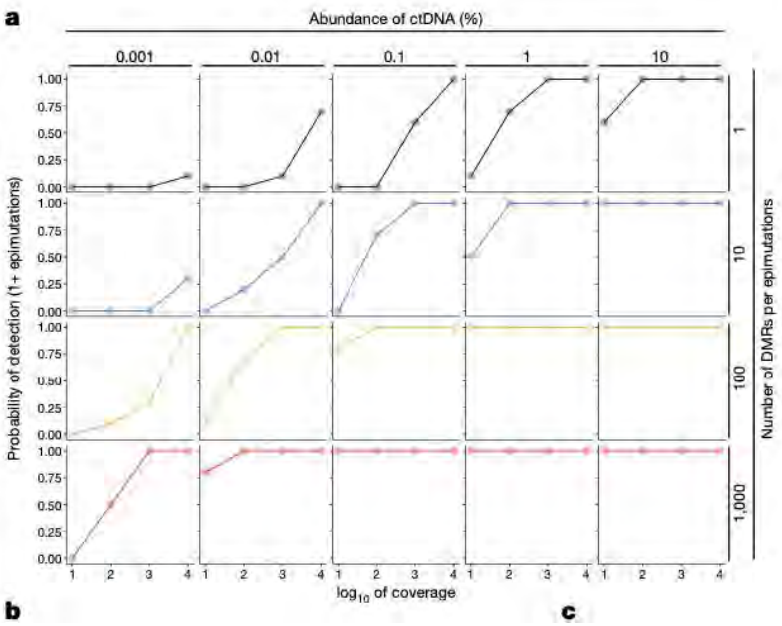
LETTER

https://doi.org/10.1038/s41586-018-0703-0

Sensitive tumour detection and classification using plasma cell-free DNA methylomes

Shu Yi Shen[1,12], Rajat Singhania[1,12], Gordon Fehringer[2,12], Ankur Chakravarthy[1,12], Michael H. A. Roehrl[1,3,4], Dianne Chadwick[1], Philip C. Zuzarte[5], Ayelet Borgida[2], Ting Ting Wang[1,4], Tiantian Li[1], Olena Kis[1], Zhen Zhao[1], Anna Spreafico[1], Tiago da Silva Medina[1], Yadon Wang[1], David Roulois[1,6], Ilias Ettayebi[1,4], Zhuo Chen[1], Signy Chow[1], Tracy Murphy[1], Andrea Arruda[1], Grainne M. O'Kane[1], Jessica Liu[4], Mark Mansour[4], John D. McPherson[7], Catherine O'Brien[1], Natasha Leighl[1], Philippe L. Bedard[1], Neil Fleshner[1], Geoffrey Liu[1,4,8], Mark D. Minden[1], Steven Gallinger[9,10], Anna Goldenberg[11], Trevor J. Pugh[1,4], Michael M. Hoffman[1,4,11], Scott V. Bratman[1,4], Rayjean J. Hung[2,8]* & Daniel D. De Carvalho[1,4]*

The use of liquid biopsies for cancer detection and management is rapidly gaining prominence[1]. Current methods for the detection of circulating tumour DNA involve sequencing somatic mutations using cell-free DNA, but the sensitivity of these methods may be low among patients with early-stage cancer given the limited number of recurrent mutations[2–5]. By contrast, large-scale epigenetic alterations—which are tissue- and cancer-type specific—are not similarly constrained[6] and therefore potentially have greater ability to detect and classify cancers in patients with early-stage disease. Here we develop a sensitive, immunoprecipitation-based protocol to analyse the methylome of small quantities of circulating cell-free DNA, and demonstrate the ability to detect large-scale DNA methylation changes that are enriched for tumour-specific patterns. We also demonstrate robust performance in cancer detection and classification across an extensive collection of plasma samples from several tumour types. This work sets the stage to establish biomarkers for the minimally invasive detection, interception and classification of early-stage cancers based on plasma cell-free DNA methylation patterns.



The analysis of circulating tumour DNA (ctDNA) has numerous

Perspective

Practical recommendations for using ctDNA in clinical decision making

https://doi.org/10.1038/s41586-023-06225-y

Received: 14 October 2022

Accepted: 16 May 2023

Published online: 12 July 2023

Check for updates

Stacey A. Cohen[1,2]✉, Minetta C. Liu[3] & Alexey Aleshin[3]

The continuous improvement in cancer care over the past decade has led to a gradual decre
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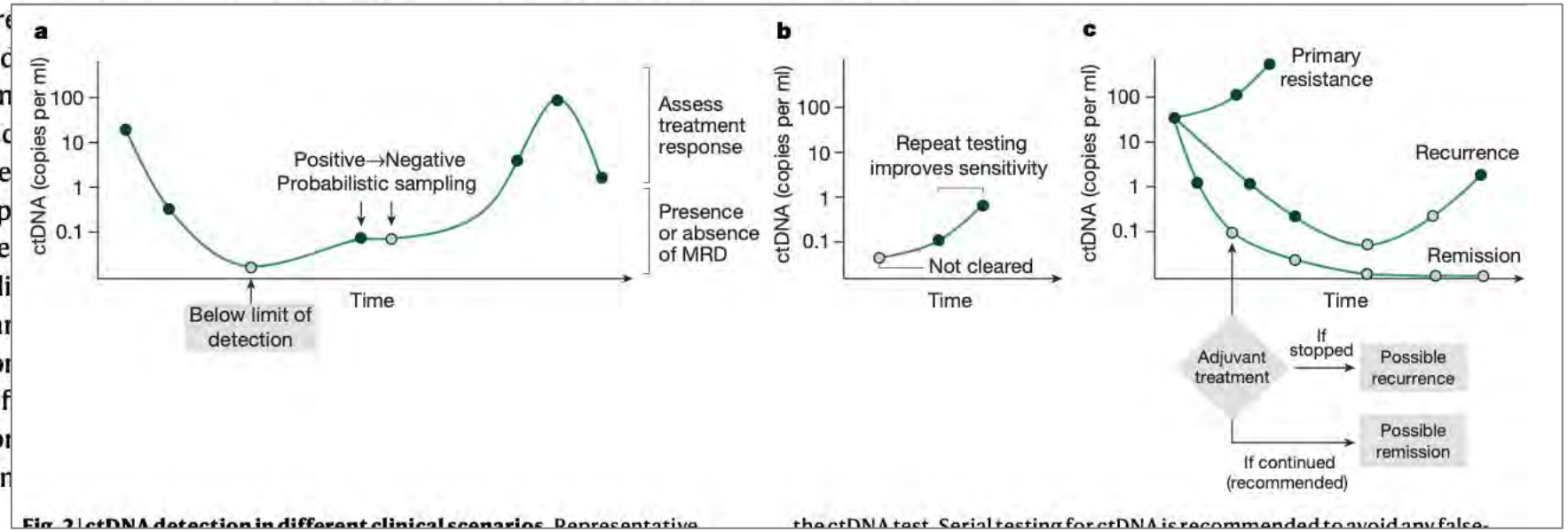


Fig. 2 | ctDNA detection in different clinical scenarios. Representative the ctDNA test. Serial testing for ctDNA is recommended to avoid any false-

Over the past 20 years, there has been an incremental and consistent improvement in cancer survival rates[1], largely attributed to more effec- (as a percentage) or tumour fraction (as the mean number of tumour molecules per millilitre), should also be considered while interpreting

Diversity & Inclusion

npj | breast cancer

www.nature.com/npjbcancer

ARTICLE OPEN

Check for updates

Racial disparity in tumor microenvironment and distant recurrence in residual breast cancer after neoadjuvant chemotherapy

Gina Kim[1,16], Burcu Karadal-Ferrena[2,3,16], Jiyue Qin[4], Ved P. Sharma[5], Isabelle S. Oktay[6], Yu Lin[2,7], Xianjun Ye[2,7,8], Saeed Asiry[9], Jessica M. Pastoriza[1], Esther Cheng[10], Nurfiza Ladak[11], John S. Condeelis[1,7,8,12], Esther Adler[11], Paula S. Ginter[13], Timothy D'Alfonso[14], David Entenberg[2,7,8], Xiaonan Xue[4], Joseph A. Sparano[15] and Maja H. Oktay[1,2,7,8]✉

Black, compared to white, women with residual estrogen receptor-positive (ER+) breast cancer after neoadjuvant chemotherapy (NAC) have worse distant recurrence-free survival (DRFS). Such racial disparity may be due to difference in density of portals for systemic cancer cell dissemination, called TMEM doorways, and pro-metastatic tumor microenvironment (TME). Here, we evaluate residual cancer specimens after NAC from 96 Black and 87 white women. TMEM doorways are visualized by triple immunohistochemistry, and cancer stem cells by immunofluorescence for SOX9. The correlation between TMEM doorway score and pro-metastatic TME parameters with DRFS is examined using log-rank and multivariate Cox regression. Black, compared to white, patients are more likely to develop distant recurrence (49% vs 34.5%, $p = 0.07$), receive mastectomy (69.8% vs 54%, $p = 0.04$), and have higher grade tumors ($p = 0.002$). Tumors from Black patients have higher TMEM doorway and macrophages density overall ($p = 0.002$; $p = 0.002$, respectively) and in the ER+/HER2- ($p = 0.02$; $p = 0.02$, respectively), but not in the triple negative disease. Furthermore, high TMEM doorway score is associated with worse DRFS. TMEM doorway score is an independent prognostic factor in the entire study population (HR, 2.02; 95%CI, 1.18–3.46; $p = 0.01$), with a strong trend in ER+/HER2- disease (HR, 2.38; 95% CI, 0.96–5.95; $p = 0.06$). SOX9 expression is not associated with racial disparity in TME or outcome. In conclusion, higher TMEM doorway density in residual breast cancer after NAC is associated with higher distant recurrence risk, and Black patients are associated with higher TMEM doorway density, suggesting that TMEM doorway density may contribute to racial disparities in breast cancer.

npj Breast Cancer (2023)9:52 ; https://doi.org/10.1038/s41523-023-00547-w

ASSIGNING AI: SEVEN APPROACHES FOR STUDENTS WITH PROMPTS

Dr. Ethan Mollick Dr. Lilach Mollick

Wharton School of the University of Pennsylvania & Wharton Interactive

June 11, 2023

Abstract:

This paper examines the transformative role of Large Language Models (LLMs) in education and their potential as learning tools, despite their inherent risks and limitations. The authors propose seven approaches for utilizing AI in classrooms: AI-tutor, AI-coach, AI-mentor, AI-teammate, AI-tool, AI-simulator, and AI-student, each with distinct pedagogical benefits and risks. The aim is to help students learn with and about AI, with practical strategies designed to mitigate risks such as complacency about the AI's output, errors, and biases. These strategies promote active oversight, critical assessment of AI outputs, and complementation of AI's capabilities with the students' unique insights. By challenging students to remain the "human in the loop", the authors aim to enhance learning outcomes while ensuring that AI serves as a supportive tool rather than a replacement. The proposed framework offers a guide for educators navigating the integration of AI-assisted learning in classrooms.

TABLE 1 SUMMARY OF SEVEN APPROACHES

AI USE	ROLE	PEDAGOGICAL BENEFIT	PEDAGOGICAL RISK
MENTOR	Providing feedback	Frequent feedback improves learning outcomes, even if all advice is not taken.	Not critically examining feedback, which may contain errors.
TUTOR	Direct instruction	Personalized direct instruction is very effective.	Uneven knowledge base of AI. Serious confabulation risks.
COACH	Prompt metacognition	Opportunities for reflection and regulation, which improve learning outcomes.	Tone or style of coaching may not match student. Risks of incorrect advice.
TEAMMATE	Increase team performance	Provide alternate viewpoints, help learning teams function better.	Confabulation and errors. "Personality" conflicts with other team members.
STUDENT	Receive explanations	Teaching others is a powerful learning technique.	Confabulation and argumentation may derail the benefits of teaching.
SIMULATOR	Deliberate practice	Practicing and applying knowledge aids transfer.	Inappropriate fidelity.
TOOL	Accomplish tasks	Helps students accomplish more within the same time frame.	Outsourcing thinking, rather than work.

Patient advocacy

https://friendsofcancerresearch.org/event/future-in-focus-digital-pathology-in-oncology-drug-development/

Friends of Cancer Research Virtual Meeting

Future in Focus: Digital Pathology in Oncology Drug Development

Tuesday, September 26, 2023

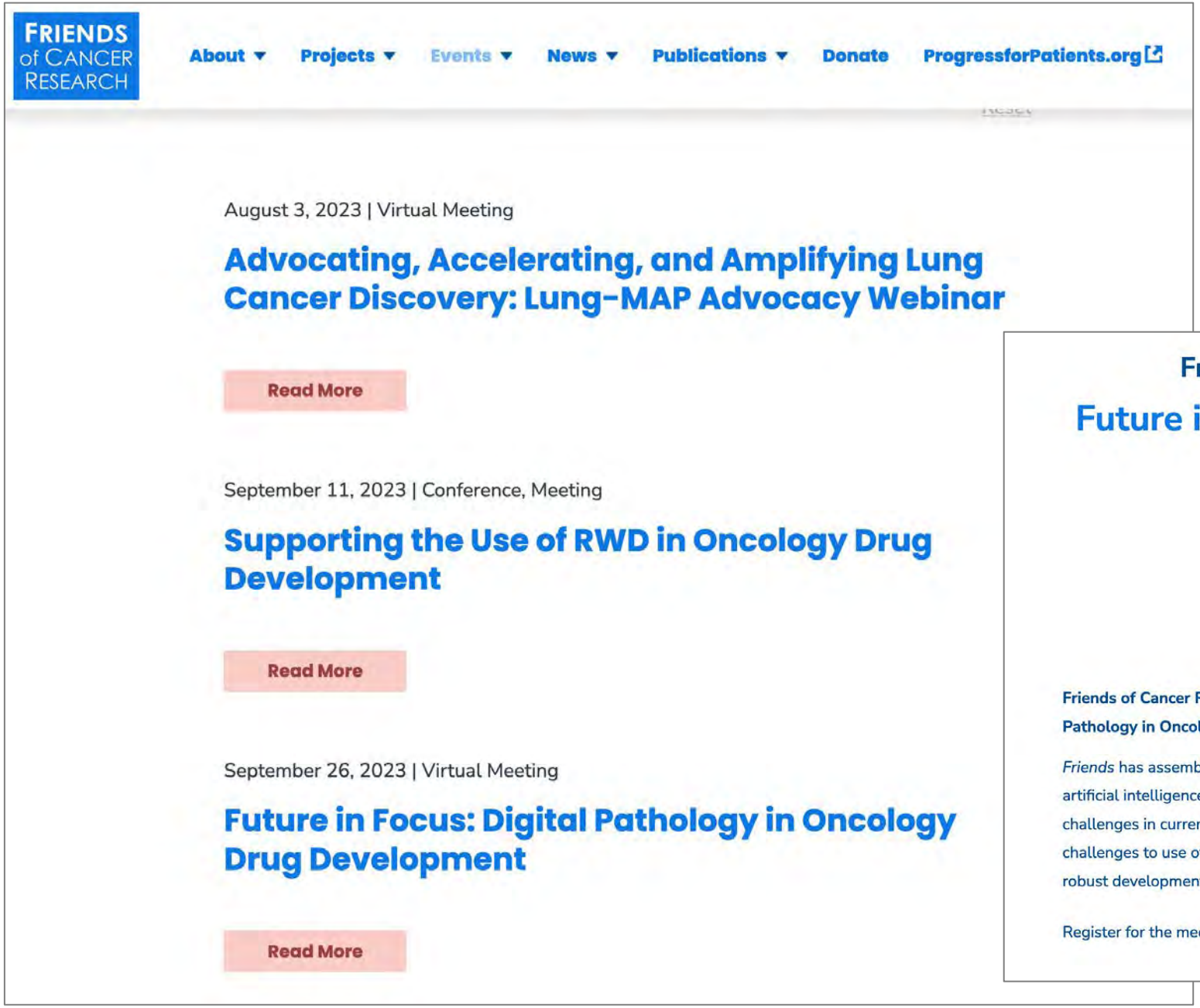
12:00PM EST - 1:00PM EST

Register Today

Friends of Cancer Research (*Friends*) is proud to announce a new virtual meeting, **Future in Focus: Digital Pathology in Oncology Drug Development.**

Friends has assembled a multi-stakeholder group to discuss opportunities for the use of digital pathology and artificial intelligence (AI)/machine learning (ML) in oncology drug development. This meeting will highlight challenges in current drug and diagnostic co-development and the unique clinical, scientific, and regulatory challenges to use of digital pathology. The panel discussion and white paper will outline proposals to facilitate robust development of digital pathology tools.

Register for the meeting above and stay tuned for additional information.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Resources

The NEW ENGLAND JOURNAL of MEDICINE

REVIEW ARTICLE

AI IN MEDICINE

Jeffrey M. Drazen, M.D., *Editor*, Isaac S. Kohane, M.D., Ph.D., *Guest Editor*, and Tze-Yun Leong, Ph.D., *Guest Editor*

Artificial Intelligence in Molecular Medicine

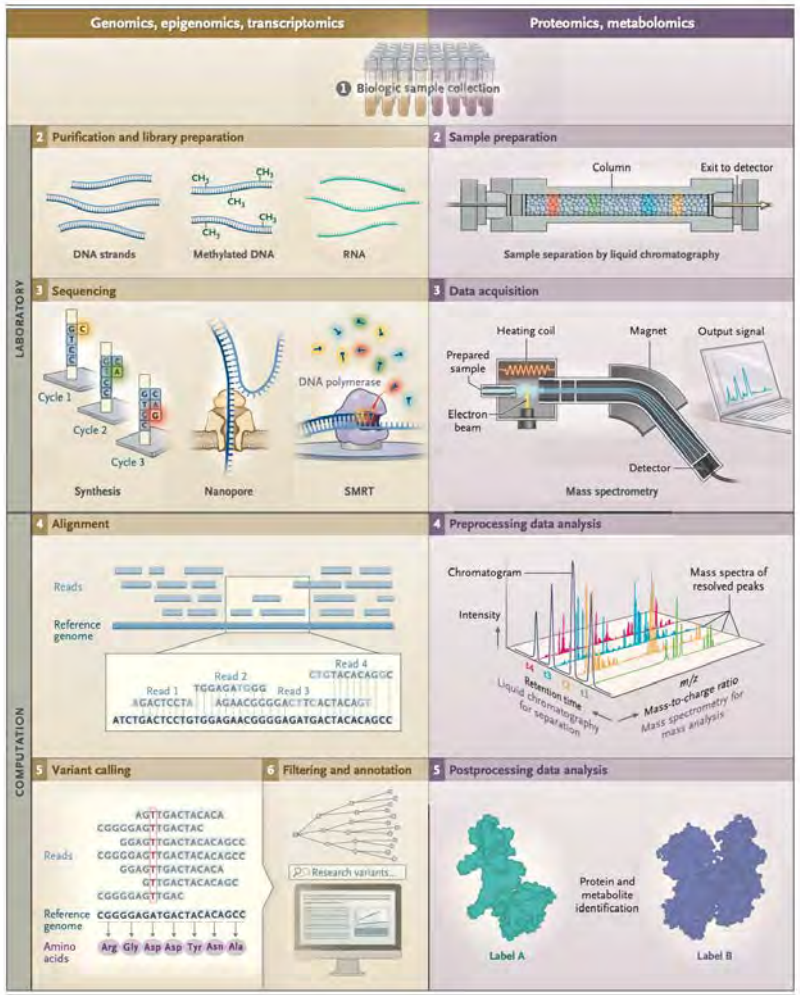
Bruna Gomes, M.D., and Euan A. Ashley, M.B., Ch.B., D.Phil.

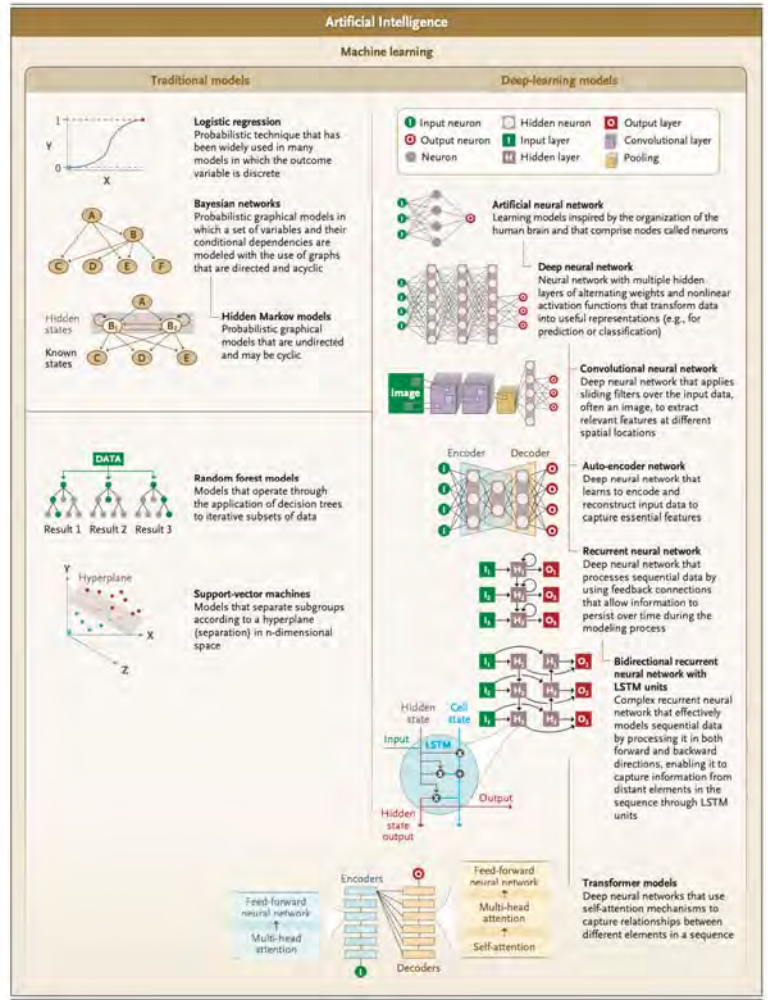
From the Departments of Medicine, Genetics, and Biomedical Data Science, Stanford University, Stanford, CA (B.G., E.A.A.); and the Department of Cardiology, Pneumology, and Angiology, Heidelberg University Hospital, Heidelberg, Germany (B.G.). Dr. Ashley can be contacted at euan@stanford.edu or at Stanford University, Falk Bldg., 870 Quarry Rd., Stanford, CA 94304.

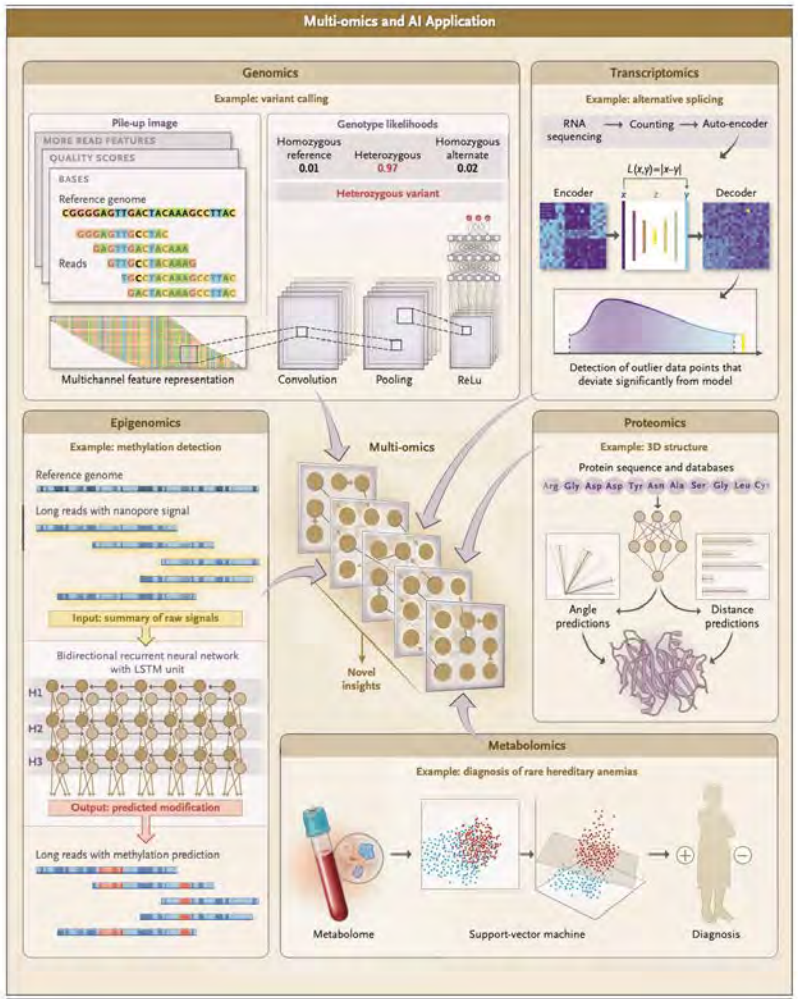
N Engl J Med 2023;388:2456-65.
DOI: 10.1056/NEJMra2204787

NEW METHODS SUCH AS GENOMIC SEQUENCING AND MASS SPECTROMETRY have prompted dramatic increases in the amount of molecular data available to scientists and health care professionals seeking more refined diagnoses and increased therapeutic precision.[1] Although the largest advances have been made in genetic sequencing of DNA and RNA, medical applications of high-dimensional measurement of proteins and metabolites are increasing.

Analytic tools have been improved in parallel to match the volume, velocity, and variety of these molecular "big data." The emergence of machine learning has proved especially valuable. In these approaches, computer systems use large amounts of data to build predictive statistical models that are iteratively improved by incorporating new data. Deep learning, a powerful subset of machine learning that includes the use of deep neural networks, has had high-profile applications


Genomics, epigenomics, transcriptomics
Proteomics, metabolomics
1 Biologic sample collection
LABORATORY
2 Purification and library preparation
DNA strands
Methylated DNA
RNA
3 Sequencing
Cycle 1
Cycle 2
Cycle 3
Synthesis
Nanopore
DNA polymerase
SMRT
2 Sample preparation
Column
Exit to detector
Sample separation by liquid chromatography
3 Data acquisition
Heating coil
Magnet
Output signal
Prepared sample
Electron beam
Detector
Mass spectrometry
COMPUTATION
4 Alignment
Reads
Reference genome
Read 1
Read 2
Read 3
Read 4
ATCTGACTCCTGTGGAGAACGGGGAGATGACTACACAGCC
5 Variant calling
6 Filtering and annotation
Reference genome
Amino acids
Arg Gly Asp Asp Tyr Asn Ala
Research variants...
4 Preprocessing data analysis
Chromatogram
Intensity
Retention time
Liquid chromatography for separation
m/z
Mass-to-charge ratio
Mass spectrometry for mass analysis
Mass spectra of resolved peaks
5 Postprocessing data analysis
Protein and metabolite identification
Label A
Label B


Artificial Intelligence
Machine learning
Traditional models
Deep-learning models
Logistic regression
Probabilistic technique that has been widely used in many models in which the outcome variable is discrete
Bayesian networks
Probabilistic graphical models in which a set of variables and their conditional dependencies are modeled with the use of graphs that are directed and acyclic
Hidden Markov models
Probabilistic graphical models that are undirected and may be cyclic
Hidden states
Known states
Random forest models
Models that operate through the application of decision trees to iterative subsets of data
DATA
Result 1
Result 2
Result 3
Support-vector machines
Models that separate subgroups according to a hyperplane (separation) in n-dimensional space
Hyperplane
Input neuron
Output neuron
Neuron
Hidden neuron
Input layer
Hidden layer
Output layer
Convolutional layer
Pooling
Artificial neural network
Learning models inspired by the organization of the human brain and that comprise nodes called neurons
Deep neural network
Neural network with multiple hidden layers of alternating weights and nonlinear activation functions that transform data into useful representations (e.g., for prediction or classification)
Convolutional neural network
Deep neural network that applies sliding filters over the input data, often an image, to extract relevant features at different spatial locations
Image
Auto-encoder network
Deep neural network that learns to encode and reconstruct input data to capture essential features
Encoder
Decoder
Recurrent neural network
Deep neural network that processes sequential data by using feedback connections that allow information to persist over time during the modeling process
Bidirectional recurrent neural network with LSTM units
Complex recurrent neural network that effectively models sequential data by processing it in both forward and backward directions, enabling it to capture information from distant elements in the sequence through LSTM units
Hidden state
Cell state
Input
LSTM
Output
Hidden state output
Transformer models
Deep neural networks that use self-attention mechanisms to capture relationships between different elements in a sequence
Encoders
Decoders
Feed-forward neural network
Multi-head attention
Self-attention


Multi-omics and AI Application
Genomics
Example: variant calling
Pile-up image
MORE READ FEATURES
QUALITY SCORES
BASES
Reference genome
CGGGGAGTTGACTACAAAGCCTTAC
Reads
Genotype likelihoods
Homozygous reference 0.01
Heterozygous 0.97
Homozygous alternate 0.02
Heterozygous variant
Multichannel feature representation
Convolution
Pooling
ReLu
Transcriptomics
Example: alternative splicing
RNA sequencing
Counting
Auto-encoder
Encoder
Decoder
Detection of outlier data points that deviate significantly from model
Epigenomics
Example: methylation detection
Reference genome
Long reads with nanopore signal
Input: summary of raw signals
Bidirectional recurrent neural network with LSTM unit
H1
H2
H3
Output: predicted modification
Long reads with methylation prediction
Multi-omics
Novel insights
Proteomics
Example: 3D structure
Protein sequence and databases
Arg Gly Asp Asp Tyr Asn Ala Ser Gly Leu Cys
Angle predictions
Distance predictions
Metabolomics
Example: diagnosis of rare hereditary anemias
Metabolome
Support-vector machine
Diagnosis

RESEARCH LETTER

AI IN MEDICINE

Accuracy of a Generative Artificial Intelligence Model in a Complex Diagnostic Challenge

Recent advances in artificial intelligence (AI) have led to generative models capable of accurate and detailed text-based responses to written prompts ("chats"). These models score highly on standardized medical examinations.[1] Less is known about their performance in clinical applications like complex diagnostic reasoning. We assessed the accuracy of one such model (Generative Pre-trained Transformer 4 [GPT-4]) in a series of diagnostically difficult cases.

Supplemental content

Methods | We used *New England Journal of Medicine* clinicopathologic conferences. These conferences are challenging medical cases with a final pathological diagnosis that are used for educational purposes; they have been used to evaluate differential diagnosis generators since the 1950s.[2-4]

We used the first 7 case conferences from 2023 to iteratively develop a standard chat prompt (eAppendix in Supplement 1)

Table. Representative Examples of AI-Generated Differential Diagnoses Compared With the Final Complex Diagnostic Challenge Diagnosis, Along With Subsequent Differential Quality Score

Final diagnosis	Final GPT-4 diagnosis	List of diagnoses	Differential quality score
Encephalitis due to Behçet disease	Neuro-Behçet disease	• Neuro-Behçet disease • Viral meningitis (eg, d • Bacterial meningitis • Tuberculous meningit • Fungal meningitis (eg • Primary central nervo • Central nervous syste • Neurosarcoidosis • Central nervous syste • Multiple sclerosis	
Regional myocarditis due to infection with *Listeria monocytogenes*	Lyme carditis	• Lyme carditis • Giant cell myocarditis • Viral myocarditis (eg, • Bacterial endocarditis • Sarcoidosis • Chagas disease (*Trypa* • Autoimmune myocard • Drug-induced myocar • Parvovirus B19 myoca • Toxoplasmosis myoca	
Erysipelothrix rhusiopathiae infection	*Streptococcus pyogenes* cellulitis with possible necrotizing fasciitis	• *S pyogenes* cellulitis v • *Staphylococcus aureu* • *Pasteurella multocida* • *Capnocytophaga cani* • *Clostridium perfringe* • *Vibrio vulnificus* cellu • Compartment syndro • Erysipelas caused by g • Lyme disease-associa	
Cerebral amyloid angiopathy-related inflammation	Autoimmune encephalitis (possibly anti-NMDA receptor encephalitis)	• Autoimmune encepha anti-CASPR2 encepha • CNS vasculitis (eg, pri autoimmune disease) • CNS lymphoma • Paraneoplastic limbic cancer, or ovarian can • Infectious encephaliti • Creutzfeldt-Jakob dis • Sarcoidosis with CNS • Progressive multifoca • Metabolic or toxic enc encephalopathy)	
Anti-melanoma differentiation-associated protein 5 dermatomyositis	Coccidioidomycosis (Valley fever)	• Coccidioidomycosis (V • Systemic lupus erythe • Disseminated histoplasmosis • Behçet disease • Mixed connective tissue disease • Paraneoplastic syndrome • Reactive arthritis • Sarcoidosis • Vasculitis (eg, granulomatosis with polyangiitis) • Parvovirus B19 infection	diagnosis)

Abbreviations: AI, artificial intelligence; CASPR2, contactin-associated protein-like 2; CNS, central nervous system; GPT-4; Generative Pre-trained Transformer 4; LGI1, leucine-rich glioma-inactivated protein 1; NMDA, *N*-methyl-D-aspartate.

Letters

RESEARCH LETTER

AI IN MEDICINE

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ARTICLE OPEN

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Integrated multimodal artificial intelligence framework for healthcare applications

Luis R. Soenksen[1,2,5], Yu Ma[3,5], Cynthia Zeng[3,5], Leonard Boussioux[3,5], Kimberly Villalobos Carballo[3,5], Liangyuan Na[3,5], Holly M. Wiberg[3], Michael L. Li[3], Ignacio Fuentes[1] and Dimitris Bertsimas[1,3,4]✉

Artificial intelligence (AI) systems hold great promise to improve healthcare over the next decades. Specifically, AI systems leveraging multiple data sources and input modalities are poised to become a viable method to deliver more accurate results and

nature machine intelligence

Article

https://doi.org/10.1038/s42256-023-00652-2

Federated benchmarking of medical artificial intelligence with MedPerf

Received: 30 October 2021

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Check for updates

A list of authors and their affiliations appears at the end of the paper

Medical artificial intelligence (AI) has tremendous potential to advance healthcare by supporting and contributing to the evidence-based practice of medicine, personalizing patient treatment, reducing costs, and improving both healthcare provider and patient experience.

Upcoming presentations

- FNIH
- Alexos Karagyris / MedPerf
- Please suggest others?

AUG 2022 (Reader Study Designs and MRMC Analysis)

JUN 2022 (Decision Summary)

JUN 2022 (DPCUS2022)

JUN 2022 (PathML)

FEB 2022 (Webinar on AI Grand Challenges)

JUN 2021 (MDIC Annual Public Forum: AI Powered Cancer Diagnostics)

MAR 2021 (Pi Annual Members Meeting)

JAN 2021 (Webinar with George Poste)

OCT 2020 (Alliance at Pathology Visions)

Events

Next steering committee meeting

August 30th 2023