Plcc Alliance

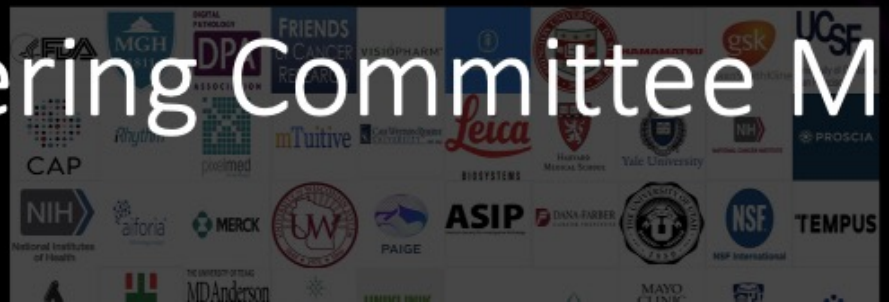
Home About Working Groups News & Events Resources Presentations Projects Publications Join

Pathology Innovation Collaborative Community

Plcc

The Alliance for Digital Pathology

A collaborative community with FDA participation

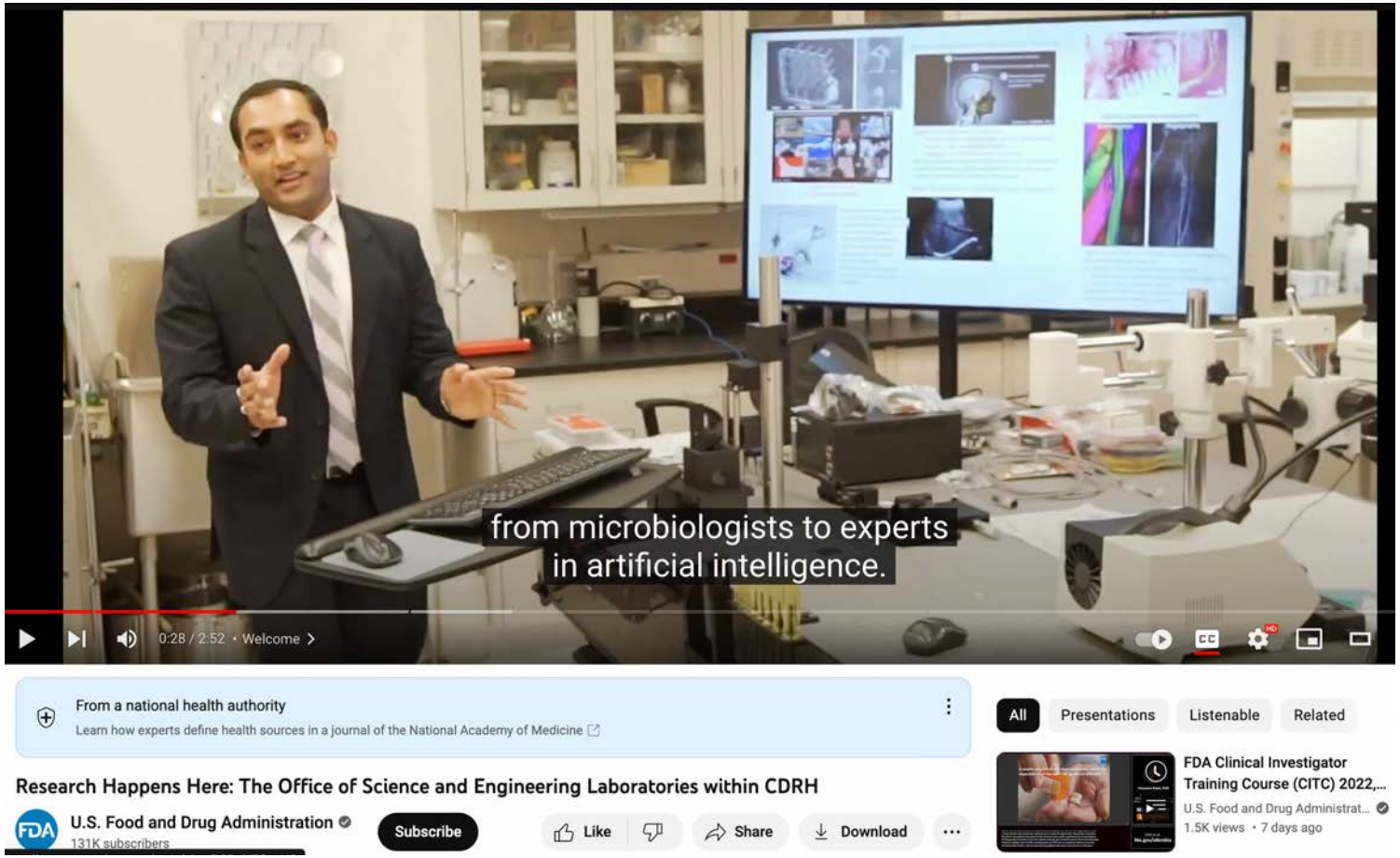


Steering Committee Meeting

December 2022

FDA

Video: Research Happens Here: The Office of Science and Engineering Laboratories within CDRH



Report on Risks and Benefits to Health of Non-Device Software Functions

&

Augmented Reality and Virtual Reality in Medical Devices

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

What Is Augmented Reality and Virtual Reality?

Augmented Reality (AR) is a real-world augmented experience with overlaying or mixing simulated digital imagery with the real world as seen through a camera or display, such as a smartphone or head-mounted or heads-up display (HUD). Digital imagery may be able to interact with real surroundings (often controlled by users). This is sometimes referred to as mixed or merged reality.

Virtual Reality (VR) is a virtual world immersive experience that may require a headset to completely replace a user's surrounding view with a simulated, immersive, and interactive virtual environment.

EHR vendors ask FDA for revisions to clinical decision support software guidance

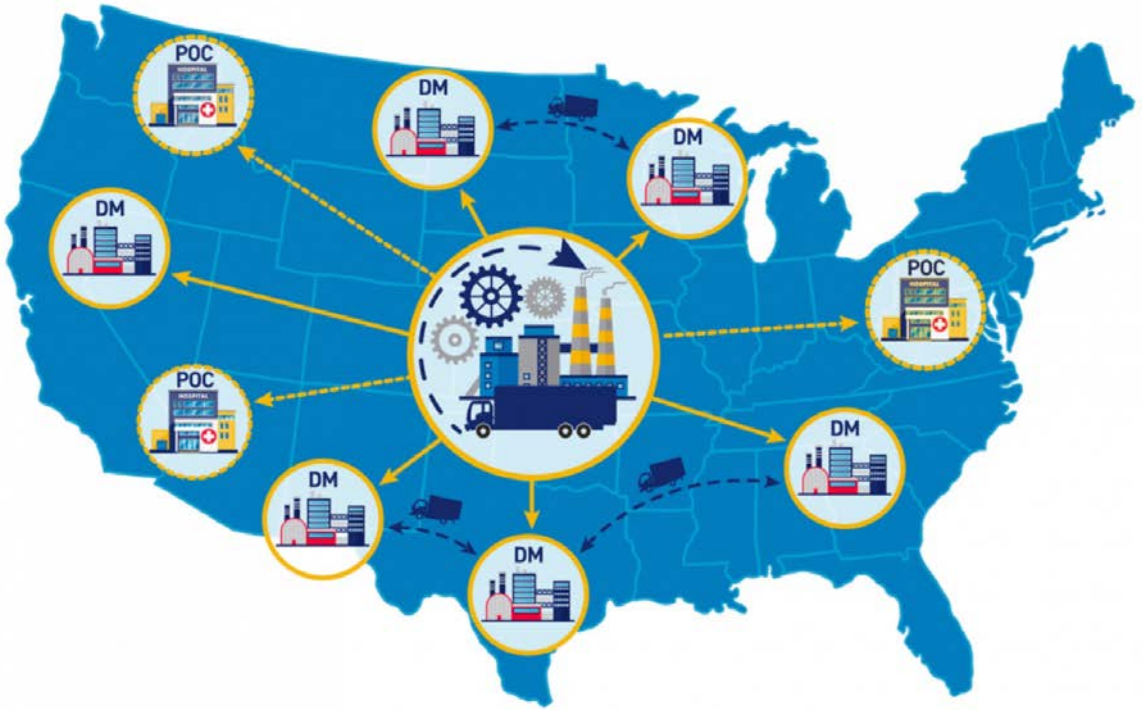
A letter from the HIMSS EHR Association outlines concerns and requests clarifications around issues such as automation bias and how the industry would transition away from legacy technologies that conflict with the guidance.

By **Andrea Fox** | December 08, 2022 | 11:45 AM

Photo: FDA

FDA Seeks Feedback on Distributed and Point-of-Care Drug Manufacturing

Subscribe to Email Updates | Share | Tweet | Linkedin | Email | Print




FDA's
RARE
DISEASE
DAY
2023
Virtual Public Meeting
• Monday, February 27, 2023
• 9:00 a.m. to 4:45 p.m. EST
Intersections with Rare Diseases
A Patient-Focused Event
#FDARareDiseaseDay
FDA
U.S. FOOD & DRUG
ADMINISTRATION
Register NOW

- FDA grants approval to atezolizumab for alveolar soft part sarcoma
- FDA grants accelerated approval to adagrasib for KRAS G12C-mutated NSCLC

- Digital Health Policy Navigator: A tool to help in determining whether your product's software functions are potentially the focus of the FDA's oversight

LEGISLATIVE UPDATES

VALID Act removed from major health policy deal

what's next?

No diagnostics reform

A provision that would have given the Food and Drug Administration more authority to regulate in-house tests developed in clinical labs like academic medical centers and hospitals was squeezed out of the agreement. While the device industry and federal regulators backed the measure, arguing it would close an oversight gap that helped Theranos thrive with unproven tests, labs argued it would hobble their ability to quickly diagnose patients.

Ultimately, those labs found sympathy with some Republicans, namely Rep. Cathy McMorris Rodgers (Wash.), who stands to lead the powerful House Energy and Commerce committee next year, two sources familiar with the deliberation said. Besides being hesitant to give the FDA more authority, Rodgers argued that the bill, called the VALID Act, had not gone through any House hearings or markup, those two people said. FDA Commissioner Robert Califf has said that if the legislation fails to make it into the omnibus, the agency will begin rulemaking itself to bring these labs under its regulatory umbrella.

VALID's omission from the bill is "disappointing" because many lawmakers in both parties supported the measure, Scott Whitaker, CEO of device lobby AdvaMed, said. "The last thing we need is more Theranos-type tests in the health care system."

Related: Congress has a chance to close the FDA's Theranos loophole

The package is also expected to include some FDA reforms connected to extending several regulatory flexibilities that Congress punted to this month to bring negotiators back to the table after they failed to reach a deal in September. At least reforms to the FDA's accelerated approval process, FDA's authority to regulate cosmetics, and policy on encouraging diversity in clinical trials are expected to make the cut, two lobbyists said.

Duke Law Journal Online

VOLUME 72 NOVEMBER 2022

AI AND THE REGULATORY PARADIGM SHIFT AT THE FDA

CATHERINE M. SHARKEY†

KEVIN M.K. FODOUOP††

INTRODUCTION

Five years ago, Dr. Bakul Patel, the current Senior Director of Global Digital Health Strategy and Regulatory Affairs for Google Health, recruited "13 engineers—software developers, AI experts, cloud computing whizzes"—to prepare for "a future in which health care is increasingly mediated by machines."[1] At that time, artificial intelligence (AI) technologies were on their way to revolutionize drug development, medical diagnostics, and health care delivery—not only

DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of the Secretary

The General Counsel
Washington, D.C. 20201

Privileged & Confidential
Attorney Client Communication
Pre-Decisional

MEMORANDUM

TO: Stephen Hahn, M.D., Commissioner of Food and Drugs

CC: Eric D. Hargan, Deputy Secretary
Brian Harrison, Chief of Staff
Stacy Amin, Deputy General Counsel & Chief Counsel
Anand Shah, M.D., Deputy Commissioner of Food and Drugs
Keagan Lenihan, Chief of Staff FDA
Danielle Steele, Counselor to the Secretary

FROM: Robert Charrow, General Counsel

SUBJECT: Federal Authority to Regulate Laboratory Developed Tests

DATE: June 22, 2020

Introduction

We have been asked by departmental leadership to review the legal bases—both substantive and procedural—for FDA's regulation of laboratory developed tests ("LDT").[1] This memorandum summarizes the results of our analyses.

Since 1992, FDA has taken the position in draft guidances, manuals, and web postings that LDTs are devices within the meaning of the Food, Drug, and Cosmetic Act ("FDCA" or "Act") § 201(h) and subject to the Agency's jurisdiction. Most recently, FDA announced on its website that

> FDA generally has not enforced premarket review and other legal requirements [with respect to LDTs]. However, LDTs for which an HHS [Emergency Use Authorization] declaration justifies a need (and that potentially meet the EUA criteria) present a higher risk. This is because they are developed to diagnose serious or life-threatening diseases or conditions that not only have serious implications for individual patient care, but also for analyses of disease progression and public health decision-making. Thus, FDA requests that

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

Search mdic.org

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

MDIC Updates

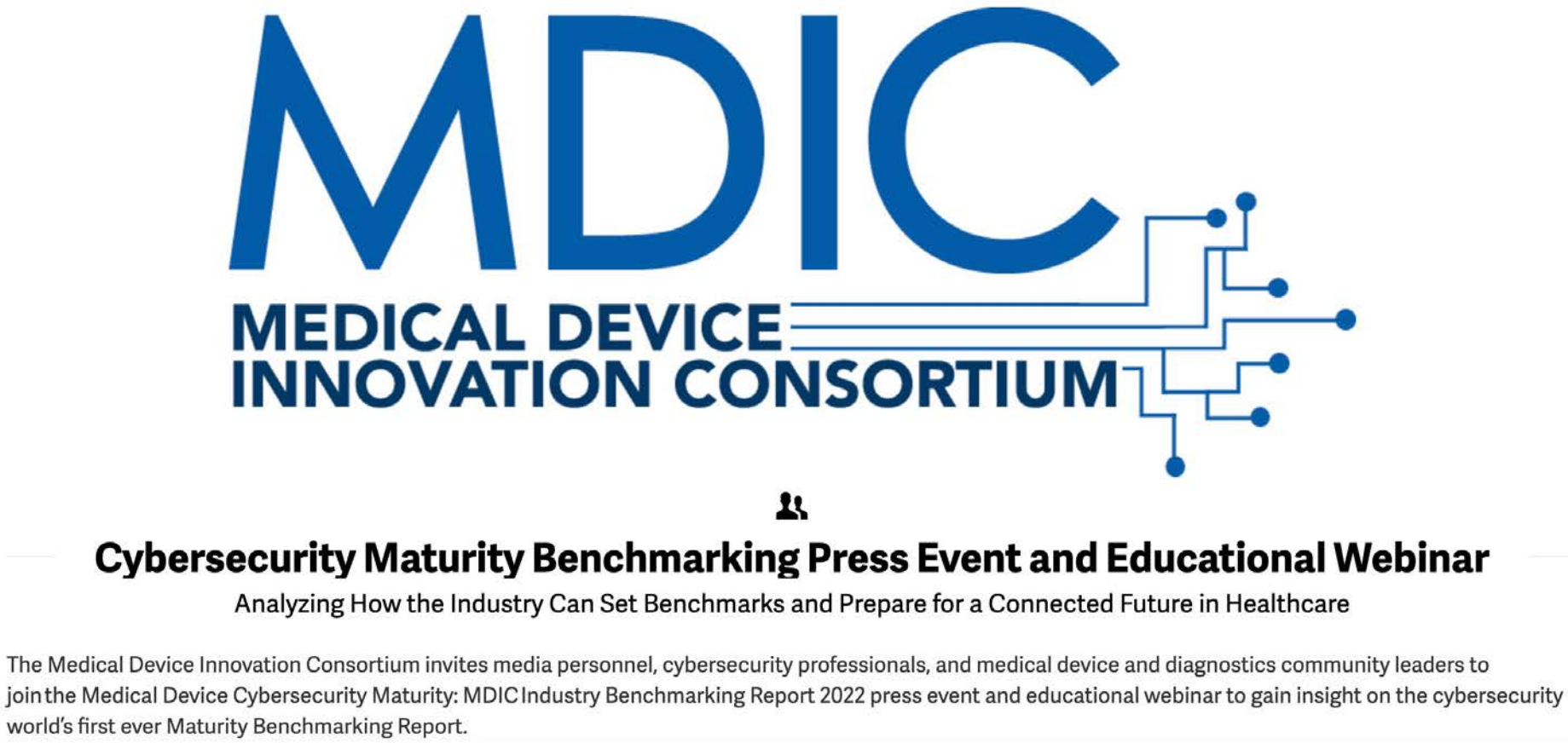
https://mdic.org/

MDIC Updates

- Cybersecurity Threat-modeling Virtual Bootcamps: 3/13-3/17, 2023

MDIC Updates

- Medical Device Cybersecurity Maturity: MDIC Industry Benchmarking Webinar and Press Event, January 23, 2023 – 1pm EST



MDIC Updates

- MDIC Publishes White Paper on Using Patient Preference Information for Coverage Decision Making

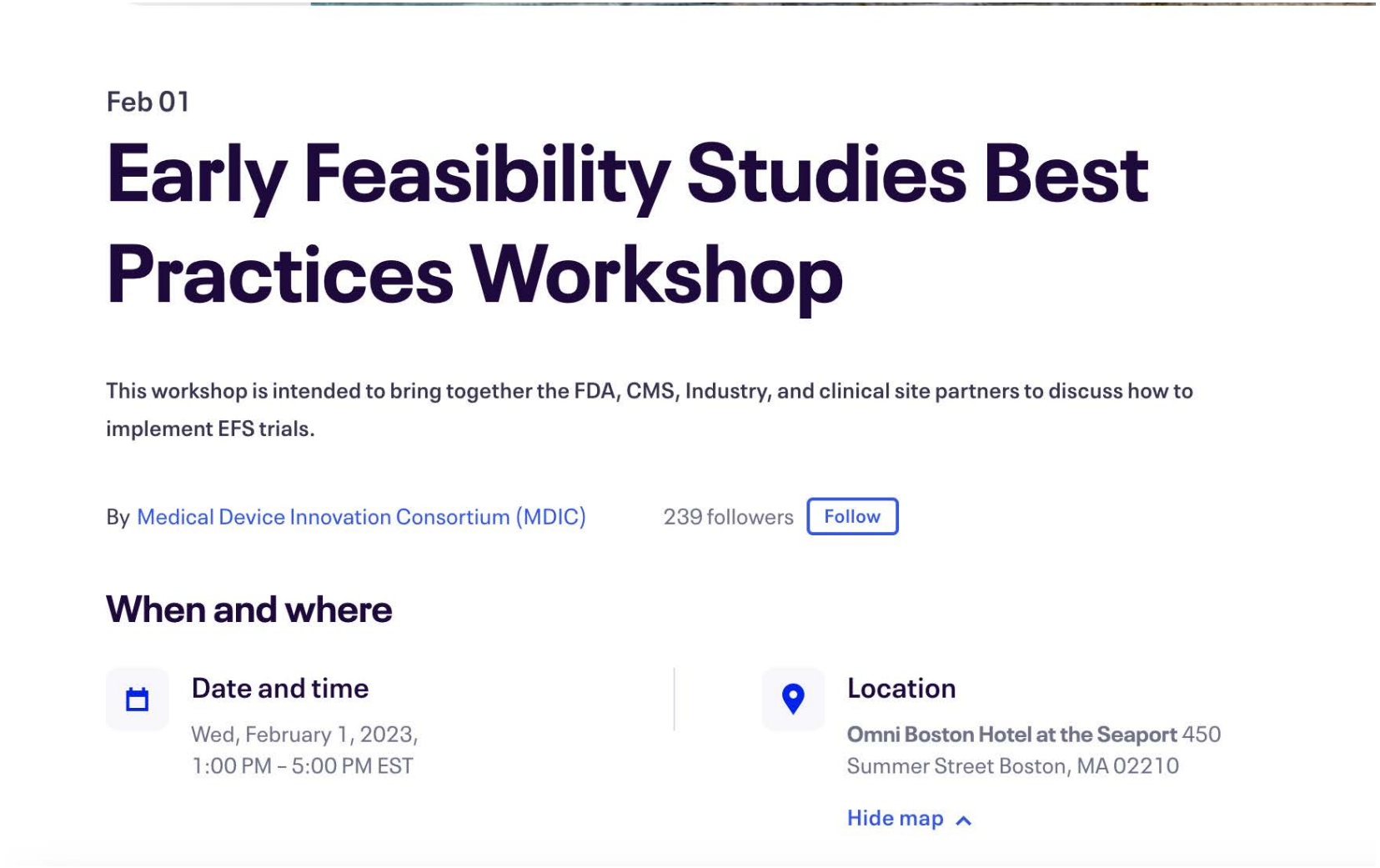
How Can Patient Preference Information Be Used in Payer Coverage Decisions and Health Technology Assessment?

The white paper *How Can Patient Preference Information be Used in Payer Coverage Decisions and Health Technology Assessment?* aims to encourage the use of patient preference information by payers and health technology assessment organizations. In this resource, MDIC clarifies the standards and role of generating this data and presenting it in a more consistent, systematic format.

As patients become more engaged with their care, healthcare stakeholders want to understand how to better incorporate patients' wants and needs into their processes. This is the first MDIC resource focused specifically on awareness of patient preference and methods as a tool for payers and the medical industry.

MDIC Updates

- Early Feasibility Studies Best Practices Workshop- February 1, 2023, Boston

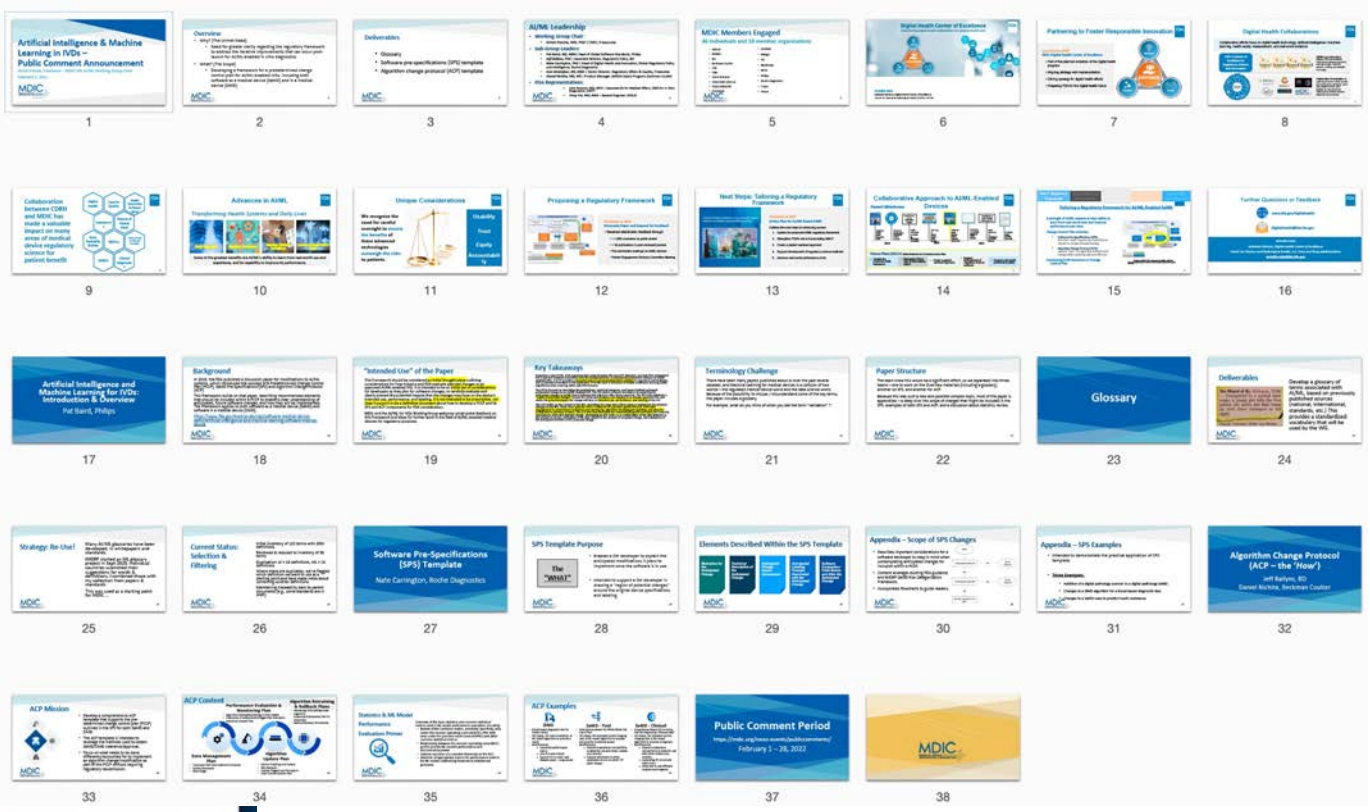


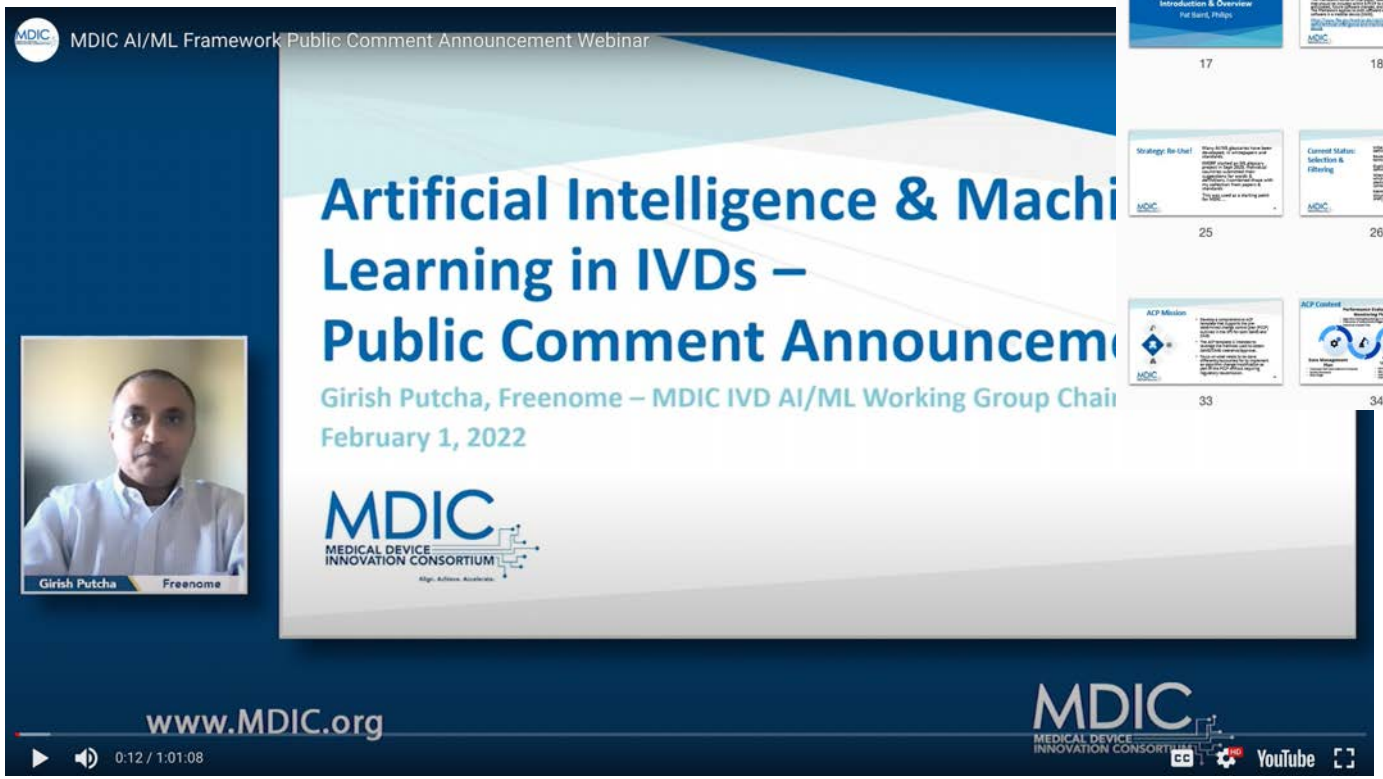
MDIC Updates

- MDIC Publishes First Landscape Analysis of 5G in Healthcare
- Please contact Noor Falah nfalah@mdic.org or Jithesh Veetil jveetil@mdic.org with any questions about MDIC initiatives

MDICx: AI/ML Framework Public Comment Q&A

- Slides and recording available





Regulatory Science in Europe

- IVD
- IVDR
- Health Data Space

Perspectives

Denis Horgan*, Mario Plebani, Matthias Orth, Elizabeth Macintyre, Stan Jackson, Jonathan A. Lal, France Dube, Marta Kozaric, Birute Tumiene, Roberto Salgado, Jack A. Schalken, Ettore D. Capoluongo and Marta Carnielli

The gaps between the new EU legislation on *in vitro* diagnostics and the on-the-ground reality

https://doi.org/10.1515/cclm-2022-1051
Received October 18, 2022; accepted November 5, 2022; published online November 22, 2022

Abstract: The background to this debate is now well-known: an EU policy decision to tighten controls on the devices and diagnostics sector led to the adoption of a regulation in 2017 with a schedule for implementation over coming years – a timetable extended still further by last-minute legislation in early 2022, to provide the sector and regulators with more time to adapt to the changes. Discussions among experts organised in April by the European Alliance for Personalized workable solutions, the obstacles remain formidable, and the potential solutions so far proposed remain more a matter of aspirations than of clear pathways.

Keywords: devices; diagnostics; *in vitro* diagnostics; *In Vitro* Diagnostic Regulation; laboratory-developed tests; legislation; policy decisions; policy framework.

Introduction

The European Union aim "to establish a robust, transparent

MDCG 2020-19

Performance study application/notification documents under Regulation (EU) 2017/746

December 2022

Council of the European Union

Brussels, 6 December 2022
(OR. en)

15520/22

SAN 640
PHARM 182
MI 894
COMPET 978

NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	Implementation of the Medical Device Regulation *- Information from the Commission*

Delegations will find in Annex an information note from the Commission on the above mentioned subject to be raised under "Any other business" at the meeting of the EPSCO Council (Health) on 9 December 2022.

Biden Administration

Administration Priorities The Record

OCTOBER 07, 2022

FACT SHEET: President Biden Signs Executive Order to Implement the European Union-U.S. Data Privacy Framework

BRIEFING ROOM › STATEMENTS AND RELEASES

Today, President Biden signed an Executive Order on Enhancing Safeguards for United States Signals Intelligence Activities (E.O.) directing the steps that the United States will take to implement the U.S. commitments under the European Union-U.S. Data Privacy Framework (EU-U.S. DPF) announced by President Biden and European Commission President von der Leyen in March of 2022.

Transatlantic data flows are critical to enabling the $7.1 trillion EU-U.S.

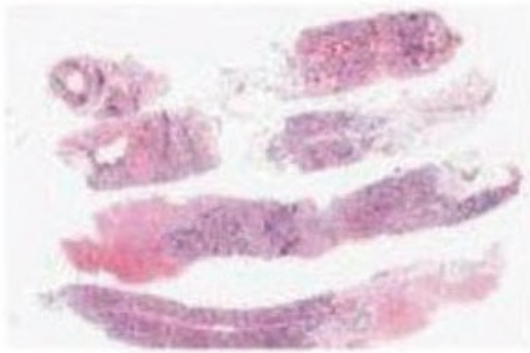
Professional Societies

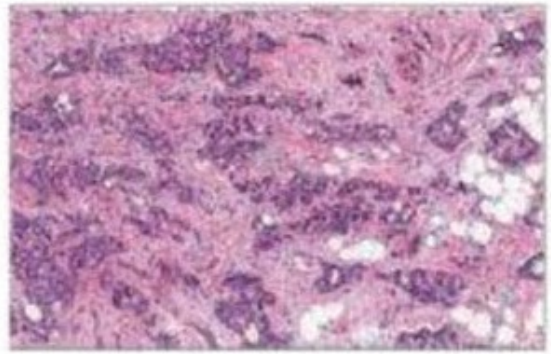
HOW TO READ YOUR PATHOLOGY REPORT

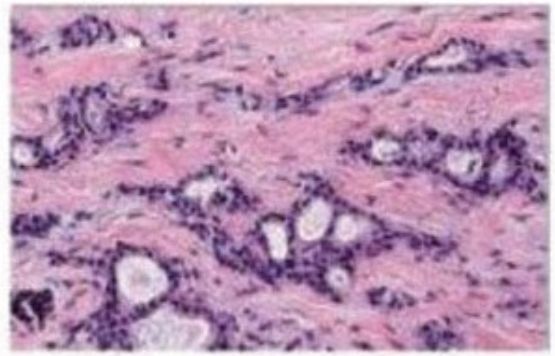
DIAGNOSIS

1. Infiltrating Ductal Carcinoma, Moderately Differentiated (SBR score 6), Right Breast Core Biopsies.
2. Ductal Carcinoma in situ, high grade.

NOTE: breast marker analysis is pending (IHC and FISH) and an addendum report will be issued. The results were reviewed by the pathologist.







ctDNA

Agilent Resolution ctDx FIRST Receives FDA Approval as a Liquid Biopsy Companion Diagnostic Test for Advanced Non-small Cell Lung Cancer

- the first liquid biopsy NGS assay approved by the FDA as a CDx

Agilent | Trusted Answers

Diversity & Inclusion

VIEWPOINT

Defending Racial and Ethnic Diversity in Undergraduate and Medical School Admission Policies

Roy H. Hamilton, MD, MS
Perelman School of Medicine, University of Pennsylvania, Philadelphia.

Suzanne Rose, MD, MSEd
Perelman School of Medicine, University of Pennsylvania, Philadelphia.

Horace M. DeLisser, MD
Perelman School of Medicine, University of Pennsylvania, Philadelphia.

On October 31, 2022, the Supreme Court heard oral arguments in cases involving Harvard University and the University of North Carolina that center on the use of race-conscious approaches in undergraduate admission policies. The Court's decisions on these cases could result in the elimination or severe restriction of the already limited use of race as a consideration in admission decisions. The experiences of institutions in which race-conscious admission policies have already been eliminated suggest that this could result in a substantive decline in students of Black race or those of Hispanic or Latino ethnicity attending major colleges and universities.[1] These Supreme Court cases focus specifically on undergraduate admission policies. There is, however, concern that reversing or restricting the use of race and ethnicity in academic admission policies could also threaten the diversity of medical schools, both directly by restricting race consciousness in medical school admission practices and indirectly by reducing the overall number of minoritized undergraduate students attending US colleges and universities who could apply to medical school.

The Supreme Court's precedent regarding race-conscious admission policies rests on the notion that it is both important and within the purview of schools to ensure diversity of viewpoints and experiences among students. In the words of Justice Lewis F. Powell Jr, author of the controlling opinion in the Court's landmark 1978 *Regents of the University of California v Bakke*

> Students who train at medical schools that are more diverse have been shown to be more comfortable treating patients from a wide range of backgrounds.

dents who train at medical schools that are more diverse have been shown to be more comfortable treating patients from a wide range of backgrounds, including Medicaid and uninsured populations.[4] Physicians are obligated to treat persons from all walks of life compassionately and equitably, and training with diverse peers prepares medical students to meet that challenge better than training in homogeneous environments. In addition, converging evidence demonstrates that, by increasing available viewpoints and intellectual perspectives, diversity improves the cognitive performance and productivity of teams in a wide range of disciplines.[5] This is an important consideration because the pedagogical model of many medical schools involves highly interactive team-based learning and problem-solving, an approach that resembles how physicians practice medicine. In short, focusing on diversity is likely to enhance the overall quality of learning in medical school.

Diversity in medical school is the pipeline to a diverse physician workforce, which in turn is essential to serving an increasingly diverse populace. In a country saddled with vast, persistent racial disparities in health access and outcomes, physicians who belong to minoritized racial and ethnic groups are far more likely to work in medically underserved areas and are more likely to enter primary care fields.[4] In addition, patients who belong to racial and ethnic minority groups report having more positive experiences with race-concordant physicians.[6] Racial diversity in medical schools is thus critical to promoting care for the most underserved segments of the patient population and providing patients from these populations with their preferred caregivers.

Racial and ethnic diversity in medical education cannot be achieved without an intentional and sustained focus on increasing the number of persons from minoritized backgrounds. Despite long-standing

THE LANCET

Log in

PERSPECTIVES | THE ART OF MEDICINE | VOLUME 400, ISSUE 10364, P1674-1675, NOVEMBER 12, 2022

Why the preoccupation with sex?

Angela Saini

Published: November 12, 2022 • DOI: https://doi.org/10.1016/S0140-6736(22)02177-8 •

"How do we know that research that's primarily done on young, White, healthy males can be extrapolated to women?" asked the President of the Society for Women's Health Research in Washington, DC, USA, back in 2011. Today, that question has become a mantra. Scientific funding bodies, researchers, and journals have dramatically stepped up their commitments to including sex as a variable in biological research. But how can we be sure that sex really is so significant in all aspects of health research? What evidence do we have that the biological differences between men and women are profound even in the areas in which our anatomies are similar?

Resources

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 8, 2022 VOL. 387 NO. 23

Tumor-Infiltrating Lymphocyte Therapy or Ipilimumab in Advanced Melanoma

M.W. Rohaan, T.H. Borch, J.H. van den Berg, Ö. Met, R. Kessels, M.H. Geukes Foppen, J. Stoltenborg Granhøj, B. Nuijen, C. Nijenhuis, I. Jedema, M. van Zon, S. Scheij, J.H. Beijnen, M. Hansen, C. Voermans, I.M. Noringriis, T.J. Monberg, R.B. Holmstroem, L.D.V. Wever, M. van Dijk, L.G. Grijpink-Ongering, L.H.M. Valkenet, A. Torres Acosta, M. Karger, J.S.W. Borgers, R.M.T. ten Ham, V.P. Retèl, W.H. van Harten, F. Lalezari, H. van Tinteren, A.A.M. van der Veldt, G.A.P. Hospers, M.A.M. Stevense-den Boer, K.P.M. Suijkerbuijk, M.J.B. Aarts, D. Piersma, A.J.M. van den Eertwegh, J.-W.B. de Groot, G. Vreugdenhil, E. Kapiteijn, M.J. Boers-Sonderen, W.E. Fiets, F.W.P.J. van den Berkmortel, E. Ellebaek, L.R. Hölmich, A.C.J. van Akkooi, W.J. van Houdt, M.W.J.M. Wouters, J.V. van Thienen, C.U. Blank, A. Meerveld-Eggink, S. Klobuch, S. Wilgenhof, T.N. Schumacher, M. Donia, I.M. Svane, and J.B.A.G. Haanen

ABSTRACT

BACKGROUND

Immune checkpoint inhibitors and targeted therapies have dramatically improved

The authors' full names, academic de-


1976
Weiden et al.,
No GVHD
J. Immunol
1990
Kolb et al.,
Leukemia infusion
Blood
1995
Mackinnon et al.,
Infusion in relapse CML
Blood
2011
Rosenberg et al.,
T-cell in Melanoma
Clin Cancer Res.
2022
Rohaan et al.,
TIL's Phase 3
NEJM

The NEW ENGLAND JOURNAL of MEDICINE

Notable Articles of 2022

A collection of articles from the *New England Journal of Medicine* selected by NEJM editors

VIEWPOINT

Accelerated Approval Is Not Conditional Approval
Insights From International Expedited Approval Programs

Gautam U. Mehta, MD
Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, Maryland.

R. Angelo de Claro, MD
Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, Maryland; and Oncology Center of Excellence, US Food and Drug Administration, Silver Spring, Maryland.

Richard Pazdur, MD
Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, Maryland; and Oncology Center of Excellence, US Food and Drug Administration, Silver Spring, Maryland.

Accelerated approval was developed in the US in 1992 as an expedited regulatory approval pathway for drugs and biologics in response to the AIDS crisis. Since then, the US Food and Drug Administration (FDA) has granted the majority of accelerated approvals in oncology, leading to earlier availability of promising therapies for patients with cancer, a median of 3.4 years before completion of the confirmatory trials that would have been necessary for regular marketing approval.[1] Success of the US accelerated approval program has prompted other international regulatory health authorities (RHAs) to develop similar expedited approval programs (**Table**[2]). Although they share a goal of providing earlier access to potentially lifesaving therapies, critical differences exist, which we compare herein.

Accelerated Approval in the US

Accelerated approval was instituted in 1992 by regulation and was codified into law under the FDA Safety and Innovation Act in 2012.[3] This law allows for "approval of a product for a serious or life-threatening disease or condition…[that] has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments."[3] Most accelerated approvals granted in oncology have relied on overall response rate as a primary end point.[1] However, overall response rate is not limited to accelerated approval and has been used to support regular approvals, particularly in rare disease settings, in those with long survivorship, and in cases where observed high response rates in initial trials would render subsequent randomized trials impractical owing to the loss voluntarily.[3] This process has lasted up to 11 months (eg, first-line bevacizumab in combination with paclitaxel for treatment of metastatic *ERBB2* [formerly HER2]-negative breast cancer). To date, 15 of 167 (8.9%) oncology indications granted accelerated approval have been withdrawn voluntarily (n = 14) or by FDA (n = 1).[5]

Promoting the timely completion of confirmatory trials can be a challenge after accelerated approval. In a recent analysis, the median time to verification of benefit was 3.4 years, whereas withdrawal took 8.8 years. Having an ongoing confirmatory trial at the time of accelerated approval was associated with a shorter median time to verification of benefit (3.1 vs 5.5 years).[1]

International Expedited Approval Programs

Since development of the US accelerated approval program, expedited approval programs have been implemented by several international RHAs (Table). Most rely on end points that are likely to predict clinical benefit; however, conditional marketing authorization (CMA) in the European Union (EU) and UK relies on a benefit-risk assessment. This has led to relatively few approvals based on single-arm clinical trial data by the EU (52% for all indications).[6] Another notable feature of programs in the EU, Switzerland, and UK is that only new molecular entities are considered for expedited approval. This contrasts with the US and others, which may also grant expedited approval for supplemental applications.

Additionally, unlike accelerated approval in the US, the expedited approvals granted by the EU, UK, Australia, and Switzerland are time limited and expire. In the EU and UK, CMA expires yearly and must be renewed with an application and interim report on outstanding obligations submitted at least 6 months before expiration.[6,7] Evaluation of each renewal application includes the risk-

Events

Next steering committee meeting

1/25/2023

UCSF-Stanford CERSI Presents the 2023 Innovations in Regulatory Science Summit

Accelerating Healthcare Innovation Through a Regulatory Lens

January 8, 2023 | 9 am - 4 pm Pacific Time

Hybrid Event: Attend in San Francisco or Virtually

CERSI
UCSF-Stanford

Panel Discussions

- Disparities in Clinical Trial Enrollment: What will it take to close the gap?
- Cross Agency Synergy to Accelerate Access to Safe and Effective Medical Products
- Building a Global Regulatory Vision for Product and Drug Development: Challenges and Opportunities
- FDA Chiefs Chat, featuring
  - Janet Woodcock, MD – FDA Principal Deputy Commissioner
  - Robert Califf, MD – FDA Commissioner, 2016-2017, 2022-present
  - Scott Gottlieb, MD – FDA Commissioner, 2017-2019
  - Margaret Hamburg, MD – FDA Commissioner, 2009-2015
  - Mark McClellan, MD, PhD – FDA Commissioner, 2002-2004

Remarks from FDA Speakers

- Robert Califf, MD – FDA Commissioner, 2016-17, 2022-present
- Janet Woodcock, MD – FDA Principal Deputy Commissioner

Poster & Networking Reception

Confirmed Speakers

Moji Christianah Adeyeye
Robert Califf
Patrizia Cavazzoni
Emer Cooke
Michael Drake
Mark Duggan
Anna Eshoo
Laura Esserman
Ricki Fairley
Lee Fleisher
Kathy Giacomini
Scott Gottlieb
Frank Gupton
Margaret Hamburg
Dan Hartman
Sam Hawgood
Mathai Mammen
Peter Marks
Jacques Mascaro
Mark McClellan
Tina Morrison
Andrew Plump
Sohail Rao
Jeff Shuren
Kuldev Singh
Janet Woodcock

Information and Registration: https://cersisummit.com

2023 PIcc meeting in person (D.C. Area)

February ?

API/PathInf. – May 22-25th

Visions/DPA – Oct 29-31st

February

March

May

Summer

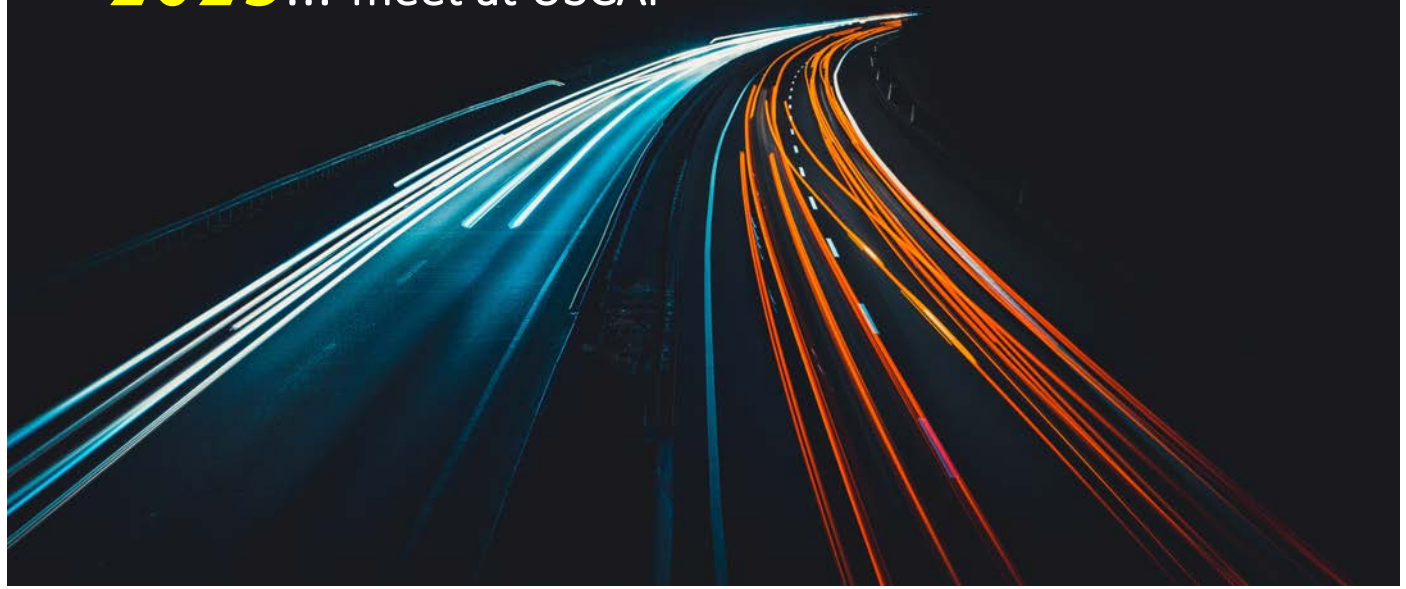
October

USCAP – March 11-16th

Summer ?

Pathology
Innovation
Collaborative
Community

2023… meet at USCAP



USCAP 112TH ANNUAL MEETING

MARCH 11-16, 2023

NEW ORLEANS, LOUISIANA

NEW ORLEANS ERNEST N. MORIAL CONVENTION CENTER

USCAP

USCAP 112TH ANNUAL MEETING

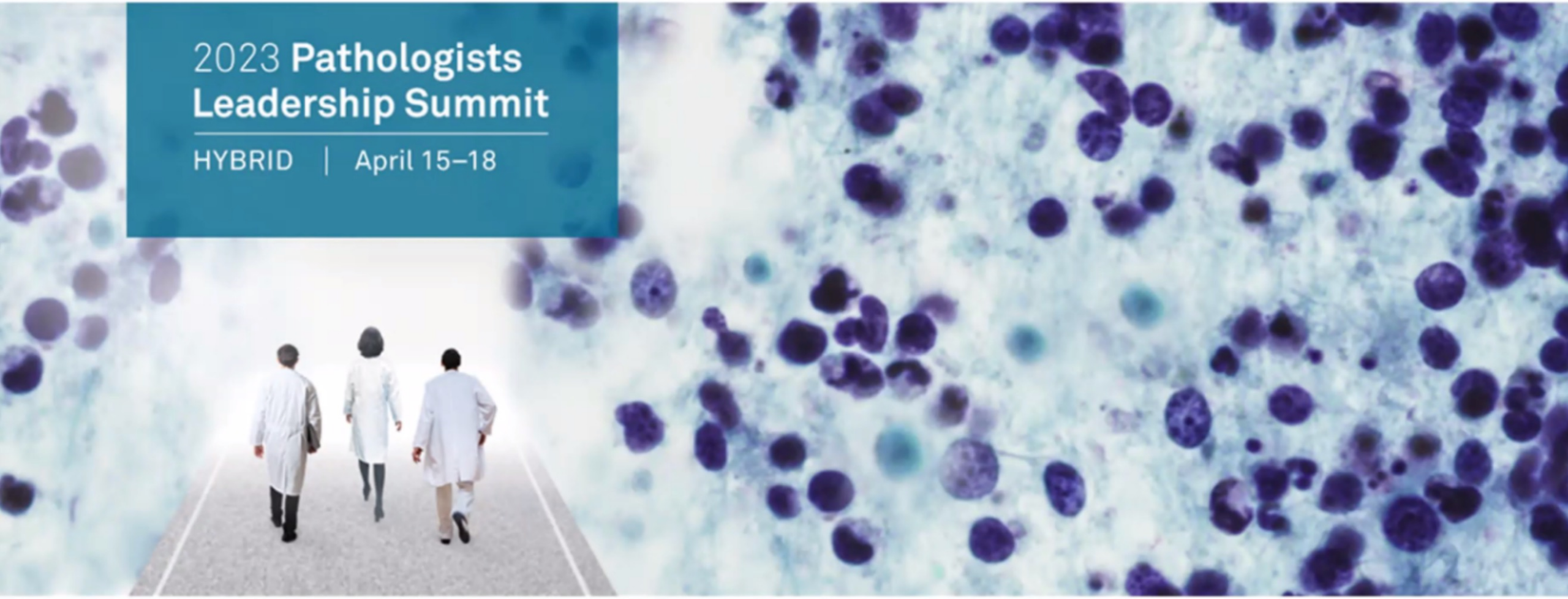
FACING THE UNKNOWN

COLLEGE of AMERICAN PATHOLOGISTS
Advocacy

AGENDA FEATURED EVENTS HOTEL & TRAVEL

2023 Pathologists Leadership Summit

HYBRID | April 15–18



2023: April(Berlin), June(Catania), Sept (Dublin)

10th World Digital Pathology & AI UCGCongress

Conference

in-person

4th to 6th April 2023
Berlin, Germany

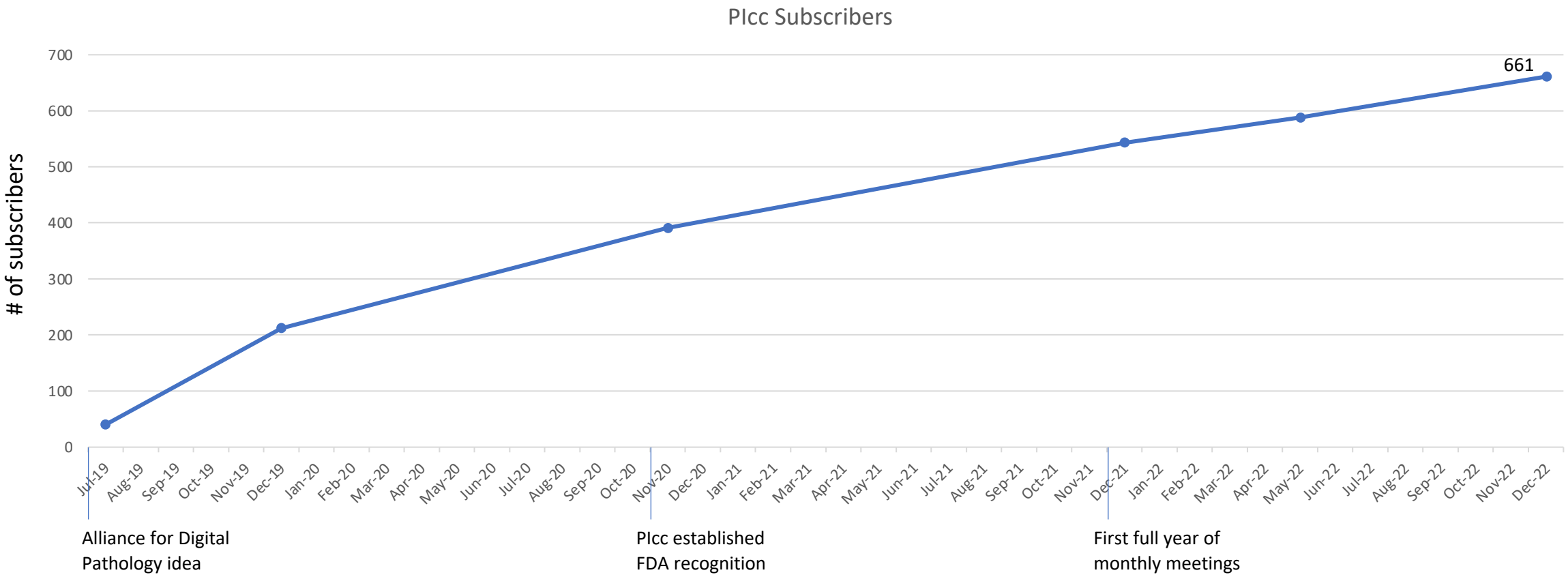
Website: https://digitalpathology.ucgconferences.com/
Contact person: Dr. Pascal Annie

Greetings. We warmly welcome you to the CME/CPD accredited 10th World Digital Pathology & AI UCGCongress (DIGIPATH2023) scheduled on April 04-06, 2023 in Berlin, Germany. The Conference theme is Digital Diagnostics and Intelligence Augmentation.

Organized by: UCGConferences
Deadline for abstracts/proposals: 31st March 2022

Pathologyinnovationcc.org Traffic

PIcc Subscribers



PIcc Inventory 2022

FDA 63

PIcc: 127

MDIC 23

WHO 14

Patient Advocacy 33

Ethics, Diversity and Inclusion 18

Projects+WG 36

Papers/Resources/Books 217

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)

PIcc presentations 5

Content	Count	minutes per item	total
FDA	63	60	3780
Picc	127	10	1270
MDIC	23	10	230
WHO	14	10	140
Patient Advocacy	33	10	330
Ethics, Diversity and Inclusion	18	20	360
Projects	36	30	1080
Papers/Resources/Books	217	30	6510
Dedicates Picc presentations	5	60	300

600 videos

14600	effort in minutes
243.3	effort in hours
60.8	effort in days (4h/day)
12.2	effort in weeks (5 days/week)

See you in 2023