Plcc Alliance

Home About Working Groups News & Events Resources Presentations Projects Publications

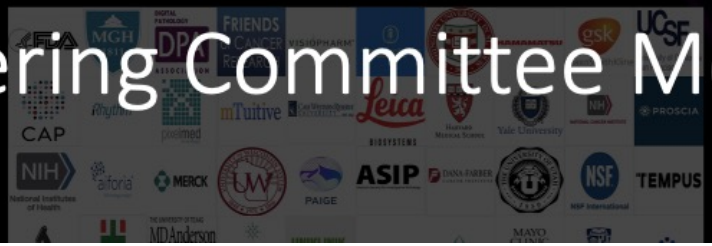
Join

Pathology Innovation Collaborative Community

Plcc

The Alliance for Digital Pathology

A collaborative community with FDA participation



Steering Committee Meeting

April 2024

FDA

MILESTONE: Two recent cleared WSI devices creating/using DICOM images

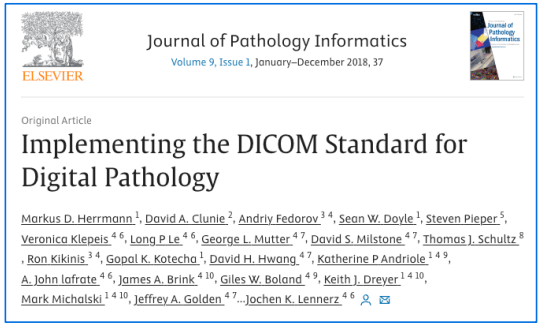
First WSI System (Philips)

April 2017

Not DICOM

"Implementing the DICOM Standard for Digital Pathology"

Nov 2018



ELSEVIER

Journal of Pathology Informatics

Volume 9, Issue 1, January–December 2018, 37

Original Article

Implementing the DICOM Standard for Digital Pathology

Markus D. Herrmann [1], David A. Clunie [2], Andriy Fedorov [3 4], Sean W. Doyle [1], Steven Pieper [5], Veronica Klepeis [4 6], Long P Le [4 6], George L. Mutter [4 7], David S. Milstone [4 7], Thomas J. Schultz [8], Ron Kikinis [3 4], Gopal K. Kotecha [1], David H. Hwang [4 7], Katherine P Andriole [1 4 9], A. John Iafrate [4 6], James A. Brink [4 10], Giles W. Boland [4 9], Keith J. Dreyer [1 4 10], Mark Michalski [1 4 10], Jeffrey A. Golden [4 7]...Jochen K. Lennerz [4 6]

FDA NEWS RELEASE

FDA allows marketing of first whole slide imaging system for digital pathology

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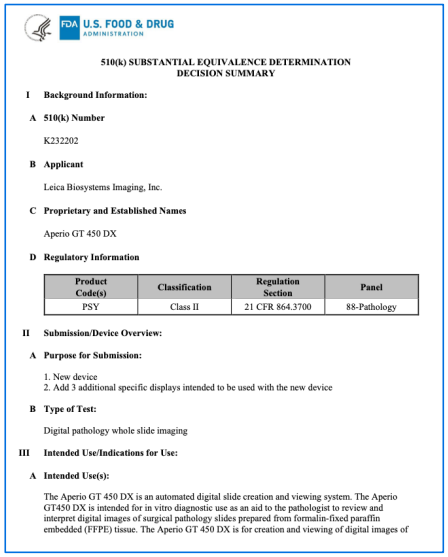
For Immediate Release: April 12, 2017

April 23rd 2024

Leica's new WSI scanner GT-450 DX



U.S. FOOD & DRUG ADMINISTRATION

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K232202

B Applicant

Leica Biosystems Imaging, Inc.

C Proprietary and Established Names

Aperio GT 450 DX

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PSY	Class II	21 CFR 864.3700	88-Pathology

II Submission/Device Overview:

A Purpose for Submission:

1. New device
2. Add 3 additional specific displays intended to be used with the new device

B Type of Test:

Digital pathology whole slide imaging

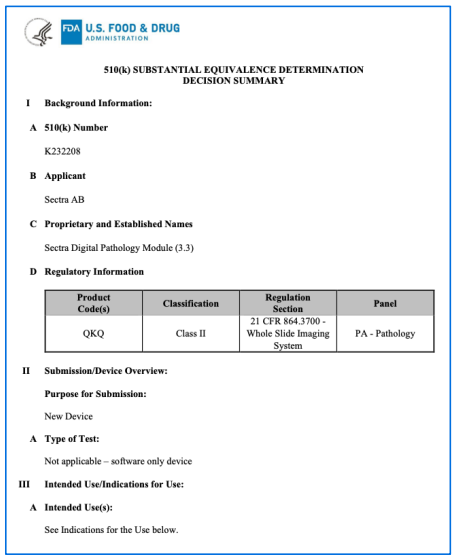
III Intended Use/Indications for Use:

A Intended Use(s):

The Aperio GT 450 DX is an automated digital slide creation and viewing system. The Aperio GT450 DX is intended for in vitro diagnostic use as an aid to the pathologist to review and interpret digital images of surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. The Aperio GT 450 DX is for creation and viewing of digital images of

April 23rd 2024

Sectra's DICOM WSI viewer



U.S. FOOD & DRUG ADMINISTRATION

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K232208

B Applicant

Sectra AB

C Proprietary and Established Names

Sectra Digital Pathology Module (3.3)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QKQ	Class II	21 CFR 864.3700 - Whole Slide Imaging System	PA - Pathology

II Submission/Device Overview:

Purpose for Submission:

New Device

A Type of Test:

Not applicable – software only device

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for the Use below.

Sectra Digital Pathology Module (3.3) is intended for use with Leica's Aperio GT 450 DX scanner and Dell U3223QE display, for viewing and management of the ScanScope Virtual Slide (SVS) and Digital Imaging and Communications in Medicine (DICOM) image formats.

Aperio GT 450 DX is comprised of the Aperio GT 450 DX scanner, which generates images in the Digital Imaging and Communications in Medicine (DICOM) and in the ScanScope Virtual Slide (SVS) file formats, the Aperio WebViewer DX viewer, and the displays. The Aperio GT 450 DX is intended to be used with the interoperable components specified in Table 1.

Table 1: Interoperable components of Aperio GT 450 DX

Scanner Hardware	Scanner Output file format	Interoperable Viewing Software	Interoperable Displays
Aperio GT 450 DX scanner	SVS	Aperio WebViewer DX	Barco MDPC-8127 Dell UP3017 Dell U3023E Dell U3223QE
Aperio GT 450 DX scanner	SVS	Sectra Digital Pathology Module (3.3)	Dell U3223QE
Aperio GT 450 DX scanner	DICOM	Sectra Digital Pathology Module (3.3)	Dell U3223QE

The Aperio GT 450 DX is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using the Aperio GT 450 DX.

Table 1: Interoperable Components Intended for Use with Sectra Digital Pathology Module (3.3)

Scanner Hardware	Scanner Output file format	Interoperable Viewing Software	Interoperable Display
Aperio GT 450 DX scanner	SVS	Sectra Digital Pathology Module (3.3)	Dell U3223QE
Aperio GT 450 DX scanner	DICOM	Sectra Digital Pathology Module (3.3)	Dell U3223QE

Vision

CDRH Mission, Vision and Shared Values

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January 17, 2024: CDRH 2023 Annual Report Now Available: The report highlights CDRH's banner year for novel medical device authorizations, cybersecurity, mammography, digital health, and more.

MISSION:

PDF Printer Version (159 KB)

The mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote the public health. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

CDRH 2023 Annual Report

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Each year, the FDA's Center for Devices and Radiological Health (CDRH) publishes an Annual Report to highlight programmatic accomplishments. The 2023 Annual Report captures CDRH's banner year for novel medical device authorizations, cybersecurity, mammography, digital health, and more.

Read the Report (PDF - 11MB)

2024 CDRH Innovation Report

CDRH is
and innov

FDA U.S. FOOD & DRUG ADMINISTRATION

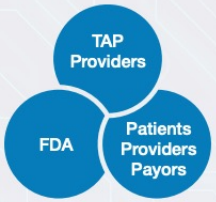
Center for Devices and Radiological Health

Collaborating with Innovators

We have long recognized that making our regulatory programs more effective, efficient, and predictable is only part of the puzzle, as innovators face a variety of challenges, including payor coverage and reimbursement. The road from concept to commercialization is fraught with obstacles, which is why it has often been called the "Valley of Death."

Over the years, we have increasingly taken actions to help innovators navigate various aspects of this challenging process that impact people's access to important medical devices. In early 2023, we launched a pilot of our **Total Product Life Cycle Advisory Program (TAP)** to proactively help innovators navigate the journey from concept to commercialization, making it more predictable, efficient, and timely. We expanded the program in the fall of 2023 and plan to continue enrolling more innovators and their devices into TAP, with a goal of enrolling up to 325 by 2027.

43
TAP devices and counting



- **Better Evidence Strategy for Faster Commercialization.**
- **Accepted Devices Qualify for Priority Review.**
- **Enables Strategic Relationship Building throughout the Device Ecosystem.**
- **Expedites Innovation.**
- **Facilitates High-speed FDA Interactions.**

CDRH Issues 2024 Safety and Innovation Reports

Reports highlight CDRH actions to advance medical device safety and innovation build on these efforts this year.

FOR IMMEDIATE RELEASE
April 17, 2024

The following is attributed to Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health (CDRH)

Today, CDRH is issuing two companion reports that detail the Center's commitment to further advance our core pillars of safety and innovation. The CDRH 2024 Safety Report is an update to our 2018 Medical Device Safety Action Plan and features steps we have taken in recent years to assure the safety of medical devices keeps pace with the evolving technology. The CDRH 2024 Innovation Report highlights our work to advance innovation and the progress we have made to make the U.S. market more attractive to top device developers.

ADVISORY COMMITTEE MEETING | MIXED

April 12, 2024 Meeting of the Oncologic Drugs Advisory Committee Meeting Announcement

APRIL 12, 2024

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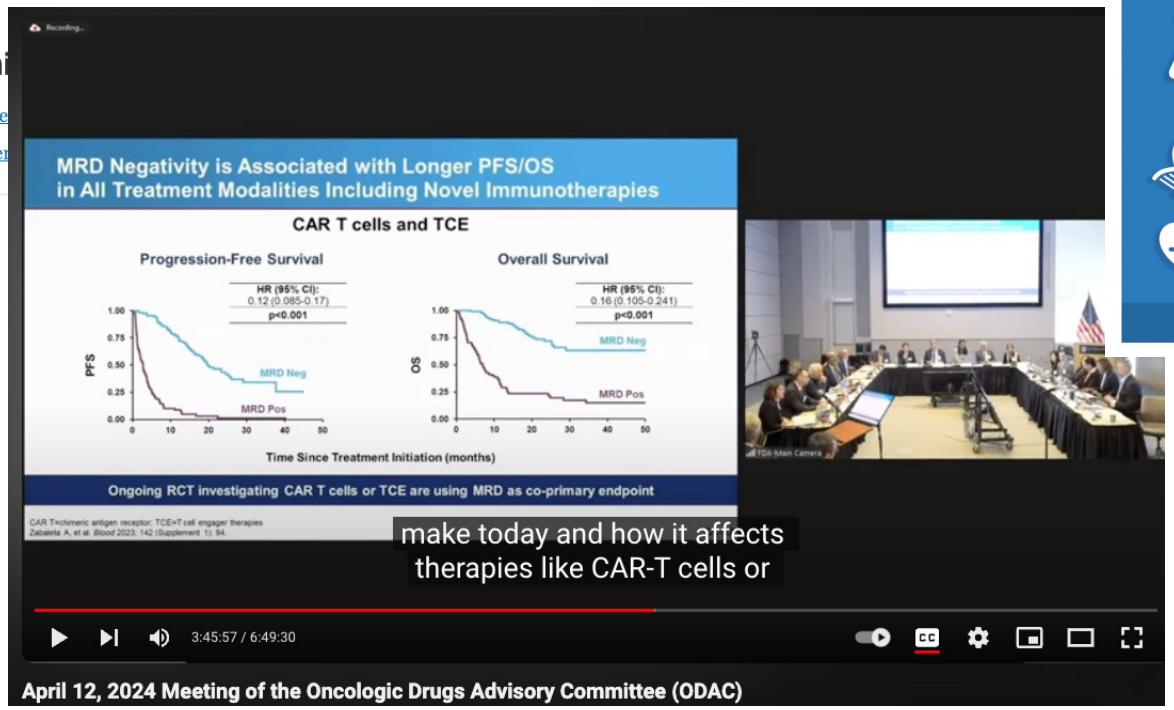
On Thi

- Mee
- Even

Date:

Time:



Advisory Committees Give FDA Critical Advice and the Public a Voice

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Please call the Information Line for up-to-date information on this hearing.

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Email: *fdaoma@fda.hhs.gov* or 301–796–4540

Medical Device Development Tools (MDDT)

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

Update: October 17, 2023

The FDA's Center for Devices and Radiological Health and the National Institutes of Health's (NIH's) National Cancer Institute are collaborating to support the small business community in developing innovative medical device development tools (MDDTs) through a new funding opportunity.

NIH/National Cancer Institute

Topic 460 - NIH/NCI 460 – Evaluation Datasets as Medical Device Development Tools for Testing Cancer Technologies

The funding opportunity is available for small businesses through **November 14, 2023**.

CDRH Unveils New Dataset to Help Improve Chemical Characterization Methods for Biocompatibility of Medical Devices

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FOR IMMEDIATE RELEASE
April 16, 2024

The following is attributed to Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health (CDRH) and Ed Margerrison, Ph.D., director of the Office of Science and Engineering Laboratories (OSEL), CDRH

Content current as of:
04/16/2024

Regulated Product(s)
Medical Devices

Tool (Link to SEBQ)	Product Area(s)	MDDT Category	Date Qual
The University of California San Francisco (UCSF) Lethal Arrhythmia Database (LAD)	Cardiology, Patient Monitoring	Other	03/2
Accelerated Testing to Prove Long-Term Material Biostability	Biostability	Non-clinical Assessment Model	08/0
Computational Tool Comprising Visible Human Project Based Anatomical Female CAD Model and Ansys HFSS/Mechanical FEM Software for Temperature Rise Prediction near an Orthopedic Femoral Nail Implant during a 1.5 T MRI Scan	Orthopedic, MR Safety Labeling	Non-clinical Assessment Model	03/3
CHemical RISk Calculator (CHRIS) - Color Additives	Toxicology, Biocompatibility	Non-clinical Assessment Model	11/2

Data as a Tool

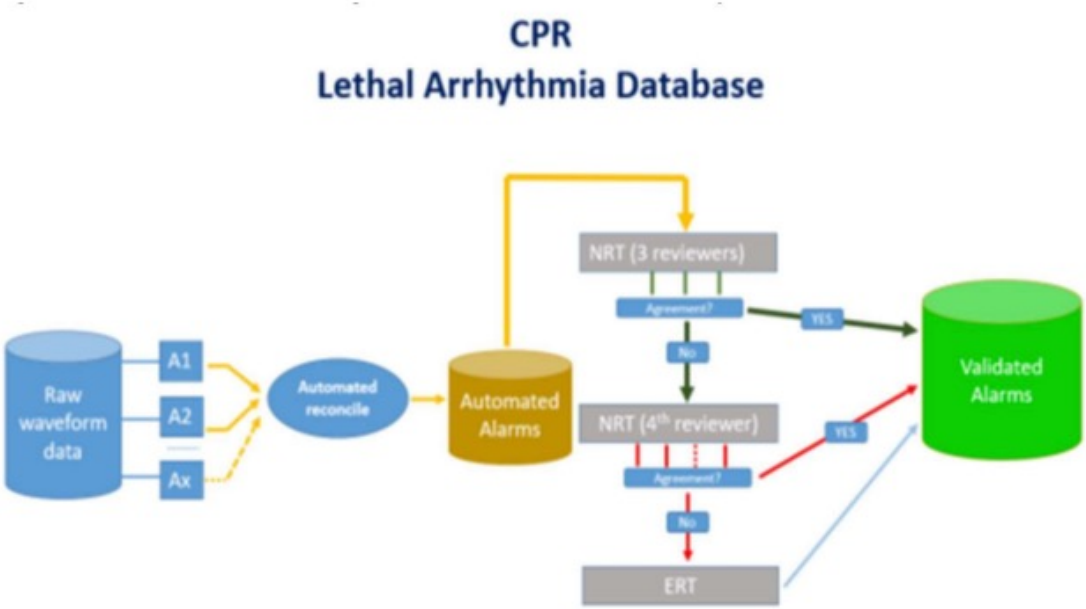

Figure 1. Overview of Validating Annotations in the Lethal Arrhythmia Database

MDDT Summary of Evidence and Basis of Qualification for

The University of California San Francisco (UCSF) Lethal Arrhythmia Database (LAD)

BACKGROUND

MDDT NAME: The University of California San Francisco (UCSF) Lethal Arrhythmia Database (LAD)

SUBMISSION NUMBER: U220727

DATE OF SUBMISSION: October 3rd, 2023

CONTACT: Fabio Badilini, Director Center for Physiologic Research
Center for Physiologic Research,
Division of Cardiology, University of California San Francisco,
505 Parnassus Avenue, Room M1182A, Box 0124
San Francisco, CA 94143-0124
Email: fabio.badilini@ucsf.edu

TOOL DESCRIPTION AND PRINCIPLE OF OPERATION

The University of California San Francisco (UCSF) Lethal Arrhythmia Database (LAD) Medical Device Development Tool (MDDT) version 1.X.X is designed to test and report the performance of computerized methods to detect lethal cardiac arrhythmias in patient monitoring systems. USCF LAD is composed of a set of digital signals (ECG waveforms, SpO2, invasive arterial blood pressure and transthoracic impedance recordings), acquired in consecutive patients admitted to an Intensive Care Unit (ICU) which includes a large set of annotated lethal cardiac arrhythmias, specifically: asystole

Catalog of Regulatory Science Tools to Help Assess New Medical Devices

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Update: January 12, 2024: The FDA is providing an updated Regulatory Science Tool (RST) Catalog that will provide additional tool search capability allow for additional capacity as the catalog continues to grow.

Regulatory Science Tools Catalog

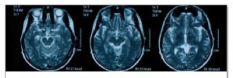
Tools Categories

- Lab Method (22)
- Computer Model (20)
- Dataset (5)
- Phantom (2)
  - Physical (1)
- Clinical Outcome Assessment (1)

Program Areas

- Cardiovascular (15)
- Medical Imaging and Diagnostics (12)
- Orthopedic Devices (8)
- Biocompatibility and Toxicology (6)
- Credibility of Computational Models (5)
- Materials and Chemical Characterization (5)
- Neurology (5)
- AI / Machine Learning (2)
- Electromagnetic and Electrical Safety (2)
- Ophthalmology (2)
- Patient Monitoring and Control (2)
- Post Market Signal Response (2)

Search Tool Catalog | Search

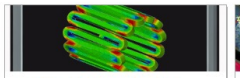


Photoacoustic Imaging Phantoms for Assessing Image Quality and Oximetry Performance

Phantom

This regulatory science tool presents a set of tissue-mimicking phantoms suitable for benchtop performance assessment of photoacoustic imaging...

Medical Imaging and Diagnostics



Workflow for Assessing the Credibility of Patient-Specific Modeling in Medical Device...

Computer Model | Lab Method

This regulatory science tool presents a method for assessing credibility of patient-specific computational models implemented in medical device software.

Credibility of Computational Models

TSL/EED/MOS (TEEM) Calculator

Lab Method

This regulatory science tool is a method that applies the ISO 10993-17 toxicological risk assessment approach to medical device extractables screenin...

Biocompatibility and Toxicology

Chemicals List for Analytical Performance (CLAP)

Dataset | Lab Method

Chemicals List for Analytical Performance (CLAP)

Biocompatibility and Toxicology | Materials and Chemical Characterization

Benchmark Validation Da... Laminar Flow in an Anato... Vascular Model of the Inf...

Dataset

This tool provides a benchmar... data set for laminar flow in an...

Regulatory Science Tools Catalog

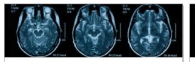
Search Tool Catalog | Search

Photoacoustic Imaging Phantoms for Assessing Image Quality and Oximetry Performance

Phantom

This regulatory science tool presents a set of tissue-mimicking phantoms suitable for benchtop performance assessment of photoacoustic imaging...

Medical Imaging and Diagnostics

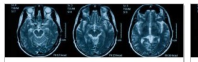


VICTRE: In Silico Breast Imaging Pipeline

Computer Model

The Virtual Imaging Clinical Trials for Regulatory Evaluation (VICTRE) computer modeling pipeline is a set of tools that allow for the replication of clinical trials...

Medical Imaging and Diagnostics

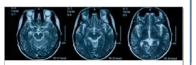


The Virtual Family: A set of anatomically correct whole-body computational models

Computer Model

The Virtual Family provides detailed three-dimensional computational models of the human anatomy including an adult male, an adult female, and two children

Orthopedic Devices | Ophthalmology | Neurology | Medical Imaging and Diagnostics | Electromagnet...



MIDA: A Multimodal Imaging-Based Model of the Human Head and Neck

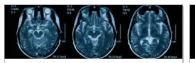
Computer Model

A tool to generate computational scientific evidence as alternative approaches to clinical

Orthopedic Devices | Ophthalmology | Neurology | Medical Imaging and Diagnostics | Electromagnet...

Method for Assessing Texture Reproduction of Camera-phone-based Medical Devices

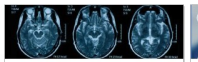
Lab Method



MCGPU: GPU-accelerated Monte Carlo X-ray Imaging Simulator

Computer Model

MC-GPU is a Monte Carlo simulation code



LCD-CT: Low-contrast Detectability (LCD) Test for Assessing Advanced Nonlinear C...

Lab Method

iMRMC: Software to do Multi-reader Multi-case Statistical Analysis of Reader Studies

Computer Model

About Manufacturer and User Facility Device Experience (MAUDE)

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Content current as of:
04/16/2024

Regulated Product(s)
Medical Devices
Radiation-Emitting Products

Topic(s)
Postmarket

On this page:

- Description of the MAUDE Database
- Limitations of Medical Device Reports (MDRs)
- Descriptions of Fields in the MAUDE database

Description of the MAUDE Database

The Manufacturer and User Facility Device Experience (MAUDE) database contains medical device reports (MDRs) of adverse events. To further promote transparency, the FDA has begun providing additional information in the MAUDE database, such as device and patient problems and patient demographic information. The FDA will continue to seek ways to improve the MAUDE database and the availability of MDR information.

The MAUDE database:

- Contains the last ten years of MDR da
- Will be updated every month to inclu
previous month.

MAUDE Data Downloadable Files

This section provides downloadable zipped data files that consist of:

- Voluntary reports since June 1993
- User facility reports since 1991
- Distributor reports since 1993
- Manufacturer reports since August 1996

This data is provided in zip files, which are updated monthly.

The MDR data is presented in tables and contains all publicly available information from the completed the MEDWATCH Form 3500. The FDA recommends downloading all types of files for the time period of interest.

Tip for Downloading Files

- When downloading the MDR data files to a database such as Microsoft Access, we recommend that you first open, then save the data file in Microsoft WORD. This will add an "end of record" marker to each MDR record that can be recognized by Microsoft ACCESS. For files such as the FOIDEV files, you may need to put in an extra character at the end of the first record prior to importing the file, otherwise the last column of data may be lost.

The following files are available: (File Sizes are approximate)

File Name	Compressed Size in Bytes	Uncompressed Size in Bytes	Total Records	Description
mdrfoi.zip	20019KB	185430KB	586204	MAUDE Base records received to date for 2024
mdrfoithru2023.zip	598951KB	5800337KB	18118160	Master Record through 2023
mdrfoiadd.zip	6664KB	61873KB	196195	New MAUDE Base records for the current month.
mdrfoichange.zip	29532KB	238353KB	720130	MAUDE Base data updates: changes to existing Base data.
patient.zip	3347KB	24846KB	585380	MAUDE Patient records received to date for 2024
patientthru2023.zip	95313KB	687674KB	18104231	Patient Record through 2023
patientadd.zip	1119KB	8341KB	196146	New MAUDE Patient records for the current month.
patientchange.zip	3612KB	23763KB	560810	MAUDE Patient data updates: changes to existing Base data.
patientproblemcode.zip	132307KB	1277965KB	18544264	MAUDE Patient records for problemcode
patientproblemdata.zip	11KB	25KB	998	Patient Problem Data
foidevthru1997.zip	6001KB	31217KB	136917	Device Data through 1997
foidev1998.zip	3205KB	17539KB	63440	Device Data for 1998
foidev1999.zip	2764KB	14798KB	52880	Device Data for 1999
device2000.zip	1932KB	9998KB	53114	Device Data for 2000
device2001.zip	2126KB	11075KB	59073	Device Data for 2001
device2002.zip	2321KB	12967KB	70384	Device Data for 2002
device2003.zip	2527KB	14242KB	77949	Device Data for 2003
device2004.zip	2803KB	14944KB	82887	Device Data for 2004
device2005.zip	3350KB	17711KB	99770	Device Data for 2005
device2006.zip	3966KB	21308KB	120486	Device Data for 2006
device2007.zip	4820KB	30277KB	172205	Device Data for 2007
device2008.zip	5521KB	34034KB	195474	Device Data for 2008
device2009.zip	6724KB	43739KB	243108	Device Data for 2009
device2010.zip	8724KB	56054KB	304407	Device Data for 2010
device2011.zip	11585KB	80802KB	446880	Device Data for 2011

Comment on Proposed Regulations and Submit Petitions

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Making Your Voice Heard at FDA

Submit Comments Online

You can submit your comments on many of FDA's proposed regulations at Regulations.gov

(See Instructions for using Regulations.gov)

Proposed Rules | Comment Online | Petitions

As a regulatory agency, FDA publishes rules that establish or modify the way it regulates foods, drugs, biologics, cosmetics, radiation-emitting electronic products, and medical devices--commodities close to the daily lives of all Americans. FDA rules have

CDRH Petitions

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A petition is a way for individuals, regulated industry or consumer groups to petition the agency to issue, change or cancel a regulation, or to take other action. The agency receives about 200 petitions yearly.

Additional information about petitions can be found on the page: **Making Your Voice Heard at FDA: How to Comment on Proposed Regulations and Submit Petitions**

Note: All documents are in PDF format.

CDRH Petitions

Search: Export Excel Show 25 entries

Docket #	Petitioner	Subject	Date Filed	Date of Interim Response(s)	Completion of Petition
FDA-1994-P-0023	MiniMed Technologies	Implantable infusion pump for insulin	07/15/1994	03/21/2003	12/02/2004
FDA-2001-A-0410	PA Department of Health	Collection kits marketed by the Osborn Group, Inc.	08/30/2001	04/04/2002	

AGILE REGULATION
MORE ON THE CONCEPT

- **Agile Regulation Framework**: A flexible approach for regulators to adapt quickly to change, integrating agile processes and flexible regulations.
- **Improvement Categories**: Focus areas include enhancing internal processes, refining regulatory design, and promoting continuous learning within regulatory agencies.
- **Implementation Strategies**: Addressing challenges like resource constraints, strategies include fostering innovation through leadership, leveraging small teams, and integrating AI. Ideas like rethinking regulator-regulated entity relationships and promoting continuous feedback were discussed for enhanced agility.

Summary: Discussing Agile Regulation

March 5, 2024

Authored by:
Dylan Desjardins
More coverage from the "Building On Regulatory Foundations" event

On November 16, 2023, the George Washington University Regulatory Studies Center and the IBM Center for the Business of Government co-hosted an event, *Building on Regulatory Foundations and Bridging to the Future*, commemorating the 30th anniversary of Executive Order 12866 and 20th anniversary of Circular A-4. The event featured several breakout sessions, including one focused on agile regulation—a framework regulators can use to manage change at speed and scale.[1]

Update CDS vs. Device

Your Clinical Decision Support Software: Is It a Device?

FDA

The FDA issued a guidance, Clinical Decision Support Software, to describe the FDA's regulatory approach to Clinical Decision Support (CDS) software functions. This graphic gives a general and summary overview of the guidance and is for illustrative purposes only. Consult the guidance for the complete discussion and examples. Other software functions that are not listed may also be device software functions. *

Your software function must meet all four criteria to be Non-Device CDS.

Summary interpretation of CDS criteria

1. Your software function does **NOT** acquire, process, or analyze medical images, signals, or patterns.
2. Your software function displays, analyzes, or prints medical information normally communicated between health care professionals (HCPs).
3. Your software function provides recommendations (information/options) to a HCP rather than provide a specific output or directive.
4. Your software function provides the basis of the recommendations so that the HCP does not rely primarily on any recommendations to make a decision.

Your software function may be non-device CDS.

Non-Device Examples

Non-Device examples display, analyze, or print the following examples of medical information, which must also not be images, signals, or patterns:

- Information whose relevance to a clinical decision is well understood
- A single discrete test result that is clinically meaningful
- Report from imaging study

AND

Non-Device examples provide:

- Lists of preventive, diagnostic, or treatment options
- Clinical guidelines matched to patient-specific medical info
- Relevant reference information about a disease or condition

AND

Non-Device examples provide:

- Plain language descriptions of the software purpose, medical input, underlying algorithm
- Relevant patient-specific information and other knowns/unknowns for consideration

Device Examples

Device examples acquire, process, or analyze:

- Signal acquisition systems
- In vitro diagnostics
- Magnetic resonance imaging (MRI)
- Next Generation Sequencing (NGS)
- Continuous Glucose Monitoring (CGM)
- Computer aided detection/diagnosis (CADe/CADx)

OR

Device examples display, analyze or print:

- Continuous signals/patterns
- Medical images
- Waveforms (ECG)
- More continuous sampling (aka – a signal or pattern)

OR

Device examples provide:

- Risk scores for disease or condition
- Probability of disease or condition
- Time-critical outputs

OR

Device examples:

- Basis of recommendations is not provided

Your software function is a device.

***Disclaimer:** This graphic gives a general overview of Section IV of the guidance ("Interpretation of Criteria in Section 520(o)(1)(E) of the FD&C Act"). Consult the guidance for the complete discussion. The device examples identified in this graphic are illustrative only and are not an exhaustive list. Other software functions that are not listed may also be device software functions.

D.C. UPDATES

OIRA Conclusion of EO 12866 Regulatory Review

RIN: 0910-AI85 **View EO 12866 Meetings**
Title: Medical Devices; Laboratory Developed Tests
Agency/Subagency: HHS / FDA
Concluded Action: Consistent with Change

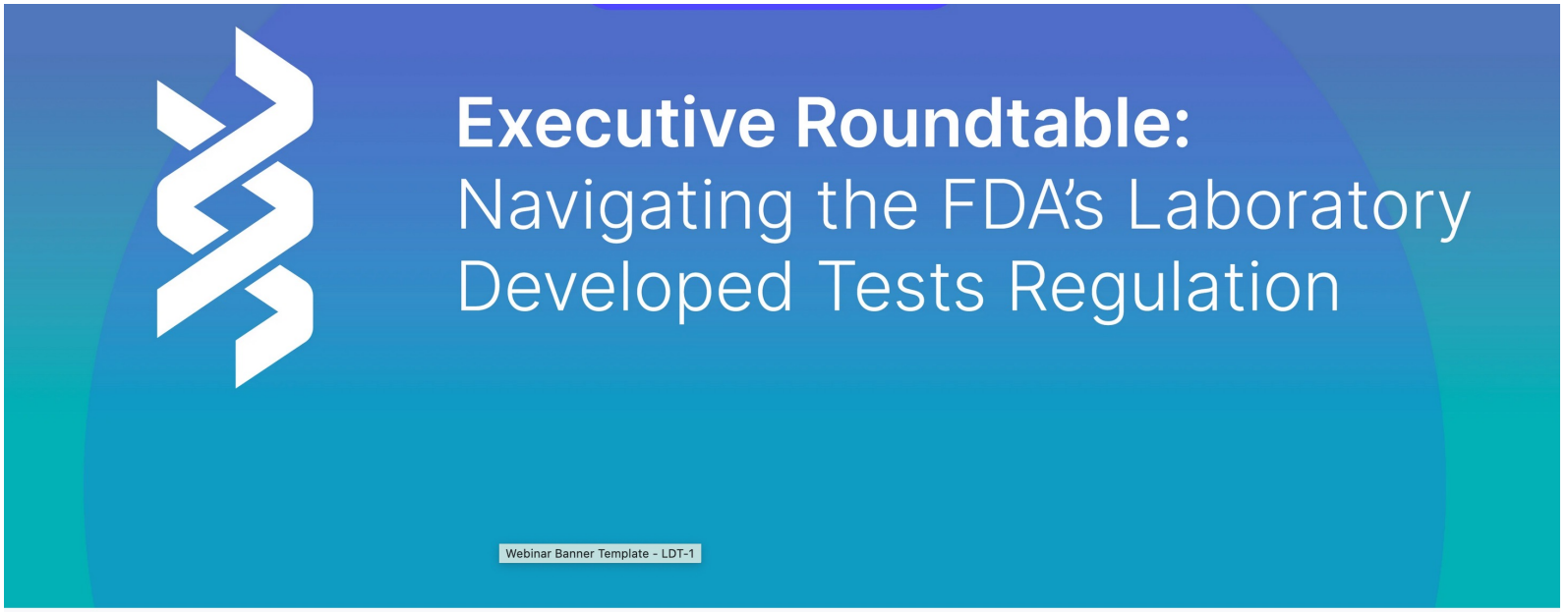
Legal Deadline: None
Publication Date:
Major: Yes
Regulatory Flexibility Analysis Required: Yes
Federalism Implications: No
International Impacts: No
Pandemic Response: No

Received Date: 03/01/2024

Stage: Final Rule
Concluded Date: 04/22/2024
Section 3(f)(1) Significant *: Yes
Economically Significant **: No
Unfunded Mandates: Private Sector
Related To Homeland Security: No
Small Entities Affected: Businesses
Affordable Care Act [Pub. L. 111-148 & 111-152]: No
Dodd-Frank Wall Street Reform and Consumer Protection Act, [Pub. L. 111-203]: No

Note:
* Following the issuance of E.O. 14094 on April 6, 2023, which amended Section 3(f)(1) of E.O. 12866, OIRA has designated regulatory actions as "Section 3(f)(1) Significant" if under that newly amended section of E.O. 12866 they are likely to result in a rule that may have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities. After April 6, 2023, OIRA no longer designated regulatory actions as "Economically Significant."

** Between September 30, 1993, when E.O. 12866 was issued, and April 6, 2023, when E.O. 14094 was issued, OIRA designated regulatory actions as "Economically Significant" if under Section 3(f)(1) of E.O. 12866 they were likely to result in a rule that may have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.



A DeciBio Consulting Webinar

Executive Roundtable: Navigating the FDA's Laboratory Developed Tests Regulation

When:

Tuesday, April 23, 2024

09:00 AM PT / 12:00 PM ET / 04:00 PM UK

Sign Up Now

First Name*

Last Name*

Regulatory Reckoning: Navigating the FDA's Laboratory Developed Tests Regulation White Paper

MARCH 19, 2024 WHITEPAPER CLINICAL DIAGNOSTICS

Stephane Budel
FOUNDING PARTNER

Maximilian Schmid, M.D.

Executive Roundtable: Navigating the FDA's Laboratory Developed Tests Regulation

Implications for Laboratories Operating LDTs

	Description	Total Dependencies	Operational Impact	Resources Impact	Financial Impact	Strategies to Thrive
Quality Systems Overhaul	Implementation of FDA compliant quality systems	High	Medium	High	High	1 Invest in scalable solutions that allow for gradual implementation to spread out the financial burden over time
Regulatory Compliance Upgrade	Registration, listing, and adverse event reporting	High	Medium	High	High	2 Partner with regulatory experts and invest in training for staff to ensure smooth transitions to new standards
Documentation & Reporting Enhancement	Medical device reporting and response to adverse events	Medium	Medium	Medium	Medium	3 Leverage digital solutions to streamline reporting processes, reducing manual labor and potential for errors
Strengthening of Validation Efforts	Additional validation studies and data analysis	High	High	High	High	4 Allocate a dedicated budget and team for continuous test validation aligned with regulatory changes
Engagement with FDA	Consultations and compliance checks	Low	Low	Low	Low	5 Designate or hire experienced regulatory liaison personnel to manage interactions and maintain a pulse on regulatory expectations

Overview of the FDA's Proposed LDT Rule

Intent

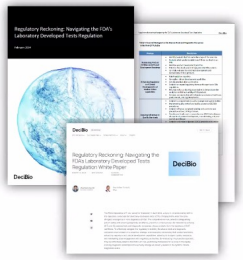
FDA's Proposed Rule is aimed at helping to ensure safety and effectiveness of Laboratory Developed Tests (LDTs)

Changes

Aspect	Status Quo	Proposed Change
Classification	LDTs not classified as IVDs	LDTs as IVDs
Oversight	Limited or no FDA oversight	Full FDA oversight
Quality System	Not uniformly required	Mandatory compliance
Adverse Event Reporting	Voluntary or not required	Mandatory

Timeline

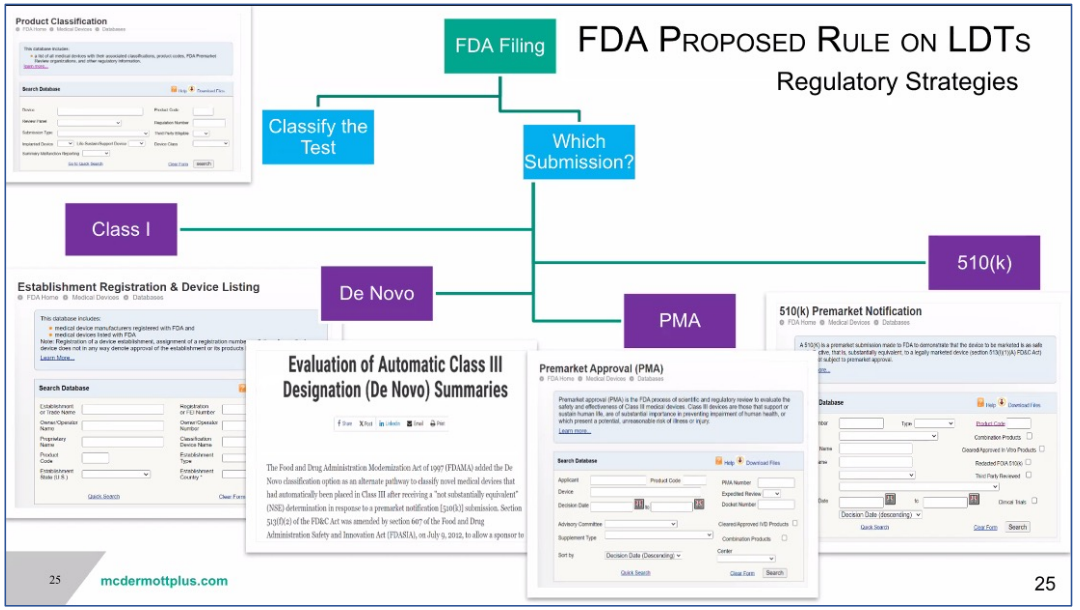
DeciBio Whitepaper



https://www.decibio.com/insights

FDA Proposed Rule on LDTs

Regulatory Strategies



Regulatory Affairs, Stakeholder Impact

IVD Manufacturer

- Compliant with QMS regulations
- Already submit to FDA
- Turnaround time concerns for review

LDT Laboratory

Varying amount of work on QMS

Limited experience with FDA submissions

Difficult decisions
- Closing up shop
- Removing tests from the market
- Decreased innovation

RUO Manufacturer

Existing limitation for selling to clinical laboratories
- Many LDTs use RUO/IUO reagents

Difficult decisions
- Potentially smaller market
- FDA submission (?)

Shannon Bennett M.S.
Regulatory Affairs, Mayo Clinic

A Policy Perspective

Bruce Quinn MD PhD

Costs	• Proposal buried colossal financials deep inside obscure online supplements • $40B cost to industry in first several years • Vast armies of nonexistent manpower (man-years in tens of thousands) • Hundreds of billions in "benefits" were not "savings," but sketchy life-year values • Project would NOT AT ALL save the government money
Time	• FDA likely to finalize by May 20 – but this is an over-hyped deadline for Congressional Review Act • CRA only matters *with a new president*, and *with a new president*, all bets are off anyway
Court	• Regulation likely to be tied up 2 years in court (and could lose)
Real World Implementation	• I predict if and when regulation moves forward it would bog down under its own weight • European IVD Regs are an important "canary in coal mine"
Down-Classification	• FDA promises (in press release) to reclassify many tests from PMA to 501K would be a big thing

Bruce Quinn, MD PhD
Founder, Bruce Quinn Associates

BRUCE QUINN ASSOCIATES LLC

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

April 1st 2024 Meeting

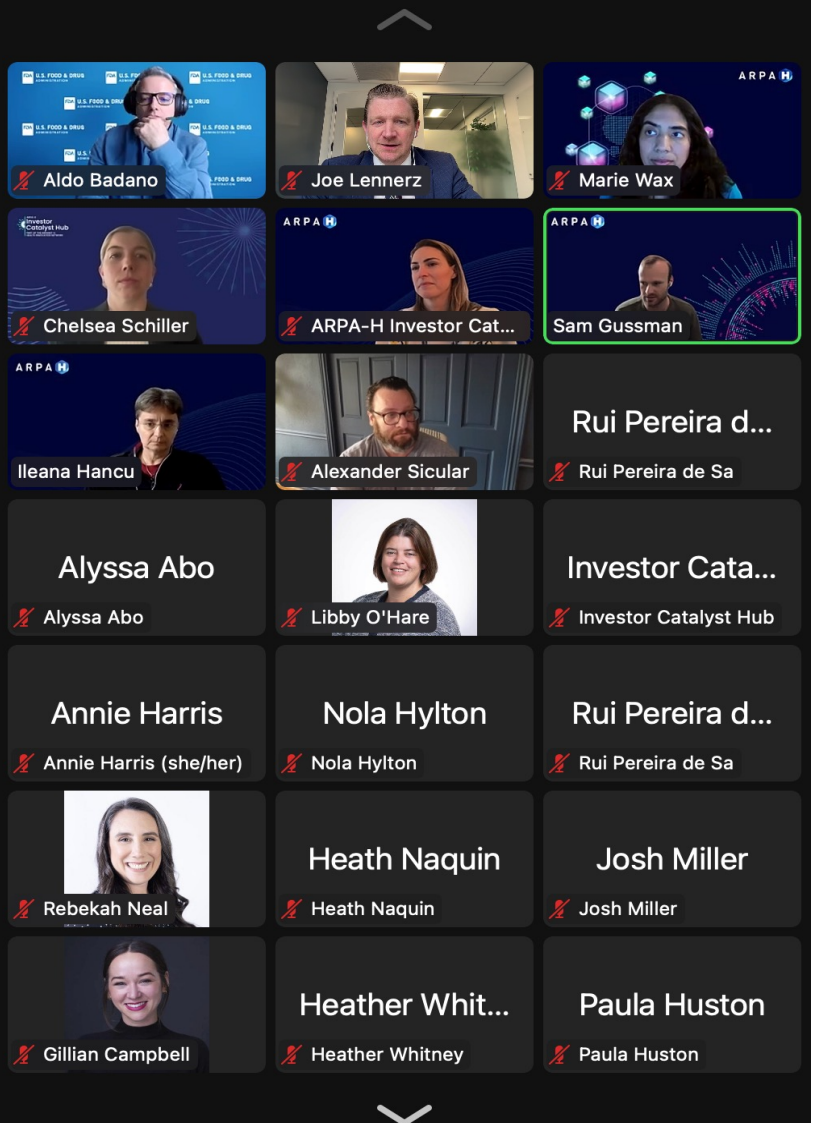
Medical Imaging Data Marketplace

APRA-H and FDA/CDRH partnership

Ileana Hancu (ARPA-H, Health Science Futures)
Aldo Badano (FDA, OSEL/CDRH)
Sam Gussman-Toh (ARPA-H, PATIO)
Chelsea Schiller (Investor Catalyst Hub)

Prepared for External Audiences

ARPA-H



What is the process and where are we now?

We are here!

FDA Collaboration

ARPA-H and FDA partner to solve for the lack of high-quality data at-scale for innovators and to prepare them for regulatory evaluation.

Landscape Analysis

Understand the landscape of organizations, stakeholders, and experts attempting to solve this problem to request their input.

Survey

Gather input to answer critical questions for solving the problem

Synthesize Results

Analyze survey data to understand trends across the healthcare ecosystem. Further investigate findings and refine program concept

Program Definition

Determine project structure, goals, milestones, business model and technical scope using insights from the survey.

Program Launch

Develop solicitation and launch the program after ARPA-H and FDA approval.

ARPA-H

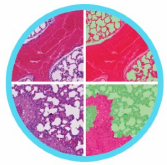
Network Survey

The Investor Catalyst (IC) Hub would like to hear from key stakeholders:

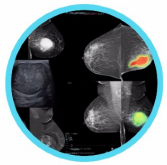
Data Users	Users that need imaging data to train and test AI/ML models.	***Q: What are your biggest challenges in finding or obtaining the medical imaging data you need?***
Data Managers	Managers that sell or aggregate medical imaging data.	***Q: How do you handle data standardization and interoperability issues?***
Data Producers	Producers who create medical imaging data	***Q: What kind of de-identification is important for a medical imaging database from which you are doing research and development?***

ARPA-H

Focus Areas



Whole-Slide Imaging for Prostate and Breast Cancer



Screening and Diagnostic Mammography

Other Digital Pathology or Radiological Imaging

Community Suggested

ARPA-H

ARPA-H FDA/CDRH Medical Imaging Data Marketplace

What if we could streamline access to **affordable**, **high-quality**, **regulatory-ready** medical imaging data to develop Software as a Medical Device (SaMD) and AI-enabled products that are safe and effective for all Americans?

- **Data access for researchers to develop their algorithms**
- **Straightforward way for data providers to monetize their assets**
  - Income source for hospitals, small businesses and other groups
- **Data for businesses to validate and test their algorithms in preparation for FDA submissions**
  - Sufficient data from **representative** populations
  - Consistent with qualifying reference standards
  - Ethical usage, data privacy and sharing considerations
- **Post-market monitoring for performance drift and evolving algorithms**

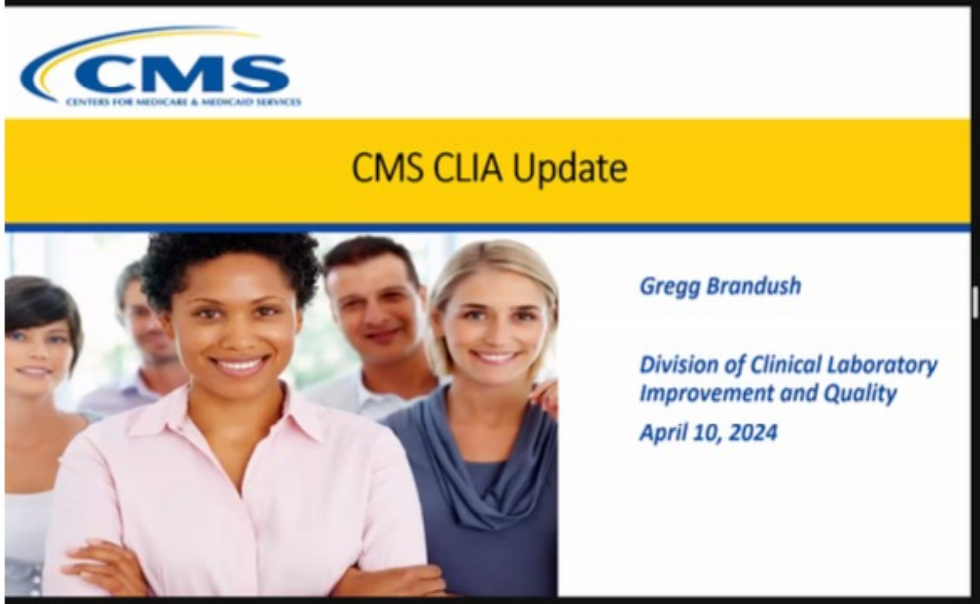
The Medical Imaging Data Marketplace

- Infrastructure for federated and centralized data workflows
- **Connections with data providers** and tools ensuring data consistency, deidentification, quality control, etc.
- Protocols for **communication between data repository and users**
- User interface to obtain applications of interest and for rapid qualitative assessment
- Self-sustaining business model balancing affordability and compensation

ARPA-H

CLIA Meeting

April 10th, 2024



CLIAC Home
Meeting
Upcoming Meeting
Past Meetings
Membership
CLIAC Charter
CLIAC Workgroups
About CLIAC
CLIA
Contact CLIAC

Upcoming CLIAC Meeting

Print

General information and meeting topics are published at least 15 calendar days in advance in the Federal Register, with detailed agendas posted prior to the meeting. Meetings are open to the public and are also webcast.

Please visit this page prior to and during the meeting to access information as it becomes available, such as updated agendas, presentations, and handouts. Public comments can also be submitted in advance of the meeting for consideration by the Committee.

Participant Information

The next meeting will be held on April 10, 2024, from 10:00 a.m. to 6:00 p.m., EDT. This is a virtual meeting. The agenda will include agency updates from CDC, CMS, and FDA. Presentations and CLIAC discussions will focus on the applicability of CLIA personnel requirements to preanalytic testing, the role of artificial intelligence and machine learning in the clinical laboratory, and the use of clinical standards to improve laboratory quality. Agenda items are subject to change as priorities dictate. Please check back for updates closer to the meeting date.

April 10, 2024 Meeting Documents

CLIAC April 2024 FRN

CLIAC April 2024 Agenda

1_Outgoing_Members

2_CDC_Update

3_CMS_Update

4_FDA_Update

OHT7 Key Activities

Premarket Activities

- PMA, 510(k), De novo request reviews
- Investigational Device Exemptions
- Humanitarian Device Exemptions
- Pre-submissions
- Breakthrough designation requests
- Premarket inspections
- CLIA waiver applications
- CLIA categorizations

Postmarket Activities

- Monitoring and Surveillance
- Postmarket Inspections
- Postmarket Studies
- Recalls
- Compliance and Enforcement Actions
- Safety communications

External Engagement & Outreach

- External training and engagement
- Public meetings
- Conferences
- Town Halls
- Inquiry responses

Emergency Use

- Emergency Use Authorizations
- Cross-agency collaborations
- Stakeholder engagement, including Town Halls

Guidance

- Issue new guidances
- Update existing guidances
- Training and webinars

Program Development & Operations

- Internal training
- Performance tracking
- Data reporting

The Basics of Artificial Intelligence and Machine Learning

Alexis B. Carter, MD
Physician Informaticist and Molecular Genetic Pathologist
Presentation for CLIAC on April 10, 2024

PIcc Project Updates

Pathology Innovation Collaborative Community

PIcc

MDIC Medical Device Innovation Consortium

PIcc Regulatory Landscape Survey

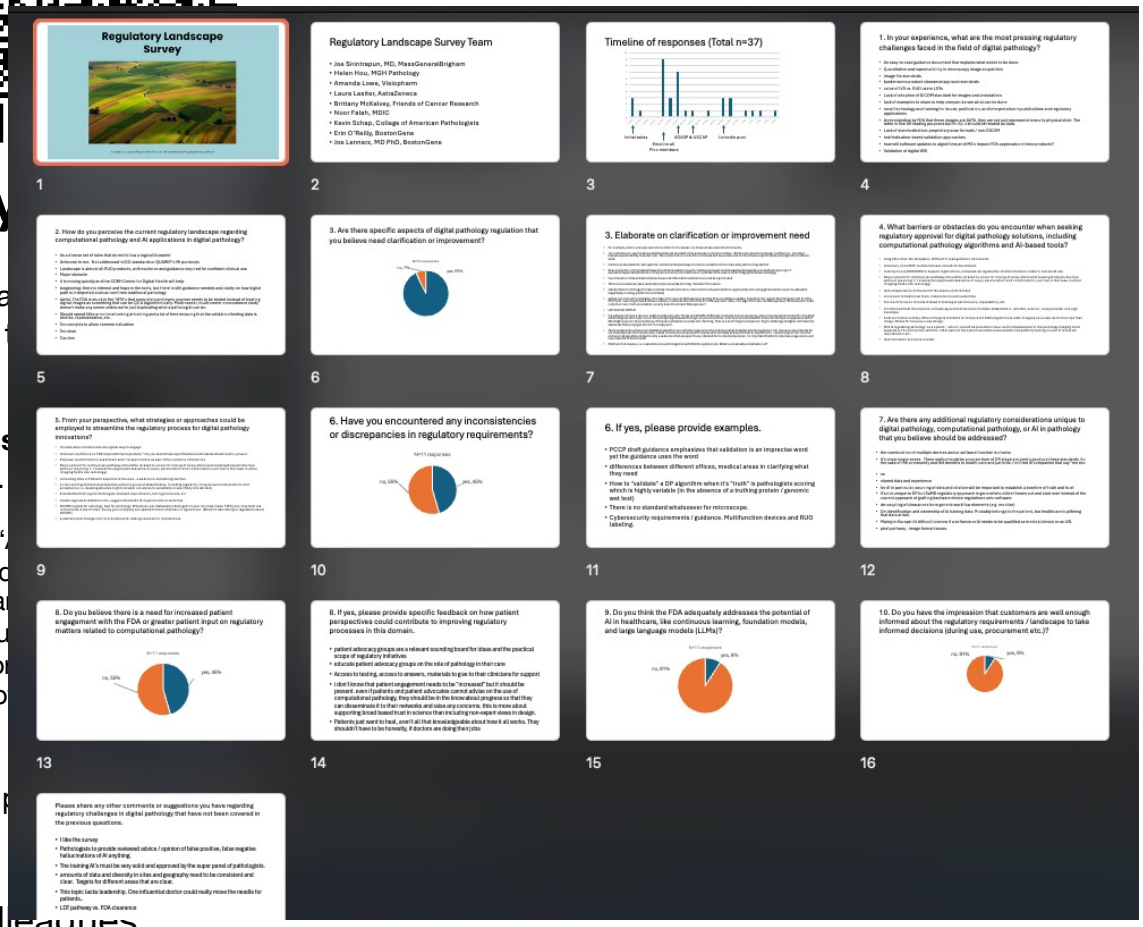
This survey aims to capture broad insights from stakeholders a
industry, healthcare providers, patients, and advocacy groups
prioritize key regulatory hurdles in these emerging fields.

When providing input, please consider that we are looking for s
questions that can be addressed using regulatory science.

For example, we are not looking for generic statements about the field ("
implemented faster"). The survey aims to collect elements that can be ac
regulatory science methods ("There is a lack of standardized protocols a
integrating AI decision support tools in digital pathology"). Collecting you
shape collaborative efforts to address these challenges through regulato
ultimately advancing the safety, effectiveness, and timely delivery of inno
solutions to patients.

Participation is voluntary, and the results of this survey will be p
PIcc website.

Please feel free to share the survey with your colleagues.



Instructions

- This slide deck will be used to present 2023 annual updates to senior leadership team in May 2024 for all collaborative communities
- Use the template on the following slides to create a succinct update
- All content must fit within the allocated space
- Follow the help text in italics when adding content

1

Pathology Innovation Collaborative Community PIcc

PIcc is a temporary regulatory science initiative that aims to facilitate innovations in pathology as well as advance safety and effectiveness evaluation, and to harmonize approaches to speed delivery to patients using collaborative, pre-competitive approaches.

www.pathologyinnovationcc.org

CDRH Liaison: *Brandon Gallas*

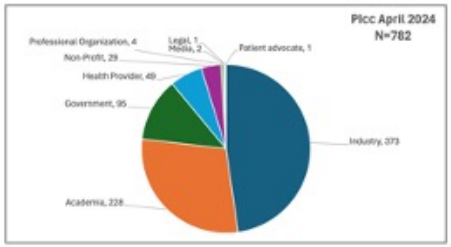
CDRH Executive Sponsor: *Ed Margerrison*

www.pathologyinnovationcc.org

2

PIcc brings together a broad range of stakeholders to accelerate the development and delivery of regulatory science initiatives in the pre-competitive space that modernize the clinical practice of pathology.

- Key aim: a clear path for regulation of pathology innovation through regulatory science
  - Inclusive organization for all stakeholders to educate each other and tackle relevant questions by using and creating applicable regulatory science tools
- CDRH engagement through representative participation and contribution



3

Collaborative Community Activities

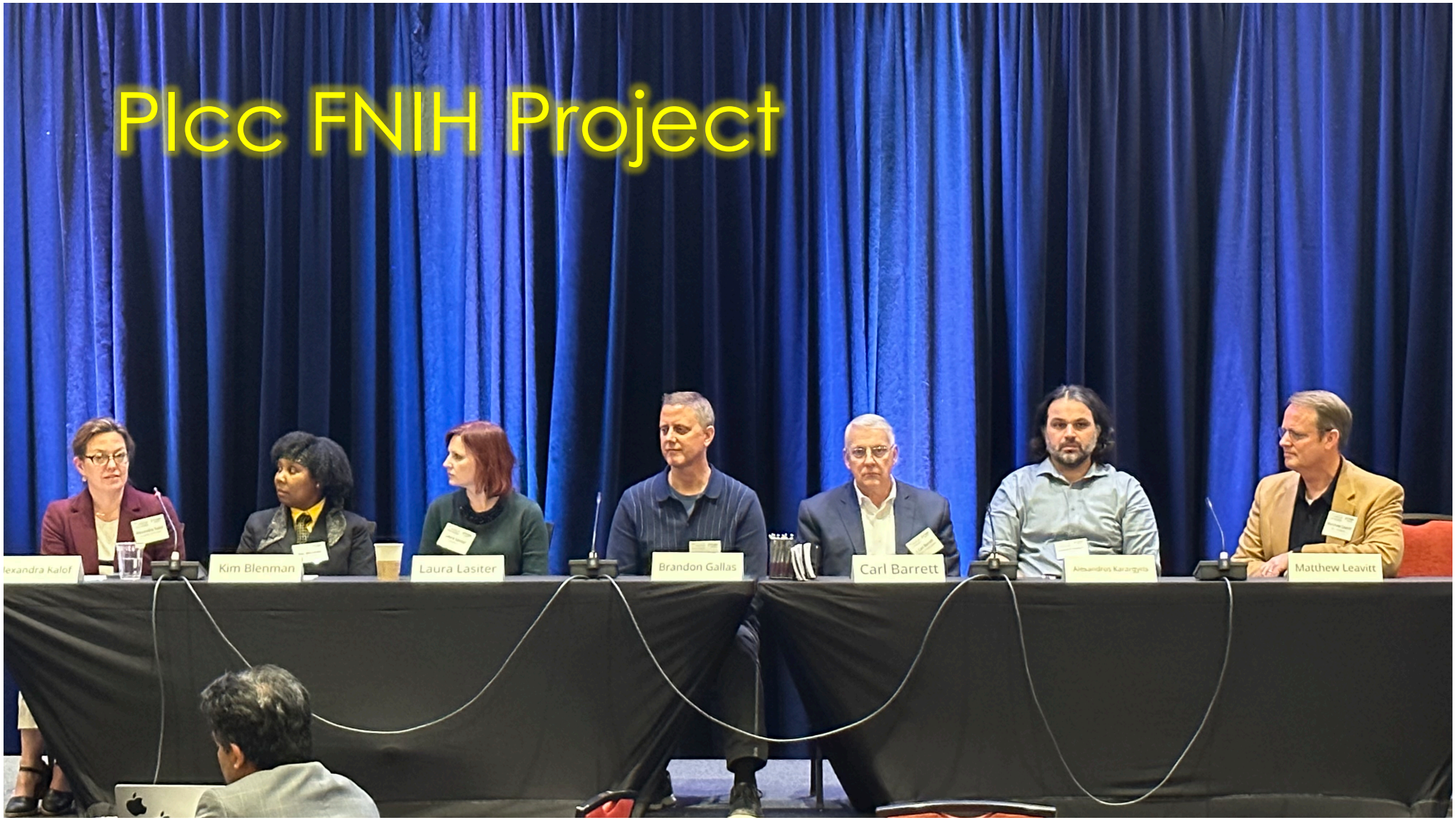
2023 Goals

- **Goals from 2022**
  - Continue meeting and sharing important information and activity in the field
  - In-person working meeting D.C. area in collaboration with MDIC (convener of PIcc)
    - Additional meet-ups at conferences of member organizations
  - Increase engagement through active member participation
  - Grow website traffic and recognition of the website as a resource through increased social media presence
- **Accomplished?**
  - New projects launched:
  - HER2-low
  - PCCP
  - data breach project
  - **Meeting**
  - In-person meeting D.C. area in collaboration with MDIC (convener of PIcc)
  - Website traffic
- **Additional**
  - FNIH Meeting with key stakeholder

2024

- *PIcc FNIH Project (multi-center data collection initiative). Multi-phase project*
- *Regulatory Science Landscape Survey*
  - *Capture key concerns in the community*
  - *Share this on website and with FDA*
- *In-person meeting (Fall)*
  - *Planning*
- *Publications*
  - *CME course (jointly with FDA)*
  - *MDDT submission experience*

4


Plcc FNIH Project
Kim Blenman
Laura Lasiter
Brandon Gallas
Carl Barrett
Matthew Leavitt

The PIcc FNIH team (so far) => want to join please email us.


Alex Karagyris


Roberto Salgado


Brandon D. Gallas


Joe Lennerz


Althea Lang


Carl Barrett


Matt Leavitt


Laura Lasiter


Amy Ly


Micah J. Sheller


Alexandra Kalof


Dana E. Connors


Brittany Mc Kelvey


Peter Mattson


Monica de Baca


Mark Stewart


Hillary Andrews

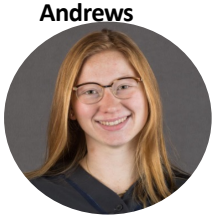

Briana M. Mills


Gary J. Kelloff


Noor Falah

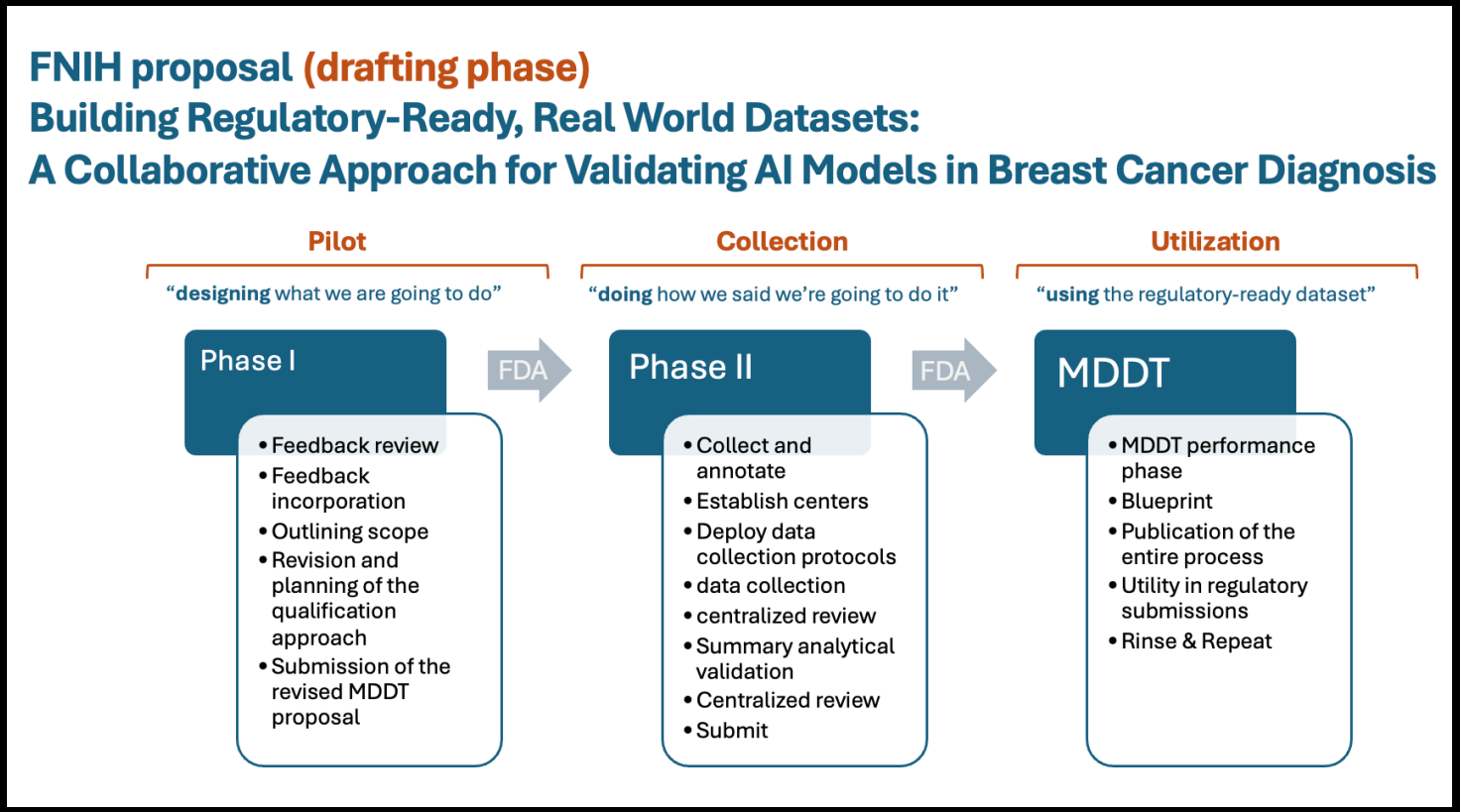

Emmett Schmidt


Marina S. Milan


Emma Gardecki


Kim Blenman

PIcc FNIH Proposal – initial draft submitted

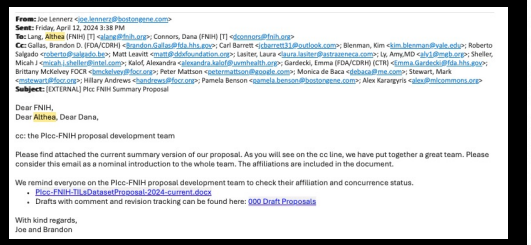


PIcc FNIH Proposal – initial draft Feedback

April 12th 2024

SUBMISSION

PIcc-FNIH Summary Proposal



From: Joe Lennerz <joe.lennerz@bostongene.com>
Sent: Friday, April 12, 2024 3:38 PM
To: Lang, Althea (FNIH) [T] <alang@fnih.org>; Connors, Dana (FNIH) [T] <dconnors@fnih.org>
Cc: Gallas, Brandon D. (FDA/CDRH) <Brandon.Gallas@fda.hhs.gov>; Carl Barrett <cbarrett31@outlook.com>; Blenman, Kim <kim.blenman@yale.edu>; Roberto Salgado <roberto@salgado.be>; Matt Leavitt <matt@sbdefoundation.org>; Lasiter, Laura <laura.lasiter@astrazeneca.com>; Ly, Amy,MD <alyl1@mgh.org>; Sheller, Micah J <micah.j.sheller@intel.com>; Kalof, Alexandra <alexandra.kalof@uvmhealth.org>; Gardecki, Emma (FDA/CDRH) (CTR) <Emma.Gardecki@fda.hhs.gov>; Brittany McKelvey FOCR <bmckelvey@focr.org>; Peter Mattson <petermattson@google.com>; Monica de Baca <debaca@me.com>; Stewart, Mark <mstewart@focr.org>; Hillary Andrews <handrews@focr.org>; Pamela Benson <pamela.benson@bostongene.com>; Alex Karagyris <alex@mitcommons.org>
Subject: [EXTERNAL] Picc FNIH Summary Proposal

Dear FNIH,
Dear Althea, Dear Dana,

cc: the PIcc-FNIH proposal development team

Please find attached the current summary version of our proposal. As you will see on the cc line, we have put together a great team. Please consider this email as a nominal introduction to the whole team. The affiliations are included in the document.

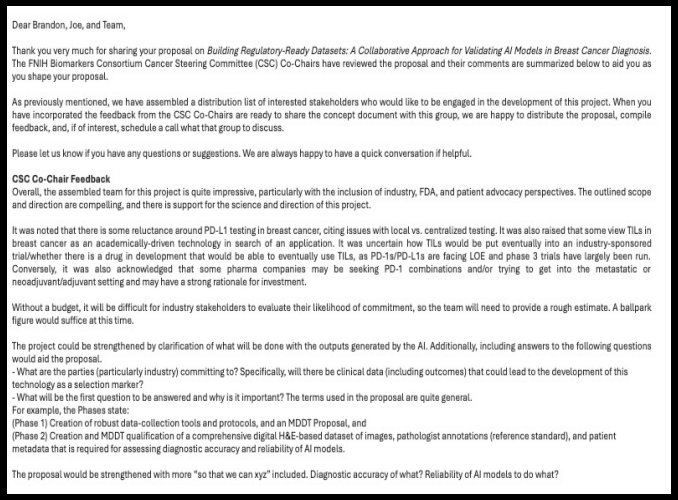
We remind everyone on the PIcc-FNIH proposal development team to check their affiliation and concurrence status.

- PIcc-FNIH-TILsDatasetProposal-2024-current.docx
- Drafts with comment and revision tracking can be found here: 000 Draft Proposals

With kind regards,
Joe and Brandon

April 22nd 2024

Feedback from FNIH
CSC Co-Chair Feedback



Dear Brandon, Joe, and Team,

Thank you very much for sharing your proposal on *Building Regulatory-Ready Datasets: A Collaborative Approach for Validating AI Models in Breast Cancer Diagnosis*. The FNIH Biomarkers Consortium Cancer Steering Committee (CSC) Co-Chairs have reviewed the proposal and their comments are summarized below to aid you as you shape your proposal.

As previously mentioned, we have assembled a distribution list of interested stakeholders who would like to be engaged in the development of this project. When you have incorporated the feedback from the CSC Co-Chairs are ready to share the concept document with this group, we are happy to distribute the proposal, compile feedback, and, if of interest, schedule a call what that group to discuss.

Please let us know if you have any questions or suggestions. We are always happy to have a quick conversation if helpful.

CSC Co-Chair Feedback
Overall, the assembled team for this project is quite impressive, particularly with the inclusion of industry, FDA, and patient advocacy perspectives. The outlined scope and direction are compelling, and there is support for the science and direction of this project.

It was noted that there is some reluctance around PD-L1 testing in breast cancer, citing issues with local vs. centralized testing. It was also raised that some view TILs in breast cancer as an academically-driven technology in search of an application. It was uncertain how TILs would be put eventually into an industry-sponsored trial/whether there is a drug in development that would be able to eventually use TILs, as PD-1s/PD-L1s are facing LOE and phase 3 trials have largely been run. Conversely, it was also acknowledged that some pharma companies may be seeking PD-1 combinations and/or trying to get into the metastatic or neoadjuvant/adjuvant setting and may have a strong rationale for investment.

Without a budget, it will be difficult for industry stakeholders to evaluate their likelihood of commitment, so the team will need to provide a rough estimate. A ballpark figure would suffice at this time.

The project could be strengthened by clarification of what will be done with the outputs generated by the AI. Additionally, including answers to the following questions would aid the proposal.
- What are the parties (particularly industry) committing to? Specifically, will there be clinical data (including outcomes) that could lead to the development of this technology as a selection marker?
- What will be the first question to be answered and why is it important? The terms used in the proposal are quite general.
For example, the Phases state:
(Phase 1) Creation of robust data-collection tools and protocols, and an MDDT Proposal, and
(Phase 2) Creation and MDDT qualification of a comprehensive digital H&E-based dataset of images, pathologist annotations (reference standard), and patient metadata that is required for assessing diagnostic accuracy and reliability of AI models.

The proposal would be strengthened with more "so that we can xyz" included. Diagnostic accuracy of what? Reliability of AI models to do what?

May 22nd 2024 – 11AM (EST)

Discussion and Revision of the
Summary Proposal