Plcc Alliance

Home About Working Groups News & Events Resources Presentations Projects Publications

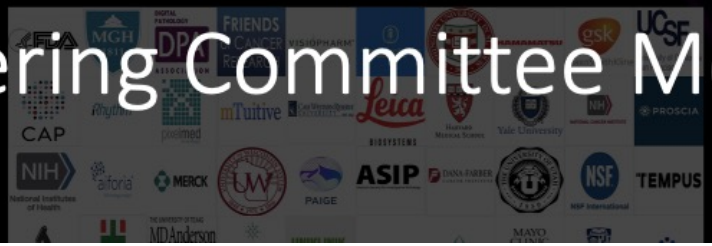
Join

Pathology Innovation Collaborative Community

Plcc

The Alliance for Digital Pathology

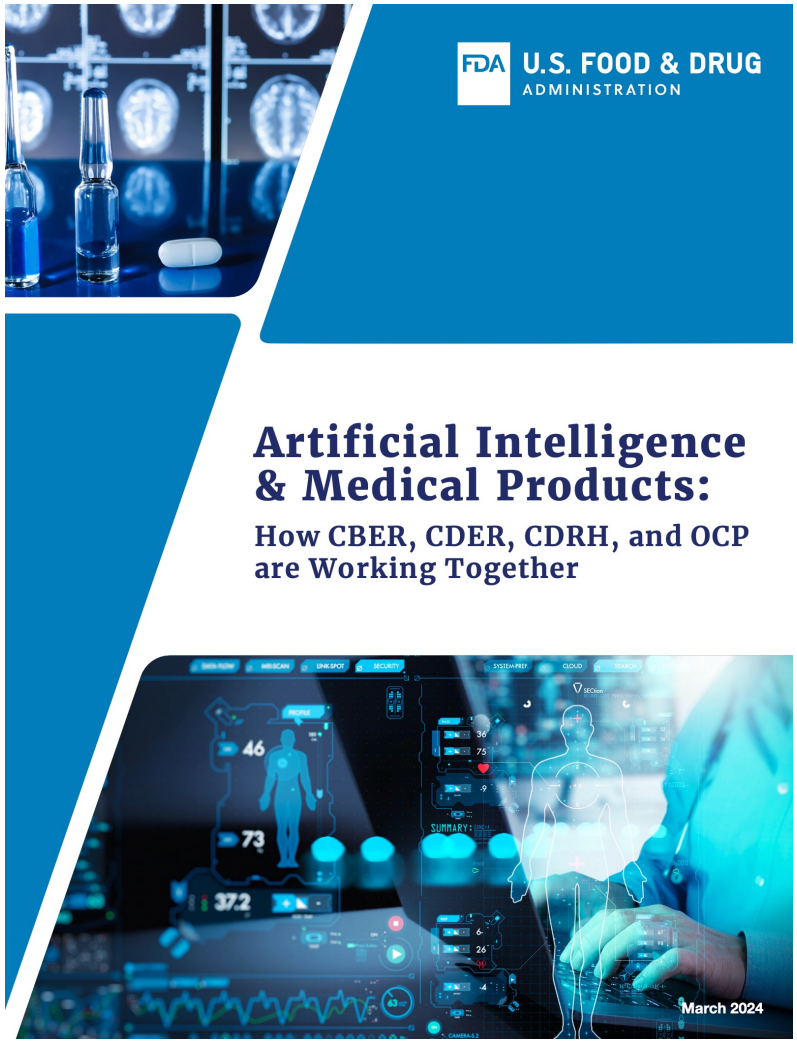
A collaborative community with FDA participation



Steering Committee Meeting

March 2024

FDA



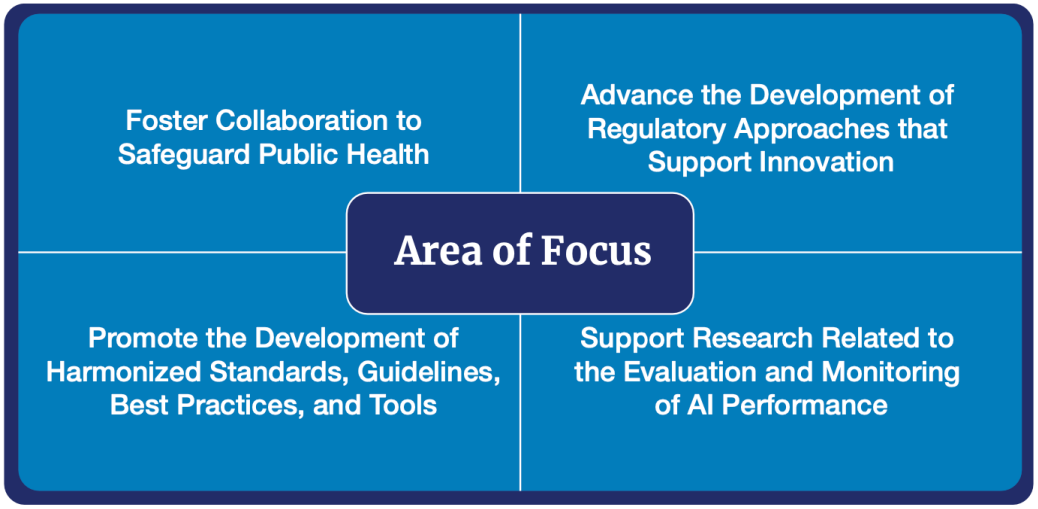


Figure 1. Four areas of focus regarding the development and use of AI across the medical product lifecycle.

GUIDANCE DOCUMENT

Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products

MARCH 2024

Download the Draft Guidance Document

Draft Level 1 Guidance

Not for implementation. Contains non-binding recommendations.

This guidance is being distributed for comment purposes only.

Search for FDA Guidance Documents

Search for FDA Guidance Documents

Submit Comments by 06/20/2024

Submit Comments Online

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the FDA considers your comment on a draft guidance before it begins work on the final version of the guidance, submit

Content current as of:
03/19/2024

Regulated Product(s)
Drugs

Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products

Guidance for Industry

DRAFT GUIDANCE

D. Data Sources

Sponsors should demonstrate the appropriateness of the proposed data source(s) to address specific hypotheses and research questions. Given that data sources used in a non-interventional study design are often generated for purposes other than research, it is important that sponsors understand the potential limitations of such data sources and determine whether those limitations can be addressed or if another data source should be pursued. Each protocol or accompanying documents should concisely describe each of the elements listed below:

- Description of the proposed data source(s), including how the data were originally collected
- Rationale for choosing the data source(s)
- Relevance of the data to the drug-outcome association of interest
- Appropriateness of the information on relevant confounding factors
- Available information on data reliability (including method of accrual from source data)
- Description of common data models used to provide a standard structure for sharing data from various sources and the rationale behind the choice of the specific model
- Available information on the timing of assessments for key data elements and completeness of these key data elements
- Explanation of how the proposed coding is appropriate based on operational definitions of key variables
- Appropriateness of the data relative to the target patient population

FDA approves safety labeling changes regarding DPD deficiency for fluorouracil injection products

Resources for Information | Approved Drugs

Oncology (Cancer) / Hematologic Malignancies Approval Notifications

Ongoing | Cancer Accelerated Approvals

Verified Clinical Benefit | Cancer Accelerated Approvals

Withdrawn | Cancer Accelerated Approvals

Other | Cancer

On March 21, 2024, the Food and Drug Administration approved safety labeling changes for fluorouracil injection products. This effort was a collaboration between FDA's Office of Generic Drugs and the Oncology Center of Excellence (OCE).

Fluorouracil injection was initially approved in 1962. The FDA became aware of additional safety information regarding the risk of serious adverse reactions related to fluorouracil use in patients with dihydropyrimidine dehydrogenase (DPD) deficiency. Revisions have been made to the Highlights of Prescribing Information and sections 5 (Warnings and Precautions) and 17 (Patient Counseling Information) of the full prescribing information to provide information about these risks. In addition, a new subsection 12.5 (Pharmacogenomics) has been added to section 12 (Clinical Pharmacology). The labeling changes align with those approved for another fluoropyrimidine drug, Xeloda (capecitabine) tablets, on December 14, 2022.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

For assistance with single-patient INDs for investigational oncology products, healthcare

Content current as of:
03/21/2024

Regulated Product(s)
Drugs

Tips for Submitting Comments on CDRH Guidance Documents

Guidance Documents (Medical Devices and Radiation-Emitting Products)

Cross-Center Final Guidance

Recent Final Medical Device Guidance Documents

Draft Medical Device Guidance

CDRH Proposed

Public comments on the FDA's Center for Devices and Radiological Health (CDRH) guidance documents are critical to the guidance development process and help us ensure our recommendations meet stakeholder needs. In accordance with 21 CFR 10.115, the FDA considers comments received and revises guidances, as appropriate. Below are some tips and recommendations, as well as some instructions on how to submit comments for a guidance.

Tips

- Submit either electronic or written comments on the guidance by the comment close date listed on the CDRH guidance web page and associated Federal Register Notice announcing the draft guidance to ensure that FDA considers your comments on the draft guidance before it begins work on the final version of the guidance.
    - You can comment on any guidance document at any time (21 CFR 10.115(g)(5)), including final guidance documents. However, comments may not be acted

Content current as of:
08/16/2023

Regulated Product(s)
Medical Devices
Radiation-Emitting Products

Breakthrough Devices Program

How to Study and Market Your Device

eSTAR Program

Breakthrough Devices Program

Safer Technologies Program (SteP) for Medical Devices

eCopy Medical Device Submissions

Total Product Life Cycle Advisory Program (TAP)

UPDATE: September 14, 2023. The FDA issued updates to the final guidance on the *Breakthrough Devices Program* to:

- Clarify how the Breakthrough Devices Program may apply to certain medical devices that promote health equity.
- Clarify considerations in designating devices, including eligible devices that may support innovation of new and existing technologies that address inequities.
- Clarify that the Breakthrough Devices Program may be available for certain non-addictive medical products to treat pain or addiction—consistent with the FDA's obligations under the SUPPORT Act.
- Clarify how the FDA discloses the Breakthrough status of designated devices once they receive marketing authorization.

On this page:

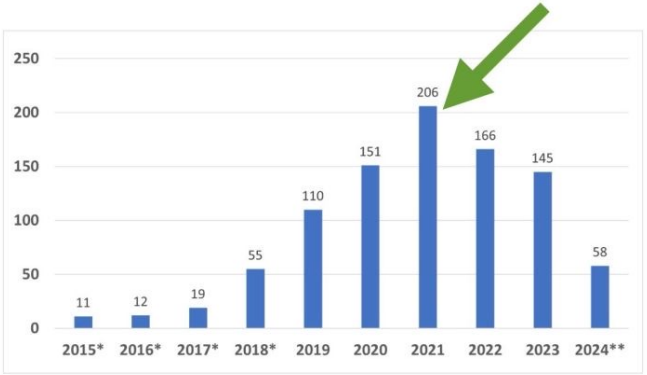
Content current as of:
03/21/2024

Regulated Product(s)
Medical Devices
Radiation-Emitting Products

Breakthrough Device Program

- This program is intended to provide patients and health care providers with timely access to certain medical devices by speeding up development, assessment, and review for premarket approval, 510(k) clearance, and De Novo marketing authorization.
- Since the launch of the program, the FDA has granted 933 Breakthrough Device designations, and authorized 95 Breakthrough Devices for marketing.
- Update.

Graph 1: Number of Granted Breakthrough Device Designations by Fiscal Year



Is my device eligible?

Devices subject to premarket approval applications (PMAs), premarket notification [510(k)], or requests for De Novo classification request are eligible for Breakthrough Device designation if the device meets both of the following criteria:

Criteria	Description	Refer to Guidance
First Criterion	The device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions	Section III.B.1
Second Criterion	The device also meets **at least one** of the following:	
	a. Represents Breakthrough Technology	Section III.B.2.a
	b. No Approved or Cleared Alternatives Exist	Section III.B.2.b
	c. Offers Significant Advantages over Existing Approved or Cleared Alternatives	Section III.B.2.c
	d. Device Availability is in the Best Interest of Patients	Section III.B.2.d

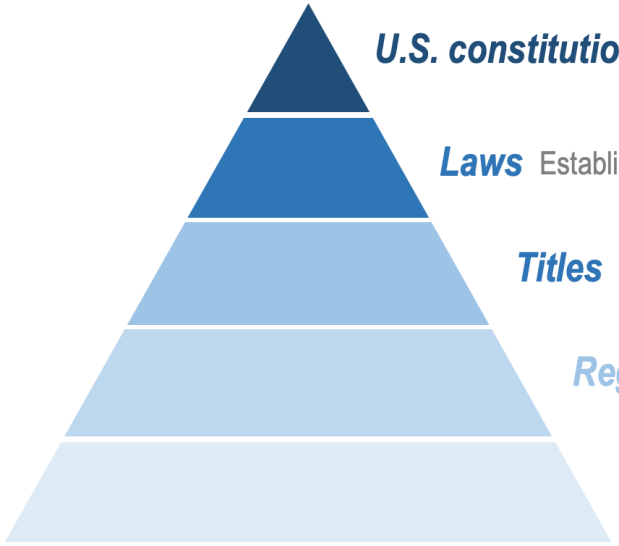
D.C. UPDATES

HEALTH POLICY ReCAP

original contribu

National Maintenance Cost for Precision Diagnostics Under the Verifying Accurate Leading-Edge In Vitro Clinical Test Development (VALID) Act of 2020

Richard Huang, MD[1]; Laura Lasiter, PhD[2]; Adam Bard, MSF[1]; Bruce Quinn[3]; Christina Young, PhD[2]; Roberto Salgado, MD, PhD[4,5]; Jeff Allen, PhD[2]; and Jochen K. Lennerz, MD, PhD[1]



U.S. constitution

Laws Establish requirements or prohibitions

Titles Chapters, subchapters, parts, sections, paragraphs, clauses

Regulations Clarify how the law will be implemented

Instruments to further clarify laws and regulations

Guidances	*Policies*	*Standards*	*Procedures*
General Recommendation Non-mandatory	*Specific in scope Mandatory**	*Acceptable Levels/controls Quantifiable*	*Detailed Steps and Components*

Federal authority to regulate rests with U.S. Congress and is delegated to a federal agency through law.

The statutory basis for a regulation may differ greatly in terms of its specificity

VALID Act (Bill)

Regulations

To be determined

Comparison

Food, Drug, and Cosmetic Act (FD&C Act)

enacted in 1938, gives the FDA authority to oversee the safety and effectiveness of these products to protect public health.

Law empowers the **FDA**

Clinical Laboratory Improvement Amendments (CLIA)

CLIA '88 is a federal regulatory framework that establishes quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results.

Law empowers **the Centers for Medicare & Medicaid Services (CMS)** to oversee CLIA regulations

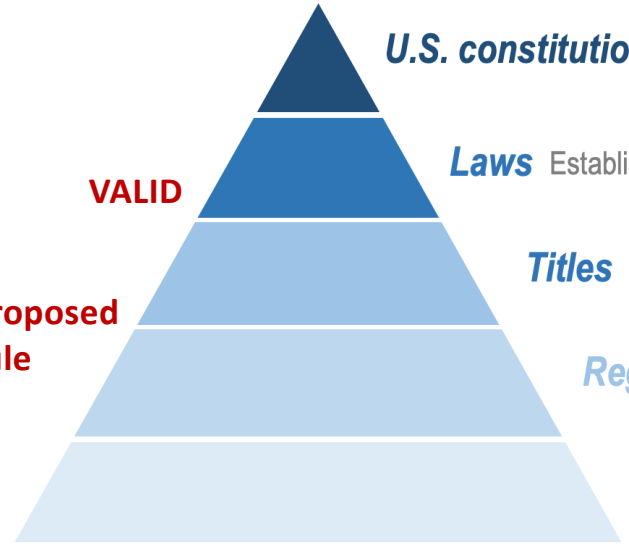
Aspect	FD&C Act (Enabling FDA Regulations)	CLIA '88 (Enabling CLIA Regulations)
Enacted Year	**1938**	**1988**
Regulatory Authority	U.S. Food and Drug Administration (FDA)	Centers for Medicare & Medicaid Services (CMS)
Focus	Regulation of various products including medical devices, pharmaceuticals, food, cosmetics, etc.	Regulation of laboratory testing for health assessment, diagnosis, prevention, or treatment of disease
Purpose	Ensure safety, effectiveness, and proper labeling of regulated products to protect public health	Establish quality standards for laboratory testing to ensure accuracy, reliability, and timeliness of patient test results
Scope	Wide-ranging, covering manufacturing, labeling, marketing, distribution, etc.	Specifically focused on laboratory testing standards and practices
Oversight	FDA oversees compliance with FD&C Act regulations through inspections, enforcement actions, etc.	CMS oversees CLIA compliance through laboratory certification, proficiency testing, inspections, etc.
Applicability	Applicable to manufacturers, importers, distributors, and other stakeholders involved in regulated products	Applicable to laboratories performing testing on human specimens for health assessment or medical diagnosis
Key Requirements	- Pre-market approval for new drugs and medical devices - Good Manufacturing Practices (GMP) - Labeling and advertising requirements - Adverse event reporting - Post-market surveillance and inspections	- Laboratory certification - Proficiency testing - Quality control procedures - Personnel qualifications - Inspection requirements
Public Health Impact	Ensures the safety and efficacy of medical products and promotes public health through proper regulation	Enhances the quality and reliability of laboratory testing, leading to accurate diagnosis and effective treatment of diseases

original contribu

HEALTH POLICY ReCAP

National Maintenance Cost for Precision Diagnostics Under the Verifying Accurate Leading-Edge In Vitro Clinical Test Development (VALID) Act of 2020

Richard Huang, MD[1]; Laura Lasiter, PhD[2]; Adam Bard, MSF[1]; Bruce Quinn[3]; Christina Young, PhD[2]; Roberto Salgado, MD, PhD[4,5]; Jeff Allen, PhD[2]; and Jochen K. Lennerz, MD, PhD[1]



Instruments to further clarify laws and regulations

Guidances	Policies	Standards	Procedures
General Recommendation Non-mandatory	Specific in scope Mandatory*	Acceptable Levels/controls Quantifiable	Detailed Steps and Components

Federal authority to regulate rests with U.S. Congress and is delegated to a federal agency through law.

The statutory basis for a regulation may differ greatly in terms of its specificity

VALID Act (Bill)

Regulations

To be determined

What is "Rulemaking"

- The terms "**rule**" and "**regulation**" are often used interchangeably in discussions of the federal regulatory process
- The Administrative Procedure Act ("APA") of 1946 sets forth the most broadly applicable federal rulemaking requirements
- **"agency process for formulating, amending, or repealing a rule."**
- Rules that fall within the scope of the agency's delegated authority and that comply with certain requirements have the force and effect of law.

March 13, 2024

A Brief Overview of the Federal Rulemaking Process in the United States

by King & Spaulding

RULEMAKING Process

- Administrative Procedure Act ("APA") of 1946
- Formal and informal process
  - (1) a statement of the time, place, and nature of public rulemaking proceedings;
  - (2) reference to the legal authority under which the rule is proposed; and
  - (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

CONGRESSIONAL OVERSIGHT AND JUDICIAL REVIEW OF FEDERAL RULEMAKING

- Congressional Review Act ("CRA"), for example, before any final rule can be effective, it must be filed with each house of Congress and the Government Accountability Office ("GAO") along with any cost-benefit analysis
- 60 days after Congress receives an agency's rule (excluding periods when Congress is in recess or adjournment), Congress can pass a joint resolution of disapproval and nullify the rule

The FDA's Proposed Rule on Laboratory-Developed Tests: Impacts on Clinical Laboratory Testing and Patient Care

Leslie Smith[1], Lisa A. Carricaburu[1], Jonathan R. Genzen[1,2*]

[1]ARUP Laboratories, Salt Lake City, UT, United States of America

[2]Department of Pathology, University of Utah Health, Salt Lake City, UT, United States of America

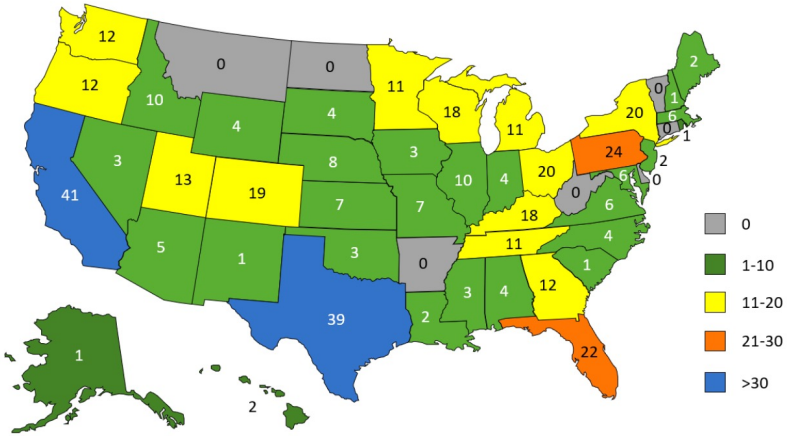
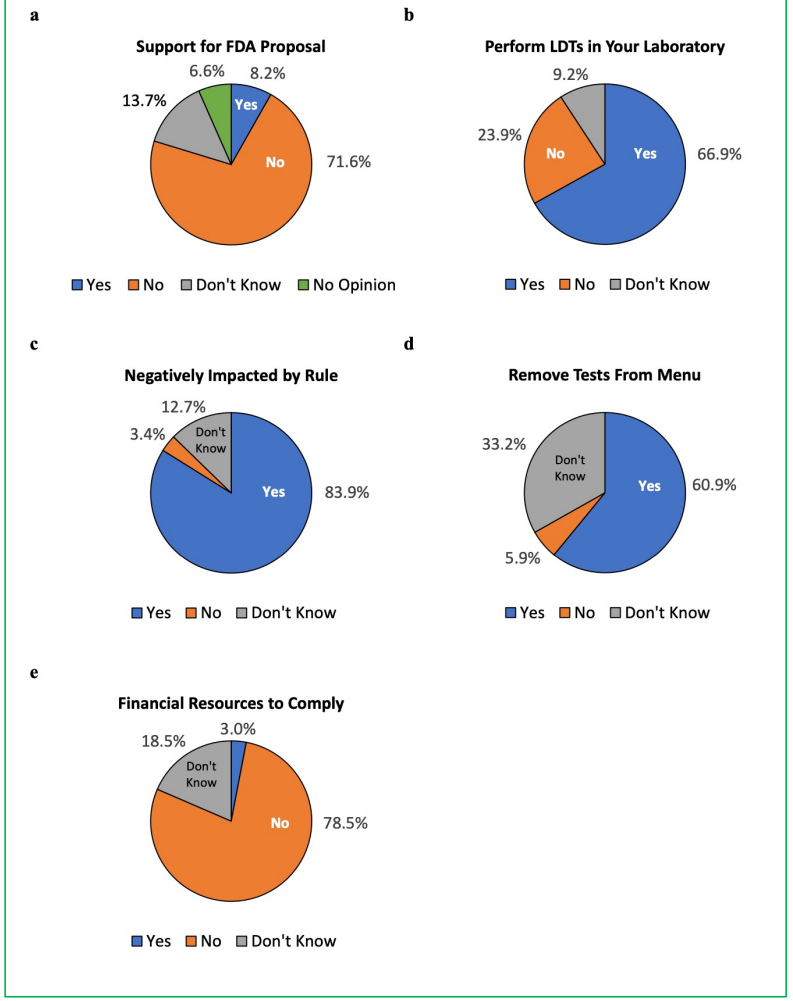


Fig. 1. Respondent institution by U.S. state. Map showing respondent institution by state (where available).



3/21/2024

ENERGY & COMMERCE
CHAIR RODGERS

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News / Press Release

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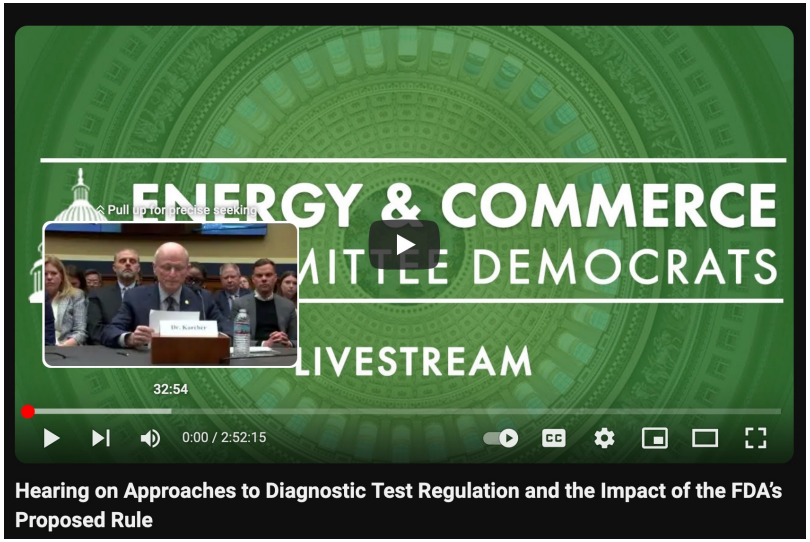
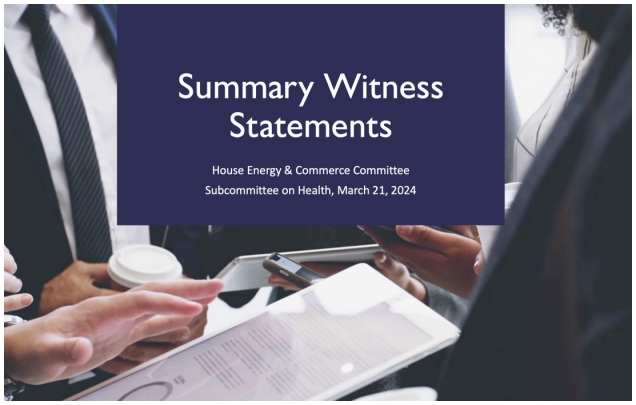
Chairs Rodgers and Guthrie Announce Health Subcommittee Hearing on Regulation of Diagnostic Tests

Mar 14, 2024 Press Release Health Hearings

Washington, D.C. — House Energy and Commerce Committee Chair Cathy McMorris Rodgers (R-WA) and Subcommittee on Health Chair Brett Guthrie (R-KY) today announced a subcommittee hearing titled "Evaluating Approaches to Diagnostic Test Regulation and the Impact of the FDA's Proposed Rule."



Hearing on Approaches to Diagnostic Test Regulation and the Impact of the FDA's Proposed Rule



Witnesses Subcommittee Hearing on Regulation of Diagnostic Tests

	Van Meer	Rothstein	Karcher	Allen	Aisner
FDA rule	−	+	−	+	−
VALID	+	+	+	+	−

03.13.2024

Ranking Member Cassidy Seeks Information from Stakeholders on Regulation of Clinical Tests

WASHINGTON – Today, U.S. Senator Bill Cassidy, M.D. (R-LA), ranking member of the Senate Health, Education, Labor, and Pensions (HELP) Committee, requested information from stakeholders on ways to improve regulation of clinical tests in the United States.

Clinical tests are essential health care resources, informing 70 percent of all clinical decisions through diagnosis, screening, staging, and managing of diseases and medical conditions. Since 1976, there have been no significant reforms to the regulation of clinical tests, even as new, innovative tests are being used in health care settings.

Recent efforts by the Food and Drug Administration to unilaterally pursue regulatory reforms through rulemaking go beyond its statutory authority and threaten patient access to timely care. Cassidy rebuked the Biden administration's executive overreach and its attempt to bypass Congress on this matter.

Cassidy hopes to use the feedback on how Congress can modernize current regulations to support innovation while ensuring these clinical tests are safe and effective to use. The deadline to submit feedback is April 3, 2024.

Read the full request here or below.

To Interested Parties:

Clinical diagnostics play a critical role in our health care system, influencing nearly 70% of all health care decisions. Diagnostic technologies are also the cornerstone of precision medicine and personalized therapies, and as such warrant oversight to ensure regulators are facilitating their continued progress, safety, and accuracy.

Stakeholders and policymakers broadly recognize the need for reform to the regulatory frameworks that oversee laboratory services and diagnostic products. In the nearly 50 years since the Medical Device Amendments (MDA) of 1976 established the Food and Drug Administration's (FDA) framework for medical devices, advancements in in vitro diagnostic (IVD) technologies have necessitated improvements to this framework to support timely patient access to safe and effective diganostics, especially those intended for special or rare disease populations. At the same time, clinical laboratory medicine has evolved in the 35 years since the Clinical Laboratory Improvement Amendments of 1988 (CLIA) were enacted, demanding standards that reflect advancements in molecular and genomic testing and ensure appropriate oversight over these tests.

In the past, Congress has considered proposals to bring needed reforms to diagnostics regulation. These efforts have been unsuccessful and have resulted in missed opportunities to implement substantive updates to both regulatory frameworks. To further guide ongoing discussion of these matters, I welcome your insights on the following topics, specifically addressing the actions Congress should pursue to meet the challenge of ensuring patient access to timely and advanced diagnostics. Please submit any responses to diagnostics@help.senate.gov by ***April 3, 2024*****.**

FDA Regulatory Framework for Diagnostics

1. *How well is FDA's medical device framework working fo improvements that should be made?*

1. *Of these specific changes, which would require Congre alone?*

2. *Does the current device regulatory framework support t that incorporate AI?*

3. *What, if anything, makes diagnostics distinct among FD attention to how AI may be used in the review of produ*

4. *Are the regulatory pathways intended to evaluate diagn genetic disorders) working?*
    a. *How could they be enhanced to accelerate and certain companion diagnostics for rare biomar*

5. *Are there regulatory hurdles to expanding the settings i (POC) tests performed in patients' homes?*

CLIA Regulatory Framework for LDTs

1. *What updates to the clinical laboratory regulatory structure latest scientific practices and safety standards?*

2. *What are your views on the effectiveness and use of the Cli (CLIAC) in providing scientific and technical guidance to in*

3. *Do the proficiency testing programs currently approved by t reflect the latest clinical standards of laboratory medicine? should receive greater consideration for HHS approval?*

4. *How well does the existing enforcement structure under CLIA requirements and taking action against noncompliance? W*

5. *Should legislative reforms address CLIA's quality system req require Congressional action, and which could be effectuat*

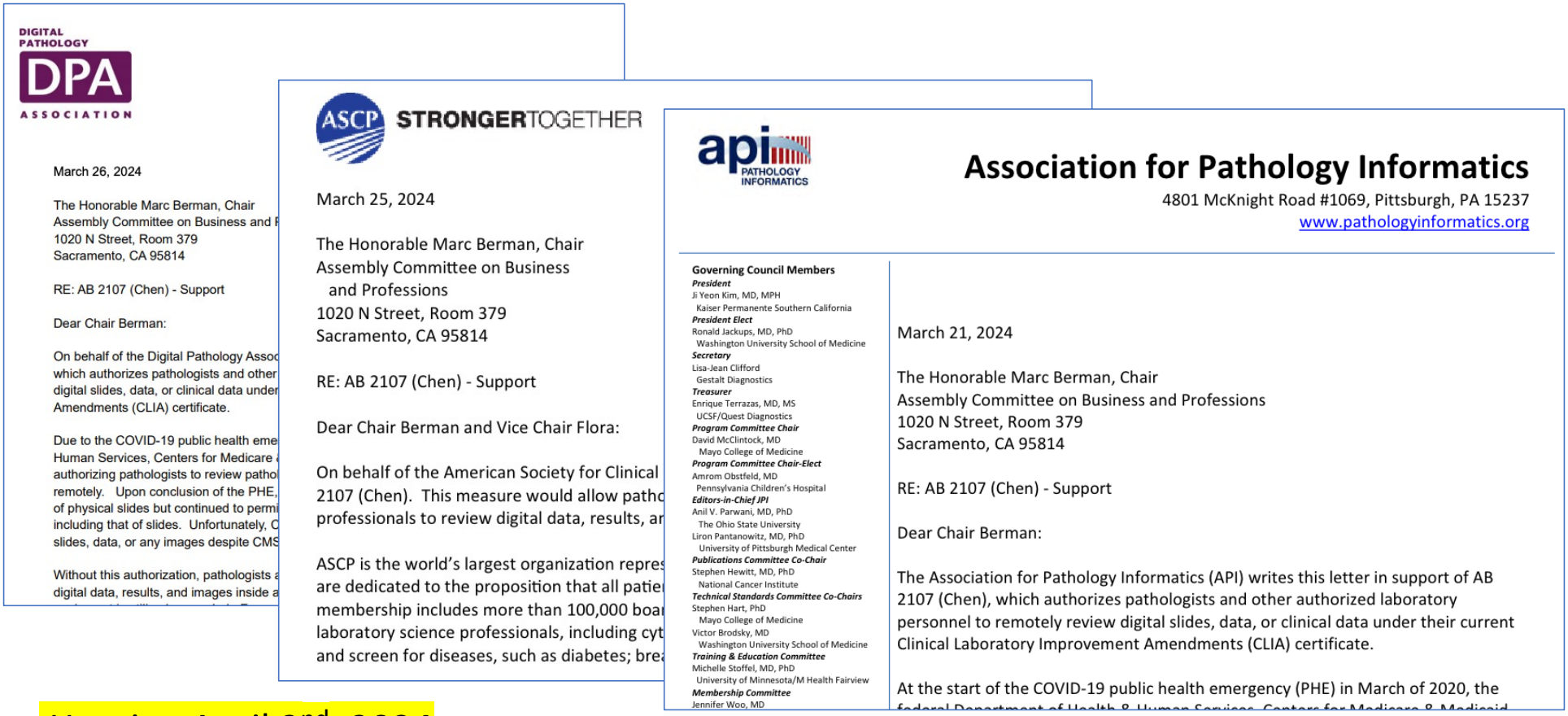
6. *Where does redundancy exist, if at all, within the current CL standards under federal and state licensure programs, as w organizations?*

7. *In considering legislative reforms to CLIA, should LDTs be d would characterize such a definition?*

8. *How should Congress consider issues relating to the practic LDTs? Should there be additional oversight of the informatic*

diagnostics@help.senate.gov by ***April 3, 2024***.

California => remote work (not allowed) => Bill AB 2107 SUPPORT LETTERs



DIGITAL PATHOLOGY ASSOCIATION

March 26, 2024

The Honorable Marc Berman, Chair
Assembly Committee on Business and
1020 N Street, Room 379
Sacramento, CA 95814

RE: AB 2107 (Chen) - Support

Dear Chair Berman:

On behalf of the Digital Pathology Assoc
which authorizes pathologists and other
digital slides, data, or clinical data under
Amendments (CLIA) certificate.

Due to the COVID-19 public health eme
Human Services, Centers for Medicare
authorizing pathologists to review pathol
remotely. Upon conclusion of the PHE,
of physical slides but continued to permi
including that of slides. Unfortunately, C
slides, data, or any images despite CMS

Without this authorization, pathologists
digital data, results, and images inside a

ASCP STRONGERTOGETHER

March 25, 2024

The Honorable Marc Berman, Chair
Assembly Committee on Business
and Professions
1020 N Street, Room 379
Sacramento, CA 95814

RE: AB 2107 (Chen) - Support

Dear Chair Berman and Vice Chair Flora:

On behalf of the American Society for Clinical
2107 (Chen). This measure would allow patho
professionals to review digital data, results, ar

ASCP is the world's largest organization repres
are dedicated to the proposition that all patie
membership includes more than 100,000 boa
laboratory science professionals, including cyt
and screen for diseases, such as diabetes; brea

api PATHOLOGY INFORMATICS

Association for Pathology Informatics

4801 McKnight Road #1069, Pittsburgh, PA 15237
www.pathologyinformatics.org

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National Cancer Institute
Technical Standards Committee Co-Chairs
Stephen Hart, PhD
Mayo College of Medicine
Victor Brodsky, MD
Washington University School of Medicine
Training & Education Committee
Michelle Stoffel, MD, PhD
University of Minnesota/M Health Fairview
Membership Committee
Jennifer Woo, MD

March 21, 2024

The Honorable Marc Berman, Chair
Assembly Committee on Business and Professions
1020 N Street, Room 379
Sacramento, CA 95814

RE: AB 2107 (Chen) - Support

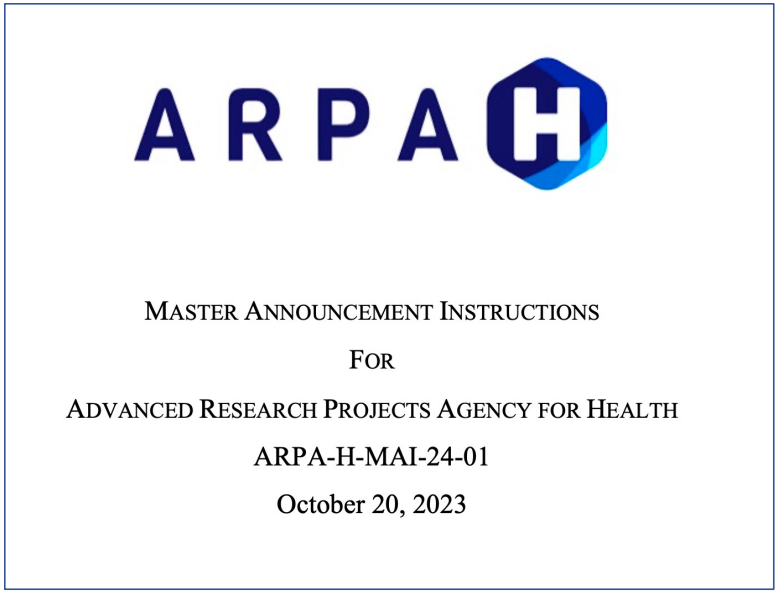
Dear Chair Berman:

The Association for Pathology Informatics (API) writes this letter in support of AB 2107 (Chen), which authorizes pathologists and other authorized laboratory personnel to remotely review digital slides, data, or clinical data under their current Clinical Laboratory Improvement Amendments (CLIA) certificate.

At the start of the COVID-19 public health emergency (PHE) in March of 2020, the

Hearing April 2nd, 2024

Cancer



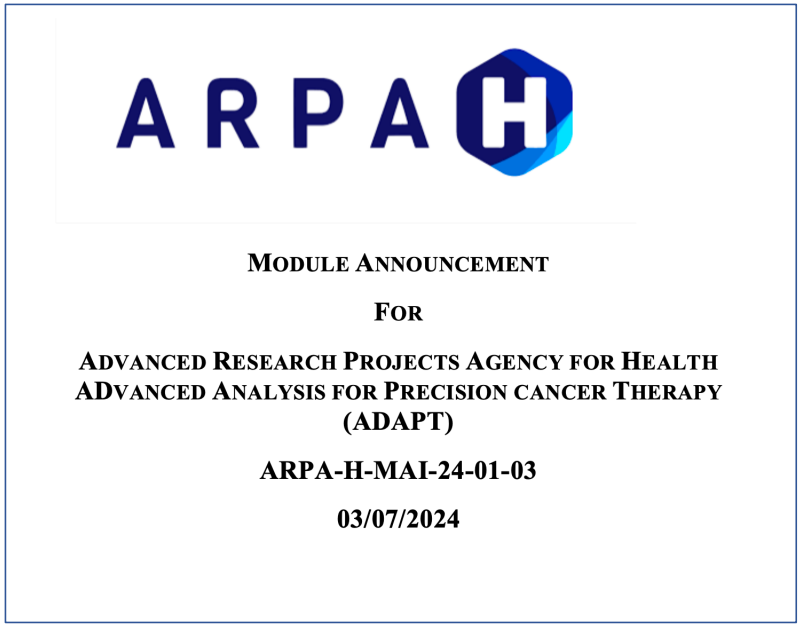
MASTER ANNOUNCEMENT INSTRUCTIONS

FOR

ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH

ARPA-H-MAI-24-01

October 20, 2023



MODULE ANNOUNCEMENT

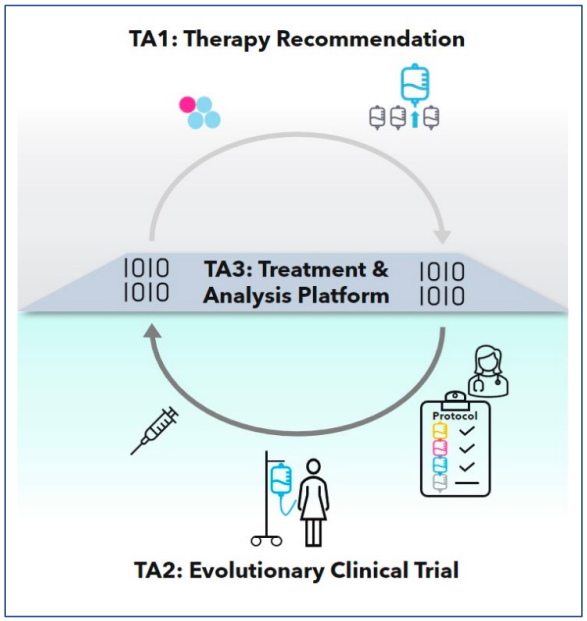
FOR

ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH
ADVANCED ANALYSIS FOR PRECISION CANCER THERAPY
(ADAPT)

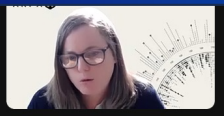
ARPA-H-MAI-24-01-03

03/07/2024

Figure 1. The ADAPT Program's TA1, TA2, and TA3 v

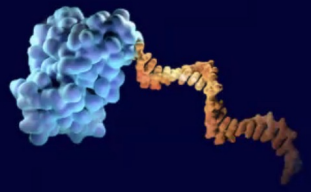


This cycle, from tumor measurement and analysis to biomarker development, testing, and implementation within the evolutionary trial, enables a new approach in the treatment of cancer patients where data rapidly, consistently, and accurately informs patient care.



Key Outcomes

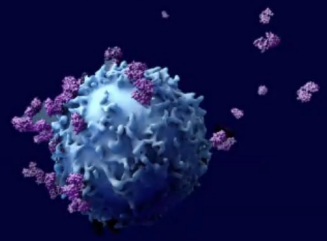
TA1: Therapy Recommendation Techniques



For the first time, a consistent mechanism will exist to build and clinically validate biomarkers for both standard of care and new therapies.

≥ 15 new biomarkers so that ≥ 90% of SOC therapies have an associated biomarker

TA2: Evolutionary Clinical Trial



Novel clinical trial design to implement biomarkers and treatment regimens targeting resistance and decrease cancer growth, leading to longer survival time.

> 50% improvement in Progression Free Survival time across multiple treatment arms

TA3: Cancer Treatment & Analysis Platform

Creation of an accessible data library and digital foundry for developing new therapeutic approaches and clinical trials.

95% of relevant clinical trial data available to the research and clinical community.

ARPA-H

Next Steps: Submit a Solution Summary

- The ADAPT Program just posted a Special Notice Request for Solution Summaries.
- A solution summary is an abstract submitted to an ARPA-H solicitation. A solution summary is not required to submit a full proposal to the ADAPT solicitation; however, it is **highly recommended** as it is an opportunity to receive "recommend full proposal submission" or "discourage full proposal submission" feedback from the ADAPT Program team.
- Solution summaries are due March 29, 2024, at 10:00 PM ET.

- Use the ARPA-H Solutions Portal at https://solutions.arpa-h.gov to submit your solution summary.

ARPA-H ADAPT Solicitation/Funding Opportunity Basics

Master Announcement Instructions (MAI) and APRA-H ADAPT Module Announcement

MAI is your manual and provides detailed instructions

MAI covers high-level instructions that are applicable to each Module Announcement

A Module Announcement provides project/ program specific technical details.

Module Announcement has unique instructions specific to the Module.

The Module Announcement will refer to the MAI; have both documents available while writing proposal responses.

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Evaluation Criteria, Stage 1

1 Overall Scientific and Technical Merit (Stage 1)
- Innovative, feasible, achievable, and complete
- An outcome that achieves the expected goals
- Technical risk(s) identification with a feasible mitigation strategy
- Intellectual Property (IP) rights structure; impact to Gov's ability to transition

2 Proposers' Capabilities and/or Related Experience (Stage 1)
- Team expertise and experience
- Experience in managing similar efforts

3 Potential Contribution and Relevance to the ARPA-H Mission (Stage 1)
- Future application, including unmet needs within biomedicine and to improve health outcomes
- Potential for interdisciplinary approach

ARPA-H ADAPT Module Announcement Basics

Notable Dates

- Module Announcement release date: 03/08/2024
- Virtual Proposers' Day: 03/15/2024
- Questions & Answers (Q&A) due date: 03/22/2024
- Questions & Answers (Q&A) release date: 04/01/2024
- Solution Summary Due: 03/29/2024
- Proposal due date: 05/06/2024

Program Schedule

- 6-year effort composed of 2 Phases
- Phase 1 is divided into 2 Stages:
  - 6-month Stage 1
  - 30-month Stage 2
- Phase 2 is 36-months
  - Phase 2 is contingent upon approval by ARPA-H leadership

Open-Source Standards

- Emphasis in creating and leveraging open-source technology and architecture
- IP rights asserted should be aligned with open-source regimes
  - Approaches that don't reflect open-source standards should describe how program objectives can be met with IP rights that are restrictive

Software Component Standards

- Existing Standards
- Existing Standard – only partial functionality
  - Do NOT prohibit or interfere with backward compatibility, and create sufficient documentation
- Include a technical plan to align with applicable standards
- Solutions outside the standards – Proposer must schedule a meeting with ARPA-H representatives to discuss the deviation prior to proposal submission

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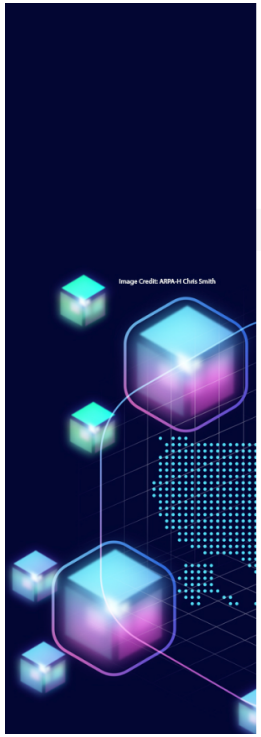
Evaluation Criteria, Stage 2

4 Price and Value Analysis/Cost Realism/Reasonableness (Stage 2)
- Price Reasonableness - Ensure the overall price is fair and reasonable (e.g., not too high no too low)
- Do prices reflect the technical goals and objectives of the solicitation and the proposed scope of work
- Value Analysis – what is the value of the research in comparison to the proposed price



ARPA-H
Investor Catalyst Hub
PART OF THE ARPANET-H HEALTH INNOVATION NETWORK

Home Register

ARPA-H/FDA CDRH: Medical Imaging Data Marketplace

Network Survey Information Session

Join us for an information session with Ileana Hancu, Ph.D, ARPA-H, and Aldo Badano, FDA CDRH

ARPA-H and FDA CDRH request feedback in the newly launched Network Survey for the Medical Imaging Data Marketplace (MIDM)!

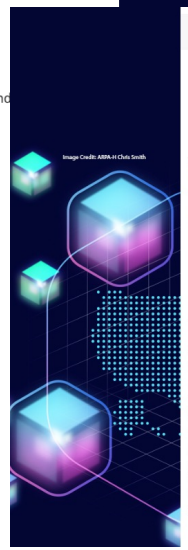
Save your seat now for the chance to learn more from ARPA-H and FDA representatives, including Dr. Ileana Hancu, ARPA-H Program Manager, and Aldo Badano, Division of Imaging, Diagnostics, and Software Reliability, Office of Science and Engineering Laboratories, CDRH, about this newly launched partnership. The information session will describe the MIDM concept, focus areas, and details of the Network Survey. **Medical imaging data users, managers, and providers** are encouraged to attend to learn more and have the opportunity to ask questions about their important role in this new initiative.

Event Info

What: Medical Imaging Data Marketplace - Network Survey Information Session
When: April 1, 1:00 - 2:00 p.m. ET
How to register: Click the button below to save your seat
Who should attend: Open to all. Medical imaging data users, managers, and providers are encouraged to attend

Register

Monday, April 1, 1:00 - 2:00 p.m. ET.



Home Register

1 Your Information
2 Confirmation

Thanks For Registering

We look forward to seeing you at the information session.

Modify Registration
Add To Calendar

Registrant Details

Full Name	Email Address	Registrant Type
Dr. Joe Lennerz	joe.lennerz@bostongene.com	

About the Medical Imaging Data Marketplace

The Advanced Research Projects Agency for Health (ARPA-H) and the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) are partnering to streamline access to affordable, high-quality, regulatory-ready medical imaging data. The agencies are exploring the development of a medical imaging data marketplace (MIDM) to expedite innovation in Software as a Medical Device (SaMD) and other artificial intelligence (AI)/machine learning (ML)-enabled medical devices.

The MIDM is the first joint effort between ARPA-H and the FDA, bringing each agency's unique expertise to address common barriers to innovation and efficient pre-market review of AI-enabled medical devices and Software as a Medical Device (SaMD). AI and SaMD are growing categories in an increasingly digital health care environment. The MIDM effort will include developing new tools that may give users of the marketplace greater confidence that the data accessed will adhere to the regulatory requirements for future pre-market authorizations. Within CDRH, the Office of Science and Engineering Labs (OSEL) will develop and establish the operating procedures and governance structure for the MIDM.

Call for Feedback!

ARPA-H FDA/CDRH Medical Imaging Data **Marketplace**

- *A self-sustaining, federated, national marketplace to catalyze transformative medical and health AI innovations*

Call for Feedback!

ARPA-H FDA/CDRH Medical Imaging Data **Marketplace**

- *A self-sustaining, federated, national marketplace to catalyze transformative medical and health AI innovations*

- Network survey to provide feedback
  - https://investorcatalysthub.org/medical-imaging/

- Email for more Information:
  - midm@arpa-h.gov