Pathology Innovation

*Collaborative Community*

# FEBRUARY UPDATES MEETING

Wednesday

February 22 at 3:00-4:00 PM ET

**PIcc2023**

*Steering committee series: Final Wednesday of every month*


# FDA

# CERSI Workshops and Training

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Advancing Regulatory Science

Regulatory Science Extramural Research and Development Projects

Advancing Regulatory Science News and Upcoming Events

Centers of Excellence in Regulatory Science and Innovation (CERSIs)

Past News and Events - Advancing Regulatory Science

Focus Areas of Regulatory Science Report


Content current as of: 12/22/2022

Topic(s)
Training & Education

The following is a list of upcoming and past CERSI workshops and training co-sponsored by FDA and CERSI academic institutions, or held by those individual universities.

## Upcoming Events

- February 17, 2023: Application of Artificial Intelligence & Machine Learning for Precision Medicine (University of Maryland CERSI)

## Past Events

### 2022 Workshops and Training

- November 9, 2022: Bridging Efficacy and Safety to the Obese: Considerations and Scientific Approaches (University of Maryland CERSI)
- July 13-July 14, 2022: Co-Processed API (University of Maryland CERSI)
- May 16-May 17, 2022: Pharmacokinetic Evaluation in Pregnancy (University of Maryland CERSI)
- May 9, 2022: Leveraging Real-World Data to Study Medication Use in Pregnancy and Lactation (Johns Hopkins University CERSI)
- May 6, 2022: 2022 Yale-Mayo Clinic CERSI Scholar Virtual Research Seminar (Yale University-Mayo Clinic CERSI) Part 1, Part 2, Part 3
- April 13, 2022: Biosimilars: A Decade of Experience and Future Directions —Strategies for Improving Biosimilar Adoption and the Potential Role of Clinical Pharmacology (University of Maryland CERSI)
- February 4, 2022: America's Got Regulatory Talent Competition (University of Maryland CERSI)
- January 26, 2022: IMPACT Bootcamp: Navigating the Journey from Digital Health Technologies to Meaningful Patient Outcomes (University of Maryland CERSI and Johns Hopkins University CERSI)
- January 9, 2022: The 2022 Innovations in Regulatory Science Summit, Movers and Shapers: The Future of Drug and Device Development (UCSF-Stanford CERSI)

https://www.fda.gov/science-research/advancing-regulatory-science/cersi-workshops-and-training

UNIVERSITY OF MARYLAND

A. JAMES CLARK SCHOOL OF ENGINEERING

About Us | Academics & Students | Research

## Event

### Application of Artificial Intelligence & Machine Learning for Precision Medicine

Friday, February 17, 2023
Virtual Event details shared upon registration
cersi@umd.edu

The U.S. Food and Drug Administration (FDA) – ir
Center of Excellence in Regulatory Science and Ir
public workshop entitled "Application of Artificia
Medicine" on **Friday, February 17, 2023**.

The purpose of this workshop is to review curren
best practices to address the rapidly changing la
learning in the setting of drug development and

**This workshop will be open to the public with**
**link. To view the agenda, please use this link.**

**FDA-MCERSI Workshop on Application of Artificial Intelligence and Machine Learning for Precision Medicine**

**Virtual Public Workshop**
February 17, 2023
10:00 AM-4:15 PM Eastern Time

**Organizing Committee**

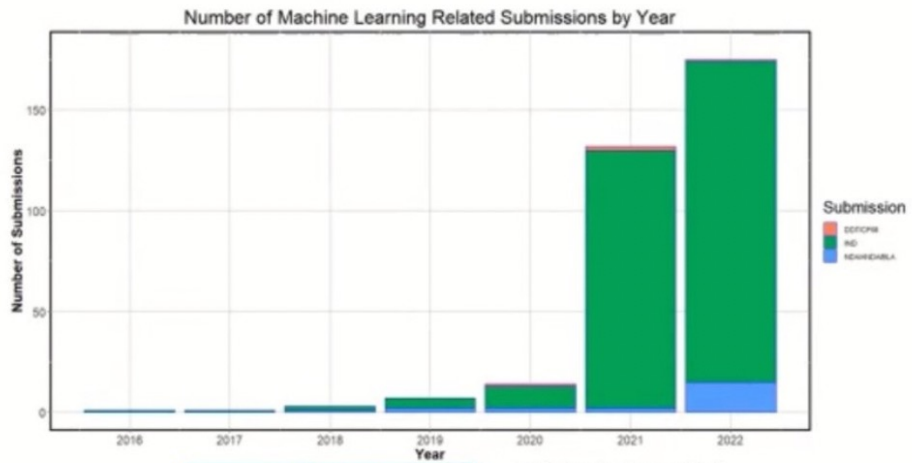
| | |
|---|---|
| Qi Liu, PhD | OCP, OTS, CDER, FDA |
| Kunal Naik, PharmD | OCP, OTS, CDER, FDA |
| Neha Mehta, MS | OCP, OTS, CDER, FDA |
| Joga Gobburu, PhD, MBA | University of Maryland, School of Pharmacy |

**WORKSHOP AGENDA:**

| | | |
|---|---|---|
| 10:00 AM – 10:05 AM | **Welcome Session (Meeting Logistics and Housekeeping)** | |
| | **Qi Liu, PhD, MStat, FCP** | Associate Director for Innovation and Partnership, OCP, OTS, CDER, FDA |
| | **Joga Gobburu, PhD** | Professor, School of Pharmacy and School of Medicine, Director of Center for Translation Medicine, University of Maryland |
| | **Kunal Naik, PharmD** | Pharmacist, OCP, OTS, CDER, FDA |
| 10:05 AM – 10:30 AM | *Keynote Speaker Interview* | |
| | **Eric Topol, MD** | Founder and Director, Scripps Research Translational Institute, Professor Molecular Medicine, Executive Vice-President, Scripps Research |
| **SESSION 1: Background and Current Landscape** | | |
| | **Moderator: Joga Gobburu, PhD** | Professor, School of Pharmacy and School of Medicine, Director of Center for Translation Medicine, University of Maryland |
| 10:30 AM – 10:45 AM | *Advancements of Differentiable Simulation for Scientific Machine Learning & AI* | |
| | **Alan Edelman, PhD** | Professor of Applied Mathematics, Computer Science & AI Laboratory, MIT, Chief Scientist, JuliaHub Inc. |
| 10:45 AM – 11:00 AM | *AI-Partnered Dynamical Model Discovery for Precision Medicine* | |
| | **James Lu, PhD** | Distinguished AI Scientist, Clinical Pharmacology, Genentech |
| 11:00 AM – 11:15 AM | *AI/ML-Enabled Drug-Disease Modeling* | |
| | **Nadia Terranova, PhD** | Head of Advanced Data Analytics, Quantitative Pharmacology, Merck KGaA, Darmstadt |

FDA-MCERSI Workshop on Application of Artificial Intelligence and Machine Learning for Precision Medicine (2/17/23 Virtual Public Workshop):

## AI/ML Submissions over Time




2016 - 2022

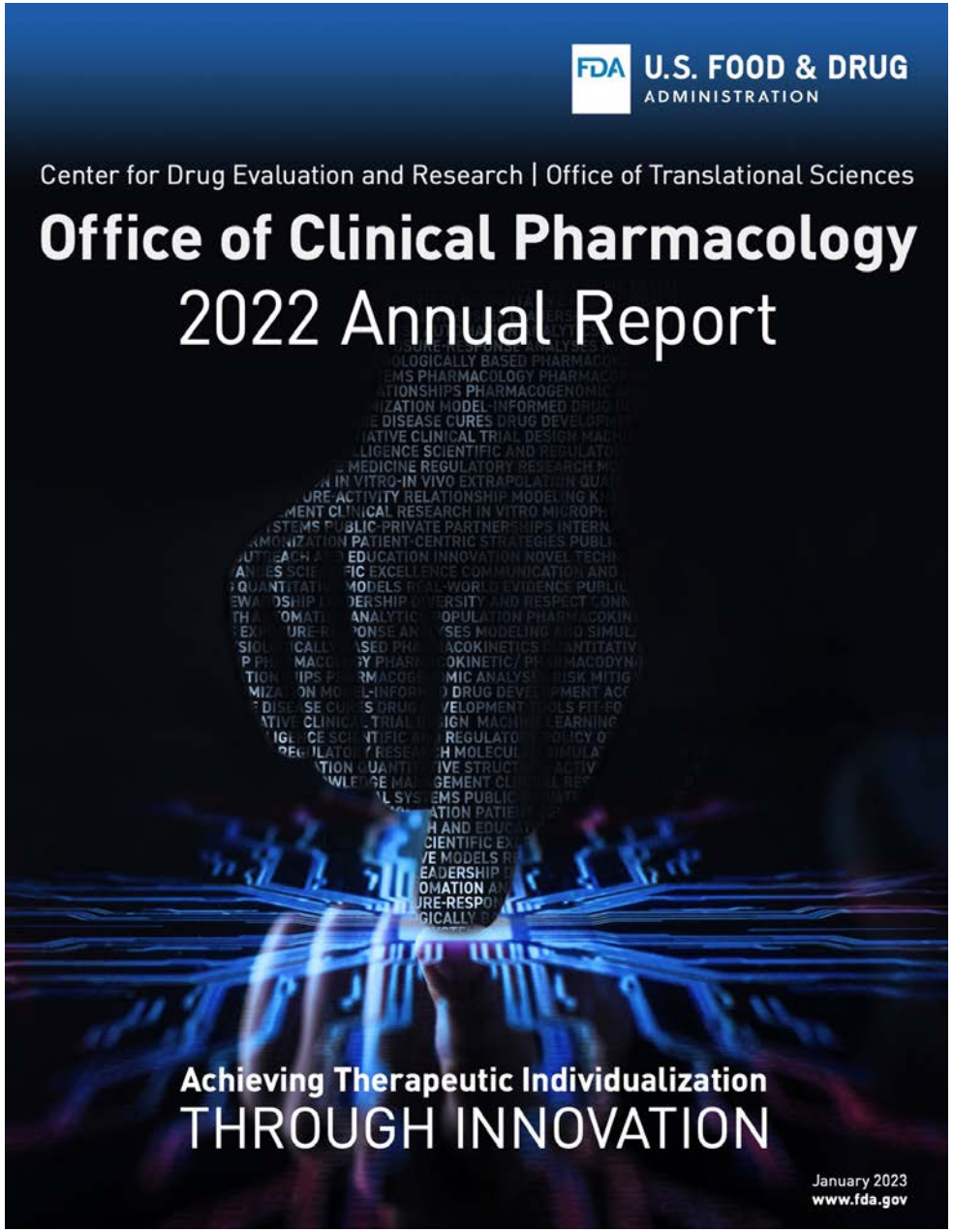
DDT: Drug Development Tool;
CPIM: Critical Path Innovation Meeting

7

## Examples in AI/ML related Submissions

- **Biomarker / Endpoint Assessment:**
  - AI algorithm is used to evaluate imaging-based biomarker as endpoint
- **Patient Selection:**
  - To use an AI-based diagnostic biomarker in conjunction with clinical assessment to enroll patients who are likely at a defined disease stage.
  - To enroll patients based on a companion diagnostic developed by using an AI algorithm linking EEGs, digital biomarkers detected through wearables, and other clinical symptoms.

12


U.S. FOOD & DRUG ADMINISTRATION
Center for Drug Evaluation and Research | Office of Translational Sciences
Office of Clinical Pharmacology
2022 Annual Report
Achieving Therapeutic Individualization
THROUGH INNOVATION
January 2023
www.fda.gov

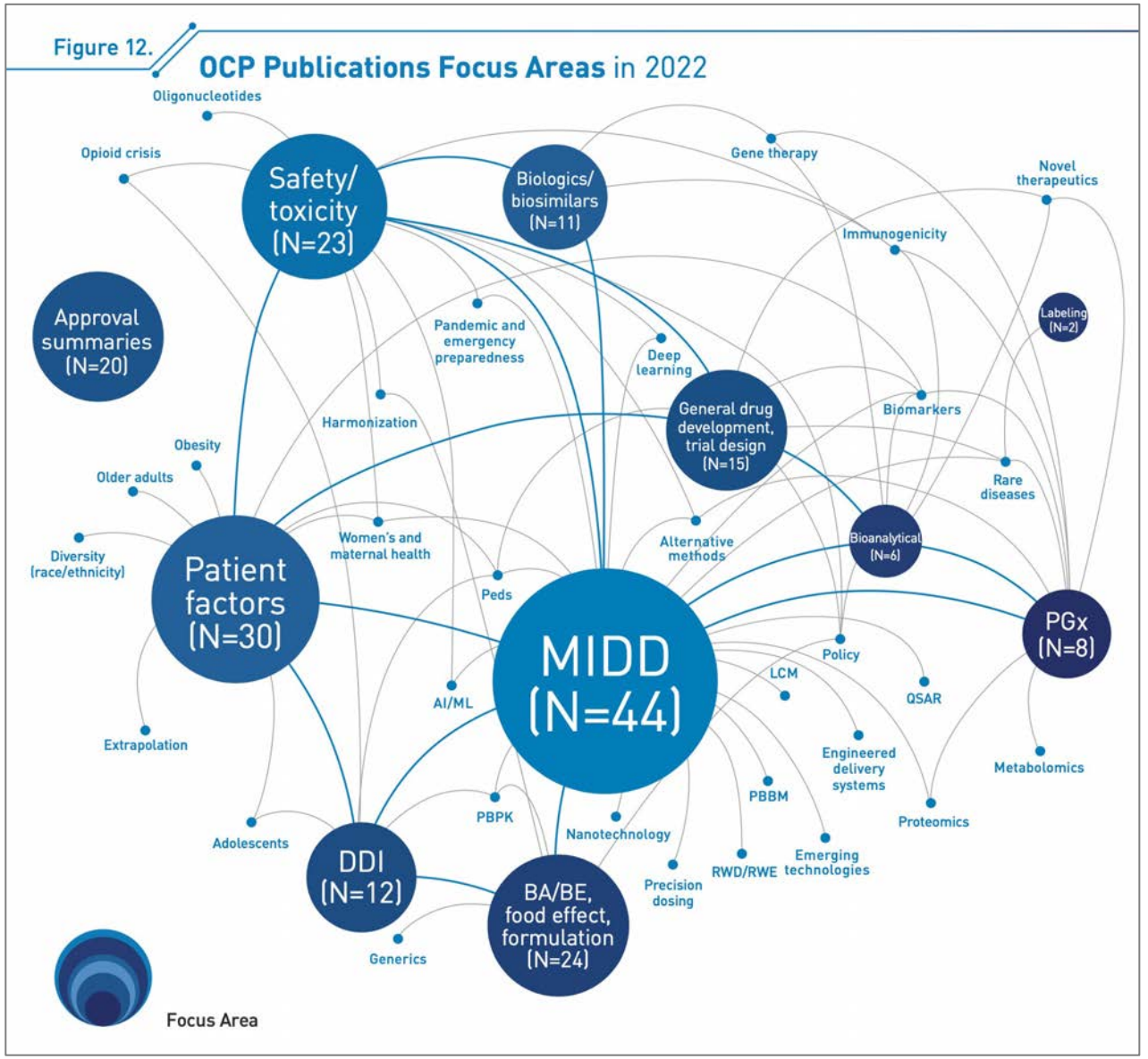


Figure 12.
OCP Publications Focus Areas in 2022
Oligonucleotides
Opioid crisis
Safety/ toxicity (N=23)
Biologics/ biosimilars (N=11)
Gene therapy
Novel therapeutics
Immunogenicity
Approval summaries (N=20)
Pandemic and emergency preparedness
Deep learning
Labeling (N=2)
Harmonization
General drug development, trial design (N=15)
Biomarkers
Obesity
Older adults
Rare diseases
Diversity (race/ethnicity)
Women's and maternal health
Alternative methods
Bioanalytical (N=6)
Patient factors (N=30)
Peds
MIDD (N=44)
PGx (N=8)
Policy
LCM
QSAR
AI/ML
Extrapolation
Engineered delivery systems
Metabolomics
PBBM
PBPK
Proteomics
Adolescents
Nanotechnology
DDI (N=12)
RWD/RWE
Emerging technologies
Precision dosing
BA/BE, food effect, formulation (N=24)
Generics
Focus Area

# PERSONALIZED MEDICINE AT FDA

The Scope & Significance of Progress in 2022

PMC

## Personalized Medicines Accounted for More Than 25% of FDA Approvals for Each of the Last Eight Years


Methodology: When evaluating new molecular entities, PMC categorizes personalized medicines as those therapeutic products for which the label includes reference to specific biological markers, often identified by diagnostic tools, that help guide decisions and/or procedures for their use in individual patients.

https://www.personalizedmedicinecoalition.org/index.cfm

# Guidance for Industry

## Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection

*DRAFT GUIDANCE*

*This guidance document is being distributed for comment purposes only.*

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Office of Regulatory Affairs (ORA)**
**Center for Drug Evaluation and Research (CDER)**
**Center for Biologics Evaluation and Research (CBER)**
**Center for Veterinary Medicine (CVM)**
**Center for Devices and Radiological Health (CDRH)**

December 2022
Revision 1

## What should I expect during an inspection?

FDA may conduct an inspection of your operation for a variety of reasons, such as a routinely scheduled investigation, a survey, or a response to a reported problem. The investigator will present credentials and "Notice of Inspection" (FDA Form 482) upon arriving at your plant. A knowledgeable person in your firm, such as the plant or production manager, preferably designated ahead of time, should accompany the investigator at all times. It is in your best interest to fully understand FDA's inspection procedures. When you are unsure of certain actions taken by the investigator, don't hesitate to ask questions.

Usually, the investigator will examine your production process, look at certain records and collect samples. At the conclusion of the inspection, the investigator will discuss with your firm's management any significant findings and concerns; and leave with your management a written report of any conditions or practices, which, in the investigator's judgment, indicate objectionable conditions, or practices. This list of "Inspectional Observations," also called an FDA Form 483, can be used by your firm's management as a guide for corrective action, since the FDA representative will not usually recommend specific corrective measures. Your firm can and should respond to the FDA-483 during the discussion with the investigator. In fact, corrective actions or procedural changes that were accomplished immediately in the presence of the investigator are regarded as positive indications of your concern and desire to voluntarily correct discrepancies.

If you do not agree with the actions being taken by the FDA or if you have a question about the jurisdiction of the agency in a particular matter, you can contact the FDA's Office of the Ombudsman to seek a resolution.

FDA Office of the Ombudsman
10903 New Hampshire Avenue
WO 32, Room 4231
Rockville, MD 20903
Telephone: 301-796-8530
FAX: 301-847-8628
E-mail: ombuds@oc.fda.gov (sending confidential information by electronic mail is not recommended)

See the FDA Center Small Business Contacts for the Ombudsman in the various FDA Centers. If FDA takes regulatory action against your firm, the Small Business Representatives are not available for guidance, since their activities are nonregulatory in nature. You should contact a district Compliance Officer for advice under those circumstances.

**Related Resources**

- Compliance Program Guidance Manual (CPGM)
- Inspection Guides
- Investigations Operations Manual

https://www.fda.gov/industry/fda-basics-industry/what-should-i-expect-during-inspection

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/compliance-program-manual

## Compliance Program Manual

FDA's Compliance Programs provide instructions to FDA personnel for conducting activities to evaluate industry compliance with the Federal Food, Drug, and Cosmetic Act and other laws administered by FDA. Compliance Programs are made available to the public under the Freedom of Information Act. (See FDA Freedom of Information Act Handbook for Requesting Information and Records from FDA.)

Compliance Programs do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used as long as the approach satisfies the requirements of the applicable statutes and regulations. FDA's Compliance Programs are organized by the following program areas:

- Biologics (CBER)
- Bioresearch Monitoring (BIMO)
- Devices/Radiological Health (CDRH)
- Drugs (CDER)
- Food and Cosmetics (CFSAN))
- Veterinary Medicine (CVM)

- https://www.fda.gov/about-fda/oce-annual-reports/2022-oce-annual-report

- Diversity Plan guidance
- Project Equity
- Project Pragmatica
- Tissue Agnostic Dev. Program
  - Draft guidance
- …

# 2022 OCE Annual Report

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**Content current as of:**
02/03/2023

## OCE Director's Message

After five years of tremendous growth since its formation in 2017, the Oncology Center of Excellence slowed the launch of new projects in 2022 to allow existing projects to grow in depth and strength.

This year, our work examined several ways the OCE could leverage its resources to modernize evidence generation in oncology drug development. That is, what could the OCE do to encourage the development of clinical trial data that responds to the modern needs of patients and their physicians. With the initiatives we began or strengthened this year, we aim to:

1. Ensure that clinical trial participants adequately reflect the demographic representation of patients with cancer for whom the products are intended—FDA's draft Diversity Plans guidance, led by Project Equity.
2. Open and complete clinical trials more quickly, using less complex trial designs seeking answers to clinical questions important to patients and their doctors—Project Pragmatica.
3. Explore the potentially more efficient development of drugs for cancers defined by molecular alterations—Tissue Agnostic Drug Development Program and draft guidance document.
4. Reform the dose optimization and dose selection paradigm in oncology drug

## Project Pragmatica

*Advancing evidence generation for approved oncology medical products*

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**Content current as of:**
02/06/2023

Traditional prospective randomized controlled trials in oncology are typically associated with significant monitoring, assessments, tests, and clinical follow up visits that can be burdensome to trial participants, investigators, and trial sponsors.

**Project Pragmatica** seeks to introduce functional efficiencies and enhance patient centricity by integrating aspects of clinical trials with real-world routine clinical practice through appropriate use of pragmatic design elements.

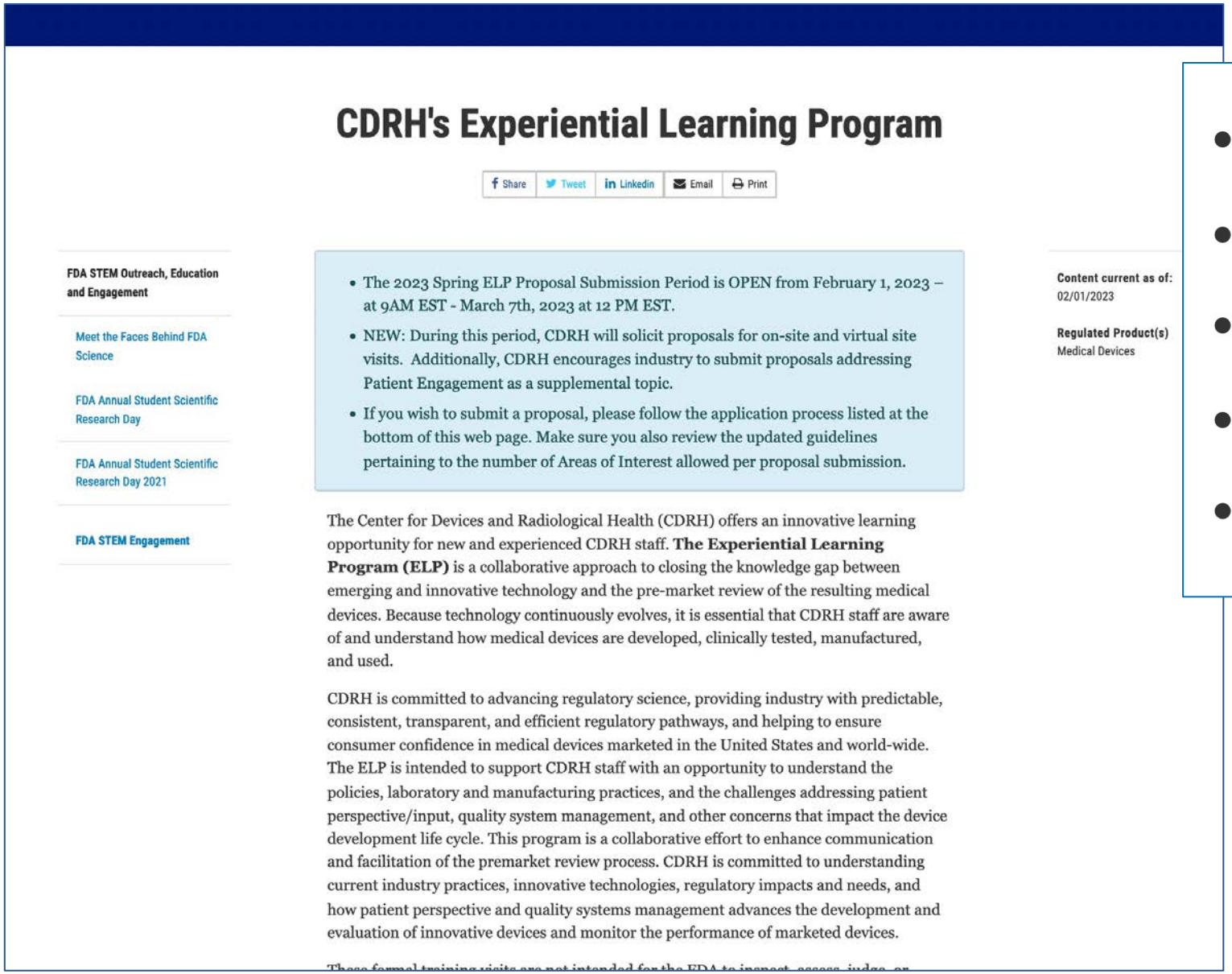
# Project Pragmatica

leads include
Drs. Donna Rivera,
Harpreet Singh,
Paul Kluetz

in addition to a **multidisciplinary team of FDA scientists** interested in efforts to make trials more efficient and patient-centric

**Project Pragmatica** seeks to introduce functional efficiencies and enhance patient centricity by integrating aspects of clinical trials with real-world routine clinical practice through appropriate use of pragmatic design elements.

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



# CDRH's Experiential Learning Program

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FDA STEM Outreach, Education and Engagement

- Meet the Faces Behind FDA Science
- FDA Annual Student Scientific Research Day
- FDA Annual Student Scientific Research Day 2021
- FDA STEM Engagement

- The 2023 Spring ELP Proposal Submission Period is OPEN from February 1, 2023 – at 9AM EST - March 7th, 2023 at 12 PM EST.
- NEW: During this period, CDRH will solicit proposals for on-site and virtual site visits. Additionally, CDRH encourages industry to submit proposals addressing Patient Engagement as a supplemental topic.
- If you wish to submit a proposal, please follow the application process listed at the bottom of this web page. Make sure you also review the updated guidelines pertaining to the number of Areas of Interest allowed per proposal submission.

**Content current as of:**
02/01/2023

**Regulated Product(s)**
Medical Devices

The Center for Devices and Radiological Health (CDRH) offers an innovative learning opportunity for new and experienced CDRH staff. **The Experiential Learning Program (ELP)** is a collaborative approach to closing the knowledge gap between emerging and innovative technology and the pre-market review of the resulting medical devices. Because technology continuously evolves, it is essential that CDRH staff are aware of and understand how medical devices are developed, clinically tested, manufactured, and used.

CDRH is committed to advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and helping to ensure consumer confidence in medical devices marketed in the United States and world-wide. The ELP is intended to support CDRH staff with an opportunity to understand the policies, laboratory and manufacturing practices, and the challenges addressing patient perspective/input, quality system management, and other concerns that impact the device development life cycle. This program is a collaborative effort to enhance communication and facilitation of the premarket review process. CDRH is committed to understanding current industry practices, innovative technologies, regulatory impacts and needs, and how patient perspective and quality systems management advances the development and evaluation of innovative devices and monitor the performance of marketed devices.

These formal training visits are not intended for the FDA to inspect, assess, judge, or

- Training Areas of Interest
- Patient Engagement
- Site Visit Format
- Application Process
- Related Resources

https://www.fda.gov/science-research/fda-stem-outreach-education-and-engagement/cdrhs-experiential-learning-program

Report to the Assistant to the President for Domestic Policy

# A Report in Response to the Executive Order on Lowering Prescription Drug Costs for Americans

Secretary Xavier Becerra | U.S. Department of Health and Human Services

Table 1. The Secretary's Selected Drug Affordability & Accessibility Models

| Area | Model | Test Question | Design |
|---|---|---|---|
| Medicare Part D | **Medicare High-Value Drug List**  | What is the impact of standardizing the Part D benefit for high-value generic drugs on beneficiary affordability, access, health outcomes, and Medicare spending? | Part D plans would be encouraged to offer a low, fixed co-payment across all cost-sharing phases of the Part D drug benefit for a standardized Medicare list of generic drugs. |
| Medicaid | **Cell & Gene Therapy Access**  | Does a CMS-led approach to administering outcomes-based agreements for certain cell and gene therapies improve beneficiary access and equity and reduce health care costs? | State Medicaid agencies would assign CMS to coordinate and administer multi-state outcomes-based agreements with manufacturers for certain cell and gene therapies. |
| Medicare Part B | **Accelerating Clinical Evidence**  | Do targeted adjustments in Part B fee-for-service payments for drugs approved by the Food and Drug Administration (FDA) under the accelerated approval pathway improve timely confirmatory trial completion and reduce Medicare spending, while maintaining or improving quality of care? | CMS would develop payment methods for drugs approved under accelerated approval, in consultation with FDA, to encourage timely confirmatory trial completion and improve access to post-market safety and efficacy data. |

# Guidance for Industry

## CGMP for Phase 1 Investigational Drugs

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

**July 2008**
**CGMP**



### Guidance for Industry
### CGMP for Phase 1 Investigational Drugs [1]

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

## I. INTRODUCTION

This guidance is intended to assist in applying current good manufacturing practice (CGMP) required under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) in the manufacture of most investigational new drugs (IND) used in phase 1 clinical trials.[2] These drugs, which include biological drugs, are exempt from complying with 21 CFR part 211 under 21 CFR 210.2(c) (referred to as phase 1 investigational drugs).

Because a phase 1 clinical trial initially introduces an investigational new drug into human subjects, appropriate CGMP help ensure subject safety. This guidance applies, as part of CGMP, quality control (QC) principles to the manufacture of phase 1 investigational drugs (i.e., interpreting and implementing CGMP consistent with good scientific methodology), which foster CGMP activities that are more appropriate for phase 1 clinical trials, improve the quality of phase 1 investigational drugs, and facilitate the initiation of investigational clinical trials in humans while continuing to protect trial subjects.

This guidance replaces the guidance issued in 1991 titled *Preparation of Investigational New Drug Products (Human and Animal)* (referred to as the 1991 guidance) (Ref. 1) for the manufacture of phase 1 investigational drugs described in this guidance (see section III). However, the 1991 guidance still applies to the manufacture of investigational new products (human and animal) used in phase 2 and phase 3 clinical trials.

The guidance finalizes the draft guidance entitled "INDs—Approaches to Complying with CGMP During Phase 1" dated January 2006; and is being issued concurrently with a final rule that specifies that 21 CFR part 211 no longer applies for most investigational products (see section III), including certain exploratory products (Ref. 2) that are manufactured for use in

[1] This guidance has been prepared by an Agency working group with representatives from the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and the Office of Regulatory Affairs (ORA), at the Food and Drug Administration.

[2] See 21 CFR 312.21(a)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 February 2023
EMA/618888/2022

# Questions and answers – Clinical Trials Information System (CTIS) and Clinical Trials Regulation (CTR)

Prepared by the Query Management Working Group

**Important notice:** The views expressed in this questions and answers (Q&A) document are not legally binding. The European Court of Justice is the only authority that can give an authoritative interpretation of Community law. This document aims at informing on the technical aspects of the Clinical Trials Regulation (EU) No 536/2014 with a view to facilitating its implementation.

| | |
|---|---|
| Period of discussion by the working group | May 2021 to June 2022 |
| CTCG endorsement | 8 February 2023 |
| Document version | 1.0 |

## 3. Useful references

This table lists the referenced documents in this Q&A with their online location.

| Reference | Location |
|---|---|
| Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014 | https://www.ema.europa.eu/en/documents/other/appendix-disclosure-rules-functional-specifications-eu-portal-eu-database-be-audited_en.pdf |
| Clinical Trials Information System (CTIS): online modular traini Module 24) | https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-ctis-online-modular-training-programme#sponsor-workspace-section |
| Clinical trials - Regulation EU No 536/2014 | https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0536 |
| Clinical trials in the European Union (CTIS) | https://euclinicaltrials.eu/ |
| Communication from the Commission — Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ('CT-3') | Communication from the Commission — Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use (CT-3) (europa.eu) |
| CTIS User support service | https://euclinicaltrials.eu/support-info/#support-user-support |
| CTFG Best Practice Guide for sponsors of multinational clinical trials with different protocol versions approved in different Member States under Directive 2001/20/EC that will transition to Regulation (EU) No. 536/2014 | https://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2018_05_CTFG_Best_Practice_Guide_for_sponsors_of_transition_multinational_clinical_trials.pdf |
| Document codes and titles in CTIS | https://www.hma.eu/fileadmin/dateien/HMA_joint/00-_About_HMA/03-Working_Groups/CTCG/2022_09_CTCG_Instruction_naming_documents_CTIS_EU_v1.4.pdf |

# LEGISLATIVE UPDATES

Feb 2, 2023 - Health

# White House announces new cancer initiatives on Moonshot anniversary

Tina Reed, author of Axios Vitals

President Biden speaks in February 2022 at an event to revive his moonshot initiative to expedite progress against cancer. Photo: Yuri Gripas/Abaca/Bloomberg via Getty Images

Administration Priorities The Record

FEBRUARY 02, 2023

# FACT SHEET: On One Year Anniversary of Reignited Cancer Moonshot, Biden-Harris Administration Announces New Actions to End Cancer as We Know It

BRIEFING ROOM › STATEMENTS AND RELEASES

One year ago, President Joe Biden and First Lady Jill Biden reignited the Cancer Moonshot, setting an ambitious, achievable goal: to reduce the death rate from cancer by at least 50 percent over the next 25 years, and improve the experience of people and families living with and surviving cancer, ultimately ending cancer as we know it today.

Administration Priorities

- **HHS is launching "CancerX," a Public-Private Partnership developed as a national accelerator to boost innovation in the fight against cancer.** HHS, ONC and Office of the Assistant Secretary for Health (OASH), is launching the "CancerX" National Innovation Accelerator Initiative, a government wide effort to develop tools, such as digital solutions to improve cancer patient care coordination and communication, new software technology to help community organizations meet cancer patients where they are, or new platforms to support patients with their post-treatment care. This new public-private partnership will drive support for and accelerate the development of biotech and health tech startups solutions focused on the continuum of cancer care, including prevention, detection, treatment, and transitions in care. Organizations whose missions are aligned with the Cancer Moonshot goals will work together to surface innovative solutions and coordinate access to research, mentorship, resources, and other collaborative opportunities. This work will help startups scale their business and work toward creating 'challenge-focused' solutions for cancer with health equity in mind. This initiative will build on previous models deployed by successful HHS InnovationX program accelerators such as KidneyX and PandemicX.

**The public and private sector is stepping up with the following new actions:**

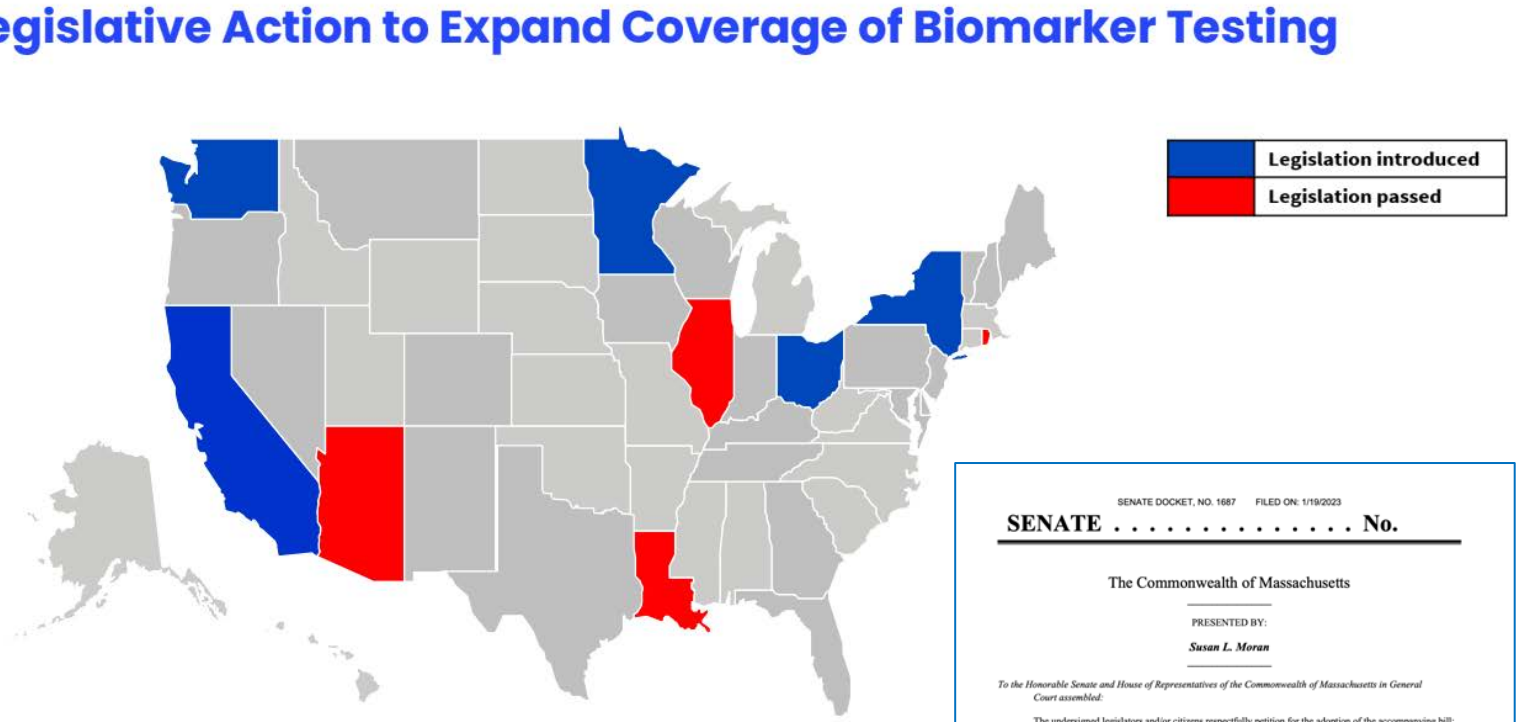
**Promoting Cancer Prevention**

- **National Minority Quality Forum (NMQF) is launching local community-based activities to increase cancer screenings in at-risk communities.** NMQF, a nonprofit, nonpartisan organization that integrates data and expertise in support of initiatives to eliminate health disparities, is

https://www.whitehouse.gov/briefing-room/statements-releases/2023/02/02/fact-sheet-on-one-year-anniversary-of-reignited-cancer-moonshot-biden-harris-administration-announces-new-actions-to-end-cancer-as-we-know-it/

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

**Insurers will have to cover biomarker testing, beginning in 2024**






SENATE DOCKET, NO. 1687 FILED ON: 1/19/2023

**SENATE . . . . . No.**

The Commonwealth of Massachusetts

PRESENTED BY:

*Susan L. Moran*

*To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:*

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to patient access to biomarker testing to provide appropriate therapy.

PETITION OF:

| NAME: | DISTRICT/ADDRESS: | |
|---|---|---|
| *Susan L. Moran* | *Plymouth and Barnstable* | |
| *Jack Patrick Lewis* | *7th Middlesex* | *1/30/2023* |
| *Michael O. Moore* | *Second Worcester* | *2/2/2023* |

## Support Insurance Coverage for Comprehensive Biomarker Testing

Biomarker testing is available for an ever-increasing range of conditions and diseases. Data shows that patients receiving targeted treatments, also known as precision medicine, experience better health outcomes, yet patient access to this type of testing has not kept pace with the rate of innovation due to a variety of factors, including:

- Lack of awareness of new testing methodologies among providers and patients;
- Absence of common testing terminology; and
- Lack of coverage or overly restrictive coverage policies by both public and private payers.

The following definition and policy principles provide advocates – including patients, providers, and industry – a roadmap for working with state policymakers to advance solutions that reduce barriers to access and promote patient outcomes.

**What is Biomarker Testing?**

Biomarkers are an essential part of precision medicine providing necessary information for appropriate therapeutic intervention. In cancer care, biomarkers are often used to help choose the best treatment for an

American Cancer Society Cancer Action Network
fightcancer.org

## Biomarker Testing: Advancing Precision Medicine in Cancer Care

**When used in the treatment of cancer, precision medicine uses information about a person's own genes or proteins to inform diagnosis, prognosis, therapy selection, and to monitor how well therapy is working.**

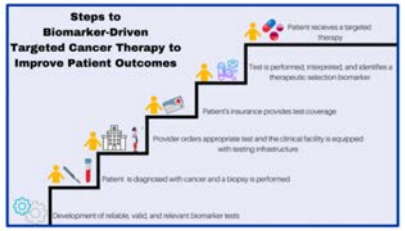
The knowledge and practice of precision medicine in cancer have been progressing rapidly and advances have led to targeted cancer therapies, which work by interfering with specific cellular processes involved in the growth, spread, and progression of cancer.

### Biomarker testing can help determine the best treatment for a patient.

Treatment with targeted therapy often requires diagnostic testing to analyze biological samples (e.g., blood, tumor tissue) taken from a patient to identify and evaluate specific biomarkers. Research shows that targeted therapy can improve patient survival and quality of life. When doctors connect patients to the most effective treatment for their cancer, patients can avoid treatments that will be ineffective or have more adverse side effects.

***Biomarkers*** are an essential part of precision medicine, providing insight into physiological processes, medical conditions, or diseases. Cancer biomarkers can include molecules like proteins or genetic alterations such as mutations, rearrangements, or fusions.

***Biomarker testing*** is the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes, but is not limited to, single-analyte tests, multi-plex panel tests, and partial or whole genome sequencing. The results of these biomarker tests can help determine the best treatment plan for a specific patient, including precision medicines.




Testing patients for specific biomarkers is integral to precision medicine in cancer care. Despite evidence pointing to the clinical benefits associated with biomarker testing, routine clinical use does not always follow, and testing rates lag behind clinical guideline recommendations.

- In a 2021 survey, 66% of oncology providers reported that insurance coverage for biomarker testing is a significant or moderate barrier to appropriate biomarker testing.[i]

American Cancer Society Cancer Action Network | 655 15th Street, NW, Suite 503 | Washington, DC 20005
@ACSCAN | @ACSCAN | fightcancer.org


Biomarker testing initiatives

Legislative attempt/incentive

…i.e., to create testing and insurance
Coverage

**Open questions:**
- Focus: prior authorization
- Which tests ?

# 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
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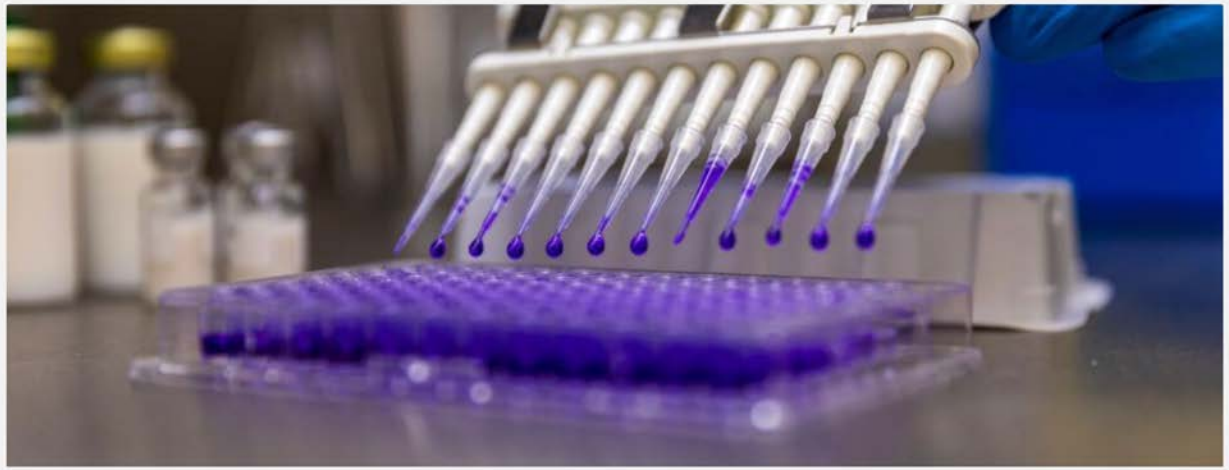


A technician uses a multi-channel pipette dropper to dispense liquid material inside a laboratory facility.

Photographer: Dwayne Senior/Bloomberg

## FDA Action on Clinical Diagnostics Poised to Gain Steam in 2023 (1)

Jan. 6, 2023, 5:30 AM; Updated: Jan. 6, 2023, 12:26 PM

- Diagnostics reform back in FDA's court
- Califf hinted at rulemaking in October

The FDA will likely rekindle its efforts to oversee diagnostic tests from laboratories after lawmakers failed to act on legislation requiring the agency to regulate them, former Food and Drug Administration officials and policy analysts say.

The agency now is likely to give itself clear authority to oversee tests regardless of

**Jeannie Baumann**
Reporter

**Celine Castronuovo**
Reporter

https://news.bloomberglaw.com/health-law-and-business/fda-action-on-clinical-diagnostics-poised-to-gain-steam-in-2023

## VALID Act Remains Priority for FDA in 2023, Says FDA Deputy Commissioner

January 18, 2023

*"CMS **will continue** to exercise enforcement discretion that allows pathologists to examine digital images and laboratory data at remote locations"*

**Statement to the**
**Clinical Laboratory Improvements Advisory Committee**
**on the**
**CLIA Regulations Assessment Workgroup**

The College of American Pathologists (CAP) appreciates the opportunity to provide written comments to the Clinical Laboratory Improvement Advisory Committee (CLIAC) on the **Clinical Laboratory Improvements Amendments of 1988 (CLIA) Regulations Assessment Workgroup Report.** As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

From our experience as an accreditor, the CAP Laboratory Accreditation Program serves clinical laboratories providing leading-edge science and technology, while ensuring clinicians and patients receive accurate laboratory testing. The CAP finds that CLIA continues to provide an adequate baseline to ensure the accuracy and reliability of clinical laboratory results. At the same time, we recognize that specific updates to CLIA are needed to address changes in practice and technology to adapt to evolving practice models. Hence, the CAP offers the following comments to the CLIAC for consideration in any


## *Clinical Laboratory Improvement Act (CLIA) Guidance*

- CMS has exercised enforcement discretion to facilitate pathologists' ability to review pathology slides remotely without the need for a separate CLIA certificate for the remote location. **Enforcement discretion is not contingent on PHE authority;** CMS will continue to exercise enforcement discretion that allows pathologists to examine digital images and laboratory data at remote locations..

nature › nature medicine › correspondence › article

Correspondence | Published: 20 October 2022

**Ensuring remote diagnostics for pathologists: an open letter to the US Congress**

Jochen K. Lennerz, Liron Pantanowitz, Mitual B. Amin, Isam-Eldin Eltoum, Meera R. Hameed, Alexana N. Kalof, Elham Khanafshar, Lakshmi P. Kunju, Audrey J. Lazenby, Kathleen T. Montone, Christopher N. Otis, Michelle D. Reid, Paul N. Staats, Christa L. Whitney-Miller, Catherine S. Abendroth, Manju Aron, George G. Birdsong, Ira J. Bleiweiss, Mary P. Bronner, Jennifer Chapman, Nicole A. Cipriani, Gustavo de la Roza, Michael J. Esposito, Oluwole Fadare, ... Erika R. Bracamonte

+ Show authors

# Discussion

# Discussion: Topic 1

- **PIcc meeting**
  - Annual meeting: requirements
  - Consensus for in-person: “yes”
  - **Time/Location**: Where and when
  - **Format**: modeled 2019 Arlington
  - **Focus**: review by main constituents to select on **one** relevant unifying project
  - Multi-stakeholder come together
  - Schedule planning meeting => FDA/MDIC/DAP/CAP/API/ASCP/Friends/open to all

# November 2019

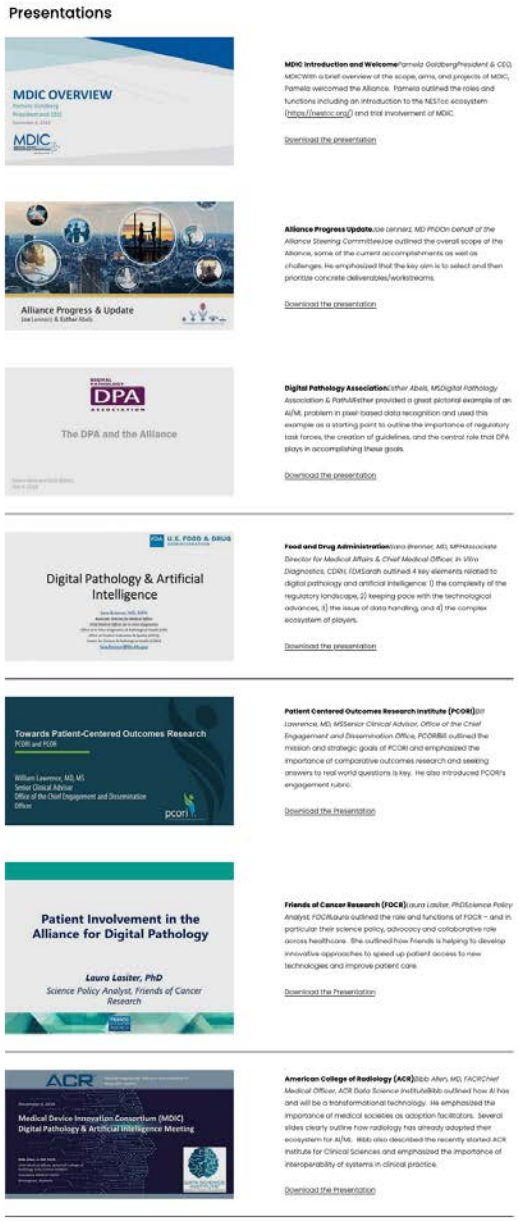
- https://pathologyinnovationcc.org/presentations/nov-2019


**The Alliance for Digital Pathology Meeting, hosted by the MDIC at the Key Bridge Marriott, in Arlington, VA, on November 4, 2019**

The aim of the meeting was to:

- Share and discuss progress in the Alliance
- Enable networking among the members/participants
- Have a full day to share and work on deliverables
- Take the content of the prior breakout sessions, continue development and derive practically relevant deliverables
- Share the content in the public domain

Please find the presentations and the results of the breakout sessions below. The project overviews can be found in the full program.




***proposal***

MDIC
FDA
DPA
CAP
ASCP
API
FOCR
…

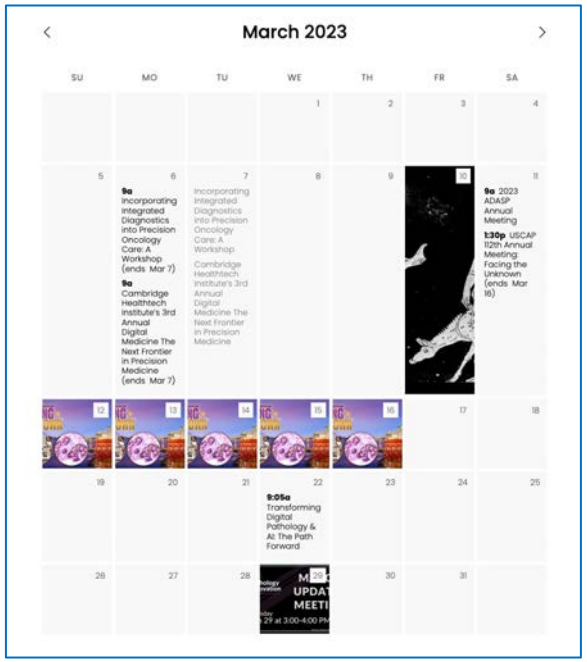
***Proposal***

Location:  near D.C. => FDA participation

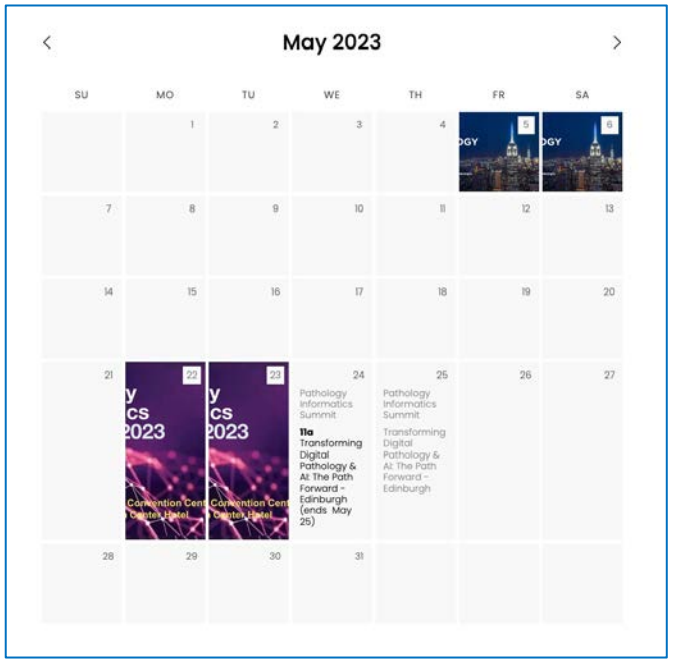
e.g., Friday or Monday; 10:00-16:00

When? Coordinate with MDIC/FDA?

| | |
|---|---|
| 10:00-12:00 | 8 groups present |
| 12:00-13:00 | Lunch break |
| 13:00-16:00 | Select relevant unifying project?<br>Co-develop project map<br>Deliverables |





# Discussion: Topic 2

- Library section for website
  - Research studies cannot be adequately featured
  - Resource section on the website where we group resources thematically
  - Solicit suggestions for themes
  - *Proposed themes*
    - Quality Management
    - Statistics
    - Genotyping
    - Writing
    - Diversity/Equity resources
    - Leadership
    - CLIA/LDT

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

**Register for the Next Threat Modeling Bootcamp!**

**+ Threat Modeling Bootcamp 1: March 13-17**

---

**Objectives & discussed topics of the MDIC threat modeling bootcamps:**

- Intensive, hands-on sessions on threat modeling.
- Learning about structured, systematic and comprehensive approach to threat modeling for engineering more secure systems from SMEs from public and private sector.
- Learning the latest updates on medical device cybersecurity and related areas from industry representatives.
- Networking opportunity with SMEs from MedTech and non-MedTech sectors to learn on cybersecurity best practices that can be incorporated into the medical device industry.
- The same training that informed the development of the Medical Device Threat Modeling Playbook.

To learn more about the bootcamp along with various other MDIC cybersecurity initiatives, email us at cybersecurity@mdic.org or contact Noor Falah at nfalah@mdic.org or Jithesh Veetil at jveetil@mdic.org

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# MDIC Updates

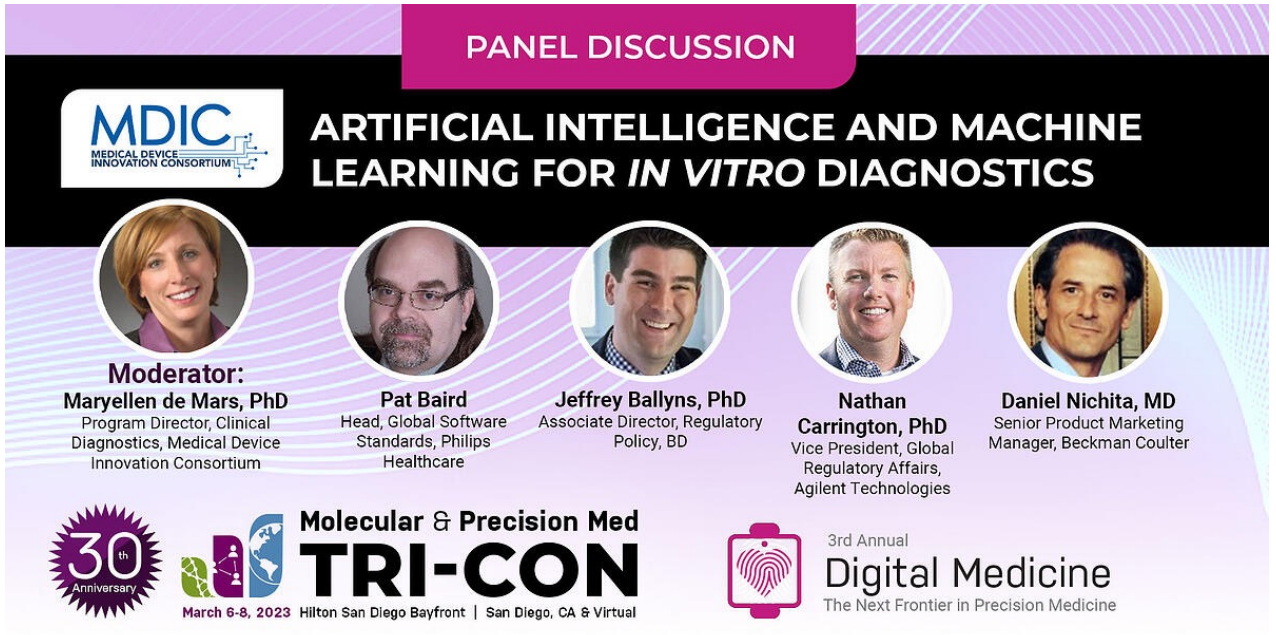
- MDIC Releases Landscape Report on Medical Device Computational Modeling and Simulation

# MDIC Updates

- Join MDIC on March 30 for an informational webinar on the Medical Device Computational Modeling and Simulation Landscape Report

# MDIC Updates

- Join MDIC at the 2023 Molecular and Precision Med TRI-CON Conference. Dr. Maryellen de Mars will moderate a lively panel on Artificial Intelligence and Machine Learning for In Vitro Diagnostics at TRI-CON



# MDIC Updates

- Cybersecurity Benchmarking Webinar available On Demand

  - Watch now and acquire key takeaways from the world's first-ever Cybersecurity Maturity Benchmarking Report and receive focused best practices on implementing the tool and report findings into your cybersecurity posture

  **Panelists:**

  - Jithesh Veetil, PhD, Senior Director of Digital Health and Technology (MDIC),
  - Chris Reed, Director of Digital Health and Product Security Policy at Medtronic,
  - Rob Suarez, Chief Information Security Officer at BD,
  - Greg Garcia, Executive Director, Cybersecurity Health Sector Coordinating Council

# MDIC Updates

## Call for Volunteers! MDIC Digital Health Software Vertical

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

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# MDIC Updates

**Seeking Subject Matter Expert volunteers to support Science of Patient Input Post-Market Patient Engagement Working Groups**

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

# MDIC Updates

## Leadership Engagement Culture Initiative

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

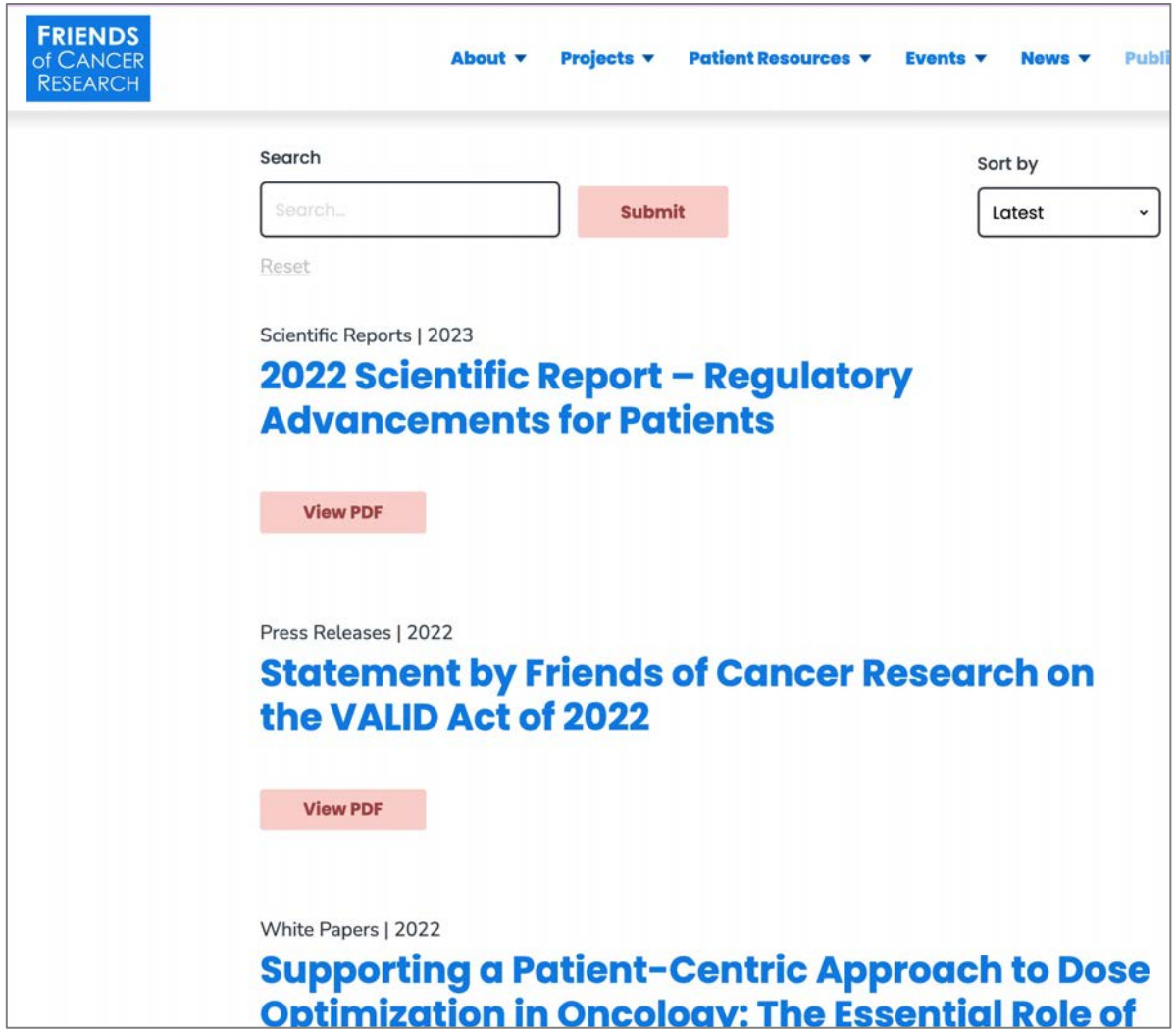
- Interested? Contact cfqcc@mdic.org to get involved with Case for Quality initiatives.

# 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

# Professional Societies Organizations


FRIENDS of CANCER RESEARCH
About
Projects
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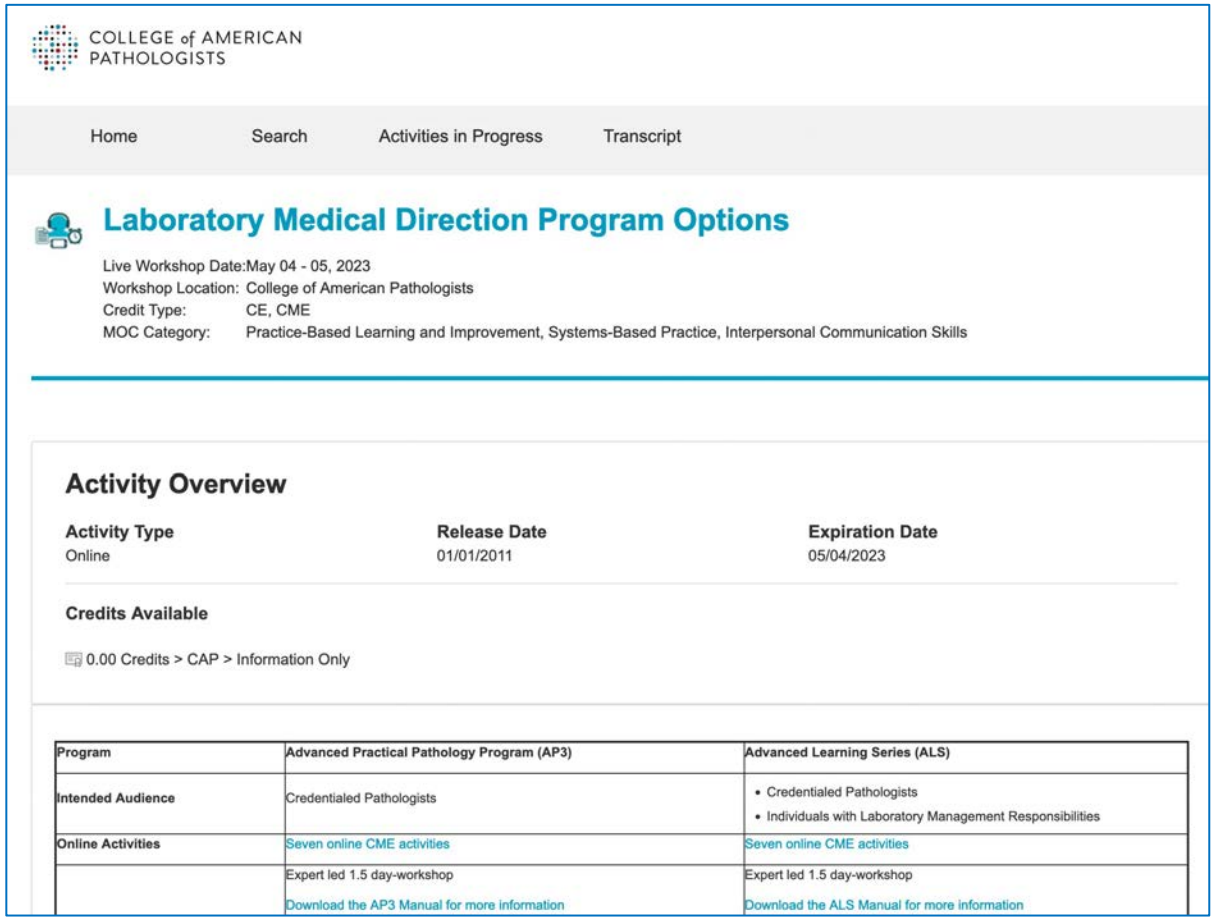
Scientific Reports | 2023
2022 Scientific Report – Regulatory Advancements for Patients
View PDF
Press Releases | 2022
Statement by Friends of Cancer Research on the VALID Act of 2022
View PDF
White Papers | 2022
Supporting a Patient-Centric Approach to Dose Optimization in Oncology: The Essential Role of


2022 SCIENTIFIC REPORT
Regulatory Advancements for Patients
FRIENDS of CANCER RESEARCH


- https://www.pathologistsleadershipsummit.org/?utm_source=CAP%20Homepage&utm_medium=Web&utm_campaign=Pathologist%20Leadership%20Summit&utm_content=February

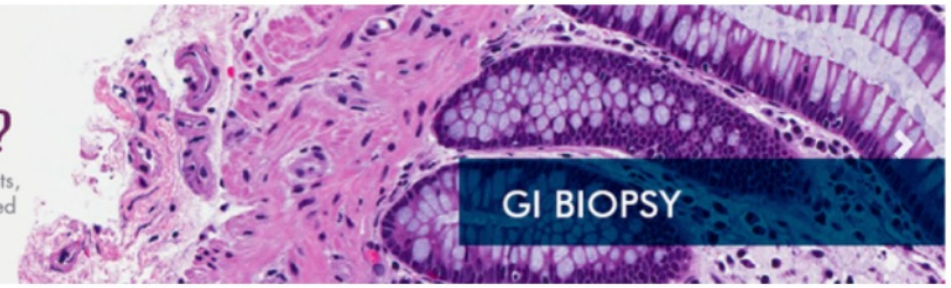


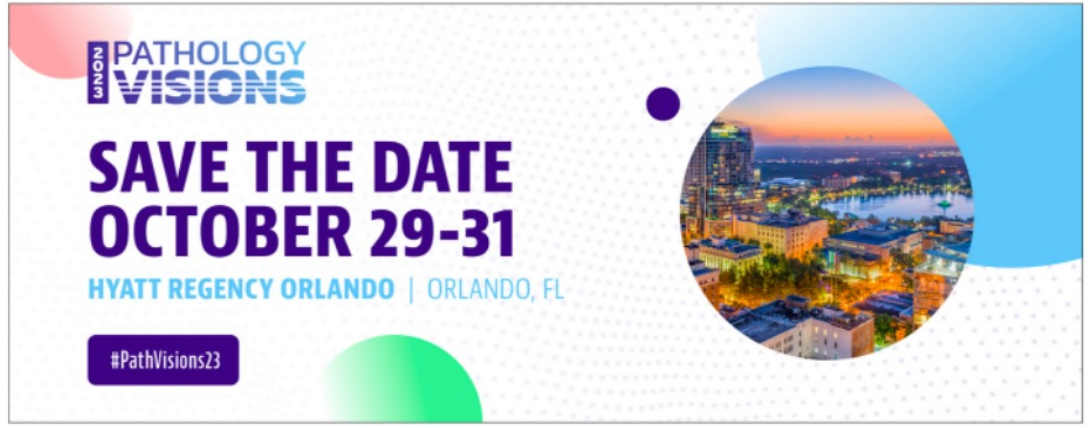

- https://learn.cap.org/lms/activity?@curriculum.id=-1&@activity.id=2864420&@activity.bundleActivityId=-1


Pathology Informatics Summit 2023
May 22-25, 2023
David L. Lawrence Convention Center and the
Westin Convention Center Hotel

## 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.




## NEWS

**What Did PathVisions22 Reveal About the Future of Digital Pathology?**

Oct 27, 2022

**Hamamatsu Photonics Announces U.S. FDA clearance for the NanoZoomer S360MD Slide scanner system for Surgical Pathology Diagnostics**

Oct 27, 2022

**Conversation with Esther Abels, President of The**



## TWITTER FEED

**Tweets from @dpatweet**

**The Digital Pathology Ass...** @dpatweet · 2h

Want a new way to network?

Join Collaborate, DPA's interactive portal. You can create your own space for topics

# Resources &Publications

**Resources**

Precision Medicine Conference: Paying for artificial intelligence in medicine (download slides)

World Medicine Association: Handbook of WMA Policies (download .pdf)

HOW THE JETSON's PREDICTED THE FUTURE AND WERE SHOCKINGLY ACCURATE (Read More)

Non-Small Cell Lung Cancer: (Research By Tumor Type)

EMory BrEast Imaging Dataset (EMBED) (Find Here)

WHO: SURVCAN Cancer Survival Statistics in Africa, Central and South America, and Asia, Volume 3 (Find Here)

NIST: AI Risk Management Framework (Read Here)

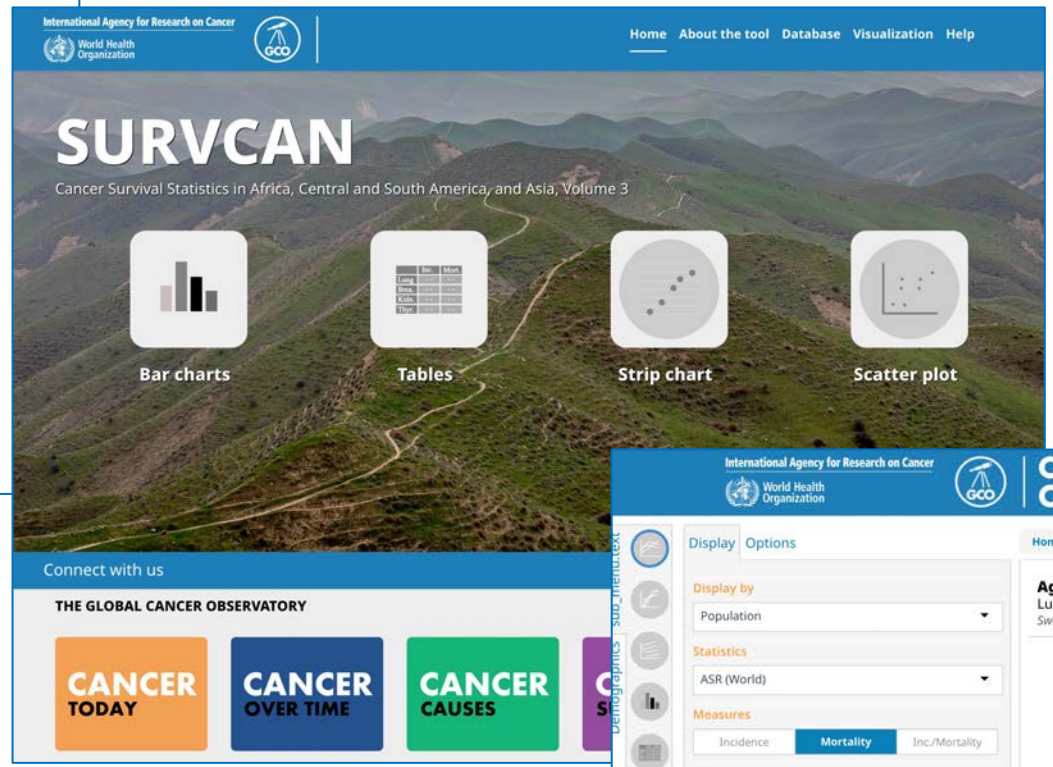
Generative AI: What's all the hype about? (Listen Here)

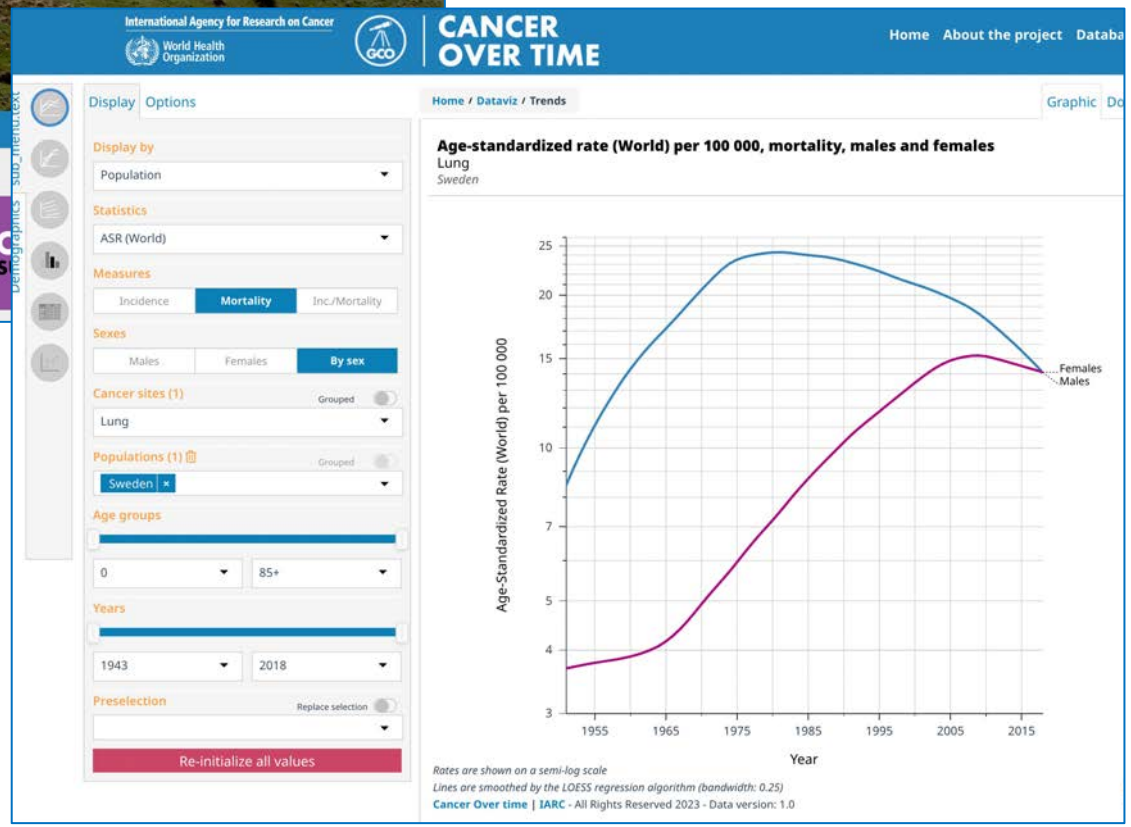
HIPAA TRAINING FOR COVERED ENTITIES (Find Here)

Research on Potential Long-Term Health Effects of Tattooing (Learn More)

Our World Data: Why is life expectancy in the US lower than in other rich countries? (Discover Here)
Industry Insights: How to Apply for a CLIA Certificate? Filling out CMS-116 (Available Here)

Meet our Health Equity Research Initiative awardees (Find Here)

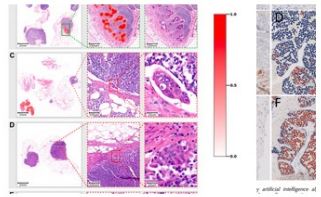



Valuable resources

Selected one… WHO

**Publications**



Khan et al. Computer-Assisted Diagnosis of Lymph Node Metastases in Colorectal Cancers Using Transfer Learning With an Ensemble Model (download .pdf)

Geneviève Belleville. Sit Down and Write Your Thesis! Practical and Motivational Tips for Scientific Writing (download .pdf)

Bracamonte et al. Communicating Uncertainty in Surgical Pathology Reports: A Survey of Staff Physicians and Residents at an Academic Medical Center (download .pdf)

Liu et al. Applications of Artificial Intelligence in Breast Pathology (download .pdf)

Sheffield et al. Cost Savings of Expedited Care with Upfront Next-Generation Sequencing Testing versus Single-Gene Testing among Patients with Metastatic Non-Small Cell Lung Cancer Based on Current Canadian Practices (download .pdf)

Sande et al. Rapid and Automated Semiconductor-Based Next-Generation Sequencing for Simultaneous Detection of Somatic DNA and RNA Aberrations in Myeloid Neoplasms (download .pdf)

Bilal et al. Role of AI and digital pathology for colorectal immuno-oncology (download .pdf)

Shamai et al. Deep learning-based image analysis predicts PD-L1 status from H&E-stained histopathology images in breast cancer (download .pdf)

Pennings et al. Copy number variants from 4800 exomes contribute to ~7% of genetic diagnoses in movement disorders, muscle disorders and neuropathies (download .pdf)

Chuprin et al. Humanized mouse models for immuno-oncology research (download .pdf)

Wilson et al. Hallmarks of neurodegenerative diseases (download .pdf)

Ravi B. Parikh and Lorens A. Helmchen. Paying for artificial intelligence in medicine (download .pdf)

Paper: The End of Endomyocardial Biopsy? A Practical Guide for Noninvasive Heart Transplant Rejection Surveillance (Continue Here)

Reclassification of the Etiology of Infant MortalityWithWhole-Genome Sequencing (JAMA)

Futibatinib for FGFR2-Rearranged Intrahepatic Cholangiocarcinoma (THE NEW ENGLAND JOURNAL OF MEDICINE)

Mismatch repair deficiency, next-generation sequencing-based microsatellite instability, and tumor mutational burden as predictive biomarkers for immune checkpoint inhibitor effectiveness in frontline treatment of advanced stage endometrial cancer (Original Research)

AI-Powered Biomolecular-Specific and Label-Free Multispectral Imaging Rapidly Detects Malignant Neoplasm in Surgically Excised Breast Tissue Specimens (Original Research)

MODERN PATHOLOGY: Expanding the Molecular Diversity of CIC-Rearranged Sarcomas With Novel and Very Rare Partners (Read More)

Cancer Debugged: Tumors are rife with bacteria and fungi. Their ubiquity is proving useful in detecting cancers, categorizing them, and even determining whether certain interventions will work. (Learn More)

Validation of a breast cancer risk prediction model based on the key risk factors: family history, mammographic density and polygenic risk (Epidemiology)

Cancer: Arginine limitation drives a directed codon-dependent DNA sequence evolution response in colorectal cancer cells (Science Advances: Research Article)

How to regulate evolving AI health algorithms (Worldview)

Locally sourced: site-specific immune barriers to metastasis (nature reviews)

Article: Erroneous Patient Tissue Contaminants in 1574 Surgical Pathology Slides (Continue Here)

Building a knowledge graph to enable precision medicine (Scientific Data)

Review: Triple-Negative Breast Cancer and Predictive Markers of Response to Neoadjuvant Chemotherapy: A Systematic Review (Continue Here)

Human-specific genetics: new tools to explore the molecular and cellular basis of human evolution (nature review)

Alzheimer's risk gene works the gut–brain axis (Read More)

BioGPT: Generative Pre-trained Transformer for Biomedical Text Generation and Mining (Read)

Environmental sustainability in cardiology: reducing the carbon footprint of the catheterization laboratory (Read Here)

Paper: Next-Generation Morphometry for pathomics-data mining in histopathology (Download Link)

Assessment of Human Resources in Medical Laboratory Sciences In Timor-Leste (Read Here)

Review: Application of Artificial Intelligence in Pathology: Trends and Challenges (Continue Here)

Paper: Assessment of Cancer Predisposition Syndromes in a National Cohort of Children With a Neoplasm (Continue Here)

Future on a Flashdrive: Timely Considerations for the Imminent Adoption of Whole Genome Sequencing in Pediatric Healthcare

(Read Here)

Burnout Interventions for Resident Physicians (Read Here)

Article: Characterization of PVL-Positive MRSA Isolates in Northern Bavaria, Germany over an Eight-Year Period (Continue Here)

Article: Oncogene-addicted metastatic non-small-cell lung cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up† (Continue Here)

Article: Spatially resolved transcriptomic profiling of degraded and challenging fresh frozen samples (Continue Here)

Article: Systematic assessment of prognostic molecular features across cancers (Continue Here)

Article: Germline predisposition to pediatric Ewing sarcoma is characterized by inherited pathogenic variants in DNA damage repair genes (Read Here)

Paper: Adult hippocampal neurogenesis in Alzheimer's disease: A roadmap to clinical relevance (Continue Reading)

Paper: How do providers of artificial intelligence (AI) solutions propose and legitimize the values of their solutions for supporting diagnostic radiology

nature reviews immunology https://doi.org/10.1038/s41577-023-00836-2

Perspective

Check for updates

# Locally sourced: site-specific immune barriers to metastasis

Ana Luísa Correia

**Abstract**

Tumour cells migrate very early from primary sites to distant sites, and yet metastases often take years to manifest themselves clinically or never even surface within a patient's lifetime. This pause in cancer progression emphasizes the existence of barriers that constrain the

**Sections**



Education in Pathology and Laboratory Medicine

# Burnout Interventions for Resident Physicians

## A Scoping Review of Their Content, Format, and Effectiveness

*Fang-I Lu, MD; Savithiri Ratnapalan, MBBS, PhD*

• *Context.*—Physicians face a high rate of burnout, especially during the residency training period when trainees often experience a rapid increase in professional responsibilities and expectations. Effective burnout prevention programs for resident physicians are needed to

ized controlled trials, 3 case-control studies, 20 pretest and posttest studies, and 5 case reports. Of the 23 studies that used a validated well-being assessment tool, 10 reported improvements postintervention. These effective burnout interventions were longitudinal and included wellness

**World view**

https://doi.org/10.1038/s41591-022-02165-8

# How to regulate evolving AI health algorithms

By David W. Bates

Check for updates

**Artificial intelligence algorithms have had mixed success in health, in part because regulation prevents them from evolving at the necessary rate.**

performance was. It identified only 183 of 2,552 patients with sepsis (7%) who did not get timely antibiotics. It also failed to find around two-thirds of patients with sepsis, despite alerting on 18% of hospitalized patients.

to regulate drugs and devices. The FDA has previously regulated software used to collect, test, prepare, store and transport blood and blood products, with the resulting software being safe but with problematic usability. Reg-

## PCCP Project


**Sec. 3308 of the Consolidated Appropriations Act 2023 includes**

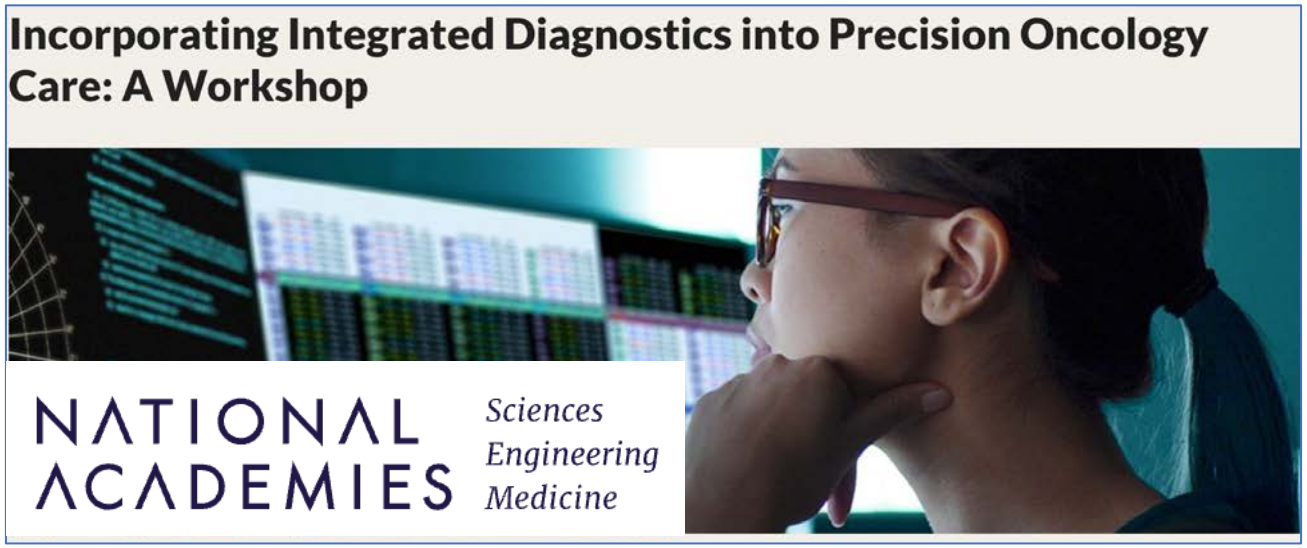
**Predetermined Change Control Plans for devices:** if a predetermined change control plan is approved or cleared, then a supplemental PMA or a new 510(k) is not required for a change to a device that is consistent with such approved or cleared plan

*In the Senate of the United States,*

SENATE AMENDMENT TO HOUSE AMENDMENT TO SENATE AMENDMENT:

# Events


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


Incorporating Integrated Diagnostics into Precision Oncology Care: A Workshop
NATIONAL ACADEMIES
Sciences
Engineering
Medicine


USCAP 112TH ANNUAL MEETING
FACING THE UNKNOWN
MARCH 11-16, 2023
NEW ORLEANS, LOUISIANA


30th Anniversary
Molecular & Precision Med
TRI-CON
March 6-8, 2023 Hilton San Diego Bayfront | San Diego, CA & Virtual
Celebrating 30 Years of Connecting the Precision Medicine Community
Register by January 20 for maximum savings – Alumni save an additional 20%

# Upcoming Plcc Meetings

- Monday, 2/27 1:00-2:00PM EST Data Breach Project Meeting 2
- Tuesday, 3/7 5:30PM EST Washington D.C. “Meet up”; Lincoln Restaurant
- Friday, 3/10 1:00-2:00PM EST Goldilocks Project Meeting 2
- Sunday, 3/12 6:00PM EDT USCAP “Meet up”; Hilton New Orleans Riverside
- Wednesday, 3/29 3:00-4:00PM EDT March Steering Committee Meeting
- Friday, 4/7 1:00-2:00PM EDT HER2-Low Project Meeting 1

*Thank you!*

# Pathology Innovation Collaborative Community

**Plcc**

The Alliance for Digital Pathology